

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 22, 2022
8 .
9 .

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

13 FOR THE PLAINTIFFS:

14 **TRACY A. FINKEN, ESQ.**
15 **JAMES R. RONCA, ESQ.**
16 Anapol Weiss
17 One Logan Square
18 13 N. 18th Street Suite 1600
19 Philadelphia, PA 19103
20 215-735-1130

21 **DANIEL NIGH, ESQ.**
22 Levin Papantonio Rafferty
23 316 South Baylen Street
24 Pensacola, FL 32502
25 850-435-70130

ROBERT C. GILBERT, ESQ.
Kopelowitz Ostrow Ferguson
Weiselberg Gilbert
2800 Ponce de Leon Boulevard
Suite 1100
Miami, FL 33134
305-384-7270

NOAH HEINZ, ESQ.
Keller Lenkner LLC
1300 I Street N.W.
Suite 400E
Washington, DC 20005
202-918-1841

ROOPAL P. LUHANA, ESQ.

Chaffin Luhana LLP
600 Third Avenue 12th Floor
New York, NY 10016
888-480-1113

FOR THE DEFENDANTS:

ANDREW T. BAYMAN, ESQ.

King & Spalding LLP
1180 Peachtree Street Suite 1600
Atlanta, GA 30309
404-572-4600

WILL SACHSE, ESQ.

Dechert LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104
215-994-4000

JESSICA B. RYDSTROM, ESQ.

Williams & Connolly
725 12th Street NW
Washington, D.C. 20005
202-434-5567

JOSEPH G. PETROSINELLI, ESQ.

Williams & Connolly
725 12th Street NW
Washington, D.C. 20005
202-434-5567

LOREN H. BROWN, ESQ.**MATT HOLIAN, ESQ.**

DLA Piper LLP
1650 Market Street
Suite 5000
Philadelphia, PA 19103
215-656-3307

MARK S. CHEFFO, ESQ.

Dechert LLP
Three Bryant Park
1095 Avenue of the Americas
New York, NY 10036

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Official Court Reporter: Pauline A. Stipes

HON. ROBIN L. ROSENBERG
West Palm Beach/Ft. Pierce, Fl
561-803-3434

Pauline A. Stipes, Official Federal Reporter

1 *THE COURT:* Good morning, everyone. You came back.
2 Let's get all of our equipment on.

3 Let's start with this: The magnifying glass that we
4 needed to review the chart that we discussed yesterday, but we
5 were going to pick up with today.

6 So, for the record, we all know why we are here. We
7 are here because we are continuing to discuss, in 20-md-02924,
8 the Daubert motions and we have a few carryover questions from
9 yesterday's epidemiology motion, and as I stated on the record
10 last evening, we are going to go into the remaining experts
11 motion.

12 We had cabined a little bit of time this morning, I
13 don't intend to use the full hour before the remaining expert's
14 motion begins.

15 So, I previewed my questions, so if you know the
16 answers to them, Mr. Cheffo, I want to let you just respond.

17 *MR. CHEFFO:* Thank you, your Honor. My partner, Mr.
18 Sachse, is going to address the issue if that is okay with the
19 Court.

20 *THE COURT:* Sure. Did we have to fly him in for this?

21 *MR. CHEFFO:* No, he has been sitting here.

22 *THE COURT:* Do you need me to repeat anything or did
23 you make note of the questions?

24 *MR. SACHSE:* No, your Honor, I did make note. Thank
25 you. Will Sachse for GSK.

1 I thought what made sense is to start by putting this
2 document in context and explaining the background and giving
3 you the timeline.

4 So, this document was created in 2019, it was after
5 the Valisure Citizen Petition first disclosed levels of NDMA in
6 Ranitidine, and regulators around the world, including EMA,
7 asked GSK and others to look into whether and why NDMA was
8 forming.

9 This master data sheet is kind of like the rough draft
10 work sheet that is to answer that question.

11 What happened was GSK, working with some outside labs,
12 they went through and collected samples from around the world
13 and tested those samples and collected the results on the
14 master data sheet. Once that baseline testing was done, GSK
15 essentially exported the data into what is known as the root
16 cause analysis, or RCA.

17 That root cause analysis is a very lengthy document,
18 about 150 pages, lots of figures, lots of tables, analysis
19 designed to answer the questions of is there NDMA in this
20 product; and if so, why?

21 That document ultimately gets shared with the
22 regulators, with EMA and FDA, and in an extra step the GSK
23 scientists who worked on the root cause analysis submitted the
24 work they had done for peer review and that ended up getting
25 published in 2020 in what is known as the King paper.

1 I am not sure, Judge, if anybody attached the King
2 paper as an exhibit to any of our motions, but I know we have
3 both cited it, and we have cited it in our brief, the Najafi
4 brief. That's DE 5698, at page 49, and the Plaintiffs in their
5 general cause challenge, that's DE 5841, footnote 83, page --
6 can't read my handwriting -- 58, maybe.

7 If your Honor does not have a copy, I actually have a
8 copy that my colleague just ran over here. I would be happy to
9 hand it up. It is useful to look at and to help put all of
10 this in context.

11 *THE COURT:* What is the name of it?

12 *MR. SACHSE:* We call it King.

13 *THE COURT:* You say it is part of the record?

14 *MR. SACHSE:* It is part of the record, your Honor.

15 *THE COURT:* Do you have a copy for Plaintiffs as well?

16 *MR. SACHSE:* Sure do.

17 *THE COURT:* That would be helpful to get from you.

18 Thank you. Great, thank you. Okay.

19 *MR. SACHSE:* So, with that background, maybe we can
20 walk through the chart. I see you have your magnifying glass
21 out.

22 *THE COURT:* You sure need it, it is so small. Maybe
23 it is the way I printed it out.

24 *MR. SACHSE:* It is not you, your Honor. I will have
25 to take my glasses off because I can't see it either.

1 The other thing -- do you have a color copy of this?

2 *THE COURT:* I don't. Do you have one?

3 *MR. SACHSE:* I do.

4 *THE COURT:* Do you have one for the Plaintiffs?

5 *MS. LUHANA:* I can see it on the screen.

6 *THE COURT:* Are you going to be putting it on the
7 screen or working off the hard copy?

8 *MR. SACHSE:* Working off the hard copy.

9 *THE COURT:* You all are younger at that table, so you
10 probably can see it. Okay.

11 *MR. SACHSE:* Okay. Hopefully, as we go through this,
12 I will hit all of your questions, but I am sure you will let me
13 know if we don't.

14 *THE COURT:* Okay.

15 *MR. SACHSE:* So, what I thought, just to orient you,
16 this is the master data sheet, this is the raw data that is
17 coming in when GSK and its outside research labs are testing
18 the product. You asked the question, was this an effort to
19 test API or finished product? The answer is both, and that is
20 what is recorded here.

21 So, just kind of starting at the left hand, and a
22 couple columns I want to focus on that are of particular
23 importance, the first is the third column, which is the
24 formulation, and that is what it says on the ten, was the
25 product tested a syrup, a tablet, or injection.

1 The second column that I think is important is about
2 halfway across, and that is the API manufacturer name.

3 You will see there are a number of different names
4 here, Saraca, S-A-R-A-C-A, Orchev, O-R-C-H-E-V, SMS, and a few
5 entries on the last page Jurong, J-U-R-O-N-G.

6 So what are these different API manufacturers?

7 To understand that we have to do a mini history lesson
8 about how GSK made its product.

9 For the overwhelming majority of the time GSK was
10 making and selling Zantac in the United States it made its
11 own API, and it made its own API in the Jurong facility in
12 Singapore. So, the Jurong facility would make the API and then
13 it would get shipped to other markets, including the United
14 States, where it would be made into finished product and then
15 shipped out to markets in the U.S.

16 So, from 1983, '84 to about 2012, Jurong is the sole
17 exclusive manufacturer of API that GSK is using.

18 Beginning in 2010, 2011, 2012, as this product is sort
19 of aging in its life cycle GSK explores using other suppliers
20 of API for the U.S. market, gets approval from the FDA in 2010
21 to use Dr. Reddy's.

22 Starting in 2012, GSK is using Dr. Reddy's and a
23 little bit of Jurong's API to make its product for the United
24 States market. Jurong stops making API in 2014, and from 2014
25 through 2017, in the U.S. GSK is using only Dr. Reddy's API.

1 Why did I go through all of that? Because if you look
2 at this six, seven page master beta sheet you will see a whole
3 lot of Dr. Reddy's, a whole lot of Saraca, some Orchev, some
4 SMS, a smattering of Jurong, all on that last page and we
5 submit that the Jurong API is what really matters, and the
6 Jurong product is what really matters in this litigation.

7 If you think about that time period, 1983 to 2012,
8 that is going to capture every -- or almost every Plaintiff in
9 this litigation in terms of the product that they got, the API.
10 Okay. So, that is why I wanted to highlight that column. I
11 will come back to that in a little bit.

12 I also should mention Saraca, Orchev, SMS never came
13 into the U.S. market. When you see Saraca results, it has
14 nothing to do with any product that ever would have been in the
15 U.S. market.

16 The next column that I think is important to highlight
17 is date of API manufacture, and that is important because these
18 products have expiration dates. One thing I learned in the
19 course of this litigation that was a little bit surprising is
20 that the expiration date can depend on which region you are in.

21 For the United States, and this is all done in
22 connection with the FDA, the expiration date for API is two
23 years and the expiration for a finished product is also two
24 years.

25 So, this chart can be a little bit confusing in that

1 regard because when you look at, for example, the API
2 expiration date, manufacturing date and expiration date, it
3 suggests a five year expiry period, when in fact in the U.S.
4 market the expiry is much shorter.

5 Now let's get to the testing. You see there is that
6 blue column and then a pink column next to it.

7 *THE COURT:* The API NDMA content?

8 *MR. SACHSE:* You got it. And now I have to take my
9 glasses off.

10 So, the API NDMA content and then the finished product
11 NDMA content.

12 What the company did, they went and collected finished
13 product to test, to do baseline testing. They also then, if
14 there was API that was used to make that product, they tested
15 the API, and the results are just tabulated here.

16 To interpret this, these numbers might be strange
17 because it is recorded in micrograms per gram, which is not
18 something that we are normally talking about in this
19 litigation. Usually we are talking about nanograms or PPM, so
20 the way I think of it is the translation essentially is
21 micrograms per gram is the same thing as PPM.

22 If you remember, the FDA, when it talked about the 96
23 nanogram average daily intake threshold, that is equivalent to
24 .32 PPM. So, when you are looking at micrograms, you can
25 consider this column PPM, and if it is .32 or below, that is

1 below the average daily intake number, that 96 nanograms. If
2 it above, it is above.

3 So, looking at the API column, those results for all
4 of the API that they got from all of the different suppliers,
5 including that handful of API they had from Jurong, they tested
6 that and record the results here.

7 They also tested, as I said, the finished product. So
8 you have results of finished product that don't line up with
9 the results for the API. And I think one question you asked
10 was, I am looking at this chart, and why is it that sometimes I
11 see the API seems to be higher than the finished product? And
12 I think -- there are a couple of answers.

13 One that I think scientists and lawyers don't like to
14 give, which is nobody is really entirely sure. What we know,
15 and what the scientists know from studying this, is that when
16 API gets made into a finished product, it seems to slow down
17 this degradation process.

18 So what is likely to have happened is, if you have API
19 sitting on the shelf and you take some of that API and you turn
20 it into product, then you have the API continuing to degrade at
21 a certain rate, the finished product perhaps degrading at a
22 slower rate, and that might explain the gap, but as I said, the
23 scientists at GSK at least, when they looked at this, no clear
24 conclusions.

25 The other thing to keep in mind, or two points to keep

1 in mind about this, is, one, there is no real consistent
2 pattern. I can't say that I went through and did a really
3 comprehensive analysis of this, but you can see just eyeballing
4 it there are results all over the lot.

5 So, sometimes the API is lower -- the API result is
6 lower than the finished product result, sometimes it is the
7 other way around. There is no real consistent pattern.

8 The other important point to keep in mind is that no
9 patient is buying API, patients are buying the finished
10 product. So the finished product results are sort of what
11 would be more apropos here.

12 So, that is kind of the chart.

13 What I would like to do is, if you flip to the last
14 page of the chart, that is where the Jurong results are, and as
15 I said, there are not that many. I did draw little arrows to
16 guide you to the columns that -- or the rows that have Jurong.

17 *THE COURT:* Yes.

18 *MR. SACHSE:* The important take-away with Jurong here
19 is that the -- I should say first of all, the rate of
20 degradation for this product is very slow overall, but for
21 Jurong, the rate of degradation is particularly slow.

22 So, when you look at the numbers, they are really,
23 really low. In most instances they are below that .32, there
24 are a couple that are a bit above, but we also need to keep in
25 mind when this testing was done in 2019, that API was made in

1 2014, so this is expired API. This is expired product in the
2 U.S. market that is being tested, and that is very low compared
3 to results that are definitely much, much higher, and we
4 acknowledge that.

5 There are Dr. Reddy's and some Saraca that are much
6 higher, but that Jurong product seems to test very, very low,
7 and this is an interesting question for the scientists. They
8 look at it and they say, what is different about Jurong?

9 It turns out that what seems to be different with
10 Jurong is that GSK took an extra step when making the API at
11 Jurong, and this extra step GSK scientists believe turned the
12 crystals into a more stable morphology. If you look at the
13 King paper, there are actually some pictures that show the
14 difference.

15 I will say that this is disputed. I think Dr. Najafi,
16 we'll hear about him later, he takes a couple of shots at it,
17 but this is at least GSK's conclusion, that there does seem to
18 be a difference in the structure, and GSK attributes that to
19 this extra step that makes the API that GSK is making more
20 stable than, for example, the Dr. Reddy's.

21 Another thing that I think is sort of very striking,
22 if you look on page three of the King paper, in the bottom
23 right-hand column there is a graph -- I will wait until you get
24 there.

25 *THE COURT:* Yes.

1 MR. SACHSE: That shows -- this is a compilation of
2 the results that GSK collected in its root cause analyses, and
3 you see those green -- very, very low green dots. That is the
4 Jurong stuff, and then you see these peaks and valleys and much
5 higher results. That is the product made with other
6 manufacturers' API. So, that is another important take-away
7 from this root cause analysis.

8 Last piece on the root cause, the GSK scientists
9 concluded that, as I mentioned, this is a slow degradation
10 pathway, and for the Jurong product in particular, GSK
11 calculated that the rate would be about .04 micrograms per
12 gram, PPM, per year, so very, very slow degradation to NDMA.

13 So this is all baseline testing, meaning you take the
14 product off the shelf, you test it immediately, that is the
15 results you get, and before I forget, you asked the question
16 about the strike throughs.

17 THE COURT: Right.

18 MR. SACHSE: The strike throughs are, whoever was
19 taking this information from the data sheet and exporting it
20 to the root cause analysis framework, when they exported it,
21 they crossed it through to say, okay, now I have exported data
22 value one, data value two, et cetera. So that is why you see
23 those strike throughs. That is all it means.

24 THE COURT: Okay. Unless there is any factual
25 description, because I have a couple more questions, and we can

1 always revisit it at the end of the day of the day, does that
2 cover all of the answers?

3 MR. SACHSE: I think it does, yes.

4 THE COURT: Did the Plaintiffs have a question or
5 comment or anything?

6 MS. LUHANA: I do want to respond to what Mr. Sachse
7 has addressed after he is done.

8 THE COURT: Are we done with the chart?

9 MR. SACHSE: Yes, your Honor, unless you have any
10 other questions.

11 THE COURT: Not at this time.

12 Response.

13 MS. LUHANA: Good morning, your Honor.

14 THE COURT: Good morning. For the record, your name.

15 MS. LUHANA: Roopal Luhana for the Plaintiffs.

16 A couple of things to know about the master data
17 spreadsheet. While it was a working draft, that ultimately was
18 attached to the root cause analysis that was submitted to the
19 FDA. A couple of things to note about the testing that was
20 done.

21 What you see is that the API in tablets both degrade.
22 It seems once a tablet forms it adds more stability and
23 possibly less NDMA may be generated, but once those tablets are
24 exposed to heat and humidity, you see far more NDMA being
25 generated.

1 So, the root cause analysis is in the record. If you
2 look at Table 39, it is page 80, you will see the Jurong
3 samples, when they are exposed to heat and humidity there are
4 thousands of nanograms of NDMA being formed.

5 So, even though Defendants have made this argument
6 that it is this morphology that makes it more stable, the first
7 thing is, for root cause analysis of Jurong there were only a
8 handful of samples that were tested, so we have limited
9 information on that.

10 In addition to that, once it is tablet and it is
11 exposed to heat and humidity far more NDMA is generated.
12 Judge, this is also all new argument. None of this was
13 discussed in the Daubert papers and it is not part of the
14 record.

15 The other thing I wanted to note is the King paper, if
16 you take a look at it, I believe it is page -- so the King
17 paper is what was published by GSK noting the results of the
18 root cause analysis. If you look at page D with Table 1, they
19 report the values that they found in the root cause analysis,
20 which is the drug substance and the tablets; however, you will
21 see the master data spreadsheet has far more values above these
22 numbers than what was published in the King paper.

23 Judge, if you take a look at some of the values you
24 see dozens of samples that are above 435 nanograms in the
25 finished dose. If you look at the API, the highest value

1 reported is 21.4 micrograms per gram, so that comes out to over
2 12,420 nanograms.

3 In terms of the API in tablets, what is important to
4 note is when you take the API at whatever time you are taking
5 it and you are making a tablet from it, the NDMA that is in the
6 API is going to be reflected in the tablet.

7 The only reason you are seeing differences is because
8 the API was made in, let's say, 2015, and the tablets are made,
9 let's say, six months later, so that is the NDMA levels
10 reflected at that time; however, as the API is degrading more
11 NDMA is formed there, but once you are making tablets from the
12 API, it is indicative of the NDMA that is going to be there.

13 I think Mr. Nigh has some additional comments to add.

14 *THE COURT:* Okay. I do want to be mindful of time.
15 We can also save some of the argument for the final arguments.
16 I want to give you a chance to respond because I realize there
17 was a factual explanation, so I wanted you to have an
18 opportunity.

19 Can we hold it?

20 *MR. NIGH:* It is about two minutes and the Defendants
21 just interjected all sorts of arguments, so I would ask if I
22 could briefly do it in about two minutes.

23 *THE COURT:* Two minutes. I am not going to hear back
24 from Defense, so save your points so that you can wrap it up
25 when we have final argument at the end. I didn't want to get

1 into this much of an argument as much as just an explanation of
2 the chart.

3 MR. NIGH: I understand. We just want to use our
4 closing for other issues. It is two minutes.

5 What I wanted to point out is the King study, they
6 want to say that that shows variability based on the API.
7 Those results are only to the API itself. When you look at the
8 root cause analysis, Table 39, and you compare GSK Jurong
9 compared to Saraca of a drug tablet, what you see is that they
10 both act similarly. They both break down due to humidity.

11 I highlight humidity because the heat is a small
12 factor, the majority of it is humidity, and you see that they
13 both break down due to humidity similarly. The numbers for the
14 GSK Jurong at 50 degrees Celsius, 65 percent relative humidity,
15 27,000 nanograms of NDMA. So I wanted to highlight that.

16 THE COURT: All right. Let me move on, if I may.
17 Thank you all for that. If I have any followup questions after
18 I digest everything on one of the breaks, I might come back.
19 If you feel something really needed to be said you could take a
20 minute or two from your final arguments. I want to make sure
21 we get through all of our questions.

22 So let me straddle -- let me see where my other
23 question was. Let's see.

24 Plaintiffs, you were going to get back to me on citing
25 to me any part of the expert report that Dr. -- that says that

1 Dr. McTiernan used adjusted non-crude numbers. As I indicated,
2 from my review she references both numbers when discussing the
3 study and does not verify which number was the one she used for
4 her analysis.

5 If you have an answer to that, can you cite it and
6 read it into the record?

7 MR. RONCA: I can read it into the record.

8 THE COURT: State your name for the record.

9 MR. RONCA: Jim Ronca for Plaintiffs. I can read it
10 and I also have it typed up. All the references are in the
11 typed up part.

12 THE COURT: How long is that there?

13 MR. RONCA: It is a whole page. I have copies.

14 THE COURT: Did you provide a copy to the Defendants
15 as well?

16 So you have the citation?

17 MR. RONCA: Page and number from the deposition and
18 pages from the reports. It is a little chopped up because, if
19 you recall, or maybe you don't recall -- I presume you reviewed
20 everything. The Adami paper was published with an error, the
21 first figure was wrong, so the initial report didn't pick that
22 up, picked up the stuff that was in the published version. The
23 peer reviewers, nobody picked it up.

24 Then there was an addendum report and then there was
25 an additional deposition where that was covered. The

1 explanation is actually in the deposition.

2 THE COURT: Okay. If it is one page, read it slowly
3 into the record.

4 MR. RONCA: Sure. I won't read that explanation, I
5 just said it. For Norgaard, bladder crude and adjusted
6 results. There are three different types of adjusted results.

7 THE COURT: Page and line.

8 MR. RONCA: I'm sorry. Page 184 and 318, page 16 of
9 the rebuttal report for Adami. Report of crude estimates are
10 pages 208 and 332, and there is a smaller subset of continuous
11 prescription adjusted numbers on page 208.

12 For liver, the crude estimates are reported on 226 and
13 341, and the adjusted for continuous prescription subset is on
14 226. For pancreas, the crude estimates are on 240 and 249, and
15 the subset for continuous prescriptions, 240. For stomach, the
16 crude estimates are on pages 259 and 362, and the adjusted
17 smaller subset of continuous prescriptions on 259.

18 The trimming is discussed in pages 103 and 127. These
19 are all in the first report. You should also look at the
20 addendum that was dated May 28, 2022, that discusses the
21 changes in the article from the first published to the
22 corrected published.

23 THE COURT: Are the quotes from the depo on that paper
24 you are reading from, too?

25 MR. RONCA: Yes. Page 730, line 3, to 731, line one;

1 page 731, line 23 to 732, line one; and page 733, line 11 to
2 page 735, line 11.

3 *THE COURT:* Okay. If I could have a copy of that, the
4 same what you gave to Defendants. You put the page and cites
5 in the record now, and you have the quotes there. Okay, thank
6 you.

7 A couple more questions. So, for the Plaintiffs,
8 putting aside legal argument, the legal question about the
9 state of the law with respect to identifying or not having to
10 identify a threshold, the number, I want to know what the
11 Plaintiffs' position is factually, factually in the record
12 evidence as to when does Ranitidine ingestion become toxic.

13 So, again, I know what the legal positions are, but as
14 a matter of record evidence, what is the Plaintiffs' position
15 on that? You know, for example, referring back to your motion
16 at 5868, page 67, there was reference to the statement the
17 Plaintiffs' general causation theory in this litigation is for
18 long term use of Ranitidine. The claim is not that Ranitidine
19 causes cancer after one dose or even a year's worth, but over
20 many years of regular use.

21 Tell me what the Plaintiffs' position is factually in
22 the record as to that question.

23 *MR. NIGH:* Your Honor, we know that it is toxic at
24 least at those cumulative threshold levels.

25 *THE COURT:* Be precise. When you say cumulative

1 threshold level, can you give me numbers?

2 MR. NIGH: Daniel Nigh for the Plaintiffs.

3 Your Honor, we know at the levels calculated on that
4 chart by Dr. Salmon that it causes a statistical significant
5 increased risk as seen in those dietary studies.

