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

CASE NO. 20-md-02924-ROSENBERG

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION.

West Palm Beach, FL
December 14, 2020

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

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THE COURT: Okay, good morning, everyone, welcome. I hope everybody is doing well and we have a successful couple days of hearings on the Motion to Dismiss.

I want to thank everyone for being available early to be admitted. We have certain procedures for how all of that is working, so I hope everybody is in who wants to be in, will continue to be allowed to come in throughout the day, and that we continue our successful streak of not really having too many technological problems throughout the Zoom proceedings that we conducted in this litigation.

We are here today in the matter of In Re: Zantac Products Liability Litigation, MDL 2924. The Court issued orders setting hearings on certain of the Motions to Dismiss filed in this litigation.

Specifically, the Court issued orders at Docket Entries 2262 and 2316, and those orders inform the parties that it would hold hearings on the Motions to Dismiss, certain of them, on December 14th and December 15th. At Docket Entry 2357 the Court indicated which motions would be heard on December 14th and which ones would be heard on December 15th.

Today, December 14th, through the Zoom platform -- I should say for the record, the Court is here in the courtroom alone with our court reporter. All other participants and presenters are appearing by Zoom given the COVID pandemic and the emphasis that this Court places on the safety of everyone.

Today the Court will hear the following motions: Docket Entry 1630, 1588, 2037, and 1585, in that order, and I believe everybody knows that that is the order that has been communicated to you.

So, when I call your motion, at that time please have the presenter for the motion turn your audio and video on, so the movant in other words. There could be a couple of you or several of you who are presenting. The movant, the persons who filed the motion, you turn your video and audio on and you make your presentation and then you turn your audio and video off, and the respondent will turn your audio and video on.

If the movant has reserved any rebuttal time, you will let me know that in advance and at that point the respondent will turn the video and audio off and the movant will come back on for the rebuttal.

Again, you can have all of the persons come on, even if only one person is making the rebuttal, but you have had two presenters, that is fine, you both or all can come on.

When the presentation is over, I would like everybody, movant and respondent, and anyone who is responsible for answering the questions that the Court may present -- I may have questions, I may not, for certain of the motions. And so all persons who have been designated to potentially answer any of the questions associated with that motion should turn their video and audio on, and then the Court will ask questions and

the person to whom the question is directed -- I won't direct it to an individual, I will direct it to the Plaintiff or the Defendant and you presumably have self designated whom you would prefer to have answer the question. If you need a moment to pause and think about it, that is fine, too.

Let's see. Now, I have allotted the following times for each motion, this is based on exchange between the Court and the parties trying to give you the time that you thought you needed, while trying to be mindful of the long days we have and to keep things moving along.

So, the time allotted for the first motion, 1630, is 23 minutes for each side. I say 23 minutes because each side has an LDC, a Leadership Development Committee member, and/or a NextGen participant. There has been discussion, with the Court's endorsement and support, that additional time be offered to any side who has included a NextGen or LDC member, so the Court has allotted and additional 3 minutes.

So, whereas the parties had contemplated 20 minutes for each side, because both side have and LDC or NextGen member, each side will have 23 minutes. For motion 1588, the Plaintiff will have 18 minutes and the Defense will have 15 minutes.

For 2037, the Plaintiff -- the Defendants will have 23 minutes and the Plaintiffs will have 23 minutes, and for 1585, the Defendants will have 18 minutes and the Plaintiffs will

have 18 minutes. So, again, those extra three minutes are in recognition of the NextGen or the LDC members.

I will say that if there are going to be any PowerPoint presentations during a motion, when I pull you on at that time you will let me know, and let me know who the person responsible for the PowerPoint presentation is, that is, who is operating the PowerPoint, because we need to give privileges to that person. So, identify who that person is so we can go through the participant list and give the appropriate privileges for that person.

When you come on as well, I will ask you whether you want me to give you any kind of a warning, tell me from the movant standpoint whether you want any rebuttal time; if so, how much, and how much warning you want both with respect to your motion and your rebuttal time. Similarly, the respondent will let me know what kind of a warning.

I would say that you should keep track of your own time as well, but I have a clock up here and am happy to do it as well.

So, I think that takes care of the preliminary matters that I wanted to go over.

So, at this point, if I could call up motion 1630, and if I could have the Defendants come up, and motion 1630 is the Defendants amended Motion to Dismiss and/or Strike consolidated consumer and third party payor class action complaints on

grounds of impermissible shotgun pleading and lack of Article III standing and incorporated memorandum of law.

So, if I could ask all counsel, please, to state your name for the record for the Defense on this motion.

MS. HOOD: Good morning, your Honor, my name is Michelle Hood, I am from Williams and Connolly and I represent Pfizer.

THE COURT: Good morning.

MR. PETROSINELLI: Good morning, your Honor, Joe Petrosinelli, I too represent Pfizer, but speaking on this motion on behalf of all Defendants.

THE COURT: Good morning.

MR. BAYMAN: Good morning, your Honor, Andrew Bayman, King and Spalding, I represent Boehringer Ingelheim, but as the case with Mr. Petrosinelli, for this motion I will be arguing on behalf of all of the Defendants.

THE COURT: Thank you all.

Let me ask you, do you want to reserve any time for rebuttal? If so, how much; and what kind of warning, if any, do you want? You have a total of 23 minutes.

MR. PETROSINELLI: Your Honor, I think the way we have divided this -- this is Joe Petrosinelli speaking for Ms. Stipes' benefit.

THE COURT: Yes, thank you. Any time anybody speaks please always state your name. Thank you.

MR. PETROSINELLI: The way we divided this, Ms. Hood is going to do an introduction to both parts of the motion, that is the shotgun pleading aspect of it and the standing aspect of it, and she will do about three minutes, and then Mr. Bayman and I have divided -- I will speak to the shotgun pleading for about ten minutes, and he will speak to standing for about 20 minutes, so that will be our 23 minutes.

We each, that is Mr. Bayman and I, would ask to reserve two of those ten minutes for rebuttal on each of those arguments.

THE COURT: Okay. Let me get this clear. In total you have 23 minutes and you are basically reserving four minutes for rebuttal.

MR. PETROSINELLI: That is correct, your Honor.

THE COURT: Okay. What kind of warning, if any, do you want on either your 19 minutes on the front end or your four minutes on the rebuttal?

MR. PETROSINELLI: I don't need any warning, but I will ask Mr. Bayman if he needs any.

MR. BAYMAN: No, your Honor, I think I am good, I will keep track of the time.

THE COURT: I am not going to keep track of your internal time, I will leave that up to you. I am mindful of 19 and four, and no warnings. With that, you may begin.

MS. HOOD: Michelle Hood, speaking on this motion on

behalf of all Defendants. Before diving into the substance, I would just like to very quickly say that I am really excited to get to present a portion of this argument today before the Court, and I appreciate the Court's support of the lesser experienced attorneys working on this litigation and the Court's efforts to create avenues for participation just like this one.

The Defendants' Motion to Dismiss the two consolidated class action complaints raises two separate grounds for dismissal. The first is the shotgun pleading nature of the complaint and the second is lack of standing.

With respect to the shotgun pleading piece, there are really two issues in the Plaintiffs' complaints that have been recognized by the Eleventh Circuit as characteristics of shotgun pleadings.

The first is a lumping together of all Defendants. The complaint is bringing a bunch of claims against a bunch of Defendants without specifying which conduct of which Defendants gives rise to which claims.

The second issue is incorporation. The complaints adopt all factual allegations into every count even though many of the factual allegations are irrelevant to many counts. As an example, the Plaintiffs bring hundreds of strict liability claims and in each of those counts they have incorporated fact sections that address alleged lack of reasonable care regarding

testing or manufacturing, as well as what Plaintiffs should have known and duties of care resulting from that knowledge.

Those allegations might be relevant to other theories of liability like negligence, but duties of care and knowledge are not elements of strict liability. In fact, Plaintiffs' strict liability counts allege that the medication was inherently unsafe.

This is a classic example of a shotgun pleading issue. The Eleventh Circuit has been emphatic about fixing shotgun pleadings right out of the gate, at the beginning of a litigation. The strategy of a Plaintiff in drafting a shotgun pleading might hinge on the hope that a Court is unlikely to find a complaint with thousands of paragraphs should contain even more content. Sometimes, though, the issue is not one of just quantity, but quality.

Due to the shotgun pleading nature of these complaints, they fail to articulate the claims with sufficient quality or really its clarity to allow the litigation to move forward in a manageable way.

The complaints, as they stand today, will absolutely -- to borrow a phrase from the Eleventh Circuit -- wreak havoc on later responsive pleadings scheduled in this case and as we get further on into the litigation when we are into summary judgment motions, class certification, even pretrial proceedings.

Here is the real rub, all of these things the Eleventh Circuit has said are problems with shotgun pleadings if you do not fix them at the outset of the litigation are exacerbated and magnified in this case because the complaints here are so much larger in paragraph and count and parties than the complaints found to be shotgun pleadings by course in the Eleventh Circuit.

Now, the way Plaintiffs try to excuse, in part, the shotgun pleading issue is to propose an expansive and novel form of standing. They argue that every Plaintiff can bring every claim against every Defendant no matter whether the Plaintiff couldn't have purchased the Defendant's product or has no ties to a certain state.

This position on standing is completely inconsistent with Eleventh Circuit precedent. The Circuit has made clear that the fairly traceable requirements of standing requires each named Plaintiff to meet the requirements of standing as to each claim asserted against each Defendant.

Plaintiffs attempt to dismiss this standing requirement as a largely academic exercise because they believe there is at least one Plaintiff that has standing to sue each of the named Defendants. So, not a single party will be dismissed if the Defendants' motion is granted.

But Plaintiffs' position here misses the effect of Defendants' argument. If the motion is granted, that will

result in the dismissal of countless claims. Take, for example, a dozen named consumer class Plaintiffs who allege they purchased Ranitidine containing products starting only in 2018. Manufacturers like Pfizer, BI, and many of the generic manufacturers had stopped selling or manufacturing the product long before 2018. These 12 named Plaintiffs also allege they purchased only prescription products. This rules out Sanofi in addition to Pfizer, BI, and many generics. Nevertheless, these 12 Plaintiffs bring 314 claims against the companies.

The complaints are replete with examples of impossibilities like this and with respect to all categories of Defendant. Finding in Defendants' favor will eliminate some of these impossible claims.

In a suit this large clarity and precision, to the extent possible, have to be driving forces. They are not in these complaints.

That concludes my introduction. I will pass things over to Joe Petrosinelli to discuss standing.

THE COURT: Thank you, Ms. Hood.

MR. PETROSINELLI: Good morning, Joe Petrosinelli. I am going to jump in on the shotgun pleading aspect of these complaints, and picking up on what Ms. Hood said, there are two problems and I will address both as to these complaints.

One is the fact that the Plaintiffs allege multiple claims against multiple Defendants, indeed almost a hundred

Defendants, without specifying which conduct of which Defendant gives rise to which claims, and this manifests itself, really, in two ways in these class complaints.

One is what I will call group pleading or collective pleading, and there are a couple of branches to that. For example, parent subsidiary and affiliated companies are lumped together in the complaint, they are defined in the early paragraphs. Early in this complaint, it is the 300 paragraphs, where you have three, four, five separate companies that are defined as one, and are never mentioned again in the next 5,000 paragraphs of this complaint. It's a classic example of shotgun cases.

There are many cases in the Eleventh Circuit and this Court that have held as much. Probably the best, most recent example is the Fox versus Loews Corporation case from the Southern District of Florida a couple of years ago. I say it is a good example because it happens to be a consumer class action complaint and there the Plaintiffs lumped together the Loews related entities, indeed only two of them in that case, and the Court said that is shotgun pleading, you have to specify which Defendant allegedly did which thing that gives rise to which claims.

And then there is the broader more fundamental problem which is (inaudible) many, many allegations in the complaint, about 90 Defendants, or explicitly group the Defendants into

brands, generics, retailers, and the like, and that creates a number of problems that the Eleventh Circuit and Courts in the sir have condemned.

One is, there are allegations in the complaint that are made against Defendants, probably the best example is the sort of allegations about knowledge and notice where the Plaintiffs say that certain publications or events over a 40-year period gave Defendants, Defendants as one, notice that there was a problem or a risk with either NDMA or Ranitidine or both.

That allegation -- those allegations culminated in a paragraph that makes the allegation that all Defendants therefore have knowledge of a problem based on these 40 years of studies and, of course, the problem is what Ms. Hood identified in the introduction, and that is that many Defendants, indeed most, got out of the Ranitidine market long before many of the studies that the Plaintiffs say gave notice to all Defendants occurred.

That allegation, by the way, your Honor, is at paragraph 609 of the consumer class complaint, and paragraph 282 of the third party payor complaint. That, to borrow a phrase from the Eleventh Circuit, defies temporal reality. It cannot be that that pleading honestly meant or could mean literally all 90 Defendants got notice of a problem from these 40 years worth of studies.

The other thing is, there are design, manufacturing, and marketing claims asserted against all Defendants, quote unquote, when elsewhere in the complaint, when certain groups of Defendants are defined, the Plaintiffs say they did not design or manufacture or market.

For example, there are design defect and manufacturing defect claims asserted against, quote unquote, all Defendants, but when the Plaintiffs -- that would include, therefore, the group that the Plaintiffs labeled the repackager Defendants, and when that group is defined earlier in the complaint, it says they didn't do anything, they didn't design it or manufacture it, all they did is, as one might guess from their title, repackage it.

That type of group pleading masks the inability to bring specific claims against specific Defendants based on specific facts.

There are dozens of Defendants named in this complaint who, as I said earlier, are named or identified in the first couple of hundred paragraphs just saying who they are and their names never appear again in the next 5,000 paragraphs of the complaint. It is a classic shotgun pleading problem.

Secondly, what Ms. Hood mentioned is this incorporation, that both class complaints incorporate 300 or more paragraphs of fact allegations into every single count. The problem with that is, as Ms. Hood said, it is not possible

that all of the fact allegations are relevant to every count, and in fact, there are dozens and dozens of allegations that are incorporated into counts that they can't possibly be relevant to. Ms. Hood's example of allegations about lack of reasonable care being incorporated into strict liability counts or fraud counts and the like, allegations about design of the product being incorporated into counts about the manufacturing of the product and vice versa.

The Plaintiffs' main response, I think, your Honor, is these are just merit issues. If the Defendants don't agree with the allegations, just file an answer and deny them. That is exactly what the Eleventh Circuit has said should not be done, no answer should be filed. Shotgun pleadings should be corrected at the beginning of the case or it wreaks havoc on the remainder of the case.

Just as an example, as your Honor knows, we are about to embark on a process probably early next year where there will be Motions to Dismiss on individual counts of the complaints. These motions that are being heard today and tomorrow were front loaded because they are broadly applicable legal motions that address most or all counts of the complaints.

But in the new year we will have motions that attack specific counts, and your Honor will get 90 Motions to Dismiss these three complaints from Defendants who are not told what it

is they did that gives rise to which claims against them.

And, finally, your Honor, the Plaintiffs can fix this. This is one thing that is easily fixable. All they have to do, if they want to sue 90 Defendants and 180 Plaintiffs they want to keep in the complaint, all they need to do is have allegations saying specifically as to each Defendant what that Defendant did, and then which of those allegations are relevant to which claims against that Defendant and why they give, according to the Plaintiffs, rise to liability.

The Plaintiffs say that will make the complaints even longer if they have to make such Defendant specific allegations.

Let me say this to the Court, two things about that. One is, in most pharmaceutical MDLs or mass torts, I think your Honor knows this, and based on my experience, I would say most of them are like this, the Plaintiffs' leadership will make a decision not to sue every Defendant in the supply chain of the product. In many, many pharmaceutical MDLs the Plaintiffs' leadership doesn't choose to sue retailers and distributors and repackagers, and even sometimes generics if there is a generic product. They will just bring a claim against the brand manufacturer and focus the litigation.

Many Plaintiffs' leaderships will not file class actions. Why? Because they know that in most pharmaceutical mass torts, class certification is almost always denied because

of the rampant individual issues. But this Plaintiffs' leadership chose to sue almost a hundred Defendants and they chose to bring class actions with 56 subclasses, and that is fine, that is their choice.

Having made that choice, they can't now say, oh, it is really difficult for us to comply with the shotgun pleading rule, and it is going to be too long of a complaint, too complex of a complaint. They have made the litigation incredibly complex. Again, that is fine, that is their job as leadership to make those decisions, but they can't now use that decision to say that they shouldn't have to specify as to each Defendant what each Defendant did.

The second thing I will say is, I am not sure it would make it longer because the Plaintiffs might find if they have to allege as to each Defendant specifically what that Defendant did, they might find that they don't have the facts to allege as to each Defendants.

In fact, as your Honor knows, the Plaintiffs have been dismissing Defendants. They have dismissed ten or 12 Defendants in the last little bit, and I think that is because, as they found out more, they realized they don't have the facts to make claims against those Defendants, and I suggest that is what would happen here.

Your Honor, the length is not the problem, it is the content, it's the lack of clarity and specificity, as Ms. Hood

said, as to which of these 90 plus Defendants did what things to give rise to what claims, and that is why repleading is required here.

I will turn it now to Mr. Bayman to discuss the standing.

MR. BAYMAN: Thank you, your Honor, Andrew Bayman arguing for all Defendants.

The Plaintiffs attempt to address the shotgun pleading infirmities that Ms. Hood and Mr. Petrosinelli have articulated by a far reaching standing theory that violates Article III jurisprudence in this District, the Eleventh Circuit, and the United States Supreme Court.

Their standing theory consists really of two components. First, each named Plaintiff has standing to sue every Defendant named in the class action complaints regardless of whether the claims asserted against a particular Defendant have any transactional, temporal, or geographic connection to that Plaintiff's alleged purchase of Ranitidine.

In other words, if a Plaintiff can sue one Defendant, he or she can sue all of them, but the Plaintiffs are suing Defendants who they concede could not have possibly injured them.

Secondly, according to Plaintiffs' theory, each named Plaintiff can bring these claims not only under the laws in which their individual claims arose, but also under the laws of

all 50 states and the additional United States territories.

So, taken together, Plaintiffs' standing theory postulates that all named Plaintiffs can sue all Defendants under any state's law and, your Honor, with respect, that is not the law.

The consequence of this standing theory was predictable. The types of complaints that Mr. Petrosinelli outlined in which -- in the consumer complaint there are 314 total counts on behalf of what was 238 Plaintiffs, now down to 183 Plaintiffs because 55 Plaintiffs have dismissed their cases because they did not want to participate in discovery, and those are brought against 94 Defendants.

The vast majority of the claims, over 250 counts, are asserted against all Defendants. The Plaintiffs don't contend that any individual could bring a suit that purports to bring the same 314 claims against the same 94 Defendants, now 93 with the dismissal of Winn-Dixie.

In fact, it is undisputed, your Honor, that a Plaintiff who purchased Zantac, for example, from Costco in Florida would lack standing to file an individual case against Walgreens under the product liability law of Montana. Plaintiffs contend that Rule 23 somehow alters this calculus if that same named Plaintiff brings the same claims as a class action. Plaintiffs are wrong.

As your Honor is aware, the United States Supreme

Court has enunciated three irreducible Constitutional minimums of standing, an injury in fact, a causal connection between the injury and the conduct complained of, and redressability.

My argument focuses on the second requirement. The Supreme Court has held that to satisfy the causal connection a Plaintiff's injury must be fairly traceable to the challenged action of the Defendant. In other words, standing must be addressed on a Defendant-by-Defendant basis. If the Plaintiff fails to plausibly connect the dots between his or her injury and the particular Defendant's conduct, then he or she cannot sue the Defendant, period.

The Supreme Court has made it clear that a Plaintiffs' burden to show standing extends not only to each Defendant he or she sues, but also to each claim.

The Supreme Court and the Eleventh Circuit have also repeatedly recognized that a named Plaintiff who personally lacks standing to pursue a claim against a particular Defendant can't manufacture his or her own standing by bringing the same claim on behalf of a class.

In other words, if a Plaintiff can't show that her injury was fairly traceable to a particular Defendant, she can't piggy-back off the standing of absent class members or even other named Plaintiffs who were harmed by that Defendant.

Not surprisingly, then, the Eleventh Circuit expressly instructs --

THE COURT: Mr. Bayman --

MR. BAYMAN: -- District Courts to ensure that a named Plaintiff has standing to bring each claim before considering whether the elements of Rule 23 have been met.

THE COURT: Mr. Bayman, that is 19:26. I just wanted to let you know. Do you want to keep going or stop?

MR. BAYMAN: Just a couple more minutes, your Honor, and I will cut back my rebuttal time.

THE COURT: Okay.

MR. BAYMAN: The Plaintiffs also, your Honor, have an argument that a Plaintiff can bring a lawsuit against Defendants under the laws of the state in which that Plaintiff does not reside, and tellingly, the Plaintiffs allege numerous counts in which it is clear on the face of the pleading that no named Plaintiff has standing under the laws of that state.

For example the State of Kansas, there is no Kansas Plaintiff, yet the Kansas Consumer Protection Act requires a consumer transaction within the State of Kansas. The Plaintiffs ignore Eleventh Circuit precedent, the Prado-Steiman case, which holds that each Plaintiff must have standing to bring an individual claim or subclaim against each Defendant.

Your Honor, for those reasons, we respectfully request that our motion be granted. Thank you, your Honor.

THE COURT: Okay, thank you.

Okay, you all used about 20 minutes and 33 seconds, so

you have the remaining time through 23 minutes for rebuttal.

I do note that there are a few people who want to enter the waiting room, so while we are making the transition from the Defendants to the Plaintiffs, if you want to come in, because we are trying not to let anyone in during the presentation. If I could ask the Plaintiffs now to turn on your audio and video so that you can be prepared for your response.

I will ask first for counsel for the Plaintiffs to state your appearance.

MR. GILBERT: Good morning, your Honor. May it please the Court, Robert Gilbert, colead counsel for the Plaintiffs and the MDL leadership on behalf of the Plaintiffs, together with my colleague, Bradford Lear.

THE COURT: Good morning.

MR. LEAR: Good morning, your Honor.

THE COURT: Okay. So, the Plaintiffs have 20 minutes. Would you like any warning?

MR. LEAR: Your Honor, I thought we had 23 minutes.

THE COURT: You do have 23 minutes, yes, 23 minutes.

MR. LEAR: Your Honor, this is Brad Lear. I am going to be making the -- presenting our prepared remarks and I think we are going to be fine on that. If I get up to 20 minutes, if you could give me that warning, that would be great. We have a little buffer this morning, at least for myself the way we are

doing this, and we will be okay.

We do have a slide show that we will put up at certain points in the argument. It would be simplest for me to run that. I understand the Court -- it may work better that with have only one person run the slide show for the Plaintiffs this morning.

THE COURT: You can run the slide show. I will make sure that you have been given permission to do that and -- let me confirm that. Yes. That would be fine.

MR. LEAR: Great. Is your Honor seeing the title page?

THE COURT: I do see that, yes. Thank you. So, we are good, the presentation shows up, and when you are ready to go, just let me know. You have a total of 23, and I will try to give you a warning at 20.

MR. LEAR: Thank you, your Honor, and I am ready. May it please the Court.

THE COURT: All right.

MR. LEAR: Your Honor, the Plaintiffs see three central questions on this motion: Are the parties before the Court properly in the suit, which is their Article III standing, that is question one.

Number two, does a Plaintiff have standing to represent class members harmed by other Defendants or class members who are in other states?

And then number three, how much detail is enough to put Defendants on fair notice of the claims being pursued against them?

The first question turns on Article III, and the second question turns on Rule 23, and then the third question turns on Rule --

THE COURT: I'm sorry. What did you say the third issue turns on?

MR. LEAR: Rule 8.

THE COURT: Okay.

MR. LEAR: I'm sorry. So, let's start, if we could, with question number one, which is standing, because that is the threshold question. It goes to the Court's subject matter jurisdiction. The requirements of Article III standing are well established.

This motion focuses really on the second prong, which is the traceability prong. The Defendants have a separate motion on injury in fact that will be argued later today, and there is no current dispute that if Plaintiffs are successful on their claims, the harms that they suffered can be redressed at judgment.

Let's look at the second prong, the one at issue, traceability. On that question we ask, have Plaintiffs alleged harm that is traceable to specific Defendants? And, of course, here there are a lot of Defendants. And the reason for that is

that we are dealing with a defective drug that was being manufactured and sold by a number of companies for three decades.

Article III standing is confirmed when for each named Defendant in the case there is at least one Plaintiff who alleges harm traceable to that Defendant. We have that here. How do we know?

Well, for certain Defendants we can directly trace the harm the Plaintiffs allege they suffered to the Defendants they allege are responsible.

I am going to share my screen, your Honor.

Let's start with Defendant GSK. We know GSK was the only company in the United States authorized by the FDA to manufacture branded Zantac for sale by prescription. So, when a consumer Plaintiff named in the class complaint alleges they purchased and took branded prescription Zantac, we know that is traceable to GSK. There were many such named Plaintiffs named in the consumer complaint and there continue to be even after Plaintiffs were dropped.

Even though not reflected on this chart, the same is true for the TPP Plaintiffs. There only prescription Zantac and Ranitidine is at issue and each of the TPP Plaintiffs issued payments for prescription branded Zantac, so each of them have alleged harm traceable as to GSK.

We use the same analysis for the retail Defendants.

The consumer Plaintiffs know where they made their purchases, and that is pleaded in the complaint, so for the claims against the retailer Defendants, we are able to directly trace which Plaintiffs have claims against which retailer Defendants. At the time the complaint was filed back in June we had at least one, and often many more named Plaintiffs for each named retailer.

Since that time, the complaint has been winnowed by dropping two retailer Defendants. For all that remain in the consumer class case there is still at least one Plaintiff with harm traceable to that Defendant.

Now, for the remaining Defendants, the other brands, the generics, the distributors, tracing the harm from the Plaintiffs to those Defendants requires an additional step. Here, at the pleading stage, we must draw an inference.

We know what type of Ranitidine containing products these Plaintiffs used, and we know the time period when these Plaintiffs were using them, but we don't know precisely who manufactured the Ranitidine each Plaintiff purchased. The consumers just know what type of Ranitidine they were taking, they know where they got it.

And that is not fatal at the pleading stage and that is because Courts have repeatedly held that when the Plaintiffs cannot identify a specific Defendant who caused them harm, but they can identify a group of Defendants who are potentially

liable for causing that harm, naming all those potentially liable Defendants is perfectly appropriate.

So, how do we go about handling those allegations in the complaints?

I will put up another slide here.

Well, we were able to determine the time periods when the brand Defendants were manufacturing over-the-counter Zantac. If we look at just those Plaintiffs who allege over-the-counter Zantac purchases, we know the total time period they allege using Ranitidine containing products, so we know at each of the times the brand Defendants were selling over-the-counter Zantac there were multiple Plaintiffs who allege they were taking Ranitidine containing products.

Similarly, we know the earliest date each of the generic Defendants could have entered the market by completing the ANDA process. Of course, unlike the brands, the generics overlap, there were multiple companies manufacturing Ranitidine at the same time, but, again, we know which consumer Plaintiffs allege they took generic Ranitidine and their allegations identify the total time period they used Ranitidine containing products.

So, taking that information together and given the scope of the claims asserted by the named Plaintiffs, it is more than plausible that there is at least one named Plaintiff, and likely many more, with traceable harm against each

manufacturer Defendant.

