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

CASE NO. 20-md-02924-ROSENBERG

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION.

West Palm Beach, FL
June 3, 2021

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

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THE COURT: Okay, good morning, everyone. We are here in the Zantac Products Liability Litigation, MDL number 2924, and we are here today and over the next couple or few days for hearings conducted on the various Motions to Dismiss that have been filed as to the latest round of pleadings that were filed in this case.

So, at Docket Entry 3548, we have the amended order regarding June 3rd and June 4th hearings on the Motions to Dismiss, and that will guide us in terms of the order of the hearings, and hopefully that was clear to everybody. We did amend it the other day, just changed the order slightly, and I appreciate that counsel have provided me the attorneys who will be presenting as to each of the motions. So, I do have that as well, so I thank you for that.

Let me make a couple of announcements.

Three extra minutes are afforded to each side in which an LDC or a next gen attorney is arguing. During the argument phase of each hearing only the attorney arguing should have their video and audio on. At the conclusion of the argument, when the Court presents its questions, all counsel arguing that motion should turn their audio and video on for the purposes of my questions.

I may refer to the amended master personal injury complaint as the AMPIC, the consolidated amended consumer economic loss class action complaint as the ELC, and the

consolidated medical monitoring class action complaint as the MMC.

To be clear, when Defense is arguing its motion, only Defense counsel's video and audio should be on, then you turn yours off. Plaintiff responds, just the Plaintiffs' counsel's video, Plaintiff off. To the extent that there is going to be any rebuttal from the Defense, and I'm going to ask you that when you come up, then you come on, and when I ask the questions, which will occur at the end of all the oral presentation by counsel, all of the attorneys participating in that motion will put their video and audio on.

The Court will be keeping track of the argument time. Before you begin your argument, if you would like the Court to give you notice before the conclusion of your hearing time, please let me know.

Furthermore, the Defendants, as the moving party, should let me know what, if any, time you want to reserve for rebuttal argument.

We will take a lunch break after the first two hearings. Feel free, and it may even be advisable, to remain connected to the Zoom link with your video and audio off during the lunch break so we do not need to spend time readmitting you to the hearing after the lunch break. I will announce when our lunch break will be at the conclusion of our second hearing.

For all of you, please remember to speak slowly when

you are presenting and answering my questions. State your name for the record before you argue and when you are answering my questions. If the Court directs a series of questions to the same counsel, you do not need to continue to state your name each time you answer a question. It should be apparent at that point who you are and the record will accurately reflect that.

Please try your best to answer the question that the Court poses. The questions are not intended to argue things that maybe you didn't argue in your oral argument. I tried to give everybody sufficient time to make your arguments. The questions are really purposeful and so I would like you to try your best to answer the question. If you need to explain your answer, explain your answer, but try to do it succinctly, sharply.

We have a lot to accomplish over the next few days and I want to make sure things move along in an efficient manner so that nobody gets fatigued, we don't have burnout, and we get through all of this and everybody feels as if you have been heard.

So, with that, the very first motion that the Court will hear is the Defendants' Omnibus Motion to Dismiss and/or Strike Amended Master Personal Injury Complaint and Incorporated Memorandum of Law. It appears at Docket Entry 3111, and I have allotted for the Defendants 18 minutes because you have LDC and/or next gen, and I have allotted 18 minutes

for the Plaintiff because you too have LDC or next gen.

So, if I could first have Defense put your video and audio on, state your name for the record and let me know whether you want me to give you any warning, whether you are going to be reserving any time for rebuttal, and we will do our best to give you the warning and let you know when your time is up before your rebuttal.

Counsel may state your name for the record and let me know how you would like to proceed.

MS. ZOUSMER: Good morning, your Honor, Julia Zousmer for Defendants. I will keep track of my time, so I don't need a warning and I don't think we need to reserve time for rebuttal.

THE COURT: Okay.

MS. NINO: Emma Nino, your Honor, on behalf of Defendants. I will be presenting argument after Ms. Zousmer.

THE COURT: Maybe when you start to make your presentation, Ms. Nino, state your name so the record reflects that we are changing.

So, I won't give you any warning, but I will keep track. I look forward to your presentation, you may proceed.

MS. ZOUSMER: Good morning, your Honor, Julia Zousmer from King & Spalding. I'm counsel for BI, but will be arguing the Omnibus Motion to Dismiss Plaintiffs' Amended Personal Injury Complaint, or the AMPIC, on behalf of all Defendants

this morning.

Plaintiffs filed their AMPIC in an attempt to cure the deficiencies for which the Court dismissed Plaintiffs' original master personal injury complaint, or the AMPIC. While Plaintiffs' AMPIC is an improvement in some ways, in other critical ways it still falls far short of what is required and fails to cure the shotgun pleading. It still seeks to impose sweeping liability on more than a hundred Defendants without alleging any Defendant specific facts for the vast majority of them.

Plaintiffs cannot get around this failure by just grouping distinct Defendants together without a factual basis to distinguish individual conduct. Because the Court has given Plaintiffs an opportunity to fix these flaws and Plaintiffs failed to do so, the AMPIC should now be dismissed with prejudice.

It is undisputed that the AMPIC still combines dozens and dozens of separate Defendants together into groups. Plaintiffs contend that the prohibition against shotgun pleading does not bar lumping Defendants together, so long as they don't also lump different groups of Defendants together, but that is not right.

As the Eleventh Circuit puts it, the relevant sin of shotgun pleading is asserting multiple claims against multiple Defendants without specifying which of the Defendants are

responsible for which acts or omissions. Plaintiffs commit this sin if they fail to give Defendants adequate notice of the grounds upon which each claim rests. The AMPIC commits this sin.

In fact, for many of the Defendants named in the AMPIC, Plaintiffs allege no Defendant specific facts other than the Defendant's state of incorporation and principal place of business. This puts us in unchartered waters with this complaint in the Eleventh Circuit.

Plaintiffs have identified no case in which the Eleventh Circuit has blessed a similar complaint where literally dozens of corporations are sued with no facts pled about their conduct other than the corporate headquarters and states of incorporation.

This is not a stylistic complaint, it is a fundamental problem with the substance of Plaintiffs' allegations. By pleading their claims in this way Plaintiffs have denied each Defendant fair notice as to what actual alleged conduct is supposed to support the claims against them.

To give just one example, the AMPIC denies all Defendants notice of the facts supporting the conclusory assertion that every Defendant had notice of the risks associated with Ranitidine. Whether, when, and how a Defendant has notice of risk information is a key and typically disputed issue in product liability cases like this one, and the AMPIC

provides no notice to any Defendant of the facts that support that assertion against it.

Instead of alleging facts how to show how each individual Defendant learned of specific risks or should have the AMPIC relies on bare assertions that all a hundred plus Defendants knew or should have known about those alleged risks. Under Eleventh Circuit law, alleging the Defendants knew or should have known of a risk is a conclusory legal allegation that is insufficient under Iqbal, and it's a particularly flawed allegation to make generally about a hundred Defendants who entered the supply chain at various points in time over almost 40 years and could not have all had the same actionable knowledge of the same information.

This is not a case where the Court can just read all of those generalized knowledge allegations to apply equally to every Defendant. For one thing, as I mentioned, the unprecedented degree to which Plaintiffs have combined so many distinct Defendants makes that reading unrealistic.

For another, Plaintiffs cite no law that actually supports doing it. The case they do cite, Crow versus Coleman, is dissimilar both on the facts and the law. On the facts, Plaintiffs in Crow named only two Defendants, the current and prior owners of land adjoining their property in a suit that was over the narrow issue of liability for damage caused by gasoline that leaked from the Defendants' property while both

individuals owned it on to Plaintiffs'.

On the law, the Court applied a liberal pleading standard predating Twombly and Iqbal and did not address the Eleventh Circuit's prohibition on shotgun pleading at all. Additionally, temporal realities preclude reading the AMPIC as making the same allegation against each Defendant individually.

Plaintiffs concede that different Defendants manufactured, promoted, and sold Ranitidine products at different times, yet the AMPIC's factual allegations cover all Defendants, even when the allegation relates to time periods in which some Defendants were not manufacturing, promoting, or selling the product.

Plaintiffs try to say they are suing individual Defendants only during the periods in which each was manufacturing Ranitidine, but while purportedly following this temporal limitation in the text of their brief, they take it all back on the next page in a footnote.

Using Pfizer as an example, that footnote argues Defendants can be liable in some states for conduct occurring long after they left the supply chain. If that is the case, then Plaintiffs claim the Defendants need only consult allegations during the time periods in which each was manufacturing Ranitidine is untrue.

Defendants must instead guess which post sale allegations apply to them, then and further guess which claims

under which state laws those post sale allegations support. This is not adequate pleading.

Plaintiffs must explain which individual Defendants had a post sale duty to warn, identify the time period during which that duty existed in the relevant state, and specify the conduct through which each Defendant breached its duty; otherwise, individual Defendants do not have adequate notice of which allegations of fact are intended to support which claims for relief.

Plaintiffs' shotgun pleading also grossly fails to meet Rule 9(b)'s heightened pleading standard for fraud based claims. The AMPIC plainly does not describe with particularity how any Defendant committed fraud. Instead, Plaintiffs generally allege that Defendants made false representations, quote, "via the media, advertising, social media, packaging and promotions, among other misrepresentations," end quote.

Defendants are entitled to understand which specific representations constitute the claimed fraud, who made the alleged statement or omission, when it was made and to whom. The AMPIC lacks these critical facts despite voluminous discovery available to Plaintiffs.

Plaintiffs now boldly claim that while they could plead these facts for each Defendant, they have not done so here because it would serve, quote, "no apparent purpose," but

that is not how the law works. Parties can't make their own individualized determinations about when and whether the Federal rules serve a purpose they find worth complying with. These are the very details required by Rule 9(b) to sustain a fraud claim at the Motion to Dismiss stage and Plaintiffs admit they failed to provide them.

The Court should, at a minimum, dismiss Plaintiffs' negligent misrepresentation claims and strike its fraudulent concealment allegations.

Now I will turn it to Ms. Nino.

THE COURT: Thank you very much.

MS. NINO: Thank you, your Honor. I am Emma Nino and I represent Pfizer in this litigation, but I am arguing today on behalf of all Defendants.

As Ms. Zousmer explained, it is our position that the AMPIC as a whole should be stricken or dismissed on shotgun pleading grounds, but certain of the individual counts fail under the Iqbal/Twombly standard as well. Specifically, our motion challenges Counts 3 through 5, 7 through 11, and 14 for failure to state a claim.

I want to start with Counts 10 and 11, which are Plaintiffs' negligent storage and transportation claims, as I think these counts are a good illustration of the pleading issues that Plaintiffs' amendment has failed to cure.

The fundamental issue with these counts is that,

because of the way they were pled, Defendants have no way of figuring out which specific Defendants allegedly did or didn't do something with respect to storage and transportation of Ranitidine products. In an attempt to make overheating or exposure to humidity across the supply claim a common issue of fact, Plaintiffs plead generally that there was widespread systematic failure by all Defendants to ensure compliance with relevant requirements, but the result is that Plaintiffs have not complied with Rule 8's requirements for notice pleading.

Their sweeping assertion about system-wide issues is unsupported by factual allegations regarding individual Defendants or factual allegations about any shipments that were allegedly exposed to excess heat or humidity. The one policy that Plaintiffs point to is a shipment of Ranitidine products through the mail without specifying which Defendant shipped which products in which areas by which common carrier.

This is simply not enough to make Plaintiffs' entitlement to relief plausible or to put each individual Defendant on notice as to the claims against it.

Plaintiffs have already had the opportunity to attempt to fix their pleading as to these claims and they have failed to do so, so we ask that they be dismissed with prejudice.

Turning next to Counts 3, 4, 7, and 9, which I will address together because these claims all rest on Plaintiffs' degradation theory, in the AMPIC Plaintiffs lay out two

different mechanisms by which they allege NDMA forms in Ranitidine products. What I will call the degradation theory is that Ranitidine degrades over time before it is ingested, particularly in conditions of high heat and humidity, and NDMA is formed in the process.

Plaintiffs also allege that NDMA forms endogenously in the body when Ranitidine is digested. This is the endogenous formation theory. In their prior pleading, allegations about both theories were intermingled, but in the AMPIC Plaintiffs break out which theory support which counts. In doing so, Plaintiffs reveal that their counts resting on their degradation theory lack factual support.

As I mentioned, Counts 3, 4, 7, and 9 rely on this theory, which makes sense because in these counts Plaintiffs argue that Defendants should have set shorter expiration dates and designed the containers for Ranitidine products differently to prevent NDMA formation over time. Shorter expiration dates or different containers could not possibly address the risk of endogenous formation of NDMA in the stomach.

A fundamental problem with these counts is that Plaintiffs fail to plead facts showing that Defendants were on notice at the time of manufacture about the alleged risk of formation of NDMA through degradation. This is true under any of the relevant standards for these claims.

Plaintiffs' opposition makes this shortcoming clear. The allegations they attempt to rely on are either conclusory, irrelevant, or not incorporated in the counts at issue, or even alleged in the complaint at all. Plaintiffs' primary argument seems to be that the molecular structure of Ranitidine itself put Defendants on notice that their products could degrade to form NDMA because Ranitidine contains both a Nitroso group and a Dimethylamine group.

This allegation is only made in Count 9 of the counts that I am addressing, the negligent container claim, and even as to that count it does nothing to support the foreseeability of the degradation mechanism. In other words, that the ingredients of NDMA are present in Ranitidine does not put someone on notice that NDMA forms over time and in response to heat and humidity.

Plaintiffs also point to two early tests that they assert gave notice that Ranitidine degrades into NDMA under conditions of heat and humidity. These are the Flora study and a 1982 study performed by GSK.

First of all, most of the allegations cited in this section of Plaintiffs' brief are not incorporated in the relevant counts. In any event, both studies address the possibility of endogenous formation of NDMA in the stomach, not degradation outside the body.

It seems that because Plaintiffs lack factual support

going to knowledge as to their degradation theory, they have decided to ignore the distinction between the two.

All of the allegations in Section 6 of the AMPIC, which is titled manufacturer Defendants knew or should have known of the NDMA risk, relate to the endogenous formation mechanism rather than the degradation mechanism. Whether or not these theories pled together are consistent, Plaintiffs can't bootstrap notice as to one to notice of the other. The duties that would flow from notice of each are different because different actions would address the different risks.

Plaintiffs have failed to allege that the risk of NDMA formation through degradation was foreseeable to Defendants. They, therefore, have not properly pled their claims for failure to warn or design defect through expiration dates or their negligent container claim.

I will turn next to Count 5, which is Plaintiffs' claim for failure to warn the FDA. As an initial matter, most of the relevant jurisdictions do not recognize claims for failure to warn the FDA at all. We don't dispute that failure to warn is a longstanding common law tort, but failure to warn the FDA is not.

The learned intermediary doctrine does not require a manufacturer to warn any and all third parties, and as the Supreme Court of Arizona explained in Conklin versus Medtronic, the FDA is not a prescriber or a health care provider.

This claim also lacks the necessary factual support to survive the Motion to Dismiss. The few Courts that have allowed failure to warn FDA claims to proceed in some circumstances have made clear that Plaintiffs must identify specific adverse events that Defendants did not report to FDA.

The AMPIC does not do this. It simply alleges that 59 percent of all time adverse event reports for Ranitidine were filed in 2020, but this allegation doesn't identify specific adverse events that were unreported.

It also doesn't plausibly support the inference that Plaintiffs use it for, that Defendants were withholding adverse event reports prior to 2020. The logical explanation for this uptick is the increased publicity surrounding the FDA investigation and the Plaintiffs' claims themselves.

It is important to point out that information from product liability Plaintiffs like the thousands in this litigation is subject to reporting requirements, often by multiple Defendants, whether or not there is an indication that the product caused the alleged injury. There is just no support for the inference the Defendants were aware of these adverse events earlier and did not report them.

Plaintiffs attempt to get around this deficiency with respect to the adverse event reports by claiming that Defendants could have warned FDA in other ways, but they have no authority for this proposition.

Plaintiffs also failed to plausibly plead how the Defendants' alleged failure to warn FDA about adverse events contributed to their injuries. The cases that Plaintiffs rely on are clear, Plaintiffs must show that if Defendants had timely reported the adverse events that information would have reached their doctors in time to prevent the harm that they suffered.

Plaintiffs theory of causation is remarkably attenuated. They don't allege that they or their physicians would have reviewed or relied on certain adverse event reports had they been submitted earlier. Instead, they rest their claim on the supposition that if Defendants had submitted additional unspecified adverse event reports to FDA, some physicians conducting studies could have reassessed Ranitidine's safety profile, resulting in an FDA order of recall that would in turn have alerted prescribers about the alleged risks of the products.

But without alleging information about which adverse events went unreported and when, they can't support an inference that earlier reporting would have prevented their injuries. This is not enough to support a plausible causal nexus for their failure to warn the FDA claims and Count 5 should be dismissed.

Lastly, I want to very briefly address Count 8, which is Plaintiffs' claim for negligent failure to test brought

under Kansas and Texas law. As outlined in our briefing, the case law makes clear that neither state recognizes failure to test as a viable stand-alone tort, but instead, view any duty to test as falling within established products liability claims like failure to warn. We therefore ask the Court to dismiss Count 8.

That concludes our presentation this morning, but Ms. Zousmer and I are, of course, happy to answer any questions that the Court may have. Thank you.

THE COURT: Thank you very much. We will do the questions at the conclusion of the Plaintiffs' presentation and at that time I will ask you to put your videos and audio back on, but now you can turn them off. Thank you for the presentations.

If we could have the Plaintiffs' counsel come on up now.

MR. HEINZ: Good morning, your Honor.

THE COURT: Good morning. Did you need any warning?

MR. HEINZ: I don't need warning, I will keep my own time. I was planning to use a PowerPoint if I could be allowed to share my screen on Zoom.

THE COURT: As long as you do it, you take control of it. You may proceed.

MR. HEINZ: It says the host has disabled screen sharing. I think the host has to allow me to share.

THE COURT: Okay. We will see if that can be done.

Not surprisingly, I am not the host, so I can't do that.

MR. HEINZ: I believe I saw something that said Magistrate Judge Reinhart might be or -- there we go, it says I can now.

THE COURT: Okay.

MR. HEINZ: Can you see that?

THE COURT: Yes, I see a blank screen, but I do see that we're ready to share.

MR. HEINZ: Okay.

THE COURT: You may proceed.

MR. HEINZ: Your Honor, may it please the Court, my name is Noah Heinz, I represent the Plaintiffs.

The Defendants' motion should be denied because on each point it applies the wrong legal standard and ignores well-pleaded facts.

There are five key points in this presentation that want to hit, consistency, shotgun pleading, why manufacturers should have known about degradation, the failure to warn through the FDA, and punitive damages.

I want to start out with our theory of the case: Ranitidine breaks down into NDMA, it breaks down in the stomach, it breaks down over time, and it breaks down in the presence of heat and moisture. Each of these forms of

degradation add together. The NDMA a Plaintiff ultimately was exposed to depends on the cumulative amount from each of those mechanisms, and NDMA causes cancer.

The complaint alleges that each Defendants' actions increased the total amount of NDMA that Plaintiffs were exposed to. So, how did they do that?

There are three buckets that correspond to the three ways that Ranitidine degrades. Bucket A is the failure to warn about cancer and NDMA. This is mostly a theory against the brand name manufacturers. They failed to warn about cancer, which caused consumers to take Ranitidine for too long, to have it with high nitrite foods, and not to be aware of the risks while they were taking it, but in the failure to warn through the FDA and the failure to test counts, the generic manufacturers, too, are in this bucket for specific states.

Next is bucket B, the failure to warn about, or properly instruct concerning, degradation over time. Both kinds of manufacturers failed to warn through expiration dates, and as a direct result of that failure the Ranitidine had years to degrade into NDMA.

Bucket C is negligence which caused the additional build-up of NDMA due to heat and moisture. There are counts about each Defendant group here. Brands and generics were negligent in two ways.

In Count 9, we allege that they used inappropriately

large containers, which exposed the Ranitidine pills to excess moisture and heat.

Count 11 also alleges they shipped the active pharmaceutical ingredient, which is even more vulnerable to degradation, under hot and moist conditions, and they also stored and transported the finished pills outside the labeled range.

Count 10 applies to the retailers and distributors and alleges that they shipped and transported Ranitidine outside the labeled range as well, which caused even more NDMA to build up.

In their brief, the Defendants made a big deal about saying that these facts are inconsistent. I didn't hear much about that in the presentation, but it is worth emphasizing that this theory is perfectly consistent.

Our opposition explained it is like if you bought a gallon of expired milk, transported it in a hot car and then put it in an unplugged refrigerator for a week. There is nothing inconsistent about saying that each of these actions made the spoiled milk worse for the person who, regrettably, ultimately drank it.

Defendants also argued in their brief again that the facts are inconsistent with the duty alleged. That is not right.

Consider the failure to warn. A Plaintiff can recover

for failure to warn if a warning is inadequate. Alleging that a label is inadequate in one way is fully consistent with alleging that it is inadequate in two ways. There is nothing in State law and certainly nothing Defendants have cited that requires a Plaintiff to allege that the inadequacy she sues under is the only problem with the label or the only thing that made the product unsafe under any theory. The facts and duties pleaded in this case are perfectly consistent.

The next point is shotgun pleading. Shotgun pleading is all about confusion and notice. Weiland notes that it is sometimes confusing to allege claims against multiple Defendants, but it calls that sin of shotgun pleading rare, and it is rare because usually "the complaint can be fairly read to aver that all Defendants are responsible for the alleged conduct." That is exactly true here.

The Plaintiffs identified which Defendants are being sued for each claim, and carefully alleged what each Defendant did or failed to do.

What Defendants seem to want is a separate complaint against each Defendant saying what each one did, but that not only would destroy the efficiency gains of an MDL by removing the ability to use master pleadings, it is not required by the law, and it wouldn't give them any more notice than the AMPIC currently does.

The cases that the Defendants cite show when

group pleading would be confusing. In Magluta, for example, an inmate was held in solitary confinement at four different prisons across at least four years. He sued 14 Defendants alleging violations of the First, Eighth, and Fourteenth Amendments, and saying that all of the Defendants were responsible for each of the acts, something like this.

The Court was saying in that case that the complaint could not be "fairly read" to say that the Defendants who worked at jails two through four were involved in the decision to place Magluta in solitary confinement in jail number one.

The same was true in Auto Alignment, the complaint itself showed that not every Defendant could be liable, but there isn't any similar problem here because the complaint can and should be read exactly as written.

Unable to explain why the complaint cannot be fairly read to allege claims against every Defendant, the Defendants try to compensate by the sheer volume of their citations, but the cited cases don't apply for various reasons.

To begin with, the Defendants cite case after case in which the complaint incorporated every paragraph by reference, a separate shotgun pleading problem that we don't have here.

For another, especially in discussing their "knew or should have known" allegations, the Defendants repeatedly cite cases involving qualified immunity, which has a heightened pleading standard that, again, doesn't apply in a case like

this.

Cases involving Government actors are especially inapplicable because the Eleventh Circuit has cautioned that more is required in suits against Government actors than in ordinary tort suits. More is required to show notice and more is required to show knowledge.

Defendants not only rely repeatedly on Government actor cases, they also cite failure to warn cases that failed because the danger was open and obvious. In that situation, what a Defendant knew or should have known is irrelevant.

The Rule 9 argument, though, departs it from pleading cases altogether, quoting a summary judgment case about preemption and failure -- about preemption and what is necessary to change the label under Federal regulations, which doesn't have anything to do with sufficiency under State law.

Under the case law that actually applies, the AMPIC is not a shotgun pleading because it can be fairly read to allege what each Defendant did.

The next point is whether Plaintiffs have sufficiently alleged that Defendants knew or should have known that Ranitidine degrades into NDMA over time and under hot or moist conditions. We have alleged that, your Honor.

As even the Defendants' cases show, negligence cases, and even more so strict liability, allow should have known allegations, and unlike State actors, pharmaceutical companies

are held to the standard of an expert in the field and they are required to test their product.

Perhaps that is why Defendants repeatedly cite summary judgment cases. They fail to provide legal authority actually dismissing cases on a Rule 12 motion for a failure to allege the Defendants should have known.

Even turning to the facts, the Defendants' position is fairly odd. They argue that even though they should have known that Ranitidine produces NDMA in the stomach, they could not have known to look into whether it already has NDMA before ingestion, but the mechanism here is not strange or surprising.

It is just heat, humidity, and time, precisely the same features that generally degrade medicines, and the mechanisms are not sharply different; both involve a Nitroso source, heat and moisture. In degradation in the stomach the heat and moisture come from the human body and the Nitroso source is from Ranitidine and food.

For degradation over time the heat and moisture come from the atmosphere, and the Nitroso and Dimethylamine come from the Ranitidine itself. This is not a bolt from the blue, especially for companies that were experts in conducting testing on their product.

If that were not enough, the molecular structure itself gave the Defendants notice. Ranitidine has both a Nitroso and a Dimethylamine, which are all the ingredients to

produce NDMA. Valisure's petition expressly flags this and indicates that scientists considering this issue would have been put on notice of the potential for degradation into NDMA simply from the structure of the molecule.

The Defendants' principal response here is to argue that the relevant counts did not incorporate the proper paragraphs. Although the Plaintiffs did not incorporate the graphic itself, the picture of the molecule, or the URL for the Valisure study when it was first cited, which is what the opposition cites on those points, the molecular structure does appear throughout the complaint, including, for example, at paragraph 393. The Valisure study is referenced more than 40 times.

Defendants cannot be surprised simply because the long-form citation was not itself incorporated by reference.

Beyond the molecular structure, early tests should have prompted the manufacturers to test for NDMA, but instead they did nothing. The critical point here is that GSK's Thomas study, which was published in 1987, removed samples of Ranitidine because the studies' authors claimed their test produced a false positive when they tested those samples.

The question that should have prompted for a reasonable manufacturer is, why? A similar thing happened with Valisure's study, they tested, got a sky high result, and then Emery pharma suspected that the heat in the test itself could

be causing a false positive if Ranitidine were heat sensitive, and so tested Ranitidine under various temperatures and found increasing NDMA.

The manufacturers themselves conducted root cause analysis after Valisure's study confirming that Ranitidine breaks down in heat and moisture.

If a suspected false positive in Valisure's study was enough for Emery pharma and for the manufacturers to test for heat sensitivity, why wasn't a suspected false positive in GSK's study enough for anyone else to test for heat sensitivity or for NDMA in the product before ingestion back in the 1980's? The answer is that it was enough for them to do so.

The Defendants' main response is that the counts do not incorporate the right allegations again, but they do. The Plaintiffs cited the long-form citations in their opposition, while paragraphs with super citations were incorporated in the counts. That is easily enough for notice.

On reply, the Defendants also raised a new argument that causation was not alleged because the complaint does not allege who consumed Ranitidine between months 20 and 24, but this misunderstands the allegation.

The complaint alleges that the failure to have an expiration date of a much shorter period of a matter of months caused Plaintiffs' cancer, that means one to two months. Essentially all Ranitidine consumption occurred between months

two and 24, so there is no causation problem. The AMPIC alleges more than enough to support the fact the Defendants knew or should have known that Ranitidine degrades.

The failure to warn through the FDA is the next point, and it is a common law theory rooted in the principle that where warning directly would be impracticable a manufacturer can, and it must, instead warn third parties who are reasonably likely to disseminate the warning. As cases like Coleman have held, the FDA, just like a ski rental shop, fits this description.

The Defendants attempt to limit the state law duty to what Federal law affirmatively requires, namely the filing of adverse event reports. But state law simply requires the most practicable warning, which has been held to encompass adverse event reports where that is the only thing that is possible.

Here, far more is possible since, unlike in the medical device amendment context, there isn't an express preemption clause that limits the theory to only things that are parallel. Defendants could have sent the FDA studies and data, they could have explained the substance of the risk, or even sent a proposed warning about the product the FDA could have posted on its website.

The same reasoning explains why the theory is not limited to medical devices. There is no state law difference

between devices and drugs, certainly none the Defendants have pointed to, and every difference in Federal law cuts the opposite way. Whereas for devices the adverse event reports were all that could be submitted, here an actual warning could have been mailed to the FDA, or the relevant data could have been submitted. If the state law is capacious enough to fit within the medical device context it must apply here where state law has much more latitude.

The Defendants are driven to citing far-afield case law, repeatedly suggesting that Conklin from the Arizona Supreme Court undermines Plaintiffs' authority, but that doesn't make any sense.

For one, California has expressly said that Coleman remains good law, and for another, the AMPIC did not allege any claims under Arizona law.

No more relevant is their citation of the Third Circuit case in Precision Airmotive, which involved an attempt to enforce FAA regulations. The Defendants put forward these distractions because they can't meaningfully dispute the case law that Plaintiffs cited in the AMPIC.

Zooming out from the case-by-case sniping, the Defendants' main argument is that a supposed majority of states, for which they cite only Illinois and Arizona, have rejected the theory, and that this Court must dismiss the claim unless Plaintiffs can provide on-point state law authority.

Even setting aside California, which has a number of cases on this, the Plaintiffs' position is easily the majority rule.