6 THE COURT: Just be very precise, because there are a
7 lot of numbers we looked at.

8 MR. NIGH: Page 233 from the Salmon report.

9 THE COURT: What numbers? Give me an example of what
10 you are talking about.

11 MR. NIGH: On the very right side it discusses -- I
12 don't have the table in front of me.

13 THE COURT: The Emery average after consumer storage?

14 MR. NIGH: Yes. So we know that for gastric cancer,
15 1.42 years; esophageal cancer, 1.81 years; bladder cancer, 3.86
16 years; pancreatic cancer, 3.86 years; liver cancer, 6.65 years.

17 THE COURT: That is the Plaintiffs' position as to
18 when Ranitidine ingestion becomes toxic for those cancers, at
19 those time periods?

20 MR. NIGH: We know that it is at least causal at those
21 time periods.

22 THE COURT: What about the amounts?

23 MR. NIGH: I say at least causal because those relate
24 to very high statistically significant increased risk, higher
25 magnitudes of effect. At lower amounts there could still be

1 lower magnitudes of effect.

2 *THE COURT:* What lower amounts? Where would I look to
3 know what you mean by lower amounts?

4 *MR. NIGH:* For example, liver cancer, on the chart on
5 page 221, liver cancer has an OR of 1.96 at those levels
6 demonstrated in the Hidajat study. That means a 96 percent
7 increased risk that is statistically significant.

8 We can see the confidence intervals go from 1.16 to
9 3.29, so at levels lower than what was demonstrated in Hidajat
10 it could still cause cancers, and Dr. Salmon did detailed dose
11 response slopes to demonstrate that.

12 *THE COURT:* Do we have a number associated with that
13 lower number?

14 *MR. NIGH:* The slopes are earlier in the report, but
15 depending on the amount of cumulative NDMA would let you know
16 the amount of increase of the risk, because the risks in
17 Hidajat are linear for liver cancer. So you can actually
18 track -- between those quartiles, you can track all the way
19 through them and see what would your increased risk be at lower
20 levels.

21 *THE COURT:* Are you able to say the levels?

22 *MR. NIGH:* I can. It would take some time. We would
23 be doing a calculation for every level on down and seeing what
24 the increased risk would be.

25 *THE COURT:* Do you want to defer answering the

1 question and maybe include that in your final remarks and think
2 about it and how best to explain it to the Court in a way that
3 the Court can understand?

4 *MR. NIGH:* Yes, your Honor.

5 *THE COURT:* Amounts, dosage, and amount of time.

6 Again, you are not waiving any legal positions you
7 have taken. I am trying to understand what the record evidence
8 is trying to tell the Court, what you are trying to tell the
9 Court through the record evidence.

10 *MR. NIGH:* I should just clarify, we know that it is
11 statistically significant at least at those levels.

12 *THE COURT:* You keep saying those levels, I just want
13 to know what are the levels.

14 *MR. NIGH:* Page 233, again that chart.

15 *THE COURT:* But you say, but they are also
16 statistically significant at lower levels. You said these --

17 *MR. NIGH:* Statistical significance is a function of
18 the design of the study, so, no. But in terms of linearity
19 along the chart you can see what the increased risk would be at
20 lower levels.

21 *THE COURT:* I want to know what are the Plaintiffs
22 relying upon. It may be the numbers are not statistically
23 significant, maybe they are. What are the numbers the
24 Plaintiffs are relying upon for the proposition of ingestion of
25 Ranitidine, when it becomes toxic, the dosage, the duration of

1 time.

2 MR. NIGH: Sure. For general causation, in the right
3 column, these levels let us know. When I say these levels, the
4 right column of page 223, Emery, after consumer storage. These
5 tell us the amount of years that it would take to reach those
6 statistically significant increased levels. So we know that it
7 is carcinogenic at those levels and total dosage is the
8 cumulative amount on the left side, which shows gastric,
9 esophageal, bladder, pancreas, liver. That is under study
10 cumulative milligrams.

11 THE COURT: It is at least that, but it also could be
12 less than that?

13 MR. NIGH: For general causation, we know that it
14 causes cancer at those levels.

15 THE COURT: Do we know that it causes cancer at any
16 other levels for general causation per the Plaintiffs'
17 position?

18 MR. NIGH: I think the Plaintiffs' position is, we
19 don't have to answer that question.

20 THE COURT: I know your legal position, so I am not
21 trying to argue with you about the legal position. I want to
22 know whether there is something in the record that tells me
23 other numbers and periods of time other than we know at this
24 level.

25 MR. NIGH: I do need more time where we can piece

1 together what the slope would tell you the increased risk would
2 be at lower levels.

3 *THE COURT:* Okay. That is what why I brought it up
4 this morning. It is not a gotcha question. I wanted to give
5 you the time to think about it and understand it. If you can't
6 answer it, not that you don't want to answer it, just tell the
7 Court you can't, but if you can, even though I understand you
8 feel you don't have to legally, I appreciate that.

9 *MR. NIGH:* I understand. Thank you, your Honor.

10 *THE COURT:* Okay. And then for both parties,
11 Plaintiffs first, I guess, a hypothetical question. I am going
12 to ask the flip side, so no one panic.

13 For the Plaintiffs, do you agree that if I were to
14 grant the Defendants' motion in its entirety as to Drs.
15 McTiernan and Moorman for all of the reasons that have been set
16 forth in their motion and argued here, that Dr. Salmon, Dr.
17 Michaels, and Dr. Le should be stricken, or would be stricken
18 for the same reasons that Dr. McTiernan and Dr. Moorman were
19 stricken?

20 And in fairness, I am going to be asking the
21 Defendants, do you agree that if I were to deny the Defendants'
22 motion in its entirety as to Drs. McTiernan and Moorman, that
23 the motion should also be denied as to Drs. Salmon, Michaels,
24 and Le?

25 Plaintiffs first. If that is a question you need to

1 think about and you want to answer at the end of the day, that
2 is fine, too. Or do you want to answer it now?

3 Come to the podium, because that is the only way that
4 our Zoom attendees can see you clearly.

5 MR. HEINZ: Noah Heinz for the Plaintiffs.

6 I think the answer is no, and that is because the
7 Defendants have provided a number of different reasons to
8 exclude Drs. Moorman and McTiernan, some of which are
9 particular to Drs. Moorman or McTiernan, depending on
10 particular things that they said in their reports. So, if
11 those reasons do not apply to the other experts then that would
12 be no reason to exclude them.

13 There are some overarching arguments, as an example,
14 saying that the active comparator for Ranitidine studies are
15 definitive and one could not come up with a reliable opinion in
16 light of what those say, if that sort of broad brush argument
17 is the one that carries the day, then it likely would apply to
18 the other experts down the line.

19 That is not the only argument that the Defendants
20 presented, so we'd say you have to look argument by argument
21 based on what they actually said and how it applies to each
22 expert.

23 THE COURT: Okay. If there is anything that you want
24 to elaborate on and have specific examples, you can save that
25 for the final presentation, that would be fine, drawing any of

1 those distinctions as to arguments made as to some and not the
2 others.

3 And from the Defendants.

4 *MR. HOLIAN:* Thank you, your Honor, Matt Holian.

5 The answer to your question is, you should also
6 exclude Drs. Salmon, Le, and Michaels even if you don't exclude
7 Drs. Moorman and McTiernan for the additional reasons that we
8 discussed in our briefs and at argument yesterday. We rested
9 on the papers for Drs. Le and Michaels, so I am happy to
10 discuss that if the Court would like to hear it, but they had
11 additional flaws.

12 But if you grant the motion on Drs. Moorman and
13 McTiernan, you should grant it on the other three for the
14 reasons that we set forth, because they can't show a
15 statistical association free of the bias and confounding that
16 the active comparator studies address. They have offered
17 opinions that are not generally accepted anywhere in the
18 medical community.

19 They haven't offered, other than Dr. Salmon who we
20 have talked about extensively, a threshold dose at which
21 anything is observed.

22 So, you would have to disagree with us on all three of
23 those in order not to exclude Drs. Le and Michaels and Dr.
24 Salmon for the reasons we have identified. Even if you
25 let Drs. Moorman and McTiernan get past that, there are

1 additional flaws that we identified in our papers.

2 *THE COURT:* Thank you. Same for Plaintiffs, if you
3 think of other things that you want to say on that issue for
4 the final arguments, that would be fine as well.

5 Thank you so much.

6 Let's move on now to the remaining expert's motion at
7 Docket Entry 5696, which has also been fully briefed and we
8 have speakers lined up. The group that was coming up -- or
9 maybe one speaker for the Defense, Ms. Rydstrom, who was going
10 to speak at 10:00, but we are starting a little early. It
11 looks like you wanted 15 minutes?

12 *MS. RYDSTROM:* Yes, your Honor. Good morning, your
13 Honor, it's Jessica Rydstrom.

14 The good news, your Honor, is that, given the
15 discussions that we had yesterday about epidemiology, we
16 actually don't think the Court needs to go any further and to
17 reach this particular motion because, as Mr. Holian just
18 explained, if there is no association under the epidemiology,
19 if Plaintiffs' experts, as we believe, can't reliably provide
20 or opine about an association in that epi, then it is the end
21 of the road because Plaintiffs' experts can't bootstrap using
22 what they told you yesterday are these secondary methodologies,
23 they can't use those to fill in holes in the epidemiology that
24 just aren't there.

25 What I am actually going to talk about is why we don't

1 see in the epidemiology that association between Ranitidine and
2 the five designated cancers, because the theories that
3 Plaintiffs' experts have articulated, these unreliable
4 endogenous formation and extrapolation from animal studies,
5 actually help explain why we don't see that in the
6 epidemiology, why it is not working that way in the human body.

7 Next slide, please.

8 These remaining opinions fall into three broad
9 buckets, and I am going to spend my time on the first one,
10 which is the endogenous formation theory.

11 The question here, your Honor, is the one that the
12 Court posed to us, which I will attempt to answer as I am going
13 through this presentation, and that is really why the
14 well-designed studies that we see that have come out recently,
15 what they don't show.

16 What they don't show is what Plaintiffs want to
17 advance here, that NDMA forms endogenously from Ranitidine
18 under real world conditions. That is the focus here, that real
19 world condition.

20 And the reason that is important, your Honor, is, in
21 part, because under real world conditions that we actually see
22 in the human body, if Ranitidine were forming NDMA endogenously
23 under those conditions, well, that would be baked into
24 the epidemiological studies that we talked about for so long
25 yesterday. We would actually see the results of that theory if

1 it were true, but it is not.

2 That real world, real people is actually a nice segue
3 to the second bucket theory that I am going to talk about, and
4 that is Plaintiffs' experts attempts to really stretch these
5 animal theories beyond where they ought fairly to go.

6 We have to be careful about that here because there
7 are very, very real differences between the way that animals
8 behave in studies and the way that NDMA or Ranitidine behaves
9 in the human body. We have problems with dose extrapolation.
10 We have problems taking one species and translating it to
11 another species, and we even have problems, as we see here,
12 your Honor, with there being different tumor sites where we are
13 seeing effects in animals that you don't see in people.

14 Finally, and very, very briefly, I want to talk about
15 that threshold issue. Specifically, not with respect to the
16 discussion that we had yesterday, but to the fact that
17 Plaintiffs' experts here really are trying to advance that
18 theory that any amount of NDMA is essentially too much, and we
19 know under the law that that is not true.

20 Next slide, please.

21 So the endogenous theory. Any discussion of this
22 theory, your Honor, has to start with these guys, Dr. Florian
23 and Dr. Gao. We have heard about them over the course of the
24 year since this paper came out. They are researchers at the
25 FDA who designed, in 2021, studies to answer precisely this

1 question: Is NDMA forming endogenously from Ranitidine in real
2 world conditions? As we can see, both of them answered that
3 question in the negative.

4 I don't actually think, your Honor, that there is a
5 real dispute that this is the starting point for any discussion
6 of the endogenous formation theory. What does it say about
7 Florian?

8 Next slide, please.

9 To be clear, there is no question that the aim of this
10 study was to answer the question that Plaintiffs' experts are
11 sort of fighting against, and that is: Is there an increase in
12 NDMA from Ranitidine inside the body under these real world
13 conditions?

14 What Dr. Florian found when he studied these
15 volunteers was, the answer is no. He found that Ranitidine
16 didn't have a significant increase, a significant affect on the
17 levels of NDMA that were found in the human body, in the urine
18 of these volunteers.

19 I expect that when Ms. Luhana gets up she is going to
20 tell you that there was a near doubling of NDMA in the plasma
21 levels. Your Honor, when you look at the paper, you see that
22 is actually not a statistically significant result.

23 But Dr. Florian did find a statistically significant
24 increase, it is just not the one that Plaintiffs' experts want
25 to focus on here, because what they found was that the thing

1 that actually does increase the amount of NDMA that is formed
2 endogenously in the body is whether or not you have a cured
3 meats diet, high in nitrites and all that bad stuff, or whether
4 you have a non-cured meats diet. That is the statistically
5 significant difference that they found.

6 Next slide, please.

7 The criticism that Plaintiffs' experts lodge here,
8 your Honor, is that it is very hard to find NDMA in urine. I
9 gather that they want to sort of say that it is like catching
10 lightening in a bottle. But Dr. Florian and his colleagues did
11 find NDMA in the urine of the volunteers that they tested and
12 they did find that statistically significant increase that I
13 just mentioned.

14 Again, it wasn't the one that Plaintiffs' experts want
15 to the talk about here. They want to suggest that there is an
16 increase between Ranitidine and placebo. Dr. Florian found
17 that there was not. He found that the thing that statistically
18 significantly increases the amount of NDMA in the urine is
19 going to be that cured meats versus non-cured meats diet.

20 The basis, I gather, for the concern about finding
21 NDMA in urine is this 1982 paper by Spiegelhalder, setting
22 aside that 1982, long time ago, methods have advanced since
23 then, the Florian paper and its findings directly refute that
24 criticism.

25 Next slide.

1 There is a very small amount of criticism, your Honor,
2 that the Florian researchers did their testing on -- gave the
3 Ranitidine on fasting conditions. They did that because one
4 thing that Plaintiffs' experts do get right is, in the litany
5 of studies that they cite about the endogenous formation of
6 NDMA not from Ranitidine, right, how NDMA can generally form
7 endogenously in the body, what those studies find is that you
8 need a very low pH. You need a highly acidic environment.

9 Dr. Florian and his colleagues said, how can we best
10 create that? We should create it with our volunteers on fasted
11 conditions. That is why they did that.

12 Next slide, please.

13 Briefly, your Honor, there are two studies that are
14 cited by the Plaintiffs' experts with respect to the findings
15 of NDMA in urine and Ranitidine. The first one, the Matsuda
16 paper, we can dismiss pretty easily because that paper is
17 actually a study not just of Ranitidine, but of a host of
18 different H2 blockers. It's essentially the class, Cimetidine,
19 Floxatidine, Famotidine, and Ranitidine, and what the Matsuda
20 researchers concluded is actually there was no difference as
21 between those four.

22 The reason I think that is important, your Honor, is
23 because for the two years of this litigation the Plaintiffs and
24 their experts have tried to suggest that there is something
25 uniquely villanous or dangerous about the Ranitidine molecule,

1 that it is special and ripe for nitrosation. What the Matsuda
2 paper shows is that is not true. What we see here is an
3 increase in this paper across those various forms of medicines
4 within the class.

5 Next slide, please.

6 The Krawczynski paper is the other paper dealing with
7 NDMA in urine that Plaintiffs' experts talk about. This was a
8 study in which the researchers took two groups of children, one
9 that had H. pylori infections and one that didn't, and they
10 gave them, importantly, your Honor, not just Ranitidine, but
11 they gave them also two different kinds of antibiotics, the
12 treatment group.

13 They gave them these antibiotics for a period of time
14 and then they stopped the treatment and they waited four to six
15 weeks. So, four to six weeks after that treatment was
16 concluded, not after it started, but after it was concluded,
17 those researchers measured the levels of nitrosamines and found
18 they had increased.

19 Now, which nitrosamines? We don't know because they
20 don't provide us that specific data in the paper, but we do
21 know that whatever it was and whatever caused that increase, it
22 could not have been the treatment that folks hadn't had for
23 four to six weeks before that.

24 Next slide, please.

25 So, I would like to move on to the in vitro, and this

1 is the Gao paper, this is the other of the two big pillars,
2 right, answering this question recently. The main criticism
3 that Plaintiffs' experts have lodged about the Gao paper is the
4 one that Dr. Panigraphy says here, because we asked him, what
5 is physiological? Do you agree that this particular study, the
6 Braunstein study, didn't include any physiological conditions?

7 He says yes, but what he then goes on to say is
8 basically, well, physiological, you have to consider a whole
9 bunch of different things. You have to consider other factors,
10 food, disease, pH, bacteria, but the Gao researchers knew that.

11 Next slide, please.

12 The very first thing that they did when they were
13 doing and concluding their experiment, is they went out and
14 they scoured the medical literature. They looked at studies of
15 endogenous formation that had been done in fasted and
16 non-fasted groups, sick people, healthy people, and when they
17 synthesized all that information what they said was, look,
18 overall these studies provided conservative cover bound.

19 So, what are we likely to see for gastric fluid
20 nitrite amounts? Less than a hundred micromolars per liter.
21 They weren't trying to answer the question, what are the ideal
22 conditions under which you can force the endogenous formation
23 of NDMA. They were asking the real world question, which is,
24 what do we see in people when we go out and look at all these
25 various studies that have been done?

Pauline A. Stipes, Official Federal Reporter

1 Just for the record, 100 micromolar is .1 millimolar,
2 and that is important because when we move to the next slide
3 what we see is that what the Gao researchers found is entirely
4 consistent with what all the other studies of endogenous
5 formation from NDMA have found, including that Tanner study.

6 And that is, at physiological levels, at levels that
7 the Gao researchers found are within what you are likely to see
8 in a human body, there is going to be no increase, no
9 endogenous formation of NDMA from Ranitidine. It is not until
10 you get to those super -- those academic can we force this
11 reaction levels that you start to see those increases.

12 Next slide, please.

13 Before I move to the animal studies, just a word about
14 a study that I believe that Plaintiffs showed yesterday, the
15 Helstrand study. You will remember there were pictures of the
16 lungs, and I think, if I remember correctly, we were told we
17 ought to all just look at the pictures. I think we should look
18 at the article, too, because in that the article what the
19 researchers attempted to do was inject the mice with cancer.

20 So, they injected them with melanoma cells and then
21 studied to see what happened and whether particular types of
22 cells metastasized. What they found was, importantly,
23 Ranitidine and another H2 blocker had the same effect.

24 So, when the Court looks at the study, we have to look
25 at the starting point, which is, they were attempting to give

1 cancer cells to these particular mice.

2 On the animal studies, very briefly, your Honor, I
3 want to talk about the Peto study because I know that is
4 something about which the Court had asked a question.

5 This study, your Honor, gives us both the problems
6 with tumor sites from animal studies, and also the problem with
7 dose, because what we saw in this study is that the rats were
8 given enormous, enormous amounts of NDMA, and even with those
9 large, large amounts of NDMA, what we saw -- we only saw
10 increases in tumors in the liver, not anywhere else in the
11 body.

12 That makes sense because the enzyme that metabolizes
13 NDMA, which is not dangerous when it is just sort of bouncing
14 around in the body, right, the enzyme that turns NDMA into
15 something that could cause DNA damage is found predominantly in
16 the liver. So it is not surprising in the Peto paper that that
17 is the only site in the rats that they found that particular
18 damage.

19 Briefly, your Honor, the Gombar paper, which is
20 another one about which the Court had asked us to pay
21 particular attention.

22 Next slide, please.

23 The Gombar paper answers two smaller questions, and
24 the first one is: Can we do the calculation that I have up
25 here on the screen? Can we take one mg per kg, and what does

1 that tell us about what that would translate to dosage-wise in
2 a human? What the Gombar paper said is, you actually can do
3 that calculation. That is not strange to say that if you gave
4 a mouse one mg per kg that would translate to -- here we have
5 70 million nanograms of NDMA in a 155 pound or 70 kilogram
6 adult.

7 The other question that the Gombar paper couldn't
8 answer is how the bioavailability of NDMA scales up for
9 animals, because what Plaintiffs' experts suggest is that small
10 animals have a tiny, tiny amount of bioavailability. That is
11 the amount of NDMA that gets past the liver and can circulate
12 in the body.

13 Big animals, they say, dot, dot, dot, and also people
14 have bigger amounts of bioavailability. That is precisely the
15 opposite of what the Gombar paper concluded. They said there
16 is no uniformly predictable relationship between those two
17 things and it is a difficult relationship, in fact, for them to
18 be able to explain.

19 What all this tells us, your Honor, is that Courts are
20 right to be cautious about extrapolating from animal studies to
21 human studies in the way that Plaintiffs' experts have
22 suggested that we do here.

23 *THE COURT:* You're at 15 minutes.

24 *MS. RYDSTROM:* Thank you very much. If I may, one
25 last slide on Dr. Panigraphy and his threshold testimony.

1 We asked Dr. Panigraphy point blank, are you going to
2 come in here and say FDA regulatory limits are reliable
3 evidence of real world cancer? And he said yes. That is
4 directly contradictory not just to what the FDA says about how
5 we should look at those ADI limits, your Honor, but also how
6 the Eleventh Circuit tells us that we should think about them
7 as well.

8 Thank you.

9 *THE COURT:* Thank you. That was slightly over 15,
10 close to 16, so Plaintiffs can have the same.

11 Let's hear now from -- is it Ms. Luhana who is going
12 to argue the Plaintiffs' position? Okay.

13 *MS. LUHANA:* Roopal Luhana for the Plaintiffs.

14 Judge, I am going to use my phone to track time. Is
15 that okay?

16 *THE COURT:* Okay.

17 *MS. LUHANA:* Judge, I am going to address Plaintiffs'
18 opposition to the Defendants' motion to exclude Plaintiffs'
19 remaining general causation expert opinions.

20 Can we go to the next slide.

21 So, Daubert and Rule 702 require the Court to
22 undertake a three-part inquiry for expert admissibility. Here,
23 with this motion Defendants have only raised that Plaintiffs
24 have not met the reliability prong. This is simply false.

25 Next slide, please.

1 The Supreme Court has stated that the reliability
2 prong requires Courts to consider four factors, is the
3 scientific method -- can it be tested, is it subject to peer
4 review, does it have a knowledgable rate of error, is it
5 generally accepted in the relevant community.

6 Next slide, please.

7 So, Defendants invite this Court to impermissibly
8 weigh the evidence. As we will discuss, Plaintiffs' experts
9 have cited to literally hundreds of peer reviewed studies which
10 allow our experts to conclude, and reliably conclude, the
11 following:

12 That Ranitidine endogenously to form NDMA; that there
13 are over 175 animal studies that not only confirm the
14 carcinogenicity of NDMA, but that NDMA forms tumors in all five
15 sites, including the esophagus, stomach, pancreas, bladder, and
16 liver.

17 Judge, we are not extrapolating doses that these
18 animals are exposed to. We are using the animal studies to
19 prove the carcinogenicity of NDMA, which is known and
20 established around the world. This is why NDMA has been banned
21 in this country from commercial use since the 2000's, and
22 lastly, that every regulatory body has concluded that
23 genotoxins like NDMA don't have a threshold.

24 This has been repeatedly declared by every regulatory
25 and authoritative body, so Plaintiffs agree with that position.

1 Next slide, please.

2 Defendants challenge the endogenous formation opinions
3 of the following Plaintiffs' experts: Drs. Panigraphy,
4 Michaels, Marletta, Le, and Najafi.