Your Honor, the same is true for the distributor Defendants. The complaints allege those Defendants distributed 90 percent of the Ranitidine containing products sold in the United States and, thus, each plausibly distributed a drug traceable to at least one of the named Plaintiffs.

So, because the class complaints plausibly allege that the named Plaintiff suffered an actual injury that is redressable by the Court, and that for each Defendant there is at least one named Plaintiff alleging harm traceable to that Defendant, Plaintiffs have satisfied our burden for establishing Article III standing. This Court has subject matter jurisdiction over these claims.

Let's turn to the second issue presented by Defendants' motion. This is where they focus most of their efforts, and it is on this question: What is the appropriate scope of the class claims pleaded in the complaints?

On this issue, Defendants advance two basic arguments. First, the Defendants argue that to plead a multi-Defendant case like this every named Plaintiff must show they have standing to pursue a claim against every single named Defendant.

Then, second, Defendants argue that the named Plaintiffs only have standing to assert claims on behalf of putative class members in the same state where the named

Plaintiff paid for the product.

These arguments share the same premise that a named Plaintiff only has standing to pursue claims for others if it is a claim the named Plaintiff can pursue for herself. But that premise has been rejected by the Eleventh Circuit in its recent Fox versus Ritz-Carlton decision. Fox makes clear that the scope of the claims that can be pursued by the class can be broader than those that have to be pursued individually by the named Plaintiff.

So, how do we apply the guidance of Fox in this case? After all, Fox involved only a single Defendant. How does that holding apply in a multi-Defendant case like this one?

This is the more unusual situation, and for that, of course, we have to look to class cases where Courts had to manage claims being brought against multiple Defendants.

We cited the cases, principally Judge Wood's opinion from the Seventh Circuit in Payton where Courts have held that a class representative harmed by one Defendant has standing to bring claims against other Defendants with whom that class representative had no direct dealings if those other Defendants harmed similarly situated class members and if there is a juridical link between all the Defendants.

Now, in our case, the juridical link that ties the parties and putative class members together is that at every point in the chain, from when these drugs were approved to be

manufactured, to when they were distributed, and then ultimately sold to the consumers, each of those transactions were subject to the regulatory framework established and overseen by the FDA.

Put differently, none of these Plaintiffs could have ever purchased this defective drug but for the FDA's authorization to these Defendants to manufacture, distribute, and sell it. That is a juridical link.

Now, the Eleventh Circuit has never expressly adopted, nor has it rejected the juridical link doctrine, but it has discussed it, and favorably in our view, and the only decision both sides have been able to cite on the point is the Moore case.

While the Eleventh Circuit in Moore did not ultimately decide the issue using juridical link, there is nothing in that decision that suggests the Eleventh Circuit was hostile to the doctrine or opposed to applying it under appropriate circumstances.

Indeed, the Court in Moore ended up doing, through a Rule 20 joinder, what the Plaintiffs sought through the application of a juridical link, but the result was the same, it added additional Defendants to the litigation that did not have a direct nexus with the named Plaintiffs.

While Defendants have cited several District Court decisions that go their way on this, we would submit the

Seventh Circuit's decision in Payton is the much more persuasive authority, especially when considered together with the favorable language from the Eleventh Circuit in Moore.

Now, that being said, Plaintiffs do recognize the juridical link doctrine is not a widely applied theory, it turns on specific circumstances, but we don't have to decide whether it applies today because, as we discussed earlier, every Defendant currently named has claims brought against it by one or more named Plaintiffs.

The decision about whether those named Plaintiffs can bring these claims against other Defendants in a representative capacity is a decision more appropriately made at class certification, but to the extent the Court is inclined to take up that issue in the context of the Defendants' Rule 12 motion, the named Plaintiffs have plausibly alleged standing under the juridical link doctrine to represent class members harmed by all these Defendants.

Now, that does not mean we are guaranteed to get a class certified on that theory, but it does mean that we have cleared the Rule 12 hurdle, and that this issue can be dealt with at the class certification stage, after discovery and when the Court has the benefit of a record to make that decision.

Your Honor, our position is even stronger on the geographical scope of the claims that can be pursued by the class representative. Plaintiffs have cited three Circuit

Court opinions that directly address this question. One is from the Second Circuit, Langan, another from the Seventh, Morrison, and then most recently from the First Circuit, In Re: Asacol. All three decisions hold that a class representative has standing to assert claims on behalf of class members from other states if she can satisfy Rule 23.

In the absence of binding Eleventh Circuit precedent, these three Circuit Court opinions are highly persuasive authority, and those decisions are consistent with, by the way, not contrary to the Eleventh Circuit's decision in Prado-Steiman. That case makes clear that a class representative must be a member of any class she seeks to represent, and that she suffered the same injury as her fellow class members.

The question is not one of geography, but rather, whether the named Plaintiffs can appropriately stand on behalf of each of the classes or subclasses she seeks to represent.

I will say it another way. The question is one of typicality, and that is a question for class certification.

Finally on this point, how do we know that Prado-Steiman does not foreclose Plaintiffs' position? Because the Court in In Re: Asacol specifically identifies that only the Second, Seventh, and then the First Circuit have taken up the question of whether class claims can extend beyond the named Plaintiffs' home state. The Eleventh Circuit has not

spoken on that point and it certainly has not foreclosed it.

Now, Defendants want the Court to ignore those three Appellate Court decisions holding that it should be decided at class certification. Instead, they want the Court to decide that issue now.

In the face of the authority the Plaintiffs have cited, that is a very aggressive position the Defendants are taking, and respectfully to them, they are inviting error on that point.

Consistent with Langan, Morrison, and In Re: Asacol, this Court should defer that issue until the class certification, but as we stand here at Rule 12, given the authority Plaintiffs have cited, it is certainly plausible that the state law causes of action pleaded in the class complaints can be certified even for those states where named Plaintiffs do not reside, or in the case of the TPPs, where they did not issue payments. So, that leaves us with the third issue, shotgun pleading.

There we ask: Have the Plaintiffs provided sufficient information in their class complaints with enough clarity for the Defendants to be on notice of the claims that they face? And the answer to that question is absolutely yes, we have.

Now, why is that?

Well, let's begin by acknowledging, as your Honor has written, there is no perfect complaint. There are many ways to

go about it. For that matter, it has been observed that no two MDLs are the same, so there is no one size fits all approach when it comes to pleading complex factual and legal issues that come up in these large scale MDLs, and this MDL certainly falls into the category of a large scale MDL.

Given the national scope of cases like this one and the need to assert claims on behalf of consumers from every state and territory, you do often see lengthy consumer class complaints, and Plaintiffs recognize that the consumer class complaint we filed here is fairly characterized as lengthy, but it is also fair to say that the consumer class complaint we filed here is in line with the length and the structure of the consumer class complaints filed in other large nationwide MDLs, including Juul and Allergan.

Let's turn from the length of the complaints to the content of the complaints because that is, as the Defendants acknowledge, what is at issue.

At the time the class complaints were filed without any discovery there was limited publicly available information regarding who manufactured, distributed, and sold this defective drug during the three plus decades before it was pulled from the shelves. So, it fell to counsel in drafting the class complaints to present the information that we do know and to account for the information that we know will have to come from discovery.

So, how did we do that?

We broke the Defendants into groups, the brands, the generics, the distributors, and the retailers. By breaking the Defendants into these groups we allege in as much detail, based on the information publicly available to us at the time, the facts that give rise to Plaintiffs' claims. We set forth separate claims for relief, and those claims identify which groups of Defendants the relief is sought against.

As the Eleventh Circuit explained in its United Technologies case, at the pleading stage Plaintiff could not possibly have had access to the inside Defendant information necessary to prove conclusively, or even plead with greater specificity, the factual basis for holding Defendant liable for another's conduct. That is why we have discovery.

At the pleading stage we assess only whether Plaintiffs' allegations are enough to raise the right to relief above the speculative level. It is hard to imagine how Plaintiffs could have pled their case with greater specificity or accuracy at this stage.

Only now, as the Defendants slowly begin producing documents and data, we are beginning to find some of the missing pieces of the puzzle, and along the way, we are taking appropriate steps to refine the claims at issue in this litigation.

Your Honor, the class complaints in this MDL were not

calculated to confuse or to frustrate the Defendants and certainly not the Court. The unifying characteristic of all types of shotgun pleadings is they fail, to one degree or another, to give Defendants adequate notice of the claims against them and the grounds for those claims.

When the Defendants assert that Plaintiffs cannot succeed on the claims they have brought or deny that certain allegations are true or could be true as to certain Defendants, those points go to the merits.

A dismissal under Rule 8 or 10 is only appropriate when, and I will quote, "it is virtually impossible to know which allegations of fact are intended to support which claims for relief," close quote. That comes from Weiland at 1325, and it is certainly not the case here.

Defendants' own merits arguments belie their point. They may disagree with Plaintiffs' claims, or against which Defendants those claims are directed, but they are clearly on notice of the claims that they face.

And to the extent that they are seeking more detailed allegations against -- specified against each Defendant, or they contend that we need more named Plaintiffs to assert the causes of action pleaded in the class complaints, with respect, the natural result would only be to increase, not to decrease, to increase the length of the complaints.

So, on this point I would simply close by saying that

counsels' intent in formulating the complaints it filed in this case was to meet our charge to present all the class claims at issue in the nationwide litigation so they can be managed as part of this MDL.

Ultimately, we are left with two questions: Do the complaints fairly put Defendants on notice of Plaintiffs' claims? Absolutely, yes, they do.

And do these complaints plausibly allege standing as to each named Defendant? Once again, absolutely, yes, they do.

That is all that is required for Plaintiffs to meet their obligations at this stage of the proceedings, and we have done so. The Defendants' motion should be denied.

Thank you, your Honor.

THE COURT: Thank you. Does that complete your argument?

MR. LEAR: It does.

THE COURT: Okay. Thank you so much. I will ask Plaintiffs to take your screen and audio off and allow the Defendants to come back in for their rebuttal, the two minutes and 27 seconds that you have left for your rebuttal. You may proceed.

MR. BAYMAN: Thank you, your Honor, Andrew Bayman again. I will be brief.

The Plaintiffs cite Morrison, Langan, and In Re: Asacol, but, your Honor, in those cases there were no

traceability problems. By contrast, here the Plaintiffs have not determined at all that each named Plaintiff has standing to sue all 93 Defendants and the Eleventh Circuit's precedent in the Prado-Steiman case mandates that before a Court even consider undertaking any form of typicality or commonality review under Rule 23, the District Court must determine the named Plaintiffs have standing to raise each subclaim.

The Langan case the Plaintiffs cite is very different from the facts here. That was one named Plaintiff suing one named Defendant. The District Court and the Eleventh Circuit must first determine that the party Plaintiff was actually injured by each of the named Defendants before doing a Rule 23 inquiry. So, those cases are not the same.

The Plaintiffs also made an argument for the first time today that there is some kind of juridical link because the Defendants participated in a Federally regulated marketing scheme by the FDA.

The argument that mere participation in a Federally regulated marketing subjects you to a Federal suit by Plaintiffs with whom you have no transactional relationship has never been recognized by the Courts, it is unprecedented and it is wrong.

Plaintiffs claim that they need discovery, your Honor, in order to determine which Plaintiffs have which claims against which Defendants. No amount of discovery can reveal

that a Plaintiff who alleges he or she purchased Ranitidine exclusively from Wal-Mart was somehow harmed by Dollar General, for example.

Finally, your Honor, the juridical link doctrine has only been recognized by one circuit, the Seventh Circuit. It cannot confer standing where it is otherwise lacking, is not a shortcut around traceability. No single Court in the Eleventh Circuit has recognized the juridical link doctrine, and even when it has been recognized, it is clear it only applies in situations where there was a contractual obligation among all the Defendants or a statute requiring common action.

In the Moore case, which is not a standing case, which mentions juridic link, each of the named Plaintiffs and all the class members had dealings with the same entity, the Land Bank. That is not what we have in this case with different Plaintiffs having different transactional relationships with different Defendants.

For those reasons, your Honor, we respectfully request that our motion be granted.

THE COURT: Okay, thank you so much.

If there is someone who needs to be admitted, our cohost can allow that person to be admitted while the Plaintiffs come on the screen. And as I said, I am going to direct questions to either Defendants or Plaintiffs and will rely upon you to have the appropriate person answer the

question.

To the Defendants, regarding standard of review, you state the Motion to Dismiss and/or Strike is brought pursuant to Rule 12. Under which Federal rule or rules are you moving to dismiss or strike? Is it just Rule 12(b)(1), or is it any other provision?

MR. PETROSINELLI: Your Honor, I can address that from the shotgun pleading aspect and Mr. Bayman can take it on the standing aspect.

On the shotgun pleading aspect, it is a Rule 12(b)(6) motion for failure to state a claim which relates to relate, because relate, which is what the shotgun pleading is based on, says that a complaint can state a claim if it, and then it goes on to say a shortened plain statement of the allegations and so on.

This came up in the briefs a little bit, your Honor, about whether this -- the Plaintiff said the motion should have been for a more definite statement under Rule 12(b), and the Eleventh Circuit has said several times, most recently in Jackson versus Bank of America, that it doesn't matter what portion of Rule 12 you bring a shotgun pleading under, whether it is 12(b)(6), 12(b), or some other rule, as long as the remedy you seek is the same, which is that you allow the Plaintiffs to replead.

As long as the remedy is repleading, the Eleventh

Circuit has said, and many District Courts have held, it could come under either Rule 12(b)(6) or Rule 12(b).

I will let Mr. Bayman answer the question with respect to the standing aspect of our motion.

THE COURT: Thank you.

MR. BAYMAN: Your Honor, with respect to the Article III standing question, that would be Rule 12(b)(1).

THE COURT: Okay. All right. This is for the Plaintiffs.

Defendants argue that fixing the class complaint should not be a difficult undertaking. They propose that each named Plaintiff file an individual complaint against only the Defendants they can sue under Rule 8. They say that those individual complaints can then be consolidated for administrative purposes into a genuine master complaint.

Do you view this as a workable solution? If not, why not?

MR. GILBERT: Thank you, your Honor, Robert Gilbert on behalf of the Plaintiffs, I will be answering this question.

We don't view this as a workable solution. We don't think in a nationwide MDL where the Court has entered an order directing the Plaintiffs to file a consolidated complaint, which is the operative pleading, that 183 different Plaintiffs should need to file 183 different class action complaints naming many of the same Defendants.

We don't think it is a workable solution. We don't think it is an easy solution. We don't think it is in keeping with what MDLs involving either consumer class cases or class actions in general have done in other similar scenarios, and so we don't view that as being the right approach.

THE COURT: Defendants also argue that if Plaintiffs insist on moving forward with only two master complaints as the operative pleadings, they must, at a minimum, specify which Plaintiffs are suing which Defendants and tie specific factual allegations to each claim.

Is this a workable solution?

MR. GILBERT: Let me respond to that, your Honor. Consistent with what my colleague, Mr. Lear, said during his presentation, to the extent that Plaintiffs, at this point in time with very little discovery, are able to tie -- trace allegations directly to specific Defendants, i.e. the retailers, or GSK in the case of prescription Zantac, those types of allegations could be made.

To the extent that at this point in time in the process, very early in the discovery process, we don't know exactly which generic manufacturer Defendants manufactured the product that Plaintiff Smith purchased and used during a five-year period, and there are multiple generic manufacturers that were authorized by the FDA to manufacture the product during that period, naming the specific Defendant is not

possible. Naming all of those generic Defendants during that period of time is possible.

The same general answer with regard to the distributors. The distributors that are named in this complaint account for 90 percent of the market. We'll never know -- I shouldn't say never. We will not know, without significant discovery, which distributors distributed which manufacturer's product to which retailers.

For the periods of time when each of these distributors were distributing this product, we could name one or more of them, and that would be as close to traceability as we could get at this point in time.

I hope that answers your question.

THE COURT: Thank you. This is to the Defendants.

Plaintiffs argue that if the Court adopts your arguments as to Article III standing the class complaints would require at least one Plaintiff in privity with each Defendant in all 50 states, Puerto Rico, and the District of Columbia. Plaintiffs claim that doing so would result in more than 5,000 named Plaintiffs in the consumer complaint with each pleading separate allegations against each Defendant.

I know you touched on it in your opening presentation, but if you could elaborate. Do you agree? And if so, do you believe that ordering Plaintiffs to replead this way would streamline the MDL?

MR. BAYMAN: Your Honor, we don't agree that that much is involved. There may be claims which -- under state law where there are uniform claims among the states, but that is the Plaintiffs' burden of showing that uniformity.

There also may be ways to have multiple Plaintiffs bring subclaims under the same state's law, but what is clear, your Honor, is the Plaintiffs' current complaint as pled, all Plaintiffs are able to sue all Defendants under all state laws, that cannot possibly be the law, that someone who took Ranitidine in Florida purchased at Costco can sue Walgreens under the law of Montana.

So, there needs to be repleading by the Plaintiffs in which they identify which Plaintiffs were harmed by which Defendants under which state's law, but that does not mean there has to be 5,000.

THE COURT: Okay.

MR. GILBERT: Your Honor, may I respond to that?

THE COURT: Yes.

MR. GILBERT: Thank you. Robert Gilbert on behalf of Plaintiffs.

First of all, I appreciate my colleague, Mr. Bayman's concession or acknowledgment that some of the state law claims may be fairly susceptible to grouping. Grouping is classically done at the class certification stage, not at the Motion to Dismiss stage.

Grouping of states where there is a similar element to prove a common law cause of action, it is recognized by multiple states, and where all those states have the same elements is a classic Rule 23 tool that Courts around this country use. It is not something that is used at the Rule 12 stage as the Defendants are urging here.

We recognize that there are certain claims in our consumer complaint that are not subject to extra territorial application.

For example, your Honor knows, as I do, that Florida's Deceptive and Unfair Trade Practices Act is not generally susceptible to extra territorial application, but negligence claims, or the easiest one of all, unjust enrichment claims, are historically susceptible to nationwide certification or group of state -- excuse me, small number of state groupings where the elements are the same.

Whichever of those we talk about, we talk about them at the Rule 23 stage, not at the Rule 12 stage.

By the way, Mr. Bayman or Mr. Petrosinelli mentioned the Jackson v Bank of America case as being decided under Rule 12. Not correct, it was decided under Rule 8. It's a classic shotgun pleading case decided under Rule 8 where the Plaintiffs did not oppose the motion for a more definite statement.

THE COURT: Thank you. This is for the Plaintiffs.

The Defendants argue that the issue of the named

Plaintiffs' standing should be determined at the Motion to Dismiss stage and before the class certification stage of the litigation.

It appeared to the Court that you did not expressly accept or reject this argument, at least in your papers.

So, can you tell the Court your position, where you feel you have pointed this out in your brief as to the decision regarding standing and the whole concept of logical antecedents, whether it is at the Motion to Dismiss stage or at the class cert stage?

MR. GILBERT: Your Honor, was that directed to the Plaintiffs or the Defendants?

THE COURT: Plaintiffs.

MR. GILBERT: Thank you, your Honor. I apologize, I was having trouble hearing the Court's question. Would you mind repeating it?

THE COURT: Sure, I'll repeat it. The Defendants argue that the issue of the named Plaintiffs' standing should be determined at the Motion to Dismiss stage and before the class certification stage of the litigation. That was in their motion at pages 36 to 37.

I did not see that the Plaintiffs expressly accepted or rejected that argument in your briefing, so I would like to know if I missed something. Where in your briefing do you accept or reject the proposition that standing should be

determined at the Motion to Dismiss stage and before the class certification stage?

MR. GILBERT: I don't have the opposition open to a specific page here, your Honor. I think that we agree with the general principle that standing of each Plaintiff against at least one Defendant must be determined at the Rule 12 stage.

Where we disagree with our colleagues on the other side is this issue about the named Plaintiffs' ability to establish standing against every Defendant.

We don't believe that that is a requisite element that needs to be proven or established at the Rule 12 stage, and that is what we have argued is consistent with not only the juridical link doctrine, but also consistent with the appellate decisions from the First, Second, and Seventh Circuits.

It is an issue that needs to be addressed in the context of Rule 23 for purposes of asserting claims against other Defendants. It is not something that needs to be addressed at this stage where we have demonstrated clearly and plausibly that each named Plaintiff has claims against at least one, if not many more Defendants.

THE COURT: When you say you agree with the general principle that standing must be determined at the Rule 12 stage, then you have a caveat as to what should be deferred to the Rule 23.

Again, could you precisely articulate what this

general principle of standing should be determined at the Rule 12 stage as distinct from that principle of standing to be determined at Rule 23? I just want to make sure I understand your position.

MR. GILBERT: I'll try to answer the Court's question.

Consistent with Lujan, obviously we need to establish at the Rule 12 stage that each Plaintiff can satisfy the three elements of standing against one or more of the Defendant parties in the case.

The question that can be deferred until the Rule 23 stage is the question about whether the named Plaintiffs have standing to assert claims on behalf of other state's consumers, whether the named Plaintiffs have standing to assert claims against other Defendants with whom they have not had direct dealings.

So, individual standing of Plaintiff Smith against Defendant GSK, or Defendant GSK and Defendant Publix, we need to establish that here. We do not need to establish here at Rule 12 that Plaintiff Smith has standing to pursue these claims on a representative basis against every single one of the Defendants. That is what the juridical link doctrine allows this Court to address at Rule 23.

That is what Asacol, Langan, and Morrison, not suggest, but dictate be addressed at Rule 23, and frankly, that is entirely consistent with the Prado-Steiman decision as well,

that at or in preparation for the class certification proceeding the Court needs to make sure that each representative Plaintiff can satisfy the typicality requirement of bringing claims on behalf of similarly situated putative class members.

I hope that distinction makes sense to the Court.

THE COURT: Thank you. Was there a response?

MR. BAYMAN: Yes, your Honor. The Prado-Steiman case makes it clear that the Court must consider standing before it can even consider any of the Rule 23 requirements. It must determine, quote, "that at least one named class representative has Article III standing to raise each class subclaim. That is at 221 F.3d 1279.

The opinion does not hold or even suggest that if one named Plaintiff has standing to bring a particular state law claim, then all the named Plaintiffs do. And there are numerous Courts in this district and district construing Prado-Steiman that have repeatedly recognized the named Plaintiffs in class actions have time and time again been prohibited from asserting claims under state law other than that from which the Plaintiffs own claim arose.

Mr. Gilbert may have misconstrued what I said earlier in terms of whether there could be claims asserted -- a claim asserted by one Plaintiff involving different state's law. I was referring to uniformity if they were bringing Federal

claims, not uniformity with respect to state claims. Nevertheless, the burden on showing uniformity rests squarely with the Plaintiffs under the Clay decision in the Eleventh Circuit.

THE COURT: For the benefit of the record, that was Mr. Bayman. Again, everyone remember to state your name before you speak, although your names are on the screen.

I do have a more extensive question on Prado-Steiman and I'll return to that in a moment.

This is a question for Plaintiffs. You cite United Technologies Corp v Mazer, 556 F.3d, 1260, Eleventh Circuit, 2009, to argue that where a reasonable investigation under the circumstances points to multiple possible tortfeasors, a Plaintiff has a good faith basis to sue each one in the alternative. That is your response at page 19.

In the consumer complaint and the third party complaint every named Defendant appears to assert claims against -- every named Plaintiff appears to assert claims against every named Defendant.

Is it your contention that United Technologies provides the legal support for all Plaintiffs to assert claims against every Defendant named in the class complaints?

MR. GILBERT: We would not rely on United Technologies for that premise, your Honor. We rely on the juridical link

doctrine, the Seventh Circuit's decision in Payton, and the Eleventh Circuit's decision in Moore, which, while not expressly adopting or rejecting it, seems to imply the joinder to other Defendants who have potential liability for the claims at issue is appropriate.

THE COURT: Thank you. I do have more extensive questions on the juridical link doctrine, so we will revisit that.

Defendants, it may be repetitive, so you don't need to repeat that what you already said, but let me ask, is there anything more on the standing? Articulate for the Court precisely what you believe the correct Article III standing analysis looks like.

In other words, does the Court need to evaluate whether there was injury in fact, traceability, addressability as to every claim brought by every named Defendant -- brought by every named Plaintiff against every named Defendant?

MR. BAYMAN: Yes, your Honor. We believe that the Eleventh Circuit and the Supreme Court case law does require that, and Prado-Steiman is one of the leading cases that supports that.

Before you can get to Rule 23, you have to determine that at least one named class representative has Article III standing to assert each subclaim to conduct the traceability analysis, which the Plaintiffs' complaint does not allow one to

do in this case.

THE COURT: Plaintiffs, you argue that, quote, "no class action could survive Defendants' confected demand that the named Plaintiffs must independently meet the requirements of standing as to each claim asserted." That is your response at page 21.

Yet, in Prado-Steiman versus Bush, 221 F.3d 1266, Eleventh Circuit, 2000, the Eleventh Circuit stated that as to standing, quote, "each claim must be analyzed separately and a claim cannot be asserted on behalf of a class unless at least one named Plaintiff has suffered the injury that gives rise to that claim," end of quote, 221 F.3d 1266, 1280.

The Defendants cited that proposition in their briefing. In your response you cite language from the Prado opinion that "the factual record was not fully developed, making resolution of individual standing claims impossible." That is at page 20, citing Prado at page 1278.

You also note that Prado was cited in a Rule 23(f) interlocutory appeal posture, and focuses on whether the named Plaintiff's injury is typical," end of quote. That's at page 22 of your response.

The Court understands those portions of your response to explain why, in your view, Prado is distinguishable. Is the Court's understanding correct? And if so, can you explain why these distinguishing facts are relevant to the Court's standing

analysis?

MR. GILBERT: I will try to answer the question as best as I understand it, your Honor.

As we said, and as is obvious, Prado-Steiman was actually our circuit's first foray into Rule 23(f) interlocutory review.

At the part of the decision that you quoted initially about each claim must be analyzed separately, and a claim cannot be asserted on behalf of the class unless at least one named Plaintiff has suffered the injury that gives rise to the claim, we believe that, consistent with the pleading, the direct traceability and the indirect traceability, or plausible traceability that Mr. Lear discussed earlier, that we have 183 Plaintiffs in this class complaint who have alleged standing for each of the claims that are brought here, for one or more of the claims that are brought here.

They clearly on their face, it is undisputed, do not have -- absent application of the juridical link, do not have the direct dealings with every single Defendant that would allow them to say I suffered harm by X Defendant, absent application of the juridical link doctrine.

This quote from Prado-Steiman about analyzing these claims was done in the context of the class certification analysis. We believe that is the appropriate time for it to be done, and we don't believe that it precludes -- in fact, we are

confident that it does not preclude Plaintiffs from the State of Florida, for example, from bringing certain claims on behalf of putative class members from other states where those claims are subject to similar standards, consistent with the opinions in Payton -- excuse me, consistent with the opinions in the decisions that I cited to the Court earlier, Asacol, Langan, and Morrison.

I hope that answers your question. It was pretty extensive and I am not sure I got it all.

THE COURT: You answered it, thank you.

This is for the Defendants. The Plaintiffs argue that even if the Court accepts Defendants' standing arguments, not a single party will be dismissed -- although I think we have seen one party dismissed, Winn-Dixie, or at least one -- since the Plaintiffs in the consumer complaint have plausibly suffered harm at the hands of every Defendant named in the consumer complaint. That's the Plaintiffs' response at 24.