Without much else, the Defendants' argument boils down to saying that every Federal Court was wrong that has recognized this theory under any state's law, no matter how careful its analysis, wherever that state does not have an on-point precedent addressing the precise issue. That truncated analysis is irreconcilable with Erie.

Erie is rooted in ensuring the results in Federal Court do not materially differ from those in State Court based on the substantive law. Federal Courts are to predict what a State Court would do, that is what comity and federalism require, not blindly side with Defendants with a qualified immunity style query of whether the right at issue is clearly established.

Requiring a State tort to be clearly established would produce a gulf between how State Courts address the question and how Federal Courts decide them, which would produce rampant forum shopping and would lead to inequitable administration of the laws in Federal Courts, exactly what Erie aims to eliminate. The Eleventh Circuit has never adopted this rule.

Every case Defendants cite involve requests to recognize new theories that State Courts had rejected or had suggested would be rejected. That isn't true here, as is

evident from the fact that most Federal Courts who have considered the issue have predicted the State would recognize this claim even in the far more challenging medical device context that narrowly circumscribes the type of warning that can be submitted.

On the facts, the Defendants' sole argument is that Plaintiffs have not sufficiently identified particular adverse events, but this ignores that more than half the adverse events that have ever been reported, and essentially every adverse event related to cancer, were filed after 2019.

Apart from that, it simply mingles the State law duty into a Federal law mold. No one would think that the ski manufacturer needed to send adverse event reports to the ski rental shop. That was maybe one option and it is an option that is available in the medical device context, but it is not the only way or even the most obvious way of complying with the state law duty. The failure to plead through the FDA claim is grounded in substantial case law and well pleaded on the facts.

The last point I want to address is punitive damages. We have alleged that the Defendants were reckless, but the Federal rules don't require the Plaintiff to plead remedies.

The simple fact is that Twombly and Iqbal apply to claims, not remedies. As Doe held, a Plaintiff does not have a claim for punitive damages, it therefore cannot be dismissed under Rule 12, which addresses failure to state a claim.

The Eleventh Circuit agrees that a request for punitive damages is not a claim. Nothing in Iqbal or Twombly would change that determination. Rule 8(a)(3) applies here, not Rule 8(a)(2). One requires the showing of an entitlement to relief, that is the language that Iqbal and Twombly focused on; the other requires only a demand for the relief sought, which is very different.

The Defendants cite case law in which punitive damages claims are dismissed, but check the reasoning of those cases. In every case the Plaintiff failed to raise this argument, meaning the Defendants' entire argument rests on forfeiture and assumptions that have gone unstated and unexamined. Plaintiffs research suggests that every Court to have actually considered the issue has ruled our way. The Supreme Court has warned that in our adversary system, when a case does not consider an argument, it cannot be relied upon for the proposition that the argument is wrong, and that applies here.

The Defendants' motion should be denied because the AMPIC pleads a consistent story that they should have known and should have acted, but instead they did nothing.

I am happy to answer any of the Court's questions.

THE COURT: Thank you very much.

If we can have all counsel who argued this motion put your video and your audio on, and I will be clear who I am directing the question to as it relates to the Plaintiffs and

Defendant, in some instances both. State your name for the record as you answer the question. Because we only have one counsel for Plaintiff, you do not need to state your name each time, Mr. Heinz.

If counsel for the defense are going to -- Ms. Zousmer and Ms. Nino, if you are going to alternate who answers a question, then state your name for the reporter.

This first question is a question actually for both the Defendants and the Plaintiffs, so I will read the question. It is kind of long, so listen carefully, I don't want to have to reread it. And the Defendants will answer first and then I will give the Plaintiffs an opportunity to answer. Again, try to be succinct in your answer, although I am not being so succinct at least in this question.

In various areas of the briefing, not just for the AMPIC omnibus motion, but for other motions as well, the Court senses that a main point of contention between the parties may be this: How fact specific can, or should, the Plaintiffs be expected to be in their allegations given that they are preparing master complaints in a massive MDL that involves dozens of Defendants and a drug that was on the market for nearly 40 years, and are preparing complaints that are meant to represent the claims of thousands of individuals across the country?

Neither side has at least explicitly argued whether

the pleading standard is, or should be, different from the master complaints such as these, or provide any legal authority on that point.

Even applying the typical Twombly plausibility pleading standard, the Court wonders whether a much greater level of generality must be permitted in the pleading than a Court might permit in a typical case involving only a handful of parties.

At the same time, the master complaints already total over 7,000 pages, and requiring the Plaintiffs to provide the fact specific, Defendant specific allegations that the Defendants often argue are required could cause the master complaints to balloon to many thousands more pages.

The same concerns arise when the Court looks at the parties' arguments concerning shotgun pleading. Doesn't the Court need to take a practicable workable approach to what it requires as to the pleading for the master complaints?

If I could have Defendants address that first and then the Plaintiff.

MS. ZOUSMER: Your Honor, this is Julia Zousmer for Defendants.

Our position would be that the pleading standard can't change because Plaintiffs have decided to make this a more complex case. They have decided to sue four types of Defendants, more than a hundred of them, under almost every

state's law, and they have to plead the case properly having now done that.

Um-m-m, that would be my general answer to your question.

THE COURT: Okay. Thank you very much.

From Plaintiffs.

MR. HEINZ: Yes, your Honor. The very first rule of the Federal Rules of Civil Procedure says to construe them in such a way as to promote fairness, justice, and efficiency, and this seems like a perfect example of when it should apply.

It is true that if the allegations were fatally flawed, that there was no notice, then Rule 12(b)(6) would mean it has to be dismissed, all that sort of thing, but there has to be some degree of recognition that the notice at issue here is about the general theories that apply in a cross-cutting way.

The specific short-form complaints and things that will be addressed at the bellwether phase are more what the details that they are talking about need to be focused on.

We think it would also be a bit unfair to consolidate everything into an MDL and then dismiss it simply because it is not possible to plead enough detail against every single Defendant when a lot of these Plaintiffs would be very happy to sue and deal with their individual case in a different court.

THE COURT: All right. Thank you very much.

This is a question for Plaintiffs.

Have you alleged -- maybe you did -- you clarified that in your presentation, so I will allow you to confirm what I think I heard you say in your presentation.

The question is: Have you alleged what the expiration period for Ranitidine products should have been? The Court had difficulty locating such an allegation. And if it is not alleged, when is the appropriate time for you to identify that period if not at the pleading stage?

I know you had a chart on that, but can you address that so I am crystal clear on it?

MR. HEINZ: Yes, your Honor. So, paragraphs 938, 1153, and 1740 would be good places to look for that.

THE COURT: I'm sorry, 938.

MR. HEINZ: 938, 1153, and 1740. There are others that are relevant, but that is the part that specifically says "a much shorter period of a matter of months."

It is true that we didn't identify the precise amount of time, but we think that is going to be a question for Daubert and for proof of when exactly enough NDMA would have broken down such that it could contribute to or cause a specific Plaintiff's cancer.

Right around the one to two month range is what we have in mind for the theory.

THE COURT: So, to be clear, paragraphs 938, 1153,

1740, perhaps others, but particularly those, a matter of months, meaning in the one to two month, so that after two months that expiration date is too long and has the effects that the complaint alleges that it has?

MR. HEINZ: Yes, that is correct.

THE COURT: But a more precise time within the one to two months would likely be at the Daubert stage?

MR. HEINZ: Well, the precise -- whether it is one or two, would be at the Daubert stage and there would be a question of if you consume it at three months, maybe it is unsafe, but there is a question of whether it was enough to cause that particular Plaintiff's cancer. All those types of things we would expect to be dealt with with expert testimony.

THE COURT: Is the allegation that within the one to two months, anything after the one to two months, that that allegedly -- the product would cause cancer in and of itself?

MR. HEINZ: It would be that it would degrade into NDMA and the NDMA would cause cancer, or at least contribute to cancer.

THE COURT: Is there a difference between causing cancer and contributing to cancer?

MR. HEINZ: I was thinking about a -- there could be a Plaintiff that had, for example, a certain amount of NDMA from something and then this is sort of the straw that broke the camel's back, and it becomes the but for cause. But no -- no

relevant distinction.

THE COURT: For Plaintiffs as well, you have -- have you alleged that any Plaintiff ingested Ranitidine between the date that you would maintain is the correct date of expiration and the expiration date listed on the packaging, and because of that developed cancer? And could you tell me where in the AMPIC you have alleged this?

So, I guess it would be between the date you maintain is the correct date of expiration, so somewhere between the one to two months, and then the expiration date that is actually listed on the packaging.

How would the Court identify those individuals?

MR. HEINZ: Yes. So, we didn't allege the precise individuals. There aren't any Plaintiffs in the master personal injury complaint. We did allege that it was sufficient to cause each individual's cancer. We think it sort of a fair inference that, of course, they consumed it between months two and 24.

We would point to allegations such as, for example, in each sub count, so I will use sub Count 7 as an example, 7-1, which is Alabama.

If you look at paragraph 1767, it talks about how the warning was inadequate, and then 1768 says that Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiff would not have consumed the volume of NDMA

that they ultimately did and would not have been harmed by NDMA. That paragraph is in each sub count as well.

The reasoning behind that is to say that Plaintiffs would have looked at the expiration date and not consumed it past that time, had it been two months, for example, and that most people consume most of their drugs within the two to 24-month period. So, that seems like a fair inference that almost every Plaintiff did consume Ranitidine within that range.

THE COURT: Have the Plaintiffs alleged how long it takes to manufacture Ranitidine, and by that, including how long it takes to get the product to the market?

MR. HEINZ: I don't believe that is alleged in the complaint.

THE COURT: Okay. This is for the Defendants.

You argue that the Plaintiffs have failed to plead causation as to their expiration date claims. What specifically about the allegations the Plaintiffs have just identified now is insufficient to plead causation?

MS. NINO: Thank you, your Honor. This is Emma Nino on behalf of Defendants.

I think your Honor's questions kind of get to the point that we make in our briefing, which is that, you know, while counsel for Plaintiffs say that it might be a fair inference that Plaintiffs took Ranitidine products toward the

end of the expiration date period, they didn't actually allege that in the complaint, and I think that really is the fundamental problem in demonstrating causation on their expiration date claim based on the four corners of the complaint itself. Plaintiff can't amend the complaint in opposition to the Motion to Dismiss.

I would also say that the mere matter of months, there is kind of the same issue with now pointing to a one to two month period when that allegation was not actually contained in the amended master personal injury complaint.

THE COURT: Okay, thank you.

MR. HEINZ: May I brief on to that?

THE COURT: Let me move on, if I could.

Maybe like a 30-second response.

MR. HEINZ: First, the matter of months portion was, and that was simply what I was elaborating on in saying one to two. It is also worth mentioning that we allege many times the bottles contained something like 200 pills. A lot of times it would be difficult to understand how many people are consuming all of their 200 pack within one or two months.

THE COURT: Okay. Question for Plaintiffs, applying the risk utility test as it is stated in Section 2 of the third restatement of torts, have you alleged that the omission of the alternative design, here a shorter expiration date, renders the product not reasonably safe; and if so, can you tell the Court

where in the AMPIC these allegations appear?

MR. HEINZ: Yes, I can point the Court to the right paragraph, just a moment. My apologies, just a moment.

So, for example, at paragraph 1754 through 1755, which is the design defect claim, also 1759 and 1758.

The basic theory is similar to the failure to warn count, alleging that because there was no expiration date, the product was unreasonably dangerous for that reason.

THE COURT: For Defense, what about those allegations that Plaintiffs have just pointed to in particular is insufficient to satisfy the element that the omission of the alternative design renders the product not reasonably safe as part of the risk utility test?

MS. NINO: Thank you, your Honor. This is Emma Nino on behalf of Defendants.

I think our concern with those allegations in terms of the existence of a reasonable alternative design is that, based on Plaintiffs' theory as explained in the presentation today, because Ranitidine, in Plaintiffs' theory, forms NDMA over time in all sorts of ways, and the one to two-month period is something new that we are hearing today, based on the allegations in the complaint it is unclear what expiration date would render the product reasonably safe if the NDMA formation in Plaintiffs' theory is something that builds over time.

So, it was just unclear from the allegations that

Plaintiffs' counsel points to what exactly a reasonable alternative design would be that would prevent any threshold level of NDMA formation and therefore render the product reasonably safe.

THE COURT: Okay. Another question for Defendants. You move to dismiss Count 7, the strict products liability count for design defect due to improper expiration dates, for Plaintiffs' failure to plead allegations that would satisfy the risk utility test or the consumer expectations test. You have not briefed which states follow which test, and upon the Court's review, that is not necessarily straightforward. Some states might even follow neither test.

How could the Court dismiss Count 7 entirely or dismiss certain state sub counts without first resolving that issue?

MS. NINO: Thank you, your Honor. This is Emma Nino on behalf of Defendants.

I think whichever test the individual state follows, whether it is the risk utility test from the third restatement of torts or the consumer expectation test from the second restatement of torts, the causation prong under both is essentially the same, and our position is that Plaintiffs have not met that causation prong as to either.

So, that is kind of a universal problem, whichever test the individual state applies, but we would also be happy

to submit our authority for which states adopt which test if that would be helpful to the Court.

THE COURT: Okay, thank you. I will let you know if that is something that the Court would need.

For Plaintiffs, the Court wants to better understand your theory of liability for Count 11. Count 10, the storage and transportation count against retailers and distributors, is titled negligence storage and transportation outside the labeled range.

Count 11 against the manufacturers is titled only negligence storage and transportation, and in Count 11 the Plaintiffs fault Defendants for overheating not only finished Ranitidine products, but API as well.

Is the Court correct in understanding that as to finished products the Plaintiffs' theory is that manufacturers heated them to temperatures above the labeled range, but because API does not have a label or labeled range, the Plaintiffs' theory is that the manufacturers heated API to some temperature above that at which the API should have been kept, or is there some alternative theory that the Court has not articulated?

MR. HEINZ: The Court is correct.

THE COURT: I am correct with what I just said?

MR. HEINZ: Yes.

THE COURT: Okay. So, if the parties could not come

up with an agreement about the temperature at which API should be kept, and if this count were to go to trial as to overheating of API, would the trial include conflicting expert testimony about the temperature at which API should be kept, and would the jury be required to resolve that issue, for the Plaintiffs?

MR. HEINZ: Yes, I would think so.

The way this would likely go would be, there would be tests on the API to see at what temperatures it degrades and how much of that ultimately gets into the finished pill, and there would be expert testimony on that topic from both experts, and there would also need to be some type of testimony to establish the relevant duty of care.

THE COURT: Anything the Defendants want to add on that particular question?

MS. NINO: Nothing from me, your Honor, unless another counsel for Defendant has anything that they wanted to add.

THE COURT: Okay. With respect to -- for Plaintiffs, is the Court to understand from reading Count 11 that it is your allegation that all of the manufacturer Defendants heated all of their finished Ranitidine products during all times that they are manufactured for duration and to a temperature that caused the formation of cancer causing levels of NDMA in all products?

I guess the followup would be, if you are not alleging

all Ranitidine was heated, the question would be which Ranitidine you maintain was heated and when, and if not at the pleading stage, when would you be called upon to identify which Ranitidine you maintain was heated or overheated?

MR. HEINZ: Right. So, the allegation would be that there is a failure to ensure temperature control and humidity control and there are some allegations about that, for example, in like 393, in around that area for particular Defendants. So, we do have some Defendant specific allegations on that point, but the allegations are meant to say that there was a general failure to ensure that the Ranitidine was not heated.

That doesn't necessarily mean that in the process of it they each heated every single pill to a certain level. The allegation is that they were negligent in not ensuring that the Ranitidine didn't get hot, for example, on a hot day.

Maybe there was nothing that would have heated Ranitidine at certain times of year, and so for that it wouldn't be hot, so the allegation isn't every single pill, just that it was a widespread failure.

THE COURT: Okay. For Defendants, you challenge Count 11, a count against you for negligent storage and transportation on plausibility pleading grounds. The MMC also pleads counts against several manufacturer Defendants for negligent storage and transportation, and you have not challenged the plausibility of these counts in the omnibus

motion directed to the MMC.

Is it your position that the negligent storage and transportation claims in the MMC are plausibly plead? If so, what about those claims in the MMC distinguish them from Count 11? Yes. So, that is the question.

MS. NINO: This is Emma Nino.

I would defer to counsel who are arguing that motion if they have a different position on this, but I would say as a general matter, taking the -- in the process of briefing the complaints, which are voluminous and the briefing process was simultaneous, we were attempting to bring our best arguments to bear as to each motion, but I wouldn't necessarily want to weigh in on the sufficiency of the valuations in the MMC because my focus was on the AMPIC.

THE COURT: No problem, and I understand that. At the right time, when counsel is on for some other motion, but remembers that that was a question I posed, and if counsel feels he or she needs to weigh in on that, by all means do that, but I don't think we need to bring up anybody now.

Okay, thank you all so much. That concludes the questions that I have for the motion at Docket Entry 3111. You can feel free to turn your screens and audio off.

I will now ask counsel for the next motion, which is the brand name manufacturers' Motion to Dismiss innovator liability claims, Counts 12 and 13 in the amended master

personal injury complaint and incorporated memorandum of law at Docket Entry 3109, first from the Defendants, and you will have ten minutes.

Did you want me to give you any warning or did you want to reserve any time, Mr. Cheffo?

MR. CHEFFO: Yes, good morning. Thank you. I would like to reserve two minutes. I think I will probably fall within that, but if you wouldn't mind letting me know, that would be great. Thank you.

THE COURT: I will do my best, so I will let you know at eight minutes. You may proceed.

MR. CHEFFO: Good morning, Mark Cheffo representing GSK, but arguing on behalf of the brand manufacturers. Let me first say it is good to see the Court, and when it is safe and appropriate, I know I speak for everyone, we are looking forward to seeing you and your staff in person.

As I said, I will be arguing the brand manufacturers' Motion to Dismiss the innovator liability claims, which is Counts 12 and 13 of the amended personal injury complaint and, as the Court notes, this relates to California and Massachusetts.

In our initial motion we argued that to demonstrate that the claims arise out of, or relate to the brand name manufacturers' activities in California and Massachusetts, Plaintiffs had to allege two things; first that the activities

were the but for cause of Plaintiff's ingestion of generic Ranitidine, and two, the brand name manufacturers should have foreseen that their activities would expose them to liability for injuries sustained by generic products.

As the Court knows, in our reply we recognized, somewhat unfortuitously, that the day or two after our brief was filed the Supreme Court came out with the Ford decision, and we have recognized that that essentially mooted the first argument with respect to but for. I am only raising that just to alert the Court that that is not on the table for today.

However, we think the second argument, which I am going to focus on in the next few minutes, is not only viable, but with all due respect, we think it remains a dispositive issue.

So, Plaintiffs must plausibly allege that Defendants should have foreseen that their activities regarding the brand name products could expose them to liability for injuries sustained from the ingestion of generic Ranitidine products. We don't think that they have, or frankly, that they can make those allegations.

The brand name manufacturers could not have foreseen that by promoting and selling their own products, whether it is months, years, or sometimes decades before, in California, that they ran the risk of being hailed into court, again, months, mostly years or decades later, to defend against injuries that

were allegedly caused by other products and other manufacturers.

As we cited in our briefs, I think this is essentially black letter law, the specific jurisdiction must be based on the conduct that the Defendant himself or herself or itself creates within the forum state, not the unilateral acts of third parties, which here, as the Court knows, they are third parties, and in many regards they are competitor products of which the brand name manufacturers have no control and no benefit from any of these sales.

I will talk in a minute about the equities, but fundamental fairness I think is very important in this Court's analysis because there is no benefit, there has been no control, and this is from competitor products.

Now, what is also important, the Plaintiffs, as your Honor knows, focused on general activities, like here is what happened years ago, here is marketing, here is sales of your products, and we think, respectfully, that kind of misses the point here.

None of the brand name manufacturers' conduct in California or Massachusetts actually relates to the innovator liability claim, as your Honor went through in some detail. This is a somewhat novel and certainly minority position, but the whole point here is that this is a failure to update the label. This is not someone saying I read a label 30 years ago

and it caused me to use this product.

It is basically that the conduct at issue here, the allegation at least is that there was some type of recklessness in failing to update the label that led the label that was on a generic product not to have the appropriate information. That is the conduct at issue here, and I think, as we have highlighted in the briefs, and we can look at the very lengthy complaints, but the Plaintiffs don't say, well, here is what happened in California, here is what happened in Massachusetts.

The reason for that is that type of information is typically done at a headquarters, right. It is usually done where the company is based, or at the very least, if it is not, it is certainly not alleged in the complaint that that type of conduct is something that occurred in these two states, and we think, again, that is a dispositive issue.

The cases talk in terms of foreseeability, fundamental fairness, fair warning, and the foreseeability aspect is not that it is foreseeable that an individual who took a product couldn't be injured. That is a level of foreseeability that is separate and apart from this analysis.

The analysis is, if you engage in conduct and market and sell and promote your product consistent with the law, the FDA approvals, should you then -- is it foreseeable, is it fair that at some point, sometimes decades later, that you should foresee that you will be sued for alleged injuries by

Plaintiffs who never took your product and it was sold and manufactured and promoted by a wholly different company.

So, we think this is very, very different than the Ford case, notwithstanding the fact that we recognize the first aspect of our motion was addressed in Ford. Ford doesn't in any way affect this. In fact, we think it is fully consistent with this argument because Ford required specific conduct of the individuals. There it is different to say we sold -- I think it was Crown Victorias and other vehicles, and therefore you should expect to be sued.

That would be an argument if I said, well, as to GSK, to the extent that we sold it in Wisconsin or Wyoming, we are not arguing that those -- that would be a different analysis as opposed to saying because we sold branded product and may have engaged, and likely did, in conduct years ago in another state, that is somehow for all time. That is basically what the Plaintiffs seem to be arguing, is that for all time these companies would be expected to be hailed into court.

I think I am probably getting to my time, so I am going to stop other than to make sure I highlight, we do have an argument also with respect to Patheon.

The Plaintiffs' own pleadings allege that Sanofi, not Patheon, controlled the label. We think they tried to get around that by -- and there is nothing with shorthanding or saying this includes for purposes of argument, so you don't

have to repeat words all the time, but that is not a mechanism essentially to change the status of a Defendant. Just by saying when I say Sanofi it includes Patheon, does not necessarily mean that Patheon is, in fact, the manufacturer who was in charge of the label. So, we have an understanding of who was in charge of the labels at different times, Patheon was not, and that cannot be corrected simply by using an umbrella term.

I am going to stop there, your Honor, and reserve the remainder of my time.

THE COURT: Okay. That was seven minutes and three seconds, so you have about three minutes left.

Okay. If we could hear from Mr. Longer, ten minutes on behalf of the Plaintiffs.

MR. LONGER: Good morning, your Honor. For Ms. Stipes' benefit, my name is Fred Longer. I am going to be arguing the innovator personal jurisdiction argument.

THE COURT: Good morning, Mr. Longer.

MR. LONGER: So, the AMPIC clearly and definitively provides more than ample factual allegations to support the assertion of personal jurisdiction over the branded Defendants for the negligent and reckless misrepresentation claims that we have asserted against them under California and Massachusetts law.

We followed the Court's prior innovator liability

order to the T. The AMPIC now has an entire section devoted to allegations of fact that place Defendants' activities in California and Massachusetts, those are paragraphs 228 to 232, all of which support personal jurisdiction.

Also, there are now two separate counts, one each, for the California and Massachusetts causes of action. In Counts 12 and 13 we clearly allege the foreseeability that Mr. Cheffo just said was lacking of the Defendants' liability based on their activities in those states, and that is at paragraphs 2670 to 2680, and 2695 to 2705.

Your Honor, the activities demonstrating a connection between the Defendants' misrepresentations in both states are alleged to be, one, they employed sales persons to educate physicians about the Zantac label and promote prescriptions of the drug; two, they conducted market research there; three, they contracted the social media outreach firms for targeted advertising and marketing in the forum states; four, they conducted medical studies to influence the medical profession; five, they advertised on the internet, television, radio, and print to promote the sale of Ranitidine products, including the label; and six, they contracted with retailers and wholesalers to expand the Zantac business.

In California, we also know that they targeted the California medical formulary.

Regarding foreseeability, we allege the Defendants'

knowledge about generic free writing made it foreseeable that their sales and marketing efforts in the forum states would encourage generic usage. That is paragraph 232-G, your Honor.

Paragraph 232-G, which Mr. Cheffo must not be aware of, states "brand name Defendants are well aware that generic manufacturers do not engage in much, if any, sales and marketing activity directed toward consumers, that most third party payors encourage or require generic use once generics enter the market. The generic manufacturer product labels must match the branded label in many material respects, and the generic manufacturers offering bioequivalent medicines with the same safety and efficacy profile free write off the sales and marketing activities of brand name manufacturers."

It was, thus, entirely foreseeable that the sales and marketing activities of brand name Defendants in California and Massachusetts would cause providers and consumers in California and Massachusetts to switch to generic Ranitidine once generic manufacturers entered the market.

Finally, your Honor, the amended complaint alleges that the brand name manufacturing Defendants were aware that their liability exposure to innovator liability claims existed because of the common law principles espoused in the restatement second, Section 311. That is at paragraphs 2670 and 2695.

We just heard that the brand Defendants refuse to

accept or acknowledge any of the allegations set forth in the complaint that describe the activities related to their sale of Ranitidine in California and Massachusetts. They refuse to accept or acknowledge the allegations that describe the foreseeability of those activities that render Plaintiffs' claims to be foreseeable.

They refuse to acknowledge that Patheon was responsible for the label along with Sanofi, as we alleged in the complaint, but the allegations in the complaint say what they say and clearly support what I am saying to you now and what we have said in our opposition.

I hate to remind the Court of something this basic, but on a Motion to Dismiss every factual allegation we assert must be accepted as true and every reasonable inference be provided in favor of the Plaintiffs, not in favor of the Defendants.

So, when I hear Mr. Cheffo say there are no allegations about where the labeling occurred at anyone's headquarters, he doesn't get a reasonable inference. That is not a fact pleaded, he doesn't get that inference. The inference is that the labeling decisions occurred around, and some of them at least occurred in California and Massachusetts, along the lines of what we are alleging.

So, as Mr. Cheffo pointed out, Ford Motor Company came out the day after their brief was filed, and that has literally

wiped away their centerpiece but for causation argument, so they now concede that but for causation is irrelevant, and their focus is entirely on foreseeability.

As I already pointed out, we alleged foreseeability as a matter of fact in paragraph 232-G, and for purposes of their Motion to Dismiss the Defendants have admitted that fact and they don't get to challenge it, although, I am sure in rebuttal Mr. Cheffo will give it a shot.

Ford Motor Company as well, your Honor, addresses foreseeability. At the Supreme Court Ford argued that it could not have foreseen those Plaintiffs' specific claims because its in forum activities did not sufficiently connect to the suits. But the Supreme Court rejected that argument of Ford's because when a corporation has continuously and deliberately exploited a state's market it must reasonably anticipate being hailed into that state's courts to defend actions based on products causing injury there.

That reasoning of the Court equally applies to the branded Defendants' misrepresentations as it did to Ford's products.

We cited Exhibit Icons where Judge Marra held that negligent misrepresentation claims are torts that can establish personal jurisdiction, especially where an out-of-state Defendant makes telephonic, electronic, or written communications into the forum and the cause of action arose

from those communications.

The Defendants ignored this case entirely in their reply. It didn't suit their narrative which focuses on them having liability for their competitor's product, but that is not what our claim in Counts 12 and 13 are about.

We are talking about the misrepresentations they made on their label which, by extension of law under Mensing and Bartlett, is the same label on generic Ranitidine. Those misrepresentations occurred in Massachusetts and they occurred in California.

We also allege that the Defendants were on notice of the common law principle in Section 311 of the restatement of torts which recognizes a duty of care when the actor's conduct creates a risk of physical harm. It has been on the books since the mid '60's and it is quoted at length in T.H. versus Novartis.

So, as a matter of fact it was entirely foreseeable that the Defendants could be held liable for making such statements in California and Massachusetts, and as the restatement points out, as we did in our opposition, there does not have to be a pecuniary benefit conferred on the Defendants. They keep harping on this narrative that it wasn't our drug that harmed these Plaintiffs, it was our competitors, but they are liable because they made misrepresentations in support of their branded versions of that product that took the form of

marketing, advertisements, and sales of the misleading labels for that drug in those states.

There is no question that they received substantial benefit in those states from that activity. They may not like the law of T.H. versus Novartis, they may not like Rafferty, but this Court has already ruled that it is indisputable that those Supreme Court rulings control these claims.

So, the quid pro quo that the Defendants contend is lacking is actually existing to the tune of billions of dollars that they have received in the sale of their own product.

So, in short, all of the requisite factual allegations for personal jurisdiction have been adequately alleged in the amended complaint.

I won't talk about legislative jurisdiction, as Mr. Cheffo avoided it, because it is the same standard, and we have already won hands down on the one, so there is no point in arguing something else that is a clear winner.

As to Patheon, they appear to be arguing a 12(b)(6) motion, your Honor, not a 12(b)(2) motion, and that is how we started out here. This Court previously ruled that Patheon is subject to general jurisdiction in Massachusetts. That ruling was undoubtedly correct because the only partner in the LLP that owns Patheon is Thermo Fisher Scientific Incorporated, whose principal place of business is Massachusetts.

