

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF FLORIDA
3 WEST PALM BEACH DIVISION
4 CASE NO. 20-md-02924-ROSENBERG

5 **IN RE: ZANTAC (RANITIDINE)** .
6 **PRODUCTS LIABILITY** . West Palm Beach, FL
7 **LITIGATION.** . October 7, 2022
8 .
9 .

10 DAUBERT HEARING (in person and through Zoom)
11 BEFORE THE HONORABLE ROBIN L. ROSENBERG
12 UNITED STATES DISTRICT JUDGE

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Official Court Reporter: Pauline A. Stipes
HON. ROBIN L. ROSENBERG
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Pauline A. Stipes, Official Federal Reporter

1 THE COURT: Good morning, you may be seated. I can
2 see everybody, no masks. The policy changed since the last
3 time you were here.

4 All right. All set?

5 Good morning, everyone. We are here in the matter of
6 20-md-02924, In Re: Zantac (Ranitidine) Products Liability
7 Litigation. It's nice to see everybody here in person and
8 those of you by Zoom. We have many attorneys, perhaps the same
9 as last time, over 50 attorneys in person, including attorneys
10 who will be presenting the motions here today. We also have
11 attorneys and parties appearing by Zoom, about 98 of you.

12 I will go through the same administrative matters that
13 we discussed a couple of weeks ago. For attorneys who are
14 presenting, when you present, please come to the podium and
15 make your presentation, speak into the microphone, speak slowly
16 so that everybody can hear you and so that Pauline can make her
17 perfect record of the proceedings.

18 For those of you on Zoom, please keep your audio and
19 video off at all times. Anybody who has a cell phone should
20 turn it off, and there can be no use of cell phones during the
21 hearings, and no one is to record the proceedings, either by
22 Zoom or in the courtroom.

23 We have scheduled hearings today on the Plaintiffs'
24 motions, and the attorneys will make the presentations. They
25 have not requested that any expert witnesses be present at the

1 hearings.

2 The motions that will be presented today are Docket
3 Entry 5841, Plaintiffs' motion to exclude Defendants' putative
4 expert opinions and general causation under Rule 702, Docket
5 Entry 5839, Plaintiffs' motion to exclude testimony of Dr.
6 Robert Gibbons, and Docket Entry 5838, Plaintiffs' motion to
7 exclude inadmissible opinions of Dr. Bernard Olsen. The
8 Defendants have responded to each of the motions and Plaintiffs
9 have filed replies.

10 The parties have prepared a schedule for the hearing
11 with my input, such that they were provided with the time they
12 requested to make their presentations.

13 As I mentioned last time, in preparation for the
14 hearings the Court has received and reviewed the briefing on
15 all of the motions and responses and replies, approximately 25
16 primary expert reports from the Defendants' and Plaintiffs'
17 experts, including their rebuttal reports, 22 deposition
18 transcripts, 40 science studies and reports. I have had the
19 benefit of two Science Days, one at the inception of the case
20 and one on December 2, 2021.

21 As with the last hearing, and this time as well, I
22 have shared with the attorneys some of the general topics I may
23 be interested in having the attorneys discuss throughout these
24 hearing and they, in turn, have shared with me their PowerPoint
25 presentations which they intend to show today, over the course

1 of the hearings today.

2 We are on a very tight schedule with much ground to
3 cover so, with that, I would like to turn it over to
4 Plaintiffs' counsel who will make the first set of
5 presentations during the beginning phase, which is the
6 introduction phase of the proceeding.

7 So, with that, I turn it over to the Plaintiffs. Good
8 morning.

9 *MS. FINKEN:* Good morning, your Honor. May it please
10 the Court, Tracy Finken on behalf of Plaintiffs.

11 Your Honor, today's hearing involves our challenge of
12 Defendants' experts who answered the wrong general causation
13 question and blinded themselves to critical evidence that went
14 against their preset conclusions. To be clear, that is why
15 they should be excluded, not because they disagree with
16 Plaintiffs' experts, which reasonable scientists can do.

17 Defendants would like us to focus on their experts in
18 a vacuum, but the Defense experts we are challenging offer
19 opinions that challenge the Plaintiffs' experts, so the
20 comparisons are necessary.

21 Unlike Defendants' experts, Plaintiffs' experts easily
22 pass Daubert because they applied reliable methodologies to
23 answer the right general causation question: Was the highest
24 realistic exposure to NDMA from Ranitidine capable of causing
25 any MDL Plaintiffs' cancer?

1 Plaintiffs' answers to that question are even stronger
2 today because the Wang study, which we spoke about during the
3 last hearing, has been published and it considered much of the
4 very evidence Defendants' experts claim no reasonable
5 methodology should, and it reports an increased risk for every
6 cancer in this litigation.

7 Wang is notable, too, because it has an active
8 comparator analysis of Ranitidine users, which Defendants
9 wrongly claimed last time is the only sort of evidence that
10 epidemiologists should weigh strongly.

11 With that in mind, I will start with the proper focus
12 of the general causation inquiry, then move to Defendants'
13 experts on epidemiology, and then move to testing.

14 If we could pull up slide one. There we go.

15 First, your Honor, what is general causation? One
16 would think this would be a settled question, and it is. As
17 our slide shows, Judge Rodgers in Abilify captured that general
18 causation analysis. The Eleventh Circuit also articulated that
19 the question is "whether a substance has the potential to cause
20 the Plaintiffs' injury."

21 Slide two, please.

22 Since this is an MDL, not a single Plaintiff's case,
23 we need to modify the Guinn test slightly. The Plaintiff's
24 injury is actually the injury suffered by any Plaintiff with
25 any one of the five designated cancers, and the Plaintiff is

1 actually each and every Plaintiff in this MDL with a designated
2 cancer.

3 That is really important to ensure this Court is able
4 to address Daubert in a consolidated proceeding, instead of
5 thousands of times in each individual case. That slight shift
6 was not necessary in the cases Defendants cite, like Chapman
7 and McClain and others, which looked at both specific and
8 general causation together, examining a particular Plaintiff.

9 The only case to address this issue head on, your
10 honor, is the Roundup case, which came to the only sensible
11 conclusion, and that conclusion was the Plaintiffs need not
12 establish any particular level of exposure. It is enough in
13 this litigation, at this stage, for the Plaintiffs to show that
14 glyphosate can cause NHL when people are exposed to the highest
15 dose people might plausibly experience.

16 The Ninth Circuit affirmed Judge Chhabria's order.

17 Next slide, please.

18 Your honor, this is a practical approach and it makes
19 perfect sense. In response to our motion Defendants claim the
20 critical question is the minimum dose, but this is unworkable
21 in a consolidated case with Plaintiffs at a wide range of
22 doses. A focus on the minimum dose would make causation no
23 longer general at all, but only a ruling that the evidence
24 failed for that particular dose.

25 To reiterate an issue of law, there are no cases that

1 equate the question of general causation to the minimum
2 threshold exposure to a substance that makes it likely to cause
3 injury. Defendants' legal error is really important today
4 because their experts relied on that misstatement of the law
5 when deciding which question to answer.

6 So it is no surprise that, with a faulty legal
7 premise, Defendants' experts answered the wrong general
8 causation question. They did not focus on high doses for long
9 periods and opine that Ranitidine could not cause cancer; they
10 focused on small doses for short periods of time then concluded
11 that Ranitidine could not cause cancer.

12 That opinion is not going to help the trier of fact,
13 your Honor. It is instead going to affirmatively mislead the
14 jury. That alone is grounds for exclusion.

15 Next slide, please.

16 So, how is NDMA relevant to general causation, your
17 Honor? NDMA is the toxin at issue in this MDL. This is just
18 like asbestos in Talc, calcium zinc in Fixodent, Benzene in
19 Varsol, and NDMA in Valsartan, yet Defendants' experts fail to
20 even acknowledge the relevance of the studies involving
21 the toxin at issue here, which is NDMA.

22 Next slide, please.

23 The Valsartan MDL involves pharmaceuticals containing
24 the exact same carcinogenic molecule, NDMA. The experts looked
25 at NDMA science and Defendants tried the same tactics that they

1 are trying here. Judge Kugler admitted Dr. Panigraphy and
2 other Plaintiffs' experts that relied on NDMA science because
3 NDMA is the relevant toxin. He rejected Defendants' arguments
4 that only studies of Valsartan itself were relevant. He also,
5 notably, excluded a number of the Defense experts.

6 Based on the same misunderstanding about what kind of
7 studies are relevant, Defendants' experts offer the same
8 unreliable opinion that they did in Valsartan, that NDMA does
9 not cause cancer, and that opinion should be excluded, your
10 Honor.

11 Next slide, please.

12 Now, Defendants make much of the fact that -- about
13 regulatory bodies not reviewing NDMA literature, and that is
14 just simply not true, your Honor. The FDA reviewed NDMA
15 literature when evaluating Zantac. Indeed, unlike Defendants'
16 experts, the FDA relied on NDMA literature in deciding to
17 withdraw Zantac from the market. It did not make that decision
18 based on Ranitidine studies. Instead, the FDA's logic was that
19 NDMA causes cancer, and so NDMA in Ranitidine is dangerous.

20 The FDA did not ignore NDMA merely because Ranitidine
21 specific studies would be good evidence, and other regulators
22 followed suit, your Honor.

23 Next slide, please.

24 Even GSK, the Defendant in this case, reviewed NDMA
25 literature in September of 2019. After learning that NDMA was

1 in Ranitidine, GSK analyzed and discussed the risks of cancer
2 based on NDMA dietary studies. That is because NDMA is
3 obviously relevant, as everyone outside this litigation,
4 including Defendants, have always agreed.

5 Next slide.

6 Now, the published Wang study confirms what
7 Plaintiffs' experts consistently concluded, that NDMA causes
8 cancer; that getting NDMA from Ranitidine is no safer than
9 getting it from any other source; and that consideration of all
10 NDMA science is relevant to the causation inquiry.

11 Wang is particularly problematic for Defendants'
12 experts because it has everything the Defendants have asked
13 for. It's a human study that looks at Ranitidine users. It is
14 a huge database, the entire country of Taiwan, 99 percent of
15 Taiwan's population of 23 million is included in that database,
16 and it uses an active comparator design that, according to
17 Defendants' own experts, though we believe they are wrong on
18 this point, automatically removes any bias or confounding, and
19 it measures dose response, concluding there is no protopathic
20 bias, the feature Defendants' experts argue affects the
21 results.

22 Next slide, please.

23 Now, Wang considered NDMA literature when it evaluated
24 Ranitidine, and Defendants have said that the scientific
25 community disagrees that NDMA literature is relevant, but apart

1 from the regulatory bodies, which always considered NDMA, look
2 at what Wang says. As Plaintiffs have consistently argued,
3 Wang analyzed the animal and dietary studies Plaintiffs'
4 experts analyzed. Defendants' experts did not.

5 In other words, even in Ranitidine specific studies,
6 the Wang study extensively analyzes NDMA literature.

7 Next slide, please.

8 The Wang study also confirms Plaintiffs' experts'
9 criticisms of Defendants' studies. Just as Plaintiffs' experts
10 did, but Defendants' experts failed to do, Wang looks at the
11 Ranitidine specific studies and identifies limitations,
12 especially "small sample size and short follow-up duration may
13 cause statistical bias and inaccurate conclusions." Wang's
14 outcome data were retrieved from formal cancer registries which
15 are more accurate than other sources.

16 Recall, your Honor, that Drs. McTiernan and Moorman
17 flagged the importance of a reliable source of cancer
18 diagnoses.

19 Next slide, please.

20 Now, defendants' experts talk a fair amount about
21 reverse causation, or what is called protopathic bias. That is
22 what Witte and others say explains many of the associations in
23 the Ranitidine studies. Defendants cannot say that about the
24 Wang study since it considered this and ruled out protopathic
25 bias.

1 Wang also shows clear dose response for multiple
2 cancers, and overall, it showed that people taking Zantac got
3 significantly more cancer after just one year of use than
4 people taking no Zantac at all, and more than people taking a
5 comparator drug.

6 Next slide.

7 So, what did Wang conclude? Defendants' experts
8 disregard or deny NDMA science at every turn. Wang's
9 conclusion exposes their shortcoming, and Wang states and
10 concludes in the published study, "However, the clear data from
11 our real-world observational study strongly support the
12 pathogenic role of NDMA contamination given that long-term
13 Ranitidine use is associated with a higher likelihood of cancer
14 development in Ranitidine users compared to the control groups
15 of non-Ranitidine users who were treated with PPIs or
16 Famotidine."

17 Defendants' experts' failure makes their opinions
18 unreliable and excludable.

19 So, let's discuss testing, your Honor.

20 Next slide, please.

21 What did the FDA say about real-world testing? Your
22 Honor, no Defendant attempted to test Ranitidine under
23 real-world conditions, despite having in-house laboratories and
24 hundreds and hundreds of scientists. That is not because they
25 dispute the general point that testing is important. Your

1 Honor, if you look at Exhibit 36, which is the FDA Working
2 Group transcript, day two, at page 129, lines 6 to 24, the FDA
3 actually endorses testing in real-world conditions -- I am
4 quoting -- "such as a hot mailbox, a glove box in a car, a
5 bathroom, or truck in the middle of summer in the southern
6 United States."

7 Let's look at what Defendants did.

8 Next slide.

9 Defendants did none of this; they never tested
10 Ranitidine under real-world conditions.

11 Next slide, please.

12 Now, Defendants have the burden to show their methods
13 are reliable. Defendants did not have to provide any evidence
14 on testing, and largely have not. Instead, Defendants' experts
15 focus on criticizing Plaintiffs' experts' actual testing and
16 opinions. This could have been admissible, your Honor, but
17 only if these conclusions had actually demonstrated real
18 problems with the testing based on reliable methodologies
19 which, of course, requires understanding what actually
20 happened.

21 Defense experts Drs. Olsen and Gibbons failed in this
22 basic requirement. Dr. Gibbons did not understand the testing
23 method or how many pills were tested and tried to turn his own
24 misunderstanding of Dr. Najafi's testing into a critique, but
25 to be reliable, Dr. Gibbons must have actually identified a

1 reason the testing is wrong, not merely that he could not
2 comprehend an expert report.

3 Dr. Olsen did address the actual testing on the other
4 hand, but Dr. Olsen misstated that the HILIC column is
5 inappropriate for testing, even though it is specifically
6 designed for polar compounds like NDMA. Worse, he relied on a
7 2020 source from Waters that contradicts his speculation
8 that testing could form artifactual NDMA.

9 Next slide, please.

10 Your Honor, Defendants' expert opinions are simply not
11 reliable. Defendants did not need to produce any experts, but
12 because they did, those experts cannot testify that there is no
13 general causation because Ranitidine does not cause cancer
14 after one prescription. They cannot ignore NDMA science when
15 regulatory bodies and Defendants themselves have said it is
16 relevant.

17 They cannot testify that Ranitidine studies of
18 short-term use means long-term consumers cannot get cancer, and
19 they cannot cast false doubt on testing methods they clearly
20 misunderstand. That is because expert testimony must be
21 reliable, and Defendants' experts' opinions are not reliable
22 and should therefore be excluded.

23 Thank you, your Honor.

24 *THE COURT:* Okay, thank you.

25 Defense opening remarks.

1 MR. BOEHM: Good morning, everybody. Good morning,
2 your Honor.

3 THE COURT: Good morning.

4 MR. BOEHM: Paul Boehm for Pfizer, and today and for
5 today's purposes I am speaking on behalf of all of the brand
6 Defendants.

7 Just a brief note, a housekeeping matter, there were a
8 few slides that were circulated yesterday that we discussed
9 with Plaintiffs' counsel that we believe were outside the scope
10 of the proffer topics for the day. We raised that with
11 Plaintiffs' counsel who respectfully disagreed with our
12 position on that.

13 We want to register an objection for the record,
14 particularly as to slides 2 and 3 in the first of their decks
15 and to slides 28 through 49 in their deck number 3.

16 THE COURT: Okay.

17 MR. BOEHM: Your Honor mentioned during your opening
18 remarks that you had provided a list of some topics for the
19 day, and if we could pull up -- Maryann, if you could pull up
20 the slides and go to slide number 2.

21 These are some of the topics, your Honor -- if we can
22 go to the next slide.

23 These are some of the topics that we thought your
24 Honor felt set the framework for the day that will be the
25 background for some of the very specific scientific issues that

1 the Court will be addressing and some of the criticisms that
2 Plaintiffs' counsel are specifically bringing as to the
3 experts.

4 In particular, I wanted to start with the first two,
5 the respective burdens of proof that the parties have here and
6 the Court's role in measuring the difference between
7 admissibility under Rule 702, and then just what is persuasive
8 and subject to cross-examination at trial, and these two we
9 think go hand in hand.

10 Go to the next slide.

11 This is not controversial, I think Plaintiffs said
12 this themselves, that the party that is offering the expert has
13 the burden to meet the standards of Rule 702. We, of course,
14 agree with that. That means that Defendants have this burden
15 when it comes to the experts we are discussing here today, just
16 as Plaintiffs have the burden with respect to all of the
17 experts that were discussed a couple of weeks ago, again, not
18 controversial.

19 There is an important distinction between Plaintiffs'
20 and Defendants' burden as it relates to application of Rule 702
21 in a case like this.

22 If we could go to the next slide.

23 The Plaintiff bears the burden of proving causation,
24 and that is important. Defendants do not bear that burden. We
25 do not bear any burden to prove or to disprove anything at all.

1 As this slide shows, the Plaintiffs have noted that themselves
2 in their briefing on this issue, that we have no burden to
3 disprove causation. We could put forward no expert witnesses,
4 or only rebuttal witnesses.

5 So, in considering the motions before the Court today,
6 and the motions we discussed a couple weeks ago, this is
7 important context, Defense experts are not offering affirmative
8 causation opinions precisely because we do not have this
9 burden.

10 The Defense experts are offering opinions that there
11 is no reliable evidence of causation, and Rule 702 still
12 applies to the methodologies and techniques that they apply in
13 reaching that conclusion. Plaintiffs bear this burden alone.

14 In fact, your Honor, as the Court may know, many
15 judges in toxic tort MDLs reach conclusions about Plaintiffs'
16 experts, that those opinions are not reliable, and then never
17 even get to the motions as to Defendants' experts because you
18 don't need to. That has happened recently in cases that I have
19 been involved in, in Viagra, in the MDL where the Court decided
20 the motions as to Plaintiffs' experts and don't even reach the
21 motions as to the Defense experts. That is a reflection of
22 this burden.

23 So, how should the Court, in thinking about the
24 briefing and hearing the arguments today, assess reliability of
25 Defendants' experts in this context?

1 Are they using the same methods here as methods that
2 they have used outside of the courtroom, or are they doing
3 something different here versus there?

4 In the case of Defense experts, it is the same.

5 Are they approaching this question consistent with the
6 broader regulatory and scientific community, or are they
7 standing apart doing something new, doing something different?

8 In the case of Defense experts, they are in lockstep
9 in their techniques and application of methodologies with the
10 broader scientific and regulatory community.

11 Are they looking at data that is most closely related
12 to the drug at issue, or are they making extrapolations based
13 on other data sets?

14 In the case of Defense experts, they are primarily
15 looking at the data most closely related to the drug at issue.

16 Are they honoring the concept of statistical
17 significance, which the Eleventh Circuit says you must do, or
18 are they ignoring it?

19 In the case of Defense experts, they are honoring that
20 concept.

21 The answers here, as we will discuss in detail as we
22 go through these experts one by one, will show that the
23 Defense experts are using broadly accepted methods, the same
24 ones used by FDA, by EMA and others in the scientific
25 community, to specifically look at the question of whether

1 Ranitidine increases the risk of cancer, specifically the
2 cancers the Plaintiffs are bringing forward here.

3 Next slide, please.

4 These are the McClain and Chapman opinions that were
5 referenced by Ms. Finken in her time. This burden, whatever
6 the number of Plaintiffs that were at issue, and it wasn't
7 one -- in some cases, it was bellwethers, in some cases it was
8 whatever number it is. This burden is the same, there is a
9 general causation burden, and that applies here just as it
10 applied in those cases, and that is what those Courts would do.

11 Maryann, can you take us to the next slide, please.

12 This is from the Abilify opinion, which your Honor is
13 obviously familiar with, from Judge Rodgers. Ms. Finken also
14 referenced this opinion. Judge Rodgers said that the very best
15 evidence, when you have it -- you don't always have it, but
16 when you have it, the very best evidence is grounded in the
17 epidemiology. Note the language, exposure to the drug. Not
18 exposure to something that might be in the drug at some unknown
19 level that is in controversy, exposure to the drug. That is
20 the question.

21 Judge Rodgers said this is the sine qua non of general
22 causation. It is an essential and absolutely necessary
23 condition.

24 I wanted to note, because another of your Honor's
25 topics on the list was specific to weight of the evidence

1 methodology. Judge Rodgers references that in the Abilify
2 opinion, and she says that whether an expert is using Bradford
3 Hill, whether they are using some other weight of the evidence
4 methodology, this requirement stays the same. You have to
5 start, the threshold issue is, does the epidemiology establish
6 a reliable consistent association between exposure to the drug
7 and the injuries that are alleged in the case.

8 That is a threshold question, and it goes to
9 admissibility. It is not a matter of persuasiveness, it is not
10 for the jury to decide based on cross-examination and how that
11 goes. It goes directly to Rule 702.

12 Next slide, please.

13 In the Eleventh Circuit, in toxic tort cases like this
14 one, Plaintiffs' burden specifically is to show well conducted
15 epidemiological studies that show a statistically significant
16 relationship between the medication and the injury that has
17 been alleged.

18 We are going to talk about threshold dose. That was
19 referenced kind of in passing by Ms. Finken, threshold dose.
20 We talked at length about that a couple of weeks ago, I will
21 not belabor that now. We will get to that later. We will talk
22 about the reliance on NDMA in occupational and dietary studies
23 as well today. Again, that was something that was discussed at
24 length a couple of weeks ago, so I won't take too much time on
25 that other than to say the Eleventh Circuit law is clear about

1 what is required under Rule 702. If you fall short on this,
2 you fall short on Daubert.

3 And that is consistent with the approach that the
4 Defense experts employed in reviewing the data that are
5 available in this case.

6 They looked first to see, just like the FDA, looked
7 first to see is there this association, is there a consistent
8 signal that we see from the epidemiological studies. You start
9 there and then you can do your Bradford Hill or whatever
10 weighing of the evidence that you need to do.

11 Next slide, please, Maryann.

12 Your Honor, of course, is familiar with the studies
13 that are on this chart.

14 This is a version of the slide that Mr. Cheffo showed
15 your Honor a couple of weeks ago, and we know that your Honor
16 is familiar with these, probably read all of these studies, at
17 least most of them. Again, I am not going to go through all of
18 this again.

19 By the way, your Honor, everybody here recognizes the
20 work that the Court has done, and the people around you have
21 done to understand this data, and I can speak for our client,
22 for Defendants, and I believe for Plaintiffs' counsel in
23 thanking you for the careful attention to studies like these
24 that you have obviously paid.

25 The point here is, without going through all of this

1 again, Defendants' experts did the same thing as the FDA, the
2 same thing as the EMA and others in looking at this data, and
3 now you have -- I know we are going to talk about Wang here in
4 just a minute, I think that gets us over a million Ranitidine
5 users, or at least close, that is in this database.

6 You heard a reference to Defense experts not looking
7 at the real-world data.

8 Your Honor, these are the real-world data, over a
9 million users, using the product under all sorts of conditions,
10 being tested based on the gold standard that is the randomized
11 control trial -- or the types of epidemiological studies that
12 are involved here.

13 You heard a lot about the Wang study, and you are
14 going to hear more about that today. Obviously, it just came
15 out. We can put that up on the slide, we could make it an even
16 dozen, and it wouldn't change anything at all. It wouldn't
17 change anything at all.

18 A couple of points in passing, and we will talk about
19 Wang a bit more later, of course.

20 First of all, Plaintiffs have criticized the
21 epidemiology study for having too short of exposure, too short
22 of followup. Wang is shorter than any other studies that were
23 already available in terms of that.

24 Secondly, when you look at the active comparator
25 results, which is what the FDA and the scientific community

1 says that is the ideal, that is where you look, only one out of
2 the five cancers shows up with an association. Four out of the
3 five don't.

4 You heard a couple of weeks ago from Plaintiffs'
5 counsel that it was bladder cancer, that is the one where they
6 said we can rely on the Ranitidine epidemiology, we don't have
7 to look at NDMA data, and we can see an association for bladder
8 cancer. For bladder cancer in the Wang study there is no
9 association. The hazard ratio is almost exactly 1.0.

10 So, what is the point? Wang, your Honor, demonstrates
11 exactly why the FDA, the EMA, and others in the medical
12 community are using -- and Defense experts are using
13 appropriate scientific methods by looking at these data and
14 considering whether the data tell a consistent story, is there
15 a consistent signal.

16 Next slide, please, Maryann.

17 Your Honor is familiar with Florian, no consistent
18 signals. That is what Wang gives, no consistent signals emerge
19 across these studies.

20 This is an important feature of the causation
21 question. You can read from the study itself. It says that
22 previous studies, including NDMA and Ranitidine studies -- I
23 just wrote this down, page two -- were contradictory, and the
24 data were not sufficient to reach definite conclusions. The
25 conflicting results of studies underlie the lack of concrete

1 evidence supporting the role of Ranitidine in cancer
2 development. No consistent signals.

3 There was a reference to Valsartan that I want to
4 mention quickly. In Valsartan, two points. First of all, it's
5 hard to know exactly what to do with that because there is no
6 written opinion, as your Honor knows. From the hearing
7 transcript, the judge, who is in New Jersey, not in the
8 Eleventh Circuit -- let's make it three points.

9 Two is, this is in New Jersey, not in the Eleventh
10 Circuit. Then third, if you look at the transcript, the basis
11 of the ruling was two things; one, that there was an FDA
12 recall, and two, company documents.

13 That is the basis of that ruling, and we know it is
14 crystal clear in the Eleventh Circuit that that cannot be a
15 primary methodology to pass Rule 702. So, under Eleventh
16 Circuit law, that would be an incorrect ruling.

17 Next slide.

18 I just want to touch base on one last topic that was
19 on your Honor's list of subjects today, and that is the
20 speculation about future science and the concept of law lagging
21 science. Of course, this has been adopted by the Eleventh -- I
22 think it has been adopted by every circuit, this concept of not
23 getting ahead of the science.

24 The Court's gatekeeper role involves making sure that
25 the scientific theories that are advanced in the context of a

1 litigation, that they don't get out ahead of what is happening
2 in the real world. That is what this concept stands for.

3 The scientific methods, and by the way, the
4 conclusions for the Defendants' experts, they are in lockstep
5 with what is happening in the real world. They aren't out
6 ahead of the science, they are in line with that science.

7 *THE COURT:* That is 15 minutes.

8 *MR. BOEHM:* Which is perfect, because I am all done.

9 *THE COURT:* Okay. Everybody is well trained.

10 Thank you, thank you for the introductions from both
11 sides.

12 Now we are moving into the epidemiology motion, and
13 Plaintiffs will go first, and you have allotted yourselves an
14 hour and 25 minutes, and then additional time on rebuttal, but
15 for your primary argument.

16 *MR. HEINZ:* Good morning, your Honor, Noah Heinz for
17 the Plaintiffs.

18 *THE COURT:* Good morning.

19 *MR. HEINZ:* Could we get the slides up, please.

20 I will be setting out the legal framework for Daubert
21 as it applies to epidemiology.

22 The first critical point is that Daubert is about
23 methodology, not conclusions. That comes from Daubert itself
24 which instructed that in deciding the admissibility of expert
25 testimony, quote, "the focus, of course, must be solely on

1 principles and methodology, not on the conclusions that they
2 generate," and this is precisely what we told your Honor at the
3 last hearing.

4 The Court must scrutinize an expert's application of
5 their methodology, but go no further. That means we will not
6 be telling you today that -- to exclude the Defendants' experts
7 because their conclusions are wrong, the jury will decide that.
8 Neither side's conclusions are at issue on Daubert.

9 Next slide.

10 Here the methodology all epidemiological experts
11 followed was to compile relevant studies, carefully scrutinize
12 strengths and weaknesses, and interpret them to discern whether
13 an association existed between the NDMA in Ranitidine and
14 cancer, then conduct a Bradford Hill analysis. That is the
15 methodology the Plaintiffs followed, that is more or less the
16 methodology that the Defense epidemiologists followed as well.

17 Next slide.

18 For that methodology to be reliable an expert must
19 consider all of the relevant evidence. As the Rezulin case
20 explains, Courts may preclude an expert from testifying in part
21 because he ignored available evidence that was vital to his
22 opinion.

23 Your Honor may remember that in defending Dr. Moorman,
24 we argued that she undisputedly had considered all relevant
25 evidence, check on this box, and Defendants' experts, as Mr.

1 Snidow will explain, did not.

2 Next slide, please.

3 Then the expert must reliably evaluate the relevant
4 evidence. The general rule under Daubert is that an expert
5 must address any gaps with reasoned explanations. That means
6 that an expert analyzing a study must explain why applying the
7 results of that study are a proper fit with the case.

8 Experts can't simply assert that the results of a
9 study for short-term smokers holds for long-term smokers. As
10 the Eleventh Circuit has explained, nothing in either Daubert
11 or the Federal Rules of Evidence requires the District Court to
12 admit opinion evidence that is connected to the existing data
13 only by the ipse dixit of the expert.

14 In the context of epidemiology, that means explaining
15 which evidence is most probative and why.

16 Next slide.

17 Recall when I defended Dr. Moorman and listed out the
18 specific consistent criteria that she used to evaluate each and
19 every epidemiological study. Those were factors like the
20 design of the study, whether it was cohort or control, the
21 exposure measurement, followup, OTC misclassification, the
22 quality of the cancer diagnosis information. Criteria like
23 that are essential to a reliable methodology, as the case law
24 confirms.

25 From the Bair Hugger case, "The key question

1 in evaluating epidemiological evidence are the extent to which
2 a study's limitations compromise its findings and permit
3 inferences about causation." The same concept appears in the
4 Hardeman v Monsanto Ninth Circuit case, the Abilify decision,
5 Deepwater Horizon, and all of the Daubert cases that each party
6 has cited, and that is because identifying and applying
7 consistent criteria is fundamental to a sound methodology.

8 The alternative is what happened in Deepwater Horizon
9 where Judge Rodgers explained, "Dr. Williams' report simply
10 contains serial lists of quotes from various studies with no
11 discussion, critique, or assessment of the quality, design, or
12 relevance of any study that she relied on."

13 That is why Judge Rodgers concluded an expert opinion,
14 even if supported by a lengthy list of case studies and
15 treatises, is not reliable without an explanation of the
16 logical steps supporting it, and, of course, the criteria have
17 to make some sense as in there have to be factors that the
18 scientific community recognizes as important.

19 As I explained last time, our epidemiologists
20 undisputedly did use criteria just like that that are relevant,
21 and as Mr Snidow will explain, the criteria the Defendants
22 used, to the extent they exist at all, were not of that sort.

23 Next slide.

24 Daubert does not allow a District Court to decide for
25 itself which studies are most probative. The Schultz case

1 explained that Rule 702 does not require or even permit the
2 District Court to choose between two studies at the gatekeeping
3 stage. Abilify, this is within the Eleventh Circuit, quoting
4 the Eleventh Circuit Quiet Technology case, explained "a
5 District Court may not evaluate the credibility of opposing
6 experts or the persuasiveness of competing scientific studies."
7 All about methodology, not at all about the underlying studies,
8 not about persuasiveness.

9 Next slide, please.

10 A good example of this is the Roundup litigation. In
11 that case there were studies, including a large Cohort Study
12 that showed no association between glyphosate and non-Hodgkins
13 lymphoma, but there were three smaller case control studies
14 that did show an association. For the Court to choose between
15 them would have exceeded the limited gatekeeping role, and so
16 both sides' experts were admitted.

17 Next slide, please.

18 The experts were properly admitted because they had a
19 reasonable basis for picking one set of the studies over the
20 other set. They explained, for example, the Plaintiffs'
21 experts, why the Cohort Study was not definitive, there were
22 misclassification problems in that study, and why the critiques
23 of the case control studies were also not devastating, they
24 could bear the weight. That is why the experts on both sides
25 got through in that case, despite conflicting science.

1 Next slide.

2 I am going to linger a bit on Judge Rodgers' approach
3 in Abilify and use it to explain why the framework I just set
4 out is consistent with the Benzene cases which the Court had
5 particular questions on.

6 Let's start with Burst and Hendrikson, which were
7 about Benzene in gasoline. That was claimed to cause a
8 condition called AML. The Defendants have argued that Burst
9 and Hendrikson show that experts must ignore evidence about the
10 toxin and focus only on the product, but they actually
11 illustrate the two factor test from Abilify, considering all of
12 the available evidence carefully and explaining how each piece
13 of evidence is weighed, and that didn't happen in Burst and
14 Hendrikson.

15 First on relevance, it is notable that experts from
16 all the Benzene cases, from many different products, including
17 Varsal, Liquid Wrench, gasoline and other solvents, analyzed
18 Benzene science extensively, as the cases cited in Plaintiffs'
19 reply at Footnote 30 confirm. That certainly happened in Burst
20 and Hendrikson where the Court expressly states that literature
21 about Benzene and gasoline were both relevant. Ignoring either
22 one would have been unreliable, and for exactly the reason that
23 Judge Rodgers explained, the first prong.

24 The problem in those cases was ignoring the gasoline
25 evidence, but that is simply an application of the more general

1 principle that experts must consider all the relevant evidence.
2 Here the same exact critique applies to the Defendants' experts
3 who failed to adequately consider the NDMA science, which is,
4 just like the Benzene literature, obviously relevant.

5 The second factor is explaining the relative weight of
6 the different evidence. The problem in Burst and Hendrikson
7 was that the experts failed to explain limitations or perform
8 any weighing for the incomplete list of gasoline studies that
9 they did look at.

10 The experts here -- the experts there, sorry, just as
11 in Deepwater Horizon, simply listed a number of studies
12 and then their end result, more like a literature review or
13 ipse dixit. That is not reliable.

14 Weighing was especially important in the gasoline
15 cases because, as the Ryan case explained and as we quoted in
16 our brief, "The Defense experts in Hendrikson and Burst opined
17 that exposure to Benzene in gasoline does not cause an
18 increased risk of AML due to competitive inhibition between the
19 variance components of gasoline that mitigates the carcinogenic
20 properties of Benzene."

21 Now, that is a mouthful, but what they were basically
22 saying is that the Benzene in gasoline, unlike the Benzene in
23 everything else, does not cause cancer because a specific
24 scientific theory had to do with the ingredients in gasoline
25 and how they worked together.

1 Because of that theory, which the literature
2 supported, the gasoline evidence was particularly important
3 because there was a good explanation of why the Benzene
4 literature wouldn't be relevant, or as relevant in that case in
5 light of the competitive inhibition. Where that theory is not
6 in the case testimony based only on Benzene has been held to be
7 appropriate, as the Ryan Court held, for example, with Liquid
8 Wrench.

9 The Benzene cases show that Defendants' experts needed
10 to carefully consider and weigh all of the evidence about the
11 toxin at issue, as every expert in those cases did, but if they
12 had an argument that something in Ranitidine counteracts NDMA
13 that explains on their theory why NDMA in Ranitidine, unlike
14 everywhere else, does not cause cancer, maybe that opinion by
15 itself could be admissible even without looking carefully at
16 the NDMA literature.

17 But Defendants have proffered no such theory here,
18 unlike the Defendants in the Burst and the Hendrikson case.
19 They have never said that the NDMA in Ranitidine is any
20 different from the NDMA anywhere else, and that is because it
21 is not. That is what the regulators have concluded and that is
22 what both sides have agreed is the case.

23 Instead, the Defendants' experts have ignored NDMA
24 science and failed to carefully weigh it without a theory for
25 why the NDMA in Ranitidine does not cause cancer, and that is

1 unreliable.

2 Thank you.

3 *THE COURT:* Thank you.

4 *MR. SNIDOW:* Good morning, your Honor, may it please
5 the Court, it's J. D. Snidow for the Plaintiffs.

6 *THE COURT:* Good morning.

7 *MR. SNIDOW:* Pull up the slides, please. Thank you.

8 Before I dive into the individual experts, I do want
9 to explain at a high level where they went wrong.

10 First, the experts answered the wrong general
11 causation question. They answered whether NDMA can cause
12 cancer at low doses and after a short followup time, even
13 though the real general causation question should focus on
14 whether NDMA can cause cancer at high doses, and after a long
15 enough time for the cancer to develop. The reason, your Honor,
16 is because there are many, many Plaintiffs exactly like that in
17 this MDL.

18 Second, Defense experts fail to consider all the
19 evidence, in particular, evidence about NDMA itself.

20 And third, Defense experts failed to consider that
21 evidence carefully.

22 Next slide.

23 I'll start with the first one. As Ms. Finken and Mr.
24 Heinz just stated, the general causation question is about
25 whether a substance can cause a disease.

1 As the Court knows, the specific causation question is
2 very different, whether the substance caused the disease in the
3 particular Plaintiff in that particular trial.

4 I will take the next slide.

5 There are a lot of places, your Honor, where that
6 distinction is very important. The one I want to focus on for
7 a few minutes is dose because it was the subject we talked a
8 lot about over the last couple of weeks and I'm sure we will
9 talk about today.

10 In this MDL every Plaintiff is going to have taken a
11 different dose of Zantac, right. Some of our Plaintiffs took
12 Zantac for just a few years, some of our Plaintiffs took Zantac
13 for decades. Some of them took it for just a couple days a
14 week, some of them took it every day.

15 Then there's storage, of course, too. Some of our
16 Plaintiffs stored Zantac in a cool dry place, others of our
17 Plaintiffs stored Zantac in hot places, like the mailbox Ms.
18 Finken was talking about, or their bathrooms, or in their cars.
19 In those places Ranitidine degrades faster into NDMA.

20 What that means is that each of the Plaintiffs also
21 ingested a different amount of NDMA. I realize that makes this
22 case a complicated one, but for general causation experts it is
23 just a fact that each of them has to grapple with, that the
24 dose for each Plaintiff is going to be different.

25 Next slide.

1 As we pointed out, Judge Chhabria in the Roundup case
2 said that for general causation you have to look at the highest
3 dose that people might plausibly experience. I want to pause
4 for a moment and briefly illustrate why that has to be true.

5 As I said, every Plaintiff in an MDL like this one is
6 going to have taken a different dose, but if there is some dose
7 that I have is labeled dose A known to be toxic down here, some
8 dose that we can look at the medical literature and say, look,
9 we don't exactly know what the minimum is, but we know if you
10 are exposed to this dose, you have a higher risk. What that
11 means is those Plaintiffs at the top right hand of my chart
12 clearly have a claim, right.

13 Now, specific causation may be different. If you have
14 the Plaintiff down there on the bottom left who took a dose and
15 we don't really know if it is enough to cause cancer, they
16 might go to trial and they might well lose on specific
17 causation, right. But for general causation, you have to look
18 at the Plaintiffs at the top right, and the reason is, because
19 for those Plaintiffs up there, how could you tell them, we know
20 that you took a dose that is higher than demonstrated to cause
21 cancer in the medical literature, but you lose.

22 How could that be? It certainly can't be we know you
23 took a dose high enough to cause cancer, but you lose because
24 other Plaintiffs in this MDL maybe took a dose that wasn't high
25 enough. That can't be right. It would defeat the entire

1 purpose of the MDL, it would arguably be a due process
2 violation for that particular Plaintiff, and that is exactly
3 why law is, for general causation in an MDL, you have to
4 consider the highest possible dose.

5 I'll take the next slide.

6 By the way, your Honor, I made it really easy on the
7 first slide by saying there is one dose that we know that can
8 cause cancer, but the reality in the science is much more
9 complicated because the way it works is, every time you do a
10 study you are going to note a different dose that is sufficient
11 to cause the disease. So maybe do one study, and we say, well,
12 now we know that dose A is known to be toxic, we know that is
13 enough to cause cancer from the medical literature.

14 Then you do another study, look at different data, it
15 might be based on entirely different kinds of data, there are
16 certainly different people, and then you do another dose that
17 you know is enough to be toxic and causes disease, on and on
18 and on, and we have way more than three studies in this
19 litigation, but that is what is going on here, different
20 scientists are looking at different data and they are coming to
21 different conclusions about what dose we know to be enough.

22 I understand as lawyers we want there to be a bright
23 line, like what is the dose that causes cancer, but that is not
24 the way it works.

25 Next slide.

1 The reason why it is not the way it works in
2 particular in this case is because, with respect to this kind
3 of carcinogen, NDMA or even Ranitidine, it is not ethical to do
4 a randomized control trial.