Defendants argue, however, that granting Defendants' motion will result in the dismissal of countless claims. That is your reply at page ten to 11.

To be clear, do Defendants argue that if the Court accepts the Defendants' standing arguments, only claims may be dismissed and not named Defendants?

MR. BAYMAN: Your Honor, we believe certainly claims would be dismissed. For example, your Honor, in my opening

argument I mentioned the Kansas Consumer Protection Act claim which requires a transaction to have occurred in the State of Kansas and there is no Kansas Plaintiff in the case.

We also believe that there will be Defendants who would be dismissed. Winn-Dixie, as your Honor noted, already was. Some Defendants would be dismissed also, although it would be mostly claims.

THE COURT: Plaintiffs, regarding the third party complaint, Defendants argue that, quote, "none of the named Plaintiffs allege that it reimbursed products from, or had any relationship whatsoever with, certain generic manufacturer Defendants, including but not limited to Ajanta, Aurobindo, Geri-Care, Torrent, and Zydus-Cadila," end of quote. That is the motion at page 27.

You did not respond to that argument, or at least the Court didn't see that the Plaintiffs responded, nor is it clear what relationship the named Plaintiffs have with those Defendants.

Do the named Plaintiffs have a relationship with those Defendants? If so, where in the third party payor complaint would that be?

MR. GILBERT: Your Honor, consistent with Mr. Lear's explanation earlier, the third party payor Plaintiffs have no way of knowing exactly which -- without discovery, exactly which generic manufacturers manufactured a particular

prescription form of Ranitidine that the third party payors reimbursed their members for.

The third party payors know the period of time that they were reimbursing their members. The third party payors knew at the time we filed the complaint generally when each of these generic manufacturers applied for or received an ANDA. That was publicly available. We knew generally the period of time up until when generic Ranitidine was withdrawn from the market.

But absent further details, information within the exclusive possession of the generic manufacturer Defendants, we have no indication from the publicly available information exactly which generic manufacturer Defendants sold or manufactured the generic form of prescription Ranitidine that was reimbursed by these third party payors.

It is similar to the explanation that Mr. Lear gave about the consumer Plaintiffs and the graph that we used that was in dark blue that shows the period of time when each of these generic manufacturers was involved in the market.

MR. PETROSINELLI: Your Honor, this is Joe Petrosinelli. May I make a comment about that?

THE COURT: Yes.

MR. PETROSINELLI: Just one thing. As I think your Honor knows, I am heavily involved in the census and one of the things about that is, we have provided -- when I say "we" I

include the generic manufacturers -- we have provided as part of the census process information to the Plaintiffs about exactly -- for every generic company, exactly what they sold, what formulation, prescription or over-the-counter, and when.

So, the Plaintiffs have that information, and that is part of what I said earlier, and this could relate to both standing and shotgun pleading, that they can replead these complaints with details like that. They have all of that information now.

Indeed, I believe that is why some of the generic companies have been dropped from the master complaint because upon seeing, for example, that a generic company had filed an ANDA and received an ANDA, but some of them have never sold the product, and now that that has been demonstrated, those companies have been dropped. So, that information is available and should be incorporated in the pleading.

MR. GILBERT: Judge, may I briefly respond?

THE COURT: Yes.

MR. GILBERT: Robert Gilbert on behalf of the Plaintiffs.

It is true that the generic manufacturers are providing and have recently provided some information regarding the period of time that they were involved in the market and what type of product they were manufacturing and putting into the market.

And Mr. Petrosinelli is correct, where we have determined, for example, that generic X never commercialized an ANDA that they received from the FDA, we have made the decision to drop them. You have seen those motions -- unopposed motions to drop coming in.

That information is part of discovery. It is informal discovery in a sense, but it's part of discovery that we had no access to at the time this consolidated third party complaint or the consumer complaint was being drafted in May and June.

THE COURT: Did any of the information you received bear on the Defendants I just mentioned as part of my question?

MR. GILBERT: Your Honor, I wish I could give you a direct answer to that.

The Defendants you just mentioned, if my memory is good, were Aurobindo, Ajanta --

THE COURT: Geri-Care, Torrent, and Zydus-Cadila.

MR. GILBERT: It did not bear -- to my knowledge, it did not bear on any of those Defendants, with the potential exception of Zydus-Cadila. I believe that Zydus-Cadila involves -- one of them is an Indian parent company and the other is a U.S. subsidiary, and I believe that we recently received some information about the Indian parent company, but I haven't mastered exactly what that information is. I don't have that at the tip of my fingers right now.

THE COURT: Well, I guess my question is, if the

Defendants are correct that none of the named Plaintiffs alleged in the third party complaint that it reimbursed products with respect to those generics, do the Plaintiffs nonetheless believe that the named Plaintiffs would have Article III standing as to those Defendants?

MR. GILBERT: The Plaintiffs believe that at the time this complaint was filed, the Plaintiffs have Article III standing based on plausible allegations of standing that they reimbursed for product during a particular window period of time during which many of these generic Defendants were manufacturing their product and putting it into the stream of commerce, yes.

Can that get better based on information that is being produced and made available by the generic Defendants pursuant to the core discovery agreements? The answer to that is, obviously, yes. To the extent that the generic Defendant are giving specific, identifiable information in the course of discovery, it only makes it better and easier for us to be more specific.

THE COURT: Are the Plaintiffs current with their dropping of Plaintiffs and Defendants based on receipt of any discovery and/or census information? Are you more or less current?

MR. GILBERT: We are more or less current. There are a couple of parties that we are still waiting for sworn

declarations from. There is one, I believe, that came in over the weekend, it will be the subject of a motion to drop filed today. But we are more or less current.

There are still discussions going on with half a dozen, I would say, Defendants and we are waiting for formal sworn declarations from those Defendants that would lead us to make a conclusion that they can or cannot be dropped.

THE COURT: Okay. Defendants, you argue that the, quote, "named Plaintiffs lack standing to assert claims on behalf of putative class members whose claims arise under other states' laws." I know you touched upon this in your argument as well. That is at page 34.

The Court understands this argument to pertain to the consumer complaint, as you note several states that the named Plaintiffs do not allege residing in or purchasing Ranitidine products from. You did not provide an equivalent discussion regarding the third party complaint.

Is the Court correct that your argument only applies to the consumer complaint?

MR. BAYMAN: Your Honor, there are similar infirmities with respect to the third party complaint because the complaint alleges that they reimbursed purchasers in far fewer than 50 states and lists a number of states at paragraphs 22, 25, and 28, where they did not claim to reimburse purchases in those states. So, therefore, they cannot bring claims for purchases

they didn't reimburse, so, therefore, the same argument applies.

THE COURT: Do you believe that you put this in your briefing papers?

MR. BAYMAN: Yes, your Honor, at page 14 of our motion, yes.

THE COURT: Okay. Thank you. This is for the Plaintiffs.

The Defendants argue that the juridical link doctrine cannot confer or substitute for Article III standing. I know we talked about it already. I want to delve into it a little further.

Further, the Defendants argue that even if the doctrine could confer standing, it does not apply to this case. They, as you, the Plaintiffs, have noted the case of Moore versus Comfed Savings Bank, 908 F. 2nd 834, Eleventh Circuit, 1990, whereby the Eleventh Circuit limited the doctrine's applicability to, quote, "a situation in which there was either a contractual obligation among all Defendants or a state or local statute requiring common action by the Defendants," end of quote. 908 F.2d at 838.

The Court does not see any place in your response where you argue that either of those two conditions discussed in Moore applies to this case. If the Court is mistaken, will you point the Court to portions of your response where you

argue that one of those conditions applies, or are you not suggesting that one of those conditions applies?

MR. GILBERT: Thank you for the question, your Honor. What we are arguing is that -- first of all, I would respectfully disagree that Moore limited the application of juridical link. I think it is clear from reading the opinion that the Court discussed it. Obviously, its holding in the case did not adopt or reject it. The Court noted that the link is most often found when there is a statute or contract requiring common action.

Here, as Mr. Lear showed us with the graphic that we put up, the common -- the statute, if you will, or regulatory framework that ties all of these parties together, the Defendants on the one side, the named Plaintiffs on the other side, as well as the putative class members, is the FDA.

This drug in its prescription form, in its over-the-counter form, would never have been authorized for sale to the U.S. public in the event the FDA didn't approve it. That is analogous, in our view, to a state statute, it is a Federal regulation.

I would say to the Court that if we look at Payton, I think we can make the point. In Payton there were two Plaintiffs from two Illinois counties who paid the bail fee. They clearly didn't pay the bail fee in the other 17 counties.

They brought -- Judge Wood, however, on the Seventh

Circuit found that they had standing to bring the claim on behalf of fellow individuals from the other 17 counties who also paid a bail fee because the Defendants took part in a similar scheme that was sustained by a contract or a conspiracy or mandated by uniform rule.

And frankly, that is what we have here, a uniform rule, the Federal regulations as mandated by the FDA with regard to the authorization to manufacture, distribute, and sell a product, which we all know now has been determined to be defective and unsafe to the consuming public.

MR. BAYMAN: Your Honor, may I address that?

THE COURT: Yes, Mr. Bayman, you may.

MR. BAYMAN: Your Honor, nowhere in their brief do they mention this juridical link based on that the Defendants are all alleged to be regulated by the FDA, and that argument is unprecedented in any circuit.

So, not only adopting the juridical link as a standing doctrine would be unprecedented in the Eleventh Circuit and violate the laws of several other circuits, this theory that they are making for the first time today that somehow all of the Defendants are in some way regulated by the FDA has never been recognized by any Court anywhere.

MR. GILBERT: Your Honor, may I reply to that?

THE COURT: Do you acknowledge that that portion of the theory of the juridical link doctrine was not put forth in

the papers, but presented here in the oral presentation for the first time?

MR. GILBERT: Do I acknowledge that it is not written down? In candor to the Court, I'd have to say it is not written in the papers, but our consumer and third party payor class complaints are replete with discussion about the FDA's role in reviewing, analyzing, authorizing, and approving the NDAs and the ANDAs that created the monster that Zantac became.

That is all over our class complaints, as well as our master personal injury complaint. To suggest that it somehow is not specified clearly enough in the papers I think is somewhat disingenuous.

THE COURT: All right. Thank you so much. That concludes the Court's questions for the first motion, 1630.

I would like to get to 1588 before we break for the lunch hour. If I could ask counsel for the Defendants, which I think, according to the chart, is Mr. Petrosinelli who will be arguing 1588, 15 minutes.

Do you want, Mr. Petrosinelli, to reserve any time for rebuttal; and if so, how much?

MR. PETROSINELLI: Yes, your Honor, Joe Petrosinelli here. I think I am only going to speak for about five to seven minutes on this motion, so I will reserve the balance for rebuttal.

THE COURT: All right. You may proceed.

MR. PETROSINELLI: Thank you, your Honor, Joe Petrosinelli again on behalf of Pfizer, but all the Defendants on this motion.

Your Honor, the reason why I am not going to speak for very long on this motion as a matter of my opening presentation is that the same fact allegations, the same roughly 300 paragraphs of fact allegations that were in the two class complaints are also in the personal injury, the massive personal injury complaint.

So, that means there are the same shotgun pleading problems that I mentioned in my prior argument, that is, group pleading as to parents and subsidiaries and affiliated companies; taking five companies and defining them as one, and then never mentioning them again in the hundreds of paragraphs, remaining paragraphs in the complaint; group pleading as to Defendants or different categories of Defendants where it can't possibly be so based on the allegations elsewhere in the complaint that truly all Defendants could be liable for or could -- the allegation could be relevant to all Defendants, or the counts could be relevant to all Defendants.

It is the same issue, but there is an additional issue in the personal injury complaint that makes it even more clearly a shotgun pleading, and that is, each of the 15 counts in the master personal injury complaint adopts by reference or incorporates by reference all prior allegations, including all

prior counts.

That is almost per se improper shotgun pleading under Eleventh Circuit law. The Eleventh Circuit has called that practice quintessential shotgun pleading, and it is not just some technicality. It has real problems associated with it, including, for example, that now that means in the manufacturing defect count there is incorporated allegations of design defect. In the negligence count there is incorporated allegations of strict liability.

And so this is a problem that must be corrected because when we get to the motions as to individual counts in these -- in this case we are talking about the personal injury complaint, or when you get to summary judgment, we do not want to be in a position where we don't know which allegations and which claim -- which allegations apply to which claims, and which counts actually are relevant to the other counts, and the like.

Never in a case like this -- when I say a case like this, I mean where you have dozens of Defendants in the master personal injury complaint, you are talking about, again, almost a hundred Defendants -- never has the Eleventh Circuit or any case approved that kind of incorporation by reference.

There are some cases, I am sure your Honor is familiar with them, in fact one of them is your Honor's, where a very small complaint where you have one Plaintiff and maybe two

Defendants or one Plaintiff and one Defendant where, if these allegations are incorporated that way, the Court says, well, because it is a pretty simple case, I can tell which allegations apply to which claims and the like, but nothing like this.

The group pleading, I also will say with respect to the personal injury complaint, is especially problematic because of the number of claims that are subject to Rule 9(b).

Rule 9(b) applies to several of the counts in the personal injury complaint. The negligent misrepresentation count, the breach of warranty count, the consumer protection claims, the allegations of fraudulent concealment, all are fraud based allegations and therefore subject to Rule 9(b), and there is no pleading -- precisely because there is group pleading, there is no pleading of the particulars of the alleged fraudulent conduct, who said what, where, and when.

What there is in some places is an allegation like the manufacturing and repackaging Defendants in media, advertisement, and promotions represented that the product was safe. That is not -- it is group pled for one thing and does not satisfy Rule 9(b). There is no specificity of which statements by which Defendants, when, where, nothing like that.

So, the group pleading feature and the shotgun pleading nature of the allegations here are particularly problematic because of the number of claims that are subject to

Rule 9(b).

The Plaintiff's responses, I would say they are two-fold. One is, in the master personal injury complaint, unlike the shotgun pleading class actions, we have short form complaints. As your Honor knows, that is the way the process is set up with the personal injury complaints, but the short form complaints have nothing to do with the shotgun pleading problem.

They provide details, or they are supposed to provide details about the Plaintiff, what product the Plaintiff allegedly took and when. They don't provide Defendant specific allegations. They don't say which allegations apply to which Defendants, or which claims of this particular Plaintiff. So the short form complaints don't -- it is apples and oranges, it has nothing to do with the shotgun pleading issues.

Secondly, they say you can group plead because you can assume that an allegation made against one Defendant, it is as if you specifically made it against all 90 plus Defendants.

Again, two problems with that. One is, it just can't be so because of temporal realities or what the complaint defines some Defendants as doing versus others, like the notice knowledge allegations that I talked about with respect to the class complaints.

Secondly, again, the Plaintiffs cite cases that say that, that in some situations, if there are multiple Defendants

and the complaint says the Defendants did this, you can assume the allegation is made individually. Those are cases where there is one or two Plaintiffs and two Defendants, or something small like that.

For example, just to pick one, the Plaintiffs cite the Sprint Solutions case from the Southern District of Florida. You had one Plaintiff -- it's a Lanham Act case, a trademark case -- one Plaintiff suing two Defendants, a husband and wife, where it says Defendants did this or that, and the Court said we can figure out -- this is a pretty simple case, we can figure out -- we can assume the allegations are made against both the Defendants in this case, related parties.

The Plaintiffs quote the portion of the Sprint Solutions case that says collective references in this situation are okay because it is so simple, but what I thought was interesting is the very next sentence of the opinion, and this is right after -- it's on page 1227 of the opinion.

It says, "collective references to Defendants most often create problems when broad allegations are directed at a large and diverse group of Defendants leaving unclear just who is alleged to have committed which acts."

That probably sounds familiar because that is this case, a broad swath of allegations directed at a large and diverse group of Defendants. All of the cases where that is so say that you must have specific allegations of which Defendant

did which thing that gives rise to which claim.

I was thinking, your Honor, what is the closest case to our case for shotgun pleading purposes? And I think it is the In Re: Auto Body Shop, antitrust MDL. This is in the Middle District of Florida, Judge Presnell's MDL, I think it is actually still open. This is an opinion from 2015. I say it is like our case because it is an antitrust class complaint against dozens of Defendants, and so it's sort of the same thing here.

And the Plaintiff said the same thing there, well, we are saying Defendants did this, or we are grouping the Defendants because it is a conspiracy, it's an antitrust case, they were all part of it, and we don't know, we need discovery to figure out. And the Court said, no, we can't get off the ground in this MDL with you saying Defendants did this when we have dozens of Defendants. You have to specify which Defendant allegedly did which thing.

It doesn't mean that you have to do that for every single allegation, and I say that with respect to this complaint and these complaints. It doesn't mean that there aren't some allegations where you could say Defendants did this if it is truly the case that all Defendants did that, and you can't provide any other specificity, but that is not true here. It wasn't true in that case.

So, the problems with shotgun pleading are just as

acute in the personal injury complaint as they are in the class complaints, and the Plaintiffs should be required to replead them as well.

I want to say one thing, it goes to your question about what rule the motion is made under, because Mr. Gilbert -- and I didn't have a chance to respond, but it applies equally here. He said the Jackson versus Bank of America case was not made under Rule 12, it was under Rule 8. That is just not correct. I looked again. The Jackson versus Bank of America case was brought under Rule 12(e), not under Rule 8.

My point about the case was, the case goes on later to say, and you can bring it as a Motion to Dismiss or you can bring it as a Motion to Strike. The key is the function, not the form, I believe is the quote from the case.

That meaning that as long as the Plaintiff has -- you're saying as the Defendant -- an opportunity to replead, you can bring it under either of those motions.

So, this complaint likewise, or this motion likewise is brought -- we brought it under Rule 12(b)(6), but it could have been brought under Rule 12(b) or 12(f). It needs to be repleaded to correct the shotgun pleading deficiencies.

Your Honor, with that, I will reserve the rest of my time for rebuttal.

THE COURT: Okay. I know I referenced the motion that

was being heard just now by docket entry, but for completion of the record this is the Defendants' Motion to Dismiss and/or Strike master personal injury complaint on grounds of impermissible shotgun pleading and incorporated memorandum of law.

With that, if we could have Ms. Goldenberg for the Plaintiffs put her video and audio on only. You will have 18 minutes. Good morning.

MS. GOLDENBERG: Good morning, your Honor. Marlene Goldenberg again. I guess I am still young enough to qualify as a young attorney, so I am here by myself.

THE COURT: Consider that a good thing.

MS. GOLDENBERG: I'll take it while it lasts.

THE COURT: Exactly.

MS. GOLDENBERG: As we have just heard and as Mr. Petrosinelli just talked about in his oral argument, the Defendants apparently aren't seeking a dismissal with prejudice at least as to this motion. This motion is a stalling tactic and it contravenes Rule 1 which prioritizes the just, speedy, and inexpensive determination of every action and proceeding.

The Defendants' cries that they need more information about what happened ring hollow when we consider everything that has already happened in this MDL. If the Defendants have their way, the pleading standard would be so elevated that we

would have to file a twelve volume anthology just to get into the courtroom, and the Eleventh Circuit law simply doesn't support that.

In a different type of case where a Plaintiff files a complaint and the parties don't talk until the Defendant files an answer or a motion, the Defendants' motion might be a little bit more believable. Here, though, the Court has carefully put into place requirements for the parties to meet and confer throughout every step of the process.

Since this litigation started, counsel for Plaintiffs have logged hundreds of hours already in meet and confer sessions with the Defendants. In doing so, the Defendants have had ample opportunities to ask Plaintiffs about the complaints that have been filed.

As proof the Defendants now do, even if they didn't before, understand the nature of the claims at issue, we have seen numerous stipulations get entered into that reflect a deep understanding of the issues in this case, including core discovery agreements. It is difficult to believe that in addition to filing five substantive Motions to Dismiss, the Defendants in this case would be comfortable entering into stipulations that define the scope of discovery if they truly were confused about the real issues at stake here.

Your Honor, I am going to share my PowerPoint with you now here.

As we have heard from the Defendants, they are alleging that we violated two of the, quote unquote, deadly sins from the Weiland case, and why don't we take each of them in turn.

We will start out with their claim that we have inappropriately grouped the Defendants in this case, and as Mr. Petrosinelli anticipated, we are relying on the Sprint Solutions case because it applies here. In addition to that, though, we, of course, have already seen that the Court in that case held that it is proper to refer to Defendants so long as they received adequate notice.

We can also direct you to Toback versus GNC Holdings where the Court found the same thing, as well as the In Re: PFT LCB Flat Panel antitrust litigation, and in both of those cases, what it really came down to was whether or not the Defendants had received adequate notice of the claims at issue.

In all three of those cases the Court found that even the collective word "Defendants" was used, so long as the Defendants in other parts of the complaint were aware of what they have been alleged to have done wrong, it wasn't a problem to use the term "Defendants."

I also did want to touch on the Fox case because that was cited in the first oral argument on shot pleading and just note that in that complaint where the different Loews entities were being discussed by the Plaintiffs, the Plaintiffs in that

case actually were, in the opinion, said to have contradicted themselves about which Defendant did what and who was responsible for what.

We don't have that issue here, so I would submit that that case doesn't really help the Court in its decision.

What is helpful, though, is the complaint itself in this case, your Honor, and what you will see is that our complaint distinguishes the Defendants where it matters.

You will see that in paragraphs 21 through 215 there is a comprehensive overview of each Defendant and their role that they have with Ranitidine. The brand manufacturers received specific notice of what they did when it came to the development, the approval, the marketing and the sales of branded Zantac at paragraphs 226 to 248.

In paragraph 251, we set forth a comprehensive table that gives every generic manufacturer notice of what ANDA is at issue -- by ANDA I mean abbreviated new drug application -- when it was approved, the type of drug that they made, and whether or not the ANDA was still active.

The repackager's role is described at paragraphs 211 and 215. Their duties are described at paragraphs 409 to 414, and the warranties and statements that they made specifically are outlined in paragraphs 425 to 431.

The distributor's roles and obligations are described at paragraphs 409 to 414, and the warranties that they made can

be found at paragraph 441.

Similarly, the retailers' roles are described at paragraphs 155 and 210. Their role in the recall is described at 288 to 289, and the warranties that they made are described at paragraph 431.

Similarly, the claims are tailored to the Defendants in each case, and what -- we don't have time to review the specific allegations in each paragraph, but I did want to highlight just a few examples of the specific allegations that are made within each one of these.

I heard Mr. Petrosinelli earlier say that it is difficult for a Defendant to understand specifically what they did wrong if allegations are incorporated from previous counts, and we will talk about this a little bit later in the PowerPoint, but Courts have found that as long as the Defendant understands what the issues are within each count, it is not really a big problem because, again, they get it.

Here in paragraph 431 of the design defect count we list eleven different ways in which the product was defective. In the manufacturing defect count at paragraph 496 we give specific examples of the manufacturing defects, including failure to adhere to current good manufacturing practices, and paragraph 536 lists a number of examples of negligent manufacturing again.

Paragraph 503 of the negligent failure to warn count

defines the duties of the Defendants at every level to provide a product with proper warnings. Paragraph 523 lists ten different ways the product was defectively designed by each Defendant, and the allegations are specific to the Defendants against whom the complaint was brought.

Paragraph 556 details the ways in which each Defendant was negligent and actually gives 20 different examples, and finally, the warranties are discussed at paragraphs 565, 576, and 582.

Now, I also heard Mr. Petrosinelli earlier say that he doesn't agree with or understand the inclusion of certain categories of Defendants in the strict liability counts, and so I wanted to give you an example from my great home state of Minnesota. We have an innocent seller statute where if, for whatever reason, a manufacturer of a product is not able to be held liable, you are allowed to sue any other entity in the chain of distribution under strict liability theories.

I can tell you that other states have similar laws, so there are strong legal bases for including the non manufacturers in the strict liability and other counts.

The Defendants next take issue with the fact that they have been alleged to have known, or we said they should have known about the link between NDMA and Ranitidine and cancer early on. Whether or not they agree with that is an issue for another day. Whether or not we have given them enough notice

to respond to those claims is the issue, and we have more than done that.

So, starting out at paragraph 310 and 311 in the complaint, what we see is that Dr. Deflora published an article that discussed the relationship between what he called toxic immunogenic effects and Ranitidine when exposed to high levels of nitrites. And beyond this, GSK not only knew about it, but addressed it in a response to a medical journal.

We also see at paragraph 316, that based on Dr. Deflora's study which was publicly available, there was a good faith basis for alleging that all of the Defendants knew or should have known that Ranitidine could degrade to form NDMA and that NDMA could cause cancer.

This is further supported by paragraph 362, which alleges that all the Defendants were on notice of Dr. Deflora's study and that they should have investigated, but failed to do so.

Beyond that, we then see more studies start to come out in 1983. There was one study that was published by seven researchers at the University of Genoa, and again Dr. Deflora publishes a confirmatory study that again supports the findings that he made in 1981. From there, your Honor, the evidence just continues to build.

In 1987, GSK then published its own study and deliberately removed any samples of gastric fluid that had been

exposed to Ranitidine because they stated it might contain a high concentration of N-nitroso compounds.

After that, in 2000, 2004, and 2008 we see additional studies come out that link Ranitidine to various types of cancers.

Based on all of this, we allege in paragraph 400 that any manufacturer or distributor should have known about the link between Ranitidine and cancer. These are highly sophisticated parties who are in the business of manufacturing, selling, and labeling Ranitidine, among other things. It is their job to know their product.

Even after this point, we continue to see the evidence build. In 2016, we see the Mitch study come out that measures the level of NDMA in the urine output of patients who have taken Ranitidine. And beyond this, we see in 2019, the reports from Valisure and Repharma and, of course, the FDA recall that brought us here today.

With all of these allegations there is more than enough information to notify the Defendants of the time period for their liability.

Turning now to the Rule 9 claims, your Honor, we have also heard the Defendants say that we haven't met the requirements of Rule 9 and what they ask for is on page nine of their notice. They ask for four different things, what statements were made, when were they made, what was in them,

and what did the Defendants get. We have more than provided them with information on all four of these categories.

What we can see as to category one is that these statements are largely encapsulated by the warranties. We see at paragraph 565, a number of statements that we expressly put the Defendants on notice of, and whether or not the Defendants agree that telling a patient that a product is safe and effective is actually a representation, they can, again, address that in their answer, but our complaint clearly tells them that this is something that was communicated to the Plaintiffs in this case.

I will also direct your Honor to paragraphs 395 to 401, 427, 555 and 556, which also talk about how the label failed to disclose to the Plaintiffs in this case that Ranitidine contained NDMA or that it could cause cancer.

There are additional paragraphs in the complaint that also put the Defendants on notice that the Defendants failed to disclose that exposure to heat, light, humidity, or the human body's natural state could cause NDMA or cancer, and you can find all of those references at paragraphs 308, 395 to 401, 405, 427, 481, 548, 555, 556, and 582. These are just some examples, your Honor.

We have, therefore, alleged with particularity the time, place, and substance of the representations that were made.

Again, your Honor, we don't have time to go through each one of these, but I did want to highlight just a few more of these paragraphs so you could see exactly what kind of detail was provided to the Defendants about the representations that they made and these are, again, laid out in the warranty and consumer protection counts, among other places.

Beyond this, the Defendants also asked for the time and the locations of these statements, and the label, first and foremost, is where all of these representations come from.

The label is what fails to disclose the NDMA content. The label is what fails to disclose the cancer risk. The label is what fails to disclose NDMA as an ingredient or a component of Ranitidine, and it also, again, fails to tell Plaintiffs not to expose the product to heat, light, or any other circumstance that could cause the drug to degrade.

