

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.** . September 21, 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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1 THE COURT: Good morning, everyone, you may be seated.
2 Thank you. Can you hear me?

3 Okay, good morning, everyone. We are here in the
4 matter of 20-md-02924, In Re Zantac (Ranitidine) Products
5 Liability Litigation. It is nice to see everybody here in
6 person and also by Zoom.

7 We have approximately 50 attorneys in person,
8 including all attorneys who will be presenting the motions. We
9 also have attorneys and parties who are appearing by Zoom.

10 I would like to go through a few administrative
11 matters first. For attorneys who are representing, please come
12 to the podium when you make your presentations, please speak
13 slowly and into the microphone so everyone can hear you, and so
14 Pauline can make her usual perfect record of the proceedings.

15 For those of you on Zoom, please keep your audio and
16 video off at all times in consideration of the presenters here
17 in court. Everyone in the courtroom should keep masks on
18 unless you are speaking. Please turn your cell phones off.
19 There can be no use of cell phones during the hearing, and no
20 one is to record the proceedings.

21 This is a big day, indeed, the parties have been
22 waiting and preparing for this day for some while. Back on
23 June 18, 2020, just over two years ago, I entered PTO 30 which
24 included a case management schedule. Within that schedule the
25 parties had agreed and I ordered that all of the Daubert

1 motions would be fully briefed and ripe by April 21, 2022. On
2 November 15, 2021, I entered a second amended PTO 65, which,
3 among other things, extended the date by which the Daubert
4 motions would be fully briefed until August 22, 2022. So, all
5 of the Daubert motions, Defendants' and Plaintiffs', have been
6 ripe now for about one month.

7 We have scheduled hearings for today and tomorrow for
8 the Defendants' motions, and September 30th for the Plaintiffs'
9 motions. The attorneys will make the presentations, they have
10 not requested that any expert witnesses be present at the
11 hearings.

12 The motion that will be presented today is Docket
13 Entry 5699, the brand Defendants' motion to exclude Plaintiffs'
14 general causation experts' opinions related to epidemiology.
15 The Plaintiffs responded at Docket Entry 5915, and the
16 Defendants filed a reply at Docket Entry 5958.

17 The parties have prepared a schedule for the hearings,
18 with my input, such that they were provided with the time that
19 they requested to make their presentations.

20 In preparation for the hearings the Court has received
21 and reviewed the briefing on all of the Plaintiffs' and
22 Defendants' motions, approximately 25 primary expert reports
23 from the Defendants' and Plaintiffs' experts, not including the
24 rebuttal reports, approximately 22 deposition transcripts,
25 approximately 40 science studies and reports, and has had the

1 benefit of two Science Days, one at the inception of the case
2 and one on December 2, 2021.

3 I have shared with the attorneys some of the general
4 topics that I may be interested in having the attorneys discuss
5 throughout these hearings and they, in turn, have shared with
6 me their PowerPoint presentations which they intend to show
7 here today and over the course of the hearings.

8 We are on a fairly tight schedule with much ground to
9 cover, so with that, I would like to turn it over now to
10 Defense counsel who will make the first set of presentations
11 during the introduction phase of the hearings.

12 *MR. CHEFFO:* Good morning, your Honor, thank you.
13 Mark Cheffo for GSK and I, along with Joe Petrosinelli for
14 Pfizer, will be doing the initial presentation here this
15 morning.

16 Your Honor stole a little bit of my thunder because I
17 was going to thank you and highlight so much of the work that
18 you and your team has done in reviewing all these records and
19 reviewing the documents and asking for things, and it is very
20 much appreciated by both sides.

21 Also, as your Honor knows, there is just going to be a
22 few of us, probably a relatively few, presenting, but to kind
23 of acknowledge the contributions that I am sure you do know of
24 all of the people who really participated in this effort, so I
25 want to thank them on both sides of our teams.

1 Your Honor, may it please the Court. Sometimes
2 lawyers have to get up and they have to explain why what they
3 said previously is different, why things have changed, but that
4 is not the case here, your Honor. We told your Honor several
5 things about Ranitidine and about the Ranitidine science from
6 day one, and they remain true now and they were true then.

7 First, the robust epidemiological data and scientific
8 information and data do not support Plaintiffs' general
9 causation theories with respect to one cancer or five cancers
10 that they have put forward here today. In fact, the
11 information that has been developed should be good news, right?
12 It should be satisfying for people who took Ranitidine, who
13 took the medicine, and may have been led to believe that it can
14 be associated with or cause cancer.

15 Second, there is no medical institution, there is no
16 scientific organization, there is no Governmental entity that
17 has ever, ever determined that Ranitidine can cause cancer,
18 much less the five cancers that the Plaintiffs proffer in this
19 MDL.

20 Third, your Honor, we showed your Honor a question.

21 Next line, please.

22 This question was important then and is important now
23 in setting the table, we believe respectfully, for your Honor's
24 analysis of the Daubert question here.

25 Just to go through it because I think there are some

1 important points that I would like to highlight: Does the
2 scientific evidence reliably demonstrate that Ranitidine use of
3 therapeutic doses of Zantac can cause any of the designated
4 cancers?

5 When you break this apart, it has to be reliable
6 scientific evidence. We will talk about that. We have to be
7 talking about, which we are here, use of the medicine at
8 therapeutic doses, not kind of petri dishes, real world use of
9 actual Zantac with respect to the specific cancers here, your
10 Honor.

11 And this is why your Honor's role is so critically
12 important as a gatekeeper. Your Honor will recall that there
13 was a Citizens Petition that was filed, and then within if not
14 hours, days, there were claims and lawsuits filed, and there
15 were at first a few, then there were tens, then there were
16 hundreds, and then there were tens of thousands. Initially,
17 the claims were that this -- Zantac essentially caused cancer
18 in virtually every body system. Essentially, it was a cancer
19 pill. Then what happened?

20 Then the data started to be developed, scientists
21 continued to do their work, and as the science was published,
22 it wasn't dozens of cancers. The Plaintiffs said, well, it's
23 ten cancers. Then they said, well, it is not ten, it is
24 actually eight cancers. No, no, it's not eight, actually we
25 are going to focus on five. And along the way, as your Honor

1 knows, tens, hundreds of thousands of claimants were
2 essentially put into the registry and cases were filed.

3 Next slide, please.

4 One of the Plaintiffs' experts who you will hear about
5 a fair amount today, this is about two years now when their --
6 two years after the MDL was established, said she essentially
7 looked at all of the data, and the evidence for the ten cancers
8 was not sufficient to support an opinion that the use of
9 Ranitidine can cause breast, prostate, kidney, lung, or
10 colorectal. So, of course, we don't take any issue with that.
11 We agree with that. Right?

12 Here is the thing, your Honor: The same body of
13 evidence, the same scientific data that led Dr. McTiernan to
14 form that conclusion, and led literally over a hundred thousand
15 of these claims to exit the registry, is essentially the same
16 data that answers the question here today with respect to the
17 other five cancers.

18 Next slide, please.

19 So, this is a quick road map, if you will, of what I
20 intend to cover today. First we'll talk about the scientists
21 and regulators, how they assessed Ranitidine use and cancer
22 risk using reliable methods. Then we will talk about how we
23 believe the Plaintiffs' experts departed from reliable
24 methodology.

25 Just as a footnote here, this entire hearing, at least

1 from our perspective, is about methodology, right. To the
2 extent that these are issues that we are talking about, we
3 believe they are Daubert issues, these are not weight issues,
4 these are not cross-examination issues. And then we will talk
5 specifically about the Plaintiffs' forest plots that they put
6 forward which we do not believe accurately portray the state of
7 the science and the take-aways from the science.

8 Next slide, please.

9 And your Honor, what happened -- we talked a little
10 bit about the Citizens Petition, so the Citizens Petition was
11 filed, and people didn't just ignore it. It was a serious
12 claim. We had a widely-used medicine and we had claims that it
13 caused a serious disease, cancer.

14 The scientific community, institutions, you can see
15 these are some of kind of household names, if you will, in
16 terms of the types of institutions, not just in the United
17 States, not just Florida, not just New York, literally all over
18 the world, Asia, Europe, and elsewhere, and they basically got
19 together and they embarked on a mission to answer the question
20 of whether Zantac, right, Zantac can cause cancer amongst the
21 people who actually used it.

22 Next slide.

23 And this is a snapshot really to make the point that
24 sometimes we have nameless, faceless institutions, but these
25 are real people, they are not lawyers. They are people who

1 dedicate their life to public service and to public health.
2 They thought this was an important question and it was a
3 question that they wanted to answer.

4 Here is the thing: Just like we, as lawyers, and
5 virtually every profession have rules of the road, folks who do
6 this have rules of the road. They have guideposts. It is not
7 a willy-nilly exercise about how are we going to determine
8 whether there is causation or not. What they did and what
9 typically is done, first, when the question is not answered,
10 you say, can we design a study?

11 Let me make one important point here. At the time
12 that this all occurred, they didn't say -- no one said the
13 question has been answered, right. We can look at occupational
14 data, we can look at dietary NDMA data and we have the answer.
15 No one said that.

16 Nor did they say the way to understand this question
17 is to do more studies of occupational data or more studies of
18 dietary, right. They didn't do that either.

19 What they did was, they said, let's follow the rules
20 of the road, you design a study, you try to address chance,
21 bias, confounding. You then conduct a study, and if you
22 believe that it was done appropriately, you submit that study
23 for publication. Of course, that is not the end of the road.
24 Then, of course, the peer review process kicks in, and if it is
25 accepted, you publish.

1 As you will see in a minute, that happened 11 times
2 with these 25 institutions, and the point of all this exercise
3 is really to see if there is an association. And I know your
4 Honor has dug deep into this, so I am not going to go into too
5 much about Bradford-Hill, but you want to find out if there is
6 an association. Then, if there is an association, is it a
7 strong association, and only if it is a strong association do
8 we then move on to Bradford-Hill. That is the process that
9 happened here.

10 Next slide.

11 As I noted, this is from Yoon, but basically all of
12 the experts said the same thing. They said, the way to answer
13 this question is to develop pharmacoepidemiologic studies, that
14 is what is needed to assess causation.

15 Next slide, please.

16 They were very thoughtful about this because, again,
17 an important issue, they were going to take a lot of time and
18 effort and initiative here, and they said, what we need to do
19 is develop comparative studies. The way I think about this is
20 really to have an apples to apples comparison and they say it
21 better than I would, which is, the clinical indications of
22 Ranitidine and other H2RAs are almost identical and a control
23 group using a similar indication drug is more appropriate than
24 the general population.

25 Just as an example, if you want to find out if a

1 headache medicine is causing some kind of adverse event or
2 problem, you want to look at people who are taking other
3 medicines or who have headaches, so you are not going to get
4 all this confounding, apples to apples. This is not a novel
5 theory, this is what all of these experts say, active
6 comparator is the way to look at this if you want the most
7 accurate, reliable data, and virtually all of these independent
8 experts say that.

9 Next slide.

10 And it is not just, you know, Cheffo or Defendants on
11 this, it is the experts, it's the FDA: It's ideal to use an
12 active comparator group taking a drug used to treat the same
13 disease. This is not kind of a novel new concept.

14 Next slide, please.

15 And they went about this process. Let me give a
16 footnote here. I think there may have been a mistake in the
17 briefing, I think it may have said that there were 7 million
18 Ranitidine patients. That was in error and I apologize for
19 that. We are clarifying, their study included over 7 million
20 people, but here is the point.

21 Next slide.

22 It was almost a million, so yes, it wasn't 7 million,
23 but it was almost a million folks who specifically used
24 Ranitidine. That is a massive number of study participants.

25 Next slide.

Pauline A. Stipes, Official Federal Reporter

1 And, you know, we have heard and will likely hear
2 about, well, if someone had medicine that they received from --
3 they live in a hot state, or it was delivered through a truck
4 that may have been heated, or they left it in their glove
5 compartment, or maybe they used it when it was in their
6 medicine cabinet; we will also hear things about, well, maybe
7 there was some type of endogenous formation, it formed in the
8 body, which, obviously, we all disagree with.

9 But here is the point about epidemiology. That is
10 kind of why we do it, because you're capturing these real world
11 people. So, if one of those 963,000 people stored their
12 medicine in the glove box or in their medicine cabinet, they
13 are captured within the epidemiology. That is the beauty of
14 these epidemiologic studies.

15 Next slide, please.

16 You have heard and you will likely also hear about
17 this kind of latency issue, well, cancer takes a long time. If
18 you look at all the letters after the folks who did these
19 studies, the Ph.Ds, the MDs, I think they know that cancer can
20 take a long time, and they designed this study with that
21 knowledge.

22 Now, no one suggests every study is perfect, but they
23 did understand that, they did look at this issue, because we
24 all know that it can take a long time. As you see -- and the
25 Plaintiffs may quibble about a year or two here or there, but

1 the point is that these studies looked at 23 years, nine years,
2 ten years, 18 years. These were long-term followup. Does it
3 mean every single individual was followed up? No. But it was
4 a concept that was on their radar, and they did investigate it.

5 Next slide.

6 And this is also important, your Honor, because I
7 think this sets the table. Around the same time that all of
8 this was developing, first, the EMA did not come out initially
9 and talk about Ranitidine, but they did understand the question
10 of -- your Honor knows the EMA is kind of the FDA analog. They
11 had some questions about nitrosamines which means in medicines
12 in general. They also said, we are looking at all the data and
13 we don't have an answer. We don't think that dietary NDMA data
14 answers the question or occupational. There are a lot of
15 different reasons, as they say, so we think that we need to do
16 additional studies. It wasn't mission accomplished at that
17 point.

18 Next slide.

19 A few months later they say epidemiologic studies to
20 assess the association between intake of nitrosamine
21 contaminated drugs and risks are desirable, but their conduct
22 is challenging. They basically say here is the way we think
23 you should be thinking about this, scientific community.

24 Next slide.

25 And then in September 2020, what we have is kind of

1 their, you know, list, if you will, their best practices, their
2 concepts of what you should do in order to answer the question.
3 You know what, your Honor, the things I just talked about,
4 about all the epidemiologists in the world's scientific
5 community, it is exactly what they did kind of independently.
6 This all coalesced. This was how the scientific community and
7 world's medical organizations decided the best way to answer
8 this question, and that is what happened.

9 Next slide.

10 The medical community did answer this question, and
11 they did speak and they spoke really loudly. What did they
12 conclude?

13 Next slide.

14 No associations.

15 Next slide.

16 No evidence that Ranitidine is associated with an
17 increased risk.

18 Next slide.

19 No compelling evidence that Ranitidine increased the
20 risk of GI cancers.

21 Next slide.

22 No evidence that exposure to NDMA through Ranitidine
23 increases the risk of cancer.

24 Next slide.

25 Ranitidine was not associated with overall cancer

1 risk.

2 Next.

3 Ranitidine did not significantly increase the risk --
4 the incidence of gastric cancer.

5 Next.

6 Ranitidine was not associated with an increased odds
7 of developing GI malignancies.

8 Next.

9 No demonstrable association between Ranitidine use and
10 future gastric cancer.

11 Next.

12 The association between Ranitidine and pancreatic
13 cancer is yet to be determined.

14 Next.

15 We did not observe any consistent or substantial
16 increase in the risk of bladder cancer.

17 Next.

18 Cardwell determined no association, they did find an
19 association with H2RAs, not with -- no association with H2RAs,
20 but they did with PPI, and their conclusion was that further
21 studies are necessary.

22 That is a pretty loud unambiguous chorus of the
23 scientific community.

24 Next slide, please.

25 It wasn't just these institutions or the EMA, it was

1 also the FDA that looked at this data and said no consistent
2 signals emerged across studies, and studies with comparison to
3 active controls found no association between Ranitidine and
4 overall or specific cancer risk.

5 Again, these are not equivocal statements.

6 Next slide.

7 And they are not alone, right. Basically, this is
8 just a snapshot, we probably could fill many other slides, but
9 the point here is that no institution, no organization, people
10 who devote their lives to public health, to cancer, to safety
11 are not out there saying that Ranitidine causes any cancer.
12 The only people who are saying that are Plaintiffs' retained
13 experts, and my friends on the other side of the V. They stand
14 alone in this, your Honor.

15 Next slide.

16 As I said earlier, and we will talk about, this is a
17 gatekeeper function, your Honor. This is a Daubert issue
18 because when you have -- as the Supreme Court has told us,
19 widespread acceptance can be an important factor in ruling
20 particular evidence admissible and a known technique which has
21 been able to attract only minimal support within the community
22 may properly be viewed with skepticism.

23 You will likely see throughout this, well, I followed
24 the right rules, I read the data, I considered it, but that is
25 not enough here. If I said to your Honor I could add three

1 things together, two plus two plus two, that is five, my
2 conclusion is going to be viewed with skepticism because just
3 saying I followed a method is not enough.

4 When you have this world's chorus saying we did this
5 process, this accepted process, and we have come to this
6 finding, you have to view with skepticism, respectfully, folks
7 who divert from those methodologies and from those conclusions.

8 Next slide.

9 So, now we are going to talk about how we believe and
10 hopefully show your Honor how we believe the Plaintiffs'
11 experts departed from these rules of the road, right, these
12 reliable methodologies that scientists outside of the courtroom
13 use.

14 Next slide, please.

15 So, this is kind of a methodological deficiency wheel,
16 if you will, and the first one we will talk about is the focus
17 on NDMA and dietary and occupational studies.

18 Next slide, please. Next.

19 So there is -- your Honor has read the reports, you
20 have read the data, you have read the depositions. There is no
21 nuance here, the Plaintiffs are all in on NDMA. They don't
22 want to talk as much about Ranitidine comparative study data,
23 but from the first page of their epidemiological brief
24 opposition they say all NDMA can cause cancer and all
25 Ranitidine degrades into NDMA. Full stop. Therefore, we don't

1 need to go any further, let's just get to specific causation.

2 Next slide.

3 Here is the problem with that. As I said, no one
4 outside the courtroom, right, the FDA, the EMA, all these
5 experts didn't say we have the answer, let's just look at this.
6 No one did that. No one even said you can do that, no one
7 suggested these questions can be answered by those types of
8 studies. So, again, that should be enough to end this inquiry,
9 but there is more.

10 These dietary studies, many of them, as you will hear
11 from Mr. Brown a little bit later -- I think it is later --
12 didn't measure NDMA specifically. These are also based on
13 questionnaires. So, no one is suggesting that these have no
14 use, but they are not what is generally accepted as use for
15 general causation analysis. Asking someone who, unfortunately,
16 had been diagnosed with cancer what you ate 15 years ago, that
17 is essentially what these do.

18 These have well-recognized limitations, recall bias,
19 measurement imprecision, how things are prepared, and I think a
20 compelling fact here is that in other litigation Dr. McTiernan
21 said, nah, I am not going to rely on this stuff.

22 Next slide.

23 Presumably, when these didn't support the hypothesis
24 there, Dr. McTiernan, in another MDL, said, no, you can't ask
25 somebody what they have eaten in the past, yet this is kind of

1 a marquis argument with the Plaintiffs and their experts in
2 this litigation.

3 Next slide, please.

4 Your Honor knows this, the Plaintiffs have also
5 focused significantly on occupational, largely one study, the
6 Hidajat study. We have the same kind of analysis here. No one
7 said mission accomplished. No one suggested you can even use
8 these to answer the question of Ranitidine use. They rely
9 largely, as I said, on the Hidajat study.

10 What is important about that, too, only ten percent of
11 the data that was used is actual data. A lot of it was
12 inference extrapolation. Of course, these are rubber worker
13 studies, right, people who work around chemicals all day long,
14 inhaling different constituents. It is not an NDMA study about
15 people who actually used Zantac.

16 Equally important, next slide, Dr. Hidajat told us
17 under oath -- to her credit, she was candid -- these studies
18 were not designed to find out questions about people who
19 actually used Ranitidine; these were studies on rubber workers
20 for NDMA. Of course, that has utility, but it doesn't answer
21 the question here before your Honor.

22 Next slide.

23 And there likely will be some back and forth, and your
24 Honor has asked some questions about this, but I think quite
25 clearly the case law clearly also supports this concept, too,

1 right, that if you want to understand whether a particular
2 product or compound caused a problem, you look at the compound,
3 and then the person, of course to the extent that information
4 is available.

5 Your Honor knows the first example is the gasoline and
6 Benzene. There the experts were excluded because they looked
7 at Benzene data as opposed to looking at Benzene in gasoline.
8 Again, that is on all fours here, right. Do we look at NDMA
9 data or do we look at Ranitidine data?

10 If the Plaintiffs are right that the Ranitidine
11 contained NDMA, then we are going to understand how that NDMA
12 functioned and to the extent it caused injury, and again, that
13 is what was done here.

14 Next slide.

15 The Burst case also basically excluded the experts for
16 focusing on just Benzene data. There were other reasons, too,
17 that wasn't the only reason, but not focusing on the gasoline
18 data.

19 Next slide.

20 And your Honor is, again, likely familiar with the
21 litigation as well there, similar concept. The claim was that
22 zinc in Fixodent caused a certain significant disease end
23 point. The Plaintiffs' expert said, let's study zinc, right,
24 then we can kind of extrapolate into Fixodent. The Courts have
25 said, no, you need to look at Fixodent data based on that.

1 That is the take-away here. The Plaintiffs in their
2 papers and we'll likely hear, well, the zinc was different,
3 maybe the gasoline and the Benzene was different here, but that
4 is kind of slicing the onion a little too thin. The point here
5 is that you don't look at component data and then try and
6 import it and extrapolate. The Courts have clearly said, if
7 you have data available, like we do here, if you want to
8 understand whether Ranitidine caused cancer you look at
9 Ranitidine in humans. That is what the experts outside the
10 courtroom have done and that is what the case law says.

11 Next slide, please.

12 As your Honor well knows, you have asked about this,
13 the experts failed to demonstrate the primary methods for
14 proving zinc in Fixodent causes myelopathy and they were
15 excluded.

16 Next slide.

17 I have talked a little bit about active comparators,
18 but let me just say this as well. Kind of another example
19 would be if you have an underlying disease that can actually
20 cause problems, let's say diabetes, people who have diabetes
21 might be at higher risk for heart attack or things like that,
22 and the active comparators here, they account for those issues.

23 So, if you want to figure out if a diabetes medicine
24 is causing an increased risk of heart disease, you would want
25 to study people who have diabetes, because if you study people

1 who weren't at an increased risk it would lead to confounded
2 results.

3 That is the situation here. People who are taking
4 acid suppressant medicines, people who have GERD, those are
5 risk factors for some of the underlying cancers that are at
6 issue here, another reason why active comparators are so
7 important.

8 Next slide.

9 Engaging in situational science, Judge Rufe talked
10 about this in the Zolof MDL. It's basically having one set of
11 rules for a certain set of facts and having another set of
12 rules for kind of a different set of facts or constellations.

13 Next slide.

14 And this is what she was talking about, if an expert
15 applies certain techniques to a subset of the body of evidence
16 and other techniques to another subset without explanation,
17 this raises an inference of unreliable application of
18 methodology. So two points, it's a methodology issue, and you
19 will also see this throughout the presentations today.

20 Next slide, please.

21 The Mirena Court also recognized this. When this
22 happens it raises a red flag that suggests motivated,
23 result-driven reasoning.

24 Next slide.

25 Mr. Petrosinelli is going to talk about dose at some

1 length, so I will be brief on that point. I will say two or
2 three things.

3 One, it is, frankly, stunning in a case like this when
4 we are talking about medicines that the Plaintiffs have offered
5 no dose, how long does it take, what dose, what is -- the
6 latency issue. None of those questions were offered.

7 It is so important, again, as Mr. Petrosinelli will
8 talk about, because not every substance that is either good or
9 bad for us causes disease. Our body is kind of an amazing
10 mechanism in the sense that there are certain thresholds.
11 Whether it's radiation, whether it's lead, whether it's
12 arsenic, whether it's X, Y, or healthy things like water, there
13 are certain thresholds. There is almost never a zero sum game,
14 and that is why the dose question is so important here as we go
15 through these hearings.

16 Next slide.

17 The Plaintiffs also rely on non-replicated
18 inconsistent findings.

19 Next slide.

20 The manual tells us the importance of the need to
21 replicate research findings across science, particularly here,
22 and also consistency. So, we don't want to have just a certain
23 finding, because we all know if you run a certain number of
24 tests in any study the likelihood of getting one finding from
25 chance is pretty high, so you need consistency. You need to

1 look at it and say, is there consistent results. You also need
2 to have replication and you need to have statistical
3 significance, as we will talk about.

4 Next slide.

5 And then there is the concept of cherry picking data.
6 Your Honor certainly knows what that is, and I think we will
7 have some examples of that.

8 Next slide.

9 This highlights really a more broad point. I think I
10 have seen some commentary from Plaintiffs that the Court's role
11 is limited, and of course it is not open ended, there is a
12 limit to this, but it doesn't mean that it should be not
13 focused on the data.

14 What the Joiner Court has told us and its progeny is
15 that your Honor is supposed to do, which is what you have, in
16 order to understand if there is cherry picking in the data, if
17 the science doesn't make sense on a granular level, that is
18 certainly within your purview. That is something that the
19 Supreme Court and others have expected Courts like your Honor
20 to be doing.

21 Next slide.

22 Now we will talk about the forest plots. I know that
23 is probably the most exciting part of your morning, so I will
24 jump right into it.

25 Next slide, please.

1 This is a refresher, really briefly, just for those of
2 us who don't spend eight hours a day staring at forest plots.
3 The way scientists kind of plot data, record data is on these
4 forest plots, and that's what this is. It looks like a T,
5 right. These are four kind of exemplar end points.

6 The first end point, what does it show? It shows a
7 non-statistically significant finding. How do we know that?
8 We know that because if the horizontal axis either crosses or
9 touches that vertical axis, that means it is not statistically
10 significant on either side, right. Then we have on the right
11 side of the box an increased risk, on the left side is a
12 decreased risk.

13 So we have the first one is not statistically
14 significant increased risk. The second is not statistically
15 significant decreased risk.

16 That brings us to end point number three. As you can
17 see, this is a statistically significant finding in the
18 increased risk category, but there is something that is notable
19 about it. You see that the line is long, or at least longer
20 than the others, and that typically represents that there are
21 fewer people in the study, so the reliability speaks to that
22 line.

23 And then the final point is a statistically
24 significant negative finding with a higher level of confidence,
25 if you will.

1 If we were looking at these, or more importantly, if
2 scientists outside the courtroom were looking at these, for
3 example, they would say a few things. One, they would say
4 there is no consistency. We have negatives, we have positives,
5 we have not statistically significant, and they would also
6 certainly say there is no replication. Someone couldn't look
7 at end point four and say, ah-ha, this is protective. Nor
8 could they look at end point number three and say, ah-ha, this
9 is a problem, this is a negative issue.

10 With that, your Honor, we are going to start with the
11 bladder. The Plaintiffs seemed to have focused on bladder, and
12 they started with it in their papers, so we will take it head
13 on and jump right in.

14 Next slide, please.

15 These are the bladder cancer data.

16 Next slide.

17 So, a few points just as a preview. What we will try
18 to do, your Honor, and I will try to explain this so we are all
19 on the same page, but to the extent we cover a particular end
20 point and it shows up in others, we are not going to keep going
21 through the same thing. You will see us graying it out. Gray
22 is our little key for either we have covered it or it doesn't
23 support the Plaintiffs' position, but I will explain that. I
24 just wanted to give a little preview of where I am going.

25 And this is from the Plaintiffs' papers. This is not

1 our forest plot, this is theirs. You have seen a lot of them,
2 but the Plaintiffs put this in their brief, and the blue
3 represents the dietary NDMA, not Ranitidine studies, and the
4 red represents the occupational studies.

5 We have talked at some length about that, we don't
6 think they are reliable, we don't think the scientific
7 community or the FDA or the EMA thinks they are reliable.

8 Next slide, please.

9 Those are in gray.

10 The next category of data points that we are going to
11 talk about -- next slide -- are those that are not
12 statistically significant. You can see they all cross the
13 axis, so they are not statistically significant. Why is that
14 important?

15 Next slide.

16 The Sandoz case tells us the burden is on Plaintiffs
17 to show that well-conducted epidemiological studies do show a
18 statistically significant relationship.

19 Also, I think it is in the briefing, Dr. Salmon
20 conceded this and Dr. Lee also in her deposition, at page 82,
21 it could be 83, testified to this point, that statistical
22 significance is needed for an association.

23 Next slide.

24 On top, a little bit of the icing on the cake, not
25 just is the table statistically not significant, the authors

1 talk about confounding, but even though it is on this slide
2 that the Plaintiffs proffer as supporting general causation,
3 their own expert says the information is not informative on the
4 relationship between Ranitidine use and bladder risk. Not
5 informative, their expert says that.

6 Next slide.

7 Then we have these two findings here, Norgaard, we
8 have the crude and the adjusted. I think, as your Honor
9 probably is aware, the crude is really just that. Before the
10 study was published, or during the process, the actual
11 scientist doing it said there is something that is confounded
12 here. The crude is not the most accurate representation, so we
13 are going to adjust it to try to address confounding, which is
14 exactly what they are supposed to do.

15 So, while the Plaintiffs have put forth the crude
16 number, which is statistically significant and positive, when
17 it is actually adjusted by the study authors, it is not
18 statistically significant and the end point moves to the left.

19 Next slide.

20 There is another thing about Norgaard. Red is an
21 indication to you, your Honor, that this was not on the
22 Plaintiffs' initial slide. So, I want to be clear to you that
23 the Plaintiffs were kind of adding a point here.

24 I think this point is important because the Plaintiffs
25 have and will talk a lot about, well, the studies, they don't

1 look at latency enough, they don't follow people enough, but
2 there was a study and there was an end point in the
3 Norgaard data where those scientists actually looked at long
4 term ten-year followup and ten plus prescriptions. Now, the
5 Plaintiffs determined not to include it on the slide, but you
6 can see what happens, the end point moves all the way over into
7 the decreased risk factor.

8 Next slide.

9 And that is undoubtedly why, when the study authors
10 themselves looked at this data -- they didn't have a dog in
11 this fight other than public health -- they said, looking at
12 all of this and reflecting routine clinical practice, we did
13 not observe any consistent or substantial increase in the risk
14 of bladder cancer in Ranitidine users. They didn't focus on
15 the crude and say, ah-ha, this is the answer. They said,
16 looking at all the data, this does not show an association.

17 Next slide, please.

18 Also not statistically significant, right, and no
19 surprise, the study authors say no associations were observed,
20 we found no evidence that exposure to NDMA through Ranitidine
21 increases the risk of cancer. That was their conclusions
22 notwithstanding the fact that it is on the Plaintiffs' chart
23 here as supporting general causation.

24 Next slide.

25 This is a truism both in science and certainly in the

1 law, when an expert relies on the studies of others he must not
2 exceed the limitations the authors themselves place on the
3 study, and there are a few core principles. I can look at the
4 data that these experts generate, then you need to look at at
5 least their conclusions, and the other thing about it is that
6 the conclusions are peer reviewed just like the data. They
7 went through the peer review process as well.

8 Next slide.

9 That brings us to the MSK study. First of all, this
10 is a non-published study. Dr. Braunstein, as your Honor knows,
11 was deposed. He was asked kind of squarely flat out, do these
12 results -- can they be used to say that Ranitidine increases
13 the risk of cancer? No, can't do that. Does this provide
14 evidence, any evidence of increased risk, much less causation?
15 He said, no, it doesn't do that, yet it is on the chart.

16 And equally important -- next slide -- Plaintiffs'
17 expert, Dr. Moorman, says these don't provide useful data. I
18 don't rely on this. This is not something that I credit as
19 part of my methodology.

20 Next slide, please.

21 Then we have Cardwell. There are three things, I
22 think, three brief points I would like to make about it.

23 First, the Plaintiffs use non-comparative data. I
24 have spoken a fair amount about active comparator, but the
25 analog to that or the other side is using general population,

1 people who are not in that group, so it is not an apples to
2 apples. It's more an apples to oranges. That is the data
3 point that is included here. When you actually look at the
4 H2RA data, you see no statistically significant finding, and
5 also, even if you were to credit this, there is no consistency
6 in replication. We will show that graphically, if you will.

7 Next slide, please.

8 The first point is, when it is compared to an active
9 comparator, the H2RA, as I indicated in my opening comments, it
10 is a statistically significant finding, but when the study
11 authors compared it to other H2RAs, which is the class of
12 medicines that Ranitidine is in, you see the finding. It is
13 basically down the middle. That is a significant finding.

14 Next slide.

15 So, what does this show us? This is -- particularly
16 when you take away all the things that even the Plaintiffs'
17 experts have said they don't rely on, or things that are just
18 not reliable based on the scientific community, this is a
19 picture of no association, certainly no strong association, and
20 no causation. It is not a picture of consistency or any
21 replication with respect to causation.

22 Next slide, please.

23 We are now going to talk about esophageal cancer.

24 Next slide.

25 We are able to go through this a little bit quicker.

1 So, the points in gray are the things I talked about already,
2 but I would like to talk about Habel just once more because --
3 next slide -- essentially Dr. McTiernan doubled down on this
4 one. This is a similar finding, but she looked specifically at
5 the esophageal findings and said it is not possible to look at
6 the associations between esophagus risk and Ranitidine use with
7 the Habel study. Full stop. Yet it is on their slide as
8 supporting it is statistically significant when their expert
9 says can't -- it is not even possible to look at this
10 association.

11 Next slide.

12 The McGwin study, your Honor probably dug deeply or at
13 least into this study, so just a few things about this. This
14 study was based on adverse event reporting. Certainly I am not
15 going to stand up here before the Court and say adverse event
16 reporting is not important, it doesn't have a place, it doesn't
17 have a role, it does. It is a blunt instrument, it is used by
18 pharmaceutical companies, the FDA, and others to signal
19 detection.

20 The problem here with using it for causation is a few
21 things. One, every time somebody files a lawsuit or a claim
22 that becomes an adverse event, so it massively skews the
23 adverse event. It is not a voluntary type thing a doctor or
24 patient would do, and this study actually captured the point
25 when you would expect to see a massive influx of adverse events

1 through litigation. So, that is one of the issues.

2 Next slide, please.

3 We have a benefit here, notwithstanding the
4 Plaintiffs' slide, of focusing on what their own experts say,
5 and Dr. Moorman said no, it is impossible, impossible to
6 calculate the risk using this type of data.

7 Next slide, please.

8 Dr. Moorman we agree with, and she is not alone. The
9 FDA basically again, as I am saying, certainly has a use,
10 certainly has a purpose, but it is a data mining tool, it is
11 not for establishing causation.

12 Next slide, please.

13 So, when we look at esophageal cancer and we account
14 for the things that the Plaintiffs' experts have said, and we
15 look at dietary and occupational as unreliable, this again is
16 the picture of no association, no strong association, no
17 causation, no consistency, no replication.

18 Next slide, please.

19 We'll turn to stomach cancer, your Honor.

20 Next slide.

21 A lot of gray because, we have talked about them, your
22 Honor, so they are either things that the Plaintiffs' experts
23 have disabused us of, dietary or occupational, or things where
24 they are just squarely statistically significant in favor of
25 protection, right.

1 So that leaves us with Liu, and I want to talk about
2 that. Your Honor may recall, I talked about that at the last
3 Science Day and it's the same data point.

4 The Plaintiffs have put up a one-year data point
5 showing a statistically significant increase in risk.

6 Next slide, please.

7 What is not included on their slide is that the
8 authors did a few things; they looked at people who took the
9 medicine and developed stomach cancer. Remember, it's the
10 Plaintiffs saying there is a long latency period here for
11 cancers. They looked at one year and they saw that first green
12 line, statistically significant. Then they looked at after two
13 years of use, and after three years, and they saw it is not
14 statistically significant, and that end point is shifting to
15 the left. What they basically said is that this suggests
16 reverse causation.

17 As a quick example -- next slide -- unfortunately, if
18 someone was to have stomach cancer that was undiagnosed, the
19 symptomology of stomach cancer, you might take something like
20 Zantac to help relieve it, then within five months, eight
21 months, 11 months, you may get diagnosed with cancer. What
22 these experts recognized, it is not the fact that you took the
23 Zantac two months ago or three months ago, it is the fact that
24 it wasn't diagnosed, right.

25 So, that is reverse causation and that is something

1 that good science tries to account for. Remember, the EMA, as
2 one of their guideposts in on of the early slides I showed the
3 Court, said account for reverse causation, bias. So that is
4 what the study authors -- they didn't say this supports
5 evidence of general causation for stomach cancer.

6 Next slide, please.

7 Once again, your Honor, when we account for the grade
8 items and the things the Plaintiffs' experts have distanced
9 themselves from, no association, no strong association,
10 certainly no causation, and there is just no consistency here.
11 This is the poster child for lack of consistency in their
12 application.

13 Next slide, please.

14 Liver cancer, we will talk about that briefly.

15 So, the Kantor study, there are two things about it.
16 You see two end points, the first is statistically significant,
17 that is regular use. That is not the comparator study that we
18 are talking about, that is the apples to oranges, not
19 necessarily the apples to apples. And then you will see when
20 they actually do the active comparator study, what happens?
21 What you would expect to happen, there is no statistical
22 significance, and the end point is almost at the axis.

23 Next slide, please.

24 That is why outside the courtroom the experts and
25 scientists who actually did this study, they didn't conclude,

1 like the Plaintiffs here are saying, or their experts are
2 saying, that this is evidence of causation. They said there is
3 not even an association between the risk of cancer when you
4 look at the active comparator studies.

5 Next slide.

6 And again, your Honor, you know probably where I am
7 going to go, to say this is a picture of no association,
8 causation, strong association, consistency, or replication.
9 This is what you would see if -- frankly, this should answer
10 the question, right? That is what we're trying to find, is
11 there an association? So this, like the others, answers that
12 question.

13 Next slide, please.

14 And then finally pancreatic cancer.

15 Next slide, please.

16 So, we've talked about all the others, you see Adami
17 and Kim are kind of on the negative side, so let's talk about
18 McDowell. I will highlight, it says ever use. That's not an
19 active comparator study.

20 One quick word on this. This goes to the situational
21 science point, so it is kind of hard to follow it sometimes.
22 Sometimes they say the Ranitidine data is not reliable, you
23 shouldn't look at it at all, but then they rely on Ranitidine
24 data. They say active comparator doesn't really answer the
25 question, you need to look at certain use, but then they will

1 rely on active comparator, so this is kind of the idea of
2 situational science.

3 Next slide.

4 Notwithstanding this finding, the study authors didn't
5 say mission accomplished, we found the answer. They say that
6 the association, not even causation, is yet to be determined.

7 Next slide.

8 And why is that? Well, this is another data point
9 that wasn't included on the Plaintiffs' chart, but again the
10 Plaintiffs have said that some of the limitations of these
11 studies is that they don't follow longer term use, or they are
12 not people who use the medicine, but in fact McDowell did look
13 at people with over six prescriptions and that data point was
14 peer reviewed, but not included here.

15 What did it show? People who actually used it longer
16 have a less incidence and non-statistically significant risk as
17 opposed to the finding that they have included.

18 Next slide, please.

19 Again, you can't look at this, I don't think, outside
20 the courtroom and people would say, ah-ha, this shows
21 association, much less strong association or causation. This
22 is the picture of no association, no consistency, and no
23 replication.

24 Next slide, please.

25 So, your Honor, before I hand the baton to my friend,

1 Mr. Petrosinelli, just to kind of recap, the scientific
2 community looked at this issue the way scientists do outside
3 the courtroom, not bound by kind of litigation influences or
4 anything on either side. They looked at it and they used
5 reliable methods. No one has challenged that.

6 The Plaintiffs' experts, in the face of that data and
7 those data points, essentially had to contort the way that they
8 have approached this, and they know how to do this the right
9 way, as we have pointed out and as you will see. You will see
10 in other situations, when they do this outside the courtroom,
11 they know how science is supposed to work.

12 Then, as we just went through, when you look at these
13 forest plots, your Honor, it is hard to come to the same
14 conclusion even as a nonscientist that the Plaintiffs are
15 asking the Court and their experts are saying is an appropriate
16 methodology.

17 Next slide.

18 The reliable literature does not support an
19 association, certainly not generally accepted that Zantac
20 causes cancer. When people and experts depart so far, so
21 astray from what the rest of the scientific community does,
22 this warrants the Court's clear attention. This focus on NDMA
23 and dietary data are not reliable or relevant. An analysis
24 of -- when you actually dig into the data, it demonstrates the
25 flaws in the Plaintiffs' methodological analysis, which is

1 really at the heart of what we are here for today and the next
2 few days.

3 With that, your Honor, I very much appreciate your
4 patience and I will turn it over to Mr. Petrosinelli.

5 *THE COURT:* All right. Thank you very much.

6 *MR. PETROSINELLI:* Your Honor, good morning.

7 *THE COURT:* Good morning.

8 *MR. PETROSINELLI:* I am going to bring us home with
9 two points that relate to the general causation inquiry here,
10 and that is the question of dose and what the Plaintiffs have
11 offered on dose, and their application of the Bradford-Hill and
12 weight of the evidence methodologies.

13 Just to jump right in on dose and what I am -- when I
14 say dose, your Honor, I am really talking about two things.
15 There is the question of threshold dose, the dose at which a
16 compound can be hazardous to human beings generally, and then
17 there's dose response relationship, which is a separate
18 concept. I will talk about both of those.

19 I am going to start with threshold dose because that
20 is easy. The Plaintiffs' experts do not offer any opinion, let
21 alone a reliable opinion, on what is the dose that supposedly,
22 in their opinion, can cause cancer in human beings, or for any
23 of these five cancers, and why didn't they do that?

24 In their brief they say a couple of things.

25 One is, they say that is a specific causation

1 question. That is their main sort of Daubert defense to that
2 point, is that we will talk about dose when we get to specific
3 causation, that is not a general causation issue. That is just
4 entirely wrong under the Eleventh Circuit case law.

5 Next slide, please.

6 I think of Chapman and McClain as the two leading
7 cases in the Eleventh Circuit on general causation issues as
8 they relate to toxic tort cases. When you read those opinions,
9 it could not be clearer, these are quotes from the opinions,
10 but just to take McClain, the burden in a toxic tort case, to
11 satisfy it the Plaintiff must, not may, must demonstrate the
12 levels of exposure that are hazardous to human beings
13 generally, that is general causation, as well as the
14 Plaintiffs' actual level of exposure. That would be specific
15 causation.

