

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

4 CASE NO. 20-md-02924-ROSENBERG

5 **IN RE: ZANTAC (RANITIDINE)** .
6 **PRODUCTS LIABILITY** . West Palm Beach, FL
7 **LITIGATION.** . December 14, 2020
8 .
9 .

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

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

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

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

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

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

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

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

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

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

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

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

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

11 So, the time allotted for the first motion, 1630, is
12 23 minutes for each side. I say 23 minutes because each side
13 has an LDC, a Leadership Development Committee member, and/or a
14 NextGen participant. There has been discussion, with the
15 Court's endorsement and support, that additional time be
16 offered to any side who has included a NextGen or LDC member,
17 so the Court has allotted and additional 3 minutes.

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

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

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

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

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

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

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

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

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

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

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

8 *THE COURT:* Good morning.

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

12 *THE COURT:* Good morning.

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

17 *THE COURT:* Thank you all.

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

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

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

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

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

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

14 *MR. PETROSINELLI:* That is correct, your Honor.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 result in the dismissal of countless claims. Take, for
2 example, a dozen named consumer class Plaintiffs who allege
3 they purchased Ranitidine containing products starting only in
4 2018. Manufacturers like Pfizer, BI, and many of the generic
5 manufacturers had stopped selling or manufacturing the product
6 long before 2018. These 12 named Plaintiffs also allege they
7 purchased only prescription products. This rules out Sanofi in
8 addition to Pfizer, BI, and many generics. Nevertheless, these
9 12 Plaintiffs bring 314 claims against the companies.

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

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

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

19 *THE COURT:* Thank you, Ms. Hood.

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

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

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

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

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

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

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

4 One is, there are allegations in the complaint that
5 are made against Defendants, probably the best example is the
6 sort of allegations about knowledge and notice where the
7 Plaintiffs say that certain publications or events over a
8 40-year period gave Defendants, Defendants as one, notice that
9 there was a problem or a risk with either NDMA or Ranitidine or
10 both.

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

19 That allegation, by the way, your Honor, is at
20 paragraph 609 of the consumer class complaint, and paragraph
21 282 of the third party payor complaint. That, to borrow a
22 phrase from the Eleventh Circuit, defies temporal reality. It
23 cannot be that that pleading honestly meant or could mean
24 literally all 90 Defendants got notice of a problem from these
25 40 years worth of studies.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 all 50 states and the additional United States territories.

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

6 The consequence of this standing theory was
7 predictable. The types of complaints that Mr. Petrosinelli
8 outlined in which -- in the consumer complaint there are 314
9 total counts on behalf of what was 238 Plaintiffs, now down to
10 183 Plaintiffs because 55 Plaintiffs have dismissed their cases
11 because they did not want to participate in discovery, and
12 those are brought against 94 Defendants.

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

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

25 As your Honor is aware, the United States Supreme

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

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

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

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

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

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

1 *THE COURT:* Mr. Bayman --

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

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

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

9 *THE COURT:* Okay.

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

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

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

24 *THE COURT:* Okay, thank you.

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

1 you have the remaining time through 23 minutes for rebuttal.

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

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

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

15 *THE COURT:* Good morning.

16 *MR. LEAR:* Good morning, your Honor.

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

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

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

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

1 doing this, and we will be okay.

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

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

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

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

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

18 *THE COURT:* All right.

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

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

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

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

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

9 *MR. LEAR:* Rule 8.

10 *THE COURT:* Okay.

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

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

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

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

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

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

11 I am going to share my screen, your Honor.

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

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

25 We use the same analysis for the retail Defendants.

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

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

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

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

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

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

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

5 I will put up another slide here.

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

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

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

1 manufacturer Defendant.

2 Your Honor, the same is true for the distributor
3 Defendants. The complaints allege those Defendants distributed
4 90 percent of the Ranitidine containing products sold in the
5 United States and, thus, each plausibly distributed a drug
6 traceable to at least one of the named Plaintiffs.

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

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

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

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

1 Plaintiff paid for the product.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 Now, why is that?

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

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

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

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

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

1 So, how did we do that?

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

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

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

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

25 Your Honor, the class complaints in this MDL were not

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

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

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

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

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

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

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

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

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

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

13 Thank you, your Honor.

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

16 *MR. LEAR:* It does.

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

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

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

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

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

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

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

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

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

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

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

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

20 *THE COURT:* Okay, thank you so much.

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

1 question.

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

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

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

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

25 As long as the remedy is repleading, the Eleventh

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

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

5 *THE COURT:* Thank you.

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

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

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

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

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

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

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

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

11 Is this a workable solution?

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

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

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

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

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

13 I hope that answers your question.

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

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

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

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

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

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

16 THE COURT: Okay.

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

18 THE COURT: Yes.

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

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

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

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

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

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

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

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

25 The Defendants argue that the issue of the named

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

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

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

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

13 *THE COURT:* Plaintiffs.

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

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

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

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

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

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

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

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

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

25 Again, could you precisely articulate what this

1 general principle of standing should be determined at the Rule
2 12 stage as distinct from that principle of standing to be
3 determined at Rule 23? I just want to make sure I understand
4 your position.

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

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

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

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

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

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

6 I hope that distinction makes sense to the Court.

7 *THE COURT:* Thank you. Was there a response?

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

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

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

1 claims, not uniformity with respect to state claims.

2 Nevertheless, the burden on showing uniformity rests squarely
3 with the Plaintiffs under the Clay decision in the Eleventh
4 Circuit.

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

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

10 This is a question for Plaintiffs. You cite United
11 Technologies Corp v Mazer, 556 F.3d, 1260, Eleventh Circuit,
12 2009, to argue that where a reasonable investigation under the
13 circumstances points to multiple possible tortfeasors, a
14 Plaintiff has a good faith basis to sue each one in the
15 alternative. That is your response at page 19.

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

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

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

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

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

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

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

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

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

1 do in this case.

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

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

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

18 You also note that *Prado* was cited in a Rule 23(f)
19 interlocutory appeal posture, and focuses on whether the named
20 Plaintiff's injury is typical," end of quote. That's at page
21 22 of your response.

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

1 analysis?

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

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

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

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

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

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

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

10 *THE COURT:* You answered it, thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 *THE COURT:* Yes.

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

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

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

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

17 *MR. GILBERT:* Judge, may I briefly respond?

18 *THE COURT:* Yes.

19 *MR. GILBERT:* Robert Gilbert on behalf of the
20 Plaintiffs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 *MR. BAYMAN:* Your Honor, there are similar infirmities
21 with respect to the third party complaint because the complaint
22 alleges that they reimbursed purchasers in far fewer than 50
23 states and lists a number of states at paragraphs 22, 25, and
24 28, where they did not claim to reimburse purchases in those
25 states. So, therefore, they cannot bring claims for purchases

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

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

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

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

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

13 Further, the Defendants argue that even if the
14 doctrine could confer standing, it does not apply to this case.
15 They, as you, the Plaintiffs, have noted the case of Moore
16 versus Comfed Savings Bank, 908 F. 2nd 834, Eleventh Circuit,
17 1990, whereby the Eleventh Circuit limited the doctrine's
18 applicability to, quote, "a situation in which there was either
19 a contractual obligation among all Defendants or a state or
20 local statute requiring common action by the Defendants," end
21 of quote. 908 F.2d at 838.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 *THE COURT:* All right. You may proceed.

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

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

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

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

1 prior counts.

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

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

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

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

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

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

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

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

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

1 Rule 9(b) .

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

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

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

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

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

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

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

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

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

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

1 did which thing that gives rise to which claim.

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

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

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

25 So, the problems with shotgun pleading are just as

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

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

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

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

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

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

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

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

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

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

12 *THE COURT:* Consider that a good thing.

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

14 *THE COURT:* Exactly.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 be found at paragraph 441.

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

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

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

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

25 Paragraph 503 of the negligent failure to warn count

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 I will also direct your Honor to paragraphs 395 to
13 401, 427, 555 and 556, which also talk about how the label
14 failed to disclose to the Plaintiffs in this case that
15 Ranitidine contained NDMA or that it could cause cancer.

16 There are additional paragraphs in the complaint that
17 also put the Defendants on notice that the Defendants failed to
18 disclose that exposure to heat, light, humidity, or the human
19 body's natural state could cause NDMA or cancer, and you can
20 find all of those references at paragraphs 308, 395 to 401,
21 405, 427, 481, 548, 555, 556, and 582. These are just some
22 examples, your Honor.

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

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

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

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

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

25 So, the specificity that is available to the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 *THE COURT:* Okay, thank you so much.

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

17 You used only 11:13 of your time originally.

18 *MR. PETROSINELLI:* Thank you, your Honor.

19 *THE COURT:* You have three minutes and 51 seconds.

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

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

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

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

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

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

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

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

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

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

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

22 Thank you, your Honor.

23 *THE COURT:* Thank you very much.

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

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

2 We can come back at 1:30, give everybody enough time
3 to regroup. We will come back at 1:30 and we'll hear then the
4 two remaining motions that were scheduled for today, 2037 and
5 1585, and we will follow the same format.

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

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

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

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

21 MR. PETROSINELLI: Thank you, your Honor.

22 MS. GOLDENBERG: Thank you, your Honor.

23 *(Thereupon, a short recess was taken.)*

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

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

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

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

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

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

4 I am sorry if that is an unfair surprise, but in
5 looking over my notes over the lunch hour, I wanted to follow
6 up with those counsel who presented on motion Docket Entry
7 1630.

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

11 Mr. Bayman, can you hear me okay?

12 MR. BAYMAN: Yes, your Honor.

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

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

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

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

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

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

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

1 issued its principles in that case.

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

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

9 *THE COURT:* Right. Is it the Defendants' position
10 that that analysis, that inquiry that was taken -- or at least
11 was addressed by a Court that received the case at the
12 interlocutory appeal stage under Rule 23, that that is the
13 standard by which a Plaintiff alleging under Rule 8 and/or Rule
14 9 in a complaint is held to that same specific claim-by-claim
15 standard, party-by-party standard?

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

20 *MR. BAYMAN:* No. I think the point that I maybe
21 didn't make clearly is that you need to show standing prior to
22 the Court even getting to the question of Rule 23. You can't
23 base standing on the experience of absent class members. Rule
24 23 can't extend the Court's jurisdiction whether you are at the
25 Rule 12 stage or the Rule 23 stage. It is immaterial.

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

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

8 *THE COURT:* Yes. State your name.

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

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

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

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

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

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

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

17 That is the holding in the case, your Honor.

18 *THE COURT:* Okay, thank you.

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

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

1 that you felt that way.

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

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

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

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

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

1 quite simply is yes.

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

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

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

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

17 *THE COURT:* Thank you. So, looking at your slide 4,
18 where you have the -- it says OTC Zantac. Would this chart not
19 suggest that the Plaintiffs can plead with similar precision as
20 to the brand name Defendants -- putting aside the doctrine for
21 a moment, is it the case that the Court would understand this
22 slide, which is representative of your allegations in your
23 complaint, that, for example, GSK and Pfizer were manufacturing
24 between '95 and on or about '98, between '98 and 2006, Pfizer,
25 2006 to 2017, BI, 2017 to 2019, Sanofi.

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

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

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

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

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

18 *THE COURT:* But for the doctrine.

19 *MR. GILBERT:* But for the doctrine.

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

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

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

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

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

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

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

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

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

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

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

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

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

25 *MR. GILBERT:* Correct, to correspond with the temporal

1 scope of their purchasers.

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

4 *MR. GILBERT:* That is correct.

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

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

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

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

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

25 *MR. GILBERT:* And who they were distributing for and

1 to whom.

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

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

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

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

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

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

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

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

4 *THE COURT:* Right.

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

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

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

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

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

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

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

1 injured them, and that is the problem.

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

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

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

16 Thank you, your Honor.

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

19 THE COURT: Very quickly.

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

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

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

1 2037 is the generic manufacturers and repackagers Rule 12
2 Motion to Dismiss consolidated consumer and third party payor
3 class action complaints on the ground of failure to allege an
4 injury and incorporated memorandum of law.

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

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

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

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

21 *THE COURT:* Okay, I will do my best.

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

1 of whether or not they can join our motion.

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

4 *MS. ZOUSMER:* Yes.

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

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

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

14 *THE COURT:* Yes.

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

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

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

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

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

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

8 *MR. PETROSINELLI:* Mr. Gilbert is correct.