5 What is telling is Defendants haven't moved to exclude
6 Dr. Zeiger, who also has provided endogenous formation
7 opinions.

8 Next slide.

9 So, Plaintiffs' experts have reviewed the relevant
10 evidence. These are just some of the studies that our experts
11 have reviewed to conclude not only that nitrosation happens
12 endogenously with Ranitidine, but also that NDMA is formed
13 endogenously in Ranitidine.

14 Next slide.

15 The studies Plaintiffs' experts have reviewed are
16 similar to exactly what GSK identified as relevant when
17 regulators asked GSK to discuss endogenous formation of NDMA
18 from Ranitidine.

19 Next slide.

20 Defendants' experts don't argue that NDMA can't form
21 endogenously from Ranitidine. Tanner, in 1982, confirmed that
22 it does. Instead, Defendants argue what physiologically
23 relevant nitrite levels are, but Defendants' experts focus only
24 on one factor, nitrite levels, which are involved in the
25 endogenous formation process. Plaintiffs' experts rely on the

1 corpus of studies showing that endogenous formation results
2 from the interplay of a multitude of factors.

3 Next slide, please.

4 Judge, as you can see, there are numerous factors that
5 impact the gastric environment and how much NDMA is produced,
6 as Plaintiffs' experts opined. If you have ulcers and GERD,
7 like Ranitidine users, you are more prone to nitrosation. You
8 will have lower acidity that results in higher pH, and that
9 results in more bacterial overgrowth, and that is a
10 perfect recipe for endogenous formation of NDMA.

11 This has been written and studied and extensively
12 discussed by our experts. Your diet is going to play a
13 critical role, your thiocyanate levels are going to play a
14 role. Your pH will play a huge role, as Gao discusses, and I
15 will get to that, as well as your stomach volume, as our
16 experts know. You can't just focus on one factor, all these
17 factors contribute to the endogenous formation of NDMA.

18 Next slide.

19 So the Gao study in 2021 was done to assess Ranitidine
20 in varying levels of sodium nitrite, pH, and gastric fluid
21 volume to assess how much NDMA would form.

22 Our experts note that the critical limitation of Gao,
23 which is acknowledged by the authors, is that it didn't include
24 gastric conditions in the presence of a meal.

25 So this is important because the gastric environment

1 impacts NDMA formation. Gao confirmed some of this.

2 Lastly, even though Gao collected over 20 studies
3 which reported nitrite levels, the majority of those studies
4 were fasting, and only one study referenced Ranitidine, and
5 unfortunately that study, when they measured the nitrite
6 levels, those samples were Ranitidine free, which was
7 problematic.

8 Next slide, please.

9 So Plaintiffs' experts, in assessing Gao, similarly
10 raised it is not just one factor, there are multiple factors in
11 the dynamic gastric environment that are necessary to assess
12 NDMA formation.

13 Next slide, please.

14 So, this is a chart from the Gao study, and as you can
15 see, the pH is on the bottom, the NDMA is on the Y axis, and if
16 you look at the factors, it is 50 milliliters of simulated
17 gastric fluid with 10 millimoles of nitrite. If you change the
18 pH, if it is 5, it is only 200 something nanograms of NDMA
19 generated. However, if you go to a pH of 1.2, that is 11,000
20 nanograms. This tells you pH plays a huge part in the
21 formation of NDMA.

22 Next slide.

23 Judge, the same thing here, if you look at
24 50 milliliters versus 250 milliliters, it is double the amount
25 of NDMA when you increase the volume in the stomach. So the

1 fasting stomach, you have very little fluid; however, if you
2 have a fed stomach, you have a lot more fluid and it will
3 generate a lot more NDMA.

4 Next slide.

5 So, the objective of the Florian study was clear. The
6 Florian study's purpose was to redo Zeng and Mitch. They
7 simply state that was the objective.

8 Florian's objective as designed wasn't to assess
9 endogenous formation of NDMA from Ranitidine. If that was the
10 purpose they would have tested the GI tract for NDMA. However,
11 the authors noted specifically that the purpose was to assess
12 the NDMA in the urine.

13 Defendants, however, impermissibly try to stretch
14 Florian beyond its objective to conclude that endogenous
15 formation does not occur in Ranitidine users, even though the
16 study authors provided that the limitation of the study is that
17 it only included healthy participants, and didn't exclude
18 formation of NDMA from the GI tract.

19 Next slide, please.

20 Plaintiffs' experts opine that the gastric environment
21 of those who suffer from GERD or ulcers, like Ranitidine users,
22 is very different than someone who is a healthy individual.

23 Next slide.

24 So, let's see what Florian really showed.

25 This is a small -- our experts opine it is a small

1 study. It is only 17 healthy participants who don't resemble
2 the Ranitidine population or their gastric environment. They
3 one 150-milligram pill with only ten nanograms of NDMA, and
4 they were given -- that was with and without a cured meat diet,
5 and then they tested the urine, which showed very little NDMA.

6 Our experts state that this has been known for decades
7 that you don't look at the urine for NDMA, it is a bad gauge
8 for it, and this has been studied and discussed, and what our
9 experts refer to and rely on to say it is a bad tracker of
10 NDMA.

11 In fact, in terms of the samples of NDMA in the urine,
12 73 percent of those samples were below detection, and even if
13 you looked at the cured meat participants in this study, if you
14 calculate the amount of nitrites they were consuming, it was
15 about 325,000 nanograms of nitrites that they were being
16 exposed to; however, that was not even showing up in the urine.

17 The highest level that you saw in the Florian study
18 was 150 nanograms in the urine, so clearly it is not a good
19 gauge of NDMA.

20 Next slide.

21 Even Defendants' toxicologist, Dr. Guengerich, agrees
22 that NDMA is metabolized quickly and it is difficult to
23 measure, and that a low fraction of NDMA would be present in
24 the plasma or urine.

25 Next slide.

1 And our experts highlight that the FDA knew this, of
2 course, as well. The FDA, in the March 2021 working group on
3 nitrosamines, said that NDMA metabolizes quickly and is
4 difficult to measure, noting only rough estimates are available
5 in the literature on endogenous formation of NDMA based on its
6 detection in blood and urine. Because of its rapid metabolism,
7 only a small fraction is excreted in urine.

8 The only purpose of Florian was simply to redo Zeng
9 and Mitch and contest those results or confirm those results.
10 It was to test the urine for NDMA and that is it.

11 Next slide. This is the right slide.

12 Our experts highlight, including Dr. Le, that despite
13 Florian's limitations the NDMA plasma levels in the Ranitidine
14 in cured meats groups were doubled compared to the placebo and
15 compared to the cured meats groups.

16 This was 17 participants, this study wasn't designed
17 to check for statistical significance of plasma levels. That
18 is why it wasn't found. Dr. Le testified it wasn't powered to
19 find this because it was designed as a urine study, but even
20 despite that, with all the issues with Florian, it is double
21 the amount of NDMA with the Ranitidine in the cured meats
22 group.

23 Next slide, please.

24 So, Plaintiffs' experts at length discuss and explain
25 why the results of Florian and Gao don't answer some of these

1 critical questions; however, scientists outside of the
2 litigation have published similar concerns and criticisms of
3 Florian and Gao, among them recognizing that Florian only used
4 a healthy population, which we discussed is very different than
5 the Ranitidine population, and that in addition to that, Gao
6 didn't include the numerous variables that exist in the human
7 stomach.

8 Next slide.

9 We talked about Matsuda. Matsuda tested 72 healthy
10 subjects and 279 patients with gastric ulcers before and after
11 Ranitidine treatment. So, Ranitidine users there had 41.2
12 percent NDMA detected in their gastric after Ranitidine use.
13 These are fasted samples without any nitrite.

14 If you look at the 6.7 nanograms it equates to, with
15 250 milliliters, close to -- it's 1,975 nanograms of NDMA. And
16 so while the Defendants say look at all the other H2RAs, they
17 are producing NDMA as well, and that is a problem with this
18 population of people, they are more prone to NDMA formation,
19 however, these other two H2RAs don't have the issues that
20 Ranitidine has. You are not getting the amount of NDMA
21 baseline because it is not degrading to form NDMA.

22 Also, these other H2RAs tertiary means that when they
23 come into contact with nitrite form NDMA. Ranitidine is a
24 three-time assassin in that regard.

25 Next slide, please.

1 Of course, our Plaintiffs have assessed Matsuda and
2 discussed this at length.

3 Next slide.

4 Krawczynski, in 2002, 30 kids were treated with
5 Ranitidine for 28 days with chronic gastritis and H. pylori
6 infections, and they had statistically significant levels of
7 nitrosamines, including NDMA specifically. They didn't
8 quantify the NDMA, that was found in this population.

9 What is important to note with Krawczynski and Matsuda
10 is the chronicity and the type of population that they are
11 measuring. So, Ranitidine users are using Ranitidine for a
12 long time.

13 Florian, you had a short study with a healthy
14 population. In terms of Matsuda and Krawczynski, it is the
15 right people, it is people who are suffering from GERD and
16 ulcers, they are more prone for NDMA to be generated in their
17 stomach.

18 This is very telling when you are seeing statistically
19 significant results with this population. Guess what? They
20 are measuring the right metric. In Matsuda they measured
21 gastric fluid. In Krawczynski they measured gastric fluid.
22 You know why? Because those are better indicators of the NDMA
23 in your body than urine.

24 Next slide.

25 So, similarly, our Plaintiffs' experts have assessed

1 Krawczynski and it has gone to the weight of the evidence to
2 support endogenous formation.

3 Next slide.

4 So, the Ozon study is from 2003 and it tested 28 drugs
5 based on their chemical structure to see if they would
6 nitrosate under simulated gastric conditions.

7 *THE COURT:* Your time is about up.

8 *MS. LUHANA:* Just one more minute. Ranitidine was
9 incubated with .13 millimoles of sodium nitrite, so that is a
10 level that Defendants are saying is physiologically relevant.
11 The tests confirm that the nitrosated Ranitidine was genotoxic,
12 it led to DNA damage and activated the DNA repair mechanisms.
13 Ranitidine, in fact, in this study had one of the greatest
14 responses to DNA repair mechanisms going into effect compared
15 to other drugs.

16 For this reason, Judge, we believe you should deny
17 Defendants' motion.

18 Thank you.

19 *THE COURT:* Okay, thank you very much.

20 So I think what we will do is shift the schedule a
21 little bit. We will take a break now. It is 10:15, and we
22 will take a break until 10:30, and we will come back and I will
23 ask some questions, and depending on how long those take, I
24 want to be fair to the group addressing Najafi, it is possible
25 we might hear on the Najafi/Davis motion before lunch,

1 depending on how long we go on the questions for the remaining
2 experts.

3 I wanted you to be prepared for that. We might take a
4 lunch break and then hear from the Plaintiffs. If the
5 questions go longer, we may keep with the schedule where you
6 are presenting after lunch. So, be flexible on that.

7 Okay, we will take a 15-minute break and be back at
8 10:30 for some questions on that motion.

9 Thank you.

10 (Thereupon, a short recess was taken.)

11 *THE COURT:* Okay, you may be seated.

12 Apparently the last comment I made before we broke my
13 mike was off. I said we were going to take a 15-minute break,
14 which we just did, and have questions now on the motion that
15 was just argued. Depending on how long those questions take we
16 may or may not get into the first part of the next presentation
17 on Najafi/Davis, which was otherwise scheduled for after lunch.

18 For those of you who didn't hear me, that is what I
19 said. Sorry about that.

20 So, questions, let's see.

21 This is a question for Plaintiffs and it relates to
22 Florian, so if the person or persons who want to answer the
23 Florian questions want to come up to the podium, that would be
24 great, and others can come to help if need be.

25 So, as I understand the Plaintiffs' position, through

1 their experts, that Dr. Najafi has criticized Florian 2021, in
2 part because the study, quote, "missed an extremely critical
3 aspect of NDMA production from Ranitidine interaction with
4 food." That is Najafi's report at page 105.

5 Do your experts explain how long after beginning a
6 meal or finishing a meal the participants in Florian 2021 would
7 have needed to have taken Ranitidine in order to satisfy the
8 requirement that Florian 2021 accounts for Ranitidine
9 interaction with food?

10 Do your experts explain generally when participants in
11 any study of Ranitidine would need to eat food in relation to
12 the time they took Ranitidine in order to account for
13 Ranitidine's interaction with food?

14 If there are specific places in your expert reports or
15 depo transcripts that you can point me to, that would be
16 helpful.

17 MS. LUHANA: Sure. Roopal Luhana for the Plaintiffs,
18 Judge.

19 Dr. Najafi had done a number of experiments, including
20 experiments with simulated gastric fluid with food to measure
21 the amount of nitrite there. He had done ham, sausage,
22 hotdogs, and one other food group, and measured how much
23 nitrite -- we'll direct you to that chart that was going to be
24 part of my endogenous formation presentation yesterday, so I
25 would highlight that.

1 In addition to that, he did testing -- this was all
2 done per the protocols that were established from Gao and
3 Braunstein. Then, the other testing he had done was mixing
4 Ranitidine with food in simulated gastric fluid, and the he
5 measured the amount of NDMA at different times intervals.

6 If we take a look at that chart -- I'm also phoning a
7 friend, my colleague, Rosemary Bogdan, who can discuss it
8 further.

9 *THE COURT:* Can you give me the timeframe that you are
10 saying?

11 *MS. LUHANA:* He started at zero hours and went several
12 hours forward. You see with ham and then Zantac, and Zantac
13 and then ham, at the 1.5 hour interval there is a significant
14 amount of NDMA being generated. I want to pull up the report
15 and direct you to the specific charts.

16 Can I quickly grab my PowerPoint?

17 *THE COURT:* Yes.

18 *MS. LUHANA:* Okay.

19 *THE COURT:* And I guess in the question, when does
20 somebody need to eat? What is the position -- what is the
21 Plaintiffs' position on that?

22 *MS. BOGDAN:* Rosemary Bogdan on behalf of the
23 Plaintiffs.

24 *THE COURT:* When would the participants in Florian
25 have needed to eat in relation to when Ranitidine was

1 administered?

2 *MS. BOGDAN:* To answer the Court's larger question
3 here, you have multiple things going on. You have Ranitidine
4 being taken, okay. Ranitidine is absorbed after oral
5 administration and it reaches its peak plasma concentration in
6 about two to three hours, but Ranitidine is unique because it
7 has two peak plasma concentrations. The first one is at two to
8 three hours and the second one is at three to six.

9 There is phenomenon called entropic hepatic
10 circulation, so basically Ranitidine is available in the system
11 for up to six hours because of the way that Ranitidine is
12 metabolized.

13 *THE COURT:* In the Florian study, what is the
14 Plaintiffs' position with respect to when the participants
15 would have needed to eat in relation to when the Ranitidine was
16 administered?

17 *MS. BOGDAN:* How I would first respond to that, your
18 Honor, is I would point to Florian's limitations, and what
19 Florian says, the authors themselves, is that this study only
20 includes healthy participants, which you heard and you have
21 seen in our briefing, and it did not exclude formation of NDMA
22 in the gastrointestinal tract that was not absorbed and
23 detected in plasma or urine.

24 *THE COURT:* I am aware of the limitations. I am
25 wondering if there is an answer to the question, when would

1 they have needed to eat relative to when they took the
2 Ranitidine.

3 *MS. BOGDAN:* They would need to eat so that they would
4 be in that window, which is from when the Ranitidine was taken
5 to six hours --

6 *THE COURT:* Any time from when the Ranitidine was
7 taken to six hours they would eat?

8 *MS. BOGDAN:* They would eat, and the food would be
9 there with the Ranitidine.

10 The issue in Florian is that they are measuring these
11 values in plasma, and when NDMA forms in the gastrointestinal
12 tract and is metabolized in the gastrointestinal tract, it
13 never reaches the plasma to be measured, and that is what they
14 are stating in the limitations in Florian.

15 They also stated in the limitations in Gao that they
16 are not assessing some physiological conditions and they don't
17 include an evaluation of gastric conditions in the presence of
18 a meal, aside from substituting in nitrite which is different
19 than the food.

20 What Emery did was actually do the Gao experiment, but
21 with food, and in the Table GG in their report they explain the
22 nitrite levels that are reached with the food and the simulated
23 gastric fluid.

24 *THE COURT:* Thank you. Going back to Florian,
25 researchers administer the Ranitidine just one minute before

1 study participants started eating breakfast. That is Florian
2 2021 at page 241.

3 Do your experts explain why this timing does not
4 account for the factor of interaction with food; and if so,
5 where?

6 MS. BOGDAN: They explain that the way that Florian is
7 measuring the NDMA is problematic.

8 THE COURT: So it is not the timing?

9 MS. BOGDAN: It is not the timing of when the drug
10 necessarily is being given with the food, because they are what
11 I would call on board at the same time. If you take the
12 Ranitidine right before you eat, they are both in the gastric
13 compartment at the same time. That is common sense.

14 The issue that they are taking were with it is that
15 NDMA can be generated endogenously in the stomach, in the
16 gastrointestinal tract, and when you are measuring plasma, that
17 is not an indication of whether NDMA was formed, and the total
18 amount of NDMA that is being formed because the NDMA, if it is
19 metabolized before it gets to the plasma, it doesn't get
20 counted.

21 Also, NDMA has a very, very short half life, so if you
22 are -- like in the Florian study when you are measuring NDMA in
23 half hour intervals in the plasma, which much of it doesn't
24 reach the plasma to begin with, and you are measuring it, it is
25 disappearing because its half life is shorter than the time

1 that they are measuring.

2 These issues are discussed in both Dr. Le's and Dr.
3 Panigraphy's report. It is poor metric to study endogenous
4 formation of NDMA, because the Florian authors state right in
5 their study that it did not exclude formation of NDMA in the
6 gastrointestinal track.

7 My colleague, Ms. Luhana, was explaining about how
8 Ranitidine can nitrosate in the intestinal track to form NDMA,
9 and the Florian study does not address that issue. It is not
10 the timing specifically, although that can be an issue with
11 regard to someone that chronically takes Ranitidine and they
12 have a baseline level in their system. That is something that
13 is also a factor out there.

14 But if you ask me, the real issue here is that the
15 Florian study, designed as a urine study -- understand that
16 these investigators were really trying to just see if the Mitch
17 paper was -- that was the whole purpose of it.

18 *THE COURT:* Well, I guess to go back to what I started
19 with, Najafi, at 105, says the study missed an extremely
20 critical aspect of NDMA production from Ranitidine interaction
21 with food.

22 *MS. BOGDAN:* That is absolutely correct because the
23 studies show that when you do the experiment with food a
24 tremendous amount of NDMA forms, and we have a slide --

25 *THE COURT:* But Florian, I thought, gave food one

1 minute before -- gave the Ranitidine one minute before eating
2 breakfast.

3 MS. BOGDAN: Yes, but Florian is only determining if
4 NDMA has formed by measuring the blood, and what happens to
5 NDMA is that it is rapidly metabolized by the human body and it
6 never reaches the plasma.

7 THE COURT: Okay.

8 MS. BOGDAN: Once it is metabolized into the
9 metolazonian ion, it is not available to be measured. What
10 Emery Pharma did is they took the food and they were able to
11 calculate how much NDMA forms in the vessel, right, and that is
12 indicative of what would be forming in the stomach.

13 THE COURT: Okay, I need to move on. Was there an
14 elaboration on that point?

15 MS. LUHANA: I wanted to bring up the slide and walk
16 you through the process.

17 THE COURT: There it is. Is that it?

18 MS. LUHANA: Yes. If you can go to slide 7. The
19 slide before, actually. Perfect.

20 So, Judge, as Ms. Bogdan was explaining, Emery did
21 test actual food in simulated gastric fluid, and they didn't
22 add sodium nitrite into the mix, so the first example you see
23 they gave Zantac and then sausage, and then they measured the
24 NDMA content in the simulated gastric fluid.

25 You see at the two hour mark there, there is 27.4

1 nanograms, and that has to be multiplied by 250 millimeters,
2 because that is the concentration in the fluid. If you look at
3 that, that would be approximately over 6,000 nanograms of NDMA,
4 6,850.

5 If you look below in terms of when the food is given
6 versus the Zantac, the second chart there, you see Zantac then
7 ham, you see NDMA being generated at the 1.5 hour mark, at 29.5
8 nanograms. The same calculation has to be done, multiply it,
9 and then you see later on, in terms of mixing it up and doing
10 the ham first and then the Zantac --

11 *THE COURT:* Just to focus the question, it really had
12 to do with timing, when to take Ranitidine in relation to the
13 food intake.

14 *MS. LUHANA:* This is showing you it does impact it
15 some. The makers of Zantac direct people to take it soon after
16 a meal or before bedtime. So, that would have been the
17 appropriate time for Florian to do the testing, however,
18 Florian wouldn't be able to measure NDMA because they weren't
19 using the appropriate gauge. It was urine and plasma as well,
20 which are not appropriate. You should be testing the gastric
21 fluid or other metrics to assess NDMA because it metabolizes so
22 quickly.

23 *THE COURT:* I am assuming some of this is going to be
24 discussed in the Najafi presentation. We can reserve
25 additional argument on this to the end, so if there is anything

1 further you wanted to say, just hold that thought, if you
2 would. I have several more questions.

3 Earlier today, for Plaintiffs, you explained that the
4 nitrite level is one of many factors that affect NDMA
5 formation. Can you explain how that level affects NDMA
6 formation? Can you also provide a range of nitrate levels that
7 would be realistic to find in the human stomach?

8 If you have expert reports or any other sources you
9 can point the Court to. If you could tell the Court, because I
10 have your presentation. Direct me to what to look at.

11 *MS. LUHANA:* It's Table GG. Importantly, as I raised
12 during my argument, the nitrite concentrations that have been
13 measured have been largely in fasting stomachs. Unfortunately,
14 that is not going to give you a true gauge of nitrite. There
15 is always that one factor and Gao confirmed that.

16 You change the volume of simulated gastric fluid,
17 there is a lot more NDMA generated, double in Gao between 50
18 milliliters and 250 milliliters. If you change the pH, there
19 is a lot more NDMA generated. Those factors play a critical
20 role.

21 However, if you look at Table GG, I believe it's page
22 100 of Dr. Najafi's report, what it does --

23 *THE COURT:* I'm sorry, what page?

24 *MS. BOGDAN:* Page 100.

25 *MS. LUHANA:* He has -- instead of adding sodium

1 nitrite and mixing it with Ranitidine and seeing how much NDMA
2 is generated or how much -- what the nitrite content is, he put
3 them in foods and put them in simulated gastric fluid, and as I
4 said before, it was per the protocols established by Braunstein
5 and Gao.

6 If you look at the sausage, 46 grams is a normal
7 serving size, if you take sausage and put it in simulated
8 gastric fluid, you have 19,100 micromolars being generated. So
9 that is 19.1 micromolars of nitrite. Similarly, if you look at
10 the bacon, that bacon is 13 grams, that is a slice of bacon.
11 You put it in simulated gastric fluid, you have
12 7,400 micromolars being generated. That is 7.4 millimolars of
13 nitrite --

14 *THE COURT:* Is there a level of sodium nitrite that
15 would be toxic to humans that has been established by anyone,
16 per the Plaintiffs' position?

17 *MS. LUHANA:* I don't believe we have discussed the
18 toxicity of nitrite; however, what you see here is Ranitidine
19 is a tertiary mean and it comes contact every single day
20 because it is taken after a meal, and after a meal these are
21 the levels that you are seeing of nitrite in the stomach.

22 It is a recipe of things, as I discussed. It is the
23 pH and the volume of the stomach. You can't isolate it, but
24 here you are seeing that there is enough nitrite clearly being
25 generated once you have a meal, and these are single serving

1 sizes.