THE COURT: Okay. That is ten minutes.

MR. LONGER: Okay, that's fine. All I was going to say is that they don't get to challenge the allegations of the complaint regarding Patheon controlling the label, and even though it's grouped with Sanofi, it controlled the label, that is the allegation.

THE COURT: Okay.

MR. LONGER: Thank you, your Honor.

THE COURT: Thank you so much. Okay, three-minute rebuttal.

MR. CHEFFO: Thank you, your Honor. I would, of course, assure my good friend Mr. Longer that I actually have read the complaint and the briefs which highlight these arguments, so they haven't really been a surprise to anyone.

But I think we have a fundamental disconnect, and everything you heard is consistent. What the Plaintiffs simply keep reiterating is that they want to talk about conduct that doesn't relate to the labeling. There is no dispute that if you are a car company, a manufacturer of pharmaceutical products, you will likely have a global footprint and engage in certain activities.

The core question here is do any of them -- and you haven't heard in their briefing, in their complaint, or in their oral argument here any tie-in, any connection between the labeling conduct, the Plaintiffs have had a full and fair opportunity to do that, and -- with respect, because ultimately

this is not a claim about -- we have claims about GSK said X, Y, Z in connection with the sale of their products, right, and there is liability.

This is a wholly separate claim. Your Honor has, and I am sure will go back if you have any doubt and read the cases that talk about it, and it is a fundamentally different cause of action. It is a failure to update the label, it is a minority position. It is an unusual law, but it is a law in California and Massachusetts, but it is -- it is relatively narrow and it is tethered again to those specific issues.

It is not all conduct, all things, can we pick anything and say, because you had that activity in a particular state, therefore you are somehow on the hook for this somewhat novel theory.

So, I am going to stop there so your Honor doesn't have to stop me.

THE COURT: Okay. Mr. Longer, you can come back on. I have some questions.

So, for the Defendants, can you cite to any MDL case where a ruling was made on personal jurisdiction based on a master complaint at the Motion to Dismiss stage?

MR. CHEFFO: Wow, your Honor. I have been involved in many, and I am sure folks on this -- I have to say the answer is yes, but honestly, probably in the 20 that I have been directly involved in, I couldn't honestly tell you off the top

of my head procedurally, but certainly that is an answer we can get to you relatively quickly.

I wouldn't think that there is any difference. In fact, I would think it is, frankly, an efficient way of addressing these issues, you know, for all the reasons that your Honors took up in such great length and detail and devotion to these issues, that this would be an appropriate issue where it can be addressed on the law and on the pleadings.

THE COURT: Well, I guess that is my question. Do you think it is an issue better addressed at a later stage in the context of individual Plaintiffs in cases? I am sensing you think not, but I want to hear your response.

In other words, are there any facts that could be developed in the record as the litigation proceeds particularly as to individual Plaintiffs that may create a clearer record as to whether specific jurisdiction exists in a specific case?

MR. CHEFFO: Thank you for that, your Honor. I think the answer is no, and I think that is why we made this motion at this point. We are, obviously, mindful that we need to be strategic and targeted and not paper your Honor with a million motions.

Here is why I think the answer is that this is perfectly appropriate, because you heard from the prior argument that this is a master pleading, maybe we don't have to

dot all the I's and cross the T's, maybe we disagree with that, but we have an ability to make these broad claims and then we can figure out later, arguably, whether they apply to specific people or not. Putting aside whether I agree with that or not, they have an ability to make those broad claims.

Here the point is that there are no claims, right, that the labeling conduct was in Massachusetts or California. If they haven't made it in the macro, the idea that we should wait for the micro would seem to be inefficient when they have had now two opportunities to tell us.

It would be a different thing if they said here are these broad allegations, X company had their headquarters, here is what they did, and then ultimately we had to determine if it impacted individual Plaintiffs.

That is not the case here. That is why this is absolutely an appropriate time, your Honor.

THE COURT: And from the Plaintiffs.

MR. LONGER: Your Honor, first of all, this is a master complaint. I am not aware of any Court that has done the dismissal that your Honor asked about.

I tend to believe that because there are going to be short-form complaints being filed, those Plaintiffs could actually articulate in their short-form complaints even more allegations than what we already say is more than ample to put the Defendants' conduct into California and Massachusetts.

THE COURT: What kind of allegations, for example?

MR. LONGER: That the individual Plaintiffs could put in?

THE COURT: Yes.

MR. LONGER: Well, they may be able to say, I read their label side-by-side in the drugstore and I relied -- I saw it was the same, I bought the cheaper one.

Certainly that type of labeling review puts the Defendants -- the branded Defendants' label into the hands of a California or Massachusetts Plaintiff, and that certainly is a fact that could lay on personal jurisdiction.

THE COURT: From the Defendants, if you are saying that the Plaintiffs haven't made any claims about labeling in California or Massachusetts -- and I am going to followup on questions about that -- why is it the Defendants didn't move to dismiss the two counts for failure to state a claim?

MR. CHEFFO: Well, because I think, your Honor, we recognized at this stage that the claim, and we went through that entire briefing on state by state, that there was sufficient case law, at least at this point, that on a Motion to Dismiss, we made a determination that it wasn't appropriate for a Motion to Dismiss.

So, that would be my answer to that question, your Honor.

THE COURT: Okay. Some housekeeping here.

Plaintiffs, Count 12 of the AMPIC, paragraph 2668, is a claim of negligent misrepresentation brought against brand name manufacturer Defendants by generic consumers in California.

Count 13, AMPIC paragraph, 2693 is a claim of reckless misrepresentation brought against brand name manufacturer Defendants by generic consumers in Massachusetts. I want to make sure I understand what in California and in Massachusetts means.

Are these counts meant to be brought by California and Massachusetts residents only; yes or no?

MR. LONGER: I think the answer is, it is intended for California claimants, or in Massachusetts. If a non California or non Massachusetts Plaintiff could through some choice of law analysis assert that claim, then I guess the claim would be available for those Plaintiffs, but the answer to your question is California, Massachusetts.

THE COURT: Residents only.

MR. LONGER: Yes, your Honor.

THE COURT: And are these counts meant to be brought in Federal Courts in California and Massachusetts only, or are they meant to be brought in other states?

MR. LONGER: As I said, your Honor, to the extent that a choice of law analysis could -- someone could apply that law, then the answer is yes. Can it be applied in Federal Court as opposed to State Court? It could be applied in both.

THE COURT: Thank you. Defendants, on page seven of your Motion to Dismiss, at Docket Entry 3109, you say "when the brand name manufacturers sold and advertised their products in California and Massachusetts they received the protection of those state's laws and tacitly consented to the possibility of litigation in connection with their own products and advertisements."

As the Court understands it, that statement is a concession that you have purposely availed -- that is the Defendants have purposely availed themselves of the privileges of conducting activities in California and Massachusetts with respect to the Defendants' own products, and thus must defend litigation stemming from their own products; is that correct?

MR. CHEFFO: That is correct, your Honor.

THE COURT: Okay. You also argue on pages seven and eight of your motion that you "did not by promoting your own products consent to litigate claims brought by all users of Ranitidine no matter what company produced or sold the medication for as long as it stayed on the market" because you "received no benefit for the sale and consumption of generic Ranitidine in California and Massachusetts, so the quid pro quo necessary to support specific jurisdiction is absent."

Is your argument that if the litigation does not involve your own product you have not purposely availed yourselves?

MR. CHEFFO: I think the answer, to be succinct, is generally yes. That is a relatively broad proposition, and I think I am limiting it to the innovator liability concept and theory here.

I could see theories -- for example, there could be a litigation where someone alleged to take two brand products and a Plaintiff can bring a lawsuit if they used it over a period of time.

To answer your question most directly, I think the issue here is, we are not trying to have a broad principle that all litigation that doesn't -- that only involves our product, I think we are focusing specifically on the innovator liability and saying there has to be certain predicates to that when we are looking at related to or arise out of. That is why we are focusing on the labeling issue.

THE COURT: I am going to get to that. I am focused more on the purposeful availment prong, and is it not the case the purposeful availment is about the particular foreign states that you purposely avail yourself of rather than the specific claims you purposely avail yourself of?

Later arise out of we will talk about in a moment relating to the claims, but I am focused on purposeful availment.

MR. CHEFFO: Right. Look, as I answered your Honor last time, to the extent a Plaintiff purchased a product that

was manufactured by a Defendant, right, in a state and that was used, typically that is going to have purposeful availment jurisdiction.

I think our point here is, to the extent that there is in other contexts purposeful availment, and there could be broad jurisdiction in terms of the types of actions and litigation that they would be subjected to, it doesn't go so far as to extend to third parties and different products.

That general principle would probably be true, you know, in a lot of different contexts. So, I don't think -- if what you are asking is, just because there is general purposeful availment, does it apply to all claims of all time, no, I don't think it does, your Honor.

THE COURT: This is for the Defendants as well. In Ford Motor Company versus Montana Defendant Ford conceded purposeful availment from the outset because of the business that Ford regularly conducts in Montana and Minnesota. That is Ford Motor Company versus Montana, 141 Supreme Court 1017, at 1028, 2021.

The Supreme Court noted that this concession was unsurprising due to its widespread sales activities in the forum states. Specifically, the Court noted that "by every means imaginable, among them billboards, TV and radio spots, print ads and direct mail, Ford urged residents of the foreign states to buy its vehicles."

In this case, Defendants admit on page seven of their Motion to Dismiss, at Docket Entry 3109, that they "sold and advertised their products in California and Massachusetts."

So, can you explain how the activities, just the activities in the forum states in Ford and the activities you have conceded here differ for the purposes of purposeful availment? This is a different question than I am going to get to regarding relating to and arising out of.

MR. CHEFFO: Yes, your Honor, I am going to try to answer that.

I would use the analogy, if Ford -- in that case, if there were a cause of action against a Chevy, someone had a Chevy car, it wouldn't be purposeful availment. So, while we concede that when we are talking about GSK's products and activities there was purposeful availment as a result of what it did in the sales and marketing and promotional activities.

I guess what I am saying is that this type of claim -- it is hard to differentiate these two issues of related to or personal availment because there was no expectation when it purposefully availed itself in selling its own products into California or Massachusetts that it was purposely availing itself for the sale of someone else's products perhaps decades down the road.

So, it is not a concept that just because it was there for one purpose, that for all purposes, particularly these

unrelated claims -- again, the Ford Chevy would be the same, just because Ford sold its Crown Victorias doesn't necessarily mean that it could be subject to a lawsuit if someone said I bought a Chevy, and there was some kind of concept there.

THE COURT: Thank you. Brief response from Plaintiffs, if you have one, on just the purposeful availment question.

MR. LONGER: Your Honor, you stole my thunder. I was going to cite to your Honor the Ford Motor Company case where Ford conceded that they had done so much business around the country that they could be found anywhere, and that they purposely availed themselves of the United States' entire market. Those same facts apply to Pfizer, apply to GSK, they can't walk away from that.

The very same analysis by the Supreme Court that it is no surprise that they purposely availed themselves of the market applies.

It is not the product, it is the misrepresentation, it is what is on the label. That information was pumped into California, it was pumped into Massachusetts. It doesn't matter that it is on a generic product or that the generic product was sold because the label on the generic product, under the duty of sameness, is the brand name's label. They can't walk away from that.

THE COURT: Okay.

Let me switch gears a little bit to the arise out of, relate to aspect of the analysis.

Plaintiffs, on page ten of your response you explain that you are "seeking to hold Defendants accountable for misrepresentations they made about Zantac, representations that failed to inform doctors and patients that Ranitidine contains NDMA and causes cancer."

You allege in the AMPIC at paragraphs 2684 through 2685, and 2709 through 2710, the Defendants falsely represented -- falsely "represented to Plaintiffs via the media advertising website, social media packaging and promotions" that Ranitidine containing products were safe and effective.

You further allege that those misrepresentations foreseeably led to generic consumers being misled about the cancer risk from generic Ranitidine and that those misrepresentations occurred in California and Massachusetts.

As a result, you claim that "it is the context related to those misrepresentations that control the jurisdictional inquiry" and thus your misrepresentation claims "relate to" Defendants' contacts, i.e. their misrepresentations.

First, have I summarized that correctly, your allegations?

MR. LONGER: I am going to accept everything your Honor said about the allegations, it looks fairly accurate. The answer is yes.

THE COURT: Okay. As I understand the case law in California and Massachusetts, which I have read, the culpable conduct underlying claims premised on this theory of liability is a brand name manufacturer's reckless or negligent failure to update the warning labels of their brand name products. For example, in Rafferty versus Merck and Company, 922 ME 3d. 1205, at 1220, 2018, the Massachusetts Supreme Judicial Court held that a brand name manufacturer Defendants' culpable conduct giving rise to a claim by generic consumers under Massachusetts is its "intentional failure to update the label on its drugs."

Can you cite to any case law in which a brand name manufacturer Defendant has been held liable to a generic product consumer for statements it made outside of the label with respect to the safety and efficacy of its product; yes or no?

MR. LONGER: In the context of this claim, I cannot.

THE COURT: Okay.

MR. LONGER: But I also haven't looked very extensively. If your Honor would prefer some supplemental briefing, I would be happy to look. Certainly the Rafferty case and the T.H. v Novartis case, those Courts found the liability existed.

THE COURT: With respect to the label. My question was anything outside of the label.

MR. LONGER: Right, with respect to the label. So,

outside of the label I am less certain of in this context.

THE COURT: Okay. Would imposing liability for misrepresentations outside of the label be an extension of the claims recognized by California and Massachusetts Courts? If so, is this Court the appropriate one to be extending the claim?

MR. LONGER: Under Federal Law, the label extends to all manner of advertisements that goes beyond just the label, so all activity that is related to the label is the label.

THE COURT: What are you citing, what authority supports that? I didn't see that in the brief.

MR. LONGER: No, it wasn't addressed. It has not been addressed until now, your Honor.

THE COURT: Is there a case that you can tell me?

MR. LONGER: I can cite to the Federal regulation, but I don't have that Federal regulation in my head.

THE COURT: Which Federal regulation?

MR. LONGER: The 21 CFR dealing with the Food and Drug Act, there are regulations about what the label includes, and advertising and the like is captured under the definition of the label.

THE COURT: So, I'm sorry, you are saying that under the Federal regulations, marketing and other activities constitute labeling, advertising, social media?

MR. LONGER: The FDA controls a lot of advertising,

your Honor, and that is because it controls the label.

So, I'm told that Section 201(k) of the CFR, and everything is labeling, your Honor, so that is the answer to your question.

THE COURT: So --

MR. LONGER: And you wouldn't be extending any California and Massachusetts law, you would actually be honoring it and applying it faithfully.

THE COURT: For the Defendants, you maintain on page six of your reply that innovator liability claims can never arise from the sale or marketing of the branded product.

Do you have any authority for the proposition that, under California or Massachusetts law, the theory cannot apply to misrepresentations outside of the labeling?

I guess connected with that question, now that we have heard an answer that I didn't see in the brief, maybe you want to respond to that as well, that I am hearing a broader definition of labeling than I might have otherwise understood, or at least understood from the briefing.

I understand the FDCA defines the term "labeling" as all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article, 21 U.S.C. Section 321(m).

MR. CHEFFO: I would say I think it is an expansion. I would also concede that labeling can be relatively broad

depending on how it is viewed, but there is a labeling -- that goes again to the issue here, the breadth and scope of what the Plaintiffs are suggesting.

Just to -- under Mr. Longer's -- from his response, every, basically -- there will be personal jurisdiction in every single case, we wouldn't need to go through this analysis because he is saying, essentially, if there was a label that was previously promulgated by a company, there is automatic jurisdiction. We submit that can't be the case or consistent with the law.

I think also what we need to look at are the specific allegations. I think your Honor asked me earlier about this. I think we have to look at the specific allegations for innovator liability and whether there is jurisdiction as to those.

Again, we haven't seen whether he is saying it is now all promotion, all marketing, all sales. There is no allegations that those types of labeling conduct, even if they were broad, were done in California or Massachusetts, which again they have to be or else the converse would be there would be personal jurisdiction for all things and all time, and that is not what Ford said.

The thing that is really important about the Ford decision, where I think it is critically important, is that there you had the same product, it was the manufacturer. So,

we are not making distinctions here about GSK's own product, so that is the real big difference here, is that it is another company.

I know that the Plaintiffs want to ignore that and say, well, this is about the company's representation, but that is not the crux of what the innovator liability theory is all about.

THE COURT: I have some more labeling questions, but let's assume the more narrow definition of labeling may be consistent with what I just read with respect to the FDCA defining labeling.

Let's assume the scenario that Mr. Longer presented in answer to my question about whether this is an issue that might be more appropriate at a different stage in the litigation, whether there are any facts that could be developed with respect to individual Plaintiffs that could enlighten the Court because, as we know, personal jurisdiction, while the Court should try to address it as early as it can, it can be addressed at other stages of the litigation. It is not if you don't address it now, it can never be raised again.

What about a store with a brand product and a generic and, you know, so you have the labels on both, and the individual Plaintiff sees both and decides to go with the generic because of what he or she reads with respect to the brand, or something along those lines, very case specific

individualized label oriented scenario, closer to asserting personal jurisdiction?

MR. CHEFFO: Here is why I would say no, and I am going to try to be as succinct as I can, your Honor. I think that is a little bit of a strawman argument, and let me tell you why.

If you go with our view and what we think the case law is in these two states, it is a reckless failure to update the label.

So, someone essentially had to make a determination not to, you know, update the label. Our point, and we think the case law supports this, that decision from a jurisdictional perspective must have been made in California or Massachusetts in order to get -- it has to relate to that. That is really what this is about. It is a very novel claim.

To your point, we know, based on the way the thing should work, the label should be the same, right, for the branded as the generic, right. That is kind of the point of innovator liability. The cases have said because they have to be the same, to the extent that you recklessly failed to update in these two jurisdictions with a little bit of different law, they are saying we are going to have a cause of action for that.

The fact that someone may see two different labels, that is really not the issue here because we would expect them

to be the same.

The question is, if someone buys the generic, and then they have a cause of action against the generic, or if they bought my client's product and they have a cause of action, can we now have a separate wholly different cause of action for someone who never marketed, promoted, sold, did anything with respect to that from a third party, does that create liability? That is where the question of who is in charge, who did the labeling activities, it is not the downstream.

That is why I answered your question earlier, your Honor, that we could do kind of discovery until we are blue in the face, or we could do individual fact sheets. That is kind of -- with all respect, that is kind of a Plaintiff punt, maybe we'll see something later.

If, in fact, they can't establish or they don't have allegations that we, the Defendants, did something in California, it is not going to matter whether someone read a label five years or ten years down the road.

THE COURT: Okay. So, let's drill down a little bit more on the labeling. Plaintiffs, in paragraph 225 of the AMPIC you allege that at all relevant times, among other activities, all Defendants in the AMPIC, including brand named manufacturer Defendants, labeled Ranitidine containing products within the judicial districts listed in the short-form complaints.

What specific labeling related activities are alleged to have occurred within those judicial districts?

MR. LONGER: Well, all of the activity that the Defendants engaged in with regard to the label is labeling, your Honor, and your Honor pointed out Section 321(m) of the U.S. Code.

The -- I'm sorry. We are kind of more focused on our allegations specific to the negligent misrepresentation claims that came later.

So, if you would, what is the question that the Court has?

THE COURT: I want to know what you are saying in 225 when you say that at all relevant times all Defendants in the AMPIC, including the brands, labeled Ranitidine containing products within the judicial districts listed in the short-form complaints.

What is labeling related activities? Are you alleging that labeling activities occurred in all judicial districts? What is labeling activities specifically?

MR. LONGER: Yes. So, the labeling activities that that paragraph is referencing is broad, but it certainly encompasses the label itself. So, just as the Defendants conceded long ago, that their activities regarding their own products occurred -- or that they would be subject to personal jurisdiction in California and Massachusetts for their own

product, and that was conceded long ago, that is the type of labeling activity that this paragraph references.

Everyone was labeling their -- everyone -- the manufacturing Defendants were labeling their products and distributing them across the country, and that labeling activity occurred around the country, in every district where a Plaintiff was named in a short-form complaint.

THE COURT: Are you alleging that the brand manufacturers made labeling decisions in California and/or Massachusetts, they made their labeling decisions there?

MR. LONGER: We are alleging that labeling decisions occurred in those states, but we --

THE COURT: Where do you allege that?

MR. LONGER: We don't have the -- where the decision was made. Let me say it differently because I think I may have misspoken.

The activities of the labeling decisions occurred in those states. Where the decisions were actually made are not alleged in the complaint.

THE COURT: Okay. You have not alleged where the labeling decisions are made, okay. I thought I heard you say earlier in answer to a question that the labeling decisions actually occurred in California and Massachusetts and that the Court should somehow be making reasonable inferences if it is not explicitly there.

Are you saying that the Court should be making reasonable inferences that labeling decisions were made in California and/or Massachusetts, that is outside of the headquarters, place of incorporation of the brand name manufacturers?

MR. LONGER: Yes, your Honor. My reaction -- or my statement, I think, was in reaction to what Mr. Cheffo had said, which was that labeling decisions occurred where the Defendants are -- at the principal places of business, and I was saying that is not in the complaint, and he is not entitled to any reasonable inference that that is the case because we did not plead that.

THE COURT: Okay. Let me stop you. I don't mean to interrupt, but I need to follow my train of thought.

I misunderstood the reasonable inference. You are saying Defendants are not entitled to any reasonable inference about labeling decisions. You didn't say the Plaintiffs are entitled to a reasonable inference by not alleging where the labeling decisions were made, that they were made in California and/or Massachusetts; is that correct?

MR. LONGER: They may have been, through a reasonable inference, because activities did take place in those states. Whether that was labeling decisions in the way that Mr. Cheffo is using that phrase is another story all together.

THE COURT: If the Court for some reason believed that

where the labeling decisions were made was relevant to its consideration and analysis of the personal jurisdiction question at issue here with respect to these two counts and the innovator liability claim, would I expect a contest between the parties if we were to -- because this is a personal jurisdiction challenge, and there is a factual dispute, would we go to competing affidavits?

Would we get into a whole other round of hearing on this, or would that be pretty simple, get to the bottom of where the labeling decisions were made, Defendants would produce affidavits, and the Plaintiffs would accept those as true, or do you see that as a jurisdictional discovery type of endeavor?

MR. LONGER: Is that directed to me, your Honor?

THE COURT: Yes.

MR. LONGER: It would be the latter. I can't imagine that I would accept an affidavit that said -- from these Defendants that said every activity occurred in, let's say, Connecticut. I am making up a state.

I would imagine that much of their activity is actually quite diffuse, and since California happens to be the largest market in the United States, and probably the largest market in the world, that labeling decisions didn't actually take place at some level in some manner in California.

It may have gone around the country to the home

headquarters, may have, but the decision-making process could easily have occurred in California, and there is just so much activity that takes place in California, and we have already pled them. The Defendants have basically admitted that in their Motion to Dismiss. For purposes of the Motion to Dismiss, all of those facts are deemed to be true.

MR. CHEFFO: Can I respond, your Honor?

THE COURT: Yes, response.

MR. CHEFFO: You haven't heard, I don't think, an answer to the question.

What I think you keep kind of asking is -- and all of that is just total speculation. They have had thousands of pages, none of that is in the complaint. No one can point to anything that is specific.

What we are talking about is that it is not even all labeling decisions, that is not what the cases talk about. They talk about responsibility for a failure to update. The Plaintiffs have now had multiple times and they have not made one single allegation, not even hinted, not even on information and belief, that there was a failure -- there was facts or information about a failure to update the warnings or the label that occurred in California or Massachusetts. It is really just that simple.

We are talking about specific jurisdiction, you know, is there specific jurisdiction, did the acts or conduct relate

to the specific claim. I know Mr. Longer now wants to talk about labeling and marketing and things that may have occurred, again, decades ago. Everything he is saying -- and he is a good advocate, I understand that.

MR. LONGER: Thank you.

MR. CHEFFO: But it relates to the conduct of the companies with respect to their products. In this unique situation and novel claim, the issue is, are there facts that are alleged in the complaint after all of this time that say that the conduct relates to a failure to update the labeling, right, that was used. That is what this cause of action is about.

It is not about all things negligent, it is not about all things marketing or promotion or people's conduct. It has to be something that was intentional on the conduct, that is where we get to the fairness, the fundamental, the foreseeability issue. It has to be something that was intentional by the company. We have gone through all of this this morning and these briefings and the complaints, and there is none of that, there is not a single allegation.

THE COURT: If I am understanding your position correctly, although you seem to concede that on some level labeling lends itself to broad connotations of marketing and advertising, but despite that comment that you made, are you adhering to a position that, within the confines of innovator

liability, labeling means labeling on the label, updating the warning, updating the label, not advertising, not commercials, not social media, but labeling?

MR. CHEFFO: Absolutely, your Honor.

THE COURT: So, your position, then, is that is what would need to relate to the context that the brand Defendants have in California and Massachusetts and that allegation is not there.

Hypothetically, if the Plaintiffs had an allegation that the Defendants failed to update their labels in California and Massachusetts, they sort of -- they talk about all of the other things the Defendants do, but then they also say that they didn't update their labels in California and Massachusetts, because now Mr. Longer is saying, well, so much happens in California that maybe that is one of the things that goes on in California, where would that put the Court?

Right now we don't have that allegation. I am taking your position to be we are now on the second round of motions, they haven't alleged what they need to, it is done, it is over, they had their chance, they lose on personal jurisdiction.

My question is, if they repled and that is what the Court believed it needed to see to link the ties to the jurisdiction with the relate to, or arising out of, the relate to, what would happen then?

MR. CHEFFO: Again, that is a fair question, right.

As an advocate, my -- you articulate my position, right, they had the time. If you tell me you are going to deny our motion, if you didn't have any other choices, I would say to you, you should grant our motion, and to the extent that the Plaintiffs could have -- and clearly define, to the extent that they identify conduct that specifically relates to, you know, a failure to update the label, a narrow issue, that specific --

THE COURT: A decision to not update the label?

MR. CHEFFO: Yes. I mean, labeling is going to be national. As we all know, whether you are in Florida or New York or California, if you pick up a particular Zantac label, or any label, it is going to be the same. We want to have everyone have the same information.

The question here for personal jurisdiction is, did any of that conduct, did any of that updating the label conduct occur or not occur in California or Massachusetts? If it did, then those would be allegations we should see to determine if they establish personal jurisdiction.

We are kind of back dooring all the merits of it, but ultimately we have to look at what the claim is and what is an appropriate, fair, foreseeable, rational basis to tether the jurisdictional analysis to the claim.

Here, what I think we are saying, I think this is consistent with what the case law is, but the appropriate analysis is, if you are going to have this relatively novel

claim that they accept, and the claim is that you failed to update that conduct for jurisdictional purposes should occur in California or Massachusetts if there is a claim. If there is not, then there is no jurisdictional basis to assert the innovator liability claim against a manufacturer. That is point number one.

The last thing I would say is, I don't feel like we are -- you know, the Court or us, are somehow catching the Plaintiffs by surprise. We have kind of briefed this, and they haven't come forward in their opposition and said, oh, by the way, we forgot X, Y, Z company is really headquartered in California and we'd like leave to -- so they have an opportunity. I think all you are hearing is that they can't make these allegations, so I think they should be dismissed with prejudice.

But, as I said, to the extent that the Court has some reluctance to do that at this point, I think a very specific leave to replead with specific instructions that the conduct about the failure to update has to be identified within these two states for each Defendant that they want to have jurisdiction, that is what I would suggest to the Court as an alternative.

MR. LONGER: Your Honor, may I speak to this?

THE COURT: Yes, please.

MR. LONGER: Mr. Cheffo has his advocate hat on, and I

want to come back to squares. Where the labeling decision were made is not the relevant inquiry. The question is, where were the representations made?

The representations were made in Massachusetts, the representations were made in California. I come back to Judge Marra's decision in Exhibit Icons. It was the representations that were sent into Florida that matter.

It doesn't matter what decision-making process was made, where the representation were conjured, it is where did the impact occurred, and the representations, the label that the branded manufacturers made occurred in California.

The generic label that had to absorb and be the same as that representation in California occurred in California, the same thing in Massachusetts.

I understand Mr. Cheffo would love us to go on this tangent, and it is a rabbit trail that leads -- it is an irrelevancy. The point is, where did the representations occur? The representations occurred --

THE COURT: But, Mr. Longer, I asked you earlier whether you were aware of any cases outside of the ones that had been discussed in the briefing where the innovator liability theory applied in a situation relating to misrepresentations outside of the label, and you said you did not know of any.

The body of case law that everybody seems to be

relying upon relates to the label, even though I understand there may be other instances where misrepresentations speak to issues outside of the label. That is kind of where I began.

MR. LONGER: The label is broadly connotated, as Mr. Cheffo would have to agree with, and that activity occurred in California and in Massachusetts, your Honor.