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

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

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

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

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

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

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

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

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

17 *THE COURT:* Make sure to speak slowly enough.

18 *MR. WINTERS:* Yes, your Honor.

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

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

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

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

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

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

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

25 Not only did the Plaintiffs fail to establish an

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

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

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

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

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

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

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

16 In that case, the FDA had sent over a dozen warning
17 letters saying the product was not approved for sale before,
18 and this is important, before any of the Plaintiffs bought the
19 product. The Eleventh Circuit went on to say it explicitly was
20 not, and again I am quoting, "addressing whether a Plaintiff
21 would have standing if she allegedly purchased, one, a product
22 that lawfully could be sold, but came with inadequate warnings;
23 or two, a product that was lawfully sold at the time of
24 purchase, but whose sale was later prohibited." That is at
25 1088, Footnote 8 of Debenardis. That footnote specifically

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

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

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

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

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

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

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

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

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

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

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

1 It is Plaintiffs' burden to establish standing under
2 12(b)(1) and 12(b)(6), and they have failed to do so.

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

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

14 *MR. STIKELEATHER:* Good afternoon, your Honor.

15 *THE COURT:* Good afternoon.

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

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

1 and any other health benefit provider.

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

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

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

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

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

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

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

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

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

21 *THE COURT:* Okay.

22 *MS. MCVEIGH:* Good afternoon, your Honor.

23 *THE COURT:* Good afternoon.

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

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

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

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

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

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

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

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

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

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

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

25 In addition to seeking damages for this behavior, they

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

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

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

15 Plaintiffs conclusory allegation that there is a
16 continuing risk to Plaintiffs is not possible under the
17 12(b)(6) standard when there is no allegation in the thousands
18 of pages of the complaint that any Defendant intends to
19 relaunch its product, or if it did, what the labeling might
20 look like or what representations may be made in connection
21 with that product.

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

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

4 Thank you, your Honor.

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

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

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

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

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

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

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

8 Indeed, Plaintiffs don't even say when --

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

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

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

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

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

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

22 *THE COURT:* Okay. Go ahead.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 *MR. HEINZ:* Good afternoon, your Honor.

8 *THE COURT:* Good afternoon.

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

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

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

23 By contrast, the merits are determined in this action
24 under State law because it is a diversity action. That means
25 52 different jurisdictions' laws apply on the merits.

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

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

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

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

25 That means that even if Defendants were correct that

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

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

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

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

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

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

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

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

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

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

25 The Plaintiffs allege that Ranitidine was misbranded

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

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

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

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

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

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

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

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

25 They also argue that there are some subsequent cases

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

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

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

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

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

1 contract the injury in fact requirement from Article III.

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

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

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

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

1 Debenardis endorsed that reasoning and it applies soundly here.

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

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

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

1 be dismissed on the merits.

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

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

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

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

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

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

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

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

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

25 After Rule of Federal Procedure 2, we know that there

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 For example, the In Re: Acumune Marketing litigation,
22 that's the Northern District of California, 12(b)(1), 12(b)(6),
23 Birmingham v Walgreens, Southern District of Florida, 12 b 1,
24 12 b 6, Hughes v Chatham, Southern District of Indiana,
25 12(b)(1), 12(b)(6), Corinthali versus Loreal, Third Circuit,

1 12(b)(1), 12(b)(6), Laredo versus Proctor and Gamble, Southern
2 District of Ohio, 12(b)(1), 12(b)(6), In Re: Schering-Plough,
3 Third Circuit, 12(b)(1), 12(b)(6), In Re: Schering-Plough
4 consumer class action, that's District of New Jersey, 12(b)(1),
5 12(b)(6).

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

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

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

18 *THE COURT:* What is the response from the Defendants?

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

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

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

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

8 *THE COURT:* Yes.

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

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

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

25 *THE COURT:* Okay. Thank you.

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

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

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

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

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

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

25 As you acknowledged in your brief, to show standing

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

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

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

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

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

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

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

1 injury in fact for every claim in the consumer complaint?

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

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

10 MR. HEINZ: That is certainly correct.

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

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

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

25 So, that is what I gleaned from the complaints

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

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

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

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

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

1 And then you have TPP -- but you do have EG. So, is
2 that what you mean, that you are just giving examples there,
3 335 to 41, and CCAC, 595 to 604? These allegations are
4 detailed and plausible.

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

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

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

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

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

1 On that point, Plaintiffs cite Bouldry versus C. R.
2 Bard, Incorporated, a case within this district, for support,
3 and that's 909 F.Supp.2d 1371, Southern District of Florida,
4 2012. In Bouldry, the Court agreed with other Federal Courts
5 that had held that in the context of medical monitoring, an
6 alleged increased risk of future harm satisfies Article III's
7 injury in fact requirement. That is at page 1374 to 1376 of
8 the case.

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

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

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

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

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

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

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

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

8 The Defendants argue that your alleged physical
9 injuries, namely NDMA accumulation, cellular and subcellular
10 damage and an increased risk of developing various cancers are
11 not legally cognizable injuries. In support they cite Caputo
12 versus Boston Edison Corporation, 1990 WestLaw 98694, District
13 of Massachusetts, 1990, Ranier versus Union Carbide
14 Corporation, 402 F.3d 608, Sixth Circuit, 2005, In Re: Berg
15 Litigation, 293 F. d 1127, Ninth Circuit, 2002, and Dumontier
16 versus Schlumberger Technology Corporation, 543 F.3d 567, Ninth
17 Circuit, 2008, and that is the Defendant's motion, pages 16 and
18 17.

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

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

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

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

12 Our primary cases for standing would be cases like
13 Bouldry and Sutton, which is Sutton v St. Jude Medical, 419
14 F.3d 568, from the Sixth Circuit, and a number of other cases
15 also cited in Bouldry. We would also rely on the Third Circuit
16 case, In Re: Paoli which specifically held that it was error
17 when the District Court applied the standard for enhanced risk
18 claims in an action for medical monitoring and that was a
19 standing case that distinguished between those two concepts.

20 There are a number of other cases that I think apply
21 by analogy like our Agent Orange case and a few others, but
22 those are the cases that we would mostly rely on and are
23 focusing on, Bouldry especially.

24 *THE COURT:* For your argument that physical injuries
25 constitute injury in fact?

1 MR. HEINZ: Yes, your Honor, that the increased risk
2 of cancer is a predicate of medical monitoring claims, or not
3 cancer necessarily, but the increased risk of disease, that
4 that also counts as a physical injury.

5 THE COURT: Question for the Defendants relating to
6 the Plaintiffs' injunctive relief sought. In the portion of
7 the Defendants' motion challenging medical monitoring as
8 injunctive relief, Defendants state that Defendants "are moving
9 as to the request for an injunction and reserve the arguments
10 that the consumer Plaintiffs failed to state claims for medical
11 monitoring under applicable states' laws." That is your motion
12 on page 21.

13 Yet, you also state that your motion is brought
14 pursuant to Rule 12(b)(1) and Rule 12(b)(6). That is in your
15 reply, page 5, Footnote 1.

16 Is this a Rule 12(b)(6) motion for failure to state a
17 claim? If it is, the Court wants to know why there was not
18 included arguments for failure to state claims for medical
19 monitoring? And if it was not a 12(b)(6) motion for failure to
20 state a claim -- but I think you said earlier that it was both,
21 so, maybe let me have you address the first part of the
22 question.

23 Are you presenting this as a 12(b)(6) motion for
24 failure to state a claim?

25 MR. WINTERS: Your Honor, this is Daniel Winters

1 again. Let me address that.

2 As you saw, our motion is broken into basically two
3 separate sections. The first is that there is no injury in
4 fact. That would eliminate or require dismissal of the entire
5 complaint, that is a 12(b)(1) and a 12(b)(6).

6 The motion goes on to say that if for some reason the
7 Court is not going to dismiss it, if they are going to give the
8 Plaintiffs an opportunity to replead, then there are definitely
9 certain things that should not be repled, one being the third
10 party payors should be limited to economic loss claims. They
11 should not be permitted to bring tort claims, and the rationale
12 behind that is in the motion.

13 Second, if they are going to have an opportunity to
14 replead, they should not be able to replead these injunctions,
15 and that is because when your Honor looks at their responses,
16 at their various pleadings, when it comes to medical
17 monitoring, over and over again they keep saying what we want
18 is a fund of money.

19 So, when the Plaintiffs have told you in filings with
20 this Court at least a half dozen times that all we want is
21 money, if the Court is going to give them an opportunity to try
22 to amend their pleadings to meet the standard, then that claim
23 at least should not be permitted because it is just a request
24 for money, not injunctive relief.

25 MR. HEINZ: May I speak to that, your Honor?

1 *THE COURT:* Yes.

2 *MR. HEINZ:* This is Noah Heinz. The Defendants make a
3 lot about a couple of scattered statements throughout the
4 debriefing, but each of those, if I recall correctly, was
5 addressed to whether the injury at issue here is redressable,
6 and both parties agree that the injury is redressable. The
7 point is that the Court could fashion a remedy.

8 We did not intend through that to concede anything
9 about the nature of that remedy, that it would merely be money
10 damages, and we don't need to explain in detail the nature of
11 the medical monitoring remedy at this stage. The pleadings do,
12 I think, a sufficient job of explaining that we do need
13 injunctive relief on the medical monitoring claims, and it is
14 far too early to demand the level of detail that the Defendants
15 claim to need here.

16 *THE COURT:* Let me follow up on that. The Plaintiffs
17 don't dispute the Defendants' point that in the consumer
18 complaint the Plaintiffs seek an injunction ordering them to
19 remove Ranitidine from the market.

20 The Court wants to make sure in can tell where in the
21 consumer complaint you expressly request that relief. If you
22 could let the Court know where.

23 I could glean that you ask the Court to "order any and
24 all appropriate preliminary and/or final injunctive or
25 equitable relief" against the Defendants. That is at page 1332

1 of your consumer complaint.

2 Is that the relevant language or is there more
3 explicit language elsewhere that the Court hasn't identified?

4 MR. HEINZ: I am not sure. That is probably the
5 appropriate paragraph, but nothing more specific is coming to
6 mind that I have in front of me.

7 MR. KELLER: Your Honor, this is Ashley Keller for the
8 Plaintiffs. Under Federal Rule of Civil Procedure 54(c), when
9 the Court enters a final judgment, even if we didn't plead all
10 of the relief that we're entitled to, the Court can and should
11 still order it.

12 THE COURT: All right. Economic loss doctrine, now a
13 question for the Defendants. The Defendants cite East River
14 Steamship Corporation versus Transamerica, 476 U.S. 858, a 1986
15 case where Defendants state that the Supreme Court recognized a
16 "majority" approach regarding the economic loss rule to support
17 the Defendants' argument that in the third party payor
18 complaint Counts 5, fraud, 6 and 9, negligent misrepresentation
19 and negligence, and 7, violation of state consumer protection
20 laws, are precluded by that rule.

21 You acknowledge that there is not one economic loss
22 rule, but rather, "several more limited rules that govern
23 recovery of economic losses in selected areas of law." That is
24 your motion, page 20, Footnote 9.

25 Defendants then state that "only one version of the

1 rule is being argued," namely that "between commercial parties,
2 claims for injury to the product itself without personal injury
3 or other property damage are contractual and not tort claims."

4 The Plaintiffs note that you, the Defendants, did not
5 identify which jurisdictions apply that majority rule. Do you
6 believe doing so is or was necessary?

7 *MR. STIKELEATHER:* Your Honor, this is Derek
8 Stikeleather for the Defendants. We don't believe it is
9 necessary in this case because the version of the economic loss
10 rule that we're talking about is its most basic iteration. We
11 could not find any state in the union that does not recognize
12 it in this context, and notably, Plaintiffs have not been able
13 to do so either.

14 Now, to do a 50-state survey at this stage of the case
15 we do not think is something that the Court would be eager to
16 get into, and would find efficient given all the demands on
17 organizing and advancing this case, but it is a very
18 significant point that they cannot point to a single state that
19 says we do not recognize it in this context.

20 And it is true that once you get into the 50-state
21 survey, and find the limits of each state, you do find nuances,
22 you do find differences, but those arise often in the context
23 of consumers where there is a tort element in the claim that I
24 ingested this drug, I think it increased my cancer risk, but I
25 also want a refund. Different states, in what can be confusing

1 analysis, can play that out differently.