2 *THE COURT:* You might not want to talk about food too
3 much because that is going to get everybody hungry, which
4 segue-ways into my next question which does have to do with
5 food, bacon in particular. I am not sure if anyone had bacon
6 this morning.

7 Back in the hearing on June 3, 2021, the Defendants
8 had represented that mathematically the amount of bacon that
9 someone would need to take to have 15 millimoles of sodium
10 nitrate in their stomach was 33 pounds. That is at Docket
11 Entry 960, at 38.

12 At that time I had asked Ms. Meeder, do you disagree
13 with what the Defendants presented at the Science Day, or at
14 that particular presentation, that is their presentation as to
15 how they translated 50 millimoles.

16 Ms. Meeder responded, your Honor, sitting here today,
17 I don't have an opinion on that one way or the other. I would
18 need to refresh my recollection from an expert. That was from
19 the transcript of the oral argument June 23, 2021, pages 216 to
20 217.

21 Are the Plaintiffs in a position today to answer the
22 question, that is, do you agree that the Defendants'
23 calculation that a person would have to eat 33 pounds of bacon
24 in order to have 50 millimoles of sodium nitrite in their
25 stomach is accurate? If you don't agree, do you have anything

1 in the record that informs me of the Plaintiffs' position of
2 approximately how many pounds of bacon a person would need to
3 eat to have 50 millimoles of sodium nitrite in their stomach?

4 MS. BOGDAN: Yes. Yes, there is something in the
5 record, and yes, I will be happy to explain. Actually, the
6 Court is very intuitive because this dovetails right into Table
7 GG which we were just discussing, which tells us the level of
8 nitrite generated by the food itself.

9 Could you hear me?

10 THE COURT: Yes, but talk into the mic.

11 MS. BOGDAN: This dovetails right back into Table GG,
12 which is the measurement of the nitrite that is generated from
13 the food in the SGF. If we look at Table GG we can see -- and
14 we are focused on bacon here, so that one serving, which is
15 13 grams of bacon, results in 7,400 micromoles of nitrite
16 concentration.

17 So, essentially, if you have four servings of bacon,
18 right -- excuse me, if you have seven servings of bacon, that
19 would result in 51,800 micromoles of nitrite concentration,
20 which puts you at that 50, which is what you are asking about,
21 50 millimoles. So, essentially 91 grams of bacon is 0.2
22 pounds.

23 So, simply, just so you just -- literally, you take
24 the amount of bacon that is in Table GG, which is --

25 THE COURT: Do you want to put the table back up? Was

1 that the one that was just up?

2 *MS. BOGDAN:* It was. You take the 7,400, which is you
3 know the amount of nitrite generated by that, if you multiply
4 the 7,400 by seven, which is seven servings, you get to over
5 50,000, which is 50 millimoles. So you would multiply the
6 serving size of 13 grams by seven, and when you convert the
7 91 grams a pound you get .2 pounds.

8 That is the power of actually using the food, because
9 it is the nitrite that is available, it is on board directly
10 from the nitrated foods and able to interact. The nitrite in
11 the food, not resting in simulated gastric fluid, it is the
12 interaction of the food with the gastric fluid. It is there in
13 the food, it is in the matrix, and that is what is missing in
14 Gao, and that is also what is missing because of the way they
15 choose to measure NDMA in Florian.

16 *THE COURT:* Let me see if the Defendants want to
17 respond. I will see if the Defendants have any response on
18 that. Do you want to come to the podium?

19 *MS. RYDSTROM:* Sure. Jessica Rydstrom, your Honor.

20 I can tell you that I have had this exact nightmare
21 where I have to stand up before a group of people and walk
22 through a mathematical calculation, so thank you for this
23 experience.

24 *THE COURT:* You will remember it fondly.

25 *MS. RYDSTROM:* I will. Thank you.

1 I can explain to the Court how it is that we reached
2 the 33 pounds back when we did. First, the Court is absolutely
3 right to focus on the nitrite level. That is exactly what we
4 see in Florian and Gao and what the papers teach us. That is
5 what forces the NDMA reaction.

6 To answer the Court's question from before, the
7 reason, of course, that Florian times the study the way that
8 they did is because an empty stomach is most acidic. So, as
9 soon as you start eating the acid levels in your stomach go
10 down, so you would expect to see that NDMA formation decreasing
11 that rate, as the stomach becomes less acidic.

12 At a very high level, your Honor, I could walk you
13 through the calculation we made. I think that it starts with
14 the Valisure study, Table 2 of that study. In that study you
15 will recall, and with all the attendant problems with Valisure
16 that we won't repeat, there was a 25 millimolar level of sodium
17 nitrite that was reported in those studies.

18 That is what Valisure did and that was the starting
19 point for this calculation. That is how we calculated it. I
20 think it was calculated based on the 25, which was the first
21 level at which you saw the increase, and not the 50, although
22 the 50 gets you an even more eye-popping number.

23 What you do is you convert the millimoles there, the
24 25 millimole calculation, and you have to go from moles to
25 grams, and in order to do that you have to take the molecular

1 weight of sodium and of nitrite, which we have calculated very
2 recently, I assume it has not changed, at 46.006 grams per mole
3 of nitrite. And then you have to go from the grams per liter,
4 because you are dealing with a volume concentration, and we
5 were trying to get to an actual concentration in grams of how
6 much bacon.

7 So when you convert that from grams per liter to
8 milligrams per liter, you end up with 1,150 milligrams of
9 nitrite per one liter.

10 When we calculated the amount, your Honor, from a
11 Grisenbeck (phon) paper, which I don't believe is in the
12 record -- this was all long before expert discovery. This
13 particular calculation wasn't a subject of expert discovery. I
14 am happy to provide the Court with a copy of that paper, but it
15 came up with an amount of .467 milligrams of nitrite in two
16 slices of bacon.

17 So, what that gives you is, to achieve that
18 concentration, that 25 millimole concentration of sodium
19 nitrite, you would have to have 4,925 slices of bacon in one
20 liter of stomach, but of course our stomachs are not that big.

21 So to go to slices in a pound -- I apologize, your
22 Honor, I am trying to slowly both for Ms. Stipes' benefit and
23 for the Court's.

24 You would assume for purposes, as we did at this time,
25 that there are 16 slices of bacon in a pound. I actually think

1 at the time we did the calculation, the estimates we found
2 online was there were 18 to 20 slices, so the fact that the
3 numbers are off means there are different assumptions that we
4 put in.

5 To go from one liter of simulated gastric fluid to one
6 millimeter of gastric fluid, you end up with .0378 of weight
7 per milliliter, and to figure out that volume of the human
8 stomach we took someone who had consumed that amount of bacon
9 and drunk half a glass of water, which we calculated at
10 121 milliliters. When you multiply that .0378 per milliliter
11 by 121 milliliters, we assume someone would not just eat bacon,
12 they would drink water, we ended up with 37.25.

13 *THE COURT:* The Defendants come up with 37.25, and the
14 Plaintiffs, you say .2. Is that the Plaintiffs' number?

15 *MS. BOGDAN:* That is correct.

16 *THE COURT:* Let me ask the Defense and then I will ask
17 the Plaintiffs after Defense, can you surmise why your number
18 is so much higher than the Plaintiffs' number.

19 *MS. RYDSTROM:* I imagine, your Honor, it has something
20 to do with what we'll hear in a bit about Dr. Najafi and the
21 testing that he did.

22 One thing that I would say is that we have heard a lot
23 about simulated gastric fluid. That is one of the variables
24 that Dr. Gao considered. They looked at simulated gastric
25 fluid when they were determining what those physiological

1 amounts of nitrites is. So, whether it is 37 pounds of bacon,
2 or 20 pounds of bacon, the point is that in order to juice that
3 NDMA formation from Ranitidine, it is very clear that you need
4 those extra high levels of nitrite.

5 *THE COURT:* Thank you. From the Plaintiffs, any
6 sense, unless you think it will be further explained in the
7 Najafi presentation, why your number is so much lower than the
8 Defendants' number on the topic of bacon?

9 *MS. BOGDAN:* Your Honor, it is because our number is
10 based on the actual measurement of nitrite in simulated gastric
11 fluid that is generated from bacon. The Defendants are taking
12 numbers that are just whole and doing these concentration
13 calculations, but they are numbers being taking and converted
14 to mass. It is a calculation that the lawyers have done, I
15 haven't seen this done by any of their experts.

16 What I am presenting to the Court is in Dr. Najafi's
17 report as far as the actual nitrite concentrations that are
18 generated in simulated gastric fluid from bacon, and that is
19 the best evidence to figure out how you reach 50 millimoles.

20 *THE COURT:* Thank you. Leaving bacon for the moment,
21 moving on to Krawczynski and Matsuda. Question for the
22 Plaintiffs.

23 Defendants argue in their remaining opinions motion
24 that your experts' reliance on in vivo studies of endogenous
25 formation is unreliable. That's at Docket Entry 5696-7. In

1 response, you assert that your experts relied on studies that
2 "consistently demonstrated that NDMA forms endogenously, naming
3 Krawczynski and Matsuda as examples. That's at Docket Entry
4 5913 at pages 6 to 7. And you also discussed Matsuda and
5 Krawczynski today during your presentation.

6 Can you explain to the Court what arguments you made
7 in your response to show that Krawczynski and Matsuda are
8 reliable? In other words, are you able to direct the Court to
9 pages in your brief where you actually make the argument, other
10 than just referring to Krawczynski and Matsuda, that Matsuda
11 and Krawczynski are reliable?

12 I want to make sure I found the right place in your
13 opposition where you are saying that.

14 *MS. LUHANA:* Roopal Luhana for the Plaintiffs.

15 Judge, they are reliable peer reviewed studies and
16 they have also been accepted in the medical and scientific
17 communities. The only ones that are saying peer reviewed
18 studies are not reliable is the Defendants.

19 *THE COURT:* Do you know offhand where in the response
20 you say that?

21 *MS. LUHANA:* I will have to pull up my response and I
22 am happy to provide that cite to you.

23 In Krawczynski I will note the Defendants are raising
24 this four to six week measurement after treatment. It was a
25 Polish publication and it was translated into English, and

1 there are 6 or 7 other places in the publication where they
2 note that the testing was done before treatment and Ranitidine
3 was given for at least four weeks and then after treatment.

4 So, interestingly enough, when GSK submitted
5 Krawczynski to regulators -- to the EMA, as well as to the
6 Japanese regulators, they never mention the fact about this
7 four to six week time period. They simply stated -- they
8 didn't state how much NDMA there was a statistically
9 significant increase of in the gastric fluid. They never
10 raised that argument.

11 This is lawyers raising these arguments for
12 litigation. However, I provide to you that these are peer
13 reviewed studies with a rate of error and they are established
14 an accepted in the medical community. The only ones that are
15 calling them unreliable are the Defendants.

16 *THE COURT:* That is fine. I want to make sure I found
17 that in your opposition so that I can match what you are saying
18 here in court with what I was reading.

19 *MS. LUHANA:* I can provide that for you.

20 *THE COURT:* I will say you will get back on that.
21 While I ask other questions maybe you will have the answer. If
22 not, maybe you can give that to me at the end.

23 Same question on Krawczynski -- another question. Am
24 I correct that the researchers in Krawczynski utilized GCMS to
25 measure the nitrosamines in children's urine? If that is

1 correct, given that the FDA previously determined that GCMS is
2 unreliable because the method itself creates NDMA, can you
3 explain to the Court how a reliable methodology could include
4 reliance on studies that use that instrument, the GCMS.

5 MS. LUHANA: Judge, it is not that GCMS unreliable, it
6 is just that Ranitidine degrades with exposure to heat. If you
7 keep Ranitidine in excessive temperatures NDMA forms, and so
8 the GCMS is calculating the amount of NDMA. The only
9 difference is, you can't tell how much of that is baseline
10 versus how much is created with the heat.

11 It is not that it is an improper methodology, and
12 specifically for Krawczynski, the differences not only -- it
13 measured urine, however it measured gastric fluid and it was
14 measuring the gastric fluid after these kids had eaten, so it
15 is sometime after, when the Ranitidine is digested, so it is
16 the NDMA that is measuring with the GCMS, and not the
17 Ranitidine.

18 THE COURT: So, is GCMS, in the Plaintiffs' view,
19 reliable or not reliable?

20 MS. LUHANA: GCMS is reliable for measurements of NDMA
21 alone. GCMS is not reliable for measurements of Ranitidine
22 because you can't tell how much is created when you are
23 exposing it to heat versus how much is already in the tablets
24 at baseline.

25 THE COURT: Doesn't GCMS apply heat that creates the

1 NDMA?

2 MS. LUHANA: With Ranitidine, yes, not with NDMA on
3 its own.

4 That is the concern, right, because if you expose
5 Ranitidine to heat -- and so this is the difference, for
6 example, if you look at Tanner, it was GCMS injection versus
7 Valisure where they exposed it to heated temperatures and kept
8 it there for 15 minutes. GSK scientists internally discussed
9 this, and they said the difference in why Tanner was reliable
10 is because it was injection and it was immediately volatilized
11 and the NDMA measured, versus with Valisure where they
12 maintained high temperatures for 15 minutes, and they discussed
13 internally those high temperatures for 15 minutes are what
14 created the extra NDMA, and then you couldn't differentiate
15 what was created with the heat versus how much was already in
16 the pill at baseline.

17 THE COURT: Does GCMS make nitrates create NDMA?

18 MS. LUHANA: I'm sorry, I don't quite understand.

19 THE COURT: Does GCMS cause nitrosamines to create
20 NDMA?

21 MS. LUHANA: GCMS is a method where you use heat, and
22 it is a very sensitive method, it's an accepted method to test
23 drugs for nitrosamines.

24 The difference with Ranitidine is it is activated by
25 heat and humidity and generates a lot more NDMA. That is why

1 it is an unstable molecule and that is why it is no longer on
2 the market. The FDA lost confidence in the ability for
3 Ranitidine to maintain below the ADI because with heat and
4 humidity, it creates a lot of NDMA.

5 That is a specific problem with the Ranitidine
6 molecule, not with all these other drugs.

7 *THE COURT:* Okay. During yesterday's hearing
8 Plaintiffs explained that studies combining results for
9 Nizatidine and Ranitidine were discounted by Plaintiffs'
10 experts because of the adverse effects of Nizatidine was not
11 the question there. However, the Court understands that, if I
12 am correct, Krawczynski put together findings for different
13 nitrosamines and did not analyze data for NDMA alone.

14 Am I correct in that statement; and if so, can you
15 explain to the Court how the Plaintiffs would reconcile their
16 experts discounting the findings with Nizatidine with their
17 reasoning for relying on Krawczynski and other studies that
18 lump together findings of different nitrosamines.

19 *MS. LUHANA:* Those are two very different points,
20 Judge. With the epidemiological study, if they are trying to
21 assess for exposure to Ranitidine is causing an increased risk
22 of cancer, it is important to look at only the people taking
23 ranitidine. When you are combining Ranitidine with Nizatidine,
24 that will not be able to assess and tell you whether Ranitidine
25 use is leading to an increase of cancer. That is why that is

1 problematic.

2 With Krawczynski, they measured a number of other
3 nitrosamines where there was a statistically significant
4 increased risk -- not risk, statistically significant levels of
5 NDMA that were found in Ranitidine, however, they found other
6 levels as well. They also excluded -- what lead me to believe
7 that they measured the amount of NDMA from the gastric fluid
8 is, they excluded all these other nitrosamines that were not
9 measured there. I can point you to that reference in the study
10 as well.

11 *THE COURT:* Okay, you will make a note of that?

12 *MS. LUHANA:* Yes. The fact of the matter is that
13 Krawczynski found increased levels of NDMA in the gastric
14 fluid, importantly, of kids who used it for a longer period of
15 time, and kids who have gastritis.

16 *THE COURT:* I will wait for you to give me the cite on
17 that.

18 Circling back to the GCMS and Krawczynski and the
19 study, the researchers gave children Ranitidine, as I
20 understand it, and then measured the nitrosamines. So, how is
21 GCMS reliable if it creates NDMA from Ranitidine?

22 *MS. LUHANA:* Because when they measuring the gastric
23 fluid it is absorbed already. They are not doing it when
24 people are taking Ranitidine at the same time. It would be an
25 aspiration risk. When they are doing the samples they provide

1 the methods when they are pulling the samples. By then the
2 Ranitidine is absorbed in the system and they are measuring the
3 actual NDMA.

4 *THE COURT:* Is that explained in the report?

5 *MS. LUHANA:* In the methods I believe it is discussed,
6 yes.

7 *THE COURT:* Would you make a note to point out where
8 that is as well?

9 *MS. LUHANA:* Sure. Again, Judge, we are going behind
10 peer reviewed literature and studies that aren't contested. It
11 went through the peer review process, and that means something.

12 *THE COURT:* These are just questions, I am not
13 suggesting anything other than that, just trying to understand
14 everything to the best I can.

15 Okay. I will move on to the topic of metabolism
16 and bioavailability of NDMA.

17 The Court wants to understand the Plaintiffs' position
18 regarding metabolism and bioavailability of NDMA. I want
19 to take it one point at a time.

20 The Plaintiffs state in their response to the
21 Defendants' remaining opinions motion, now I'm quoting, "the
22 level of NDMA in the blood following oral administration is
23 primarily controlled by the amount metabolized in the liver."
24 That is Docket Entry 5913.

25 The Plaintiffs then provide data from animal

1 studies to assert that rats have an 8 percent bioavailability
2 of NDMA, whereas monkeys have 49 percent bioavailability, pigs
3 have 67 percent bio availability, and dogs have 93 percent
4 bioavailability of NDMA. That is at Docket Entry 5913, at
5 pages 13 through 14.

6 Good so far? Am I citing it correctly?

7 *MS. LUHANA:* I think so.

8 *THE COURT:* I will take that as a yes. There is a
9 smile, so I will say yes, that is right.

10 So, now I want to make sure I understand, does that
11 statement mean, for example, that 92 percent of NDMA is
12 metabolized in the livers of rats, whereas 51 percent is
13 metabolized in the livers of monkeys, and 33 percent of NDMA is
14 metabolized in the livers of pigs?

15 *MS. BOGDAN:* Yes.

16 *THE COURT:* Okay. So, you also state that "because
17 NDMA's bioavailability is higher in larger experimental animals
18 compared to rodents, NDMA's carcinogenic activity can be more
19 aggressive and result in many more tumor types in humans as
20 opposed to rodents." That is at Docket Entry 5913 at 14.

21 Do you agree that -- or is this statement stating that
22 humans are similar to larger animals, and therefore their
23 bioavailability of NDMA is higher than rat bioavailability?

24 *MS. BOGDAN:* Absolutely, your Honor.

25 *THE COURT:* During yesterday's hearing explaining

1 Hidajat's conversion of inhalation exposure to oral exposure,
2 it was argued that Hidajat calculated over 90 percent
3 bioavailability of inhaled NDMA in humans which, you stated,
4 confirmed the reliability of her extrapolation because it is a
5 similar bioavailability to oral exposure.

6 What is the Plaintiffs' position as to the specific
7 percentage of bioavailability of NDMA in humans?

8 *MS. BOGDAN:* All of the bioavailability studies,
9 because NDMA is such a potent known genotoxic molecule, have to
10 be done in animals. You cannot deliver a large dose to a human
11 to measure the bioavailability.

12 What the scientists need to do is go to the best
13 evidence we have of bioavailability, which would be the larger
14 animals, which consistently -- the monkey, obviously, the swine
15 and the dogs all exhibit much higher bioavailability of NDMA,
16 which means that it bypasses the liver and is available in the
17 systemic circulation.

18 Again, a rapidly metabolized molecule, etc., but it is
19 bioavailable in the human body, and the reason that is
20 important is that if you focus just on a rat study and you're
21 looking at tumors only in the liver, if 90 percent of NDMA goes
22 into a rat's liver, then that is where you are going to look
23 for the tumors, as they did in the Peto study primarily.

24 But and with larger animals, the bioavailability is so
25 much greater that it ends up in the systemic circulation.

1 *THE COURT:* So the human bioavailability is analogous
2 to the 49 percent for monkeys, 67 percent for pigs, and 93
3 percent for dogs.

4 *MS. BOGDAN:* Right, and those are the three peer
5 reviewed studies where they have actually given doses of NDMA
6 to the animals to be able to study that.

7 *THE COURT:* Is there a particular percentage? I just
8 named three.

9 *MR. NIGH:* Your Honor, if I may, Dr. Le specifically
10 calculated this in her report and she demonstrated that it is
11 greater than 90 percent.

12 *THE COURT:* Do you have the cite there?

13 *MR. NIGH:* I don't have the actual cite, I just know
14 that it is an unchallenged opinion from the Defendants.

15 *THE COURT:* If you could make a note of it.

16 The Plaintiffs also seem to say in their briefing "It
17 is generally accepted that NDMA is metabolized similarly in
18 human tissue and rodent tissue." Docket Entry 5913 at 12. But
19 in your response, as a reminder, you say rodents have a
20 bioavailability of 8 percent.

21 I want to understand the statement that NDMA is
22 metabolized similarly in human tissue and rodent tissue and the
23 8 percent bioavailability that rodents have.

24 *MS. BOGDAN:* When we are speaking about the act of
25 metabolism we are talking about the cytochrome P 450 enzymes

1 and the way that it is metabolized is the same, but the sites
2 of the metabolism are different.

3 The way that the actual cells in the tissues
4 metabolize NDMA in the rat liver is similar to how the human
5 liver metabolizes NDMA, but because the bioavailability is
6 different, the human body has the opportunity to metabolize the
7 NDMA at all the these different sites which have these very
8 important cytochrome P 450 enzymes that metabolize NDMA.

9 It is not the mechanism of how the tissues metabolize
10 that is different, it is the fact that the sites are different
11 because of the NDMA reaching those sites in much larger
12 proportions because it bypasses the liver and thus more
13 developed in larger animals.

14 *MS. LUHANA:* Just to add to that, Judge, with rats it
15 is being metabolized largely by the liver, 80 to 90 percent,
16 whereas the human body, it is being metabolized by many other
17 organs. In fact, the Hikura studies, which Dr. Salmon and many
18 of our other experts cite to, specifically talk about how
19 humans are more sensitive to NDMA in rats, seven times more.

20 In addition to that, in terms of the metabolism in the
21 DNA forming, that similarity is discussed by WHO, and other
22 organizations as well. We could provide those cites for you
23 also.

24 *THE COURT:* Are they in the record already?

25 *MS. LUHANA:* Yes.

1 THE COURT: Okay. Okay. Do different sites matter,
2 then, in terms of where the cancer can form? Am I
3 understanding that is what you are saying?

4 MS. BOGDAN: Yes, because the NDMA needs to be
5 metabolized in order to do the damage that it does and disrupt
6 the DNA.

7 So, it is the metabolism of the NDMA at these
8 different sites, one is bioavailability, bypasses the liver, is
9 available in the systemic circulation, and then it is the
10 ability of these different parts of the body to actually
11 metabolize the NDMA, because the cytochrome P 450's are
12 available in all of these sites.

13 Our expert, Dr. Panigraphy, goes through in depth each
14 of the sites and explains how the tissue and the cellular
15 studies show the NDMA can be metabolized in those five
16 designated cancer areas.

17 THE COURT: Okay, thanks.

18 Let's move on to -- let me move on to the animal
19 studies, so Gombar.

20 Can you just briefly explain how the Plaintiffs'
21 experts relied upon Gombar 1990, in other words, which experts
22 relied on the study and what proposition did these experts rely
23 upon that study to show? Very succinctly.