5 The way this would work for dose with most
6 pharmaceuticals, if you want to know if you have enough dose to
7 cure a certain disease or to cause a certain side effect, you
8 do a dose ranging trial. You do a randomized control trial
9 very early on in the drug's development, you intentionally give
10 certain doses of the drug to different people in different
11 amounts, and from that you can get pretty good data about what
12 the actual minimum dose is to cause a certain outcome.

13 You just can't do that here when you are trying to
14 figure out whether NDMA or Ranitidine causes cancer, and there
15 are really two reasons. I have one here, it's because it would
16 be unethical to administer Ranitidine to a patient to determine
17 if it causes cancer.

18 The other reason, of course, is because cancer has
19 this long lag time. It takes a long time for cancer to
20 develop, and so it is something that is difficult to do in a
21 randomized control trial.

22 So the upshot of all of that is that we have to look
23 at dose information that we can glean from other sources. You
24 can look at NDMA that people consumed in food, which are the
25 dietary studies, you can look at NDMA that people encountered

1 at work, which is our occupational studies. Yes, you can look
2 at NDMA that people consumed in Ranitidine itself.

3 From that you can glean information about what dose is
4 for sure enough to cause cancer, or I should say enough to
5 increase the risk of cancer.

6 Next slide.

7 What I want to contrast these doses that I show here
8 with is the concept of threshold dose, which is something that
9 Defendants have spent a lot of time on and I believe are going
10 to spend a lot of time on.

11 Next slide.

12 So the threshold dose is different than what I have
13 been talking about, it is the minimum dose that could
14 theoretically cause cancer, just theoretically, and for a
15 genotoxin like NDMA our experts opine that dose is very, very,
16 very low, approaching zero.

17 That is not the kind of thing that is ever going to
18 show up in scientific literature. It's not the kind of thing
19 we are relying upon here to show that we have actually
20 demonstrated that our Plaintiffs took doses that demonstrates
21 that cause cancer, but it is true and it is something that is
22 analytically different than the types of sufficient doses
23 demonstrated that that I have talked about.

24 Next slide.

25 That is why Defendants are wrong to put up slides like

1 this one, that Dr. McTiernan doesn't have an opinion on
2 threshold dose. I'll say i think they are also wrong to use
3 such an unflattering picture of her, but that's neither here
4 nor there.

5 As they point out here, Dr. McTiernan doesn't really
6 have an opinion on the theoretical minimum dose that is needed
7 to cause cancer, but that is okay, she doesn't need to for
8 general causation purposes. As I said, so long as the
9 literature demonstrates that doses that our Plaintiffs
10 realistically took are enough, then it doesn't matter what the
11 theoretical how low can you go floor is because she has done
12 what she needs to.

13 Next slide.

14 As Ms. Finken pointed out, we think the Defendants are
15 just wrong to say that a threshold dose needs to be
16 demonstrated.

17 We have looked pretty extensively in the case law, and
18 to be totally level with the Court, there is not a ton of case
19 law defining these separate issues, but the closest it comes I
20 think is this case, the Schultz case in the Seventh Circuit.

21 What the Schultz case did is they looked at two
22 statements made by this expert, Dr. Gore, and I want to focus
23 on them for a moment. The first statement that Dr. Gore made
24 was, if a person is exposed to 11 person years, I believe, of
25 Benzene, then they would be at an eight times greater risk of

1 developing AML.

2 That is the kind of dose that I have been describing
3 as the plainly toxic dose, the clearly harmful dose. We know
4 it is enough. If you take 11 years of Benzene, apparently you
5 get an eight times higher risk.

6 The second box, though, the second statement that Dr.
7 Gore made is that with carcinogens like Benzene it is
8 theoretically possible that any amount of exposure could be
9 enough.

10 That is similar to the two concepts we have been
11 talking about here. Defendants want to focus on that second
12 one, and they want to say, look, their epidemiologists, they
13 can't say for sure what the floor is, they are telling you it
14 could theoretically be zero, that is grounds for exclusion.
15 That is not what the Schultz case said, in fact it said exactly
16 the opposite.

17 Next slide.

18 The Court said it is important to understand the
19 difference between these two statements. The first statement
20 says that scientific studies confirm the danger if you are
21 exposed to at least ten years of Benzene. All right.

22 The second statement says that no one is sure whether
23 ten years is enough, maybe it is five years, maybe it is one
24 year, or maybe it is none.

25 That second box is the threshold dose that the

1 Defendants keep talking about. The first box is about how much
2 is enough as demonstrated in the literature.

3 What the Schultz Court said is that second box really
4 doesn't matter. The Court said that second statement may have
5 been unnecessary, because it is, but there is no rule requiring
6 the exclusion of expert testimony just because the expert
7 digresses into a collateral issue to explain where the frontier
8 of research lies.

9 That is exactly what is going on in this case when we
10 talk about -- when Defendants, I should say, talk about
11 threshold dose. As I will get to in a moment, the literature
12 certainly demonstrates that our Plaintiffs took enough NDMA to
13 increase the risk of cancer. Could it be lower than that? Of
14 course it could. That is an academic question, or as the
15 Schultz case says, a collateral issue about where the, quote,
16 "frontier of research lies."

17 The next slide.

18 That is why they are wrong to say what they do about
19 Dr. Moorman here, and again not the most flattering picture I
20 have ever seen of her. They say that in her opinion -- they
21 ask her, in your opinion, could a single dose of Ranitidine
22 cause cancer? And she says what is exactly scientifically
23 correct, that theoretically she doesn't believe that there is a
24 threshold dose for this molecule, any level could increase
25 risk.

1 That really doesn't matter. That is about where the
2 frontier of research is, it is an academic question, but for
3 these purposes, it is not the dose that counts.

4 Next slide.

5 Now, to be fair to the Defendants, in a different case
6 that question really could matter because if you had a
7 substance and you had an MDL where none of the Plaintiffs took
8 a dose that was even conceivably enough to cause cancer, or
9 whatever it is, that would matter, right. If the threshold is
10 above anything any of your Plaintiffs took, then Gannon should
11 lose on general causation.

12 That is what you see in the case law when they talk
13 about dose being a general causation issue, because there are
14 certainly cases where it could be, and there are two that we
15 have talked about in this litigation where that is exactly what
16 happened.

17 Next slide.

18 In McClain the Court noted that the dose of ephedrine
19 in Metabolife was about half of what the FDA allowable limits
20 were, which is quite different than what we have here where the
21 doses were so much higher than the FDA limit that the FDA
22 pulled the product from the market. The Court noted that the
23 amount of ephedrine, which is the substance in Metabolife,
24 doesn't exceed the amount of ephedrine in a ton of other
25 products, but then here is the critical thing: In McClain they

1 didn't have any opinions about what level of exposure was
2 enough.

3 So, in that kind of situation where there is very
4 little amount of a product -- of a substance in a product, and
5 you don't even know if that amount is enough to cause the
6 disease in any of the Plaintiffs, that is a general causation
7 problem. That is what was going on there. It is just not the
8 situation here where a large, large number of our Plaintiffs,
9 and I will get to them, we know did take enough.

10 Next slide.

11 That is also what happened in Chapman, which as the
12 Court noted, all substances potentially can be toxic, and that
13 is true, and that you want to look for a dose and effect, and
14 that is true. Then the Court noted that the experts in that
15 case, nor the articles on which they rely, determined actually
16 how much Fixodent must be used for how long to increase the
17 risk of a copper deficiency.

18 Again, exactly the same situation, if you do get in a
19 situation where you can't be sure that any of the Plaintiffs
20 ingested enough of the substance to cause the disease, that is
21 a general causation problem.

22 What I will submit to the Court is that throughout
23 this litigation Defendants have basically been assuming that
24 this is the fact pattern that we are in here, but it is not.
25 The way you know it is not -- turn to the next slide -- is

1 because there are so, so many of our Plaintiffs who clearly
2 took enough Zantac to have an increased risk of cancer.

3 I think we said last week in our brief that 60 percent
4 of the Plaintiffs in the registry have more than ten years of
5 use. I will give three examples to the Court just to make it a
6 little more concrete.

7 Next slide.

8 Timothy Chilcott, a Plaintiff on the registry, used
9 Zantac from 2001 to 2017, then he got bladder cancer in 2017;
10 Christine Smith used Zantac from 2009 to 2019, she is diagnosed
11 in 2019 with pancreatic cancer, and unfortunately she
12 ultimately passed away.

13 A similar use situation with Charlotte Carter, she
14 used cancer (sic) from 2000 to 2016, she was diagnosed in 2016,
15 and she ultimately developed bladder cancer.

16 So, for general causation, your Honor, you have to
17 have in mind these cases because if it is true -- and I am
18 about to show exactly why it is true -- but if it is true that
19 one year is enough, or three years is enough, or frankly, for
20 these three ten years of Zantac use is enough, maybe there will
21 be problems on specific causation for these Plaintiffs, but you
22 can't look at these facts and the use of literature I just
23 talked about and say, you lose on general causation. That just
24 doesn't work.

25 I'll take the next slide.

1 I wasn't really making up those numbers when I said
2 one year, three years is enough. As I said, you can't just
3 pick one dose that is demonstrated to cause cancer because the
4 reality is, when you look at different data sources you are
5 going to get different information about doses that are
6 demonstrated to be enough.

7 I have listed a number of them here. I am going to
8 describe in detail a few of them. Just so the Court knows, the
9 one year is from the Wang study, the three years is from the
10 Cardwell study, and the rest of the figures are the ones that
11 Drs. Salmon and Panigraphy generated by going what I call
12 bottoms up, by looking at what NDMA doses were enough to cause
13 cancer in the NDMA studies, and then looking it up, how much
14 Zantac you need to take to get to those doses.

15 They are different methodologies, to be sure, but each
16 of these is a dose that is demonstrated in the literature to be
17 enough.

18 Next slide.

19 Here is Dr. Salmon discussing the Cardwell study. The
20 Cardwell study looked at three years of usage and noted that
21 there is a statistically significant increase in the risk of
22 bladder cancer.

23 I think counsel in their opening said the most
24 important thing is to look at exposure to the drug, that is a
25 quote. What happens when people are actually exposed to the

1 drug. We, of course, think you should look at that plus some
2 other material as well, but even taking just that, this is
3 exposure to the actual drug.

4 In Cardwell, people took Ranitidine for three years
5 and they developed a risk of bladder cancer that was
6 statistically significant. So for general causation the
7 question should just be, well, are there other Plaintiffs in
8 this MDL who took Zantac for more than three years and
9 developed bladder cancer? The answer to that is yes. I just
10 showed you two examples of them. There are thousands more.

11 Next slide.

12 Just to show the Court that Dr. Salmon is exactly
13 correct on this, this is what the Cardwell paper showed: For
14 people who took more than 1,095 daily doses of Zantac, which is
15 three years, they got a 43 percent increase in risk, and that
16 result is statistically significant.

17 Next slide.

18 The Wang paper confirms this result and confirms what
19 our experts have been saying all along. This is the graph in
20 Wang for liver cancer, I'm sure we will be talking more about
21 it later, but you can see visually what is going on here. That
22 blue line is the users who took no Zantac at all, and you can
23 see what their risks of cancer were when they followed them
24 over time. Then once you look at people who took it for 90
25 days, or six months, or nine months, or a year, those lines go

1 way, way, way up.

2 This is conclusive evidence of dose response, which is
3 of course, a primary methodology, but for these purposes, the
4 point I am trying to make is that this shows definitively that
5 many, many Plaintiffs in this MDL took Zantac for plenty long
6 enough to have caused their cancer, and to keep beating a dead
7 horse, that is the question that matters for general causation.

8 I'll take the next slide.

9 Similar result for stomach cancer for real patients
10 who took Zantac for more than a year, they developed a
11 33 percent increase in risk.

12 Next slide.

13 And I will say that is a tough pill to swallow for
14 Defendants and their experts, as we will talk about, because we
15 have heard for two weeks about how important it is to look at
16 the Ranitidine epidemiology, and not just any Ranitidine
17 epidemiology, but active comparator studies.

18 They have described them as ideal. They have said
19 that everyone thinks they are more appropriate, and they have
20 criticized our criticisms. I will get to some of the
21 criticisms in a moment, but for these purposes I will say we
22 think they may be overstating the case a little bit, but to the
23 extent they are right, what Wang and Cardwell are, are
24 Ranitidine epidemiology with an active comparator design and it
25 showed that our Plaintiffs took doses that were sufficient to

1 cause cancer.

2 I'll take the next slide. One more, actually. Thank
3 you.

4 So I know that is very long wind up, probably even
5 longer than I wanted to go, but that is really what Defendants'
6 experts got wrong here. They focused on the Plaintiffs all the
7 way down at the bottom who took Zantac for very short periods
8 of time, and they ignored the Plaintiffs up here who took
9 Zantac for very long periods of time. That is just a
10 fundamental error about the question presented at the general
11 causation phase versus the specific causation phase.

12 Judge, just be clear on one point, it is not that it
13 is never going to matter how much people took of Zantac. In
14 specific causation at this particular trial for one of those
15 Plaintiffs down there at the bottom left, they are, of course,
16 free to argue that for that person they didn't, in their view,
17 take enough Zantac to cause cancer, but it does not provide a
18 reason why there is no general causation for those Plaintiffs
19 way, way up there at the right when we know that those doses in
20 the decades are plainly enough.

21 The next slide.

22 The clearest example of the error made by Defense
23 experts on this point is in the studies that they relied upon.

24 Those studies looked at the weakest cases, allowing
25 patients with just one or two prescriptions of Zantac to be

1 included in the database, and that is an error when the general
2 causation question has to focus on the strongest case.

3 Again, in the context of a trial where someone took
4 one prescription, they used it for very short periods of time,
5 those studies are, of course, relevant, but these are supposed
6 to be general causation experts from the Defendants, and if
7 that is true, they have to focus on the much different question
8 of whether it is possible that any of our Plaintiffs got cancer
9 from Zantac.

10 Next slide.

11 So, in very simple terms, this is the analytical gap
12 that Defendants' experts tried to jump. They looked at studies
13 that show cancer risk after short usage and short followup, and
14 from those studies, they tried to conclude that Zantac does not
15 cause cancer after long usage and long followup, and that is
16 just the kind of analytical gap that Daubert forbids because
17 that question that I have put in the gray box is the one that
18 matters for general causation purposes, not the one in the
19 other one.

20 I'll take the next slide.

21 It is not just about dose, although I have been
22 spending a lot of time on it, but it is also about followup.
23 Over the past couple of weeks I think sometimes these
24 distinctions have gotten blurred, but I want to make it very
25 clear, when we talk about dose, we are talking about the

1 difference between a person who just took a little Zantac
2 versus a lot. I think the Court understands that.

3 For followup, though, it is very different. What we
4 are talking about is, did you look at patients who took Zantac
5 and wait for one year to see if they develop cancer or did you
6 wait 30 years? Of course you want to wait for 30 years because
7 if you look at any carcinogen, including smoking by the way,
8 and see if someone gets cancer the year after they started
9 smoking you just are not going to see very much.

10 Next slide.

11 That is why the WHO and the IARC preamble says what it
12 does. It says that if you want to disprove the risk of a
13 carcinogen, if you want to provide evidence of lack of
14 carcinogenicity, as it says here, you can't use studies that
15 are shorter than about 30 years.

16 Now, I want to pause on something because we will get
17 into it when we get into Wang. The opposite of this statement
18 isn't true. You do sometimes see cancer risk in studies that
19 are shorter than that, but that is because if you see a signal
20 that appears in the study that is not looking for as long as it
21 usually takes to develop cancer, that is an especially strong
22 signal.

23 The opposite just isn't true. If you don't see a
24 signal in a study that doesn't wait long enough, it doesn't
25 tell you very much. If you do see a signal in a study that

1 doesn't wait very long, that is even more powerful evidence
2 that there is an association.

3 Next slide.

4 Turning to the individual experts, Dr. Witte in his
5 report attempts to cure this problem with the literature. If
6 you look at this chart that he prepared about the studies he
7 relied upon, he puts in a column that says time period that
8 makes it look like these studies were very, very long. Yoon
9 says 2009 to 2018, Iwagami says 2005 to 2018. It makes it seem
10 like these studies must have followed these patients, or
11 perhaps looked at patients who had been exposed to the drug for
12 nine years and the 13 years.

13 The reality is, the Iwagami study only had two years
14 of followup. That was the median amount of time that people
15 were followed in that study.

16 Your Honor, if you look at a study of a carcinogen and
17 wait two years, you should be surprised if you see an increased
18 risk because that is just not long enough for cancer to develop
19 in most patients.

20 Next slide.

21 As far as I can tell, Defendants have realized that
22 this is a problem, because I think they are going to show you a
23 slide that looks like this one.

24 When you read the slide it looks like the Norgaard,
25 Adami, Iwagami studies have these very, very long time

1 associated with them, but that is because what they decided to
2 do here is literally blur the concept between exposure of how
3 long people have used the drug and followup time. If you look
4 at the blue chart that is exactly what they said they have done
5 here. I suspect what they have done is added the exposure time
6 and followup periods for all of these studies.

7 The fact of the matter is, if you look at Iwagami, it
8 says 13.7, but in reality the median followup time in that
9 study was just two years.

10 In response to that, Defense experts really have no
11 choice but to disagree with the studies' own authors because
12 most of those authors acknowledge that this is a major
13 limitation in their studies. Dr. Yoon writes that the overall
14 followup is not long enough to assess the onset of cancer. He
15 said he saw that and then was asked if he agreed, and he said
16 that he did.

17 Next slide.

18 Dr. Vaezi, for his part, did acknowledge in the
19 abstract that you do need to get good data on exposure to make
20 sure you have good data on timing, dose, and duration. He said
21 he thought that was key.

22 Next slide.

23 The problem, though, came when he actually looked at
24 the studies because the fact of the matter is, there is not a
25 study that has ten solid years of exposure data where people

1 took Zantac for that kind of length of time.

2 So, what Dr. Vaezi did, and frankly what a number of
3 the experts did that I will show you, is they made an
4 assumption, and the assumption was this: If you took ten
5 prescriptions of Zantac, that automatically means that you were
6 using Zantac for ten years, and that is just not true.

7 I don't even think you need to be a scientist to
8 understand it. If you got ten prescriptions, maybe it was ten
9 months, maybe it was one year, maybe it was two years, but
10 there is not a one-to-one correlation between the number of
11 prescriptions that you have and the number of years you are
12 using the drug.

13 Next slide.

14 Because that is not true, one of their experts, Dr.
15 Terry, had to admit that it was wrong. We asked her, do you
16 agree that if they are 30-day prescriptions, perhaps that would
17 mean ten months of use? And she said she had to admit that
18 that would be the lower bound.

19 Dr. Terry also admits that followup time is critical
20 when doing studies like this. She said that given the long
21 induction time of many of the specific cancer types, you need
22 to look -- sorry, you need to make sure that the medicine has
23 been used for a longer duration prior to cancer diagnosis.

24 Next slide.

25 The problem is that Dr. Terry said that she didn't

1 actually know what the latency for Ranitidine is, but she said
2 that it was ten or 20 years for some solid tumors, and the
3 vast, vast majority of the studies that she and the other
4 Defense epidemiologists relied upon had followup periods that
5 were nowhere, nowhere near that long.

6 Next slide.

7 Dr. Chan agreed on the exposure point, again in the
8 abstract. He said in an epidemiological study one would find
9 exposure with the best available data.

10 Next slide.

11 The problem was that Dr. Chan said in the case of
12 Ranitidine he didn't understand how exposure levels would be
13 defined.

14 Instead of doing that -- go to the next slide -- he
15 again made this assumption that the other experts made, that
16 somehow if you take ten prescriptions of a drug, that you would
17 be taking Ranitidine for ten years.

18 I don't know where these experts got that assumption
19 from. As Dr. Terry acknowledged, it is just not true, and what
20 is really going on here is that they know that they need
21 studies that have that kind of dosage data to be able to say
22 anything meaningful about general causation. In the studies
23 they are looking at is just not there, so to try to bridge that
24 gap they made this assumption that is false, your Honor.

25 Next slide.

1 We asked Dr. Chan pretty directly, can you tell us any
2 study that actually looks at what happens when people use
3 Zantac for five or more years? The answer he gave us was the
4 Kantor study.

5 Next slide.

6 If you actually look at Kantor, you don't see this
7 five year number here anywhere. In fact, what you see is that
8 people could be in the Kantor study if they used Zantac for
9 most of the days of the week for the last four weeks, and even
10 those authors said they were unable to examine associations by
11 dose or to distinguish short-term versus long-term use.

12 I'll take the next slide.

13 Switching to followup for a moment, Dr. Chan also
14 agrees that for there to be an association you need to make
15 sure you have a long enough followup period.

16 I'll take the next one.

17 But then Dr. Chan had to admit that he didn't really
18 know what the latency period of Zantac was, that he didn't
19 think they had any data to go on. The reason why that is a
20 problem is because these experts have an opinion that these
21 studies show that there is no association.

22 If they don't know what the actual lag time is, if
23 they don't know how long you need to look in order to see if
24 Zantac causes cancer, then they can't be sure the studies they
25 are relying on were actually long enough to pick up a signal

1 that was there.

2 Next slide.

3 Dr. Hatten did agree in the abstract that if an
4 outcome has a long latency period that you are not going to see
5 it, if you look at too short of a followup time. I think Dr.
6 Hatten might have said it most directly, it is not possible to
7 see an outcome of interest if the latency period is long and
8 the observation time is short, and that is true.

9 Next slide.

10 When it came to analyze the actual studies, Dr. Hatten
11 ignored the fact that the patients had low exposure, ignored
12 the fact that there was short followup time, and then he
13 ignored the other issues with the studies that we have been
14 talking about for two weeks now, misclassification, lack of
15 over-the-counter data, and lack of data on confounding.

16 I want to pause for a moment and say a variation of
17 what i said before on does, but it's worth repeating with
18 respect to all of these.

19 To the extent a study that is not well designed does
20 show a risk, that is putting aside certain types of confounding
21 which we will talk about, very good evidence that there is in
22 fact a risk, if it shows up it is sometimes surprising if the
23 studies are designed like these.

24 For these experts, the important point we need to make
25 to you is, the opposite is not true. If you are going to have

1 an opinion that Ranitidine doesn't cause cancer in the sorts of
2 cases that are at issue in this MDL, then you need studies that
3 are very, very well designed, that have enough dose in order to
4 replicate the actual Plaintiff population we are looking at and
5 that actually waited long enough to see if those cancers
6 actually developed.

7 Next slide.

8 All right. Turning to my second point, the experts
9 failed to consider and assess all of the evidence.

10 Now, this is a very different criticism that the kinds
11 of criticisms that Defendants made against our experts. I did
12 not understand them to be arguing that any of our experts
13 missed large buckets of evidence, or didn't spend enough time
14 weighing them, or anything like that. Their criticism was just
15 that they thought their studies were better than ours.

16 The criticism I am going to make is plainly a Daubert
17 one because it goes straight to the heart of their
18 methodologies.

19 I'll take the next slide.

20 If you look at our methodologies that we employed with
21 our epidemiologists versus the ones that they employed with
22 theirs, I do think you will see a real meaningful difference.
23 Dr. McTiernan and Dr. Moorman carefully considered all the
24 studies, they thoroughly evaluated their strengths and they
25 thoroughly evaluated their weaknesses.

1 As the Court knows by this point, there are studies in
2 this litigation that help one side more than the other.

3 What our experts did is, they looked at those studies,
4 they acknowledged the strengths of them, even when they were
5 perhaps more helpful to the Defendants, they acknowledged the
6 weaknesses of them, even when they were perhaps more helpful to
7 us, and they ultimately explained how each of those studies fit
8 into their broader conclusion.

9 That is not what the Defense experts did.

10 Next slide. Go back one. Thank you.

11 Dr. Witte, for example, focused almost exclusively on
12 the epidemiology that compared Ranitidine users with those who
13 used H2 blockers. I know Defendants quibble with this and say
14 he really considered everything, but for this part of Daubert
15 to mean anything it has to mean more than that the expert put a
16 certain set of materials on his reliance list or put them in
17 the discussion section.

18 In order to really grapple with this literature, which
19 is very complicated, the expert needs to go through each of the
20 studies and actually candidly evaluate what is good about them,
21 what is not. That is what our experts did, that is not what
22 Dr. Witte did.

23 Next slide.

24 Dr. Chan, it is even clear, he said in his report
25 there is just no basis to review what he deemed to be less

1 relevant literature, by which he meant studies that were run on
2 NDMA and cancer risk. In his deposition I think he even said
3 that he didn't look at those NDMA studies until he first
4 noticed them in the Plaintiffs', our expert reports.

5 Next slide.

6 The reason why that is a problem is because the NDMA
7 literature is certainly relevant to the general causation
8 question here. There's no dispute that Ranitidine --
9 NDMA vapor inhaled at work and foods analyzed in the dietary
10 studies all contain NDMA. There is no dispute that this NDMA
11 molecule is identical, whatever the delivery mechanism, and
12 there is no dispute that once it is in the body NDMA behaves
13 exactly the same way regardless of how it first ended up there.

14 That is critical, your Honor, because it explains why
15 this case is just like the Ryan case of Benzene in mineral
16 spirits, and now Burst or Hendrikson where the Benzene was in
17 gasoline. There they actually were arguing that the underlying
18 chemical behaves differently in gasoline, but Defendants here
19 don't even argue that the NDMA in Zantac behaves differently
20 than the NDMA consumed in foods or inhaled at work.

21 Next slide. Two more actually. Thank you.

22 Dr. Vaezi, in his deposition, said that he considered
23 the NDMA studies somewhat irrelevant, so he didn't pursue them
24 any further.

25 Dr. Terry, in her report, made clear her belief that

1 only cancer outcome studies of Ranitidine can reliably address
2 potential increased risk. For that reason, she said, she
3 focused on those studies which compared Ranitidine users and
4 she largely ignored the broader literature on NDMA.

5 Next slide.

6 So, before I move on to my last point, I want to pause
7 and just give a concrete illustration of what I mean when I say
8 that our experts employed different methods than their experts
9 did when evaluating the literature.

10 This is Iwagami, and as I said, it has some pretty
11 major limitations. 96 percent of the patients took Ranitidine
12 for less than six months, the median followup was only 2.4
13 years, 72 percent of the patients were under 50 years old,
14 which meant that they are very unlikely to develop cancer in
15 the first place, and, of course, this study lumped together
16 Ranitidine and Nizatidine.

17 So what did our experts do with this study? It has
18 real strengths, too, right. It is a very large study, has lots
19 of cancer cases, it had data based on dispensation of the
20 pills, it had some dose data.

21 Next slide.

22 What our experts did is, they described the strengths,
23 the large databases, they described the weaknesses, the limited
24 followup, the combination of the drugs, and described what role
25 the study played in their overall conclusions.

Pauline A. Stipes, Official Federal Reporter

1 Next page.

2 In fact, if you look at Dr. McTiernan's report, this
3 process goes on for seven pages just for Iwagami alone.
4 Obviously Daubert is not a competition about who can type the
5 most pages. I am not saying that, I get it. But these are
6 very complicated issues over which scientists vigorously
7 disagree and that really deserve a detailed analysis. That is
8 what Dr. McTiernan did just for this study.

9 Next slide.

10 That is not how Dr. Vaezi dealt with it. He described
11 the strengths, of course, because Defendants really liked the
12 outcome of that study, but he didn't describe the weaknesses
13 and he did not assess the applicability to this case.

14 I will show you, if you take the next slide.

15 This is Dr. Vaezi's entire analysis of the Iwagami
16 study, one paragraph. It is, admittedly, a kind of long run-on
17 paragraph, but that is the entirety of the analysis that he
18 did.

19 Again, there is no requirement that an expert write a
20 certain amount on a study, it is not a writing competition, but
21 to really analyze a study like this and give it its proper due,
22 given the complexity, I think it is fair to say it takes a lot
23 of time, a lot of effort, and frankly, a lot of pages.

24 Our experts did all that and theirs did not.

25 Next slide.

1 In fact, this is the closest that Dr. Vaezi came to
2 identifying limitations in the Iwagami study. At the beginning
3 we get one opening clause that kind of back handedly
4 acknowledges that the overall median length of the followup on
5 the study was relatively short, 2.4 years, but then he
6 immediately goes on to say that is alleviated by these other
7 features of the study.

8 The only other limitation that I think he acknowledges
9 is he notes the criticism by Plaintiffs' expert that this study
10 combined Ranitidine and Nizatidine, but he says that ignores
11 the underlying NDMA hypothesis, and that is it.

12 I think at this point the Court realizes that there
13 are studies that cut in different ways in this litigation, but
14 to give a coherent opinion in this case an expert needs to
15 candidly acknowledge what the strengths and limitations of the
16 study are. That is what our experts did and I just don't think
17 that this qualifies as a candid explanation of what is really
18 going on in Iwagami.

19 Next slide.

20 Last, what role did Iwagami play in Dr. Vaezi's
21 opinion? We just don't know. All we have is that one
22 paragraph where he goes through a couple of talking points and
23 then says what the study results are. That is not enough to
24 demonstrate that the methodology he used to analyze this
25 literature is reliable.

1 Next slide.

2 My last point: The experts failed to carefully review
3 the evidence as required by Abilify.

4 Beginning with Dr. Hatten, Dr. Hatten has an opinion
5 that NDMA does not cause cancer, but he did not conduct a
6 Bradford Hill analysis on NDMA itself. He says here that he
7 informally evaluated the NDMA under Bradford Hill, but
8 respectfully, your Honor, an informal Bradford Hill analysis is
9 just not a thing. As the Court knows, Bradford Hill is a
10 complicated method of determining causation. It is not
11 something that you can just say that you did informally.

12 Next slide.

13 Aside from NDMA, even Dr. Hatten's Ranitidine specific
14 Bradford Hill analysis is inadequate. Instead of going through
15 each type of cancer, he simply lumps them together under the
16 title of cancer and opines that Ranitidine doesn't cause
17 cancer.

18 Next slide.

19 That is not what you are supposed to do, and it is not
20 what our experts did. For Dr. Moorman, these are the pages
21 that she spent talking about each type of cancer. She does a
22 separate Bradford Hill analysis, eight pages for bladder, eight
23 pages for pancreatic, 50 pages in total.

24 Next slide.

25 So, for comparison, what did Dr. Hatten do for the

1 entirety of his Bradford Hill analysis? Again, one single
2 paragraph, not separated out by any cancer types, all cancers
3 lumped together, one paragraph total.

4 Next slide.

5 Dr. Witte is similar on this front, instead of doing
6 what our experts did in performing a Bradford Hill analysis of
7 each type of cancer, he simply lumped every type of cancer
8 together, called it human cancer, and then performed a single
9 Bradford Hill analysis on it. That just is not sufficient to
10 qualify as a careful review.

11 Next slide.

12 In addition to that general problem, Dr. Witte makes
13 several other errors that demonstrate his lack of careful
14 review. This is his report in the section on bladder cancer.
15 He says that the four active comparator studies did not show an
16 association between Ranitidine use and bladder cancer. But if
17 you actually look at the report, the studies go four for four.
18 Every single one of the studies he identified as a comparator
19 shows an increased risk either numerically or statistically.

20 In the fourth study, the Habel study, it shows an
21 increased risk as well.

22 Next slide.

23 In response to that, he has to do what a lot of the
24 Defense experts do, which is to contradict what the authors of
25 the study said, because the Cardwell study in the discussion

1 suggestion says the use of Ranitidine, particularly long-term
2 use, was associated with an increased risk of bladder cancer,
3 and Dr. Witte in his deposition has to call this invalid.

4 Next slide.

5 Confounders. When it comes to confounders, Dr. Witte
6 noted in his report his view that it is critical to measure the
7 data on smoking, because is the patients taking one drug versus
8 another drug are more likely to smoke, then the cancer rate for
9 that drug might be artificially elevated. In fact, Dr. Witte
10 mentioned smoking more than 50 times in his report.

11 Next slide.

12 He also admitted in his deposition that this effect
13 could bias studies in either direction. In other words, he
14 admitted that if patients in the comparator group smoked more
15 than patients in the Ranitidine group, then the results of the
16 study would show an artificially low risk for Ranitidine.

17 So far, so good on the theory, your Honor, we agree
18 with this wholeheartedly.

19 I'll take the next slide.

20 It seems like Defendants agree with that point as well
21 because this is a slide they have from their deck. They know
22 that smoking is a strong confounder in bladder cancer studies,
23 so you want to control for it. So, what you think would happen
24 is that Dr. Porter would place the greatest weight on studies
25 that did control for smoking, given the emphasis he puts on

1 smoking as a confounder in his report.

2 Next slide.

3 So, if you look at the actual studies, the Adami,
4 Norgaard, Yoon, and Iwagami studies don't have any smoking data
5 at all, but Dr. Porter places great emphasis on those studies.

6 Two of the studies, Cardwell and Kim, do have smoking
7 data. The problem for the Defense experts is that the two
8 studies that do have smoking data cut strongly against the
9 Defendants. The Cardwell study shows a statistically
10 significant increase in bladder cancer risk, even though
11 controlled for smoking, and the Kim Y study showed the Zantac
12 users were less likely to smoke than users of the comparator
13 drug.

14 Next slide.

15 So, what is Dr. Witte's response? Dr. Witte's
16 response I think is going to end up being an important one
17 today.

18 Dr. Witte said that by using an active comparator
19 design the studies were somehow, quote, "indirectly controlling
20 for alcohol and tobacco usages, even though the study didn't
21 actually measure alcohol and tobacco usages."

22 I suspect that we will see whether Dr. Porter agrees
23 that the Wang study was indirectly controlling for smoking, but
24 for now, my point is a slightly different one.

25 This is something that a lot of the Defense experts

1 say, that these active comparator studies by virtue of their
2 design are somehow insulated from any confounding. Your Honor,
3 that is just not correct.

4 We will talk about it more when we talk about Wang
5 later, and Defendants are probably going to acknowledge that it
6 is not correct, but I'll tell you now, it is just not
7 incorrect. Even in an active comparator study you always have
8 to think about confounders.

9 To be perfectly fair, that effect can cut in either
10 direction. You can get situations where the results are
11 confounded in a way that makes them look unrealistically high.
12 I think the Defendants are going to show you a chart on coffee
13 and cancer risk that illustrates that point, but you can also
14 get results where the confounding obscures a real association.

15 Next slide.

16 Based on the limited data that we have on these
17 confounders, that second option where the confounding obscures
18 the association appears to be what is going on, because the
19 data we have from Kim YD shows that Ranitidine users are less
20 sick, use less tobacco, use less alcohol, and had less of all
21 of these confounders than the comparator groups did.

22 Active comparators will not fix this problem, that is
23 what Defendants experts failed to recognize.

24 Next slide.

25 I have an example here, although I think the Court

1 probably understands, if it is true that the users of Zantac
2 smoked less than the users of the comparator drug that is going
3 to make Zantac look safer and make the comparator drug look
4 more dangerous for reasons having nothing to do with whether
5 the drug is actually safe or unsafe. That is why you need
6 to -- sorry. That is why the Cardwell study controlled for
7 smoking and why Dr. Porter and the other experts should have
8 credited that over studies that didn't control for it.

9 What did Dr. Terry do? She did not discount the
10 studies with no smoking data, Yoon, Adami, and Norgaard.

11 Next slide.

12 Instead, she did something inexplicable; she looked at
13 one of the only studies that did have smoking data and she
14 criticized it for having incomplete smoking information.

15 Next slide.

16 The same for Dr. Porter. These studies are fairly
17 similar at a high level, they use active comparators, they have
18 the same type of comparisons, but one primary difference is
19 that the Cardwell study does control for smoking and the Yoon
20 and Norgaard do not control for smoking.

21 You would think, based on this, that he would credit
22 the Cardwell study and discount the Yoon and Norgaard study.
23 What Dr. Porter does is exactly the opposite and the reason is
24 obvious, they like the results of Norgaard, they don't like the
25 results of Cardwell, but that kind of litigation driven

1 reasoning is simply not permitted by Daubert and Abilify.

2 Next slide.

3 That kind of litigation reasoning is on display
4 elsewhere in Dr. Porter's expert report. For example, here is
5 his discussion of the consistency prong of Daubert for bladder
6 cancer. Every single one of these studies shows an increased
7 risk. Some of them are higher than others, some of them are
8 statistically significant, some of them aren't, but every
9 single one of these studies showed a higher risk for the
10 patients who took Ranitidine versus the patients who took the
11 comparator drug.

12 Next slide.

13 Speaking of consistency, I want to pause on this sound
14 bite from the Florian study that Defendants have shown to the
15 Court a couple of times, showed the Court again today, and I
16 suspect are going to continue to show the Court.

17 What I think the Defendants want to do with this quote
18 is say, look, Judge, the FDA has looked at the epidemiology and
19 they say no consistent signals have emerged, but that is just
20 not true.

21 At this point, I know the Court has read the Florian
22 study enough to know that it is really a study about how much
23 NDMA ends up in the patients' urine after taking Zantac. It is
24 not a systematic review of the epidemiology. The best evidence
25 of that is the Florian study does not even cite two of the

1 studies that existed at that time, McDowell and Liu. of
2 course, Florian is now seriously out of date given that six on
3 point studies have come out after it, including importantly
4 Cardwell and Wang.

5 Defendants and their experts don't mention this. They
6 just make it seem like Florian is the decisive word on whether
7 Zantac causes cancer, even though that is factually not true
8 and logically impossible given Florian's publication date.

9 Next slide. One more. Thank you.

10 The last point I want to make applies to a few of
11 their experts. I don't know if they didn't read the relevant
12 literature carefully, or were just being imprecise, or got
13 confused, or were trying to be intentionally misleading, but a
14 number of their experts, including Dr. Vaezi here, said the
15 public health organizations had looked at the data and decided
16 that NDMA does not cause cancer in humans.

17 Next slide.

18 Dr. Chan says essentially the same thing, that he
19 didn't think anyone looked at evidence in human studies and
20 determined that NDMA was genotoxic.

21 Next slide.

22 That is obviously not true. The Court knows this. We
23 have gone through many of these by now. I am not going to show
24 each of these classifications, but suffice it to say that
25 health authorities around the world looked at human data and

1 concluded that NDMA is a probable human carcinogen.

2 Next slide.

3 Here is an example of one of them doing it. This is
4 the NTP and its classification on NDMA. It reviews not just
5 literature from animal studies, not just literature from human
6 tissue studies, but literature from human epidemiology studies
7 as well, so Defendants and their experts are wrong to say that
8 this classification is based solely on animals. It is just not
9 the case.

10 Next slide.

11 Of course, GSK has done the same thing when they were
12 evaluating NDMA when NDMA was first discovered in Ranitidine.
13 They note that NDMA is a genotoxin and they note that it is
14 highly likely that NDMA is carcinogenic to humans potentially
15 at low dose exposure.

16 What is interesting about this document is not just
17 what it says, but also what it doesn't say. Over the past two
18 weeks, and I'm sure we'll hear more today, Defendants have made
19 clear their theme, NDMA is carcinogenic in animals and you just
20 don't need to worry about cancer in humans unless the dose is
21 very, very, very high. I think that is a fair characterization
22 of their argument.

23 But if you look at this document and look at what they
24 were saying before they realized they were being sued, there
25 was no mention of threshold dose, quite the opposite. GSK says

1 exposure should be reduced to the extent possible. There's no
2 mention of any massive dose required to cause cancer, quite the
3 opposite. GSK says that even low doses are cause for concern.
4 There's no mention of this being a problem that is somehow
5 unique to animals.

6 GSK says that it is highly likely, not possibly, not
7 theoretically, not even probably, but highly likely that NDMA
8 is carcinogenic in humans.

9 The next slide.

10 The reason why I want to end with GSK's own words, is
11 because that is something the Valsartan Court lasered in on.
12 The same molecule was at issue in that litigation, NDMA, the
13 same underlying science. We have here much stronger evidence
14 on Ranitidine than they had here in Valsartan, but the
15 underlying evidence about NDMA is, of course, exactly the same.

16 The Valsartan Court noted that even the Defendants
17 there acknowledge that NDMA is a carcinogen, relying on the
18 types of documents that I was just showing the Court.

19 In Judge Kugler's view, at least for these purposes,
20 that was the end of the road, nothing more was required.

21 Next slide.

22 In fact, in the Valsartan Court's view, the actions of
23 Government agencies, plus the Defendants' own words were enough
24 to get Plaintiffs there, past the association element, and from
25 there he moved on to Bradford Hill. After going through that

1 Bradford Hill analysis the Valsartan Court did two things.

2 First he denied the Defendants' Daubert motions
3 concerning NDMA and cancer, that includes with respect to Dr.
4 Panigraphy, by the way, who employed an analogous method in
5 that case, and he granted Plaintiffs' Daubert motion with
6 respect to some of the Defense experts.

7 Now, obviously I am not arguing estoppel or that you
8 have to rubber stamp Judge Kugler's opinions on NDMA or
9 anything like that, and that is because, again, the focus of
10 Daubert is about methodology, not conclusions. That said, what
11 the judge did in Valsartan, which is the only other major NDMA
12 case I know of, is instructive.