2 There is a clear majority rule, however, we think it
3 is unanimous that when you are talking about a third party
4 payor, an HMO seeking a pure refund on the theory that this
5 product was no good, not that we ever took it, not that it ever
6 created any risk to us, but we don't think it is a good
7 product, we want our money back, and there is no tort element
8 whatsoever in that case, there is not a state in the union that
9 looks at that and says you have both a contract claim and tort
10 claim.

11 We think for the advancement and management of this
12 litigation it would be prudent at this point to either plead
13 what are the states that recognize this, because the two
14 examples that they provided in their briefing -- given time to
15 research, prepare, and file a brief, they provided two
16 examples, one that does not even speak to the economic loss
17 doctrine, and one that sought recovery for the collateral
18 effect of opioid addiction, which, sure, that does not apply to
19 the economic loss doctrine. That is far beyond seeking a
20 refund. So, we have no quarrel with those cases.

21 The example we have here is an instance where we
22 believe there is no state that would not apply the economic
23 loss doctrine, and we think it is telling the Plaintiffs can't
24 provide a single example.

25 *THE COURT:* Are you seeking dismissal, then, of Counts

1 5, 6, 7, and 9 only as to certain states' laws?

2 MR. STIKELEATHER: We would say dismissal of those
3 counts as to all states because in every one of those states
4 what the third party payors have is a pure contract claim, and
5 they brought claims for warranty, breach of express warranty.
6 Those claims would remain, but the tort based claims would be
7 removed from the case.

8 THE COURT: What is the Plaintiff's response?

9 MR. HEINZ: Your Honor, it doesn't seem fair for the
10 Plaintiffs -- for the Defendants, sorry, to simply invoke the
11 economic loss rule and then say that they think it that applies
12 in all 50 states and then force us to respond. I don't think
13 that is an adequate way of briefing it.

14 If your Honor would like additional briefing on this
15 topic, I suppose it could be that we would find more nuances in
16 this area.

17 Also, the Defendants claim that they are making a
18 blanket rule that would be easy to check, but they provide so
19 many nuances that I can't even (inaudible) what the scope of
20 the research would be. They say in this context limited to
21 specific types of HMOs that we won't be able to find a case.
22 It might just be that in a lot of states those types of cases
23 just don't exist. We do know of states in which the economic
24 loss rule doesn't apply to a large number of things, including
25 when there is injury to the product itself.

1 We don't think that it was our burden to go through in
2 detail each of the cases and allow them to have particular
3 cases that they can then snipe at on reply. That is not a fair
4 way to do debriefing and it is not an efficient way to do it.

5 *THE COURT:* That actually does dovetail into the next
6 question that I have for you where you do note that if the
7 issue of economic loss rule "were examined in detail,
8 Plaintiffs would brief state law nuances distinguishing among
9 Defendants that committed independently wrongful actions,
10 employed certain forms of marketing, fraudulently concealed or
11 other exceptions."

12 That is the brands' response adopting the motion at
13 page five -- I am sorry, that is the response to the brands'
14 adoption motion, excuse me. So, that is your response, the
15 Plaintiffs.

16 So what would that briefing entail and at what stage
17 would you envision this occurring?

18 I note in the quote, as I just read it, you said other
19 exceptions. I also want to know what you meant by other
20 exceptions. Did you mean exceptions to states' economic loss
21 rules? If you could address that for the Plaintiffs.

22 *MR. HEINZ:* Yes, your honor, this is Noah Heinz.

23 We did mean exceptions to the economic loss rule, as
24 the Defendants explained, in the opioids case there was an
25 exception. There might be a number of other exceptions. We

1 haven't taken the time to canvas all the states and think
2 through the facts that might be relevant.

3 It seems that it might be the type of thing that would
4 be suited to a later stage where there is detailed state law
5 briefing, rather than at this initial stage that deals with
6 crosscutting motions, but I am not sure I have a view on the
7 best time to do it. Mr. Keller might have a better view on
8 Plaintiffs' position on when it should be briefed.

9 *THE COURT:* It is true in large part, if not fully,
10 that the first round of motions were intended to try to address
11 certain crosscutting issues. There is contemplated depending
12 on the outcome of the Court's ruling, a second -- should there
13 be repleading on some or all of the complaints, a second round
14 of motions.

15 Mr. Keller, what do you think it looks like, the
16 Plaintiffs' response of examining in detail, Plaintiffs would
17 brief state law nuances, distinguishing among Defendants that
18 committed independently wrongful acts, employed certain forms
19 of marketing, fraudulently concealed, or other exceptions.
20 Would that come in the form of an amended complaint or some
21 other procedural juncture in the case?

22 *MR. KELLER:* I don't think -- this is Ashley Keller
23 for the Plaintiffs, your Honor.

24 I don't think it would come solely in the form of an
25 amended complaint. Not to be flippant in my answer, but we'll

1 brief it as soon as the other side does, and at whatever point
2 your Honor deems the other side efficiently to present these
3 issues, but we have to know what we are shooting at. We can't
4 just respond to an admiralty case and an ALR article and be
5 expected to announce all of the nuances and exceptions of a
6 doctrine that has a majority rule, a minority rule, and lots of
7 exceptions and dispensations to it.

8 The burden for a 12(b)(6), if that is going to be the
9 procedural posture that it's raised, is on the Defendants
10 first, and to couch it in a certain way to demonstrate why the
11 allegations in the well-pleaded complaint fail under state law,
12 and then we get to oppose and offer distinctions and
13 demonstrate to the Court that their arguments are incorrect.

14 It is difficult for us to do in a vacuum when we are
15 just looking at a 1986 Supreme Court case that is obviously not
16 on all fours with the precedent in the 52 jurisdictions for
17 which the class claimants bring claims.

18 *THE COURT:* That is an interesting point you bring up
19 about the burden. Movant has a burden to show why a claim
20 doesn't survive perhaps.

21 Does the Plaintiff have a burden to plead a viable or
22 plausible claim? I imagine you would say yes. So, how does
23 the state law nuances -- let's say the majority of claims,
24 hypothetically, are not plausible claims under state laws for
25 some of the reasons the Defendants have argued, and that is a

1 hypothetical. Does the Plaintiff have a burden to come forward
2 in plausibly pleading their claims and point to those state
3 laws where a viable claim can be pled?

4 *MR. KELLER:* Of course, your Honor. Yes, we have a
5 burden to plead and ultimately to prove every element of a
6 cause of action under state law. We think we have adequately
7 done that.

8 If the Defendants disagree with us and say we don't
9 think that you have adequately done that, the proper way to
10 address it at this procedural posture is through a 12(b)(6)
11 where they point out based on law, not just ipse dixit at an
12 oral argument, here are all of the cases that show that they
13 haven't actually checked all the boxes as Plaintiffs, they
14 haven't properly pleaded all of the elements of the claims
15 under the law of Ohio, or Michigan, or whatever jurisdiction
16 they want to invoke, here is relevant authority that shows we
17 are right. Then we get to oppose that.

18 So, we have met our initial burden of pleading what we
19 think in good faith are complaints that state claims. If they
20 have a problem with that, they could file a 12(b)(6) that
21 properly goes through all of the legal authority that
22 demonstrates, in their view, that is not true. That is the
23 proper sequencing we think.

24 *MR. STIKELEATHER:* May I respond, your Honor?

25 *THE COURT:* Yes.

1 MR. STIKELEATHER: This is Derek Stikeleather for
2 Defendants. Our reply brief contains authority that cites New
3 York law, Florida law, Pennsylvania law, Ohio law, New Jersey
4 law. We certainly have put forward cases and we think the
5 seminal case is the Supreme Court's East River decision, which
6 has been so influential it has been cited over a thousand
7 times. This is not an obscure doctrine or obscure admiralty
8 court that is issuing this ruling.

9 The Plaintiffs' position says you have to give us 52
10 cases before we will give you one. We just want one case that
11 says between two sophisticated commercial parties with the
12 ability to allocate risk, a claim for simple refund based on
13 the premise that the product wasn't as represented in your
14 warranty states a tort claim. Not one case have we received
15 yet for that.

16 THE COURT: All right. Question for the Plaintiffs:
17 Defendants argue that any Plaintiff seeking monetary damages
18 for personal injury must assert their claims through the master
19 personal injury complaint, not the class complaints.

20 You disagree with that position and state that "the
21 MPIC is not a class complaint, and adding those claims there
22 would not streamline this MDL." That is in your response at
23 24. PTO number 31, that's one of the pretrial orders the Court
24 entered, states that "Plaintiffs shall file a master personal
25 injury complaint on behalf of all Plaintiffs asserting personal

1 injury claims." That is page 2 of PTO number 31.

2 Of what consequence is it that the MPIC is not a class
3 complaint?

4 What would be the impact if the Court ordered that all
5 of the personal injury claims are to be asserted in the MPIC?
6 Question for the Plaintiffs.

7 *MR. HEINZ:* This is Noah Heinz.

8 I think our main point there was simply that it
9 wouldn't add to the efficiency to move the claims in that
10 direction.

11 The more fundamental point, though, is we don't think
12 these claims are personal injury claims within the sense meant
13 by the Court in the pretrial order. It seems that the
14 distinction was meant to be the type of trial that would be
15 required, the type of proceeding to generally streamline it,
16 not that it is a particular kind of injury that underlies a
17 medical monitoring claim.

18 We think if that order were to be entered, it seems
19 like it would not add efficiency, it would just be maybe
20 clearer insofar as it restricts all of the injuries technically
21 to one place, but it wouldn't actually conceptually fit with
22 what this Court has been trying to do.

23 *MR. KELLER:* Your Honor, Ashley Keller for the
24 Plaintiffs.

25 Your Honor obviously knows what you meant by your

1 order better than I do, but perhaps being a little bit too
2 priggish, I would emphasize the word "personal" in personal
3 injury. The medical monitoring claimants are proceeding in a
4 putative class action, so obviously they have their own
5 personal injuries, but they are proceeding in a representative
6 capacity on behalf of others.

7 So, our understanding of the order was that you didn't
8 mean for the master personal injury complaint to include class
9 allegations, but obviously it would be a housekeeping matter,
10 and if you prefer us to move medical monitoring claims over to
11 the MDIC, we could amend and do that and accommodate whatever
12 your Honor thinks is the most efficient way to proceed.

13 *THE COURT:* Thank you. Did the Defense have any
14 response to that answer?

15 I guess included in the question, how, if at all,
16 would restricting all personal injury claims to the MPIC
17 streamline the MDL?

18 *MR. WINTERS:* Your Honor, we think it would streamline
19 the MDL and it would do so in a very nice fashion. Right now
20 we are looking at claims splitting apparently. I have personal
21 injury, but I am not bringing a personal injury complaint. You
22 can't do that. What happens then if one of these people
23 develop cancer; are they then going to be able to also bring a
24 cancer personal injury complaint, or was that subsumed by this
25 consumer class, which, you know, also includes people who don't

1 want medical monitoring or won't qualify for medical monitoring
2 or can't have medical monitoring?

3 So, if you are going to claim that I have personal
4 injuries and that entitles me to damages, including medical
5 monitoring, then the place to bring that where it can be most
6 efficiently dealt with is on the personal injury side, not as
7 part of an amalgamation of a consumer class action where the
8 linchpin of your argument is that I bought a worthless product.

9 MR. HEINZ: May I briefly respond to that, your Honor?

10 THE COURT: Has either side had experience in any
11 other MDL, for example, as to where medical monitoring claims
12 have been brought, whether they have been brought in class
13 consumer master complaints or personal injury master
14 complaints? No.

15 Okay. Mr. Heinz, did you want to make a point?

16 MR. HEINZ: I did want to respond to the charge that
17 there is claims splitting, and that would depend on the
18 substantive state law in most states, and perhaps all, I am not
19 entirely sure, but in most states that allow medical monitoring
20 it doesn't subsume or preclude a subsequent claim of another
21 sort. We don't think that would actually be a problem under
22 the laws of the specific states that do allow medical
23 monitoring.

24 THE COURT: Okay. All right. Thank you so much.
25 That was a long session, and that concludes that session.

1 Given the hour, I am sure everybody -- Ms. Stipes can
2 use a break. We will take a 15-minute break. We will all be
3 back at 3:45. Stay logged into the meeting so we don't have to
4 readmit you, but turn your video off and audio off. We will be
5 back in 15 minutes for the last motion that will be heard
6 today, which is 1585.