24 MS. BOGDAN: The Gombar studies, and there are three
25 of them, are the studies that support the bioavailability of

1 NDMA in large mammals.

2 *THE COURT:* So that is the proposition?

3 *MS. BOGDAN:* That is the proposition. It also
4 supports the metabolism of NDMA with the short half life that I
5 referred to earlier when I was speaking with regard to the
6 endogenous in Florian of between seven and 21 minutes, which
7 goes to the rapid metabolism.

8 The Gombar studies are cited by our experts with
9 regard to bio availability as well as metabolism of NDMA.

10 *THE COURT:* Offhand do you know which experts relied
11 on that for those propositions?

12 *MS. BOGDAN:* I believe Dr. Panigraphy, I believe they
13 were mentioned by -- I don't want to misstate, I don't want to
14 over state or leave someone out because many experts relied on
15 those. Dr. Le definitely speaks to them. Dr. Panigraphy
16 definitely speaks to them. Salmon definitely speaks to them.
17 But there may be others that have who referenced them as well.
18 I would like to be complete for the Court.

19 *THE COURT:* That is something you might want to make a
20 note if you want to supplement on that.

21 So subject matter extrapolation.

22 For the Plaintiffs, do you agree that in order to meet
23 the helpfulness prong of Daubert one must show that expert
24 opinions and studies they relied upon are a "fit" to the
25 general causation question in the litigation?

1 *MS. LUHANA:* Can you repeat the question, Judge?

2 *THE COURT:* You see discussed in the case law, the fit
3 to general causation. Do you think that that is part of the
4 helpfulness prong of Daubert?

5 *MS. BOGDAN:* The animal studies in this particular
6 situation, especially when you can't do randomized control
7 trials with humans because it is a known genotoxic carcinogen
8 are very informative and they are one piece of the puzzle,
9 especially when you cannot -- and all the experts have agreed
10 that you could never run a randomized control trial with
11 people so --

12 *THE COURT:* Right. I am trying conceptually, to make
13 sure I am thinking about it the same way you are, that when you
14 think of the issue of fit to general causation, whether it is
15 animal studies have a fit to general causation to humans, or
16 any other type of study, but in this case we have been talking
17 about animal studies that fits -- goes within the helpfulness
18 prong of Daubert.

19 *MS. BOGDAN:* It is one of the helpfulness prong, it is
20 also one of the Bradford-Hill criteria with regard to
21 plausibility. As the Court so aptly asked about the metabolism
22 being the same between animal tissues and cells in humans, the
23 qualitative part of that, not where it happens, that is very
24 instructive.

25 Certainly, as far as the carcinogenicity studies that

1 show that NDMA causes cancer in every animal that has been
2 subjected to it are very important and part of the general
3 causation totality of the evidence.

4 So, yes, they are important. I think they have to be
5 considered, especially in light of the situation where we are
6 talking about a genotoxin like NDMA.

7 *THE COURT:* Okay. Let me followup on that question.

8 So fit is part of the helpfulness prong, among others,
9 so, in doing that, do -- does that therefore mean that experts
10 need to explain how they extrapolate from animals to humans? I
11 am taking it one step at a time.

12 I know you discussed animal studies being used to show
13 the carcinogenicity of NDMA. Are you in agreement that
14 whatever you are learning and your experts are putting forward
15 with respect to the animal studies, they must explain how that
16 is extrapolated to humans, or are you not using the animal
17 studies for that purpose?

18 *MS. BOGDAN:* We have the human epidemiology --

19 *THE COURT:* Are you using animal studies to fit humans
20 to extrapolate from or --

21 *MS. BOGDAN:* Extrapolation is the applicability to
22 them, so the animal studies show us what organs and tissues --
23 and they reinforce what we also know from the human
24 epidemiology. It is a combination of all of this full body of
25 evidence. So the animal studies allow the investigators to

1 actually administer NDMA, which you cannot do to humans.

2 *THE COURT:* Did the experts anywhere explain how they
3 extrapolated on the basis of a species or on the bases of a
4 dose, or are they not setting out to do that?

5 I can't tell whether you are saying the experts don't
6 need to do that because the animal studies were not used for
7 that purpose, or they did do that and I haven't found that.

8 *MS. BOGDAN:* If you are speaking of dose, the human
9 epidemiology studies were used.

10 *THE COURT:* Not the animal studies.

11 *MS. BOGDAN:* We don't need to use animal studies for
12 dose because we have human epidemiological studies for dose.

13 *THE COURT:* Very clearly state what the animal studies
14 are being used for.

15 *MS. BOGDAN:* The animal studies are being used to show
16 the carcinogenic nature of NDMA. They are also being used to
17 show how NDMA is metabolized in the body. They are also being
18 used to show where NDMA can cause harm in the body, because we
19 have rat studies, but we also have a plethora of studies that
20 are mentioned in Dr. Panigraphy's report.

21 There are animal cell and tissue studies, but also
22 human cellular and tissue studies that show the harm that NDMA
23 does to both, which allows there to be this comparison with he
24 similar metabolism as far as how the tissues deal --
25 before that are formed, et cetera.

1 *THE COURT:* So, are there parts of the brief that
2 explain how the experts have taken the information from the
3 animal studies and applied them to humans? I am calling it
4 extrapolation or fit, but we can call it whatever makes sense.

5 *MS. BOGDAN:* I would let one of my colleagues answer
6 to the briefing. I can tell you the expert reports discuss the
7 use of animal studies in this fashion.

8 *THE COURT:* Right. Maybe you can make a note of that
9 and we can circle back. I want to know where the experts have
10 relied upon, if they have, and the Plaintiffs have argued that
11 to rely upon the animals both for how and why they were able to
12 draw inferences about humans based on what they observed in
13 animals.

14 *MS. LUHANA:* Judge, we will take a look at those cites
15 for you, but it is a body of evidence, the totality of
16 evidence. So, when IARC is reviewing NDMA and its
17 carcinogenicity, it is reviewing the animal studies, it's
18 looking at the mechanistic studies, and it's looking at the
19 epidemiology. So it is one piece of the puzzle that is
20 supporting it and --

21 *THE COURT:* Right. I understand that is the
22 Plaintiffs' position, but I am taking it piece by piece. I
23 want to focus on this piece.

24 *MS. LUHANA:* IARC, who says qualitatively you can use
25 this data for humans because it is being metabolized similarly,

1 and those are the conclusions of scientists all around the
2 world about NDMA, but we'll look at the cites during a break
3 and provide them to you.

4 *THE COURT:* And one followup from the Defendants, if
5 you want to say anything, because it was one of the arguments
6 you made that the animal studies are not a fit, and that the
7 Plaintiffs did not extrapolate on the basis of dose or species.
8 I am paraphrasing one of the arguments the Defendants made in
9 that regard.

10 Is there anything that you, in light of what the
11 Plaintiffs have said, that you want to be heard on that issue?
12 If you don't, that is fine.

13 *MS. RYDSTROM:* Yes, very briefly.

14 *MS. BOGDAN:* Your Honor, if I may, I might have had a
15 little bit of tunnel vision when you asked me a question
16 earlier with regard to timing of Ranitidine and food, and I was
17 answering it in a mechanistic way with regard to the half life
18 and the P plasma concentration.

19 I don't want the Court to take my comments to
20 undermine some of the criticisms in our experts' reports with
21 regard to the fact that if the food was already on board and
22 already was in the process of digestion and the nitrate was
23 readily available when Ranitidine was taken, then it would
24 result in more formation of NDMA as opposed to taken on the
25 fasting stomach, which has a low nitrite level, and then the

1 food ends up getting put on top of it.

2 That is a different order that is articulated in our
3 reports, and that is something different than what I was
4 answering.

5 So, if you were asking about that, because of my
6 tunnel vision on, I tend to go right to, you know, half life
7 and P plasma concentration and all the things that make this
8 case so fun, but if you are asking about that, then there is an
9 issue with regard to whether Ranitidine hits a fasting stomach
10 or whether Ranitidine hits a full stomach that already has food
11 that is in the digestive process and nitrite available from
12 that.

13 I wanted to make that clarification. Maybe I did
14 answer what you were asking, but in the event I did not, I want
15 to make sure I clarified that.

16 *THE COURT:* Thank you, I appreciate that.

17 Maybe before Defense speaks, I am going to go back to
18 the extrapolation question for whomever can answer it.

19 During their presentation earlier today, I thought I
20 heard Plaintiffs' counsel state that the experts did not
21 extrapolate from animal studies. I guess I should premise the
22 question with, did I hear that correctly? Can you confirm
23 whether that is in fact the position of the Plaintiffs?

24 And if your experts did extrapolate, that is where I
25 wanted to know, you know, the pages in the briefing where you

1 argue the experts conducted the dose extrapolation, but it came
2 from what I thought I heard, a comment earlier today that the
3 experts did not extrapolate from animal studies.

4 What is the Plaintiffs' position.

5 MS. BOGDAN: With regard to dose, the Plaintiffs did
6 no extrapolation from animals for the doses that would increase
7 the risk of cancer in humans. We have human studies for that.
8 It was done off the dietary studies, the Hidajat study. We did
9 not extrapolate from animal studies because we have human
10 information.

11 With regard to using the animal studies as part of the
12 totality of the evidence, for the reasons that I previously
13 stated, biomechanism, bioplausability, carcinogenicity of NDMA,
14 and an analysis of how the metabolisms are the same, the rate
15 of metabolism of NDMA, the animal studies are very instructive
16 on those issues. If you are asking about dose, that is all
17 being done off of human studies.

18 THE COURT: Dose response, dose extrapolation.

19 MS. BOGDAN: Human studies.

20 THE COURT: Did the Defendants want to make a point on
21 that?

22 MS. RYDSTROM: Very briefly, your Honor. Jessica
23 Rydstrom, your Honor.

24 If the question is, in the face of what we know about
25 humans, what does this tell us, what do these animal studies

1 tell us, I think Ms. Bogdan and I might be in heated agreement
2 because the answer is not much.

3 We know, in the face of the human epidemiology that we
4 discussed yesterday, that that can't be overcome by these
5 animal studies. The reason for that are those three -- the fit
6 problem arises with those three arrows that I had on the slide
7 about species to species, amount, and the site of tumors, and
8 to take one example, your Honor, it is the bioavailability
9 question that you asked before.

10 I guess I would say this, that on the one hand the
11 Plaintiffs' experts criticize Florian because they say the
12 plasma levels -- wasn't able to detect NDMA in the plasma
13 levels, and on the other hand they tell us that the
14 bioavailability in humans is expected to be 90 percent, and
15 that is a tension that I think is difficult to resolve.

16 One thing about the bioavailability, in the animal
17 studies what we see is these massive doses, not a dose response
18 question, but massive doses that are being given to animals,
19 and what happens when that occurs is that the liver is actually
20 swamped in its ability to metabolize the NDMA, so you would
21 expect that when you are giving massive doses of NDMA to
22 animals, that more -- that is exactly what you would see, that
23 more is available in the blood stream because the liver's
24 ability to metabolize it is basically overcome.

25 There are big differences, your Honor, between the way

1 that species -- perhaps not the mechanism by which the NDMA is
2 metabolized, but the availability and amount of that enzyme
3 that metabolizes NDMA is different between humans and mice.

4 So, that is one reason -- that is one thing that
5 potentially explains that finding in the Gombar paper that it
6 is not just a matter of saying small body, low bioavailability;
7 big body, big bioavailability. That is one of the reasons why
8 you have hit on this fit question, making it difficult to make
9 the leap there from animals to humans.

10 I would say the last thing is, we do have some human
11 data from Ranitidine about bioavailability, and that is from
12 the Florian plasma levels. They measured the amount of NDMA
13 after folks had taken Ranitidine that got into the bloodstream
14 and what they found was that there was not a statistically
15 significant increase as between Ranitidine and placebo, your
16 Honor.

17 *THE COURT:* Okay. Thank you very much.

18 Since it is only 20 to 12:00, that maybe what we could
19 do is have Mr. Bayman present, on your schedule, for 25
20 minutes. That would bring us to five minutes after 12:00, then
21 we could break for lunch before we hear from Plaintiffs and
22 then Defense rebuttal on the Najafi/Davis motion.

23 It is the brand Defendants' motion to exclude opinions
24 and testimony of Plaintiffs' experts, Ramin Najafi, Ph.D. and
25 Charles Davis, Ph.D. and other experts who rely on their

1 opinions. So you may proceed.

2 MR. BAYMAN: May it please the Court, Andy Bayman on
3 behalf of Boehringer Ingelheim and the brand Defendants.

4 Your Honor, it is odd that the history major would get
5 an analytical testing motion to argue, but I do have Mr. Bosso,
6 our new member of the LDC, who has a Master's in pharmacy,
7 available to answer any of the Court's technical questions, but
8 when you look at this motion, your Honor -- next slide -- you
9 don't have to be a history major to know that it really boils
10 down to three simple take-aways.

11 Emery never produced its data in a form that would
12 enable us to ask Dr. Najafi questions at his depositions in
13 order to verify the reliability of his data. Emery rejected
14 its own pre-litigation testing methods, and NDMA levels for
15 Zantac. And finally, after being retained for litigation,
16 Emery and Dr. Najafi used testing methods that no one else uses
17 and reported significantly higher levels of NDMA than anybody
18 else.

19 As my colleagues explained yesterday, your Honor,
20 there is a huge body of scientific evidence that answers the
21 question of whether ingestion of Ranitidine can cause cancer in
22 humans. The FDA and peer reviewed authors have established
23 reliable data on the levels of NDMA in Ranitidine drug
24 products.

25 Plaintiffs, however, weren't satisfied with that, and

1 they hired Dr. Najafi to redo testing with a unique methodology
2 that he developed for this litigation to report significantly
3 elevated levels of NDMA.

4 Moreover, Dr. Najafi ignores or rejects all data other
5 than his own, including the validated publicly available
6 results from the FDA and other peer reviewed authors, and this
7 is the most classic example of impermissible and inadmissible
8 cherry picking and it is the exact type of opinion that the
9 Court, in its role as gatekeeper, should not allow the jury to
10 consider.

11 Next slide.

12 Even though the science at issue in this motion
13 centers on analytical chemistry, I want to start with a concept
14 that might save the Court some time and energy. Emery's
15 analytical data is not sufficient to establish general
16 causation. In fact, Dr. Najafi is not providing an opinion
17 that Ranitidine can cause cancer.

18 Plaintiffs' counsel candidly acknowledged this fact in
19 the statement from Dr. Najafi's deposition, but if the
20 Plaintiffs can't come forward with sufficient evidence
21 demonstrating that Ranitidine causes any of the five cancer
22 types, there is no need for the Court to even consider this
23 analytical data.

24 Next slide.

25 Your Honor, one of the topics you asked the parties to

1 discuss is the standards and controls used during Emery
2 Pharma's studies. Now, the Plaintiffs would have the Court
3 believe that any work done by Emery, because it is a lab, is
4 necessarily valid.

5 In their opposition they quote the reference manual
6 statement that, quote, "when analytical work is performed in
7 certified highly experienced laboratories there is a reasonably
8 high likelihood that analytical results are reliable."

9 Dr. Najafi himself admits and Defendants' expert, Dr.
10 Olsen explains in his report, Emery did not follow any
11 generally accepted laboratory standards when it conducted the
12 litigation testing that Dr. Najafi relies on.

13 The manual provides, as you can see, that the lab
14 should have developed standard operating procedures and quality
15 control procedures, and it warns that it is very difficult to
16 confirm reliability when analytical work is done in
17 laboratories or by individuals who cannot provide evidence of
18 certification or longstanding quality control procedures.

19 These procedures are necessary to make sure there are
20 no problems or flaws that could cause the results to be invalid
21 or unreliable and so they can be identified and corrected.

22 Dr. Najafi and Emery did not follow any such
23 well-recognized standards, arguing those aren't necessary when
24 you are doing research.

25 Next slide.

1 Here is what Dr. Najafi says about the standards:
2 "The work that we have done for the Plaintiffs were not done
3 under GLP and GMP."

4 There are well-recognized and generally accepted
5 standards that apply to analytical chemistry laboratories and
6 these are some of them. There is no dispute that standards
7 exist, your Honor, but Dr. Najafi claimed that the standards at
8 his lab are not written down anywhere, and he could not
9 identify them, and he testified that he did not follow these
10 kinds of standards in his litigation testing.

11 Next slide.

12 "As a result, there were no SOP's provided to us by
13 anybody or by the Government or by ourselves."

14 So he didn't follow any SOP's. He claims in his
15 report that Emery Lab is a current good manufacturing practice,
16 and good laboratory practice, compliant laboratory, but he
17 admitted that none of the work that Emery did for the
18 Plaintiffs in this litigation complied with those standards.

19 In fact, he uses phrases like we adhere to the highest
20 standards. Those are exactly the kind of phrases that the
21 Eleventh Circuit rejected in the McClain opinion. The expert,
22 O'Donnell, in that case said he followed, quote, "broad
23 principles of pharmacology" and the Eleventh Circuit said those
24 kind of sweeping broad statements like that without anything to
25 back them up are of little value.

1 Next slide.

2 Emery's lack of compliance with any generally accepted
3 standards is evident in his testing. As the Court knows, the
4 Plaintiffs bear the burden of proving that each step in Dr.
5 Najafi's testing, analysis, and opinions is reliable.

6 So, the threshold question is whether the Plaintiffs
7 can prove by a preponderance of the evidence that a measurement
8 itself is accurate. That requires proof that the analytical
9 method was reliable or all analyses and conclusions drawn from
10 the faulty test results would be unreliable. If the answer to
11 that question is no, there is no need to continue.

12 Next slide.

13 So, the first step is, when looking at analytical
14 testing and trying to determine whether it is reliable, have
15 they proven that the analytical method is reliable? If the
16 answer to that question is yes, that doesn't end the inquiry.

17 The next question is whether the measurements are the
18 results of a properly designed peer reviewed methodology that
19 uses standard scientific principles, such as randomization or
20 proper sample selection. Again, if the answer to that question
21 is no, the Plaintiffs fail to meet their burden.

22 Finally, even if the first two elements are met, the
23 third step is whether the inferences the experts have drawn
24 from the study are reliable or, as the Supreme Court warned in
25 the Joiner case, is there too great an analytical gap between

1 the opinions and the data and the facts. In other words, can
2 an expert reliably apply the experimental findings to a real
3 world scenario.

4 For purposes of this argument, we will show how Dr.
5 Najafi's opinions are unreliable at each step.

6 Next slide.

7 The first issue I want to discuss is whether the
8 Plaintiffs have failed to produce sufficient data to provide
9 the reliability of Emery's data. They have not done that, and
10 as a result, the Defendants were not able to ask Dr. Najafi any
11 questions about the reliability of his data.

12 In particular, your Honor, Dr. Najafi has not produced
13 any chromatograms that he will authenticate. Your Honor has
14 heard a lot in this case about the importance of chromatograms.
15 Chromatography is a method by which scientists measure the
16 presence of or amount of a substance present in a sample.

17 During testing, through an instrument, each compound
18 is separated and measured. These measurements appear as peaks
19 on a chromatogram. A chromatogram then gets processed or
20 integrated, providing final results.

21 This processing can be done impartially by the machine
22 itself or it can be manually processed by the analyst who
23 replaces the machine's judgment with his or her own judgment,
24 but being able to review a process chromatogram is necessary to
25 evaluate the reliability of the reported results.

1 Certain types of processing can lead to artificial
2 over estimation of the amount of NDMA, so having access to the
3 chromatograms is critical for determining the reliability of a
4 measurement.

5 Next slide.

6 Defendants assert the Plaintiffs have not even
7 provided any necessary support for Dr. Najafi's opinion
8 and there is no way for them to meet their burden proving that
9 his testing and his opinions are reliable, as required under
10 Daubert and Rule 702.

11 To this day, he has not produced -- Dr. Najafi has not
12 produced any processed chromatograms that he will authenticate.
13 The Plaintiffs don't dispute that, but the argument is very
14 simple, your Honor. 702 requires that the experts' testimony
15 be based on sufficient facts and data and it is critically
16 important that the underlying facts and data be available for
17 review so the parties can understand the methodology and so
18 other experts can review the same information and offer
19 opinions about the data's reliability.

20 Next slide.

21 Now, Plaintiffs could have met their obligations under
22 the rules and produced Dr. Najafi's chromatograms in any of
23 these three formats, in pdf, raw data on a hard drive, or
24 Plaintiffs could have allowed Defendants and their consultants
25 to visit Emery, as Dr. Najafi offered, to view the data on

1 Emery's computer.

2 Next slide.

3 First, pdf's. Plaintiffs and Dr. Najafi repeatedly
4 said pdf's were not an option, but their arguments as to why
5 they were not an option are undermined by the evidence.

6 First Dr. Najafi claimed the chromatograms couldn't be
7 printed or exported due to the sheer size of the file. There
8 are two things wrong with that. First, outside of the
9 litigation, Dr. Najafi and Emery have no issue in providing
10 process chromatograms.

11 Through third-party discovery we found that Emery was
12 able to and did export chromatograms to pdf for non-litigation
13 clients. In fact, it did so in a report of its initial
14 Ranitidine testing for Valisure that you can see up on the
15 screen, your Honor.

16 Second, the Defendants accomplished what Dr. Najafi
17 said was impossible. We filed a declaration of Dr. Mark
18 Benotti who generated pdf reports from Dr. Najafi's raw data,
19 and he said these took one to two minutes to generate and quite
20 literally amounted to pressing a button in the master
21 proprietary software.

22 Your Honor, more importantly, chromatograms can be
23 printed to pdf, and Emery's own 30(b)(6) designee, Dr. Najafi's
24 daughter, says Emery does this in the course of its business.
25 Yet, today, your Honor, standing here we still have seen no

1 paper chromatograms produced by Dr. Najafi.

2 I don't know, after having looked at their slides,
3 whether they intend to offer some of those as part of their
4 presentation, and I will address that in the rebuttal, but as
5 of right now we have received no paper processed chromatograms.

6 Secondly, your Honor -- next slide -- Emery could have
7 produced the data in raw -- native format on its hard drive.

8 In early May, after repeated requests by the Defense,
9 Plaintiffs finally produced a hard drive in the proprietary
10 software mass center, but Dr. Najafi claimed that the data he
11 produced might have been corrupted or manipulated, and maybe
12 was not even his data.

13 So, despite seeing the data exactly as it was produced
14 and exactly as it would appear on Emery's computer, Dr. Najafi
15 refused to answer any questions about that data.

16 This is despite the fact that the Defendants showed
17 him the pdf's of the chromatograms that were produced by our
18 consultant off Emery's hard drive. When he saw those, he
19 claimed he couldn't recognize them.

20 The Defendants then actually plugged in his hard drive
21 and showed him the exact data as it appears on a computer
22 within the proprietary software, but again, he refused to
23 acknowledge that it was his data.

24 Instead, Dr. Najafi specifically said the data had to
25 be viewed on his computer at Emery Pharma, and let's listen to

1 what he said.

2 "The first question on that is, the way I understand
3 what you are saying, is that we would be required to look at
4 the results on your computer to be able to see how the
5 chromatograms really look; is that right?

6 "Objection to the form.

7 "That is exactly what I meant."

8 In fact, Dr. Najafi issued an invitation not once, but
9 three times for the Defendants to visit Emery and look at the
10 information on his computer.

11 Next slide.

12 "And I went one step further and invited, you know,
13 the Defense experts to come to our lab and spend a day in front
14 of our computer and be able to actually walk through all of our
15 files, and if they had any question our team would be able to
16 answer them. So we even suggested that. I don't know if you
17 got the word, but --

18 "Objection.