16 In the Fixodent case, the Eleventh Circuit opinion in
17 the case, same thing, neither of their general causation
18 experts offered opinions about how much Fixodent must be used
19 for how long.

20 Next slide, please.

21 District Courts in the circuit after McClain and
22 Chapman have, of course, applied this methodology. I have here
23 two of Judge Rodgers cases. She would be happy I said it here
24 twice already in my presentation, her two most recent cases
25 assessing general causation in toxic tort cases. The Deepwater

1 Horizon piece of it that she got from Judge Barbier when the
2 Florida residents made claims couldn't be clearer. The burden
3 on general causation must demonstrate the levels of exposure
4 that are hazardous to human beings generally, and she noted the
5 same in Abilify.

6 So, the question is, what have the Plaintiffs done and
7 said with respect to that? Let's look at what they have said
8 in their briefing because this statement that they made I
9 thought was quite extraordinary and supremely relevant to what
10 we are talking about.

11 Next slide, please.

12 I don't know if your Honor saw this because this is in
13 their motion to exclude the Defense experts, the motion that is
14 being heard next week, but this is what they say. Their
15 general causation theory -- so we are not talking about specific
16 causation -- in the litigation is for long-term use of
17 Ranitidine. The claim is not, not that Ranitidine causes
18 cancer after one dose or even a year's worth, but over many
19 years of regular use.

20 That is a pretty extraordinary statement for a couple
21 of reasons.

22 One is, they have conceded as a general causation
23 matter, meaning we should get summary judgment whatever
24 happens -- and we will talk about this when we get to the
25 summary judgment motions -- that if someone takes Ranitidine

1 for a year, they are not claiming they have proof, reliable
2 proof or even any proof of general causation.

3 Now, the second thing that is interesting about the
4 statement is what they are saying from a general causation
5 perspective, they tell us, is it is many years of regular use.
6 That is not a dose, that is not a frequency, that is a
7 description. That is what is missing here.

8 What they have to tell us is how many years, what is
9 regular use, how many doses, in other words, of the product.

10 Those are the two components of exposure in a toxic
11 tort case, the quantity of the exposure and the duration of the
12 exposure. This is what McClain and Chapman say must be part of
13 a general causation presentation to be reliable, and they
14 haven't done it. All they have said is many years of regular
15 use.

16 Let's see what their experts have said.

17 Next slide.

18 Dr. McTiernan, no opinion. We asked her point blank
19 on this issue of threshold dose and duration. We first asked
20 her about Ranitidine. I don't have an opinion on that.

21 Then, because they say, well, the Ranitidine data is
22 not the key data, it is the NDMA data, we said, okay, NDMA.
23 Don't have an opinion on that. You might wonder where the 47
24 nanograms came from. She had testified that there was a
25 dietary study that showed -- tried to estimated levels of NDMA

1 and it showed an increased risk with every 47 nanograms, or
2 something like that. And we said, okay, put aside whether that
3 is accurate or not, how long, how long would it take for each
4 of the cancers -- if you ingested 47 nanograms could you say
5 would cause or could cause cancer? Don't have an opinion on
6 it, I can't tell you.

7 Next slide, please.

8 Dr. Moorman went the opposite way, she went with the
9 single pill theory. We asked her for both Ranitidine and NDMA,
10 can a single pill of Zantac cause cancer? And her theory is,
11 well, if it is a genotoxic compound, which means it can alter
12 the DNA, then theoretically one pill could do it, any level of
13 exposure could cause cancer, and the same thing with NDMA.

14 I think the Plaintiffs realize that that is a Daubert
15 loser. Under the case law, McClain is the best case on this,
16 this is what the expert said, any dose could cause it.

17 Next slide, please.

18 So, the Plaintiffs back pedaled. I don't know if your
19 Honor saw this, this is a brief filed last week, this is their
20 reply in support of their Daubert motions filed last Wednesday.
21 They say, well, Dr. Moorman is correct that a single molecule
22 could cause cancer because if it is a genotoxin there is no
23 safe dose, but, but, we, the Plaintiffs, are not arguing here
24 as a general causation matter that a single pill or molecule
25 could cause cancer as a legal matter.

1 When they say as a legal matter, they mean to satisfy
2 Daubert, of course. So, now we are back to square one. They
3 are not saying that any dose could cause cancer, but they won't
4 tell us what the dose is. They say many years of regular use.
5 That does not satisfy McClain and Chapman.

6 Now, I saw on their slides for today they sort of make
7 two more points. One is, they say the Eleventh Circuit cases
8 say you don't have to give a precise dose. Of course that's
9 true. No one is talking about they have to say it is 150.5
10 nanograms for 3.7 years. That level of specificity is not what
11 is required, but some numbers are required, that is what the
12 case law says, a range, an estimate, and they don't do it.
13 They won't do it.

14 They have explicitly disclaimed it for the reasons we
15 talked about, either because they mistakenly thought it was a
16 specific causation question, or they didn't think that they had
17 to provide any more specificity.

18 That is a fatal defect at the most threshold level, no
19 pun intended, of their Daubert general causation presentation
20 under the case law.

21 Dose response, separate concept, which is, put aside
22 this question of threshold dose, let's say there was no
23 threshold dose, let's pretend for a moment, or whatever the
24 threshold dose is. At a certain point the concept of dose
25 response is that as the exposure increases, the risk increases

1 for the outcome, and whether -- the slope of the line depends
2 on how quickly the risk increases.

3 What does the Eleventh Circuit tell us about that?

4 Next slide, please.

5 It tells us something pretty clear. The single most
6 important factor to consider in a toxic tort case when you are
7 dealing with general causation, and we are talking about
8 general causation here -- and I have McClain and Chapman up
9 again and you see in McClain, this is what I mentioned before,
10 their general causation expert said any level is too much and
11 wouldn't give any numbers or any specificity about a dose
12 response relationship, and the Court said not going to be
13 admissible. And of course, in McClain, as you know, they
14 actually reversed a jury verdict in favor of the Plaintiffs on
15 this question.

16 So, what do the Plaintiff's experts say about dose
17 response relationship?

18 Next slide, please.

19 Dr. Moorman can't say anything about it with respect
20 to the Ranitidine studies because their position, as you know,
21 is the Ranitidine studies have these limitations, they don't
22 follow the patients long enough, they don't measure precisely
23 enough the exposure, and so Dr. Moorman says, I cannot tell you
24 what the shape of that dose response line looks like. I can't
25 describe anything about dose response from those studies.

1 And I think Dr. McTiernan does the same.

2 The one expert they have who actually does try to
3 tackle dose response is Dr. Salmon, and so you will hear from
4 Mr. Holian in much more detail about that later, but his
5 methodology, the way that he tries to construct a dose response
6 curve for both Ranitidine and NDMA is totally unreliable,
7 unmoored to any science anywhere. That is the one expert they
8 have who tries to do it, but they have to do it, they have to
9 have reliable evidence of a dose response relationship.

10 Where they tell us -- when I say reliable evidence,
11 where they tell us what number of years increases the risk at
12 what doses, that is the dose response relationship, and that is
13 what the case law says they have to provide as a matter of
14 general causation, the single most important factor, and they
15 don't have it.

16 So, for those kind of two independent reasons relating
17 to dose, they can't satisfy the general causation.

18 Let me shift topics to my second topic, which is the
19 application of the Bradford-Hill analyses that were done.

20 Next slide, please.

21 We have addressed in the briefs that not all their
22 experts conducted a Bradford-Hill or weight of the evidence or
23 applied either of those methods, but some did.

24 Next slide, please.

25 The first thing I want to say about it is emphasize

1 what Mr. Cheffo mentioned, of course I think this point is not
2 in dispute. You don't even get to a Bradford-Hill analysis
3 unless you have reliable evidence of an association, and for
4 all the reasons Mr. Cheffo described, they don't have any
5 reliable evidence of an association, and therefore you would
6 not get to the question of whether it is causal, which is what
7 Bradford-Hill does.

8 This is Judge Rodgers' Deepwater Horizon opinion, but
9 there are plenty of opinions that say this. So, what I am
10 addressing now is, let's assume they get past that, even if
11 there were reliable association in the data.

12 Next slide, please.

13 So, what does case law tell us? There is a rich body
14 of pharmaceutical MDL case law on the application of the
15 Bradford-Hill method or the weight of the evidence method. The
16 Mirena and Zolofit opinions are probably the leading pharma MDL
17 opinions on this question.

18 Judge Engelmayer's opinion in Mirena is like a Daubert
19 tour de force, it is an amazing explanation of all the things
20 we have been talking about today, frankly.

21 What you glean from this are two concepts, and they
22 are kind of separate in my mind. One is that if you are going
23 to apply a Bradford-Hill method, you have to rigorously explain
24 how you weighted the criteria.

25 In other words, you can't just say, which is what the

1 Plaintiffs' experts do here, I weighed all of the criteria, I
2 gave appropriate weight to this or that. That doesn't get you
3 past Daubert. You have to rigorously explain how it is that
4 you weighted it.

5 So, for example, if the association that is seen in
6 the epi studies is weak, you know, it is one point something,
7 which is basically what it is in all of the Ranitidine epi
8 studies, and frankly, most of the NDMA studies, but you are
9 going to conclude causation, you have to say, well, yes, the
10 association was weak, I admit that, but the dose response
11 relationship was so strong, and the consistency was so strong,
12 that those two factors I weighted heavier than the strength of
13 association, something like that.

14 You don't just say I went through all of the nine
15 factors, I weighed them appropriately, and this is how I came
16 to my judgment.

17 The second thing is shown in the Zoloft quote, which
18 is, you can't just explain how you weighed them, but there has
19 to be a scientific method of weighting. In other words, you
20 can't say I weighted the strength of association less than
21 these other factors, and so I am done under Daubert, I passed
22 Daubert because I told you how I weighed them.

23 You have to weigh them in a reliable way. The
24 weighing has to be supported by science, and what you will hear
25 later on when you hear about Dr. McTiernan and Dr. Moorman, you

1 will see how they addressed and weighted some of these factors
2 and they did things inconsistent with how they did it with
3 their peer review publications, inconsistent with prior
4 testimony, inconsistent with the way that the FDA or the EMA
5 used these factors, inconsistent with the study authors. I'll
6 talk about that in a second. Those are the two things you have
7 to do under Bradford-Hill that are absent here.

8 Next slide, please.

9 I thought this would be interesting. I know your
10 Honor knows many of these judges and many of their MDLs. There
11 has been an abundance of pharmaceutical MDLs in the past
12 several years -- I guess Deepwater Horizon is not
13 pharmaceuticals -- these are all products MDLs, but all of them
14 but that one are pharmaceutical ones where these judges --
15 these are experienced MDL jurists -- tackled the issue of the
16 application of a weight of the evidence or Bradford-Hill
17 approach in assessing general causation, and every single one
18 of these Courts excluded the opinions under Daubert, every
19 single one.

20 Why is that? I think there is always case specific
21 things. You can never look at one case and say I can now do
22 the same thing because the studies are different and so on, but
23 I think you can glean three things in common that these cases
24 had.

25 Next slide.

1 In all of these cases, the scientific community had
2 studied the issue and no one outside of the courtroom had
3 concluded causation, no regulator, no medical organization, no
4 medical college, no peer review literature. No one had
5 concluded causation.

6 The second thing is that the Plaintiffs experts -- I
7 should say in all of these cases basically, there may be some
8 exceptions, these were highly qualified epidemiologists and
9 other experts on the Plaintiffs' side. In other words, the
10 Defendants didn't challenge qualifications of these experts.

11 Judge Rodgers, I think, in her Deepwater Horizon
12 opinion says, impeccably qualified experts, and in all of these
13 cases these highly qualified experts purported to apply
14 Bradford-Hill or weight of the evidence, and they concluded
15 causation, notwithstanding no one else had.

16 The third thing is that the Plaintiffs' experts, in
17 applying the Bradford-Hill factors, they exceeded the
18 conclusions of the authors of the studies on which they relied,
19 the very studies on which they relied. When I say exceeded the
20 conclusions, I don't just mean, your Honor, they concluded
21 causation and the studies didn't, because epidemiologic studies
22 don't often talk in terms of causation.

23 What they did that was different than the study
24 authors and some of the things you just heard about from Mr.
25 Cheffo, the authors' analyses of their own data and what their

1 data means, the authors' discussion of how they controlled for
2 confounding or couldn't control for confounding, the analysis
3 within the studies and conclusions the authors reached about
4 their own data, the experts in all of these cases exceeded
5 those conclusions, offered opinions that were inconsistent with
6 those conclusions.

7 All of these things are present here.

8 Next slide, please.

9 I want to talk about in my two minutes -- Mr. Cheffo
10 stole some of my minutes -- Abilify. There are, of course,
11 some cases in which they weren't excluded. Why? Look at Judge
12 Rodgers opinion in Abilify. There was an epidemiologic study
13 of Abilify, the product in question, that showed statistically
14 significant massive increased risks of the diseases in
15 question. Look at the relative risks, five to almost eight,
16 highly statistically significant.

17 Next slide.

18 Look what Judge Rodgers said, broad scientific
19 consensus about the existence of an association, the opposite
20 of what we just talked about in the other MDLs. All the
21 regulatory agencies had concluded as much, and the study
22 unchallenged in the literature, totally different than what we
23 have here.

24 Next slide, please.

25 And Judge Chhabria in Roundup, I just wanted to point

1 out the standard he set out which does take into account those
2 for general causation. But look at what Judge Chhabria said,
3 it is a close question, he said that four or five times, and he
4 says, in the Ninth Circuit my perception is that there is more
5 deference to experts in close cases than might be appropriate
6 in some other circuits. What are the other circuits he cites?
7 The third and the Eleventh. If Judge Chhabria were here I
8 think he would say, if I was in the Third or Eleventh Circuit I
9 would have granted this Daubert motion. That is what he is
10 telling us here.

11 Next slide.

12 Judge, finally, the Plaintiffs say the human
13 Ranitidine epidemiology leaves the question open. We don't
14 think that is true for the reasons Mr. Cheffo just explained,
15 but let's say it were true. What does that mean for the law?
16 What that means is the Daubert motions have to be granted, that
17 you can't conclude causation, because in the real world, if the
18 human Ranitidine epidemiology left the question open because
19 there wasn't long enough followup and because there wasn't
20 enough information about dose, we know what scientists would
21 say because we saw what scientists did.

22 They didn't say, as Mr. Cheffo pointed out, oh, we
23 have this 20 years worth of NDMA dietary research, that answers
24 the question. We can fill that gap with that research. What
25 would they do? They would do more studies on Ranitidine. They

1 would follow these populations for two or three more years and
2 see if the increased risk of cancer that the Plaintiffs say is
3 bound to pop up because you didn't -- that is what they would
4 do.

5 What they would not do is do what the Plaintiffs have
6 done here and say, then let's look at lesser levels of
7 evidence, the dietary and occupational stuff by analogy.

8 Next slide, it's my last slide.

9 That is because law has to lag science. Your Honor
10 has seen this quote, it is in McClain, I think it originated in
11 the Seventh Circuit. This is Judge Seibel's -- she had the
12 first Mirena MDL, there were two, and what does it mean? I
13 like the way that she describes it. It is not that I am
14 saying -- she excluded the experts. It's not that they are
15 insincere, it is not that Dr. McTiernan and Dr. Moorman haven't
16 convinced themselves that there is enough evidence for them to
17 believe there is causation, or it is not that some day it might
18 not be validated -- I don't think so here -- but it is not
19 that, it is that the law can't wait.

20 You judge the science as it is today, and as it is
21 today, there is no reliable evidence of causation, and that is
22 why our motions fundamentally should be granted.

23 Thank you, your Honor.

24 *THE COURT:* Thank you very much.

25 Okay. You are just over by two minutes. Certainly

1 the Plaintiffs can have an extra two minutes if they need it.

2 On our schedule we have a 15 minute break now.

3 So let's see, it is 10:18, so that means we should
4 return at 10:33, and then we will pick up with the Plaintiffs'
5 presentation and go right into the Defense rebuttal before we
6 break for lunch.

7 We will be in recess until 10:33. We will see you
8 back then. Thank you.

9 (Thereupon, a short recess was taken.)

10 *THE COURT:* Okay. From the Plaintiffs.

11 *MS. FINKEN:* Good morning, your Honor, Tracy Finken on
12 behalf of Plaintiffs.

13 *THE COURT:* Good morning.

14 *MS. FINKEN:* I am going to address certain issues
15 today and then my colleague, Daniel Nigh, will address some
16 other issues when I am finished.

17 Your Honor, like Mr. Cheffo said, we also told you
18 several things on day one in this case that were true then that
19 are still true today. Many of those things that we told you
20 back then remain undisputed, and I think it is really
21 important, your Honor, that we don't lose sight of the fact
22 that, one, all Ranitidine degrades to form NDMA.

23 Two, NDMA is a known genotoxic carcinogen, that is not
24 disputed.

25 Three, Ranitidine has been globally recalled because

1 it contained NDMA, a known genotoxic carcinogen.

2 And four, we told you back then, and we are going to
3 show you today as well, that there has been consistency
4 demonstrated across all categories of evidence that
5 the exposure to the NDMA, the genotoxic carcinogen in
6 Ranitidine, can increase the risk of the five cancers that we
7 are alleging in this case.

8 Mr. Nigh will go into some of the epidemiology and
9 dose responses, but I just wanted to address that up front.

10 One of the other things, your Honor, that we agree
11 with from Defense's presentation is that there has been an
12 abundance of MDL judges who have tackled the general causation
13 issue similar to this case, however, the difference is, and at
14 a cursory review of those Daubert opinions, not one of those
15 cases has the overwhelming abundance of evidence that we have
16 in this case. And we will go through that in more detail as we
17 go forward.

18 So, to begin, your Honor, the question is relatively
19 straightforward, the issue is whether the NDMA in Ranitidine is
20 capable of causing the five cancers at issue. Defense counsel
21 admitted that this was the issue in front of this Court in
22 July.

23 Now, today they seek to reframe the issue so that it
24 only is about Ranitidine and exclude any evidence about NDMA,
25 and they seek to have this Court and Plaintiffs' experts put

1 blinders on and ignore any evidence regarding NDMA. Your
2 Honor, this simply defies logic.

3 Make no mistake, this case has always been about the
4 genotoxic carcinogen NDMA. If Ranitidine did not degrade to
5 form NDMA it would still be on the market today, the Defendants
6 would still be making billions of dollars a year on this
7 product, but it is not. It cannot be found in the United
8 States. Every scientific authority and regulatory authority
9 agree in the world, they agree that NDMA is a genotoxic
10 carcinogen. This has been known for more than 50 years, your
11 Honor.

12 So, under Eleventh Circuit precedent, there are two
13 types of cases when it comes to toxic torts, and I am going to
14 briefly discuss those, and they are outlined in McClain versus
15 Metabolife, which Mr. Petrosinelli talked about in some detail.

16 So, under Eleventh Circuit precedent, to determine the
17 answer to the question we just posed, the Court needs to look
18 at, one, whether it is generally accepted in the medical and
19 scientific community that NDMA can cause cancer. If the answer
20 to that question is yes, then the case proceeds to case
21 specific causation and extensive Daubert analysis does not need
22 to be undertaken in this stage.

23 If the Court determines that the answer to that
24 question is no, then the Court must conduct a Daubert analysis
25 of Plaintiffs' experts' general causation opinion.

1 To frame the question under McClain category one, is
2 it generally accepted in the scientific community that NDMA can
3 cause cancer, and that question is applied without regard to
4 specific dose, and we cite to authority demonstrating that in
5 our brief, specifically the Williams versus International Paper
6 case.

7 The answer to the question whether the medical
8 community generally recognizes that NDMA causes cancer is
9 unequivocally yes, your Honor. Every single regulatory -- next
10 slide, please. I'm sorry, can you go back two slides.

11 Every single scientific or regulatory authority in the
12 world agree that NDMA is a genotoxic carcinogen. The
13 Defendants admit that NDMA is a genotoxic carcinogen. Your
14 Honor, this has been established since 1978, when IARC first
15 undertook an evaluation of this substance, and what they found
16 was that NDMA is a probable human carcinogen, meaning it is a
17 likely human carcinogen, and should be regarded for practical
18 purposes as if it were carcinogenic to humans.

19 Now, IARC determines whether an agent is a carcinogen
20 through a very rigorous process. They convene an expert panel
21 of scientific experts in multiple disciplines from all around
22 the country, all around the world, and all of those scientists
23 gather all the relevant data information, look at the quality
24 of the studies and read it, then they weigh the evidence and
25 make a determination on the carcinogenicity of the agent. That

1 is what IARC did in 1978. It is vetted across a large group of
2 experts and it is meant to simulate a peer review process by
3 doing it in a panel format.

4 Defendants make much of the fact in their papers that
5 the human evidence is limited and therefore IARC has not
6 classified NDMA as a Category I known human carcinogen. That
7 was true in 1987, which is the last time that IARC actually
8 reviewed NDMA as a carcinogen. It was in 1987, your Honor. At
9 that point in time the epidemiological evidence in humans was
10 limited, but since then dozens and dozens of studies have come
11 out in peer reviewed publications that establish an association
12 between NDMA exposure and cancer, and that increased risk is
13 evident whether the exposure is through diet, whether it is
14 through air, whether it is through water, whether it is through
15 Ranitidine, or whether it is through other drugs.

16 IARC has never re-evaluated the classification since
17 that point in time in light of all this additional human
18 epidemiological evidence that has come out.

19 Your Honor, Plaintiffs' experts are well suited to
20 recognize this because multiple of Plaintiffs' experts have
21 served on IARC working group panels. Dr. Melnick has reviewed
22 over a hundred agents for carcinogenicity for IARC. Dr. Zeiger
23 has sat on the expert IARC working group panels, Dr. McTiernan
24 has sat on IARC expert working group panels. They are well
25 suited to undertake this issue.

1 The Defendants have not proffered a single expert that
2 has been an invited expert on an IARC working group panel to
3 look at the carcinogenicity of an agent.

4 In 2002, your Honor, the World Health Organization
5 issued a report -- I am not sure what is going on with my
6 slides, bit it is not following what I am doing.

7 In 2002 the World Health Organization issued a
8 report which said that NDMA is clearly carcinogenic, and highly
9 likely to be carcinogenic to humans at relatively low levels of
10 exposure.

11 This report -- I know your Honor is already familiar
12 with it, but this report included a review of the dietary NDMA
13 epidemiology at that time, in 2002.

14 What the World Health Organization determined was that
15 the evidence in 2002 fulfilled in part the traditional criteria
16 for causality, and that can be found on page 22 and 23 of the
17 World Health Organization report, the 2002 report.

18 Since 2002, there have been dozens of peer reviewed
19 studies in well respected journals that demonstrate an
20 increased risk of cancer with exposure to NDMA.

21 Most recently, your Honor, in 2022, the Agency for
22 Toxic Substance and Disease Registry, which is typically
23 referred to as the ATSDR, they determined that there were human
24 epidemiological studies demonstrating associations between
25 exposure to NDMA and various cancers. In fact, ATSDR evaluated

1 the same dietary and occupational studies that Plaintiffs'
2 experts evaluated, and they concluded that the carcinogenicity
3 of NDMA is widely recognized, that can be found on page 4 and 5
4 of the 2022 ATSDR review of NDMA.

5 Last, your Honor, and most tellingly, the Defendants
6 themselves admit that NDMA causes cancer.

7 GSK, in 2019, after the news broke that Ranitidine
8 contains NDMA, conducted a health hazard assessment pertaining
9 to NDMA, and they did it because the news broke that Ranitidine
10 contained NDMA.

11 What they did was, and this is really telling, GSK
12 evaluated the animal mechanistic and human epidemiology,
13 including the dietary NDMA studies that Plaintiffs' experts
14 evaluated, and they found that NDMA is a genotoxic carcinogen
15 and exposure should be reduced to the extent possible.

16 GSK came to the same conclusion as the World Health
17 Organization in 2002, and they concluded it is considered
18 highly likely, highly likely that NDMA is carcinogenic to
19 humans, potentially at low levels of exposure. This was on
20 September 25, 2019, your Honor.

21 GSK further admitted that there is no qualitative
22 differences in metabolism of NDMA between humans and rodents or
23 other animals and that there is no reason to believe that
24 humans would respond qualitatively differently.

25 GSK also, in 2019, examined the human dietary NDMA

1 studies and found evidence of a positive association with
2 evidence of dose response for NDMA and gastric cancer, among
3 others, and they also found that there was consistency among
4 studies.

5 Defendants' company witnesses also admit that NDMA is
6 a genotoxic carcinogen besides GSK. BI agrees that NDMA was a
7 carcinogen. The head of Boehringer Ingelheim's
8 pharmacovigilance, Dr. Robert Buchberger, admitted that NDMA is
9 a carcinogen and it should be evaluated closely. Pfizer agreed
10 than NDMA is a carcinogen, Dr. Arthur Ciociola, who is the VP
11 of research and development. Sanofi agreed that NDMA was a
12 carcinogen, Dr. Claude Kugel, Sanofi testing head.

13 And, your Honor -- my slides are not keeping up with
14 my presentation, but if you look at our slide deck, and I know
15 that you have a copy of it, there is a picture on slide 14 of
16 animals exposed to Ranitidine that also showed signs of cancer,
17 and they show the effect of Ranitidine on cancer metastasis,
18 and what you see when you look at that picture, which should be
19 the next slide -- the next slide, the next slide -- okay, it is
20 lagging.

21 Your Honor, once you look at that picture, what you
22 will see is there are mouse organs on the right-hand side that
23 were exposed to NDMA in Ranitidine and they are laden and
24 riddled with tumors. The mouse organs in the left-hand side
25 were not exposed to the NDMA in Ranitidine, and you can see a

1 noticeable difference in those two pictures. A picture is
2 really worth a thousand words.

3 Last, your Honor, Dr. Zeiger, who is one of the
4 Plaintiffs' experts in this case, he is a member of the FDA
5 working group on nitrosamines and pharmaceuticals and
6 extensively published in this area, and Dr. Zeiger, he
7 opines that the carcinogenicity of NDMA has been established,
8 well established among the scientific and regulatory
9 communities in the U.S. and internationally for more than 50
10 years. NDMA is generally accepted by the scientific and
11 regulatory communities in the U.S. and internationally as a
12 genotoxic and carcinogenic.

13 Tellingly, your Honor, Defendants have not moved to
14 exclude the opinions of Dr. Zeiger. He is not subject to any
15 of the motions that we are presenting this week. His opinions
16 are unchallenged and they are unrebutted.

17 There is simply, your Honor, no genuine dispute of
18 material fact that the NDMA, including the NDMA in Ranitidine,
19 is a genotoxic carcinogen, and that is why Ranitidine has been
20 recalled globally. The same holds true for every other drug
21 that has been found to contain NDMA, whether that is Valsartan,
22 Metformin, or Nizatidine, they have all been recalled because
23 they contain a carcinogen.

24 Unlike zinc in Fixodent or Benzene in gasoline, which
25 are some of the cases that Defense cite to, NDMA has no

1 beneficial practical purpose. It is exclusively used to induce
2 cancerous tumors in laboratory experiments.

3 In fact, the pharmaceutical industry routinely uses
4 NDMA as a positive control in carcinogenicity studies, and
5 there are studies that have been produced in this very
6 litigation, your Honor, where pharmaceutical companies have
7 used NDMA in this fashion. Plaintiffs' experts also routinely
8 use NDMA to induce cancer in animals, as do Defense experts
9 such as Dr. Gingrich.

10 Your Honor, moving on to the second category under
11 McClain for a toxic tort, that is conducting a general
12 causation -- a full Daubert analysis on general causation, and
13 it is to determine whether or not Plaintiffs' experts'
14 methodology is reliable.

15 The question at -- in that scenario is whether
16 Plaintiffs' experts applied reliable methodology such that
17 their testimony could assist the jury in determining whether
18 the NDMA in Ranitidine is capable of causing bladder, stomach,
19 esophageal, liver, and pancreatic cancer.

20 Now, two Courts have already evaluated this issue and
21 determined that the answer to this question is yes. First,
22 Judge Kugler in the District Court of New Jersey, under a
23 Daubert standard; and second, Judge Smith in the Illinois State
24 Court under a Frye standard.

25 Plaintiffs are confident, your Honor, that when you

1 finish your review and evaluation of all of the methodologies
2 and the evidence that the Court will also find in favor of
3 Plaintiffs on this issue.

4 So, going to the traditional Daubert inquiry, there
5 are three requirements. The first is qualifications, the
6 second is whether the methodology used is reliable, and the
7 third is whether the testimony assists the trier of fact.

8 Now, Defendants are not disputing that Plaintiffs'
9 experts are not qualified in this case. So, the question is
10 really going to come down to whether the experts applied
11 reliable methodologies such that their testimony could assist
12 the jury in determining whether the NDMA in Ranitidine is
13 capable of causing cancer. Plaintiffs submit that the answer
14 to this questions is yes, your Honor.

15 Daubert is about the methodology, not the conclusions,
16 and our experts' methodologies are unassailable and have been
17 highly recognized in the Eleventh Circuit and elsewhere as
18 reliable and sound. All of our experts have analyzed the issue
19 the same as they would in their professional practices. They
20 have conducted a search of all of the relevant literature.
21 They evaluated and weighed the evidence using their scientific
22 judgment and expertise, and they found reliable association and
23 applied the Bradford-Hill factors to determine whether there is
24 a causal link.

25 Your Honor, if you look at a plain reading of our

1 experts' reports, they discuss how they reviewed the evidence
2 with the same rigor that they use in their other work, and what
3 Plaintiffs' experts have done, and that is all of them across
4 the board, Dr. McTiernan, Dr. Moorman, Dr. Salmon, Dr. Le, Dr.
5 Panigraphy, Dr. Michaels, they all looked at the totality of
6 the evidence, they weighed that evidence using their own
7 professional judgment, they found a reliable association and
8 consistency across multiple categories of evidence, and then
9 they applied the Bradford-Hill factors and they reached their
10 causality opinions.

11 Bradford-Hill has been found to be a reliable method
12 under Daubert in this Court by your Honor in the past, as well
13 as in a multitude of Circuit Courts around the country, and it
14 is also set forth in the Reference Manual for Scientific
15 Evidence as a reliable methodology applied by experts.

16 Now, your Honor, scientists may reliably apply the
17 Bradford-Hill factors but reach different conclusions, and as
18 long as they are using their scientific judgment and expertise,
19 they are explaining why they find certain studies informative
20 and why they find other studies not informative, and they
21 explain all this and reach their conclusion, then those experts
22 should be permitted to proceed to a jury for a factual
23 determination.

24 It is about the methodology, not the conclusions,
25 because the same -- similar experts in a similar discipline can

1 look at the same evidence and they may weight it differently,
2 and that is an issue for the jury to decide.

3 They can apply the Bradford-Hill factors reliably and
4 reach different conclusions, and that is permissible under the
5 law. Judge Rodgers in Abilify states that in her opinion.

6 Your Honor, you have aptly noticed in the past that
7 the gatekeeping role is limited under a Daubert analysis. It
8 is not intended to supplant the adversary system, the
9 cross-examination, or the role of the jury, and the real role
10 of Daubert is to keep true junk science out of the courtroom.
11 It's to keep junk science away from a jury, and that is not
12 what we have here.

13 There is a huge body of evidence that supports our
14 experts' opinions and all have been cited to extensively in the
15 reports. There have been more than 500, 600 references that
16 these experts rely upon to support their opinions.

17 Going back to Eleventh Circuit standards, in Abilify
18 Judge Rodgers listed the three primary methodologies that
19 experts can rely upon un reaching their opinions. One is
20 epidemiological studies; two is assessing a dose response
21 relationship; and three is a background risk of the disease.

22 It is not required that the experts meet all of those
23 methodologies, they only need one, your Honor, and that is
24 noted by Judge Rodgers in the Abilify opinion. What we have
25 here is the experts cite multiple supportive studies for each

1 cancer that demonstrate an association between exposure to
2 NDMA, including the NDMA in Ranitidine, and the five cancers at
3 issue here. So, there is consistency across all categories of
4 evidence.

5 In addition, experts who have reliably applied the
6 three primary methodologies can also bolster their opinions
7 with secondary methodologies. Those secondary methodologies,
8 which should be on the next slide if my PowerPoint is keeping
9 up with me -- here we are.

10 The secondary methodologies are biological
11 plausibility, case studies, adverse event reports, animal
12 studies, and in vitro studies. What we have here, your Honor,
13 is the Plaintiffs' experts relied on all of these
14 methodologies. They looked at all of the primary
15 methodologies, as well as all of the secondary methodologies.
16 They considered all of it, and what they found were consistent
17 trends across all categories of evidence, and that is how they
18 reached their conclusions.

19 Next slide.

20 So, your Honor, one of the things that we have heard
21 about today quite a bit is dose response. I think it is
22 important to really discuss what dose response actually means.

23 Dose response is evidence that a change in the amount
24 of exposure is associated with an increased risk, and simply
25 put, if the amount of NDMA exposure increases, the risk of

1 cancer increases.

2 In this case there is evidence of dose response, it is
3 in animal studies as well as in human epidemiological studies,
4 but this shouldn't be conflated with dose. Dose response as a
5 scientific concept is different than dose, which is an
6 individual case specific causation inquiry as whether or not a
7 Plaintiff had enough dose of the toxin to cause their injury.

8 Dose response is evidence in the scientific studies
9 that the increase in exposure caused an increase in risk. It
10 is as simple as that, your Honor, and there is that evidence
11 across multiple studies, which Mr. Nigh will discuss shortly,
12 as long as I haven't used up all of his time.

13 Your Honor, Mr. Petrosinelli pointed out very clearly
14 that in McClain versus Metabolife that the experts need not
15 quantify the precise numbers about a dose response
16 relationship. It is enough to show that dose response exists
17 in the epidemiological studies.

18 Your Honor, I want to address some of the other
19 arguments that Defendants have made that are without merit.

20 The appropriate question is whether the NDMA in
21 Ranitidine can cause cancer at the highest realistic dose any
22 one Plaintiff in this litigation may have been exposed to. It
23 is not the minimum dose, it is the highest dose.

24 Secondly, there has been found to be a reliable
25 association such that a Bradford-Hill analysis was appropriate.

1 In fact, their own internal toxicology experts who reviewed
2 this issue founded an association. So, to sit here and say
3 there is no association is just not credible.

4 Your Honor, additionally, the NDMA and the Ranitidine
5 epidemiology are both relevant to the question of whether the
6 NDMA in Ranitidine causes cancer. Both categories of evidence
7 are relevant to this question. We cannot lose sight of the
8 fact that this case is about NDMA, which is the carcinogen in
9 Ranitidine.

10 This case is not like the Benzene cases and it's not
11 like the Chapman and Fixodent cases, and I will explain why in
12 a moment.

13 Going back to the first issue, which is about the
14 highest possible dose, for purposes of general causation we
15 respectfully direct the Court's attention to the Roundup
16 Daubert opinion as persuasive authority where the Court
17 acknowledged that at the general causation phase Plaintiffs
18 need not establish any particular level of exposure, but that
19 Plaintiffs only need show that the agent can cause the disease
20 when people are exposed to the highest dose that people might
21 plausibly experience.

22 To put that into context, your Honor, in this case, in
23 the registry more than 60 percent of the registry claimants had
24 exposure for more than ten years. Okay. And that is a really
25 important point when we are evaluating some of the Ranitidine

1 epidemiological studies that Defendants cite to as being so
2 informative. They are not looking at Plaintiffs that have
3 chronic use like we have in this case.

4 Your Honor, Defendants have tried these identical
5 arguments about there not being a reliable association, such
6 that a Bradford-Hill analysis was inappropriate, that Mr.
7 Petrosinelli just said to you previously. They tried these
8 arguments in Valsartan and Judge Kugler swiftly shut them down
9 and, your Honor, he also determined that Bradford-Hill and
10 weight of the evidence are acceptable methodologies to assess
11 this issue and permitted all of the Plaintiffs' experts to
12 proceed forward. He actually excluded several of the Defense
13 experts for not reliably assessing the issue.

14 Your Honor, Courts often look at the underlying
15 chemical in a product in a toxic tort such as this. In certain
16 cases, for example, the Benzene cases that they cite, it is
17 about Plaintiffs who are exposed to Benzene in gasoline, and
18 the Burst case, which is one of the cases that Defendants cite
19 to, actually supports our experts being permitted to proceed
20 because in Burst they excluded the expert because the expert
21 only looked at the Benzene studies and did not look at the
22 gasoline studies.

23 The expert in Burst actually went so far as to say the
24 gasoline studies are irrelevant, are irrelevant to the issue,
25 and that, the Court found, was not reliable methodology, to

1 completely ignore one category of evidence that is relevant to
2 the causation inquiry.

3 Here, your Honor, Plaintiffs' experts looked at both
4 the Ranitidine epidemiology and the NDMA epidemiology, so it
5 differs from the Burst case. The experts here looked at all of
6 the relevant evidence to reach their conclusions and they found
7 consistency throughout.

8 In addition, your Honor, there is the Henricksen case,
9 which Defendants also cite to, which is an opinion also about
10 an exposure to Benzene in gasoline, and that particular case
11 same thing, it said, because gasoline exposure is a source of
12 Benzene exposure, which Benzene was the carcinogen at issue in
13 that case, evaluations of both the gasoline and its toxic
14 component Benzene are obviously relevant to the Plaintiffs'
15 case, and that is what we have here, your Honor.

16 Going and looking at the Chapman and the Fixodent
17 cases, which are also cases that Defendants cite to in their
18 papers and have cited to up here, again, it is not like this
19 one.

20 In those cases, there was no, zero, supportive
21 epidemiology regarding the substance or the toxin at issue,
22 there was none. The toxins that were being addressed were not
23 identical.

24 In those cases they were referring to a zinc calcium
25 compound which was in Fixodent and not zinc acetate, which is

1 what the science that they were looking at pertained to. The
2 compounds were different and there was evidence that there were
3 differences in the bioavailability of the zinc calcium compound
4 compared to the zinc acetate compound.

5 There is no such evidence here that NDMA in Ranitidine
6 is any different from NDMA in the diet, or NDMA in contaminated
7 water, or NDMA from inhalational exposure at work. There is no
8 evidence that has been proffered by Defendants to suggest there
9 is a difference.

10 Your Honor, there are forest plots in my presentation,
11 which, as I said, is lagging so it is not up on the screen,
12 but -- there it is. You can see here, this is the Ranitidine
13 epidemiology on these forest plots. This is only Ranitidine
14 epidemiology, and for all of the five cancers you can see that
15 there are multiple studies, not all, but there are multiple
16 studies that show a point estimate to the right of 1, which
17 demonstrates an increased risk.

18 Mr. Nigh will go through that in more detail shortly.

19 So, your Honor, just to sum it up briefly, given the
20 fact that each expert in this case that the Plaintiffs have
21 offered have conducted a comprehensive search of the literature
22 the same way that they would do in their own practice, they
23 reviewed all of the relevant evidence, they evaluated the
24 strengths and the weaknesses of the studies, they articulated
25 that in their report, why they found certain studies to be

1 informative, why they found studies that were not informative,
2 and they found an association, and once they found that
3 association, based on the totality of the evidence,
4 they applied the Bradford-Hill factors in reaching their
5 conclusions, which is a reliable methodology, and their
6 opinions should be permitted to proceed to a jury for a factual
7 determination.

8 Last, your Honor, there are a couple of things that I
9 want to address that were in the slides that we were provided
10 by Defendants yesterday. I feel like I need to address some of
11 the misstatements in some of those slides.

12 First, on slide 30 of their presentation they put up a
13 chart, you might recall, and it had a whole bunch of different
14 organizations on it, American Cancer Society, American Lung
15 Society, Pancreatic Cancer Network, all the different
16 organizations, and they state that no medical or scientific
17 organization identifies an association between Ranitidine use
18 and any type of cancer, and they list all of the organizations,
19 plus a dozen more that I just mentioned.

20 Your Honor, there is not one shred of evidence that a
21 single one of those organizations that they put up on the
22 screen has ever assessed the question of whether Ranitidine use
23 is associated with any type of cancer, zero evidence.

24 You know what those organizations do recognize? That
25 NDMA can cause cancer. That is what they do recognize.

1 Secondly, Defendants state on slide 9 of their
2 presentation that independent researchers studied the
3 Ranitidine question, and then they provided a dozen or so
4 slides to support that these researchers found that Ranitidine
5 does not cause cancer.

6 This is a blatant misrepresentation of the evidence.
7 An independent researcher who conducts a single study cannot
8 state with certainty that Ranitidine does not cause cancer.
9 That is not how the epidemiological studies work.

10 The same holds true for the Florian study, none of
11 these researchers have evaluated the totality of the evidence
12 beyond the four corners of their own study, so they cannot make
13 that determination.

14 No one has conducted a systematic review of all of the
15 evidence to assess causality except for Plaintiffs' experts.
16 It did not happen and to suggest that an individual researcher
17 who conducted a single study could conclude that Ranitidine
18 definitively does not cause cancer is just false.

19 The most that they could represent is that an
20 individual researcher did not find evidence of an association
21 in the four corners of their study, and Mr. Nigh, my colleague,
22 will explain to you why the findings aren't a surprise based
23 upon the study design.

24 Just to put it in perspective, your Honor, for
25 example, a study that is designed to assess the carcinogenic

1 effects of smoking one carton of cigarettes likely won't find
2 an increased risk of cancer, but we know that smoking causes
3 cancer. That has been established. The best that that study
4 can tell you is that smoking one carton of cigarettes doesn't
5 demonstrate an increased risk of cancer in that particular
6 study. You have to look at the strengths and the weaknesses of
7 each individual study to reach a conclusion.

8 Third, the independent researchers that Defendants put
9 up are not so independent. The Adami study was conducted by
10 consultants for Sanofi in this very litigation, have not been
11 disclosed by Defendants. They were not independent. To
12 suggest they were is simply not true.

13 Last, your Honor, one point that I would like to bring
14 to your Honor's attention. You have instructed us not to --
15 arguments that have not been briefed at the hearing today.
16 Based upon our review of the presentations that were provided
17 to us yesterday, it seems apparent that there will be new
18 arguments being made at the hearing for certain experts that
19 were not addressed in the briefing, and to the extent that your
20 Honor considers those, we may be requesting an opportunity to
21 file a surreply to address those arguments because they were
22 never raised in the original briefing on this case.