7 *(Thereupon, a short recess was taken.)*

8 THE COURT: Okay. Our next and last motion for the
9 day is Docket Entry 1585, brand name manufacturer Defendants'
10 Motion to Dismiss Plaintiffs' innovator liability claims and
11 incorporated memorandum of law.

12 If we could have the Defense counsel turn their videos
13 on. They have done that, and you will get 18 minutes for this
14 motion.

15 Would you let me know how -- first, if you could
16 introduce yourself for the record, and then let me know whether
17 you want to save any time for rebuttal and whether you want any
18 warnings.

19 MR. CHEFFO: Thank you. This is Mark Cheffo, I am
20 with my colleague, Jonathan Tam. The way we would like to break
21 it down, with your Honor's permission, is Mr. Tam will take the
22 first three minutes, I would like to go for about ten minutes
23 and reserve five minutes. I will try to time myself. If I do
24 go over, if you'd let me know, that would be great. If I go
25 over a minute or so I will take it off my rebuttal.

1 *THE COURT:* So, 13 and five?

2 *MR. CHEFFO:* Yes.

3 *THE COURT:* All right. Okay. With that, then, you
4 may proceed.

5 *MR. TAM:* Good afternoon, your Honor, my name is
6 Jonathan Tam, I am from Dechert and I represent GSK. Today, as
7 Mark indicated, I will set the stage for the brand
8 manufacturers' Motion to Dismiss --

9 *THE COURT:* Hold on. We couldn't go the whole day
10 with perfection of our technological systems here.

11 Mr. Tam, can you try talking again. That was your
12 dress rehearsal. Now you get to start all over again. Okay.

13 *MR. TAM:* Thank you, your Honor. Plaintiffs claims
14 should be dismissed for a very simple reason, it is undisputed
15 that the brand manufacturers did not manufacture, market,
16 distribute, or sell the generic Ranitidine that the Plaintiffs
17 allege they ingested.

18 Courts around the country have rejected innovator
19 liability claims because they violate a bedrock principle of
20 products liability law, that is, the Plaintiffs must assert
21 that the Defendants' product caused the Plaintiff's injury.

22 The Eleventh Circuit in Guarino recognized the
23 overwhelming national consensus that a brand name manufacturer
24 cannot be liable for injuries caused by the ingestion of a
25 generic form of a product. Indeed, your Honor has also

1 dismissed innovator liability claims. In the Dietrich case
2 your Honor ruled a product manufacturer cannot be held liable
3 under any theory of liability if the Plaintiff never used that
4 manufacturer's product.

5 That is precisely the issue that we have here. Your
6 Honor's decision is in line with more than 100 decisions
7 nationwide, including seven Federal Courts of Appeal that have
8 rejected innovator liability, and the 48 states that have
9 either rejected it or not expressly adopted the theory.

10 Now, Plaintiffs don't engage with the mountain of
11 authority rejecting innovator liability; instead, they invite
12 this Court to be the first in the country to recognize that
13 theory in dozens of jurisdictions and this Court should decline
14 that invitation.

15 Under the Erie doctrine and under the Guarino case,
16 Plaintiffs have the burden to identify an authoritative case in
17 each state that directly recognizes innovator liability, and
18 with the exception of two states, California and Massachusetts,
19 Plaintiffs have not met their burden, far from it.

20 Outside of those two states, innovator liability is
21 simply not a cognizable claim and this Court should join the
22 overwhelming national consensus in rejecting that theory.

23 Now, for California and Massachusetts Plaintiffs,
24 there are two independent bases for dismissing those cases.
25 The first is that the Court lacks personal jurisdiction over

1 the brand manufacturers, and Courts, including in the recent
2 Henry decision, have recognized the lack of personal
3 jurisdiction is a bar to innovator liability claims.

4 Second, another independent reason is that applying
5 California and Massachusetts law to a brand manufacturer's out
6 of state conduct would violate due process.

7 With that, your Honor, I am going to pass the baton to
8 Mr. Cheffo. Thank you.

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

10 *MR. CHEFFO:* Good afternoon, your Honor. I am Mark
11 Cheffo and I represent GSK, but I am going to present the
12 argument in connection with the innovator liability issue on
13 behalf of the brand manufacturers. I will reserve five
14 minutes.

15 Your Honor, in a pre-motion or pre-hearing order,
16 indicated that you would like to hear, among other things, the
17 jurisdictional issue, so if it's okay with the Court, I will
18 jump in and start right there.

19 Lack of personal jurisdiction is an independent
20 grounds (inaudible) all innovator liability claims across all
21 of the remaining states. Your Honor knows that some of these
22 states have been conceded by the Plaintiffs. This issue
23 applies in all of those remaining states.

24 Because California and Massachusetts are the only
25 states that recognize innovator liability, as you just heard

1 from Mr. Tam, we did in our briefing and will today talk about
2 the Plaintiffs from those states, but as I indicated, this
3 argument would apply, the jurisdiction, across the various
4 other jurisdictions.

5 The U.S. Supreme Court's 2017 decision Bristol Myers
6 Squibb is directly on point and is very instructive here for
7 this jurisdictional issue. Before I get to that, a predicate
8 is also an Eleventh Circuit decision that we cited in our
9 brief, it's the jet charter case, and what the Court said was
10 that a Federal Court sitting in diversity can assert personal
11 jurisdiction over the defendant only if the State Court in the
12 forum could do so.

13 Because the State Courts here cannot assert personal
14 jurisdiction over the brand manufacturers for the California
15 and Massachusetts innovator liability claims, consistent with
16 the Supreme Court's ruling in BMS, this Court, respectfully,
17 does not have specific jurisdiction for those claims.

18 There are, as you have seen in the briefing, I think
19 it's five Plaintiffs who have actually brought lawsuits in
20 certain jurisdictions which are the principal places of
21 business. These arguments apply to the crushing number or
22 overwhelming majority with respect to the claims asserting in
23 innovator liability.

24 Now, as a threshold matter, California and
25 Massachusetts Plaintiffs must first establish specific

1 jurisdiction over the brand name manufacturers. Specific
2 jurisdiction is present only if the claim, quote, "arises out
3 of or relates to the Defendant's contact with the forum." That
4 is the heart, the principle of the Bristol Myers Squibb Supreme
5 Court decision.

6 The Court also said there must be affiliation between
7 the forum and the underlying controversy, principally an
8 activity or occurrence that takes place in the forum state and
9 therefore -- it is therefore subject to the state's regulation,
10 again the BMS decision.

11 The problem here is that the Plaintiffs have not
12 alleged suit related contacts in California or Massachusetts.
13 The Plaintiffs can only establish specific jurisdictions for
14 claims involving Ranitidine products that the brand name
15 manufacturers actually made and/or sold and where the
16 Plaintiffs purchased them and consumed them in their home
17 states. This is black letter tort 101, your Honor, and that is
18 why we have only seen this doctrine recognized in so few
19 jurisdictions.

20 In those cases where the manufacturer manufactured,
21 sold, there was consumption, and there was purchase in the
22 states, the brand name manufacturers "purposely availed
23 themselves of the privilege of selling Zantac in the
24 Plaintiffs' home state and the claims arose out of those
25 activities."

1 Plaintiffs have no suit related contacts for claims
2 based on generic Ranitidine because the brand name manufacturer
3 did not manufacture or distribute those products. These are
4 different than your traditional tort claims. The generic
5 Ranitidine reached the Plaintiffs' home states solely through
6 the actions of the generic manufacturers. The Supreme Court
7 has said multiple times that "unilateral activity of a third
8 party" (inaudible).

9 *THE COURT:* Wait, Mr. Cheffo. You are freezing from
10 time to time. I think it might be your system, not mine, but I
11 don't know for sure.

12 Pick up with the Supreme Court said multiple times.
13 Ms. Stipes thinks if you speak a little slower that might aid
14 in the issue of you freezing.

15 Try to pick up from where you just left off.

16 *MR. CHEFFO:* Yes, your Honor, thank you. I will try
17 to slow down. I apologize if it is on my end.

18 The Supreme Court has repeatedly held that "unilateral
19 activity of a third party," in this case the generic
20 manufacturers, "cannot satisfy the requirement of contact with
21 the forum state." And that is the *Walden versus Fiori* case,
22 2014.

23 So, a growing number of Courts have also rejected
24 specific personal jurisdiction in cases relying on innovator
25 liability claims. Mr. Tam referenced the *Henry* case.

1 *THE COURT:* Wait, wait, Mr. Cheffo. You did freeze.

2 You stopped where it said Mr. Tam recognized or -- I
3 think there might be an internet connection issue on your end.
4 No problem, so we will have to take it step by step so we don't
5 miss anything. Pick up the sentence with Mr. Tam.

6 *MR. CHEFFO:* Of course, as Murphy's Law would have it,
7 I had a perfect connection until I get to argue today. I am
8 sorry for that.

9 Mr. Tam referenced the Henry case. The Henry case is
10 important because it is a California case from the Eastern
11 District of California, and it is a recent case from March 31,
12 2020. In the Henry case, there was no jurisdiction because,
13 quote, "the attenuated legal theory of innovator liability" --
14 (screen freezing.)

15 *THE COURT:* Hold on. Hold on. It happened again. I
16 think the last word we caught was attenuated theory. If you go
17 to audio only, maybe that will help, because you freeze and the
18 audio also freezes. Do you want to try that?

19 I stop the clock each time this happens.

20 Pick up with that sentence again that I just said.
21 That was the last we caught.

22 *MR. CHEFFO:* Yes, your Honor. In the Henry case,
23 there was no jurisdiction because the attenuated legal theory
24 of innovator liability did not tie Plaintiffs' claims to
25 Defendants' activities in California, and the same is true

1 here.

2 The Plaintiffs have tried, unsuccessfully, to
3 distinguish the Henry case really on two grounds. First, the
4 Plaintiffs claim that Henry sued the ABA holders of a
5 medication that was not bioequivalent to the drug at issue.
6 That is not correct. The Plaintiffs in Henry took a generic
7 medication alleged that was "virtually identical" to and had
8 the same chemical formulation as the brands, so it is a
9 consistent case.

10 The Plaintiffs also focus on the difference, or the
11 perceived difference in the scope of marketing between the
12 Henry case and what may have occurred here, but again, that is
13 a distinction without a difference. It just goes to degree,
14 not substance.

15 The only conduct by the brand name manufacturers that
16 is arguably relevant to the innovator liability claims, the
17 labeling decisions, did not take place in California or
18 Massachusetts. There is no allegation that that occurred.
19 Plaintiffs never alleged that the brand name manufacturers took
20 any actions in California or Massachusetts that affected the
21 content of generic Ranitidine labeling.

22 What the Plaintiffs try to do is essentially create a
23 bit of a slippery slope or a parade of horrors by suggesting
24 that it is the brand name manufacturers' position that Court's
25 will not have personal jurisdiction in any traditional failure

1 to warn claim since manufacturers make their labeling decisions
2 at their headquarters and then let third parties distribute the
3 medications, but that is not the case at all, your Honor.

4 We recognize traditional legal theories, and in the
5 standard product liability cases there is a jurisdictional
6 nexus between the manufacturer that made the medicine, sold the
7 medicine, found its way to the home state, and where the
8 Plaintiff actually used an alleged injury. That is not the
9 case with any of these innovator liability claims.

10 My final point with respect to the jurisdictional
11 issues is, the Plaintiffs argue that there was some
12 jurisdictional nexus created by prior marketing before there
13 was generic products available, but in order to establish
14 specific jurisdiction over the brand name manufacturer based on
15 marketing activities, Plaintiffs would have to show that, one,
16 such marketing of brand Zantac somehow caused them to take
17 generic Ranitidine, that is the Waite Eleventh Circuit case.

18 They would also have to show the second prong, that
19 the brand name manufacturers should have foreseen years or even
20 decades before that their marketing of brand name Zantac in
21 California or Massachusetts would expose them potentially to
22 product liability suits based on the generic Ranitidine
23 equivalent. That also is from the Oldfield versus Pueblo case
24 in the Eleventh Circuit, 2009.

25 Plaintiffs have not made either allegation. Any

1 causal relationship between the alleged tort in this case and
2 brand name manufacturers' advertising is too remote.

3 Your Honor, you have been gracious enough, I know you
4 have given me a minute or two, I would just touch upon the
5 innovator liability and then turn it over to my colleagues on
6 the other side to address.