I also wanted to address something the Defendants brought up in their brief, which was a reference to what they call vague statements to the media. At this point, we don't have access to every single advertisement the Defendants put out, but I did want to direct you by way of example to paragraph 328 where we talk about an advertisement that told consumers like the Plaintiffs here that Ranitidine is appropriate for people who have just consumed foods high in nitrites such as tacos or pizza.

So, the specificity that is available to the

Plaintiffs at this point in time has been provided as much as we can.

Again, the content of the statements, I don't want to spend too much time on this because it is really similar to the first aspect of the test, but we told the Defendants what they have said and where they said it.

And fourth, what the Defendants got out of this was the Plaintiffs purchase and ingestion of Ranitidine and the profits that flowed from there.

Based on all of this, what the Defendants are asking for is what this Court called a demand that was overly particular. An analogous case here is Roche Diagnostics Corporation where the Court looked at a lengthy complaint involving 44 Defendants and found that if the Plaintiffs were required to articulate every single time one Defendant did something, the complaint would just be too long.

The same thing would happen here. The Defendants being grouped into categories is not inappropriate. They all had the same role with the same active ingredients and the same drug. So, the allegations are specific and have struck the balance that is necessary to put them on notice without providing a novel or two.

So, turning to the second, quote unquote, sin that the Defendants have alleged that we violated, I do want to start by being honest with the Court, our complaint does have a

paragraph at the beginning of each count that incorporates the previous allegations into the first one.

If the Court wants us to, we will be happy to amend our complaints to put at the beginning of each count that we incorporate by reference each factual allegation set forth in paragraphs 1 through 52, rather than all that come before it and that would just incorporate the facts. The Court could also take care of this via interlineations. But none of that is actually necessary because the case law that engages with this sin once again turns to the underlying principle of notice.

I will direct your Honor to the Watts case and the Dane case that are highlighted up on the slide here where again the Court found that, yes, technically the Plaintiffs should not have incorporated all of their previous allegations, but because the counts were specific enough, because the facts were specific enough, the Defendants actually have received the notice that was due to them and nothing actually needed to happen for the Defendants to be able to respond substantively to the complaint.

The Court found that, you know, under those circumstances, that is enough.

Even beyond that, here you have seen the Defendants file five lengthy Motions to Dismiss and we have also seen them agree to the discovery stipulations. It is hard to believe

that just because these simple paragraphs exist at the beginning of the complaint, the subsequent paragraphs that follow that we discussed earlier aren't enough.

I will wrap up, your Honor, by just citing your opinion in Isaias where you noted that a complaint doesn't have to be perfect, but rather, sufficient. We, of course, always aim to get everything right that we possibly can. When we can't do that, we meet and confer, as we have here. I think the Defendants have had more than ample opportunity to have their questions answered.

With that, I will stop and wait for questions at the end.

THE COURT: Okay, thank you so much.

We will have Mr. Petrosinelli back for any rebuttal. Ms. Goldenberg, you may go off for now. Mr. Petrosinelli come on.

You used only 11:13 of your time originally.

MR. PETROSINELLI: Thank you, your Honor.

THE COURT: You have three minutes and 51 seconds.

MR. PETROSINELLI: Thank you, Your Honor, I will try to do it shorter than that. This is Joe Petrosinelli.

I am very glad Ms. Goldenberg put up the allegations of the complaint that the Plaintiffs were relying on to show that this purportedly was not a shotgun pleading.

If your Honor will look, Ms. Goldenberg put up the

allegation at paragraph 582 about warranty claims which says Defendants, meaning all 90 plus Defendants, represented through their labeling, advertising, and marketing materials that the products were safe, and that is what the Plaintiffs say satisfy both their shotgun pleading burden and their Rule 9(b) burden.

It is not even close, your Honor. Under 9(b), there is no time, place, and which of the 90 Defendants made which representations when. And what is particularly troubling, of course, is it is asserted against the manufacturer Defendants, that count, which included the generics. Generics don't market or promote their products. How could it possibly be so that they are subjected to liability for representations made in marketing and promotions when they don't do that? It is just a symptom of the problem of the shotgun pleading here.

The same with the negligence count, it is a laundry list of things that Defendants, all 90 plus, supposedly did wrong, like designing and manufacturing the product, when the complaint says repackager Defendants, or other Defendants like distributors, don't design or manufacture the product. It's the same issue as in the class complaints.

I will also say, I think Ms. Goldenberg said it is not a problem here because there are no inconsistencies or contradictions in the complaint. There are. I just pointed them out to you where the Defendants are alleged to do certain things, but they don't include marketing or manufacturing, and

then later in the counts they are included in those counts.

Finally, I will say the cases that Ms. Goldenberg cites, it is what I said to the Court in my opening argument, these are cases where, like Isaias, your Honor will know that case because it was your case, it was one Plaintiff and one Defendant. Watts is one Plaintiff and three Defendants.

In those cases, the Courts have been able to say, including your Honor, look, I understand that it is technically a shotgun pleading and an incorporation of allegations and the lack of specificity as between Defendants, but it is a short complaint and I can understand what allegations relate to which Defendants.

There is no case anywhere in the Eleventh Circuit where you have a hundred Defendants and you have not only a hundred Defendants, but Defendants at every stage of the supply chain where the Court has said it's okay to have allegations about all Defendants, or it is okay to group parents and subsidiary companies in the early paragraphs and don't ever mention them again. There is no case that allows that type of shotgun pleading, and that is why similarly here this complaint should be repleaded.

Thank you, your Honor.

THE COURT: Thank you very much.

I don't have any questions relating to this motion, so we are going to break for the lunch hour.

It is 12:16, so -- let me just think for a moment.

We can come back at 1:30, give everybody enough time to regroup. We will come back at 1:30 and we'll hear then the two remaining motions that were scheduled for today, 2037 and 1585, and we will follow the same format.

I don't remember us discussing this, consistent with how we have done it in the past, whether we want everyone just to stay in so that they all don't need to be admitted again. Let me confirm that is how we were contemplating doing it.

I think everybody turns their video and their audio off. Make sure you do that so we don't know what you are up to over your lunch hour, although hopefully nothing that you would need to hide from us. Turn your videos and audios off.

I want to thank our cohosts for letting -- there appears to be 160 people in, and that was done very seamlessly, allowed us to get started right on time, and I very much appreciate it. So, keep your video and audio off, but stay tuned in.

We will resume at 1:30. Thank you so much, and have a nice lunch.

MR. PETROSINELLI: Thank you, your Honor.

MS. GOLDENBERG: Thank you, your Honor.

(Thereupon, a short recess was taken.)

THE COURT: All right. Good afternoon, welcome back, everyone.

Let me read you a technical announcement here. I understand that because the Court is utilizing both audio and video feeds for today's hearings, that for some, but not all of you, the Zoom speaker is tracking to my audio feed instead of the video of me. We have been configuring that setup in the courtroom over lunch, but it reduced the audio quality.

To have better access during the video questioning, the best thing to do is to click on the top right hand, you will see a blue button there with three dots in it, and a drop down menu will provide an option to pin video. If you want to switch then back to speaker view for the attorney responses, you will need to unpin the video.

Hopefully that will help. I don't understand that there was anyone who couldn't hear me, but perhaps you couldn't see me, which isn't a bad thing but understand if you want to see everything going on. That is my understanding as to how you can resolve that issue. If you have any ongoing problems, communicate as you have in the past and we will try to address that.

Let me remind everybody who is speaking, again, always state your name before you speak, please speak slowly, particularly when you are citing cases, so we can ensure that we get everything down properly, the case citations and everything that you are saying. I will try to remind you if it seems like you are speeding up.

Before we move on to 2037, I did want to ask if the attorneys for 1630 could come back on. I had a question or two.

I am sorry if that is an unfair surprise, but in looking over my notes over the lunch hour, I wanted to follow up with those counsel who presented on motion Docket Entry 1630.

So, let's see, we are waiting for Mr. Lear, Ms. Hood. I apologize because you were not on notice of this. So, you look like you are all back. Thank you so much.

Mr. Bayman, can you hear me okay?

MR. BAYMAN: Yes, your Honor.

THE COURT: So, Plaintiffs address the significance of the Prado case being decided at the Rule 23(f) stage. Plaintiffs argue that the language that you cited was in the context of a class certification analysis, in other words, the language I also cited earlier about the claim-by-claim, party-by-party analysis, that it be done before class certification, but was in the context of, as Mr. Gilbert noted, I believe this circuit's first consideration of a Rule 23(f) interlocutory appeal. I wanted to give you a chance to respond.

What and how should the Court rely on Prado, notwithstanding that difference? What should the Court glean from the language in Prado regarding the type of analysis to

undertake for standing purposes given that at least that case was considered in the context of a Rule 23(f) interlocutory appeal?

MR. BAYMAN: Your Honor, Andrew Bayman again. The Prado-Steiman case was -- actually it was -- it involved the settlement of some claims of some individuals' disability type claims, individuals with learning differences and other challenges and, really, we were citing that not for -- what was happening is, the Court was looking at the various subclass settlements, and what the Court said was before you can enter into -- what the Eleventh Circuit said was before you can do the Rule 23 analysis of those factors, the Court must first determine whether the class representatives have standing.

In fact, the Court said "a claim cannot be inserted on behalf of a class unless at least one named Plaintiff has suffered the injury that gives rise to that claim."

That is what they felt was the infirmity in some of the claims that were being settled in that case, was that there was not at least one class representative who had suffered the injury that gave rise to the claims.

So, the Court's analysis was that you had to do standing, you had to look at standing before you could even consider the Rule 23 requirements, and the Court had to make sure at least one representative had Article III standing to raise each subclaim. That is the posture in which the Court

issued its principles in that case.

THE COURT: So, is it possible that, you know, at that point, before the Court was considering whether class certification as to certain subclasses was appropriate that, at a minimum, it needed to assure itself that the class representative for that particular subclaim had standing?

MR. BAYMAN: Suffered the injury that was traceable to the Defendant's conduct, that is correct, your Honor.

THE COURT: Right. Is it the Defendants' position that that analysis, that inquiry that was taken -- or at least was addressed by a Court that received the case at the interlocutory appeal stage under Rule 23, that that is the standard by which a Plaintiff alleging under Rule 8 and/or Rule 9 in a complaint is held to that same specific claim-by-claim standard, party-by-party standard?

Did you see any difference, I guess is -- any distinguishing aspects of it given the different procedural postures? We are at the MTD stage and that was at the Rule 23 stage.

MR. BAYMAN: No. I think the point that I maybe didn't make clearly is that you need to show standing prior to the Court even getting to the question of Rule 23. You can't base standing on the experience of absent class members. Rule 23 can't extend the Court's jurisdiction whether you are at the Rule 12 stage or the Rule 23 stage. It is immaterial.

That is why there are a number of cases that follow Prado-Steiman that make the determination at the Rule 12 stage. I think what we glean from those cases is standing should always be assessed at the earliest possible stage, and we know clearly with this complaint there are standing problems, so now is the time to do it, rather than wait until the Rule 23 stage.

MR. GILBERT: Your Honor, may I briefly respond?

THE COURT: Yes. State your name.

MR. GILBERT: Robert Gilbert on behalf of the Plaintiffs. Thank you, your Honor.

Prado-Steiman is not a settlement situation. Prado-Steiman, as I noted earlier, was the first foray of the Eleventh Circuit into the Rule 23(f) interlocutory appeal rule.

Prado-Steiman doesn't discuss Rule 12. Prado-Steiman doesn't discuss subject matter jurisdiction at the inception of the case. Prado-Steiman stands for the unremarkable proposition that before you grant -- and I want to say grant -- but before you rule on class certification, at the time you are called upon to make the class certification decision, that you have to put us to the test at that point in time to make sure that we have a Plaintiff, a named Plaintiff representative who can stand in on behalf of each subclass or subclass claim that is being advocated for certification.

There may be some class claims or subclass claims where at the time of certification you find we can't meet that

test. There may be others, and hopefully there will be many, where you find that we can and do meet that test.

But Prado-Steiman says nothing about addressing this issue at the Rule 12 initial motion place where we are today, and it is just plain incorrect to suggest that it does.

MR. BAYMAN: Your Honor, if I may, Mr. Gilbert is correct, this was not a settlement class, but the parties were in agreement that there were classes that should be certified, and what the Defendants contended was that a single class certified by the District Court was too broad and that the Plaintiffs didn't demonstrate that the claims of the named class represented -- possessed the requisite typicality with the claims at large. The Court held "the District Court must ensure that at least one of the named class representatives possesses the requisite individual or associational standing to bring each of the class's legal claims."

That is the holding in the case, your Honor.

THE COURT: Okay, thank you.

Mr. Gilbert, you argued that Article III standing is confirmed if one of the named Plaintiffs alleges harm that is traceable to a Defendant. You suggested at this stage that the Plaintiffs' harms are more directly traceable to certain Defendants than others.

So, I wanted to see if I can get some clarification as to certain categories of Defendants in the class complaints

that you felt that way.

I am looking back at your PowerPoint, for example, and I think on what was slide 3 with the retailers, you set out in detail -- maybe Mr. Lear was presenting on this, so if it is Mr. Lear or Mr. Gilbert who wants to answer.

But you set out in detail where each named Plaintiff purchased a Ranitidine product. Setting aside for a moment the juridical link doctrine, does this chart demonstrate that each named Plaintiff can plead with precision which retailer Defendant his or her harms are traceable to?

MR. GILBERT: It means actually, your honor, that each named Plaintiff has already pleaded the specific retailer or retailers that she or he purchased their product from and, therefore, as to the retailer Defendants, the traceability issue is resolved.

THE COURT: So, when you have certain Plaintiffs alleging claims against retailers other than the ones that are listed on slide 3, which you do in your class complaint, is the way in which you are arguing you are permitted to do that, and not running afoul, for example, of Article III standing requirements through the jur -- I practiced this word more than anything else to prepare for today -- the link doctrine?

MR. GILBERT: Judge, Robert Gilbert. You and I both practiced it a lot, and I still make mistakes with it more times than you could imagine. The answer to your question

quite simply is yes.

THE COURT: That is the basis in which you will take, for example, a consumer Plaintiff in paragraph 31, going off slide 3, who is aligned with Albertsons, but that Plaintiff can state a claim against Walgreens; that is your theory, and that is how you address Article III standing attacks on the consumer complaint.

MR. GILBERT: I am looking at the exhibit that Mr. Lear put up. Robert Gilbert again. Sorry.

Let's use the Amazon line because on the Amazon line, on the right-hand side, which is the updated version, it shows one named Plaintiff has alleged that she or he purchased their Ranitidine or Zantac product from Amazon.

If that named Plaintiff is asserting claims in this class complaint against other retailers, it is based on the juridical link doctrine.

THE COURT: Thank you. So, looking at your slide 4, where you have the -- it says OTC Zantac. Would this chart not suggest that the Plaintiffs can plead with similar precision as to the brand name Defendants -- putting aside the doctrine for a moment, is it the case that the Court would understand this slide, which is representative of your allegations in your complaint, that, for example, GSK and Pfizer were manufacturing between '95 and on or about '98, between '98 and 2006, Pfizer, 2006 to 2017, BI, 2017 to 2019, Sanofi.

If you put aside the doctrine, could Plaintiffs allege with that degree of particularity, based on the timeframe that you, yourselves, the Plaintiffs have outlined in your own complaint as to which entity was manufacturing when among the brands with precision?

MR. GILBERT: Robert Gilbert on behalf of the Plaintiffs, Judge.

The answer is yes, but there are many Plaintiffs who purchased over-the-counter brand Zantac over an extended period of time that crosses more than one of these timeframes.

So, for that type of Plaintiff, she would be alleging, for example, if it was across all four timeframes, that she purchased brand name over-the-counter Zantac from each of the four brand name Defendants for that period of time.

Conversely, to use your example, if she purchased brand name over-the-counter Zantac only between 2006 and 2017, the allegation could be more specific as to BI.

THE COURT: But for the doctrine.

MR. GILBERT: But for the doctrine.

THE COURT: All right. As to generics, slide 5, what are we to glean from the Plaintiffs' ability to plead with greater precision as to the generics, putting the doctrine aside?

MR. GILBERT: The generics and the distributors are the most difficult of all and let's just talk about the

generics -- again Robert Gilbert -- since you have the slide in front of you.

As you can see from figure 5, there are many generics that manufactured generic Ranitidine in both prescription and over-the-counter form over an extended period of time. Absent someone having saved a prescription label which would provide a code that would indicate who manufactured their prescription generic Ranitidine, and that is not a frequent occurrence, absent that specific exception, it is not possible at this stage to winnow down the generics except within a temporal period of time.

So, for example, if Plaintiff Smith alleges that she took generic prescription Ranitidine between 1997 and 2002, we can know from looking at this chart that there are Apotex, Mylan, Sandoz, Heritage, Wockhardt, Contract Pharmacal, and Dr. Reddy's that all fall into that area, but we can't know, cannot know at this stage of the proceedings precisely which one manufactured that generic prescription Ranitidine.

To take it one step further, because I think it is very important for the Court to appreciate this issue, some of these companies, some of these generics manufactured product under private label for retailers.

So, for example, if a generic manufacturer manufactured generic over-the-counter Ranitidine for Walgreens between 1997 and 2002, we don't know which of those generic

manufacturers did that because Ms. Smith purchased her, I think it was called Wal --

THE COURT: Just a moment. Somebody needs to mute themselves who just came on. Sorry. Can you repeat that?

MR. GILBERT: Yes. We don't know at this stage of the proceedings who was manufacturing that product under private label for Walgreens, using my hypothetical, so we can plead that between 1997 and 2002, for example, Plaintiff Smith purchased her generic over-the-counter Ranitidine from Walgreens and that the following generic manufacturers could have been the Defendants that manufactured it, but we can't be more specific than that at this stage of the proceeding.

THE COURT: Okay. But you can narrow it down to a subset of the generics as opposed to all the generics if you know the period of time.

MR. GILBERT: We can. I just want to close by saying the following: I know from reading the allegations that a number of these Plaintiffs in the consumer class complaint allege that they purchased their generic product over a 10 to 20-year period. So, what that means is that we will be including many, if not most, or perhaps all of the generic manufacturer Defendants in those particular instances.

THE COURT: For those persons who allege they took the product over a 10 to 20-year period of time.

MR. GILBERT: Correct, to correspond with the temporal

scope of their purchasers.

THE COURT: Right. But each Plaintiff has his or her own temporal period.

MR. GILBERT: That is correct.

THE COURT: With the repackager and the distributor Defendants, you didn't have a chart on that, how would you go about pleading with greater precision as to those groups?

MR. GILBERT: At this stage, your Honor, with respect to the distributor and repackager Defendants, I, candidly, don't know how we could plead with more specificity, especially with regard to the distributor Defendants. The distributor Defendants account for 90 percent of the market over the period of time this drug was on the market.

It is highly likely, it is certainly plausible that all three or four of the distributor Defendants distributed the brand name Zantac or the generic Ranitidine that each of the named Plaintiffs ultimately purchased somewhere at one point in time. We don't have any records from distributors at this point in time, and to my knowledge, we don't have any records from relabelers at this point in time.

The generic information is starting to come in, but nothing has come in from distributors or relabelers yet.

THE COURT: Nothing has come in as to when they were relabeling and distributing?

MR. GILBERT: And who they were distributing for and

to whom.

I am just going to pick one name that easily comes to mind, AmerisourceBergen. We don't know if they were distributing Apotex generic Ranitidine to anyone, to any retailer, or if they were distributing it to every retailer, or if they were distributing it to Walgreens only.

THE COURT: Is that the subject of a current discovery request either in an RTP or interrogatory, or pursuant to your core discovery agreement? Is that a pending request right now?

MR. GILBERT: I apologize, Judge, I can't answer that question.

THE COURT: That's okay. We can take that up later. We have a status conference later this week. Why don't you hold that thought and maybe by the end of the week you might have an answer to that, and we will have a more robust discussion on that.

MR. GILBERT: That is a great idea. Thank you, Judge.

THE COURT: Lastly, as to the third party payor complaint, can the named Plaintiffs plead with greater precision as to the brand name Defendants and the generic manufacturer Defendants? I didn't see a PowerPoint on that one.

MR. GILBERT: I believe my answer would be the same with regard to the brand name Defendants based on their specific period of time -- oh, on the brand name prescription

that is easy because GSK was the only brand manufacturer that manufactured prescription Zantac, and the TPP complaint is all about prescription product.

THE COURT: Right.

MR. GILBERT: With regard to the generics, I would adopt the same answer that I gave you earlier.

MR. BAYMAN: Your Honor, may I address that one point?

THE COURT: Yes. It's Mr. Bayman?

MR. BAYMAN: Andrew Bayman, yes, your Honor.

The problem is, all the Plaintiffs have sued all the Defendants when they know that certain Defendants could not have possibly caused their injury.

For example, the Plaintiffs say in their brief that 33 consumer Plaintiffs purchased Zantac, Ranitidine in some form during each of the time periods that a brand name Defendant sold Zantac. So, that means that only 33 Plaintiffs could conceivably have claims against all four branded Defendants, but yet 86 percent of the other named Plaintiffs are suing all four of the branded Defendants as well.

They say as many as 180 consumer Plaintiffs purchased and consumed Ranitidine when the 22 generic Defendants were selling it, but that means that at least 58 Plaintiffs were not even purchasing Ranitidine when a single generic Defendant was selling it, yet those Plaintiffs are suing all the generic Defendants. They are suing people who could not have possibly

injured them, and that is the problem.

It all turns on juridical link, your Honor, which not only has not been recognized in this circuit, but as we cited in our brief, the Ninth Circuit recently looked at the juridical link doctrine in a case involving an FDA regulated product, that is surgical gowns, where two companies manufactured the same surgical gown and the named Plaintiff sued both of them.

The Ninth Circuit earlier this year held that the named Plaintiff's alleged injuries could not be traceable to Howard Health, the Defendant from which the Plaintiff did not purchase the gowns, nor could the Plaintiff represent a class of purchasers who did buy from Howard.

You have to be injured, and that injury has to be traced to the Defendant that caused your harm.

Thank you, your Honor.

MR. GILBERT: Judge, could I respond quickly on the Ninth Circuit decision?

THE COURT: Very quickly.

MR. GILBERT: Bahama Surgery from the Ninth Circuit, number one, an unpublished opinion. Number two, I don't think it has to do with juridical link at all. Thank you.

THE COURT: I am going to say it, juridical. There. Okay. Thank you so much.

If we could have the Defense counsel for the 2037, and

2037 is the generic manufacturers and repackagers Rule 12 Motion to Dismiss consolidated consumer and third party payor class action complaints on the ground of failure to allege an injury and incorporated memorandum of law.

So, you all have 23 minutes and do you want to divide your time up? If so, how, and any kind of warnings? Maybe start with introducing yourselves for the record, everybody who is on the screen, and then I would ask whoever can address that question about how you want to divide your time up and what kind of warnings so you can let me know.

MR. WINTERS: Yes, your Honor, this is Daniel Winters from Holland and Knight.

If I could start off with the timing. I will be addressing the injury in fact argument. Derek Stikeleather will be addressing the issue of the economic loss doctrine, and then my associate, Amy McVeigh, from Holland and Knight will be addressing the issue of the injunctive relief.

We would like to reserve three minutes of our 23 minutes for response, and if you could give us a warning at about the 15 minute mark or so, that would be helpful.

THE COURT: Okay, I will do my best.

MR. WINTERS: Judge, one other issue for timing here, I understand that there is also going to be time given to the brands, I believe five minutes, and I believe that Julia Zousmer is going to be arguing that for the brands on the issue

of whether or not they can join our motion.

THE COURT: Is that what you all agreed among yourselves?

MS. ZOUSMER: Yes.

THE COURT: If you did, I am happy to oblige that. You are saying that the generics have 20 -- 23, and you are going to divide it 20 and three, and on top of the 20, the brands want five on the front end and no rebuttal.

MS. ZOUSMER: That is correct, your Honor. This is Julia Zousmer from King and Spalding for the brands. Five on the front end is great for me.

MR. GILBERT: Judge, may I interrupt? This is Robert Gilbert. May I address the Court?

THE COURT: Yes.

MR. GILBERT: Your Honor, with respect, that is not the agreement that was reached with the Defense leads and Special Master Dodge on Friday.

The total time allotted for the generics and the brands was 20. It was originally 15, five was added to it in order for the brands to make their joinder argument. I am sure Mr. Petrosinelli will confirm that. You added three minutes to that this morning in order to recognize that younger lawyers would be participating.

It was not supposed to be 20 plus five, that is not what we discussed.

THE COURT: There was a lot of back and forth, I wanted agreement from everybody. Mr. Petrosinelli, do you have a point of view on what the parties had agreed to?

MR. PETROSINELLI: Good afternoon, your Honor, Joe Petrosinelli. It's a good thing I didn't take my tie off.

THE COURT: You might as well just sit tight and wait for the unexpected.

MR. PETROSINELLI: Mr. Gilbert is correct.

THE COURT: Okay. That is what I thought as well, but if the parties had agreed otherwise, I wasn't going to get in the way of that.

In light of that, you have a total of 23. How do you want to divide that so the brands get their time? I guess it is up to you, you don't even have to tell me. I am going to keep track of your 20 and your three, and you are free to divide it however you want within that.

So, I will just leave it up to you to do that?

MR. WINTERS: Yes, your Honor, I guess we will try to move along as expeditiously as possible. I apologize for the misunderstanding. When we saw the emails, I did not realize that five minutes was coming out of this as well, but we'll adjust on the fly and deal with that.

THE COURT: All right. I appreciate it. With that, let me start the clock and turn it over to the Defendants, plural.

MR. WINTERS: Thank you, your Honor, Daniel Winters, Defense counsel for Glenmark, and on this motion on behalf of the generics and the repackagers.

Your Honor, the consumers and third party payors have asserted various causes of action against the Defendants which oscillate between contract and tort claims. They allege a defective product, but they want contract damages.

They jump between these different theories because an injury is a necessary element in all of these claims, and they seek to disguise the fact that they have not satisfied the requirement that factual allegations must plausibly and clearly allege an injury in fact. Mere conclusory statements do not suffice.

The consumer and third party payors seek to hold the Defendants liable for failure to fix or warn of a defect and its attendant health risk. This is a products claim.

THE COURT: Make sure to speak slowly enough.

MR. WINTERS: Yes, your Honor.

That is a products claim, but the pleadings make clear the Ranitidine did not cause Plaintiffs' bodily injury.

Plaintiffs also fail to allege that the Ranitidine did not relieve their heartburn or related conditions.

For instance, in paragraph 251, Plaintiff Dave Gerber alleges that he used Ranitidine containing products from 1990 to 2019, that is 30 years. A reasonable inference that one can

draw from 30 years of continuous use is that the product worked exactly as intended, yet the Plaintiffs assert they purchased a worthless product.

That is the very definition of a conclusory statement given the factual allegations in the complaints. These infirmities require dismissal of the complaints. We believe the Plaintiffs should not be given the opportunity to amend both because the Court offered them that opportunity and they declined it, and because the facts will not change, meaning Plaintiffs that used Ranitidine to treat their conditions found it worked, and that is not going to change.

However, in the event that the entire complaint is not dismissed, my colleagues will address two issues. First, Derek Stikeleather will address how the economic loss doctrine bars the third party payors tort claims, and my associate, Amy McVeigh, will address how the injunctions are improper.