23 My colleagues will identify when that is the case
24 during their arguments about the specific experts.

25 With that, your Honor, I am going to turn over the

1 floor to Mr. Nigh, assuming I haven't used all of the time, and
2 I will let him talk to you about epidemiology and dose.

3 Thank you.

4 *THE COURT:* Okay. Thank you very much. You have used
5 35 minutes.

6 *MR. NIGH:* Could we go to slide 59.

7 Good morning, your Honor, Daniel Nigh for the
8 Plaintiffs, may it please the Court.

9 *THE COURT:* Good morning.

10 *MR. NIGH:* Your Honor asked about, in your questions
11 that you presented to us, the dose response of NDMA and
12 Ranitidine, including how much NDMA and for what length of time
13 a person must ingest NDMA and Ranitidine to cause the
14 designated cancers.

15 Now, the Defendants, in their presentation, would seem
16 to pretend that we never addressed this question, and I am
17 floored because it is actually extensively addressed in Dr.
18 Salmon's presentation. There are numerous pages on this. The
19 same thing for Dr. Panigraphy, it is extensively addressed.
20 Dr. Salmon does an extensive analysis to show the lifetime
21 cumulative exposures of NDMA it would take to statistically --
22 to reach a statistically significant increased risk of the five
23 cancers in the NDMA studies. Dr. Panigraphy does this as well.

24 Now, again, Mr. Cheffo stated that it is stunning that
25 Plaintiffs have offered no experts on the dose that would lead

1 to increased risk of cancers. Of course we did. That is in
2 there. Dr. Salmon also demonstrates how long Plaintiffs would
3 need to ingest Zantac to reach the lifetime cumulative
4 exposures of NDMA it would take to reach statistically
5 significant increased risk of the five cancers in the NDMA
6 studies.

7 This slide is an excerpt of the chart that shows
8 precisely that. Dr. Panigraphy does this as well.

9 Lifetime cumulative exposures addressed by Salmon and
10 Panigraphy address how long, how often, and how much Ranitidine
11 use it would take to reach the increased risk of cancers
12 demonstrated in the NDMA dietary and occupational exposure
13 studies.

14 Dr. Salmon ties this analysis to whether we only look
15 at Defendants' and FDA's baseline testing. So, if you only
16 consider that, that is the first column under baseline. That
17 shows how many years it would take to reach lifetime cumulative
18 exposures that would have led to increased risk for each of
19 these cancers. That column is there.

20 The very next column shows the other part of the
21 equation is that the baseline testing levels, as we'll
22 demonstrate as we get further to Dr. Najafi's presentation on
23 day two, are only a small part of the equation. That is
24 what is the NDMA before the consumer ever even purchases the
25 product and opens up the bottle and places it in a common

1 place. Even so, the baseline is even under represented because
2 it doesn't demonstrate how long these products may be in the
3 shipping and supply chain.

4 Many of the products are a much longer period of time.
5 We have demonstrated evidence in this case that some products
6 actually take years from the time they are manufactured as a
7 finished dose product until the time that the consumer even
8 purchased the product, let alone that the consumer has the
9 expectation with a three-year expiration date that they can use
10 that product through to the end of that three-year expiration.

11 Dr. Salmon also ties the analysis to that second part
12 of the equation, what happens after you open up the bottle,
13 what happens as a result of these other conditions, and when
14 you add in or look at the extra amount of NDMA that is actually
15 forming inside of the product, how long does it take to get
16 these five cancers based on the NDMA dietary and occupational
17 exposure studies.

18 How long does it take to get these cancers, that is
19 the complete story, and that is the column on the right. We
20 can see under that analysis, that analysis is how long does it
21 take to get statistically significant increased risk seen in
22 the dietary and the occupational exposure studies.

23 Finally, for bladder cancer, based on Ranitidine
24 epidemiology alone, Dr. Salmon also calculated cumulative
25 exposures to reach statistically significant increased risk of

1 bladder cancer from Ranitidine use, and demonstrated that
2 Plaintiffs will obviously reach those cumulative exposures in
3 this litigation.

4 He couldn't calculate cumulative exposures for the
5 other four cancers based on Ranitidine epidemiological studies
6 alone because none of the other Ranitidine studies had the
7 defined daily dose, known as DDD, information necessary to do a
8 cumulative exposure calculation.

9 In all of the Defendants' briefing they never
10 adequately or specifically attack Dr. Salmon's or Panigraphy's
11 lifetime cumulative exposure calculations. It is being raised
12 for the first time today.

13 In the Valsartan MDL, another NDMA contaminated
14 medication case, this was extensively addressed, and there are
15 numerous cases that admitted evidence of lifetime cumulative
16 exposures, similar to the lifetime cumulative exposure analysis
17 that Dr. Salmon did, and they are admitted for the purpose of
18 both proof of the dose question both for general causation and
19 specific causation, and this is precisely why these lifetime
20 cumulative exposure calculations were admitted in the Valsartan
21 MDL as proof of the dose question for general causation and
22 should be admitted in this Court.

23 I would also like to point out that one of the slides
24 that the Defendants raised on the Chhabria decision tried to
25 suggest that our standard is higher here than the Ninth

1 Circuit, but that slide also says, as the Third Circuit and the
2 Eleventh Circuit, the Valsartan MDL is in the Third Circuit,
3 and this opinion has been admitted in the Third Circuit.

4 In addition to that, Salmon also demonstrated through
5 thorough analyses regarding dose response relationship for each
6 of the studies.

7 Let's turn to page 52, slide 52, please.

8 Now, next I want to address the Defendants' markup of
9 our bladder cancer forest plots.

10 As I understand the Defendants' methodology and their
11 approach to this case, for the Defendants to prevail in showing
12 no association between Ranitidine use and bladder cancer the
13 Defendants must hit the royal flush, or the superfecta, or the
14 triple bars on the slot machine. They have to line up on every
15 one of these arguments and take away every one of these to
16 demonstrate no association.

17 Let's talk about why it is not true. The dietary
18 studies.

19 First, they must convince your Honor that no reliable
20 expert would ever include NDMA dietary studies in their
21 analysis whatsoever. Well, even GSK and the EMA included NDMA
22 dietary studies in their analysis.

23 Second, Hidajat, they must convince your Honor that no
24 reliable expert would ever include Hidajat in their analysis
25 whatsoever. Again, even GSK and the EMA, when they were

1 looking at the issue of Ranitidine and cancer, included those
2 studies in their analysis.

3 Third, they must convince your Honor that because one
4 Plaintiff expert gave Habel no weight, that no other Plaintiff
5 expert can give Habel any weight whatsoever, which simply is
6 not the legal standard, and the Defendants have not established
7 that that is the legal standard.

8 Fourth, they must convince your Honor that no reliable
9 expert would ever include crude risk estimates in their
10 analyses, even when the adjustments in the study are not well
11 documented and questionable, which again simply isn't the legal
12 standard and the Defendants have not established this.

13 Fifth, next the Defendants cherry pick their best
14 result in a sub analysis. We don't have any sub analyses on
15 this chart. We don't have what happens after one year lag,
16 five year lag, ten year lag, unless they didn't give us a
17 primary analysis without that in the study. That is what each
18 of the forest plots do, they just give you the primary analysis
19 in the study and every study that looked at the issue of
20 Ranitidine and cancer, and/or NDMA and cancer.

21 So, the Defendants cherry pick their best results
22 included in the forest plot. Even though that finding is not
23 statistically significant they inject it in there.

24 But there are numerous sub analyses even in the
25 Norgaard study that they avoided including, including that when

1 a ten-year lag is applied for bladder cancer there is a
2 statistically significant increased risk of bladder cancer for
3 Ranitidine users compared to H2RA users, and the same is true
4 for Ranitidine users compared to PPI users when applying only a
5 five year lag period.

6 They omit the longer lag time analyses for Norgaard
7 despite insisting upon inserting the longer lag time in the Liu
8 for the gastric cancer.

9 Also, for Cardwell, they didn't insert the
10 statistically increased risk for long-term exposure for
11 Ranitidine users compared to nonusers, for Ranitidine compared
12 to PPI, and the non-statistically significant increased risk
13 for long-term exposure for Ranitidine compared to H2RA. Any
14 way you look at that study, the long-term risk in Cardwell are
15 elevated for Ranitidine compared to whichever group you look
16 at.

17 Now, there are numerous more favorable sub analyses
18 that show increased risk, with many being statistically
19 significant. In this case we have -- between these various
20 studies there are thousands of sub analyses, and the Defendants
21 are cherry picking a few to put on their forest plots.

22 We did not include these sub analyses on the forest
23 plots; however we will later show that even with the forest
24 plots created by the Defendants' experts with the sub analyses
25 that the Defendants' experts chose to include, that there is

1 clearly an association between Ranitidine use and bladder
2 cancer.

3 Finally, they must convince your Honor that
4 significant results could not be included that statistically --
5 non-statistically significant results cannot be included by any
6 reliable expert methodology. Even though the reference manual
7 does not require rejecting non-statistically significant
8 results, the Supreme Court of the United States discusses how
9 experts are permitted to include non-statistically significant
10 results, and the American Statistical Association encourages
11 considering results regardless of whether the P value crosses
12 .05. That is an update in 2016.

13 Now, in the interest of time, I won't go through the
14 Defendants' manipulation of the rest of our forest plots for
15 the other four cancers as my same arguments made for their
16 manipulation of the forest plots for the bladder cancer would
17 also apply to the other four.

18 Can we go to slide 60.

19 Now I will talk about statistical significance.

20 The reference manual specifically states that
21 epidemiologists have become increasingly sophisticated in
22 addressing the issue of random error and examining the data
23 from a study to ascertain what information they believe about
24 the relationship between an agent and a disease, without the
25 necessity of rejecting all studies that are not statistically

1 significant.

2 So, the reference manual doesn't follow rejecting the
3 non-statistically significant studies, as the Defendants have
4 done in the forest plots.

5 Next slide, please.

6 The FDA relies on data that it is not statistically
7 significant. The Supreme Court of the United States, in 2011,
8 points this out. The FDA similarly does not limit the evidence
9 it considers for purposes of assessing causation to
10 statistically significant results.

11 Next slide.

12 Statistical significance is not required by the law.
13 They also state, the Supreme Court, Courts frequently permit
14 expert testimony on causation based on evidence other than
15 statistical significance. As these Courts have recognized,
16 medical professionals and researchers do not limit the data
17 they consider to the results of randomized clinical trials or
18 to statistically significant evidence.

19 Next slide. Actually, if we can go now to the first
20 slide.

21 Now, I also want to address one more thing the
22 Defendants raised. The Defendants assert in broad strokes that
23 the same data analyzed by Dr. McTiernan and Moorman for
24 rejecting the five cancers that were not designated is the same
25 data, or comparable data, for the other five designated

1 cancers, but this is utterly false.

2 It is easy to explain with kidney and breast cancer
3 briefly. Neither kidney nor breast cancer demonstrates
4 increased risk of cancer due to exposure to NDMA in the Hidajat
5 occupational study. On the other hand, the five designated
6 cancers do demonstrate this.

7 In addition, kidney nor breast cancer demonstrate
8 increased risk of cancer in the dietary studies. That
9 specifically assessed exposure to NDMA. On the other hand,
10 most of the five designated cancers do.

11 What I want to do now is, I want to discuss the topics
12 that I am going to go through in my presentation.

13 I want to show first off that the Ranitidine
14 epidemiology itself shows increased risk for the five cancers.
15 We are going to discuss the Y.D. Kim study because it is the
16 study on the forest plots that the Defendants present in their
17 papers, and it is an outlier. It is one of the only studies
18 that shows a statistically significant decreased risk.

19 Other Ranitidine active comparator studies that I will
20 talk about, how they would bias results toward the norm, but
21 even with that bias, many of those studies show increased risk
22 and statistically significant increased risk, and then also,
23 the NDMA dietary and occupational studies, and then we will
24 talk about the dose response and is there enough dose for
25 general causation, which I covered somewhat already.

1 Let's go to the next slide.

2 First, the Ranitidine epidemiology shows increased
3 risk for all five of the cancers that we are looking at here
4 today, and not just increased risk, but statistically
5 significant increased risk, and then there are other studies
6 that also show increased risk in addition to that.

7 If we can go to the next slide.

8 First, the Cardwell study for bladder cancer shows
9 that overall a 22 percent increased risk when you compare
10 Ranitidine users to nonusers, also when you compare Ranitidine
11 users to PPI users, statistically significant increased risk.
12 When you are looking at three plus years, 43 percent increased
13 risk, statistically significant when you compare Ranitidine
14 users to nonusers. Also statistically significant when you
15 compare Ranitidine users to PPI users, and non-statistically
16 significant increased risk when you compare Ranitidine users to
17 H2RA users.

18 Next, next slide.

19 But in addition to that, we can see multiple other
20 studies. Every study on bladder cancer, the primary result is
21 to the right of 1. Every study demonstrates an increased risk
22 of bladder cancer. The Habel study, 56 percent increased risk.
23 That one combined kidney cancer and bladder cancer. Had they
24 just looked at bladder cancer it may have been even more of an
25 increased risk.

1 Norgaard, 11 percent increased risk. Kantor,
2 30 percent increased risk. Yoon, 41 percent increased risk.

3 Next slide, please.

4 Gastric cancer, Liu, when they apply a one year lag.
5 They don't have a result without a one year lag, so we took
6 that first result, 42 percent, statistically significant
7 increased risk. Habel, the gastric cancer is combined with the
8 esophageal cancer, but a 142 percent increased risk for those
9 two combined.

10 Next esophageal cancer, Adami, 30 percent,
11 statistically significant increased risk. Habel, 142 percent
12 increased risk. Adami, 9 percent increased risk, not
13 statistically significant.

14 Next slide.

15 Liver cancer, 91 percent, statistically significant
16 increased risk when you compare Ranitidine users to nonusers.

17 Next.

18 Kantor compared to Lansoprazole, still a 15 percent
19 increased risk. Now, it is important to understand, as the
20 authors have also discussed in many of these studies, that PPI
21 also has multiple studies that carry -- that demonstrate an
22 increased risk of liver cancer, but Kantor, 15 percent
23 increased risk, not statistically significant. Tran, 41
24 percent increased risk when they used the Scotland database.
25 When they used the U.K. bio bank, 82 percent increased risk.

1 Next.

2 For pancreatic cancer, McDowell, 37 percent,
3 statistically significant increased risk, and Habel,
4 160 percent increased risk.

5 Those are the epidemiological -- the Ranitidine
6 epidemiology, and we would submit to your Honor that the
7 Ranitidine epidemiology is actually quite favorable for these
8 five cancers.

9 In addition, we want to address some of the
10 shortcomings of the Ranitidine epidemiology, and a lot of the
11 reasons as to why the Ranitidine epidemiology cannot be taken
12 alone, but you must look at the other epidemiology in terms of
13 the NDMA in the diet and the NDMA in the occupation, because
14 that is the carcinogen.

15 Next slide.

16 Now, the Defendants would raise that there are some
17 statistically significant increased risks on one side, there
18 are some statistically significant decreased risks on the other
19 side, so they kind of wash out. Really what wasn't raised and
20 what you don't see in those forest plots is that nearly every
21 one of the statistically significant decreased risks is one
22 study alone, the Y.D. Kim study. We will talk about that.

23 Next slide. Next slide, please.

24 Reality is that Kim is an outlier.

25 Next slide.

1 To understand some of the reason behind why Kim is an
2 outlier we need to go back to when Kim was first shown to the
3 world, and that is when it was shown to the world in the DDW
4 2020. This is where it came out. Surprisingly, Mohy-ud-din
5 also came out around the same time. Mohy-ud-din never got
6 published, but I am going to talk about a lot of the
7 similarities between the two.

8 They both use the Explorer's database, that's the
9 database of U.S. prescription users, and they both have a
10 similar timeframe. Then, in addition, they both compare
11 Ranitidine to Famotidine, and then they are also both abstracts
12 of the DDW 2019.

13 Next slide.

14 Now, we got internal documents from the Mohy-ud-din
15 study, and what those documents showed was that Mohy-ud-din
16 actually went a step further. Using the same Explorer's
17 database they compared Ranitidine users to nonusers, but Kim
18 never looked at that issue, and that is why this is extremely
19 important, because when you compare the incidents of cancer
20 with Ranitidine versus general population, with adjustment for
21 risk factors, you get results that are wild and it explains
22 something wrong with this database, just terribly wrong.

23 We are not standing up here today to say that studies
24 should demonstrate what this study did, a six fold increase in
25 all cancers, 600 percent increase of all cancers. Looking at

1 ours, pancreatic cancer, an 878 percent increased risk; bladder
2 cancer, a 989 percent increased risk; liver cancer, 912 percent
3 increased risk; esophageal cancer, 1,039 percent increased
4 risk. Those are wild results and they demonstrate a serious
5 flaw with the Explorer's database altogether.

6 Let's take a look at the next slide.

7 We are going to discuss what some of those flaws
8 likely are in the Kim database, some of the signals that gave
9 us. The Kim Y. D. database even admits that the Ranitidine
10 cohort consistently displayed lower prevalence of common risk
11 factors for gastrointestinal malignancies. It may be that when
12 adjusted for every common risk factor for each cancer the
13 adjusted ORs for the Ranitidine cohorts may increase.

14 Next slide.

15 What does this mean? Well, when we compare ranitidine
16 to Famotidine, we see some issues that show that the Y. D. Kim
17 study does not meet that Federal guidance -- guideline that the
18 Defendants showed earlier to compare a similar population of
19 users. The Famotidine users are not similar to the Ranitidine
20 users.

21 Tobacco use, the Ranitidine (sic) users smoked more,
22 they drank more, they had diabetes more often, they were obese
23 more often, they had cirrhosis more often, they had IBD,
24 irritable bowl disease, more often, they had gastritis more
25 often. These are all risk factors for cancer.

Pauline A. Stipes, Official Federal Reporter

1 Next slide.

2 The Mohy-ud-din study even looked at some risk factors
3 that Kim never looked at and found even more problems that
4 obviously wouldn't have been adjusted by Kim.

5 We asked Dr. Wang, the Defense expert, Doctor, as you
6 considered the Kim study, did you consider the Famotidine
7 population is a more diseased population than the Ranitidine
8 population? Well, I guess this is a recent set of data and in
9 these studies it is a little unclear. You just presented both
10 abstracts and it does appear that they both appear to show that
11 the risk factors we discussed were lower in the Ranitidine
12 cohort.

13 Next slide.

14 Often times a picture is worth a thousand words and
15 the picture demonstrates this.

16 Incident rate charts often times are fantastic to be
17 able to determine if you are looking at the more diseased
18 population, otherwise discussed as protopathic bias in some
19 regards, or -- and then over time you can look to see is the
20 amount of cancers increasing or decreasing between those two
21 comparators.

22 What you will see is even in the Kim Y. D. study the
23 Famotidine users were a more diseased population right out of
24 the gate. They have a much higher increased incident of
25 cancers, and that is all the way through until you get down and

1 you start to see the gap narrow, years seven to eight, eight to
2 nine, and nine to ten.

3 This is the reason why long term followup is extremely
4 important, especially when you start from behind, because if we
5 had actually gotten further along we may have been able to see
6 in this study do the results now flip and Ranitidine long term
7 is more cancers than Famotidine. The key here is, if it is
8 short term, a lot of times the short term is not going to be
9 due to a carcinogen from ingesting the drug. Most of those
10 take a longer period of time.

11 Now, we are not saying it can't happen short term, but
12 the majority of them, and the vast majority of them, happen
13 long term. So, what is happening short term? Those are the
14 risk factors that the individual people exposed in the group,
15 that is what they are bringing to the table. That is the short
16 term on an incident rate.

17 Now let's look at the next chart. Recent epidemiology
18 that has not yet been peer reviewed and published, I will
19 represent that, but in terms of getting these sorts of
20 incidence rate charts that are very valuable, it shows exactly
21 what we are saying, that pancreatic cancer, when they compared
22 non-Ranitidine users to Ranitidine users, you will notice at
23 the very beginning they are pretty tight, pretty close. That
24 is not strong evidence of protopathic bias.

25 What you see over time is the gap widens, over time

1 the risk from Zantac becomes more and more apparent.

2 Next slide.

3 In liver cancer we see the same thing, tight at the
4 beginning and over time we see the separation between the two.

5 This is why time and time again we are encouraging
6 that these Ranitidine active comparator studies, the biggest
7 flaw they have is just short-term followup, and you need
8 long-term followup to be able to see a lot of these risks, to
9 see the separation.

10 Next slide.

11 Gastric cancer, we see the same thing, tight at first,
12 separation thereafter.

13 Next slide.

14 Even in the Norgaard study, we got a draft of that
15 publication and I will represent to your Honor that the
16 Norgaard study, to call this an independent study is a stretch.
17 It has all the same authors as the Adami study except they took
18 off the Sanofi author and they took off the exponent author
19 from Adami, and it is set up very similar.

20 If you look at the study itself, the charts even all
21 look similar because they obviously followed the template of
22 what had occurred with Adami and the other, the exponent
23 author, beforehand.

24 Now, what this draft showed is that the increased risk
25 of bladder cancer for Ranitidine users over time separates.

Pauline A. Stipes, Official Federal Reporter

1 This incident rate chart never made its way into a published
2 study, we'd represent quite likely because of the bias.

3 Next.

4 Now, Defendants cherry picked the FDA guidance on
5 active comparators. It actually says selection of an
6 appropriate comparator group or control group, but a control
7 group means user versus nonuser. They are not saying that it
8 is ideal, it is better to do an active comparator versus a user
9 versus nonuser. They are saying you can look at each of those,
10 but if you are going to do -- in cohort studies, if you are
11 going to do a comparator study, it is ideal to use a group
12 taking a drug used to treat the same disease with the same
13 level of disease severity.

14 So we have demonstrated already why Kim does not live
15 up to that ideal comparator. Famotidine is not the same level
16 of disease severity as Ranitidine.

17 Next slide.

18 Now, I want to address a lot of shortcomings in these
19 studies, but I will address them kind of as a whole in the
20 interest of time.

21 They all have -- many of them have numerous flaws,
22 most importantly is they don't have enough usage. The only one
23 that demonstrates real long term usage and explains the amount
24 of long term usage is the Cardwell study, and that one actually
25 shows 1,095 DDD, that is the defined daily dose. They are

1 actually looking at is it 300 milligram, 150, 75. Well, DDD
2 would be 300 milligrams, so they are actually looking at the
3 dose and the amount of time for that dose and how often.

4 None of the other studies do that. The only ones that
5 come close would be Adami and Norgaard, and they only have ten
6 prescriptions. We don't know what those ten prescriptions are,
7 that information is not in there. It could be one month, three
8 months, we don't know, but if it is one month, that is only ten
9 months of usage. That is not really long term usage.

10 Next, there is not a long enough followup -- actually
11 let's go back to the slide before.

12 There is not a long enough followup, and this is
13 crystal clear in the studies. All the study authors say the
14 same thing, that they are not looking at long -- you know,
15 looking at the full picture of cancer development, they are
16 only looking at the front end of the bell-shaped curve.

17 They are missing important data on confounders. Adami
18 and Norgaard are terrible for this, and we will talk about that
19 later on. They are missing accurate exposure measurement, they
20 are not accounting for over-the-counter use, Adami and Norgaard
21 don't do this.

22 You will see when you look at what -- the experts have
23 also analyzed this, and they recognized that the
24 over-the-counter usage for Ranitidine users is much, much
25 higher so they are not captured in Adami or Norgaard compared

1 to the other H2RAs, and compared to PPI. That is an extreme
2 problem.

3 Some of these studies lump in Nizatidine with
4 Ranitidine. We are not bringing a Nizatidine case here. We
5 don't have any evidence on the amount of exposure -- on the
6 amount of NDMA in Nizatidine. It is low. There is a reason
7 Plaintiffs haven't brought cases on Nizatidine.

8 Next.

9 What do all these things do? Short term usage, short
10 term followup, non-differential misclassification in the form
11 of the problems with over-the-counter usage, or not capturing
12 all the usage, a lot of these studies start decades after
13 Ranitidine users would be using Ranitidine, and so if they
14 switch to a PPI, no credit for the Ranitidine users, they push
15 the results toward the normal. I will suggest even with that
16 push and pressure towards the norm we still have plenty of
17 studies, we talked about that at the beginning, that
18 demonstrate increased risk for these five cancers.

19 *THE COURT:* You have about four minutes, that is
20 giving you the extra two.

21 *MR. NIGH:* Okay. Finally, even the IARC says that
22 experience from studies of cancers in humans indicates that the
23 period from first exposure to the development of clinical
24 cancer is sometimes longer than 20 years, therefore latency
25 periods shorter than 30 years cannot provide evidence of lack

1 of carcinogenicity, but that is precisely what the Defendants
2 are trying to use it for.

3 They are the ones trying to use it for lack of
4 carcinogenicity, we are not, and the IARC says that is
5 inappropriate.

6 Next slide.

7 This is how the epidemiology should be structured, you
8 should have the -- on the top it should be 30 plus years, and
9 you should separate the groups to where only the Ranitidine
10 users are at the bottom.

11 Next slide.

12 This is what it actually looks like. You actually
13 have some Zantac users that are in the top group because they
14 would never know if they used Zantac, and then on the bottom,
15 you don't have much exposure to the Zantac, and most of the
16 studies are less than ten years. A few are just a little bit
17 longer than ten years.

18 Next slide.

19 None of the Defendants' studies had a long enough
20 followup. Kantor, Kim, Iwagami, Kumar, Tran, Yoon, they are
21 all seven or less years, and each of these study authors admit
22 this.

23 Next slide.

24 So you can see, they are all saying that it is not
25 long enough. Yoon says the overall followup period is not long

1 enough to assess the onset of cancer. Adami says the most
2 severe shortcoming of our study is limited number of
3 participants with long term followup. Kantor says we did not
4 capture long term outcomes. Iwagami, longer followup,
5 especially among those with high cumulative dose may be
6 warranted. Kumar, longer followup is necessary. They all
7 address the same issue.

8 Even the reference manual discusses this, the absence
9 of epidemiological data is due in part to the difficulties in
10 conducting cancer epidemiology studies, including the lack of
11 suitably large groups of individuals exposed for a sufficient
12 period of time, long latency periods between exposure and
13 manifestation of disease, the high variability in the
14 background incidents of many cancers in the general population,
15 and the inability to measure actual exposure levels.

16 I want to turn our attention to slide 57, and I will
17 do this quickly.

18 We do have multiple studies that demonstrate a
19 statistically significant increased dose response. We see it
20 in the Cardwell study, Adami, Hidajat, Low, De Stefani, De
21 Stefani 2001, Larsson, Lavecchia, Pobel, Ronca. These all
22 demonstrate that as you increase the amount of Ranitidine, the
23 amount of cancers increase, or if you increase the amount of
24 exposure to NDMA, the cancers increase.

25 *THE COURT:* That would be your time. Are you done or

1 do you have another minute or two?

2 MR. NIGH: I have one more slide. It is slide 51.

3 Them Hidajat, we have heard Defendants argue that
4 inhalation exposure is irrelevant for oral exposure issues.
5 That is inaccurate. There is a formula for this that
6 toxicologists commonly use, how to extrapolate from inhalation
7 to oral. Why would they create a formula if you are not
8 supposed to use it? It is used all the time.

9 They look at how do you compare skin absorption to
10 oral, how do you compare inhalation to skin exposure. There
11 are formulas for this because oftentimes we want to know the
12 data in one study, we want to see what it would be like for
13 another route.

14 Now, the FDA says to use caution when you are looking
15 at this, but that is precisely what Dr. Salmon and Dr. Le did,
16 they used caution and due diligence to see that the
17 bioavailability from inhalation would be similar to the
18 bioavailability from oral exposure. Dr. Le calculated it,
19 greater than 90 percent gets into the bloodstream from
20 ingestion. That makes it similar to the bioavailability.

21 With that, the other issue is that they would argue
22 there is other carcinogens, rubber dust, rubber fumes. Dr.
23 Hidajat in long detail explained that study measures the amount
24 of exposure to NDMA in certain parts of the factory and the
25 amount of exposure to rubber dust and rubber fumes in other

1 parts of the factory.

2 It actually shows in the vulcanizing department you
3 get high amounts of NDMA, but not -- you actually have low
4 amounts of rubber dust and rubber fumes. That exposure there
5 lets us have confidence that the increased risk seen for NDMA
6 is due to NDMA, not some unforeseen circumstance or some other
7 carcinogen.

8 That is all. Thank you.

9 *THE COURT:* Thank you.

10 Okay, the Defense has an opportunity to present a
11 rebuttal, and you had five minutes, but Plaintiffs went over by
12 an additional two above and beyond the additional two they got,
13 so you have seven minutes.

14 *MR. PETROSINELLI:* Mr. Cheffo gave me some minutes
15 back, so I will talk a little bit, because he stole my minutes.

16 I am just going to do a couple of law points, Roundup,
17 because I didn't get to address it. The framing of the general
18 causation issue, I think I said before we agree because it
19 incorporates the concept of dose.

20 There is one thing that Roundup says that the
21 Plaintiffs showed, the opinion says, all the Plaintiffs have to
22 do is show the highest dose that humans could be exposed to,
23 and if they do that reliably, then they get all the other
24 doses, too. That is not the law in the Eleventh Circuit.
25 Chapman and McClain are clear that it is not about highest

1 dose, it is about lowest dose. You have to have a threshold
2 dose and then dose response, so that is just not Eleventh
3 Circuit law.

4 The second thing is the Roundup opinion makes
5 reference to a reasonable jury standard, like what does a
6 reasonable jury -- could a reasonable jury conclude about the
7 evidence. That, too, is not the standard in the Eleventh
8 Circuit, and honestly, I don't think is correct under Rule 702.
9 It is a preliminary question for the Court. In other words,
10 the Court has to make a preliminary, as the Eleventh Circuit
11 says, threshold assessment of reliability.

12 I think your Honor knows this from your work with the
13 Rules Committee, there is an amendment to Rule 702 that is
14 about to happen, and the amendment is to address this very
15 question, that there is some confusion about whether there is
16 some reasonable jury standard or it is a standard for the
17 Court, and the amendment is going to add the words "the
18 proponent demonstrates to the Court" that it is more likely
19 than not A, B, C, and D in the rule.

20 This is a hot topic in Rules Committee land, and it is
21 clear that it has nothing to do with the reasonable jury
22 standard, it is the Court that has to make the assessment.

23 The final thing, just a comment on what said about my
24 piece, please, I urge the Court to look at Dr. Salmon's chart,
25 as I know you will, that Mr. Nigh showed as their proof of that

1 response. Mr. Holian is going to address why the methodology
2 that resulted in it is totally unreliable, but let's assume it
3 was perfect methodology.

4 Look at some of the lines on the chart, kidney cancer,
5 at a 900 nanogram dose, that was the highest FDA dose, he
6 calculated it would take 47 years of use to have an increased
7 risk of cancer. Done, stipulated, you can enter summary
8 judgment right now on any kidney cancer case. No one took
9 Zantac for 47 years.

10 That chart sort of highlights the need for the dose
11 opinion, put aside whether it is even methodologically sound.

12 What you also heard from Mr. Nigh is the Zantac
13 studies, the epi studies are too short, there is not enough
14 information on dose, not enough followup. That is precisely
15 why -- we don't agree with that, but that is precisely why in
16 the Eleventh Circuit you must give the threshold dose and the
17 dose response curve, and they don't have any evidence at all on
18 threshold dose and any reliable evidence on dose response.

19 I will turn it over to Mr. Cheffo.

20 *THE COURT:* Okay. Thank you.

21 *MR. CHEFFO:* Your Honor, I think now we are even.

22 I just have three quick points. The first is, you saw
23 a lot of those charts about increased risk, but what you didn't
24 see, right, are what the study authors say they mean. You have
25 what Mr. Nigh and his colleagues think they mean, but we didn't

1 hear or see what the study authors actually deal with.

2 We also heard that no study author can kind of make
3 that determination because they are essentially inside. Well,
4 that is certainly not true because they read the literature,
5 but even if it was, that is what the EMA and FDA are for. They
6 actually did look at all the data and they have determined
7 essentially consistently that there is no association.

8 Counsel made a point of things outside the record, so
9 I don't want to harp too much on this, but you saw things like
10 draft studies or we got this Norgaard from some subpoena or
11 wherever they got it from, internal documents. None of those
12 were reviewed or relied upon by the experts, which is what I
13 thought this was about, so we can talk about them, but they are
14 not reliance materials there.

15 Second, the internal documents, you saw one, you may
16 see others, a few points on them. Largely they are from 2019,
17 when this was all kind of hypothesis generating and they are
18 all fully consistent with the way science works. They identify
19 issues, they look at existing data, and they say here we are
20 going about this process. So, if you look at the end of the
21 story and you pull the thread, what you will see are both
22 internal and external documents that are fully consistent with
23 the science outside the courtroom.

24 Just a word on dose, too. We have heard, kind of as
25 advertised, that the vast majority of this presentation and

1 probably the next few days will be on NDMA, and your Honor is
2 ultimately going to have to determine whether looking at
3 Ranitidine data is more reliable than looking at all these
4 other NDMA issues.

5 Genotoxin, you know, the point, we should put this in
6 a bubble and no one should touch this because -- and these are
7 my words, but the point is, this is so highly toxic that there
8 is really no acceptable use. Well, you have also seen and you
9 know from the data this is in cottage cheese, it's in beer,
10 it's in charcuterie. Who kind of regulates all that? That is
11 FDA. Has the FDA come out and said, oh, my gosh, this is a
12 genotoxin, one drop, one molecule, if you have that cottage
13 cheese you are at a higher risk of cancer? Of course not.
14 This is why we look at the epidemiologic studies because, as I
15 said earlier, our body is an incredible thing. We can get
16 sick, we can get disease, but there are a lot of things that we
17 are exposed to in cottage cheese, in charcuterie, in beer, that
18 doesn't rise to the level of disease, and that is why these epi
19 studies are so powerful, because they look at real world use.

20 With that, your Honor, thank you for your time.

21 *THE COURT:* Okay. Thank you all very much. That was
22 a very productive morning.

23 That brings us to our lunch hour, so we have allotted
24 an hour for lunch. We are about 15 minutes behind what we had
25 anticipated, otherwise we are doing very well.

1 We have allotted 11:45 to 12:45, but we are closer to
2 12:00, so we will come back one o'clock and be ready to go into
3 the Defense presentation.

4 You had allocated for the epidemiology motion 5699, we
5 will push that back to one o'clock and otherwise try to follow
6 the schedule as we had outlined.

7 The courtroom will remain open, so if you need to keep
8 papers, that is fine. Have a good lunch and we will see you
9 back at one o'clock.

10 (Thereupon, a luncheon recess was taken.)

11 * * *

12 *THE COURT:* Okay, you may be seated. Thank you.

13 All right. We now have the team presenting at what
14 was 12:45, now 1:00 o'clock, the Defense first. It looks like
15 you have several speakers. However you want to present the
16 epidemiology motion at Docket Entry 5699.

17 You wanted a hundred minutes. You may proceed.

18 *MS. CANAAN:* Let me slide up. Perfect. Go to the
19 next slide, please.

20 So, your Honor, I will be arguing the motion relating
21 to Dr. McTiernan. Dr. McTiernan proffers the opinion that
22 Zantac causes the five cancers at issue, and she proffers this
23 opinion based on the weight of the evidence methodology.

24 So, to get to this opinion, Dr. McTiernan first
25 considers the Ranitidine epidemiological studies, and she

1 concludes that they are largely not informative. She says they
2 are largely not informative due to various methodological
3 limitations. There is an issue, she claims, with low dose,
4 duration of Ranitidine use, short followup, and exposure
5 misclassification.

6 Because of these purported problems with Ranitidine
7 studies, Dr. McTiernan said she had to extrapolate from
8 epidemiological studies of dietary NDMA, of rubber workers, and
9 studies of nitrite and nitrate that are potential precursors of
10 NDMA to reach her conclusions about Ranitidine.

11 Also, to the extent that she considered any Ranitidine
12 studies to be informative, Dr. McTiernan gave more weight to
13 finding above 1.0 in the direction of an increased risk than to
14 findings below 1.0 in the direction of a decreased risk, and
15 finally, Dr. McTiernan interpreted all findings above 1.0 as an
16 increased risk irrespective of their magnitude and statistical
17 significance.

18 Next slide, please.

19 Your Honor, Dr. McTiernan's methodology is unreliable
20 and inadmissible under Rule 702.

21 Although I have four reasons listed on the slide, and
22 each one is independently sufficient to exclude Dr. McTiernan,
23 there is a common theme here, your Honor. At every single step
24 Dr. McTiernan's methodology was reverse engineered to get to a
25 predetermined conclusion that Ranitidine increases the risk of

1 the five cancers.

2 To get to that conclusion she had to depart from
3 well-established principles like statistical significance. She
4 had to rely on studies that she previously rejected as
5 unreliable. She had to cherry pick results across the
6 epidemiological landscape, and she had to apply a glaringly
7 inconsistent and irreconcilable methodology to the
8 epidemiological data.

9 Next slide.

10 First of all, despite 14 large population based
11 studies specifically examining the association between
12 Ranitidine and the five cancers, Dr. McTiernan relied largely
13 on non Ranitidine epidemiological data in reaching her
14 conclusions.

15 Next slide.

16 In fact, as you can see, your Honor, she testified
17 that she never even considered whether Ranitidine specifically
18 was associated with any specific cancer type, and, your Honor,
19 I have the word association underlined here because there is
20 nothing wrong with considering other sources of data as part of
21 a Bradford-Hill analysis if and when you get to a reliable
22 association.

23 Earlier we heard Mr. Nigh say no reliable expert would
24 ever exclude Hidajat, no reliable expert would ever exclude
25 dietary studies from his or her analysis.

Pauline A. Stipes, Official Federal Reporter

1 We are not saying that these other lines of evidence
2 should be entirely excluded, that we should throw them out. We
3 are saying you need to get a reliable association that is not
4 due to chance and confounding before you get to Bradford-Hill.
5 If you get to Bradford-Hill you can consider whatever lines of
6 evidence you may see fit, but you I need to get to
7 Bradford-Hill reliably.

8 To get to Bradford-Hill, you first need an association
9 between the specific exposure and the specific outcome at
10 issue, and that specific exposure here, your Honor, is
11 Ranitidine.

12 Next slide, please.

13 Now, in her report, Dr. McTiernan reviewed four
14 buckets of epidemiological data. She reviewed the Ranitidine
15 studies, the dietary NDMA studies, the rubber industry studies,
16 and studies lumping all nitrosamines, nitrites, and nitrates
17 together.

18 She ultimately concluded that most of the Ranitidine
19 studies were not informative with respect to the question of
20 whether Ranitidine increases cancer risk.

21 Next slide, please.

22 *THE COURT:* Ms. Canaan, could you speak up a little
23 bit into the microphone so everybody can hear you, including on
24 Zoom. Thank you.

25 *MS. CANAAN:* Is this better, your Honor?

1 *THE COURT:* It is better for me, but it was fine for
2 me to begin with, but there are others. We will let you know.

3 *MS. CANAAN:* Will do.

4 In fact, your Honor, just a few months ago Plaintiffs
5 strenuously argued to this Court that Dr. McTiernan considered
6 all, every single one of the Ranitidine studies to be
7 completely uninformative and that therefore Defendants needed
8 no additional time to cross-examine Dr. McTiernan about
9 entirely uninformative studies.

10 Next slide, please.

11 So, while brushing aside most of the Ranitidine
12 studies, Dr. McTiernan placed heavy reliance on dietary NDMA
13 studies. Your Honor heard a great deal earlier today about the
14 methodological limitations of dietary studies generally. Dr.
15 McTiernan is certainly well aware of these issues. She is
16 aware of these issues because she was a member of an advisory
17 panel of experts at World Cancer Research Fund.

18 As we discussed at Science Day, your Honor, WCRF is a
19 well respected worldwide organization whose mission is to
20 review and synthesize research on the human diet and cancer
21 risk. That is what they do.

22 What they do is they synthesize their conclusions into
23 these monographs that relate to specific cancer types.
24 Importantly, WCRF has issued monographs on each of the five
25 cancers at issue in this litigation.

1 Next slide, please.

2 As you can see here, WCRF includes dietary NDMA in its
3 2016 stomach cancer monograph, and it is included under limited
4 evidence, no conclusion, meaning that no conclusions about
5 cancer risk can be reached. As you can also see, dietary NDMA
6 is keeping company here with things like eggs, milk, coffee,
7 and tea.

8 Next slide, please.

9 For all the other cancers, including esophageal,
10 liver, pancreatic, and bladder, NDMA is not even mentioned, not
11 at all.

12 That means that the data on dietary NDMA and these
13 other cancer types were not sufficient to even warrant panel
14 consideration of WCRF.

15 Next slide, please.

16 So, you may be wondering, your Honor, what did Dr.
17 McTiernan, herself a former panel member of WCRF, have to say
18 about this? Well, we asked her, of course, at her deposition,
19 and Dr. McTiernan complained that WCRF has not updated their
20 review of NDMA since 2005, but that, your Honor, is plainly
21 contradicted by WCRF's 2015 systematic literature review on
22 stomach cancer that, as you can see, clearly shows individual
23 four core studies were considered as part of the 2015 review,
24 yet absolutely no changes were made to the NDMA classification
25 in the stomach cancer monograph.

1 Importantly, your Honor, there are no post 2015
2 dietary studies that Plaintiffs are relying on in this
3 litigation on stomach cancer.

4 And so, the other thing that I want to point out about
5 this, your Honor, as you can see, on top there it says number
6 of publications RCTs/cohorts, and that is a really critical
7 point, your Honor. In their systematic reviews, WCRF does not
8 even consider, they don't even consider case control studies.

9 Next slide, please.

10 So, as your Honor may remember, case control studies
11 start with cases, and these are people who have the disease,
12 and then they compare them to controls, and those are people
13 who don't have the disease, and typically cases and controls
14 are then questioned about their past exposure. What did you
15 eat, for example.

16 Now, unlike in case control studies, in cohort studies
17 you start with people who are exposed and people who are not
18 exposed, and then you follow them to see who will develop the
19 disease and who will not develop the disease. The reason why
20 this matters, your Honor, is that case control studies of
21 cancer risk are notoriously prone to recall bias.

22 So, what is recall bias? Recall bias, simply put,
23 means that patients are more likely to recall exposures that
24 may explain their diagnosis. A cancer patient is
25 more motivated to remember things that may explain why he or

1 she got cancer, and as a result, recall bias artificially
2 inflates risk estimates in case control studies.