THE COURT: Your position is the labeling is broadly connotated, and you gave CFR 201(k) as the basis, that it would include advertising and commercials, and that all occurred in California, and therefore that relates to an innovator liability claim that a Court in California --

MR. LONGER: That generated the market for the generic products, and it's 21 CFR 201.5. Your Honor cited to 21 U.S.C. 321(m). Labeling is broadly connotated and it just encompasses just about everything which the label touches.

So, that label was disseminated in California. The activities that resolve -- or that took place around that dissemination occurred in California. The Plaintiffs' claims that took the generic product relate to that activity, and that activity occurred in California. They cannot walk away from that. It also occurred in Massachusetts. I don't mean to slight Massachusetts, but California is a bigger state.

MR. CHEFFO: Your honor, that just simply is not the case. What counsel is trying to do is basically, again, a little bit of slight of hand here, go back and keep telling you

that there were things that GSK did with respect to its own product and that is what you should look at. I think we have talked about it at some length, but that is what he is talking about here.

The simple issue here is failure to update. Their claim is that if someone buys a generic medicine, there is somehow a claim that, even though it was not manufactured by a company, there is some liability that attached. To the extent the cases talk specifically about that, they talk about the updating of the label. They don't talk about advertising and marketing and broad issues. It is what happened with respect to a failure to update.

We can go around until I think we are all blue in the face, but you will not hear, and have not heard, and I am not here to testify, but there are no allegations and there can't be any allegations that these companies had labeling type issues as are contemplated in the innovator liability cases in California or Massachusetts. It doesn't occur in -- it occurs in headquarters.

The simple answer is, they haven't alleged it. If they want an inferences drawn, the easy way to have addressed that was to make allegations. They haven't done it.

THE COURT: Mr. Cheffo, are you agreeing with the basis of labeling as 21 CFR 201.5? It's drugs, adequate directions for use. Adequate directions for use means

directions under which the layman can use a drug safely and for the purposes for which it is intended. Directions for use may be inadequate because, among other reasons, of omission in whole or in part or incorrect specification of -- and I think it is subsection A, maybe, that is what Mr. Longer is relying upon -- statements of all conditions, purposes or uses for which such drug is intended, including conditions, purposes or uses for which it is prescribed, recommended or suggested in its oral, written, printed, or graphic advertising and conditions, purposes, or uses for which the drug is commonly used, except that such statement shall not refer to conditions uses or purposes for which the drug can be safely used only under the supervision of a practitioner.

I don't think the other provisions, subsections which go through G necessarily apply.

Are we in the same ballpark of discussion here that you agree that 21 CFR 201.5, drugs, adequate directions, kind of more -- we are talking about labeling encompasses broader representations, such as graphic advertising, printed, other written means of commercial dissemination of information, yes, and then, but Plaintiffs haven't alleged that the Defendants did those sorts of things, made those kind of decisions in California and Massachusetts.

I am trying to understand where the dispute is.

MR. CHEFFO: No, fair. I am not going to take issue

at all with the CFR. I agree the way you just read that is right. If you would indulge me for 30 seconds. I think we also have to look at the practical impacts. You don't have to be a pharmaceutical expert, just a citizen.

When generic medicines usually go on the market, there usually isn't advertising, marketing or promotion, so there is basically the label. What these cases are typically about is someone goes to the drugstore because a doctor wrote it or they continued on, and they get a medicine.

These claims -- so, the Plaintiffs could arguably have whatever claims or theories they have against the manufacturer of that, but here they are basically saying there was a failure to update the label because there is no more marketing and promotion.

In the context of what we are talking about, these theories and these claims, I think we do have to overlay the regulatory scheme, but look at the practical effects. Right. They are basically saying there has to be a label on the bottle that somehow mirrors the brand, and the claim in those two states is that you failed to update it. That is specifically what we are talking about.

That is why I have been pointing the Court to this idea that if it is a reckless failure to update, then the allegation should be, here is where those decisions were or should have been made in connection with these states, and if

it is in California or Massachusetts, then arguably there would be jurisdiction. If that conduct that relates to or arises out of the failure to update is not in California or Massachusetts, just like in any other analysis, there would be no jurisdiction because there is no arising out of or related to, and it would be unfair and inequitable.

I don't know if that answers your Honor's question.

THE COURT: Yes. We are going to wind down. Going to the decision aspect of what you are saying, is it just kind of an implicit thing when you are talking about something like labeling, it is not that the label came into California, but you are saying for purposes of personal jurisdiction and the relating to the claim of innovator liability, it actually has to be the labeling decision? Where do we get that concept?

MR. CHEFFO: I think we get that arising out of or related to. We look at what the issue is and I think we overlay that with the fundamental fairness and the foreseeability. Right.

Remember, we start with the fact that coming into, right, is not -- I made what I thought were -- obviously had concessions with respect to our products, our company and the other brandeds, but we don't have a situation where something is coming into California that any of the brand manufacturers sold or promoted or marketed.

So we first start with it is a separate company,

separate product, there was a unilateral determination by those companies, as is their right, but there was no effort, intention, or effort by any of the brand name Defendants to subject themselves to jurisdiction by selling generic. That was totally outside of their control or benefit, so that is the first starting point.

Then you say, well, to the extent there is liability for failure to update someone else's product sold in another state, used by someone else, that you don't have any revenue from, where were those decisions made. That is what you look at.

This is very different than Ford. That is why I think there is this extra level of equity and foreseeability that is really important for the Court to focus on.

THE COURT: Okay. One final question for Mr. Longer. If, I am not saying I am, but if, hypothetically, the Court were to require for purposes of personal jurisdiction as to these two claims there be an allegation relating to conduct by the brands as it relates to labeling decisions with respect to updating their labels, and that such allegations would have to be that this was done in California and Massachusetts in order for there to sufficiently plead personal jurisdiction, if, hypothetically, the Court were to require that, could the Plaintiff do that?

Do you have discovery to allow you to do that or

another basis to --

MR. LONGER: The Defendants never raised this as a factual matter, so there is nothing to really argue against, but discovery is discovery.

The point that I would like to make, your Honor --

THE COURT: Can you answer the question? Would you replead or would you have to think about that?

If you don't know the answer, that is okay, too, but I just want to make sure I hear the answer.

MR. LONGER: I don't know the answer right now, and discovery is ongoing. If they want us to take jurisdictional discovery, it would have been nice if they had raised that in their motion with an affidavit and put some evidence up that we would have to challenge. That never occurred.

But the point here, your Honor, is it is unnecessary. The Court is being directed in a manner that is unnecessary. It is not relevant to the claim.

THE COURT: I understand --

MR. LONGER: The label was --

THE COURT: Mr. Longer, I do very much understand your position, I do.

I am simply -- and I have not made a decision. It is a hypothetical question, and the question was, if the Court were to view the argument from the standpoint of what it believed would need to be alleged to satisfy specific

jurisdiction and it concluded that allegations relating to labeling decisions with respect to updating the label was necessary, would the Plaintiffs be able to make that allegation?

MR. LONGER: At this point, I don't know, your Honor.

I would almost be willing to concede the point that I don't know, but there may be somebody that knows more about this than me, but I don't know where these decisions were made, but again, they are irrelevant to the inquiry that is before the Court.

THE COURT: Right.

MR. LONGER: If you take this to the furthest point north, T.H. versus Novartis could not have been argued in California because there would be no jurisdiction against Novartis because it is a Switzerland company.

Again, this is not the proper inquiry, and I really encourage the Court not to accept these arguments because they are irrelevant. The label itself is the misrepresentation.

There were more activities on top of that, but I only need the label. The label doesn't say this can cause cancer.

THE COURT: But you did focus a lot on marketing and sales force, so maybe you put the Court on a path in a different direction by all of those allegations as if to suggest that was the basis and what relates to the innovator liability claims.

MR. LONGER: All of that activity is related, your Honor, and I must say in all candor, your Honor's ruling on innovator liability asked us broadly talk about all of their activities that could relate to this. I gave you the kitchen sink, your Honor, there was a lot of activity.

But remember, the label is all that is required, and they distributed the label to both coasts, let's say it that way, both coasts. They are bi-coastal. And those representations which were exported to those states are what give rise to the cause of action, and that is what -- and I say give rise, all it has to do is relate to the cause of action, and that is sufficient under Ford Motor Company to render personal jurisdiction against the Defendants.

THE COURT: Okay. I don't think you made that precise argument in your briefing, correct, what you just said? The actual distribution of the product with the label is what is giving rise to the relate to.

I am hearing that, which is fine.

MR. LONGER: We didn't have to because Ford Motor Company came out.

THE COURT: Well, you think you didn't have to, and you may be right, but I want to make sure that I am hearing that for the first time, because I don't recall reading that.

All right. I believe I do thoroughly understand the parties' positions, so we accomplished that. I do thank you

for the lively engagement of the topic.

With that, why don't we come back at 1:15. We will be ready to go into the motion at Docket Entry 3115, which is the brand manufacturer Defendants Motion to Dismiss RICO claim and consolidated amended consumer economic loss class action complaint.

I would suggest, as I mentioned earlier, that maybe you want to keep your Zoom link up, but by all means, turn your mute button on so we don't hear what goes on over lunch. Turn your video off, and we will turn them back on -- well, many of you don't have to turn them back on at all. But for the presenters, you will be ready to turn them back on at 1:15.

Have a nice lunch, and we will see you back at 1:15.

(Thereupon, a luncheon recess was taken.)

THE COURT: All right. Welcome back, everyone.

If we could have counsel for the 3115 for Defense, Mr. Bayman. Good afternoon.

MR. BAYMAN: Good afternoon, your Honor.

THE COURT: Do you need me to time you, warn you, give you rebuttal, anything like that?

MR. BAYMAN: Yes, please, your Honor. I would like a two-minute warning and I would like to reserve two minutes for rebuttal.

THE COURT: So, you have a total of 15, so you want two-minute rebuttal, that gives you 13, and you want a

two-minute warning. So I will give you a warning at 11 minutes?

MR. BAYMAN: Yes, your Honor.

THE COURT: All right. Ready to go.

MR. BAYMAN: May it please the Court, I am Andrew Bayman, lead counsel for Boehringer Ingelheim and counsel for the brand manufacturers in arguing this motion. This is the Motion to Dismiss the Plaintiffs' RICO claim in the ELC or economic -- consumer economic class action complaint.

Relying on nothing more, your Honor, than backwards looking speculation and conclusory unsupported assertions, the ELC attempts to recast what is lawful routine sale of an FDA approved over-the-counter medication as a criminal enterprise.

As a growing number of Courts have held under similar circumstances, Plaintiffs should not be able to establish a RICO violation based on the lawful and independent operations of four competitors that sold OTC Zantac during different times over multiple decades from as far back as 1995, when over-the-counter Zantac was first launched, until 2019.

Plaintiffs' RICO claims should be dismissed.

Specifically, your Honor, Plaintiffs' RICO claims fail as a matter of law for at least two separate reasons. First, the RICO Plaintiffs lack statutory standing to assert any claim under RICO. Under the indirect purchaser rule, a Plaintiff who purchased a product from a retailer cannot assert RICO claims

against the product manufacturer.

Even if the indirect purchaser rule did not bar Plaintiffs' claims here, they would still be subject to dismissal for lack of statutory standing because Plaintiffs have not alleged a cognizable injury to business or property as required by the plain test of the RICO statute, or that any such injury was proximately caused by the Defendants' alleged conduct.

Second, the RICO claims have not plausibly alleged facts supporting an inference that the conduct alleged in the ELC fits even the most basic elements of a civil RICO claim.

With our limited time today, I am going to focus on two elements. A Plaintiff must plausibly allege a common or coordinated criminal purpose and a relationship among the alleged participants animated by that criminal purpose. Courts require this because RICO is not intended to police ordinary business conduct or even to convert all business fraud allegations into RICO conspiracy liability. As the Eleventh Circuit has said in the Cisneros case, RICO cannot be invoked every time a group of people allegedly cause an injury.

Plaintiffs allege, at best, parallel conduct by competitors who marketed and sold OTC Zantac at different times. They cannot make a single direct allegation of coordination. They do not cite any communications, not a single one, between any two Defendants about this implausible

scheme. Instead, they ask the Court to connect imaginary dots based on what is routine conduct in the pharmaceutical injury.

Moreover, a Plaintiff must allege a pattern of racketeering activity. To do so the Plaintiffs here were required to, but fell far short of satisfying basic elements of even one alleged act of fraud.

Let me address the arguments in turn. In Apple versus Pepper, the Supreme Court explained the indirect purchaser rule as follows. If manufacturer A sells to retailer B, and retailer B sells to consumer C, then C may not sue A.

As the Court explained, the indirect purchaser rule is a bright line rule that admits of no exceptions.

If that rule applies here, there is no doubt that Plaintiffs' RICO claims are barred because no Plaintiff alleges that he or she purchased over-the-counter Zantac directly from any brand name manufacturer Defendant.

Perhaps recognizing this, Plaintiffs resort to arguing that the indirect purchaser rule does not apply to RICO claims, but every Circuit Court that has analyzed this issue has rejected their argument.

Further, Congress modeled RICO's civil action provision on the civil action provision of the Federal antitrust rules.

Thus, as Judge Moreno recently explained in the In Re: Takata Air Bag MDL, it logically follows that the limits the

Supreme Court has placed on antitrust standing, including the indirect purchaser rule, apply in the RICO context as well.

Judge Moreno dismissed the RICO claims of the Plaintiffs who did not purchase the product at issue directly from the Defendants, and said such claims ask the Court to go beyond the first step of causal analysis and run afoul of the motivating principles the Supreme Court has set forth in its RICO proximate cause cases.

None of the cases the Plaintiffs cite involve RICO claims by Plaintiffs who were indirect purchasers of the product and none of them mention, let alone address, the indirect purchaser rule.

In fact, Plaintiffs ignored the cases most directly on point, Rickman versus BMW of North America. In Rickman the Plaintiffs asserted a RICO claim based on a product manufacturer's alleged concealment of the fact that the BMW vehicles they purchased were allegedly equipped with emissions defeat devices. None of the Plaintiffs, however, purchased the vehicles directly from BMW, and as the Court explains, this meant their claims were absolutely barred by the indirect purchaser rule, just as the Plaintiffs' RICO claims should be barred here.

Setting aside the indirect purchaser rule, your Honor, Plaintiffs' RICO claims are barred because they have not alleged a cognizable injury to business or property as required

by the RICO statute.

Plaintiffs' theory of injury is predicated on their allegation that Zantac increases their risk of cancer. They do not allege that they over paid for Zantac because it wasn't effective; rather, they allege that they would not have purchased Zantac in the first place had they known of this alleged cancer risk, but as the Eleventh Circuit explained in the Grogan versus Platt case, the ordinary meaning of the phrase "injured in his business or property" excludes personal injuries, including pecuniary losses that flow therefrom.

Finally, even if the Plaintiffs' theories were not foreclosed by binding Eleventh Circuit authority, the Plaintiffs disappointed expectations in the product they purchased and their alleged lost benefit of the bargain are not a cognizable injury to business or property within the meaning of the RICO statute.

The cases Plaintiffs cite do not support their argument that they have alleged a cognizable injury to business or property. The In Re: Valsartan case addresses Article III standing, which is not limited to injury to business or property and not the more demanding standard required by RICO.

They ignore the Roberts versus Scott Fetzer case which expressly held that expectancy type benefit of the bargain damages are not available under RICO.

Even if the Plaintiffs had alleged a cognizable injury

to business or property, Plaintiffs have not alleged that any such injury was the but for or proximate cause of their claimed injuries.

To allege proximate causation, Plaintiffs must show a direct connection between the Defendants' alleged racketeering activity and their claimed injuries. Here, the Plaintiffs do not allege any facts about their purchases of Zantac, the reason why they purchased Zantac, any materials they considered when they purchased Zantac, whether they purchased OTC Zantac on the advice of a doctor, or how many times they purchased it.

In the absence of these types of allegations, they cannot show that their claimed injuries were directly caused by the Defendants' alleged racketeering conduct.

Plaintiffs cannot point to a single allegation in the ELC that connects these alleged misrepresentations made by the Defendants to their purchases of OTC Zantac and they have not shown the direct connection as the Supreme Court requires.

Although first party reliance is not required in all cases, it is required in cases like this one. Plaintiffs' failure to connect the dots between the Defendants' alleged misrepresentations and their claimed injuries is especially glaring given that many of the Plaintiffs repeatedly purchased Zantac for more than 20 years.

It is far more plausible to infer from these allegations that these Plaintiffs continued to purchase Zantac

because it worked, rather than to infer a connection between the Defendants' alleged racketeering conduct and the Plaintiffs' purchases, which is simply not there.

Plaintiffs have also failed to adequately plead the most basic RICO elements. They do not satisfy the twin elements of common criminal purpose and relationship. The purpose must be both common and criminal.

Even a plausibly pleaded business fraud case is not RICO absent evidence of common coordinated criminal purpose. The purpose must be not merely parallel, but it must be coordinated and shared.

In the Cisneros case, the Eleventh Circuit held a RICO Plaintiff must plausibly allege the participants shared the purpose of enriching themselves through a particular criminal course of conduct.

In Judge Ruiz's Lewis versus Mercedes-Benz case, the Court held Plaintiff must allege with enough factual detail that members of the enterprise were actively collaborating to achieve an improper motive.

Similarly, the Eleventh Circuit in the Almanza case says where Defendants acted in parallel, that does not show that they had relationships among each other with respect to the actual carrying out of what they were each doing individually. The purpose not only must be common, but it also must be criminal, to make money by fraud common, not by

ordinary business dealings.

As the Court in Cisneros held, a Plaintiff must show facts that plausibly support the inference that the Defendants were trying to make money by fraud, rather than opposed to the obvious alternative explanation, which was they were simply trying to make money.

Judge Ruiz in Lewis said "RICO is not a run-of-the-mill consumer protection statute, as its goal is to combat organized crime, not to police routine commercial dealings."

The ELC does not satisfy Rule 12 on common or criminal purpose. The Defendants are competitors who sold Zantac at different times over multiple decades from 1995 to 2019. The other cases we cite in our moving papers involve conduct that occurred at the same time, yet the Court rejected the RICO claims. Here the conduct did not even occur parallel in most cases.

Plaintiffs allege in their RICO claim that the Defendants fraudulently worked together to get OTC Zantac approved. How is it plausible that BI, that did not acquire Zantac OTC until 2006, and Sanofi, which did not acquire OTC Zantac until 2017, acted in concert and had a common purpose to engage in alleged criminal fraud with GSK and Warner Lambert, which was not acquired by Pfizer until 2000, when OTC Zantac was launched in 1995?

THE COURT: That is 11 minutes and 24 seconds.

MR. BAYMAN: Thank you. The best example of the lack of common coordinated conduct is the fact that the ELC is utterly silent on any communications between even any two Defendants, and the Courts look to specific interactions and specific communications in order to prove RICO.

In your Honor's RICO opinion from earlier this year, DJ Enterprises versus Google, you said that the Eleventh Circuit case law illustrates the degree of specificity that is required to plausibly plead a common purpose, and that a Plaintiff alleging a common purpose must plead concrete facts to support a non-speculative inference that the alleged members of the RICO enterprise shared the common purpose.

Courts look squarely for the allegation that would most logically support criminal purpose, communication among the participants. There is none of that here, there is no criminal purpose here, your Honor, and the Plaintiffs RICO claim should fail.

The Plaintiffs have not put forward enough facts with respect to each predicate act to make it independently indictable as a crime. They have not adequately alleged reliance, as Rule 9(b) requires, and they have made threadbare allegations.

Finally, Plaintiffs allege a duty to disclose only in conclusory terms in the ELC. They don't plead the source of

this duty as there is no duty in the Eleventh Circuit because there is no special relationship between the parties, as recognized by the Ayres versus GMC Court.

For these reasons, we request dismissal of the Plaintiffs' RICO claim. Thank you, your Honor.

THE COURT: Thank you. That was exactly 13. You reserve two minutes for rebuttal.

From Plaintiffs. State your name for the record.

MS. ANTULLIS: Yes. Sorry, I am getting my notes up.

THE COURT: Sure. Did you want any warning?

MS. ANTULLIS: I think when I have a minute left a warning would be helpful. I think I will be okay.

THE COURT: Okay.

MS. ANTULLIS: Good afternoon, your Honor, may it please the Court. My name is Dory Antullis, I am here on behalf of the class Plaintiffs.

Before we get into the meat of the Defendants' argument, I would like to highlight four pivotal allegations the Defendants are silent on in their RICO motion.

One, Ranitidine degrades into NDMA, and NDMA is a potent carcinogen.

Two, the NDMA in Defendants' Zantac was a material safety risk that made it unfit for human consumption.

Three, Defendants knew of the material safety risk and were recklessly indifferent to it.

Four, Defendants did not disclose the risk to consumers, the FDA doctors, or the scientific community.

These allegations are all sufficiently pleaded and highly plausible and Defendants have waived their right to challenge them in the RICO claim.

As you look at the allegations, your Honor, we ask you to do so through the lens of what Defendants do not challenge here because the plausibility of our enterprise and racketeering allegations really crystallize when you accept as true that Defendants knew or recklessly disregarded that OTC Zantac had a material safety risk as they agreed to seek FDA approval, manufacture it, market it, buy it, or sell it.

What the Defendants do challenge is the following: Injury, proximate causation, common purpose, relationships, and racketeering, and I will take each argument in that order.

First, there is injury. Plaintiffs paid money for a worthless product. As Judge Kugler held in Valsartan, an MDL dealing with the exact same carcinogen, a medication containing NDMA is objectively worthless or worth less. Whether pocket loss, over payment, paying money for an objectively worthless product is a classic RICO injury to property that has nothing to do with personal injuries, and is not expectation based or ascertainable.

One need only look at the two Scott Fetzer orders to see the difference. In 2009 the Court found the difference in

value between a new vacuum cleaner and an old one constituted a RICO injury, and he rejected McLaughlin v. American Tobacco as inapposite, as it is here.

In 2010, Plaintiffs changed their theory of injury to a loss in value placed on the Plaintiffs' perception of newness. The Court found that loss was unavailable.

Here, the presence of NDMA does not turn on perception or expectation. It is a fact and it has a quantifiable impact on Zantac's economic value. Ironworkers v. AstraZeneca does not dictate a different result. There, benefit plans sued manufacturers for causing them to purchase more expensive prescription drugs by telling them those drugs were safer and better for treating certain conditions.

The Eleventh Circuit found no injury because the plans didn't allege the drugs were unsafe or ineffective as prescribed, and because the plans were able to anticipate and absorb some level of fraud and account for that in premiums to insureds.

Here, in contrast, the Plaintiffs were individual consumers, their injuries are not based on the price between Zantac and other antacids, OTC Zantac was unsafe regardless of any condition, like in Avandia, and whatever role Plaintiffs' doctors did or didn't play, they weren't learned intermediaries because Plaintiffs purchased OTC drugs, not prescriptions, and because Defendants concealed the presence of

a potent carcinogen from them, which the Plaintiffs specifically plead.

Second, there is a proximate cause. On the one hand, Defendants told consumers directly and through omission that OTC Zantac was safe. For example, they said OTC Zantac had been prescribed safely for years. Zantac made partial disclosures, like OTC Zantac is doctor trusted, that gave rise to a duty to disclose the material safety risk under Kemp v. AT&T.

It is black letter law in consumer cases that exposure is alleged when there is a nationwide, decades long marketing campaign. That is the tobacco cases, including Defendants' own authority, McLaughlin v. American Tobacco, and that is what the Plaintiffs allege here.

Ray II notably lacked those marketing exposure allegations. Moreover, an undisclosed safety risk that makes a drug unfit for human consumption is far more material than the omission in Ray II. It is not at all obvious that a reasonable person would choose not to purchase a $125 plane ticket simply because the source of a $9 fee is not disclosed.

It is highly plausible that any reasonable consumer would have acted differently had they known of the NDMA risk, and Plaintiffs allege precisely that, they would not have purchased the drug.

On the other hand, Defendants omitted the safety risk

in NDMA applications and adverse event reports, and some of them conducted damning studies that they did not publish that would have put the FDA and scientists, and thus Plaintiffs, on notice of the material safety risk. As in Chrysler-Dodge-Jeep Ecodiesel, reliance by regulators was part of the chain that kept OTC Zantac on the market.

We don't have to guess what the FDA would do had they known because they did it. The FDA ordered a market withdrawal.

Third, there is Illinois Brick. The Supreme Court and Eleventh Circuit have cautioned against importing standing requirements from the antitrust analog into RICO. It is not surprising that in the 44 years since Illinois Brick was decided there is not a single Eleventh Circuit decision analyzing its application to RICO, let alone applying it, and very few district courts have considered the issue.

In GolTV, Judge Altonaga explicitly rejected the application of the indirect purchaser rule to bar a RICO claim precisely because there was no in-circuit support applying the rule. Instead, she affirmed that the only Eleventh Circuit standard for RICO standing is proximate cause.

The only reported decision that we are aware of in the Eleventh Circuit that applies the indirect purchaser rule to RICO is Takata II. Even there Judge Moreno conducted what was, in essence, a proximate cause analysis looking at the

directness of the injury. He ultimately held that the injuries of Plaintiffs who were second in line purchasers were derivative of first in line consumer Plaintiffs. So those injuries failed under either standard, proximate cause, as Mr. Bayman noted, and the indirect purchaser analysis.

In In Re: Insulin, Judge Martinotti noted that where district courts are not bound by controlling Circuit authority, they have found the rule does not apply to RICO, and he cited EpiPen as an example.

Like in Avandia, International Teamsters, In Re Ecodiesel, and EpiPen, and innumerable other consumer class actions where RICO has gone forward, notwithstanding the existence of a distribution chain, Plaintiffs here are intended targets of Defendants' fraud. Their injuries were a direct result of the Defendants' conduct and no one else could have standing to sue for that harm, so they must.

Fourth, there is common purpose. Plaintiffs allege that Defendants shared the purpose of selling an unsafe, unsellable product by representing it as safe, and by concealing the material safety risk from everyone. That works under Al-Reyes and Odom v. Microsoft. Unlike in Cisneros v. Petland or D.J. Lincoln Enterprises, Plaintiffs here allege many detailed facts that support a strong inference of a shared purpose.

All Defendants knew of the material safety risk. Even

so, GSK and Pfizer and their predecessors worked together to secure the FDA's approval for OTC Zantac and to sell it to consumers as safe, which was false.

GSK continued to manufacture the drug for Pfizer and to hold the trademark rights for years, even after Pfizer was the sole NDA holder in the U.S., meaning they both held an ongoing stake in OTC Zantac sales, which again could only be maintained by perpetuating the fraud.

Even after it fully divested its OTC Zantac rights in the U.S., GSK continued manufacturing for Pfizer, and it sold OTC Zantac abroad. When BI purchased OTC Zantac it also knew, or quickly discovered the risk, and yet continued to sell the product to consumers telling them it was safe, meaning it shared in the purpose of selling OTC Zantac by fraud.

Same too for Sanofi, and we know BI continued to manufacture for Sanofi, and that Sanofi continued nearly identical marketing. These are no more "business activities" than the asset hiding fraud in Al-Reyes was marriage as usual.

Plaintiffs facts, taken together, demonstrate that Plaintiffs' common purpose allegations are not only highly plausible, but far more plausible than the alternative, that the Defendants all knew the same thing but never discussed it with each other.

For example, the only way GSK and Pfizer did not share a common purpose when they worked together to secure approval

and share in the profits of OTC Zantac is if one of them did not know the material safety risk. We allege they did know. It is highly plausible that a sophisticated company like BI would only acquire and sell a drug that they knew was unfit for human consumption if it could guarantee that the revenue stream would continue.

We don't need an explicit communication to tell us this. Judge Ruiz said in Lewis v. Mercedes-Benz that Plaintiffs don't have to plead smoking gun emails to support a strong inference for common purpose. We just have to plead sufficient facts to make a common purpose fact highly plausible, and we do.

Also, it makes no difference whether the Defendants regularly compete or that no more than two Defendants actually sold OTC Zantac at a time. What matters is that they came to share the purpose of engaging in illegal activity, and not one of them ever affirmatively withdrew from that purpose.

As the Courts held in Chrysler-Dodge-Jeep Ecodiesel and Odom v. Microsoft, Defendants cannot hide behind the cover of business as usual.

Fifth, there are relationships. So the Defendants attempt to cabin their relationships to lawful commercial arrangements, relying on Almanza v. United Airlines, but this is not Almanza.

The sum total of the facts there were, international

airlines all had flights into Mexico; they joined an organization to coordinate compliance with Mexican law and signed a contract to obey the law, and according to Plaintiffs, the airlines each broke the law.

Based solely on the fact that they all did what they said what they would not do, Plaintiffs asked the Court to infer relationships via an illicit agreement, but they alleged no facts showing that there was any agreement outside of the one to obey the law. While this was enough to show a common purpose, it did not show relationships among the Defendants.

We are not resting on bare allegations that each Defendant sold the drug with a material safety risk and we are not manufacturing relationships from thin air. We plausibly plead exactly how these Defendants were related.

GSK and Pfizer and their predecessors agreed to work together to develop and sell OTC Zantac. GSK agreed to manufacture for Pfizer and held the trademark rights for years via another agreement. Pfizer sold the NDA rights to BI and BI agreed to manufacture for Sanofi while Sanofi continued BI's marketing.