7 What I would just point out, and I think Mr. Tam did a
8 fine job of setting the table here, despite Plaintiffs' claims
9 that innovator liability is the majority view, it has only been
10 accepted in California and Massachusetts. Plaintiffs are
11 asking this Court essentially to go where no Court has gone
12 before. They are asking this Court to be the first in the
13 country to recognize innovator liability in 33 jurisdictions
14 still at issue.

15 And notably, in response to the retailers' Rule 12
16 motion, Plaintiffs asked this Court to take a restrained view
17 of its Erie predictions, yet here they are asking the Court to
18 make new law and go farther than any Court has gone before.

19 We have cited the case law that we respectfully submit
20 holds that the Court should not predict that a state's highest
21 court would break from traditional tort principles in the
22 absence of a clear directive, and it really is a bedrock
23 principle of product liability law that a Plaintiff has to use
24 the Defendant's product in order to bring such a lawsuit, and
25 your Honor, albeit under Florida law, in the Dietrich case came

1 to precisely that conclusion.

2 Now, in conclusion --

3 *THE COURT:* You are -- Mr. Cheffo, you are at 14
4 minutes. I just wanted to let you know.

5 *MR. CHEFFO:* Okay. In conclusion, your Honor, we have
6 cited a mountain of cases, there are a hundred cases that go
7 this way, the Guarino case, the Darvon Darvocet, the Henry case
8 and others. We don't think that the way the Plaintiffs have
9 distinguished the cases that they have conceded is
10 distinguishable from the cases that they have not, and
11 as Guarino said, there's a mountain of evidence that rejects
12 innovator liability.

13 Thank you, your Honor.

14 *THE COURT:* Okay, thank you. You used 14:30 of your
15 18, so you have some time left.

16 All right. Let's have the Plaintiffs' counsel come
17 on, and state your name for the record and you have a total of
18 18 minutes.

19 *MR. LONGER:* Good afternoon, your Honor, Fred Longer
20 on behalf of the Plaintiffs. I would like to introduce Je Yon
21 Jung, who is one of our fearless members of our Leadership
22 Development Committee. This is her first MDL and it will be
23 her first argument in this MDL, but she is ready to go. Take
24 it away, Ms. Jung.

25 *THE COURT:* Great. Thank you so much.

1 MS. JUNG: Your Honor, may I test my PowerPoint to
2 ensure that it is up?

3 THE COURT: Sure.

4 MS. JUNG: Do you see my screen, your Honor?

5 THE COURT: I do, yes. Okay, you are all set.

6 MS. JUNG: I need to move my gallery out of my way.

7 Good afternoon, your Honor. May it please the Court,
8 Je Yon Jung on behalf of the Plaintiffs and the Plaintiffs
9 Steering Committee.

10 Defendants posit three arguments in their Motion to
11 Dismiss. First, they contend that no jurisdiction other than
12 California and Massachusetts recognizes Plaintiffs' negligent
13 misrepresentation.

14 Second, they contend that there is no personal
15 jurisdiction available over the Defendants.

16 Third, they contend that due process is offended by
17 holding them accountable under the laws of California and
18 Massachusetts.

19 Before I turn to responding to the Defendants'
20 specific arguments, it is important to lay out the framework of
21 the issues before the Court. What is the correct way for the
22 Court to go? Is it really going where no one else has gone
23 before?

24 When you distill this case down to the basics, the
25 brand name Defendants must be responsible for this warning

1 label, for their warning label for the brand and generic drug
2 users here. The Defendants' perverse and unreasonable position
3 is that nobody is responsible for the Plaintiffs' claims for
4 negligent misrepresentation. That simply cannot be the case.

5 The resolution of this Motion to Dismiss is not as
6 complicated as Defendants claim, and not as novel. The correct
7 way for this Court to resolve this motion requires us to take a
8 step back, dispense with fancy fictional terms like innovator
9 liability, and go back to our first year of law school, as Mr.
10 Cheffo said, civil procedure and torts 101.

11 We have a clear framework for this Court to resolve
12 the Defendants' Motion to Dismiss. With the Hatch-Waxman
13 Amendment and the Supreme Court cases, namely Wyeth and
14 Mensing, what the Federal framework does is that it provides a
15 number of indispensable and key facts.

16 What do we know? We know that this pharmaceutical
17 industry is highly regulated, perhaps an unprecedented level of
18 regulation. We are talking about generic drug products that
19 very likely affect every single person at some point in their
20 life. These drug products are ingested or otherwise delivered
21 into our bodies. These drugs can be dangerous and potentially
22 deadly. In this case, we are talking about a drug, Zantac,
23 that causes cancer.

24 There is no greater imbalance of information than the
25 one between the brand name manufacturer and the consumer. The

1 brand manufacturer is the expert, they are the one that created
2 the warning label related to the generic consumer, who is
3 innocent. In fact, this drug product is so highly regulated
4 that the Federal regulatory scheme mandates, mandates that
5 before a new drug is approved the brand name manufacturer must
6 ensure the drug is safe and effective and that the warning
7 label accompanying that alleged safe and effective drug is
8 accurate and adequate, which duty continues through the life of
9 the drug.

10 The brand name manufacturer is always responsible for
11 its warning label. That is the responsibility it acquired when
12 it received the exclusive monopoly benefit with the drug's
13 approval.

14 Finally, generic manufacturers have the duty of
15 sameness and must use the same warning label as the brand name
16 manufacturer. As the Supreme Court stated in Wyeth, the brand
17 name manufacturer bears responsibility for the content of its
18 warning label at all times. It is charged both with crafting
19 an adequate warning label and ensuring that its warnings remain
20 adequate as long as the drug is on the market.

21 These are the facts and circumstances and framework
22 that are clear and unequivocal. While the parameters and
23 framework for resolving the question before the Court has been
24 established at the Federal level by the Supreme Court and
25 Congress, all parties agree here that resolution of the

1 Plaintiffs' specific negligent misrepresentation claims are
2 substantive state law questions in each applicable state.

3 So, back to the basics. As we said, under Erie, a
4 Federal Judge sitting in diversity must make a substantive law
5 decision for each state. This requires an interpretation of
6 state law, just as this Court stated in its order requiring
7 supplemental briefing. Despite Defendants' characterization,
8 Erie neither requires the Court to expand nor restrict state
9 law. The Court must make a prediction using
10 reasonable evidence available for making this determination, no
11 more and no less.

12 Other than the six jurisdictions where the issue has
13 already been resolved, the Court will have to make a
14 determination of state law based on relevant evidence such as
15 relevant intermediate state precedence, analogous decisions,
16 considered dicta, scholarly works, and any other reliable data.

17 The Federal drug policy scheme regarding warning
18 labels creates the duty owed by the brand name manufacturers to
19 the generic consumers. There is no requirement, as Defendants
20 seem to suggest, that a Federal District Judge should not make
21 a prediction if it leads to recognizing a claim on behalf of a
22 Plaintiff in any particular state. That simply is not what
23 Erie requires, and that simply cannot be correct.

24 We know that the majority of the State Supreme Courts
25 that have considered this issue have found that the brand name

1 manufacturers owe a common law duty to consumers adjusting
2 generic bioequivalent drugs of the brand name manufacturers'
3 drugs, although the Alabama Legislature abrogated the State
4 Supreme Court in that case. These majority State Supreme Court
5 opinions did what this Court must do and looked to relevant
6 common law principles, and reasoned analysis to arrive at the
7 likely outcome, principles applied to the facts at issue here.

8 As the majority of State Supreme Courts have done
9 this, the Court must look to available guidance. Plaintiffs
10 have provided at least four common and reasonable
11 considerations where the other Supreme Courts looked at and
12 where it is reasonable to look here. Where you will find
13 guidance, foreseeability, restatement Section 311, restatement
14 Section 552, and Rowland factors, including their public policy
15 considerations.

16 It is axiomatic that a tortfeasor is responsible for
17 foreseeable harms caused even to a third person based on their
18 misrepresentations.

19 Plaintiffs' negligent misrepresentation claims are not
20 extraordinary and they are not new theories of liability.
21 Foreseeability has been around for some time. I think we all
22 remember Palsgraf from law school. We are not asking the Court
23 to extend principles of common law, rather, we are asking the
24 Court to apply already existing principles to the facts at
25 hand.

1 As Judge Sessions in Kellogg versus Wyeth stated in
2 interpreting Vermont law, "to recognize a brand name drug
3 manufacturer's duty to generic customers does not recognize a
4 new cause of action or enlarge an existing one." The
5 Court should not unduly restrict common law principles when
6 there is no reasonable basis for such restriction. A Federal
7 Judge in a diversity case does not equate to an automatic thumb
8 on the scale against Plaintiffs if the State Supreme Court has
9 not already decided the specific facts under its common law.

10 Judge Sessions again in Kellogg versus Wyeth stated he
11 simply applied the basic precepts of Vermont's negligence law
12 to ascertain whether legally cognizable duty exists, and he
13 concluded that it does.

14 So, is it foreseeable that a brand name Defendant
15 would owe a duty to generic consumers who rely on the label
16 written by the branded manufacturer? As set forth in Novartis,
17 it is entirely foreseeable that the warnings included, or not
18 included, on the brand name drug warning label would influence
19 the dispensing of the generic drug. It is not speculative, it
20 is not based on probabilities or likelihoods. It is entirely
21 foreseeable.

22 In fact, it is notable to a legal certainty that it
23 will be liable for any deficiencies in its warning label that
24 will appear in the generics' warning label and liability should
25 follow. It is a mandatory requirement that the warning labels

1 on the brand name manufacturers' drug warning label will be
2 used on the generic drug's warning label. You can't get around
3 that.

4 How can a brand name manufacturer have a duty
5 regarding its warning label on the brand name drug, but that
6 duty not extend to any and all of the consumers who must rely
7 upon that label, including generic customers?

8 The Federal regulatory scheme, coupled with state
9 negligence laws are not intended to place consumers at such an
10 unfair disadvantage. The Seventh Circuit in *Peschar* succinctly
11 set forth what this Federal framework really means. The
12 Hatch-Waxman Act allows manufacturers of branded drugs to be on
13 the hook for mislabeling on their generic counterparts.

14 In such a case, the brand name manufacturer can be
15 said to have caused any mislabeling by a generic drug
16 manufacturer even if the branded manufacturer had no hand in
17 the manufacture or distribution of the drug or the warning
18 labels.

19 Foreseeability is the common thread in any duty
20 analysis, that is the linchpin. It makes sense. It is about
21 fairness and expectations. It also makes sense that applying
22 this age old principle is not difficult to do on the facts
23 before us. The brand name manufacturer's label is the
24 negligent misrepresentation that caused the harm. There are no
25 surprises and it is a legal certainty, they must be the

1 responsible party.

2 States that would recognize Section 311 of
3 restatement of torts would find a brand name manufacturer owing
4 a duty here. One who negligently gives false information to
5 another is subject to liability for physical harm. Under
6 Section 311, comment B, even third party harms are covered
7 under a negligent misrepresentation involving risk of physical
8 harm.

9 Comment C proposes that liability applies to advice
10 given gratuitous and where the actor purports to have special
11 knowledge. All of those factors are at play here.

12 Defendants' supplemental brief summarily dismisses
13 Section 311 as requiring an affirmative misstatement. That is
14 exactly what happened here. The brand manufacturers' label
15 affirmatively stated that the drug was safe and effective.

16 Section 552 of the restatement second of torts
17 provides another strong indication that brand name Defendants
18 should be held responsible for harms resulting from negligently
19 supplied information. The brand name manufacturer, in the
20 course of its business, supplied false information to the
21 generic drug users, and they suffered injury and loss because
22 of the failures in the brand name manufacturers' warning
23 labels.

24 These are not new principles, but they are principles
25 that must be applied under these fairly unique circumstances

1 that the Federal regime created where the brand name
2 manufacturers' warning label must be used by the generic
3 manufacturers. Essentially, the brand name manufacturers set
4 in motion the Palsgrafian bomb that harms the generic consumer
5 across the train tracks, and it knew that it would.

6 Another strong indicator in consideration for finding
7 state law liability are the Rowland factors or their
8 equivalent. We identified six states and Puerto Rico that have
9 followed and applied the Rowland factors for determining the
10 law of products liability. Not surprisingly, the Rowland
11 factors emphasized foreseeability prominently in their
12 analysis.