Let me jump into how do the Plaintiffs fail to allege a cognizable injury. We should begin our analysis with Rivera v Wyeth Industries, Fifth Circuit, 2002. The Plaintiffs had taken a pain medication that was later withdrawn from the market due to reports of liver failure. The proposed class sought economic damages for Plaintiffs who did not have liver failure on the theory they were denied the benefit of the bargain and they wanted their money back.

Not only did the Plaintiffs fail to establish an

injury in fact, the Fifth Circuit explained that the Plaintiffs could not prevail by establishing the Defendants had physically harmed other consumers, rather, the injury must be personal. As the Court stated, the consumer paid for an effective painkiller and she received just that, the benefit of the bargain.

A long line of cases has since adopted the reasoning of Rivera, which includes cases like Heingold (phon) v Pfizer, Hughes versus Chatham, Corintahli (phon) v Loreal, and Medley v Johnson. They all agree with the premise of Rivera that you cannot switch between claims that the product was defective and contract damages related to the return of money. Each stands for the proposition of when the product worked as intended, it was not worthless.

Likewise, Courts in this District have agreed with Rivera's no injury analysis, dismissing cases where there are no allegations that the product did not work for its intended use. Examples include Iron Workers v Astrazeneca, Eleventh Circuit, 2011, and Birmingham versus Walgreens, Southern District of Florida, 2014, which both dismissed, no injury products cases, citing the rationale in Rivera.

Finally, in 2018, the Third Circuit in In Re: Johnson and Johnson Talcum Powder also adopted the reasoning of Rivera. That related to claims of ovarian cancer and talcum powder. The Court again looked at this on Plaintiffs' attempt to

oscillate between warning products claims and contract claims for damages. The Plaintiff did not have cancer, and the powder worked as intended for her, therefore there was no injury and the dismissal was proper.

Given that line of cases, how do the Plaintiffs here try to get around that? Plaintiffs' opposition relies almost entirely on Debenardis versus IQ Formulations, however, it does so in a manner that is both contrary to the facts of that case, and expressly disavowed by that Court.

The Eleventh Circuit expressly stated that its opinion was limited to the specific facts alleged in that case, and I am quoting here, "that the Plaintiffs purchased dietary supplements that Congress, through the FDCA and the DSHEA, had banned from the sale with the purpose of preventing consumers from ingesting an unsafe product."

In that case, the FDA had sent over a dozen warning letters saying the product was not approved for sale before, and this is important, before any of the Plaintiffs bought the product. The Eleventh Circuit went on to say it explicitly was not, and again I am quoting, "addressing whether a Plaintiff would have standing if she allegedly purchased, one, a product that lawfully could be sold, but came with inadequate warnings; or two, a product that was lawfully sold at the time of purchase, but whose sale was later prohibited." That is at 1088, Footnote 8 of Debenardis. That footnote specifically

cited with approval the In Re: Johnson and Johnson Talcum Powder case from the Third Circuit which had adopted the reasoning of Rivera.

It is not surprising that the Debenardis Court made this distinction. That is because there is no private right of enforcement for a misbranding claim.

The Food, Drug and Cosmetic Act, at Section 337, as well as the case law, including Bachman, Ellis versus C. R. Bard, Eleventh Circuit, 2002, and Birmingham v Walgreens make that clear. Private rights of action to declare something misbranded do not exist.

And Plaintiffs' recent response to the brand name manufacturer Defendants' joinder motion, and that response is at 2300 on the docket, acknowledges this crucial distinction between what is legally sold and illegally sold as defined by Debenardis.

In that submission the Plaintiffs explain that, and I am quoting the Plaintiffs here, "the difference in the statutory scheme may mean that at some point branded Zantac was unlawful to sell, but that generic Ranitidine was not since FDA regulations do not allow abbreviated new drug application holders to add warnings that differ from the branded drugs."

In other words, Plaintiffs are at a loss to explain how the generic manufacturers could have illegally sold Ranitidine.

Finally, let me address the idea that perhaps the consumer Plaintiffs have alleged a personal injury.

First, if that is what they are really asserting, a personal injury, they need to clearly say that, otherwise they are guilty of impermissible claims splitting. If they have personal injuries, they can and they must bring those claims in a personal injury lawsuit. A consumer class action for the return of the purchase of a product is not the proper place to bring a personal injury claim.

In fact, they don't allege, really, personal injuries with any kind of specificity. Their statements about cellular damage are conclusory. The facts that each Plaintiff actually pleads, and it is repeated over a hundred times in their complaint, is that a Plaintiff took Ranitidine, they did not know of the presence of NDMA, and had they known of it, they would not have purchased it.

That is not a personal injury. No individual Plaintiff claims cellular damage. They do not allege when such damage occurred, how such damage occurred, or who told them such damage occurred. It is not alleged. In fact, the proposed class includes purchasers of the product, not even consumers. That is at paragraph 734 of the complaint.

So, someone who purchased the product for a family member or someone else to use is a member of this class. How could a purchaser possibly have cellular damage? They can't.

It is Plaintiffs' burden to establish standing under 12(b)(1) and 12(b)(6), and they have failed to do so.

Plaintiffs' factual allegations establish that they received what they paid for, an effective treatment for heartburn and indigestion, without any demonstrable physical injury. Therefore, the consumers and the third party payors suffered no injury in fact. Since there can be no recovery where there is no cognizable harm, the class action claims should be dismissed in their entirety. That is the basis for our injury in fact argument.

At this point, I will turn it over to Mr. Stikeleather who will address the economic loss doctrine and the third party payor.

MR. STIKELEATHER: Good afternoon, your Honor.

THE COURT: Good afternoon.

MR. STIKELEATHER: Apart from the dispositive argument Mr. Winters just made about there being no injury, and also the conclusive arguments that you will have tomorrow on preemption, the economic loss doctrine by itself bars the tort claims that are brought by the third party payor Plaintiffs.

Now, I want to stress here that we are limiting our economic loss argument only to the third party payor Plaintiffs because these are all commercial entities, sophisticated companies that identify themselves as health insurance companies, HMOs, self-funded health and welfare benefit plans,

and any other health benefit provider.

Now, the basis of the economic loss doctrine, which is articulated most famously in the Supreme Court's East River case, states that when you bring a product related claim that fails to allege, A, that the product caused any physical injury, which is most common in any negligence or tort case because someone has been hurt, if you don't have that and you have no damage to anything other than the product itself, what you really have is a contract claim.

And the economic loss doctrine limits you to the remedies that are available under contract law, and these are remedies that the third party payors have to the extent that they have meritorious contract claims.

The critical part here is that these third party payors are not only sophisticated business entities with the ability to allocate risk and contractually allocate how any dispute would be resolved, they are parties who have never ingested this drug. They are completely removed from any tortious aspect of this case, and the remedy they seek is simply a refund. This is a claim, they did not get the benefit of the bargain and they want their refund.

Now, the response from Plaintiffs has been, well, until you do a 50 state survey, we are not going to address this, but that is not required because these facts are in the dead center of where the economic loss doctrine applies at its

zenith. These are sophisticated parties seeking a pure contractual refund claim.

What is most notable in the Plaintiffs' response is they said at a later point we will address it, and we have the cases that show this is not universally accepted, but their cases do not show that.

They cite the In Re: EPI Pen case, which deals with antitrust and RICO standing, virtually nothing to do with economic loss, and they deal with the National Prescription Opiate litigation, which does involve third party payors, does involve a claim for economic loss, and the doctrine does not apply because that claim involved great collateral damage, the addiction and overdose treatment and related diseases, all physical injuries, that came from the alleged misrepresentations about opiates.

So, if the Plaintiffs wanted to poke a hole, they just need to cite one case, one state that does not apply this doctrine as we have advocated it here, and they cannot do so.

Next, our colleague, Amy McVeigh, will address the injunctive relief and medical monitoring.

THE COURT: Okay.

MS. MCVEIGH: Good afternoon, your Honor.

THE COURT: Good afternoon.

MS. MCVEIGH: I will be presenting today on Plaintiffs' claims for injunctive relief as found in the

consumer class action complaint, in their seven medical monitoring causes of action, as well as their violation of state consumer protection statute claims.

Let's start with them one at a time, and start with medical monitoring. In order to state a claim for an injunction a Plaintiff has to allege an irreparable injury and also that monetary damages are not enough to compensate for that injury.

THE COURT: Let me let you know that is the 15 minute mark of your 20 minutes.

MS. MCVEIGH: Okay. Thank you. As we just heard from Mr. Winters, Plaintiffs have failed to assert any recognized injury in the consumer class action complaint. Even if they had, their medical monitoring claims would still fail because all they are asking for are monetary damages.

They outline the contours of their proposed program in paragraph 1541 of the complaint, and there they say that it would consist of, quote, "a trust fund in an amount to be determined to pay for the medical monitoring of everyone who has taken Ranitidine containing products."

They say this over and over again. In their opposition to the shotgun pleading motion they say they are seeking damages for the medical expenses necessary to monitor for cancer and also the future costs of medical monitoring. That is on pages three and four.

They characterize the medical monitoring program as a simple one, ordering the Defendants to create a fund to pay for medical monitoring. This exact type of medical monitoring program was examined in the Barraza v C. R. Bard case, and found to be a claim for money damages, not injunctive relief.

We can contrast this with the situation in Donovan v Philip Morris where there the Plaintiffs requested and needed specialized medical screenings with novel testing that was not available to the general public or through health insurance. The Court had to oversee the hiring of medical personnel, the purchase of specialized equipment, create studies and create registries. There, the Plaintiffs could not purchase the testing that they required at all, and here the Plaintiffs haven't alleged anything like that.

So, despite asking for an injunction, all they really want the Court to do is to make the Defendants write a check, and that is a claim for money damages, not injunctive relief.

Separate from their medical monitoring counts, Plaintiffs have also asked this Court for an order enjoining Defendants from engaging in certain unspecified future actions. They allege that the Defendants violated state consumer protection laws when they sold Ranitidine to consumers without telling the consumers that the product was inherently ineffective and unreasonably dangerous.

In addition to seeking damages for this behavior, they

ask this Court to issue an order enjoining these unfair or deceptive acts or practices in the future.

The Eleventh Circuit has said in the Gagliardi case that an injunction cannot be fashioned when the prospect of future injury is only speculative. There must be an actual likelihood of injury. Even the cases that the Plaintiffs cite in opposition say that something more than mere possibility is required.

As we know, Twombly and Iqbal require a Plaintiff to plead allegations that would raise the right to relief above a speculative level. Here, they don't offer any specifics, so it is difficult to tell exactly what they want this Court to do. What we do know because it is alleged in the complaint is that no Defendant is selling Ranitidine right now.

Plaintiffs conclusory allegation that there is a continuing risk to Plaintiffs is not possible under the 12(b)(6) standard when there is no allegation in the thousands of pages of the complaint that any Defendant intends to relaunch its product, or if it did, what the labeling might look like or what representations may be made in connection with that product.

This Court would necessarily, if it were to issue this injunction, have to base it on hypothetical facts and situations that are not found in the complaint itself. Because there is no basis in the complaint to order the Defendants to

refrain from any particular action in the future, the Plaintiffs have failed to state a claim for injunctive relief here as well.

Thank you, your Honor.

THE COURT: Thank you. You have a minute and a half. Did you want to do the brands? Your mute is on.

MS. ZOUSMER: Julia Zousmer on behalf of the branded Defendants.

We agree with the arguments made by the generics and those arguments apply equally to the brands for four reasons.

First, Plaintiffs do not have standing to assert economic injury claims for alleged worthlessness of brand name Zantac because Plaintiffs do not assert that Ranitidine products of any kind were ineffective for intended purposes. They did not allege, nor could they, that branded versions of the product were less safe or effective than the generic versions.

Instead, Plaintiffs' allegations confirm they obtained the benefit of the bargain for branded Zantac just as they did for generic Ranitidine.

Plaintiffs try to distinguish the brands by pointing exclusively to the Eleventh Circuit case Debenardis v IQ Formulations which, as Mr. Winters already explained, is completely different in both statutory framework and fact than the statutory framework or facts found here.

Plaintiffs argue that depending on how other issues in the litigation are decided, the brands may be distinguishable for standing purposes because the brands could have changed the Zantac label under the CDB process, and therefore may have been selling Zantac illegally at a time when the generics would not have been doing the same. This is an admittedly hypothetical distinction.

Indeed, Plaintiffs don't even say when --

THE COURT: I'm sorry, you have to slow down, but also that's the 20 minutes. Maybe finish the sentence.

MS. ZOUSMER: Plaintiffs don't even say when Zantac supposedly became illegal to sell.

THE COURT: Okay. You will have three minutes left and you all decide how you want to allocate that.

MS. ZOUSMER: I could continue using it up front if that would be okay with counsel for the generics, but I defer to them.

THE COURT: Do you want to have the remainder of your time used now or save some, so that the brands can finish?

MR. WINTERS: Your Honor, if the brands need another minute or two to finish, we will let them do that.

THE COURT: Okay. Go ahead.

MS. ZOUSMER: Thank you very much. Second, as Mr. Stikeleather persuasively argued, the economic loss doctrine bars a third party payor tort claim. GSK is the only brand

Defendant named in these tort based counts and Plaintiffs have failed to articulate any reason why these same claims asserted against GSK should meet a different fate.

Like the third party payors and generic Defendants, GSK is also a sophisticated commercial entity. There is no claim that third party payors were physically injured by paying for Zantac manufactured by GSK or anyone else. Therefore, GSK should not be treated differently for the purposes of this motion.

Third, the generic medical monitoring arguments also apply equally to the brands, and in fact Plaintiffs opposition to the brands joinder concedes that their injunctive relief arguments are similar for both the brand and generic Defendants.

Instead, Plaintiffs attempt to distinguish the brands by arguing that the remedy sought may vary because the brand and generic Defendants' knowledge of Ranitidine may have differed and the brand Defendants may have known more.

In addition to being speculative, this is a distinction without a difference. Whether, when, and what a Defendant knew about Ranitidine simply has nothing to do with the Plaintiffs need for medical treatment or future medical monitoring.

Lastly, Plaintiffs' request for Ranitidine products to be withdrawn from the market is also moot with respect to brand

Defendants because branded Zantac has been taken off the shelves just like generic Ranitidine.

Plaintiffs argue that the branded Defendants have made statements in defense of our product that make clear the voluntary decision exception to mootness applies to us with even greater force, but the branded Defendants' opinions about our own product have no bearing on the FDA regulated process of returning a withdrawn product to market. Like generic Ranitidine, any return to market of branded Zantac will be subject to FDA oversight and procedures, inherent in would be a determination that Zantac was safe and effective for its intended use.

Thank you very much, your Honor. That concludes my argument.

THE COURT: Thank you. That is the 23 minutes, so there won't be a rebuttal.

We ask that the Plaintiffs now come on in response. If you would just state your name as you are speaking.

MR. KELLER: Thank you, Ashley Keller for the Plaintiffs. I have a limited role today, if it pleases the Court. I am going to have Mr. Heinz run with the presentation and then join you again for the Q and A.

I just want to echo Ms. Hood's sentiment thanking the Court for encouraging us to allow young lawyers an opportunity to speak, and Mr. Heinz fits the bill. I am going to hand the

Zoom over to him, return for the Q and A, and if the Court is amenable, I will let Mr. Heinz field the questions, but I would like to reserve the right to potentially jump in once or twice to maybe augment some of his responses.

THE COURT: Yes, absolutely. That goes for everybody. Okay, mr. Heinz.

MR. HEINZ: Good afternoon, your Honor.

THE COURT: Good afternoon.

MR. HEINZ: My name is Noah Heinz, I am an associate at Keller Lenkner and represent the Plaintiffs.

In my presentation today I want to address five points. First, the distinction between subject matter jurisdiction and the merits; second, economic injury in standing; third, medical monitoring in standing; fourth, the economic loss rule; and fifth, the so-called injunction claim that the Defendants seek to dismiss on a number of different grounds.

First, what is the difference between subject matter jurisdiction and the merits and why does it matter here? One difference is the source of law. Subject matter jurisdiction is a matter of Federal law and it follows from Article III of the Constitution, the cases or controversies requirement.

By contrast, the merits are determined in this action under State law because it is a diversity action. That means 52 different jurisdictions' laws apply on the merits.

Another difference is the content of the law. Lujan versus Defenders of Wildlife gives three prongs to standing, injury in fact, traceability, and redressability, and the only one relevant to this motion is injury in fact. That is the content of the law for jurisdiction, but for the merits it varies not only by jurisdiction, but also by each count, which means that there could be 52 different merits laws for each count that we have alleged in our complaint.

That is what makes it so peculiar that the Defendants argue that everything could be dismissed with prejudice based on their injury argument, because they haven't cited to State law that would actually justify that by giving you the details in 52 different jurisdictions of why each count needs to be dismissed on injury on the merits.

Now, another difference between jurisdiction and the merits is a priority rule. This comes from Steel Co, and the Supreme Court in that case held that if the Court has two questions, one on jurisdiction and one on the merits, the Court must address the jurisdictional question first, and it also explained why.

Quote, "Jurisdiction is the power to declare the law and when it ceases to exist, the only function remaining to the Court is that of announcing that fact and dismissing the cause."

That means that even if Defendants were correct that

injury could be a basis for dismissal either on the merits or on standing, this Court would have to dismiss on standing grounds. That would mean a dismissal without prejudice.

The Judge in the Debenardis case explains a very important implication of that. It means that the Plaintiffs could refile in State Court, and that is because State Courts don't all have a similar or even analogous case or controversy requirement. So, that means that instead of adjudicating the issues here on the merits, it would be refiled in State Courts and decided there, potentially 52 different class actions.

The Defendants couldn't remove those cases under the Class Action Fairness Act, or any other ground of removal, because after prevailing upon this Court that there is no standing they would be judicially estopped from removing and that means the doors to Federal Court would be closed.

Mr. Winters explained that he wanted the complaint to be dismissed without the opportunity to amend. It seems like that is what they might be getting at with the with prejudice or without prejudice, but they are actually quite different. Even if there were no leave to amend, if it was a dismissal on standing, the Plaintiffs would have the ability to refile.

The second point is economic injury and standing. The Plaintiffs allege that they purchased Ranitidine, which is a worthless drug because it degrades into NDMA, which is a potent carcinogen. They want their money back and that is a perfectly

fine injury in fact. The Eleventh Circuit has called economic injury the epitome of an injury in fact.

The case of Debenardis supports our view. In that case a class sued the makers and sellers of a supplement, and they didn't argue that they paid a premium for that supplement. They didn't argue that the supplement caused them physical personal injury, that they had any symptoms. They didn't even argue that the supplement didn't perform exactly as the sellers of it claimed it would.

Instead, they simply said that because it was illegal to sell under the Food, Drug and Cosmetics Act it was a worthless drug and so they needed their money back. The Court endorsed that view. It reasoned in two steps.

First it explained in the typical defective product case there is going to be a reduction in value as a result of the defect in the product, but there still is going to be some value left, but it explained, quote, "sometimes a product is rendered valueless as a result of a defect if it is a fundamental flaw, that is, and then the Plaintiffs can recover the full price."

One such situation, the Court went to to explain, is where the product is illegal to sell. Quote, "where Congress judged a product insufficiently safe for human ingestion it is of no value." And that is the case here.

The Plaintiffs allege that Ranitidine was misbranded

and adulterated and therefore illegal to sell under the Food, Drug and Cosmetics Act. That is in the third party payor class action complaint at paragraphs 335 through 41, and in the consumer class action complaint in paragraphs 595 through 604. There are many more paragraphs, but those are the most relevant ones.

That is not simply because something that is illegal to sell is automatically worthless merely because of that fact. It is because Congress made a particular kind of judgment in the Food, Drug and Cosmetics Act about what types of things are safe for people to consume, and it judged that a misbranded or adulterated drug or supplement would be unsafe, and for that reason illegal, not for a different reason, and that is what makes it an injury in fact.

The Defendants don't have any good responses to this. In their opening motion they consign Debenardis to a footnote. On reply, they gave a couple more attempts, but none of them are persuasive.

They first said it is a different statutory scheme. That is simply not true, it is the same Food, Drug and Cosmetics Act, and the logic of it is also the same. In that case it was a supplement and in this case it's a drug. In both cases it goes to the safety of the product and whether Congress deemed that sort of product to be too unsafe for people to consume and consequently for people to sell.

So, it applies here even though the statutory scheme is in some very narrow sense different for supplements or for drugs. It is worth noting also that the definition of adulteration and misbranding in the Food, Drug and Cosmetics Act is the exact same statutory subsection for supplements and for drugs.

They also argue that one difference in Debenardis is the supplement was illegal to sell, but here the Defendants argue Ranitidine was legal to sell. That doesn't actually distinguish the cases, and that is simply because in Debenardis they explain that the Defendants disagreed as well that the supplement was illegal to sell, they contested that fact. They said it is a totally different ingredient that the FDA has said would adulterate a product.

Nonetheless, the Eleventh Circuit explained that they had to credit the allegations in the complaint, and because of that, they held that at the Motion to Dismiss stage there still was standing.

The same is true here. Of course the Defendants are going to contend that their product is not misbranded and adulterated, but that is what the complaints plead and they can't dodge that by simply saying that the Court shouldn't credit it. On a Motion to Dismiss the complaint has to be understood as true.

They also argue that there are some subsequent cases

that explain that Debenardis is sort of limited in some small way, and they cite cases like Doss versus General Mills about Cheerios.

That doesn't apply either because they fail to quote the most important part of that, and this is just one illustration, this is true of a number of other different cases that they cite.

In Doss, the Court explained, Doss does not allege that she purchased any boxes of Cheerios that contained any Glyphosate, much less a level of Glyphosate that is so harmful that Cheerios are presumptively unsafe and therefore worthless. The same type of failure to quote relevant passages explains most of the cases that they cite.

There is another reason that this Court could find that Ranitidine is worthless. Instead of basing it on the FDCA, this Court could base it on State law. Debenardis cited a Florida consumer protection statute and explained that, under that statute, the supplement at issue there would also be worthless.

It is true that the actual holding of the case only said that looking to Federal law is an acceptable way to look at worthlessness for a product, but there is no reason to limit the logic in that way, and that is simply because, as we know from cases like the recent en banc Miranski (phon) decision and from Spokeo versus Robins that Congress cannot expand or

contract the injury in fact requirement from Article III.

What it can do is recognize factual injuries that people actually face in the real world, and when Congress does that, Congress will defer to their factual judgment. That is exactly what happened in Debenardis, and there is no reason that Courts should not also defer when states make similar types of judgments. In fact, Courts like Spokeo have also said that you want to look to common law analogies in determining whether Plaintiffs have standing.

A second and independent basis for standing in this case is a reduction in the price that the Plaintiffs would have been willing to make as a result of the defect in this case.

So, the best case for this is Aqua Dots, which was discussed in the Debenardis majority opinion. There, there was a group of parents that sued because they had purchased a toy, it was a number of beads and adhesive, and if a child swallowed it, it was toxic. The parents of the children who swallowed it weren't the ones who sued. All the parents whose children did not swallow the beads are the ones that sued.

And the Seventh Circuit still found that there was standing because they wouldn't have paid as much if they had known that was toxic. Quote, "The Plaintiffs' loss is financial. They paid more for the toys than they would have had they known of the risks that the beads posed to children. A financial injury creates standing." That is at page 751.

Debenardis endorsed that reasoning and it applies soundly here.

The next point is standing for the medical monitoring claim. The medical monitoring Plaintiffs in this case ingested a high level of NDMA. They have been injured at a cellular and subcellular level and as a result, they have a need for medical monitoring because they have a heightened risk of developing the cancers that NDMA reliably causes. They have to get -- diagnose that, otherwise the cancer would be more difficult to treat later, by the time they had clearer symptoms that would be easier to find. The consumer class action complaint, paragraphs 715 and 723, alleges these injuries.

The uniform case law supports the view that medical monitoring claims can be heard in Federal Court. We cited the Agent Orange case, Sutton, In Re: Paoli, and Bouldry (phon) from this district. The Defendants didn't cite those cases, they didn't distinguish those cases, and they didn't cite any cases that held that medical monitoring claims cannot be heard in Federal Court. They are simply silent on the issue.

They also argue that the medical monitoring claims can be dismissed on the merits. That is simply not possible in light of their concession in Footnote 10 of their opening motion that they are not moving to dismiss the medical monitoring claim on the merits under State law. All they are saying is that there wasn't enough injury for standing. So it couldn't possibly be that the medical monitoring claims should

be dismissed on the merits.

The next point is economic loss. There have been a number of times throughout this briefing where the Defendants have made sweeping claims about what all sorts of state law must be because they declare it to be so. We have complained in other briefing that the Defendants engage in a tactic of briefing by appendix.

Your Honor, here the Defendants had no briefing and no appendix. They didn't cite any state law that discussed the economic loss rule. All they cited to this Court is a 1986 admiralty case and a 1989 ALR article.

There is no way to dismiss four separate counts for negligence, the negligent misrepresentation, and for the fraud claims and consumer protection statutes merely on the basis of their claim to this Court that it would be a good idea because the economic loss rule makes a lot of sense and the parties here are sophisticated parties. That is not how briefing is supposed to work and that's not meeting their standard under Rule 12(b)(6).

State law is nuanced, there are majority rules and minority rules and it applies under different situations. A perfect example of this is the dispute over the opioids case. We cited one example to show that the law is actually nuanced, that in Ohio the negligence claim there survived Judge Polster's ruling. They said that was a special exception and

then pointed out a later Michigan case, a negligence case in which the claim was dismissed under the economic loss rule.

But it doesn't actually prove their point, and that is because the rule there was the Michigan present physical injury rule for negligence. The Court actually held that the fraud claim in that later ruling didn't die under the economic loss rule. We think this shows our point in two different senses.

It first shows that there are differences in state law, Ohio versus Michigan for negligence, for example. It also shows that there are important differences and nuances between the counts that the Defendants want to dismiss on this ground.

For example, under Michigan law, the negligence count was out, but the fraud count was in. There is no reason to simply dismiss because the Defendants invoke the words economic loss. They need to cite cases or statutes that actually apply to this action.

The last point is the Defendants' request to dismiss the so-called injunction claims. I want to be very clear here, there is no such thing as an injunction claim. There are claims and there are remedies. It might have been true perhaps a hundred years ago, before the Rules of Federal Civil Procedure were put into place. The Plaintiffs had to file a certain form of action that pleaded a particular kind of relief, but those days are long gone.

After Rule of Federal Procedure 2, we know that there

is but one form of action, and that is a civil action, and that is what was brought here. They have no Rule 12(b)(6) cases, and that is because Rule 12(b)(6) is about the failure to state a claim. It is not about the failure to request the right kind of remedy. That is not something the Courts dismiss.

Every case they cite is about class certification, and that is because in a class certification context it does matter whether the relief is legal or equitable under Rule 23(b)(2) or Rule 23(b)(3). We are happy to brief that issue next year when this Court has given us a scheduled briefing for class certification, but it has no relevance on a Rule 12 motion whatsoever and there is no reason to dismiss it, and it can't be done under Rule 12(b)(6) in any event.

They also argue that under certain statutes there can't be an injunction to stop selling because in their opening motion they argued that it would be moot. We responded to that and we said there are cases such as Friends of the Earth versus Laidlaw and the Eleventh Circuit case in Sheely that explain the voluntary cessation exception to mootness.