The Defendants all knew of the material risk when they entered into these agreements, or came to know them shortly thereafter, and continued to sell the product. You cannot lawfully arrange to commit fraud.

Also, each time the U.S. NDA changed hands key

employees who worked on the OTC Zantac product went from one company to the next, and Defendants belonged to industry groups aimed at funding, directing, or influencing clinical studies, industry positions, and regulatory decisions, all of which paved the way for the Defendants to knowingly sell an unsafe drug.

It is through these very same relationships that Defendants conducted the affairs of the enterprise and each did their part to accomplish the enterprise's common purpose of selling OTC Zantac at fraudulent means.

Sixth, there is racketeering. Plaintiffs allege numerous specific examples of the Defendants knowingly misrepresenting via the mails and wires that OTC Zantac was safe, and omitting the material safety risk to convey that same message. That is fraud.

Plaintiffs describe these messages in great detail, including where they were placed, in what medium, by which Defendant, and when. The Plaintiffs include many actual advertisements that convey the same messages over and over.

OTC Zantac has been safely and effectively prescribed for decades. It was not, because a potential carcinogen cannot be safely prescribed. OTC Zantac is doctor trusted, but Defendants concealed the material risk from doctors, the FDA, and scientists. OTC Zantac can and should be taken with high nitrite foods. It is not safe to do so.

OTC Zantac is safer than PPIs, again creating the impression that it is safe. It is not. Captain Zantac brought home that message with a fireman, an authority figure conveying trust and safety. Of course, all the Defendants shipped OTC Zantac with false or misleading labels and packaging.

These allegations go far beyond those that Judge Moreno rejected in Takata II. They don't require the Court to cobble together evidence of fraud from business communications that have alternative explanations because the misrepresentations in the Defendants' marketing alone are plainly fraudulent on their face.

Remember, Defendants knew or were recklessly indifferent to the risk. So, each time they conveyed the message that OTC Zantac was safe, they broke the law.

Plaintiffs also allege examples where Defendants used the wires and mails to communicate with industry groups and the FDA. These too are predicate acts in furtherance of the conspiracy, even if no fraudulent message was transmitted.

Last, as Defendants --

THE COURT: That is 14 minutes.

MS. ANTULLIS: I am just about done now. That is great.

As Defendants note in their motion, where goes the Plaintiffs 1962(c) claim, so goes their conspiracy claim. The parties really didn't brief the issue, but under the particular

facts of this case, we agree with the Defendants.

In conclusion, your Honor, we ask that you deny the Defendants' motion in its entirety. If you do think that dismissal is warranted, we ask you to do so without prejudice. This is the first time that you have heard argument on the Plaintiffs' RICO claim, and we have not had the benefit of your guidance.

Thank you, your Honor.

THE COURT: Okay, thank you.

There is two minutes left for the Defense.

MR. BAYMAN: Thank you, your Honor.

Ms. Antullis seems to be saying that it must be a criminal enterprise for businesses to allegedly withhold safety information from purchasers, but that argument didn't save the Plaintiffs in the Lewis case who alleged that Mercedes-Benz and its dealerships withheld a potentially fatal safety defect from consumers that they knew or should have known about.

Moreover, Ms. Antullis argued that Judge Ruiz says there was not a need to have a smoking gun, explicit communication between the RICO Defendants, but Judge Ruiz said, as in Cisneros, the first complaint here is to avoid allegations about specific interactions between various alleged participants in the enterprise and not only silent in the origins or scope of the alleged scheme.

The Plaintiffs alleged that the Mercedes dealerships

learned of the defect at different times and alleged they colluded and collaborated with each other, and with other associates in the Mercedes RICO enterprise, but there are not enough concrete allegations to permit the Court to make a reasonable inference that the Plaintiffs acted together to conceal the defect in order to sell as many class vehicles as possible.

Here the Plaintiffs argue independent activities by competitors at different points in time who marketed and sold the drug at different points in time. As I said, GSK launched Zantac OTC in 1995, but BI did not get the drug until 2006, nor did Sanofi until 2017. It is implausible that they could have conspired with GSK in some common criminal scheme that is required under the RICO case law.

Ms. Antullis also mentioned -- or certainly referenced that there was some duty to disclose the risks, the alleged risks of Zantac.

The Plaintiffs have no response to the binding Eleventh Circuit authority that we cite that they failed to adequately plead a duty to disclose because no such duty exists in the Eleventh Circuit absent a special relationship between the parties. That is the Ironworkers case that --

THE COURT: That is your time, if you want to finish the sentence.

MR. BAYMAN: By contrast, the Plaintiffs' authority is

the Kemp case that Ms. Antullis cited, because there the Eleventh Circuit found the duty to disclose based on a partial misrepresentation theory in which the Plaintiff personally relied on the alleged partial disclosure, which we don't have here.

Thank you, your Honor.

THE COURT: Thank you. I have a few questions, if both counsel want to have your video on.

Can I ask Plaintiffs to clarify that I heard you correctly. One of the arguments that the Defendants made on page 20, footnote 4 of their motion at 3115, was that it was unclear to them whether Plaintiffs were asserting a separate RICO claim for conspiracy under 1962(d).

Did I hear you say Plaintiffs are not pursuing a 1962(d) conspiracy claim?

MS. ANTULLIS: No, no, your Honor. What I said was that their only challenge to the 1962(d) claim was that it was predicated on the conspiracy pleaded in 1962(c). That was their only argument to it.

THE COURT: I don't think Plaintiffs responded to that footnote about whether you were pursuing 1962(d).

Is it the Plaintiffs' intention that the count is directed both to violations of Section 1962(c) and (d)?

MS. ANTULLIS: It is, your Honor. We just didn't challenge it, or respond to it in the opposition, because we

agree with the Defendants' assessment that in this particular case there wouldn't be a 1962(d) claim if you chose to dismiss the 1962(c) claim.

THE COURT: Okay. If I didn't dismiss (c), you are pursuing (d) as well?

MS. ANTULLIS: That is our intention, your Honor.

THE COURT: Okay. Plaintiffs, viewing in the light most favorable to the Plaintiffs, it appears that Plaintiffs allege a single act fraud scheme, concealing the danger of Zantac which was perpetrated over a long period of time by multiple Defendants against thousands of victims.

What is the Plaintiffs' best case for how that kind of behavior meets the definition of patterned racketeering activity?

MS. ANTULLIS: I am not sure what you mean by a single act fraud case.

THE COURT: Well, are you -- do you disagree with that, that there is more than one scheme that is being alleged?

MS. ANTULLIS: The predicate -- I am sorry.

THE COURT: Go ahead.

MS. ANTULLIS: So, the predicate acts are every time they send out a misrepresentation in marketing over the wires that says Zantac is safe or it is doctor trusted, each one of those is a predicate act.

THE COURT: So, all of those predicate acts, then,

that relate to concealing the danger of Zantac sort of combined make up the pattern, and that meets the definition of pattern racketeering activity?

MS. ANTULLIS: Yes, it does, but they also -- they shipped Zantac labels that didn't have a warning, so it is misrepresented that way, and had incorrect expiration dates. They also failed to disclose to the FDA in their NDA applications and GSK to the FDA where it was not disclosed. And, you know, we didn't allege it specifically in the RICO claim, the adverse event reports, they didn't put it in there either.

There are other communications where industry groups putting out Ranitidine -- clinical studies that don't disclose a risk for cancer that they know is present.

So each of those is part of the pattern. Yes, the predicate acts, two or more predicate acts within ten years establishes a pattern, and we do allege far more than two on behalf of each Defendant.

THE COURT: Defense response, what is the Defendants' best case for why this is not a pattern?

MR. BAYMAN: Even if we take the Plaintiffs' assumptions as true, which we vehemently disagree with because what Ms. Antullis described, a lot of it is routine in the pharmaceutical industry, it was for the purpose of making money rather than committing the fraud, they still have to satisfy

the elements for mail and wire fraud. They haven't done it.

They also have not proven any kind of common criminal purpose by actors who were acting in concert. They have independent acts by different companies at different times, but they don't have the common criminal purpose that is required for RICO.

THE COURT: Okay. Plaintiffs, what have you alleged to be the distribution chain for OTC Zantac?

In other words, where in the ELC have you set forth the allegations regarding the distribution chain? Are there paragraphs that actually describe the order of the entity that the OTC Zantac passes through before arriving in the hands of the consumers?

MS. ANTULLIS: So, I believe that those allegations are in the economic loss complaint or in the -- I guess in the ELC. I will say they are not specifically pleaded or incorporated into the RICO claim, specific allegations regarding distribution chain.

THE COURT: So, how is the Court to conclude what the distribution chain is? Isn't that something that is relatively important or relevant to the indirect purchaser rule analysis to the extent that the Court engages in that?

I know it is the Plaintiffs' position that doesn't apply to RICO, but nevertheless, it is part of the briefing. How does the Court come to understand, appropriately so at the

Motion to Dismiss stage, what the distribution chain is, what the Plaintiff is acknowledging, alleging, accepting, and therefore the Court can accept as true the --

MS. ANTULLIS: I believe each Plaintiff alleges in their individual paragraph where they purchased the product. I don't believe that we alleged -- I don't actually know whether we have alleged somewhere else how a particular product got from GSK to Walgreens, but we do allege where they purchased the product, and who it was manufactured by.

And so, I think for the purposes of establishing distribution chain for the indirect purchaser rule analysis, we don't dispute that GSK or Pfizer or BI manufactured a product and that Plaintiffs did not purchase their products directly from the manufacturer, it went through a chain to a retailer or an authorized dealer or retailer where they did purchase the product.

Our point on indirect purchaser was not -- we certainly don't allege, as I said, somebody called up Pfizer and wanted the product. Our point is that they were the victims of the Defendants' false marketing. They meet proximate cause in that way.

If you accept as true that the marketing is false, that they relied on it, were exposed to it, there is a material omission, then that establishes that they were proximately harmed by the marketing.

Theoretically, if we were going to apply the indirect purchaser rule in the Eleventh Circuit to bar a claim like this, then what I would say is that there is no RICO claim. There is no ability for anybody to seek relief on behalf of this conduct, even if, you know, say retailers purchased the product and it was worthless. They didn't purchase it in reliance on advertisements. There is no -- that chain of causation gets broken for a retailer like Walgreens or distributors.

In fact, there are no retailer Plaintiffs in this MDL, and so, that would make RICO -- it would make an unrecoverable injury, under RICO, under proximate cause. Retailers wouldn't be able to seek relief, and so only consumers, conceivably, are directly in line.

When you look at cases that apply the purchaser rule, like Takata, BMW and Avandia, what is being passed through is an inflated price that is absorbed at different levels in the chain, but the consumers there, the Plaintiffs there who bring their claims also failed for lack of proximate cause. There is an overlap. There is no difference in the cases from what the indirect rule would dictate and what proximate cause would dictate to be true, in particular in Takata.

So, you know, there are no cases in the Eleventh Circuit addressing this exact situation and even the Third Circuit where -- the McCarthy decision is a Third Circuit level

opinion, there is also a decision that talks about the directness of the harm and misrepresentations. In Avandia the drugs they paid for went through the distribution chain all the way down to consumers, the insureds. Because of the directness of harm, the conduct itself put the third party payors first in line, they were -- they satisfied proximate cause.

In Avandia, which came out after McCarthy, the Third Circuit said that was enough for RICO.

THE COURT: I want to go back to the distribution chain and make sure I understand. For example, in paragraph 487 of the ELC, I want to make sure I am understanding that you are alleging there that each Plaintiff purchased a product that was manufactured by a particular brand name manufacturer Defendant, not that they purchased OTC Zantac directly from that brand name manufacturer Defendant.

MS. ANTULLIS: That is correct, your Honor.

THE COURT: Does the Defendant want to say anything about the distribution chain? We are hearing a description of it without there actually being an allegation. I don't know it was necessarily a disputed issue, but I wanted to make sure I understood what the Plaintiffs' position was.

MR. BAYMAN: I don't think so, your Honor. There is no dispute that these Plaintiffs didn't purchase directly from the brands, and there is no allegation that the retailers were part of any RICO conspiracy.

THE COURT: Okay. All right. You are off the hot seat, that is it, no more questions. Thank you.

MR. BAYMAN: Thank you, your Honor.

THE COURT: All right. The next motion we have is Docket Entry 3116, the Defendants' Omnibus Motion to Dismiss and/or strike consolidated medical marketing cross action complaint and consolidated amended consumer economic loss class action complaint and incorporated memorandum of law.

We have allotted 23 minutes for the Defendants because we do have an LDC and/or next gen attorney who will be arguing, at least in part. State your name for the record. Let me know if you want any warning and if you are reserving any time for rebuttal.

MR. PETROSINELLI: Good afternoon, your Honor, Joe Petrosinelli, nice to see you. I represent Pfizer, but will be arguing this motion on behalf of all Defendants.

I will let Ms. Cohan introduce herself, and then I will tell you what our request is for timing.

MS. COHAN: Good afternoon, your Honor, Lindsey Cohan for GSK, but like Mr. Petrosinelli, I will represent the Defendants pertaining to the ELC.

MR. PETROSINELLI: Your Honor, what we have decided to do, I will address arguments relating to the medical monitoring and Ms. Cohan will address the economic loss complaint. We would like to reserve a total of two minutes for rebuttal, and

if your Honor could give us -- really Ms. Cohan, she is going second, a one-minute notice maybe at the 20 minute mark.

THE COURT: Okay.

MR. PETROSINELLI: Just so we know where we are when we get there.

THE COURT: All right. You may proceed.

MR. PETROSINELLI: Thank you, your Honor, Joe Petrosinelli again here.

I want to talk about the medical monitoring complaint. We raised a number of different arguments, quite a few, in the papers, and I am happy to answer questions about any of them, but I will focus on just a couple in my opening remarks. The first is claims splitting. I think it is a major issue here with the medical monitoring complaint.

As the Court knows from reading the briefs, 51 of the 52 named Plaintiffs in the medical monitoring complaint are also named Plaintiffs in the economic loss class complaint. One thing I think there is no dispute is that that that is claims splitting.

Those 51 Plaintiffs by definition have split their claims, asserting medical monitoring claims in one complaint, and economic loss claims in another complaint, and that violates the Eleventh Circuit's rule or prohibition -- the Eleventh Circuit has used both of those terms -- against claims splitting. I don't think there is any dispute about that.

The Plaintiffs have two responses. One is, they say the claims splitting doctrine does not apply in class actions, and respectfully, I think that is just not correct as a legal matter.

Indeed, in the Vanover case, which is the Eleventh Circuit case that officially set forth the claims splitting doctrine in this circuit -- I mean, many district courts had applied it before, but it is the first Eleventh Circuit case, and in Vanover, the Eleventh Circuit, in setting forth the rule and the test, followed a Tenth Circuit case called Katz, which is a class action case.

There are many other Courts in the circuit, both before and after Vanover, and we cited a few in our papers, that have recognized the claims splitting doctrine in the context of class actions.

In fact, for reasons I will get to in a second, it is even more important in class actions because the Plaintiffs are not only purporting to represent themselves, but a class of individuals to whom they would owe duties if they were certified as class representatives, and it creates all sorts of issues of adequacy, typicality, when there are split claims, when the class reps split their claims. So, I don't think that argument is correct.

I think the real argument is, they say that your Honor permitted the claims splitting in the Court's ruling in

December that dismissed without prejudice the then economic loss class complaint, and that is just not what happened.

Your Honor said in that order, quite correctly, and indeed, I think it was at our request, that if the Plaintiffs here, Plaintiffs' leadership, wants to have a medical monitoring class action, and they want to have an economic loss class action, those need to be separated. You can't have these two class actions within one because it would create all sorts of chaos down the road, and your Honor pointed out some of the things that could happen in ordering that.

The Court didn't say, and when you do that, have the exact same Plaintiffs be the named Plaintiffs in both complaints. That is, there is nothing in the Court's order that says you are allowed to claims split.

I think that would cause not only what I just mentioned, problems down the road when we get to the Rule 23 certification briefing, problems with the adequacy of class representatives who have split their claims and the absent class members wouldn't necessarily know that. It would create typicality problems, beyond that, case management problems. Your Honor, you could imagine any number of outcomes here.

For example, what would we do if one of the cases were certified as a class, and the other one wasn't, what would you do with the 51 Plaintiff's individual actions that are now only individual actions? And what if they are remanded to different

districts for trial? It is just everything that the claims splitting doctrine is trying to avoid would happen, or could happen if the Plaintiffs were allowed to split their claims and be named representatives in both complaints.

So the Plaintiffs say, well, that is not fair because we shouldn't -- these 51 individuals shouldn't have to give up half of their claims, and we agree.

No one is arguing that these 51 Plaintiffs have to give up any claims, but they can't be named class representatives in both complaints, and in our reply brief we suggested, and we heard the argument from the Plaintiffs, an easy fix here, which is that the 51 Plaintiffs have to be dropped as -- without prejudice as named Plaintiffs in the economic loss complaint, and then if they want to continue to assert economic loss claims in their individual capacity, they can add them to their medical monitoring complaint.

Of course, this happens all the time. Your Honor, I am sure, has seen in many class actions a Plaintiff will bring claims on behalf of a class, but then will also assert their own individual claims in the class complaint. That is all that would have to happen here, but the Plaintiffs don't seem to want to do that.

If they don't want to do that, then, as we said in our motion, the medical monitoring claims of these 51 Plaintiffs have to be dismissed with prejudice under the claims splitting

rule. That is what happens as a remedy under the claims splitting rule, the claims that are split are dismissed with prejudice.

So, one of those two things has to happen, and either one would be fine. That is claims splitting.

The second thing I wanted to address, your Honor, was the states that recognize medical monitoring. So now, on a substantive point of law, and it's a pure question of law, the medical monitoring, of course, is only recognized by a minority of states in this country. In fact, the Plaintiffs have pleaded only claims under the laws of 14 states, but in fact two of those states, Montana and Indiana, don't recognize medical monitoring, and there is no basis for the Court to predict, under Erie, that the high courts in those two states would do so.

Just to ground the analysis, I wanted to talk about a couple of principles that your Honor cited, actually the innovator liability ruling back in December, that I think are particularly important here, two principles of Eleventh Circuit law on Erie prediction.

One is that when a Federal Court is asked to predict that a state high court that has not ruled on an issue -- and here the Montana and Indiana Supreme Courts have not ruled on whether medical monitoring is a recognized claim or remedy. When a Federal Court is asked to do that, it should be very

cautious and wade only gingerly into that prediction, and there has to be some pretty clear evidence that the state supreme court would do so.

I think that is the rule your Honor followed in the innovator liability ruling in finding that many -- declining to find that many state supreme courts would recognize that theory of liability. The same is true of medical monitoring. That is in the Guarino case in the Eleventh Circuit that the Court cited.

The second principle is that, generally, the Eleventh Circuit has said when a -- a Federal Court should presume that a state high court would follow the majority rule. That is the Bobo versus Tennessee State Valley Authority case. Again, your Honor cited it in the Court's innovator liability ruling. And here only, even in the best of worlds, 14 states recognize medical monitoring as a claim or a remedy. It is clearly the minority rule. The majority rule is, it is not recognized.

With those principles in mind, I will talk first of all about Montana because it is the easiest one. In over a hundred years of Montana reported cases, there is only one case, a trial court decision from 20 years ago, a case called Lamping, where the Court said that Montana should recognize a cause of action for medical monitoring. That is it.

That is the quintessential example of a situation where in the Eleventh Circuit, and I think really in any

circuit, a Federal Court should not predict that that state's high court would recognize that tort.

I will say two things about that. One is, the Eleventh Circuit has said in a case called Mesa Air that trial court decisions should not be used -- certainly alone should not be used to make an Erie prediction.

At a minimum, if there are these sort of secondary sources like trial court decisions or treatises that are being used, they have to -- the language in the Eleventh Circuit cases is "convincingly" demonstrate that the state's high court would recognize whatever claim is being asked to be recognized. That is the Guideone Elite Insurance case from the Eleventh Circuit.

Another thing I will say is, since Lamping no other Montana court in 20 years has followed it to analyze and grapple with this issue and said, yes, we think Montana should recognize a medical monitoring claim.

So, for those reasons, I think there is no basis for the Court to accept the Plaintiffs' invitation to predict that Montana would recognize this cause of action.

As to Indiana, there actually are some cases and all of them go in favor of our position. There is a Federal District Court case called Hunt by the then Chief Judge of the Southern District of Indiana saying expressly Indiana does not recognize medical monitoring as a claim.

There is a State of Indiana trial court decision in a pharmaceutical products liability medical monitoring class action, exactly what we have here, called Johnson, in which the Court again expressly said Indiana does not recognize medical monitoring as a claim.

Then there is an Indiana appellate court decision called Ott, a products liability case, an exposure case, where the Court said if you are exposed to a compound, in that case it was asbestos, you have no claim unless you have current physical injury or a current injury to your property. There is no claim under Indiana law in that products liability setting.

So, the only thing the Plaintiffs cite is there is an Indiana Appellate Court case called Gray, in which the Court said in the context of a nuisance claim, not a products liability claim, not a negligence claim, which is the only claim pleaded here under Indiana law, that in a nuisance claim a Plaintiff could get medical monitoring as a remedy.

Then there is a Federal Court case, again in a nuisance claim, that followed that called Allgood.

The Plaintiffs say here it doesn't matter that it was only a nuisance case, that is not important, but it is critically important. In fact, it was dispositive in those cases because in Indiana nuisance claims are statutory. In the State of Indiana a nuisance claim is defined by statute, and under the nuisance statute in Indiana, a Plaintiff can recover

if he or she experiences discomfort, I think the language is offensive to the senses.

In other words, the Courts have said in Indiana, and the statute reflects, there is no requirement in a nuisance claim in Indiana to have a current physical injury, or a current property injury.

It was on that basis that the Gray Court and the later Allgood Federal Court said, well, if you have a statutory tort that does not require proof of current physical injury, then the Plaintiff could get medical monitoring as a remedy because medical monitoring, likewise, does not require proof of current physical injury.

That is not true in Indiana for negligence claims, which are the claims pleaded here in this medical monitoring complaint. A Plaintiff pleading a negligence claim has to show current physical injury or current property in jury, and the Plaintiffs, by admission in the medical monitoring complaint, are not alleging that.

And so, under Indiana law, there is just no basis again to accept the Plaintiffs' invitation to predict that the state's high court would accept a medical monitoring claim.

There are, your Honor, a number of pleading defects where we show that the Plaintiffs haven't sufficiently pleaded the elements of a medical monitoring cause of action, even in the twelve states that we acknowledge do recognize the claim,

and that they just sort of recite the elements of a medical monitoring claim, but I don't want to take up Ms. Cohan's time.

I want to give her time to address the consumer class complaint, so I would be happy to answer any questions your Honor has about the pleading defects when we have our Q and A session. Thank you, your Honor.

THE COURT: Thank you.

MS. COHAN: Good afternoon, your Honor, Lindsey Cohan for Defendants.

There are a number of issues in the briefing relating to the ELC. Today I am going to specifically focus on the standing, consumer protection, and learned intermediary arguments that we raise there. However, I am happy to address any questions the Court may have as it relates to any other arguments when we get to the Q and A session.

I will note, however, with the Court's permission, to the extent there are any questions specific to the generic manufacturers, I may hand that over to my colleague, Mr. Winters, to address.

First, as to standing, by its nature the ELC does not allege any physical injury, but instead relies on the theory that the Ranitidine purchased by Plaintiffs was worthless, and therefore they have suffered an economic injury, but Plaintiffs don't plead any facts demonstrating that the Ranitidine they purchased was, in fact, worthless.

They don't plead that the Ranitidine purchased did not work as intended, or that it did not resolve their indicated symptoms or conditions. To the contrary, Plaintiffs' theory in respect to many aspects of this litigation in large part rests on their sustained use of Ranitidine because it was effective in treating those conditions.

Article III standing requires Plaintiffs to plead injury in fact. The ELC Plaintiffs were not injured. They bought a drug to treat a condition, and the drug treated that condition.

While they allege that some individuals may have been injured by the failure to disclose certain risks, Plaintiffs do not allege that they, themselves, are the people who suffered such injuries. Plaintiffs only response is that they never would have purchased the product in the first place if it had come with a cancer warning.

Regardless if that is true, once the product is purchased, used, and effective, and there is no adverse health effect, and to be clear, there is none alleged here, there is no injury.

As this Court in Green v. PepsiCo found, and many others cited in the Defendants' briefing, even when alleged impurities are present in a product, so long as the product purchased is the product received, and there was no resulting physical injury, Plaintiffs are not denied the

benefit of their bargain and do not have viable economic loss claims.

Plaintiffs' theory that NDMA is inherent in Ranitidine, whether in the drug as it exists from day one, or as a result of eventual degradation, distinguishes this case from the cases on which Plaintiffs rely to claim that the drug is worthless or that they suffered some economic loss.

In those cases, the defect was the result of the addition of some defect to the original product, meaning that the product received was different from what the Plaintiff was intending to purchase.

In those cases, economic loss can be determined by the difference between the value of the product as it was delivered versus the value of the product as it should have been delivered.

For instance, in In re Valsartan, the presence of NDMA in generic drugs was found to be -- Plaintiffs were found to have a viable economic loss claim because the results of the NDMA was the alleged failure of generic manufacturers to adhere to good manufacturing practices. The NDMA resulted in the generic version no longer being the bioequivalent of the brand name drug, which is what Plaintiffs were intending to purchase.

Thus, the Valsartan Court concluded that Plaintiffs did not receive what they intended to purchase, an unadulterated bioequivalent of the brand name drug, but that is

not the case here. The product promised was Ranitidine and the product delivered was Ranitidine.

Thus, there is no difference in value between the FDA approved Ranitidine Plaintiffs claim they should have received and the FDA approved Ranitidine that they did receive.

Nor is this case like Debernardis, in which the Court found that the drugs, in essence, were per se worthless because they could not be lawfully sold at the time Plaintiffs purchased them. The Ranitidine purchased by Plaintiffs here was expressly approved for sale by FDA at the time the Ranitidine was purchased.

Debernardis, in fact, made clear that was not intended to address the issue presented in this case, which is whether there is standing if the product purchased was lawfully sold, but allegedly came with inadequate warnings, or whether there is standing when the product purchased was later removed from the market.

At bottom, because Plaintiffs purchased Ranitidine, the Ranitidine is what they received, Plaintiffs do not allege that the Ranitidine they purchased was not effective in treating their conditions, and because they do not allege any adverse physical effect as a result of their ingestion of Ranitidine, they do not have an injury in fact and cannot satisfy Article III standing.

Importantly, however, even if the Court were to accept

that Plaintiffs have standing based on allegations that Ranitidine contains NDMA, or because Plaintiffs failed to warn -- or because Defendants failed to warn of an alleged cancer risk associated with Ranitidine, Plaintiffs claims against non-brand Defendants still must be dismissed.

As this Court previously ruled, such design defect and warning claims are preempted as to the generic distributor and retailer Defendants.

THE COURT: That is 20 minutes.

MS. COHAN: Okay. Quickly, I'll just say the Plaintiffs' claims are barred by the statutory exemptions and the consumer protection statutes because all of their claims stem from FDA approved labeling, which included FDA's approval of the drugs as safe and effective without a cancer warning.

So, claims based on the fact that it should have been an -- it should have contained a cancer warning should fall within that statutory exemption.

And I think it is undisputed that Plaintiffs failed to plead any allegations as to their physicians, what their physicians would have done, whether their physicians would have changed their prescribing decisions, and therefore they have not adequately pled proximate causation, and their claims as to prescription Ranitidine manufacturers should be dismissed.

THE COURT: Okay. That leaves you the two minutes that you wanted for rebuttal.

Okay. So, if we could now hear from the Plaintiffs with respect to this motion. We have Ms. Meeder and Ms. Fegan.

Ms. Meeder, did you want a warning?

MS. MEEDER: No, your Honor. Jessica Meeder on behalf of the Plaintiffs. I will be handling the medical monitoring portion and Ms. Fegan will handle the economic loss. I think we are okay without a warning.

THE COURT: Okay, great. You may proceed.

MS. MEEDER: Your Honor, Defendants seek wholesale dismissal of the medical monitoring complaint with prejudice.

Their motion presents four primary arguments, and I know they didn't touch on each of these points, but I would like to. Hopefully you are okay with it being a little bit out of order.

First, have the Plaintiffs impermissibly split their claims?

Second, do Plaintiffs have to plead a specific threshold level of exposure and describe the details of the protested diagnostic program to plausibly allege medical monitoring?

Third, must Plaintiffs' claims under Indiana and Montana law be dismissed on Erie grounds?

And fourth, have Plaintiffs failed to plausibly allege that Defendants knew or should have known that Ranitidine degrades to NDMA before ingestion?

The answer to each question is no, and in arguing otherwise, the Defendants misrepresent our allegations and misstate the law.

First, as to claims splitting, I have to admit, your Honor, I am surprised about the Defendants' argument here. We did what they asked for, and their argument today is different than what they argued before the Court several months ago. It is also contrary to your recent order.

You directed us to plead the class medical monitoring and class economic loss claims in separate complaints, and you thoughtfully clarified that that order was without prejudice to the Plaintiffs' substantive claims.