13 In addition to foreseeability, it is notable that
14 three of the Rowland factors emphasize public policy
15 considerations. These public policy considerations are of
16 no small importance here. These squarely land in favor of the
17 Plaintiffs and against the brand name Defendants.

18 If the legal and Congressional framework tells us
19 nothing else, it tells us that the consumer should be protected
20 and prioritized over the brand name manufacturers. The brand
21 name manufacturers are not innocent unwitting partners here.

22 They not only have the legal duty and responsibility
23 for the warning labels, they should also have the moral blame
24 when injuries result from those very warning labels. They are
25 the only ones that can change the warning label and prevent

1 harm.

2 Brand name manufacturers already have a continuing
3 duty to warn of the potential risks as soon as there is
4 reasonable evidence of hazardous association with a drug and a
5 causal relationship need not have been proved.

6 By virtue of the Federal framework, brand name
7 manufacturers owe a duty to both its own consumers and the
8 consumers of the generic drug. The generic consumer who
9 develops cancer by relying on the brand name manufacturers'
10 inadequate warning label is innocent.

11 Outlined in our supplemental brief we identified 35
12 jurisdictions where this Court's review should find viable
13 Plaintiffs' claims and duties against the brand name
14 manufacturers and follow the majority view given common and
15 reasonable evidence.

16 In sum, when the Court conducts its Erie valuation
17 just as it should, and not the Defendants' false presumption
18 that Plaintiffs should not be able to recover against anyone
19 for their injuries, there is no other entity that can legally
20 and morally be responsible for the Plaintiffs' claims but for
21 the brand name manufacturers.

22 Now I will move to the Defendants' second argument,
23 which is about personal jurisdiction. Our suit arises out of
24 the brand name manufacturer Defendants contacts with the forum
25 states.

1 Brand name manufacturer Defendants, at a minimum,
2 provided warning labels that were included in the products that
3 were marketed and are sold in every forum state at issue. The
4 offending contact at issue is the warning label that was
5 marketed by the brand name manufacturer Defendants in the forum
6 states. The contact is not, as the Defendants claim, the
7 decisions regarding the warning labels.

8 If you follow Defendants' argument to their
9 conclusion, their position is that the brand name Defendants
10 cannot be sued anywhere by users of the generic version of its
11 drug, not in home states, not in states where they marketed and
12 sold their product, not anywhere.

13 In fact, even if the brand named Defendants home
14 states conducted choice of law analysis and decided to apply
15 California law, for example, somehow Defendants reject that
16 decision as well.

17 No brand manufacturer could claim that it could not
18 reasonably anticipate that it would be hailed into court where
19 they sold and marketed with the warning label in every corner
20 of our country and commonwealth territories. Indeed,
21 Defendants' motion at page ten concedes that there is
22 sufficient jurisdiction where they did business and where they
23 sold their product.

24 As well pled throughout the Plaintiffs' PI master
25 complaint we clearly allege that the brand name manufacturer

1 Defendants' conduct in the forum state establishes personal
2 jurisdiction. Plaintiffs are not referring to any third
3 parties or even the generic manufacturers' contacts in the
4 forum states. It is the brand name Defendants' sales efforts
5 and warning labels that entered each state at issue here which
6 created the market, by the way, for the generic drug users.

7 Defendants' curious position that it only made warning
8 labeling decisions in their home states is not present anywhere
9 in the Plaintiffs' master complaint and they mistakenly suggest
10 that Defendants did not expect their warning label to be
11 included in every bottle and package disseminated throughout
12 this country. That is contrary to Federal statute and law.

13 Importantly, in addition to the specific jurisdiction
14 concessions brand name Defendants already made, they also
15 concede general jurisdiction. The only question that remains
16 in those home states court's decision is whether another
17 state's law, i.e. California or Massachusetts for example,
18 should apply. This is the standard choice of law analysis.

19 Finally, the third argument Defendants make is that
20 due process is also offended by holding Defendants liable for
21 activities in California and Massachusetts. The due process
22 analysis also employs a minimum contact analysis and for the
23 same reasons the Defendants' arguments fail regarding personal
24 jurisdiction, they fail here as due process is satisfied.
25 Defendants' conduct is the same liability inducing conduct at

1 issue in Plaintiffs' negligent misrepresentation claims, and
2 Defendants concede jurisdiction.

3 Defendants are taking the unreasonable and unsupported
4 position that the claim cannot be pursued against them
5 anywhere, even in their home states, and not even after a
6 choice of law analysis. That is not what due process means.

7 In conclusion, your Honor, this Court cannot ignore
8 the Federal framework through which the substantive state law
9 reviews must be completed. If Defendants' arguments are
10 believed, there is no state where Plaintiffs can bring their
11 claims and no entity against whom to bring their claims.

12 It truly would be a perverse result for this Court to
13 adopt the Defendants' position here within the clear Federal
14 framework under which the brand name manufacturer is
15 responsible for the warning label, but not responsible for the
16 injuries that result in the misrepresentation of that very
17 warning label. That is not an acceptable result and
18 Defendants' Motion to Dismiss should be denied.

19 Thank you, your Honor.

20 *THE COURT:* Thank you very much.

21 All right. Defense has about three minutes and a
22 half -- three and a half minutes for any rebuttal.

23 *MR. CHEFFO:* Thanks, your Honor. I will keep my
24 picture off.

25 Briefly, your Honor, if these claims were so

1 established and so well recognized, as we just heard, these
2 very skilled lawyers who are representing the Plaintiffs would
3 not have conceded the 15 jurisdictions out of the box before we
4 even argued this today.

5 According to cases, a hundred cases, including from
6 the Sixth, Eighth, Tenth, Eleventh Circuits have rejected these
7 claims. We still haven't heard a discussion of Guarino other
8 than, essentially, a footnote in their brief or the Darvon
9 case.

10 Basically, their entire argument is largely for both
11 personal jurisdiction and with respect to the innovator
12 liability rests on foreseeability. The Eleventh Circuit did
13 not base its decision in Guarino on foreseeability principles,
14 rather, the Court, like many others, rejected that innovator
15 liability theory because it seeks to impose liability on a
16 company for injuries caused by a product the company did not
17 make, a result that has no basis in Florida law, citing your
18 Honor's decision.

19 Similarly, the Darvon, Darvocet case doesn't rely on
20 foreseeability. When the Sixth Circuit affirmed dismissal of
21 innovator liability claims for 22 different states it did so
22 not because the claims lacked foreseeability, but because the
23 claims lacked pleading or proof.

24 Essentially, the Sixth Circuit acknowledged that it
25 was foreseeable that purchasers of generic medication would

1 rely on the brand name label giving the regulatory requirement
2 that generic product labels follow the brand, but nevertheless,
3 the generic customers alleged injuries were not the foreseeable
4 result of the brand manufacturers' conduct, so said the Sixth
5 Circuit, but of the labeling laws under which the brand
6 manufacturers have no control, this is from the decision,
7 because none of the states where the Plaintiffs lived had
8 departed from the "well settled threshold requirement that the
9 Plaintiffs assert that the Defendants' product caused the
10 Plaintiffs' injury, the Plaintiffs claims failed as a matter of
11 law," foreseeability notwithstanding, your Honor.

12 The restatement arguments, just briefly, the first
13 that was cited, it basically is inapplicable here. It talks in
14 terms of a specific misrepresentation. This case, at best as
15 to the labeling issues, is with respect to a failure to warn.

16 The 522 section, which, by the way, was not cited in
17 any of the cases that -- the two cases that adopted innovator
18 liability, California and Massachusetts, is not cited, but
19 nonetheless, it deals with pecuniary interest.

20 With that, your Honor, I think I am going to stop and
21 your Honor, I am sure, will have some questions for us.

22 *THE COURT:* Thank you. Yes. Everybody can -- all
23 counsel on this motion can turn your video and audio on. Mr.
24 Cheffo, if you prefer to keep your video off, that is fine,
25 too.

1 This is a question for the Defendants. Your Motion to
2 Dismiss does not refer to any Federal Rule of Civil Procedure.
3 Under which Federal rule or rules are you moving to dismiss.

4 *MR. CHEFFO:* Under 12(b)(6) with respect to the
5 innovator liability claims and 12(b)(2) with respect to the
6 jurisdictional claims.

7 *THE COURT:* For the Plaintiffs: In your response, it
8 does not appear that you respond to the Defendant's arguments
9 regarding a fundamental principle of products liability law.

10 For a Plaintiff to assert a valid products liability
11 claim, the Plaintiff must allege that they were injured by a
12 product manufactured, distributed, or sold by the Defendant.
13 This principle is known as product identification.

14 Rather, you say that, quote, "the MPIC asserts valid
15 claims sounding in negligence and negligent misrepresentation,"
16 end of quote, and then you proceed to discuss at length why
17 brand name manufacturers owe a duty of care to generic
18 Ranitidine consumers. That is your response at page 9.

19 As supporting authority you cite to Section 311, as
20 you showed the Court here today, of the restatement second of
21 torts which discusses negligent misrepresentation, and you cite
22 also to the same California Supreme Court case that you
23 highlighted here today, *T.H. versus Novartis Pharmacy*
24 *Corporation -- Pharmaceutical Corporation*, 407 P.3d 18
25 *California*, 2017, in which the Court held that the generic

1 consumer's negligence and negligent misrepresentation claims
2 against brand name manufacturers were viable.

3 You also cite to the Massachusetts Supreme Court case
4 *Rafferty versus Merck and Company, Inc.*, 479 Massachusetts 141,
5 2018, in which the Court held that the generic consumers could
6 proceed against brand name manufacturers on a very limited
7 theory of recklessness for failure to warn. The Court notes
8 that the Massachusetts Supreme Court held that the Plaintiff's
9 consumer protection and general negligence claims were not
10 viable.

11 So, as to claims sounding in negligence and negligent
12 misrepresentation, the Court construes what Plaintiffs
13 categorize as valid claims "sounding in negligence and
14 negligent misrepresentation" to include Counts 4, 5, 6, 7, and
15 8, negligent failure to warn, negligent product design,
16 negligent manufacturing, general negligence, and negligent
17 misrepresentation.

18 I want to ask whether that interpretation is correct
19 for the Plaintiffs.

20 *MS. JUNG:* Your Honor, with respect to -- I am sure
21 Mr. Longer will jump in -- the negligent misrepresentation
22 claims here, we are talking about the cases where we have
23 warning label that was used by the generic manufacturers
24 because of the brand name manufacturers, so if you have the
25 negligent misrepresentation, it would be the negligent

1 misrepresentation of the brand.

2 So, to go back a little bit on the state issue, we
3 have to look at the specific states and the specific common law
4 in those particular areas to identify if there is a narrower
5 common law than in the other states, and we believe that the 35
6 jurisdictions would allow for the negligent misrepresentation
7 claims here.

8 *THE COURT:* Right, but I want to make sure I
9 understand as to which counts. You talk about claims sounding
10 in negligence and negligent misrepresentation. I want to be
11 very, very clear, are those referring to Counts 4, 5, 6, 7, and
12 8 of the complaint?

13 *MR. LONGER:* Your Honor, if I may jump in, Fred
14 Longer. We are referring more specifically to Counts 7 and 8,
15 just the negligence and negligent misrepresentation counts.

16 *THE COURT:* When you say more specifically, just 7 and
17 8, not 4, 5, 6?

18 *MR. LONGER:* That's correct.

19 *THE COURT:* As to strict liability claims, Counts 1,
20 2, and 3 are labeled as strict products liability claims.
21 That's in the personal injury complaint, paragraphs 453 to 499.

22 Question for the Plaintiffs, do you concede that these
23 claims would fail under your theory of liability for lack of
24 product identification?

25 *MS. JUNG:* I am fairly certain Mr. Longer is dying to

1 answer this question, so I will pass it to him.

2 *THE COURT:* Okay.

3 *MR. LONGER:* Fred Longer, your Honor. In a word,
4 never.

5 *THE COURT:* Have any Courts held that strict product
6 liability claims are viable under your theory of liability?

7 *MR. LONGER:* I am not aware of any that are directly
8 on point, your Honor. I am aware of some jurisdictions that
9 have provided that both -- that our theory survives even in a
10 strict liability jurisdiction because they also recognize
11 negligence, and these claims transcend from strict liability
12 into negligence theories, which is why they are being pursued
13 as such under the negligence and negligent misrepresentation
14 counts of the complaint.