3 By contrast, in cohort studies recall bias is not an
4 issue because exposure is determined before the person got the
5 disease. That is the whole definition of a cohort study, the
6 exposure is determine prospectively, not retrospectively.

7 Next slide, please.

8 Because of recall bias, WCRF explicitly states that
9 they do not review -- they do not routinely review dietary case
10 control studies, they don't even consider them.

11 Yet, contrary to the methodology that she applied as a
12 panel member of WCRF, Dr. McTiernan relied on 39 dietary case
13 control studies in this litigation as purported evidence of
14 cancer risk.

15 Next slide, please.

16 Moreover, your Honor, Dr. McTiernan was the
17 Plaintiffs' expert in the Talc and ovarian cancer litigation,
18 and in that litigation Dr. McTiernan explicitly rejected
19 dietary case control studies as reliable evidence of cancer
20 risk. At the Daubert hearing at that litigation she testified,
21 if you want to know what somebody's previous diet effect of
22 cancer risk is, it is very difficult to do that in a case
23 control study. The person has already changed diet, you can't
24 ask somebody what they have eaten in the past.

25 Next slide, please.

1 Similarly, at her deposition in the Talc litigation,
2 Dr. McTiernan listed limitation after limitation after
3 limitation of dietary case control studies that make them
4 unsuitable for studying cancer risk. Let's listen to what she
5 had to say.

6 "Nutrition variables are very difficult to ascertain
7 for exposure because, as opposed to use of talcum powder
8 products which might be used once or twice a day, nutrition
9 variables are occurring sometimes 50 to a hundred times a day.
10 The amount people eat, what they are eating, how often they are
11 eating, the variables are so difficult to collect that they --
12 the results from case control studies are of concern to some
13 investigators."

14 So, in the Talc litigation dietary case control
15 studies are unreliable according to Dr. McTiernan, but in this
16 litigation, virtually all the dietary studies that she relies
17 on are in fact case control studies. There is simply no way to
18 reconcile Dr. McTiernan's testimony in the Talc litigation and
19 her opinions in this litigation.

20 Next slide, please.

21 To be very clear, if she didn't rely on case control
22 studies of dietary NDMA Dr. McTiernan would not be able to
23 reach her conclusions that dietary NDMA increases cancer risk.
24 For bladder, pancreas, liver, and esophagus there are no cohort
25 studies showing a statistically significant increased risk in

1 any primary or overall analysis.

2 There is one study for esophageal cancer that finds
3 one statistically significant increased risk in a sub group
4 analysis, only in men, but again, no study for esophageal
5 cancer overall shows an increased risk.

6 Similarly for stomach cancer, although there is one
7 study, the Larsson study, that reports an increased risk, when
8 all the cohort studies were added together in one analysis,
9 including that Larsson study, there was absolutely no
10 association.

11 So, if Dr. McTiernan applied the same methodology here
12 that she applied as a panel member at WCRF, or the methodology
13 that she advocated as a paid expert in the Talc litigation,
14 your Honor, she could not have reached the conclusion that
15 dietary NDMA increases cancer risk.

16 Next slide, please.

17 Now, Dr. McTiernan's extrapolation from the rubber
18 industry studies is similarly problematic. In fact, Dr.
19 McTiernan agrees that the dose and length of exposure in those
20 studies may not have been accurately ascertained, if at all.

21 She also agrees that how inhaled NDMA may compare to
22 NDMA ingested, such as with a Ranitidine tablet, is entirely
23 outside her area of expertise.

24 Next slide.

25 Finally, Dr. McTiernan's reliance on the nitrite and

1 nitrate studies contains even more logical leaps. By way of
2 example, Dr. McTiernan relies on studies of nitrate levels in
3 municipal water and cancer risk. In essence, what she is
4 saying is this: These studies are relevant because once
5 ingested, some of the nitrates may convert to nitrites, and
6 then some of the nitrites will then form nitrosamines. By the
7 way, your Honor, there are over 300 nitrosamines, they are all
8 different.

9 She says, one of those nitrosamines may be NDMA. It
10 is an assumption stacked upon assumption stacked upon
11 assumption.

12 Next slide.

13 So, your Honor, I submit that Dr. McTiernan's
14 extrapolation from these studies of nitrates, of nitrites, of
15 all of those combined, not to mention rubber workers in
16 England, is a quintessential example of what the Joiner Court
17 called simply too great an analytical gap between the data and
18 the opinions proffered.

19 Next slide.

20 Now, in addition to embracing the dietary rubber
21 worker and nitrate studies, Dr. McTiernan also improperly
22 discounts the Ranitidine studies, and in particular, the active
23 comparator analyses that Mr. Cheffo addressed earlier that
24 compare Ranitidine to other acid suppressing drugs like PPIs
25 and H2 blockers.

1 Next slide, please.

2 Now, reportedly Dr. McTiernan has used active
3 comparators in her own studies of medications and cancer risk,
4 and she agrees in her report that active comparator analyses
5 are a strength over Ranitidine studies because they control for
6 confounding by indication.

7 Next slide.

8 In fact, your Honor, we can readily see how active
9 comparators control for confounding in Ranitidine studies.
10 What you have in front of you is a forest plot of the results
11 from studies that compared Ranitidine to the general population
12 of nonusers of any acid suppressants, and you can see that most
13 of the risk estimates are to the right of 1, in the direction
14 of an increased risk.

15 Now, if we compare this forest plot to the results
16 that we have from active comparator Ranitidine studies --

17 Next slide, please.

18 -- your Honor, you can plainly see that all the risk
19 estimates shift to the left, in the direction of no association
20 or a decreased risk.

21 Next slide, please.

22 Now, Dr. McTiernan discounted the Ranitidine active
23 comparator studies for the following four reasons: First, she
24 says PPIs and other H2RAs, they also increase the risk of
25 cancer, so any increased risk for Ranitidine in analyses

1 comparing Ranitidine to these other drugs will be obscured.

2 Second, she says Famotidine users, they are not a good
3 comparator, they are too different from the Ranitidine users.

4 Third, she says the doses and durations of Ranitidine
5 were insufficient to cause cancer, they were too low.

6 Fourth, she says followup was not long enough to allow
7 for other cancers to develop, and as you will see, your Honor,
8 there is simply no factual basis for any of these claims.

9 Next, please.

10 First, at her deposition Dr. McTiernan walked back her
11 claim that PPIs increase cancer risk. In fact, she could not
12 name a single cancer that PPI use was even associated with,
13 much less causally associated with.

14 Next slide.

15 Second, at her deposition, she also walked back her
16 opinion that other H2 blockers increased cancer risk,
17 testifying unequivocally, no, it is not my opinion.

18 Next, slide, please.

19 Third, Dr. McTiernan claims that Famotidine users are
20 different from Ranitidine users, and that therefore, she says,
21 a general population or a nonuser comparator is better. For
22 example, with respect to the Mohy-ud-din study, this is what
23 she writes in her report, Ranitidine and Famotidine differ
24 substantially in many ways that are related to cancer, and she
25 actually faults the investigators for not presenting the

1 analysis of Ranitidine users versus the general population.

2 This claim, your Honor, is objectively contradicted by
3 the data. As you can see on the right side both Ranitidine --
4 and these are baseline characteristics directly lifted from the
5 Mohy-ud-din in abstract.

6 Both Ranitidine and Famotidine users were almost three
7 times more likely to smoke than the general population. Both
8 Ranitidine and Famotidine users were more than five times more
9 likely to be obese than the general population, and they were
10 more than three times more likely to use alcohol than the
11 general population.

12 Of course, we all know that smoking and obesity and
13 alcohol are well established risk factors for cancer.

14 So, this is exactly, exactly why active comparators
15 are key to controlling for confounding in studies of acid
16 suppressants like Ranitidine and cancer risk, and exactly why
17 every recent study, every investigator designed their study
18 with an active comparator design.

19 I will submit, your Honor, that for an expert to look
20 at this data from the Mohy-ud-din abstract and to say that the
21 general population comparator is a better comparator than
22 Famotidine, I will submit that is the mark of an advocate for a
23 cause.

24 Next slide, please.

25 Another criticism that Dr. McTiernan has of the

1 Ranitidine studies is that the patients were not followed long
2 enough after exposure to Ranitidine to develop cancer, but at
3 her deposition she couldn't tell me how long the followup must
4 be to detect any particular cancer after Ranitidine exposure.

5 Next slide, please.

6 And although in her report Dr. McTiernan claims that
7 for a rare end point like cancer, folks must be followed for
8 decades. In her own peer reviewed studies of medication and
9 cancer risk, she didn't follow folks for decades. In fact,
10 most of the time she followed folks a fewer number of years
11 than the Ranitidine study followup that Mr. Cheffo addressed
12 earlier today.

13 Next slide.

14 Moreover, Dr. McTiernan's speculation that longer
15 followup would reveal increased cancer risk is objectively,
16 objectively contradicted by the data, your Honor. From Iwagami
17 to Kantor, to Norgaard, Ranitidine study authors specifically
18 considered this issue, and they determined that longer followup
19 did not lead to an increased risk of cancer.

20 On the forest plot, orange lines represent shorter
21 followup, blue lines represent longer followup. For bladder
22 cancer, for example, as you can see, your Honor, longer
23 followup of more than ten years did not increase cancer risk.

24 In fact, in most cases, longer followup moved risk
25 estimates to the left in the direction of a decreased risk.

1 Next slide, please.

2 And lastly, Dr. McTiernan speculated that the dose or
3 duration of Ranitidine use were insufficient to cause cancer,
4 but again, when pressed at her deposition, she acknowledged
5 that she doesn't have an opinion about what dose or what
6 duration of Ranitidine will show an increased risk.

7 Next slide, please.

8 And again, Dr. McTiernan's speculation that higher
9 doses or longer durations may lead to an increased risk of
10 cancer, it is squarely contradicted by the data.

11 Here again orange lines represent lower dose and
12 duration while the blue lines represent higher dose and
13 duration. As you can see, in most instances, higher dose or
14 duration of Ranitidine use moved risk estimates to the left in
15 the direction of a decreased risk.

16 The only time you really see a stark differences is
17 for esophageal cancer, all the way on top. You can see that
18 low dose of Ranitidine was associated with an increased risk
19 because the dose was not high enough to protect from GERD,
20 while higher doses of Ranitidine were associated with a strong
21 protective effect.

22 You know, earlier we heard from Mr. Nigh that the
23 Adami study purportedly showed dose response. I will submit,
24 your Honor, objectively looking at this data from the Adami
25 study, it is not possible, it is not scientifically possible to

1 draw that conclusion.

2 Next slide, please.

3 And in case there is any doubt as to what actual true
4 dose and duration response actually look like, this is a forest
5 plot showing how increasing dose and duration of smoking
6 relates to the risk of bladder cancer.

7 As you can see, your Honor, with every incremental
8 increase in dose or duration there is a reliable and consistent
9 movement of risk estimates toward the right in the direction of
10 an increased risk.

11 So, the bottom line here is this: Dr. McTiernan's
12 criticism of the Ranitidine studies, from active controls, to
13 dose and duration, to length of followup, they are objectively
14 contradicted by the Ranitidine data. They have no reliable
15 basis in fact.

16 Next slide, please.

17 Dr. McTiernan's third methodological flaw is that, by
18 her own admission, she assigned greater weight to study results
19 that favored her conclusion.

20 Next slide, please.

21 In fact, in her expert report Dr. McTiernan
22 specifically states that because of the purported bias toward
23 the null in the Ranitidine epidemiological studies, she gave
24 less weight to the relative risks that were not greater than 1,
25 and put more weight on relative risks that were greater than 1.

1 In other words, she put more weight on positive
2 findings in the direction of an increased risk and she
3 discounted negative findings in the direction of a decreased
4 risk.

5 Next slide.

6 Your Honor, I will submit there is no epidemiology
7 test in the world that supports this quintessentially result
8 driven weight methodology. It is not surprising, your Honor,
9 when scientists reliably and impartially consider
10 epidemiological literature, they don't say this is a bad study,
11 but gee, I will cherry pick out the results that are in the
12 direction of an increased risk. Nobody does that.

13 If it is a bad study, then you either don't consider
14 it or you give the entire study less weight in your assessment.
15 What you don't do is, you don't pick out the risk estimates
16 that you like and give them more weight.

17 Next slide, please.

18 As another Court put it, under certain circumstances,
19 it is not scientifically reliable to generally attack
20 epidemiological studies as fundamentally flawed while at the
21 same time selectively plucking favorable numbers that are not
22 statistically significant, yet that is exactly what Dr.
23 McTiernan did here.

24 Next slide, please.

25 Moreover, Dr. McTiernan's basis for giving more weight

1 to relative risks above 1.0 is this purported bias towards the
2 null from misclassification of Ranitidine exposure.

3 I will demonstrate, your Honor, that like other
4 criticisms of the Ranitidine studies, this criticism also has
5 no basis in fact.

6 Next slide, please.

7 So, I want to start first by explaining Dr.
8 McTiernan's argument about misclassification bias.

9 So, most, although not all, your Honor, not all --
10 there are some studies of Ranitidine that look -- specifically
11 look at over-the-counter use, but most of the studies,
12 Ranitidine studies, are cohort studies that compare people who
13 are exposed to prescription Ranitidine to people who are not
14 exposed to prescription Ranitidine.

15 So, Dr. McTiernan posits that some of these folks in
16 the not exposed group may have been exposed to over-the-counter
17 Ranitidine, and investigators didn't encounter that.

18 She the posits that if a sufficiently high number of
19 these over-the-counter users are included in unexposed
20 controls, and if Ranitidine in fact increased the risk of
21 cancer, then these over-the-counter users could have diluted,
22 they could have obscured the observed association, and so the
23 Ranitidine studies could have therefore underestimated the
24 actual true risk. That is her argument.

25 Next slide, please.

1 Now, there are numerous problems with Dr. McTiernan's
2 assessment of purported misclassification. I am only going to
3 focus today on the top four issues of her assessment.

4 Next slide, please.

5 First of all, Dr. McTiernan speculates, she speculates
6 that misclassification occurred in the first place. In her
7 deposition she conceded that she cannot say that even a single
8 person was definitively misclassified in any Ranitidine study.

9 Next slide, please.

10 Second, Dr. McTiernan never attempted to estimate the
11 magnitude, right, the magnitude of any bias from purported
12 misclassification of exposure in Ranitidine studies. By
13 contrast, Defendants' epidemiologist, Dr. Andrew
14 Chen, concluded that even if up to 90 percent of
15 over-the-counter Ranitidine use was misclassified in these
16 Ranitidine studies, this would have a very small effect on the
17 risk estimates.

18 Next slide, please.

19 Third, Dr. McTiernan admits that all biases have to be
20 considered when interpreting study results. That is a critical
21 point, your Honor.

22 Next slide, please.

23 She also admits that in the Ranitidine studies
24 protopathic bias, also known as reverse causation, and
25 confounding by indication tend to result in spurious and false

1 increased risks, and the study authors say the same thing. For
2 example, the Adami authors wrote that potential confounding by
3 indication reverse causality favors spurious positive
4 associations.

5 Next slide, please.

6 And yet, while Dr. McTiernan claims 34, no less than
7 34 separate times in her report that misclassification of
8 exposure underestimated risk in Ranitidine studies, she never,
9 not once, states that other biases could have over estimated
10 risk, and this despite her admission that you have to consider
11 the combined effect of all the biases.

12 Next slide.

13 Lastly, but perhaps most importantly, Ranitidine study
14 authors considered this issue, they considered the possibility
15 of misclassification of exposure due to over-the-counter
16 Ranitidine use, and these study authors concluded that the
17 active comparator analyses minimize the likelihood of any
18 resulting bias.

19 For example, the Adami authors wrote that the
20 magnitude of any bias would be limited in the comparison
21 between users of Ranitidine and other H2RAs. The Norgaard
22 study authors wrote we would expect concomitant use of
23 over-the-counter Ranitidine to be low.

24 By the way, there was a claim made earlier about the
25 Norgaard study authors being purportedly biased, and I will

1 submit, your Honor, that the basis for the claim, frankly,
2 appears to be just the fact that some of these study authors
3 coauthored a study earlier with Drs. Adami and Chang. There is
4 really no reliable, much less scientific basis for this claim.

5 So, for all these reasons, your Honor, Dr. McTiernan's
6 claims, the purported misclassification of over-the-counter
7 Ranitidine use under estimated cancer risk, it has no basis in
8 fact, and it is contradicted by the Ranitidine study authors.

9 That is yet another reason why Dr, McTiernan's
10 methodology that gives more weight to positive findings than to
11 negative findings is completely unreliable and inadmissible,
12 your Honor.

13 Next slide, please.

14 Dr. McTiernan's fourth critical methodological failing
15 is that she disregarded statistical significance and applied an
16 inconsistent and litigation driven methodology.

17 Next slide, please.

18 In her report Dr. McTiernan states that every relative
19 risk other than 1.0 indicates an association, irrespective of
20 its magnitude or statistical significance. Dr. McTiernan's
21 definition of association conflicts with the Reference Manual
22 on Scientific Evidence that explicitly incorporates the concept
23 of statistical significance into its definition. The reference
24 manual says more or less frequently than one would expect by
25 chance alone.

1 Now, Dr. McTiernan's definition of association is also
2 at odds with Dr. Moorman's concession that when there is no
3 association between an exposure and an outcome, one would
4 expect to see risk estimates clustered around 1, with some
5 estimates greater than 1 and some less than 1.

6 Next slide, please.

7 Moreover, Dr. McTiernan's definition of association is
8 also patently litigation driven. As you can see here, your
9 Honor, in her Zantac report a non-statistically significant
10 relevant risk of 1.5 or 1.6 is described as an increased risk,
11 but in her Talc report a non-statistically significant relative
12 risk of 1.4 is described as no association, and in her
13 published peer reviewed studies, even a borderline
14 statistically significant finding like you can see on the
15 bottom of 1.6 with a lower confidence interval of 1.0 is a
16 borderline statistically significant increased risk.

17 She still calls it no association because that 1.0
18 overlaps, that confidence interval overlaps the line of unity.
19 So, there is absolutely no consistency here, your Honor.

20 Next slide, please.

21 Indeed, in her deposition, Dr. McTiernan did not even
22 attempt to explain why a relative risk of 1.06 was an increased
23 risk in her Zantac report, but a relative risk of 1.4 was no
24 association in her Talc report.

25 Next slide, please.

1 Even more importantly, your Honor, Dr. McTiernan
2 applies her definition of association inconsistently to the
3 data that supports and does not support her opinion.

4 For example, in her Zantac report she claims that any
5 relative risk other than 1.0 indicates an association, whether
6 positive or negative, but in the same report, when she
7 discusses a Ranitidine study with a relative risk below 1.0 in
8 the direction of a decreased risk now, she calls it no
9 association.

10 So, for Ranitidine above 1 is an increased risk, but
11 below 1 is not an increased risk. This is a quintessentially
12 result driven and unreliable methodology.

13 Next slide, please.

14 In fact, your Honor, there are 80 separate risk
15 estimates below 1.0 in the Ranitidine epidemiological studies
16 that specifically relate to the five alleged cancers, 80 risk
17 estimates, yet not once does Dr. McTiernan describe them as a
18 decreased risk. By contrast, virtually every single risk
19 estimate above 1.0, even a 1.05 and a 1.06 is described as an a
20 increased risk.

21 Next slide, please.

22 And there are many other examples of Dr. McTiernan's
23 inconsistent methodology. For example, she rejects the Iwagami
24 study, which of course finds no increased risk of cancer with
25 Ranitidine, and she rejects it because she says combining

1 Ranitidine and Nizatidine users into one group is highly
2 problematic. She says it is highly problematic because you are
3 not seeing the specific effects of Ranitidine, yet at the same
4 time she embraces studies of all nitrosamines combined.

5 As I mentioned earlier, there are more than 300
6 different nitrosamines, only one of which is NDMA. She
7 embraces studies of processed meats that she admits contain
8 many different nitrosamines, in addition to numerous known
9 carcinogenic chemicals, like polycyclic aromatic hydrocarbons
10 for example, so group one carcinogens.

11 She embraces studies of nitrite and nitrate, which she
12 admits may or may not form nitrosamines which may or may not be
13 NDMA. Again, your Honor, there is absolutely no consistent
14 methodology here.

15 Next slide, please.

16 Similarly, Dr. McTiernan rejects Zantac's study
17 analyses that lump all the different cancer types together, and
18 these also happen to be the analyses that find no increased
19 risk, and she rejects them because she says you have to look at
20 the individual cancers.

21 We agree with that, your Honor, you have to look at
22 the individual cancers, yet in the same breath, she relies on
23 NDMA studies that lump all cancers together and extrapolates
24 form these studies -- from these results that NDMA increases
25 the risk of all cancer. Again, this a completely

1 irreconcilable and inconsistent methodology.

2 Next slide.

3 And here is another example. Dr. McTiernan stated in
4 her report that crude or unadjusted, meaning -- by not adjusted
5 meaning not adjusted for any confounding variables. She says
6 crude relative risks could be confounded and therefore are not
7 informative. That makes sense. And yet, after she learned at
8 her deposition that she erroneously reported and relied on
9 elevated crude risk estimates from the Adami study, Dr.
10 McTiernan changed her tune and she decided that she can rely on
11 raw or crude data for her opinions.

12 By contrast, Dr. Moorman, Plaintiffs other
13 epidemiologist, reported the correct adjusted risk estimates
14 from the Adami study, and she does not rely on the crude data
15 from the Adami study that Dr. McTiernan relies on.

16 Next slide, please.

17 Now, Courts and scientific authorities are in accord
18 that reliance on non-statistically significant data, on lumped
19 exposure data, on lumped outcome data, on crude data, these are
20 all red flags, these are all indicia of an unreliable
21 methodology. But I will submit, your Honor, that even more
22 compelling in Dr. McTiernan's case is that she employs these
23 methodologies situationally, depending on whether or not they
24 advance her bottom line.

25 She interprets non-significant risk estimates above 1

1 as an increased risk, but does not interpret those below 1 as a
2 decreased risk. She rejects lumped exposure and outcome data
3 when it is not helpful, but she relies on it when it is
4 helpful.

5 She rejects crude data, saying it is confounded, that
6 is what she says in her report, but once she realized that she
7 mistakenly included all the crude risk estimates from the Adami
8 study in her report, she pivots and now she says it is totally
9 fine to rely on crude data.

10 Next slide, please.

11 That is the one glaring, overarching, underlying
12 methodological flaw in Dr. McTiernan's methodology. Mr. Cheffo
13 referred to it earlier, it is situational science. Simply put,
14 Dr. McTiernan applies whatever method is expedient to get to
15 her desired conclusion. That is the antithesis of reliable
16 science, your Honor. It has no place in the courtroom and it
17 must be excluded.

18 Thank you, your Honor.

19 *THE COURT:* Okay, thank you very much. That was about
20 45 minutes. Now we are going to hear on Dr. Moorman.

21 *MR. BROWN:* Your Honor, I am Loren Brown, I am arguing
22 the motion to exclude Dr. Moorman.

23 *THE COURT:* Good afternoon.

24 *MR. BROWN:* Okay. Let's pull up the slide deck.

25 Your Honor, I guess it would make sense to start with

1 Dr. Moorman's general causation opinions. You know the five
2 cancers at issue by now, so I don't need to belabor that. As
3 you also know, Dr. Moorman decided not to render causation
4 opinions on four other cancers that she actually analyzed, and
5 I will briefly touch on that in a minute, but before I do that,
6 I want to give you a brief outline of my points today.

7 Next slide, please.

8 So, your Honor, we have divided this into three parts.
9 This probably sounds familiar already, but we are going to talk
10 in the first part about the association part of Dr. Moorman's
11 analysis, and we are going to break that into two groups. The
12 first group is going to be her evaluation of the Ranitidine
13 studies, and why that was improper and unreliable. Then I will
14 focus mostly on the dietary studies. I know it says
15 occupational studies here, but in the interest of time, I will
16 try to cut through that and talk about her reliance on the
17 dietary studies, and why that wasn't reliable.

18 Then we are going to talk about Dr. Moorman's
19 Bradford-Hill analysis and some of the key components of that.
20 We are not going to go through every factor, but three of the
21 relevant components we will talk about, and if, and only if I
22 have time either now or in any rebuttal, we will talk about the
23 general acceptance factor as applied to Dr. Moorman.

24 The reason why I have singled that out for Dr. Moorman
25 is because Dr. Moorman, as you will see in her report and in

1 her work in the record that we have submitted, puts a lot of
2 emphasis on the whole principle of general acceptance, and we
3 have cites to that in the record.

4 Next slide, please.

5 So, with that, your Honor, I would like to turn to the
6 analysis that purportedly supports Dr. Moorman's general
7 causation opinions.

8 In this case, as you can see by now, I point out first
9 that the steps that need to be taken in a case like this appear
10 to be undisputed. As we can see here in the reference manual,
11 there is no dispute that the first step is to review the
12 available studies to determine whether there are alternative
13 explanations for any apparent association or observed
14 difference, namely alternative explanations such as bias and
15 confounding.

16 There is also no dispute about the second step, and
17 that is to consider how guidelines for inferring causation from
18 an association applied to the available evidence. The
19 guidelines Dr. Moorman used here, as you have heard already,
20 are the Bradford-Hill criteria, which are fine, though we
21 obviously have problems with how she applied the criteria in
22 this case.

23 I am going to start by spending some time on the way
24 that Dr. Moorman applied step one, and in particular, the
25 method she used to weight the epidemiological data before

1 concluding that there is a valid association between Ranitidine
2 use and all five cancers now at issue.

3 Next slide.

4 I thought it would be helpful to talk about Dr.
5 Moorman's analysis of the Ranitidine studies in three parts.

6 The first part is her analysis of these active
7 comparator studies, and why that was improper and why it is
8 unreliable. Then we are going to talk about the heavy reliance
9 that she placed on the nonuser studies, putting them above all
10 other studies, and why that was improper and unreliable.

11 And then I want to say a few words about the weighting
12 criteria that she used and picked and how she applied those
13 criteria and the standards or lack of standards that she used
14 in doing that.

15 Next slide, please.

16 Now, your Honor, we received the first indication of a
17 process without appropriate standards very early in Dr.
18 Moorman's deposition when we asked her about the main evidence
19 or factors that distinguished the five designated cancers from
20 the other four.

21 As you can see here, Dr. Moorman's opinion regarding
22 the other four cancers, which is on the left taken directly
23 from her expert report, but as you can see on the right, when
24 we asked her to identify any factor, any factor at all, and I
25 asked her this a few different ways, that distinguish the five

1 designated cancers from the other four she evaluated, she could
2 not identify anything other than to say the five cancers have
3 the strongest evidence.

4 Now, that was just the first red flag that came to our
5 attention. I know Mr. Nigh provided an explanation on why they
6 are pursuing five over the other four this morning, but that is
7 not what Dr. Moorman said at all.

8 Next slide, please.

9 Now, let's talk about Dr. Moorman's weighting of the
10 studies for all five cancers at issue, your Honor. We
11 constructed this chart based on how Dr. Moorman weighted all
12 the observational studies in her report. She confirmed all of
13 these designations in her deposition.

14 As you can see here, Dr. Moorman strongly weighted
15 only four studies, all of which compared Ranitidine users to
16 nonusers, and all of which came from what we have been calling
17 the Scottish database.

18 And then below these studies, in her hierarchy, Dr.
19 Moorman moderately weighted four dietary studies and one
20 occupational study. Then finally, at the bottom of her
21 hierarchy, those studies receiving the lowest weight reflected
22 here on the right, she put all the active comparator studies
23 that were specifically designed to evaluate the Ranitidine and
24 NDMA question after 2019, when the issue arose.

25 She also gave little or very little weight to three

1 nonuser studies, Habel, Tran, and Kim, even though Plaintiffs'
2 counsel referenced their studies earlier today.

3 One additional note, your Honor, relates to the
4 Cardwell study you have heard a lot about already. While Dr.
5 Moorman weighted the nonuser part of the Cardwell study, which
6 you see on the left, that study also included an active
7 comparator analysis.

8 Dr. Moorman did not rely on the active comparator
9 analysis in Cardwell, and as we'll discuss in a few minutes,
10 she has significant problems with active comparator analyses in
11 all of these Ranitidine studies. For Cardwell, she did not
12 even include the H2RA active comparator results in the data
13 summary that is part of her expert report.

14 So, your Honor, you know by now the result of grouping
15 the Ranitidine studies this way, the active comparator studies
16 would show no evidence of an increased cancer risk for any of
17 the five cancers, more or less get put to the side.

18 The nonuser dietary and occupational studies, which do
19 contain some statistically significant results for some of the
20 five cancers, become the most significant part of Dr. Moorman's
21 foundation.

22 We don't believe this was a product of a reliable
23 methodology, your Honor, and now I am going to try to explain
24 why.

25 Let's go to the next slide.

1 So, first, I am probably not going out on a limb when
2 I say that the most significant issue to resolve on this motion
3 is whether it was reliable for Dr. Moorman to reject the active
4 comparator analyses in favor of the nonuser analyses, the
5 dietary studies, and the occupational studies. That is why it
6 is point one in this outline.

7 Next slide.

8 Now, before I address the specific foundational
9 problems with Dr. Moorman's analysis of these Ranitidine
10 observational studies, I think it makes sense to briefly review
11 some of the core undisputed principles that relate to
12 observational studies generally.

13 As you know by now, this case does not involve
14 randomized clinical trials in which the groups being compared
15 are well matched at baseline; instead, all the experts in this
16 case are operating in a much more challenging world of
17 observational studies where the reliability of the study data
18 rises and falls on the similarity of the groups being compared
19 at baseline.

20 With the exception of the medication of interest being
21 given to one group, researchers want to get as close as they
22 can to what Mr. Cheffo described as an apples to apples
23 comparison at baseline. The further we get away from apples to
24 apples, the bigger the confounding problem. That is the
25 potential that a difference observed at the end of the study is

1 due to population differences that existed from the start
2 rather than due to an effect of the medication being studied.

3 Here you can see the numerous statements in the
4 reference manual about the significance of confounding in any
5 case that turns on observational data like this one.

6 Next slide.

7 And so, when a researcher finds an association between
8 a medication and a disease, like Dr. Moorman purportedly did by
9 rejecting the active comparator studies and instead relying
10 on the Ranitidine nonuser studies, it is methodologically
11 critical to determine whether the association is valid as
12 opposed to being the result of confounding.

13 Next slide.

14 Now, in her expert report, Dr. Moorman says that
15 she addressed confounding, but before we get into that I think
16 we need to be clear when we talk about confounding in this case
17 because we have two major types that we need to be mindful
18 of when we evaluate whether it was valid for Dr. Moorman to put
19 all the active comparator studies at the bottom of her pile in
20 favor of other studies, including the dietary and occupational
21 studies.

22 So, what you see here is a Venn diagram that shows the
23 cancer risk factors that can confound any analysis of
24 Ranitidine users. Certainly these include conditions that
25 patients take Ranitidine for, that is conditions that

1 Ranitidine is designed to treat, and that also increase the
2 risk of many cancers.

3 As you have heard many times already, these are called
4 confounders by indication and Dr. Moorman acknowledges these
5 confounders at least for certain of the cancers, gastric,
6 esophageal, and she says possibly liver cancer.

7 The other important group of risk factors, though,
8 relate to conditions of lifestyle choices that a patient
9 doesn't necessarily take Ranitidine for, but which are more
10 common in Ranitidine users and nonusers, and which can also
11 confound an analysis.

12 Smoking is a good example, and Ms. Canaan made
13 reference to that a few minutes ago. Smoking can contribute to
14 reflux disease and it increases the risk of almost all types of
15 cancer, but patients do not take Ranitidine to treat their
16 smoking. These are residual confounders, and it is equally
17 important to be able to control for them in any analysis.

18 If information about these factors isn't available in
19 a database, you obviously can't control for them and
20 confidently rule out residual confounding as the explanation
21 for any observed difference, especially whereas here the
22 observed differences are very small. As you will see in a few
23 minutes, that is a big issue.

24 Next slide, please.

25 Now, both types of confounding are well-recognized

1 challenges for researchers trying to determine whether a
2 particular medication increases the risk of certain types of
3 cancer, and that is why the scientific community universally
4 recognizes that active comparator designs are the best designs
5 to address these challenges. As you can see here, even Dr.
6 Moorman agrees with this principle, at least in general and at
7 least with respect to confounding by indication.

8 Now, both types of confounding are critical in the
9 validity of Dr. Moorman's rejection of the active comparator
10 studies, as well as her heavy reliance on the nonuser studies.

11 Next slide, please.

12 So, what is Dr. Moorman's stated basis for rejecting
13 the active comparator analyses in favor of nonuser analyses,
14 dietary studies, and occupational studies in this case?

15 Well, she claims that the active comparator studies
16 are appropriate only when two assumptions are met, namely, that
17 the comparator drug is not associated with the outcome of
18 interest, here five different kinds of cancer, and that the two
19 medications being compared are used to treat similar
20 conditions.

21 Here, however, she argues that neither of these
22 assumptions are met, and that is why she does not accept the
23 active comparator results in this case, and at least part of
24 why she gave these studies little or very little weight in her
25 analysis.

1 So, now I want to talk about each assumption that Dr.
2 Moorman claims is unmet.

3 Next slide, please.

4 Your Honor, here is why Dr. Moorman says neither
5 assumption is met. First she claims that other H2RAs which
6 have not been linked to NDMA still cause the same cancers for
7 other reasons; and second, that patients who take other H2RAs
8 are different and I guess sicker than patients who take
9 Ranitidine.

10 For these reasons she claims that active comparator
11 analyses are inappropriate in this case and mask a cancer risk
12 that is associated with the use of Ranitidine.

13 Next slide.

14 So, moving to the first point, Dr. Moorman went and
15 found some studies in the literature which allegedly showed
16 that other H2RAs can increase the risk of certain cancers.

17 Just to give us a background on this, she cited five
18 studies. Those five studies looked only at gastric,
19 pancreatic, and liver cancer, not the other two. None looked
20 at bladder or esophageal cancer.

21 Moreover, as you can see on the right, two of those
22 five looked only at the cancer risks of PPIs, not other H2RAs,
23 and that is why we have red lines crossing out those studies,
24 and of the three studies that did look at other H2RAs, one,
25 Lin, as you can see on the right, found that they had a

1 protective effect.

2 Another, Laoveeravat, found no association after the
3 authors excluded a study with the most extreme results, and the
4 last one on the list here is a little more complicated. It was
5 a meta analysis where the authors ranked these studies
6 according to their quality. The only study that was ranked by
7 the authors as having a high quality reported that the
8 association was probably not causal, and most likely due to
9 confounding by indication.

10 So, this was the foundation for that opinion.

11 If we could go to the next slide, please. Next slide,
12 please.

13 More significantly, your Honor, when we asked Dr.
14 Moorman questions about her contention that other H2RAs are
15 improper comparators, she made a number of significant
16 admissions.

17 First, she admitted that she didn't really do a full
18 causal analysis of that claim or do a Bradford-Hill analysis of
19 any kind, that is on whether other H2RAs caused these cancers.
20 She admitted that she has never shared this view outside of
21 this litigation, peer reviewed or otherwise.

22 She did not recall whether FDA approved labels for any
23 of the other H2RAs warn of an increased cancer risk. They
24 don't.

25 She is not aware of whether FDA, IARC, or the American

1 Cancer Society, or any other institution has concluded that
2 other H2RAs increase cancer risk. They haven't.

3 She couldn't name any medical guidelines that suggest
4 patients should stop taking H2RAs because of increased cancer
5 risks. There simply aren't any.

6 This claim has no reliable basis or support outside of
7 this litigation, and it is a foundational pillar of Dr.
8 Moorman's decision to reject the active comparator analyses.
9 Throughout her report and in contrast to what the Plaintiffs
10 say in their briefs, this is Dr. Moorman's first and foremost
11 reason for rejecting all the active comparator analyses in her
12 report.

13 Next slide, please.

14 The second claim, as you see here at the bottom of
15 this slide, is equally unreliable. Here Dr. Moorman cited one
16 study, Kim, the same study that Mr. Nigh spent about 15 minutes
17 criticizing, to support her claim that Ranitidine users are
18 significantly different from users of other medications in the
19 same class.

20 To support this claim Dr. Moorman cites one study to
21 which she assigns low weight overall in her own report, and
22 even Dr. Moorman admits in other parts of her report and in her
23 deposition that one study doesn't reliably establish anything.

24 Moreover, other researchers, such as Dr. Iwagami, have
25 criticized Dr. Kim's method of evaluating these differences,

1 probably for the same reasons that -- or at least some of the
2 reasons that Mr. Nigh was criticizing Kim. Mr. Nigh described
3 the study that Dr. Moorman relied on to establish these
4 differences as an outlier and unreliable, and he said there was
5 something terribly wrong with Kim's database.

6 That is the foundation for the second claim.

7 If we could go to the next slide, please.

8 More importantly I'd say, nobody else in the medical,
9 scientific, or regulatory communities have said that active
10 comparator studies are problematic because of meaningful
11 differences in these populations, let alone more problematic
12 than nonuser, dietary, and occupational studies.

13 Nobody has suggested the differences between
14 Ranitidine users and other H2RA users are masking a cancer risk
15 associated with Ranitidine use. Indeed, researcher after
16 researcher, as you can see, explain that they chose active
17 comparators to reduce confounding and to minimize population
18 differences at baseline.

19 As you heard from Mr. Petrosinelli, as a matter of law
20 taking positions that are in such conflict with the authors
21 themselves is another major red flag under Daubert.

22 So, the two major reasons why Dr. Moorman found active
23 comparator analyses to be invalid are themselves flawed and not
24 based on a reliable evidentiary foundation.

25 Next slide, please.

1 So, let's talk about the reliability problems
2 associated with Dr. Moorman's analysis of the nonuser studies.

3 Next slide.

4 I guess I will start with what is undisputed. First,
5 your Honor, there is no dispute that each of these five cancers
6 have risk factors or confounders that need to be controlled for
7 in the analyses.

8 Next slide.

9 As you can see in this slide, there is also no dispute
10 that the failure to control for these risk factors due to
11 missing or incomplete information could result in an over
12 estimate of the risk, particularly if the exposed group,
13 meaning the group taking Ranitidine, has a higher prevalence of
14 some of the risk factors.

15 We asked Dr. Moorman about this in her deposition and
16 she conceded that if the exposed group had a higher prevalence
17 of some of the risk factors than the unexposed group, then
18 failure to control for that could result in an over estimate of
19 the relative risks.

20 Next slide, please.

21 Now, things start to become disputed when we are
22 talking about whether the nonuser studies that Dr. Moorman
23 heavily weights were able to control for key risk factors.

24 On the left you can see that Dr. Moorman suggests that
25 these authors did adjust for these confounders, but on the

1 right you can see that the authors themselves acknowledged that
2 they still could not control for a number of key risk factors
3 due to missing information, and as a result, they could not
4 rule out confounding as an explanation for their results.

5 You can see in Cardwell acknowledging that he was
6 unable to control for several bladder cancer risk factors. In
7 Tran, the main limitation is that we cannot control or rule out
8 confounding. In Liu, we are not able to adjust for H. pylori,
9 an important risk factor for gastric cancer.

10 Next slide, please.

11 Now, in this next slide, your Honor, you see a chart
12 that illustrates the key risk factors that could not be
13 controlled for in Dr. Moorman's heavily weighted studies. The
14 information supporting this chart was taken directly from the
15 publications.

16 The red boxes identify risk factors for which there
17 was no information in the study database. The yellow boxes
18 identify risk factors for which the information was limited.
19 The point is that the major risk factors could not be
20 controlled for nonuser analyses, and the authors acknowledge
21 the baseline imbalances in these groups could easily explain
22 small differences that they observed. Dr. Moorman just looked
23 past these significant limitations and acknowledgments by the
24 authors.

25 Next slide.

1 Mr. Petrosinelli already mentioned the case law here
2 within the Eleventh Circuit showing that experts cannot exceed
3 limitations imposed by study authors, and that being one reason
4 why Courts exclude experts in this circuit.

5 Next slide, please.

6 Now, your Honor, I want to spend a few minutes talking
7 about some of the other criteria that Dr. Moorman said she
8 weighted heavily and that support her view that nonuser
9 studies, dietary studies, and occupational studies are superior
10 to the active comparator studies.

11 Next slide.

12 Now, as can you see on this slide, Dr. Moorman says
13 that she gave greater weight to three criteria. Your Honor has
14 asked about some of this in the questions leading up to the
15 hearing. So, first, how did Dr. Moorman decide that these
16 criteria should get the greatest weight and how did she apply
17 them to the Ranitidine study data?

18 Next slide.

19 Now, in her academic career, Dr. Moorman often used
20 established peer reviewed scales to weight epidemiological
21 studies. In fact, some of the studies that she cited in her
22 report used these established scales that I just mentioned.
23 Here, instead Dr. Moorman used what she described as her own
24 qualitative judgment or qualitative rating of the studies.

25 I am going to now talk for a few minutes about these

1 criteria and how they were defined and applied here.

2 Next slide, please.

3 So, let's start with followup time.

4 We started by asking Dr. Moorman to tell us what
5 adequate followup time would be in this context. She couldn't
6 tell us what duration of followup would be adequate in her
7 opinion, and instead said that it is a continuum, and you see
8 that here.

9 Next slide, please.

10 When you look at followup time on a continuum, at
11 least objectively, it would be impossible to rationalize why
12 all the active comparator studies are at the bottom of Dr.
13 Moorman's pile, even below dietary and occupational studies,
14 and why certain nonuser studies are at the top.

15 In this chart, for example, you can see that some of
16 the active comparator studies shaded blue, Norgaard and Adami
17 in particular, have longer durations of followup than all the
18 nonuser studies Dr. Moorman relies on, and there certainly is
19 no pattern that could support Dr. Moorman's weighting decisions
20 based on followup time.

21 Next slide, please.

22 Let's now talk about sample size.

23 We have the same problem with sample size. We asked
24 Dr. Moorman to tell us what constitutes an adequate sample size
25 in this context, and again she refused to give a number or

1 range and instead said it is on a continuum.

2 Next slide.

3 Now, when you look at the studies organized by sample
4 size, namely by the number of cancers in the study, again,
5 there is no pattern that would support a decision to give all
6 the active comparator analyses little or very little weight and
7 to give nonuser studies heavy weight.