You didn't tell us we had to go find new Plaintiffs or that those who sought to bring these claims, the named Plaintiffs are actual people, could no longer pursue them in the class complaint. So we followed the Court's order.

Now the Defendants would have both us and you undo what you directed and there is no reason to do that. As we explain in our papers, we haven't impermissibly split our claims. None of the policy issues underlying the claims splitting doctrine are at issue here, and under that doctrine, as well as an MDL judge, you have the discretion to manage the class claims in the way that you find is most efficient, which was why you issued your recent order.

Second, Defendants argue that Plaintiffs can't

plausibly state a medical monitoring claim unless they identify a specific threshold level of exposure and outline the details of the diagnostic program, but medical monitoring is a fact-intensive inquiry that requires expert testimony. It is not a question of law to be decided under Rule 12.

In the Petito case out of the Third DCA, the Court explained that after a Plaintiff proves a need for monitoring, it is the Court's job to determine how much and what type of diagnostic testing is needed and how it will be conducted. There Plaintiffs alleged exposure through ingestion, just like Plaintiffs do here, and it was enough.

In Trujillo and Allgood, the Courts reiterated that the elements of medical monitoring are questions for the trier of fact, and so it is not appropriate to decide at the pleading stage whether the factors have been satisfied. So a Plaintiffs' allegations of the necessary diagnostic testing have to be accepted as true.

In In re Paulsboro, the Court explained that a Plaintiff seeking medical monitoring relief only needs to allege direct exposure to harmful chemicals and an increased risk of disease connected to that exposure.

Further, Twombly does not require a Plaintiff to plead damages or relief, here the diagnostic program, with specificity.

Defendants asked for more than what Rule 12 requires,

and our claims are plausibly alleged. We describe the mechanism and extent of exposure. Each Plaintiff ingested one to two tablets of Ranitidine a day for years. One tablet contains more than 3,000 times the FDA acceptable daily limit of NDMA. The drug creates additional NDMA in the body. So, Plaintiffs are exposed to staggering doses of NDMA over an extended period of time, which increased their risk of cancer.

We plausibly allege that the increased risk of disease warrants diagnostic testing that is reasonably necessary and different from routine medical care.

These are all factual allegations the Court must accept as true. Though they claim that these allegations aren't enough, the Defendants don't directly address any of our arguments or explain why Rule 8 requires Plaintiffs to plead expert testimony. Instead, they rely on a single case, Riva, for the proposition that a threshold level of exposure is required, but that is not the law, and it is not what Riva held.

The Riva Plaintiffs did not plausibly allege an injury because they said that the risk of harm existed beyond the threshold, but they never identified it and didn't allege they exceeded it. They didn't causally connect the chemical at issue to the cancer at issue in humans, and they didn't plausibly allege toxicity, but none of those issues exist here.

We allege that NDMA is carcinogenic to humans and

identify supporting animal and epidemiological studies. We allege the exposure was significant enough to cause cancer.

We don't allege risk based on a particular threshold level, so it doesn't need to be identified, but even if a threshold level of exposure was required, we still alleged it, the FDA's 96 nanogram limit, which each tablet exceeded by orders of magnitude. Riva does not support the Defendants' position, and the Trujillo Court explained this.

Defendants further argue, absent identified threshold level of exposure, anyone who consumes any amount of Ranitidine, no matter how small, will get medical monitoring, but this is a red herring.

The only claims before the Court are the named Plaintiffs' claims, and each named Plaintiff alleges years of excessive NDMA exposure. Whether there is a risk of disease at a lesser level of exposure isn't at issue, and the impact and relevance of the FDA's acceptable daily limit can't be considered at this stage either.

Further, Defendants' cited cases are all distinguishable. There Plaintiffs either failed to allege other aspects of the claim, failed to plead a serious disease or significantly increased risk of disease, or failed to allege exposure. The MMC doesn't suffer from any of these deficiencies.

Defendants next request dismissal of Plaintiffs'

claims under Indiana and Montana law, pursuant to Erie, but again they are wrong in both regards. Medical monitoring is not a novel claim, it is a natural application of general tort principles.

In Indiana, the intermediate appellate court already recognized medical monitoring and, under Erie principles, this Court is obligated to follow that, absent compelling evidence otherwise.

Defendants would like to state some difference between that Gray case and our case because of the presence of negligence claims here, but in Gray, the Court did find that an injury to health is constituted by risk of disease. Injury to health is one of the types of injuries you can show for nuisance under Indiana law.

The Allgood Court actually did pertain to negligence counts as well. There Plaintiffs allege -- excuse me, your Honor -- nuisance and negligence, and that Court noted that medical monitoring is available in Indiana as a remedy for tortious conduct, which, indeed, is what cases generally state across the country.

Indiana law does not state that a Plaintiff exposed to a hazardous substance only has an injury if they exhibit symptoms or receive a diagnosis. Defense counsel cited the Ott case, but that case was asbestos specific and it was interpreting a statute of repose that is inapplicable here,

where exposure occurred over a long period of time.

The other Federal cases that Defendants cite never analyzed this issue in any way at all, so the authority to look to is Gray and Allgood, plus general medical monitoring principles that we have outlined in our brief.

In truth, Defendants' only argument as to Montana is that trial court opinions don't matter. We never said that the mere existence of a trial court opinion meant that the Court had to follow it. Certainly Erie requires the Court to look at it as a piece of evidence. We also provided other reasons why that opinion should be accorded significant weight.

What we said was that it wasn't challenged at all by any other Court in the 21 years since its publication, it hasn't been overruled by the legislature, it has been relied upon by other Courts. We cited one of those in our brief. It was written in a state where there is no intermediate appellate court at all, and medical monitoring cases continue to be litigated in Montana. We cited those as well.

Defendants also challenge the consistency and adequacy of certain negligence claims in our complaint, ignoring our well pleaded allegations. I think that these issues were addressed well this morning with respect to the AMPIC, but there are just a few points I would like to make.

First, Defendants argue specifically as to the expiration date claims and product container claims that we

don't plausibly allege they were on notice that Ranitidine degrades to form NDMA pre-ingestion. For the same reasons as to the AMPIC, we also allege that plausibly here.

For example, Ranitidine contains the necessary elements of NDMA, published studies dating back to the 1980's found NDMA in the body after Ranitidine consumption, and more recent studies, which we say Defendants could and should have conducted earlier, reveal that Ranitidine degrades into NDMA when subjected to heat and humidity pre-ingestion. That is paragraphs 230 to 275 and 292 to 302.

Each piece of this information should have prompted the Defendants to investigate further, particularly given that they are experts, they studied Ranitidine before manufacture, and they had a continuing duty to test it. We explicitly allege that the drug's pre-ingestion degradation was known or knowable at the time of manufacture, so we plausibly both of these claims.

Defendants also argue that expiration date, product container, and storage and transport claims are actually inconsistent because they reference endogenous formation. In many respects this is the same argument they make as to the AMPIC. It is both illogical and belied by the MMC.

The primary expiration date allegations that complete Section 5-B explain that the Defendants should have known that Ranitidine degrades to form NDMA both before and after

ingestion, endangering Plaintiffs. So they should have set their product expiration dates to account for these risks, warning Plaintiffs to consume the drugs shortly after purchase. That is all this count says.

We don't allege that the Defendants should have used the expiration dates to somehow warn that the drug forms NDMA post ingestion.

The product container and storage and transport claims don't reference endogenous formation in the way the Defendants claim. Their citations are wrong. So, consistent with what counsel explained this morning, there is just no inconsistency in any of these counts.

Finally, as to the failure to warn consumers through the FDA counts, we incorporate arguments by co-counsel regarding the AMPIC because the complaints are lockstep in this manner.

In sum, each of Defendants' arguments in support of dismissal with prejudice are based on a misapplication of the law or a disregard of Plaintiffs' allegations as pled. We respectfully request that their motion be denied.

THE COURT: Thank you.

MS. FEGAN: Good afternoon, your Honor, Elizabeth Fegan on behalf of Plaintiffs with respect to the Motion to Dismiss the economic loss complaint. I am going to follow Ms. Cohan's outline and address the issues that she raised in

her argument.

First, with respect to Article III standing, here we allege that the economic loss Plaintiffs did not receive the benefit of the bargain. The key here is that benefit is not a stand-alone word, it is part of a phrase. Benefit of the bargain is the principle that any party who reaches a duty must pay the other an amount that puts them in the same financial position as if the duty had been fully performed.

Here, we allege that the Plaintiffs did not receive what they bargained for. They bargained for an effective heartburn relief medicine that did not cause cancer or put them at the risk of causing cancer. They did not receive a drug which provided heartburn relief and that did not expose them to a known carcinogen, and for that reason, the Plaintiffs have alleged that they either wouldn't have bought the product and that the product was worth zero.

That is the epitome of an economic injury recognized by the Eleventh Circuit in MSPA. Here, your Honor, the Lewis v. Mercedes-Benz case which came out in March is directly on point.

There the Plaintiffs allege that there was a headrest with cheap plastic in Mercedes-Benz cars and over time that plastic would degrade and cause those headrests to spontaneously eject and hit you in the back of the head, a serious safety defect.

There, seven of the nine class representatives had not actually experienced the ejecting or exploding headrest, and the Court said at first blush, the idea that because the headrest hadn't malfunctioned, and therefore, at first blush, Defendants' argument that there was no economic injury made sense.

But the Court there said that this was a ticking time bomb, and that type of safety defect where the defect would degrade over time, the plastic would degrade over time, and had the risk of causing injury, and therefore, had the Plaintiffs known that this defect existed, that they wouldn't have purchased the cars or would have paid less is a class economic loss.

That is exactly the same thing here. Whether we are talking about degrading plastic or we are talking about Ranitidine that can degrade into NDMA, Plaintiffs here have alleged they would not have purchased it.

They don't need to sit, as the Lewis Court called it, on a ticking time bomb and wait to actually develop cancer to allege that they would not have purchased it or to alleged that they suffered a concrete financial loss.

This makes this case also very similar to the Aqua Dots case. The Aqua Dots case in the Seventh Circuit was about toy beads that children would play with, that when mixed with water could turn into the date rape drug. There the Plaintiffs

allege they would not have purchased these beads for their children had they known they would degrade into a date rape drug when mixed with water.

The Court there basically rejected the Defendant's argument that the Plaintiffs didn't have standing because the children of these class representatives had not actually swallowed the beads and experienced the effects of a date rape drug. Instead, the Court said just because the members of the class did not suffer physical injury does not mean that they were uninjured.

Again, that is like out Plaintiffs here, just because our Plaintiffs yet have not developed cancer doesn't mean that they were uninjured in buying a product that degrades into NDMA and has the risk of causing cancer.

In Defendants' reply they cite to Ikie versus Allergen, (phon) but that case is not on point. They cite to it for the idea that mere regret or disappointment doesn't give rise to damages or injury, but there, there was no defect in the product. The product there were eye drops, and the dosage in the bottles of eye drops was more than the Plaintiffs could use.

So, the idea was that the Plaintiffs were complaining about leftover drops, that they bought too much, and there the Court said, well, you are disappointed that you bought too much or too big of a bottle, but that doesn't give rise to injury.

That is primarily different than when you are talking about a product with a real safety defect, as we have alleged here.

Your Honor, with respect to the affirmative defenses that Defendants have raised, and in particular starting with the Learned Intermediary Doctrine, affirmative defenses are not appropriate for dismissal -- to cause dismissal on a 12(b)(6) motion.

First, the Learned Intermediary Doctrine only applies to prescription drugs. So, even if this Court were to apply it at this stage, it does not apply to the over-the-counter products that Plaintiffs have alleged in the complaint.

Second, it is not ripe, it is a fact base question. Most of the cases that both sides cite deal with summary judgment, motions for directed verdict after trial. But ultimately, if this Court looks at the facts that we have alleged, we have alleged that the Defendants warned no one. Warning no one means they have did not warn the physicians, so on the facts we have alleged in the complaint the Learned Intermediary Doctrine does not apply.

Finally, your Honor, we have briefed, and I won't go through it all here, the idea that most states apply either a heeding or rebuttable presumption with respect to causation when applying the Learned Intermediary Doctrine. What this means is that, had a warning been given, the Court can instruct the jury to presume that that warning would have been heeded.

So, had the Defendants given the warning at the appropriate times, that warning would have been heeded by the physicians and would have changed prescriptions. In fact, we see that with respect to the recall at large.

Once it comes out that this is a problem and that NDMA results from Ranitidine and causes cancer, the product is withdrawn.

Finally, your Honor, with respect to the Consumer Protection Act safe harbor affirmative defense, again, this is not ripe because it is a fact based question, but really this is just an argument of preemption dressed in the context of Consumer Protection Act claims.

Here, the Consumer Protection Act claims only provide safe harbor if an act is specifically authorized, not if an area is generally regulated, and just because the FDA regulates medicines does not give rise to the complete deletion of Consumer Protection Act claims in the context of pharmaceutical litigation.

Therefore, your Honor, we ask that the Motion to Dismiss be denied.

THE COURT: Okay, thank you very much.

We will turn it back to Defense for your remaining two-minute rebuttal.

MS. COHAN: Hi, your Honor, Lindsey Cohan again for Defendants. Just a couple quick points that I wanted to

address.

First, as to the Learned Intermediary Doctrine, there is no dispute that it applies in the context of this case, and the Eleventh Circuit in Tutwiler v. Sandoz rejected a Plaintiffs' claims where they failed to allege any claim that the prescribing physicians received the warning or that they would have changed their prescribing decisions had a different warning been given.

Thus, it is completely appropriate for this Court to consider that lack of allegation at this phase of the litigation. Tutwiler affirmed a 12(b)(6) dismissal. In fact, Tutwiler rejected as sufficient the same allegations that Plaintiffs are trying to make here.

In Tutwiler, Plaintiffs maintained that they made sufficient allegations to overcome the Learned Intermediary Doctrine by saying all physicians in the U.S. were inadequately warned. The Eleventh Circuit rejected that, finding that Plaintiff was required to plead specifically as to her physician and her physician's prescribing decisions.

Respectfully, Plaintiffs are in the same boat, they have not pled as to their physicians or their physicians's prescribing decisions, and therefore, their claims should be dismissed.

Finally, I will just say that I feel as though the Plaintiffs really have not addressed this Court's recent ruling

in Ezcurra v. Monsanto with respect to the consumer protection safe harbor provision. There, this Court determined the allegations that the Roundup product violated Florida's Consumer Protection Statute because it did not include a cancer warning, that those claims fell within the statute safe harbor provision.

Importantly, Ezcurra was decided under the Florida Consumer protection Statute, which is one of the more narrow consumer protection statutes that Plaintiffs identify in their briefing. But as the Court explained, the EPA's approval of the Roundup label without a cancer warning necessarily meant that the EPA found that the label adequately warned of the risks associated with the product and were not false or misleading in the absence of a cancer warning.

THE COURT: That is a little over two minutes.

MS. COHAN: Okay.

THE COURT: Okay, great, thanks. Bear with me one minute.

Okay. So, I think we are going to take our mid-afternoon break, because I do have questions related to this motion, so I would ask that all counsel be ready to come back on.

We will take a 15-minute break. It is 2:46, so we will come back at 3:01, and we will engage in question and answers related to this last motion.

You can leave your -- stay connected, but turn your video off and mute yourselves and we will see you back at 3:01. Thanks.

(Thereupon, a short recess was taken.)

THE COURT: Okay. Sorry, we are a couple of minutes late. We can have counsel come back on this motion.

All right. So, let's just pick up where we began with Defenses' argument on claims splitting.

First, Mr. Petrosinelli, could you repeat what you said with respect to why couldn't the 51 Plaintiffs be dropped as named Plaintiffs. Just say it exactly the way you said it, and I want to turn to the Plaintiff and give them an opportunity to respond to just that one aspect of what you said.

MR. PETROSINELLI: Yes, your Honor. The 51 Plaintiffs who are named in both the medical monitoring and the economic loss complaint, they could be dropped as named Plaintiffs in the economic loss complaint without prejudice to their individual claims, and if they want to plead an economic loss claim, they can add it to their medical monitoring class complaint as non-class claim, as many class representatives do.

THE COURT: Okay. Without getting into the merits of claims splitting, which I have a couple of questions on, I want the Plaintiffs to have the opportunity to respond to that.

MS. MEEDER: Your Honor, to make sure I understand, I

think what the Defense is suggesting is that named medical monitoring Plaintiffs now state individual economic loss claims also in the medical monitoring complaint. If that is true, that is not what we were asked to do.

We separated the claims out for clarity of injury, which was something Defendants had quibbled with earlier on, so that we could clarify what injury related to what counts, but that is also inefficient. These named Plaintiffs are actual Plaintiffs, they have elected to pursue their claims as class claims as class reps.

So, for the convenience of the Court and the parties, we distributed those claims in two separate complaints, but there was never an understanding that their ability to bring a certain type of claim would somehow be implicated by the previous orders.

THE COURT: Is it the bringing of the claim or is their status as the named representative that, Mr. Petrosinelli, you are focused on?

MR. PETROSINELLI: The status as a class representative, that is the problem, is being a class representative in two class complaints. That's why it would be fine if they brought the economic loss claim in their individual capacity in their medical monitoring class complaint, and then they wouldn't split their claims.

THE COURT: What if there was just one master

complaint that had medical monitoring class claims and economic loss class claims and the same 51 named Plaintiff representatives and they were bringing it in the alternative.

Is that a problem in your view?

MR. PETROSINELLI: I think it would be a case management problem. Having two separate class actions with separate class claims of an entirely different nature, one related to economic loss and one related to medical monitoring would -- I just think when you got to the certification stage, it would cause all sorts of confusion and complications, especially because -- remember, your Honor, there are 181, currently, named class representatives in the economic loss complaint.

So, now you would have people -- some people who were purporting to be class representatives only in economic loss, and some in both. It just seems to me like a case management challenge.

THE COURT: Okay. Let me follow up with you, then, on one additional question relating to claims splitting. As I understood claims splitting, the rule against claims splitting requires a Plaintiff to assert all of its causes of action arising from a common set of facts in one lawsuit. That is the Vanover versus NCO case, 857 F.3d 833, Eleventh Circuit, 2017.

So, I guess, my first question is, as for the master complaint, isn't there just one lawsuit before the Court, and

that is the MDL, albeit several different master pleadings? So that is the first question. Would you agree with that?

MR. PETROSINELLI: I don't. My view of the Vanover case and the claims splitting cases is that, obviously that wasn't an MDL case, but they are focused on the complaints. In many of these claims splitting cases there are two complaints in the same court before the same judge. They are not MDLs and they still apply the claims splitting analysis.

Obviously, here you have an MDL with two complaints in this case before the same judge. I don't see any material difference between those two scenarios for purpose of a claims splitting analysis.

THE COURT: Okay. All righty. Let me quickly address two other points that were addressed in Defense argument, and then get on to some other questions.

Question for the Plaintiffs, with respect to the arguments that were being made with respect to Montana and the Erie prediction and the Lamping case, which is a trial court case, there is no appellate level, no Supreme Court, what would you say is the Erie analysis that the Court undertakes, you know, when it has one trial court opinion?

It happens to be 20 years ago. I don't know that that is the most significant aspect of it. Briefly walk me through how you would have the Court make the Erie analysis based on one trial court opinion.

MS. MEEDER: Certainly, your Honor. I don't think it is just about one trial court opinion. I think the Erie principles require the Court to consider all information that could be probative of how a state Supreme Court would determine the issue, and so, the Lamping decision, while a trial court decision, is also very thorough and well reasoned.

In its analysis, it cites other established medical monitoring cases like Friends For All Children and Ayers out of New Jersey. It is a very methodical analytical approach.

The Court doesn't identify anywhere in its opinion any Montana law that would run contrary to accepting medical monitoring as an independent claim. So, it is not only the existence of the opinion, it is the weight of the opinion based on the depth of its analysis, plus its other aspects of Montana law. The defendants don't point to any other aspect of Montana law that would preclude medical monitoring as a claim.

It is also other details, like the fact the case is still standing. There are still cases being litigated there, there are other Federal Courts that have relied upon that case, and no one has overruled it, the legislature hasn't either, i think all of those come together under the rubric of issues that the Court should look to when evaluating Erie.

THE COURT: When you say it is still being litigated, you are saying since that opinion, Plaintiffs are bringing cases and alleging medical monitoring claims and they are

moving through the system?

MS. MEEDER: Yes, your Honor. Thank you for pointing that out, that may not have been clearly stated. I think we identified in our papers some other cases in Montana where medical monitoring is addressed. I will also note there are other MDLs where medical monitoring in Montana remains live as well.

THE COURT: Okay. And you believe you cited those in your briefing?

MS. MEEDER: I did, your Honor.

THE COURT: If you could briefly respond to Indiana and the argument that it perhaps is limited to nuisance because of the particular way in which the nuisance statute is drafted in Indiana.

MS. MEEDER: I don't think the fact that nuisance in Indiana is a statutory claim really has anything to do with this. The reality is that there are numerous Courts around the country that adopt medical monitoring both as to nuisance, negligence, and any other tort claim. An example is California. I believe the Albright case out of Maryland is also both a nuisance and negligence case, and the Allgood case, which was the Southern District of Indiana, included both nuisance and negligence claims.

I think what the Defendant was really getting to was whether by statute the definition of an injury for nuisance

doesn't require the Court to look to actual or present physical injury, but actually, if you read the Gray opinion, you will see that what the Court did was say that a risk of disease, like what we allege here, is an injury to health, and I don't know how that is really any different than what would be required for nuisance -- I am sorry, for negligence.

Also, in tort law even in Indiana, nuisance and negligence are not mutually exclusive claims. I was reading nuisance cases in Indiana anticipating this type of question and there are cases where the Court talks about nuisance as being underlied by negligent conduct.

So, the idea that these are two dichotomous causes of action is simply not borne out in law.

THE COURT: What weight, if any, do you believe the Court gives to the Erie analysis that it remains a minority view, 14 or so jurisdictions, albeit not as minority as innovator liability, but nevertheless, a minority? Where does that fit into the Erie analysis in your view?

MS. MEEDER: I think it is true that that does bear some weight, but again, Defendants never actually demonstrated why medical monitoring is a minority view. If you read through the case law that addresses medical monitoring, there are really only about a handful, maybe less than ten state courts that have refused to adopt it.

I would push back a little bit on this idea that it is

some out there type of claim. I do think it is something the Court should consider, but again it should look to cases where state have declined to adopt medical monitoring and note that they typically do so because there is some other principle of state law that prohibits them from accepting it.

For example, in Oregon there was already case law establishing an actual physical injury as required for negligence, so it wasn't possible for the Court to then analyze medical monitoring and decide that in the absence of that injury it was appropriate, unless that was changed at a different level. Those types of breadcrumbs just don't exist here, your Honor.

THE COURT: All right. Still a question for Plaintiffs. I want to -- much has been said about the Court's last order with respect to what you could or could not do, so I want to walk through it and I want to make sure you understand and I understand that you understand before we get to the next series of questions.

You will recall in the Court's prior order on injury in fact that the Court struck all allegations of physical and/or personal injury from the ELC. That was at Docket Entry 2515, at pages 46 to 48. The Court noted, however, that the Plaintiffs "without any prejudice to their substantive claims, may seek leave of Court for an alternative pleading to allege their class physical injury and/or medical monitoring claims."

That was at page 47.

Plaintiffs subsequently motioned to certify a question for interlocutory appeal at Docket Entry 2693. In that motion, Plaintiffs argued that because of the Court's order on preemption for brand named manufacturer Defendants, they could no longer allege economic loss claims premised on personal injury. The Court denied the motion without prejudice and re-clarified that its prior order did not preclude the Plaintiffs from pleading as they described.

The Court cited language from its order on injury in fact, namely that Plaintiffs could seek leave of Court for an alternative pleading for alleged class physical injury and/or medical monitoring claims. Docket Entry 2716, at 2.

Plaintiffs appear to have accepted the Court's invitation, if you will, in part, as they sought leave to file the medical monitoring complaint, and declined the invitation in part, as Plaintiffs did not seek leave to file a class personal or physical injury complaint. That is, Plaintiffs injury in the ELC appears to be solely based on the economic injury.

Is my understanding correct of what you have understood and what you have done? Is there anything that I just said that is wrong in your view?

MS. MEEDER: No, your Honor.

THE COURT: Okay. So, in other words, you understood

that Plaintiffs had the right to seek leave to file a class personal/physical injury complaint?

MS. MEEDER: I think that is true, your Honor, and there was a difference in the --

THE COURT: Well, you think? I mean, is the question -- did you understand you had that right, like yes or no?

MS. MEEDER: Yes, your Honor.

THE COURT: I don't want to put words in your mouth, but it is important that I know what you understand and don't understand. It has been a point of some motion practice here.

So, you understood that you had the right, the Plaintiffs, to seek leave to file a class personal/physical injury complaint?

MS. MEEDER: Yes.

THE COURT: Okay. Okay. This is for the Plaintiffs. Some of the named Plaintiffs allege that they purchased Ranitidine products, while others allege that they purchased and used Ranitidine-containing products.

So compare -- for example, in the ELC, paragraph 126, Plaintiff Sharon Tweg "purchased Ranitidine containing products, with ELC 158, Plaintiff Rafael Bermudez "purchased and used Ranitidine containing products." For purposes of your theory of injury-in-fact and standing, does it matter whether a Plaintiff in the ELC purchased and used as opposed to merely

purchased the product? If it matters, please tell me why.

MS. FEGAN: With respect to the ELC complaint, your Honor, it does not matter. Someone could have purchased it for household use and the person who paid the money is the one that suffers the injury.

THE COURT: Okay. Do the Defendants think that this pleading distinction matters for purposes of standing?

MS. COHAN: I do, your Honor. This is Lindsey Cohan for Defendants. This goes to the point -- Plaintiffs for the first time raised the Lewis v. Mercedes-Benz argument as to standing. That was not in their opposition, but nevertheless, that case really hinged on the fact that the Defendants there claimed that Plaintiffs had to wait for the defect to arise before Plaintiffs could bring their claims.

That is just not the case here. Defendants aren't saying that Plaintiffs have to wait until they develop cancer to bring their claims. The fact of the matter is that Plaintiffs don't allege that they are at risk of developing cancer, the only claims that they are bringing are for their economic loss.

In fact, the Plaintiffs, to your question, don't even have to have ingested the product, and therefore wouldn't even be at risk of developing cancer, unlike the case in Mercedes where they purchased a vehicle and therefore were at risk of suffering the defect of the exploding headrest. That is just

not the case here where Plaintiffs didn't have to have ingested the product.

THE COURT: Is your position that whether they purchased or purchased and used, neither is sufficient for purposes of standing, but in any event, it is definitely not sufficient for standing if it is just purchased, like that is really not enough?

MS. COHAN: I do think that is a fair characterization, your Honor.

THE COURT: So the use matters in your view.

MS. COHAN: I think the allegations of use would depend, and we just haven't seen those, to be fair, in the economic loss. If those allegations of use were accompanied by allegations of physical injury, then that would be very different. Here, where we just have economic loss that is completely untethered to ingestion or injury, then there is no standing.

THE COURT: I guess, since there is no physical injury being alleged, then why would this matter?

MS. COHAN: I say that only to rebut the claim that the Lewis v. Mercedes case applies here, because there the risk was imminent to the purchaser. Here, we don't know that the risk was imminent because we don't know that that purchaser was actually going to use the product, or did ever use the product, I should say.

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

THE COURT: Yes.

MS. FEGAN: An assumption is being made that the Lewis class representatives didn't purchase the car for their 16 year old son, for example. There, use is not at issue. The only person who can claim a financial injury is the person who paid for the particular product. This is similar in Aqua Dots, it's the children who played with the beads. There was no risk of a parent ingesting a bead that had turned into a date rape drug.

So, the idea here is the out-of-pocket loss flows to the purchaser regardless of use.

THE COURT: All right. This is a question for both sides. Maybe Defense can answer it first, then Plaintiffs.

Some of the standing cases that the parties cite in their briefing involve durable goods that could be resold or returned, such as the toys in Aqua Dots and the cars in Takata Airbags. Other cases involve nondurable goods, such as the drugs in Debernardis, the shampoo in Medley, and the cereal in Doss.

For purposes of the potential to inflict an economic injury, does it matter whether a product is durable or nondurable, Defense?

MS. COHAN: I think in this respect, your Honor, while potentially relevant because they are not going to return the product and the value of the product is -- there is not an

overpayment offset where they would return half a bottle of shampoo.

I think here more relevant is the claim by Plaintiffs that the defect is inherent to the product itself as opposed to added to the product after the fact, and I think that goes in some part to the question of durable use because, for example, in the case of Aqua Dots where there they were manufactured in some respects inconsistent with how they should have been manufactured and those products could be returned, and they could have gotten a product that was manufactured in the way that it was supposed to.

Ranitidine, however, if their challenge is that Ranitidine can never be manufactured safely, then those products cannot be returned for, let's say, safe Ranitidine.

THE COURT: Do the Plaintiffs want to say anything on that issue?

MS. FEGAN: Your Honor, there is no requirement in the case law that a product has to be returned in order to allege a financial injury.

THE COURT: This is a question for Plaintiffs. Debernardis posed two questions to ascertain standing. Number one, does a purchaser acquire a worthless product when he purchases an adulterated supplement; and if so, did the Plaintiffs adequately allege that the supplements they purchased were adulterated.