15 *THE COURT:* Right, but I am talking now about the
16 strict liability claims.

17 *MR. LONGER:* So, again, we are -- we are pursuing
18 these from a negligence standpoint. In jurisdiction that only
19 apply strict liability, I believe that -- and Mr. Cheffo raised
20 this -- there were 11 jurisdictions that we are not pursuing
21 this claim in because they are either strict liability
22 jurisdictions or there is a product liability act and the like.

23 *THE COURT:* Mr. Cheffo, did you want to respond?

24 *MR. CHEFFO:* Just to say, your Honor, it's -- so, I
25 understood that at least they were largely proceeding in

1 California, but one of the issues I think we had is to try to
2 understand, if you will -- I don't mean to be pejorative -- but
3 kind of where the lines the Plaintiffs have drawn. For
4 example, there are four states where the Plaintiffs have
5 conceded this issue where the highest Courts rejected innovator
6 liability, so that is relatively straightforward.

7 There are seven states where the Plaintiffs do not
8 contest -- concede this issue where the product liability
9 statutes require product identification. But of the remaining
10 states at issue, there is also Colorado, Connecticut,
11 Mississippi, Oregon, North Carolina that have similar statutes
12 that also warrant rejection of the innovator liability for lack
13 of product identification. In other words, in addition to the
14 ones they have looked at, there are actually many others.

15 They basically conceded four states where they don't
16 contest this issue where intermediate Courts, Federal Courts
17 applying the law have rejected innovator liability, but then
18 you look at the remaining states and 22 of those have case law
19 from intermediate, state, or Federal Courts explicitly
20 rejecting the theory.

21 I can give you those, if you'd like, your Honor, there
22 are 22. I don't want to drive the Court Reporter crazy if not
23 necessary.

24 To us, it is all of the cases, but even within the
25 framework and the rubric the Plaintiffs have set out in terms

1 of their concessions it is hard to draw parallels for us.

2 *THE COURT:* Mr. Longer, I want to be clear, you are
3 not arguing that you can pursue a strict liability claim under
4 a theory of negligence, correct?

5 *MR. LONGER:* We are not pursuing a strict liability
6 claim under a theory of negligence. They are distinct
7 theories, your Honor, and the theory behind what the Defendants
8 and what everyone is calling innovative liability is a
9 negligent misrepresentation claim. It is not a strict
10 liability claim.

11 Some jurisdictions that apply strict liability may
12 allow for this theory still to be pursued.

13 *THE COURT:* Do you have an example of a jurisdiction
14 that would allow a strict product liability claim to be
15 pursued? I am just wondering why you are persisting in Counts
16 1, 2, and 3 against the brands and trying to understand --

17 *MR. LONGER:* So, the -- I am thinking it is Nevada,
18 your Honor, but I may be mistaken on that. Let me just look.

19 I don't have that at my fingertips, your Honor, but
20 certainly in our supplemental briefing we address those
21 jurisdictions that still apply strict liability, and the claim
22 has sufficient authority within that jurisdiction to allow the
23 claim to permit -- to proceed.

24 *THE COURT:* If there were no jurisdictions, upon the
25 Court's review, that permitted a strict product liability claim

1 to proceed under the theory of liability that you are putting
2 forth for lack of a product identification, would you agree at
3 that point that, at a minimum, Counts 1, 2, 3 that are labeled
4 strict liability claims wouldn't survive?

5 MR. LONGER: I'm struggling with the question because
6 of the premise, your Honor. The strict liability theories that
7 we are pursuing are, in essence, about failure to warn,
8 negligent -- I am sorry, failure to warn, design defect, and
9 manufacturing defect.

10 The claims regarding, let's call it innovator
11 liability are not presented within those counts. They are
12 presented in Counts 7 and 8.

13 So, that is the disconnect. I'm sorry, I am trying to
14 answer your Honor's question directly, but I am struggling with
15 the question because --

16 THE COURT: Okay. So, you are only proceeding -- I
17 guess that would also take care of breach of warranty claims,
18 Counts 9 and 10? In other words, you are not -- or Count 11,
19 violation of consumer protection, deceptive trade practice
20 laws, or unjust enrichment in Count 12, none of those are --

21 MR. LONGER: They are not at issue on this theory of
22 recovery.

23 The theory of recovery, the essence of this claim, is
24 a negligence theory, so that is why we allege negligence and
25 negligent misrepresentation. That is Count 7 and Count 8.

1 So, if you go back to the Novartis case, the
2 California case, and the Rafferty case that your Honor
3 mentioned, it is in our briefing, the essence is still
4 negligence. Massachusetts went a little bit further and said
5 they wanted a recklessness standard, but they still went back
6 to squares in terms of establishing that the foundational
7 building blocks of this claim are negligence.

8 And in part, that is because the -- there is this
9 product identification principle that I have heard Mr. Cheffo
10 describe, I know it is in the Darvon and Darvocet case, and
11 your Honor mentioned it, it is -- that is embedded in Florida
12 law, and I am sure your Honor is more than familiar with that
13 issue having drafted the Dietrich opinion. But, again,
14 those -- that is not the foundation of this claim.

15 In those states where you must pursue -- or must have
16 purchased the Defendant's product, that is not the 35
17 jurisdictions that we have announced. I heard Mr. Cheffo say
18 that there is, I think five jurisdictions where there are
19 product liability statutes on the books similar to others,
20 however, what he didn't mention is that there is case law
21 interpreting those statutes not to require product
22 identification or what I call privity analysis.

23 So, there are distinctions, there are nuances
24 throughout the jurisdictions, 35 at issue here, and it's -- you
25 have to look at each one and see whether or not those states

1 provide the indicia that are sufficient and supportive of the
2 claim, and if there is indicia -- and obviously we disagree
3 that you have to have authoritative decision that directly
4 recognizes the claim. That is putting the thumb on the scale.

5 I heard Mr. Tam make that representation. That is
6 certainly not the law, that is not even what for Guarino says.

7 Guarino does not require that, Guarino just says that
8 you have -- when attempting to forecast state law, you can't
9 venture into uncharted waters of state substantive law, and
10 then it cites to the Douglas Asphalt case, which says that you
11 can't expand state tort law absent state authorities suggesting
12 the propriety of doing so.

13 We have given your Honor a number of authorities where
14 there is more than propriety of doing so, there is ample
15 authority, and I could give those examples right off the top of
16 my head.

17 *THE COURT:* Let me see if I can get to the bottom of
18 some confusion.

19 So, in the conclusion of the Defendants' motion, page
20 20, it says, the brand name manufacturers respectfully ask this
21 Court to dismiss all innovator liability claims asserted by
22 Plaintiffs in this MDL.

23 So, what did the Defendants have in mind when they
24 said all innovator liability claims? Did you know which
25 claims, counts you were referring to at the time of writing

1 that conclusion, or do you know now?

2 MR. CHEFFO: I think we have some clarity based on
3 your Honor's questioning, so I will try and answer your
4 question directly. Our bottom line was to cover the waterfront
5 for all the reasons we have talked about. To the extent --
6 this goes back to the shotgun pleading an other issues. To the
7 extent that any claim was being asserted against us, we were
8 moving on all of them.

9 What I think we heard from Mr. Longer's response to
10 your question is that they were only asserting negligence based
11 claims, so this may be easy. To the extent that they are not
12 asserting those other claims, as we have just heard, against
13 us -- and frankly, it is hard to understand how they could
14 since these aren't products that were manufactured and sold by
15 a Defendant or used in a state by an individual. So, we think
16 those were are clear.

17 Now, to the extent that they are based in negligence,
18 for the reasons I said, we think also those should be
19 dismissed, and our understanding was at least the Massachusetts
20 and California were largely negligence based claims, if that
21 answers your question.

22 THE COURT: So, just to be clear, you weren't clear
23 when you wrote your conclusion, so you left it open when you
24 said all innovator liability claims.

25 Mr. Longer, I understood you today to say the only

1 innovator liability claims present in the master personal
2 injury complaint at Docket Entry 887 are Counts 7, which is
3 general negligence at page 119, and Count 8, negligent
4 misrepresentation, at page 124.

5 So, I should construe the Defendants' motion to really
6 only be directed at those two counts; is that accurate?

7 MR. LONGER: Fred Longer, your Honor. Yes, and may I
8 add one point, your Honor? We do not present the language
9 "innovator claim."

10 THE COURT: I know that.

11 MR. LONGER: Innovator liability does not appear in
12 the complaint. What we are saying is they negligently
13 misrepresented their label and it impacted generic users, and
14 that is the essence of Section 311 of the restatement of torts,
15 and that is what gives rise to liability.

16 THE COURT: I do understand you have not used that.
17 Where in your response did you make clear that it was just
18 Counts 7 and 8, if you did at all?

19 MR. LONGER: I don't believe that we felt it incumbent
20 upon us to make that representation. We said very specifically
21 in our negligence and negligent misrepresentation claims and
22 that, I thought, established the principles or the location, if
23 you will, within the master personal injury complaint.

24 THE COURT: Okay.

25 MS. JUNG: Your Honor, this is Je Yon Jung. If I may

1 add one point, this is on Counts 7 and 8, negligence and
2 negligent misrepresentation. Those are on behalf of the brand
3 name manufacturer consumers as well as the generic consumers,
4 so it is for both of those consumers.

5 *THE COURT:* Okay. So, Mr. Cheffo, then, are the
6 Defendants, with this clarification, only seeking to dismiss
7 Counts 7 and 8 in Docket Entry 1585?

8 *MR. CHEFFO:* Well, so -- no, no, your Honor, because
9 what I -- maybe I am trying to understand exactly what the
10 Plaintiffs' position is.

11 We are saying essentially all of the claims -- there
12 is only a predicate -- if someone never used the brand
13 manufacturers' product, any claim has to be as a result of
14 innovator liability. Right? We think there couldn't have been
15 claims for design, all of the other claims. I think what we
16 are hearing is the Plaintiffs are saying they are not pursuing
17 those types of claims against the brand manufacturers. So, to
18 the extent that is not clear from their pleadings where they
19 say everything against everyone, then yes, those should be
20 dismissed for the reasons we have heard today.

21 Your Honor has asked on the merits, to the extent that
22 they are pursuing those claims in addition to the others which
23 your Honor should say are dismissed because they are not being
24 pursued, then on the merits they should be dismissed.

25 Am I being clear, your Honor?

1 *THE COURT:* I am going to go back to the Plaintiff.
2 Are the only claims against the brand manufacturers --

3 *MR. LONGER:* Your Honor, Fred Longer. May I speak?

4 *THE COURT:* I think we need clarification, the Court
5 does, and the Defendants do.

6 *MR. LONGER:* I am having trouble. Can you hear me?

7 *THE COURT:* I can hear you.

8 *MR. LONGER:* So, we are only pursuing these theories
9 under Counts 7 and 8. The fact that the Defendants' motion was
10 poorly articulated and just said the claims, and they didn't
11 focus on where the claims were presented was not a burden that
12 we felt we had to correct.

13 What we always said was that our theories are based on
14 negligence and negligent misrepresentation. Those claims are
15 only found in Counts 7 and 8. So, you don't need to dismiss
16 any other claims, they are not even at issue.

17 *THE COURT:* Well, I mean, the movant would tell me if
18 they are at issue or not. The movant generally is the one who
19 indicates what is being sought, what relief is being sought.

20 Again, I go back to the conclusion, the brand name
21 manufacturers respectfully ask the Court to dismissal all
22 innovator liability claims asserted by Plaintiffs in this MDL.

23 The Plaintiffs are saying the only -- although they
24 don't adhere to the terminology, but we will call it that just
25 for clarity of discussion. The Plaintiffs are saying the only

1 innovator liability claims asserted by Plaintiffs in the master
2 personal injury complaint are Counts 7 and 8.

3 And so, my question then is, is that what the
4 Defendants are seeking to have dismissed in their motion,
5 Counts 7 and 8, based on that representation?

6 MR. CHEFFO: Your Honor, I am glad you are drilling
7 down on it, so I want to make sure that we are clear as well.

8 Here is what I would say, if what you asked the
9 Plaintiff and what he said is that all of these other counts
10 other than 7 and 8 do not apply to the brand manufacturers, if
11 that is the point, then yes, we are only moving against the
12 ones that they say apply to us.