8 I know this slide is busy, but what we tried to do is
9 plot the studies by sample size for each of the five cancers.

10 The nonuser studies that Dr. Moorman assigned heavy
11 weight to are highlighted with orange dots next to them, and
12 you can see that many of the active comparator studies that Dr.
13 Moorman put at the bottom of her weighting scale have larger
14 sample sizes than the nonuser studies she weights heavily.

15 Now, I realize that Cardwell has the largest sample of
16 cases for bladder cancer, but it is important to note again
17 that Cardwell also has an active comparator analysis, and Dr.
18 Moorman rejects all the active comparator analyses for the
19 reasons we have previously discussed.

20 Next slide.

21 So, the last of Dr. Moorman's three heaviest weighted
22 criteria that I would like to talk about is ascertainment of
23 exposure, or put a different way, misclassification of
24 exposure. Ms. Canaan spoke about this in the context of Dr.
25 McTiernan.

1 As I'm sure you know by now, Dr. Moorman also claims
2 that unmeasured use of OTC Ranitidine somehow contaminated
3 these studies and obscured an increased cancer risk that we
4 can't see in the relative risk estimates that we have in these
5 studies.

6 We believe this claim is pure speculation and not
7 supported by any actual data from the studies, and that
8 response applies both with respect to the amount of
9 misclassification in any group of any study and the impact that
10 any alleged misclassification had on the risk estimates.

11 Here, as you can see, Dr. Moorman concedes she is
12 unable to quantify either the amount of misclassification in
13 any group in any study, or the impact that such
14 misclassification had on the results.

15 Next slide.

16 Yet another red flag on this misclassification issue
17 relates to the positions Dr. Moorman takes regarding certain
18 studies in particular. For example, while she claims that
19 misclassification of exposure is of particular concern in the
20 Adami and Norgaard studies, the researchers in these studies
21 specifically considered this issue and concluded that any
22 misclassification due to OTC use was limited, and that it would
23 not affect the results.

24 Dr. Moorman not only failed to provide data to support
25 her claims about misclassification, but the authors themselves

1 analyzed the issue based on their own data and reached an
2 opposite conclusion. And again, Mr. Petrosinelli mentioned the
3 cases, McClain and Accutane, in which experts have been
4 excluded for, among other reasons, interpreting data in ways
5 that conflict with the study authors' interpretations of their
6 own data.

7 Next slide, please.

8 I think it is also important to point out that no
9 other researcher or in the peer reviewed medical community has
10 suggested that the study results Dr. Moorman diminishes are
11 invalid due to a misclassification or an exposure problem.

12 Here we asked Dr. Moorman to name any, any that she
13 could not -- any that has said that, and she could not do that.
14 In the interest of time, I am not going to read the whole
15 quote, but you can see in the answer she is not recalling
16 anyone who claims that misclassification of exposure had an
17 impact on the point estimates, P values, or confidence
18 intervals that were reported in those studies.

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

21 Now, just in case Plaintiffs say we are looking at
22 each of these factors in a vacuum, we thought it would be
23 helpful to provide a couple of examples that combine all three
24 of these factors so you could see just how inconsistent the
25 data are with Dr. Moorman's weighting decisions.

1 The first example on the left is a pancreatic cancer
2 example comparing Adami, which Dr. Moorman weights as low,
3 meaning below dietary and occupational studies, and McDowell,
4 which Dr. Moorman weights strongly. Adami has a longer
5 followup and much longer sample of cases than McDowell. Both
6 these studies use prescription drug databases in which OTC use
7 can't be measured.

8 Again, based on application of these factors, it would
9 be impossible to rationalize how Adami receives little weight
10 and McDowell receives heavy weight according to these factors.
11 This is further evidence of an inherently unreliable process.

12 The bladder cancer example on the right highlights the
13 same problem, but in the interest of time, I will leave this
14 for the Court's consideration and move to Dr. Moorman's
15 reliance on the dietary studies.

16 Next slide.

17 Now, on these dietary studies, I am going to make
18 three points, your Honor. The first is, while the Plaintiffs
19 claim that these dietary studies fill a gap in the Ranitidine
20 data, we don't believe that is true. The dietary studies are
21 not any more informative on the key parameters that we have
22 been talking about than the Ranitidine studies, and I will talk
23 about that.

24 The second point is that the dietary studies do not
25 reliably correlate NDMA levels with the five cancers. Most of

1 these studies, at least the ones that Dr. Moorman moderately
2 weighted, don't even measure NDMA at all. The ones that do,
3 for the reasons that Ms. Canaan got into in detail, do not
4 reliably link those levels with an increased risk of the five
5 cancers.

6 But even if they did, the method Dr. Moorman used to
7 correlate NDMA levels in the dietary studies with real world
8 Ranitidine levels is speculative and unreliable. Nobody else
9 in the entire medical, scientific, and regulatory community has
10 tried to do that and used the dietary and occupational data as
11 a surrogate for Ranitidine use like what Dr. Moorman has done
12 in her report.

13 Next slide, please.

14 So, first, let's talk about followup time and whether
15 Dr. Moorman's basis for relying on the dietary and occupational
16 studies is even valid. In other words, what gap do these
17 studies really fill? This is a visual representation of the
18 mean or median followup period in the Ranitidine studies as
19 compared to the dietary studies Dr. Moorman gives the most
20 weight.

21 Dr. Moorman's claim that followup in the dietary
22 studies is appreciably longer is simply incorrect. The
23 followup periods for these two different bodies of evidence are
24 quite comparable. Even the dietary study with the longest
25 followup, Keszei, has a followup period that is nearly

1 identical to the mean or median followup period in two
2 Ranitidine studies, Norgaard and Adami in particular.

3 Our main point is that the evidence doesn't support a
4 claim that dietary and occupational studies are needed to fill
5 any gap in the Ranitidine studies, and again, nobody in the
6 peer reviewed literature has made a similar claim or attempted
7 to use these studies in the manner Dr. Moorman is using them
8 here.

9 The epidemiology that is available for Ranitidine at
10 this point is extensive, as both Mr. Cheffo and Ms. Canaan got
11 into, and there is simply no suggestion in this large body of
12 evidence that cancer risks suddenly may appear out of nowhere
13 more than a decade after a patient stops taking a medication.
14 There is just no suggestion of that in the data that we have.

15 Next slide, please.

16 So, let's talk further about the dietary studies the
17 most fundamental problem I would highlight is that the vast
18 majority of dietary studies relied on by Dr. Moorman, not Mr.
19 Nigh or the Plaintiffs' attorneys, Dr. Moorman, are not NDMA
20 dietary studies at all, meaning they did not measure NDMA at
21 all.

22 Rather, they were evaluating the potential cancer
23 risks associated with the various foods we have been talking
24 about, with whatever potentially bad substances are in them.
25 The point is that even if one accepts that some amount of eggs

1 or meat or fish could cause cancer, one could not reliably
2 determine from these studies an amount of NDMA that caused the
3 five cancers. As I said, the vast majority did not evaluate
4 NDMA.

5 Next slide, please.

6 You can see that here in this next slide. Of the 39
7 studies Dr. Moorman gives any weight, 39 do not attempt to
8 quantify the amount of NDMA in the foods being studied. For
9 almost all these studies assessing the cancer risk associated
10 with NDMA exposure was not part of the study.

11 Because your Honor asked about the Ronco study, we
12 should add that we did not include Ronco in the seven at the
13 bottom here because specific NDMA levels or ranges are not
14 included in that paper.

15 Next slide, please.

16 Now, let's look more closely at the seven dietary
17 studies that had information about NDMA levels.

18 First, out of the seven, Dr. Moorman herself notes
19 that the NDMA estimates in two of them, Zheng -- 2021 NDMA
20 estimates are anonymous and likely erroneous. She gives little
21 or no weight to Rogers, Loh, and De Stefani, three more, based
22 on their extensive limitations.

23 She gives moderate weight to two studies, this Jakszyn
24 study and Keszei study. I think your Honor asked about both of
25 those. She relies on bladder cancer data from Jakszyn

1 and esophageal cancer data from Keszei, though Keszei also
2 showed no difference for gastric cancer, and Dr. Moorman left
3 that part out of her analysis.

4 So, in the interest of time, I am not going to be able
5 to do a deep dive into these two dietary studies that are left,
6 but just as an example, you can see on the right what the
7 authors in Jakszyn concluded, our are findings do not support
8 the hypothesis that red meat and meat related compounds,
9 including NDMA, are associated with the risk of developing
10 bladder cancer. Again, Dr. Moorman is stretching beyond what
11 the authors are willing to do on their own.

12 Next slide, please.

13 Now I want to talk about the unique methodology that
14 Dr. Moorman used to try to correlate the dietary and
15 occupational studies to the alleged NDMA levels in Ranitidine
16 that patients took over time.

17 Dr. Moorman claims the dietary studies are
18 informative because the levels of dietary NDMA in those studies
19 are comparable to the levels in tested lots of Ranitidine. As
20 we have just seen, the NDMA levels in the vast majority of
21 dietary studies aren't actually measured, and the remaining
22 studies do not reliably correlate specific NDMA levels with the
23 cancers at issue here.

24 Now, with respect to the Ranitidine part of Dr.
25 Moorman's analysis, Dr. Moorman does not specify the total

1 amounts or amounts per day of NDMA that she assumed patients
2 were ingesting from Ranitidine at a time. She said she relies
3 on NDMA levels reported in FDA's press release, and that might
4 be why your Honor was asking questions about the press
5 releases, but as you will note, that press release contains
6 only the highest and lowest NDMA test results ranging from zero
7 to 860 nanograms.

8 We have no information on what number in that range
9 Dr. Moorman is relying on as a basis to equate the NDMA levels
10 patients were exposed to over time from Ranitidine to the NDMA
11 levels reported in the dietary studies.

12 Next slide, please.

13 It is important to note that Dr. Moorman did not
14 analyze any actual test results. We asked her about that. To
15 illustrate the problem with that we created a graph that
16 contains the FDA's testing of Sanofi's Ranitidine product.

17 As you can see, FDA actually tested 19 lots of
18 Sanofi's Ranitidine. The overwhelming majority of results, 16
19 of 19, were below the FDA's acceptable limit for NDMA. They
20 were below the lowest NDMA amounts in many of Dr. Moorman's
21 weighted dietary studies.

22 I think this tells you why Dr. Moorman didn't at least
23 try to determine a mean or median value within that range.
24 That number would not correlate well with the numbers
25 Plaintiffs are relying on in the dietary studies.

1 From this graph you could see how hard it would be to
2 try to come up with any reliable estimates of what patients
3 actually ingested in the real world. Dr. Moorman did not
4 provide a reliable methodology to do that, and we are just
5 talking about the levels for 2019.

6 Next slide, please.

7 Dr. Moorman's assumptions about the levels of NDMA in
8 Ranitidine before 2019 are even more problematic and
9 speculative.

10 While the FDA reported a range of test results in
11 2019, it also said that it has no scientific evidence regarding
12 the level before 2019. Dr. Moorman ignored this part of FDA's
13 statement. Instead, Dr. Moorman tried to extrapolate back and
14 do what the FDA itself said it couldn't do. She just assumed
15 the same zero to 860 or 890 nanogram range for all other years.

16 There is simply no reliable way for Dr. Moorman to
17 determine how much, if any, NDMA was in any given Ranitidine
18 pills on average or otherwise over any given period of time.
19 Nobody else has tried to do that, not even the FDA, and
20 litigation is not a place to test new methodologies like this
21 for the first time.

22 Mr. Petrosinelli and Ms. Canaan discussed some of the
23 law that would support that statement.

24 Next slide. Next slide.

25 My colleague is moving me along here, your Honor.

1 THE COURT: You have 14 minutes left.

2 MR. BROWN: Okay. I am going to talk about the
3 Bradford-Hill analysis quickly, particularly strength of
4 association, dose response, and replication inconsistency.

5 I think, because both Ms. Canaan and I are likely
6 going over, we were going to ask if we could take some of our
7 rebuttal time -- a little longer here and take some of our
8 rebuttal time down.

9 THE COURT: Sure.

10 MR. BROWN: Thank you.

11 First, strength of association, your Honor, there
12 really is no dispute about how important this is in the context
13 of observational studies that produce very low risk estimates
14 and significant confounding challenges. Bradford-Hill puts it
15 first on his list for a reason.

16 Next slide, please. I lost track here.

17 Just talking about strength of association and
18 referencing Bradford-Hill puts this first on his list for a
19 reason.

20 Let's go to the next slide.

21 He does that because in the observational study world
22 it is notoriously difficult to attribute very small risk ratios
23 below 2.0, let alone below 1.5 to a drug effect. I remember
24 your Honor asking a question about this even at Science Day a
25 number of months ago.

1 You need such strong evidence beyond a risk estimate
2 above 1.0, and -- or below 2 -- 1.5, I should say, in order to
3 conclude that any small observed difference is due to the
4 medication in question and not population differences that
5 existed from the start, or even the play of chance.

6 Dr. Moorman acknowledges that here in the slide,
7 conceding that a confounder doesn't need to be very strong to
8 explain weaker risk estimates that are below 2.0.

9 Next slide, please.

10 Here you can see that Dr. Moorman did not even try to
11 perform a valid analysis of the relative risks for each cancer.
12 You need relative risks in order to analyze the strength of
13 association and Dr. Moorman says it would be impossible to
14 provide one for any of the five cancers.

15 Here, Dr. Moorman provides no specific risk estimates
16 that allegedly reflect the strength of association for each
17 cancer.

18 She knows how important it is to do that because in
19 her report she repeatedly refers to other analogous examples of
20 cause and effect relationships and always includes risk
21 estimates, MP values and confidence roles. She didn't do that
22 here and we believe her failure to do that here invalidates her
23 entire Bradford-Hill analysis from the start.

24 Let's go to the next slide. And the next slide.

25 I want to talk about dose response for a minute, your

1 Honor.

2 Here, seven different research groups evaluated their
3 data for the presence of a dose response, and with the
4 exception of the nonuser part of Dr. Cardwell's analysis, Dr.
5 Moorman simply didn't like what they found. So instead, as you
6 can see on the left of this slide, she claimed that the studies
7 were so inadequate that you can't really describe anything
8 about dose response, including studies she strongly weighted.

9 Instead of properly analyzing dose response, she also
10 claimed that a single Ranitidine pill can cause each of these
11 five cancers.

12 Doctor -- oh, Dr. Petrosinelli mentioned this earlier
13 this morning.

14 *MR. PETROSINELLI:* Thank you.

15 *MR. BROWN:* This is not a valid analysis of dose
16 response. It's the Plaintiffs' burden of proof to put forward
17 reliable expert evidence to support the Bradford-Hill criteria,
18 including dose response, and dose response is one of the most
19 important factors in this circuit.

20 I'm going to rap it up and talk about the last factor,
21 your Honor.

22 Next slide. Next slide. Next slide.

23 Replication and consistency. In the interest of time,
24 I am not going to read these sections of Dr. Moorman's report,
25 but as you will see, I think it is fair to say that Dr. Moorman

1 recognizes the importance of both replication and consistency.

2 Next slide.

3 Of particular importance here, Dr. Moorman also
4 recognizes how important it is to replicate findings outside a
5 single database or country that a particular study was drawn
6 from. Epidemiologists like Dr. Moorman typically insist on
7 replication because they need to confirm the findings based on
8 a single database aren't simply an artifact of the database or
9 unique to the population being studied.

10 In her deposition, Dr. Moorman confirmed more than
11 once how important it is to replicate findings in different
12 countries and populations. In the interest of time, again, I
13 won't read the testimony, but you can find it on pages 136 and
14 137 of her deposition.

15 Next slide, please.

16 Now, while Dr. Moorman recognized the importance of
17 replication, she abandoned this important Bradford-Hill factor
18 in relation to her analysis of the Ranitidine studies. Indeed,
19 every study that Dr. Moorman strongly weighted in this case
20 came from a single database in Scotland with a population just
21 under 5.5 million.

22 The Plaintiffs spent a lot of time in their briefs
23 talking about how the Ranitidine studies that Defense experts
24 rely on do not apply to their U.S. Plaintiffs, but neither Dr.
25 Moorman nor the Plaintiffs explain how they can extrapolate

1 findings from a single database in Scotland to all of their
2 U.S. Plaintiffs.

3 Last couple of slides.

4 By contrast, as you can see here in this slide, Dr.
5 Moorman gave little weight to all the rest of the Ranitidine
6 studies, 11 in all, which examined populations around the
7 world, including studies in the United States where this
8 litigation was brought.

9 Next slide.

10 Here, again, your Honor, I won't read the quote, but
11 rest assured that Dr. Cardwell himself acknowledged that his
12 findings in the Scottish database needed to be replicated in
13 other settings, meaning other populations, and that is exactly
14 how Dr. Moorman interpreted it.

15 Last slide.

16 This will be it, your Honor. If we zoom out of the
17 Scottish database and evaluate the consistency of findings
18 across the studies Dr. Moorman did not weight heavily, there is
19 very consistent evidence of no increased risk, and that gets to
20 the heart of the Daubert problem in this case.

21 What you see here is what I just said. On the right a
22 consistent pattern of no increased risk when comparing
23 Ranitidine users to users of other H2RAs. In Dr. Moorman's own
24 words, this is exactly what one would expect to see if there is
25 no association between an exposure and an outcome that has risk

1 estimates clustered around 1, with some estimates greater than
2 1, and some less than 1.

3 In contrast, on the left next to the orange dots, you
4 see selective nonuser analyses that Dr. Moorman heavily
5 weighted and that show some numerical or statistical
6 differences between nonusers and Ranitidine users.

7 In summary, your Honor, Dr. Moorman used a flawed
8 weighting methodology as a basis to elevate certain nonuser
9 studies from a single database in Scotland and then she used an
10 equally flawed process to invalidate all the active comparator
11 studies which showed no consistent evidence of an increased
12 risk for any of the five cancers. This is not a reliable
13 methodology, and it is why her testimony should be excluded.

14 Thank you.

15 *THE COURT:* Okay, thank you.

16 There is about five minutes left in this main portion,
17 and then you had reserved 20 for your rebuttal.

18 *MR. HOLIAN:* Your Honor, I had planned on talking 20
19 minutes. I can keep that to 15. Would your Honor like me to
20 go now or do you want to take a break?

21 *THE COURT:* We are going to take a break, but we were
22 going to take a break after this presentation.

23 *MR. HOLIAN:* I want to be sure the Court would prefer
24 I do 15 minutes now, but if your Honor would prefer to take the
25 break and then have me go right after the break --

1 *THE COURT:* Okay. Now you are going to speak about
2 the experts Le, Salmon, and Michaels. Do you want me to tell
3 you when 15 minutes is up?

4 *MR. HOLIAN:* Unlike some of my colleagues, your Honor,
5 I have a timer in front of me.

6 *THE COURT:* You may proceed.

7 *MR. HOLIAN:* Thank you, your Honor. My name is Matt
8 Holian, I represent Sanofi, I'm here on behalf of all the
9 Defendants today. I will be talking about Drs. Salmon, Le, and
10 Michaels.

11 A couple of points to put these three experts in
12 context. Unlike Drs. McTiernan and Moorman, they are not
13 epidemiologists, but their epidemiology opinions suffer from
14 some of the same defects as those you heard about from Mr.
15 Brown and Ms. Canaan earlier today with regard to the other
16 experts, which I have shown on this slide, but won't read in
17 the interest of time. There are additional reasons these
18 experts should be precluded as well.

19 Let's go to the next slide.

20 I will start with Dr. Salmon. He also offered
21 epidemiology opinions, but should be precluded from offering
22 those because he offered opinions on statistical significance
23 that were inconsistent with what he said outside of litigation,
24 and offered unreliable dose response opinions with regard to
25 NDMA and Ranitidine.

1 Outside of litigation, Dr. Salmon has recognized the
2 importance of statistical significance. In a book chapter he
3 wrote, shown here on the left, he favorably cited hierarchy
4 classification scheme and noted that a conclusion of sufficient
5 evidence of a causal relationship depends on statistically
6 significant results.

7 Your Honor, this isn't a book chapter he wrote 40
8 years ago and never updated, he pulled extensively from that
9 book chapter in the report he submitted here, but when it came
10 time for the section that appears on the left, he omitted that
11 quotation, and instead wrote that statistical significance is
12 not a threshold that must be reached, and he drew a causation
13 opinion based on a pattern of results that he admitted a
14 considerable portion of which were not statistically
15 significant.

16 Now, turning to Dr. Salmon's dose response analysis, I
17 want to start by showing you the end product of his work.
18 First, in a chart on the left of the slide you will see he
19 calculated NDMA dose response slopes from the dietary and
20 occupational epidemiology studies. Don't worry, the actual
21 specific numbers on the chart you won't have to read. I just
22 wanted to show you the key charts in his report.

23 He then converted those NDMA dose response slopes into
24 the chart on the right, where he calculated an incremental risk
25 for Ranitidine.

1 As I will show you, in deriving his NDMA dose response
2 opinions Dr. Salmon used an unreliable methodology. He stacked
3 the deck in the studies that he chose, cherry picked data
4 within studies, and he used an unprecedented method to combine
5 results across studies.

6 With regard to the first step, Dr. Salmon's report
7 summarizes 28 NDMA epidemiology studies. Of those, he
8 calculated cumulative lifetime NDMA exposure for 20 studies,
9 those shown in black, the others are shaded in gray.

10 Of those 20, he included 11 in his dose response
11 analysis, and omitted the other nine. And how did he pick
12 which ones to include?

13 Well, as your Honor can see here, he did his dose
14 response calculations using only the studies on the left, those
15 that showed a statistically significant dose response. He left
16 out the studies on the right because they did not show a dose
17 response.

18 You can see here in red Dr. Salmon's own assessment of
19 those studies, it is the definition of an unreliable
20 methodology that could only yield one result. It's not that he
21 couldn't do the math, your Honor, for the studies on the right
22 that weren't significant, he could have. It's that if he had
23 done the math, it could show there wasn't a dose response for
24 NDMA, or it at least could have materially affected his
25 results. His explanation, that the studies were uninformative.

1 Now, it gets worse. Dr. Salmon didn't just cherry
2 pick across studies, he also cherry picked within studies in
3 the Keszei study, for example, you will see here on the right
4 the authors reported eight different results, four different
5 types of cancer for men and for women.

6 When Dr. Salmon chose to do his dose response analysis
7 he didn't look at all eight, he looked at two, one that was
8 statistically significant, a sub type of esophageal cancer in
9 men, and one that wasn't significant, but that he said was
10 close, a sub type of gastric cancer, again, only in men.

11 His explanations? Well, he said the data for the six
12 that he left out -- he said the data for the six he left out
13 are a classic example of what data would look like when IARC
14 would say an association cannot be determined. In other words,
15 he left out the data that would undermine his dose response
16 calculations.

17 And he defended his cherry picking of the
18 statistically significant results by saying, well, I can
19 only reasonably rely on statistically significant results
20 because that is, quote, "the usual standard of scientific
21 reliability."

22 Of course, if that is true, your Honor, Plaintiffs'
23 entire general causation case falls apart. Again, a
24 quintessential example of a results driven methodology.

25 It gets worse again. He didn't just stop there. What

1 did he do with those 11 studies that he cherry picked? He did
2 not follow the procedures for a meta analysis, which, as your
3 Honor may know, is where scientists weight studies based on the
4 number of events, and the Plaintiffs tried to defend what Dr.
5 Salmon did in their briefs by reference to that method, but the
6 Court should not be deceived.

7 Dr. Salmon did not perform a meta analysis, he didn't
8 weight the studies in any way, he just averaged them. What
9 that means is a study with a thousand cancers gets weighted
10 equally as a study with ten cancers. Nobody in the world
11 thinks that is a reliable way to combine study results.

12 Not surprisingly, when asked at his deposition, can
13 you point us to anybody who has ever done that, he admitted he
14 could not. No one had ever used this unprecedented
15 methodology.

16 So, when you stack the deck by cherry picking studies,
17 when you cherry pick data within studies, and then you use an
18 unprecedented method to combine those studies, that makes your
19 conclusions a house of cards.

20 It gets worse a third time, your Honor. Dr. Salmon
21 didn't just calculate the NDMA dose response slopes and leave
22 it at that; he then applied those calculations to try to derive
23 the risk for patients who took Ranitidine. So, he is stacking
24 the deck with his studies, he is cherry picking within studies,
25 he is coming up with a single average estimate of risk, and

1 then using that to calculate hazard ratios for patients who
2 take Ranitidine.

3 That analysis is based on multiple analytical leaps.
4 He assumes every dose of Ranitidine contains a thousand
5 nanograms of NDMA. He assumes the average Ranitidine user
6 takes it for at least ten years based on unspecified
7 prescription records, although he admitted at his deposition he
8 didn't review any prescription records, and said this was a
9 hypothetical illustration.

10 He solely based his calculations for bladder,
11 pancreas, and liver cancers on the Hidajat study, which you
12 have heard us discuss, and he abandons statistical
13 significance. He doesn't present any P values or confidence
14 intervals for any of these hazard ratios, so there is no way to
15 assess their reliability and there is no way to assess the
16 error rate.

17 Your Honor mentioned having reviewed 40 scientific
18 studies preparing for this hearing. I'll bet you not a single
19 one presented hazard ratios without confidence intervals or P
20 values. That is just not done.

21 Perhaps recognizing all of these tenuous assumptions,
22 at his deposition he retreated from this model and labeled it
23 a, quote, "purely hypothetical example." It's question upon
24 question upon question upon question, all built on a house of
25 cards. It is exactly the kind of unreliable speculation and

1 junk science that Rule 702 forbids.

2 So, that was Dr. Salmon's quantitative dose response
3 analysis.

4 At his deposition, Plaintiffs' counsel tried to
5 resurrect his dose response opinion by distinguishing that from
6 what they called his categorical dose response analysis, which
7 is basically just looking at individual studies, so let's look
8 at that.

9 We have talked a lot about the importance of dose,
10 both dose response and the separate idea of a threshold dose,
11 so I have quoted here some language from the McClain decision.

12 I wanted to show you what a dose response graph would
13 look like if there was consistent evidence of a dose response.
14 Your Honor, this graph measures two different ways to measure
15 the use of Ranitidine on the horizontal axis, the number of
16 prescriptions on the bottom, daily dose on the top, and has the
17 risk ratio on the vertical axis.

18 This is what it would look like in a single study if
19 there was a dose response, with the lines sloping upward, the
20 risk ratio going up, as the use of the medication at issue
21 increased.

22 Scientists, your Honor, don't just eyeball that, they
23 run specific statistical tests to ensure that what they are
24 seeing are not chance findings.

25 This is what it would look like if there were

1 consistent evidence of a dose response, multiple studies all
2 sloping upward, and many of them statistically significant.
3 That is what the picture should look like if there is a dose
4 response.

5 This is what the graph looks like if you show the
6 Ranitidine dose response data. I show here the active
7 comparator results, but the nonuse results are very similar.

8 As you will see -- there we go -- there is no clear
9 dose response, most of the lines go down. None of the dose
10 response results were statistically significant.

11 There is one more, the Cardwell study, and those dose
12 response results were only significant when they compared
13 Ranitidine users to nonusers, and only at the very highest
14 dose. Dr. Salmon relies heavily on that result, even though
15 the Cardwell authors specifically noted that there was little
16 evidence of a difference when you compare Ranitidine users to
17 users of other H2 blockers.

18 When you look at that Cardwell line, your Honor, what
19 you see again is Dr. Salmon emphasizing the data that supports
20 his opinion and downplaying the rest.

21 Now, you heard Mr. Nigh talk about the defined daily
22 dose measure, but as you will see in the Iwagami study, the red
23 dotted line also used that measure of defined daily dose, and
24 if Ranitidine consistently increased the rate of cancer, the
25 more prescriptions people filled, these lines wouldn't look

1 this way, your Honor.

2 Notwithstanding this data, Dr. Salmon comes to the
3 conclusion that there is a dose response for Ranitidine, not
4 just for bladder cancer, but for all five cancers.

5 Where does that leave him in relation to the rest of
6 the medical community? On an island.

7 Dr. Salmon said the data present clear evidence of a
8 dose response. He says that for every type of cancer, although
9 he said it is only supportive for pancreas and liver, but that
10 is contrary to what you already heard from Plaintiffs'
11 epidemiologists who say that Ranitidine dose response data were
12 not informative, and it is contrary to what the study authors
13 include. Because Dr. Salmon's dose response analysis is
14 unreliable, his Bradford-Hill analysis is unreliable and he
15 should not be allowed to offer a general causation opinion to a
16 jury.

17 I will close, your Honor -- we will rest on the papers
18 or discuss in rebuttal Drs. Le and Michaels, but I made a
19 commitment to Ms. Stipes to keep this to 15 minutes, so I will
20 end on this slide.

21 This is the chart that Mr. Nigh started with, he said,
22 but the Defendants haven't talked about this chart that shows
23 the duration of these studies.

24 In fact, Dr. Salmon's duration analysis is built on
25 his earlier work and it continues his pattern of cherry

1 picking. This chart, your Honor, is on page 223 of his 223
2 page report. If you look at page 221, that is where you see
3 the inputs, the assumptions Dr. Salmon makes to come to these
4 figures.

5 What you will see is, for each of the five types of
6 cancer he picks one NDMA epidemiology study to calculate the
7 hazard ratios for liver, bladder, and pancreas cancer, solely
8 the Hidajat study, which you have heard us talk about
9 extensively.

10 For esophageal cancer he uses the Keszei study, but
11 again, he only picks one sub type of esophageal cancer, and
12 only in men.

13 He also cherry picks the product testing data that he
14 uses to calculate this chart. The FDA max number there, your
15 Honor, the NDMA milligram per year of .31, that is based on
16 pulling the absolute maximum result from all of the tests that
17 FDA did from all of the manufacturers, and he assumes that
18 every person who took Ranitidine gets exposed to that level for
19 the whole time they take it.

20 Even when you make those assumptions, Judge, you will
21 see -- Dr. Petrosinelli stole my thunder -- that for bladder,
22 pancreas, and liver cancer you have to take that extreme level,
23 you have to be exposed at that extreme level for at least 27
24 years. You can see it slightly shorter for gastric and
25 esophagus.

1 That doesn't get the Plaintiffs there so they have to
2 overlay on top of that all of Dr. Najafi's testing to try to
3 shorten those durations.

4 Your Honor, I will close by saying, you will hear more
5 about that tomorrow, that is not a reliable way to answer the
6 call in McClain to say how much is too much, and the Plaintiffs
7 can't have it both ways. They can't say the Ranitidine
8 epidemiology is too short. It doesn't answer the question if
9 the durations in Dr. Salmon's analysis hold true, because if
10 they did and if Dr. Najafi's test results were actually
11 experienced by patients taking Ranitidine, you should see it in
12 the Ranitidine epidemiology.

13 Thank you, your Honor.

14 *THE COURT:* Thank you. That was 15 minutes.

15 That leaves you with ten minutes for your rebuttal.
16 Is that what -- you agree?

17 *MR. HOLIAN:* Yes.

18 *THE COURT:* It is 2:55. We will be in a 15-minute
19 break, so we will come back at 3:10 and then we will hear from
20 the Plaintiffs.

21 So we will be in recess.

22 (Thereupon, a short recess was taken.)

23 *THE COURT:* You may be seated. Thank you.

24 Okay. Now we can hear from Plaintiff's counsel. Is
25 it Mr. Ronca who is going first as to Dr. McTiernan?

1 Do I need to give you any kind of a warning or do you
2 have the time covered?

3 MR. RONCA: I have the timer.

4 THE COURT: Okay. Good afternoon.

5 MR. RONCA: I have not appeared before you before,
6 your Honor, I am Tracy Finken's partner. I am here today to
7 argue in opposition to Defendants' motion to exclude the
8 testimony of Ann McTiernan. We urge the Court to deny the
9 motion.

10 Ann McTiernan is a full professor of epidemiology at
11 the Fred Hutchison Cancer Center affiliated with the University
12 of Washington, where she was previously director for a decade.

13 Most of her over 400 peer reviewed studies relate to
14 cancer. She has extensive experience in both diet and cancer
15 risk with over 130 studies, and cancer risk of medications and
16 supplements with over 70 studies, including cancer risk of
17 aspirin, Tamoxifen, and Vitamin D, in other words, pills you
18 are taking and which may or may not increase the risk of
19 cancer.

20 Dr. McTiernan is the only epidemiologist in this
21 litigation who has served on both an IARC working group and at
22 WCRF on an expert advisory panel.

23 Next slide, please.

24 She has done studies, peer review, and grant review
25 for the most important cancer institutions and agencies in this

1 country, including the National Cancer Institute and the
2 Women's Health Initiative, and many international institutions
3 also.

4 She has been involved in one other litigation, the
5 Talc litigation, where she passed all of her review, and
6 frankly, the Defendants don't seriously challenge her
7 qualification to testify in this case.

8 As the other speakers have done, I will give you a
9 little bit of a road map. I don't have a road map slide, but I
10 will let you know when I am changing topics, because it might
11 be clear in my head, but might not be so easy for the listener.

12 First I am going to talk about the accepted scientific
13 method Dr. McTiernan employed in reaching her opinions. After
14 that, I am going to talk about the research question in this
15 case. Third, dose response. Fourth, dose, including the legal
16 question regarding dose. Fifth, a discussion of the active
17 comparator studies that we have heard so much about today.

18 Sixth, I want to give a detailed example of how Dr.
19 McTiernan delved into the studies to find their true strengths,
20 weaknesses, and weight, which defeats the Defendants' arguments
21 of cherry picking and a predetermined result.

22 So, I think that will be instructive because we'll
23 dive in, maybe not like we are supposed to as lawyers and
24 judges, but looking at it the way a scientist looks at it.

25 Seventh, we are going to talk about the

1 inconsistencies of the studies in finding an increased risk of
2 the five cancers, and as I will show later -- we have heard a
3 lot about there being no association, you need an association
4 before you get to the Bradford-Hill criteria. I am going to
5 show a lot of associations.

6 Then, if I have time, I want to rebut some of the
7 specific Defense allegations related to the World Cancer
8 Research Fund, the reference to Dr. McTiernan's testimony in
9 the Talc litigation, and if I have time, some of the partial
10 statements made by the Defense in their papers.

11 Let's go to the next slide.

12 The scientific method employed by Dr. McTiernan is a
13 weight of the totality of the evidence and then the application
14 of the Bradford-Hill criteria for causal inference. The method
15 is well accepted in both science and law.

16 As was made clear in the Abilify case, the weight of
17 the evidence approach can be considered reliable provided the
18 expert considers all the available evidence carefully and
19 explains how the relative weight of the various pieces of the
20 evidence led to her conclusion.

21 This method requires the expert to exercise judgment,
22 which requires the expert to describe each step in the process
23 by which she gathered and assessed the relevant scientific
24 evidence. Dr. McTiernan met that burden by accumulating and
25 reviewing the totality of the evidence in exhaustive detail.

1 Sometimes we lawyers like to see bright lines, like
2 the fact I did a road map, one, two, three, four, five, six,
3 this is what you have to prove. In science, and actually in
4 law, judgment sometimes, and often frequently, is the result of
5 the research.

6 So, in science, judgments are made all the time and
7 based on science, governments, institutions, medical
8 facilities, physicians, make decisions all the time based on
9 scientific judgment. So, there is nothing wrong with a
10 judgment being made once the evidence is carefully reviewed.

11 It doesn't have to meet some abstract criteria. It is
12 a judgment, and if it is done properly, it is admissible.

13 Now, the first item is a systematic search and
14 accumulation of all the scientific studies and literature for
15 review. The Defendants do not even challenge the completeness
16 of Dr. McTiernan's search and gathering of the evidence.
17 Totality of the evidence is not an issue.

18 Next slide.

19 In the Abilify case Judge Rodgers detailed five
20 factors to be shown when using the weight of the evidence
21 method, and I want to align that with that list of things that
22 Dr. McTiernan did, which I took out of her report.

23 First is whether an association is shown.

24 This comes from the data in the study, not only the
25 results, but all the factors that lead to those results. The

1 review Dr. McTiernan employed was applied study by study,
2 including the study type and design, most case control and --
3 mostly they were case control and cohort studies, and the
4 design is important. Okay.

5 If you look at the particulars of the design and make
6 an expert judgment on whether the design can even give you the
7 answer that the study is supposed to give.

8 Second, the population source and specifics of the
9 population. For example, how young or old is the population.
10 You will have a hard time finding a lot of cancers in a very
11 young population, or as I heard in a lecture once, you won't
12 find a lot of post menopausal symptoms if you only do a study
13 of college women.

14 Depending on the population you are looking at, in
15 this case in particular there was one study where more than
16 half of the participants were below age 40, meaning you are not
17 going to find many cancers in that more than half.

18 Another study only looked at patients who were men and
19 who had H. pylori. Now, if you are trying to find out whether
20 exposure to Ranitidine can increase the risk of cancer for
21 people with H. pylori, that would be a good study. Is it
22 generalizable to everyone? Probably not, but that is what the
23 expert needs to look at specifically study by study.

24 The expert needs to look at the risk ratios, including
25 relative risk, statistical testing. Yes, there is a debate

1 about statistical testing. Yes, it should be done in every
2 case. No, it is not the sine qua non of this is the answer.
3 If it is statistically significant you count it, and if it is
4 not statistically significant you don't count it.

5 That is not so. Statistical significance only
6 measures the chance in that data set, not the chance overall.
7 If the data set is poor, then it doesn't matter if it is
8 statistically significant. Again, things that experts need to
9 review when doing a systematic review.

10 Dose, including the amount and duration, dose response
11 and the outcome definition and measurement, in other words, how
12 was the outcome determined. Was it pathology reports? Was it
13 medical records? Was it insurance codes? This is why the FDA
14 has concerns about electronic databases being used because, why
15 was that code being used? That code is being used to pay a
16 bill, not -- and those kind of electronic databases are not
17 research databases.

18 There are large research databases. The dietary
19 studies that are used in this case, one of them uses, for
20 example, EPIC, which is a giant research database created in
21 ten countries in Europe to study diet, set up by researchers,
22 not insurance codes.

23 You can see from Dr. McTiernan's report that she
24 considered each of these in detail study by study.

25 Now, the second item is alternative explanation for

1 the association, and this includes issues of confounding and
2 bias, and other sources -- in other words, did we get the
3 result because of some problem with the study itself?

4 I am not going to delve into all those various
5 definitions of bias and confounders because there are many. I
6 know the Court has exhaustively read all the reports and seen
7 it over and over again. But they are important to review, and
8 when we get to that example I mentioned that we were going to
9 talk about, you will see an example of where that comes in.

10 Some of the bias, like watering down a study
11 population, can also reduce the amount of risk. On the other
12 hand, if you overstate certain outcomes because of the study
13 population, you can get a higher risk where it really shouldn't
14 be there.

15 Experts need to review that and make judgment calls on
16 what the value of a study is based on that and, as Judge
17 Rodgers put it, there are alternative explanations for the
18 association.

19 Next, rank reliable explanations, in other words,
20 weighing the studies. I am going to rank them, I am going to
21 weigh them based on all those other things that I reviewed,
22 study by study, and finally consider all the relevant now
23 available evidence, and so that is all the relevant and
24 available evidence.

25 The Defendants in this case very clearly want to limit

1 the review to Ranitidine specific studies, even though the
2 contaminant is NDMA. They don't want us to look at the NDMA
3 studies, but the NDMA studies are relevant. They may not be
4 the most important evidence, but the NDMA studies are relevant
5 to the question that we are raising here.

6 Second, compare consistency between studies. I will
7 show that to you later, I hope. Compare to results of animal
8 studies, compare to the results of in vitro studies.

9 For example, if the substance doesn't cause cancer in
10 any animals or none of the in vitro studies come up with a
11 genotoxic or a carcinogenic, but you see an increased risk in
12 human studies, there is a question. Well, is it this toxic
13 agent or is it something else?

14 When they are consistent, when the animal studies show
15 cancer, when the in vitro studies show carcinogenicity, when
16 the human studies show an increased risk of cancer, that is a
17 consistency that can support an opinion.

18 Case reports, like FDA adverse event reports, there is
19 the McGwin study, it should be considered. It was considered
20 in this case, but Dr. McTiernan didn't give it any weight, just
21 gave it weight as a signal.

22 Then the last thing the expert has to do is integrate
23 the evidence using professional judgment. This is where you
24 apply what is commonly called the Bradford-Hill criteria, or
25 viewpoints or factors. None are required, one would be

1 sufficient if it were strong enough, but the important thing is
2 for the expert to take all the information that we just talked
3 about and condense it, look at it within the concept of those
4 viewpoints and then come to a scientific judgment about whether
5 a connection can be made between a particular toxic agent and
6 cancer.

7 In this case, Dr. McTiernan first did a lengthy
8 discussion of all of the studies and the databases that
9 supported those databases, where did that data come from, and
10 then she went through a detailed examination of each cancer
11 separately, and then applied the Bradford-Hill criteria.

12 She did three things, and I am going to point this out
13 now. I don't have time to give you specific examples.

14 Many times -- in those representations that the
15 Defendants made here today, they took a piece from the general
16 discussion and a piece from the Bradford-Hill discussion and
17 tried to say that those two things were the same thing, but in
18 the first piece, that is when Dr. McTiernan is going through
19 all the specifics of the studies, and the second piece is where
20 judgments are being made.

21 There is a fair amount in the Defendants' papers of
22 taking parts of sentences without what went before and what
23 went after, two or three words in quotes, and calling that what
24 Dr. McTiernan said, or taking one quote out of a 13-hour
25 deposition. Okay. That is fine as long as everyone who is

1 making a decision relating to this keeps in mind that there is
2 a longer answer there, or the answer might have been at the
3 next question, and when you pull out a snippet, it doesn't
4 necessarily reflect everything that happened in the 13 hours.

5 Go to slide 5.

6 So, the Defendants don't even dispute that this is the
7 right method. In fact Dr. Terry, who is one of the Defendants'
8 epidemiology experts, basically gives the same description in
9 her report on pages 20 and 21.

10 Go to 6, please.

11 It just follows on from what I just said.

12 So, the important note in this is that Dr. Terry
13 agrees that there are no perfect studies, and because there are
14 no perfect studies, let alone perfect observational studies, it
15 is important for an expert with the type of qualifications that
16 Dr. McTiernan, or for that matter Dr. Terry has, to review.

17 Two experts reviewing the same data could come to
18 different scientific judgments, but that doesn't mean that
19 either judgment is either more persuasive or better. It just
20 means that they have a disagreement, and those disagreements,
21 as I understand the case law, are decided by juries.