Applying those questions to our case and substituting adulterated supplement with misbranded drug, how would you answer these questions and why?

MS. FEGAN: Your Honor, Debernardis focused on a product that the Plaintiffs claimed was worthless because it didn't comply with certain technical specifications by the FDA. Here, we actually allege that the product is defective and misbranded because it turns into and causes a safety defect, it turns into NDMA.

In this context, we think that we are beyond Debernardis. We are not alleging a technical defect, we are alleging a safety defect, and when we are talking about whether that safety defect we're more in the realm of Lewis and the other cases that we cited that talk about whether that safety defect is material, and actually, under many consumer protection laws, safety is presumed to be a material omission if it is not disclosed.

Your Honor, I appreciate that in the first round we relied heavily on Debernardis, but after stepping back and looking at the case law, we think we are actually beyond Debernardis because we are not relying on just a technical defect.

THE COURT: Bear with me, I have a few more Debernardis questions because it is an Eleventh Circuit case, albeit they said it was limited. I will get into other cases

as well, but just stick with me for a minute.

In analyzing the second question, the Debernardis Court noted that the new dietary supplement, DMBA, was presumptively adulterated.

Is it the Plaintiff's position that there is a presumption of misbranding in our case?

MS. FEGAN: No, your Honor, there is not.

THE COURT: The Court went on to say that the Plaintiffs adequately alleged that the supplements they purchased were adulterated, meaning the FDCA banned their sale.

What is the proper analogy of this statement to our case? Do the Plaintiffs' allegations that Zantac was misbranded mean that the FDA banned its sale?

MS. FEGAN: Your Honor, I think what we have alleged are the facts of what actually happened, and the facts of what actually happened are that when the material safety defect was disclosed, the recall was implemented and it was in fact withdrawn from the market.

This isn't a case where we have to go back and create some type of but for world or try to say what would have happened, but it is still being sold. We actually can see in real world time what happened.

I don't know if I am answering your question directly, but I think we have to hear -- rather than talking about presumptions or talking about what could have happened or would

have happened, we look at what actually happened.

THE COURT: Is a voluntary recall, nevertheless, different than the FDA banning a drug?

MS. FEGAN: It is, your Honor, however, what I think we see here is that there was no need for the FDA to ban it because across the board every single manufacturer stopped selling it.

THE COURT: Okay. The Debernardis Court concluded that the Plaintiffs had standing because they allegedly experienced an economic loss when they purchased a product that the FDCA banned from sale because it was presumptively unsafe.

I am kind of wrapping up the steps that Debernardis went through. Anything different that you want to add in terms of how that very conclusion applies to our case, or do you feel you have said it in answering the other questions?

MS. FEGAN: Your Honor, I think I have generally said it, but I do think at the end of the day -- I can't remember if it was Mr. Petrosinelli or Mr. Cheffo talked about the Defendants sold this drug to make money. They wouldn't have withdrawn the drug from the market if it wasn't worthless.

In that context, your Honor, we have alleged facts that demonstrate not only did the Defendants withdraw the drug from the market, underlying their belief they could no longer make money on it, but that is consistent with Plaintiffs' position that they would not have purchased it had the

disclosures been made, and therefore it is worthless.

THE COURT: Okay. This is for both sides, but we can stick with the Plaintiff for a moment and then go to the Defense.

What is the significance of Debernardis' limiting language that it was not deciding whether a consumer who alleges he purchased a product that could not legally be sold under a different statutory scheme acquired a worthless product; and furthermore, that the decision is limited to the specific facts alleged in the case, that is where the Plaintiffs purchased dietary supplements that Congress, through the FDCA and the DSHEA, had banned from sale with the purpose of preventing consumers from ingesting an unsafe product?

MS. FEGAN: Your Honor, I think the limitation language is, in part, why, in looking at the facts here we have gone beyond that and going into other case law, ultimately, because our facts demonstrate that this was not a case about presumptions based on what the FDA did or didn't do, but based on real world facts. I don't think it really has that much impact one way or the other.

THE COURT: Okay. From the Defense.

MS. COHAN: Your Honor, I think the limiting language in Debernardis is very important here and demonstrates why the holding in Debernardis can't be translated beyond that case where the issue was that the product sold and purchased could

not be lawfully sold at the time it was sold, so de facto, it was a worthless product.

Here, the product sold was approved for sale by the FDA and there is no allegation at present that, you know, Defendants were not selling their FDA approved medications in compliance with the FDA approved labeling. I think those are very important distinctions in this case.

THE COURT: Do Plaintiffs agree that there are no allegations consistent with what Defense just said?

MS. FEGAN: No, your Honor, we don't agree with that. In fact, our allegations go beyond any FDA approved label. When we talk about package size, for example, the FDA does not regulate package size. We talked extensively about expiration dates in the CBE regulation and the ability of manufacturers to move separately from the FDA.

So, in fact, we also allege extensively the information that was withheld and not disclosed to the FDA. So, I don't agree with what Defense counsel has said in terms of the entirety of what we have alleged being approved by the FDA.

THE COURT: Following up with Plaintiffs, Debernardis cited to the Ninth Circuit case in Franz which involved a lotion that qualified as a "drug" under the FDCA, but not approved by the FDA. The Franz Court held that the consumer suffered an injury in fact when she allegedly spent money to

purchase a product that should not have been sold because it was illegal to sell.

But Zantac was approved by the FDA. How do you argue that the holdings in cases like Debernardis and Franz, but now I am talking about Franz, apply to this case given those factual differences?

I am asking the same type of question, I recognize that, but in slightly different ways, because there are a series of cases that very much seem to go to this notion of something being approved by the FDA or not approved, illegal to sell. I want to make sure I understand your position with respect to each of these cases.

MS. FEGAN: Yes, your Honor. There are a series of cases that talk about products that couldn't have been sold, but they don't allege material safety defects.

I think that is what really makes this case different, and the idea that the FDA approved a product and therefore, regardless of its safety defect, no Plaintiff can recover is just not the law.

THE COURT: So, you are not putting your case in the bucket of cases that found standing based on illegal to sell, whether it be because the FDA took some action or -- actually, I think in most of those cases, if not all of them, the FDA actually did take action.

Are you not putting your case -- this case in that

bucket of cases, is it a different theory of standing?

MS. FEGAN: I think it is parallel, but it goes beyond those cases because the FDA does regulate a number of areas and the FDA requires that manufacturers go through it in order to sell their particular products, whether it is a lotion, a cosmetic, or particular drug, and if they haven't gone through those processes, yes, they have to withdraw it, and that is an illegal product to sell.

But even where a product had gone through those processes, if there is a safety defect, an undisclosed safety defect and we don't go beyond what the Federal Government requires, then we are allowed to bring claims based on those omissions. Our case is not being consistent with those cases, but goes beyond it because we are talking about a material undisclosed safety defect.

THE COURT: One of the concerns raised, I know its not necessarily in the opinion, but in the oral argument if you listen to it in Debernardis by one of the judges on the panel, was that might this not open the floodgate to economic injury standing cases.

In other words, what is to keep any Plaintiff, or group of Plaintiffs, from alleging the product was misbranded, the product was defective, the product was adulterated, it should not have been sold -- yes, it did what it was supposed to do, in other words, you know, it didn't cause physical

injury, but if I knew these things about this defect, I wouldn't have bought it.

Wouldn't that allow just about any and every case with those allegations -- I am not saying it can be proved at the end of the day, and there is a difference, presumably, in the quality of different merits in cases, but is that what economic injury, standing injury in fact principles are meant to be?

MS. FEGAN: Your Honor, I don't think anything about this case is going to open the floodgates to further litigation. I think we have to fundamentally go back to the principles of state law that recognize benefit of the bargain damages. Benefit of the bargain damages has been around -- the principle has been around for as long as state law economic loss claims and Consumer Protection Act claims.

Certainly, is state legislature were concerned, they wouldn't recognize the statutory right to bring a Consumer Protection Act claim and wouldn't recognize benefit of the bargain or out-of-pocket loss damages as a recovery for omissions or deceptions.

So, you know, we are not trying to push the envelope here or create something new, and I think, again, because we are talking about a material safety defect, if you think about other cases where this has been brought, like the Takata Airbags, or in Lewis the exploding headrest, the idea that someone couldn't recover unless they were actually killed by an

exploding airbag or a headrest, or unless they actually get cancer is just not the law under state Consumer Protection Act claims.

THE COURT: Aren't a lot of those benefit of the bargain cases, though, in the context of I purchased a box of something and it was only half full, so I didn't get the benefit of the bargain, things along those lines? So I understand benefit of the bargain has been around awhile and economic injury, but my reading of those cases, those were sort of -- that there was either a physical injury alleged, or if there is not a physical injury, that there was -- that someone didn't get the benefit of the bargain insofar as they just didn't get the package they bargained for, or it didn't do what it was supposed to do, or I am returning it because it was missing a wheel, or something along those lines.

This does seem a little bit different than all of those benefit of the bargain cases that have been around awhile. Maybe I am mistaken. Do you disagree?

MS. FEGAN: I do disagree, your Honor. I think that compared to the cases where the packaging contains less than you bargained for, here you are bargaining for a drug that is going to help you, not hurt you, and what you got was a drug that is going to hurt you, when you could have bought Tums or something else on the market that could treat the condition that you were buying this for, but wasn't going to put you at

risk of life.

I think, fundamentally, that is why the benefit of the bargain is not just about benefit, it is about the entire bargain that someone made, and here the bargain was for a safe and effective drug, not just an effective drug.

THE COURT: So, you chose not to bring physical injury allegations, yet, it is being -- yet, the strength of your argument seems to be based on the -- that it wasn't safe, which kind of goes back to my earlier predicate question about did you understand what you could do and couldn't do, and you said you could.

It might be why it is a little perplexing to the Court.

So it is unsafe. What I am hearing from your argument is, if somebody alleges something is unsafe and they paid for it, they have economic injury. Anyone -- is that right? You allege it is unsafe -- there are different levels of unsafety.

You have a lot of allegations in your complaint, don't get me wrong, but distilled down to what you are saying, someone could bring a one-page complaint and tell me they bought something, it was allegedly unsafe, they wouldn't have bought it if they knew it was unsafe, and they have standing and it is based on economic injury and the case should proceed.

Is that the correct analysis?

MS. FEGAN: Certainly for 12(b)(6), your Honor. I can

see where the Court is drawing a line in this gray area of just what is that safety risk, and certainly that is part of what is developed in the context of causation, and whether a jury, or at summary judgment the Court would find that that safety risk was sufficient enough to rise to the level of being material, would it meet the proximate cause requirements, but in 12(b)(6), absolutely, your Honor.

If you allege that a product has a safety risk and hear that it could cause cancer, that is sufficient under benefit of the bargain law to state a claim.

THE COURT: That is an interesting point you raise. I did have a question about that, not unlike what I asked about jurisdiction in terms of you can consider jurisdiction at different stages of the case, you can consider standing, albeit you try to get to it at the front end if you can.

Are there particular facts that can be developed on the record beyond, obviously, the pleading stage and the 12(b)(6) that would further illuminate this issue?

For example, am I understanding what you just said to say that perhaps, once we get into individual Plaintiff discovery and we learn, let's just say hypothetically, gee, the risk was not so great, it wasn't so harmful, or it wasn't as harmful as alleged, would that bear -- should that bear on the Court's consideration of standing, and would that be the more -- if yes, would that be a reason why the Court would want

to consider that at a later point, or does that have nothing to do with the analysis of standing?

MS. FEGAN: Your Honor, if ultimately the proof showed that the drug was not dangerous, or did not create NDMA, absolutely, I think we lose. But at this point, that is not the allegations, and certainly that is not bearing out in the case at large.

But the idea here that we would decide the level of safety that makes a product worthless on a 12(b)(6) motion where we have alleged not just our belief, but underlying studies, underlying work that was done by Valisure and others, that is sufficient at this stage to make the allegations of safety plausible, and that is as far as we need to go at this stage.

THE COURT: I see. Okay. Let me hear the Defense response on that.

What I am hearing is, the level of safety matters, and that ties into whether something is worthless or not, which would tie into, arguably, whether there is standing or not.

Would Defense at least agree that those kinds of facts would more likely bear out over time during the litigation and perhaps this issue should be considered at a later stage when the Court has more on the record as to just what that level of safety risk is to identify just what that -- what the merits of that worthless or worth less argument is to then be able to

precisely rule on standing, and get it right?

MS. COHAN: Your Honor, I don't think that is necessary because Plaintiffs don't allege that they suffered any actual risk as a result of ingesting their drug. They allege I bought the product, I used it, it worked. Apparently there were warnings that should have been given because some people might be injured by it, but I was not one of those people that was actually injured.

So, it is hard to understand where they have any injury here. Again, it goes back to this injury in fact. Is it because they might have been at risk of developing some injury? But they don't allege that they are actually going to or have developed that injury. That is just not present in this case.

THE COURT: Put the injury aside, but just as sort of the, you know, the lack of safety independent of injury, it was just -- you know, discovery will presumably enlighten the Court in ways that it is not enlighted right now about the level of safety of the drug. So, absent -- they are not alleging physical injury, and it is that lack of safety tied to worthless or not being worthless, depending on what the facts bear out, so --

MS. COHAN: I understand where the Court is going because it seems if the product was even more unsafe than we thought originally isn't that more persuasive evidence that

they wouldn't have purchased the product otherwise, but I think, again, it just misses the mark on is there an injury alleged here.

And whatever the safety risk was, to the extent Plaintiffs have not actually alleged an injury or the risk of developing an injury, which is not alleged in this complaint, there remains no injury whatever the level of risk is.

THE COURT: Okay. Following up with Defense, you have made the point Plaintiffs don't allege physical injury or that the Ranitidine they purchased was ineffective, so therefore they can't assert that Ranitidine was worthless due to the alleged presence of an impurity. You make that argument at 3116 at page 40.

Debernardis did suggest that such allegations are sufficient, but not necessary to establish standing, 942 F.3d 1086, and in Ezcurra, the Court followed Debernardis and said that "allegations of physical injury or product inefficacy are sufficient, but not necessary to establish standing." That is at 477 F. Supp. 3d, at 1264.

What is the import of that principle to this case?

MS. COHAN: I think the import of that principle really goes to the heart of the benefit of the bargain. For instance, if you buy a product that is not what it is marketed to be or what it is supposed to be, you can recover your loss for the difference in the product you received from the product

that you purchased.

If there is in addition physical loss, obviously, or physical injury, obviously that is an additional injury that would suggest that the product did not work or was not sold as intended.

So, I think that is really the difference here as opposed to where Ranitidine itself is the product that they are complaining of and there is simply no difference between the product that was promised and the product that was received.

THE COURT: Okay. Plaintiffs, in Defendants' reply they argue that the Court should look to In re Metformin Marketing and Sales Practices Litigation, 20-cv-02324, slip opinion District of New Jersey, May 20, 2021, so it's a recent opinion, when evaluating the issue of standing.

Like the Plaintiffs in this case, the Plaintiffs in Metformin allege that the Defendants' drugs contained unacceptable levels of NDMA. In Metformin the District Court held that the Plaintiffs had no standing to assert economic loss claims due to the purchase of allegedly worthless NDMA containing drugs where the Plaintiff failed to allege that they personally suffered an injury traceable to the Defendants' conduct. They argue that at Docket Entry 3508 at 21.

You distinguished a number of Defendants' cases, including Doss, Greene, Medley and Riva on the basis that the Plaintiffs in those cases did not allege purchasing worthless,

one word, products, or that they would not have purchased the products. Docket Entry 3429 at page 39.

The Metformin Plaintiffs alleged both and still the complaint was dismissed. How relevant is Metformin to the Court's standing analysis?

MS. FEGAN: Your Honor, I think it has very little relevance. There is very little analysis in the opinion itself that walks through the case law in this area, so it is hard to tell how the Court got to that particular conclusion.

I think more relevant is the Valsartan decision where there is analysis. It is a drug that has NDMA and has the risk of causing cancer. So, I think ultimately this goes to an issue of underlying analysis, and relying on a conclusion alone when there are quite a few cases that really analyze this issue is just not something I think we should do.

THE COURT: Okay. You do argue, Plaintiffs, that by alleging that Defendants' products were worthless, one word, you simultaneously allege that the products were worth less, two words, than the price paid for the products. You argue that at Docket Entry 3429, page 36.

The Plaintiffs in Valsartan offered a similar theory of injury, namely that they received "a less valuable product because of the failure to receive the benefit of their bargain." That's at 2021 WestLaw 100204, at 8, District of New Jersey, January 12, 2021.

The District Court rejected that theory, the worth less, two words, because the Plaintiffs did not allege facts which would permit a fact finder to allege the purported injury without resorting to mere conjecture. That is at page nine of the opinion.

Do you believe that you have alleged facts that would allow a fact finder to value the purported injury without resorting to conjecture; and if so, how?

MS. FEGAN: Yes, I think fundamentally Plaintiffs' position is that this particular product was worth zero, but ultimately, at least in the cases that I have litigated in the pharmaceutical area, this is a question for the economists and how they will calculate damages, and under an econometric analysis, where that pans out.

But ultimately, for purposes of today, we have certainly alleged that the Plaintiffs would not have purchased it, and that it was worth zero. This is not a price premium case given the nature of the NDMA, the risk of cancer, and the fact that it was recalled.

THE COURT: Right. I am not reading it as a price premium case, but two different theories I think are being pled, worthless, one word, and worth less, two words. Right?

MS. FEGAN: Yes, I think that that's right and I think one subsumes the other, but ultimately, for purposes at this stage, I don't think anything more is needed.

THE COURT: Okay. Okay.

MS. COHAN: Your Honor, could I briefly respond to that?

THE COURT: Sure.

MS. COHAN: I think both are being argued, the worthless and worth less, but I think Plaintiffs concede both are not pled. Here they have merely pled Plaintiffs would not have purchased the product if they had been aware of the alleged cancer risk. In addition, in their briefing throughout they have said that the product is worth zero dollars.

So, I do think that, despite that argument, that is not something they have followed through on.

THE COURT: Well, I guess you do argue it at 3429 at page 36. Are you putting that forth as a theory, the worth less, two words? I know you are saying it is subsumed, but I think the Defense should know what you are arguing right now.

MS. FEGAN: Your Honor, when I think of worth less as two words, I think of drug price premium cases, and i will commit this is not a price premium case, this is not about a slight overcharge and what it would have cost versus a competitor. We are talking about a drug that was recalled because it causes cancer, and in that context we are saying it as one word, it is worthless.

THE COURT: We don't want the other attorneys to think we are ignoring them, so let's talk about the MMC for a moment

in terms of some of the topics that were raised in the argument and maybe some that weren't.

Defendants, you haven't challenged the AMPIC or the MMC on the basis of the Learned Intermediary Doctrine. Was that a concession that the allegations in those complaints were sufficient as related to that doctrine?

MR. PETROSINELLI: Your Honor, Joe Petrosinelli here.

I will let Ms. Cohan talk about the consumer class complaint, but on the medical monitoring complaint, we -- and this relates to another question your Honor asked earlier of Ms. Nino about the negligent storage and transport claim, and you asked her why was that challenge in the personal injury complaint and not in the medical monitoring complaint.

The truth is that we had so many challenges to the medical monitoring complaint we had to make some choices in terms of where we spent our pages, and although we mentioned in a couple of places the storage and transport claim and the medical monitoring complaint, we just didn't argue it.

The same arguments apply because the arguments in the personal injury complaint -- or the allegations in the personal injury complaint as to those claims are the same allegations in the medical monitoring complaint.

So, for the same reasons, no, it wasn't a concession, and the same with the Learned Intermediary Doctrine, we had to spend our pages in a certain way, and we decided to spend it

the way that we did.

THE COURT: In the AMPIC and the MMC, the Plaintiffs allege that the Defendants failed to warn Plaintiffs prescribing physicians about the risks and effects of Ranitidine and that the Plaintiffs' prescribing physicians would not have prescribed Ranitidine had they received adequate warnings.

So, I am just curious, if that was -- I guess that is in the MMC and the AMPIC, but not in the ELC.

MR. PETROSINELLI: Right. I will let Ms. Cohan answer, but I think that is the point that she was making about the learned intermediary as it applies to the economic loss complaint, but I will defer to her.

THE COURT: I mean, I guess I am wondering, is it as simple as if the Plaintiffs were to transport that language that is absent into the ELC -- I am not saying they will or they won't, or I would ask them to or not, but does that kind of address the Learned Intermediary Doctrine issue?

MS. COHAN: I think, your Honor, that we would have to see how that was pleaded, but I think to your point, there was obviously the decision to not plead it in the ELC for whatever reason. We know that those allegations were made in the MMC and the AMPIC. So, having had now two shots to replead the ELC, I think we don't agree that they should have another opportunity to add those allegations, they had that chance.

But I think it does demonstrate the just overall absence of those allegations from the ELC.

THE COURT: So, for Plaintiffs, I don't want to get into work product discussions, so answer as you wish, but why are those allegations in two of the complaints, but not in the other?

Were you challenged in the same way that we all are because there is so much paper and so many arguments, and all of our heads are spinning that someone missed it, and it should be in the ELC?

MS. FEGAN: Your Honor, it is certainly an easy add to the ELC if the Court deems it necessary, but I would like to just back up on this for a second.

Ms. Cohan earlier cited Tutwiler as requiring this allegation, but I think what is important to know is that Tutwiler applied Alabama law, and we don't even bring an Alabama law claim against GSK, prescription manufacturer, and again, this just applies in the prescription context.

If you look at page 34 of our opposition, we cite other state laws where that allegation is not required. So, part of the problem here and the way the Defendants have attacked this is, they have made very broad sweeping arguments as to particular allegations that are required.

But, for example, in Porter versus Eli Lilly, we cite it on page 34 of our brief, the Court stated that what the

doctor might or might not have done had he been adequately warned is not an element Plaintiff must prove as part of our case and it is not even something that need be alleged.

Certainly we could add that allegation if the Court finds it important. It is something that we do believe in, but I think part of the problem here is this idea that we are trying to apply one statement applying a single state law broadly when, in fact, we don't even have an Alabama claim against GSK.

THE COURT: I don't think Alabama is the only state that has language like that.

MS. FEGAN: That's correct, your Honor, however this really arises in the context of an affirmative defense and this idea of whether you can have a presumption of causation where Plaintiffs allege that the warning wasn't given, period.

This is not about a warning that was given and wasn't sufficient; this is about the complete omission of a warning, and in that context different states follow this heeding presumption versus a rebuttable presumption and that really gets into the underlying facts and is just not appropriate at this stage.

THE COURT: I understand both sides disagree about what needs to be pled, but can I confirm my understanding of this discussion, which is, if the Court, for whatever reason, concludes that is necessary to plead for the purpose of

addressing learned intermediary, that the Plaintiffs would readily amend their ELC to add the type of language, I guess, that you have in your AMPIC and MMC. Maybe you would even add more in light of the arguments you have seen by Defense, but at a minimum, you would add what you already have with the other two?

MS. FEGAN: Absolutely.

THE COURT: And Defense, I understand, number one, doesn't think there should be any replead. And number two, if there is a replead, you kind of have to see what is repled, and you are kind of unwilling to commit yourselves to sort of saying, well, yeah, if they pled what they pled in the AMPIC and MMC that would be sufficient, because you are not really acknowledging that a concession that what was pled in those complaints is sufficient, but I am hearing that it was more of a product of maybe there were too many issues to challenge, and so that one just didn't get picked up as to those complaints.

MS. COHAN: I think that is right, your Honor. It is hard for us to agree in the abstract, and also mindful of your Honor's order that subsequent Motions to Dismiss based on individual state law issues about the adequacy rather than the absence of allegations would present different issues for Defendants.

THE COURT: Do you see this as one of those state law issues? We have PTO 61 that talks about sort of state law

issues being considered at a later point. Would you put this issue in that bucket?

MS. COHAN: I think if we were talking about the adequacy of allegations as opposed to the absence of allegations, it would be a different animal, and you see that throughout the decisions that we have made about the arguments that we have made to not, you know, delve into state law issues where there is difference about the evidence or the facts that they have to plead to get to certain things.

Only where the state law is fairly consistent have we done that, but in the absence of those allegations with respect to the learned intermediary, I think the law is clear that without those allegations we could not overcome proximate causation. We haven't pled proximate causation.

THE COURT: To recap what I think I understood you to say is, it is possible, if I were to allow a replead and they were to come back with similar allegations, you might find that for purposes of now that might be okay, but you would want to preserve your right, as with other state specific doctrines, laws, that we would take that up in terms of the nuances of the different state laws, and how they apply the doctrine at the appropriate time for PTO 61, like bellwether stage.

MS. COHAN: I think that is fair, your Honor.

THE COURT: Do Plaintiffs agree that it possibly falls in that bucket as well?

MS. FEGAN: In the context of bellwether, yes. That is different than what we have alleged in the economic loss complaint. Perhaps we have bellwether certification, but I don't think it applies directly on point.

THE COURT: Well, I mean, to the extent that the states say different things about the doctrine, we wouldn't necessarily get into that at this master pleading stage, but if the Court found it necessary for you put the kind of language that is in the AMPIC and MMC so it is no longer omitted, that perhaps we can all agree that you have sufficiently plead -- I am not committing anyone to a position, but thinking out loud, that you have pled what you needed to at the 12(b)(6) stage, but recognizing states apply the doctrine differently, we have a PTO that talks about dealing with certain state-related issues at a later stage in the case, is that --

MS. FEGAN: Yes, your Honor, correct.

MS. MEEDER: Your Honor, may I be heard on one related issue that we started that questioning with?

THE COURT: Yes.

MS. MEEDER: I think that Defense counsel started by trying to incorporate some learned intermediary arguments into the MMC. I just want to reiterate, as the Court pointed out, those arguments were not made in the briefing. So, to try and bootstrap them now into the complaint because they ran out of space is simply not something that should be acceptable.

THE COURT: Okay. I didn't construe Defendants as making a new argument today that they didn't make in their papers, or rather, explaining why something might not have been made directed to the MMC. I heard them say it wasn't like a concession or anything, but it is not like they are -- I didn't hear them making a new argument that I am going to go back and include that as part of their motion.

MS. MEEDER: Okay, your Honor. That's fine. I understood it differently, but I am happy to be wrong about that.

THE COURT: Am I right about that, Defense.

MR. PETROSINELLI: You are, your Honor, yes.

MS. MEEDER: Thank you, your Honor.

THE COURT: For Plaintiffs, Defendants argue that you "failed to plead that diagnostic testing exists that would make early detection of any alleged cancer injury possible." That is at Docket Entry 3116 at page 24.

You respond that you plausibly allege that you require "medical monitoring which would include, but is not limited to baseline tests and periodic diagnostic examinations." Docket Entry 3429 at page 26, citing the MMC at paragraph 980.

If the Court finds the Defendants' argument is persuasive, and if you were to replead, again, this is hypothetical questions, could you allege on a replead that diagnostic testing exists to make early detection of the

subject cancers possible?

And I guess, if so, what would you plead? What diagnostic test would you allege to exist?

MS. MEEDER: Your Honor, I understand you to be asking if we could plead the specific tests, because we do plead generally that there are baseline and other diagnostic tests that exist. I am understand we are talking about the specific tests.

If your Honor would like us to replead this with more specificity, we are able to do so.

THE COURT: I am sorry, I don't think you even plead that they exist. You plead that medical monitoring, which should include -- I could be wrong, but it is not limited to -- should include, but is not limited to baseline tests and periodic diagnostic examinations. That is at page 26. There is a lot of stuff to cover, so I could get it wrong.

I am not even sure that you allege that it exists. Maybe tell me where you allege that.

MS. MEEDER: At paragraph 980 we allege that the program will facilitate treatment and interventions that will mitigate the development of the health effects associated with the subject cancers, which is a defined term.

We also allege --

THE COURT: You don't use the word "exists" there. I don't know if you meant that they currently exist or not.

MS. MEEDER: I think it is a reasonable inference from the totality of our diagnostic testing allegations that that type of testing exists. We go through that there is a need for specialized testing which isn't normally given to the public, there is an available monitoring regime that we are requesting. So, I do think that we allege that they exist.

THE COURT: I am going to get to the regime element, but I look at that as different than the diagnostic testing element. I didn't see the "exists." If you had to replead, could you allege that the diagnostic testing, which is an element of medical monitoring, does exist, and would you actually be able to allege what that diagnostic testing is?

MS. MEEDER: If the Court would like us to replead, we are able to do that. If you are asking if we could replead specific medical tests, I expect that we could also do that. I don't have that information at my fingertips here today.

THE COURT: Is that what Defense is saying is lacking, is it just the word "exist"?

My review of the case law seems to be that, at a minimum, you have to plead that it exists, and maybe it is a fair inference, but I didn't see the word "exist", so it was not clear to me whether the Plaintiffs were pleading that or not. Do you think that the case law supports they need to go even further and plead what diagnostic tests exist at this stage or just that diagnostic tests exist?

MR. PETROSINELLI: I do, your Honor. I think they have to -- for sure they have to plead that they exist, but there are several cases that say you have to plead -- it doesn't have to be an exhaustive list, but you have to plead what they are, because if you just say they exist, that is pleading the element of the claim.