13 Next slide. One more.

14 What the Court did was exactly the right thing, he
15 looked at the methodology of the Defendants' experts and he
16 found them lacking. Obviously every expert has a different
17 methodology, I'm not disputing that, but for Dr. Flack, he
18 noted that the expert had failed to consider a lot of the
19 relevant literature, just like the Defense experts here did by
20 failing to really analyze the NDMA literature, and he noted
21 that they failed to consistently apply a recognized
22 methodology.

23 For Dr. Wei the effect was also similar. Dr. Wei
24 essentially opined that because one of the Plaintiffs' experts
25 had bad methods that meant NDMA did not cause cancer. The

1 Court realized why that didn't work logically.

2 With respect to NDMA, that is by and large what
3 Defendants' experts do here as well, they criticize our experts
4 and the underlying studies and say that they have limitations
5 and then jump straight to the conclusion that NDMA doesn't
6 cause cancer. The Court in Valsartan wouldn't let them do
7 that, and I don't think the Court should do so here either.

8 Next slide.

9 I will close where I started. Our experts answered
10 the right general causation question, whether any Plaintiff in
11 the MDL could have plausibly gotten cancer from Zantac. Their
12 experts answered the wrong question, relying on studies showing
13 what happens to patient populations that were much younger,
14 exposed to far less Zantac, and with much shorter followup
15 times.

16 Our experts carefully considered all the evidence,
17 even the ones relied upon heavily by Defendants' experts, and
18 carefully explained them. Their experts did the opposite,
19 ignoring huge swaths of evidence and failing to give them an
20 explanation.

21 Finally, our experts reviewed the evidence carefully.
22 You have heard very little of this over the past two weeks from
23 the Defendants. They don't say our experts identified the
24 wrong literature. They don't say that they used the wrong
25 methods to identify it. They don't say they didn't call out

1 the right strengths and weaknesses. They just don't like the
2 conclusions, but that is not our criticism of their experts.

3 As we pointed out, methodologies are quite different
4 in their rigor. Their treatment of Bradford Hill was sometimes
5 nonexistent or broadbrush or woefully brief. Their treatment
6 of confounders reveals results oriented reasoning made for
7 litigation, and more than one of them was simply confused about
8 what the scientific community really says about NDMA.

9 For these reasons, and those stated in our briefs, we
10 ask the Court to exclude the opinions of Dr. Terry, Dr. Witte,
11 Dr. Porter, Dr. Chan, and Dr. Hatten.

12 For Dr. Guengerich and Dr. Chodosh we ask the same
13 thing, but we rest on our brief due to time constraints.

14 *THE COURT:* Thank you.

15 *MR. SNIDOW:* I will turn it over for Dr. Wang to
16 Ms. Goldenberg.

17 *THE COURT:* Okay. I thought you wouldn't come in that
18 short. You still have about twelve minutes.

19 *MS. GOLDENBERG:* Good morning, your Honor, Marlene
20 Goldenberg for the Plaintiffs, and may it please the Court. I
21 am here to talk about Dr. Wang.

22 Go to the next slide, please.

23 As the Court knows, Daubert is not about conclusions,
24 but about methodology. So, to be clear, we are not disputing
25 that Dr. Wang is qualified to offer his opinions, and we are

1 also not disputing that Dr. Wang could have offered his
2 conclusions about Ranitidine and cancer risk if he had employed
3 a reliable methodology in support of them. The problem is that
4 Dr. Wang made several errors that rendered his methodology
5 unreliable and inadmissible under Daubert.

6 Next slide, please.

7 Dr. Wang appears to apply a weight of the evidence
8 approach to evaluating the risk of cancer from Ranitidine.
9 There is no problem with that approach. Many of our experts
10 used that approach, too, as the Court will see from the Abilify
11 opinion quoted here, and other Courts in the Eleventh
12 Circuit have blessed that approach, too.

13 But when an expert uses the weight of the evidence
14 approach, as Dr. Wang did, it comes with three strings
15 attached. First, the expert must consider all of the available
16 evidence, not some of it, not just a select bit of it, not just
17 the evidence that is helpful to his or her side; all of it, and
18 that is what our experts did.

19 Second, the expert must consider each piece of
20 evidence carefully. That means the expert needs to give more
21 than lip service to having read a study.

22 And third, the Court (sic) must explain how the
23 relative weight of each piece of the evidence led to his or her
24 conclusion.

25 Next slide.

1 Dr. Wang failed to do each of these things. Let's
2 start with the first string. Dr. Wang simply did not consider
3 all of the available evidence.

4 Next slide, please.

5 As the Court surely remembers from last week,
6 Plaintiffs' experts relied upon several different categories of
7 evidence, including dietary studies, occupational studies,
8 animal studies, and human epidemiology, but Dr. Wang relied
9 almost exclusively on human Ranitidine epidemiology and did not
10 meaningfully consider the other categories of evidence.

11 As the Ranitidine epidemiology has been discussed by
12 others in our group, I will only add that studies purporting to
13 study Ranitidine users are hardly grounds for ruling out
14 carcinogenic effects when, like the Adami and Norgaard studies,
15 they only require levels of use that are far less than what
16 Plaintiffs in this case took.

17 Yet, these Ranitidine epidemiology studies are the
18 basis Dr. Wang uses to conclude that Ranitidine does not cause
19 cancer at the allegedly low doses, which we will discuss
20 momentarily.

21 Next slide, please.

22 Now, to be clear, Dr. Wang paid lip service to these
23 other kinds of studies by listing them in the background
24 section of his report, but when it came time to actually
25 perform his Bradford Hill analysis, everything except the human

1 Ranitidine epidemiology all but disappeared. He mentions them
2 in one single sentence in the analogy section.

3 In all of the other sections it's just human
4 Ranitidine epidemiology alone. Dr. Wang could have testified
5 that he was unpersuaded by these other forms of evidence, but
6 he didn't. He just pretended that they weren't there. This
7 can't be enough to meet the standard for considering all of the
8 available evidence required under Daubert.

9 Next slide, please.

10 Even if that were enough to somehow check the box in
11 considering all of the available evidence, there is no question
12 Dr. Wang did not do so carefully.

13 Next slide, please.

14 For starters, there just wasn't enough time for Dr.
15 Wang to have done a careful review. In his report he says he
16 reviewed more than 580 documents, but his timekeeping records
17 reveal that he spent only 18 and a half hours reviewing them.
18 That works out to one to two minutes, not per page, per
19 document. As everyone in this courtroom knows, it takes more
20 than one to two minutes to read these studies and that shows in
21 Dr. Wang's report.

22 These are dense, extremely complicated, and often
23 quite lengthy pieces of medical literature. It is simply not
24 enough time for Dr. Wang to have performed a careful review as
25 required under Abilify and by Daubert.

1 Next slide, please.

2 Perhaps unsurprisingly, given the time he spent, Dr.
3 Wang's lack of careful review led to serious errors in his
4 report. For example, he relied on a 2022 study by Chan which
5 looked at the cancer risk from Valsartan. The problem with
6 that is that the Chan 2022 study looked at Valsartan before the
7 drug was ever contaminated with NDMA.

8 Next slide, please.

9 Now, that is obviously a huge error given that it is
10 entirely irrelevant whether Valsartan without NDMA causes
11 cancer. We confronted him with that in his deposition and he
12 essentially admitted the slip up on pages 142 and 143 of his
13 transcript, acknowledging that if the Valsartan in the study
14 wasn't contaminated with NDMA, then the study would not be
15 informative about NDMA, which is an obvious point. That means
16 the study cannot form the basis for a reliable opinion in this
17 case.

18 Next slide, please.

19 Then in his deposition Dr. Wang also admitted he had
20 no idea when the Valsartan actually become contaminated with
21 NDMA.

22 Next slide, please.

23 For another example, Dr. Wang testified to his belief
24 that NDMA is not carcinogenic in primates, namely monkeys, and
25 in support of that, he testified that he was relying upon

1 the Thorgeirsson study.

2 Next slide, please.

3 Now, this opinion about NDMA not causing cancer
4 in monkeys was something of a surprise to us, given that the
5 WHO says that NDMA is carcinogenic in all species examined, and
6 the WHO said that almost a decade after the study that Dr. Wang
7 said he was relying on. So then we went and looked at the
8 Thorgeirsson study to see what it actually said.

9 Next slide, please.

10 What it actually says is nothing at all like what Dr.
11 Wang thought. It notes that DMNA, which is another
12 abbreviation for NDMA, was given to 11 monkeys, then it appears
13 that four of them died after six months. For the seven that
14 lived longer, one died of cirrhosis and the other six died of
15 toxic hepatitis.

16 Now, I guess we can debate exactly what that shows
17 about the safety profile of NDMA in monkeys, but it certainly
18 does not suggest that NDMA is somehow not a carcinogen in
19 primates.

20 Next slide, please.

21 Dr. Wang also testified in his deposition that the
22 primates in the study lived long enough to develop cancer in
23 response to NDEA, another nitrosamine that is so much more
24 potent than NDMA that the FDA's interim threshold limits for
25 NDEA are one-third of what they are for NDMA. That another

1 more potent carcinogen killed the monkeys first says nothing
2 about the absence of NDMA's carcinogenicity in primates, but
3 that is what Dr. Wang read it as. This again is not evidence
4 of the kind of careful review required by Daubert.

5 Next slide, please.

6 The last point I want to make about Dr. Wang's lack of
7 care in reviewing the evidence relates to dose. Dr. Wang does
8 not know how much NDMA is actually in the Ranitidine that these
9 Plaintiffs took because he only relied upon baseline testing
10 results performed on pristine Ranitidine. He doesn't know how
11 much NDMA formed in real-world conditions, over time, at
12 increased temperature and humidity levels, during storage and
13 shipment, and endogenously in the body.

14 Next slide.

15 He basically admitted this in his deposition,
16 conceding that he had no information about how much NDMA forms
17 when Ranitidine ages or is exposed to real-world conditions.

18 Next slide, please.

19 And the reason that this is a problem is because Dr.
20 Wang's opinions are based on an assumption about how much NDMA
21 was actually in the Ranitidine that patients consumed. Indeed,
22 Dr. Wang goes so far as to say that it is not biologically
23 plausible for Ranitidine to cause cancer given the amount of
24 NDMA in the drug that Plaintiffs consumed.

25 As we just saw, Dr. Wang actually has no idea how much

1 NDMA was in the Ranitidine that Plaintiffs took. He can't even
2 give a ballpark. Despite his admission in the deposition that
3 more NDMA forms with time, temperature, and humidity, Dr. Wang
4 made no effort to account for this in giving his opinions. He
5 just ignored this universally acknowledged fact and pretended
6 it didn't exist. That methodology is not reliable.

7 Next slide, please.

8 Going back to our slide on dose, you can see why that
9 is a problem. If Dr. Wang does not know the maximum amount of
10 NDMA that a patient could have taken, then he has no basis on
11 which to say the dose was lower than the amount necessary to
12 cause cancer.

13 Next slide, please.

14 And he certainly has no basis to say that the highest
15 dosed Plaintiff was too small to cause cancer, and that is the
16 relevant question for general causation. He just assumed
17 without any basis whatsoever that the dose was too low.

18 Next slide, please.

19 The last reason to exclude Dr. Wang is
20 straightforward. An expert has to explain the relative weight
21 that he or she applied to each piece of evidence, and Dr. Wang
22 didn't do this at all. As we have discussed, he essentially
23 failed to analyze the studies other than human Ranitidine
24 epidemiology at all, and he certainly did not explain the
25 weighting that he gave to varying pieces of evidence that he

1 did not consider.

2 For these reasons, your Honor, Dr. Wang's testimony
3 should be excluded under Daubert.

4 Thank you.

5 *THE COURT:* Thank you. All right. Perfect. You came
6 in within your time.

7 Our schedule shows that we are going to take a
8 15-minute break now. It is 10:30, that means we come back at
9 10:45 and we will see everybody at 10:45.

10 (Thereupon, a short recess was taken.)

11 *THE COURT:* All right. You may be seated.

12 Okay, are we all set from Defense?

13 *MR. BOEHM:* Yes. Good morning, your Honor. Paul
14 Boehm for Pfizer and speaking on behalf of all of the brand
15 Defendants.

16 My colleague, Angela Pyo, and I will be addressing
17 several of the issues that Plaintiffs have raised in their
18 brief that they dub the general causation brief. It has been
19 referred to also as the epidemiology brief. We will be
20 addressing some of the issues that cut across the experts, so
21 they will apply to not just one, but more than one, and in some
22 cases all of the experts.

23 If we can go to the next slide, Maryann.

24 These are the four specific issues that Ms. Pyo and I
25 will be addressing. Ms. Pyo will take the first two and then I

1 stand back up and take numbers three and four.

2 Before I hand the microphone off I wanted to note that
3 although Ms. Pyo is not technically part of the Leadership
4 Development Committee, she is an associate at our firm and
5 otherwise would meet all of the requirements for that and I am
6 pleased to be presenting with her this morning.

7 *THE COURT:* Okay, excellent, welcome.

8 *MS. PYO:* Angela Pyo for Defendants.

9 I will start with Plaintiffs' claim about active
10 comparator studies.

11 Next slide, please.

12 Your Honor has already heard a bit about this a couple
13 weeks ago in the context of why Plaintiffs' experts are
14 unreliable for discounting and ignoring the active comparator
15 studies.

16 As a quick refresher, the active comparator studies
17 are those that compare groups of people taking drugs for
18 similar indications, and because they are taking drugs for
19 similar indications we know that they are similar groups of
20 people, that we are comparing apples to apples, and that
21 reduces confounding.

22 Of course, because this case is about Ranitidine the
23 active comparators here will be other H2 blockers and PPIs.
24 Today we are talking about the flip side of the coin from a
25 couple weeks ago. Plaintiffs are faulting Defense experts for

1 relying on these active comparator studies.

2 They claim that the comparators themselves, the other
3 H2 blockers and PPIs, might be carcinogenic, and if that is
4 true, that would reduce any contrast between the group that
5 took the Ranitidine and the group that took the comparator.

6 There is just no evidence to support these claims.
7 Plaintiffs' own experts don't support them, the FDA doesn't
8 support them, and the broader scientific community doesn't
9 support them.

10 Next slide, please.

11 Plaintiffs lack evidence showing that the comparators
12 themselves can increase the risk of cancer. Although
13 Plaintiffs' experts in their reports suggest that these
14 comparators might increase the risk of cancer, they walk those
15 statements back in their depositions.

16 Both Drs. McTiernan and Moorman, when asked, they
17 stated that they had not done an evaluation of the science
18 behind their assumptions that these comparators could increase
19 the risk of cancer, and when asked, Dr. Moorman said that she
20 couldn't point to a single regulatory agency or medical
21 guideline that suggested other H2 blockers could increase the
22 risk of cancer.

23 Next slide, please.

24 What the regulatory agency, what the FDA has said is
25 that the active comparator design is ideal. In a guidance for

1 industry on the best practices for conducting
2 pharmacoepidemiologic safety studies the FDA said that
3 selecting an appropriate comparator is a critical part of
4 designing such a study, and that it is ideal to use an active
5 comparator.

6 Next slide, please.

7 The broader scientific community agrees. Yoon
8 explains that pharmacoepidemiologic studies are needed for
9 clinically relevant causality assessment, and then goes on to
10 say that the most appropriate way he found to design such a
11 study is to use an active comparator.

12 As your Honor is familiar with the several recent
13 studies addressing the carcinogenicity of Ranitidine, several
14 other experts in the scientific community have concluded the
15 same and have also designed their studies to include an active
16 comparator.

17 Next slide, please.

18 This all ties into the Daubert standard that Mr.
19 Boehm was talking about earlier. A key factor in assessing
20 reliability is to look at whether the expert and their methods
21 have enjoyed general acceptance in the broader scientific
22 community, and as we just discussed, the FDA and the broader
23 scientific community, they have endorsed active comparator
24 studies as a way to look at cancer risks.

25 Defense experts and their methods enjoy widespread

1 acceptance. It's Plaintiffs' criticism that stands alone, and
2 that opinion should be viewed with skepticism.

3 Next slide, please.

4 I will next discuss Plaintiffs' criticism of Defense
5 experts' reliance on the existing body of Ranitidine
6 epidemiology because they claim that several of the studies
7 fail to account for over-the-counter use.

8 Several of these studies are designed so that there is
9 a group that took prescription Ranitidine and a group that did
10 not. Plaintiffs claim that some of the people in the
11 nonexposed group may have been exposed to over-the-counter
12 Ranitidine. They were therefore misclassified and that could
13 reduce the contrast between the group that was supposed to be
14 exposed to Ranitidine and the group that was not.

15 Once again, your Honor, there is no evidence that this
16 occurred. When asked at her deposition, Dr. McTiernan said
17 that she couldn't identify a single person in any of these
18 studies who had actually been misclassified.

19 Moreover, all of the comparators during the time
20 period of these studies also had over-the-counter counterparts.
21 There is just no basis to believe that the usage for Ranitidine
22 over-the-counter use was materially different than
23 over-the-counter use for any of these comparators.

24 Next slide, please.

25 Most importantly, the study authors themselves

1 considered whether there could be misclassification bias and
2 concluded that there wasn't. Adami notes that because all the
3 comparators were similarly impacted by over-the-counter use
4 over time the effect, if any, would be limited.

5 Norgaard observed that because the proportion of
6 over-the-counter sale of Ranitidine increased during the study
7 period, if there really were misclassification bias, we would
8 expect to see different risks for someone who took Ranitidine
9 in the 1990's compared to someone who took it in the 2000's,
10 but we didn't see that kind of attenuation.

11 No other researcher or peer reviewer in the medical
12 community has looked at these studies and said that
13 misclassification bias invalidates the results.

14 So once again, your Honor, Defense experts are in line
15 with the medical community and that is a signal of reliability.

16 Thank you, your Honor.

17 *THE COURT:* Thank you very much.

18 *MR. BOEHM:* Again for the record, Paul Boehm for
19 Pfizer and for all of the brand Defendants.

20 Your Honor, I am going to turn to the next slide which
21 shows us the third of Plaintiffs' criticisms that Ms Pyo and I
22 will be addressing. As your Honor knows, some of my colleagues
23 will be standing up and talking about applications of these
24 criticisms as they apply to individual experts, and also there
25 are some individual specific issues that will be addressed

1 during that portion of today's discussion.

2 The third criticism that Plaintiffs make that we will
3 be addressing, your Honor, is, as you know, they criticize the
4 Ranitidine epidemiological data. They say that it leaves a
5 gap, that is in their brief, it leaves a gap, and we already
6 heard all about how their experts purport to fill that gap, and
7 we have discussed whether or not that is permissible.

8 The issue today is whether it was methodologically
9 reliable or unreliable for Defendants' experts to use these
10 Ranitidine epidemiological data in the way that they have, in a
11 way that is consistent with how FDA treated it, how EMA treated
12 it, how others in the scientific community have treated this
13 data.

14 It is important, your Honor, just to start by going
15 back to something that we discussed earlier this morning, which
16 is, what is the law in the Eleventh Circuit.

17 The law in the Eleventh Circuit specifically asks
18 Courts, when evaluating Rule 702, to consider whether or not
19 the epidemiology related to the drug shows an association, and
20 that is fundamentally the issue that we are addressing here as
21 it relates to Defendants' experts. That is what they did, and
22 you remember Judge Rodgers in the Abilify opinion said, that is
23 the sine qua non of general causation.

24 If we can go to the next slide. Thank you.

25 If the studies have limitations, the way science works

1 and what the law in this circuit says, it doesn't mean you make
2 the test easier. You don't move the goal posts a little
3 closer. You don't look to find other paths to get to
4 causation.

5 In science you might do more studies, you are always
6 looking for more information, that is a process that is
7 ongoing, but one of the core tenets is the null hypothesis.
8 Some people have told me not to talk about the null hypothesis
9 here today because it sounds too wonky, but it is a key premise
10 of all scientific inquiry.

11 You start with it and the null hypothesis basically
12 says you have an assumption that there is not an association,
13 and then you try and disprove that null hypothesis. In the
14 courtroom the way that gets translated is in the form of
15 Plaintiffs burden of proof that we discussed earlier.

16 If the epidemiology doesn't reject the null
17 hypothesis, which is what FDA and EMA and others have said when
18 they say there is no consistent signal, that is their
19 conclusion, then you don't fill the gap with extrapolation,
20 with deductive reasoning, with in some cases speculation.

21 Here Plaintiffs' characterization of the Ranitidine
22 epi aren't even quite right based on testimony from their own
23 experts. This is Dr. Moorman referring to the Adami study.
24 This study in particular, along with some others, has a longer
25 followup than the Wang study that we have heard about a bit

1 this morning.

2 Next slide, please.

3 Again, Adami. Adami had a median followup of 14
4 years. Norgaard the same, a median followup of 14 years.

5 Next slide, please.

6 Again, looking at the epidemiology about exposure to
7 the drug and looking for consistency and replication, that is
8 the first step. That is the threshold issue under Rule 702
9 when you are talking about toxic tort cases.

10 Again, that is how FDA did it, that is how EMA did it,
11 that's how Defendants' experts did it, and that is how the
12 broader scientific community has done it.

13 That is the question when it comes to this issue, was
14 it okay, under Rule 702, for Defense experts to use the
15 Ranitidine epidemiological data in the way they have? They did
16 it in the way that is broadly accepted in the scientific
17 community. They did it in the way they have done it outside of
18 the courtroom. It is reliable.

19 Now, Mr. Snidow, at one point he said something that I
20 thought was interesting. He said associations that you see in
21 poorly designed studies, that is especially strong evidence of
22 causation. I was just waiting for where it says that in the
23 reference manual. That is not in any case I know of, it's not
24 in the reference manual. The reference manual says the
25 opposite. That is not the law.

1 You look for replication and consistency. That is
2 what you do, you look for replication and consistency. That is
3 what the reference manual says.

4 He also talked about criticisms that they have about
5 our experts' use of Bradford Hill analysis, and they said it
6 was too shallow, they didn't go deep enough into Bradford Hill.
7 Some of the people here at the table will talk about the
8 specific application that certain of the experts applied in
9 doing their Bradford Hill analyses.

10 The point I am going to make now is simply that
11 Bradford Hill applies when you have an established consistent
12 association. That is what the law says, that is what the
13 reference manual says.

14 If you don't have a consistent, replicated, reliable,
15 unbiased association, you don't get to the Bradford Hill
16 criteria. The experts on the Defense side, they did it kind of
17 like belt and suspenders, go ahead and look at some of the
18 issues, but their conclusion was that you didn't actually get
19 past that threshold issue.

20 Let's go to the next slide, please.

21 This is the Florian article, FDA statement. I believe
22 Mr. Snidow called it a sound bite and he said it was out of
23 date.

24 The point is that what the FDA said in this
25 publication remains exactly true. That is the point. You can

1 look at the two studies that Mr. Snidow referenced, he said
2 this came out before Cardwell and it came out before the Wang
3 study.

4 Well, if you look at those two studies, they come out
5 totally different on bladder cancer. Cardwell had the bladder
6 cancer finding that the Plaintiffs like, and Wang shows 1.0
7 hazard ration on bladder cancer.

8 On Wang you have four out of the five cancers at issue
9 here, no association. The only one they have is liver. That
10 is the point. That is the point. You are looking for
11 consistency, you are looking for replication, and here we have
12 the opposite.

13 And when you don't have a consistent signal, you don't
14 just get a look for alternative routes to causation.

15 Next slide, please, Maryann.

16 We heard some discussion at length, actually, about a
17 threshold dose issue, which your Honor knows was a subject that
18 the parties discussed at great length a couple of weeks ago.
19 It wasn't clear how, if at all, Mr. Snidow meant to apply that
20 discussion. Slides 28 through 49, those are the ones I
21 objected to at the beginning.

22 It wasn't clear to me how he intended to apply that
23 discussion to the opinions of the Defendants' experts. It took
24 52 slides, I kept track, before Mr. Snidow said anything about
25 Defendants' experts.

1 In any event, he is wrong on the law.

2 Let's look at what the Courts have to say. He
3 mentioned McClain, he tried to make it sound like McClain said
4 something that it doesn't.

5 In McClain the issue was that the expert couldn't say
6 how much was too much, could not establish any minimum
7 threshold dose, and noted that issue is the single most
8 important factor to consider. Same issue in Abilify, a general
9 causation expert has to establish -- who is trying to establish
10 causation affirmatively should address what levels of exposure
11 the risk emerges as. Where is it that you have it pop up.

12 They have flipped this, and you heard a reference to
13 Judge Kugler, the Valsartan Judge, and you saw what I said
14 earlier. Remember this morning I said we don't have an
15 opinion, we just have a transcript. It is not in the Eleventh
16 circuit, but we know that judge actually made his ruling based
17 on two things: One, company documents; two, the withdrawal of
18 the product from the market.

19 I believe Mr. Snidow said for that judge that was the
20 end of the inquiry, he stopped there, that was enough. If you
21 look at the jurisprudence in the Eleventh Circuit, it
22 specifically says you can't do that. That is not enough to get
23 past Rule 702.

24 I haven't investigated what the is law in New Jersey,
25 but I know that is not the law here.

1 Next slide, please.

2 Here are some of the statements the Plaintiffs have
3 made in the briefing about this issue. It is important because
4 they say there is some threshold dose, there is some amount of
5 exposure, and we are not saying that every Plaintiff who has
6 had every amount would meet this threshold. There is some
7 threshold dose, we are just not quite going to tell you what it
8 is.

9 Then we had that slide that Mr. Snidow showed, I think
10 slide 33, where he put down -- he pointed down at the left-hand
11 corner and he said minimum dose, that means the lowest dose
12 that theoretically could cause cancer.

13 It is not about theoretical, you have to have
14 scientific evidence, that's what the law is. You have to have
15 scientific evidence that establishes that association at that
16 level of exposure, not theoretical speculation. That is a
17 misstatement of the law, completely wrong. We didn't see any
18 cases that said that. It is not the law.

19 I put up this quote from the transcript of the
20 September 21st hearing when your Honor was asking some
21 questions about this. We heard Plaintiffs' counsel respond to
22 those question by saying, well, there might be a conflict of
23 interest with a particular Plaintiff, and maybe they would have
24 to come in, and they might disagree with something that is
25 being said here about dosage, might be a little unfair to hold

1 that against them. You heard kind of a muddled version of that
2 again here today.

3 We have all these Plaintiffs, we will deal with all
4 this later, that is the idea. Let's just push that question
5 aside, we'll deal with it later. It all goes to specific
6 causation. That is not the law, you can't do that.

7 Next slide, please.

8 Now, Plaintiffs' counsel suggested that we used an
9 unflattering photo of Dr. McTiernan. If that is the case, we
10 apologize. I am personally sensitive to unflattering photos.

11 The point here is, Dr. McTiernan didn't have an
12 opinion as to threshold dose. If you apply that to the law we
13 just looked at, if you look at Abilify and look at McClain,
14 that means you don't have a causation opinion under Rule 702.

15 Next slide, please.

16 And we know that this also is not permissible under
17 Eleventh Circuit law. You can't just say any exposure at all,
18 a single pill, that is enough. Again, you can't do that. You
19 can't skip this inquiry at this stage.

20 Next slide, please.

21 All right. This is the last of the four issues that
22 Ms. Pyo and I will be addressing during this section. It is
23 the argument that the Defendants' experts don't consider the
24 NDMA studies that the Plaintiffs' experts have used to fill the
25 gap, that gap that you heard as it relates to the Ranitidine

1 epidemiology. They say we ignored them, and I think we heard
2 that again from Mr. Heinz, I think he said they ignored them.

3 We want to clarify, and you will hear more about this
4 when we get to the specific individual experts, it is just not
5 correct. The reality is they looked at those studies and they
6 concluded about those studies the same thing that everybody
7 else in the scientific community outside of this courtroom has
8 concluded about them, which is that you cannot use them to
9 establish risk when it comes to Ranitidine, and you cannot use
10 them to measure risk when it comes to Ranitidine.

11 It doesn't mean you have ignored them. You don't have
12 to put them in a closet and pretend like they don't exist.
13 They have a purpose, they generate hypotheses, you look at them
14 for various other ideas and reasons, but the point is, under
15 the law and actually as it works in the real world, you can't
16 use them for that purpose.

17 That is the point and that is the point we are making
18 and that is the point that Defense experts are making and that
19 is the issue.

20 Next slide, please.

21 The Plaintiffs engaged Dr. Hidajat. You have heard a
22 lot about the Hidajat study. They engaged her as an expert in
23 the case probably in hopes that they might be able to get her
24 to endorse the use of her study for the purposes that they were
25 trying to use it for, and she didn't quite go along with that.

1 When she was actually asked specifically about whether
2 you could use the study for this purpose, she said, no, it was
3 designed to look at occupational exposure and that means in a
4 working day, long exposure over a lifetime. It's a totally
5 different setting.

6 Next slide, please.

7 Dr. McTiernan, this is in the Talc litigation, she was
8 an expert in the Talc litigation. You will remember this from
9 a couple of weeks ago.

10 In that setting she said, you can't really use these
11 dietary studies to establish risk or to measure risk, they are
12 just not reliable for that purpose. It doesn't mean you
13 pretend like they don't exist or you have to put them away in a
14 closet, you just can't use them for this purpose. That is what
15 she said in the Talc litigation, and we are hearing something
16 different from Plaintiffs here in this case.

17 Next slide, please.

18 Now we get to these two cases that we have heard a lot
19 about, the Fixodent and the Benzene case. I want to talk
20 briefly about those.

21 The law here in the Eleventh Circuit, and in other
22 Courts, it lines up with how this works in the real world.

23 Courts have found that this kind of extrapolation from
24 adjacent or different bodies of data, it is interesting, you
25 can come up with ideas and theories about it, but it is

1 impermissible, it's impermissible under Rule 702, because it is
2 not sufficiently reliable to actually sustain the causation
3 burden that Plaintiffs have.

4 It goes to reliability, doesn't go to weight. This
5 wouldn't be a cross-examination point, it is an admissibility
6 issue. Mr. Heinz said -- you know, again, Mr. Heinz said
7 Defense experts are just completely ignoring it, and I want to
8 emphasize again, not saying that, you just can't use it to
9 establish and measure risk. There are too many analytical
10 gaps, too many leaps of logic, too much deductive reasoning and
11 not enough hard actual data. That is what the cases say about
12 this.

13 Go to the next slide.

14 One of the topics on the Court's list for today is the
15 role in determining admissibility rather than weighing
16 persuasiveness, and again, this is an issue that goes directly
17 to admissibility and reliability.

18 Defendants' experts' treatment of these studies was
19 not to ignore them, but it was to properly situate them in a
20 way that accords not only with the scientific practices, the
21 same things that the regulatory bodies and other scientists
22 have situated them in the context of Ranitidine, they have done
23 the same thing, but in the context of what we see in the law
24 that, under Rule 702, you can't do this type of leaping.

25 Your Honor, thank you for your time. I am not sure

1 how many minutes we have used up, but it might be helpful if
2 you could help us out on that.

3 *THE COURT:* 25.

4 *MR. BOEHM:* With that I thank your Honor and pass the
5 microphone to my colleague, Mr. Tobey.

6 *THE COURT:* All right. Thank you.

7 *MR. TOBEY:* Good morning, your Honor.

8 *THE COURT:* Good morning.

9 *MR. TOBEY:* My name is Stanley Tobey and I will be
10 defending Dr. Witte on behalf of all the brand Defendants
11 today.

12 As background, your Honor, Dr. Witte is a
13 world-renowned cancer epidemiologist. There is really not a
14 major challenge to his experience or credibility, but just for
15 background, for over a decade he was the head of the division
16 of cancer epidemiology at UCSF, and now he serves as the vice
17 chair of the Department of Epidemiology and Public Health at
18 Stanford University. He is actually a senior editor of one of
19 the leading epidemiology journals which published about twenty
20 of the papers that people have been presenting to you in this
21 case.

22 Next slide, please.

23 So, your Honor, there are four main critiques that
24 Plaintiffs have lodged against Dr. Witte, and we are going to
25 take on all of those, but what I would like to do is walk

1 through Dr. Witte's methodology and how he approached this
2 question, the same way scientists all over the world approached
3 this question. In doing so it will provide a window into how
4 credible scientists around the world decided what was a
5 reliable set of evidence and what was not.

6 Next slide, please.

7 To level set on the law, your Honor, as you know from
8 the Rider case, scientific evidence must fit the Plaintiffs'
9 theory of causation. That is going to be a theme I keep
10 returning to. There must be that fit. You have to look to the
11 reliable evidence that addresses specifically the proper
12 research question, otherwise your results are simply
13 unreliable.

14 Next slide, please.

15 What did Dr. Witte do first? He defined the relevant
16 research question. I know there is a lot on this slide, your
17 Honor, but what it shows is remarkable consistency.

18 Everybody, including Plaintiffs, began with the same
19 issue, the question of finding small amounts of NDMA in some
20 lots of Ranitidine. So, what did scientists do? They went to
21 work and they formed the research question, and the proper
22 research question was, does Ranitidine cause cancer? That is
23 exactly how your Honor framed it in PTO 77, the limited
24 question is whether Ranitidine can cause one of the five
25 designated cancers.

1 That is exactly how Dr. Witte framed it, too. It is
2 how EMA framed it, it how FDA framed it, it is how the vast
3 majority of researchers outside of this courtroom framed the
4 question. Plaintiffs stand alone. Only Plaintiffs have asked
5 this Court to focus on NDMA rather than Ranitidine when
6 Ranitidine is the exposure in question.

7 Next, Dr. Witte said what is the reliable body of
8 literature that addresses that properly framed research
9 question? This is an important methodological step, your
10 Honor. Even the best intentioned researchers can have a
11 tendency, when they don't find the answer they want in one body
12 of evidence, to continue looking to other bodies of evidence in
13 hopes of finding something that supports their hypothesis.

14 Dr. Witte points out in his report scientists approach
15 it differently. They set the relevant body of evidence, he
16 uses the phrase of priority, in advance, and that restrains
17 them from making analytic leaps, or resorting to unreliable
18 bodies of evidence. Again, you see, your Honor, Plaintiffs
19 stand alone, only they said let's broaden this universe beyond
20 the evidence that fits the question and port in these other
21 bodies of data.

22 Just one point, we mentioned Florian on this slide,
23 and you heard from Mr. Snidow that, in Plaintiffs' view,
24 Florian is old news. What is critical about Florian is the
25 methodology. How did FDA address this question? They looked

1 at Ranitidine epidemiology and they applied active comparators
2 to reduce confounding and bias. That is the methodology that
3 they found reliable and that remains true today.

4 Next slide, please.

5 Your Honor, Dr. Witte did not just look at Ranitidine
6 evidence and he certainly did not ignore the so-called NDMA
7 science, by which Plaintiffs just say means dietary and
8 occupational studies. He spent a great deal of his report
9 looking carefully and explaining why those studies don't fit
10 the question before the Court.

11 Now, to zoom out, Dr. Witte has published over 250
12 peer reviewed epidemiology studies, including nutritional and
13 dietary studies. He is certainly familiar with those
14 methodologies, and he appreciates that they have their place,
15 but he also explains very carefully why they don't have a place
16 here. They simply do not fit the question.

17 So, what does Dr. Witte say? Two broad points and
18 then we will drill down a little bit.

19 First, he points out that from a scientific
20 perspective, extrapolating from NDMA studies
21 requires speculation, whereas studying Ranitidine
22 specifically reflects the actual real world question here.

23 Dr. Witte said there is only one way to test what the
24 effects of NDMA in Ranitidine are at the doses people actually
25 took them and with whatever quantum of NDMA may or may not have

1 been in those particular pills, and that is to look at the
2 studies of Ranitidine human epidemiology.

3 Dr. Witte makes another really good point. He says
4 looking at NDMA alone does not account for the real-world net
5 effects of NDMA in Ranitidine. Everything happens within a
6 biological context. The way NDMA is consumed in radishes or
7 rubber fumes is not the same as when NDMA is consumed with
8 Ranitidine.

9 We have heard all kinds of things about Ranitidine
10 adjusting pH, and the effects of Ranitidine with or without
11 food. All of that has to be taken into account, and there is
12 only one body of evidence that does that. That is looking at
13 the real-world exposure, which is Ranitidine.

14 Next slide, please.

15 Dr. Witte drills down and talks a little bit about the
16 Hidajat study and why that study and others like it do not fit
17 the question before the Court, and what Dr. Witte says is,
18 first let's look at the internal limitations of that study, and
19 he points out several, but the big one here that is indicative
20 is Dr. Hidajat took a single year of data from a rubber factory
21 and she extrapolated it over decades to make assumptions about
22 the effects of that exposure.

23 Now, Dr. Witte points out that is a pretty shaky basis
24 within Hidajat for Dr. Hidajat's own conclusions. Then Dr.
25 Witte points out that is not what Plaintiffs are doing. They

1 are trying to take that shaky foundation and extrapolate it to
2 a wholly unrelated question. That is simply not a reliable
3 method. It is why nobody outside this courtroom has done it.

4 Now, Dr. Witte also talks about some of the specific
5 problems of Hidajat in terms of extrapolating. So, let's zoom
6 out. Why do Plaintiffs believe it is okay to look at NDMA and
7 other exposures? They have said this in their briefing. They
8 say NDMA is NDMA, it is the same molecule. They believe these
9 studies can isolate the effects of NDMA and then they can port
10 those effects into Ranitidine and say, see, there is no
11 difference. If it is like that here, it is like that there.

12 Dr. Witte points out even Dr. Hidajat doesn't believe
13 that basic assumption holds up. Dr. Hidajat talked about the
14 challenges and the impossibility of disentangling the effects
15 of NDMA from the dozens of other chemicals in rubber fumes,
16 including known human carcinogens. She said, I can't
17 disentangle which thing is causing which. That directly
18 undermines Plaintiffs' whole assumption that they can isolate
19 NDMA and then apply it through some conversions and assumptions
20 here.

21 Even Dr. Panigraphy, one of Plaintiffs' experts, has
22 said, and it is obviously true under Rule 702, if Dr. Hidajat's
23 measurements are unreliable here, then all the people who piled
24 on to Dr. Hidajat's work, Dr. Panigraphy, Dr. Salmon, all of
25 that is also unreliable.

1 Next slide, please.

2 Your Honor, this is a busy slide, and we are not going
3 to go through it all, but the busyness is by design. We
4 thought it would be helpful to show you just the number of
5 compounding assumptions that it takes to translate, in
6 Plaintiffs' view, from rubber factories or dietary studies to
7 the people here, people who actually took Ranitidine.

8 At the bottom of this tower you see the problems
9 internal to those bodies of evidence, like you heard Mr. Boehm
10 say, the World Cancer Research Foundation found limited
11 evidence in the dietary studies, but then Plaintiffs keep
12 piling assumptions. They don't have a direct dose in
13 Ranitidine because they are extrapolating, so they use Dr.
14 Najafi's estimations and they extrapolate from those, and it
15 keeps going.

16 In fact, on the rubber factory side they have to
17 travel through animal models. There is a mouse model in there,
18 your Honor, because they don't know how else to go from
19 inhaling NDMA to consuming it in a pill. That is simply not a
20 reliable basis.

21 Let me say one thing, your Honor, about the burden of
22 proof because they talked about the Fixodent case and the gas
23 cases, and you heard them say, well, you haven't proved that
24 our tower here is unreliable. That is simply not the law.
25 Plaintiffs, under Rule 702, bear the burden to show that their

1 extrapolations and analytic leaps are reliable, that they can
2 make these comparisons. They simply cannot do it.

3 Next slide, please.

4 Obviously Dr. Witte did not ignore NDMA science, he
5 explained why it didn't fit.

6 Then he turned to the reliable body of evidence, and
7 what he did was, he tested the Ranitidine data for valid
8 associations. Plaintiffs claim that apparently "none of these
9 associations are valid, but Witte does not explain why."

10 Well, Witte does explain why. He defines validity
11 very clearly, and consistent with the reference manual, a valid
12 association is one not due to chance, bias, or confounding.

13 So, how did Dr. Witte and other credible
14 epidemiologists rule out chance, confounding, and bias? Your
15 Honor, you have heard all of these generally accepted
16 techniques. I will run through them quickly.

17 He applied the standard control for bias and
18 confounding of active comparators. To hear Plaintiffs talk
19 about it, active comparators are something Defense experts
20 concocted up for this case. Ms. Pyo showed you the evidence,
21 FDA, EMA, all the reliable authorities say this is the best in
22 class for controlling bias.

23 But Dr. Witte didn't stop there, he evaluated dose
24 response and he said you have to find a consistent dose
25 response across the various studies. He also reduced the role

1 of chance by applying the statistical test of significance.
2 You set the threshold in advance and you don't depart from it
3 like Plaintiffs' experts did.

4 And finally, he also assessed bias and confounding by
5 looking at effect size. Dr. Moorman, one of Plaintiffs'
6 experts, agreed here. She said, results under 2.0 are suspect,
7 they are simply too small and you need to be very, very
8 suspicious of them because they can reflect noise, confounding,
9 and bias that is residual despite your best efforts to control.