19 "I will represent to you that I have not heard of this
20 invitation, but thank you."

21 "So if he sees something other than what we see, then
22 obviously I would send him a ticket -- buy him a ticket to come
23 here and just look at our computer directly from here. That is
24 the bottom line. That is what I originally had suggested, that
25 we have the expert, Olsen, whoever, wanted to come out here and

1 spend a day just going through our computer. We would be happy
2 to host them, but by me -- by us sending you some raw data, and
3 then you guys opening it into your own system and potentially
4 manipulating it and potentially, you know, essentially, you
5 know, changing it, then obviously it won't work, but that is
6 what I have been saying. If you go back to the records you
7 will see that I have said that three times at least.

8 "Okay. Motion to strike, as not responsive, and I
9 will represent to you there have been no changes made to these
10 files that were sent -- copied and sent by Emery Pharma to us.

11 "Now, as to the invitation, we would gladly accept it,
12 and we can be there next week with Dr. Benotti and other folks,
13 and go through the data so that we can obtain an accurate set
14 of data. We will definitely take you up on your invitation and
15 we will talk with counsel about getting that on schedule. We
16 appreciate that.

17 "It would be my pleasure.

18 "Wait, stop."

19 Plaintiffs' counsel put a stop to Dr. Najafi's
20 invitation.

21 Next slide, please.

22 And subsequently in an email rejected the invitation
23 by Dr. Najafi, or withdrew the invitation by Dr. Najafi to
24 visit Emery's facility.

25 So, to date, the Plaintiffs have refused to

1 authenticate Dr. Najafi's data in any useable format, not in
2 pdf, not in hard drive, not even in an on-site inspection, and
3 we were unable to ask Dr. Najafi any meaningful questions, to
4 evaluate the reliability of his data.

5 In fact, the Plaintiffs have not even offered an
6 expert who can testify about the reliability of Emery's
7 chromatograms. Therefore, the Plaintiffs cannot meet
8 their burden of demonstrating the reliability of the data under
9 Rule 702, and not a single expert can testify to this.

10 In fact, Dr. Najafi -- go ahead.

11 "What do you mean some or -- some and all? Did you
12 review all the chromatograms or some of them?

13 "No, I did not review all of them. I reviewed some of
14 them.

15 "Have you reviewed the chromatograms that underlie
16 these values?

17 "I have reviewed some of them. I don't primarily rely
18 on chromatogram, I rely on the data that my team provides to
19 me, and I don't go to the underlying data. Like this morning,
20 they provide me tables and those tables I rely on."

21 Next slide.

22 So, Dr. Najafi didn't evaluate the underlying data
23 behind his chromatograms, but our experts looked at what was
24 printed off in pdf format by Dr. Benotti from the hard drive
25 and they found the data was unreliable, and specifically Dr.

1 Bumpus, who is now chief scientist at FDA, said the
2 chromatograms were so poor that they have no scientific value.

3 Next slide.

4 So, without the underlying data the Plaintiffs can't
5 prove the reliability of Dr. Najafi's result and they cannot
6 get past the first prong of their burden, and the Court need
7 consider nothing further.

8 Moving on to the second question, Dr. Najafi
9 repeatedly rejected established generally accepted methodology,
10 and instead used methods that were designed by his team which
11 drove up the levels of NDMA.

12 Next slide.

13 This slide shows some of the ways Dr. Najafi deviated
14 from generally accepted methodologies. Notably, instead of
15 using one of two validated methods for the baseline testing
16 that FDA designed and made available to scientists in September
17 and October, that is the Reverse-Phase, liquid chromatography
18 mass spectrometry, Dr. Najafi used his own HILIC method for
19 this particular analysis. No one else has done that, your
20 Honor.

21 He also designed consumer experience testing
22 purporting to show how Ranitidine tablets could degrade with
23 simulated tests that no one else, no other researcher or
24 regulator has ever used.

25 So at each of these steps Dr. Najafi has deviated from

1 generally accepted methods and selected his own methods, which
2 drove up the levels of NDMA. His methods are not reliable,
3 they're not generally accepted, and the render his opinions
4 inadmissible.

5 I want to talk for a minute, because your Honor asked
6 a question about the HILIC method.

7 Next slide.

8 As you will see, Emery used HILIC for its litigation
9 testing, but each of these other researchers, whether it be
10 Government agencies like the FDA, like Health Canada, like the
11 Australian agencies or other researchers use the Reverse-Phase.
12 In fact, Emery itself used the Reverse-Phase in the testing it
13 did on Ranitidine for NDMA as part of its Citizens Petition
14 before it was retained in this litigation.

15 Next slide.

16 That begs the question then, your Honor, if the
17 pre-litigation Citizens Petition is the result of a reliable
18 method, why, then, after being retained in litigation did Emery
19 use a different method?

20 Next slide.

21 Not surprisingly, as you will see here, your Honor,
22 Emery's HILIC method generated much higher levels of NDMA than
23 those reported by any other researcher.

24 This demonstrates just some of the significant
25 differences with HILIC as compared to the generally accepted

1 peer reviewed method used by the FDA and others.

2 At the time that Emery did it pre-litigation testing,
3 yo will see -- using the reverse method, you will see the
4 results there, and then when it switched to HILIC for no
5 apparent reasons the results are significantly higher, and he
6 relies in his report only on his litigation testing and, in
7 fact, ignores and rejects his pre-litigation testing.

8 Next slide.

9 This figure really shows how far afield Emery's
10 results were from all the other researchers who looked at this
11 question, and it is not the fact that he used a methodology
12 that is not generally accepted, but it is also that he ignores
13 or rejects all other discrepant data in arriving at his
14 opinions, and that is the type of opinion that should not be
15 considered by a jury.

16 Next.

17 Your Honor, we heard a little bit about his
18 simulations. His simulations also drive up the amount of NDMA.
19 Here on the left is Emery testing of product that was stored
20 under real world room temperature conditions, for nearly four
21 years and it experienced less than one nanogram per week of
22 NDMA formation on average, but for the same product under
23 Emery's room temperature simulation the rate of NDMA rose to 72
24 nanograms per week.

25 In other words, the same product and purportedly under

1 the same conditions, the simulation that no one else has done
2 and has not been peer reviewed results in a significantly
3 higher rate of NDMA formation compared to what actually
4 occurred in the real world.

5 Similarly, your Honor, Dr. Najafi's incubated meat
6 simulations are also significantly flawed and not accepted in
7 the scientific community. They do not take into account, for
8 example, the effect of stomach contents emptying over time, and
9 Dr. Najafi assumes that there is the same amount of stomach
10 contents over a four-hour period. It is a result oriented
11 approach.

12 The testing was did designed to say -- or to look at
13 what food, when it comes into contact with Ranitidine, creates
14 NDMA. They didn't cook the meats. The meats were precooked,
15 so they were not in a condition that most consumers would
16 experience when they consumed the meat, and they didn't account
17 for some of the things that other models that are generally
18 accepted for simulating digestive fluids contains.

19 So, simply, this is Dr. Najafi's own methodology that
20 has not been peer reviewed, that has not been adequately
21 documented and should be inadmissible.

22 Your Honor, this is significant because Daubert warns
23 that when experts reach a conclusion that other experts in the
24 field would not reach the trial Court should be suspicious
25 about the principles and methods and that they may not have

1 been faithfully applied.

2 Next slide.

3 *THE COURT:* You are just about at 25 minutes.

4 *MR. BAYMAN:* Okay. Your Honor, again, we are going --
5 have other examples of where Dr. Najafi's testing simply is not
6 generally accepted, it is his own unique methodology, and he
7 finds inconsistent results.

8 Lastly, your Honor, and very briefly, the Court asked
9 us to address why Dr. Najafi's -- why the confidentiality order
10 in this Court would prevent Dr. Najafi from producing something
11 in the peer reviewed literature and, your Honor, the answer to
12 that is very simple, there is nothing about the confidentiality
13 order in this case that would prevent him from submitting to a
14 peer reviewed journal.

15 In fact, he said in communications with the FDA that
16 in fact -- go ahead to the last slide. Right there.

17 He said that he had an ongoing study and he hoped to
18 publish it in peer reviewed literature, and then he said later
19 that his research is not published in a peer reviewed journal
20 and that is because it was not of publishable quality.

21 So, there is nothing that would have prevented him
22 from publishing it if it were of publishable quality.

23 Thank you, your Honor.

24 *THE COURT:* Okay, thank you very much.

25 We will take our lunch break. It is 12:08, and I

1 think we allotted an hour, so we will come back at 1:08, and we
2 will pick up with the Plaintiffs' response to the Najafi/Davis
3 motion and then the rebuttal, and then we will probably go into
4 some questions then, unless I want to take a break before the
5 questions, before we move into the motion for summary judgment.

6 So, we will be in recess for one hour, until 1:08.
7 The courtroom will remain open, and we will everybody back
8 then.

9 (Thereupon, a luncheon recess was taken.)

10 *THE COURT:* All right. Thank you, you may be seated.

11 Okay, the Plaintiffs on the Najafi/Davis 5698 motion.

12 *MR. NIGH:* Your Honor, I am going to use a stopwatch
13 on my phone if that's all right.

14 *THE COURT:* Yes, I have a backup here, too.

15 *MR. NIGH:* Good morning, your Honor, Daniel Nigh for
16 the Plaintiffs.

17 *THE COURT:* Good -- well, actually, it is afternoon.

18 *MR. NIGH:* Good afternoon. Defendants chucked a lot
19 of spaghetti at the wall hoping to see what sticks, but I am
20 going to jump around the slides to be more responsive to
21 Defendants' arguments.

22 First, I wanted to just take note that the Defendants'
23 videos, those excerpts they had of Najafi's testimony are
24 completely taken out of context, and even cut him off
25 mid-sentences, where he provides more detailed responses in

1 other parts of his deposition. It is just a complete
2 disservice.

3 I want to address Defendants' allegation that Emery
4 Pharma never produced its data in a form that would enable us
5 to ask Dr. Najafi questions at deposition.

6 This is utterly false. We produced an over 200-page
7 expert report with very detailed information and this was a
8 pdf. When Anna Najafi was asked how reports are typically
9 kept, and she answered, we have a Word doc in a pdf format of
10 reports, she is referring to reports, like the 200-page report
11 Najafi produced, and for this litigation, it was produced as a
12 pdf, just like for all their reports.

13 What Defendants are asking about are all the native
14 underlying data. Emery Pharma does not store those underlying
15 data as pdf's, and Dr. Najafi does not review those data as
16 pdf's. Defendants created their own problems with reviewing
17 this underlying data, and I would refer to our response to the
18 motion to strike and Dr. Steffy's report that explains this
19 thoroughly.

20 Defendants' reliance and insistence on printing an
21 8700-page pdf of this underlying data is precisely why they
22 couldn't adequately question Dr. Najafi about it. That is not
23 how he reviews the data.

24 To explain this briefly by analogy, it is like taking
25 a Microsoft Excel spreadsheet with a thousand columns and

1 printing this on paper. That data would be printed on over a
2 hundred pages, that would be nonsense, but rather than even
3 attempt to tape the order of the columns together from one to a
4 thousand, they are put together entirely out of order by the
5 Defendants in their pdf.

6 That is how Defendants printed out their 8700 pages of
7 pdf's for the underlying data, and even worse, Defendants then
8 at deposition only show a few pages, of this Excel of columns
9 500 to 510, and showed only that to Najafi at deposition and
10 asked detailed questions. Najafi says, I need to see columns 1
11 to 100 to even understand these columns at 500 to 510. I
12 review this data together, and without that I wouldn't be able
13 to know if the data at columns 500 to 510 are corrupted.

14 At deposition, Defendants can't show him columns 1 to
15 100, but rather say you are free to take a look at our jumbled
16 up 100-page Excel that is completely out of order, good luck.

17 Defendants' problems at deposition were created by
18 their own actions, possibly intentionally or through their own
19 experts' nescience. Defendants admitted that none of their
20 experts hired to criticize Najafi had ever even used Agilent or
21 mass software, which is what Najafi and Emery Pharma use, and
22 many analytical chemists across the country, they use this to
23 conduct and analyze data from LC-MS/MS.

24 Now, Defendants argue that we never produced this
25 material in a meaningful way. That is completely false, and

1 explained thoroughly in our response to the motion to strike,
2 and Dr. Stefanis' report. We produced this data and made a
3 format how it should be produced, just like how Excel
4 spreadsheets should be produced and are produced in this
5 litigation.

6 We purchased two hard drives with all the files in
7 native format that Defendants could have used and still could
8 use currently, but decided not to do so in an adequate way.

9 Defendants claim that Emery Pharma never produced
10 chromatograms that he could authenticates. That is completely
11 false. We produced them in a format he could have
12 authenticated if they showed it to him in a format that he was
13 used to using.

14 Now, let's take a look at slide 51.

15 These are screen shots of the video we sent to
16 Defendants how Emery Pharma and Najafi view and analyze the
17 data. We offered to record a video of the desktop view for how
18 Emery Pharma views all of their results from Agilent MassHunter
19 on the computer, and we sent this specific detailed video
20 showing Emery Pharma's view for the validation testing and
21 numerous tests it samples. The video scroll, it scrolls all
22 the way down, and shows all the testing of these various
23 samples with the validation.

24 This would have had the information -- slide 55 -- but
25 the Defendants rejected this offer, rejected by Luke Bosso,

1 Defense counsel. This would have had all of the information in
2 the order Najafi requested to view these chromatograms. We
3 gave them a video that was eight minutes long and showed all
4 the information of the testing in this run, with all the
5 validation steps and Defendants rejected any further videos.

6 Defendants also didn't even prepare their pdf's in an
7 order consistent with how this video demonstrates Najafi viewed
8 results. Even today with the native data Defendants have, they
9 could load up on an Agilent MassHunter system and view all the
10 information the same way Najafi views it, but they insist on
11 relying on an 8,700 page pdf.

12 Defendants created their own issues with viewing the
13 underlying data either intentionally or through their experts'
14 nescience.

15 Now, as Steffy states in his declaration, an Agilent
16 MassHunter, the original native data generated from the
17 LS-MS/MS analysis is preserved and remains unchanged. The data
18 may be reviewed and processed, but the original unaltered data
19 is always intact, paragraph 9.

20 When MassHunter is used to properly process that data,
21 the software will always generate the same native data
22 chromatogram and results, paragraph 9. Steffy confirmed this
23 with the Emery data produced to Defendants which always
24 generated the same chromatogram and values to 15 significant
25 figures, paragraph 15.

1 With that original native data, it is possible for any
2 trained analyst to generate the chromatogram and other
3 numerical results and determine the amount of an analyte like
4 NDMA in a given sample. The analyst, by using the original
5 native data, can evaluate and interpret the chromatogram and
6 data to arrive at the result. That is Steffy's detailed
7 affidavit submitted in the motion to strike.

8 Your Honor, keep in mind that Defendants will not do
9 their own testing to see if Emery's testing data is accurate or
10 to support their baseless accusations. They could have done
11 this.

12 Well, I should correct myself, they may have done this
13 testing with undisclosed consulting experts, but that evidence
14 is not presented here today.

15 Emery Pharma presented all their detailed protocols as
16 to how they ran each of their experiments. Defendants had ever
17 ability to try and replicate this, and they didn't, or they did
18 so with the undisclosed experts and consultants.

19 Defendants had every ability to run their own testing
20 that simulated real world experiences, especially what happens
21 when a consumer breaks the seal on the bottle and the
22 medication is susceptible to humidity, but they have never done
23 this extremely relevant testing.

24 Next, I am going to discuss Defendants' claims that
25 Plaintiffs have not demonstrated that the analytical method is

1 reliable, we have.

2 Slide 21, please.

3 Emery Pharma used the method FDA approved, LC-MS/MS.

4 Next slide.

5 In October, of 2019, the FDA announced this accepted
6 method. Here is what it looks like.

7 Next.

8 Now, this is a diagram of the LC-MS/MS. The UPLC on
9 the left feeds into the LC-MS/MS. The ESI ionizes the
10 compounds in less than 20 milliseconds, and the QQQ process
11 separates the compounds to make sure only NDMA is detected.
12 This LC-MS/MS method has been utilized and validated by
13 thousands of publications, and accepted by FDA testing for
14 testing and detecting NDMA.

15 Next slide.

16 Now, Defendants argue that Emery's use of a HILIC
17 column somehow inflated results, yet they don't provide one
18 shred of evidence of this allegation, no evidence to suggest
19 that the HILIC column could somehow inflate results, none.
20 Only that it is a different column than FDA's initial method in
21 October of 2019.

22 Next slide, and next one after that.

23 To understand why Emery chose a HILIC column, it is
24 important to understand that NDMA is a polar hydrophilic
25 compound. That is not disputed. It is in multiple studies,

1 it's everywhere.

2 Next slide.

3 As discussed by Waters, HILIC compounds have been used
4 since 2003, as you can see in the highlight there, to separate
5 extremely polar compounds like NDMA. Defendants' assertion
6 that Emery choosing a different column than FDA's initial 2019
7 method is somehow using an unreliable methodology is flawed.

8 Next.

9 Every investigator testing NDMA since FDA's initial
10 2019 method has used a different column. FDA's 2019 method
11 proposed the Ace Excel column. GSK used the Phetametic Synergy
12 column. Other authors used the Shipmac column and Kinetex
13 column, and even the FDA researchers in Florian used a
14 different column, the Kinetex Biphenyl column. Defendants'
15 arguments about the column are a red herring without any basis.

16 Next slide.

17 Now, Defendants' assertion that Emery Pharma did not
18 follow approved methods is baseless and they conflate ideas.
19 They try to argue that not following CGMP or GLP standards or
20 the SOPs based on those standards makes Emery Pharma's
21 methodology unreliable, but this, too is a baseless accusation.

22 First off, it is important to understand that Najafi's
23 testimony about SOPs is taken out of context. SOPs, that
24 statement, to the analytical chemist, in the pharmaceutical
25 industry is a term of art that to them and Najafi means CGMP

1 SOPs. These standards apply to pharmaceutical development to
2 gain approval to sell a drug or to manufacture a drug that is
3 approved.

4 Emery Pharma follows these guidelines when they are
5 applicable for their pharmaceutical work. You see, unlike
6 Defendants, who chose all seasoned defense expert veterans,
7 Plaintiffs chose an expert whose majority of work, even
8 currently, is for pharmaceutical manufacturers, similar to the
9 Defendants in this litigation who are pharmaceutical
10 manufacturers.

11 The standards that are applicable to Emery Pharma's
12 testing are published in the Analytical Procedures and Methods
13 Validation for Drugs and Biologics, an FDA guidance document.
14 Specifically, this FDA guidance document requires analytical
15 method validation for specificity, linearity, accuracy, and
16 precision.

17 Next.

18 The ICH also suggests these guidelines as well.

19 Next.

20 Now, I will go through these very quickly, but they
21 followed all of these protocols. First, Emery Pharma's
22 validation showed specificity, like seen on the screen.

23 Next.

24 Also, Emery Pharma's validation shows linearity and
25 range, like seen on the screen.

1 Next.

2 Also, Emery Pharma's validation shows accuracy, like
3 seen on the screen.

4 Next.

5 Emery Pharma's validation shows precision.

6 Next.

7 Emery Pharma's validation shows sensitivity.

8 Next.

9 And finally, Emery Pharma's method shows n matrix
10 accuracy.

11 Now, most importantly, if Defendants' theories were
12 true about Emery Pharma's method causing artifactually more
13 NDMA created, then n matrix accuracy would have failed, but it
14 didn't, so it shows them that it is not creating artifactual
15 NDMA.

16 Next, next.

17 Now, Emery's extensive validation done in accordance
18 with FDA, ICH, and USP guidelines proves the Emery LC-MS/MS
19 method is accurate, precise, linear, and specific for NDMA.
20 The passage of all these criteria through objective testing
21 proves that the Emery LC-MS/MS method is valid. In short, it
22 is suitable for its intended purposes.

23 I am going to skip a couple of slides here for time
24 purposes. Skip, skip, skip, and skip.

25 Now, Defendants -- I will address this again,

1 Defendants' allegations are baseless. Defendants' assertion
2 that NDMA forms at the MS source is baseless, as none of the
3 sources cited report any observation of an in-source conversion
4 of Ranitidine to NDMA. It doesn't happen because that small
5 time that it has to ionize is less than 20 milliseconds, in an
6 LC-MS/MS. That is why the FDA approves this method.

7 Next, and next, we'll skip that.

8 Now, Emery Pharma followed extensive quantification
9 protocols as well, they are all stated here. You can see this
10 for quantification of NDMA for Ranitidine by LC-MS/MS for
11 Ranitidine syrups, injectables, and effervescent tablets.

12 Next.

13 Extensive quantification protocols for the stability
14 assessment of Ranitidine towards NDMA formation by LC-MS/MS in
15 simulated gastric fluid again. Again, these are all the
16 protocols the Defendants could have analyzed and done the
17 testing themselves, or if they had issues with how it was done,
18 this is where they could have looked at it.

19 Next.

20 Nitrosation assay procedure, the NAP, and related
21 procedures to evaluate NDMA production from baseline.

22 Next.

23 And Emery Pharma's consumer experience testing is
24 grounded in published literature and established guidelines.
25 These are the studies supporting the conditions used for their

1 vehicle conditions testing. They are all in our papers.

2 Next.

3 This is the published literature supporting the
4 conditions for bathroom testing. It is in our published
5 papers.

6 Next.

7 These are the established ICH guidelines for climatic
8 zones that Emery Pharma's zone testing is grounded in, and the
9 zone testing that Dr. Salmon relies upon.

10 Next.

11 This is the published literature that is the basis of
12 Emery Pharma's SGF testing.

13 Next.

14 Along with Braunstein and Gao, this is the published
15 literature that supports Emery's SGF study with food.

16 Next.

17 Now I want to skip to slide 58, and we are going to
18 discuss the Defendants' allegations about confidentiality
19 order.

20 Defendants' arguments that Emery Pharma should have
21 published their literature are disingenuous. First, products
22 liability testing is admitted as evidence all the time in
23 courts where they weren't peer reviewed. That is not the
24 standard.

25 Most importantly, Defendants insisted on

1 confidentiality that handcuffed publishing these results.

2 First, Defendants insisted that Emery Pharma sign this document
3 that would potentially put Emery Pharma at sanctions if they
4 violated it.

5 Next.

6 Judge Reinhart's order that accompanied the production
7 of Defendants' products to Emery Pharma demonstrates that Emery
8 Pharma was directed to use this product testing, and you can
9 see it there highlighted, the second part, for litigation
10 related purposes only. And this document was drafted by the
11 Defense counsel.

12 Next.

13 We can see more orders that show the same thing, they
14 are all based on the same language.

15 Next.

16 There's BIPI, we have Patheon, there are numerous of
17 these.

18 Now I want to go ahead and skip to slide 7.

19 Now, Defendants claim that Emery Pharma's testing are
20 inconsistent with all other testing is false. They are just
21 not showing you the testing that is consistent. Defendants
22 want to focus only on Defendants' and FDA's baseline testing of
23 pristine product. You can see that here in the upper left-hand
24 corner. That is baseline Defendant, FDA, that's the pristine
25 product.

1 What they don't show you is that other baseline
2 testing has shown results that are actually very similar to
3 Emery Pharma. One of them is Braunstein, another one, TGA,
4 that is the counterpart to the FDA, and another one is actually
5 Sanofi's own testing, which is another data point.