That is the Iqbal Twombly problem because that is an element -- under any state that recognizes medical monitoring, that is an element of the claim, that diagnostic tests exist that would enable early detection of the alleged disease. You have to say that, I agree with the Court for sure, but that just parrots the element of the claim.

Then you have to say what they are, and we cited a number of cases that hold that, and then your Honor is going to get to the next stage. Then you have to say that they exist, what they are, and that they are different than what the normal population would get, because then that is not a part of medical monitoring.

MS. MEEDER: Your Honor, may I respond?

THE COURT: Yes.

MS. MEEDER: I don't think that that is required at all, and the error that Defense counsel makes is assuming that this is an element of the claim that has to be pled with Iqbal/Twombly specificity. As we explain in our papers, it is not. The program itself and what that all entails and how it

differs from routine medical care is actually the remedy.

THE COURT: Isn't it different from state to state? In some states it is a remedy, in other states it is actually a claim, a cause of action?

MS. MEEDER: I think that conflates two issues, your Honor. It is true that in some states medical monitoring is a free-standing claim, and in other states medical monitoring is an aspect of damages for underlying tortious conduct, but in laying out what is required for those claims for damages, in both instances the program itself is the remedy, it is not an element of the claim.

That makes sense given that really what Defense would be asking us to have to do is to powwow with our experts ad nauseam prior to actually filing the complaint to carefully elucidate each specific test that was required for the subject cancers and that is not something that is required. It is also well beyond the standard.

THE COURT: Okay. I won't call it an element, I will just say the regime, how is that? Defendants argue that Plaintiffs -- "that Plaintiffs fail to plead that their proposed monitoring regime differs from routine examinations that they would normally undergo as members of the public." That's at Docket Entry 3116 at 25.

Defendants argue that this is a formulaic recitation of the required element. They make that argument at page 26 at

3116.

The Plaintiffs respond that you plausibly allege that "the latent injuries from which Plaintiffs, the class members, suffer require specialized testing with resultant treatment that is not generally given to the public at large," and that the testing is "different from that normally recommended in the absence of exposure to the risk of harm." That's at Docket Entry 3429 at page 26, citing to the MMC, paragraph 979.

If the Court finds the Defendants' argument persuasive, could you want to replead to provide factual allegations to support how your proposed regime differs from what is given to the public at large; and if so, how would you do that?

MS. MEEDER: Setting aside the fact that we have outlined our position that that is not something that is required, your Honor, sitting here today, I don't know that we could plead that level of detail.

THE COURT: What level of detail are you able to plead?

MS. MEEDER: I think we pled it. Expert discovery is ongoing, some of these issues might be addressed at class certification and will certainly be addressed in expert reports. But there may be a bit measure more of explanation that we could plead, but I don't know that it would be

substantial, your Honor.

THE COURT: I was looking back at the Petito versus A.H. Robbins case, 750 So.2d 103 at 106 to 107, a Florida District Court of Appeals 2000 case.

I want to ask you, are those not elements when the Court lays out this is what needs to be shown for medical monitoring:

Number one, exposure greater than normal background levels; number two, to a proven hazardous substance; three, caused by the Defendants' negligence; four, as a proximate result of the exposure Plaintiff has a significantly increased risk of contracting a serious latent disease; five, a monitoring procedure exists that makes the early detection of the disease possible; six, the prescribed monitoring regime is different from that normally recommended in the absence of the exposure; and seven, the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles.

MS. MEEDER: Your Honor, those are requirements that a Plaintiff has to prove in order to achieve medical monitoring, and this is in the context of a case where the Court is adopting medical monitoring as a free-standing claim in the state, but if those were just elements, what would the damages or the remedy be?

The damages or the remedy are the diagnostic program,

and the clue to that is that the Court explained that after the Plaintiff proves that they need monitoring, the Court is the one -- and actually I think there is a footnote that says it is an entirely separate proceeding, but the Court is the one that determines what tests are required, how frequently, how they will be provided, etc.

I think that further illustrates why it is a remedy and not an element in the way that I believe Defendants are trying to make it.

THE COURT: Is the remedy the regime or is it money in a fund to fund the regime?

MS. MEEDER: I think it is both, your Honor. In some states it is not a fund, it might be damages, but it is still the remedy.

Let me clarify, the program is still the remedy, whether it is manifested by a fund or by a monetary payment.

THE COURT: Okay. Well, if they were considered to be elements, it does seem like the way it is pled, it is pled sort of in a conclusory way. It is pleading the element without the factual predicate for the element.

You are saying you would need expert input to plead any factual support for the elements, or whatever we will call it, of the monitoring regime, like you don't have that now, that has to be something developed later on?

MS. MEEDER: What I am saying, your Honor, is that the

details of the regime, whether it be the type of testing that is necessitated, how specifically it differs for Plaintiffs in the class from what routinely would be provided, those certainly are things that we would require expert testimony on, expert opinion on. That is what all the case law also explains, and that is another reason why Courts routinely find that these type of details don't need to be plead.

THE COURT: What does the Defense point to to respond -- is there a particular case that you are relying upon or one that you can give us an example --

MR. PETROSINELLI: Your Honor, your Honor.

THE COURT: -- where a Plaintiff has adequately pled, at least by that Court's view of the necessary pleading to on this topic, this element?

MR. PETROSINELLI: Two things, your Honor. First of all, we cite a number of cases at pages 13 and 14 of our motion, so that is Docket Entry 3116, where Courts have found these are the very elements we are talking about. They call them elements because -- I can't say in every state, but in most states it is like Florida where these are elements of the claim, not the remedy. The remedy is the money that you pay either directly to the Plaintiffs or to a fund.

I completely agree with your Honor's observation on that, but these cases we cite say you have to plead these elements.

I will tell the Court, I am involved in some of these cases, and it is -- I have been involved in lots of medical monitoring class action cases in states where it is recognized and the Plaintiffs plead just what we are talking about, which is they plead these tests exist, this is what they are, certain types of scans, X-rays, blood testing, and so on, and here is why these types of test at these ages are not recommended to the general population, and it is not exhaustive.

It is not preclusive of later on in the case when you get to expert reports and experts fleshing out more things, fewer things, but it provides the factual level of detail to state a plausible claim, not just the elements of the offense. You see this all the time.

In fact, in these cases that are cited, at least the ones that I was involved in, when the Court ordered repleading, that is what the Plaintiffs did, they repleaded a complaint that had certain tests specified and why those tests were not recommended to the general population, and that is what I think needs to be done here.

Obviously, there will be an expert report some day that would in more detail lay out exactly why these tests are predictive of disease, and why they are required, and how reliable they are. That level of detail, obviously, is not needed in a complaint, but what the tests are and they exist, and they are different than what you give to the general

population, that is required.

THE COURT: I know you cited a lot of cases, I could pull them up, but in interest of time, I am not going to. It sounds like those were cases where the Court found that the recitation of the element wasn't sufficient.

The cases you are involved in, or are referencing, and you have seen repleading, is there a cite you can point to?

MR. PETROSINELLI: Yes. For example, one of the cases we cite that I happened to be involved in is the Bell versus 3M case in the District of Colorado where the Court found the bare recitation of the elements was not good enough, and then the Plaintiffs repleaded and they had a whole list of, as I recall, it has been a few years, but a whole list of tests that they were proposing and so on.

I think in the Menkes case, another case from the Eastern District of Pennsylvania that I was involved in, that was further ago, but I believe the same thing. It is not that difficult, if there is a legitimate claim for medical monitoring, that is that there are tests that could detect, in this case cancer early, and that are not recommended to the general population, you don't have to talk to an expert very long to know what they are if they truly exist.

So, it is not that difficult to do and I am sure -- I have seen dozens of medical monitoring complaints that do that.

THE COURT: Okay. Plaintiffs, your medical monitoring

complaint contains a large number of citations to scientific studies and to Government documents, primarily from the FDA. Many of those citations contain hyperlinks so the Court can view the documents. Pursuant to cases such as Horsley versus Feldt, 304 F.3d 1125, Eleventh Circuit, 2002, the Court can consider attachments to complaints when those attachments are central to the Plaintiffs' claim, and the content of the documents is not in dispute.

I would like to know if you agree that I can consider those documents, and would you agree that the scientific studies and Government documents are central to your claims and are not in dispute?

MS. MEEDER: I think that your Honor's statement of the law is accurate, and I also think that the articles that we have cited and the other things in our complaint are relevant to our complaint or we wouldn't have cited them.

Sitting here today, I can't speak to say that every single one is not in dispute for the facts for which they are asserted. I know there has been a substantial amount of citations in our complaint, I just, your Honor, today don't know for sure if the Defendants dispute the aspects of each of those cited documents or not.

THE COURT: Your position is, I can consider them.

MS. MEEDER: If they aren't in dispute, your Honor. I guess what I am saying is, I don't disagree with the statement

of the law that you could consider them if they are not in disputed. I don't know if they are not in dispute.

THE COURT: Is the Defendants in a position to tell me whether the Governmental documents, primarily from the FDA, the scientific studies are in dispute or not? I know there is dispute about what they mean and how they apply, and all of that, but just that --

MR. PETROSINELLI: No, I would think they are not in dispute. They are what they are, so I don't have any issue. I think the Court can and actually should consider them.

THE COURT: Okay. Plaintiffs, do you agree that you cannot state a claim for medical monitoring in any state just for any exposure to a toxic substance, that is, there must be some sort of significant exposure, not just any exposure?

MS. MEEDER: I think that the law overall states it either needs to be, like your Honor noted, a significant exposure, an increased exposure, a greater than background level of exposure, something to that effect.

THE COURT: Okay.

MS. MEEDER: I would also add that the claim is based not just on the exposure, but on the associated risk of disease.

THE COURT: Okay. Given that answer, so, at approximately what point does an increased risk of cancer become a substantial risk of cancer? At what level of

specificity do you believe you need to plead this?

MS. MEEDER: We are talking about specifically the risk of cancer now --

THE COURT: Yes.

MS. MEEDER: -- not exposure?

THE COURT: Yes.

MS. MEEDER: I don't know that I have seen a particular articulation of what that is, if that is even a number.

I will say that I have read cases saying that you don't have to articulate the increase in risk in order to prevail on the claim. Taken as a whole, if you look at our medical monitoring allegations and look at the consistency and duration of use by the Plaintiffs, the amount of NDMA we allege in even one tablet --

THE COURT: I am going to get to all of that. I just wanted to understand. You have acknowledged that it is not enough just to allege exposure to a toxic substance, that there needs to be some sort of significant exposure, not just any exposure, it needs to substantially increase the risk of cancer.

My question was: At what point does an increased risk of cancer become a substantial increased risk of cancer, and what level of specificity is needed, in your view, to plead this?

MS. MEEDER: I think that to the degree of risk -- what substantial increased risk means is an expert question. When we are looking at the nature of the exposure, that is also an expert question, and we plausibly allege it by demonstrating significant exposure through the amount of medication consumed, the amount of NDMA that was created.

It is similar to, say, an air pollution case where someone doesn't allege the specific amount of air pollution, particulate, whatever it is, in what they breathe, but they are alleging they were exposed to it around them, and that is the sufficient --

THE COURT: In what allegations in the MMC do you rely to show the amount of NDMA in each Ranitidine pill? If it easier for you to answer the question, you can tell me what the amount is, if you know generally which allegations. I just want to be sure I am following along.

So, again, what are the allegations in the MMC that you are relying upon to show the amount of NDMA in each Ranitidine pill?

MS. MEEDER: Your Honor, I believe we cited the paragraphs in our papers and would be happy to pull them for you shortly.

What we said was that, first of all, the Plaintiffs took a typical therapeutic dose every year, which was defined as one or two tablets, and then we say that there were tests

that showed NDMA levels as high as 3,000 times the maximum limit, and that a level above 96 nanograms per day exceeds the FDA acceptable --

THE COURT: Right. I am familiar with those numbers, the 3,000 and the 96.

MS. MEEDER: Right.

THE COURT: I wasn't really sure exactly where I was looking in the MMC to see if there was a clear indication of what you are relying upon to show the amount of NDMA in each Ranitidine pill.

MS. MEEDER: Your Honor, if you could give me one moment.

THE COURT: I don't want to derail us too much. Maybe someone else can be looking at that and can message you. I will have a few more questions, but I am well aware of the 96 and the 3,000 nanogram allegations.

MS. MEEDER: So, your Honor, maybe this is what you are asking for. In the introduction we say tests revealed levels as high as 304,000 nanograms. Is that what you were looking for,your Honor?

THE COURT: Well, I found it in the introduction. Is that where it is, in the introduction?

MS. MEEDER: I would have to double check, your Honor, to confirm.

THE COURT: Okay. And plausibly alleging -- in

alleging your claim for medical monitoring, are you relying upon anything other than Ranitidine's propensity to form NDMA?

MS. MEEDER: No, your Honor, just, you know, all the circumstances we have outlined in our complaint. That is what we rely on.

THE COURT: Okay. Now, this goes to something you just said about the therapeutic doses. I wanted to know if you could point me to where in the MMC you rely upon where you -- what paragraphs you are relying upon to show the frequency with which the Plaintiff consumed Ranitidine.

I know on page eight of your response, in footnote three, you contended that "all medical monitoring Plaintiffs took therapeutic doses of Ranitidine." And for support you cite to paragraph 975 of the medical monitoring complaint, but paragraph 975 does not appear to contain information about the frequency of the Plaintiff's dosages. It only states the Plaintiffs ingested Ranitidine at various times as part of their treatment. It doesn't say anything about therapeutic doses.

You also cite to the individual Plaintiff's allegations of dosage, but I have been unable to locate the frequency of the Ranitidine use in those paragraphs.

For example, you cite to paragraph 93, but in paragraph 93 you only allege that the Plaintiff used Ranitidine products from 2009 to 2020. There is no allegation as to the

frequency of use, nor is there a reference to the therapeutic doses.

When you give me a class definition, you define the class as being anyone who used Ranitidine without any qualification about frequency. That is at paragraph 993 in the medical monitoring complaint.

The closest the Court has come to ascertaining the frequency of use is going back to the introduction, the typical recommended dose of Ranitidine for peptic ulcer disease in adults is 150 milligrams twice daily, or 300 milligrams once nightly for four to eight weeks, and maintenance doses of 150 milligrams once daily.

Is that what the frequency is? I mean, I just want to be clear what the allegation is so I know what I am relying upon. It is not so clear, which is why I am asking the question.

MS. MEEDER: I think it is clear from the complaint that all of the Plaintiffs -- let me go back.

The introduction states, as you noted, your Honor, that the typical recommended dose of Ranitidine is one or two tablets a day in varying dosage, and what we then allege for each Plaintiff is that they regularly took -- I should say they used these products and they specified a dosage if they knew it, and they specified a year range during which they took it, and as a result of that consumption, they are at an increased

risk.

So, I think we connect the therapeutic or the common dosage which was stated in the introduction to the Plaintiffs' specific allegations to testing that today we have shown certain levels of NDMA in each pill.

THE COURT: Are you saying the Court should draw a reasonable inference that the frequency with which Plaintiffs consumed Ranitidine is that which is typically recommended, that is, they took 150 milligrams twice daily, or 300 milligrams once nightly for four to eight weeks?

MS. MEEDER: Yes, your Honor, and that is consistent where, for example, Plaintiffs are discussing prescription use, or something like that. Typically, it would be a therapeutic dosage that was being provided.

THE COURT: Okay. Two more questions for you and then I will turn to the Defense and then we will conclude. We are almost done.

Plaintiffs, in the medical monitoring complaint, paragraph 281, you allege certain tests were performed by Valisure that detected NDMA in Ranitidine. One of these tests used 500 (sic) milli-moles of sodium nitrite.

I want to know what you think I can do, based on that allegation. Am I able to try to understand what 500 -- 50 milli-moles of sodium nitrate is? Can I ascertain mathematically what the equivalency of that is?

I ask that in the context of the following:

We had a hearing way back when, when we first started this case, on law and science, and the Defendants represented that mathematically the amount of bacon that someone would need to eat to have 50 milli-moles of sodium nitrate in their stomach was 33 pounds. That's at Docket Entry 960 at 38.

Are you able to tell me if that is accurate, or if it isn't, how many pounds of bacon, for example, you would say 50 milli-moles of sodium nitrate is? What is the Court to do with that? What is the Court permitted to do with that? What would you like the Court to do with that?

The Court has to understand, you know, what you allege and the Defendants need to understand. Right now, I am just interested in my own understanding.

MS. MEEDER: Your Honor, I don't think that the Court needs to evaluate how much bacon includes how many milli-moles of sodium nitrate. The operative point here is that the testing demonstrated that when there was a nitrate present NDMA was formed in greater levels.

That is the operative point for our complaint and it puts the Defendants fairly on notice about the idea that Ranitidine degrades to form NDMA under these conditions.

There is no dispute the Defendants didn't tell the Plaintiffs, for example, not to consume the Ranitidine with nitrates. In fact, they told them the opposite. I think that

is all that the Court needs to do at the 12(b)(6) junction at this aspect of the pleading.

THE COURT: Do I take that to mean also -- do you disagree with what the Defendants presented at the science -- their presentation as to how they translated the 50 milli-moles?

MS. MEEDER: Your Honor, sitting here today, I don't have an opinion on that one way or the other. I would need to refresh my recollection from an expert.

THE COURT: What about from the Defense on that? Well, it is maybe less about the accuracy of what you presented, but what is the Court permitted to do? We have a study included in a complaint, everyone agrees the Court can rely upon it, it has this reference of 50 milli-moles of sodium nitrate.

If the Court is truly trying to understand the complaint and evaluating Motions to Dismiss and all of the complicated issues that have been presented, what is the Court permitted to do with a figure like that?

MR. PETROSINELLI: Your Honor, I think this highlights the problem that your last series of questions have gotten at and that we briefed, which is the failure of the Plaintiffs to plead what is the threshold level of NDMA at which they claim someone has an increased risk of cancer or could be harmed, and that these Plaintiffs were exposed to those levels by virtue of

the dosage and whatever frequency they took it is a huge problem.

Your honor is looking at these studies, the FDA reports, the table that you mentioned from the Valisure study, and there is no way to evaluate what it means and how it fits into the Plaintiffs' theory.

The problem -- to your Honor's question about the FDA documents, and can you take those into consideration, here is the fundamental problem on this point in this section that you've talked about. That table is at paragraph 281, but that whole section, the Plaintiffs cite the 96 nanogram acceptable daily level of NDMA, and then they cite the animal and human studies where the levels were higher and lower than that. Then they cite the FDA tests which found levels in samples of Ranitidine that were higher and lower than that, and then they cite the Valisure and Emory tests, which are most higher and some lower.

What is the level at which -- remember, these are medical monitoring claims. One of the elements of medical monitoring, the very first element under most state's laws, certainly Florida, is that you were exposed to higher than background levels, meaning a level more than all of us get.

We all eat food that has NDMA in it, and so the question is, what are Plaintiffs claiming is the threshold level at which medical monitoring is justified. They have not

pleaded that, because to your Honor's questions, they have pleaded a bunch of studies, tests, and regulatory limits that all over the map on that, from zero to a million nanograms.

These particular Plaintiffs, these 52 Plaintiffs, what levels have they pleaded -- the answer I think is no -- that they were exposed to a level greater than what puts them at an increased risk of cancer.

So, I think that is a major defect in the pleading of these medical monitoring claims, and so when your Honor turns to a chart like the one you just asked about at paragraph 281, there is no way for the Court or the Defendants, frankly, to understand what the Plaintiffs are saying about that chart. There are a bunch of high numbers, there is some sodium nitrate in there. There is no pleading about what is significant about that chart that would entitle these Plaintiffs to a medical monitoring remedy.

I think we are right about the science day presentation, I think Mr. Cheffo did it, and he did say what your Honor said. I am sure Mr. Cheffo didn't know that on his own, I think our experts calculated that for us. Your Honor doesn't have experts to calculate what these numbers mean.

So, I don't know that there is anything that the Court can do with that particular paragraph, especially when it is not tethered to an allegation about what is the level of NDMA that the Plaintiffs are alleging puts that at an increased risk

of cancer, and do these 52 Plaintiffs, have they been exposed to that level; and if so, to what extent.

That is one of the main pleading defects in the complaint.

THE COURT: Any response from the Plaintiff? Then I have one more question for you.

MS. MEEDER: Yes, your Honor, a couple of points. First, science day was an early informational session and was without prejudice. Setting that aside, Defendants remain wrong that there is some requirement Plaintiffs plead a threshold number level of exposure, and you need only look at other medical monitoring cases as evidence.

For example, if someone breathes in air with a carcinogen in it, they don't quantify the amount of air they breathe. If someone drinks ground water that gets contaminated with TCE -- and these are all medical monitoring cases in the literature -- we don't quantify how much TCE was in what they drank. At most, they might discuss how much water they drank and how frequently, which is exactly what the Plaintiffs do here.

There is one case out of the one court in the Northern District of California that the Defendants rely on for threshold and it doesn't even say what they say it says. I just don't think that is a requirement under 12(b)(6).

THE COURT: How about how the Court construes

paragraph 281?

MS. MEEDER: I think that I touched on this a little bit earlier, which is that paragraph 281, when viewed in the detailed other allegations of the complaint, is further evidence that Ranitidine degrades to form NDMA in the body when taken with nitrates, for example.

Read together, that is just one piece of information, scientific evidence, that we provide to support our allegations of exposure. There is also the allegation that the FDA concluded the levels of NDMA were dangerously excessive, the fact that the medication was withdrawn, that the Defendants found evidence of NDMA in all the product they tested.

Each of these is a piece of information, a factual allegation that supports our exposure allegations, and the facts that we have available here are actually far in excess of what most Courts have before them when confronting a 12(b)(6) motion, your Honor.

THE COURT: One of the studies you cite is the Stanford study, that is at the AMPIC paragraph 27, and when I used the link you provided to me, the publisher says that the study was retracted because the measurements in the study were unreliable. Do you think I can or should conclude that the allegation based upon the retracted study is plausible? What do I do with that?

MS. MEEDER: Your Honor, off the top of my head, I am

not sure what paragraph allegation that corresponds to, but I don't think that your Honor should draw that conclusion from that withdrawn study.

I believe that this might have been discussed in some other context, but part of the issue with the study was that the actual mechanism used to perform it created the thing they were trying to test. There is clearly a lot of expert-related discussion to be had about the study, but I don't think that renders an allegation per se implausible.

If your Honor would like, I'd be happy to track down what paragraph that tracks to in the MMC.

THE COURT: Okay. Just a couple of followup for the Defense.

So, do you have a point of view as to at what point an increased risk of cancer becomes a substantial increased risk of cancer, that is, at what level of specificity you are arguing that Plaintiffs must plead at the 12(b)(6) stage?

And I will go back to Plaintiff if you want to look at paragraph 367, but I'll let Defense answer the question. If counsel wanted to supplement anything, you can, but, you know, it is true, we are at the pleading stage, we are not reviewing expert reports and science, and things of that nature.

I didn't mean to suggest in any way anything that I learned on that initial day way back when is something that the Court is considering, you know. It is presumably outside the

four corners of the complaint.

The larger question is, what can the Court do with all of this information you have given? It is in the complaint, 281, 50 milli-moles, so I want to put that in proper context.

What is the Defense's point of view, based on the law, as to what level of specificity the Plaintiffs must plead to adequately plead that element of medical monitoring relating to the substantial risk of cancer?

MR. PETROSINELLI: I think they have to plead both, as I said before, the threshold level at which an increased risk starts, so whatever -- we think it's -- we don't think there is any level that Zantac causes, but it is their complaint, so they would have to plead what is the threshold level at which they contend they are at an increased risk of cancer, again, because that is the only way to state a claim for medical monitoring under any jurisdiction that recognizes medical monitoring, and then they would have to plead that that increased risk is of some medical significance.

I suppose that is their call as to what they would claim is significant enough to get the remedy, but they would have to plead that.

THE COURT: What role does the FDA's voluntary recall play in the allegation that Ranitidine causes a substantial increase in the risk of cancer? Where do you believe that that factors in?

MR. PETROSINELLI: It factors in in the sense that it contradicts it. That is part of the problem with the citation of these tests, the FDA letter in response to the Emory Pharma and Valisure citizens petitions, which is cited in the footnotes that your Honor was referring to in the complaint.

For example, that report, if you look at it, or that letter says that the FDA conducted tests on 180 Ranitidine samples, and they found levels above 96 nanograms in 42. That means that three-quarters of the samples the FDA tested did not have -- had below the 96 nanograms that the FDA says is the acceptable daily intake with a wide margin of safety, because that is what the regulatory agencies do.

How does that support plausibly the allegations in the complaint that there is a significantly increased risk of cancer? It doesn't.

The other thing about the FDA response is that it didn't say anything about we think this presents a significant increased risk of cancer. It asks for a voluntary withdrawal, which the manufacturers did because they had these inconsistent or differing test results depending on which sample they looked at.

So, what the FDA said ultimately is, we asked for this withdrawal, ask you to study it, and if you can demonstrate a way that you can manufacture and it is not going to show levels of NDMA above the 96 nanograms, then come back to us and we can

talk about it.

In other words, it wasn't take this product off the market and we never want to see it again because it causes cancer. There is nothing of the sort in the FDA's responses on that. It is just to the contrary. It is, we have found some samples that had more than 96 nanograms, we found most didn't, we need to understand it better, and in the meantime, we ask for a withdrawal.

The answer to your Honor's question, which was to what extent did the FDA reports -- or how did they play into the plausibility of the Plaintiffs' allegations, they don't. They contradict the Plaintiffs' allegations. That is why it is so important that they say -- or allege what is the level they are claiming at which there is a increased risk of cancer, because it can't be based on the FDA reports, because the FDA report said nothing of the sort.

THE COURT: Okay. Was there any response from Plaintiff on that point, and then if you want had to followup on the previous question.

MS. MEEDER: Your Honor, I will confess I forgot the previous question.

THE COURT: He wanted to know what paragraph, because I asked that question about whether the study would render --

MS. MEEDER: Again, I think that this is a forest for the trees problem. The FDA requested a recall of Ranitidine

because it degraded to NDMA, which I hope there is no dispute is a carcinogen, the only valid use of which it to cause cancer in lab rats.

Regardless of whether the FDA said you can sell it or not, or it is forever inherently dangerous or not, I don't know that any of that is really relevant given what we have alleged in our complaint, which is that both pre-ingestion and post ingestion it degrades to form NDMA at levels hugely in excess of the FDA's 96 nanogram unit, and the quantification of risk that counsel is now, for the first time, saying that we ought to put in our complaint is not supported by the case law, and I don't know that it is even a fair reading of the complaint to somehow claim they are not on notice about what Plaintiffs allege caused an increased risk of cancer.

The Plaintiffs, as identified in the complaint, specified how much Ranitidine they took, we specify what we understood testing to reveal for each pill, and taken in concert with all the other scientific evidence, that is enough to state a claim.

This granularity dependency is not appropriate for 12(b)(6). That is a question for experts, maybe part of it is something we touch on in class cert, and some of it is even a question of fact. Causation is often a question of facts.

I think we are way far down the line from what was actually the true inquiry presented by the Court today which,

thankfully, is much easier than what we are talking about here.

The first question your Honor referenced I think was about the Stanford study, and I did find that paragraph.

Excuse me. I believe that in the recent filing it is Docket Entry 3533. We explained more about the retraction of that study in footnote two and why the evidence, or the results presented by the study was simply something Defendants already confirmed themselves and other reasons why the retraction isn't the big deal the Defendants are making them out to be.

THE COURT: All right. I think Ms. Meeder had the last word. So, we will conclude for the day. That is pretty good, we finished by 5:00. You might think that is too long, but I think that is pretty good.

So, thank you all, a lot of work, I appreciate it, very helpful argument. It was long and everyone must be tired, either watching, listening, or arguing, but I can't tell you how helpful it is to the Court. I really appreciate it, and everybody did a great job, everybody.

So, with that, we will follow the schedule for tomorrow. Everything seemed to go seamlessly, at least from my standpoint it did. I didn't hear about any snafus. I hope everybody easily got in. Thank you for helping, our special master and everybody else, with the technical aspect getting everybody in. We lost some participants, we were as high as 142. I guess it wasn't so interesting toward the end.

We will start again tomorrow morning. You know what the schedule is, and pretty much the same routine. The only thing I would just say, just maybe for the benefit of the distributors if you are listening, maybe if the two in the morning go quickly, it is possible that 3107 could be heard in the morning before -- because I know I indicated it was an afternoon hearing.

Our special master would let me know if that is setting any bells off. If counsel are not available don't worry. Maybe, if we end up at 11:30, and we are finished with 3112, maybe we can do 3107 then, maybe.

That is the only one I can anticipate changing, and I do appreciate the fact that you are keeping the 7th open in the event we have a continuation of the hearing either with followup questions or whatnot, and I think that is it.

So, everybody have a really nice evening and I look forward to seeing you all tomorrow. Take care.

MR. PETROSINELLI: Thank you, your Honor.

MS. FEGAN: Thank you, your Honor.

(Thereupon, the proceedings concluded.)

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

Date: June 8, 2021

/s/ Pauline A. Stipes, Official Federal Reporter

Signature of Court Reporter