10 I am not going to retread active comparators, I think
11 you probably have heard enough for a lifetime on active
12 comparators. But Dr. Witte makes a really interesting example
13 in his testimony about the importance of active comparators,
14 and he actually looks to the study that Plaintiffs like so
15 much, the Cardwell study, and what he says is that database had
16 some information on smoking, and so McDowell, the first person
17 to study it, tried to control for smoking, took that data and
18 controlled.

19 What Dr. Witte planned out is, you would suspect if
20 you had isolated and controlled all the smokers, you wouldn't
21 see any remaining effects for prescription nicotine because it
22 just kind of stands to reason, if you take out everyone who
23 ever smoked there is really not any reason for them to take
24 prescription nicotine except to quit smoking.

25 What Dr. Witte found when he looked, though, was even

1 after McDowell controlled for smoking, there was a 1.54
2 association in that database between prescription nicotine
3 users and cancer. That is an effect size bigger than the one
4 they claim for Ranitidine.

5 What does that tell you? Residual confounding, even
6 when you try to control for specific variables, exists. That
7 is why you want active comparators. Dr. Witte doesn't say
8 active comparators magically cure everything, you want to
9 control measured and unmeasured bias with all the techniques
10 available given a certain data set.

11 That is what he did when he looked at the data, and as
12 your Honor knows, when Cardwell added an active comparator to
13 that same study the bladder finding went away.

14 Next slide, please.

15 Another interesting point, your Honor, we haven't
16 really talked yet about why active comparators are critical to
17 the dose response analysis that you have seen. As you know,
18 dose response is another one of the factors that Plaintiffs are
19 trying to show.

20 What Dr. Witte explained was, you can have confounding
21 within a dose response if you don't apply active comparators.
22 The reason is, if you are just comparing to nonusers, people at
23 the low end of the dose curve are typically healthier, people
24 at the high end who need more medication tend to be sicker.

25 So, just comparing them within the curve could be

1 reflecting bias of different populations, but if you compare
2 all of those points to other people taking the same type of
3 medication, the same class, you get rid of that confounding to
4 some degree and leave only the effect of the drug in question.
5 That is a very important thing to keep in mind when we look at
6 some of these studies.

7 Next slide, please.

8 So, what did Dr. Witte find, your Honor? We use
9 bladder as an example here because, until this week, bladder
10 was the cancer that Plaintiffs were very excited about.

11 Dr. Witte looked at this evidence and he didn't cherry
12 picked, he had non-use comparisons, PPI comparisons, active
13 controls, H2RAs all in his chart. He put the best evidence at
14 the top, which is comparisons to other drugs in the same class,
15 then he put the intermediate comparisons in the middle, and
16 then he put the least controlled, most subject to bias
17 comparisons at the bottom, and he looked at what that showed.

18 He noted that when you applied active controls signals
19 in the non-user population disappeared. He looked and said all
20 of these risk ratios are well below 2.0, which Dr. Moorman
21 tells us makes them highly suspect for residual confounding.
22 He noted that there were no statistically significant findings,
23 not even a consistent pattern of statistical significance.

24 If we can go to the next slide.

25 He also looked at the dose response relationship, and

1 as you see here, two strong studies doing dose response, one
2 shows an upward trend, one shows a downward trend. That is not
3 the consistency in the data that would let Plaintiffs meet
4 their burden.

5 And merely as a side note, your Honor, I don't want to
6 get in the weeds, but Plaintiffs keep saying that Norgaard is
7 shorter than Cardwell and it's only ten months long. If you
8 look at Plaintiffs' own expert, Dr. Le, who assessed the
9 Pottegard study, those prescriptions were three-month
10 prescriptions in Norgaard, so it is actually 2.5 years versus
11 three years respectively looking at a similar exposure period.

12 Next slide.

13 Let's talk about Wang a little bit. Does Wang change
14 the picture?

15 One thing that the Wang authors and Dr. Witte clearly
16 agree on is following statement: "Conflicting results of
17 studies underlie a lack of concrete evidence supporting the
18 role of Ranitidine in cancer development."

19 That is on page two. That is what the Wang authors
20 said when they assessed the entire body of literature up to
21 their study. That is what Dr. Witte did and he came to the
22 exact same conclusion. So, does Wang move the needle? As you
23 have heard from Mr. Boehm, Wang only has one statistically
24 significant active comparator result and that is liver, which
25 is a cancer you heard barely anything about before today, but

1 now Plaintiffs are rallying around it.

2 When you look at the totality of the data and you
3 apply the FDA criteria of consistency and replication, you see
4 here, your Honor, there is simply no pattern that anyone could
5 hang their hat on. You have one significant result below 1.0,
6 you have one significant result above 1.0. You have two others
7 that are below the risk line, so decreased risk, but not
8 significant.

9 Over on the right you have a similar comparison of
10 dose responses, Wang found an upward trend. Adami, and they
11 like to pick on Adami, he was the chair of the Department of
12 Epidemiology at Harvard School of Public Health, he can do a
13 study. He saw a downward trend, and an important thing here,
14 your Honor, is Adami's was an H2RA active control.

15 The dose response that Plaintiffs want to rely on in
16 isolation is compared to non-users. It doesn't have that
17 control for bias, but even if you took Wang's numbers at face
18 value, and there are certainly methodological flaws that one
19 could spend a lot of time pointing out, at face value this is
20 not the picture of consistency that is any reliable basis to
21 draw an association, much less causation.

22 Next slide, please.

23 Dr. Witte, applying these generally accepted methods,
24 reached the same conclusion that everybody else has reached,
25 all the regulatory bodies, the vast majority of independent

1 experts, there is simply no valid association free of chance,
2 confounding, and bias in the data that exists.

3 Next slide, please.

4 Mr. Snidow put this slide up, let's talk about it.
5 Dr. Witte responded in advance to McTiernan's and Moorman's
6 criticism that the Ranitidine data is somehow too short to draw
7 conclusions from.

8 What Dr. Witte did was, he said, hey, Dr. Moorman, she
9 cites an IARC study. We know how Plaintiffs like to analogize
10 to diet. IARC did a dietary study of red meat and found an
11 association with colon cancer, and Moorman held that up and
12 said, see, this is a dietary study, it caused cancer, so
13 therefore NDMA in Ranitidine must cause cancer.

14 What we showed here, your Honor, is there is no
15 meaningful difference in the length of studies, in the IARC red
16 meat study that Plaintiffs liked and in the Ranitidine cohort
17 studies that should be the focus of this analysis.

18 Now, A couple of interesting points. Mr. Snidow
19 seemed to imply there was some duplicity in the calculations
20 here. This is how IARC calculated duration, this was their
21 study. We made the same calculation that IARC used and showed
22 apples to apples that their study that did find a valid
23 association, where one existed, was no longer than the studies
24 we have.

25 As Dr. Witte said, this length of study that we see is

1 par for the course in cancer epidemiology and it is certainly
2 sufficient to find real associations where they exist, which is
3 not the case here.

4 Next slide, please.

5 Dr. Witte didn't stop there in responding to this
6 strawman of studies are too short. He said, let's look at
7 Cardwell. Plaintiffs love Cardwell, Plaintiffs called Cardwell
8 a study of long term risk, 18 years total. They say finally a
9 study with the length they want.

10 Well, Witte says I agree, and look at the finding.
11 When you apply the best controls for bias and confounding,
12 active comparators, quote, this is Cardwell, "there was little
13 evidence of a difference in bladder cancer." The lone finding
14 that they want to hang their hat on simply goes away when you
15 apply the best controls in a study that they concede is of
16 sufficient length.

17 Next slide, please.

18 So Mr. Snidow said something interesting, and I think
19 maybe it was a Freudian slip, but it is really telling. He
20 said, IARC says it takes 30 years duration to disprove a cancer
21 risk.

22 That is not what this court of law is about. No one
23 is trying to disprove a cancer risk, and they do this
24 throughout, your Honor, and it is something to watch out for,
25 the flipping of the burden. They have the burden to establish

1 the totality of reliable evidence as it exists supports a valid
2 causative effect.

3 They can't even get to association, but they don't get
4 to flip the burden and say, well, you don't have 30 years to
5 disprove it. That is simply not the way science works and it
6 is certainly not the way Rule 702 works.

7 Now, this is a point that Mr. Boehm made and I won't
8 belabor it, but going back to that question of fit from Rider,
9 let's assume that Dr. Witte is wrong and there is some gaping
10 hole in the Ranitidine literature, it is not long enough or
11 whatever. That is not an invitation to fill that gap
12 with evidence not deemed reliable in the first place to answer
13 the question. That is exactly why we set the body of evidence
14 on priority so that you don't then resort to NDMA in radishes
15 or NDMA in rubber when the question is NDMA in Ranitidine. It
16 is simply too great an analytical gap.

17 Just a point on dose, your Honor. You heard this
18 theoretical debate, dose above the line, dose below the line,
19 what do people have to show. It is kind of missing the point.
20 There is no reliable evidence here of any dose being associated
21 with cancer in actual studies of humans who took Ranitidine in
22 the real world. They can argue all day about where they want
23 the dose to be. They don't have an association, there is no
24 dose at all right now to talk about.

25 Next slide, please.

1 Dr. Witte, consistent with Bradford Hill, consistent
2 with the reference manual, said there is not even an
3 association here, certainly not a perfectly clear-cut
4 association like Bradford Hill required to proceed to that next
5 analysis, so he says, I am not doing it, it stops here.

6 But as a rebuttal expert, he saw that Plaintiffs did
7 it, and so he pointed out some factors that negate their
8 Bradford Hill analysis. He wasn't doing his own primary
9 Bradford Hill, and so when they critique him for not talking
10 about everything that is missing the point.

11 He was showing how they can't win even on their own
12 terms, the science simply isn't there.

13 So, in sum -- next slide, please -- Dr. Witte is a
14 window into the generally accepted methods of the larger
15 scientific world. He picked the right question, he picked the
16 right body of evidence, and he applied the standard controls
17 for chance, confounding, and bias, and found that there was no
18 evidence of any relationship between real-world Ranitidine use
19 and any of the cancers alleged that survives true scientific
20 scrutiny.

21 That is the problem fundamentally that Plaintiffs have
22 here in all of these motions is, when they ask you to strike
23 the methodology of Dr. Witte they are asking you impliedly to
24 strike the methodology of FDA, EMA, Harvard, all of these
25 people that you have heard about. There is simply no one out

1 there doing what Plaintiffs want you to do, so that is why it
2 is their motions that must be stricken as unreliable and the
3 motion against Dr. Witte should be denied.

4 Thank you, your Honor.

5 *THE COURT:* Thank you. That is 51 minutes.

6 *MS. CANAAN:* Good afternoon, your Honor, Eva Canaan
7 for Defendants. Can you hear me well?

8 *THE COURT:* Yes.

9 *MS. CANAAN:* Your Honor, I am going to argue
10 Defendants' opposition to Plaintiffs' challenges to Drs. Chan,
11 Vaezi and Porter.

12 Next slide, please.

13 Dr. Chan, your Honor, he has impeccable credentials,
14 he is the director of cancer epidemiology at Massachusetts
15 General Hospital, he is the co-leader of the cancer
16 epidemiology program at Harvard. He is also a practicing
17 gastroenterologist and vice chair of clinical research in
18 gastroenterology at Massachusetts General Hospital.

19 He is one of the most cited researchers in the world.
20 He is the director of the National Cancer Institute's Board of
21 Scientific Advisers. I also want to point out that Dr. Chan
22 was an advisory group member at IARC. I only raise that
23 because Plaintiffs have claimed at the last hearing that none
24 of the Defendants' experts have served on an IARC panel. That
25 is obviously not true.

1 Now, Dr. Chan's expertise is really uniquely suited to
2 this litigation. As a gastroenterologist, he treats GERD and
3 other conditions for which acid suppressants are taken. He
4 routinely prescribes H2 blockers and PPIs, and there is really
5 no one more qualified than Dr. Chan to talk about these
6 medications, to talk about the populations that take them,
7 right.

8 For example, he sees literally on an everyday basis
9 how likely his patients with GERD are to be obese, to smoke, or
10 to use alcohol, and so Dr. Chan brings this unique clinical
11 expertise to the study of cancer epidemiology, with a
12 particular focus on the four GI cancers alleged in this
13 litigation.

14 In fact, your Honor, Plaintiffs themselves have
15 recognized Dr. Chan's unique fit, so to speak, for the issues
16 in this litigation and they have approached him as a potential
17 expert candidate.

18 Next slide, please.

19 Dr. Chan has reviewed the totality of epidemiological
20 evidence in this litigation and he has concluded that it does
21 not support a conclusion that Ranitidine has a true
22 association, let alone a causal relationship, with any type of
23 cancer.

24 Next slide, please.

25 Plaintiffs' challenge to Dr. Chan really boils down to

1 three claims. First, they contend that he ignored NDMA
2 epidemiology; second, they claim that he failed to account for
3 dose and duration of use in the Ranitidine studies; and third,
4 they claim that he failed to account for length of followup in
5 the Ranitidine studies.

6 Next slide, please.

7 So, let's start with Plaintiffs' first claim, that Dr.
8 Chan purportedly ignored NDMA epidemiology. Simply put, the
9 claim is false.

10 Next slide.

11 Although Dr. Chan appropriately focused on the
12 Ranitidine epidemiology in his causation analysis, he did not
13 ignore any NDMA studies. In his report Dr. Chan has a section
14 titled Epidemiology Studies of NDMA and Cancer Outcomes. That
15 section, your Honor, is literally 33 pages long, so it is
16 pretty hard to miss. Dr. Chan states unequivocally in his
17 report that he systematically reviewed the entire body of
18 epidemiological literature on NDMA and the cancer outcomes
19 alleged by the Plaintiffs.

20 Now, today we heard a somewhat different story from
21 what Plaintiffs put in their brief. Today we heard, oh, Dr.
22 Chan, he never looked at the NDMA studies until he saw them in
23 Plaintiffs' reports.

24 First of all, even if that were true, there is nothing
25 wrong with that. He is a rebuttal expert, that is what

1 rebuttal experts do.

2 Secondly, it happens to be not true because he was
3 asked this precise question at his deposition, and at page 38,
4 line 25 to page 39, line 9 he explained that he had reviewed
5 many of these NDMA studies even before he saw the Plaintiffs'
6 reports. He didn't think they were important enough to include
7 in his report, but when he saw Plaintiffs' reports he
8 systematically reviewed the entire body of literature and he
9 included 33 pages discussed in his report.

10 Next slide, please.

11 Now, in their brief Plaintiffs go even further and
12 they say because Chan ignored the NDMA epidemiology he offers
13 no opinion on the carcinogenicity of NDMA. Again, nothing
14 could be further from the truth. After his 33-page long review
15 of NDMA epidemiology, Dr. Chan concluded that the extant
16 epidemiological literature does not establish a true
17 association between either medication related, dietary, or
18 occupational NDMA exposure in any of the five cancers.

19 Moreover, your Honor, he reaffirmed this opinion time
20 after time after time at his deposition when he was asked
21 questions about these issues.

22 So, the bottom line here is Plaintiffs' claims that
23 Dr. Chan didn't review the NDMA epidemiology or didn't have
24 opinions about it, they are just flatly contradicted by Dr.
25 Chan's report and his sworn testimony, your Honor.

1 Next slide, please.

2 Now, Plaintiffs' second claim is that Dr. Chan
3 purportedly failed to account for dose and duration in the
4 Ranitidine studies.

5 Next slide, please.

6 Again, your Honor, the claim is plainly contradicted
7 by the language of Dr. Chan's report. In fact, literally for
8 every single type of cancer alleged in this litigation, Dr.
9 Chan specifically analyzed the Ranitidine study findings for
10 both high exposure and long-term use and concluded that they
11 simply do not support an increased risk.

12 Next slide, please.

13 Now, what is also critical about Dr. Chan's assessment
14 of dose and duration of Ranitidine use is his unique clinical
15 expertise. So one of the criticisms that we heard earlier
16 today from Plaintiffs is that for some of the studies, like the
17 Adami study, for example, we know that the patients redeemed
18 more than ten prescriptions, but we don't know exactly how many
19 months or years of Ranitidine use that is.

20 So, at his deposition, Dr. Chan explained that GERD
21 and peptic ulcer disease are chronic conditions, much like
22 diabetes, for example, and so especially for patients that have
23 redeemed more than ten prescriptions of an acid suppressant
24 medication like Ranitidine Dr. Chan said these are chronic
25 patients, they are taking it on a long-term basis.

1 Again, plaintiffs don't like this opinion, your Honor,
2 and that is not surprising. That is not surprising because
3 they don't have a gastroenterology expert. In fact, they don't
4 have a practicing clinician expert who can contradict Dr. Chan
5 on these points.

6 Next slide, please.

7 So, Plaintiffs' last claim is that Dr. Chan
8 purportedly failed to account for the length of followup in the
9 Ranitidine studies.

10 Next slide, please.

11 Again, however, the claim is flatly contradicted by
12 Dr. Chan's expert report. Dr. Chan explained that in study
13 after study after study longer follow-ups simply did not result
14 in higher risk estimates for cancer. As you can see on the
15 screen, your Honor, in many cases the opposite was true, longer
16 followup resulted in decreased risk estimates for cancer.

17 Next slide, please.

18 Moreover, and this is important, your Honor,
19 Plaintiffs' claims that the followup in the Ranitidine studies
20 was not long enough are also contradicted by Plaintiffs' own
21 cancer biologist, Dr. Panigraphy. Dr. Panigraphy testified at
22 his deposition that he would see a measurable effect of NDMA on
23 cancer outcomes from a year to a couple of years.

24 Your Honor, every single Ranitidine study followed
25 patients for much longer than that.

1 So, the bottom line is this: Plaintiffs' attacks on
2 Dr. Chan are objectively contradicted by his report and his
3 deposition testimony and your Honor should deny Plaintiffs'
4 motion as to Dr. Chan.

5 Next slide, please.

6 So now moving on to Dr. Porter. Dr. Porter is an
7 expert on bladder cancer. He is a practicing urologist as well
8 as an epidemiologies. He has served on the National Cancer
9 Institute's bladder cancer task force, he has coauthored
10 national comprehensive cancer network clinical practice
11 guidelines for bladder cancers. He really brings unique
12 expertise to the review of the data on bladder cancer in
13 this litigation.

14 Again, Plaintiffs do not have an expert with actual
15 clinical expertise on bladder cancer, nor do they have an
16 expert who has focused on the epidemiological study of bladder
17 cancer in the way that Dr. Porter has.

18 Next slide.

19 So Dr. Porter proffers an opinion that the existing
20 epidemiological evidence does not support a true increased risk
21 or causal association between Ranitidine exposure and bladder
22 cancer.

23 Next slide, please.

24 Now, Plaintiffs' challenge to Dr. Porter is based on
25 two claims. First, they claim that he improperly found no

1 association between Ranitidine and bladder cancer; and second,
2 they contend that he didn't perform a proper Bradford Hill
3 analysis. As I will show, your Honor, both claims are
4 meritless.

5 First, Plaintiffs claim that Dr. Porter improperly
6 found no association between Ranitidine and bladder cancer.
7 However, this claim is premised, first of all, on a
8 misrepresentation of Ranitidine data on bladder cancer; and
9 secondly, it is premised on a rejection of the principles of
10 statistical significance.

11 Next slide, please.

12 So, first of all, Plaintiffs included this forest plot
13 of Ranitidine and bladder cancer in their brief and today they
14 put it up on a slide with the title, How Is This Not
15 Consistency?

16 And they claimed in the brief and today that this
17 bladder cancer forest plot shows every result reported by
18 Defendants' bladder cancer expert report, every result exceeds
19 the 1.0 null hypothesis and therefore each result shows an
20 increased risk.

21 And yet, despite emphasizing that they purportedly
22 included every result, Plaintiffs have excluded numerous risk
23 estimates, specifically noted in Dr. Porter's expert report,
24 from this forest plot.

25 Next slide, please.

1 So, what you see here, your Honor, are all the risk
2 estimates from Dr. Porter's report, including the ones
3 Plaintiffs omitted.

4 As you can see, when all the risks are added to the
5 forest plot there are at least four risk estimates to the left
6 of 1.0, and importantly, those include the analyses from the
7 Norgaard study with the highest dose and the longest duration
8 of use -- the longest followup. I apologize.

9 Of course, the recently published Wang study that we
10 have heard so much about today, your Honor, also found
11 absolutely no association between Ranitidine and bladder
12 cancer. The risk estimates were 1.03 and 1.04. That is
13 absolutely no association, contrary to what you have heard
14 today.

15 Equally important, your Honor, the vast majority of
16 the risk estimates in this forest plot are not statistically
17 significant. As you can see, they overlap the line of unity,
18 they overlap 1.0.

19 Next slide, please.

20 While Plaintiffs reject the principles of statistical
21 significance and claim that every single study of Ranitidine
22 showed an association with bladder cancer, their own expert,
23 Dr. Le, disagrees with them. Dr. Le testified unequivocally at
24 her deposition that when a confidence interval includes 1.0,
25 that shows no statistical association. That is how she

1 interpreted risk estimates in her report.

2 So, Plaintiffs' views on statistical significance are
3 not shared even by their own expert, much less the rest of the
4 scientific community.

5 Next slide, please.

6 Now, Plaintiffs also accuse Dr. Porter today of not
7 being consistent in the way in which he assessed confounding by
8 smoking in the Ranitidine study, but Dr. Porter's methodology
9 was entirely consistent.

10 First of all, Dr. Porter explained that smoking is by
11 far the strongest risk factor for bladder cancer. In fact, he
12 notes in his report that 50 percent of bladder cancers in the
13 United States are directly attributable to smoking.

14 And third, and this is a really critical point, your
15 Honor, Dr. Porter explains that it is extremely difficult to
16 control for smoking through statistical adjustment in
17 epidemiological studies, and that is because people do not
18 accurately report if they smoke, how much they smoke, and how
19 often they smoke. When you have a disease like bladder cancer
20 that is so heavily determined by smoking, even a small amount
21 of residual confounding by smoking can result in false or
22 spurious increased risks.

23 Next slide, please.

24 This is an example that Dr. Porter provides in his
25 expert report and one that your Honor can readily find simply

1 if you Google, your Honor, bladder cancer and coffee.

2 What you will find is that epidemiological studies
3 have consistently reported a statistically significant
4 increased risk for coffee in bladder cancer, and not just a
5 statistically significant increased risk, but consistent
6 evidence of dose response.

7 For example, in this meta analysis that Dr. Porter
8 cites in his report, this is a meta analysis combining 17
9 studies, they all control for smoking, and you see a
10 statistically significant dose response for every additional
11 daily cup of coffee.

12 So, what does that mean for coffee drinkers like
13 myself? Well, your Honor, the generally accepted explanation
14 among epidemiologists, as well as IARC, is that all of the
15 studies of coffee and bladder cancer are confounded by smoking.
16 Coffee drinkers tend to smoke more and so smoking confounds the
17 association between smoking and bladder cancer even though all
18 these studies attempt to adjust for smoking in their
19 statistical analyses.

20 Because smoking is such a strong confounder it really
21 acts like a surrogate for exposure and creates this false
22 appearance of a dose response.

23 Again, even though all these studies attempt to
24 control for smoking there is still residual confounding that
25 leads to false evidence of increased risk and false evidence of

1 dose response.

2 Earlier we heard today Plaintiffs saying that the
3 Cardwell study purportedly controlled for smoking, but what the
4 Cardwell authors actually said, and this is on page seven of
5 their study, they say smoking and alcohol were incomplete and
6 did not capture detailed information on the extent of exposure,
7 and consequently there remains the possibility of residual
8 confounding.

9 That is exactly why it is so difficult to control for
10 smoking in statistical analyses, your Honor.

11 Next slide, please.

12 So, because smoking information is so difficult to
13 accurately ascertain and then so difficult to control for
14 statistical analyses, Dr. Porter concluded that an active
15 controlled analysis is the best way to control for smoking.

16 Dr. Porter also notes in his report that because of
17 their side effect profile, PPIs are less likely to be
18 prescribed to smokers than H2 blockers, and for that reason he
19 concluded that other H2 blockers are an ideal comparator group
20 for Ranitidine. Of course, as you can see on the left side,
21 the Ranitidine study authors reached the exact same conclusion.

22 Next slide, please.

23 Now, once we focus on the studies that compare
24 Ranitidine to other H2 blockers, we see absolutely no
25 statistically significant increased risks in any primary

1 analysis for bladder cancer, nor do we see any evidence of dose
2 response, because the only evidence of dose response, as was
3 mentioned earlier, was from the Cardwell study that came from a
4 non-user analysis, not from an active controlled analysis.

5 So Dr. Porter's conclusion that there was no reliable
6 association between Ranitidine and bladder cancer, it flowed
7 naturally from his stated methodology in his expert report.

8 Next slide, please.

9 Again, your Honor, Dr. Porter's conclusion is entirely
10 in line with the conclusions of the Ranitidine study authors.
11 Plaintiffs' claims to the contrary are really belied by the
12 plain language of these studies.

13 Next slide.

14 Now, Dr. Porter also looked at the dietary and rubber
15 worker studies, and he concluded that they simply do not
16 support an increased risk. Jakszyn, 2011, a cohort study of
17 dietary exposure and bladder cancer, found no increased risk of
18 bladder cancer with dietary NDMA. As you may recall from the
19 last hearing, dietary cohort studies are the only types of
20 studies that WCRF, World Cancer Research Fund, even considers
21 in their assessment of diet and cancer risk. They don't
22 consider case control studies because of the issues with
23 selection and recall bias with those studies.

24 On the other hand, we have a study like Ronco, 2014,
25 which is a case controlled study, the type of study that WCRF

1 would not consider, and they did report an increased risk with
2 NDMA, but they also reported an increased risk for cheese,
3 whole milk, and total eggs. In fact, if you look at the odds
4 ratio for eggs, your Honor, 4.05, that is over a 300 percent
5 increased risk. It is twice as high as what they reported for
6 dietary NDMA.

7 Finally, as you heard earlier so I won't belabor it,
8 the Hidajat study of the rubber workers, it is simply not
9 relevant, and Dr. Porter concludes this in his report, because
10 these rubber workers are exposed to a variety of different
11 chemicals, including Class I carcinogens, and the authors in
12 the peer reviewed study explicitly acknowledge that it is very
13 hard to disentangle what exposures in this industry cause which
14 types of cancers.

15 Next slide, please.

16 Plaintiffs' second challenge to Dr. Porter is that he
17 purportedly did not perform an accurate Bradford Hill analysis.

18 Of course, as you have heard before from Mr. Boehm,
19 Dr. Porter did not even need to conduct a Bradford Hill
20 analysis because he reliably concluded that there is no true
21 association that is not due to chance, bias, or confounding for
22 Ranitidine and bladder cancer.

23 So, for all of the other points raised in Plaintiffs'
24 briefs, we will rest on the papers and we ask that your Honor
25 deny Plaintiffs' motion to Dr. Porter.

1 Next slide, please.

2 Lastly, I am going to address Plaintiffs' challenge to
3 Dr. Vaezi. Like Dr. Chan, Dr. Vaezi is a gastroenterologist,
4 as well as an epidemiologist. He is the associate chief and
5 clinical director of the division of gastroenterology at
6 Vanderbilt University. He is the coauthor of the American
7 Gastroenterology Association's guidelines on GERD, which
8 specifically address the management of GERD with acid
9 suppressant medications like Ranitidine.

10 Next slide, please.

11 Dr. Vaezi proffers the opinion that the
12 epidemiological evidence does not support a reliable
13 association or causal relationship between Ranitidine and any
14 cancer type.

15 Next slide, please.

16 Plaintiffs' challenge to Dr. Vaezi again boils down to
17 three claims. First, they say he ignored NDMA epidemiology;
18 second, they contend that he misrepresented opinions of
19 scientific organizations on NDMA; and third, they claim that he
20 failed to account for and misinterpreted dose and duration of
21 Ranitidine use.

22 Next slide, please.

23 Focusing on the first claim, that Dr. Vaezi
24 purportedly ignored NDMA epidemiology, I think we can dispense
25 with this one quickly.

1 Next slide, please.

2 Dr. Vaezi's report states very clearly that he
3 reviewed all studies that reported on quantifiable NDMA
4 exposures and risks of the five alleged cancers. Then he goes
5 on to explain that these studies that he reviewed included NDMA
6 contaminated non-Ranitidine medication studies, they included
7 dietary NDMA studies, and they included occupational NDMA
8 studies.

9 Next slide, please.

10 Again Plaintiffs misrepresent Dr. Vaezi's sworn
11 testimony when they claim that Vaezi testified under oath that
12 he never once reviewed a single NDMA epidemiology study.

13 Again, your Honor, even a cursory glance at Dr.
14 Vaezi's deposition testimony you can see that is simply not
15 true. He made clear that he reviewed the dietary studies, he
16 reviewed the rubber manufacturing studies, again underscoring
17 what he already stated very plainly in his expert report.

18 Next slide, please.

19 Plaintiffs' second claim that Dr. Vaezi misrepresented
20 opinions of scientific organizations on NDMA, your Honor, this
21 claim is equally meritless. To the contrary, Dr. Vaezi made it
22 perfectly clear that NDMA is not a known human carcinogen.
23 That is unassailably true, your Honor, and exactly what IARC,
24 EPA, and ETA stated their guidelines.

25 Next slide, please.

1 Now, Plaintiffs twist Dr. Vaezi's words. This is what
2 we heard earlier today, that they claim that he testified that
3 IARC and other organizations had concluded definitively that
4 NDMA does not cause cancer in humans.

5 That is a complete misrepresentation of Dr. Vaezi's
6 opinion. What Dr. Vaezi actually testified to and what you see
7 on the left side, your Honor, is that these organizations have
8 not determined that NDMA is definitively a cause of cancer in
9 humans. Again, that is unassailably true.

10 Next slide, please.

11 And Plaintiffs' last argument is that Dr. Vaezi failed
12 to account for and misrepresented dose and duration of
13 Ranitidine use in Ranitidine studies.

14 Next slide, please.

15 The claim is squarely contradicted by Dr. Vaezi's
16 expert report. As you can see, your Honor, Dr. Vaezi routinely
17 assessed dose and duration in the Ranitidine studies and he
18 concluded as part of his Bradford Hill analysis that not only
19 he is there no evidence of a reliable gradient, meaning no
20 evidence of dose response, but many studies showed the risk
21 estimates decrease with higher doses or longer durations of
22 use.

23 Next slide, please.

24 Finally, Plaintiffs' claim that Dr. Vaezi somehow
25 confused followup with the exposure period because he testified

1 that, for example, for the patients in the Adami study who
2 filled at least ten prescriptions and were followed for more
3 than ten years, that these were long-term users of Ranitidine.

4 In fact, Dr. Vaezi testified, based on his clinical
5 experience as a gastroenterologist, that these are chronic
6 patients who are taking the medication to treat their chronic
7 disease. He said when patients fill ten prescriptions of
8 Ranitidine, there is no reason to expect that they are not
9 going to fill the 11th prescription.

10 There is every reason to expect that they would
11 continue to use their medication to treat their chronic
12 disease. Frankly, your Honor, if the Plaintiffs had a
13 practicing clinician expert who prescribes these drugs, I
14 suspect he or she would tell them the exact same thing.

15 The Adami authors in fact reached the same conclusion.
16 In their published peer reviewed paper they state that the
17 analysis of ten plus prescriptions were meant to capture
18 long-term users of Ranitidine.

19 So, for all of these reasons, your Honor, Plaintiffs'
20 challenge to Dr. Vaezi has no merit and should also be denied.

21 Thank you, your Honor.

22 *THE COURT:* Thank you. That's an hour and 18 minutes.

23 *MR. SHEEHAN:* Tom Sheehan, your Honor, on behalf of
24 the Defense. I am going to try and be quick here. I won't be
25 too quick on your fingers, Pauline, but I will try and move

1 along here.

2 I am going to be defending the motions against Dr.
3 Terry and Dr. Wang.

4 This is the Wang study, so very careful and important
5 point of clarification here, Tim Wang, Defense expert, is not
6 the author of the Wang study you have heard so much about, and
7 these are not the slides I need, actually.

8 So, if we could find -- I want to start with Mary Beth
9 Terry. I don't know who has that, somebody behind the curtain
10 here.

11 *THE COURT:* I will stop the clock. Are we going a
12 little out of order?

13 *MS. POWER:* Yes, your Honor, Caroline Power for the
14 Defense, and I will be speaking to Dr. Hatten.

15 If we could have the slides up for Dr. Hatten, please.
16 If I could have the first slide.

17 Your Honor, Dr. Benjamin Hatten is a medical
18 toxicologist and emergency physician with training in
19 epidemiology and biostatistics. He offers the core opinion
20 that there is no reliable basis supporting that either
21 Ranitidine or NDMA exposure from Ranitidine causes any of the
22 five designated cancers.

23 Next slide, please.

24 He incorporates a number of scientific principles in
25 his methodology, and I won't rehash them all, but I do want to

1 revisit the null hypothesis that you have heard about today.
2 We talked about the burden of proof. It remains Plaintiffs'
3 burden of proof to show causation in this case, and the
4 scientific community has a parallel framework.

5 Scientists in the real world begin with the assumption
6 that there is no association, there is no causation, and it is
7 on the burden of the evidence -- it's the evidence burden to
8 show that there is consistent, replicated, and convincing
9 scientific proof that there is, in fact, an association.

10 When experts like Dr. Hatten and others opine that the
11 evidence is insufficient, they are not taking on the burden of
12 proving no causation, they are simply stating that the null
13 hypothesis persists and this is an appropriate approach under
14 accepted scientific principles.

15 Next slide, please.

16 In their papers Plaintiffs levy four main criticisms
17 against Dr. Hatten, and like in many instances in this case,
18 they conflate the Ranitidine aimed criticisms and the NDMA
19 criticisms all together.

20 So, starting with the first one -- next slide, please
21 -- Plaintiffs argue that Dr. Hatten did not assess the
22 Ranitidine studies with his evaluation of the -- excuse me --
23 NDMA studies, but that is besides the point, your Honor. Dr.
24 Hatten focused on what he found to be the most reliable
25 studies, the Ranitidine studies.

1 I would like to pause here for a moment and address
2 some of the things that Plaintiffs' counsel said earlier today.

3 First, we heard so much about dose, and dose is
4 precisely why Dr. Hatten found the Ranitidine studies to be the
5 most reliable because, as he states here, Ranitidine use
6 inherently accounts for the level of NDMA exposure related to
7 Ranitidine use.

8 Mr. Snidow mentioned that NDMA levels could vary
9 drastically based on things like storage conditions or an
10 individual Plaintiff, but that is captured in these studies.

11 Second, Mr. Snidow mentioned that Dr. Hatten ignored
12 dose duration and followup, and your Honor, that is just not
13 true. On pages 63 to 65 of his report he looks specifically at
14 studies that have the longest use, the longest followup, and on
15 page 65, he concluded there were no associations seen between
16 long-term use of Ranitidine and any of the five designated
17 cancers even when limiting the literature to cohort studies
18 with at least ten years of followup.

19 Finally, Plaintiffs have asserted today and at the
20 last hearing that all NDMA is the same, but, your Honor, that
21 also is not true. As Dr. Hatten explains with regard to the
22 dietary NDMA studies, those are indirect evidence because
23 dietary studies necessarily involve a number of different
24 nitrites, not to mention all the other components of food.

25 With regard to occupational data, at page 54 of his

1 report Dr. Hatten explains that inhalation exposures do
2 not involve first pass metabolism in the liver, unlike oral
3 exposures. In addition, "reliable quantitative information on
4 the absorption of NDMA following inhalation," is not available.
5 There Dr. Hatten is quoting the Liteplo 2002 WHO study that has
6 been submitted to the Court, your Honor.

7 So, getting back to some of the criticisms Plaintiffs
8 levy in their briefs, while Dr. Hatten did base his core
9 opinions on Ranitidine studies, he did consider that NDMA data.

10 Next slide, please.

11 What did he conclude? The evidence is indirect, the
12 associations are weak and unreliable, and there are sporadic
13 and inconsistent associations based on assumptions.

14 Next slide, please.

15 Plaintiffs argue that Dr. Hatten failed to conduct a
16 formal Bradford Hill analysis, and I think Mr. Snidow said
17 there is no such thing as an informal Bradford Hill analysis.
18 As you have heard throughout the day, your Honor, there is no
19 such thing as a Bradford Hill analysis in the absence of an
20 association, and here Dr. Hatten concluded there was no
21 reliable association.

22 Next slide, please.

23 To the extent Plaintiffs point to Bradford Hill
24 factors in levying their criticisms, Dr. Hatten considered
25 those factors when assessing if an association exists. For

1 instance, we just talked about his review of the longest
2 studies with the longest followup. That dose response Bradford
3 Hill factor is inherent in that analysis.

4 Next slide, please.

5 Finally, as a belt and suspenders approach, your
6 Honor, Dr. Hatten did walk through the Bradford Hill factors
7 and how they apply to the Ranitidine studies as a whole.

8 Next slide.

9 Now, switching gears to the NDMA focused criticisms,
10 the Plaintiffs argue in their papers that Dr. Hatten
11 misrepresents how the scientific organizations classify NDMA.
12 To be clear, Dr. Hatten opined that NDMA is not a human
13 carcinogen, which is to say an established human carcinogen.
14 This is consistent with scientific organizations that consider
15 it a probable human carcinogen, potential, or of unknown
16 relevance.

17 Your Honor, this is more than just semantics, these
18 specific labels are the kind of precise language that
19 scientists use and rely upon to accurately reflect the data and
20 the significance of that data.

21 Next slide.

22 And again, your Honor, the Plaintiffs argue Dr. Hatten
23 should have conducted a Bradford Hill analysis on the NDMA
24 data, but there is no Bradford Hill analysis in the absence of
25 an association.

1 Next slide.

2 To bring it all together, your Honor, Dr. Hatten's
3 considerations of all these different kinds of evidence, which
4 he carefully weighed, he explained his conclusions on each, all
5 of this gets to the core question of why we are here today. He
6 looked at them within the context of how they inform the
7 potential NDMA exposures related to Ranitidine use.

8 For those reasons, your Honor, and all the reasons
9 explained in our papers, the motions against Dr. Hatten should
10 be denied.

11 *THE COURT:* Okay, thank you very much. We are at 126.

12 *MR. SHEEHAN:* All right. We should be good to go. I
13 will try to be brief in the interest of time. Tom Sheehan on
14 behalf of the Defense.

15 If we could bring up the slides for Dr. Terry. I was
16 told we were good to go, and yet here we are. Okay. I think I
17 will get into it, your Honor -- oh, my gosh, there is a ghost
18 in the machine when I get up here I guess.

19 I am speaking on behalf -- I am going to defend the
20 motion against Dr. Terry.

21 Go to the next slide, please.

22 Dr. Terry, I will not belabor her qualifications, she
23 heads up the Comprehensive Cancer Institute at Columbia
24 University, she's on the board of scientific advisers for the
25 National Cancer Institute. Obviously her qualifications to

1 opine are not challenged here.

2 She offers the opinion that, after reviewing the
3 epidemiologic evidence, there is not support for a valid
4 association or causal relationship between use of Ranitidine
5 and development of any of the five designated cancers, much
6 like other experts you have already heard about.

7 Next slide, please.

8 What are the challenges then? You have heard many of
9 the same criticisms, Plaintiffs allege that Dr. Terry ignored
10 NDMA studies, that she ignored limitations in the Ranitidine
11 epidemiology studies relating to dose, relating to length of
12 followup, duration, that type of thing. And finally, there is
13 sort of an individual attack on Dr. Terry related to a supposed
14 inconsistent approach to case control studies.

15 Go to the next slide, please.

16 So, with respect to ignoring NDMA data, you know, it
17 doesn't take much to look at a report and see she that
18 evaluated the NDMA data. She spends about 25 pages going
19 through it, and when you get right down to it, the Plaintiffs
20 don't like her interpretation of that data. Much like the
21 scientific community at large, much like regulators, she
22 basically offers the opinion that those data, two-fold.

23 They do not provide reliable evidence to establish
24 that exposure to NDMA in either the diet or occupational
25 setting is a cause of human cancer, but more importantly, you

1 can't take those studies and extrapolate from them to draw
2 reliable conclusions about cancer risk with Ranitidine use.

3 Next slide.

4 This is very, very similar to what the EMA determined
5 when they looked at this data. The Plaintiffs cite to the EMA
6 document in their challenge to Defense experts, but what they
7 don't provide the Court is the interpretation that EMA had of
8 the exact same body of data.

9 The EMA looked at exposure to NDMA in the diet, they
10 looked at exposure to NDMA in occupational settings like
11 Hidajat. In fact, they looked at 33 separate studies
12 evaluating exposure to NDMA separate and apart from anything to
13 do with Ranitidine.