6 When you asked if we could -- FDA max, Sanofi
7 considered those pieces of Sanofi testing -- Dr. Salmon
8 considered those pieces of Sanofi's testing in forming his
9 conclusions.

10 Next.

11 Now, to put this into context, before April of 2020,
12 the FDA was only doing baseline testing and allowing Ranitidine
13 with less than or equal to 96 nanograms to continue to be on
14 the market. At some point before the recall they did do some
15 stability testing, but that is not their testing published
16 initially. That is not the testing Defendants are showing to
17 your Honor.

18 The testing they are showing you is only the baseline
19 testing.

20 Next, next.

21 Now, Defendants argue that Emery Pharma's results were
22 somehow different for the petition that they filed -- that they
23 filed compared to their litigation results, but that is because
24 specifically Emery Pharma didn't know to test for humidity back
25 then, they only tested for heat.

1 We have learned now that humidity is much more the
2 driving factor and plays an even larger role than heat, in
3 showing how much NDMA breaks down.

4 This is the petition they filed, they filed on heat
5 alone, and heat alone was enough to show that Ranitidine was
6 unsafe.

7 In 2020, the FDA granted Emery Pharma's request, in
8 January, 2020, to recall all Ranitidine in the United States.
9 Emery Pharma isn't some maverick, this shows instant
10 credibility.

11 Defendants also argue that Najafi didn't publish this
12 January 2020 Emery Pharma petition. That is what they closed
13 with, but this was well explained, because Najafi -- what
14 Defendants didn't tell you is that Najafi stated that he didn't
15 need to publish these results. The FDA responded to this
16 petition and recalled all Ranitidine in the United States.
17 That is much more of a scientific impact than a publication.

18 Next.

19 Somehow Defendants dispute -- next.

20 Somehow Defendants dispute that Emery Pharma wasn't
21 responsible for this recall, or at least in part, but even
22 their own expert admits to this.

23 Go ahead and play the video, please. There, might be
24 a delay.

25 Well, if you go back to that prior video, you can see

1 the deposition transcript of Dr. Wang at page 134, line 21, to
2 135, line 3, where he admits that Emery Pharma is responsible,
3 at least in part, for FDA's decision to recall all Ranitidine
4 in the United States.

5 Next.

6 Now, your Honor asked if there was some other data
7 that was relied upon, for Salmon's FDA max number. Yes.
8 Sanofi's own testing that they didn't include in their 19
9 results that they showed your Honor shows this.

10 You see, they tested only two batches that would
11 simulate real world experience of what a consumer, our
12 Plaintiffs, would have purchased before opening the bottle and
13 then additional NDMA forming.

14 They presented these results that NDMA formed because
15 the regulators required them. As you can see here, it says, in
16 the meantime, comparison of this result of 5.24 PPM to the one
17 obtained on the retained samples of the same batch, their
18 retained sample, that would be their baseline testing that they
19 want to rely on, their retained sample is only .73 PPM.

20 So we can already see a sevenfold increase just with
21 the passage of time, let alone opening up the bottle. These
22 aren't extreme conditions. 24 degrees Celsius, that is
23 77 degrees Fahrenheit.

24 To suggest that storage conditions has an influence on
25 NDMA content in the drug product, and when you average just

1 these two results, they are right there, it exceeds Salmon's
2 FDA max number. He explains this as support for his FDA max
3 number.

4 Now, in addition, I want to go to slide 18 and --

5 *THE COURT:* Can I ask real quick, this screen 12, is
6 that part of -- in the record?

7 *MR. NIGH:* Yes.

8 *THE COURT:* Where does that come from?

9 *MR. NIGH:* I couldn't tell you precisely, but we can
10 get you that answer.

11 *THE COURT:* Okay. So screen 12. Thanks.

12 *MR. NIGH:* Yes.

13 Next, Braunstein, their testing demonstrates 824
14 nanograms to 1440 nanograms per 150 milligrams of NDMA at
15 baseline. The Defendants' own expert admits that these testing
16 results would be their baseline testing results. That is Dr.
17 Bumpus. She admits that because she is citing the language
18 from the Gow study that says this would have been their
19 baseline results. These results are actually higher than Emery
20 Pharma's results.

21 Next.

22 And as you can see, I want to go to -- if we can go
23 back to the GSK document, I don't have the slide number, but
24 it's a few slides before this, it shows GSK testing.

25 I only have a few more points, but I want to show

1 this, too, because GSK's root cause analysis of accelerated
2 testing demonstrates that at 50 degrees Celsius, 65 percent
3 relative humidity, there are 26,730 nanograms in a 150
4 milligram tablet.

5 I am sure the Defendants will come up here, and they
6 will say, well, 50 degrees Celsius, that is not a real world
7 condition, but the point on this that you can see is, when you
8 look at 70 degrees, and you look at 60 degrees, those results
9 aren't that much different than at 50 degrees. What is the
10 driving factor? The humidity.

11 So, that is the question that needs to be answered,
12 how much forms in real world conditions after you open up the
13 pill bottle and suspect the pills to humidity. Some of these
14 pill bottles have 150 pills in them. Our consumers, our
15 Plaintiffs, they don't open up the bottle and down all 150, it
16 is over time, after the seal is broken, and they place these in
17 common spots, like the medicine cabinet, or in the car, in the
18 sun and the shade.

19 I also want to show, for Saraca -- there was this
20 argument that somehow Saraca with a different crystallization
21 might show different levels of NDMA. That is for the API
22 because the root cause analysis does not demonstrate that. You
23 can look at the Saraca, and you can see at 50 degrees
24 Celsius -- no, before that, don't change that. Thank you.

25 At 50 degrees Celsius, 65 relative humidity, you are

1 seeing similar results. It's not any different. When you
2 apply humidity to the pill it breaks the liner and you see more
3 NDMA coming, or it slowly degrades the liner and you see the
4 NDMA.

5 Next, and next. I have one last slide.

6 Now, this begs the question how much NDMA forms in the
7 real world? And the FDA -- the Defendants keep wanting to rest
8 on the FDA as if their baseline testing that they published in
9 October, and November, 2019 was their ultimate answer. It was
10 not.

11 After that, they did stability testing and they
12 showed -- they weren't confident that any Ranitidine wouldn't
13 have excessive amounts of NDMA, so everything was recalled in
14 April, 2020.

15 Fast forward even further to that, the FDA convened a
16 panel of experts, and on March 29, 2021, these exact questions
17 were being raised by these experts who posed the following:
18 "Yeah, I mean I think there is a big focus on, you know, real
19 world conditions, right, you know, the hot mailbox, the glove
20 box in the car, you know, the human bathroom."

21 Emery Pharma didn't come up with this stuff
22 themselves. "You know, I mean, if you think about those
23 things, you know, what does it experience in the truck in the
24 middle of the summer in the southern U.S., you know, so before
25 it gets to the shelf."

1 Emery Pharma's testing --

2 *THE COURT:* It's time.

3 *MR. NIGH:* This is my last thing. Emery Pharma's
4 testing answered this important question, asked by the FDA
5 panel. The testing results are accurate and reliable and
6 grounded in the validation and the guidelines established by
7 the FDA, ICH, and USP.

8 Thank you, your Honor.

9 *THE COURT:* Thank you.

10 Okay. So now we have the rebuttal of five minutes.
11 Plaintiff went over by about 51 seconds. If you need a little
12 more time, 51 seconds or so, but otherwise five minutes.

13 You may go.

14 *MR. BAYMAN:* Thank you, Judge, just briefly. You
15 know, Mr. Nigh spent a long time talking about that we rejected
16 their offer to provide videotapes. What they offered to do was
17 to do a series of screen shots and videotape those screen
18 shots, so there is no way to toggle back and forth.

19 What he didn't say is that not -- Dr. Najafi said the
20 only way to do it would be on Emery's computer, there, and he
21 invited us to come three times, and they rejected that
22 invitation. He said that is the only way to see the
23 chromatograms, and even though they can produce reports, none
24 of their reports contain any chromatograms.

25 And, so, that is why the offer of video was rejected.

1 With respect to the confidentiality, your Honor, in
2 the quote from Judge Reinhart's order that it is not to be used
3 for commercial purposes, that means -- that is for Customs
4 reasons. That means they couldn't take the product and sell
5 the product. It did not mean they could not publish the
6 results of their testing. And in fact, Dr. Najafi intended to
7 publish the results of his testing and he testified it was not
8 of publishable quality.

9 Mr. Nigh mentioned matrix accuracy. They have no
10 experts to support that at all. They have no expert who has
11 actually demonstrated that the HILIC method achieves better
12 separation. There is simply no support. This is just -- and
13 the Daubert cases warn of this.

14 They are asking you to rely on what Dr. Najafi says
15 without any proof of what standards he followed. He says, oh,
16 yeah, we follow standards, but he doesn't provide the
17 standards. He doesn't say what the standards are, that he
18 follows, just that we follow standards. That is what the
19 Eleventh Circuit in McClain found fatal with Dr. O'Donnell's
20 opinions.

21 The explanation about heat is really a red herring
22 because what you need to do is compare apples to apples to
23 compare the baseline testing, and there was other testing done,
24 including the GSK testing, Mr. Nigh mentioned, but that is in
25 no way intended to simulate real world conditions, which is

1 what this litigation is about, what do consumers in the real
2 world -- what levels of NDMA did they find, not some super
3 heated samples to test to degradation. It is a different
4 experiment.

5 Dr. (sic) Nigh mentioned Emery's data with respect to
6 the FDA recall, and that it was a basis of the recall. Dr.
7 Najafi testified that -- was asked if he was aware that the FDA
8 relied solely on their own testing when requesting a recall of
9 Ranitidine, and he said, I believe so. Dr. Najafi's testing
10 was not the basis for the FDA's request that the product be
11 removed from the market.

12 Again, it is important to point out that the results
13 that were shown of the testing and how Emery's testing
14 pre-litigation and post-litigation differed from the others.
15 Those were all baseline testing, that was apples to apples.
16 And, so, that is what -- that is the important measurements.

17 Mr. Nigh said a few times that Emery's levels are
18 consistent with levels that are provided by others, or
19 supportive of the levels that are provided by others, in other
20 people's testing. Well, if that is the case, the Plaintiffs
21 don't need Emery, they have that other testing data to rely on.

22 At the end of the day, your Honor, it still gets back
23 to the fact that you are being asked to find this -- they have
24 the burden of proving that his data is reliable, and you are
25 being asked to find that it is reliable and allow a jury to

1 consider it when they have provided no standards.

2 They have provided nothing more than Dr. Najafi's
3 statements saying broadly, we follow standards, but I can't
4 show them to you and I can't tell you where they are written
5 down.

6 They are relying on his testing, which has never been
7 peer reviewed, and the Daubert cases say how important peer
8 review is a factor to be considered. Never been peer reviewed,
9 never been done by anybody else, and these simulations that are
10 intended to mimic real world conditions do not.

11 He did not test Ranitidine by putting it in a glove
12 box, that was a simulated test, not in a glove box of the car.

13 So, your Honor, for those reasons and others that are
14 detailed thoroughly in our brief, we would ask that you grant
15 the motion and exclude Dr. Najafi under Rule 702 and the
16 Daubert case law.

17 Thank you.

18 *THE COURT:* Thank you. Okay, just a few questions.
19 So, this is for both sides. Maybe I will start with the
20 Plaintiffs.

21 Can you explain -- I know you touched on it, but what
22 your record -- you know, what you have put forth -- in other
23 words, I don't want anything outside the record, but distill it
24 down for me what you have put forth in the record about what
25 the hydrophilic interaction liquid chromatography, the HILIC,

1 is, how it works, how it is, or is not different than normal
2 phase and Reverse-Phase chromatography.

3 Break it down like you are explaining it to a lay
4 person and then, if the Defendants have a point of view about
5 that, since I know you have challenged it, again, anything from
6 the record, you can present that as well.

7 And I guess, you know, for background, let me fill it
8 out for the Plaintiffs.

9 So, I want to understand -- if you want to make notes
10 so you have kind of a list, you may want to incorporate it into
11 one answer.

12 You got the first question. So, my followup questions
13 are going to be along these lines if you want to make notes.
14 They kind of all go together. For which studies did Emery
15 Pharma use HILIC as part of its method of chromatography, and
16 for which studies did Emery Pharma use a different method, such
17 as normal or Reverse-Phase chromatography?

18 The Plaintiffs state in their response that different
19 columns were used for different studies. That is at Docket
20 Entry 5914, page 17.

21 The validation summaries attached to Dr. Najafi's
22 report in Appendix A, that is at Docket Entry 5698-10, at page
23 167 to 71, indicate that the chromatography method was
24 Reverse-Phase, and that's at HPLC.

25 The Court understands from Dr. Najafi's rebuttal

1 report that with respect to at least some of the studies that
2 is a typo. And that is at Docket Entry 5698-11, page 13.

3 One last part, and if you need me to repeat anything,
4 that is fine. During Dr. Najafi's deposition, he was asked
5 about whether Emery Pharma's method of chromatography could
6 have artificially generated NDMA.

7 This is kind of a different question, but I will ask
8 it and I can repeat it. He stated that there was a published
9 note indicating that this does not happen. That is in his
10 deposition at page 520, lines 3 to 16.

11 So that question is going to go to, do you know what
12 he was referring to, and has it been or can it be made
13 available to the Court?

14 So, I kind of mixed the note part in with the
15 chromatography, but that is kind of the long and short of what
16 I am interested in.

17 *MR. SELIGNAN:* I am Matthew Selnigan for the
18 Plaintiffs, S-E-L-I-G-N-A-N. This is my first time appearing.

19 To answer your three questions, first, the HILIC
20 column. So, our discussion of the HILIC column in our response
21 to their motion to exclude is the first time we talked about
22 it, and the reason is, as Mr. Nigh pointed out, every single
23 test uses different columns. So there was never any reason to
24 think that it was important for Dr. Najafi to talk about the
25 specifics of the HILIC column, why it was a justifiable

1 methodology in the LC-MS/MS process until the Defendants raised
2 that issue.

3 So, once the Defendants raised that issue, we
4 responded to that in our brief, and that is on page 38 of our
5 response.

6 In that response we cited to publically available
7 information, reports by Waters Corporation, which is the
8 manufacturer of HILIC columns, and other publically available
9 studies explaining the nature of the NDMA molecule, that HILIC
10 columns are particularly well suited to cause greater
11 separation in the chromatograph, the liquid chromatography,
12 than other columns for specific types of molecules that are
13 highly polar and hydrophilic, namely NDMA.

14 So, that is the explanation for why Dr. Najafi used
15 the HILIC column, and those are the sources that we relied on
16 in explaining that.

17 And again, it wasn't in the report because nobody
18 thinks that the column is actually a big -- makes a difference,
19 which again is why all of the studies use different --

20 *THE COURT:* Did he use it pre-litigation or just
21 post-litigation?

22 *MR. SELIGNAN:* Post litigation.

23 *THE COURT:* Do you know why he changed?

24 *MR. SELIGNAN:* The reason for the change is that the
25 pre-litigation, pre petition testing served a different

1 purpose. What it was intended to do at that point is to
2 demonstrate not precision -- or not accuracy of finding out
3 exactly how much NDMA, but showing the proposition that heat
4 could cause an increase in NDMA.

5 So, the non-HILIC column was adequate for that
6 purpose, it was adequate for the purpose of what the petition
7 was for.

8 When it comes time to do the litigation testing, where
9 it is extremely important to show precisely how much NDMA is
10 formed in different circumstances, in the baseline testing, in
11 the consumer experience testing, then the more accurate HILIC
12 column was better suited for that purpose.

13 Okay. Then your second related question is, which
14 studies that Dr. Najafi performed used the HILIC column and
15 which didn't. The answer to that is, he used them for all of
16 the studies except for those that used liquid, the SGF in
17 particular.

18 The reason for that is the HILIC column -- because
19 there is a liquid matrix involved, the HILIC column isn't going
20 to perform as well when you are using a liquid matrix as
21 opposed to a tablet, which is the baseline testing. I believe
22 the distinction there is the HILIC column is used except when
23 the liquid matrix would have made it unsuitable in the SGF
24 testing.

25 *THE COURT:* Is that made clear, in your opinion, in

1 his report?

2 MR. SELIGNAN: I think your Honor made reference to
3 the fact that there might be some typos. I will go back and
4 check that and confirm that the report accurately reflects what
5 the actual column used for each of the experiments.

6 THE COURT: Could you define polar and hydrophilic?

7 MR. SELIGNAN: Yes. Hydrophilic means attracted to
8 water, and a polar compound is one where the electrical charge
9 between the different parts of the molecules is different. So,
10 water is H, and then two O's, and as a result of that
11 triangular structure, it is polar, part of the molecule has a
12 positive charge and part of the molecule has a negative charge.

13 As a result of that, it is retained by different
14 substrates in a column differently than a nonpolar column -- a
15 nonpolar substance would be. As a result of that, different
16 types of columns, so in a non-HILIC column, you would have
17 something like silica packed in there, that type of substance.
18 It wouldn't be as good at retaining these differentially
19 charged molecules, where the positive charge of the molecule
20 and the negative charge of the molecule are located at
21 different physical ends of the molecule.

22 As a result of that, for a non-polar molecule, a
23 silica, ordinary Reverse-Phase column would be appropriate;
24 however, there is better separation in the -- as you put the
25 sample through the chromatograph for a polar substance it is

1 going to be retained better when the column, HILIC, is suited
2 to retaining these polar hydrophilic compounds.

3 Now what that means is, as you put the sample through
4 the column, because the column is hydrophilic, and you have a
5 polar compound, NDMA, NDMA is going to be attracted to the
6 substance inside the column to a greater degree than otherwise
7 and so it is going to travel through the column more slowly,
8 and that is going to provide greater separation and therefore
9 greater accuracy in the ultimate test.

10 *THE COURT:* Okay. And the note?

11 *MR. SELIGNAN:* So, a substantive response, Mr. Nigh
12 responded to this a little bit, there is absolutely no basis to
13 think that there is artifactual creation of NDMA in the MS
14 process.

15 So, just by the way of contrast, the Valisure
16 pre-petition testing showed astronomical amounts of NDMA, and
17 Emery Pharma determined that a lot of that was artifactual and
18 the reason was because it used gas chromatography rather than
19 liquid chromatography, which involves heating the sample for
20 several minutes to well over 100 degrees Celsius.

21 So, that testing procedure and gas chromatography can
22 create artifactual NDMA. That is exactly why the FDA
23 recommended using liquid chromatography, and in particular
24 LC-MS/MS. In the MS process there is no indication, no reason
25 to believe that in the 20 milliseconds that the sample is

1 passing by the ionization diode that it would create
2 artifactual NDMA.

3 You mentioned there is a published note. I don't have
4 that citation with me right now, but we can get that to you.

5 *THE COURT:* Right. Dr. Najafi said that there was a
6 published note, and you can check his deposition at page 520,
7 lines 3 to 16. So I want to know, what is the note?

8 Apparently Dr. Guengerich tried to find it on a
9 website, he believed he found it, and he said at Docket Entry
10 5698-8, 9 to 10, he thought maybe Dr. Najafi was relying on
11 figure 10, in the Waters note, but that applies to a
12 different ionization technique, APCI.

13 So I just want to know what he is talking about.

14 *MR. SELIGNAN:* We will track that down for you. Just
15 for some greater context here, the LC-MS method is the method
16 that was recommended by the FDA. It begs belief to think that
17 they would recommend a method that would create artifactual
18 NDMA.

19 *THE COURT:* Okay. Did the Defendants want to address
20 the HILIC --

21 *MR. SELIGNAN:* Thank you, your Honor.

22 *THE COURT:* Thank you very much.

23 -- column, since you raised it as a challenge, one of
24 a number of challenges to the Plaintiffs' methodology?
25 Plaintiffs point out that different techniques are used.

1 You might need to come to the podium.

2 MR. BAYMAN: Your Honor, I was just going to say I
3 think you have hit the nail on the head. Emery is the only
4 entity to use HILIC to test for NDMA and Ranitidine, and they
5 did it only after they were retained in litigation. We think
6 that speaks volumes. I am going to let my colleague, Mr.
7 Bosso, answer the more technical parts of your question.

8 THE COURT: Hello, Mr. Bosso. Maybe take into account
9 Plaintiffs' response that they showed the one screen where
10 different studies were being conducted by different -- using
11 different technology, different columns all the time, and just
12 because it is different, what is the problem?

13 MR. BOSSO: Yes. So, one piece of context to be
14 directly responsive to that, is that all the columns they
15 showed you were Reverse-Phase columns.

16 THE COURT: All the columns they showed on their
17 screen?

18 MR. BOSSO: Right, all the ones they are comparing it
19 to, when they are saying different people are using different
20 columns, those ultimately result in Reverse-Phase LC-MS method.
21 The only person who is using a column that is a HILIC method is
22 Emery. So let me explain to --

23 THE COURT: How do you know that all the other ones
24 were Reverse-Phase? Is that in the record?

25 MR. BOSSO: Well, Dr. Olsen's report goes through the

1 various published literature, and notes that everyone else
2 before has used Reverse-Phase, and that is in his report.

3 *THE COURT:* So some variation, but it is a
4 Reverse-Phase. This is not Reverse-Phase.

5 *MR. BOSSO:* Right. The exact column, being used is a
6 complete red herring.

7 *THE COURT:* So, it is not the column, it is that
8 Reverse-Phase was not used, that is your challenge?

9 *MR. BOSSO:* Right. When you use -- so, let me give
10 you some context about this.

11 When FDA validated its method, if you pull up those
12 FDA validations, which are part of the record, you can actually
13 see that FDA demonstrated that when Ranitidine and NDMA come
14 out of that column and are exposed to that high heat during
15 volatilization, that they exit separately so that the test
16 isn't going to be confounded.

17 The true thing you have to remember is that the
18 particles have to be separated from each other. That is
19 literally the definition of chromatography.

20 So FDA, when they validated their method, they
21 demonstrated that Ranitidine elutes separately from NDMA. Now,
22 all those published literature that we have talked about, they
23 take into account the Reverse-Phase method that ensures they
24 elute separately. What HILIC does -- in Reverse-Phase, I
25 believe NDMA comes first and Ranitidine comes second. HILIC

1 reverses the order, where Ranitidine will come first and NDMA
2 comes second.

3 What ends up happening is, when you change that
4 method, you have to ensure that you are getting proper
5 separation, and the only justification in the record that
6 Plaintiffs or Dr. Najafi have ever made for why HILIC was the
7 better method than FDA's method or better than their Citizen
8 Petition method was because they say it should account for
9 better separation, but there is not one bit of proof that there
10 is actually better separation.

11 In fact, Dr. Olsen, in his rebuttal report, addresses
12 this, because he looked at the data that was given on the hard
13 drive, although there is an open question that Dr. Najafi
14 claims it was corrupted, but assuming it is not corrupted, he
15 looked at it and said they are not separating NDMA from
16 Ranitidine, so they are eluting at the same time, which means
17 they are going to enter the detector at around the same time,
18 and during that transition, it is 300 degrees Celsius, higher
19 than what Valisure used.

20 Now, their claim is it is only 20 milliseconds, so it
21 is so short that they have zero data to support the fact that
22 20 milliseconds isn't enough. In fact, Dr. Olsen considered
23 this, and there is an Alshuri (phon) paper, Alshuri 2020, that
24 he cites in his supplemental report that uses liquid injection,
25 GCMS, which is a little bit different than what Valisure used,

1 but essentially it is also an instantaneous fraction of a
2 second heat applied to the Ranitidine molecule, and he found
3 that even a very short period of time can artifactually
4 separate NDMA from Ranitidine.