13 What wasn't clear is that because the way the
14 Plaintiffs have pled everything here, they seem to allege
15 everything against everyone, so to the extent there are other
16 claims other than 7 and 8 that they are alleging against the
17 brand manufacturers, we think the only way that they can do
18 that, since we didn't make the product or sell the product, is
19 under the innovator liability theory which we don't think
20 applies.

21 So, to the extent that they are asserting those
22 claims, innovator liability bars them. If they are telling us
23 today that they are not and they never were intending to assert
24 them against the brand manufacturers, then no, we can have a
25 stipulation those are gone and they are not against us.

1 MR. LONGER: Your Honor, Fred Longer.

2 This complaint is a master complaint, it pleads
3 against all of the Defendants in this action. Some Plaintiffs
4 who took generic drugs are asserting claims against branded
5 manufacturers under negligence theories, which would be in
6 Counts 7 and 8, but, your Honor, other Plaintiffs in this
7 litigation who are not the ones that we are specifically
8 talking about because -- because those Plaintiffs have other
9 claims against the branded or generic manufacturers.

10 This is -- the problem with this motion, if you will,
11 your Honor, is that this is a partial -- they are splitting
12 claims. We are asserting claims for negligent
13 misrepresentation. Some of the negligent misrepresentation
14 claims apply to the generic users who were harmed because of
15 the branded label, but a branded user could still have a
16 negligent misrepresentation claim, so you can't dismiss the
17 count because other plaintiffs in this litigation are
18 participating through the master personal injury complaint.

19 This is a carve out of a theory of liability that
20 encompasses negligence and negligent misrepresentation. It is
21 that thin. There are other negligent aspects to the case that
22 will still proceed even if the Court were to grant the
23 Defendants' motion that we can't state a claim for innovator
24 liability anywhere other than in California and Massachusetts.

25 It is a poorly articulated motion. We tried to

1 address it as best we could by saying we are focused on the
2 negligence and negligent misrepresentation foundations that
3 underlie the innovator liability theory of recovery. To that
4 end, I think I have added as much clarity as I can.

5 Those theories are encompassed in Counts 7 and 8, but
6 they are not the exclusive theories pronounced or described in
7 Counts 7 and 8.

8 *MR. CHEFFO:* Your Honor, I am not going to really
9 address the -- that our motion is not clear enough. The reason
10 we have been going back and forth on this for 20 minutes is
11 because the Plaintiffs don't even know who is bringing the
12 claims against who and can't really articulate it, and that has
13 been the problem.

14 The issue here is that no one is suggesting in a
15 personal injury case, if someone alleges that they used a
16 particular manufacturer's product and sold it, we couldn't be
17 clearer about that, we have other defenses.

18 To the extent someone is saying I never used this
19 particular product that was manufactured and sold by this
20 particular Defendant, no matter what theory it is, we think no
21 state other than California and Massachusetts, no matter what
22 the theory, no matter what the ground, no matter what the claim
23 is, they should be dismissed.

24 It is still not a hundred percent clear to me what Mr.
25 Longer is saying. We are over interpreting their complaint and

1 no one who is asserting innovative liability is ever going to
2 bring a claim against us, and it is only 7 and 8, well, then
3 they can stipulate to that and we can save the Court some time
4 and move on.

5 For the innovator liability negligence claim, the
6 motion is ripe with respect to Counts 7 and 8. That is really
7 where we can't seem to get an answer from the Plaintiff. Are
8 people who never used products and violate the fundamental
9 principles of tort law and others, are they suing under all
10 these theories or is it just the negligence claims?

11 *MS. JUNG:* Your Honor, if I may, Je Yon Jung. There
12 is a lot of confusion. We are talking in the motion about the
13 negligence and negligent misrepresentation that the brand
14 manufacturer made against the consumers. That is the very
15 narrow issue we are talking about here.

16 However, the other counts and the other claims, there
17 may be claims by brand manufacturer consumers against the brand
18 manufacturer, generic consumers against the generic
19 manufacturers, but this particular issue is only talking about
20 the negligence of the brand manufacturer and the negligent
21 misrepresentation they made on their warning labels that made
22 it to the generic consumers.

23 *THE COURT:* Well, the other counts -- assuming for a
24 moment that premise, is it fair to say then the Plaintiffs are
25 not bringing any other count other than 7 and 8 against the

1 brands, that is of the 15 counts in the personal injury
2 complaint, the Plaintiffs are not bringing any other count
3 other than 7 and 8 against the brands for ingestion of a
4 generic product? The Plaintiffs are not seeking to hold the
5 brands liable under any other count other than 7 and 8 for a
6 product that was manufactured by a generic. Is that an
7 accurate statement?

8 MR. LONGER: Yes, your Honor. Fred Longer, yes.

9 THE COURT: Okay.

10 MR. LONGER: Those theories are -- this is a very
11 narrow aspect of the case. The Defendants have some case law,
12 as we've briefed and as Your Honor knows, in a couple of
13 states -- in Alabama it has been abrogated by statute. The
14 Supreme Court of Alabama found that this theory of recovery is
15 valid and states a cause of action in Alabama except the
16 legislature took it away.

17 We know in Iowa, because they found that product
18 identification issues under Iowa state law would preclude the
19 claim, they refuse to adopt this theory. The same thing
20 applies in West Virginia, and that is -- that is how narrow
21 this is.

22 THE COURT: Okay. I appreciate it. I do want to move
23 on to some jurisdictional questions, but this is how I
24 understand it.

25 The motion was seeking to dismiss innovator liability

1 claims. I know that is not what the Plaintiff calls it, that
2 is what the Defendant calls it, so I am calling it that because
3 the Defendant is the movant. The only innovator liability
4 claims are 7 and 8. That does not mean that those are the only
5 claims against the brands, but those are the only innovator
6 liability claims against the brands.

7 So, the motion is directed to 7 and 8, and I suppose
8 to the extent that in another day and another round of
9 briefing, should that be appropriate, I am not suggesting that
10 will happen or should happen, if there are other arguments that
11 the brands have with respect to the other counts, they may be
12 raised, but they have fully addressed their innovator liability
13 claims in their motion, and you are saying, Plaintiffs, that
14 that means that only applies to Counts 7 and 8, right?

15 *MR. LONGER:* Correct, your Honor.

16 *THE COURT:* Understood, Mr. Cheffo, that makes sense?

17 *MR. CHEFFO:* It does. If they are not asserting any
18 claims other than those against us, then we have no reason to
19 move against them other than --

20 *THE COURT:* They are not asserting any other innovator
21 liability claims against the brands.

22 *MR. CHEFFO:* Yes, meaning people who have not used our
23 products.

24 *THE COURT:* Okay. Let's move on because it is late.
25 I didn't expect that amount of time on that question, but that

1 was important.

2 So, now, on the jurisdictional issues, Plaintiffs, in
3 paragraphs 21 through 36 of the master personal injury
4 complaint you list the brand named Defendants and the states
5 and countries in which they are incorporated and have their
6 principal places of business, in other words, where they are
7 citizens.

8 As the Supreme Court explained in Daimler AG versus
9 Bauman, 571 U.S. 117, at 138 to 139, 2014, it is only in an
10 "exceptional case" that a "corporation's operations in a forum
11 other than its formal place of incorporation or principal place
12 of business may be so substantial and of such a nature as to
13 render the corporation at home in that state," and consequently
14 subject to general jurisdiction in that state.

15 Do you contend that any of the Defendants are subject
16 to general jurisdiction in any state other than the states in
17 which they are incorporated and have their principal places of
18 business as you have listed them in the master personal injury
19 complaint?

20 *MR. LONGER:* Fred Longer, your Honor. No.

21 *THE COURT:* Okay. Defendants, do you contest any
22 allegations in paragraphs 21 through 36 regarding in which
23 states and countries the Defendants are incorporated and have
24 their principal places of business?

25 *MR. CHEFFO:* Your Honor, I don't have all of that in

1 front of me, there are a lot of Defendants, but I would say
2 generally no. If it is the state of incorporation and
3 principal place of business, we agree those would be one of two
4 places.

5 *THE COURT:* Okay. Question for the Defendants:
6 According to paragraph 35 of the master personal injury
7 complaint Defendant Patheon Manufacturing Services, LLC,
8 referred to by Plaintiffs within the category of Sanofi
9 Defendants, is a citizen of Massachusetts because its sole
10 member, Thermo Fisher Scientific, Inc., has its principal place
11 of business in Massachusetts. Thus, Massachusetts would have
12 general personal jurisdiction over Defendant Patheon
13 Manufacturing Services.

14 Massachusetts is one of two states that recognizes
15 Plaintiffs' theory of liability, albeit in a limited way.
16 Plaintiffs must allege Defendants acted recklessly.

17 Does Sanofi specifically dispute that Patheon
18 Manufacturing LLC is a citizen of Massachusetts?

19 *MR. CHEFFO:* Your Honor, I apologize, that is a fair
20 question, but a very specific one for a client that I don't
21 represent. If one of my colleagues from Sanofi is able to jump
22 in, if not, we can get you that answer expeditiously on what
23 their position is with respect to Patheon. Is that okay, your
24 Honor?

25 *THE COURT:* Sure. Is there anybody from Sanofi who is

1 able to easily pop on?

2 *MR. AGNESHWAR:* Your Honor, this is Anand Agneshwar, I
3 represent Sanofi. I believe that is right, but I would need to
4 confirm that. If I could have until tomorrow morning to do
5 that, I will do that and report back at the beginning of the
6 hearing tomorrow if that is okay.

7 *THE COURT:* Sure, that would be fine. Thank you.

8 *MR. AGNESHWAR:* Thank you.

9 *THE COURT:* And I guess just to further contemplate
10 that question, Mr. Agneshwar or Mr. Cheffo, so my question
11 began with whether Sanofi disputes whether Defendant Patheon is
12 a citizen of Massachusetts. If not, my followup question was
13 going to be, how should that impact the Court's analysis on the
14 issue of personal jurisdiction? Are Plaintiffs at liberty to
15 bring claims under their theory of liability against Defendant
16 Patheon Manufacturing LLC?

17 *MR. AGNESHWAR:* Yes, your Honor, Patheon is a separate
18 company from Sanofi, it is not a Sanofi company. Sanofi is not
19 responsible for it. So, if counsel for Patheon is on, they
20 might be the one more appropriately situated to answer the
21 question.

22 It is true that there has been a business relationship
23 between Sanofi and Patheon. I don't think that impacts any
24 claim that the Plaintiffs could make against Sanofi.

25 *THE COURT:* Okay. Well, is there counsel for Patheon

1 on the call?

2 Well, there was no fair notice in that regard, so that
3 is fine. Maybe one of Defense coleads can pass that question
4 along and maybe that can be addressed tomorrow, if that is all
5 right.

6 MR. CHEFFO: Yes, your Honor, I will take
7 responsibility to try to do that.

8 THE COURT: Okay. Great. You will be happy to know I
9 don't have any more questions. Not too bad, it is 5:08.

10 So, that concludes our hearing day. Thank you,
11 everyone, for your patience and your helpful presentations and
12 engagement with the Court on the Court's questions. I am most
13 appreciative of that.

14 I look forward to seeing those of you who will be
15 arguing your motions tomorrow. The motions tomorrow will
16 follow the exact same format that we followed today. We should
17 all have an easy time with that.

18 Pretty much it looks like the order has been set
19 already, 1582 will be argued first, then 1583, 1584, and 1580,
20 and with respect to 1582, 23 minutes for the Defendants and 20
21 minutes for the Plaintiff, 15 minutes for 1583 for both
22 Defendants and Plaintiffs, 18 minutes for 1584 for Defendants
23 and 15 minutes for the Plaintiff, 18 minutes for the Defendant
24 on 1580 and 15 minutes for the Plaintiffs.

25 You will let us know who will be operating any of the

1 PowerPoints, although that all seemed to go very smoothly today
2 as well.

3 Let me make sure I am not forgetting any
4 administrative matters. We will have you come in at the same
5 time you came in, in the same sequence today with those of you
6 popping on at 9:40, the others at 9:50. Thank you again to
7 liaisons and others who are helping admit participants. There
8 have been quite a few of you throughout the day.

9 Have a nice evening, everyone, and I look forward to
10 seeing you tomorrow morning. We will begin formally at 10:00
11 a.m. Have a nice evening. Bye-bye.

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

13 * * *

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

16
17 Date: December 17, 2020

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

19 Signature of Court Reporter
20
21
22
23
24
25

Pauline A. Stipes, Official Federal Reporter

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