14 What did they find? They said definite conclusions
15 cannot be drawn at this stage. Effect sizes and especially
16 dose response relations should be interpreted with great
17 caution, and they called for further research. That is just
18 with respect to NDMA itself, again, nothing to do with
19 Ranitidine.

20 What does EMA then say about how to assess cancer
21 risk with Ranitidine?

22 If we could go to the next slide.

23 They then go on to say there is a way, a method to
24 reliably assess cancer risk with Ranitidine, and here is what
25 you should do. You should focus on Ranitidine specific

1 epidemiology. You should employ methodologic principles that
2 we have listed here. You should compare Ranitidine to an
3 active control, like an H2RA or a PPI. You have heard it ad
4 nauseam at this point, that is the best way to control for
5 confounding that relates to the underlying conditions for which
6 these medications are prescribed.

7 You should employ a lag time. You should evaluate
8 reverse causation and protopathic bias and confounding within
9 these studies.

10 The reason I bring this up, your Honor, is because
11 this is the methodology that EMA set out to investigate,
12 whether or not there is an increased risk of cancer with
13 Ranitidine use. It is exactly the methodology that Dr. Terry
14 employed when investigating that same question, much like other
15 Defense experts.

16 Go to the next slide.

17 So, what is the next claim? That she ignored
18 limitations in the Ranitidine studies.

19 Go to the next slide.

20 I think even a cursory glance at a report, you know,
21 sort of belies this allegation of ignoring certain features.
22 So, Dr. Terry provided at the end of her report a table that
23 listed various methodologic considerations and study design
24 features for all of the Ranitidine studies that she evaluated,
25 and you can see across the top here she looked at how those

1 studies assessed exposure.

2 She looked at how long those studies followed patients
3 who had been prescribed Ranitidine. She looked at whether
4 there were any analyses done to assess intensity of exposure or
5 duration of exposure, and she listed and evaluated all of the
6 confounders for every Ranitidine epidemiology studies.

7 We have a couple of questions here. These are
8 basically the allegations that were put forth by Plaintiffs,
9 that Dr. Terry had assumed higher exposures or longer followup
10 periods, or cherry picked certain confounders to analyze. What
11 is the answer to that question?

12 If we could go to the next slide.

13 I am hoping it is -- it is a no, she did not cherry
14 pick anything to analyze.

15 If we could go to the next slide.

16 So, how did she apply this? It is true, your Honor,
17 that there are studies that assessed exposure differently. It
18 is true that there are studies that within their database
19 followed patients for shorter or longer periods of time, and
20 that actually provided reassurance to Dr. Terry that there was
21 no signal of increased risk associated with exposure to
22 Ranitidine.

23 She actually looked at that and said, hey, this
24 study -- for example, I think we heard about Iwagami earlier
25 today -- had a shorter median followup. There are studies like

1 Adami or Norgaard that have longer periods of followup, 15
2 years. If you extend it out to the absolute maximum, over 20
3 years in some cases.

4 Nowhere across those different methodologic features,
5 different ways of assessing exposure, different ways of
6 assessing duration of use, was there any consistent signal of
7 even an association between use of Ranitidine and any of the
8 five designated cancers.

9 Go to the next slide.

10 So, what is the last claim? I won't spend a lot of
11 time on this. They say she approached case controls
12 differently with respect to Ranitidine litigation than she did
13 in an interview or a lecture that she gave.

14 Go to the next slide.

15 And she explained very clearly at her deposition that
16 case control studies have their place, and they can be very
17 useful under certain circumstances if you can reliably execute
18 them.

19 So she gave the example, if you are asking a woman who
20 gave birth whether she breastfed her child, that is a very
21 different construct methodologically than asking that same
22 woman how much broccoli did you eat six months ago, a year ago,
23 five years ago. It is very exposure dependent. It is also
24 very dependent on the magnitude of the association.

25 Where you have small risks, like we do here, 1.2, 1.4,

1 1.6, that type of thing, those are exactly the types of risk
2 estimates that are subject to the biases that are inherent to
3 the case control design, and that's exactly why the World
4 Cancer Research Fund elevates cohort study designs over case
5 control study designs in evaluating dietary factors and cancer
6 risk.

7 *THE COURT:* So that is 1:35. I misspoke when I said
8 1:45. You allotted yourselves an hour and 35. So it is 1:35
9 now. If I have confused anyone -- are you the last speaker for
10 the Defense or are there others?

11 *MR. SHEEHAN:* I have one more expert to do. I can do
12 it in a matter of just a couple minutes honestly.

13 *MR. BOEHM:* Your honor, I believe each side had a
14 total of one hour and 40 minutes, unless that was changed.

15 *THE COURT:* That is fine. The agenda I have says
16 10:40 to 12:15, but you think it is 1:40?

17 *MR. BOEHM:* That is my understanding.

18 *MS. FINKEN:* Your Honor, in the revised schedule you
19 changed it and took five minutes off each side on this motion.

20 *THE COURT:* Okay. I know there has been some back and
21 forth. Why don't you try to get through your presentation and
22 whatever additional time you get in, the Plaintiff will be
23 given as well.

24 *MR. SHEEHAN:* Okay. For all the reasons I have
25 explained, the motion as to Dr. Terry should be denied.

1 If we could pull up the next section here, Dr. Wang.
2 As I said before, he is not the author of the Wang study.

3 *THE COURT:* State clearly on the record which doctor
4 this is so there is no confusion.

5 *MR. SHEEHAN:* I am defending the motion against Dr.
6 Timothy Wang, Defense expert.

7 Dr. Wang is very well qualified, and he combines two
8 areas of expertise, really he is a clinician, treats patients
9 with gastrointestinal diseases, and he is a cancer researcher
10 that looks at the biological mechanisms specific to
11 gastrointestinal cancers.

12 Go to the next slide.

13 He offers the opinion, much like other Defense
14 experts, that there is not evidence supporting that therapeutic
15 use of Ranitidine causes any of the GI cancers being alleged.

16 Next slide.

17 This is just for your information, your Honor, there
18 is a lot of opinions that he offers that are simply not
19 challenged. For example, he looked at all of the Ranitidine
20 lifetime animal carcinogenicity studies, and he did that
21 because that is the exposure of interest here. Animals given
22 high doses of Ranitidine over their lifetimes did not develop
23 cancer.

24 He looked at whether there was evidence that
25 Ranitidine caused a mutagenic effect in like test tube in vitro

1 type studies. It didn't, and offered those opinions. Those
2 are unchallenged. In fact, all of the opinions here are
3 unchallenged.

4 If we could go to the next slide.

5 So they claim certain challenges to Dr. Wang's
6 opinion. I don't think you heard a lot about them today during
7 the argument. For example, they didn't articulate the
8 challenge with respect to a threshold level of NDMA in animals.
9 I will quickly go over it.

10 Dr. Wang -- keep going.

11 Dr. Wang evaluated that issue looking at the animal
12 data to see where there is actual evidence of a statistically
13 significant difference in tumor formation in animals versus
14 those animals that did not get NDMA. Lo and behold, you needed
15 to get to 65,000 nanograms per kilogram per day before you
16 would observe a statistically significant difference in the
17 rate of tumor formation.

18 In these studies, such as the Peto study, they
19 examined much lower doses, but they did not observe a
20 statistically significant difference at those lower doses.
21 Obviously that is the basis for his opinion with respect to the
22 level of NDMA required to induce tumor formation in animals.

23 Next slide.

24 They say that his opinions about the monkey studies,
25 the primates, are wrong.

1 Go to the next slide.

2 Plaintiffs are just wrong about this. The study
3 authors themselves clearly state all of the compounds except
4 DMNA -- that is just another acronym for NDMA -- were
5 hepatocarcinogens, caused cancer in the liver of the monkeys.
6 They specifically call out NDMA and say that didn't happen.

7 So the Plaintiffs next approach is to say, well, in
8 2002 the WHO said all animal species. You can take a look at
9 that document for yourself, your Honor. The WHO document from
10 2002 actually articulates the species where cancer was
11 observed. It does not include any primate species, and it's
12 not just mice, rats, and hamsters, but I will freely admit
13 there are other animals, there's frogs, there's newts, there's
14 amphibians.

15 They simply don't address the primate data in any way,
16 shape, or form. There is not a single reference or citation to
17 any of the primate data, so that is a bit of a red herring
18 there.

19 Go to the next slide.

20 They say his levels about endogenous NDMA, this is
21 again separate and apart from anything to do with Ranitidine,
22 just background levels. You and I sitting here are probably
23 generating some level of NDMA just as natural human physiology.
24 Dr. Wang offered opinions about those levels based on the data.

25 If we could go to the next slide.

1 He freely admits that they are variable, that they are
2 estimated, but the important point, your Honor, is that the
3 primary route of exposure -- we can see down at the bottom of
4 this slide, the Plaintiffs cite to this document, the ATSDR
5 report, the draft document from 2022. The primary route of
6 exposure to NDMA is through endogenous production, again,
7 nothing to do with Ranitidine at all.

8 Where there is no evidence that ingestion of
9 Ranitidine contributes to endogenous formation of NDMA, setting
10 that aside, the primary route through which human beings are
11 exposed to NDMA is just natural human physiology.

12 If you could go to the next slide.

13 Finally, they say his Bradford Hill analysis is
14 not reliable. I won't belabor this point.

15 Next slide.

16 You have heard from numerous people today you don't
17 even get to Bradford Hill if you don't have a reliable valid
18 association. Plaintiffs complain that he failed to consider
19 the non-Ranitidine epidemiology, not true. He considered it.

20 Like many, many others, he determined, number one,
21 that it did not rise to the level of a valid association
22 between exposure to NDMA and dietary and occupational studies
23 in development of cancer. Number two, it is not appropriate to
24 apply that data to draw conclusions about Ranitidine.

25 He also considered the Ranitidine data, did not see a

1 valid association. There was no reason to apply Bradford Hill.
2 He did it again in response to the Plaintiffs' experts. There
3 was no consistent association, no magnitude of association, not
4 even temporality, given some of the designs where you are
5 unsure whether protopathic bias is at play.

6 For those reasons, his Bradford Hill analysis was
7 entirely reliable and the challenge to Dr. Wang should be
8 denied.

9 Thank you, your Honor.

10 *THE COURT:* Thank you very much. The Plaintiffs can
11 take some additional time if they want, if you need it. You
12 are otherwise allotted ten minutes for your rebuttal. So if
13 you need some more time, that is fine.

14 *MR. SNIDOW:* Good afternoon, your Honor. Do you mind
15 if I have my laptop up here?

16 *THE COURT:* That is fine. I have mine here.

17 *MR. SNIDOW:* I want to start with their experts.
18 Counsel said that I waited too long before getting into it the
19 last time, although I might ask why they had slides about Dr.
20 Moorman and Dr. McTiernan in their deck, but this time I will
21 start with theirs and then go to some of the more general
22 themes.

23 What I noticed in their presentation, and perhaps the
24 Court did as well, is that they were very long on talking about
25 what their experts' conclusions were and how well supported

1 their experts' conclusions were in the medical literature, but
2 you heard very little on why the methodologies that they
3 employed were reliable under Daubert.

4 The reason why that is important, your Honor, is of
5 course, as we keep emphasizing, Daubert is about methodology.
6 Perhaps if their experts had employed different methodologies
7 and, frankly, done a more careful review, they could have still
8 given some of the same opinions, but that is not what they did.

9 If I could have my slide deck up, please. Might not
10 get it.

11 *MR. SHEEHAN:* Now you feel my pain.

12 *THE COURT:* You can keep talking until it comes up.

13 *MR. SNIDOW:* I will. I was going to show the slides.
14 You have heard no explanation for the slide that I showed about
15 why it is appropriate to make a one paragraph Bradford
16 Hill analysis that lumps all cancers together. We heard no
17 explanation of why it is okay to spend just one paragraph on
18 these very complicated studies and not talk about the
19 limitation hardly at all.

20 We heard no explanation at all, at all, of why ten
21 prescriptions automatically means ten years of use, and that is
22 because it doesn't. That is something that their experts used
23 as an assumption in their opinions.

24 We heard no explanation of how active comparators
25 indirectly control for any confounding. We heard not

1 explanation of why a reliable expert would rely on a study
2 about Valsartan from before Valsartan was contaminated with
3 NDMA. We've heard no explanation of how an expert can review
4 500 studies in under two minutes per study.

5 The reason I am focusing on this stuff is because this
6 is about the methodologies. I know at some point these types
7 of hearings can start to sound like people sniping at each
8 other and nitpicking experts.

9 What I want to emphasize is there is a categorical
10 difference between the kinds of criticisms that the Defendants
11 make about our experts and the kinds of criticisms we are
12 making. They are attacking our conclusions. We are attacking
13 their methodologies and that is fundamentally different.

14 I will take Bradford Hill as an example. I pointed
15 out how short their Bradford Hill analyses are and how,
16 frankly, cursory.

17 The only response that I heard from them is, I think a
18 fair characterization, something like, well, we didn't have to
19 do that anyway. That is fine. If they didn't think they had
20 to and didn't want to include that in their expert report that
21 is up to them, but the fact is they did include Bradford Hill
22 analyses in their report.

23 Counsel said there is no Bradford Hill without an
24 association. Apparently there is because it is in all of those
25 expert reports, they are just not very detailed and they just

1 don't analyze the literature in a way that allows them to do it
2 reliably.

3 Under Daubert, if you are going to apply a
4 methodology, you have to do it reliably. You don't have to do
5 it if you don't want to, but if you do, you have to do it
6 reliably.

7 Turning to threshold dose, counsel said that I said
8 two things about threshold dose that I want to clarify. The
9 first thing he said is that I said that it was irrelevant. I
10 want to pull up slide 39 and make this crystal clear, because I
11 hope I didn't say that and it is not what I meant to say.

12 Slide 39, please.

13 Right. What I said was, no, threshold dose can be
14 relevant in a case where the evidence shows that all of the
15 Plaintiffs took a dose that is well below even the minimum
16 theoretical dose. My point was just that it is not this case.
17 It is relevant perhaps in other litigations, just not here.

18 The second point was he said I didn't show any case
19 law on this issue of threshold dose. I want to make clear that
20 is not accurate either.

21 If I could go to slide 36.

22 This Schultz case is directly on point. What they are
23 criticizing Dr. McTiernan and Dr. Moorman for is what is going
24 on in that second bucket, for having an opinion about what the
25 theoretical minimum dose of NDMA that could pose a cancer risk

1 is. Again, there is an academic debate about that, I am not
2 going to get into it because I, frankly, don't think I have to.

3 Yes, our experts, and a number of other authorities,
4 have the opinion that if you want to know the truth, the real
5 threshold dose is very low. This is not the only substance
6 that works that way. It is true of a lot of carcinogens.

7 One example is actually ultraviolet sunlight.
8 Scientists -- obviously if you stay out in the sun a long, long
9 time it increases your risk of cancer. Scientists, if you
10 look, say ultraviolet light, there might not be a threshold.
11 That is obviously at the small limit, it is a theoretical
12 possibility, but that is what is going on in the second box.

13 Next slide.

14 I don't think there is any way to get around this case
15 law because it's crystal clear. The Schultz Court looks at
16 that second box about the opinion that the threshold is very,
17 very low or nothing, and says although it is unnecessary, that
18 doesn't mean that the experts' opinion should be excluded.

19 Again, that makes perfect sense in a world where we
20 know, as we do here, that the Plaintiffs in this actual MDL
21 took doses that were much, much higher, not just in zero, not
22 just in the theoretical threshold, but doses demonstrated in
23 the medical literature to increase the risk of cancer.

24 Now, counsel says on active comparators that we
25 categorically don't like them, we are opposed to active

1 comparator studies. I want to make clear that is not true.
2 Active comparators are useful to the extent that they are well
3 designed and to the extent that they answer the actual question
4 presented. But there are a couple -- on the point of active
5 comparators, we don't think it is the only thing that you
6 should focus on, but we agree they are useful.

7 What counsel said was, and I'll quote here, they don't
8 have any association at all between human Ranitidine and any
9 dose at all, and they also said that we have to look at what
10 happened out there in the real world, and we have to look at
11 studies that, in their view, "inherently account for dose of
12 NDMA," by which they mean active comparator studies.

13 Let's look at slide 46.

14 This is Cardwell, this is out there in the real world.
15 This is a study that is human Ranitidine data and includes
16 dose. This is a study that apparently inherently accounts for
17 the amount of NDMA that people consumed.

18 What it showed for bladder cancer is that when people
19 took more than three years, they had a 43 percent statistically
20 increased risk.

21 Counsel said he didn't want to get into null
22 hypothesis, he thought it was too wonky. I am happy to spend a
23 few words on it. When the study here says that it is
24 statistically significant, what it is saying -- I don't think
25 you will hear any dispute about this -- is that the authors

1 were able to rule out the null hypothesis. That is 1 in the
2 confidence interval there you see in parentheses.

3 So, it is actually not true. Sure there is a null
4 hypothesis. In Cardwell they were able to rule it out, and you
5 see that by the fact that that 1.05 there is greater than 1.

6 Slide 47.

7 The Wang paper confirms this result. This is an
8 active comparator analysis done in Wang. This study shows
9 actual dose. This study shows -- this study "inherently
10 accounts for the dose of NDMA," as Defendants put it. What
11 they are saying there is whatever the dose of NDMA that can
12 cause cancer is, that dose has to be embedded in Ranitidine.
13 Well, if that is true, the people who took Ranitidine in this
14 Wang study took that dose and we know what happened. For
15 people who took it for just 90 days, they go a little bit more
16 cancer. For people who took it for six months, even more
17 cancer, and people who took it for nine months, even more
18 cancer, and after a year that gap is large.

19 The other thing I meant to point out about this chart
20 this morning and just forgot is this X axis, the line there at
21 the bottom, the one that ends at 18. What that is showing is
22 years of followup. That is the other point that we keep coming
23 back to.

24 What we have to understand about this literature, the
25 longer you wait when looking at patients, the greater that risk

1 shows in this gap, and does your Honor see where it says 3
2 there at the bottom? That is the risk after three years.

3 You can probably tell where I am going with this. If
4 you cut the Wang study off at three years and only look at what
5 happened, you probably see some small difference in risk, but
6 it is, frankly, not very big.

7 It is only until you wait until the full followup
8 periods are established that you really see that, yes, it is
9 true that people who took Zantac for more than one year got a
10 lot more cancer than people who took it for shorter periods of
11 time, and certainly more than people who didn't take Zantac at
12 all.

13 That, of course, is the problem that we identify with
14 the active comparators the Defendants brought up. It's not
15 that active comparators are bad, it's not that they don't
16 reduce confounding somewhat. They definitely do those things.

17 If I could have slide 83.

18 But what active comparators do not fix are problems
19 like these. You can compare Ranitidine to people who didn't
20 take Zantac, or you can compare it to a PPI, or you can compare
21 it to an H2 blocker, or whatever drug you want, but if you are
22 looking at patients who didn't take Zantac for very long and
23 you have a Plaintiff population, some of whom took Zantac for a
24 very long time, it is just not answering the question.

25 The same thing with followup, if you cut off this --

1 not cut off. If you have a median followup of 2.4 years in a
2 study, that is really not telling you very much about what
3 happens after ten years, 15, or 30 years of followup.

4 Counsel asked for a citation for the proposition that
5 poor followup time, poor exposure information can -- even
6 studies that have those features, when they do show up it
7 shows -- it means that there might be even greater association.
8 I want to show two points on that.

9 The first is on slide -- sorry, not a slide, it's a
10 citation to the reference manual. In the reference manual, on
11 pages 589 and 625, or I know your Honor sometimes does control
12 F for certain terms, if you control F for bias toward the null,
13 you will see discussions on this.

14 I know I am running out of time, but I want to be
15 clear on one thing because we will get to this in a moment.

16 What I actually said was there are certain types of
17 ways in which studies are poorly designed where if you do see a
18 signal that means that there might be something even greater
19 there. Those types are the following things:

20 If you have poor exposure classification, if you have
21 short followup time, and if you have non-differential
22 misclassification, if you are just not categorizing the
23 Plaintiffs very well.

24 If you look at those kinds of studies that are not
25 accurately capturing the signal from the noise and you still

1 see an association, that is very powerful. If you don't see an
2 association that doesn't mean that there isn't one necessarily,
3 because a better designed study might have picked it up.

4 There is one exception to that that I want to lay down
5 because I don't want to be accused of misstating it, and that
6 is when you have confounding. If you have confounding -- she
7 is right about the coffee and the tobacco and the cancer stuff.
8 If it is true that coffee drinkers smoke more and you compare
9 people who drink coffee to people who didn't drink coffee and
10 you measure cancer outcomes, you are going to think that coffee
11 causes cancer, even though it doesn't.

12 But, and there is an important but here, all the
13 evidence we have suggests that in this case it cuts in the
14 other direction. On that, I want to show slide 104.

15 What we are almost certainly dealing with, based on
16 the limited data that we have, is a situation where the people
17 who took Zantac actually smoked less. It is the opposite of
18 the coffee situation.

19 If you want proof on that just look at the next slide,
20 or maybe the one before, 103. These are the results from the
21 Kim study, which is one of the few that actually had data on
22 tobacco use. What this it shows is the opposite of the
23 coffee example. People who took Ranitidine smoked less than
24 the people who took Famotidine. That is going to make
25 Ranitidine look safer than Famotidine for reasons that have

1 nothing to do with whether Zantac causes cancer or not.

2 I will close with slide 121.

3 Returning to our criticisms, if you start out
4 answering a different general causation question, that is a
5 problem under Daubert, and a methodological one. If you fail
6 to consider and assess all of the evidence carefully, that is a
7 problem under Daubert. If you fail to carefully review the
8 evidence, that is a problem as well.

9 If Defendants' experts had answered the right question
10 and applied more reliable methods, they probably still could
11 have reached some of the conclusions, but they didn't, and for
12 these reasons we ask that you exclude them.

13 Thank you.

14 *THE COURT:* All right. Thank you.

15 Have we settled on 45 minutes for lunch? Okay. Let's
16 make it even, let's call it 40 minutes, and we'll say 1:30. We
17 will be back at 1:30 and pick up from there.

18 Have a good lunch.

19 (Thereupon, a luncheon recess was taken.)

20 *THE COURT:* You may be seated.

21 All right. I am going to ask a few questions. I know
22 we are a little tight on time so I might stop and pick them up
23 later if we have time. We have a lot of different parts of the
24 schedule this afternoon for some questions.

25 Okay. So this is going to be for both parties, so

1 both of you listen carefully, and when it is time for one of
2 you to answer you can come to the podium.

3 I have to state a preface first, so bear with me.

4 Plaintiffs, in your briefing you rely upon regulatory
5 agency findings and methodologies in assessing causation for
6 NDMA and Ranitidine. For example, in your omnibus motion, on
7 page 75, you criticize Defense expert Dr. Witte because, as you
8 argue, he did not rely upon human studies of NDMA.

9 You assert that his methodology is not permissible and
10 support your assertion by stating that, quote, "The FDA
11 obviously did not consider only studies focused on Ranitidine
12 in deciding to pull Zantac from the market," end of quote.

13 You also cite to findings by the World Health
14 Organization's International Agency for Research on Cancer,
15 IRAC, and the National Toxicology Program, NTP. That is your
16 motion at page 11.

17 Defendants, in your response you state that, quote,
18 "Plaintiffs' approach to epidemiology wrongly conflates
19 precautionary regulatory standards with the scientific rigor
20 required by this circuit in a causation analysis," end of
21 quote. That's at Docket Entry 5968 at 47.

22 I did ask both parties to come prepared today to
23 discuss case law regarding regulatory thresholds and the role
24 of agency findings in assessing causation. The Eleventh
25 Circuit has clear case law regarding the role of regulatory

1 findings in assessing causation.

2 In the case Williams versus Mosaic Fertilizer, LLC,
3 889 F.3d 1239, Eleventh Circuit, 2018, the Eleventh Circuit
4 cautioned against what they described as the methodological
5 perils of relying on regulatory thresholds to establish
6 causation. That's at pages 1246 to 47.

7 The Court explained that the biggest problem stems
8 from the potential difference in purpose between regulatory
9 standards and toxicological dose response calculations.
10 Regulatory standards often build in considerable cushion in
11 order to account for the most sensitive members of the
12 population and prophylactically protect the public; in other
13 words, they are protective, while dose response calculations
14 aim to identify the exposure levels that actually cause harm;
15 in other words they are predictive. That's at page 1247.

16 Likewise, the Eleventh Circuit in McClain versus
17 Metabolife International, Inc. 401 F.3d 1233, Eleventh Circuit,
18 2005, explains the agency approaches, and specifically the
19 FDA's approach, differ from the analysis of causation in a
20 courtroom because "the FDA will remove drugs from the
21 marketplace upon a lesser showing of harm to the public than
22 the preponderance of the evidence or the more likely than not
23 standard used to assess tort liability."

24 The Court in McClain clarifies that it, quote, "is not
25 rejecting public health rules from consideration in a Daubert

1 analysis," and clarifies that, rather, the trial Court needs to
2 understand the meaning of agency rules, 1249 to 50.

3 For both parties, Plaintiff first, then Defense -- and
4 you can answer from your desk, just speak into the microphone
5 because I am going back and forth.

6 Do you agree that, under Eleventh Circuit case law,
7 regulatory threshold levels and regulatory findings regarding
8 public health are made using a lower burden than the
9 preponderance of the evidence standard required in this
10 courtroom for establishing causation?

11 MR. SNIDOW: Your Honor, this is JJ Snidow for the
12 Plaintiffs. We do agree. May I elaborate?

13 THE COURT: You agree?

14 MR. SNIDOW: I do.

15 THE COURT: Defense, do you agree?

16 MR. BOEHM: Yes, your Honor, we do agree.

17 THE COURT: Okay. Back to the Plaintiff, do you agree
18 that the Eleventh Circuit has determined that regulatory
19 standards are not intended to serve the purpose of establishing
20 exposure levels that actually cause harm, but rather, are
21 usually overly cautious in order to protect the public?

22 MR. SNIDOW: I think it depends on the substance at
23 issue, your Honor.

24 THE COURT: Okay.

25 MR. SNIDOW: If you want a little more, I can provide

1 it.

2 *THE COURT:* A sentence more.

3 *MR. SNIDOW:* I would say I think there was an
4 adjective that was usually or generally in there that you read.
5 I think that's correct.

6 *THE COURT:* Yes.

7 *MR. SNIDOW:* Obviously, we are not arguing that just
8 because the FDA pulled Zantac from the market that is by itself
9 enough evidence of general causation, which I think is probably
10 what the Court is getting at. It is obviously not. We are not
11 saying, look, they pulled it from the market, there is nothing
12 else to do. We wouldn't have done the expert reports if that
13 were enough.

14 *THE COURT:* Okay. From Defense.

15 *MR. BOEHM:* Your Honor, we certainly agree with the
16 fact that a recall or a withdrawal would not constitute
17 reliable evidence under 702. Beyond that, I don't think that
18 is all that these cases state.

19 They state that there is a different standard that
20 regulatory agencies are applying in contrast to the one that
21 the Court applies in applying Rule 702 analysis, that they are
22 distinct and different and have different purposes. It is not
23 just as to a recall, but it is a more robust case law on that
24 point.

25 *THE COURT:* Okay. Thank you.

1 Plaintiff, in your slide you cite to the hearing
2 transcript from Valsartan in New Jersey, 2022, in which Judge
3 Kugler asked the Defendants to explain why there was a recall
4 by Government agencies if, as Defendants claim, there was no
5 association between NDMA and cancer. Judge Kugler confirms
6 that "the association element has been clearly demonstrated
7 both through all the action by the Government agencies and
8 through the words of the Defendants themselves."

9 For the Plaintiffs, can you explain how you reconcile
10 Judge Kugler's opinion, which is from the District of New
11 Jersey, with the Eleventh Circuit's precedent?

12 *MR. NIGH:* Your honor, I would start out by saying
13 that in the Valsartan decision Defendants made all the same
14 arguments that they have made here, many of the same arguments
15 on not to look at NDMA literature, our arguments on threshold,
16 we have calculated lifetime cumulative exposures.

17 All the same arguments were well briefed, and there
18 are many more statements in that transcript, and all those
19 Defendants' arguments were denied.

20 Now, specifically on this point, the question on
21 association, it is not just the regulatory statements, but it
22 is also the statements that were made by company witnesses and
23 some of those same sort of things we have at play here where
24 company witnesses have recognized that NDMA itself is a
25 carcinogen.

1 So, we do believe that there is association here on
2 that, but we have way more evidence here as well on
3 association, and that was presented thoroughly here this
4 morning.

5 *THE COURT:* Thank you. Any response from the
6 Defendants?

7 *MR. BOEHM:* Your Honor, we take it that the premise of
8 the question is one that we would agree with, that Judge Kugler
9 was not applying Eleventh Circuit law in reaching his
10 determination in that case.

11 *THE COURT:* Okay. I am going to go back to Plaintiffs
12 for a moment. You focused on, it seems from the statement I
13 read, not on the Government agency portion of what he said
14 because that would not necessarily be consistent with what you
15 have just agreed is Eleventh Circuit law. So, is the emphasis
16 there on the words of the Defendants themselves, and is that
17 consistent with Eleventh Circuit law to satisfy Daubert, what
18 company witnesses say?

19 *MR. SNIDOW:* Well, a couple things. One, in our view,
20 the Third Circuit law on this point is nearly identical to
21 Eleventh Circuit law. I think that the Hardeman Court in the
22 Ninth Circuit --

23 *THE COURT:* Use the microphone.

24 *MR. SNIDOW:* Sorry. If the Court looks at the
25 Hardeman versus Monsanto opinion from the Ninth Circuit, there

1 is that paragraph where it talks about Defendants' arguments
2 that the law in different circuits is more or less leaning on
3 Daubert. What the Ninth Circuit there says is that the Ninth
4 Circuit law on Daubert is the same as the Eleventh Circuit and
5 the Third Circuit. So, I don't think there are materially
6 different Daubert rules between the circuits.

7 On the Court's general question about the importance
8 of regulatory agencies, just two points. One is WHO and IARC
9 are not actually regulatory bodies. The FDA, of course, is.

10 The second point is, we are not relying exclusively on
11 the FDA's recall or, frankly, even what the FDA has said, but
12 those are obviously relevant. It's relevant both what the FDA
13 said about Zantac and what the FDA said about NDMA when
14 evaluating Zantac, and that is, of course, what we say the
15 Defendants should have done. They should have certainly
16 considered the underlying NDMA literature, that it is relevant,
17 and they didn't.

18 *THE COURT:* Are you familiar with any Eleventh Circuit
19 case that says that the law in the Eleventh Circuit is the same
20 in other circuits, or any other circuit case that analogizes to
21 the Eleventh Circuit offhand?

22 *MR. SNIDOW:* Not offhand, your Honor. Hardeman
23 qualifies for everything you have asked for except it being
24 from the Eleventh Circuit. I don't know of an Eleventh Circuit
25 analog.

1 *THE COURT:* Okay. Thanks. Defense, your position on
2 regulatory standards, relevant or not relevant to the question
3 of general causation?

4 *MR. BOEHM:* Certainly how the regulatory community,
5 alongside the scientific community, more broadly approach the
6 scientific question informs the general acceptance prong of the
7 reliability analysis under Rule 702. That is part of what we
8 were saying about Defendants' experts, that the methods that
9 they apply, the approach that they take in evaluating the
10 relevant data here is consistent with those that are used and
11 applied by the broader regulatory and scientific communities,
12 and that is an indicia of reliability under Rule 702.

13 In terms of regulatory findings, decisions to, for
14 example, take the product off the market or take other
15 precautionary measures, that in the Eleventh Circuit has been
16 found to be a separate analysis, one that is fully distinct
17 from the Daubert trilogy that this Court undertakes in
18 assessing reliability of experts' testimony in litigation.

19 *THE COURT:* Thank you. Plaintiffs, on pages 103 to
20 104 of your omnibus motion you argue that Dr. Guengerich's
21 opinion that there are threshold levels of NDMA below which
22 Ranitidine does not cause cancer in humans is flawed.
23 You explain that Dr. Peto concluded otherwise and found no
24 indication of a threshold.

25 In the next sentence you state, "The FDA utilizes a

1 non-threshold linear dose response methodology based on the
2 Peto data to calculate an acceptable daily limit, ADL, for NDMA
3 of 96 nanograms a day."

4 Can you explain further how the FDA's calculation of
5 the acceptable daily limit of 96 nanograms a day supports your
6 argument that there are no threshold levels of NDMA below which
7 Ranitidine does not cause cancer?

8 *MR. NIGH:* Your Honor, those are really two different
9 ideas, but the idea of a threshold means is there any -- is
10 there a level as to which below it there is no increased risk
11 at all. The 96 nanograms is an acceptable increase risk that
12 the FDA has stated, but they don't say there is no risk at 96
13 nanograms. In fact, they have multiple FDA statements where
14 they recognize that they would there be no NDMA in the
15 medications, but they are going to set 96 nanograms as the
16 acceptable risk.

17 *THE COURT:* Okay, thank you. Plaintiffs, let's see,
18 in your reply and your presentation this morning you cite to a
19 hearing transcript from Valsartan to argue that NDMA which has
20 been found in Ranitidine is the relevant toxin in this
21 litigation. That is at Docket Entry 6011, at page 31.

22 You also cite to Burst versus Shell Oil Company, 2015
23 WestLaw 3755953 in support of the proposition that studies of
24 NDMA are relevant to the carcinogenicity of Ranitidine.

25 In Burst, on page 9, the Court states, "Because

1 Benzene is a known human carcinogen and because all gasoline
2 contains Benzene, the Court recognizes that literature
3 pertaining to Benzene is generally relevant to the causation
4 question at issue."

5 This first question is for the Defendants.

6 Is it your argument that NDMA is not generally
7 relevant to the question of whether Ranitidine is carcinogenic,
8 that is, do you concede that the question of whether NDMA is
9 carcinogenic is relevant to the question of whether Ranitidine
10 is carcinogenic or not? What is the Defendants' position on
11 that?

12 *MR. BOEHM:* We'd have to concede that there is some
13 level of relevance. The point that we have made is that it is
14 not enough. Even if you establish that fact, it is not enough
15 to meet the requirements under Rule 702 for reliability as
16 applied by Courts in the Eleventh Circuit, which very
17 specifically indicate you have to look at exposure to the drug
18 and it would be too great a leap of logic, it would be too
19 great an analytical gap to extrapolate based on NDMA data,
20 shoving aside the existing robust database of Ranitidine
21 epidemiology.

22 *THE COURT:* Okay. Plaintiffs, in Burst the Court goes
23 on to state the following on page ten: "The Court finds that
24 although evaluation of the Benzene literature is generally
25 relevant to Dr. Infante's ultimate opinion, it alone cannot

1 provide a reliable basis for Dr. Infante's opinion. While
2 seemingly all scientific authorities recognize Benzene as a
3 carcinogen, none recognizes gasoline as a carcinogen and
4 Defendants have offered several justifications for why exposure
5 to Benzene in gasoline should be evaluated differently than
6 exposure to Benzene generally."

7 The Court ultimately finds that the Benzene studies
8 alone did not provide sufficient grounds to support the
9 expert's general causation opinion.

10 Can you explain why the Defendants' expert's reasons
11 why exposure to NDMA from dietary and occupational sources
12 should be evaluated differently from exposure to NDMA in
13 Ranitidine, why that is not an acceptable justification such as
14 the one in Burst for why exposure to Benzene in gasoline should
15 be evaluated differently than exposure to Benzene generally?

16 *MR. HEINZ:* Yes, your Honor. Noah Heinz for the
17 Plaintiffs.

18 I would say that the type of explanation in the Burst
19 case was about competitive inhibitions, so that they said it is
20 not just a question of the amount of Benzene, which if you are
21 just talking about the amount, you could look at Benzene
22 specific literature addressing that.

23 The issue was that within gasoline it was counteracted
24 by Toluene, and so was not carcinogenic in that context. The
25 Defendants' experts, to my recollection, do not provide any

1 similar explanation for why the NDMA in Ranitidine would act
2 differently. All they say is that there is too little in it.

3 To the extent you are talking about the amount, you
4 should still look to the NDMA literature to see how much NDMA
5 you need.

6 It is also notable that I think a lot of the experts,
7 I'm not sure if all of them do, but certainly many of them say
8 they don't know how much NDMA is in Ranitidine, so the nature
9 of the justification is much smaller in this case as compared
10 to Burst.

11 *THE COURT:* Thanks. Any response from Defense?

12 *MR. BOEHM:* Just, your Honor, that the form of
13 reasoning by analogy that we just heard from Mr. Heinz and that
14 we have heard at other points in our discussions and in the
15 briefing is in cases like Abilify and McClain and others in the
16 Eleventh Circuit found not to be reliable under Rule 702. You
17 cannot make that leap. It is reasoning by analogy, it is not
18 evidence as to the actual drug at issue.

19 *THE COURT:* Thank you. I will try to get in two more
20 questions and then I'll pause, and then if we have time at the
21 end, I might pick up some more of these questions.

22 For Plaintiffs, in your reply and in your slides you
23 explain that a District Court's role at the Daubert stage is
24 not to evaluate experts' conclusions, the credibility of
25 opposing experts, or the persuasiveness of competing studies.

1 You state that, rather, the Court's role is to assess whether
2 experts employed a reliable methodology, at Docket entry 6011
3 at 27.

4 You are correct that the Court's role is not
5 to evaluate the persuasiveness of any study, nor the conclusion
6 as to the credibility of any expert.

7 Do you agree, however, that in order to fulfill the
8 Court's role of evaluating the reliability of the methodologies
9 followed by the experts in this litigation the Court needs to
10 examine the studies each expert relies upon to determine how
11 the experts reach their conclusions and whether it was reliable
12 to reach the conclusions that they did based on the literature,
13 and that this process is different than considering the
14 persuasiveness of the studies or the experts' conclusions
15 because it looks at the process of how and why the conclusion
16 was reached, not the persuasiveness of the conclusions or
17 studies themselves?

18 *MR. HEINZ:* Yes.

19 *THE COURT:* Defense, do you agree as well?

20 *MR. BOEHM:* We agree as well, your Honor.

21 *THE COURT:* Okay. Plaintiffs, in your slides and in
22 your omnibus motion at Docket Entry 5841 you quote In Re:
23 Abilify, 299 F.Supp.3d 1291, at 1311, Northern District of
24 Florida, 2018, stating "A scientific methodology that turns on
25 weighing the totality of the evidence is reliable only if the

1 expert considers all available evidence carefully, and explains
2 how the relative weight of the various pieces of evidence led
3 to his conclusion."

4 In your reply you argue that "only Defendants' experts
5 consider less than all the evidence, gerrymandering the
6 studies in a manner at odds with how IRAC, the WCRF, and their
7 ilk approach causation." Docket Entry 6011 at 14.

8 You argue that Defense experts Drs. Chan, Witte,
9 Terry, Vaezi, and Hatten "ignored" or "did not consider" -- and
10 that is in quotes, ignored is in quotes and did not consider is
11 in quotes from your brief -- the NDMA epidemiology.

12 In their response and in their presentation today the
13 Defense argued that their experts, Chan, Witte, Terry, Vaezi,
14 and Hatten considered all of the evidence, including NDMA
15 studies, and that is at Docket Entry 5968, at 58.

16 Can you, Plaintiffs, explain what you mean by the
17 terms "considered" and "ignored". Is your argument the
18 Defendants' experts did not review the NDMA epidemiology at
19 all, or that although they reviewed it, they did not rely upon
20 it, or something else?

21 *MR. SNIDOW:* Yes, your Honor. Our argument is not, at
22 least for most of them -- I don't have it in front of me. For
23 most of them the argument is not that they didn't consider it
24 in the sense of it doesn't appear in their report, they don't
25 have it on their reliance list, something like that.

1 But to read Abilify fairly, the word "consider" has to
2 mean more than just did you put it on your materials considered
3 list. If the Court looks at the reports and depositions,
4 especially if the Court compares those reports to the reports
5 that our experts prepared, you will see a real difference in
6 how thoroughly the experts considered the NDMA literature, and,
7 frankly, the Ranitidine literature.

8 Our experts went through it in great detail with
9 respect to the NDMA literature, their experts -- it varies
10 expert to expert, but by and large didn't. Does that answer
11 the Court's question?

12 *THE COURT:* Yes. Any brief response? Then we will
13 move on.

14 *MR. BOEHM:* To the extent I just heard Plaintiffs'
15 counsel, as I believe I did, concede that Defense experts did
16 review the NDMA data, then we certainly agree with that, and we
17 have discussed at length how they approached that data, and I
18 won't repeat that now.

19 *THE COURT:* All right. Thank you. We will maybe pick
20 up with some more epidemiology questions in a bit.

21 Now a bit off schedule, but hopefully not -- no one is
22 going to miss their flight. I am going to end on time
23 regardless of where we are for all of you to make your flights.
24 Don't worry about that.