22 So, Dr. McTiernan followed scientific method, when a
23 study had a good solid foundation, she put extra weight on it.
24 When a study was riddled with problems, like short exposure or
25 short followup periods, lack of dose information, and on and on

1 and on, then she called it, and she put less weight on that
2 study.

3 Throughout her report she explained in detail,
4 exhausting detail, exactly what she was doing, and the bottom
5 line of the argument so far is that the Defendants do not
6 challenge Dr. McTiernan's qualifications. How could you?
7 Defendants do not challenge the breadth and depth of the
8 evidence that Dr. McTiernan accumulated, and they do not
9 challenge the method, the design of the method that she used.

10 What the Defendants challenge is the way Dr. McTiernan
11 evaluated the studies. Defendants want the Court to decide
12 which studies should be considered and which are the better
13 studies.

14 As stated by Judge Chhabria in the Roundup, the
15 Daubert inquiry does not require or even allow a District Court
16 to exclude an expert's opinion merely because the Court is not
17 persuaded that the expert's read of the evidence is the best
18 one, or make conclusions on the persuasiveness of the proper
19 evidence.

20 The test is not the correctness of the expert's
21 conclusions, but the soundness of her methodology, and applying
22 the Bradford-Hill criteria involves a certain amount of
23 subjectivity, and experts disagree when doing that. This is
24 not my word, these are the words from the Roundup case. The
25 Court's job is to make sure that the expert's methods are not

1 so far outside the realm of reasonable scientific practice that
2 the testimony would be unhelpful to the jury. So far outside
3 the realm of scientific practice, that is not what we have
4 here.

5 Now, next slide, please.

6 So, Dr. McTiernan's charge was to look at all cancer
7 and exposure to Ranitidine, and in particular the lawyers, us,
8 told her to look specifically at ten designated cancers, and
9 she did.

10 She went through each one with the depth and rigor
11 that I just described, and then she turned back and she said to
12 the Plaintiffs, in my opinion, for five of these cancers there
13 is sufficient evidence to show an increased risk of harm --
14 increased risk of cancer when exposed to Ranitidine, and we are
15 talking about chronic exposure, long-term exposure, not very,
16 very short exposure.

17 But she also said, on the five other cancers, in my
18 opinion, there is not enough evidence for me to say that. I am
19 telling all the Plaintiffs who filed lawsuits based on the
20 other five cancers I cannot help them. It doesn't matter that
21 more cancers than that got past Daubert in the Valsartan case,
22 and it doesn't matter that other cancers, other than the five,
23 got past in a State case recently. That didn't matter to Dr.
24 McTiernan because Dr. McTiernan is not cherry picking her
25 results.

1 If she were cherry picking her results, if she had a
2 predetermined result, then she would have gone with ten
3 cancers, or eight cancers, or seven cancers. She wouldn't have
4 eliminated five cancers or cancers that have gotten by in other
5 Courts.

6 I mean, she probably wanted to help us, but told us
7 she couldn't, and this is the best evidence, I think, that
8 there was no cherry picking.

9 And just as an aside, my very able opponent, Mr.
10 Cheffo, pointed out this morning that both Dr. McTiernan and
11 Dr. Moorman did not use the same data -- did not use data to
12 favor the Plaintiffs with respect to those cancers.

13 So, this is what happens when you try to go from
14 something that was said earlier and put it into your prepared
15 remarks. I apologize for slipping up a little bit.

16 Next issue, we are going to go to the research
17 question. What is the research question? If you look at the
18 papers you are going to see it two ways, NDMA in Ranitidine, or
19 Ranitidine containing NDMA. Which is it? This is a
20 distinction without a differences.

21 Next slide.

22 The issue in the case is not Ranitidine. The
23 Plaintiffs have not offered an expert report saying the
24 Ranitidine molecule causes cancer. Ranitidine is not off the
25 market because of the Ranitidine molecule, it is off the market

1 because it turns itself into NDMA. It is a salt and it breaks
2 down, particularly if it is wet, and it becomes a different
3 substance, part of it, depending on how long, more and more of
4 it, and it carries it into the human body.

5 NDMA is a toxic contaminant and NDMA is the
6 cancer-causing agent. No matter how you phrase that, that is
7 the research question.

8 And the Defendants want to phrase it Ranitidine
9 containing NDMA because they want you to isolate your focus
10 only on the Ranitidine specific studies.

11 Now, next slide, please.

12 Now, I want to talk about dose and dose response at
13 this point. It was brought up before, and part of my argument
14 comes out of something the Defendants say the failure to
15 address dose and the complete absence of dose response is also
16 fatal to the Plaintiffs' expert opinions.

17 I am not sure how the Defendants can make this
18 statement because Dr. McTiernan covered both of those subjects
19 in spades, I mean in detail, and to say that, for example,
20 complete absence of dose response information, that is jut
21 wrong if you read her report.

22 Next slide, please.

23 Let's take a look. Dr. McTiernan specifically
24 discussed dose response in each study. For example, in Adami,
25 on page 127 and 128, dose medication was not assessed in

1 relation to cancer, therefore dose response was not presented
2 in the paper. She did that for every study. Every dietary
3 study, every Ranitidine study, every occupational study, she
4 looked in the data from the study and said, did the authors
5 address dose response, and then made a comment.

6 So, to say that she didn't take those responses into
7 account is just wrong.

8 Let's look at another example, Cardwell. In Cardwell
9 they had a defined daily dose. They knew how much Ranitidine
10 each subject was getting, and for how long, and they were able
11 to define it down into years.

12 So, what Cardwell showed was if you looked at people
13 with one year of exposure, they had a certain risk, and if you
14 looked at people with three years of exposure, they had a
15 higher risk. Who is that against? Nonusers, which is the
16 background risk.

17 The bottom line is that Dr. McTiernan talked about
18 dose response and whether or not that information was in the
19 study for each study.

20 Next slide.

21 You know, the point, this comes out of a recent
22 Eleventh Circuit case, Williams versus Mosaic Fertilizer, is
23 that a specific amount of dose is not required, particularly
24 when we are talking about general causation. What the Court
25 requires, what the Eleventh Circuit requires is that the expert

1 lay a reliable groundwork for determining the dose response
2 relationship.

3 How do you have that groundwork? You start with the
4 foundation, you look at the studies themselves. You see what
5 dose response information they have, and when you get to your
6 totality of the evidence, your systematic review, and you get
7 to your Bradford-Hill, you talk about the biological grading or
8 dose response. If I get more, do I get more cancers? That
9 makes sense, and that is exactly what Dr. McTiernan did here.

10 The Defendants want to characterizes this as, Doctor,
11 what is the minimum dose a person needs to be exposed to
12 Ranitidine in order to get cancer? That is not the question.
13 It is not the question. It isn't dose.

14 It is the question of whether a realistic dose can
15 lead to an increased risk of cancer at this stage.

16 Next slide, please.

17 So, let's talk about dose. I jumped myself here by
18 not having the slide up, but whether a reasonable jury could
19 conclude that the NDMA in Ranitidine is capable of causing
20 human cancer at the highest realistic dose. Think of, for
21 example, Roundup, which is the landscaper who sprays Roundup
22 all week, every day, 300 days a year, and wears no protection.
23 If that person could potentially get cancer, and there is
24 evidence to support it through this type of a review, then the
25 Court should pass on -- whether an individual got cancer, it

1 should pass that on to the jury.

2 Now, I want to get into the concept of dose here, and
3 I think I might be getting ahead of myself, but I will do it
4 now anyway.

5 So, your Honor, what the reference manual talks about
6 in respect to dose is -- and even dose response, is that at the
7 general causation level, the reason why the question is phrased
8 this way is because you've got a whole set of individual
9 Plaintiffs out there, and at the specific causation level other
10 factors are going to come into play in determining whether that
11 individual got cancer, other factors that don't play in now.

12 For example, I mentioned before about a person has H.
13 pylori or doesn't have H. pylori. What if the Plaintiff was a
14 smoker, and had diabetes, and was overweight, and got cancer,
15 versus a person who was clean living and younger, and didn't
16 have any genetic propensity toward a cancer, and takes
17 Ranitidine and gets a cancer.

18 Those types of analyses, which the reference manual
19 calls differential etiology, similar to differential diagnosis,
20 need to be done at the case specific level once you show on
21 general causation that realistic doses, the doses you can get
22 from the drug, could cause cancer.

23 Next slide.

24 So, in Dr. McTiernan's evaluation and in her report
25 there are two answers to this question.

1 There are Ranitidine specific studies with actual
2 doses of Ranitidine taken by actual patients, for example, and
3 the best example is the Cardwell study where they know, define
4 daily dose, how many days, how many milligrams they are
5 getting, and they see an increased risk of cancer, those are
6 realistic doses. Those are doses being taken by real people.

7 So, a realistic dose in this case, at least for
8 bladder cancer, is answered, but a secondary way of proof is
9 through human NDMA exposure studies through diet and
10 occupation, because if NDMA is the toxin, and you know how much
11 NDMA people are being exposed to, then you can answer the
12 question about whether or not the doses in the pills, where we
13 know some of the testing is on that, is equivalent to the kind
14 of dose of NDMA you get or exposure to NDMA you get from, let's
15 say, beer. Okay.

16 So -- and again, another aside. Beer manufacturers
17 went to great lengths to get rid of the NDMA in beer some years
18 ago. Why? For the same reasons that Ranitidine is off the
19 market. Okay.

20 Next slide, please.

21 Okay. So, I already mentioned McDowell and how
22 specific the dose is in McDowell. Some studies try to use
23 prescriptions as a proxy for dose without knowing whether the
24 amount prescribed was 75 milligrams, 150 milligrams, 350
25 milligrams, could even be 600 milligrams, and for how long.

1 Was the prescription for two weeks, 30 days, 60 days, 90 days?
2 If you don't know those things prescriptions can be a poor
3 proxy for exposure.

4 What if you had -- let's think of the study that
5 looked at ten prescriptions. Are the ten prescriptions one
6 this year, one this year, one this year, one this year, or are
7 they all in a row, or it said greater than ten, how many of
8 those people had 50 prescriptions versus how many only had ten?

9 Those types of considerations have to go into the
10 determination of what weight you put on the dose information in
11 the studies that you are looking at.

12 This is the kind of thing that Dr. McTiernan did
13 through and through and through her report.

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

15 Okay. Active comparators. So, the Defendants say
16 that the Plaintiffs' experts disregard the key control against
17 false positives in Ranitidine studies and in pharmaco
18 epidemiology generally, active comparators.

19 That is not what happened. Dr. McTiernan and Dr.
20 Moorman reviewed each study and how they used active
21 comparators. Adami, for example, had little information on why
22 the various H2RAs and PPIs were prescribed. So, there is no
23 way to know if the drugs were given for similar disease
24 conditions.

25 This is important, and Dr. McTiernan said this several

1 times in her deposition and in her report, but the thing you
2 need to look at when you are trying to determine if your study
3 is balanced by using an active comparator is, what is the data
4 in the study.

5 I am going to show you later when I do those examples,
6 in, for example, the Adami study they didn't have the data on
7 why the drugs were being prescribed, although they could have
8 gotten it. The study should show this percent of them are
9 getting it for GERD, and this percent are for Barrett's
10 esophagus, and this percent for erosive gastritis, and this
11 percent for ulcers, and then you would know if the two groups,
12 the Ranitidine group or the PPI group, or maybe a third group,
13 another H2RA group, you would know that they actually are
14 balanced.

15 It is not scientifically -- maybe legally they want it
16 to be this way, maybe in argument they want it to be this way,
17 but it is not legally appropriate to make a determination
18 simply because you say this is an active comparator study and
19 that takes care of everything. That is not the way it goes.

20 In particular, I want to point out the guidance that
21 was referred to several times. That guidance says it is not
22 intended to be prescriptive with regard to the choice of a
23 study design or a type of analysis, and does not endorse any
24 particular type of data, resource, or methodology. It does not
25 provide a framework for determining the appropriate weight of

1 evidence to be given to studies.

2 That is the same document that the Defendants are
3 referring to. For active comparator studies to work you have
4 to have the same disease, the same level, the same severity in
5 the exposed cohorts, and there are other factors, too.

6 What if your formulary pays for Ranitidine and doesn't
7 pay for Cimetidine; you are going to get Ranitidine, not
8 because of your condition, but because of the formulary. That
9 is a factor in that FDA guidance.

10 Next slide.

11 Now, this is going to lead into that example I want to
12 give. I am calling this false accusations of cherry picking.
13 That might be a little strong, I wish I could take that word
14 back, but I already typed it up.

15 The Defendants said that Dr. McTiernan relies on the
16 unadjusted data in Adami, so she picked the unadjusted data or
17 crude data from Adami because it was more favorable, but she
18 relies on the adjusted risk estimates from Norgaard. That is a
19 criticism, that is not what she did.

20 Next slide.

21 This is the example I told you about. Three studies
22 from the same database in Denmark, the Potagard study, the
23 Adami study and the Norgaard study, all discussed on pages 121
24 to 132 of Dr. McTiernan's report.

25 Dr. McTiernan analyzed all aspects -- next slide --

1 and first in the Potagard study, that was a screening study, it
2 looked at lots and lots and lots of drugs. There was a high
3 value for stomach cancer that favored the Plaintiffs. What did
4 Dr. McTiernan do with that? She did not include it in her
5 causation. If she were cherry picking, she would try to, but
6 she did not include it at all.

7 Next slide.

8 In her addendum report Dr. McTiernan describes when
9 she saw the corrected Adami study that she saw some anomalies
10 in the numbers, so let's look at that.

11 This is a busy slide, I'm just showing you that I
12 copied these right out of the studies themselves.

13 So, on the left in blue are the crude, on the right
14 are the adjusted or corrected or adjusted numbers.

15 What Dr. McTiernan noticed when she looked at that
16 was -- next slide -- for most of them, when you look at the
17 Ranitidine and you compare the crude to the adjusted the cases
18 went down and the person years went up.

19 For the other H2RAs the cases went up and the person
20 years went down, and the effect of that is you compress all the
21 results toward the null value, toward 1.0. That is what the
22 adjustments did, and as she said in her report, Dr. Adami did
23 not describe in the published paper what the basis for these
24 changes were.

25 It is called trimming, you are trimming it because

1 your data sets don't match, so you try to trim to get them to
2 match up better, but it doesn't always come out accurately.

3 So, for Adami, Dr. McTiernan used the crude, which she
4 reserved the ability to do. All the way in the beginning of
5 her report she said that if I find there are problems in the
6 study, I may use the crude; otherwise she used all adjusted.

7 And in fact -- next slide -- with respect to Norgaard,
8 from the same university, same data, she used the adjusted risk
9 which is lower than the crude risk. So, a cherry picker would
10 have used the crude risk in Norgaard because it is higher and
11 it is statistically significant, but Dr. McTiernan did not do
12 that because she is not a cherry picker. She used the adjusted
13 risk, which is lower and didn't have that statistical testing
14 significance.

15 So, when you look inside the studies what you see
16 is -- and I have given at least three examples now where Dr.
17 McTiernan could have gone the other way and did not.

18 Next slide.

19 Now, remember I mentioned before about how well are
20 the indications listed in the study, because active comparator,
21 similar indications. Here is the data that Adami had in their
22 study for gastroesophageal reflux, Barrett's esophagus, and
23 gastric or duodenal ulcer, less than seven and a half percent
24 information, and it's probably less than that, because some
25 people probably had two of those things.

1 You can't assume just because it is an active
2 comparator study this is taken care of, especially in a study
3 that had no information on smoking, had no information on
4 drinking, and several other high risk factors.

5 Next slide.

6 Also, there is an issue of the size of the cohort that
7 Dr. McTiernan noticed. In Adami, now same cohort, Ranitidine
8 users from Denmark, Adami went from one prescription and
9 Norgaard went from two prescriptions and when you he went to
10 two prescriptions, that cut out two-thirds of the people.

11 What does that mean? That means that two-thirds of
12 the people only had one prescription. How many cancers does
13 anybody expect to see from one prescription? None. What does
14 that does is, it dilutes the numbers and brings the odds ratios
15 down.

16 Next slide. Next one. That was my two-thirds slide.

17 And the Defendants claim that the Plaintiffs' experts
18 rely on supposedly weak associations.

19 Next slide.

20 They quote from the reference manual that anything
21 less than 2.0 is noise. Well, that is not from the reference
22 manual -- it is from the reference manual, but it is from a
23 footnote, and it's one commentator said that.

24 The reference manual itself says in the text, while
25 this reasoning has a certain logic as far as it goes, there is

1 a number of significant assumptions and important caveats, and
2 it goes into them. We don't have time to go into them now.

3 Next slide.

4 In In Re Roundup the Court said, although the
5 magnitude of the observed association in each individual study
6 was not especially large -- another Bradford-Hill criteria --
7 consistency allayed his concerns about chance and bias, leading
8 him to ultimately conclude that case control studies
9 demonstrate a significant strength of association.

10 Next slide.

11 Similarly in Abilify, talking about association is
12 consistently observed by different researchers using different
13 methods on different populations.

14 Next slide.

15 All right. You have seen forest plots today made by
16 lawyers. Dr. McTiernan didn't use any forest plots because
17 they can be misleading. They don't say anything about the
18 strength of the studies, or whether there is confounders, it is
19 just the results. Okay. But they can be useful and Dr. Terry,
20 one of the Defense experts, did use it, and so, this is bladder
21 cancer.

22 Next slide.

23 This is not something that we created, this is
24 something the Defense experts created. All right.

25 Next slide. There we go, okay.

1 For bladder cancer -- first of all, 16 out of the 20
2 results are to the right of 1, and five of them are
3 statistically significant. Here is the associations that we
4 are talking about, Judge. They say there is no valid
5 associations.

6 These are not the results that the Plaintiffs picked,
7 these are the results the Defendants picked, yet it still shows
8 consistency on the right side of 1, and five statistically
9 significant increased risks, and I defy anybody to look at this
10 and not see a pattern, a pattern of increased risks.

11 There are various reasons why these studies have wider
12 or narrower confidence intervals. Those are the things that
13 Dr. McTiernan discussed in all that detail she was going
14 through, the reasons for that, but you can't walk away from the
15 results. There are five statistically significant results,
16 five associations.

17 Next slide.

18 This is Dr. Porter, another Defense expert. This
19 slide represents every single bladder result he reported in his
20 report. I took his deposition, he confirmed it. All of them
21 are to the right of 1.

22 Next slide.

23 This is Dr. Vasi, another Defense expert, his forest
24 plot. Very similar to Dr. Terry's forest plot, five results
25 that another Defense expert reported on that are to the right

1 of 1.

2 Next slide, please.

3 Let's not limit it to bladder, let's look at stomach
4 and gastric cancer. This is Dr. Terry's chart.

5 Next slide.

6 Now, if we take Dr. Cherry's -- Terry's chart -- I
7 think I reversed it, I said cherry tart -- Dr. Terry's chart,
8 take out the Y Kim study, which is a bad study, a poorly done
9 study, take out those results, what do you see? You see, I
10 think, almost every one is either close to 1 or to the right.
11 There is only one outlier far to the left and that is Dumar,
12 and one of the ones to the right is statistically significant,
13 and I call that an association.

14 Next slide.

15 Let's look at liver cancer, okay.

16 Next slide.

17 Add the line at 2, since 2.0 seems very important to
18 certain people.

19 Let's go to the next slide, which will take out Kim.

20 Okay. So, again, an expert could see a pattern here,
21 an expert could see three of the study results approaching 2.
22 An expert could see a pattern here of one study being
23 statistically significant. Okay.

24 So, two other things. I have two minutes according to
25 my colleague, and I will try to cover these fast. Okay.

1 One is this complaint about the World Cancer Research
2 Fund, WCRF, and they don't rely on control studies, and that
3 Dr. McTiernan used a different methodology with respect to that
4 than she did for this report.

5 Okay. This is explained by Dr. McTiernan in her
6 testimony. WCRF relies mostly on meta analysis. Usually you
7 can't use case control studies in meta analysis, but Dr.
8 McTiernan also said that for certain types of cancers and for
9 certain case control studies they do consider case control
10 studies.

11 The second thing that was pointed out -- she describes
12 a whole process that really has nothing to do with this case
13 because the purposes of that organization are different than
14 our purposes here.

15 The bottom line is that they do consider case control
16 studies, and you know, it was pointed out in Ms. Canaan's
17 presentation that NDMA was not considered -- it was considered,
18 I think, limited, no association, limited, no conclusion,
19 limited, no conclusion.

20 Dr. McTiernan explained that that was based on the
21 2005 to 2007 data, and Ms. Canaan showed you earlier that there
22 is a table that shows four additional studies that are on their
23 list, but in the 2018 version, two years later, which is also
24 referenced in their briefs and in the PowerPoint you saw today,
25 it literally says that the following exposures were not updated

1 as part of the 2015, and the last time they did it was 2005 to
2 2007, and listed right there is NDMA.

3 Dr. McTiernan was right, it was not updated. If they
4 had all the data they had now, like the Hidajat study, they may
5 well have put it up in a different category.

6 The Defendants want to say everything is fixed in
7 time, because that was the conclusion in 2005 to 2007, it
8 applies now, without looking underneath in the same document on
9 page 41.

10 Real quickly on Talc, your Honor, I think this is easy
11 to get. In Talc, for your exposure, you are talking about can
12 I remember if I used talcum powder on my body. Some people use
13 it every day, and they can say I used it every day for five
14 years. That is one type of exposure, and that is easier to
15 remember and has less recall bias.

16 On the other end are dietary studies where you have
17 like 150 or 200 items on a food frequency questionnaire, and
18 people fill that out and there are worries about the accuracy.

19 Now, there are plenty of studies validating that
20 method, and huge studies that were relied on in this case, like
21 the Epic study, that rely on that method.

22 There is a place in between that the Defendants didn't
23 talk about, and that is when you are talking about a specific
24 nutrient like beer, or meat, or certain types of meat, and when
25 you ask people to recall those things, your recall bias is much

1 less than it would be if it was 150 things and more than if it
2 is one thing.

3 It is not that simple to look through the lens and
4 say, recall bias wrecks all of Dr. McTiernan's opinions. It
5 does not. You have to look at the individual studies, which is
6 what Dr. McTiernan did. I think I said it ten times now.

7 So, there is really no question about qualifications,
8 there is no question about the election of the method, no
9 question about the amount of material she reviewed. The only
10 question is, how did she do the studies?

11 And we believe that she did them in the way they
12 should be done, in a way that is reliable, in a way that meets
13 all the scientific standards, and in a way that a jury could
14 understand, so we ask the Court to let this case go through the
15 gate.

16 *THE COURT:* Okay. Thank you very much.

17 *MR. RONCA:* Thank you, your Honor.

18 *THE COURT:* That was going on 50 minutes. Mr. Heinz
19 is next for Dr. Moorman.

20 *MR. HEINZ:* Good afternoon, your Honor, may it please
21 the Court.

22 *THE COURT:* Good afternoon.

23 *MR. HEINZ:* Could I be permitted to use my cell phone
24 in airplane mode to track my time?

25 *THE COURT:* Yes, you may.

1 MR. HEINZ: My name is Noah Heinz, I am going to talk
2 about Dr. Moorman. Before I start that, I want to say that I
3 wouldn't be able to argue here today were it not for the Court
4 setting up the Leadership Development Committee and the full
5 support of the co-leads, and I am highly thankful for the
6 opportunity.

7 I am first going to talk about Dr. Moorman's
8 qualifications and her methodology. After that, I will rebut
9 six lines of argument that I heard from the reply in the
10 briefing, and also from Mr. Brown's presentation about Dr.
11 Moorman, and then last, I am going to apply Daubert case law
12 and try to wrap it up in that way.

13 I am going to return to the case law at the end, but I
14 think it is helpful to think about it now as I go through the
15 arguments and draw out two points from Abilify.

16 The first point is that reliable methodology has to
17 have at least one of three primary methodologies, including
18 epidemiology, dose response, and background risk. So, that is
19 the first point.

20 As you are listening to these arguments, think about
21 did Dr. Moorman have at least one of those three.

22 The second point is that judges should not evaluate
23 the persuasiveness of the different studies. That is also
24 something to consider, so you have to have one of the primary
25 methodologies, but it is not supposed to be about the

1 persuasiveness of the individual study.

2 Qualifications.

3 Dr. Moorman's qualifications are largely conceded by
4 the Defendants, and for a very good reason. She has a Ph.D. in
5 epidemiology. She is obviously qualified to talk about that.
6 She has published 150 publications on cancer, or many of them
7 are on cancer, not necessarily all of them, and she has been a
8 tenured professor at Duke Medical School where she has taught
9 epidemiology for almost -- more that 20 years. She retired
10 just last year actually.

11 There is not much question that Dr. Moorman is
12 qualified, and again, Defendants essentially agree.

13 So, methodology. That is what Daubert is supposed to
14 be about, methodology, and not conclusions.

15 What did Dr. Moorman do? She looked at all of the
16 evidence, considered everything for Ranitidine, everything for
17 NDMA, and then weighed it and applied Bradford-Hill, so looking
18 at all the evidence.

19 Defendants agree she looked at all the evidence. They
20 didn't say that she missed anything important. Check on that,
21 undisputed.

22 What did she do next? She evaluated each of the
23 different studies, whether that is on Ranitidine or on diet or
24 animal studies, any different type of study, and looked using a
25 few different criteria, and there is a lot of focus on just

1 three criteria, and those are important, talking about dose,
2 followup, the size of the study, that kind of thing.

3 Dr. Moorman considered more than just that, and I
4 would say, as we said in our brief, you know, it really came
5 down to six or seven factors, it kind of depends on how you
6 count it, but I will say six that she went through.

7 First was the study type, that was something to
8 consider. Is it a case control study, is it a cohort study,
9 what type of a case control, for example. This really matters
10 because different critiques apply differently to different
11 studies.

12 I saw some things that were a little bit confusing on
13 some of the slides, things like there is a followup period for
14 case control studies, things like that. Dr. Moorman explains
15 in her report there really isn't such a thing as a followup
16 period for a case control study, for example, so it is really
17 apples and oranges at that point. You can't apply the exact
18 same followup paradigms to case control studies. That is the
19 first thing, the study type.

20 Second is study size. That is self explanatory. If
21 it is a lot of people that means something.

22 The third is exposure to Ranitidine or NDMA, and this
23 has -- the first is the most obvious thing, the dose. What is
24 the dose? Was it just anybody who ever took Ranitidine, who
25 ever had any NDMA? That is going to be a little bit less

1 useful, maybe a little bit useful. Or does it have very
2 detailed information about it? For example, defined daily
3 dose.

4 That would mean you need not only the number of
5 prescriptions, but also is it 75 milligrams, 150 milligrams,
6 350 milligrams? How many times did the person take it? There
7 is a lot of information that goes into dose beyond just the
8 prescriptions even if you have that.

9 The next thing, which is still on exposure, is the
10 accuracy of the exposure information. There is a world of
11 difference between asking people what they did, self reported
12 information, for example, did you take Ranitidine in the last
13 30 days, compared to pharmacy records, because people don't
14 necessarily know what type of medicine they took. They might
15 think it was Ranitidine, but it was actually Cimetidine.
16 People often make mistakes on surveys. Dr. Moorman pointed
17 that out, for a couple of the studies that the numbers didn't
18 quite work out. So you really care about accurate data that
19 comes from pharmacy records or something like that.

20 This is really a big concern that you heard from Mr.
21 Nigh with the Kim study, for example, it really fits into this
22 bucket, that it was an aggregated database and it was from
23 insurance claims, and there are a lot of questions with that
24 kind of data. How accurate is it, and what kind of conclusions
25 can you draw from it? And Dr. Moorman certainly considered

1 that for this criteria.

2 The fourth one is the followup time, so whether the
3 followup time was adequate to detect cancer from long-term
4 exposure to Ranitidine, and it is fairly obvious why that would
5 be important, and to sort of think about why it might be, I
6 want you to think about the chart that you saw the Defendants
7 put up about cancer and smoking.

8 They said this is what dose response looks like, and
9 then they had ten years, and it looked to me like about 1.2.
10 It had 20 years, and it went higher, 30 years, it went higher,
11 40 years, it went higher, 50 years, it went higher.

12 If you had something like a followup of just one or
13 two years and dose information that was just one or two years,
14 you would be below the very first part on that mark, so it
15 would be less than 1.2. You would barely be able to track
16 anything, so the followup is critically important.

17 Next is whether the study accounted for
18 over-the-counter use, other things like that, switching from
19 one acid suppressant to another. This criteria is really all
20 about misclassification.

21 There are a couple of different forms of that.
22 Switching is an obvious one, you were using one medication and
23 then used another one. It is hard to classify where that
24 person should fit, but over-the-counter is another example.
25 You're taking a different drug from the one that is tracking in

1 the survey, only looking at the prescription records.

2 The last one would be whether the study accounted for
3 bias, and confounders, obesity, smoking, alcohol use, and other
4 medical conditions, things like that. Again, Defendants agree
5 that Dr. Moorman identified all the right bias and confounding
6 factors. They conceded that and said, yes, she caught all of
7 them. They just disagree with how she applied that. So, this
8 criteria is definitely right.

9 She applied these criteria consistently. She looked
10 at each study and went through each and evaluated it.
11 Honestly, they haven't found an inconsistent example where
12 whiles she said that three years was a long followup in one
13 study, but short in another. There is no inconsistency of that
14 sort that they identified, and it is also useful in thinking
15 about how consistent Dr. Moorman was in applying these
16 criteria.

17 Think about the criticisms we heard about the
18 Plaintiffs' forest plots. You heard from the Defendants, well,
19 Dr. Moorman and Dr. McTiernan didn't highly value the Habel
20 study, for example, the McGwin study, the MSK study, and all of
21 those showed an increased risk. It's very indicative that
22 different methodology is being applied honestly.

23 The reason for that is when you look at these
24 criteria, those studies are not going to be considered of very
25 high weight if you are applying it honestly.

1 Some things are really worth stopping and thinking
2 about here. The Defendants have not said these are the wrong
3 criteria. They haven't said that there is an important
4 criteria missing from this, there should have been eight or
5 nine, and it was actually more important than one of these.
6 They agree these are very important criteria to consider for
7 studies, she got the right ones.

8 So, really all of the action is at the next phase, the
9 application phase, the weighting of the studies. These are the
10 right criteria, it is consistent, but are they applied in the
11 correct way.

12 I am going to get into the Defendants' critiques. The
13 way I count them, I think there are six.

14 I'd venture to say these are really in the weeds. I
15 think these are a little bit boring and the question you should
16 ask is, is this really a Daubert issue or is this kind of a
17 fight for the experts, but we can see as we go through them.

18 The first one is weighting methodology. I didn't hear
19 much about today in the presentation. In the reply they really
20 harped on it and said, did Dr. Moorman use the Newcastle or
21 AHRQ criteria, or a weighting system of that sort, a
22 methodology of that sort. Dr. Moorman answered, I don't know,
23 I don't think so, not necessarily.

24 On redirect she basically agreed that she followed the
25 same factors that those more formal systems agreed with, but,

1 you know, she didn't necessarily follow that exact system in
2 that exact way, and there is no case that actually says one has
3 to do that.

4 The Defendants experts didn't follow either of these
5 systems, and there is no legal authority indicating that this
6 is actually something that is required, and even if it were
7 required, the criteria themselves are not in the record, but
8 you can find them pretty easily online and confirm they are
9 really the same criteria that I just laid out. Everyone agrees
10 on the basic things that a study needs to have to be of more
11 weight or less weight.

12 The next point that they say is that the weighting is
13 inconsistent, and there are a couple of different points on
14 this in the reply there was kind of a comparison of the
15 Cardwell study, the Ronco study, and Norgaard. You saw a bit
16 more of that in the slide presentation. How could you possibly
17 reconcile these?

18 I am not going to go through every example, but I
19 think the key thing is, if you are using multiple different
20 factors, you can find inconsistency with respect to any one of
21 them, and that is really not a problem at all.

22 For example, if you were doing a study of Ranitidine
23 and you just had to take half a pill, for example, but you
24 followed someone for a hundred years, it would be kind of
25 ridiculous to weight that study at a very high level, but that

1 is exactly what you would say if followup were the only
2 criteria.

3 Followup isn't the only criteria, you have to get a
4 weighted average of all of the criteria to get a high weight.
5 That is basically the way it works.

6 So, looking at Cardwell, Ronco, and Norgaard in
7 particular, let's go through their criteria.

8 The first one, what kind of study is it? Cardwell
9 studies nested case control, and that is also what Ronco is,
10 and then Norgaard is a cohort study, okay. So, that tells you
11 followup is going to be more important for Norgaard. There is
12 not going to be sort of a direct analogy to followup for
13 Cardwell or Ronco.

14 Then, number two, the study size, it is also important
15 to think with the study size what the study is, because case
16 control will have fewer participants necessarily, so that is
17 why it is kind of more fair to look at the number of cancers
18 rather than the number of participants because of the way the
19 statistics work out when using a case control versus a cohort
20 study, but they didn't emphasize the study size as being an
21 important thing.

22 The third factor is the exposure, and here is where it
23 really starts to become obvious why Dr. Moorman thought
24 Cardwell was a better study than Norgaard. So, Cardwell had
25 actual pharmacy records and details about what pills people

1 used, and that meant you could get a defined daily dose. They
2 could bracket people into zero to 180 days, all the way up to
3 more than three years because you had that data on the actual
4 dose people used.

5 Norgaard didn't have any of that. What Norgaard had
6 was two prescriptions and then up to ten prescriptions. They
7 may have had a five prescription cut as well, but you don't
8 know how many pills are in the prescription. You don't know
9 the strength of the prescription, 75, 150, 300, and it is just
10 basically true that ten prescriptions really isn't that many
11 prescriptions at all, so it should be considered a very low
12 dose study.

13 Then, with the Ronco study, you know, there is a bit
14 of a difference when you are talking about a dietary study
15 versus a pharmaceutical study because almost nobody, when they
16 are talking about what they eat, they are filling out a
17 questionnaire and they say, well, I have a steak about once a
18 week. It would be a little bit ridiculous to think that was
19 the only steak they ever had in their life, and next year they
20 are going to have no steaks ever again. That is just not
21 empirically the way people eat.

22 Dr. Moorman discussed that at page 49 of her report,
23 Dr. McTiernan talks about that as well, that diets are very
24 consistent over time, and that is absolutely not true for
25 pharmaceutical drugs, and you can see that in the Adami versus

1 Norgaard, for example, that two-thirds of the cohort took only
2 one prescription. You are just never going to get numbers like
3 that in a dietary study.

4 That means that it makes sense to think of a dietary
5 study as a longer term, talking about something that is more
6 consistent over time, and you can make that assumption safely
7 for dietary studies where you can't make it for pharmaceutical
8 studies.

9 The fourth one is followup, and again, there isn't as
10 much of a concern with followup for a nested case control
11 study. Norgaard had 14 years. 14 years is a lot better than
12 some of the studies that are at issue in this litigation, but
13 it is not nearly as good as IARC suggests, which is 30 years if
14 you're trying to say there is no risk of cancer.

15 It gets partial credit for that, but not a huge degree
16 of weight, and that is what Dr. Moorman said as well.

17 And the fifth issue, misclassification, and here there
18 is a serious concern over misclassification in the Norgaard
19 study and there is less of one in the Cardwell study. The
20 Defendants say, oh, nobody cares about misclassification, none
21 of the study authors talk about that, but that is not true at
22 all.

23 We cite it in our papers, and you can see when you
24 read the studies that a bunch of them say the limitation is we
25 weren't able to get over-the-counter drugs, we weren't able to

1 study them or track them, there might be a risk of
2 misclassification.

3 Now, Cardwell dealt with this and said it's probably
4 not a big problem because only ten percent of the drugs sold
5 here are over-the-counter medication. Ten percent, you are
6 probably not going to get a huge amount of misclassification
7 just from that.

8 The Norgaard study in Denmark, as Dr. Moorman pointed
9 out, it was 83 percent by the end of the study, 83 percent of
10 Zantac was sold over the counter in Denmark. You are going to
11 get a lot more misclassification, and so reasonably you give a
12 little bit less weight to the study by Norgaard.

13 Last point, bias and confounding. Norgaard didn't
14 track relevant features that you want for bias and confounding.
15 It didn't have information about smoking or alcohol. It didn't
16 have other information on obesity, for example, or other
17 confounding factors that would be important, confounding
18 factors that Cardwell did control for.

19 They say, well, there is only limited data for
20 smoking, but they said they controlled for it. They had a lot
21 of information, more than 80 percent of information on it, and
22 they tried to control for it in other ways to guess at the
23 18 percent, 20 percent, whatever, they were missing, and
24 Cardwell thought he had controlled for it.

25 Norgaard just has no information at all, and you can

1 say that an active comparator study is going to be better at
2 controlling for bias than actually measuring the different
3 confounding factors and statistically controlling for it, but
4 it is certainly not crazy to think measuring for it and
5 controlling for it statistically is a little bit better if you
6 are trying to study something, and that is what Dr. Moorman
7 reasonably concluded.

8 So, let's see. Yes, I think that is fairly obvious,
9 just applying the criteria and going through them you can
10 easily come to the conclusion that Cardwell is very good, Ronco
11 is kind of in the middle, and Norgaard is not a very high
12 weight, and there is no inconsistency in the principal example
13 that they came up with.

14 They have on their slide 21 in their presentation and
15 that say the Tran study and the Liu study didn't have very good
16 information on bias and confounding, but if you actually read
17 the slide, it is really not that bad actually.

18 It said it did control -- the quote on the slide said
19 they did control for age, sex, smoking, and alcohol in the Tran
20 and Liu study, and then the parade of horrors, the things
21 they didn't control for was, "incomplete or unknown exposures."
22 Okay, sure, could have been confounded by incomplete or unknown
23 exposures, that is true of every study, but it is pretty good
24 to have information on smoking and alcohol, and it wasn't
25 unreliable of Dr. Moorman to say that that is worth a bit of

1 weight.

2 The third point the Defendants attack apart from the
3 weighting is over-the-counter misclassification. They come
4 close to saying this just isn't a thing, and they blame Dr.
5 Moorman for not quantifying it, but she explained in her
6 report, and they haven't really demonstrated why this is wrong,
7 that if you don't have the data at all, there is no way to
8 quantify the effect of the data.

9 Dr. Chan says he can, Dr. Moorman says that she can't.
10 It is not the role on Daubert to say, well, actually there was
11 a calculation that you could have performed as an
12 epidemiologist to quantify this and you don't understand how to
13 do it.

14 It is fairly intuitive and not unreliable to say if
15 there is no information on the misclassification, there is no
16 way to calculate the exact size of the effect. What you can do
17 is, well, if it is 83 percent of the market it is going to be
18 more of a problem than if it is ten percent of the market, and
19 that is what Dr. Moorman reasonably concluded as to the
20 Norgaard and Cardwell studies.

21 There was even less information for some of the other
22 studies, so she flagged it as an issue that she considered and
23 used it to reduce the weight of some of these studies.

24 Most of the studies affirmatively admit that this is a
25 limitation, so she is definitely not out on a limb here.

1 On reply, on page 39, the Defendants come back and say
2 Norgaard and Adami didn't think it was a problem and here is
3 what they said. This is Norgaard. "Over-the-counter
4 medication is more expensive. We would expect concomitant use
5 of over-the-counter Ranitidine to be low."

6 This is kind of a weird thing to say when it is
7 83 percent of the market. It is more expensive, but it is
8 still sort of dominates. That might mean there is something
9 strange going on about the people that are purchasing
10 Ranitidine in Denmark for at least certain periods of the
11 study, but the authors don't say anything about that.

12 In my mind that is not really a sufficient response,
13 and Dr. Moorman didn't consider it sufficient either. Adami
14 says any bias would be limited because all major H2RAs were
15 similarly impacted by over-the-counter use.

16 In the first place, this isn't true. It isn't true
17 because Ranitidine is an older drug, and went OTC faster, so
18 there is a reasonable chance that more people would have
19 purchased it that way.

20 Also, you can look up statistics on what the market
21 share is, and they could have done that instead of just
22 assuming that it would be equivalent for all the different
23 H2RAs.

24 There is sort of a deeper problem here. The deeper
25 problem is there is an assumption that, well, if both of the

1 medications that you are comparing are sold over the counter,
2 then there is no bias, but this doesn't make any sense. The
3 concern is that some people in the H2RA group, and some people
4 in the Ranitidine group are misclassified, meaning they didn't
5 just take Ranitidine, or they didn't just take the H2RA.

6 Saying, well, true, some people need -- sure, A group
7 may have also taken Ranitidine, but some people in the
8 Ranitidine also took H2RAs, doesn't eliminate the bias at all.
9 If what you are measuring on two arms of an active comparator
10 study are two populations of people that took both drugs, you
11 are just going to get a result that is biased toward the null.
12 It doesn't wash itself out. They both independently would bias
13 it toward the null because there is going to be less of a
14 difference between the two arms of the study, so that response,
15 as Dr. Moorman found, is not sufficient.

16 The fourth point that they raise is that active
17 comparator -- the reasoning on active comparators, it doesn't
18 withstand scrutiny. They spend a lot of time on this and
19 really kind of miss a number of points that she made, but the
20 response to it is on her -- in her rebuttal report on page 5,
21 and she says, "my criticism of the active comparator studies
22 were based on two broad concerns with the studies. First, key
23 assumptions of the proper use of the active comparator studies
24 were not met."

25 That is what you heard about, that was the only thing

1 you heard about, that premise, and I will talk about that in a
2 little bit.

3 Then second, and we emphasize this in our brief, the
4 active comparator studies had numerous other limitations and
5 sources of bias, including an incomplete assessment of
6 Ranitidine, misclassification of exposure, inadequate followup
7 time, inappropriate study populations, for example, they are
8 too young, lack of information on important potential
9 confounders, and potential conflicts of interest. You have
10 heard a lot about Adami, it's sort of a reference to that.

11 That list of criteria should sound familiar because it
12 is the same exact weighting criteria that I have been talking
13 about for this entire presentation.

14 The point is, even if Adami was not an active
15 comparator study or Norgaard was not an active comparator
16 study, there are completely different reasons that are
17 independently sufficient why it should get less weight and that
18 are fully consistent with her methodology and well explained.

19 Let me address the points that they made about why,
20 they say, it is a proper active comparator.

21 Dr. Moorman gave two reasons. The first is evidence
22 of increased risk, and on this, there is assure, and PPIs.
23 They don't really say anything about PPIs. They basically seem
24 to agree that PPIs do increase risk for cancer, and so that
25 kind of leads to a question. So, what about all of those

1 active comparator studies with PPIs, are they biased to the
2 null?