We explained it failed to meet the three prongs there, first, because the Defendants have not promised never again to sell Ranitidine; second, they vigorously dispute liability; and third, they recalled the product with an eye to this very litigation, and that means it is not moot.

On reply they didn't address this, they didn't

distinguish Sheely, they didn't distinguish Friends of the Earth versus Laidlaw. They simply repackaged their argument and said that it would be an advisory opinion, but that is not a substantive response on anything. The case is not moot. It wouldn't be advisory either because it wouldn't change the legal relationship of the parties and change what they are allowed to do.

Also, there is no reason for this Court to credit the Defendants' protestations that if it were back on the market that would necessarily mean that the FDA believes it to be safe. The complaints already allege that the Defendants sold an unsafe drug notwithstanding FDA regulations saying they can't do that.

The final point is the joinder motion, and all due respect, this seems to be much ado about nothing. Our primary submission, which we reiterated in our opposition to the joinder motion, that the arguments the generic Defendants provided are fundamentally flawed, they're flawed on injury, on economic loss, on medical monitoring, on everything, and they should just be denied entirely both as to them and as to any Defendant that wants to join them.

We also explain that they may not be identically situated to the brand Defendants because they made no different amount of things. They may operate in different areas, the regulatory regime might be somewhat different. These are

simply alternative arguments if this Court finds the issue to be a very, very close one.

We don't think that it needs to be discussed for a great amount of time because our primary submission is that all the arguments are fundamentally flawed and the motion should be denied as to all Defendants.

THE COURT: Okay, thank you very much. And we can have all of the attorneys come on for the motion 2037, the Plaintiffs and the Defendants, so the Court can direct its questions to the parties.

Just state your name, if you would, before you answer the question, whoever is answering the question.

This is for Defendants. Again, I will leave it up to the Defendants as to who you want to answer the question.

In Plaintiffs' response opposing your motion to dismiss for failure to allege injury Plaintiffs state that if your motion is brought under 12(b)(6), Rule 12(b)(6) for failure to state a claim "the analysis depends on the elements of substantive state law and would need to be decided under the framework of an Erie prediction, not the constitutional standing inquiry for redressable economic injury." That is the response at page 11. Those are the ECF pages, when I am referring to the pages.

Defendants state in their reply that the Defendants brought the motion under 12(b)(1) for lack of Article III

standing, and under 12(b)(6).

Do you agree with the Plaintiff that an Erie analysis is necessary if the motion is made pursuant to Rule 12(b)(6)?

MR. WINTERS: Your Honor, this is Daniel Winters on behalf of the Defendants. No, we do not. The standards here are clear, 12(b)(1), there can be two types of attack. One is a facial attack, that is on the four corners of the complaint, and the other is a factual attack.

What we brought here is a facial attack, it is on the four corners of the complaint, they failed to allege an injury in fact. The case law makes clear that that standard is almost identical to the 12(b)(6) standard, that the Court will read the complaint, it will give them the reasonable inferences, but they still must do so with particularity, and they still must do so with not just conclusory statements.

If you look at the cases that we cited throughout our briefs, both the moving brief and the reply brief, there are literally dozens of cases where this issue is discussed and cases are dismissed for standing without a discussion of state law on both 12(b)(1) and 12(b)(6).

For example, the In Re: Acumune Marketing litigation, that's the Northern District of California, 12(b)(1), 12(b)(6), Birmingham v Walgreens, Southern District of Florida, 12 b 1, 12 b 6, Hughes v Chatham, Southern District of Indiana, 12(b)(1), 12(b)(6), Corinthali versus Loreal, Third Circuit,

12(b)(1), 12(b)(6), Laredo versus Proctor and Gamble, Southern District of Ohio, 12(b)(1), 12(b)(6), In Re: Schering-Plough, Third Circuit, 12(b)(1), 12(b)(6), In Re: Schering-Plough consumer class action, that's District of New Jersey, 12(b)(1), 12(b)(6).

Our pleadings are literally pregnant with examples of this being done under both 12(b)(1) and 12(b)(6), without it being necessary to get into individual state law claims.

THE COURT: For the Plaintiffs, given your position that a proper Rule 12(b)(6) motion requires state specific analysis, what is the scope of the analysis that you have in mind?

MR. HEINZ: It would depend on exactly what they are trying to dismiss. So, we would say that if they think there needs to be injury, they would need to actually explain the elements of the claims and why. If there is no injury under their definition, the claim fails.

THE COURT: What is the response from the Defendants?

MR. WINTERS: Your Honor, we have done that under the Federal standard of no injury in fact.

What they have done here is, they have oscillated between tort and contract. You heard in counsel's presentation that they want economic damages. That is contract. And they want it because, according to them, NDMA degrades and causes cancer. That is product liability.

The Courts have made clear in all of the cases that we cited, beginning with Rivera, continuing on through the other cases, up through In Re: Johnson and Johnson Talcum Powder, as cited by Debenardis, when you try to oscillate like that between contract and tort you do not have an injury in fact and your case is dismissed.

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

THE COURT: Yes.

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

I think the distinction between contract and tort proves that they are truly making a merits argument, not an Article III argument. Article III doesn't care about contract versus tort and whether state law allows a recovery under one path or the other. Article III is concerned with this Court's adjudicatory authority.

If a state says this type of injury has to be pursued under contract rather than tort, that is a merits determination that the state has made and that the Court can adjudicate. It would result potentially in a 12(b)(6) dismissal, but the distinctions between contract law and tort law are obviously Erie predictions made under state substantive law. They are not concerned with Article III case or controversy definitions under Lujan.

THE COURT: Okay. Thank you.

For Plaintiffs, as the best the Court can tell, you argue that Plaintiffs have alleged cognizable injury in three ways. First, you state Plaintiffs have suffered "pocketbook injury" through purchasing or reimbursing for a worthless drug that should not have been available for sale because it was adulterated and/or misbranded. That is page 15 and 16 of your response.

Second, you state the Plaintiffs have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring. That's page 22 of your response.

Third, you state physical injury by noting that they are now subject to the accumulation of NDMA in their bodies, have suffered cellular and subcellular damage, and have an increased risk of developing various types of cancers. Response at page 23.

First, is the Court correct that those are your three theories for injury in fact?

MR. HEINZ: Yes, your Honor, I believe that is correct.

THE COURT: Okay. Now, in the Eleventh Circuit case, the Prado-Steiman case that we discussed at length earlier today relative to the other motion, the Court states that when evaluating Article III standing, each claim must be analyzed separately, that's 221 F.3d 1266, 1280, Eleventh Circuit, 2000.

As you acknowledged in your brief, to show standing

one must allege an injury in fact which is fairly traceable to the challenged action of the Defendant, and it must be likely that the injury is redressable by a favorable decision. Those are the elements set forth in Lujan versus Defenders of Wildlife, 504 U.S. 555, 1992.

Please assume for the sake of this question that the Court must undertake a claim by claim analysis.

Regarding Plaintiffs' pocketbook injury, are Plaintiffs alleging that this injury constitutes injury in fact for every claim in the consumer complaint and the third party complaint?

MR. HEINZ: I think we would argue that. There might be an exception, but if so, it is not coming to mind.

THE COURT: Regarding Plaintiffs' economic losses and expenses due to medical monitoring, are Plaintiffs alleging that this injury constitutes injury in fact for only those counts entitled "Medical Monitoring" in the consumer complaint? Namely, Counts 45, 67, 139, 167, 238, 280, and 302. You might not have the paragraphs committed to memory, but the ones that are entitled Medical Monitoring.

MR. HEINZ: I think that is the only thing that it would be applied to. Yes, I think that is right.

THE COURT: Regarding Plaintiffs' NDMA accumulation, cellular damage, subcellular damage, and increased risk of cancers, are Plaintiffs alleging that these injuries constitute

injury in fact for every claim in the consumer complaint?

MR. HEINZ: It would probably as to the people that ingested Ranitidine. For the class of people that would include people who purchased it, but didn't ingest it, then it likely would not.

THE COURT: The Court notes that the named Plaintiffs in the third party complaint do not allege any of these physical injuries. Is the Court correct that this theory of injury is not relevant to the third party complaint?

MR. HEINZ: That is certainly correct.

THE COURT: Okay. Plaintiffs again, returning to the pocketbook injury. You allege that you demonstrate standing by alleging economic injury through purchasing and reimbursing for a drug that had long been misbranded and/or adulterated, and was thus economically worthless. That is your response at page 16.

In the class complaints you cite multiple ways in which a drug may be adulterated and/or misbranded, and I think you also referenced certain paragraphs in your presentation, under the Food and Drug Act, and that is the consumer complaint paragraphs 598 to 599, and the third party complaint, paragraphs 184 to 185.

I am not sure if you cited others during your presentation, but that is what I gleaned from your briefing.

So, that is what I gleaned from the complaints

themselves, so 598 to 599 in the consumer complaint and third party complaint, 184 to 185, relating to the misbranding and adulteration, but then in your response you cite paragraphs 595 to 604 in the consumer complaint as your basis for arguing that "Ranitidine has, and has long been, misbranded and adulterated." That is in your response at page 16.

Is that the complete list of paragraphs in the consumer complaint that support your argument, the ones that you cited in your response, 595 to 601 in the consumer complaint? I just want to be clear that I am following.

MR. HEINZ: Your Honor, I don't think that was meant to be an exhaustive list, it was just the most relevant list. Especially the section title on that we thought was very exemplary of the general point, but we also think a number of other factual allegations throughout the complaint would support an inference, that is, it is misbranded and adulterated under the terms of the FDCA.

Probably those are not all the paragraphs that are relevant. We could provide a supplemental briefing drawing your attention to all of the paragraphs that are relevant, but I think it is more than just those paragraphs.

THE COURT: All right. Well, it doesn't say these are examples. It says, second, both the TPP complaint and the consumer complaint allege that Ranitidine is, and has long been, misbranded and adulterated.

And then you have TPP -- but you do have EG. So, is that what you mean, that you are just giving examples there, 335 to 41, and CCAC, 595 to 604? These allegations are detailed and plausible.

MR. HEINZ: That is correct, and I believe we gave the title of that section, so we were referring to that section of the complaint, but it is not the only section that would support our argument.

THE COURT: Is there anywhere else in the brief where you have outlined what else supports the argument?

MR. HEINZ: I don't think so, except in the general sense that we explain the factual basis for harm, and that there is NDMA in it, all of that would be relevant to the Federal standard for misbranding and alteration, but I don't recall anywhere in particular that I want to draw your attention to.

THE COURT: Okay. With respect to medical monitoring, this is a question for the Defendants, Plaintiffs state they suffer and will suffer economic losses and expenses due to the need for ongoing medical monitoring. That is the response at page 22, the ECF page.

I did not see where the Defendants addressed the issue of whether suffering economic losses associated with medical monitoring constitutes a cognizable injury for purposes of Article III standing.

On that point, Plaintiffs cite Bouldry versus C. R. Bard, Incorporated, a case within this district, for support, and that's 909 F.Supp.2d 1371, Southern District of Florida, 2012. In Bouldry, the Court agreed with other Federal Courts that had held that in the context of medical monitoring, an alleged increased risk of future harm satisfies Article III's injury in fact requirement. That is at page 1374 to 1376 of the case.

What is your response to Plaintiff's argument on this point?

MR. WINTERS: Your Honor, this is Daniel Winters. Going back to that, this then gets us back into the issue of the shotgun pleading, and putting all these claims and asserting all of them on behalf of everybody.

In these types of claims you are talking about specific individuals who are making specific allegations under a very small subset of states.

The Plaintiffs here seem to be trying to bootstrap this into making it a claim for every Plaintiff on every claim for their injury in fact. That is not permissible.

That again gets them back to the -- they oscillate between tort and contract damages. They have to have an injury in fact, and they have not done so.

So, you know, if they are trying to narrow it down to certain Plaintiffs in certain states are alleging certain

injuries, and they say that is sufficient, then that is what they should plead. That is not what is in their complaint currently, and we are moving on their current complaint, the one you gave them an opportunity to amend, and they declined.

THE COURT: Okay. On physical injury, the NDMA accumulation, cellular and subcellular damage, risk of cancer, question for the Plaintiffs.

The Defendants argue that your alleged physical injuries, namely NDMA accumulation, cellular and subcellular damage and an increased risk of developing various cancers are not legally cognizable injuries. In support they cite Caputo versus Boston Edison Corporation, 1990 WestLaw 98694, District of Massachusetts, 1990, Ranier versus Union Carbide Corporation, 402 F.3d 608, Sixth Circuit, 2005, In Re: Berg Litigation, 293 F. d 1127, Ninth Circuit, 2002, and Dumontier versus Schlumberger Technology Corporation, 543 F.3d 567, Ninth Circuit, 2008, and that is the Defendant's motion, pages 16 and 17.

The Plaintiffs distinguished several of these cases by noting that they do not address standing or state law on medical monitoring. That is your response at page 23 and 24. To support your position that such physical injuries are legally cognizable you cite to one Massachusetts case, Donovan versus Phillip Morris, 914 N.E. 2d 891, Massachusetts, 2009, which noted that the Plaintiffs needed to show at least, quote

unquote, "subcellular changes" that substantially increase the risk of serious disease for their medical monitoring claims.

Is the Court correct that you rely only on Donovan to support your argument that your physical injuries constitute injury in fact?

MR. HEINZ: I don't think so, your honor. Sorry, this is Noah Heinz for the Plaintiffs. That case was mostly to show that the Caputo case that they relied on was not actually addressing medical monitoring and standing, it was addressing Massachusetts law on the merits, and on the merits, as we explained, under Donovan, Massachusetts law supports us.

Our primary cases for standing would be cases like Bouldry and Sutton, which is Sutton v St. Jude Medical, 419 F.3d 568, from the Sixth Circuit, and a number of other cases also cited in Bouldry. We would also rely on the Third Circuit case, In Re: Paoli which specifically held that it was error when the District Court applied the standard for enhanced risk claims in an action for medical monitoring and that was a standing case that distinguished between those two concepts.

There are a number of other cases that I think apply by analogy like our Agent Orange case and a few others, but those are the cases that we would mostly rely on and are focusing on, Bouldry especially.

THE COURT: For your argument that physical injuries constitute injury in fact?

MR. HEINZ: Yes, your Honor, that the increased risk of cancer is a predicate of medical monitoring claims, or not cancer necessarily, but the increased risk of disease, that that also counts as a physical injury.

THE COURT: Question for the Defendants relating to the Plaintiffs' injunctive relief sought. In the portion of the Defendants' motion challenging medical monitoring as injunctive relief, Defendants state that Defendants "are moving as to the request for an injunction and reserve the arguments that the consumer Plaintiffs failed to state claims for medical monitoring under applicable states' laws." That is your motion on page 21.

Yet, you also state that your motion is brought pursuant to Rule 12(b)(1) and Rule 12(b)(6). That is in your reply, page 5, Footnote 1.

Is this a Rule 12(b)(6) motion for failure to state a claim? If it is, the Court wants to know why there was not included arguments for failure to state claims for medical monitoring? And if it was not a 12(b)(6) motion for failure to state a claim -- but I think you said earlier that it was both, so, maybe let me have you address the first part of the question.

Are you presenting this as a 12(b)(6) motion for failure to state a claim?

MR. WINTERS: Your Honor, this is Daniel Winters

again. Let me address that.

As you saw, our motion is broken into basically two separate sections. The first is that there is no injury in fact. That would eliminate or require dismissal of the entire complaint, that is a 12(b)(1) and a 12(b)(6).

The motion goes on to say that if for some reason the Court is not going to dismiss it, if they are going to give the Plaintiffs an opportunity to replead, then there are definitely certain things that should not be repled, one being the third party payors should be limited to economic loss claims. They should not be permitted to bring tort claims, and the rationale behind that is in the motion.

Second, if they are going to have an opportunity to replead, they should not be able to replead these injunctions, and that is because when your Honor looks at their responses, at their various pleadings, when it comes to medical monitoring, over and over again they keep saying what we want is a fund of money.

So, when the Plaintiffs have told you in filings with this Court at least a half dozen times that all we want is money, if the Court is going to give them an opportunity to try to amend their pleadings to meet the standard, then that claim at least should not be permitted because it is just a request for money, not injunctive relief.

MR. HEINZ: May I speak to that, your Honor?

THE COURT: Yes.

MR. HEINZ: This is Noah Heinz. The Defendants make a lot about a couple of scattered statements throughout the debriefing, but each of those, if I recall correctly, was addressed to whether the injury at issue here is redressable, and both parties agree that the injury is redressable. The point is that the Court could fashion a remedy.

We did not intend through that to concede anything about the nature of that remedy, that it would merely be money damages, and we don't need to explain in detail the nature of the medical monitoring remedy at this stage. The pleadings do, I think, a sufficient job of explaining that we do need injunctive relief on the medical monitoring claims, and it is far too early to demand the level of detail that the Defendants claim to need here.

THE COURT: Let me follow up on that. The Plaintiffs don't dispute the Defendants' point that in the consumer complaint the Plaintiffs seek an injunction ordering them to remove Ranitidine from the market.

The Court wants to make sure in can tell where in the consumer complaint you expressly request that relief. If you could let the Court know where.

I could glean that you ask the Court to "order any and all appropriate preliminary and/or final injunctive or equitable relief" against the Defendants. That is at page 1332

of your consumer complaint.

Is that the relevant language or is there more explicit language elsewhere that the Court hasn't identified?

MR. HEINZ: I am not sure. That is probably the appropriate paragraph, but nothing more specific is coming to mind that I have in front of me.

MR. KELLER: Your Honor, this is Ashley Keller for the Plaintiffs. Under Federal Rule of Civil Procedure 54(c), when the Court enters a final judgment, even if we didn't plead all of the relief that we're entitled to, the Court can and should still order it.

THE COURT: All right. Economic loss doctrine, now a question for the Defendants. The Defendants cite East River Steamship Corporation versus Transamerica, 476 U.S. 858, a 1986 case where Defendants state that the Supreme Court recognized a "majority" approach regarding the economic loss rule to support the Defendants' argument that in the third party payor complaint Counts 5, fraud, 6 and 9, negligent misrepresentation and negligence, and 7, violation of state consumer protection laws, are precluded by that rule.

You acknowledge that there is not one economic loss rule, but rather, "several more limited rules that govern recovery of economic losses in selected areas of law." That is your motion, page 20, Footnote 9.

Defendants then state that "only one version of the

rule is being argued," namely that "between commercial parties, claims for injury to the product itself without personal injury or other property damage are contractual and not tort claims."

The Plaintiffs note that you, the Defendants, did not identify which jurisdictions apply that majority rule. Do you believe doing so is or was necessary?

MR. STIKELEATHER: Your Honor, this is Derek Stikeleather for the Defendants. We don't believe it is necessary in this case because the version of the economic loss rule that we're talking about is its most basic iteration. We could not find any state in the union that does not recognize it in this context, and notably, Plaintiffs have not been able to do so either.

Now, to do a 50-state survey at this stage of the case we do not think is something that the Court would be eager to get into, and would find efficient given all the demands on organizing and advancing this case, but it is a very significant point that they cannot point to a single state that says we do not recognize it in this context.

And it is true that once you get into the 50-state survey, and find the limits of each state, you do find nuances, you do find differences, but those arise often in the context of consumers where there is a tort element in the claim that I ingested this drug, I think it increased my cancer risk, but I also want a refund. Different states, in what can be confusing

analysis, can play that out differently.

There is a clear majority rule, however, we think it is unanimous that when you are talking about a third party payor, an HMO seeking a pure refund on the theory that this product was no good, not that we ever took it, not that it ever created any risk to us, but we don't think it is a good product, we want our money back, and there is no tort element whatsoever in that case, there is not a state in the union that looks at that and says you have both a contract claim and tort claim.

We think for the advancement and management of this litigation it would be prudent at this point to either plead what are the states that recognize this, because the two examples that they provided in their briefing -- given time to research, prepare, and file a brief, they provided two examples, one that does not even speak to the economic loss doctrine, and one that sought recovery for the collateral effect of opioid addiction, which, sure, that does not apply to the economic loss doctrine. That is far beyond seeking a refund. So, we have no quarrel with those cases.

The example we have here is an instance where we believe there is no state that would not apply the economic loss doctrine, and we think it is telling the Plaintiffs can't provide a single example.

THE COURT: Are you seeking dismissal, then, of Counts

5, 6, 7, and 9 only as to certain states' laws?

MR. STIKELEATHER: We would say dismissal of those counts as to all states because in every one of those states what the third party payors have is a pure contract claim, and they brought claims for warranty, breach of express warranty. Those claims would remain, but the tort based claims would be removed from the case.

THE COURT: What is the Plaintiff's response?

MR. HEINZ: Your Honor, it doesn't seem fair for the Plaintiffs -- for the Defendants, sorry, to simply invoke the economic loss rule and then say that they think it that applies in all 50 states and then force us to respond. I don't think that is an adequate way of briefing it.

If your Honor would like additional briefing on this topic, I suppose it could be that we would find more nuances in this area.

Also, the Defendants claim that they are making a blanket rule that would be easy to check, but they provide so many nuances that I can't even (inaudible) what the scope of the research would be. They say in this context limited to specific types of HMOs that we won't be able to find a case. It might just be that in a lot of states those types of cases just don't exist. We do know of states in which the economic loss rule doesn't apply to a large number of things, including when there is injury to the product itself.

We don't think that it was our burden to go through in detail each of the cases and allow them to have particular cases that they can then snipe at on reply. That is not a fair way to do debriefing and it is not an efficient way to do it.

THE COURT: That actually does dovetail into the next question that I have for you where you do note that if the issue of economic loss rule "were examined in detail, Plaintiffs would brief state law nuances distinguishing among Defendants that committed independently wrongful actions, employed certain forms of marketing, fraudulently concealed or other exceptions."

That is the brands' response adopting the motion at page five -- I am sorry, that is the response to the brands' adoption motion, excuse me. So, that is your response, the Plaintiffs.

So what would that briefing entail and at what stage would you envision this occurring?

I note in the quote, as I just read it, you said other exceptions. I also want to know what you meant by other exceptions. Did you mean exceptions to states' economic loss rules? If yo could address that for the Plaintiffs.

MR. HEINZ: Yes, your honor, this is Noah Heinz.

We did mean exceptions to the economic loss rule, as the Defendants explained, in the opioids case there was an exception. There might be a number of other exceptions. We

haven't taken the time to canvas all the states and think through the facts that might be relevant.

It seems that it might be the type of thing that would be suited to a later stage where there is detailed state law briefing, rather than at this initial stage that deals with crosscutting motions, but I am not sure I have a view on the best time to do it. Mr. Keller might have a better view on Plaintiffs' position on when it should be briefed.

THE COURT: It is true in large part, if not fully, that the first round of motions were intended to try to address certain crosscutting issues. There is contemplated depending on the outcome of the Court's ruling, a second -- should there be repleading on some or all of the complaints, a second round of motions.

Mr. Keller, what do you think it looks like, the Plaintiffs' response of examining in detail, Plaintiffs would brief state law nuances, distinguishing among Defendants that committed independently wrongful acts, employed certain forms of marketing, fraudulently concealed, or other exceptions. Would that come in the form of an amended complaint or some other procedural juncture in the case?

MR. KELLER: I don't think -- this is Ashley Keller for the Plaintiffs, your Honor.

I don't think it would come solely in the form of an amended complaint. Not to be flippant in my answer, but we'll

brief it as soon as the other side does, and at whatever point your Honor deems the other side efficiently to present these issues, but we have to know what we are shooting at. We can't just respond to an admiralty case and an ALR article and be expected to announce all of the nuances and exceptions of a doctrine that has a majority rule, a minority rule, and lots of exceptions and dispensations to it.

The burden for a 12(b)(6), if that is going to be the procedural posture that it's raised, is on the Defendants first, and to couch it in a certain way to demonstrate why the allegations in the well-pleaded complaint fail under state law, and then we get to oppose and offer distinctions and demonstrate to the Court that their arguments are incorrect.

It is difficult for us to do in a vacuum when we are just looking at a 1986 Supreme Court case that is obviously not on all fours with the precedent in the 52 jurisdictions for which the class claimants bring claims.

THE COURT: That is an interesting point you bring up about the burden. Movant has a burden to show why a claim doesn't survive perhaps.

Does the Plaintiff have a burden to plead a viable or plausible claim? I imagine you would say yes. So, how does the state law nuances -- let's say the majority of claims, hypothetically, are not plausible claims under state laws for some of the reasons the Defendants have argued, and that is a

hypothetical. Does the Plaintiff have a burden to come forward in plausibly pleading their claims and point to those state laws where a viable claim can be pled?

MR. KELLER: Of course, your Honor. Yes, we have a burden to plead and ultimately to prove every element of a cause of action under state law. We think we have adequately done that.

If the Defendants disagree with us and say we don't think that you have adequately done that, the proper way to address it at this procedural posture is through a 12(b)(6) where they point out based on law, not just ipse dixit at an oral argument, here are all of the cases that show that they haven't actually checked all the boxes as Plaintiffs, they haven't properly pleaded all of the elements of the claims under the law of Ohio, or Michigan, or whatever jurisdiction they want to invoke, here is relevant authority that shows we are right. Then we get to oppose that.

So, we have met our initial burden of pleading what we think in good faith are complaints that state claims. If they have a problem with that, they could file a 12(b)(6) that properly goes through all of the legal authority that demonstrates, in their view, that is not true. That is the proper sequencing we think.

MR. STIKELEATHER: May I respond, your Honor?

THE COURT: Yes.

MR. STIKELEATHER: This is Derek Stikeleather for Defendants. Our reply brief contains authority that cites New York law, Florida law, Pennsylvania law, Ohio law, New Jersey law. We certainly have put forward cases and we think the seminal case is the Supreme Court's East River decision, which has been so influential it has been cited over a thousand times. This is not an obscure doctrine or obscure admiralty court that is issuing this ruling.

The Plaintiffs' position says you have to give us 52 cases before we will give you one. We just want one case that says between two sophisticated commercial parties with the ability to allocate risk, a claim for simple refund based on the premise that the product wasn't as represented in your warranty states a tort claim. Not one case have we received yet for that.

THE COURT: All right. Question for the Plaintiffs: Defendants argue that any Plaintiff seeking monetary damages for personal injury must assert their claims through the master personal injury complaint, not the class complaints.

You disagree with that position and state that "the MPIC is not a class complaint, and adding those claims there would not streamline this MDL." That is in your response at 24. PTO number 31, that's one of the pretrial orders the Court entered, states that "Plaintiffs shall file a master personal injury complaint on behalf of all Plaintiffs asserting personal

injury claims." That is page 2 of PTO number 31.

Of what consequence is it that the MPIC is not a class complaint?

What would be the impact if the Court ordered that all of the personal injury claims are to be asserted in the MPIC? Question for the Plaintiffs.

MR. HEINZ: This is Noah Heinz.

I think our main point there was simply that it wouldn't add to the efficiency to move the claims in that direction.

The more fundamental point, though, is we don't think these claims are personal injury claims within the sense meant by the Court in the pretrial order. It seems that the distinction was meant to be the type of trial that would be required, the type of proceeding to generally streamline it, not that it is a particular kind of injury that underlies a medical monitoring claim.

We think if that order were to be entered, it seems like it would not add efficiency, it would just be maybe clearer insofar as it restricts all of the injuries technically to one place, but it wouldn't actually conceptually fit with what this Court has been trying to do.