25 Now we will move into the Gibbons motion at Docket

1 Entry 5839. Is that where we are, just ten minutes?

2 MR. NIGH: Yes. i might take a little time for
3 rebuttal.

4 THE COURT: You have rebuttal time, five minutes. Ten
5 minutes now.

6 MR. NIGH: Can we go ahead and pull up the Gibbons
7 slides.

8 THE COURT: State your name again for the record.

9 MR. NIGH: This is Daniel Nigh for the Plaintiffs.

10 Your Honor, I will argue that the Court should exclude
11 Defendants' expert Dr. Robert Gibbons under Rule 702 and the
12 Daubert line of cases.

13 Defendants offer Dr. Gibbons as a rebuttal witness
14 against Dr. Davis' statistical analysis. Much of Dr. Gibbons'
15 opinion is actually an attack on Emery Pharma's testing. Dr.
16 Gibbons' opinions are predicated on pervasive misunderstandings
17 of the facts of Emery Pharma testing. His methodology in
18 reaching those opinions is thus unreliable and his opinions
19 therefore should be excluded.

20 Next slide.

21 First, Dr. Gibbons critiques Dr. Davis' analysis for
22 purportedly using too small a sample size, but Dr. Gibbons'
23 opinion is based on a misunderstanding of Emery Pharma's
24 testing. Dr. Gibbons' error is straightforward, he doesn't
25 even know how large a sample size Emery Pharma used. For

1 example, in Emery Pharma's consumer experience testing Dr.
2 Gibbons simply didn't know how many pills were tested.

3 "Question: Do you know how many total samples were
4 run in looking at whether or not NDMA increases as a result of
5 sun, shade, and shower? How many total pills were tested?"
6 His answer is: "I believe it was a total of 25."

7 He is wildly off. In reality, the sun, shade, and
8 shower study tested at least 400 pills and had over 200
9 observations of the average amount of NDMA. And the climactic
10 zone study tested at least 150 pills and 80 observations
11 of average amount of NDMA.

12 He was wildly off on the total amount of samples that
13 he thought were tested, yet he criticized that issue. In fact,
14 Emery Pharma tested substantially more than the FDA.

15 Dr. Gibbons' critique of Dr. Davis' statistical
16 analysis thus ignores the facts in the record that show the
17 significant sample sizes that Emery used in its testing.
18 Because his opinion is disconnected from the facts, it should
19 be excluded in its entirety.

20 Next slide.

21 Dr. Gibbons did not understand Emery's study design.
22 Second, Dr. Gibbons critiques the study design that Emery
23 Pharma used in its testing, but as Defendants concede, that
24 critique is based on the failure to understand how Emery
25 Pharma's testing was done, and this was found in the

1 Defendants' briefing at page eight where they quote, "although
2 he carefully reviewed Dr. Najafi's report, it was unclear
3 how Emery actually designed the experiments."

4 Defendants try to recast Dr. Gibbons' failure to
5 understand Emery Pharma's testing as a problem with the
6 testing. That places the burden in the wrong place. For Dr.
7 Gibbons' opinion to be reliable it must be based on the actual
8 facts of Emery Pharma's testing, not his false misimpressions
9 of it.

10 Next slide.

11 Indeed, Dr. Gibbons' basic misunderstanding of Emery
12 Pharma's pill testing undermines his opinion. For example, Dr.
13 Gibbons' inaccurate guesses about Emery Pharma's sample sizes
14 were the result of his failure to understand how that pill
15 testing is conducted. He assumes that the ID numbers in Dr.
16 Davis' report identify an individual pill that was subjected to
17 all possible numbers of, for example, shower cycles, and that
18 the same pill was tested after each number of cycles.

19 That is completely incorrect. As Dr. Davis' report
20 explains, the ID numbers refer to the lot or batch number for a
21 collection of pills. Because testing pills using LC/MS-MS
22 necessarily destroys the pill tested, it can't be tested
23 multiple times.

24 Emery Pharma tested multiple pills from each batch or
25 lot. A different pill, and usually multiple pills, would be

1 tested after each different number of cycles, but the total
2 number of pills tested was therefore much higher than Dr.
3 Gibbons inaccurately assumed.

4 That is just one example of Dr. Gibbons' pervasive
5 misunderstanding of how Emery Pharma's testing was conducted.
6 Those misunderstandings undermine the reliability of all of his
7 opinions, which should therefore be excluded in their entirety.

8 Next slide.

9 In addition to these factual misunderstandings, Dr.
10 Gibbons also levies entirely unsupported criticisms of Dr.
11 Davis' statistical analysis likely because, as he admitted in
12 his deposition, Dr. Gibbons has no experience running
13 statistical analyses on results from pill testing whatsoever,
14 and that led to many of these problems.

15 Next slide.

16 Next, for example, Dr. Gibbons critiques Emery Pharma
17 for not using a random sample of pills in its testing. That
18 purported requirement is inapplicable to pill testing, and
19 indeed impossible to satisfy. Emery Pharma tested pills that
20 it received from the Defendants. At that point Ranitidine had
21 been withdrawn from the market.

22 Dr. Najafi testified at his deposition that Emery
23 Pharma tested a sample of the pills that it received. It was
24 impossible to test a random sample of pills that millions of
25 people had already purchased and millions of people had already

1 ingested.

2 For that reason, GSK did not use a random sample of
3 pills when it performed its root cause analysis, nor did the
4 FDA use a random sample of pills when it conducted its own
5 testing of Ranitidine, nor, for that matter, did any other
6 laboratory that has conducted pill testing of Ranitidine.

7 Dr. Gibbons cites no source to support his unorthodox
8 view that Emery should have used an impossible random sample,
9 and he gives no reason whatsoever why that impossible standard
10 should apply to Emery Pharma, but not to the FDA or to the
11 Defendants themselves.

12 Dr. Gibbons' baseless opinion is thus inconsistent
13 with widely accepted scientific practice and should therefore
14 be excluded.

15 Next slide.

16 Finally, Dr. Gibbons opines that Dr. Davis failed to
17 perform a power calculation prior to Emery Pharma selecting the
18 pills that it tested. That once again demonstrates Dr.
19 Gibbons' failure to understand pill testing, a field in which
20 he admits he has no experience.

21 If Dr. Gibbons understood pill testing he would know
22 that a power calculation is not commonly set up beforehand to
23 establish how many pills need to be tested, nor to extrapolate
24 results to the population. For that reason, when the
25 FDA tested the pills and reported the results the FDA did not

1 perform a power calculation before testing to determine how
2 many pills needed to be tested to extrapolate the results to
3 all Ranitidine pills in the market.

4 In addition, GSK, when testing for their root cause
5 analysis that was later peer reviewed and published, also did
6 not perform power calculations. Dr. Gibbons does not
7 explain why Dr. Davis and Emery Pharma should be held to a
8 novel standard that the FDA itself does not consider applicable
9 to pill testing.

10 Next slide.

11 Dr. Gibbons ignores the statistical tests that are
12 applicable. As Dr. Davis opined, his results are statistically
13 significant. Dr. Gibbons provided no response to Dr. Davis' P
14 test regarding the sun, shade, shower, and zones consumer
15 experience testing.

16 As Dr. Davis opined, all 25 slopes, 25 of 25, of Emery
17 Pharma's consumer experience testing were positive in the
18 shower test, that is, all 25 slopes show that the more heat and
19 humidity that Ranitidine is exposed to, the more NDMA forms.
20 The likelihood that all slopes would be positive by random
21 chance is 6 in 100 million, which is a lower chance than
22 getting hit by lightening in any given year. Dr. Gibbons does
23 not refute this.

24 Because Dr. Gibbons' opinion regarding power
25 calculations are disconnected from the generally accepted

1 practices in the field, it should be excluded.

2 Thank you, your Honor.

3 *THE COURT:* Okay, thank you.

4 And from the Defense.

5 *MR. TOBEY:* Good afternoon, your Honor.

6 *THE COURT:* Good afternoon.

7 *MR. TOBEY:* Danny Tobey on behalf of all brand
8 Defendants. I will be presenting our opposition to Plaintiffs'
9 motion against Dr. Gibbons.

10 Pull up the slide, please. Next slide.

11 So, at the outset, your Honor, it is helpful to frame
12 what Dr. Gibbons did and didn't do.

13 As this Court is well aware, Plaintiffs hired a
14 chemist named Dr. Najafi to perform pill testing on samples of
15 Ranitidine to ostensibly detect levels of NDMA under various
16 simulated conditions.

17 The Court has already heard Defendants' critiques of
18 those chemistry methods, not least of which that Dr. Najafi
19 used different testing techniques before litigation, and then
20 once he was hired as a litigation consultant of course got
21 different results as a consequence.

22 Plaintiffs also hired a statistician, and that
23 doctor's name is Dr. Davis. His job was to take the outputs
24 from Dr. Najafi and be able to extrapolate them through
25 statistics to presumably all people or all Plaintiffs in the

1 case who took samples of Ranitidine.

2 Now, Defendants hired their own statistician, Dr.
3 Gibbons, to review Dr. Davis' statistical methods and that is
4 what we are here to talk about today.

5 Next slide, please.

6 The first take home point, your Honor, is, like Drs.
7 Salmon and Panigraphy, which you heard at the last hearing, Dr.
8 Davis' model relies on the inputs from Dr. Najafi's testing.
9 So, if Dr. Najafi's outputs, which become the inputs of these
10 statistics, are unreliable, then these models are also
11 unreliable, too. That is the core of Rule 702, that valid
12 opinions must be based on sufficient facts and data.

13 If the Court were to strike Dr. Najafi's unique
14 testing, the all the follow on models would also fall without
15 further analysis.

16 Next slide, please.

17 We are going to put Dr. Najafi and his chemistry
18 methodology to the side now and talk about statistics. Dr.
19 Gibbons is a statistician, he is here as a rebuttal expert to
20 talk about Dr. Davis, and what Dr. Gibbons did was point out
21 several very, very basic statistical flaws when someone sets
22 out to do what Dr. Davis did, which is create a statistical
23 model that can be reliably generalized to a much larger
24 population.

25 What did Dr. Gibbons point out? Dr. Davis did not use

1 random samples, he did not power his study for
2 generalizability, he did not correct for false positives from
3 multiplicity, and he treats related variables as independent.

4 Next slide, please.

5 So, what do Plaintiffs say in response? You heard a
6 lot of this, Dr. Gibbons simply doesn't know what he's doing,
7 he is unfamiliar with pill testing. Dr. Gibbons never said
8 that, but in reality, Dr. Gibbons is a biostatistician. That
9 is the same discipline that Dr. Davis is trained in.

10 In particular, Dr. Gibbons has received the Harvard
11 award for lifetime contributions to the field of biostatistics,
12 he received the Outstanding Statistical Application Award for
13 Drug Safety Studies, and he actually authored the National
14 Academy of Medicines's recommendation, which was adopted by the
15 U.S. Congress and enacted by the FDA to create a statistical
16 drug safety monitoring network. Needless to say, Dr. Gibbons
17 knows how to apply statistics to pharmaceuticals.

18 Next slide, please.

19 Plaintiffs then critique Dr. Gibbons and say, well, he
20 didn't understand Dr. Najafi's testing methodology, so clearly
21 he can't opine because he doesn't know these basic things.

22 This is a bit putting the cart and the horse in the
23 wrong position. What they don't realize is, Dr. Gibbons was
24 clearly criticizing the information that was missing from Dr.
25 Davis' report that he should have had from Dr. Najafi in order

1 to make reliable assessments.

2 You can see this in the chart here, the things that
3 they criticize Dr. Gibbons for on the right-hand side. Dr.
4 Gibbons is actually saying I should have known these things,
5 these things should have been available. He says there is a
6 lack of any details on how these were collected by Dr. Najafi.
7 They don't provide any specific information on how the samples
8 were identified.

9 On the left-hand column, your Honor, you see that Dr.
10 Davis doesn't know these things either. He says, no, I wasn't
11 involved with that. Do you have any idea how those samples
12 were chosen? No. He says, I don't know that, I have no way of
13 knowing that. So, Plaintiffs can't criticize Dr. Gibbons, one,
14 for pointing out that important information was missing that,
15 two, their own expert didn't know. At the end of the day, your
16 Honor, no one knows exactly what Dr. Najafi did.

17 Next slide, please.

18 So another critique that you heard here, your Honor,
19 is that Dr. Gibbons criticized that the sample size is too
20 small, and they say, well, he doesn't understand pharmaceutical
21 statistics, but Dr. Davis said the exact same thing, your
22 Honor. This is a trend, you have seen it in the last side and
23 you see it in this slide, that often times they are criticizing
24 Dr. Gibbons for things their own expert conceded.

25 Dr. Davis said many times the sample sizes were too

1 small. He had to amend his protocol post hoc because once he
2 got the actual samples it was too small to analyze, extremely
3 small sample size.

4 Next slide, please.

5 You also heard Dr. Gibbons was criticized because he
6 didn't know the number of pills that were destroyed in the
7 making of these chemistry analyses. That is a bit of a gotcha,
8 your Honor, because the number of pills is entirely irrelevant
9 to the statistical question that Dr. Gibbons was looking at.

10 As you know, your Honor, statisticians look at the
11 number of observations, and observations have to be defined,
12 and here Emery's spreadsheet and Dr. Davis' report said
13 clearly, the spreadsheet includes one record for each unique
14 observation as defined by batch or lot number. The
15 observations were batches. If Dr. Najafi used two pills from
16 that batch, or ten pills from that batch, or a hundred, it
17 doesn't matter. What he ended up with was an average NDMA
18 level for each particular batch.

19 That was the unit of currency that Dr. Davis analyzed,
20 and therefore it was the unit of currency that Dr. Gibbons
21 analyzed. As Dr. Davis said, from each observation in the data
22 set, it is the average level from more than one pill tested
23 from the lot number.

24 Next slide, please.

25 Next, you just heard this from Plaintiffs, they

1 criticize that Dr. Gibbons was wrong for suggesting that basic
2 statistical concepts like randomization and power
3 calculations should not apply here, and Dr. Gibbons disagrees,
4 for sure. He says, as a preliminary matter, it is important to
5 note you can't generalize to a large random population if you
6 start with a biased sample. That is statistics 101.

7 Likewise, if you don't do a power calculation, you
8 have no reliable measurement of whether your results have the
9 statistical power to be generalized.

10 Next slide, please.

11 Plaintiffs kind of create a strawman, and I am not
12 going to belabor this because the Court was just asking
13 questions clearly delineating between what regulators do for a
14 precautionary measure, such as a recall, and what scientists do
15 when they are assessing biological truths, statistical
16 generalizations, things where the actual numbers matter because
17 you are going to be extrapolating from them to a larger
18 population.

19 It is true, when the FDA wanted to answer a simple
20 question, is there really NDMA in some lots of Ranitidine, they
21 grabbed a few samples, they tested them, they found very small
22 amounts, they likened it to amounts in food, but that is all
23 they needed to know. Same thing with GSK, those were spot
24 tests to see is there something here at all.

25 What did FDA do when it published a scientific study

1 where the results mattered because they wanted to generalize
2 conclusions from those data to larger data? That is the
3 Florian study. They randomized their sample so it would be
4 generally applicable, and they calculated the power. The USP
5 General, the U.S. Pharmacopeia says the exact same thing, when
6 possible, use of a random process is considered the most
7 appropriate way of selecting samples.

8 Dr. Davis is not here performing a precautionary
9 regulatory function, he is setting up a framework where they
10 can ostensibly extrapolate from Dr. Najafi's flawed chemistry
11 to speculate about what any given Plaintiff might have taken in
12 a particular pill, and that is where power and randomization
13 and all those important safeguards come in because that is not
14 a reliable methodology.

15 Next slide, please.

16 Another critique that Dr. Gibbons made was Dr. Davis
17 ran hundreds of experiments without correcting for the effect
18 of multiplicity. Multiplicity sounds complicated, but it is
19 actually really understandable in the sense of if you just run
20 enough tests, eventually you are going to get some false
21 positives. I like to think of it as throwing darts at a dart
22 board. I could be the worst dart player on earth, but if I
23 throw enough darts, some of them are going to land in the
24 middle.

25 It is not an insurmountable problem. Statisticians

1 have ways to correct for multiplicity to say I have run this
2 many trials, therefore I am going to adjust my parameters.

3 Next slide, please.

4 Dr. Davis did not do that, and he specifically said in
5 his protocol I am not adjusting for multiplicity. He knew the
6 right thing to do, but he did not do it because he knew his
7 effects would go away.

8 What did the Plaintiff say in their briefing in
9 response to that? They said, well, goose, gander, glass
10 houses, Dr. Gibbons did not even adjust for multiplicity when
11 he conducted his own analysis. What Plaintiffs aren't
12 realizing here is, Dr. Gibbons was running a simulation of the
13 effect of multiplicity.

14 He took all of Najafi's data, scrambled it so it was
15 random, then ran the number of tests that Dr. Davis ran and
16 showed that even when the data was scrambled so it was all
17 random chance he generated multiple, multiple false positives.
18 He was demonstrating the effect of multiplicity and it would
19 have been a strange way to conduct that experiment to correct
20 for multiplicity.

21 Next slide, please.

22 Now, another critique that Dr. Gibbons made was that
23 Dr. Davis treated variables that were interrelated as if they
24 were independent. Again, this is just a basic statistical
25 error. If your variables have interdependence, there are ways

1 to test for that, and then there are ways to extrapolate taking
2 that into account.

3 Dr. Davis didn't do that, he treated every single one
4 of his parameters as if it were its own independent variable.
5 Take, for example, manufacturing plant and then temperature
6 control. He treated those as two completely separate tests.
7 When he got a positive one, he said great. When he got a
8 positive on the other, he said great, look at all these things
9 I am finding.

10 What he didn't account for was these things are
11 interrelated. Each manufacturing plant has its own related
12 temperature control, has its own storage, has all kinds of
13 variables that are interrelated. There are corrections for
14 that, Dr. Davis didn't make them.

15 What happens then as a result is, not only are there
16 all the false positives from multiplicity, there are false
17 positives because you're double counting your findings. You
18 are saying, ah-hah, temperature matters and factory matters,
19 when in fact that is really one finding, not two, and this
20 error was propagated over and over.

21 Next slide, please.

22 So, in sum, what did Dr. Gibbons do? He is a renowned
23 biostatistician, but it didn't take his skill level to make
24 these assessments. He said if you want to create a reliable
25 sample to randomize and extrapolate from, you have to have a

1 random starting point so it's reflective. You have to
2 power your study so there is some objective criteria about
3 extrapolation. You have to correct for false positives and you
4 have to correct for interdependence. Dr. Davis did none of
5 these things.

6 This is not something disputed by Plaintiffs, they
7 just try to minimize these critiques. That does not rehab Dr.
8 Davis' unreliable statistical methodology, and it certainly
9 doesn't disqualify Dr. Gibbons. There is nothing unreliable
10 about pointing out a failure to apply the most basic
11 statistical controls.

12 Thank you, your Honor.

13 *THE COURT:* Thank you. Any rebuttal?

14 *MR. NIGH:* Yes, your Honor. Daniel Nigh for the
15 Plaintiffs. I will be brief.

16 Defendants discuss Gibbons' experience with monitoring
17 for drug safety, but monitoring for drug safety is much
18 different than pill testing for impurities or carcinogens.

19 Next, Defendants defended Gibbons' multiplicity
20 criticisms, however, Dr. Davis testified that multiplicity
21 adjustments are not applicable to safety issues, and that makes
22 sense.

23 Think about all the epidemiology studies in this case
24 that your Honor has reviewed. Some of them have many analyses
25 that the authors have investigated and not a single one of

1 those study authors in those epidemiology studies have adjusted
2 for multiplicity.

3 Defendants raise Florian, and again, Florian has
4 numerous statistical analyses conducted and multiplicity was
5 never applied. In Defendants' own root cause analysis,
6 including GSK's root cause analysis that was published in the
7 King study, also had no multiplicity applied to those analyses.

8 That is because the clear majority view is that
9 applying multiplicity to safety issues, including pill testing
10 for a carcinogen, is not appropriate, and therefore Gibbons'
11 opinions related to multiplicity would be confusing to the jury
12 and should be excluded.

13 Now, power calculations. The only support Defendants
14 cite to for power calculations is the Florian study.
15 Defendants discuss Florian's power calculation and suggest that
16 because Florian did it, then Gibbons should have, but this
17 reasoning is very flawed.

18 First, Dr. Gibbons did not cite to Florian or even
19 consider it. This is because Florian's power calculation is
20 irrelevant and for an entirely different purpose. Florian did
21 a power calculation to see if they had enough subjects for
22 measuring urine and plasma differences within individuals, and
23 because of their concern with only having 17 individuals and
24 understanding these individual differences, whether they were
25 testing enough individuals to possibly detect statistically

1 significant differences.

2 This power calculation by Florian was on patients, not
3 pill testing, and as Dr. Davis explained, the power calculation
4 for whether enough pills were tested to possibly detect
5 statistically significant results is irrelevant. Why? Because
6 Dr. Davis' analyses showed clear statistically significant
7 results, including a six in a hundred million chance that the
8 findings were due to chance, clearly statistically significant,
9 so clearly enough power to reach statistical significant
10 findings.

11 Again, Florian wasn't about pill testing. GSK's root
12 cause analysis that tested pills and was peer reviewed and
13 published in the King study, GSK did not perform a power
14 calculation, and the FDA did not perform a power calculation.

15 Further, for randomization neither GSK's testing or
16 the FDA, or any other testing for pills, has this sort of
17 randomization requirement that the Defendants suggest because
18 this is simply not required.

19 Defendants try to excuse Gibbons' pervasive
20 misunderstandings of Najafi's testing because there are a few
21 things that Davis didn't know. The key difference is that
22 Davis didn't know about a few issues related to Emery Pharma's
23 testing, but those issues were irrelevant to his analysis. He
24 didn't need to know those issues.

25 The issues relevant to Gibbons' analyses regarding how

1 many pills were tested and his criticisms were clearly
2 relevant.

3 And finally, Defendants conflate the number of samples
4 and observations for a particular statistical tool with overall
5 number of samples and observations, and they do this to try and
6 rescue Gibbons' pervasive misunderstanding of important
7 relevant aspects of how pill testing is done, including that
8 each pill can only be tested once and that power calculations
9 and randomization are generally not done for pill testing.

10 Dr. Davis also confirmed that the sample sizes used
11 for the analysis that he did perform were sufficient.

12 Thank you, your Honor.

13 *THE COURT:* All right. Thank you.

14 Let's move into the Olsen motion, Docket Entry 5838.
15 From the Plaintiffs.

16 *MS. BOGDAN:* Good afternoon, your Honor, Rosemarie
17 Bogdan for the Plaintiffs.

18 May it please the Court, I will argue that the Court
19 should exclude the opinion of Dr. Bernard Olsen, a rebuttal
20 witness against Dr. Najafi and Plaintiffs' other experts who
21 reference Emery Pharma's testing. I will focus on three of Dr.
22 Olsen's opinions.

23 First, he claims that Emery failed to follow
24 irrelevant laboratory standards, which they now concede are
25 inapplicable. In truth, Emery followed detailed protocols that

1 confirmed the reliability of its testing.

2 Second, he claims that Emery's LC/MS-MS technique
3 created artifactual NDMA resulting in inaccurately high
4 measurements. In truth, the published literature and Emery's
5 own data confirmed that its technique is accurate and reliable
6 and does not create artifactual NDMA.

7 Third, he claims that Emery's testing results are
8 outliers. In truth, Emery's results are comparable to
9 Defendants' own testing of non-pristine product like Sanofi's
10 21-month plus room temperature stability testing and the
11 Braunstein study's baseline testing. Olsen's opinions are thus
12 disconnected from the facts of Emery's validated reliable
13 testing and should therefore be excluded.

14 Next slide, please.

15 First, Dr. Olsen criticized Emery for allegedly
16 failing to follow proper protocols. That is a bait and switch.
17 He first accused Emery for failure to follow GLP and cGMP
18 standards, but now Defendants concede on page six of their
19 brief that these are specific regulatory requirements that do
20 not apply in this context.

21 Next slide, please.

22 And Defendants' experts like Dr. Lindsley concede that
23 they themselves do not comply with cGMP and GLP either when
24 doing research and development testing. Defendants thus fall
25 back to the position that Emery allegedly did not follow any

standards at all. This is simply false.

Next slide, please.

Here are Emery's extensive experimental protocols governing its testing. These pages and pages of protocols draw directly from the FDA, GSK's root cause analysis, from peer reviewed studies like Braunstein and Gao. They specified the equipment, materials, reagents, calibration standards, quality control samples, detailed testing procedures, and much more.

Next slide, please.

By contrast, let's look at the protocols Dr. Olsen himself used for his own testing in a different case, Cephalon versus Watson Pharmaceuticals. This is his protocol in its entirety for his testing of CO2 in fentanyl. It fails to specify much of what Emery's protocols detail, and it lacks numerous parameters that Olsen now claims are necessary, like dated protocols, an explanation of how the analyst chose the tablets, missing sources where the analyst purchased materials, lists of common laboratory equipment like a mortar and pestle.

Dr. Olsen basically testifies that Emery should do as he says, not as he does, but Dr. Olsen used those protocols that you see because he recognizes they are more than sufficient, as are Emery's.

Next slide, please.

The truth is that Emery followed generally accepted scientific principles and standards that confirm the

1 reliability of its reproducible testing results. Dr. Olsen's
2 opinion should therefore be excluded.

3 Next slide, please.

4 What is Olsen's theory about the column? Dr. Olsen
5 suggests that artifactual NDMA "could be created" in Emery's
6 LC/MS-MS testing technique by heating the sample, leading to
7 inaccurately high results. That contention is rank speculation
8 that flies in the face of refuting facts that Dr. Olsen
9 ignores.

10 Next slide, please.

11 Emery's data itself shows that its testing using a
12 HILIC column did not create artifactual NDMA. If it did, then
13 every single test would show high levels, but that is not what
14 Emery's data showed. For example, this sample showed an NDMA
15 level of 5.2 nanograms, other tablets tested at 7.2, 21.4,
16 15.2, 19.4 nanograms, and so on.

17 Emery's validation, including in matrix accuracy
18 testing, conclusively demonstrates that any hypothetical
19 artifactual NDMA would be consistent across runs, and given the
20 low testing results just discussed, is non-existent.

21 Dr. Olsen's speculation that Emery's testing was
22 consistently biased high by artifactual NDMA is impossible to a
23 core with these low testing results, which again confirms that
24 Emery's testing is reliable and follows generally accepted
25 scientific standards.

1 Emery's other data confirms this point. Emery tested
2 the exact same sample lot with HILIC and the reverse phase
3 column that Defendants prefer, and those two tests of the exact
4 same lot using the two columns show strikingly similar results.

5 Emery tested pills from Sanofi lot 19D452U using both
6 the HILIC and reverse phase columns. For the HILIC the
7 measurement was 11.9 nanograms. That is reflected in Figure A
8 on page 162 of Najafi's report.

9 For the reverse phase, that exact same lot ranged from
10 3.6 to 16.3 nanograms, that is on page 190 -- excuse me, 90 to
11 91 of Najafi's report. Those results were essentially
12 identical. That again refutes Dr. Olsen's speculation that the
13 HILIC columns lead to artifactual NDMA.

14 Next slide, please.

15 Olsen's unfounded theory misunderstands the relevant
16 scientific facts and literature. Defendants ignore a critical
17 fact about this allegation, any artifactual NDMA due to heat
18 would occur during the mass spectrometry stage of the
19 testing when an analyte is ionized, but Defendants' and FDA's
20 testing also exposes the alluded analyte to an MS source, and
21 all of these MS stages heat the sample for mere milliseconds,
22 many orders of magnitude shorter than the fifteen minutes of
23 heating that created artifactual NDMA in Valisure's gas
24 chromatography technique.

25 Next slide, please.

1 As we explained at the previous hearing, HILIC columns
2 are specifically designed to separate highly polar compounds
3 like NDMA. Defendants offer no rebuttal to that, so Defendants
4 speculation that it won't adequately separate NDMA in
5 Ranitidine is worse than speculation, it is demonstrably false.

6 Even if a HILIC column eluted NDMA and Ranitidine at
7 the same time, Dr. Olsen's speculation that the MS source would
8 convert that Ranitidine to NDMA is again refuted by the facts.

9 Next slide, please.

10 Here is Figure 10 in the Waters note that Olsen cites
11 as support for his, quote, "theory". But it actually shows the
12 opposite. Figure 10 shows the chromatographic data when the LC
13 column eluted the Ranitidine into the MS source, and the
14 chromatographs in the red box show a spike for NDMA when
15 the NDMA eluted. Below that red box the chromatograms show a
16 spike for Ranitidine when Ranitidine eluted.

17 Next slide, please.

18 If there were artifactual NDMA creation it would show
19 a second NDMA spike in the area shaded in yellow, but that
20 second spike doesn't exist. That confirms that the MS source
21 does not convert Ranitidine into NDMA.

22 Next slide, please.

23 And indeed, the Waters note labels this
24 chromatograph as confirmation of endogenous NDMA. In other
25 words, the authors concluded that the NDMA was not an artifact

1 caused by the MS source.

2 Dr. Olsen's contrary opinion thus conflicts with the
3 data in the Waters note that refutes his speculation, which
4 Daubert forbids. Indeed, the Waters note confirms the
5 reliability of Emery's testing. Olsen also misunderstands the
6 Yamamoto study. In fact, this paper discusses the possibility
7 of a matrix effect for detecting NDMA, meaning the measurements
8 of NDMA would be suppressed, not artificially elevated.

9 Dr. Olsen ignores these facts which demonstrate that
10 Emery's testing was reliable in accord with scientific
11 standards. That failure to consider all the facts in forming
12 his opinion is fatal under Daubert. His speculation about
13 artifactual NDMA should therefore be excluded.

14 Finally, Dr. Olsen's claim that Emery's testing
15 results are outliers ignores the relevant evidence. The
16 results he looks at largely tested pristine product which
17 yields lower results.

18 Emery's results are fully in line with results of
19 comparable testing of real-world conditions, like Sanofi's
20 21-month room temperature stability testing ranging from 110 to
21 786 nanograms, and the Braunstein study baseline testing
22 ranging from 824 to 1,440 nanograms, and note that the low end
23 of this range was comparable to Emery's average.

24 This shows that when you look at the relevant
25 evidence, studies that tested NDMA levels in comparable

1 real-world conditions, Emery's results are no outliers. Dr.
2 Olsen's opinion ignores that evidence and so should be
3 excluded.

4 Thank you.

5 *THE COURT:* Thank you. And from the Defense.

6 *MR. FRIEDMAN:* Good afternoon, your Honor, Robert
7 Friedman for the Defense.

8 I am going to address the first criticism of the
9 Plaintiffs, then I will turn it over to my colleague, Mr.
10 Bosso, to address the more complicated scientific criticisms.

11 Meanwhile, a little bit about Dr. Olsen, and we will
12 get the slide in a second, but he has a Ph.D. in analytical
13 chemistry, he has served on the Board of the U.S. Pharmacopeia
14 for about 25 years, including sitting on their expert
15 subcommittee on nitrosamine impurities, and importantly, he has
16 written over 55 publications, including a treatise on the HILIC
17 analytical chemistry method that we are going to talk about in
18 a second.

19 So needless to say, his qualifications are not being
20 challenged here.

21 If I could have the next slide, please.

22 What Dr. Olsen did is what most rebuttal experts do,
23 is he reviewed Dr. Najafi's work and identified problems with
24 it, and this slide is not meant to be exhaustive and I am not
25 going to really go through it, it is just some examples of how

1 Dr. Olsen looks at part of what Dr. Najafi did and identified
2 an issue.

3 So, for example, the last one, Dr. Najafi wants to
4 tell the jury that the Defendants' product -- that the testing
5 that he did was validated and consistent and Dr. Olsen's
6 opinion is, it is not, and he goes on to explain why.

7 This is perfectly appropriate -- next slide -- because
8 this is what rebuttal experts do. They do not have to disprove
9 the work of the expert they are challenging. They simply are
10 allowed to criticize or rebut the methodology or opinions of
11 another expert, and that is precisely what Dr. Olsen did here.

12 There are some criticisms in the briefing that Dr.
13 Olsen didn't actually do his own testing and disprove the
14 results, or he can't say as a factual matter that the results
15 are wrong, but that is not required of a rebuttal expert like
16 Dr. Olsen.

17 Next slide, please.

18 These are the four criticisms laid out in the motion
19 and I am going to start with the first one related to the
20 standards.

21 Jump two more slides, please.

22 What is Dr. Olsen's opinion? Which we say is
23 undeniably correct. It is that Dr. Najafi did not apply any
24 standards, and what he saw when he looked at Dr. Najafi's
25 report is, Dr. Najafi said, well, my lab is cGMP/GLP compliant,

1 implying that he followed those standards, and Dr. Olsen said,
2 no, he didn't.

3 At his deposition, Dr. Najafi said that is true, I
4 didn't, but I didn't have to. Well, we never -- Dr. Olsen was
5 never arguing that he had to. The point Dr. Olsen was making
6 is that he doesn't identify any standards that he used.

7 Now, the Plaintiffs have come back and said, no, no,
8 here are some protocols he followed, but protocols are not
9 standards. Protocols are specific to particular tests, and
10 they are step by step how you do a particular test. They are
11 not how you conduct tests as a general matter, how do you
12 document them, how do you run your laboratory properly so that
13 other scientists can review it.

14 We know they are different because Dr. Najafi admitted
15 it. At his deposition he was asked, what standards did you
16 apply? On page 140, lines 4 to 14, he said, well, the
17 standards I applied are "generally acceptable scientific
18 principles. They are not written anywhere that I can go and
19 point you to."

20 If the answer to the question was, well, they are the
21 protocols, he would have just said they are the protocols, but
22 he didn't. He said my standards are not written down anywhere,
23 they are not the CGMP standards, they are not any NIH
24 standards, they are not any standards that different companies
25 and different organizations can follow.

1 So, Dr. Olsen's opinion that Dr. Najafi didn't follow
2 any standards in doing his testing is undeniably correct.

3 With that, I will turn it over to my colleague, Mr.
4 Bosso, to address the other two criticisms.

5 *THE COURT:* Okay. Thank you.

6 *MR. BOSSO:* Good afternoon, Luke Bosso for BI and on
7 behalf of all brand Defendants.

8 *THE COURT:* Good afternoon.

9 *MR. BOSSO:* Plaintiffs also argue that Dr. Olsen
10 cherry picked data. This is essentially the outlier opinion
11 you just heard about. Normally, when people say that an expert
12 cherry picks data it is because there are some data they
13 ignored which would undermine their opinion. Plaintiffs have
14 not identified any true apples to apples data set that would
15 undermine Dr. Olsen's opinion.

16 What you see on the screen -- I know we have given
17 this graph in various forms before and a version of this was in
18 Dr. Olsen's report -- is an apples to apples comparison because
19 it compares baseline to baseline and it compares unexpired
20 tablets to unexpired tablets.

21 Now, what Plaintiffs just got up and compared their
22 results to is saying Emery's baseline testing is similar to
23 Sanofi's stability testing and similar to Braunstein's
24 simulated gastric fluid study where you put it in with -- in a
25 simulated incubation and then test it. Those are not baseline

1 testing results, those aren't comparable, these are the data
2 that you can actually compare them to.

3 They also criticized them because they were pristine
4 samples. I want to note that Emery, pre-litigation, a hundred
5 percent of those samples were from the market, so if those were
6 pristine samples, that is because the storage and transport
7 processes ensured that the products got to the market with very
8 little NDMA present.

9 FDA, that included samples from the market, Cabillo
10 included samples from the Spanish marketplace, Al-Shiri
11 included samples from the Saudi Arabian marketplace. These are
12 real-world samples that you compare them to.

13 The true issue is that Dr. Najafi wants to tell the
14 jury, I tested these Ranitidine products and my samples are
15 actually representative of what you get on the market, and Dr.
16 Olsen says, wait, we have all this data that is actually from
17 the market and it is entirely inconsistent. Plaintiffs have no
18 good answer but to point you to stability results and simulated
19 gastric fluid studies which are just inapplicable.

20 The next slide.

21 Next I am going to address the third argument.
22 Defendants' position is that Plaintiffs are misconstruing Dr.
23 Olsen's opinions so I want to start by first outlining exactly
24 what his opinions are.

25 First, Dr. Najafi in his report and his deposition

1 continuously says that Ranitidine is highly unstable and
2 affected by temperature. This is critical because his testing
3 actually exposes Ranitidine to 300 degrees Celsius. Plaintiffs
4 can speculate that while Dr. Najafi says, you know, Ranitidine
5 degrades everywhere, in a hot car, in a bathroom, even at room
6 temperature, at around 20 degrees Celsius, in this testing that
7 uses even higher conditions, this is the one place on earth
8 where Ranitidine is stable.

9 Now, Plaintiffs can speculate, but outside litigation
10 researchers actually prove that their methods do not cause
11 artifactual NDMA formation.

12 So, we heard a lot about the Waters 2020 note today.
13 Those researchers were actually doing the work necessary to
14 validate their method, and they can actually point to testing
15 that they did to show we considered this issue, we confirmed it
16 was not causing artifactual formation, and therefore the method
17 is validated.

18 Dr. Najafi has never demonstrated that for his method,
19 and since that is required to say that your method is
20 validated, he cannot continue to say that he sufficiently
21 validated his method. Plaintiffs essentially recast this as a
22 "volatilization theory" which is a term that does not appear
23 anywhere in Dr. Olsen's report or in his deposition.

24 Next slide, please.

25 Essentially the scientific community agrees with Dr.

1 Olsen's criticism about how Emery or Dr. Najafi failed to
2 validate his method. In fact, as you heard earlier, Dr. Olsen
3 relies on Waters 2020, which has that same graph you saw
4 earlier. I will explain exactly why.

5 Now, Dr. Najafi's reliance on Waters 2020 is
6 completely misplaced, and this was discussed both by Dr. Olsen
7 and Dr. Guengerich.

8 Waters 2020 uses a different method than Dr. Najafi.
9 Waters uses a reverse phase separation followed by an
10 ionization technique called APCI, whereas Dr. Najafi used the
11 HILIC separation followed by an ionization technique called
12 electrospray.

13 This is saying trying to extrapolate from Waters to
14 Emery is just a complete apples to oranges, yet Dr. Najafi is
15 forced to do this extrapolation because he has not conducted
16 that testing himself.

17 Likewise, while Dr. Najafi attempts to use Waters 2020
18 to justify the fact that he didn't actually do this
19 demonstration himself, and that he doesn't need to demonstrate
20 separation of Ranitidine API from the other impurities, Waters
21 disagrees and specifically says, despite the finding in Table
22 10, separation of API from the impurities is critical.

23 And finally, it cannot be lost that in Waters 2020,
24 those lines you saw on those graphs, those were chromatograms,
25 processed chromatograms that those researchers put forth into

1 the scientific community to prove that their methods were
2 validated.

3 Still to this day, in this MDL there has not been a
4 single processed chromatogram produced by Plaintiffs that Dr.
5 Najafi will authenticate on his own. I am going to show you a
6 chromatogram that our consultant has generated, but that they
7 dispute as being an accurate representation.

8 Let's go to the next slide.

9 I want to show you empirical evidence because you said
10 that Dr. Olsen doesn't have a bit of proof for this, but I
11 actually want to show you the real empirical evidence we have.

12 As you can see here, there are four chromatograms.
13 Two of the chromatograms on the left are Dr. Najafi's
14 calibration solutions, meaning that there is no Ranitidine in
15 these samples. The top chromatogram measures NDMA and the
16 bottom measures the internal standard version of NDMA.

17 Contrast that with the left side, the sample
18 contains -- or the right side, this has Ranitidine in it, the
19 top measuring NDMA, and the bottom measuring internal standard
20 version.

21 On three of these four chromatograms you see clean and
22 well-resolved peaks, and importantly, in these three
23 chromatograms there is no potential for artifactual NDMA
24 formation either because, one, there is no Ranitidine in the
25 sample or, two, because internal standard version of Ranitidine

1 molecule never degrade into internal standard version of NDMA.
2 But the place where you can actually get artifactual NDMA
3 formation is this red circle. This is all NDMA appearing in
4 the Ranitidine sample.

5 Dr. Olsen has reviewed these chromatograms, and
6 chromatograms like this, and said that there is no way that a
7 reliable chromatographer would look at this and proceed to
8 actually rely on this result.

9 It is hard to tell on this figure, but there is an
10 asterisk next to this 1.803, and that is because although the
11 computer didn't recognize this as a valid peak, an analyst at
12 Emery manually went in and overrode the decision and said, I am
13 still going to use this as a peak.

14 This is the same type of chromatogram that has been
15 used for all of the baseline, stability, and zone testing that
16 serves as the basis of extrapolation by other experts, like you
17 heard Dr. Davis, Dr. Salmon, Dr. Panigraphy, and I believe Dr.
18 Le.