3 The Defendants don't seem to agree with that, but they
4 stay pretty quiet on it, and there is good reason why they
5 don't really talk about PPIs, because the Kim S study, for
6 example, expressly says in the study, we didn't do an active
7 comparator with PPIs because PPIs might be associated with
8 cancer, and so did not conduct a study on PPI as an active
9 comparator.

10 Then she cited a number of studies saying the same
11 principles, the same mechanism, the same reason PPIs could
12 cause cancer seems like it should apply to H2RAs and she
13 explained what that mechanism is, and then cited a number of
14 studies.

15 They really got pretty far into the weeds talking
16 about each particular study and why actually if you look at it,
17 it doesn't fully support it to the same extent. I really
18 question whether at this point it is a Daubert issue. Does
19 this make the analysis completely unreliable because on one
20 weighting factor, talking about one reason why this active
21 comparator study wasn't quite as good, she didn't do enough
22 analysis in their view because five studies were not quite
23 enough to say that one of the drugs was associated with cancer?

24 It seems like asking quite a lot for her to have done
25 an independent Bradford-Hill analysis on every H2RA before

1 saying I have concerns about this, it is a reason to weight the
2 studies a little bit less, which is really all Dr. Moorman
3 said.

4 The next reason is the severity of the indications and
5 how diseased the population is, and the Kim Y D study does
6 support that, does say H2RA and Ranitidine population have
7 different disease levels and that could make a differences.

8 At first, they basically join the party in saying the
9 Kim Y D study is a very bad study, we agree with that, but i
10 also misses the point because if the criticism is going to be
11 analysis of Ranitidine over time, it doesn't necessarily mean
12 that they get the population statistic about who smoked wrong.

13 That is kind of a more basic fact about the database
14 that we would hope is still pretty accurate. The fact is the
15 other database that they want to use, that they rely upon,
16 didn't collect this information, so we can't really compare and
17 see in Denmark is this actually true. Because the authors
18 didn't collect the information this is one thing we have to go
19 on, and it is a reason to think that other H2RAs are not an
20 ideal active comparator.

21 And also, of course, Dr. Moorman cited FDA guidance in
22 discussing this and the Defendants don't disagree that if she
23 is right about the severity of the indications and the diseased
24 populations, then it is a pretty good reason to discount the
25 active comparator studies at least a bit.

1 The fifth point is the dietary studies, and there is a
2 number of different attacks here. I heard a lot about Ronco
3 and Keszei that I, frankly, was not expecting to hear. I
4 didn't see any of that in the briefs and saw a number of things
5 that were a little bit new about other things.

6 But one thing that stood out is, Mr. Brown said that
7 Dr. Moorman had no testing data, that she has no basis for
8 saying that any amount of NDMA in dietary studies is similar to
9 any amount of NDMA in Ranitidine studies.

10 Your Honor asked about the GSK master data sheet. I
11 believe that was one of the things we were supposed to be
12 prepared to discuss. That is cited in Dr. Moorman's materials
13 considered list.

14 It is really just not true that she didn't have access
15 to information about the testing of Ranitidine and, you know,
16 the FDA did release a bit more detail than just the top and
17 bottom of the range for a bunch of different manufacturers.

18 So, she had a fairly reasonable basis to say that
19 directionally the dietary studies were consistent with the
20 amount of NDMA in Ranitidine, and that is what she said on page
21 45 of her report. The dietary studies, it's between 400
22 nanograms and 300 nanograms of NDMA, and that is comparable to
23 the amount of NDMA in Ranitidine.

24 I understand Defendants want to say there is pretty
25 much no NDMA in Ranitidine, something like that, but that is

1 not a reason to say that her estimate saying that these are
2 reasonably comparable is unreliable since there is ample reason
3 to think that Ranitidine is certainly over the minimum ADI that
4 the FDA set, because otherwise it wouldn't have been pulled
5 from the market.

6 So, the 30 to 400 estimate that Dr. Moorman talked
7 about seems eminently reliable.

8 They also criticized saying some dietary studies
9 quantified, some of them didn't quantify NDMA. A lot of the
10 ones that did quantify NDMA got more weight, and Dr. Moorman
11 explained that if it just looked at meat and didn't talk about
12 NDMA that much, mostly just looked at it to say it is
13 consistent with my argument, consistent with my opinions, not
14 saying that it greatly adds weight to the opinions, and that
15 seems about the right thing to do when you have a large volume
16 of studies.

17 Some of them are stronger, and some are a little less
18 relevant, but also some of the studies, even if they didn't
19 precisely quantify NDMA, did talk about tertiles or quantiles
20 and say that, well, if you had less NDMA versus more NDMA the
21 risk increased. That is not the same as exactly quantifying
22 it, but it certainly is suggestive of what happens as more NDMA
23 is added to foods and you can still assume that, based on what
24 the human diet is, it is not going to be wildly dramatically
25 different.

1 You can say for a given study that looks at a given
2 diet, the 25th percentile compared to the 75th percentile shows
3 an increase. That is going to tell you something about dose
4 and dose response that is helpful and that is also what Dr.
5 Moorman did.

6 The last point that they attack is the Bradford-Hill
7 analysis and they really focus on strength, dose response, and
8 consistency, so I will try to hit each of those.

9 The first is the strength, and in the reply I got the
10 sense that they just wanted Dr. Moorman to calculate a relative
11 risk, just add everything together and then come up with a
12 number that is the strength of the association with respect to
13 each cancer.

14 That would really be false precision. There isn't a
15 clear way, when you are talking about different studies,
16 different methodologies, dietary studies, occupational studies,
17 to say, you know, I think it is exactly 1.3, 1.6, something
18 like that. It would be a little bit fake, a little bit
19 unscientific. There isn't any way to calculate it like that.

20 What she did do is, for example, on page 108, she
21 said, this is for bladder cancer, the relative risks reported
22 in the studies described above were 1.11 to 1.56 for Ranitidine
23 use, 1.2 to 2.82 for occupational exposure to NDMA, 1.12 to
24 2.16 for dietary NDMA exposure, and 1.2 to 1.47 in the meta
25 analysis and cohort study of processed meat in relation to

1 bladder cancer.

2 This is about the strength of the association, and
3 then she says these relative risks are of similar magnitude to
4 several other exposure disease associations that are generally
5 accepted to be causal associations as described in the
6 introduction to the report, including oral contraceptives and
7 breast cancer, menopausal estrogen and breast cancer, passive
8 smoking and lung cancer, residential radon exposure and lung
9 cancer, and Trichloroethylene exposure and kidney cancer.

10 What she is saying there is, here is the range and an
11 exposure of that strength is very consistent with associations
12 that are considered causal, and then gives specific examples,
13 and that certainly is taking due account of the importance of
14 the strength of an association.

15 Since the Defendants quoted Sir Bradford-Hill, it is
16 worth quoting him back as well exactly on this point where he
17 says in the very same lecture, people are too quick to dismiss
18 a cause and effect hypothesis merely because the association is
19 slight. There are many occasions in medicine when in truth
20 this is so.

21 So, he is saying, yeah, if you have an association
22 that is ten times, 15 times, that is pretty good, but if you
23 have a smaller association, it's more in the range that Dr.
24 Moorman just said for bladder cancer, that doesn't mean that it
25 couldn't be causal, it certainly still could be causal.

1 The next point is dose response. She discusses dose
2 response in detail. She cites a number of studies, dietary and
3 occupational studies, but also Ranitidine studies that as NDMA
4 risks go up, the -- as NDMA goes up, the risks go up for
5 cancer, and that is all in the report in a lot of detail.

6 A big part of their attack here is talking about the
7 minimum dose, and they say what would be the absolute minimum
8 that could possibly cause cancer, and they sort of try to trick
9 Dr. Moorman and say, well, could one pill do it? Well, it is a
10 mutagen, it's a genotoxin. In theory one pill could do it, it
11 could cause cancer, but, you know, could could mean something
12 like there is a one in a billion chance. It is a very small
13 chance, it is not a zero chance, but it is a very, very small
14 scientific risk.

15 What she said is consistent with the best science, and
16 as Dr. Moorman explained, genotoxins don't have a threshold,
17 they don't have a minimum amount below which it is impossible
18 that they cause cancer, but that is not quite the same thing
19 that people mean in lawsuits when they say what is the minimum
20 dose that can cause something.

21 Because the minimum dose that can cause something, if
22 you were to say there is a one in a billion chance that this is
23 going to and so it can cause, the Court would say, the jury is
24 going to have to find this by a preponderance at some point, so
25 one in a billion isn't really going to cut it even at the

1 general causation stage.

2 So, I'd venture that the statement is scientifically
3 accurate, but it doesn't mean that Dr. Moorman is giving any
4 possible exposure as the only way to get over the general
5 causation jump.

6 Also, I would like to mention they didn't ask a
7 question that would have been really, really easy and very
8 relevant to general causation in this case, which would have
9 been something like, you know, Dr. Moorman, would someone who
10 took Ranitidine regularly for ten years get enough NDMA for
11 that to cause cancer? And she would have said yes, and that
12 certainly would be enough to get over the general causation
13 hump as a legal matter. It isn't just about what the minimum
14 possible dose is, but whether there are people that could have
15 been over a dose that would cause cancer.

16 Also, the dose response in Cardwell, for example,
17 after three years there is clear evidence of dose response, and
18 none of the other studies even had detailed enough information
19 to get that far.

20 So, a lot of the dose response information where they
21 are saying Adami doesn't show it, and Cardwell doesn't show it,
22 again, when you are comparing two prescriptions to ten
23 prescriptions, that would be almost like saying, well, if you
24 smoke 100 cigarettes versus 150 cigarettes next month, or over
25 the course of two months, is there a dose response

1 relationship?

2 All you are really going to track is noise at that
3 point, the amount is so low. Their chart said for ten years of
4 pack a day smoking you are going to get a 1.2 increase. So
5 when you are talking about doses this tiny, the dose response
6 analysis is essentially meaningless, and that is what Dr.
7 Moorman said.

8 She didn't rely on the Norgaard and Adami and all the
9 other dose response sub analyses because the amounts are so low
10 that you would not expect to find a dose response for
11 Ranitidine given the science of how NDMA can cause cancer.

12 The third point is consistency and, you know, frankly,
13 the studies here on Dr. Moorman's view and on Plaintiff's view,
14 with the exception, probably, of the Kim study, the studies
15 here really are consistent, and the reason the studies here are
16 consistent is because a number of them simply aren't looking in
17 a place where one would expect to find an increased risk of
18 cancer.

19 That is true in the -- I keep going to the Adami and
20 Norgaard studies, but they are good examples for demonstrating
21 the point, but how about the Iwagami study, for example, where
22 he had a 2.4 years of followup, and the median age was
23 somewhere around 40. If you give someone Ranitidine or
24 Nizatidine, it's hard to tell in that study, for just a year,
25 maybe two years or less, and then followup for 2.4 years, you

1 are just not going to expect to find anything at all.

2 So, it is not inconsistent to say that there is a no
3 association finding there, but there is a positive association
4 when you look in this different way, and that indicates that
5 there is a consistent finding, which is what Dr. Moorman did.

6 The last point I want to discuss is the case law,
7 basically trying to apply the case law to the critiques that we
8 heard from the Defendants and just say, are these Daubert
9 issues, or are these issues for the jury?

10 The Eleventh Circuit case law such as Chapman and
11 McClain say that you have to have at least one of three primary
12 methodologies, epidemiology, dose response, and background
13 risk.

14 You can also have a secondary methodology, a plausible
15 biological mechanism, for example. We have a lot on that. The
16 Defendants haven't really challenged how plausible the
17 mechanism for cancer formation is. Animal studies, the
18 Defendants haven't challenged that. Tissue studies, adverse
19 event studies, haven't really challenged those, they actually
20 do support it.

21 So, the only question is, is there at least one of the
22 primary methodologies to sort of hook on the secondary
23 methodologies to say that there is at least a reliable opinion?
24 We'd certainly say that the answer here is yes.

25 So, look at the examples in the case law where there

1 wasn't enough. McClain, it was ephedrine and caffeine no
2 epidemiology at all and a pharmacologist and treating physician
3 testified in that case and they cited no studies. They just
4 relied on general hypotheses about what ephedrine and caffeine
5 might do in combination.

6 They weren't even particularly plausible hypotheses
7 because ephedrine and caffeine are in hundreds of consumer
8 products all over the place, and there really isn't any
9 evidence that they do cause strokes or the other medical issues
10 in that case.

11 This case really isn't anything like that. There
12 certainly are some studies and there certainly is some
13 calculation of background risk, for example.

14 What about Chapman? In Chapman they looked at calcium
15 zinc in Fixodent, and again, no epidemiology at all, no dose
16 response, no background risk. They said they didn't know,
17 couldn't calculate those things.

18 Instead, what they tried to say is, based on what we
19 know about zinc, you know, probably if you have too much zinc
20 you will get not enough copper in your body, and then once you
21 have not enough copper, it causes other conditions, and they
22 didn't have any other studies demonstrating any individual link
23 in the chain.

24 To make things worse, the information they had about
25 zinc wasn't even about calcium zinc, it wasn't even about the

1 relevant type of zinc that was in the Fixodent product. That
2 was why they were out in Chapman.

3 Here, the Defendants are not saying there is no
4 epidemiology. They are not saying there is no dose response
5 and they are not saying that there is no background risk. They
6 are just saying the studies that they like are better and
7 actually counteract the studies that the Plaintiffs like such
8 that you can't come to an opinion at the end of the day, but
9 that is fundamentally not a Daubert question.

10 One last thing. The only case that they have where
11 there actually was a study is the Allison versus McGhan case,
12 but there there were 19 studies that went against Plaintiffs
13 and the Plaintiffs claimed four that were in support, but three
14 were about something else entirely, and then there was one
15 study, just one, with a 1.24 relative risk, and the expert
16 said, ah-ha, one study, this is it, we have causation.

17 But he didn't explain why the one study was any better
18 than the 19 studies. He didn't have any plausible explanation
19 of why it could possibly outweigh the 19 other studies, and the
20 Eleventh Circuit said, in a case that extreme you can't just
21 say without any explanation why you valued that one over the
22 other, and I would suggest that we are nowhere near that here.

23 Here there are studies on both sides, and with respect
24 to every single study an explanation in Dr. Moorman's report,
25 based on her criteria, explaining this is why I say this study

1 isn't worth very much, this is why I say this other study is
2 worth more, and they don't say the criteria are bad. All they
3 say in an incredibly detailed presentation is trying to fight
4 each one.

5 That really runs headlong into Schultz, a Seventh
6 Circuit case that we quoted. Rule 702 does not require or even
7 permit the District Court to choose between two studies at the
8 gatekeeping stage, doesn't require it, doesn't permit it, but
9 bringing things a bit closer to home, what about the Abilify
10 case?

11 Here is a quotation from Abilify on 1372: To the
12 contrary, a District Court may not evaluate the credibility of
13 opposing experts or the persuasiveness of competing scientific
14 studies. That is quoting the Eleventh Circuit case Quiet
15 Technology versus Hurel-Dubois.

16 Again, you can't compare the persuasiveness of studies
17 at Daubert it is supposed to just about is there no
18 epidemiology, is there no dose response.

19 Roundup is exactly the same. In Roundup there were a
20 bunch of cases -- a bunch of studies on Monsanto's side, a
21 couple of studies on the Plaintiffs' side, and Judge Chhabria
22 said, you know, as -- with a quotation from Daubert, this is
23 shaky, but admissible.

24 Judge Chhabria also said something else. He said,
25 maybe in the Eleventh Circuit, under McClain, this could be a

1 challenging thing, but you know who disagreed with that? The
2 Ninth Circuit disagreed with that.

3 If you look at Hardeman versus Monsanto, which is that
4 case on appeal, at pages 961 to 962, the Ninth Circuit says,
5 McClain, we agree absolutely with McClain. There is no
6 difference in the standard in the Ninth Circuit compared to the
7 Eleventh Circuit, and then affirmed Judge Chhabria saying,
8 using the same standard that would apply in the Eleventh
9 Circuit this was absolutely the right way to do it.

10 Mr. Petrosinelli for the first time, this never
11 appeared in their briefs, says Roundup, that case is
12 inconsistent with the Eleventh Circuit, that it wouldn't come
13 out the same way here, and their reasoning first is based on
14 something Judge Chhabria said that the Ninth Circuit disagreed
15 with, and I will trust the Ninth Circuit on that question.

16 Then also said there is a difference because in
17 Roundup they talked about, the way the Plaintiffs framed it
18 here, is there a realistic dose, the Plaintiff with the best
19 case could possibly say it causes their cancer, and the
20 Defendants say that is just not the case here, in the Eleventh
21 Circuit you have to have the minimum dose, but this really
22 doesn't make any sense.

23 What that means is, if you can't calculate the exact
24 minimum dose threshold, even if you are totally above any
25 plausible threshold, you are going to be thrown out on general

1 causation, and that doesn't make any sense in an MDL where
2 there are going to be people who have had 20 years of exposure,
3 people who have five years of exposure. It is just going to be
4 about can you calculate the exact minimum dose.

5 That is not faithful to the general causation inquiry.
6 They also say, it is not even something the Eleventh Circuit
7 has ever said. McClain and Chapman were both cases about
8 specific Plaintiffs. The also had specific causation at issue
9 and so the analysis blended a little bit.

10 The concern in those cases, and really what they are
11 getting at is, if you can't show that the Plaintiff had above a
12 minimum dose that would cause it, then you get thrown out at
13 general causation, and that is probably true. If the minimum
14 dose is something like you have to have a thousand pills of
15 Ranitidine every day, yes, that is not going to quite cut it,
16 but that is not the same as playing gotcha games on calculating
17 the minimum dose, when clearly someone who took ten years of
18 Ranitidine would be well over.

19 So, the basic question when you consider the critiques
20 against judge -- against Dr. Moorman is whether this case is
21 with Abilify and Schultz and Roundup, where there are different
22 studies with and different levels of persuasiveness, or if this
23 a case like McClain or Chapman or Allison where all the
24 evidence is on one side. There is no epidemiology, there is no
25 dose response, and there is no assessment of background risk.

1 Respectfully, I would submit, your Honor, when you
2 look at the degree of effort that they are putting in to
3 discuss each study and say the way that they weighted this
4 particular study is wrong, they are really talking about
5 persuasiveness, they are really talking about something that is
6 not a Daubert issue at all, that is only an issue for the jury.

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

8 Were we able to mute the person? We have control of
9 that?

10 All right. Now the concluding portion of the
11 Plaintiffs' presentation.

12 *MS. LUHANA:* Good afternoon, Judge.

13 *THE COURT:* Good afternoon, almost good evening.

14 *MS. LUHANA:* Good to see you. Roopal Luhana for the
15 Plaintiffs.

16 Judge, I am addressing the majority of the Plaintiffs'
17 response to Defendants' motion to exclude Dr. Salmon's general
18 causation opinions. My colleague, Mr. Nigh, will address some
19 other points at the end of my presentation on Dr. Salmon as
20 well.

21 I feel compelled to raise that, unfortunately,
22 Defendants have raised specific arguments in their presentation
23 today that were never raised in their brief.

24 We believe Defendants waived these arguments and
25 should be precluded from raising them, as you instructed in

1 your order.

2 You received my slide presentation yesterday which was
3 responsive to the Defendants' briefing to exclude Dr. Salmon;
4 however, I do not plan to go through the majority of my slides
5 in an effort to address Defendants' new arguments that
6 completely conflate issues and misrepresent what Dr. Salmon
7 did, and I have actually incorporated some of the Defendants'
8 PowerPoint slides into my presentation.

9 We will rely on our briefing to address the crux of
10 Defendants' arguments in their brief.

11 So, let's start with Dr. Salmon's qualifications.

12 Can we go to the next slide.

13 Dr. Salmon is a heavily credentialed toxicologist, he
14 has a BA, an MA, a Ph.D from the University of Oxford with a
15 focus in biochemistry.

16 He has over 30 years of experience at the EPA. His
17 life's work has focused on leading health hazard and cancer
18 risk assessments, conducting dose response assessments and
19 carcinogenic potency modeling, developing guidelines for cancer
20 risk assessment methodology.

21 That is in line with what he did here for his report.
22 He did a qualitative and quantitative assessment on NDMA and
23 the NDMA in Ranitidine specifically.

24 Despite his qualifications, Defendants say he is not
25 qualified to review the epidemiology. Defendants cite no case

1 law to support their position, nor could they. Dr. Salmon
2 testified that he routinely evaluated epidemiology in
3 conducting hazard assessments at the EPA.

4 For example, when you assess carcinogens you are
5 looking at animal studies, you are looking at mechanistic data,
6 you are looking at the epidemiology, and he testified that he
7 routinely did that. He has also authored epidemiological
8 articles.

9 Next slide.

10 Tellingly, in McClain the Eleventh Circuit upheld the
11 District Court's decision to exclude a non-epidemiologist
12 because he didn't review epidemiology. Clearly Dr. Salmon is
13 qualified to review epidemiology and appropriately did so here.

14 Next slide, please.

15 So, let's go through his methodology.

16 Next slide.

17 Dr. Salmon searched and reviewed over 1100 scientific
18 publications. He then discussed each piece of relevant
19 evidence in an over 240 page report in detail. He assessed, he
20 analyzed, and he discussed strengths and weaknesses
21 individually of each piece of evidence. He applied the
22 Bradford-Hill considerations thoroughly to conduct a weight of
23 the evidence analysis where he reviewed all of the relevant
24 evidence, including studies that were statistically significant
25 and those that weren't for his Bradford-Hill guidelines.

1 He conducted a separate quantitative dose response
2 assessment where he used statistically significant studies to
3 do his dose response assessment, and his dose response slopes.
4 This is in fact, Judge, the standard that is set up by the WHO
5 and IARC.

6 Ironically, Defendants criticize Dr. Salmon for doing
7 things inconsistently outside of litigation versus in the
8 courtroom, when in fact he was extremely consistent.

9 Go to Defendants' slide 3. Next slide.

10 So, on one hand, Defendants state that Dr. Salmon,
11 outside the litigation relies on statistically significant
12 studies, indicating that that isn't something he did here, and
13 then here, they say in his report that he is cherry picking and
14 stacking the deck because he is using statistically significant
15 studies for his dose response calculations. Defendants'
16 position simply doesn't make sense.

17 On this slide, Judge, on the left-hand side is a
18 chapter that Dr. Salmon wrote, that is published. It is a
19 summary of the IARC guidelines describing what is considered
20 sufficient evidence from human studies.

21 The quote here, though, is taken out of context
22 because if you look at the rest of the quote, it goes on to
23 state that epidemiological investigations are complex and they
24 are sometimes insensitive, and therefore you need to take into
25 account case reports and mechanistic evidence to come to

1 causality assessments.

2 On the right side, Judge, is page 11 of his report
3 where Dr. Salmon is in fact citing to Bradford-Hill. The
4 sentence that is actually omitted, Dr. Salmon says, Hill
5 expressly warned that too much focus is spent on
6 statistically -- statistical significance and the value of P,
7 such that no significant difference was dangerously being
8 interpreted as no difference, and thus a reasonable approach is
9 necessary to interpret the data and weigh the evidence whatever
10 the value of P.

11 So, this is exactly what Dr. Salmon did for his
12 Bradford-Hill analysis, he considered and weighed each and
13 every study.

14 Importantly, Defendants are complaining what Dr.
15 Salmon did for his Bradford-Hill analysis was his dose response
16 calculations. What Dr. Salmon did here, his analysis is
17 reliable, it's robust, it's complete, and consistent with his
18 experience and his expertise as a toxicologist.

19 Next slide, please. Next slide.

20 So, Dr. Salmon conducted a quantitative dose response
21 assessment. He identified source data, he scoured all
22 available studies and data to find where NDMA exposure was
23 specifically quantified and cancer association was studied. He
24 calculated lifetime cumulative exposure based on study
25 parameters to ultimately calculate the amount of NDMA exposure

1 that was associated with a particular cancer.

2 He calculated a dose response curve based on the
3 statistically significant diet and occupational studies, and
4 the he calculated dose response assessment and tied it to the
5 NDMA exposure levels found in the FDA the Defendants and
6 Emery's testing, which ultimately showed that Ranitidine users
7 are exposed to enough NDMA in their Ranitidine pills to cause
8 each of the five designated cancers.

9 Judge, Dr. Salmon was so thorough that he reviewed
10 every study that discussed NDMA, and to the extent that the
11 study quantified NDMA dosage and assessed association of cancer
12 he included it in his report.

13 So, Defendants' criticisms about him omitting studies
14 are clearly misplaced. So, let's take a look at the next
15 slides, which are slides 6 and 7 from Defendants' presentation.

16 So, Dr. Salmon's discussion of all the studies
17 confirms that he did not conduct dose calculations because the
18 data wasn't there.

19 So, let's go through some of these studies that are
20 grayed out.

21 Look at the Straif study and go to his report, page
22 56. He says he didn't quantify NDMA exposure specifically
23 because exposure levels were only calculated at high, medium,
24 low, or had missing data, so he was unable to do the
25 calculations.

1 Then you look at Vlaanderen, which was a rubber worker
2 study, and once again nitrosamine levels were not estimated.
3 Then you go to De Stefani 2012, it's a case control cancer
4 study that didn't report NDMA intakes. You look at Gonzalez,
5 that is page 64, the study authors didn't report NDMA intakes,
6 so he couldn't do the calculations.

7 So, while Dr. Salmon discussed all these study
8 findings for his Bradford-Hill analysis and weighed all these
9 studies and discussed them in detail at length, he couldn't do
10 the dose calculations because the data wasn't provided in the
11 study.

12 Go to the next slide.

13 So these studies on the right, Dr. Salmon didn't admit
14 any of these studies. He discussed them and included them for
15 his Bradford-Hill analysis, but he didn't include them for his
16 dose response assessment because that is not the WHO standard
17 methodology. These were studies that quantified NDMA and he
18 did those calculations, but they weren't statistically
19 significant.

20 So, here they say that Dr. Salmon said the results are
21 uninformative. I want you to look at that testimony, 188:12 to
22 191:17. There he testifies that the studies are informative in
23 so many other ways, but not for dose response calculations.

24 Go to the next slide, so slide 8. Okay, go forward.
25 Sorry. Thank you.

1 As I stated earlier, while Defendants haven't
2 criticized Dr. Salmon's dose response calculations until today,
3 they previously conflated concepts with his dose response
4 curves. While the Defendants criticized Dr. Salmon for using
5 statistically significant studies to calculate the dose slopes,
6 and quantify the amount of NDMA exposure necessary to cause a
7 statistically significant increased risk of cancer, they cite
8 to no support for that, their position.

9 In fact, their position is contradicted by the
10 standard that calculates dose response curves. The WHO
11 specifically spells it out and says for dose response you
12 should do exactly as Dr. Salmon did.

13 You use the best representative study to calculate
14 risk to use statistically significant study results to
15 calculate dose response assessment. It's right there, you take
16 a reliable study, it has to be identified, where the exposure
17 of the study population can be estimated with acceptable
18 confidence and cancer incidence is statistically significant
19 and you choose the best representative study.

20 That is exactly what he did, he used a reliable
21 methodology established by WHO.

22 Defendants, unfortunately, continue to conflate
23 concepts, and I don't know if it is because it's lawyers
24 interpreting science, but that is not what Dr. Salmon did. He
25 reviewed and assessed and analyzed all the studies, and then he

1 did a separate quantitative analysis, a dose response
2 calculation specifically as WHO directs.

3 Next slide.

4 Similarly, the IARC program of chemical safety
5 provides that dose response relationships should be supported
6 with statistically significant differences. So Dr. Salmon
7 assessed and analyzed literally all the studies, as I said, for
8 his Bradford-Hill analysis; however, for his dose response
9 assessment he used statistically significant studies that are
10 consistent with standard methodology.

11 Next slide.

12 Then Defendants attack Dr. Salmon for pooling the dose
13 response slopes together, which is truly a red hearing.
14 Defendants don't raise what impact his illustrative slope
15 averages had on his dose response assessments because while he
16 presented those averages as illustrated and as a hypothetical,
17 he didn't use them for his dose response assessment.

18 Also, while the Defendants call it an unprecedented
19 methodology, if you look at Exhibit 84 that they provided, that
20 discusses how the EPA pools elevated tumor incidents for same
21 cancer sites. So, here they criticize Dr. Salmon for pooling
22 the averages together, but he did that to show an illustration
23 of what the slopes are it you just calculate the mean.

24 In fact, Dr. Salmon, for his dose response assessment,
25 he used the individual statistically significant dietary and

1 occupational studies for his analysis.

2 Go to the next slide.

3 So this, Judge -- go back, go back to that pooling.

4 So this is once again Defendants' slide, and you will
5 see he calculated the individual dose response slopes for each
6 of these statistically significant studies, and then he did a
7 mere calculation of the mean slope. So he was showing that, he
8 didn't use the mean slopes for any of his analysis for his dose
9 response calculations.

10 On the right-hand side he provided a hypothetical, and
11 this is more so for specific causation down the road. If you
12 had individuals who were taking Ranitidine for ten years and
13 each pill has 1,000 nanograms, how much would the hazard ratio
14 increase for those pooled cancers.

15 He testified this was a hypothetical, this is just
16 illustrative. I am not using this for my dose response
17 calculations to tie it to the actual amount of NDMA in these
18 Ranitidine pills, which is what he did.

19 He looked at the testing, he looked at the diet and
20 occupational studies, assessed the increased risk of cancer and
21 what amount of NDMA it took to get there, lifetime cumulative
22 exposure, and then he tied it to the actual NDMA that was being
23 found in these pills, and that was at various points.

24 That was at baseline based on NDMA levels found in
25 Defendants' own testing, as well as Emery's testing, and then

1 looking at it after zone exposure testing to introduce it to
2 the elements when people are opening their pills and they
3 expose them to heat and humidity, and seeing what the rise is.

4 He did all those calculations in his chart to show
5 that the levels that you are seeing in these pills -- the
6 levels that you are seeing in these diet studies and
7 occupational studies are equivalent to the levels that you are
8 seeing in the Ranitidine pills. That is what the chart is all
9 about.

10 Go to the next slide.

11 And this is what I was raising in terms of -- this is
12 De Stefani in 1998, where Dr. Salmon went about and did the
13 individual dose calculation for this study.

14 Go to the next slide.

15 So, Judge, on this slide they say Dr. Salmon is on an
16 island of his own, and here he is saying that there is clear
17 evidence of dose response and citing Cardwell.

18 That is the only Ranitidine study that he says
19 provided dose response. Dr. Moorman's and Dr. McTiernan's
20 quotes are in agreement on Cardwell and the other Ranitidine
21 studies.

22 If you take a look at Defendants' cite, where they got
23 these quotes from, if you look at the complete quote they go on
24 to say, yeah, the Ranitidine studies don't show dose response
25 except for Cardwell. You don't see he that on the screen here,

1 however it is noted.

2 In addition to that, every other study that he is
3 saying is clear dose response, he is relaying on the diet and
4 occupational studies, and not the Ranitidine studies.

5 I am going to turn it over to my colleague to make
6 some final points. Thank you for your time, Judge.

7 *THE COURT:* All right. Okay, four minutes.

8 *MR. NIGH:* Good afternoon, Judge, may it please the
9 Court.

10 I will address a few issues regarding Dr. Salmon with
11 the balance of our time, and we are not going to use any
12 slides, but I wanted to address some of the new issues that the
13 Defendants have raised for the very first time here today. It
14 is not in their briefing, and I will address some of those
15 issues.

16 First, Defendants use a graph on Ranitidine dose
17 response addressing dose response in Ranitidine studies. That
18 was never presented in any briefing or any expert report and it
19 is very misleading.

20 First, it attempts to put DDD, defined daily dose, on
21 the same horizontal axis as number of prescriptions, but is
22 woefully inaccurate and doesn't appear in any expert report,
23 nor would it.

24 At the top, the DDDs don't even match the Cardwell
25 study. Cardwell had 366 to 1,095 DDD, and 1,096 plus. They

1 don't have those numbers at the top, they have 730, not 1,095.
2 This is important.

3 Next, on the scale Defendants attempt to equate ten
4 prescriptions with 1,095 DDD. That is wrong. We don't know
5 the length of the prescription or the strength of the
6 prescriptions in Adami or Norgaard, but if each prescription
7 was for only one month for 150 milligrams, then at ten
8 prescriptions, that would only have a DDD of 150. That is
9 nearly ten percent of the 1,095 DDD, yet in that chart it
10 attempts to equate the two.

11 Now, the purpose of that is, that is nearly ten
12 percent of the 1,095 DDD, and on the dose response chart, that
13 finding from Adami and Norgaard should have been at the very
14 start of the DDD response in Cardwell, between 1 to 182.

15 Looking at that, it would have made it clear that all
16 the dose response results for Adami and Norgaard would be
17 shrunk and compressed to the far left on that dose response
18 chart, and then it would highlight precisely what Dr. Salmon
19 stated when he stated that the Ranitidine epidemiology studies,
20 that of them only Cardwell for bladder cancer had enough
21 information to do a dose response analysis for Ranitidine
22 studies.

23 He also did a dose response analysis from the NDMA
24 studies.

25 Finally, Defendants attempt to include Iwagami for all

1 cancers on that same dose response chart. That study can't be
2 used for dose response for Ranitidine. Nearly 60 percent of
3 the users in Iwagami used Nizatidine and that analysis is a
4 dose response analysis combined for Ranitidine and Nizatidine.
5 It doesn't tell us the dose response information for
6 Ranitidine.

7 Next I will address some criticisms raised by the
8 Defendants for the very first time regarding Salmon's
9 calculation of a lifetime cumulative exposure. These
10 criticisms are not in their papers and they should be waived,
11 but I will address them.

12 Calculating lifetime cumulative exposures based on
13 statistically significant results only is not cherry picking.
14 That is how lifetime cumulative exposures are supposed to be
15 done, and that is actually more conservative than including
16 non-statistically significant results. It would take less time
17 to reach those results.

18 Now, Defendants also want to blame Salmon for not
19 doing a meta analysis, but this is also disingenuous for three
20 reasons.

21 Meta analysis for these types of data would have been
22 inappropriate, and if Salmon did it, they would have complained
23 that he did it, because doing a meta analysis on different
24 study designs at different end points would be inappropriate.

25 Finally, just a couple of more points. Doing a meta

1 analysis for a lifetime cumulative exposure analysis is not
2 required.

3 Just like Defendants have cited no legal authority or
4 even any scientific authority for nearly all of their
5 criticisms of Salmon's meta analyses that they are raising for
6 the first time here today, Defendants have cited no legal or
7 scientific authority regarding this issue.

8 This hearing is the first time Defendants raised the
9 allegation that a meta analysis for a lifetime cumulative
10 exposure analysis is required and Salmon avoided this, just
11 like this hearing is the first time the Defendants chose to
12 raise nearly all of their allegations regarding Dr. Salmon's
13 lifetime cumulative exposure analysis, and therefore these
14 arguments are waived and should not be considered.

15 *THE COURT:* Okay.

16 *MR. NIGH:* We will also rest on the papers related to
17 Le and Michaels, and any rebuttal regarding those two experts
18 should be disallowed. Thank you.

19 *THE COURT:* Defendants have ten minutes left for your
20 rebuttal.

21 *MS. CANAAN:* Your honor, can we ask for a five-minute
22 break?

23 *THE COURT:* Yes. We will be in recess until 5:20 or
24 so.

25 (Thereupon, a short recess was taken.)

1 THE COURT: Okay. Your rebuttal.

2 MR. HOLIAN: Thank you, your Honor.

3 THE COURT: Ten minutes, right?

4 MR. HOLIAN: I don't think I will need to take that,
5 your Honor, it should be less.

6 I want to make four points. First I want to address
7 right up front this notion of waiver, that we have somehow
8 waived arguments about Dr. Salmon.

9 I was listening very closely to the Plaintiffs to hear
10 what it was they thought was new. It wasn't that we moved on
11 dose response, that is in pages 57 to 59 of our opening brief.
12 It is not our criticism of Dr. Salmon for relying on dietary
13 and occupational NDMA epidemiology. That is on page 57 of our
14 opening brief.

15 It can't be that Dr. Salmon relies on Dr. Najafi's
16 testing, because that is in the testing motion where we moved
17 to exclude any expert who relied on it.

18 I think what seemed to strike a nerve was the graph
19 where I showed what the dose response data looked like. Your
20 Honor saw that data dozens of times today in different ways on
21 forest plots. It is on many, many, many of the experts'
22 reports, including theirs. It is just a different way to show
23 what a dose response curve should look like if there is
24 consistent evidence of a dose response and contrast that to
25 what it does look like here. It is lawyer argument, but it is

1 throughout the record.

2 This point about meta analysis is simply responding to
3 one sentence in the Plaintiffs' opposition where they said, oh,
4 no, people combine things all the time, they do meta analysis,
5 in defense of what Dr. Salmon did.

6 There is no waiver here of any of the arguments that I
7 made today, your Honor.

8 Second point, dose. I want to draw things back a
9 little bit. You heard a lot of information about all these
10 studies, but I think one thing that we have been crystal clear
11 about as the Defense is the importance of dose, both a
12 threshold dose and dose response.

13 Dr. Salmon is the only one who has suggested that the
14 Ranitidine epidemiology establishes a dose response, and he is
15 the only one who has purported to do any calculations to show
16 what the threshold dose is at which you should start to see an
17 effect. Drs. McTiernan and Moorman did not claim there is any
18 threshold dose, you saw that in their testimony, and they did
19 not claim that the Ranitidine epidemiology establishes a dose
20 response.

21 Without a threshold dose, the Plaintiffs can't meet
22 the call in McClain that an expert has to say how much is too
23 much. Again, it doesn't have to be incredibly precise, 3.2
24 years of exposure at 873 nanograms, but it has to be something
25 more than long-term use.

1 Without a dose response, which McClain says is the
2 hallmark of general causation in a toxic tort case, the
3 Plaintiffs can't reliably use the Bradford-Hill criteria to
4 conclude general causation.

5 So, because Dr. Salmon is the only one who purports to
6 identify a threshold dose and the only one arguing that the
7 Ranitidine epidemiology establishes a dose response, his
8 exclusion is fatal to the Plaintiffs' general causation
9 arguments.

10 Third, you heard Ms. Luhana discuss the standards that
11 Dr. Salmon referenced and saying it is perfectly acceptable to
12 only look at statistically significant results when you
13 are trying to assess a dose response, but those guidelines that
14 she cited, one slide was from the World Health Organization
15 about how you derive air quality guidelines.

16 The other was the IPCS guidelines on environmental
17 toxicology. Those are guideline values that environmental
18 toxicologists, which is what Dr. Salmon is, those are
19 guidelines they use to figure out, using the worst case
20 assumptions, what is the highest level to which people can be
21 exposed so that we can be sure below that there is no risk of
22 harm.

23 The Eleventh Circuit has made clear that is totally
24 different than what you do in a toxic tort case where the
25 question is not what is the dose at which there isn't harm; it

1 is what is the dose at which there is harm. In McClain, the
2 Eleventh Circuit has been clear, a Court performing the
3 function you are should not mix those two things up, they are
4 very different standards.

5 By the way, if you read those two documents carefully,
6 they actually endorse the importance of statistical
7 significance in deriving reliable conclusions. For example, in
8 the IPCS document that Plaintiffs' counsel cited, the very next
9 sentence says, if you have results that aren't statistically
10 significant, then that suggests the level of exposure is,
11 quote, "without biologically significant adverse health
12 effects."

13 So, don't confuse Dr. Salmon porting in environmental
14 toxicology risk assessments, precautionary regulatory
15 standards, with the Court's role here.

16 The last thing that I want to do is draw the lens back
17 a little bit from the blizzard of data and information you
18 heard today. I want to talk about one thing you didn't hear
19 today, which is the Plaintiffs coming forward and identifying
20 anybody else in the world who has concluded that Ranitidine
21 causes cancer.

22 The cases talk about general acceptance is relevant
23 factor under Daubert, and it not just the general acceptance of
24 methods, it's are these conclusions accepted because, as the
25 Advisory Committee notes to the 2000 amendments to Rule 702, if

1 an expert purports to use a method that is generally used, like
2 weight of the evidence or Bradford-Hill, but reaches a
3 conclusion that nobody else has reached, then a Court sitting
4 where your Honor is, applying Rule 702, should suspect that the
5 methods were not faithfully applied.

6 That is exactly what has happened here. The case law
7 is clear that the words weight of the evidence and
8 Bradford-Hill are not magic talismans that the Plaintiffs'
9 experts or the Plaintiffs lawyers can invoke and thereby shield
10 themselves from any scrutiny by the Court.

11 The Court, in exercising its gatekeeping role, has to
12 look carefully at whether those methods were reliably applied,
13 and here they were not.

14 The FDA has looked at this issue and it has spoken in
15 peer reviewed literature. The EMA has looked at this issue and
16 it has spoken. They have both concluded the evidence does not
17 reliably establish that Ranitidine causes cancer. The peer
18 reviewed scientific literature has examined this question over
19 and over and over, and not once in a peer reviewed study has
20 anyone concluded this establishes that Ranitidine causes
21 cancer.

22 So, this is not a case where we need information to
23 fill in the gap. The only people in the entire world who say
24 Ranitidine causes cancer are the experts retained by the
25 Plaintiffs, and the Court should not allow a jury to

1 second-guess the decisions of FDA, EMA, and the rest of the
2 scientific community.

3 The Court should exercise its gatekeeping function and
4 conclude that the Plaintiffs have not faithfully applied --
5 Plaintiffs' experts have not faithfully applied the weight of
6 the evidence or Bradford-Hill methodology and it should grant
7 our motion and exclude them under Rule 702.

8 Thank you, your Honor.

9 *THE COURT:* Thank you very much.

10 That is all of the formal presentation for the day. I
11 want to thank everyone. Clearly a lot of hard work and effort
12 went into it. They were extremely helpful, so thank you to
13 everybody who presented and all of those who helped in putting
14 together the presentation.

15 On the agenda we did leave a line there that I may
16 take some time to ask questions, and I also put aside tomorrow
17 morning before the first set of motions are being argued.

18 I am going to use a little bit of the time now, I hope
19 not too much, because it has been a long day. I know are all
20 tired, so bear with me for just a few questions. They may not
21 be all the questions.