MR. KELLER: Your Honor, Ashley Keller for the Plaintiffs.

Your Honor obviously knows what you meant by your

order better than I do, but perhaps being a little bit too priggish, I would emphasize the word "personal" in personal injury. The medical monitoring claimants are proceeding in a putative class action, so obviously they have their own personal injuries, but they are proceeding in a representative capacity on behalf of others.

So, our understanding of the order was that you didn't mean for the master personal injury complaint to include class allegations, but obviously it would be a housekeeping matter, and if you prefer us to move medical monitoring claims over to the MDIC, we could amend and do that and accommodate whatever your Honor thinks is the most efficient way to proceed.

THE COURT: Thank you. Did the Defense have any response to that answer?

I guess included in the question, how, if at all, would restricting all personal injury claims to the MPIC streamline the MDL?

MR. WINTERS: Your Honor, we think it would streamline the MDL and it would do so in a very nice fashion. Right now we are looking at claims splitting apparently. I have personal injury, but I am not bringing a personal injury complaint. You can't do that. What happens then if one of these people develop cancer; are they then going to be able to also bring a cancer personal injury complaint, or was that subsumed by this consumer class, which, you know, also includes people who don't

want medical monitoring or won't qualify for medical monitoring or can't have medical monitoring?

So, if you are going to claim that I have personal injuries and that entitles me to damages, including medical monitoring, then the place to bring that where it can be most efficiently dealt with is on the personal injury side, not as part of an amalgamation of a consumer class action where the linchpin of your argument is that I bought a worthless product.

MR. HEINZ: May I briefly respond to that, your Honor?

THE COURT: Has either side had experience in any other MDL, for example, as to where medical monitoring claims have been brought, whether they have been brought in class consumer master complaints or personal injury master complaints? No.

Okay. Mr. Heinz, did you want to make a point?

MR. HEINZ: I did want to respond to the charge that there is claims splitting, and that would depend on the substantive state law in most states, and perhaps all, I am not entirely sure, but in most states that allow medical monitoring it doesn't subsume or preclude a subsequent claim of another sort. We don't think that would actually be a problem under the laws of the specific states that do allow medical monitoring.

THE COURT: Okay. All right. Thank you so much. That was a long session, and that concludes that session.

Given the hour, I am sure everybody -- Ms. Stipes can use a break. We will take a 15-minute break. We will all be back at 3:45. Stay logged into the meeting so we don't have to readmit you, but turn your video off and audio off. We will be back in 15 minutes for the last motion that will be heard today, which is 1585.

(Thereupon, a short recess was taken.)

THE COURT: Okay. Our next and last motion for the day is Docket Entry 1585, brand name manufacturer Defendants' Motion to Dismiss Plaintiffs' innovator liability claims and incorporated memorandum of law.

If we could have the Defense counsel turn their videos on. They have done that, and you will get 18 minutes for this motion.

Would you let me know how -- first, if you could introduce yourself for the record, and then let me know whether you want to save any time for rebuttal and whether you want any warnings.

MR. CHEFFO: Thank you. This is Mark Cheffo, I am with my colleague, Jonathan Tam. The way we wold like to break it down, with your Honor's permission, is Mr. Tam will take the first three minutes, I would like to go for about ten minutes and reserve five minutes. I will try to time myself. If I do go over, if you'd let me know, that would be great. If I go over a minute or so I will take it off my rebuttal.

THE COURT: So, 13 and five?

MR. CHEFFO: Yes.

THE COURT: All right. Okay. With that, then, you may proceed.

MR. TAM: Good afternoon, your Honor, my name is Jonathan Tam, I am from Dechert and I represent GSK. Today, as Mark indicated, I will set the stage for the brand manufacturers' Motion to Dismiss --

THE COURT: Hold on. We couldn't go the whole day with perfection of our technological systems here.

Mr. Tam, can you try talking again. That was your dress rehearsal. Now you get to start all over again. Okay.

MR. TAM: Thank you, your Honor. Plaintiffs claims should be dismissed for a very simple reason, it is undisputed that the brand manufacturers did not manufacture, market, distribute, or sell the generic Ranitidine that the Plaintiffs allege they ingested.

Courts around the country have rejected innovator liability claims because they violate a bedrock principle of products liability law, that is, the Plaintiffs must assert that the Defendants' product caused the Plaintiff's injury.

The Eleventh Circuit in Guarino recognized the overwhelming national consensus that a brand name manufacturer cannot be liable for injuries caused by the ingestion of a generic form of a product. Indeed, your Honor has also

dismissed innovator liability claims. In the Dietrich case your Honor ruled a product manufacturer cannot be held liable under any theory of liability if the Plaintiff never used that manufacturer's product.

That is precisely the issue that we have here. Your Honor's decision is in line with more than 100 decisions nationwide, including seven Federal Courts of Appeal that have rejected innovator liability, and the 48 states that have either rejected it or not expressly adopted the theory.

Now, Plaintiffs don't engage with the mountain of authority rejecting innovator liability; instead, they invite this Court to be the first in the country to recognize that theory in dozens of jurisdictions and this Court should decline that invitation.

Under the Erie doctrine and under the Guarino case, Plaintiffs have the burden to identify an authoritative case in each state that directly recognizes innovator liability, and with the exception of two states, California and Massachusetts, Plaintiffs have not met their burden, far from it.

Outside of those two states, innovator liability is simply not a cognizable claim and this Court should join the overwhelming national consensus in rejecting that theory.

Now, for California and Massachusetts Plaintiffs, there are two independent bases for dismissing those cases. The first is that the Court lacks personal jurisdiction over

the brand manufacturers, and Courts, including in the recent Henry decision, have recognized the lack of personal jurisdiction is a bar to innovator liability claims.

Second, another independent reason is that applying California and Massachusetts law to a brand manufacturer's out of state conduct would violate due process.

With that, your Honor, I am going to pass the baton to Mr. Cheffo. Thank you.

THE COURT: Okay, thank you very much.

MR. CHEFFO: Good afternoon, your Honor. I am Mark Cheffo and I represent GSK, but I am going to present the argument in connection with the innovator liability issue on behalf of the brand manufacturers. I will reserve five minutes.

Your Honor, in a pre-motion or pre-hearing order, indicated that you would like to hear, among other things, the jurisdictional issue, so if it's okay with the Court, I will jump in and start right there.

Lack of personal jurisdiction is an independent grounds (inaudible) all innovator liability claims across all of the remaining states. Your Honor knows that some of these states have been conceded by the Plaintiffs. This issue applies in all of those remaining states.

Because California and Massachusetts are the only states that recognize innovator liability, as you just heard

from Mr. Tam, we did in our briefing and will today talk about the Plaintiffs from those states, but as I indicated, this argument would apply, the jurisdiction, across the various other jurisdictions.

The U.S. Supreme Court's 2017 decision Bristol Myers Squibb is directly on point and is very instructive here for this jurisdictional issue. Before I get to that, a predicate is also an Eleventh Circuit decision that we cited in our brief, it's the jet charter case, and what the Court said was that a Federal Court sitting in diversity can assert personal jurisdiction over the defendant only if the State Court in the forum could do so.

Because the State Courts here cannot assert personal jurisdiction over the brand manufacturers for the California and Massachusetts innovator liability claims, consistent with the Supreme Court's ruling in BMS, this Court, respectfully, does not have specific jurisdiction for those claims.

There are, as you have seen in the briefing, I think it's five Plaintiffs who have actually brought lawsuits in certain jurisdictions which are the principal places of business. These arguments apply to the crushing number or overwhelming majority with respect to the claims asserting in innovator liability.

Now, as a threshold matter, California and Massachusetts Plaintiffs must first establish specific

jurisdiction over the brand name manufacturers. Specific jurisdiction is present only if the claim, quote, "arises out of or relates to the Defendant's contact with the forum." That is the heart, the principle of the Bristol Myers Squibb Supreme Court decision.

The Court also said there must be affiliation between the forum and the underlying controversy, principally an activity or occurrence that takes place in the forum state and therefore -- it is therefore subject to the state's regulation, again the BMS decision.

The problem here is that the Plaintiffs have not alleged suit related contacts in California or Massachusetts. The Plaintiffs can only establish specific jurisdictions for claims involving Ranitidine products that the brand name manufacturers actually made and/or sold and where the Plaintiffs purchased them and consumed them in their home states. This is black letter tort 101, your Honor, and that is why we have only seen this doctrine recognized in so few jurisdictions.

In those cases where the manufacturer manufactured, sold, there was consumption, and there was purchase in the states, the brand name manufacturers "purposely availed themselves of the privilege of selling Zantac in the Plaintiffs' home state and the claims arose out of those activities."

Plaintiffs have no suit related contacts for claims based on generic Ranitidine because the brand name manufacturer did not manufacture or distribute those products. These are different than your traditional tort claims. The generic Ranitidine reached the Plaintiffs' home states solely through the actions of the generic manufacturers. The Supreme Court has said multiple times that "unilateral activity of a third party" (inaudible).

THE COURT: Wait, Mr. Cheffo. You are freezing from time to time. I think it might be your system, not mine, but I don't know for sure.

Pick up with the Supreme Court said multiple times. Ms. Stipes thinks if you speak a little slower that might aid in the issue of you freezing.

Try to pick up from where you just left off.

MR. CHEFFO: Yes, your Honor, thank you. I will try to slow down. I apologize if it is on my end.

The Supreme Court has repeatedly held that "unilateral activity of a third party," in this case the generic manufacturers, "cannot satisfy the requirement of contact with the forum state." And that is the Walden versus Fiori case, 2014.

So, a growing number of Courts have also rejected specific personal jurisdiction in cases relying on innovator liability claims. Mr. Tam referenced the Henry case.

THE COURT: Wait, wait, Mr. Cheffo. You did freeze.

You stopped where it said Mr. Tam recognized or -- I think there might be an internet connection issue on your end. No problem, so we will have to take it step by step so we don't miss anything. Pick up the sentence with Mr. Tam.

MR. CHEFFO: Of course, as Murphy's Law would have it, I had a perfect connection until I get to argue today. I am sorry for that.

Mr. Tam referenced the Henry case. The Henry case is important because it is a California case from the Eastern District of California, and it is a recent case from March 31, 2020. In the Henry case, there was no jurisdiction because, quote, "the attenuated legal theory of innovator liability" --

(screen freezing.)

THE COURT: Hold on. Hold on. It happened again. I think the last word we caught was attenuated theory. If you go to audio only, maybe that will help, because you freeze and the audio also freezes. Do you want to try that?

I stop the clock each time this happens.

Pick up with that sentence again that I just said. That was the last we caught.

MR. CHEFFO: Yes, your Honor. In the Henry case, there was no jurisdiction because the attenuated legal theory of innovator liability did not tie Plaintiffs' claims to Defendants' activities in California, and the same is true

here.

The Plaintiffs have tried, unsuccessfully, to distinguish the Henry case really on two grounds. First, the Plaintiffs claim that Henry sued the ABA holders of a medication that was not bioequivalent to the drug at issue. That is not correct. The Plaintiffs in Henry took a generic medication alleged that was "virtually identical" to and had the same chemical formulation as the brands, so it is a consistent case.

The Plaintiffs also focus on the difference, or the perceived difference in the scope of marketing between the Henry case and what may have occurred here, but again, that is a distinction without a difference. It just goes to degree, not substance.

The only conduct by the brand name manufacturers that is arguably relevant to the innovator liability claims, the labeling decisions, did not take place in California or Massachusetts. There is no allegation that that occurred. Plaintiffs never alleged that the brand name manufacturers took any actions in California or Massachusetts that affected the content of generic Ranitidine labeling.

What the Plaintiffs try to do is essentially create a bit of a slippery slope or a parade of horribles by suggesting that it is the brand name manufacturers' position that Court's will not have personal jurisdiction in any traditional failure

to warn claim since manufacturers make their labeling decisions at their headquarters and then let third parties distribute the medications, but that is not the case at all, your Honor.

We recognize traditional legal theories, and in the standard product liability cases there is a jurisdictional nexus between the manufacturer that made the medicine, sold the medicine, found its way to the home state, and where the Plaintiff actually used an alleged injury. That is not the case with any of these innovator liability claims.

My final point with respect to the jurisdictional issues is, the Plaintiffs argue that there was some jurisdictional nexus created by prior marketing before there was generic products available, but in order to establish specific jurisdiction over the brand name manufacturer based on marketing activities, Plaintiffs would have to show that, one, such marketing of brand Zantac somehow caused them to take generic Ranitidine, that is the Waite Eleventh Circuit case.

They would also have to show the second prong, that the brand name manufacturers should have foreseen years or even decades before that their marketing of brand name Zantac in California or Massachusetts would expose them potentially to product liability suits based on the generic Ranitidine equivalent. That also is from the Oldfield versus Pueblo case in the Eleventh Circuit, 2009.

Plaintiffs have not made either allegation. Any

causal relationship between the alleged tort in this case and brand name manufacturers' advertising is too remote.

Your Honor, you have been gracious enough, I know you have given me a minute or two, I would just touch upon the innovator liability and then turn it over to my colleagues on the other side to address.

What I would just point out, and I think Mr. Tam did a fine job of setting the table here, despite Plaintiffs' claims that innovator liability is the majority view, it has only been accepted in California and Massachusetts. Plaintiffs are asking this Court essentially to go where no Court has gone before. They are asking this Court to be the first in the country to recognize innovator liability in 33 jurisdictions still at issue.

And notably, in response to the retailers' Rule 12 motion, Plaintiffs asked this Court to take a restrained view of its Erie predictions, yet here they are asking the Court to make new law and go farther than any Court has gone before.

We have cited the case law that we respectfully submit holds that the Court should not predict that a state's highest court would break from traditional tort principles in the absence of a clear directive, and it really is a bedrock principle of product liability law that a Plaintiff has to use the Defendant's product in order to bring such a lawsuit, and your Honor, albeit under Florida law, in the Dietrich case came

to precisely that conclusion.

Now, in conclusion --

THE COURT: You are -- Mr. Cheffo, you are at 14 minutes. I just wanted to let you know.

MR. CHEFFO: Okay. In conclusion, your Honor, we have cited a mountain of cases, there are a hundred cases that go this way, the Guarino case, the Darvon Darvocet, the Henry case and others. We don't think that the way the Plaintiffs have distinguished the cases that they have conceded is distinguishable from the cases that they have not, and as Guarino said, there's a mountain of evidence that rejects innovator liability.

Thank you, your Honor.

THE COURT: Okay, thank you. You used 14:30 of your 18, so you have some time left.

All right. Let's have the Plaintiffs' counsel come on, and state your name for the record and you have a total of 18 minutes.

MR. LONGER: Good afternoon, your Honor, Fred Longer on behalf of the Plaintiffs. I would like to introduce Je Yon Jung, who is one of our fearless members of our Leadership Development Committee. This is her first MDL and it will be her first argument in this MDL, but she is ready to go. Take it away, Ms. Jung.

THE COURT: Great. Thank you so much.

MS. JUNG: Your Honor, may I test my PowerPoint to ensure that it is up?

THE COURT: Sure.

MS. JUNG: Do you see my screen, your Honor?

THE COURT: I do, yes. Okay, you are all set.

MS. JUNG: I need to move my gallery out of my way.

Good afternoon, your Honor. May it please the Court, Je Yon Jung on behalf of the Plaintiffs and the Plaintiffs Steering Committee.

Defendants posit three arguments in their Motion to Dismiss. First, they contend that no jurisdiction other than California and Massachusetts recognizes Plaintiffs' negligent misrepresentation.

Second, they contend that there is no personal jurisdiction available over the Defendants.

Third, they contend that due process is offended by holding them accountable under the laws of California and Massachusetts.

Before I turn to responding to the Defendants' specific arguments, it is important to lay out the framework of the issues before the Court. What is the correct way for the Court to go? Is it really going where no one else has gone before?

When you distill this case down to the basics, the brand name Defendants must be responsible for this warning

label, for their warning label for the brand and generic drug users here. The Defendants' perverse and unreasonable position is that nobody is responsible for the Plaintiffs' claims for negligent misrepresentation. That simply cannot be the case.

The resolution of this Motion to Dismiss is not as complicated as Defendants claim, and not as novel. The correct way for this Court to resolve this motion requires us to take a step back, dispense with fancy fictional terms like innovator liability, and go back to our first year of law school, as Mr. Cheffo said, civil procedure and torts 101.

We have a clear framework for this Court to resolve the Defendants' Motion to Dismiss. With the Hatch-Waxman Amendment and the Supreme Court cases, namely Wyeth and Mensing, what the Federal framework does is that it provides a number of indispensable and key facts.

What do we know? We know that this pharmaceutical industry is highly regulated, perhaps an unprecedented level of regulation. We are talking about generic drug products that very likely affect every single person at some point in their life. These drug products are ingested or otherwise delivered into our bodies. These drugs can be dangerous and potentially deadly. In this case, we are talking about a drug, Zantac, that causes cancer.

There is no greater imbalance of information than the one between the brand name manufacturer and the consumer. The

brand manufacturer is the expert, they are the one that created the warning label related to the generic consumer, who is innocent. In fact, this drug product is so highly regulated that the Federal regulatory scheme mandates, mandates that before a new drug is approved the brand name manufacturer must ensure the drug is safe and effective and that the warning label accompanying that alleged safe and effective drug is accurate and adequate, which duty continues through the life of the drug.

The brand name manufacturer is always responsible for its warning label. That is the responsibility it acquired when it received the exclusive monopoly benefit with the drug's approval.

Finally, generic manufacturers have the duty of sameness and must use the same warning label as the brand name manufacturer. As the Supreme Court stated in Wyeth, the brand name manufacturer bears responsibility for the content of its warning label at all times. It is charged both with crafting an adequate warning label and ensuring that its warnings remain adequate as long as the drug is on the market.

These are the facts and circumstances and framework that are clear and unequivocal. While the parameters and framework for resolving the question before the Court has been established at the Federal level by the Supreme Court and Congress, all parties agree here that resolution of the

Plaintiffs' specific negligent misrepresentation claims are substantive state law questions in each applicable state.

So, back to the basics. As we said, under Erie, a Federal Judge sitting in diversity must make a substantive law decision for each state. This requires an interpretation of state law, just as this Court stated in its order requiring supplemental briefing. Despite Defendants' characterization, Erie neither requires the Court to expand nor restrict state law. The Court must make a prediction using reasonable evidence available for making this determination, no more and no less.

Other than the six jurisdictions where the issue has already been resolved, the Court will have to make a determination of state law based on relevant evidence such as relevant intermediate state precedence, analogous decisions, considered dicta, scholarly works, and any other reliable data.

The Federal drug policy scheme regarding warning labels creates the duty owed by the brand name manufacturers to the generic consumers. There is no requirement, as Defendants seem to suggest, that a Federal District Judge should not make a prediction if it leads to recognizing a claim on behalf of a Plaintiff in any particular state. That simply is not what Erie requires, and that simply cannot be correct.

We know that the majority of the State Supreme Courts that have considered this issue have found that the brand name

manufacturers owe a common law duty to consumers adjusting generic bioequivalent drugs of the brand name manufacturers' drugs, although the Alabama Legislature abrogated the State Supreme Court in that case. These majority State Supreme Court opinions did what this Court must do and looked to relevant common law principles, and reasoned analysis to arrive at the likely outcome, principles applied to the facts at issue here.

As the majority of State Supreme Courts have done this, the Court must look to available guidance. Plaintiffs have provided at least four common and reasonable considerations where the other Supreme Courts looked at and where it is reasonable to look here. Where you will find guidance, foreseeability, restatement Section 311, restatement Section 552, and Rowland factors, including their public policy considerations.

It is axiomatic that a tortfeasor is responsible for foreseeable harms caused even to a third person based on their misrepresentations.

Plaintiffs' negligent misrepresentation claims are not extraordinary and they are not new theories of liability. Foreseeability has been around for some time. I think we all remember Palsgraf from law school. We are not asking the Court to extend principles of common law, rather, we are asking the Court to apply already existing principles to the facts at hand.

As Judge Sessions in Kellogg versus Wyeth stated in interpreting Vermont law, "to recognize a brand name drug manufacturer's duty to generic customers does not recognize a new cause of action or enlarge an existing one." The Court should not unduly restrict common law principles when there is no reasonable basis for such restriction. A Federal Judge in a diversity case does not equate to an automatic thumb on the scale against Plaintiffs if the State Supreme Court has not already decided the specific facts under its common law.

Judge Sessions again in Kellogg versus Wyeth stated he simply applied the basic precepts of Vermont's negligence law to ascertain whether legally cognizable duty exists, and he concluded that it does.

So, is it foreseeable that a brand name Defendant would owe a duty to generic consumers who rely on the label written by the branded manufacturer? As set forth in Novartis, it is entirely foreseeable that the warnings included, or not included, on the brand name drug warning label would influence the dispensing of the generic drug. It is not speculative, it is not based on probabilities or likelihoods. It is entirely foreseeable.

In fact, it is notable to a legal certainty that it will be liable for any deficiencies in its warning label that will appear in the generics' warning label and liability should follow. It is a mandatory requirement that the warning labels

on the brand name manufacturers' drug warning label will be used on the generic drug's warning label. You can't get around that.

How can a brand name manufacturer have a duty regarding its warning label on the brand name drug, but that duty not extend to any and all of the consumers who must rely upon that label, including generic customers?

The Federal regulatory scheme, coupled with state negligence laws are not intended to place consumers at such an unfair disadvantage. The Seventh Circuit in Peschar succinctly set forth what this Federal framework really means. The Hatch-Waxman Act allows manufacturers of branded drugs to be on the hook for mislabeling on their generic counterparts.

In such a case, the brand name manufacturer can be said to have caused any mislabeling by a generic drug manufacturer even if the branded manufacturer had no hand in the manufacture or distribution of the drug or the warning labels.

Foreseeability is the common thread in any duty analysis, that is the linchpin. It makes sense. It is about fairness and expectations. It also makes sense that applying this age old principle is not difficult to do on the facts before us. The brand name manufacturer's label is the negligent misrepresentation that caused the harm. There are no surprises and it is a legal certainty, they must be the

responsible party.

States that would recognize Section 311 of restatement of torts would find a brand name manufacturer owing a duty here. One who negligently gives false information to another is subject to liability for physical harm. Under Section 311, comment B, even third party harms are covered under a negligent misrepresentation involving risk of physical harm.

Comment C proposes that liability applies to advice given gratuitous and where the actor purports to have special knowledge. All of those factors are at play here.

Defendants' supplemental brief summarily dismisses Section 311 as requiring an affirmative misstatement. That is exactly what happened here. The brand manufacturers' label affirmatively stated that the drug was safe and effective.

Section 552 of the restatement second of torts provides another strong indication that brand name Defendants should be held responsible for harms resulting from negligently supplied information. The brand name manufacturer, in the course of its business, supplied false information to the generic drug users, and they suffered injury and loss because of the failures in the brand name manufacturers' warning labels.

These are not new principles, but they are principles that must be applied under these fairly unique circumstances

that the Federal regime created where the brand name manufacturers' warning label must be used by the generic manufacturers. Essentially, the brand name manufacturers set in motion the Palsgrafian bomb that harms the generic consumer across the train tracks, and it knew that it would.

Another strong indicator in consideration for finding state law liability are the Rowland factors or their equivalent. We identified six states and Puerto Rico that have followed and applied the Rowland factors for determining the law of products liability. Not surprisingly, the Rowland factors emphasized foreseeability prominently in their analysis.

In addition to foreseeability, it is notable that three of the Rowland factors emphasize public policy considerations. These public policy considerations are of no small importance here. These squarely land in favor of the Plaintiffs and against the brand name Defendants.

If the legal and Congressional framework tells us nothing else, it tells us that the consumer should be protected and prioritized over the brand name manufacturers. The brand name manufacturers are not innocent unwitting partners here.

They not only have the legal duty and responsibility for the warning labels, they should also have the moral blame when injuries result from those very warning labels. They are the only ones that can change the warning label and prevent

harm.

Brand name manufacturers already have a continuing duty to warn of the potential risks as soon as there is reasonable evidence of hazardous association with a drug and a causal relationship need not have been proved.

By virtue of the Federal framework, brand name manufacturers owe a duty to both its own consumers and the consumers of the generic drug. The generic consumer who develops cancer by relying on the brand name manufacturers' inadequate warning label is innocent.

Outlined in our supplemental brief we identified 35 jurisdictions where this Court's review should find viable Plaintiffs' claims and duties against the brand name manufacturers and follow the majority view given common and reasonable evidence.

In sum, when the Court conducts its Erie valuation just as it should, and not the Defendants' false presumption that Plaintiffs should not be able to recover against anyone for their injuries, there is no other entity that can legally and morally be responsible for the Plaintiffs' claims but for the brand name manufacturers.

Now I will move to the Defendants' second argument, which is about personal jurisdiction. Our suit arises out of the brand name manufacturer Defendants contacts with the forum states.

Brand name manufacturer Defendants, at a minimum, provided warning labels that were included in the products that were marketed and are sold in every forum state at issue. The offending contact at issue is the warning label that was marketed by the brand name manufacturer Defendants in the forum states. The contact is not, as the Defendants claim, the decisions regarding the warning labels.

If you follow Defendants' argument to their conclusion, their position is that the brand name Defendants cannot be sued anywhere by users of the generic version of its drug, not in home states, not in states where they marketed and sold their product, not anywhere.

In fact, even if the brand named Defendants home states conducted choice of law analysis and decided to apply California law, for example, somehow Defendants reject that decision as well.

No brand manufacturer could claim that it could not reasonably anticipate that it would be hailed into court where they sold and marketed with the warning label in every corner of our country and commonwealth territories. Indeed, Defendants' motion at page ten concedes that there is sufficient jurisdiction where they did business and where they sold their product.

As well pled throughout the Plaintiffs' PI master complaint we clearly allege that the brand name manufacturer

Defendants' conduct in the forum state establishes personal jurisdiction. Plaintiffs are not referring to any third parties or even the generic manufacturers' contacts in the forum states. It is the brand name Defendants' sales efforts and warning labels that entered each state at issue here which created the market, by the way, for the generic drug users.

Defendants' curious position that it only made warning labeling decisions in their home states is not present anywhere in the Plaintiffs' master complaint and they mistakenly suggest that Defendants did not expect their warning label to be included in every bottle and package disseminated throughout this country. That is contrary to Federal statute and law.

Importantly, in addition to the specific jurisdiction concessions brand name Defendants already made, they also concede general jurisdiction. The only question that remains in those home states court's decision is whether another state's law, i.e. California or Massachusetts for example, should apply. This is the standard choice of law analysis.

Finally, the third argument Defendants make is that due process is also offended by holding Defendants liable for activities in California and Massachusetts. The due process analysis also employs a minimum contact analysis and for the same reasons the Defendants' arguments fail regarding personal jurisdiction, they fail here as due process is satisfied. Defendants' conduct is the same liability inducing conduct at

issue in Plaintiffs' negligent misrepresentation claims, and Defendants concede jurisdiction.

Defendants are taking the unreasonable and unsupported position that the claim cannot be pursued against them anywhere, even in their home states, and not even after a choice of law analysis. That is not what due process means.

In conclusion, your Honor, this Court cannot ignore the Federal framework through which the substantive state law reviews must be completed. If Defendants' arguments are believed, there is no state where Plaintiffs can bring their claims and no entity against whom to bring their claims.