19 Last, I want to address just a few points made by
20 Plaintiffs. First, Plaintiffs -- this is about the low
21 findings argument. Plaintiffs argue that if artifactual
22 formation was occurring, it would occur in every sample of
23 Ranitidine. This argument, however, is belied by Dr. Najafi's
24 own opinions.

25 In his rebuttal report, on page 13, Dr. Najafi writes

1 "The exact batch/lot of products dictated the course of NDMA
2 formation from Ranitidine. In fact, no two Ranitidine batches
3 have behaved identically when exposed to stress or stability
4 conditions." He goes on to say, "It is possible that some
5 Ranitidine drug products may only generate a few nanograms of
6 NDMA."

7 So having low artifactual formation in some samples
8 and high artifactual formation in other samples is entirely
9 consistent with Dr. Najafi's own opinion.

10 Additionally, n matrix accuracy, they argued that, and
11 as far as I can tell based off the current record, there is no
12 evidence that Dr. Najafi ever conducted n matrix accuracy
13 testing for his HILIC method, and I will give you a cite. I
14 know it is generally hard to cite a negative, but on page 11 of
15 Dr. Najafi's rebuttal report he indicates that he performed n
16 matrix accuracy only for two types of samples, effervescent
17 tablets and injectables.

18 Notably, the methods for these two types of samples
19 was reverse phase and not HILIC.

20 Lastly, conceptual separation. Plaintiffs continue to
21 argue that they have evidence that the HILIC method should
22 separate NDMA from Ranitidine. First, this is something that
23 needs to be tested with empirical evidence; and second, there
24 is a fundamental flaw in Plaintiffs' reasoning.

25 The true issue is whether NDMA is separated from

1 Ranitidine, but Plaintiffs do not put forth even conceptual
2 evidence of how Ranitidine reacts within the HILIC column. So,
3 looking just at NDMA is insufficient to tell you whether there
4 will be separation between NDMA and Ranitidine.

5 As for the remaining arguments, we are fine to rest on
6 the papers and ask this Court to deny Plaintiffs' motion.

7 *THE COURT:* Okay. Thank you very much.

8 Any rebuttal from the Plaintiffs?

9 *MR. SELIGMAN:* Yes, thank you, Matthew Seligman for
10 the Plaintiffs on rebuttal.

11 Can we pull up the first rebuttal slide.

12 I am going to focus today about this issue about
13 artifactual NDMA formation and whether that is apparent in the
14 chromatograms that Emery itself produced.

15 This is Figure 2 that appears on page 15 of
16 Defendants' opposition brief, and so, what is going on here is
17 that the Defendants are suggesting that the NDMA peak in the
18 chromatogram on the left, which was created by the FDA, shows a
19 clear spike without any indication of an artifact, an
20 unidentified detector response, and so it is reliable, whereas
21 Dr. Najafi and Emery's NDMA peak on the right is more
22 complicated and therefore is unreliable.

23 Now, this comparison is inapt and misleading for a
24 variety of reasons.

25 Next slide.

1 The FDA chromatograph that was displayed in Figure 2
2 of the brief was not from LC/MS-MS chromatography, it was from
3 LC/HR-MS chromatography, a completely different technique, and
4 that really matters. The difference here is that in LC/HR-MS
5 chromatography the separation -- difference between LC/HR-MS
6 and LC/MS chromatography really matters in this context.

7 The difference is that LC/HR-MS chromatography
8 separates the analyte from the sample only using the column,
9 not using the mass spectrometry. What the means is, as is
10 widely recognized in the scientific community, LC/HR-MS is just
11 not as accurate and not as precise in fluctuations in a sample.

12 As a result of that -- if we go to the next slide --
13 you can see that the chromatograph on the left is just smoother
14 than the one at the right, and that is because the technique is
15 not picking up small variations.

16 Now, you will also note that on the left, the
17 chromatogram, the baseline is not zero, the baseline is at
18 about 50 to 60 of the relative magnitude, so there is a
19 detectable response there, and that matters for another reason
20 as well, which is that the Defendants here are comparing apples
21 and oranges, even taking aside the different techniques in
22 these two chromatograms.

23 Next slide.

24 This is -- unfortunately, the slide is a little bit
25 off, but what this slide will show is that in that very same

1 FDA report using the LC/HR-MS technique, what you don't see
2 here is actually the baseline is about 90 to 95 of what the
3 ultimate peak is, so I will just describe it to you. It is
4 basically a horizontal line with some squiggles on it and then
5 a tiny little hump.

6 What that shows is that when the FDA, using its
7 LC/HM-RS process, and actually and tested drug product, that is
8 a pill that has all of the complications in the matrix that
9 Emery tested, then it found that you have an extremely high
10 detector response with just a tiny little hump on top of that.

11 So, that is why Emery decided to use LC/MS-MS, rather
12 than LC/HR-MS, which is what so many other of the Defendants
13 did. The FDA actually did testing using LC/MS-MS as well, and
14 we can see the difference in what the chromatographs look like.

15 Next slide, please.

16 Here is another report about a month later. This is
17 from October 17, 2019, where the FDA set forth its protocols
18 and its methodology for using LC/MS-MS of Ranitidine drug
19 products. Let's look at what those chromatographs look like.

20 Next slide, please.

21 This is a chromatograph using LC/MS-MS just for water,
22 nothing else. You can see that the line is squiggly, there is
23 a lot of noise, and the reason is because the methodology of
24 LC/MS-MS is extremely effective at picking up small variations
25 in the signal. That is the advantage of LC/MS-MS.

1 Let's look at what the FDA found when it applied
2 LC/MS-MS methodology to an NDMA sample.

3 Next slide.

4 Here is what it looks like, and you can again see that
5 there is a lot of noise in here because the methodology is
6 highly effective at picking up small variations in the signal.

7 If we compare this chromatograph back to the ones that
8 the Defendants represented was somehow unreliable -- next
9 slide -- we can see, well, actually, it is not that different
10 from the one on the right, there are squiggles, but there is
11 also a clearly defined spike.

12 That just undermines the comparison that the
13 Defendants are trying to make here between the FDA's
14 chromatograph using a different methodology of a pristine API
15 as opposed to the actual drug product.

16 Now, there are other problems in the comparison as
17 well. What we find in these types of chromatographs and
18 LC/MS-MS are these squiggles are called baseline imperfections,
19 and they are absolutely routine in the science. The question
20 is: How big are they and how does the analyst deal with them?
21 The answer of how big they are really matters.

22 Next slide.

23 *THE COURT:* That is five minutes.

24 *MR. SELIGMAN:* I will wrap up in a second.

25 *THE COURT:* Okay.

1 *MR. SELIGMAN:* Here we have two different
2 chromatographs from two different samples. We can see the top
3 one where the NDMA was about 100, and the bottom one where the
4 NDMA was about 16,000. The baseline imperfections are about
5 the same absolute magnitude always. What that means is that
6 the very high values that you see in some of Emery's sample
7 testing isn't explained by these alleged baseline
8 imperfections.

9 Instead, it is only extraordinarily small variations
10 that you find from the inherent sensitivity of the LC/MS-MS
11 process and only for small readings of NDMA.

12 Thank you.

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

14 Let's go into the last, the Wang presentation, which
15 is a total of 15 minutes, and then we will take a break after
16 that.

17 We are going to hear from Defense first on that one.

18 *MR. PETROSINELLI:* We have to retrieve Mr. Cheffo.

19 *THE COURT:* I didn't give notice. Is he nearby?
20 Otherwise, one of you can just jump in.

21 You're busted, the one time the Court goes out of
22 order. We were going to take a break, but we will do the 15
23 minutes, you get ten, Plaintiffs have five, and then we will
24 have some questions and then closing and make sure everyone
25 gets out on time.

1 MR. CHEFFO: Thank you, your Honor, Mark Cheffo for
2 the Defendants. Good to see your Honor.

3 We asked for an opportunity, so thanks for a chance to
4 do that. I understand you may have some questions about our
5 stipulation, but I am going to address where we are on this
6 right now, in ten minutes.

7 This study was just published. The Plaintiffs have
8 submitted some supplemental reports, so we wanted an
9 opportunity to share some initial thoughts and observations
10 about the study so you are not kind of left without that.

11 As I was listening today, a few things, I was thinking
12 situational science, maybe I am nerding out and also cherry
13 picking. It also felt a little bit like I was watching a
14 tennis match because on the one hand, we have heard so much
15 about, prior to today, active comparators and all the problems,
16 and we really shouldn't pay much attention to it, but yet,
17 today when we see the Wang study, lots of slides, active
18 comparators, maybe they're not so bad.

19 In the Wang study there is actually a statistically
20 significant protective finding for liver for PPIs, but we have
21 also heard a lot of stuff about maybe that is kind of
22 confounding because of PPIs.

23 Si, I think as we go through some of the slides you
24 will see that it is kind of like which way is it? Because the
25 Plaintiffs can't have it both ways. I think they said early

1 on -- there are two things. Ms. Finken said this supports an
2 increased risk for all of the cancers at issue here, and Mr.
3 Snidow said this is a real problem for our experts.

4 I think it is just the opposite, and we will talk
5 about the one finding, the statistically significant liver
6 cancer finding, but when you look at everything else in the
7 study, it is absolutely consistent with everything that we, but
8 more importantly our experts have said to you literally since
9 the beginning of this litigation.

10 Next slide, please.

11 So, you know, it is important to look at kind of what
12 the authors say and what they don't say, what they do and what
13 they don't do.

14 The authors -- this came out last week. Previous
15 studies, including studies on NDMA and studies looking at
16 Ranitidine were contradictory. The data were not sufficient to
17 reach definite conclusions. The conflicting results of studies
18 underlie the lack of concrete evidence supporting the role of
19 Ranitidine in cancer development.

20 That is kind of stunning, that essentially the
21 Plaintiffs have gone all in on this study. I am not going to
22 talk about the specifics other than to say lots of paper, ink
23 spilled on this. This basically says exactly what we are
24 saying, it feeds into the law lag, science, and everything
25 else, which is this study says, as of last week there is

1 contradictory and there is a lack of concrete evidence.

2 That is exactly the point here, that the world's
3 community has looked at this, they are submitting a study that
4 says there is no there there with respect to causation.

5 Next slide, please.

6 How much time have we heard about followup? I think
7 you may recall from Dr. McTiernan, they made the same kind of
8 argument, well, the followup is a problem, but then we showed
9 you that her own studies were right in the middle, but again,
10 you can't have it both ways.

11 This study is followup right in the middle of the
12 other active comparator studies, so if it's a problem for all
13 of them, certainly it would be a problem for Wang that their
14 experts are saying you should rely on it.

15 Next slide, please.

16 We saw this slide today. Well, the really good
17 studies are the ones that address confounding for smoking. The
18 ones that get time out, the X, they are the ones that don't
19 address it.

20 What is missing from this? Wang. It would be on the
21 left hand, the time out side with the X boxes. So, again,
22 situational science, is it good to do it, is it not good to
23 address confounding? Can't have it both ways.

24 Next slide, please.

25 I want to take a minute on this because you have seen

1 snippets, unfortunately, today. I think maybe twice we saw a
2 finding for bladder cancer from Cardwell and then you saw it
3 kind of switched quickly, and then there was this assumption
4 that this study and these studies kind of -- don't look over
5 here because they show causation for all of the cancers, but
6 this is what this study does.

7 When the Plaintiffs say it is actually supportive of
8 them or gives our experts a problem, it is hard to understand
9 that when you look at the data.

10 They looked at a number of different cancer end
11 points, but I obviously put up the five because those are the
12 five that are at issue here.

13 You heard a little bit about this earlier, Mr. Boehm
14 mentioned this. When they looked at bladder and esophagus,
15 there is no statistically significant finding, zero. That was
16 their big focus two weeks ago, but we didn't hear anything
17 about bladder from the Wang case.

18 If anything, this completely undercuts everything they
19 have been saying about bladder and esophagus just on its face
20 from statistically significant findings. We are trying to give
21 you all the information, so you see gastric, pancreatic, and
22 liver, there are statistically significant findings. This is
23 nonuse, but we want to present all to be fair to the Court.

24 Then you go to the next column, the dose response.
25 They didn't do a dose response for esophagus and bladder

1 because essentially it was supposed to be confirmatory, more
2 information reliability, but they didn't pass go with respect
3 to those, so they didn't do a dose response.

4 They did do a dose response for gastric and
5 pancreatic, and when they did the dose response, which you have
6 seen charts from the Plaintiffs today and before that that is
7 really important, what they find is no dose response, their
8 study for these four cancers, and this is in nonuse.

9 They do find it -- obviously I am not ignoring liver,
10 there's checks right below, but they kind of do pass go on
11 these four guideposts with respect to liver, but I also think
12 it is important that we kind of understand what this study says
13 and what it doesn't say.

14 Then, when they look at the active comparators, which
15 we have heard a lot about and certainly the most reliable type
16 of analysis, you see again no association, no statistically
17 significant association other than liver, so that is
18 compelling.

19 Then, there was also a PPI finding, and again, it was
20 only statistically significant with respect to liver, and the
21 point again there is what I raised earlier, when you look at
22 the PPI finding from this study, it is statistically
23 significant protective, so that is at odds with a lot of what
24 we have heard about from the tension.

25 Next slide, please.

1 So, you know, context is everything. You have heard
2 probably more than you will ever want to in your next
3 litigations consistency and replication, it is going to start
4 rolling off your tongue like it does with us, but again, we
5 didn't come in a few weeks ago, or before the Wang study, and
6 say, look at this, it is protective, and these are data points
7 that answer the question.

8 What we said and would say now is, when you look at
9 Kim, Yoon, and Iwagami, Wang is not the only study out there,
10 this shows, at best, no association. There is protection here
11 in the Kim study, but when you look at Wang you can't just
12 ignore everything else that is in the world's literature.

13 At best, this says one positive finding, one
14 protective finding, and the other two that on the left side,
15 but they certainly don't show any causation. They aren't like,
16 ah-ha, mission accomplished on this.

17 Next slide, please.

18 This idea of consistency, right, is -- I won't repeat
19 this much more, but this is from Dr. Moorman, right, that
20 judgments on causality by epidemiologists typically are not
21 based on a single study or even a few results. We agree with
22 that.

23 Where does this take us? This takes us to the point
24 which I think is fully consistent with, frankly -- to the
25 extent good lawyers on both sides try to have themes or have a

1 thematic approach to this, our thematic approach is you can't
2 cherry pick, right. If you like active comparators and you
3 think they are compelling and important, then you have to take
4 the good with the bad.

5 If you basically want to look at a particular study,
6 you can't basically say, oh, just look at the liver cancer
7 finding and that supports everything that we say, and will give
8 their experts a lot of problems when in the same ten -- 18-page
9 study it also shows data points that are at odds, fully
10 inconsistent with everything the Plaintiffs have told you with
11 respect to the other four cancers.

12 And as I said, with respect to the liver cancer
13 findings, and maybe our experts will have more to say on the
14 validity of that, but for today's purpose, taking it as a valid
15 point, even if it were accurate, even if it were true, it
16 doesn't change anything because, at most, we have one over
17 here, one over here, two in the middle, and that is not
18 causation, your Honor.

19 *THE COURT:* Thank you. And from the Plaintiffs, you
20 have asked for five minutes.

21 *MR. SNIDOW:* Could I have the Defendants' slide 4 up
22 again for a second. I won't get to it for a moment.

23 Before I dive in, I think it is worth taking a pause
24 and clarifying what actually happened in Wang because it is
25 easy to get lost in the distractions.

1 That study, which included 99 percent of the
2 population of the entire country of Taiwan, which although it
3 is a small island, it's one that is pretty dense, about the
4 size of Florida, they went back in the registry and matched
5 cohorts of 50,000 people. This is exactly the kind of study
6 design the Defense said is the most reliable. We heard it last
7 week, we heard it again today, gold standard, most like a
8 randomized control trial, top of the line, the list goes on.

9 What they did, and this is so critical, is they looked
10 at these matched cohorts, which were designed to be as
11 identical as possible across a variety of characteristics, and
12 they compared which group got more cancer. They did it for
13 Ranitidine versus non-Ranitidine, and the answer was that the
14 people who took Ranitidine got more cancer.

15 They did it with a comparator to a heartburn
16 medication, and the answer again was the people who took
17 Ranitidine got more cancer. That is powerful evidence that
18 what our expert has been saying is reliable, and is powerful
19 evidence to what the Defendants answered in their expert
20 reports really wasn't the right general causation question at
21 all.

22 I want to be clear on one thing, we can talk about
23 statistical significance, but I don't want this to get lost in
24 the weeds because it is just true. When they looked at those
25 50,000 cohorts in that study, the cohort who took Ranitidine

1 got more cancer for every single type of designated cancer in
2 this litigation. Those are the numbers. We can talk about
3 significance, but those are the numbers.

4 A few other points. Primary methodologies. As the
5 Court knows, the Eleventh Circuit has this three primary
6 methodology thing. On background risk, if the Court looks at
7 Table 2 you will see that the Wang study authors quote the
8 background risk for each of the designated cancers as well as
9 the risk for people using Ranitidine.

10 Dose response, that's Table 3, I talked about it this
11 morning, but it is true, at least for liver and for stomach
12 cancer the dose response there is clear, and for pancreatic,
13 our experts get into it, but there is a dose response as well.

14 Epidemiology is the third primary methodology, and if
15 the Court looks at the conclusion section of Wang, it is, of
16 course, an epidemiology study, and what those study authors
17 conclude is that in their real-world study their results
18 suggest a real link between Ranitidine and cancer.

19 Next, Wang looks at and confirms all of the criticisms
20 of the Defendants' studies that we have been lodging all along.

21 I showed a slide -- Ms. Finken showed a slide of it
22 this morning, they looked at the Iwagami and the Yoon study.
23 Defense counsel earlier tried to make it seem like, well, look,
24 they noted that there were inconsistencies, they were going
25 against the grain.

1 What actually happened was good science. The Wang
2 study authors said, huh, we showed a real result here, in past
3 studies they got a null, no signal emerged. What happened?
4 What the Wang study author said was that in those two studies,
5 the ones it looked at, Iwagami and Yoon, it was the low
6 followup, and they identified the low number of subjects. That
7 is exactly what our experts have been saying.

8 Similarly, I showed you that chart in my earlier
9 presentation with the lines diverging. If the Court is
10 interested in knowing why we have been saying all along, well,
11 I know you have these active comparator studies, but how much
12 Zantac did those people take, the reason is because the lower
13 the dose of Zantac that people took in Wang, the lower their
14 cancer rate and the harder it is to distinguish a real
15 association.

16 The same with for lag time. If you look at that same
17 chart, if you go out 18 years the risk is very clear. If you
18 look at only three years the risk is not so clear, and that is
19 critical given that the Defendants' studies that they say are
20 the gold standard and that you have to laser like focus on are
21 very, very short.

22 Just to be clear, we are not cherry picking. I said
23 it before, but I will say it again in case you thought maybe I
24 misspoke, in the abstract active comparator studies is a good
25 thing. It absolutely does reduce the risk of confounding by

1 indication.

2 But when you look at an active comparator study, you
3 have to evaluate it on its own merits. You have to look at not
4 just did it do an active comparison, whether it was structured
5 in a way that is going to detect the actual risk that you are
6 looking for.

7 I did want to say two bars on smoking.

8 *THE COURT:* Well, I know you all negotiated your time,
9 so why don't we keep it to what you all agreed to.

10 Okay, all right. So, we will take a ten-minute break.
11 So it is 3:13, we will be back at 3:23, and I will ask a few
12 questions and then we will do the closing. I will try to get
13 you out by 4:30 so nobody is stressing about their flights. Be
14 back at 3:23.

15 (Thereupon, a short recess was taken.)

16 *THE COURT:* Okay, I have a few questions and then I
17 have some more questions, so try to give quick answers to the
18 best that you can so we can get through this, and then I will
19 turn it over to counsel for closing, which I will do no later
20 than 4:10, maybe even sooner, and you have allotted 20 minutes
21 for your closing.

22 So, question -- this goes back to epidemiology for the
23 Plaintiffs. In your omnibus motion in support of your argument
24 that Defendants' experts failed to apply the Bradford Hill
25 criteria, you state "the Defense experts disregard the

1 associations that have been found in multiple observational
2 studies and ignore the conclusions of the study authors
3 themselves."

4 Can you explain the importance of your assertion that
5 the Defendants' experts ignored the conclusions of the study
6 authors as succinctly as you can?

7 State your name before you respond.

8 *MR. SNIDOW:* If memory serves, that was the situation
9 where the study authors themselves said the study is not long
10 enough for them to predict the risk, to the extent it is there,
11 and the witness in question said, I disagree with that, I think
12 it is long enough.

13 Our view is that that indicates that particular expert
14 didn't review the literature in a way that is proper. Frankly,
15 I don't think standing by itself that is probably grounds for
16 exclusion under Daubert, but -- sorry, the other one, Tracy is
17 reminding me.

18 In Cardwell the study authors noted there was an
19 association, which there was, and the expert said that the
20 association was invalid. So our view is that it is an
21 indication that that particular expert didn't conduct the kind
22 of review that is required under Daubert.

23 I am not sure standing by itself that one thing would
24 be enough, but that is how it is played into our argument.

25 *THE COURT:* Okay. On a more general level, what is

1 the problem, I guess not with any particular -- the Cardwell
2 or -- just generally, the Plaintiffs' position on an expert
3 disagreeing with the conclusions of the study authors.

4 MR. SNIDOW: I think it depends on the situation. It
5 is hard to answer in the abstract, Judge. For example, to the
6 extent that the study actually reports an association
7 numerically, and one epidemiologist is looking at all of the
8 associations, the fact that the study authors didn't call out
9 an association in that study, if you look at it in context with
10 the other studies, it could still be evidence of association.

11 If it is something where the expert is just wrong
12 about a fact in the study and one of the study authors is
13 saying something contrary to the expert, then I think that is
14 grounds to be concerned.

15 I feel like I am not answering the Court's question,
16 but it is hard to answer in the abstract.

17 THE COURT: Okay. Response from the Defense.

18 MR. TOBEY: Danny Tobey, your Honor. I think that is
19 a reference to Dr. Witte, and what he said was he disagreed
20 with that conclusion, but in his analysis he only applied it in
21 as far as that author reached in his own conclusion, so he
22 stayed within that boundary for his application.

23 THE COURT: Okay. Defendants' position generally on
24 if an expert is disagreeing with the conclusions of a study
25 author.

1 MR. PETROSINELLI: Your Honor, we think that is a
2 critical factor under Daubert. The McClain case is probably
3 the leading case in the Eleventh Circuit on this issue where it
4 pointed out that when the Plaintiffs' experts were reaching
5 general causation opinions based on studies where the authors
6 not only had not reached causation opinions, but also had
7 explained the results of their studies and why they thought the
8 point estimates were this or that, and that Plaintiffs' experts
9 disregarded it, that was grounds for exclusion.

10 It indicates a methodological defect, and as we
11 pointed out two weeks ago, that is a main problem with the
12 Plaintiffs' experts.

13 THE COURT: Okay. Thank you.

14 MR. SNIDOW: Your Honor, Ms. Finken just reminded me
15 of something that I think is important.

16 I believe the case law is that experts shouldn't
17 disagree with the conclusions of the study authors without
18 explaining why in a way that is reliable under Daubert. So, we
19 argue, and correctly, that the things that we deemed their
20 experts were ignoring were things that they hadn't adequately
21 explained for ours. This goes back to the general point I was
22 making all morning, they do a much more fulsome analysis and
23 explain exactly why they are saying what they are saying.

24 THE COURT: Thank you. For Plaintiffs, in your
25 omnibus motion, Docket Entry 5841, you state that the

1 Defendants' experts asked the following question, "Assuming
2 each Plaintiff is typical of the subjects in the human
3 epidemiological Ranitidine studies did Ranitidine cause her
4 cancer?" Docket Entry 5841, at 9 through 10.

5 You state that Defendants answer the question with no,
6 and state the answer is "unsatisfying" because "many Plaintiffs
7 are not like the typical ones in the human epidemiological
8 studies and those studies do not measure the long-term effects
9 of Ranitidine use."

10 Can you clarify why many of the Plaintiffs are not
11 "like the typical ones in the human epidemiological studies?"
12 Is there any additional reason apart from your assertion that
13 epidemiology does not measure the long-term effects of
14 Ranitidine use?

15 *MR. SNIDOW:* Can I give you the second one first? One
16 large one is dose, or exposure as it is sometimes referred to
17 in the literature. It is true that a lot of the Plaintiffs in
18 the MDL took Ranitidine for much longer than were measured in
19 the studies that the Defendants' experts rely on.

20 As I said, in our registry 60 percent of the
21 Plaintiffs took Ranitidine for more than ten years. That is
22 just not true for a lot of the subjects that were in the
23 studies that the Defendants rely upon.

24 Sorry, your Honor, would you remind me of the first
25 part of your question?

1 *THE COURT:* Why many of the Plaintiffs are not like
2 the typical ones in the human epidemiology studies.

3 *MR. SNIDOW:* That is hard to say. It depends on the
4 study, how it is designed, where the study was located in the
5 world, what data set they were relying upon. I will give one
6 concrete example, your Honor, it is not a complete answer,
7 there are lots of reasons.

8 Some of the studies included age cutoffs that make the
9 cohorted issue more like the Plaintiffs in others. In Wang I
10 think the cutoff was 40. They excluded patients under 40
11 because people under 40 are not likely to get cancer. In some
12 of the studies the Plaintiffs relied on, I showed you the data,
13 the median age was 54, 56, which is a patient population that
14 is not likely to get cancer.

15 If the Court is asking why that is, I am not sure I
16 can answer that. It really just depends on the study and how
17 they pick their cohort, but the fact remains is, in a general
18 causation case where you have to consider the highest possible
19 dose taken, and the longest followup time that is possible, you
20 do need a study that mimics those parameters and all the other
21 ones we point out in the brief.

22 Their studies don't for whatever reason, and I am not
23 criticizing them, but it is just they don't.

24 *THE COURT:* Is there any brief response?

25 *MR. PETROSINELLI:* It would not be very brief, but I

1 will give this brief response. What you heard at the end about
2 this whole issue of for general causation you must look at what
3 the highest dose of Plaintiff in this MDL could be is
4 completely wrong, totally inconsistent with Eleventh Circuit
5 case law. I was going to address that in closing, but I can do
6 that now.

7 *THE COURT:* Okay. Plaintiffs, in your omnibus motion
8 you state, "Even despite the significant flaws and limitations
9 in the designs of the Ranitidine human epidemiological studies,
10 there still exists evidence of an increased risk of bladder,
11 liver, pancreatic, esophageal, and stomach cancer with exposure
12 to Ranitidine," at page 69.

13 I understand your position to be that the human
14 epidemiological studies are unreliable for a number of reasons,
15 including that they did not, as you state, have enough followup
16 time; however in your motion you state that despite the reasons
17 why they cannot be relied upon, that they provide evidence that
18 supports your experts' opinions.

19 Can you explain how you reconcile these two ideas?

20 *MR. SNIDOW:* Yes. That is one of the things I was
21 going to get into on Wang. Do you remember in the Defendants
22 chart they said Wang was the same length of time -- I think
23 this is one of the things you are getting at.

24 So, if you want to know whether a substance causes
25 especially a long-term disease like cancer, and you study it

1 for 30 years and you don't see anything, that won't tell you --
2 that might tell you something very important.

3 If you are followup time is low, and you don't see
4 anything, that can be for one of two reasons, either there is
5 really no association, or there is an association and you
6 didn't wait long enough for it to show up.

7 Both sides have used cigarettes all day, it's an easy
8 one. If you imagine a study that looked at people who smoked a
9 lot of cigarettes, but then you waited one year to see if they
10 got cancer, you might not see anything. If you waited three
11 years, you might not see anything. If you waited five years,
12 given cigarettes, you actually might see something, and that
13 would be really, really powerful evidence of association, but
14 the fact that Wang is the same -- given that Wang did show an
15 association, the fact that Wang was the same length as some of
16 the Defendants' studies doesn't undermine our general point
17 that ideally you want to wait for 30 years.

18 *THE COURT:* Putting aside Wang, just more generally
19 how your experts can rely on studies that they deem unreliable.

20 *MR. SNIDOW:* They are unreliable in one direction, and
21 i know it might sound like gerrymandering, but it is true for
22 this particular point. It is not that they are unreliable, you
23 throw them in the waste bin. It's that if you are using them
24 for the proposition that we have definitively shown that there
25 is no cancer risk, which is what Defendants want to use it

1 for -- they want to say, look, the questions have been
2 answered, we looked, it is unreliable for that purpose.

3 But to the extent there is an increased risk in those
4 studies, that is particularly powerful evidence that something
5 is going on given that you didn't even wait very long to start
6 looking for that risk.

7 Is that helpful? I am trying to explain it in a
8 couple of different ways.

9 *THE COURT:* If you find a study unreliable and
10 presumably the methodology is unreliable, so how do you rely
11 upon it in part, but not for other things, calling it in part
12 unreliable, but otherwise not?

13 *MR. SNIDOW:* Because it is unreliable for a particular
14 purpose. We are not saying it is unreliable for any use you
15 might want to have for it. I get what the Court is asking, you
16 said it is unreliable, throw it away. That is not what we are
17 saying.

18 What we are saying is, to the extent you want to use
19 it to say there is no risk of cancer, you really do need to
20 wait for 30 years. That is what the IARC preamble says. If
21 you do actually end up seeing a risk at a shorter time period,
22 that is telling evidence that something is going on.

23 *THE COURT:* Is their case law that you are aware of
24 that speaks about reliability related to particular purpose,
25 such like in the case law where it can depend on purpose?

1 MR. HEINZ: I can't think of case law addressing
2 reliability in particular in that way. I will say I think the
3 word reliability kind of has strong Daubert connotations and
4 the meaning in the brief was bias toward the null, and that is
5 what Dr. McTiernan explains at length in her report.

6 It's the concept that we discuss using a colorful
7 analogy on page 76 of our opposition brief, that's at DE 5915,
8 where we say if you imagine someone getting ready to do a race,
9 and they get sick the day before, maybe they have a sprained
10 ankle or something like that, if the person wins the race that
11 tells you something remarkable about that runner. If the
12 person who loses the race it really doesn't tell you that much
13 because they were sick and had a sprained ankle.

14 That is sort of the point with a lot of these studies,
15 there is bias toward the null. So, given that bias, if you
16 still find a signal, that is extraordinary evidence that can be
17 relied upon to find an association.

18 If you don't find a signal, it doesn't necessarily
19 mean that much on the other side because it is bias toward the
20 null, but it doesn't mean it is unreliable in the sense that it
21 is completely useless. It simply means that you need to take
22 the conclusions, you know, in light of the study design to see
23 how to evaluate it overall.

24 THE COURT: Response.

25 MR. PETROSINELLI: Your Honor, what you have just

1 heard is the argument that their experts made, that the
2 Ranitidine epidemiology is unreliable if it doesn't show an
3 effect, but it is reliable if it shows an effect. That is the
4 antithesis of sound science.

5 There is no case that says anything like what they
6 just said the reference manual says nothing of the sort. You
7 cannot -- it's what Mr. Cheffo was saying earlier, you can't
8 have it both ways. To say that we are going to find a study
9 reliable if it shows an effect, but not reliable if it doesn't
10 is grounds for exclusion under Daubert.

11 *THE COURT:* Okay thank you. Plaintiff, in your
12 omnibus motion you state that numerous in vitro and in vivo
13 studies have attempted to analyze nitrate levels in the stomach
14 and the most are not reflective of real world conditions for
15 Ranitidine use because, based upon the label instructions for
16 Zantac it should be taken 30 to 60 minutes before or after
17 meals or at bedtime.

18 In this section are you referring to Florian as one of
19 the studies that was not reflective of real-world conditions
20 due to the timing of when Zantac was administered, the
21 researchers in Florian having administered Ranitidine one
22 minute after starting a meal, which falls squarely within the
23 window of Zantac's label instructions of a 60-minute window
24 either before or after meals?

25 *MS. FINKEN:* Your Honor, Tracy Finken. So, to answer

1 your question, yes, we are including Florian in that analysis,
2 and Florian gave Zantac immediately upon waking after a 12-hour
3 fast. There was no water taken with it, nothing in the stomach
4 contents, and then they were directed to start eating and eat
5 during a 25-minute window.

6 The Zantac label, and it depends on the indication,
7 because how it is labeled for people to take the drug is based
8 on the indication they are taking it for, and it differs
9 between prescription use versus over-the-counter use.

10 The prescription use, how Zantac is labeled, there are
11 multiple different ways based upon the conditions they are
12 taking it for. For example, if they are taking it for
13 maintenance of healing ulcers, the label recommendation is to
14 take it once at bedtime. If they are taking it for GERD or
15 gastroesophageal reflux disease, the label indication is to
16 take 150 milligrams twice a day, and if they are taking it for
17 erosive esophagitis, they are supposed to take it four times a
18 day.

19 This very different from what was done in the Florian.

20 *THE COURT:* What about the part of the label that says
21 30 to 60 minutes before or after the meal?

22 *MS. FINKEN:* That is referring to the over-the-counter
23 use, your Honor, that is a different label than the
24 prescription use. For over-the-counter use it is recommended
25 for twice daily with water 30 to 60 minutes before eating food

1 or drinking beverages that cause heartburn.

2 Typically, what we have seen and what our experts have
3 said, and what I believe I referred to your Honor the last time
4 we were here, was the White article, which is referenced on
5 page 55 of Dr. Marletta's report.

6 They criticize Florian for this very reason, because
7 taking the pill and then immediately eating first thing in the
8 morning is not typically how people take this. You are taking
9 it later, taking it with the evening meal when the stomach is
10 not entirely empty. People have been drinking and eating all
11 day, so that affects pH, which is this whole multi factorial
12 analysis that Ms. Luhana did. I don't know if you remember her
13 very lovely slides that she put up last week, but it is multi
14 factorial.

15 It affects the pH, it also affects the nitrite levels
16 in the stomach, the bacteria in the stomach. All those change
17 throughout the course of the day when you are taking Zantac,
18 and Florian doesn't measure those types of variables because of
19 the timing when it was taken.

20 Your Honor, you don't have to believe me on Zantac
21 affecting those different variables, Defendants' own clinical
22 studies show this point, and I can point your Honor to one of
23 the publications, which is the Thomas publication, and I will
24 get the cite for to you.

25 *THE COURT:* I have to limit it because I have to move

1 on.

2 MS. FINKEN: Thomas is a publication based on a
3 clinical trial that GSK did, and what Thomas shows is that the
4 pH is affected, the nitrate levels are affected, and the
5 nitrosamine in the stomach is affected for people who are
6 taking Zantac. That is in the published literature, and I can
7 get you the cite if your Honor wants it, but it is cited in our
8 briefing.

9 THE COURT: Okay. Any brief response from Defense?

10 Ms. RYDSTROM: As your Honor knows, the reason the
11 Florian researchers designed the study the way they did was to
12 maximize -- to see if they could maximize the amount of
13 endogenous formation of NDMA that they could see in Ranitidine
14 users, and they did that by putting fasting -- giving the
15 Ranitidine to fasted users when the stomach is very highly
16 acidic, and then asking them to eat because that decreases the
17 acidity, so capturing the spectrum that Ms. Finken was talking
18 about.

19 When they did that, as your Honor is well aware, what
20 those researchers found is there was not the increase that
21 Plaintiffs are attempting to tell the Court exists with respect
22 to endogenous formation of NDMA from Ranitidine.

23 THE COURT: Okay. Thank you all very much.

24 I am going to shift gears here. A couple of days ago
25 the Court received Docket Entry 6041, Plaintiffs' expedited

1 motion to submit supplemental expert reports and incorporated
2 memorandum of law, Docket Entry 6046, the brand Defendants'
3 response to the Plaintiffs' expedited motion to submit
4 supplemental expert reports, and then at Docket Entry 6047, the
5 joint stipulation regarding supplemental expert reports.

6 I communicated through our special master that for
7 purposes of the hearing today you could talk about the Wang --
8 just to be clear, the Wang C-H-U-N, hyphen, H-S-I-N-G, that is
9 the first name, study, and you all did that, but I precluded
10 there being any discussion about the supplemental reports
11 because the Court hasn't ruled on the motion yet.

12 I have a couple questions about your stipulation, so
13 whoever you want to designate for each of your sides is fine.

14 As I see it, there are two aspects of the stipulation
15 that I wanted to address. One is that there is no depositions
16 on the general causation amendments or supplements and the
17 other is that there would be limitations on what the experts
18 could discuss in their supplements or their amendments.

19 The Court has some concern about a lack of depositions
20 insofar as -- as you know, the experts haven't been here
21 because you all didn't feel that you needed them, and the Court
22 didn't either at the Daubert hearings. In large part it is
23 because I have every study and every deposition transcript,
24 which have been very helpful, particularly the deposition
25 transcripts, and the deposition transcripts do allow the Court

1 to see how the experts defend their opinions under scrutiny of
2 questioning from the other side.

3 So, I believe the transcripts to these depositions
4 have been important to the Court's ability to understand the
5 Daubert issues. It's not to say you haven't done a good job
6 summarizing the study, it is not that the Court has difficulty
7 in understanding the study, but what the Court needs to
8 understand is the study in the context of the expert opinion
9 and then how that fits in with other opinions, which dovetails
10 into the other issue, which is, you know, limitations on what
11 experts may be able to say should the Court permit any
12 amendments or supplements.

13 I [read the stipulation that you are not saying, you
14 know, it is open season to alter prior opinions, but rather
15 to -- or to defend prior opinions, but rather to -- because
16 certainly those opinions have been out there for ten months, so
17 we really don't want that happening, but rather, that the
18 agreed upon stipulation is contending that the parties will be
19 permitted to render an opinion on Wang, the new study.

20 Really what I want to hear your input on is the notion
21 of the deposition and the degree to which, if the Court is
22 going to allow this, we supplement. I already see in the
23 Defendants response you have some objections to certain areas
24 in which the Plaintiffs have gone, you argue, outside of the
25 Plaintiffs' supplemental reports in going beyond just

1 discussing Wang.

2 But the reality is that there probably does need to be
3 a little leeway for, I would imagine, for example, the
4 Defendant, if you were going to depose one -- if we were going
5 to have depositions and you were going to depose one of the
6 Plaintiffs' experts again you are not just going to be asking
7 about Wang, but if the expert said something about Wang and you
8 think it is inconsistent with something that expert said about
9 something else, I would think you would want to ask about that
10 something else.

11 So, you know, I am interested in what you have to say.
12 If there is truly a desire to supplement, and if the Court is
13 telling you that the Court believes it is helpful to the Court
14 to have the depositions, I would think you would need and be
15 ready and have available those experts from the Plaintiff.

16 We can just focus on the Plaintiffs' experts now
17 because we can look at this -- we can stage it, but look at it
18 first from the standpoint of the Defendants' motions which we
19 heard two weeks ago challenging the Plaintiffs' experts, now
20 the Plaintiffs want to come forward with some supplemental
21 reports, that the Plaintiffs' experts should be made available
22 immediately for deposition.

23 One of my first questions is, are the Plaintiffs'
24 experts whom Plaintiffs seek to supplement their report, and
25 maybe that is consistent with all the supplements you have

1 attached, which include pretty much all your epidemiology
2 experts -- you have McTiernan, Moorman, you know who you have,
3 Salmon, I believe, and -- are they all available on a moment's
4 notice to subject themselves to a deposition by the Defendants
5 strictly on their supplement -- Michaels you have -- on their
6 supplemental report -- you have Le as well -- on Wang only?
7 But to the extent that the answer to the question leads the
8 Defense to ask another question that may relate to another
9 opinion.

10 It's not that the Plaintiffs' experts can change their
11 opinion at all, at all. They have been deposed, they have
12 written reports, they have written rebuttal reports, we have
13 had hearings, but to be subject to cross-examination.

14 So let's start with that question, I guess, from the
15 Plaintiffs. Have you conferred -- they certainly got the
16 supplemental reports done quickly, so they must have some time
17 on their hands. I mean over the next two weeks?

18 *MS. FINKEN:* Tracy Finken for Plaintiffs, your Honor.
19 I can certainly discuss it with them. I have not because we
20 had an agreement with the Defense that we didn't want to take
21 further depositions at this point in time, but at the point
22 that we would get to a bellwether trial we would have limited
23 depositions on this specific supplement for both sides, the
24 Plaintiffs and the Defendants.

25 *THE COURT:* Do you want the Wang supplements to be

1 considered for general or specific only? If it is for specific
2 only it seems like I don't need to address the issue today.

3 MS. FINKEN: No, we have stipulated that they would be
4 for part of general causation. Just to be clear, your Honor,
5 the supplements don't change our experts' opinions. It's a
6 piece of evidence that they evaluate and may use to bolster the
7 opinions that they already gave.

8 So, the methodology that they used when they evaluated
9 this study is the same methodology that they used to evaluate
10 all the other myriad of studies that they evaluated to reach
11 their conclusions.