22 Whoever you think is most appropriate to answer the
23 question can come forward. Even if it is more than one person,
24 that is fine, just state your name on the record when you come
25 forward so we get who is answering the question.

1 This is just kind of housekeeping. I know that in one
2 of the inquiries I made, both the Plaintiffs and the Defendants
3 emailed me kind of a chart on study duration and sample size.
4 So I want to thank you for that.

5 Is there any reason why I could not ask you to have
6 that filed on the docket, notice of filing, so that I have it
7 formally as part of the record? Would that be acceptable to
8 the Plaintiffs?

9 *MS. FINKEN:* Yes, your Honor.

10 *THE COURT:* From the Defense?

11 *MR. CHEFFO:* Yes, your Honor.

12 *THE COURT:* That was easy. Okay. This I sort of
13 alerted to as well, one of the topics, so this is for both
14 parties. Defense first, since they were your motions today.

15 In your view, what is the current opinion of the FDA
16 and the EMA on the dangers of Ranitidine? What document or
17 documents should I look at to locate that opinion?

18 I would ask everyone, try to answer the question, and
19 if you have to explain, you can explain, but I know we are
20 trying to keep it -- does that sound familiar -- try to keep
21 the answers as brief as possible. I am not looking for
22 argument as much as kind of the information.

23 *MR. CHEFFO:* Yes, your Honor. To try and be brief,
24 there was a quote that I put up that I think does state the
25 most recent FDA pronouncement. Also, the Florian study is an

1 FDA study and I think that is there. I am not aware that they
2 have done anything to say anything inconsistent with that, and
3 I think the same is true for the EMA slide that we put up.

4 *THE COURT:* So whatever FDA and EMA slide you used, as
5 well as the Florian study, would be, in the Defense's view, the
6 opinion of the FDA and the EMA generally, including on the
7 dangers of Ranitidine.

8 *MR. CHEFFO:* That's correct, your Honor.

9 *THE COURT:* Thank you. From the Plaintiffs.

10 *MR. RONCA:* Jim Ronco for the Plaintiffs, your Honor.

11 So, the product it still off the market. You could
12 look at the EMA report from 2020, however, five of the most
13 important studies were not yet published, so they didn't have
14 them.

15 In addition, we don't think you can look at Florian
16 because they did not do a complete review. They are talking
17 about a couple of sentences in an article on the urinary
18 content of NDMA, and Florian didn't comment on seven of
19 fourteen Ranitidine specific studies regarding cancer.

20 *THE COURT:* All right. So this will be for Defendants
21 first.

22 This has to do with the 5912-5, that document which I
23 know I put you on notice that I wanted to ask about, and I
24 received word that it was fine, even though it is a sealed
25 document. Can I get confirmation that discussing that document

1 is not a problem from Defense?

2 It was in the list of topics that I had circulated.

3 MR. CHEFFO: Yes, your Honor, that is fine to discuss
4 it.

5 THE COURT: Okay. Okay. So, in the Plaintiffs'
6 response, the Plaintiffs cite to this document and I just want
7 to make sure I am reading the document correctly. So, if we
8 look at the document -- do you have that in front of you?

9 Does Defense have it in front of you?

10 MR. CHEFFO: I don't, your Honor, but I think I know
11 what you are talking about.

12 THE COURT: You might need one of these to read it, a
13 magnifying glass.

14 MR. CHEFFO: I am sure I will need that as well, your
15 Honor.

16 THE COURT: Tell me when you have it.

17 MR. CHEFFO: We can try and find it. The other
18 suggestion, obviously you are the Judge, but if you'd like us
19 to get it and be prepared to discuss it first thing in the
20 morning, I can do that, since I don't know if I have it here
21 right now.

22 THE COURT: Okay, that is fine.

23 Let me let you know what the questions are if you want
24 to make note of them. It looks like the document memorializes
25 GSK tests of both API, that is raw product used to make

1 Ranitidine and Ranitidine that was made from the API, and the
2 tests were for NDMA.

3 So, that is my first question, am I correct, yes or
4 no, and do you need to explain anything?

5 So, do you need me to repeat that question?

6 MR. CHEFFO: No, I think I got it.

7 THE COURT: The next question is, there is a column --
8 let me get it in front of me.

9 There is a column that reads: API NDMA content, and I
10 want to just confirm that that reflects the results of the API
11 tests for NDMA. That's the next question.

12 Then relatedly, there is a column entitled Product
13 NDMA Content, and I want to confirm my understanding that that
14 is the results of the Ranitidine pills for NDMA content that
15 were made from the API.

16 My next question is, why are there columns with a
17 strike through the data? So, there is like a strike through on
18 some of the columns and I want to know why. And then I wanted
19 to know -- this really is a question for both sides, so both
20 sides should take note.

21 I suppose, you know, if the Plaintiffs have a
22 different view of the answers that the Defendants give
23 tomorrow, you should be prepared to tell me why.

24 The other question is whether the parties would agree
25 that as a general matter the tested API resulted in a higher

1 NDMA number than the tested Ranitidine, and if you don't agree
2 with that statement, I would like to hear why.

3 And then I would like to hear an explanation on why
4 the tested API would have or could have resulted in more NDMA
5 than tested Ranitidine pills from the same API.

6 I guess relatedly, just an understanding of why was
7 the document made and is there anything further that you want
8 to tell me about it that would help me understand it.

9 Okay, so we can get answers from that.

10 *MR. CHEFFO:* Thank you, your Honor, for that
11 opportunity. We will be prepared tomorrow for that.

12 *THE COURT:* Okay. Let's see here.

13 While we are on charts, let's move to another one for
14 a moment.

15 This has to do with the Dr. Salmon chart on page 223
16 of his expert report dated January 24, 2022. So, I think this
17 would best be directed to the Plaintiffs initially, and I know
18 a couple of you spoke about Dr. Salmon's chart. Feel free if
19 you need to share in the answer.

20 So, the Plaintiffs, in your opening introduction,
21 showed this slide, I think it was number 59, and it summarized,
22 as you explained, Dr. Salmon's dose response analysis. I want
23 to make sure I understand it.

24 The chart comes from page 223 of the Salmon expert
25 report. Do you have that in front of you? Do the Plaintiffs

1 have that in front of you?

2 MR. NIGH: Yes, your Honor.

3 THE COURT: That was Mr. Nigh for the record.

4 So, as I understand it, and this is a question to have
5 you confirm if I am right or not, the first column on the chart
6 labeled Study Cumulative MG, milligrams, comes from page 221 of
7 the expert report. On page 221, Dr. Salmon uses data from Loh,
8 De Stefani, Keszei, and Hidajat. Am I correct so far?

9 MR. NIGH: Yes, your Honor.

10 THE COURT: As I understand it, what Dr. Salmon is
11 estimating is the amount of NDMA one would have to consume to
12 have a substantial measurable increase in risk from NDMA.

13 Is that correct?

14 MR. NIGH: As pertaining to those specific dietary
15 studies. He also did a dose response analysis across all the
16 studies, but as pertaining to those specific dietary studies in
17 Hidajat --

18 THE COURT: Right. I should have asked the next
19 sentence. He is using data from those studies to compute the
20 number?

21 MR. NIGH: That is correct, your Honor.

22 THE COURT: So, in other words, you have confirmed
23 that everything I said was correct, so does that mean, for
24 example, that one would have to -- looking at that first
25 column, one would have to consume, for example, 3.2 milligrams

1 of NDMA in order to have a risk of gastric cancer, and that is
2 based upon data contained in the De Stefani study?

3 *MR. NIGH:* Somewhat, with a little bit of a nuance.
4 They he would have to consume 3.2 milligrams of NDMA to have a
5 statistically significant increased risk of 2.07, as seen in
6 the dietary studies. It doesn't answer the question of at what
7 lower level could there still be increased risk. He has other
8 analysis for that.

9 *THE COURT:* Okay. With respect to the second column
10 that is labeled FDA Max, as I understand it, does this column
11 use the highest amount of NDMA that the FDA detected in its
12 tests, that is .31755 milligrams? Is that correct?

13 *MR. NIGH:* He defines FDA max as the highest amount of
14 products that was intended for the U.S. in testing by the
15 Defendants or the FDA. There are obviously other test results,
16 and he explains as to why he looked at highest, other test
17 results in other countries that were much higher than that
18 testing for the Defendants and the FDA, baseline testing.

19 *THE COURT:* And going on from there, using that
20 number, he then goes on, does he, to figure out how many years
21 it would take to reach the measurable significant increase in
22 cancer risk that is in the first column?

23 So, in other words, it would take 10.08 years to reach
24 the significant level contained in the first column for gastric
25 cancer. Is that accurate?

1 MR. NIGH: Yes, if you only look at baseline levels of
2 the pristine product tested by FDA and Defendants.

3 THE COURT: Now, the third column, as I understand it,
4 uses the average amount of NDMA that Emery Pharma found, and
5 then using that number, just like the FDA max number, figures
6 out how many years one would have to consume Ranitidine to get
7 to a significant cancer increase. Is that correct?

8 MR. NIGH: The significant cancer increased risk in
9 the study. So he does again in the -- he has other analyses
10 that show lower increased risk, but for that study, that is the
11 amount.

12 I do want to add that that is just based on Emery
13 Pharma's baseline testing, opening up the bottle, test the
14 pill, none of the other consumer experience issues.

15 THE COURT: Okay, thank you.

16 The fourth column, am I understanding that this column
17 adds NDMA to the FDA's max tested NDMA based upon consumer
18 storage testing? Is that correct?

19 MR. NIGH: Yes, and specifically he used the more
20 conservative zone analyses, even though those numbers were much
21 lower than the additional amount seen in the bathroom, sun, and
22 shade testing, and he explains that, and he explains that this
23 was done for general causation purposes.

24 THE COURT: So, in other words, that comes from page
25 218 of the report where he looks at, just as you said, zone

1 storage testing from Emery Pharma because the FDA did not
2 conduct zone storage testing. Is that right?

3 *MR. NIGH:* Somewhat, mostly. The FDA did do some
4 stability testing later, that is what led to the recall in
5 April 2020, but for the most part he did that testing because
6 the FDA didn't publish those results and the Defendants have
7 not done that testing whatsoever.

8 *THE COURT:* Based upon that data from Emery Pharma, is
9 it correct that Dr. Salmon concludes that the NDMA in a
10 Ranitidine pill would be increased by a multiple of 2.5 to
11 account for NDMA generated from heat and humidity?

12 *MR. NIGH:* Yes, just relying on the zones. He also
13 calculated previously that it would be even higher if you look
14 at the bathroom, car, sun, shade, and shower.

15 *THE COURT:* That is why, turning back to the chart,
16 the NDMA in the fourth column, .79 milligrams per year, is 2.5
17 times higher than the NDMA in the FDA max column, column 2. Is
18 that correct?

19 *MR. NIGH:* Yes, your Honor.

20 *THE COURT:* So .79 milligrams per year is 2.5 times
21 higher than .31755. Is that correct?

22 *MR. NIGH:* Yes, your Honor.

23 *THE COURT:* The fifth column, this column, is it
24 correct, adds NDMA to the Emery Pharma NDMA average column, the
25 third column? Is that correct?

1 MR. NIGH: Sorry, I lost where you were.

2 THE COURT: The fifth column, it appears -- let me
3 tell you what I think, and you tell me if I'm right. This
4 column adds NDMA to the Emery Pharma NDMA average column, the
5 third column. This time Dr. Salmon is using a number
6 2.25 milligrams per year, and I think that number, correct me
7 if I am wrong, comes from page 220 of his report where he
8 references testing that Dr. Najafi did, and based upon that
9 testing, Dr. Najafi found an average amount of NDMA from
10 consumer storage testing.

11 Dr. Salmon then -- he takes Dr. Najafi's numbers,
12 converts them into an amount of milligrams per year, and that
13 is how we get the fifth column. Is all of that correct?

14 MR. NIGH: That is accurate, yes, your Honor.

15 THE COURT: So, it appears to the Court that the
16 studies that Dr. Salmon has relied upon to construct this chart
17 are very much intertwined with the Defendants' Daubert motions.

18 For example, the first column, study cumulative
19 milligrams, the amount of NDMA necessary to result in a
20 measurable cancer risk increase, comes from the dietary studies
21 in Hidajat, the occupational study, but the Defendants have
22 argued, among other arguments, that no reliable methodology in
23 this case, in this MDL, could use those studies, that is the
24 dietary studies and the occupational Hidajat study, to form a
25 causation opinion.

1 I am going to ask both sides, this is hypothetically,
2 if the Court were to agree with the argument and conclude that
3 the dietary studies and the occupational studies could not be a
4 part of a reliable methodology, what is the Court to make of
5 this chart? Does it become unusable because the entire chart
6 is premised upon the dietary and occupational studies?

7 I would like to get the Plaintiffs' view on that, and
8 then I have the flip side of that for the Defendants.

9 *MR. NIGH:* In the context of dose response, dose
10 response is oftentimes looked at in a toxic tort on the
11 carcinogen itself.

12 So, we would state that that is a different question
13 than how epidemiologists weigh various studies.

14 If your Honor were to rule that the dietary and
15 occupational exposure studies couldn't even be used for that
16 purpose, then this chart would not be relevant; however, he did
17 also calculate a cumulative dose response specifically for
18 bladder cancer based on Ranitidine epidemiological studies.

19 *THE COURT:* Similarly for the Defendants, if the Court
20 were to conclude that the dietary studies and Hidajat study can
21 be a part -- is considered by the Court as a part of reliable
22 methodology, would the Defendants agree that at least that
23 column of the chart would survive their Daubert challenge as to
24 Dr. Salmon?

25 *MR. HOLIAN:* No, your Honor, we would not, because

1 what Dr. Salmon is doing here again, he is cherry picking a
2 single NDMA epidemiological study to do these calculations. He
3 is picking the very best result that he want to pick. He is
4 using Hidajat for three of these cancers.

5 If the Court were to hold, yes, you can extrapolate
6 from the dietary and occupational studies, that still doesn't
7 mean you can only pick the one that gets the best result for
8 you. On top of that, it is also, in our view, unreliable to
9 take the absolute highest result that the FDA got, that
10 .31755 --

11 *THE COURT:* I will get into that in a moment.

12 *MR. HOLIAN:* So, you can't cherry pick within the
13 dietary and occupational and you can't cherry pick the exposure
14 that you're looking at in order to add those numbers together.

15 The last thing I'd say, your Honor, is sometimes these
16 calculations get cloaked in mystery. If you look at this, the
17 first column and the second column, all Dr. Salmon is doing is
18 dividing the study cumulative milligram in that first column by
19 .31755, all the way down.

20 I believe Mr. Nigh said that it is unscientific to do
21 calculations that way, and we agree.

22 *THE COURT:* Okay. Now, a related question to the
23 Plaintiffs' first, the chart uses data from Emery Pharma, from
24 Dr. Najafi, which is also the subject of a Defendant Daubert
25 challenge. If the Court were to grant that motion and exclude

1 Dr. Najafi from testifying, does that mean that the column
2 about Emery Pharma becomes unusable?

3 Similarly, the column on consumer storage testing,
4 which comes from Emery Pharma, becomes unusable?

5 MR. NIGH: Your Honor, I'm sorry, I missed a piece of
6 that. There are a lot of moving parts.

7 THE COURT: Do you want me to say it again?

8 MR. NIGH: Yes.

9 THE COURT: A related question, the chart uses data
10 from Emery Pharma, from Dr. Najafi, which is also the subject
11 of Defendant Daubert challenge.

12 If the Court were to grant the motion and exclude Dr.
13 Najafi from testifying, does that mean that the column about
14 Emery Pharma becomes unusable?

15 Similarly, would the column on consumer storage
16 testing, which comes from Emery Pharma, become unusable?

17 MR. NIGH: It is difficult to answer that in a vacuum
18 because, as we will discuss tomorrow, there are a lot of other
19 data points that could also be used and are consistent with Dr.
20 Najafi's results, that demonstrate that as they are exposed to
21 more heat and humidity, we see additional amounts of NDMA.
22 That is even in Sanofi's own testing.

23 THE COURT: But if Dr. Najafi is not -- does not
24 survive, that was the premise of the hypothetical, so not just
25 as to the storage, but I know you are going to discuss other

1 things tomorrow with respect to Dr. Najafi, but I am --

2 MR. NIGH: My point is, there would still be support
3 for some of these numbers other than FDA max that are part of
4 the record, other than Najafi's testing.

5 THE COURT: Other than Najafi's testing, all of his
6 testing.

7 MR. NIGH: Yes.

8 THE COURT: Okay. Did you want to add something?

9 MS. LUHANA: Yes. Judge, I would also note that the
10 Defendants have done significant testing, and we will talk
11 about the master data spreadsheet tomorrow where you will see
12 values that are way above 435 nanograms that meet these
13 parameters.

14 In addition to that, the root cause analysis,
15 Defendants did test the pills, two batches, at extreme
16 temperatures, well, some were high temperatures, and with
17 humidity, and we can discuss those results as well, which get
18 us to these points that Dr. Najafi has come to without Emery's
19 data.

20 THE COURT: Thank you. Same question on the flip side
21 for the Defendants, if Dr. Najafi -- if the Daubert motion as
22 to Dr. Najafi is denied, do the Defendants agree that at least
23 the columns of the chart based on Dr. Najafi's data would
24 survive their Daubert challenge as to Dr. Salmon?

25 MR. HOLIAN: No, we wouldn't, because you have to have

1 a hypothetical on top of a hypothetical. You have to agree you
2 could use the dietary and occupational NDMA epidemiology to
3 start this chart at all.

4 So, if the hypothetical is they get past that and Dr.
5 Najafi also doesn't get excluded, there is still a great big
6 problem with this chart, which is, if this is a reliable way to
7 look at the data, then why doesn't it show up in the Ranitidine
8 epidemiology?

9 In that far right column, the number of years it takes
10 under his analysis to show a significant risk in the increase
11 of gastric cancer is 1.4 years, and the highest time period is
12 liver cancer, 6.5 years. That is well within the followup
13 time, the exposure analysis, everything else in the Ranitidine
14 epidemiology we have seen.

15 So there, your Honor, I'd say it can't be reliable to
16 cobble dietary and occupational epidemiology with max FDA
17 tests, cobble it with Dr. Najafi's testing and say, ah-ha, we
18 have a dose response and a dose threshold, because it is not in
19 the Ranitidine epidemiology.

20 If you have epidemiology answering the question that
21 is the center of this whole case, you can't just say cast that
22 aside, cobble together these other things in order to derive a
23 general causation opinion, particularly because you don't even
24 get to the dose response part of the Bradford-Hill analysis
25 unless the Plaintiffs first prove a statistically significant

1 association that is free of bias, which they haven't done.

2 MR. NIGH: Your Honor, may I respond to one small
3 point in that statement?

4 THE COURT: Yes.

5 MR. NIGH: The statement that it is not consistent
6 with the Ranitidine epidemiology literature, I think the
7 Defendants are conflating followup and usage dramatically here.
8 Those are two separate issues, and those compound along with
9 the other issues that we discussed.

10 In terms of liver cancer, a Ranitidine epidemiology
11 study that discusses a median of 6.5 years, where is that? On
12 the flip side, bladder cancer, there is a study that shows a
13 statistically significant increased risk at three or more
14 years, or 10,095 DDD, which actually might be a little higher
15 than three years.

16 What do you see there? The result is consistent,
17 3.86. None of the other Ranitidine studies have that sort of
18 use to show that consistency.

19 THE COURT: The Plaintiffs aren't suggesting, though,
20 in any way that this chart uses Sanofi data; is that correct?

21 MR. NIGH: This chart does not use Sanofi data.

22 THE COURT: Okay. So, the chart uses an average value
23 from the Emery Pharma tests, and I understand that an average
24 value may be an appropriate, or a reasonable number to use in
25 these sorts of calculations, but the FDA number used on the

1 chart isn't an average, it is a maximum value.

2 As the Court understands it, the FDA tests resulted in
3 a range of numbers. Is it the Plaintiff's position that the
4 causation question in this MDL may be premised not on an
5 average value of those tests, but a maximum value?

6 MR. NIGH: That is only part of the premise. The
7 other part of the premise is that the -- these levels from the
8 FDA are only the baseline testing on pristine product. We are
9 going to demonstrate that. Later, the FDA demonstrated that
10 there was significantly more NDMA that is forming after their
11 baseline testing. That is what led to the recall in April
12 2020.

13 In addition to that, there are all sorts of other test
14 results that may not have been the specific Ranitidine
15 specifically designed to go to the U.S., but they also
16 demonstrate much higher levels, and they are relevant to the
17 question, they are the same compound. So, that was all part of
18 the thought of using that number.

19 THE COURT: So, then, are the Plaintiffs saying that
20 it is plausible to assume that what you have referred to, I
21 think certainly today, what you call the therapeutic dose, the
22 highest dose that a Plaintiff could have received in this case,
23 flowed from the maximum value and not the average value?

24 MR. NIGH: That is not -- the FDA max is not saying
25 that at all. The FDA max is chosen, realizing those three

1 issues that I just explained previously. So, it is not based
2 on a legal standard.

3 It is based on those three issues that, one, the FDA,
4 when they did additional testing that led to the recall of all
5 Ranitidine in the United States, that was after their baseline
6 testing. They found excessively more NDMA. That is what led
7 to the recall in the United States.

8 Two, there are all sorts of testing on product that
9 wasn't designated for the U.S. that we know, but shows much
10 higher levels of NDMA on the same molecule.

11 So, those are the sorts of issues why I would say that
12 that is not necessarily the maximum result or the highest
13 level.

14 *MR. HEINZ:* Your Honor, it is also important to keep
15 the legal question in mind here. This would be deciding the
16 case for every Plaintiff in this MDL, and so following the
17 Plaintiffs' framing of the general causation question, the
18 highest sort of plausible or realistic dose anyone could have,
19 the question is, could any Plaintiff have had a consistent
20 number of pills with 800 nano grams of NDMA?

21 If that is even plausible, we should be given the
22 opportunity to try to prove that, even if the Court concludes
23 that we would need to make an additional evidentiary showing on
24 that point.

25 *THE COURT:* Okay.

1 MR. PETROSINELLI: Your Honor, that is totally wrong.
2 That is not the legal standard in the Eleventh Circuit, but
3 unless you want to hear that now, I will save that until
4 tomorrow.

5 THE COURT: We will save that for tomorrow, something
6 to look forward to. I am going to wind down. I just have a
7 couple more.

8 This is for the Plaintiff. The Defendants have cited
9 to or quoted a couple of times, I have one time, but I think it
10 was two times, that things that the Plaintiffs have said in
11 their briefing -- the Plaintiffs' motions, which we are going
12 to hear next week, so one example is on page 67 of Docket Entry
13 5868, and I don't expect you to have right at your fingertips.

14 It reads: Plaintiffs' general causation theory in
15 this litigation is for long-term use of Ranitidine. The claim
16 is not that Ranitidine causes cancer after one dose or even a
17 year's worth, but over many years of regular use, and it goes
18 on.

19 So, my question is: Do you agree that I can rely upon
20 those statements even though you made them in your motion when
21 I am considering the Defendants' motion?

22 I guess it would be vice versa, if I can rely upon
23 something the Defendants may have said in response to your
24 motion in their motion, but it arose today in the context of
25 statements that the Plaintiffs made in their motion.

1 I want to get your position that you don't disagree
2 that I could rely upon this is something the Plaintiffs have
3 said, albeit in their motion, when I am considering the
4 Defendants' motion, and the Plaintiffs' position vis-a-vis the
5 Defendants' motion.

6 MR. HEINZ: Your Honor, at previous hearings you said
7 that an LDC member could give an answer, and then if it is
8 wrong, can be rescued.

9 THE COURT: This is your free pass. Do you want to
10 take a stab at it?

11 MR. HEINZ: I'll give a free pass answer, and then if
12 Mr. Gilbert or Ms. Finken disagree, they can swoop in.

13 Certainly the briefing began as a unified whole, there
14 are a number of cross references, and sometimes even citations
15 to exhibits, and so there is certainly no intent to take an
16 inconsistent position, and as far as the record, we would say,
17 you know, you could consider both of them holistically.

18 As far as the judicial estoppel question or something
19 in there, I don't have a clear view on that. I do think, you
20 know, it would be potentially a little unfair if in fighting
21 for general causation where there might be a conflict of
22 interest with a particular Plaintiff who has maybe a theory
23 that is not mainline, it might be a little bit unfair to hold
24 that against them, but that might need to be briefed at a later
25 point.

1 *THE COURT:* Okay. I am trying to understand the
2 answer. I can use what the Plaintiff said or not?

3 *MR. HEINZ:* You can use it to the same extent as if it
4 appeared in the briefing for this motion.

5 *THE COURT:* All right. Anybody standing up to -- no
6 supplement. Okay. You did well, no swooping in.

7 So, again for the Plaintiffs, in your opening
8 introduction, or maybe two of your slides cited to, I think,
9 the Wagner study that I think it was published after the
10 general causation expert reports were rendered in this case,
11 and I think you might have even noted that.

12 But I want to make sure you agree that I can't
13 consider a study when it didn't form the basis of any expert's
14 opinion, and no one has moved to amend expert reports or things
15 of that nature. Would you agree with that, from the
16 Plaintiffs.

17 *MS. FINKEN:* Your Honor, are you referring to the Wang
18 study?

19 *THE COURT:* Maybe the Wang, it was 2020. It wouldn't
20 have been 2022, it was 2020. I don't remember what screen it
21 was. You know what I am speaking about, and would you agree
22 that your experts didn't rely upon that, and therefore I can't
23 really consider it?

24 *MR. HEINZ:* Yes, and I don't believe it was cited in a
25 report, it has not yet been published. If it were to be

1 published, we might try very quickly to move to supplement, but
2 the limited point for which it was put forward was just this is
3 sort of fast developing, and nowhere near as settled as far as
4 what the outside experts beyond the litigation have concluded,
5 and for that limited purpose.

6 As far as acceptance, we think you can consider it
7 just because it goes to rebutting the Defendants' arguments
8 rather than something that the expert herself relied upon.

9 *THE COURT:* To clarify, I can or cannot consider it?

10 *MR. HEINZ:* Our position is you can --

11 *THE COURT:* Do you have an argument separate from the
12 study in other words that you are using in your rebuttal? The
13 study, which isn't finalized and hasn't been relied upon by any
14 of your experts, I can't rely upon it.

15 *MR. HEINZ:* That is right. The limited point for
16 which we cited it was something like this is not a settled
17 issue, and it is sort of atmospherically relevant to the extent
18 you might otherwise think that some of the issues are settled,
19 but certainly not as a basis of any expert's opinion.

20 *THE COURT:* Okay. It was Wang, and it was 2022, so I
21 got the year wrong and the name of the study wrong.

22 *MR. CHEFFO:* Your Honor, I think the answer to that
23 was they agree you can't rely on it, it wasn't published, it
24 hasn't been peer reviewed, it hasn't been relied on by the
25 experts.

1 *THE COURT:* Right. To the extent the Plaintiffs have
2 another support for that argument, I suppose you will point to
3 Court to whatever support at some point. I am not going to
4 rely upon Wang 2022 for that proposition.

5 *MR. HEINZ:* Yes, your Honor.

6 *THE COURT:* For the Plaintiffs, Defendants made the
7 point that in other studies that Dr. McTiernan has authored or
8 coauthored she used followup times that were shorter than the
9 followup times in the Ranitidine epidemiology studies.

10 I wanted to know if you have a response to that.

11 *MR. RONCA:* Your Honor, Jim Ronca for the Plaintiffs.
12 In 400 studies, you could find some studies that are shorter
13 and some studies that are much longer. I think they cited to
14 three.

15 You could do the same thing with how statistical
16 significance, 0.05, or confidence levels are dealt with.
17 Because you have coauthors, you have journals with different
18 requirements, so could you find some studies where they might
19 have said if it is not statistically significant, there is no
20 association. You could find the opposite.

21 I know in our briefing we pointed out that there were
22 times when Dr. Chan, for example -- I think we pointed out five
23 examples where he had a result that was not statistically
24 significant that he called an association in his studies. We
25 throw that around a lot, his study, her study.

1 Sometimes you are the senior author or sometime you
2 are the first author, sometimes you are very involved,
3 sometimes you are only applying data. To pull three studies
4 out of the air and say this is inconsistent with everything she
5 has done -- she has done 400 studies, she was cross-examined
6 for 11 hours. If that is the best you've got, it is not that
7 much.

8 *THE COURT:* Would your answer be the same for Dr.
9 Moorman?

10 *MR. NIGH:* Your Honor, I would add one more thing. It
11 was also a one dimensional examination, only looking at
12 followup. We didn't look at the other issues that may have
13 made it a more reliable study.

14 *THE COURT:* I was just asking about followup. I
15 recognize that. Would it be the same general answer on Dr.
16 Moorman as well?

17 *MR. HEINZ:* Yes, your Honor, with a modification that
18 it is 150 instead of 400. I will say I don't specifically
19 recall the examples being in the brief, so we didn't have time
20 to canvass the 150 to find counter examples.

21 To the extend the Court finds that to be a
22 particularly persuasive bit of evidence, we might ask to be
23 able to look that up and give counter examples if it wasn't in
24 the briefing, but we think the correct response is that it
25 really isn't very probative.

1 *THE COURT:* This will be my final question for this
2 evening.

3 For the Plaintiffs, earlier in the presentations
4 Plaintiffs made the representation that Dr. McTiernan did not
5 rely upon a crude number in the Norgaard study even though she
6 had the opportunity to do so. I think the argument by
7 Plaintiffs was, and I may be paraphrasing, if Dr. McTiernan
8 wanted to cherry pick the data, she would have relied upon the
9 crude number, which was higher, but instead she relied upon the
10 adjusted number, which was lower.

11 You might need to take the evening and get back to me
12 tomorrow, but I wanted you to show me, if you could, where in
13 her expert report she states that she used the adjusted
14 non-crude number. From my review, she seems to reference both
15 numbers when discussing the study, that is the Norgaard study,
16 but does not clarify which number was the one she used for her
17 analysis.

18 I wasn't able to find anything on this topic in her
19 deposition either. Is that something you could look at, unless
20 you know the answer?

21 *MR. RONCA:* I don't know the answer off the top of my
22 head, your Honor. We will look at it tonight, but the argument
23 was in response to what the Defendants said, but I will look at
24 it tonight.

25 *THE COURT:* Okay. You will be happy to know we will

1 call it an evening. That might cut out some of the question
2 time for tomorrow. So, maybe for those of you who are
3 presenting, and you think you are starting at 10:00 for your
4 presentation -- I know you will be here at 9:00 anyway, but we
5 might start your presentation a little early.

6 It sounds like Defense is going to get back to me on
7 answers to that question about that one chart, and if the
8 Plaintiffs have any followup on what I just asked, and if I
9 think of another question or two between now and tomorrow, I
10 might have another question or two.

11 I suspect we should be able to start the presentations
12 a little earlier than 10:00. Again, tomorrow we are starting
13 with the remaining expert motion, which is at 5696.

14 So, with that, you all are really anxious to go. You
15 are all standing, let the record reflect, and have a nice
16 evening. Go get something to eat and relax everybody, and get
17 a good night's sleep.

18 (Thereupon, the hearing was concluded.)

19 * * *

20 I certify that the foregoing is a correct transcript
21 from the record of proceedings in the above matter.

22
23 Date: September 24, 2022

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

25 Signature of Court Reporter

Pauline A. Stipes, Official Federal Reporter

MR. BROWN: [5] 132/20 132/23 160/1 160/9 162/14 MR. CHEFFO: [12] 5/11 103/20 260/10 260/22 261/7 262/2 262/9 262/13 262/16 263/5 264/9 281/21 MR. HEINZ: [12] 206/19 206/22 206/25 277/13 279/5 279/10 280/2 280/23 281/9 281/14 282/4 283/16 MR. HOLIAN: [10] 165/17 165/22 166/3 166/6 176/16 254/1 254/3 270/24 271/11 273/24 MR. NIGH: [33] 77/5 77/9 97/20 100/1 250/7 253/15 265/1 265/8 265/13 265/20 266/2 266/12 266/25 267/7 267/18 268/2 268/11 268/18 268/21 268/25 269/13 270/8 272/4 272/7 272/16 273/1 273/6 275/1 275/4 275/20 276/5 276/23 283/9 MR. PETROSINELLI: [5] 40/5 40/7 101/13 162/13 277/25 MR. RONCA: [6] 177/2 177/4 206/16 261/9 282/10 284/20 MS. CANAAN: [4] 106/17 109/24 110/2 253/20 MS. FINKEN: [4] 55/10 55/13 260/8 280/16 MS. LUHANA: [3] 239/11 239/13 273/8 THE COURT: [95] 2/17 40/4 40/6 54/23 55/9 55/12 77/3 77/8 97/18 99/24 101/8 103/19 105/20 106/10 109/21 109/25 132/18 132/22 159/25 160/8 165/14 165/20 165/25 166/5 176/13 176/17 176/22 177/3 206/15 206/17 206/21 206/24 239/6 239/12 250/6 253/14 253/18 253/22 253/25 254/2 259/8 260/9 260/11 261/3 261/8 261/19 262/4 262/11 262/15 262/21 263/6 264/11 265/2 265/9 265/17 265/21 266/8 266/18 267/2 267/14 267/23 268/7 268/14 268/19 268/22 269/1 269/14 270/18 271/10 271/21 272/6 272/8 272/22 273/4 273/7 273/19 275/3 275/18 275/21 276/18 277/24 278/4 279/8 279/25 280/4 280/18 281/8 281/10 281/19 281/25 282/5 283/7 283/13 283/25 284/24 . .05 [1] 84/12 .31 [1] 175/15 .31755 [4] 266/12 268/21 271/10 271/19 .31755 milligrams [1] 266/12 .79 [2] 268/16 268/20 .79 milligrams [2] 268/16	268/20 / /s [1] 285/24 0 0.05 [1] 282/16 02924 [1] 3/4 1 1,000 [1] 248/13 1,039 [1] 91/3 1,095 [6] 95/25 250/25 251/1 251/4 251/9 251/12 1,096 [1] 250/25 1.0 [13] 107/13 107/14 107/15 124/1 127/19 128/15 128/17 129/5 129/7 129/15 129/19 161/2 198/21 1.05 [1] 129/19 1.06 [2] 128/22 129/19 1.11 [1] 228/22 1.12 [1] 228/23 1.2 [5] 211/9 211/15 228/23 228/24 232/4 1.24 [1] 235/15 1.3 [1] 228/17 1.4 [3] 128/12 128/23 274/11 1.47 [1] 228/24 1.5 [3] 128/10 160/23 161/2 1.56 [1] 228/22 1.6 [3] 128/10 128/15 228/17 10,095 [1] 275/14 10.08 [1] 266/23 100 [1] 231/24 10016 [1] 1/24 10036 [2] 2/3 2/13 108 [1] 228/20 1095 [1] 2/13 10:00 [2] 285/3 285/12 10:18 [1] 55/3 10:33 [2] 55/4 55/7 11 [7] 11/1 35/21 164/6 168/10 170/1 243/2 283/6 11 percent [1] 88/1 1100 [1] 241/17 1113 [1] 1/25 1130 [1] 1/15 1185 [1] 2/2 11:45 [1] 106/1 121 [1] 197/23 127 [1] 190/25 128 [1] 190/25 12:00 [1] 106/2 12:45 [2] 106/1 106/14 12th [2] 1/24 2/5 13 [2] 1/14 186/4 13-hour [1] 185/24 130 [1] 177/15 1300 [1] 1/20 132 [1] 197/24 136 [1] 163/13 137 [1] 163/14 1372 [1] 236/11 14 [5] 62/15 108/10 160/1 217/11 217/11 142 [2] 88/8 88/11 15 [13] 4/2 19/16 55/2 88/18	88/22 105/24 144/16 165/19 165/24 166/3 174/19 176/14 229/22 15-minute [1] 176/18 150 [10] 96/1 194/24 205/17 206/1 208/6 216/9 231/24 251/8 283/18 283/20 150 milligrams [2] 210/5 251/7 150.5 [1] 45/9 16 [2] 158/18 202/1 160 percent [1] 89/4 1600 [1] 1/14 1650 [1] 2/9 18 [2] 3/23 14/2 18 percent [1] 218/23 180 [1] 216/2 182 [1] 251/14 1841 [1] 1/22 188:12 [1] 245/21 18th [1] 1/14 19 [5] 158/17 158/19 235/12 235/18 235/19 19103 [2] 1/15 2/10 191:17 [1] 245/22 1978 [2] 58/14 59/1 1987 [2] 59/7 59/8 1998 [1] 249/12 1:00 o'clock [1] 106/14 2 2.0 [4] 160/23 161/8 200/21 203/17 2.07 [1] 266/5 2.16 [1] 228/24 2.25 milligrams [1] 269/6 2.4 [2] 232/22 232/25 2.5 [3] 268/10 268/16 268/20 2.82 [1] 228/23 20 [11] 53/23 97/24 165/17 165/18 168/8 168/10 186/9 202/1 208/9 211/10 238/2 20 percent [1] 218/23 20-md-02924 [1] 3/4 20-md-02924-ROSENBERG [1] 1/3 200 [1] 205/17 2000 [1] 257/25 20005 [2] 1/21 2/6 2001 [1] 99/21 2002 [7] 60/4 60/7 60/13 60/15 60/17 60/18 61/17 2005 [4] 111/20 204/21 205/1 205/7 2007 [3] 204/21 205/2 205/7 2011 [1] 85/7 2012 [1] 245/3 2015 [4] 111/21 111/23 112/1 205/1 2016 [2] 84/12 111/3 2018 [1] 204/23 2019 [10] 61/7 61/20 61/25 90/12 104/16 136/24 159/5 159/8 159/11 159/12 202-434-5567 [1] 2/6 202-918-1841 [1] 1/22 2020 [8] 3/23 14/25 90/4 261/12 268/5 276/12 280/19
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2 2020... [1] 280/20 2021 [3] 4/2 5/2 156/19 2022 [10] 1/5 4/1 4/4 60/21 61/4 264/16 280/20 281/20 282/4 285/23 21 [4] 1/5 4/1 186/9 219/14 212-790-5351 [1] 2/3 215-656-3307 [1] 2/10 215-735-1130 [1] 1/15 218 [1] 267/25 22 [3] 4/4 4/24 60/16 22 percent [1] 87/9 220 [1] 269/7 221 [3] 175/2 265/6 265/7 223 [4] 175/1 175/1 264/15 264/24 23 [2] 14/1 60/16 24 [2] 264/16 285/23 240 [1] 241/19 25 [2] 4/22 61/20 25 institutions [1] 11/2 25th [1] 228/2 27 [1] 175/23 28 [1] 168/7 2:55 [1] 176/18	47 [5] 43/23 44/1 44/4 103/6 103/9 49 [1] 216/22 5 5.5 million [1] 163/21 50 [7] 3/7 57/10 63/9 114/9 195/8 206/18 211/11 500 [1] 67/15 5000 [1] 2/9 51 [1] 100/2 52 [2] 81/7 81/7 5351 [1] 2/3 5567 [1] 2/6 56 [1] 244/22 56 percent [1] 87/22 561-803-3434 [1] 2/17 5696 [1] 285/13 5699 [3] 4/13 106/4 106/16 57 [3] 99/16 254/11 254/13 5868 [1] 278/13 59 [3] 77/6 254/11 264/21 5912-5 [1] 261/22 5915 [1] 4/15 5958 [1] 4/16 5:20 [1] 253/23 6 6.5 [2] 274/12 275/11 60 [2] 84/18 195/1 60 percent [2] 70/23 252/2 600 [3] 1/24 67/15 90/25 600 milligrams [1] 194/25 64 [1] 245/5 65 [1] 4/2 67 [1] 278/12 7 7 million [3] 12/17 12/19 12/22 70 [1] 177/16 70130 [1] 1/18 702 [8] 102/8 102/13 107/20 172/1 236/6 257/25 258/4 259/7 725 [1] 2/5 730 [1] 251/1 75 [2] 96/1 216/9 75 milligrams [2] 194/24 210/5 75th [1] 228/2 8 80 [3] 129/14 129/16 218/21 800 [1] 277/20 82 [1] 28/20 82 percent [1] 88/25 83 [1] 28/21 83 percent [4] 218/9 218/9 220/17 221/7 84 [1] 247/19 850-435-70130 [1] 1/18 860 [2] 158/7 159/15 873 [1] 255/24 878 [1] 91/1 888-480-1113 [1] 1/25 890 [1] 159/15	9 9 percent [1] 88/12 90 [3] 100/19 125/14 195/1 900 [1] 103/5 91 percent [1] 88/15 912 [1] 91/2 961 [1] 237/4 962 [1] 237/4 963,000 [1] 13/11 989 [1] 91/2 9:00 [1] 285/4 A a high [1] 215/4 abandoned [1] 163/17 abandons [1] 171/12 Abilify [14] 42/5 52/10 52/12 52/13 67/5 67/17 67/24 179/16 180/19 201/11 207/15 236/9 236/11 238/21 ability [1] 199/4 able [20] 17/21 32/25 92/17 93/5 94/8 114/22 140/17 146/23 147/8 157/4 189/9 191/10 207/3 211/15 217/25 217/25 239/8 283/23 284/18 285/11 about [330] above [14] 101/12 107/13 107/15 124/1 129/10 129/19 131/25 135/9 161/2 228/22 237/24 238/11 273/12 285/21 absence [3] 99/8 190/15 190/20 absent [1] 50/7 absolute [3] 175/16 230/7 271/9 absolutely [7] 111/24 115/9 128/19 130/13 216/24 237/5 237/9 absorption [1] 100/9 abstract [3] 119/5 119/20 180/11 abstracts [2] 90/11 92/10 abundance [3] 50/11 56/12 56/15 academic [1] 148/19 accept [1] 141/22 acceptable [6] 71/10 105/8 158/19 246/17 256/11 260/7 acceptance [6] 17/19 133/23 134/2 257/22 257/23 281/6 accepted [11] 10/25 18/5 19/14 39/19 57/18 58/2 63/10 178/12 179/15 229/5 257/24 accepts [1] 155/25 access [2] 226/14 250/21 accomplished [3] 14/16 20/7 38/5 accord [1] 131/17 according [4] 114/15 143/6 153/10 203/24 account [10] 22/22 34/13 36/1 36/3 36/7 53/1 191/7 229/13 242/25 268/11 account is [1] 191/7 accounted [2] 211/17 212/2
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