It truly would be a perverse result for this Court to adopt the Defendants' position here within the clear Federal framework under which the brand name manufacturer is responsible for the warning label, but not responsible for the injuries that result in the misrepresentation of that very warning label. That is not an acceptable result and Defendants' Motion to Dismiss should be denied.

Thank you, your Honor.

THE COURT: Thank you very much.

All right. Defense has about three minutes and a half -- three and a half minutes for any rebuttal.

MR. CHEFFO: Thanks, your Honor. I will keep my picture off.

Briefly, your Honor, if these claims were so

established and so well recognized, as we just heard, these very skilled lawyers who are representing the Plaintiffs would not have conceded the 15 jurisdictions out of the box before we even argued this today.

According to cases, a hundred cases, including from the Sixth, Eighth, Tenth, Eleventh Circuits have rejected these claims. We still haven't heard a discussion of Guarino other than, essentially, a footnote in their brief or the Darvon case.

Basically, their entire argument is largely for both personal jurisdiction and with respect to the innovator liability rests on foreseeability. The Eleventh Circuit did not base its decision in Guarino on foreseeability principles, rather, the Court, like many others, rejected that innovator liability theory because it seeks to impose liability on a company for injuries caused by a product the company did not make, a result that has no basis in Florida law, citing your Honor's decision.

Similarly, the Darvon, Darvocet case doesn't rely on foreseeability. When the Sixth Circuit affirmed dismissal of innovator liability claims for 22 different states it did so not because the claims lacked foreseeability, but because the claims lacked pleading or proof.

Essentially, the Sixth Circuit acknowledged that it was foreseeable that purchasers of generic medication would

rely on the brand name label giving the regulatory requirement that generic product labels follow the brand, but nevertheless, the generic customers alleged injuries were not the foreseeable result of the brand manufacturers' conduct, so said the Sixth Circuit, but of the labeling laws under which the brand manufacturers have no control, this is from the decision, because none of the states where the Plaintiffs lived had departed from the "well settled threshold requirement that the Plaintiffs assert that the Defendants' product caused the Plaintiffs' injury, the Plaintiffs claims failed as a matter of law," foreseeability notwithstanding, your Honor.

The restatement arguments, just briefly, the first that was cited, it basically is inapplicable here. It talks in terms of a specific misrepresentation. This case, at best as to the labeling issues, is with respect to a failure to warn.

The 522 section, which, by the way, was not cited in any of the cases that -- the two cases that adopted innovator liability, California and Massachusetts, is not cited, but nonetheless, it deals with pecuniary interest.

With that, your Honor, I think I am going to stop and your Honor, I am sure, will have some questions for us.

THE COURT: Thank you. Yes. Everybody can -- all counsel on this motion can turn your video and audio on. Mr. Cheffo, if you prefer to keep your video off, that is fine, too.

This is a question for the Defendants. Your Motion to Dismiss does not refer to any Federal Rule of Civil Procedure. Under which Federal rule or rules are you moving to dismiss.

MR. CHEFFO: Under 12(b)(6) with respect to the innovator liability claims and 12(b)(2) with respect to the jurisdictional claims.

THE COURT: For the Plaintiffs: In your response, it does not appear that you respond to the Defendant's arguments regarding a fundamental principle of products liability law.

For a Plaintiff to assert a valid products liability claim, the Plaintiff must allege that they were injured by a product manufactured, distributed, or sold by the Defendant. This principle is known as product identification.

Rather, you say that, quote, "the MPIC asserts valid claims sounding in negligence and negligent misrepresentation," end of quote, and then you proceed to discuss at length why brand name manufacturers owe a duty of care to generic Ranitidine consumers. That is your response at page 9.

As supporting authority you cite to Section 311, as you showed the Court here today, of the restatement second of torts which discusses negligent misrepresentation, and you cite also to the same California Supreme Court case that you highlighted here today, T.H. versus Novartis Pharmacy Corporation -- Pharmaceutical Corporation, 407 P.3d 18 California, 2017, in which the Court held that the generic

consumer's negligence and negligent misrepresentation claims against brand name manufacturers were viable.

You also cite to the Massachusetts Supreme Court case Rafferty versus Merck and Company, Inc., 479 Massachusetts 141, 2018, in which the Court held that the generic consumers could proceed against brand name manufacturers on a very limited theory of recklessness for failure to warn. The Court notes that the Massachusetts Supreme Court held that the Plaintiff's consumer protection and general negligence claims were not viable.

So, as to claims sounding in negligence and negligent misrepresentation, the Court construes what Plaintiffs categorize as valid claims "sounding in negligence and negligent misrepresentation" to include Counts 4, 5, 6, 7, and 8, negligent failure to warn, negligent product design, negligent manufacturing, general negligence, and negligent misrepresentation.

I want to ask whether that interpretation is correct for the Plaintiffs.

MS. JUNG: Your Honor, with respect to -- I am sure Mr. Longer will jump in -- the negligent misrepresentation claims here, we are talking about the cases where we have warning label that was used by the generic manufacturers because of the brand name manufacturers, so if you have the negligent misrepresentation, it would be the negligent

misrepresentation of the brand.

So, to go back a little bit on the state issue, we have to look at the specific states and the specific common law in those particular areas to identify if there is a narrower common law than in the other states, and we believe that the 35 jurisdictions would allow for the negligent misrepresentation claims here.

THE COURT: Right, but I want to make sure I understand as to which counts. You talk about claims sounding in negligence and negligent misrepresentation. I want to be very, very clear, are those referring to Counts 4, 5, 6, 7, and 8 of the complaint?

MR. LONGER: Your Honor, if I may jump in, Fred Longer. We are referring more specifically to Counts 7 and 8, just the negligence and negligent misrepresentation counts.

THE COURT: When you say more specifically, just 7 and 8, not 4, 5, 6?

MR. LONGER: That's correct.

THE COURT: As to strict liability claims, Counts 1, 2, and 3 are labeled as strict products liability claims. That's in the personal injury complaint, paragraphs 453 to 499.

Question for the Plaintiffs, do you concede that these claims would fail under your theory of liability for lack of product identification?

MS. JUNG: I am fairly certain Mr. Longer is dying to

answer this question, so I will pass it to him.

THE COURT: Okay.

MR. LONGER: Fred Longer, your Honor. In a word, never.

THE COURT: Have any Courts held that strict product liability claims are viable under your theory of liability?

MR. LONGER: I am not aware of any that are directly on point, your Honor. I am aware of some jurisdictions that have provided that both -- that our theory survives even in a strict liability jurisdiction because they also recognize negligence, and these claims transcend from strict liability into negligence theories, which is why they are being pursued as such under the negligence and negligent misrepresentation counts of the complaint.

THE COURT: Right, but I am talking now about the strict liability claims.

MR. LONGER: So, again, we are -- we are pursuing these from a negligence standpoint. In jurisdiction that only apply strict liability, I believe that -- and Mr. Cheffo raised this -- there were 11 jurisdictions that we are not pursuing this claim in because they are either strict liability jurisdictions or there is a product liability act and the like.

THE COURT: Mr. Cheffo, did you want to respond?

MR. CHEFFO: Just to say, your Honor, it's -- so, I understood that at least they were largely proceeding in

California, but one of the issues I think we had is to try to understand, if you will -- I don't mean to be pejorative -- but kind of where the lines the Plaintiffs have drawn. For example, there are four states where the Plaintiffs have conceded this issue where the highest Courts rejected innovator liability, so that is relatively straightforward.

There are seven states where the Plaintiffs do not contest -- concede this issue where the product liability statutes require product identification. But of the remaining states at issue, there is also Colorado, Connecticut, Mississippi, Oregon, North Carolina that have similar statutes that also warrant rejection of the innovator liability for lack of product identification. In other words, in addition to the ones they have looked at, there are actually many others.

They basically conceded four states where they don't contest this issue where intermediate Courts, Federal Courts applying the law have rejected innovator liability, but then you look at the remaining states and 22 of those have case law from intermediate, state, or Federal Courts explicitly rejecting the theory.

I can give you those, if you'd like, your Honor, there are 22. I don't want to drive the Court Reporter crazy if not necessary.

To us, it is all of the cases, but even within the framework and the rubric the Plaintiffs have set out in terms

of their concessions it is hard to draw parallels for us.

THE COURT: Mr. Longer, I want to be clear, you are not arguing that you can pursue a strict liability claim under a theory of negligence, correct?

MR. LONGER: We are not pursuing a strict liability claim under a theory of negligence. They are distinct theories, your Honor, and the theory behind what the Defendants and what everyone is calling innovative liability is a negligent misrepresentation claim. It is not a strict liability claim.

Some jurisdictions that apply strict liability may allow for this theory still to be pursued.

THE COURT: Do you have an example of a jurisdiction that would allow a strict product liability claim to be pursued? I am just wondering why you are persisting in Counts 1, 2, and 3 against the brands and trying to understand --

MR. LONGER: So, the -- I am thinking it is Nevada, your Honor, but I may be mistaken on that. Let me just look.

I don't have that at my fingertips, your Honor, but certainly in our supplemental briefing we address those jurisdictions that still apply strict liability, and the claim has sufficient authority within that jurisdiction to allow the claim to permit -- to proceed.

THE COURT: If there were no jurisdictions, upon the Court's review, that permitted a strict product liability claim

to proceed under the theory of liability that you are putting forth for lack of a product identification, would you agree at that point that, at a minimum, Counts 1, 2, 3 that are labeled strict liability claims wouldn't survive?

MR. LONGER: I'm struggling with the question because of the premise, your Honor. The strict liability theories that we are pursuing are, in essence, about failure to warn, negligent -- I am sorry, failure to warn, design defect, and manufacturing defect.

The claims regarding, let's call it innovator liability are not presented within those counts. They are presented in Counts 7 and 8.

So, that is the disconnect. I'm sorry, I am trying to answer your Honor's question directly, but I am struggling with the question because --

THE COURT: Okay. So, you are only proceeding -- I guess that would also take care of breach of warranty claims, Counts 9 and 10? In other words, you are not -- or Count 11, violation of consumer protection, deceptive trade practice laws, or unjust enrichment in Count 12, none of those are --

MR. LONGER: They are not at issue on this theory of recovery.

The theory of recovery, the essence of this claim, is a negligence theory, so that is why we allege negligence and negligent misrepresentation. That is Count 7 and Count 8.

So, if you go back to the Novartis case, the California case, and the Rafferty case that your Honor mentioned, it is in our briefing, the essence is still negligence. Massachusetts went a little bit further and said they wanted a recklessness standard, but they still went back to squares in terms of establishing that the foundational building blocks of this claim are negligence.

And in part, that is because the -- there is this product identification principle that I have heard Mr. Cheffo describe, I know it is in the Darvon and Darvocet case, and your Honor mentioned it, it is -- that is embedded in Florida law, and I am sure your Honor is more than familiar with that issue having drafted the Dietrich opinion. But, again, those -- that is not the foundation of this claim.

In those states where you must pursue -- or must have purchased the Defendant's product, that is not the 35 jurisdictions that we have announced. I heard Mr. Cheffo say that there is, I think five jurisdictions where there are product liability statutes on the books similar to others, however, what he didn't mention is that there is case law interpreting those statutes not to require product identification or what I call privity analysis.

So, there are distinctions, there are nuances throughout the jurisdictions, 35 at issue here, and it's -- you have to look at each one and see whether or not those states

provide the indicia that are sufficient and supportive of the claim, and if there is indicia -- and obviously we disagree that you have to have authoritative decision that directly recognizes the claim. That is putting the thumb on the scale.

I heard Mr. Tam make that representation. That is certainly not the law, that is not even what for Guarino says.

Guarino does not require that, Guarino just says that you have -- when attempting to forecast state law, you can't venture into unchartered waters of state substantive law, and then it cites to the Douglas Asphalt case, which says that you can't expand state tort law absent state authorities suggesting the propriety of doing so.

We have given your Honor a number of authorities where there is more than propriety of doing so, there is ample authority, and I could give those examples right off the top of my head.

THE COURT: Let me see if I can get to the bottom of some confusion.

So, in the conclusion of the Defendants' motion, page 20, it says, the brand name manufacturers respectfully ask this Court to dismiss all innovator liability claims asserted by Plaintiffs in this MDL.

So, what did the Defendants have in mind when they said all innovator liability claims? Did you know which claims, counts you were referring to at the time of writing

that conclusion, or do you know now?

MR. CHEFFO: I think we have some clarity based on your Honor's questioning, so I will try and answer your question directly. Our bottom line was to cover the waterfront for all the reasons we have talked about. To the extent -- this goes back to the shotgun pleading an other issues. To the extent that any claim was being asserted against us, we were moving on all of them.

What I think we heard from Mr. Longer's response to your question is that they were only asserting negligence based claims, so this may be easy. To the extent that they are not asserting those other claims, as we have just heard, against us -- and frankly, it is hard to understand how they could since these aren't products that were manufactured and sold by a Defendant or used in a state by an individual. So, we think those were are clear.

Now, to the extent that they are based in negligence, for the reasons I said, we think also those should be dismissed, and our understanding was at least the Massachusetts and California were largely negligence based claims, if that answers your question.

THE COURT: So, just to be clear, you weren't clear when you wrote your conclusion, so you left it open when you said all innovator liability claims.

Mr. Longer, I understood you today to say the only

innovator liability claims present in the master personal injury complaint at Docket Entry 887 are Counts 7, which is general negligence at page 119, and Count 8, negligent misrepresentation, at page 124.

So, I should construe the Defendants' motion to really only be directed at those two counts; is that accurate?

MR. LONGER: Fred Longer, your Honor. Yes, and may I add one point, your Honor? We do not present the language "innovator claim."

THE COURT: I know that.

MR. LONGER: Innovator liability does not appear in the complaint. What we are saying is they negligently misrepresented their label and it impacted generic users, and that is the essence of Section 311 of the restatement of torts, and that is what gives rise to liability.

THE COURT: I do understand you have not used that. Where in your response did you make clear that it was just Counts 7 and 8, if you did at all?

MR. LONGER: I don't believe that we felt it incumbent upon us to make that representation. We said very specifically in our negligence and negligent misrepresentation claims and that, I thought, established the principles or the location, if you will, within the master personal injury complaint.

THE COURT: Okay.

MS. JUNG: Your Honor, this is Je Yon Jung. If I may

add one point, this is on Counts 7 and 8, negligence and negligent misrepresentation. Those are on behalf of the brand name manufacturer consumers as well as the generic consumers, so it is for both of those consumers.

THE COURT: Okay. So, Mr. Cheffo, then, are the Defendants, with this clarification, only seeking to dismiss Counts 7 and 8 in Docket Entry 1585?

MR. CHEFFO: Well, so -- no, no, your Honor, because what I -- maybe I am trying to understand exactly what the Plaintiffs' position is.

We are saying essentially all of the claims -- there is only a predicate -- if someone never used the brand manufacturers' product, any claim has to be as a result of innovator liability. Right? We think there couldn't have been claims for design, all of the other claims. I think what we are hearing is the Plaintiffs are saying they are not pursuing those types of claims against the brand manufacturers. So, to the extent that is not clear from their pleadings where they say everything against everyone, then yes, those should be dismissed for the reasons we have heard today.

Your Honor has asked on the merits, to the extent that they are pursuing those claims in addition to the others which your Honor should say are dismissed because they are not being pursued, then on the merits they should be dismissed.

Am I being clear, your Honor?

THE COURT: I am going to go back to the Plaintiff. Are the only claims against the brand manufacturers --

MR. LONGER: Your Honor, Fred Longer. May I speak?

THE COURT: I think we need clarification, the Court does, and the Defendants do.

MR. LONGER: I am having trouble. Can you hear me?

THE COURT: I can hear you.

MR. LONGER: So, we are only pursuing these theories under Counts 7 and 8. The fact that the Defendants' motion was poorly articulated and just said the claims, and they didn't focus on where the claims were presented was not a burden that we felt we had to correct.

What we always said was that our theories are based on negligence and negligent misrepresentation. Those claims are only found in Counts 7 and 8. So, you don't need to dismiss any other claims, they are not even at issue.

THE COURT: Well, I mean, the movant would tell me if they are at issue or not. The movant generally is the one who indicates what is being sought, what relief is being sought.

Again, I go back to the conclusion, the brand name manufacturers respectfully ask the Court to dismissal all innovator liability claims asserted by Plaintiffs in this MDL.

The Plaintiffs are saying the only -- although they don't adhere to the terminology, but we will call it that just for clarity of discussion. The Plaintiffs are saying the only

innovator liability claims asserted by Plaintiffs in the master personal injury complaint are Counts 7 and 8.

And so, my question then is, is that what the Defendants are seeking to have dismissed in their motion, Counts 7 and 8, based on that representation?

MR. CHEFFO: Your Honor, I am glad you are drilling down on it, so I want to make sure that we are clear as well.

Here is what I would say, if what you asked the Plaintiff and what he said is that all of these other counts other than 7 and 8 do not apply to the brand manufacturers, if that is the point, then yes, we are only moving against the ones that they say apply to us.

What wasn't clear is that because the way the Plaintiffs have pled everything here, they seem to allege everything against everyone, so to the extent there are other claims other than 7 and 8 that they are alleging against the brand manufacturers, we think the only way that they can do that, since we didn't make the product or sell the product, is under the innovator liability theory which we don't think applies.

So, to the extent that they are asserting those claims, innovator liability bars them. If they are telling us today that they are not and they never were intending to assert them against the brand manufacturers, then no, we can have a stipulation those are gone and they are not against us.

MR. LONGER: Your Honor, Fred Longer.

This complaint is a master complaint, it pleads against all of the Defendants in this action. Some Plaintiffs who took generic drugs are asserting claims against branded manufacturers under negligence theories, which would be in Counts 7 and 8, but, your Honor, other Plaintiffs in this litigation who are not the ones that we are specifically talking about because -- because those Plaintiffs have other claims against the branded or generic manufacturers.

This is -- the problem with this motion, if you will, your Honor, is that this is a partial -- they are splitting claims. We are asserting claims for negligent misrepresentation. Some of the negligent misrepresentation claims apply to the generic users who were harmed because of the branded label, but a branded user could still have a negligent misrepresentation claim, so you can't dismiss the count because other plaintiffs in this litigation are participating through the master personal injury complaint.

This is a carve out of a theory of liability that encompasses negligence and negligent misrepresentation. It is that thin. There are other negligent aspects to the case that will still proceed even if the Court were to grant the Defendants' motion that we can't state a claim for innovator liability anywhere other than in California and Massachusetts.

It is a poorly articulated motion. We tried to

address it as best we could by saying we are focused on the negligence and negligent misrepresentation foundations that underlie the innovator liability theory of recovery. To that end, I think I have added as much clarity as I can.

Those theories are encompassed in Counts 7 and 8, but they are not the exclusive theories pronounced or described in Counts 7 and 8.

MR. CHEFFO: Your Honor, I am not going to really address the -- that our motion is not clear enough. The reason we have been going back and forth on this for 20 minutes is because the Plaintiffs don't even know who is bringing the claims against who and can't really articulate it, and that has been the problem.

The issue here is that no one is suggesting in a personal injury case, if someone alleges that they used a particular manufacturer's product and sold it, we couldn't be clearer about that, we have other defenses.

To the extent someone is saying I never used this particular product that was manufactured and sold by this particular Defendant, no matter what theory it is, we think no state other than California and Massachusetts, no matter what the theory, no matter what the ground, no matter what the claim is, they should be dismissed.

It is still not a hundred percent clear to me what Mr. Longer is saying. We are over interpreting their complaint and

no one who is asserting innovative liability is ever going to bring a claim against us, and it is only 7 and 8, well, then they can stipulate to that and we can save the Court some time and move on.

For the innovator liability negligence claim, the motion is ripe with respect to Counts 7 and 8. That is really where we can't seem to get an answer from the Plaintiff. Are people who never used products and violate the fundamental principles of tort law and others, are they suing under all these theories or is it just the negligence claims?

MS. JUNG: Your Honor, if I may, Je Yon Jung. There is a lot of confusion. We are talking in the motion about the negligence and negligent misrepresentation that the brand manufacturer made against the consumers. That is the very narrow issue we are talking about here.

However, the other counts and the other claims, there may be claims by brand manufacturer consumers against the brand manufacturer, generic consumers against the generic manufacturers, but this particular issue is only talking about the negligence of the brand manufacturer and the negligent misrepresentation they made on their warning labels that made it to the generic consumers.

THE COURT: Well, the other counts -- assuming for a moment that premise, is it fair to say then the Plaintiffs are not bringing any other count other than 7 and 8 against the

brands, that is of the 15 counts in the personal injury complaint, the Plaintiffs are not bringing any other count other than 7 and 8 against the brands for ingestion of a generic product? The Plaintiffs are not seeking to hold the brands liable under any other count other than 7 and 8 for a product that was manufactured by a generic. Is that an accurate statement?

MR. LONGER: Yes, your Honor. Fred Longer, yes.

THE COURT: Okay.

MR. LONGER: Those theories are -- this is a very narrow aspect of the case. The Defendants have some case law, as we've briefed and as Your Honor knows, in a couple of states -- in Alabama it has been abrogated by statute. The Supreme Court of Alabama found that this theory of recovery is valid and states a cause of action in Alabama except the legislature took it away.

We know in Iowa, because they found that product identification issues under Iowa state law would preclude the claim, they refuse to adopt this theory. The same thing applies in West Virginia, and that is -- that is how narrow this is.

THE COURT: Okay. I appreciate it. I do want to move on to some jurisdictional questions, but this is how I understand it.

The motion was seeking to dismiss innovator liability

claims. I know that is not what the Plaintiff calls it, that is what the Defendant calls it, so I am calling it that because the Defendant is the movant. The only innovator liability claims are 7 and 8. That does not mean that those are the only claims against the brands, but those are the only innovator liability claims against the brands.

So, the motion is directed to 7 and 8, and I suppose to the extent that in another day and another round of briefing, should that be appropriate, I am not suggesting that will happen or should happen, if there are other arguments that the brands have with respect to the other counts, they may be raised, but they have fully addressed their innovator liability claims in their motion, and you are saying, Plaintiffs, that that means that only applies to Counts 7 and 8, right?

MR. LONGER: Correct, your Honor.

THE COURT: Understood, Mr. Cheffo, that makes sense?

MR. CHEFFO: It does. If they are not asserting any claims other than those against us, then we have no reason to move against them other than --

THE COURT: They are not asserting any other innovator liability claims against the brands.

MR. CHEFFO: Yes, meaning people who have not used our products.

THE COURT: Okay. Let's move on because it is late. I didn't expect that amount of time on that question, but that

was important.

So, now, on the jurisdictional issues, Plaintiffs, in paragraphs 21 through 36 of the master personal injury complaint you list the brand named Defendants and the states and countries in which they are incorporated and have their principal places of business, in other words, where they are citizens.

As the Supreme Court explained in Daimler AG versus Bauman, 571 U.S. 117, at 138 to 139, 2014, it is only in an "exceptional case" that a "corporation's operations in a forum other than its formal place of incorporation or principal place of business may be so substantial and of such a nature as to render the corporation at home in that state," and consequently subject to general jurisdiction in that state.

Do you contend that any of the Defendants are subject to general jurisdiction in any state other than the states in which they are incorporated and have their principal places of business as you have listed them in the master personal injury complaint?

MR. LONGER: Fred Longer, your Honor. No.

THE COURT: Okay. Defendants, do you contest any allegations in paragraphs 21 through 36 regarding in which states and countries the Defendants are incorporated and have their principal places of business?

MR. CHEFFO: Your Honor, I don't have all of that in

front of me, there are a lot of Defendants, but I would say generally no. If it is the state of incorporation and principal place of business, we agree those would be one of two places.

THE COURT: Okay. Question for the Defendants: According to paragraph 35 of the master personal injury complaint Defendant Patheon Manufacturing Services, LLC, referred to by Plaintiffs within the category of Sanofi Defendants, is a citizen of Massachusetts because its sole member, Thermo Fisher Scientific, Inc., has its principal place of business in Massachusetts. Thus, Massachusetts would have general personal jurisdiction over Defendant Patheon Manufacturing Services.

Massachusetts is one of two states that recognizes Plaintiffs' theory of liability, albeit in a limited way. Plaintiffs must allege Defendants acted recklessly.

Does Sanofi specifically dispute that Patheon Manufacturing LLC is a citizen of Massachusetts?

MR. CHEFFO: Your Honor, I apologize, that is a fair question, but a very specific one for a client that I don't represent. If one of my colleagues from Sanofi is able to jump in, if not, we can get you that answer expeditiously on what their position is with respect to Patheon. Is that okay, your Honor?

THE COURT: Sure. Is there anybody from Sanofi who is

able to easily pop on?

MR. AGNESHWAR: Your Honor, this is Anand Agneshwar, I represent Sanofi. I believe that is right, but I would need to confirm that. If I could have until tomorrow morning to do that, I will do that and report back at the beginning of the hearing tomorrow if that is okay.

THE COURT: Sure, that would be fine. Thank you.

MR. AGNESHWAR: Thank you.

THE COURT: And I guess just to further contemplate that question, Mr. Agneshwar or Mr. Cheffo, so my question began with whether Sanofi disputes whether Defendant Patheon is a citizen of Massachusetts. If not, my followup question was going to be, how should that impact the Court's analysis on the issue of personal jurisdiction? Are Plaintiffs at liberty to bring claims under their theory of liability against Defendant Patheon Manufacturing LLC?

MR. AGNESHWAR: Yes, your Honor, Patheon is a separate company from Sanofi, it is not a Sanofi company. Sanofi is not responsible for it. So, if counsel for Patheon is on, they might be the one more appropriately situated to answer the question.

It is true that there has been a business relationship between Sanofi and Patheon. I don't think that impacts any claim that the Plaintiffs could make against Sanofi.

THE COURT: Okay. Well, is there counsel for Patheon

on the call?

Well, there was no fair notice in that regard, so that is fine. Maybe one of Defense coleads can pass that question along and maybe that can be addressed tomorrow, if that is all right.

MR. CHEFFO: Yes, your Honor, I will take responsibility to try to do that.

THE COURT: Okay. Great. You will be happy to know I don't have any more questions. Not too bad, it is 5:08.

So, that concludes our hearing day. Thank you, everyone, for your patience and your helpful presentations and engagement with the Court on the Court's questions. I am most appreciative of that.

I look forward to seeing those of you who will be arguing your motions tomorrow. The motions tomorrow will follow the exact same format that we followed today. We should all have an easy time with that.

Pretty much it looks like the order has been set already, 1582 will be argued first, then 1583, 1584, and 1580, and with respect to 1582, 23 minutes for the Defendants and 20 minutes for the Plaintiff, 15 minutes for 1583 for both Defendants and Plaintiffs, 18 minutes for 1584 for Defendants and 15 minutes for the Plaintiff, 18 minutes for the Defendant on 1580 and 15 minutes for the Plaintiffs.

You will let us know who will be operating any of the

PowerPoints, although that all seemed to go very smoothly today as well.

Let me make sure I am not forgetting any administrative matters. We will have you come in at the same time you came in, in the same sequence today with those of you popping on at 9:40, the others at 9:50. Thank you again to liaisons and others who are helping admit participants. There have been quite a few of you throughout the day.

Have a nice evening, everyone, and I look forward to seeing you tomorrow morning. We will begin formally at 10:00 a.m. Have a nice evening. Bye-bye.

(Thereupon, the hearing was concluded.)

* * *

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

Date: December 17, 2020

/s/ Pauline A. Stipes, Official Federal Reporter

Signature of Court Reporter