12 I don't know that a deposition is going to give that
13 much more information other than what has already been
14 established through the depositions, the reports, and argument
15 and all the briefing that we have done, but certainly if your
16 Honor requires it, we can speak to the experts and get their
17 availability for testimony.

18 We certainly would be willing -- if you we decide to
19 have another hearing, we can talk to them about whether or not
20 they could be available to answer your questions via Zoom on
21 the particular supplement if that is more helpful to your Honor
22 than another lengthy deposition taken by Defendants.

23 THE COURT: I wouldn't imagine the depositions should
24 be lengthy, like the ones that were initially taken, they
25 should be limited. I am making the point that we could all

1 reasonably anticipate that you are going to have to mention
2 another study or another opinion, it is not going to be so
3 narrowly tailored to just Wang.

4 What the Court wants to understand again, as I said
5 before, is not just the experts' opinion about Wang in
6 isolation, but how that also comports or, arguably, doesn't
7 comport with their overall expert opinion on the myriad of
8 other things we have heard about.

9 What about from the Defense? I know you have reached
10 a stipulation that you don't think depositions are necessary.
11 What I am suggesting to you is that I have found them to be
12 helpful to me. Can I say whether these will have an added
13 degree of helpfulness? I don't know. I just know what has
14 been helpful to me so far has included the scrutiny by which
15 all of the experts, Plaintiffs and Defense, come under when
16 they have to answer the questions of the very talented lawyers.

17 *MR. CHEFFO:* Your Honor, this is an easy one. I will
18 say this is consistent, Ms. Finken and I had the opportunity to
19 negotiate a lot of these things, but what we always say,
20 frankly, is yes, but this is subject to what the judge wants
21 and what is helpful to the Court. It doesn't really matter
22 what we think is best, ultimately it is what is best for you.

23 From our perspective, yes. The answer is if we can do
24 this in a few weeks -- I will tell you one of the reasons --
25 there were two reasons, I think you have addressed it, at least

1 from the Defense perspective, we were concerned. Your Honor
2 has taken Herculean efforts to get us here to today and we
3 didn't want this to be like, well, this person is away, then
4 it's Thanksgiving, and we are talking about this in January,
5 February.

6 *THE COURT:* No, we are not going to be talking about
7 this in January, February, or even November.

8 *MR. CHEFFO:* Then you have given us a lot of comfort.
9 Then there is always kind of the back fill, what is your name,
10 and let's talk about this study. You are going to be the
11 arbiter of reading it, so that is why we put in the language
12 that, to the extent people went beyond Wang -- but to get back
13 to where I started, we will work with the Plaintiffs. If we
14 can do this expeditiously in a few weeks, and frankly, if
15 someone is unable to do it, I suppose the remedy could be there
16 is no supplemental report.

17 *THE COURT:* That's my thinking, that if you want the
18 supplemental report you make the expert available for the
19 deposition. You can't have one without the other, and I feel
20 that if they were that available to write the report, they
21 should be -- they have some time on their hands and counsel
22 would be cautioned that you should be very measured and
23 reasonable in the taking and defending of the depositions.

24 It is for a very specific purpose, it is how are they
25 considering this new study, what does it mean to them, and then

1 anything they say about it, if that triggers, well, wait a
2 minute that doesn't jive with what you said about this other
3 study, then sure, you ask that question, but it emanates from
4 the original question, which is about the Wang study.

5 To repeat myself, there will be no review, no one is
6 changing their opinions, and no one is bolstering a prior
7 opinion or elaborating on a prior opinion. It is explaining
8 what Wang means to the expert, and if on cross-examination they
9 need to explain how that is consistent with another opinion
10 about and another study that would be the extent of going
11 outside a discussion of Wang.

12 That seems pretty straightforward to me. There should
13 not be many objections in the deposition, and I would say that
14 if there is an objection, you just object and save it so it is
15 in the transcript and keep going. When I read it, I know these
16 depositions, not as well as you do, but I know them well, and I
17 will realize when I feel somebody is going astray and trying to
18 do a redo as opposed to just answering a question.

19 It would be a lot easier on me to not have to read a
20 ton of pages of objections and going back and forth, and just
21 sticking with the mission. I want to make sure there is
22 clarity on the mission. Is it abundantly clear to everybody
23 what would be the purpose of these depositions?

24 MS. FINKEN: Yes, your Honor, it would be. I think
25 what would be helpful, a couple of things if you will indulge

1 me for a minute.

2 Typically when we take depositions of our experts we
3 have the benefit of the rebuttal expert reports before those
4 depositions go forward. The Defendants negotiated with us the
5 ability to serve their rebuttal supplemental reports by
6 October 14th, so we would ask the Court's indulgence so that we
7 can get the rebuttal reports before we provide our experts for
8 deposition. That's one.

9 THE COURT: Let me stop you there. So Defense is
10 agreeing that each one of your experts who will speak to the
11 supplemental reports shall issue a rebuttal report by the 14th?

12 MR. CHEFFO: That's right, your Honor. This may
13 change so I may get booted off the island, but I think our plan
14 was to have one, maybe two, so we are not going to have a ton.
15 We can get them ready for the Plaintiffs.

16 THE COURT: Those will be available by the 14th.

17 MS. FINKEN: Our experts?

18 THE COURT: The Defense will have the rebuttal reports
19 by the 14th.

20 MS. FINKEN: Yes. The second point I was going to
21 make is that we would request the ability to depose their
22 experts on their supplemental reports as well, in a
23 limited scope, of course, and --

24 THE COURT: Let's stop there. If I want to stage this
25 so that I want to look at it in the context of the Plaintiffs'

1 motions -- the Defendants' motions to the Plaintiffs' experts,
2 is there any reason why the Plaintiffs would have to take the
3 Defendants' experts' depositions in the context of the
4 Defendants' motions? Just like I have staged the hearings, if
5 we are trying to --

6 *MR. SNIDOW:* Yes, your Honor, if we are going to
7 have -- if this is going to be what the Court understands is
8 the expert's view of what Wang is, we of course want their
9 experts on the record to confirm where possible whether they
10 agree with our experts, whether they disagree with our experts.
11 That is critical.

12 *THE COURT:* That is presuming you will have additional
13 briefing. Are you contemplating additional briefing?

14 *MR. CHEFFO:* No. Your Honor, there are two things on
15 this. One is, and let's not lose sight, this is a motion --
16 the Plaintiffs could have just submitted this -- we didn't
17 object to the study. We've told you law lags science, we
18 didn't say law ignores science. We could have said here is a
19 study to read, but they have gone further. They said we have
20 these, some are 25 pages, some are five pages. They want to at
21 the 11th hour submit this.

22 So, for that privilege and your discretion, you are
23 basically saying, okay, and then we are going to have a
24 deposition of them. It doesn't go further -- this is what I'm
25 concerned about, it's never ending, then there is going to be a

1 supplemental brief.

2 They are asking for something that is discretionary at
3 this point. Last week you specifically asked them, are you
4 relying on this study? Now, in fairness they said something
5 like, well, it hasn't been published, but they also said, no,
6 no, we are just showing you, it's for another purpose. Now
7 they are saying we want to supplement and talk about it.

8 I think a fair resolution here would be if they want
9 to do that, then they should be deposed. We have agreed we
10 will give them the rebuttal reports so they will have the
11 perspective, but going two more steps, to briefing and deposing
12 our experts, seems far afield for the privilege of an 11th hour
13 supplementation of the record.

14 *THE COURT:* Why not let the Court receive the
15 supplemental reports, the rebuttal reports, the depositions of
16 the Plaintiffs' experts based on their supplemental reports, so
17 I am really receiving the study, the supplemental reports, and
18 however many persons you choose to have deposed, and I will
19 decide whether I need more briefing and a hearing or anything
20 of that nature. I will know whether I need anything more than
21 that.

22 *MR. GILBERT:* Judge, may it please the Court. We will
23 do whatever the Court directs, but I rose because I think it is
24 fundamentally unfair to allow Defense experts to serve
25 supplemental reports in response to ours. They can say

1 whatever they want.

2 *THE COURT:* I'm sorry, what is unfair?

3 *MR. GILBERT:* What is unfair is to allow the
4 Defendants' experts to serve rebuttal reports to say whatever
5 they want.

6 *THE COURT:* You all just asked for that, to have that
7 before the depositions.

8 *MR. GILBERT:* If I may finish. To allow the
9 Defendants -- the stipulation we submitted provides that the
10 Defendants, by October 14th, would submit supplemental rebuttal
11 reports in response to what we served and attached to our
12 motion. That is in the stipulation. The stipulation also
13 provided for no depositions, but the Court would like
14 depositions, and you suggested that --

15 *THE COURT:* I haven't accepted the stipulation yet. I
16 had you file it so it would be part of the record so we could
17 talk about it, but I haven't adopted it because I had a lot of
18 questions.

19 Let me ask you this: What if the Defendants didn't --
20 I am not sure it is okay or not okay with them, but what if you
21 just did your supplemental reports and the experts were subject
22 to a deposition?

23 *MR. GILBERT:* Without a supplements Defense report --

24 *THE COURT:* I am asking, what is the Plaintiffs' view
25 on that?

1 MR. GILBERT: If that is how it was limited, that
2 would be better as long -- in keeping with your prior
3 discussion about a very narrow targeted deposition.

4 THE COURT: What about the Defendants view on that?

5 MR. CHEFFO: Coming back to the principle here, which
6 is the Plaintiffs are asking for something extraordinary, for
7 all these reports, and it is true, getting back to we didn't
8 agree in the stipulation, I am referring to that because we are
9 hearing right now -- Mr. Gilbert is saying, you know, we can't
10 just have an expert report from the Defendants without taking
11 deposition, but that is what the stipulation was. They did
12 agree to that. We were going to submit it by next week and
13 that would be the record.

14 Now you are saying, which is fully fair, that you want
15 to have depositions of the experts. I think where you were
16 going is, we should have an opportunity to submit one or two
17 expert reports, right, because that is fair, and then we should
18 take their depositions. If you need more, then obviously you
19 will get it.

20 The flip side is that is conditional upon -- they want
21 to submit and supplement the record. If they don't want to
22 have the records and they just want to say here is the Wang
23 study, here is the citation, rely on it, then that is fine,
24 too. If they are asking for things they should also have some
25 efficiency here so we can get on with your Honor being able to

1 rule here.

2 *THE COURT:* Okay. What is the problem with the
3 original stipulation plus the depositions?

4 *MR. GILBERT:* My friend, Mr. Cheffo, always talks
5 about the goose, gander rule. The problem with it is, if your
6 Honor is going to accept the supplemental rebuttal reports from
7 Defense experts responding to ours, without allowing us to
8 cross-examine them as to what they put in them, that is
9 fundamentally unfair.

10 *THE COURT:* So the ability to cross-examine them on
11 their report.

12 *MR. GILBERT:* Correct.

13 *THE COURT:* What would be the Defense's choice, no
14 rebuttal or rebuttal and have your one or two experts deposed?

15 *MR. CHEFFO:* I am trying to answer your questions
16 directly I have a bit of a constituency, so could I talk to
17 them about that choice?

18 *THE COURT:* I know two of you are making closing and
19 probably want to be involved in the discussion, but we still
20 have time, but I would like to get this resolved before you
21 leave. Maybe somebody else can get on the phone with the
22 experts and find out what their schedule looks like over the
23 next couple of weeks. There are a lot of people here.

24 This is all conditional on this happening very
25 quickly, very quickly.

1 MR. CHEFFO: I can give you an answer in five minutes,
2 your Honor.

3 THE COURT: Your experts are available?

4 MR. CHEFFO: What we are going to do, what our choice
5 is.

6 THE COURT: What answer are you giving?

7 MR. CHEFFO: Whether we take a deposition with the
8 supplemental or not.

9 THE COURT: If you have one or two, it is less of an
10 issue, scheduling two depositions as opposed to five. So the
11 questions out there, depos and reports from the Defense, and
12 then for both sides, availability of your experts. So maybe
13 someone can be making phone calls to find out. Then we can go
14 into closing and wrap it up with what we have learned from our
15 research over the next 20 minutes.

16 MS. FINKEN: As far as our experts' availability, and
17 we can certainly reach out to them, that is fine, whatever your
18 Honor wishes, but it would be helpful to know if there was
19 going to be a time limitation on the deposition. For example,
20 in the past when there was a supplement with Adami, they asked
21 for additional time to depose Dr. McTiernan and that was
22 limited by Judge Reinhart to 47 minutes I believe.

23 THE COURT: Why don't you talk about that. I think
24 they should be limited. I think you all should be reasonable,
25 you don't want to waste money and time. It is narrow, and

1 there shouldn't be a bunch of objections. You can make them
2 for the record, but you should keep going and I will sift
3 through what I find helpful and what I don't. Why don't you
4 include that as part of your conversation.

5 *MS. FINKEN:* I can, your Honor. Just to be clear, it
6 is a lot easier for us to get our experts' availability. If it
7 is going to be a 30, 45-minute deposition, we can find that
8 time.

9 *MR. CHEFFO:* There was a 25-page supplement.

10 *MS. FINKEN:* On one study, though, it shouldn't take
11 that long for them to be able to question her the same way as
12 it was for the Adami supplement and it was very lengthy as
13 well.

14 To the extent that your Honor will limit the
15 deposition in time, I do not foresee a problem and we can make
16 our experts available over the next two weeks for a very
17 limited deposition.

18 *THE COURT:* If you are not getting the rebuttal until
19 the 14th, you are looking at the week of the 17th and the week
20 of the 24th.

21 Why don't you see, and I think they should be limited.
22 Counsel could talk while we hear the closing, and if you can't
23 agree, tell me what your respective proposals are and I will
24 make a decision. I will surprise you and rule from the bench
25 on the amount of time for the deposition. I am confident you

1 can work it out. You all have worked out most everything.

2 Okay, let's move into our concluding remarks.

3 MR. GILBERT: Would you be kind enough to give me a
4 warning when I have a minute left?

5 THE COURT: You have ten minutes. Do you want me to
6 give you a nine minute warning?

7 MR. GILBERT: Please.

8 THE COURT: Okay.

9 MR. GILBERT: Thank you, your Honor.

10 May it please the Court, Robert Gilbert for the
11 Plaintiffs. Once again our thanks to the Court and your staff
12 for your extraordinary engagement in this very important matter
13 and a special shout out and our gratitude to Ms. Stipes for
14 your dedication to providing us with the most accurate record
15 of these proceedings.

16 Your Honor, throughout these proceedings we have
17 consistently said this Court's gatekeeping role is limited to
18 reviewing expert methodologies, which includes examining each
19 experts' explanation for their conclusions. That is why the
20 Seventh Circuit in Schultz and Judge Rodgers in Abilify
21 instructed that Daubert does not permit a Court to pick and
22 choose which studies are better or worse in answering the
23 general causation inquiry.

24 Conclusions are off limits, reasonably explained
25 judgment calls are off limits, and weighting some studies

1 differently from the experts' weightings is also off limits.

2 Two weeks ago we promised you we would faithfully
3 apply this the black letter law when we got to our motions
4 challenging the Defense experts and we made good on that
5 promise today. We are not attacking their experts'
6 conclusions.

7 While we believe the best evidence shows that exposure
8 to NDMA in Zantac can cause all five designated cancers, we
9 recognize that competing evidence would allow a reasonable
10 scientist to reach a contrary conclusion. That is why, at this
11 stage, the focus must only be on methodology, and it is
12 methodology where we focused our motions.

13 The first point I want to hammer home is that
14 Defendants are inviting the Court to reach its own conclusions.
15 Two weeks ago, the Defendants paid lip service to the relevant
16 law and tried to mask their attacks on legal conclusions as
17 attacks on methodology.

18 Today their approach was exposed for what it really
19 is, an invitation for the Court to move from the role of
20 gatekeeper to the role of fact finder. Once again, the legal
21 question, as we have talked about ad nauseam for the past three
22 days for general causation is whether the highest realistic
23 exposure to NDMA from Ranitidine could have caused any MDL
24 Plaintiffs cancer, but rather than defending their own experts'
25 methods or attacking our experts' approach for answering those

1 questions, what did the Defendants do?

2 They insist on the answer they like and they attack
3 the answers they don't. If that is not arguing conclusions in
4 contravention of Daubert, I really don't know what is.

5 Mr. Boehm said this when he told you Florian proved,
6 quote, "there is no consistent signal," unquote, essentially
7 arguing that the Court must accept this one sentence from
8 Florian as a matter of law.

9 The way they justify asking the Court to reach that
10 conclusion is by asking your Honor to pick and choose how to
11 weigh the studies, ignoring the teachings of Schultz, Roundup,
12 Valsartan, and countless other Daubert decisions, pay no heed
13 to Hidajat, dietary studies, or the broad consensus on NDMA's
14 carcinogenicity. Only active comparator studies of Ranitidine
15 are relevant.

16 Plaintiffs' experts noted serious limitation with
17 these studies for evaluating the general causation question,
18 short followup times, short periods of use, misclassification
19 bias, and confounders in the patient populations. In many
20 cases those critiques mirror the confessions made by the
21 authors of the studies themselves.

22 How do the Defendants respond? Not by disagreeing
23 with our experts and the study authors, but by pounding the
24 table and saying that no reasonable scientist could rely on
25 those limitations when deciding how much weight to give the

1 studies.

2 That is pure argument by lawyers. There is no
3 authority to support the proposition that our experts were not
4 allowed to discount flawed active comparator studies. There is
5 no authority that allows a gatekeeper to make these sort of
6 scientific judgment calls.

7 On the subject of active comparator studies, the new
8 Wang study, as we have all discussed, shows an increased risk
9 of each of the five designated cancers. Our experts say this
10 study fortifies their conclusions. What do Defendants say?

11 After previously telling the Court that active
12 comparator studies are the only game in town, they wave their
13 hands and claim that Wang now actually supports them, its
14 findings are just noise, and you must view Wang in context with
15 studies they like. Apparently the sands are shifting. You are
16 only allowed to look at active comparator studies and now you
17 can't positively weight one that is bad for them if there are
18 others they like.

19 That is not the law. Abilify called an
20 epidemiological study showing an association, plus an expert
21 opinion that the association is causal, quite, and I quote,
22 "powerful evidence of general causation." And that is Abilify
23 at page 1307.

24 It is obvious they want you to reach the general
25 causation conclusion rather than evaluate the merits of the

1 experts' methodology, and we respectfully suggest that the
2 Court should decline that invitation.

3 I have to correct opposing counsel for
4 mischaracterizing Judge Kugler. They claim he admitted that
5 Dr. Panigraphy based only -- they claim he admitted Dr.
6 Panigraphy based only on internal Defendant documents and FDA
7 determinations. They claim Judge Kugler found an association
8 based only on a regulatory finding and internal admissions.
9 They claim because that that is because the Third Circuit law
10 is different, but none of that is true.

11 The record from Valsartan specifically reflects what
12 Judge Kugler said, and I don't have time to read it aloud, but
13 the record speaks for itself.

14 The second concluding point is that Defendants'
15 experts had unreliable methods because they answered the wrong
16 question, didn't weigh all the evidence to answer it, and
17 didn't consider it carefully.

18 The general causation question is a simple one, and it
19 is one we entrust to juries: Could the exposure to NDMA in
20 Zantac have caused any MDL Plaintiffs' cancer. Plaintiffs
21 theory, as we told you last time, is not and has never been
22 that a short period of Zantac use with very few pills ingested
23 is sufficient to cause cancer. NDMA is undeniably dangerous to
24 humans, but it takes more than a little to measurably increase
25 the risk of the five designated cancers, and even after

1 exposure to enough NDMA, cancer takes time to form.

2 Every single expert in cancer knows about this latency
3 period, and even Defendant's experts, when they are being
4 honest, acknowledge that undeniable fact.

5 In light of our theory of the case, it is obviously
6 not helpful to evaluate whether short-term use of Ranitidine
7 causes cancer after short followup period, but that is
8 precisely the question Defendants' experts answer. They focus
9 on studies with short followup times and limited exposure.

10 For example, the Adami study, which the Defendants
11 love and was done by a Sanofi consultant, looks at users with
12 only ten Zantac prescriptions. In fact, two-thirds of that
13 study are patients with one prescription. Our experts point
14 out that a serious flaw of Adami is it focused on short-term
15 users because one or even ten prescriptions do not equate to
16 years or decades of use that match the MDL registry population.

17 Defendants' experts don't even have to agree with
18 ours. Perhaps they could have come up with a scientifically
19 valid explanation for why someone who filled at least ten
20 prescriptions would be highly likely to continue taking Zantac
21 year after year to match the registry.

22 If they had done that, both Plaintiffs' and
23 Defendants' experts could testify.

24 *THE COURT:* That's nine minutes.

25 *MR. GILBERT:* Thank you. If they had done that, even

1 though our experts would vigorously disagree, at least they
2 would be attempting to use Adami to answer the right question.

3 By focusing on the wrong question it is no surprise
4 that Defendants reached their conclusions without considering
5 all the relevant evidence, running afoul of Abilify.

6 Your Honor, in summary, as you consider Plaintiffs'
7 Daubert motions, we ask that you ask yourself the following
8 questions:

9 One, which set of experts were intellectually honest?

10 Two, which experts candidly acknowledged the evidence
11 that cut against their client's position and explained it?

12 Three, which undertook the rigorous and complete
13 scientific inquiry that Daubert demands?

14 We submit that the only answer to those questions is
15 that Plaintiffs' experts did and Defendants experts did not.
16 For that reason you should exclude the Defendants' experts.

17 Thank you.

18 *THE COURT:* Thank you. That was about ten minutes and
19 19 seconds.

20 From Defense.

21 *MR. PETROSINELLI:* Thank you, your Honor, Joe
22 Petrosinelli here. If I could get a one minute warning, too,
23 that would be great.

24 *THE COURT:* Yes.

25 *MR. PETROSINELLI:* Your Honor, I am here to talk about

1 some legal principles to bring us home here. I want to pick up
2 on a couple things we just heard from Mr. Gilbert. He said
3 conclusions are off limits. Of course that is an inaccurate
4 statement of the law. Chapman, all the Eleventh Circuit cases
5 quote Joiner that said, conclusions and methodology are not
6 entirely different. Chapman in particular says that the Court
7 should go on and judge whether there is too great an analytical
8 gap between the conclusions and the methods, and that is a lot
9 of what our position has been.

10 I want to talk about the issue of dose because that
11 has been a huge focus two weeks ago and today.

12 Mr. Gilbert just cited Schultz, a Seventh Circuit
13 case, Roundup, a Ninth Circuit case, and Valsartan, a District
14 of New Jersey case.

15 As I said to you earlier, they have said two weeks
16 ago, and then they are all in today, that in an MDL, to get
17 past general causation in a toxic tort case all you have to do
18 is show a dose that -- the highest level of exposure, duration
19 and dose that anyone in the MDL had, and then everyone in the
20 MDL, even the lowest dose people, pass general causation. That
21 is completely contrary to Eleventh Circuit law and, frankly,
22 MDL practice.

23 Next slide, please.

24 I showed you this slide two weeks ago. These are the
25 quotes from McClain and Chapman, and the Plaintiffs said today,

1 well, those were single Plaintiff cases, they were not an MDL.

2 Number one, that is not true actually. McClain had
3 four Plaintiffs in it, and of course Chapman was part of an
4 MDL, it was a single Plaintiff case, but Judge Altonaga had the
5 MDL. So that is number one.

6 Number two, nothing in these cases say this only
7 applies when it is only a single Plaintiff, this wouldn't apply
8 in an MDL. Of course it does apply in MDLs. When I hear the
9 suggestion that you only look at general causation with the
10 highest doses, and if we can show a study that has that dose we
11 pass everything, I know a lot of MDL judges would be shocked to
12 hear that statement.

13 Judge Gergel, in the Lipitor MDL, Judge Bryer, one of
14 the most experienced MDL judges in the country, in the Celebrex
15 MDL, these are pharmaceutical MDLs where they said, Plaintiffs,
16 you have to show us the dose, and what they found was at the
17 highest dose you can get past general causation, but at these
18 lower doses, no, there is not reliable evidence.

19 Under the Plaintiff's logic, if that were true, if
20 their standard were true, those cases would have said, oh, you
21 get past the highest dose, so everyone comes in, that is not
22 the way the law works, in the Eleventh Circuit for sure, and
23 certainly in pharmaceutical MDLs.

24 Next slide, please.

25 What have we learned? Remember two weeks ago the

1 Plaintiffs made this statement, and you asked them, could you
2 rely on this, and they said yes. Their general causation
3 theory is many years of regular use, and you might remember
4 some frustration two weeks ago because you and we kept asking,
5 what is the reliable evidence, how many years, what does
6 regular use mean, and they really couldn't answer it two weeks
7 ago.

8 We saw about 25 slides today where they tried to
9 answer it finally. What did we see?

10 Let's look at the next slide.

11 These are Plaintiffs' slides you saw today, and I
12 heard Mr. Snidow begrudgingly finally admit, albeit in his
13 rebuttal argument, that threshold dose matters, because he
14 said, using this slide, well, you could have a dose that is
15 above the dose that anyone in the Plaintiff pool could have.

16 Number one is, I said that is not the standard, it is
17 not what the highest dose a person has, but the point that we
18 have made is that they have no reliable evidence of what the
19 threshold dose is. What is the dose at which human beings
20 generally who use Ranitidine can have an increased risk of
21 cancer? That is what they have to show.

22 By the way, I should say, of course our motions as to
23 their experts and their motions as to our experts highlighted
24 the issue of they have no reliable evidence of an association
25 between Ranitidine use and any cancer at any dose. So it is

1 sort of like if that question is decided in our favor, it
2 doesn't really matter what the threshold dose is. They don't
3 even have that.

4 If we were going to get to this -- next slide,
5 please -- this is what they told you today their dose is. They
6 say they have identified numerous doses shown to cause cancer,
7 and they have six doses along the side there.

8 Now, number one, they have five cancers here, they
9 have to say what is the dose from a general causation
10 standpoint that could cause each of these five cancers
11 separately. It is not the same dose, it couldn't possibly be
12 because of the different cancers and different organs involved.

13 So, these numbers here are from all different cancers,
14 number one.

15 Number two, this is nothing more than what we talked
16 about two weeks ago. You see the numbers 3.8, and above that,
17 6.6, 7.5, that is Dr. Salmon and Dr. Panigraphy's charts, we
18 talked about that two weeks ago, that were based on the Hidajat
19 study and NDMA dietary studies, not Ranitidine epidemiology.
20 So that is those four numbers.

21 Then the three years is from Cardwell, the bladder
22 cancer finding, which I will talk about in a second, and the
23 one year is the new Wang study. Now they say we have -- at
24 least we have three years and one year for bladder cancer and
25 liver cancer, not the other three.

1 They have no -- this chart shows you, they have no
2 dose testimony, minimum threshold dose, which they have to show
3 in the Eleventh Circuit, based on Ranitidine epidemiology for
4 three of the five cancers, so those are gone under the Eleventh
5 Circuit law.

6 Now let's look at these two.

7 Next slide, please.

8 They showed you this to support their three years for
9 bladder cancer. This is what Cardwell shows, and this is in
10 fact data from Cardwell. It is the comparison with the nonuse
11 population. Mr. Snidow, I am sure he misspoke, said that this
12 was data comparing Ranitidine to the active comparator from
13 Cardwell. That is inaccurate.

14 This is comparing Ranitidine use to nonusers. What
15 Cardwell then did, as you know, is compared Ranitidine users
16 with active comparator groups and the association went away.
17 There was no dose response, there was no association at any
18 dose. So they have nothing on bladder cancer.

19 And then finally -- next slide, please -- the latest
20 is on Wang, and this is a chart that Mr. Tobey showed earlier
21 today. Yes, in the active comparator study Wang, that study
22 showed a dose response relationship in the active comparator
23 group. Of course Adami, which did it for liver cancer, a dose
24 response analysis, showed no dose response relationship.

25 So, you have one study that did and one that didn't.

1 No reliable scientist would conclude, even if Wang was the only
2 study, would conclude that this is reliable evidence of dose
3 response, but surely not when you have Adami which has longer
4 followup than Wang, that that would be a reliable finding.

5 Next slide, please.

6 What you saw today moreover is lawyer argument. Dr.
7 Moorman and Dr. McTiernan, they don't say any of this, they say
8 none of this. Dr. Salmon and Dr. Panigraphy had the charts
9 that we talked about. But on the Ranitidine epidemiology they
10 were asked, "they" meaning Dr. Moorman and Dr. McTiernan, point
11 blank in their depositions, tell us what the dose response
12 curve is for Ranitidine use in any of the five cancers.

13 This is what Dr. Moorman said about the Ranitidine
14 studies: You really can't describe anything about dose
15 response, other than she notes the Cardwell finding on nonuse.

16 This is lawyer argument that they are sort of flailing
17 for an answer on this. They didn't have one two weeks ago,
18 they had one today. It is no better than they were two weeks
19 ago. They have no reliable evidence on dose or dose response
20 for any of the five cancers.

21 *THE COURT:* That's nine minutes.

22 *MR. PETROSINELLI:* This is my last slide.

23 Your Honor, I leave you with the fundamental
24 methodological point here, both as it relates to our motions
25 and as it relates to their motions, which is the law lags

1 science point.

2 In all these cases, and I told you this two weeks
3 ago -- I don't know if you remember i showed you the slide with
4 all the pharmaceutical MDLs that have excluded general
5 causation opinions, and all of these judges make the same
6 points that the Eleventh Circuit has made, which is that we are
7 not saying this is junk science, quote unquote.

8 We are not saying these experts aren't qualified. We
9 are not saying these experts don't honestly believe that the
10 evidence is good enough for them, but they can't -- you can't
11 get ahead of the science, and the science here has not
12 concluded, no one outside this courtroom has concluded that
13 there is a causal relationship.

14 Look at what has happened, Wang now comes out. We can
15 fight about what it means and what it doesn't mean. The
16 science, maybe it will develop more, maybe it will develop in
17 their favor. I don't think so based on what you see in Wang
18 and other studies. But, as the Eleventh Circuit says, you have
19 to accept the state of the science as it is, and
20 methodologically the state of the science as it is does not
21 show reliable evidence of a causal association.

22 Thank you, your Honor.

23 *THE COURT:* All right. Thank you. It looks like
24 everybody came back in to report on hopefully an agreement on
25 how you see a path forward for the supplemental reports and

1 depositions.

2 If there is anyone who needs to catch a flight, you
3 should feel free to leave. Don't worry that I would be judging
4 you if you left.

5 *MR. MADERAL:* Good afternoon, your Honor, Frank
6 Maderal for the Plaintiffs. There was a back and forth that
7 Plaintiffs wanted to clarify that we had with your Honor a
8 moment ago. When Ms. Finken was speaking of the purpose of the
9 supplements she said the experts are not changing
10 methodologies, they are not changing their conclusions, they
11 are bolstering their opinion with this additional piece of
12 evidence that has just come out.

13 After a few back and forths after that, what we are
14 not doing with the new expert reports -- I don't know if this
15 was intentional or not, but one of the things your Honor
16 mentions was you said we are not bolstering the opinions, and
17 Ms. Finken agreed.

18 So, I think we have an inconsistency there, and I do
19 think it is important for the Plaintiffs, our position is that
20 we are indeed bolstering for the purpose of the 702 analysis
21 the opinions with the supplement of the Wang report, if that is
22 clear.

23 *THE COURT:* Maybe I shouldn't have used that word.

24 You can't redo your opinions, but you have a new study
25 and you want to tell the Court how your experts have included

1 this study in their opinion, and so that is what I want to
2 know.

3 *MR. MADERAL:* That is correct, your Honor. Thank you.

4 *THE COURT:* Okay. That was the easy part.

5 *MS. FINKEN:* He just felt left out.

6 *MR. MADERAL:* That was the easy part.

7 *MR. CHEFFO:* We have some good news and maybe some not
8 good news. We did talk.

9 *THE COURT:* That is good.

10 *MR. CHEFFO:* That is good news. I wanted to tell you
11 the good news. In terms of timing, and Ms. Finken will tell
12 me, we could probably agree on timing of when it should occur.
13 Like by the 14th we would submit our supplement. The next
14 week, to the extent there are depositions of Plaintiffs, it
15 would be that next week, and then the following week would be
16 the depositions. So we know kind of by the 28th or 29th of
17 October at the latest that it was all done.

18 *THE COURT:* Defense rebuttal report on the 14th, and
19 depositions on the week of the 17th and 24th?

20 *MR. CHEFFO:* Yes, a week after that.

21 *THE COURT:* 14th to the 21st?

22 *MR. CHEFFO:* Realistically probably the following
23 week, like you said.

24 *THE COURT:* So by the 21st?

25 *MR. CHEFFO:* Right, before we put it in stone, we have

1 a fundamental disagreement on the amount of time that we would
2 take.

3 *THE COURT:* Okay. First of all, who would be deposed?

4 *MR. CHEFFO:* Anybody who wants to continue to have
5 their report considered.

6 *THE COURT:* Anyone who wants to do a supplemental
7 report based on Wang will be deposed.

8 *MR. CHEFFO:* It wouldn't be any more than the five who
9 have already done it, but if somebody said I check out, then we
10 wouldn't depose them.

11 *THE COURT:* No more than five. The Plaintiffs, right,
12 no more than five?

13 *MS. FINKEN:* Of the Plaintiffs' experts, yes, your
14 Honor.

15 *THE COURT:* Did we decide for Defense?

16 *MR. CHEFFO:* We are in that process, but as I said to
17 you, I don't think it will be more than two, it could be one.
18 Either one or two.

19 *THE COURT:* We have agreed on that. We can't agree on
20 how long the depositions will take?

21 *MR. CHEFFO:* I basically proposed -- and again, beauty
22 is in the eye of the beholder. We thought that of the five
23 experts, because some are longer than not, we would have -- for
24 three of the experts we would have no more than three hours,
25 and two of the experts we would have no more than two hours to

1 take these, and that seems to be the way these depositions go,
2 you can't do too much more than that.

3 The Plaintiffs were thinking 45 minutes to an hour,
4 which I said was completely unacceptable, and I said we would
5 oppose the motion because you can't really do that.

6 *THE COURT:* What was the Plaintiffs' position on how
7 long the depos should take?

8 *MS. FINKEN:* Your Honor, what we offered up was
9 similar to what Judge Reinhart had ordered previously with the
10 other supplement on the Adami study, which is a 45 minute to
11 one hour deposition. This is a limited deposition regarding
12 one study. Four out of the five expert reports that were
13 served were six pages or less, your Honor. It certainly does
14 not require two to three hours of cross-examination, especially
15 given the fact that most of these experts have already sat
16 through a ten to 12-hour deposition. Dr. McTiernan has already
17 sat for 13 hours of cross-examination on her report and her
18 supplemental reports.

19 An additional three hours on top of that we believe is
20 unnecessary for purposes of asking about one study and one
21 supplement.

22 *MR. CHEFFO:* First of all, it is not just one study.
23 Dr. McTiernan's report is 27 pages, and going back to principle
24 number one, this is something that is discretionary.

25 The idea that we are quibbling about a little bit of

1 time when the Plaintiff are asking for 45 minutes to an hour
2 when they were able to mobilize all these people on three days
3 and essentially work around the clock seems not consistent with
4 that.

5 MS. FINKEN: Your Honor, as of an hour ago Defendants
6 didn't feel it was necessary to take a single deposition of any
7 of these experts on the supplement. Now they are saying they
8 require three hours, and it is excessive, your Honor. They
9 have already sat for 12 to 13 hours. This is a single study
10 that you are requesting that they be cross-examined about, and
11 they should not be subjected to one to three hours of
12 cross-examination. Thank you.

13 MS. CANAAN: Your Honor, may I say a couple of words
14 about Dr. McTiernan's deposition? One of the first questions I
15 asked her -- she submitted a supplemental report on the Adami
16 study because she was not able to answer any question about the
17 Adami study previously. The first question I asked, are you
18 relying on the Adami study for your opinions? She took
19 literally 15 minutes, we counted, to answer that question.
20 That is why we, respectfully, are asking for three hours.
21 Thank you.

22 MS. FINKEN: Your Honor, I would like to add, we know
23 that the Court wants these depositions and that the Court feels
24 they are necessary, and to the extent the questions are asked
25 of our experts they will be responsive. They can do that

1 within an hour time frame.

2 I would suspect that if the Defendants do not believe
3 they are responsive to those questions they will be back in
4 front of the Court with their complaint. That is something
5 that has happened, it has been denied by Judge Reinhart
6 multiple times that they have brought a request for additional
7 time because they believed Dr. McTiernan was unresponsive, and
8 Judge Reinhart disagreed on the record. He said he did not
9 agree with Ms. Canaan's position, and that he believed Dr.
10 McTiernan was responsive during that deposition.

11 *THE COURT:* When you are talking about your overall
12 time, how have you discussed direct and cross?

13 *MR. CHEFFO:* Well, there are a few little things in
14 our stipulation, and you raise a good question, your Honor.
15 Two issues we raised, if this drags on your Honor is addressing
16 that. Second, this is back filling. I don't think the
17 suggestion here is that there is clarifying recross, but this
18 shouldn't be an opportunity for a full trial type of thing.

19 So I think within that, it would be -- we would get
20 the three hours, and if they wanted to ask some clarification
21 questions that were fair, just like we would, then that would
22 be outside, and that should be limited to 15 minutes, 20
23 minutes, whatever it is.

24 *THE COURT:* Whatever time you are agreeing to, that is
25 for the Defense and then the Plaintiff would take --

1 *MS. FINKEN:* We have addressed this previously with
2 Judge Reinhart and how we addressed it is, if the Defendants
3 have a one hour block of time to take the deposition, they can
4 reserve from that time rebuttal, and then Plaintiffs have an
5 equal amount of time, whether it is the one hour, we would have
6 an equal amount of time to do a direct of our witness after the
7 fact, and they can reserve their rebuttal.

8 This has happened with every deposition we have taken
9 in this case so far. To limit us being able to rehab witnesses
10 to ten minutes when they are requesting a three hour deposition
11 is patently unfair, your Honor.

12 *THE COURT:* Other than not agreeing on how long the
13 deposition should take, what else -- we talked about 10/14 for
14 the Defendants' supplemental reports, depositions completed by 10/24.
15 When would the Defendants be?

16 *MR. CHEFFO:* The following week.

17 *THE COURT:* You should try to get this done by the end
18 of October. Maybe we say Plaintiffs deposition -- if you want
19 to look at the calendar, we have the week of the 17th, the week
20 of the 24th, and October 31st, and that goes into November.

21 *MS. FINKEN:* Respectfully, your Honor, we would be
22 able to schedule this much quicker if you gave us a deadline
23 for all of them, instead of staggering Plaintiffs and the
24 Defense. To the extent that we can maneuver them -- if you
25 want them all done, for example, by October 31st, and issue

1 that order, Plaintiffs and Defense, we can work among
2 ourselves.

3 *THE COURT:* Isn't that when you had to get your
4 depositions done last year? Are we having deja vu?

5 *MR. CHEFFO:* If we do on the 14th, a Friday, we
6 provide our reports, we have the following week, until the
7 21st, to do the Plaintiffs' experts, and then we have until
8 October 28th, before Thanksgiving, to finish. The first week
9 is theirs, and then the week to do the one or two depositions
10 of ours, and we are done by the 28th.

11 *THE COURT:* What other issues do you think need to be
12 addressed?

13 *MR. CHEFFO:* There was something in the stip that
14 maybe you can agree, I think we did, which is, if we don't --
15 we are trying not to pile on and have all of our experts file
16 reports, but if the Court would allow the experts to pass, we
17 would put a footnote that we would have an opportunity to
18 submit a supplemental report after the fact. We would like to
19 make sure we are not waiving that.

20 Rather than force us to do it all by the 14th, we
21 would like to be more surgical about it.

22 *MR. GILBERT:* Your Honor, that is unacceptable to
23 Plaintiffs. That was part of a negotiated stipulation which
24 the Court has not accepted. As part of that stipulation the
25 Defendants waived the right to take any depositions. We are

1 not agreeing to that any further unless -- any expert they want
2 to put up for a supplemental report, they can put them up now
3 on general causation.

4 MR. CHEFFO: It seems like we are trying to do what I
5 thought we were doing, which is trying to string this out to
6 December or January. Now they are going to force us to file
7 reports that say the same thing and then subject them to
8 depositions. I am not really sure what the ask here is.

9 THE COURT: Okay. Anyone else want to be heard on any
10 other issue as it relates to this? No. Okay.

11 All right. Happy Friday, safe travels, good to see
12 everybody. Sorry to have to end on a little bit of a
13 contentious note, but I appreciate everyone's presentation
14 today. Thank you very much.

15 (Thereupon, the hearing concluded.)

16 * * *

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

19
20 Date: October 10, 2022

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

22 Signature of Court Reporter
23
24
25

Pauline A. Stipes, Official Federal Reporter

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