5 So the issue is that NDMA and Ranitidine are coming
6 out at about the same time from Emery's chromatograms and that
7 high heat is applied.

8 Now, when researchers validate their methods,
9 validation has to take into account all sorts of different
10 parameters. It is an affirmative obligation of the researcher
11 to demonstrate that their methods are accurate.

12 Now, if you have the potential that you have not ruled
13 out the fact that you might be artifactually increasing
14 NDMA you cannot claim your method has been validated.

15 There is a second point that goes along with this.
16 Dr. Najafi, in his deposition, it was not a trick question, we
17 asked him, if you are not using GOP, if you are not using GMP,
18 can you tell me what standards you are relying on? He said, we
19 are not relying on anything, it is not written anywhere, it is
20 just general principles.

21 *THE COURT:* I think some of my questions are going to
22 get into that. Anything more you wanted to say on --

23 *MR. BOSSO:* Well, for the validation, now there is a
24 claim that -- today, now they are claiming that FDA, USP, all
25 these different organizations have a validation standard that

1 they followed.

2 Part of that validation standard, if you bring it
3 up -- which might be part of the record, we will have to
4 check -- it actually requires investigators that if you have an
5 FDA approved method that you want to depart from, you have to
6 take the same samples and test it under both methods and make
7 sure you are getting the same result.

8 Emery could have taken the same tablet sample and
9 tested it under the Reverse-Phase method, recommended by FDA,
10 tested it and confirmed these results are the same.

11 *THE COURT:* Your position is this is a departure from
12 the FDA method, and as such, it would have had to have been
13 validated?

14 *MR. BOSSO:* And it was not properly validated.

15 *THE COURT:* Let's hear a response from the Plaintiffs
16 on that point.

17 *MR. NIGH:* Yes, your Honor. I have a quick response,
18 and some others might want to respond on the technical issues.

19 *THE COURT:* I am sorry. Just on that FDA policy that
20 you were just referring to, is that what you said, Defense, you
21 weren't sure if it was in the record?

22 Can you all check that and maybe in our concluding
23 comments let me know. If it is not, for some reason, can you
24 check with the Plaintiffs to see if there is any objection to
25 it being made part of the record? I think since it is probably

1 a public document there shouldn't be a problem, but I would
2 like to close the loop on that.

3 *MR. NIGH:* Thank you, your Honor.

4 Your Honor, first off, the method that they are
5 speaking about in those guidelines using two different samples,
6 one from this method, one from the other, the method is
7 LC-MS/MS. That is not applicable.

8 *THE COURT:* Did Emery use Reverse-Phase
9 chromatography, yes or no?

10 *MR. NIGH:* I would refer to my others on this issue.
11 That is not a method. Reverse-Phase or non Reverse-Phase is
12 not a method spoken to by the guidelines. The method is
13 LC-MS/MS.

14 *THE COURT:* I just want to understand, was Emery using
15 Reverse-Phase or not?

16 *MR. SELIGNAN:* The answer is yes, but only for certain
17 tests, the SGF tests, the ones that use liquid, and they used
18 HILIC column for the baseline testing and consumer experience
19 testing.

20 There is a distinction, between HILIC --

21 *THE COURT:* Do you believe his study makes that clear,
22 his report makes it clear?

23 *MR. SELIGNAN:* I think it does. We can offer further
24 clarification.

25 *THE COURT:* If you could look at that report and tell

1 us if he makes it clear and where he distinguishes that. To
2 the extent that Reverse-Phase was not used, do you agree with
3 the position taken by the Defendants that that would constitute
4 a departure from FDA policy such that it would need to be
5 validated?

6 MR. SELIGNAN: No. Even if it were a new methodology,
7 Emery Pharma did everything that could be done to ensure the
8 accuracy using the HILIC column.

9 First, for some context, if there was some difference
10 in the methodology that made a difference in the accuracy of
11 the results, for example, potentially because of artifactual
12 creation of NDMA, then why is GSK's baseline testing almost
13 identical in its result to Emery Pharma's baseline testing?

14 If the HILIC column is not -- the HILIC column is used
15 for baseline testing by Emery, so if HILIC -- the HILIC column
16 is an invalid method an inaccurate method, and as speculated
17 for the first time today by Defendants, somehow elutes in the
18 wrong direction, such that there can be the creation of
19 artifactual NDMA in the MS part of the process, that can't
20 explain why the baseline testing is virtually identical when
21 you use a Reverse-Phase column as GSK did.

22 Now, beyond that, what Emery Pharma itself did to
23 confirm that there is no artifactual generation of NDMA using
24 the HILIC column is they validated it. Among other things,
25 what they did, is they used the exact experimental setup, put

1 in a known amount of NDMA, and then tested how much came out
2 the other end. So, that data is in the report, and we
3 presented it again here today in our Power Point presentation.

4 *THE COURT:* Right. My next set of questions actually
5 goes to the validation summary tables.

6 *MR. NIGH:* Your Honor, I have one more response, to
7 the Defendants' suggestion, and that was this response of the
8 Alshuri paper, liquid injection in GCMS, that is not support at
9 all, for that there might be some NDMA artifactual creation in
10 less than 20 milliseconds in an LC-MS/MS situation.

11 Those criteria, those data are not apples to apples.
12 Now the Defendants are trying to use some other methodology to
13 say somehow this would have created additional amounts of NDMA.

14 If they really wanted to raise that argument with any
15 basis, and we are moving to exclude that argument, because
16 there is no basis at all from Dr. Olsen for that argument, if
17 they wanted to do so, Dr. Olsen is an analytical chemist.
18 Analytical chemists don't just surmise, make guesses,
19 assumptions, they test. He had every ability to test that
20 assumption, that if he wanted to see if the HILIC
21 column actually generates additional amounts of NDMA, as he
22 surmises or guesses, he could have tested it.

23 He never did, therefore that opinion should be
24 inadmissible.

25 *THE COURT:* Okay. Okay, thank you. Moving on to the

1 topic of validation summary tables, Dr. Najafi and the
2 Plaintiffs point to the validation summary tables in Appendix A
3 to Dr. Najafi's report at Docket Entry 5698-10, at page 167 to
4 71, to demonstrate that Emery Pharma's chromatography methods
5 were validated.

6 What do these validation summaries demonstrate, and
7 what don't they demonstrate? In other words, what is the Court
8 to glean from the summaries?

9 So, I have the summaries, and we can take one of them,
10 and I don't know whether we want to have Plaintiffs answer
11 first, and then if Defense wants an opportunity to respond --
12 some of the followup questions I have, like for the Plaintiffs,
13 for example, are the validation summary tables in Appendix A to
14 Dr. Najafi's report all of the validation summaries for all of
15 the testing that Emery Pharma conducted for this litigation?

16 So, for example, is the summary table labeled
17 Validation Summary Table for NDMA Quantitation in Ranitidine in
18 SGF, that is Docket Entry 5698-10, at 168, a summary both of
19 the simulated gastric fluid, SGF study, with food, and for SGF
20 testing without food. The summary doesn't mention anything
21 about food, or more specifically meat.

22 That is kind of a subset, but if you want to take -- I
23 am looking at -- I don't know if you have one in front of you.

24 *MR. SELIGNAN:* One moment, your Honor.

25 *THE COURT:* 5698-10, it's on page 167, of 214.

1 *MS. BOGDAN:* We are trying to pull those up, your
2 Honor, and I don't have them right in front of me, but there
3 are validation summary tables for each of the type of testing
4 that Emery Pharma performed.

5 There is one for -- in the matrix of the SGF, there is
6 another one for in pills, there is another one for the syrups.

7 *THE COURT:* Right. I wanted somebody to walk me
8 through one of them to explain it, because there are similar
9 descriptions for each.

10 *MS. BOGDAN:* If I could have it up on my screen so I
11 could walk you -- we could take the walk together, so to speak.

12 *THE COURT:* What about the ELMO, does somebody have
13 access to the ELMO there?

14 Why don't you look at that and we can come back to
15 that question.

16 *MS. BOGDAN:* I have one of them up, I have the MAP
17 study one up.

18 *THE COURT:* MAP is fine, I also wanted 5698-10, page
19 167 of 214.

20 Do you want to walk me through that one?

21 *MS. BOGDAN:* Sure. It has a short description of the
22 method, it talks about the matrix, and to further elaborate
23 with regard to the difference between the HILIC method and the
24 Reverse-Phase method, the Reverse-Phase method was used for all
25 the matrixes that were of a liquid nature, the SGF studies, the

1 syrups, the injectables, while the HILIC was used for the
2 tablets.

3 That is because when you are running these things
4 through you have different solvents that you are using to run
5 these through the columns. So, when you are dealing with a
6 slurry and a syrup -- this is me explaining it, but all of this
7 is accomplished by them going through their protocols and their
8 validations, and really why we need experts in cases, to
9 explain things, with that caveat.

10 So, the SGF was used for all of those types of
11 matrixes, because you are using a solvent that is compatible
12 with the SGF, the meat that is in there. The syrup, it has
13 different excipients, it is goopy, as opposed to the HILIC when
14 they were just taking a solid, which is all tablet testing, and
15 the stability testing and consumer experience testing was
16 tablet based.

17 They used it for the API, again a solid, and that is
18 really the difference, and it was because they were optimizing
19 methods to be the best method to detect depending on what they
20 were looking for.

21 Then it talks about the analyte, which is the target,
22 that is what you are trying to find, then the internal
23 standard. That is a -- basically a check and a balance that
24 they put in NDMA in every single sample that they tested.

25 They put in the NDMA D6, which is similar to NDMA, but

1 it isn't NDMA, so that they can quantify that on the back end.
2 They are telling you the calibration concentrations, that is
3 sort of the sensitivity. They can detect as low as five
4 nanograms and up to 1,000.

5 They then go through their QC concentrations, which is
6 quality control. That is when they are testing to see when
7 they have a known amount of NDMA, that is the amount that is
8 coming out on the other side. So they are getting accuracy and
9 precision because they know what they are putting into the
10 system and they are detecting it on the back end. They are
11 talking about the lower limit of quantification on this, which
12 is that five nanograms.

13 Linearity is when you put in .5 NDMA, you get out .5,
14 put in 10 NDMA, you get 10, put in a hundred of NDMA, you get a
15 hundred, when you put in 500, you get 500.

16 And the response, and I think Daniel clicked through
17 that, but that linearity, you saw that line, it was perfect.
18 You can always make a line through two dots, but to make a
19 perfect line through eight, is showing a high degree of
20 accuracy of detecting the compound.

21 Then, with regard to the QC accuracy, that is giving
22 you those percentages with regard to how close it is to what
23 they know was put in, and then the QC percent, that is actually
24 calculated off of a hundred, so with a hundred, they were
25 within 1.23 percent.

1 That is the summaries. There were also validation
2 protocols that spelled out everything they did, and
3 importantly, in the hard drive that we provided to the
4 Defendants, all of the validation data for all the validations
5 they did on every single method for every study they conducted
6 were in and the raw data was available as well.

7 *THE COURT:* Okay, thank you.

8 *MS. BOGDAN:* You're welcome.

9 *THE COURT:* Anything that Defense wanted to briefly
10 respond to as it relates to the question regarding the
11 validation summary tables?

12 *MS. BOGDAN:* I just had one other point to make, and I
13 don't think it was made, but with regard to the artifactual
14 formation of NDMA, when Emery did their testing, there were
15 samples that tested that had very low levels of NDMA in the
16 samples. If you look at their data sheet that is attached to
17 their report, you will see certain lots, certain batches with
18 low levels of NDMA.

19 If NDMA was being created by the method, you would
20 have no low levels. There are levels under a hundred, there
21 are levels that are under 20, there are levels that are under
22 15, there are -- this is the same method being used to test all
23 these batches. If the ionization source was creating NDMA you
24 would not have those values.

25 You know, that is like a common sense explanation, and

1 it is also rooted in the chemistry, but it is really easy to
2 understand. If there is a problem with the process, it would
3 be a problem with the process.

4 *THE COURT:* Okay, thank you.

5 Any brief response from the Defense?

6 *MR. BOSSO:* I wanted to quickly clarify that when they
7 talk about some of the parameters, like perfect lines and being
8 able to see when you put in this much NDMA you get this much
9 NDMA out, all of those samples do not contain Ranitidine.

10 So, the big problem that has been raised with the
11 HILIC method relates to whether the Ranitidine molecule is
12 going to confound the results. So, pointing to this data does
13 not answer that question.

14 And Plaintiffs counsel specifically said analytical
15 chemists do not surmise, make assumptions, or guess, but they
16 are surmising, making assumptions, and guessing that their
17 method offers better separation although it has never been
18 demonstrated.

19 That is it.

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

21 *MS. BOGDAN:* May I respond quickly? The n matrix
22 accuracy test that my colleague, Daniel Nigh, spoke to about
23 originally is actually putting NDMA, a known amount, in with
24 Ranitidine and it is seeing if that known amount comes out the
25 other side.

1 THE COURT: Okay, thanks. Okay, this is one more
2 question for the Defendants.

3 The validation summary table for NDMA quantitation in
4 Ranitidine in SGF 5698-10, I believe that the Defendants have
5 argued that this is insufficient to show the method of
6 validation. You contend that in your motion at Docket Entry
7 5698, at pages 42 to 43.

8 You start off by saying: Despite the need to
9 specifically validate the method within each meat matrix, Dr.
10 Najafi did not validate his method for any of the meat
11 matrixes, and then you have several citations and you go on to
12 quote from the Bumpus report and things of that nature.

13 So, can you explain to the Court what should the
14 summary have included to show method validation for the SGF
15 study with food?

16 MR. BOSSO: Yes. So, the issue here is that, again
17 that FDA guidance that we're were going to check about having
18 been put in the record specifically notes you have to test --
19 validate within each matrix.

20 Now, Plaintiffs have made the claim, which is clearly
21 unsupported, that simply validating SGF alone is the same as
22 SGF plus all these various meats. As you noted, people like
23 Dr. Bumpus and Dr. Guengerich looked at this and said there
24 needs to be a validation of SGF ham matrix, there needs to be a
25 validation of SGF bacon matrix, but there is no validations

1 whatsoever that have those. The only validation is SGF alone,
2 and that is the issue.

3 Do you have any questions about that?

4 *THE COURT:* No. I probably should have asked the
5 Plaintiffs first, the question I had, so you could tell me if
6 it changes your answer. So, let's hear from the Plaintiffs on
7 this question.

8 Are the validation summary tables in Appendix A to Dr.
9 Najafi's report all of the summaries for all of the testing
10 that Emery Pharma conducted for this litigation? For example,
11 the summary table labeled Validation Summary Table for NDMA
12 Quantitation in Ranitidine in SGF, Docket Entry 5698-10, at
13 168, a summary both for the simulated gastric fluid study with
14 food and for SGF testing without food?

15 The summary doesn't mention that, so Plaintiffs, are
16 you able to answer that question?

17 *MS. BOGDAN:* The simulation --

18 *THE COURT:* Both for simulated gastric fluids study
19 with food and for SGF testing without food.

20 *MS. BOGDAN:* It is the validation protocol for the SGF
21 testing, and it is our position that the validation done for
22 the SGF study, as far as measuring accurately in SGF, is that
23 validation covers the SGF studies.

24 *THE COURT:* With food and without food?

25 *MS. BOGDAN:* With food and without food, yes. And

1 importantly, within each SGF study they also did a control of
2 meat alone, as well as Zantac alone, to be able to check as to
3 whether or not either of those things in the SGF would generate
4 NDMA, so it is n test or n matrix validation that is done. Dr.
5 Najafi speaks to that during his testimony.

6 So, you know, Defense is sort of giving you an apple,
7 when we are dealing with a whole fruit basket, and again,
8 outside of, you know, what -- if the Court would like, I can
9 explain all the different controls -- it is all in Dr. Najafi's
10 report why these things were done within the food studies
11 themselves.

12 You know analytical chemistry is certainly an
13 experimental science, and they did all of these things as they
14 went through every one of their studies, rooted in methodology,
15 in the peer reviewed studies, and then they did many checks and
16 balances to verify their results, and there is an n matrix
17 validation done for the SGF studies, and it looks to -- and if
18 you want to go through the report, you can see the controls
19 that they did, and those controls are to make sure that NDMA is
20 not being generated simply from the meat alone, and that is
21 part of that validation process.

22 *THE COURT:* Okay. Thank you.

23 Are Defendants taking the position that there should
24 have been a separate validation done for SGF study with food
25 and a separate one for without food when you say the summary is

1 insufficient?

2 MR. BOSSO: Yes, it actually needs to be a separate
3 validation for each food type. So it is not just with food or
4 without food, it is actually -- if they want to measure in
5 bacon, it is bacon.

6 A matrix by definition is all the molecules within the
7 sample, so if you are changing the matrix by adding food, you
8 can you not longer rely on the same validation, because it is
9 outside the matrix.

10 THE COURT: Is that in the same policy statement you
11 referred to earlier?

12 MR. BOSSO: The policy statement says that you have to
13 test within each matrix. The definition of a matrix, I am not
14 sure if it would clarify it, in the document, but our expert
15 reports do cover this issue.

16 THE COURT: Okay. All right. Manual integration,
17 this is for the Plaintiffs, have a complete set of
18 chromatograms that you would acknowledge accurately depict
19 Emery Pharma's data been filed anywhere in the record?

20 The Court understands that there was disagreement
21 during Dr. Najafi's deposition over whether the chromatograms
22 being shown to him accurately depicted the laboratory's data.

23 The Court is asking because it would like to have some
24 understanding of the extent of Emery Pharma's manual
25 integration, when processing its chromatography results,

1 whether manual integration was conducted more frequently during
2 some studies than others, because the Defendants have contended
3 on page 41 of their motion, that, "many of the Emery Pharma
4 integrations were manual," and I didn't see where the
5 Plaintiffs responded concerning the extent of manual
6 integration.

7 So, could you address that first part of the question?

8 *MS. BOGDAN:* By its very nature of LC-MS/MS, your
9 Honor, it is electronic data, it is generated, there are
10 millions and millions of data points. So, the chromatograms
11 that are generated from the LC-MS/MS data, as my colleague, Mr.
12 Nigh, explained, they are set, they are preserved data. It is
13 locked down by the program, so the chromatograms that are
14 generated from that data out of MassHunter are the native
15 chromatograms.

16 *THE COURT:* So, is the complete set part of the Court
17 record?

18 *MS. BOGDAN:* Pardon me?

19 *THE COURT:* Is a complete set of the chromatograms
20 part of the record?

21 *MS. BOGDAN:* We were not able to give the Court the
22 raw data, it looks like gobbledygook, symbols and that type of
23 thing. It has to be put through a widely available and well
24 utilized system, which is Agilent, which is one of the main
25 sellers and makers of LC-MS/MS systems, as well as software.

1 MassHunter is just Agilent, it is their proprietary software
2 system.

3 So, I could not give the Court the raw data, it would
4 looks like it looks, as far as when you put it in a Word
5 document, you can't look at it that way.

6 What is important to understand here is that the
7 native data and all the data that we provided to the Defendants
8 actually creates the chromatograms, and they can be looked at.
9 So, there are issues with the pdf's and their production, and
10 Dr. Najafi cannot verify someone else's production.

11 *THE COURT:* How would the Court ascertain the
12 frequency or lack of frequency of manual integration performed
13 by Emery Pharma?

14 *MS. BOGDAN:* Manual integration, that is a matter of
15 interpretation. It is something that experts do. The fact
16 that the system gives you an auto integration, meaning it draws
17 a line for you, but then it is actually imperative, and as Dr.
18 Najafi explained during his testimony, for an analyst, a
19 trained and skilled analyst to look at that line.

20 It is also by described by Mr. Steffy in his
21 declaration, and then that is the judgment of the expert as to
22 where that line is drawn.

23 The information is fully available in the LC-MS/MS
24 MassHunter system, but the idea that more manual integration is
25 bad, auto integration is good, that is completely something

1 that is up to and in the province of an expert to be able to
2 explain, because if the computer, for example, is -- you are
3 running an SGF meat matrix, right, it is not necessarily used
4 for that.

5 So, the analyst has to make that call, you know --

6 *THE COURT:* I have to have you wrap up the answer. I
7 have a lot more questions.

8 *MS. BOGDAN:* If the Court would like the data, we can
9 provide the data, and we provided it to everybody, and it is
10 absolutely something that any skilled chemist can analyze and
11 look at, and quite frankly, the Defendants do not disagree that
12 the native data can be processed. They can look at it.

13 Every one of their experts could have taken this data
14 and done their analysis on it and done a comparison with the
15 results that Emery has, they just haven't done it.

16 *THE COURT:* Okay. For the Plaintiffs, the Defendants
17 contend in their motion that Dr. Najafi "has not produced any
18 audit trails," which the Court understands would be trails that
19 shows sequences of integrations that were made to
20 chromatography data.

21 The Court understands that Plaintiffs argue that the
22 software program Emery Pharma uses called the MassHunter
23 automatically saves the original unaltered data, but in terms
24 of the original -- in terms of a trail showing how the
25 quantities that Dr. Najafi includes in his expert report would

1 derive from the original data, did Emery Pharma maintain such
2 trails; and if so, have they been filed in the record so the
3 Court would have a sense of what they look like?

4 *MS. BOGDAN:* What the Defense is referring to would be
5 a CGMP or GLP type of audit trail, I am assuming, which
6 obviously this was not CGMP or GLP work. Those standards are
7 specifically for a drug or manufacturing of a drug that is for
8 sale for people. Research and development is done with the
9 protocols and with all of the checks and the balances and all
10 the protocols and everything we provided to the Court following
11 accepted practices, which were outlined in the peer reviewed
12 studies, et cetera.

13 With regard to your question, I don't want to -- the
14 printouts of the pdf's that Benotti created, while they don't
15 accurately reflect the data that was given, as explained by Dr.
16 Steffy, it is not for me to explain, but there are little
17 asterisks on those where you can see what he printed, if there
18 are manual integration, but the audit that you are talking
19 about, there is nothing in the native data that shows that.

20 However, if you take the computer-generated
21 chromatogram from the native data, and you see where the line
22 is drawn, and you take that line, which is a matter of expert
23 judgment -- this is, you know, outside of the locked down data,
24 this is interpretation, which we talked about in our papers,
25 different. They have experts, a lot of them, they could all do

1 their own interpretation, they are choosing not to.

2 But you could take that line on the chromatogram and
3 move it, and when you move it, it shows you the quants, how
4 meaning how much NDMA is in the sample.

5 *THE COURT:* I understand.

6 *MS. BOGDAN:* So, if it is showing the quant that Emery
7 reported, it is the auto generated one, you just move the line.

8 *THE COURT:* That is pretty much what the Court would
9 look to.

10 *MS. BOGDAN:* Yes.

11 *THE COURT:* Got it. From the Defendants, other than
12 the quote from the Rule 30(b)(6) deposition that you included
13 on slide 13 of your presentation, is there evidence that is in
14 the court record that Emery Pharma has generated and produced
15 chromatograms in pdf format for other clients or in other
16 litigation?

17 *MS. LUHANA:* I am sorry, Judge, could I raise one
18 point?

19 *THE COURT:* I want them to answer. I am just worried
20 about time. In answering another question you can supplement
21 it.

22 With the Defendants answer to the question, I just
23 asked, if you have a brief response to any of the argument from
24 Plaintiffs regarding integration.

25 *MR. BOSSO:* For the first question, the evidence we

1 gave you, is all the evidence we have. We got that through
2 discovery and it was limited to just Ranitidine testing.

3 Those were the only reports we had, so it is not that
4 many reports, but a hundred percent of the reports had
5 chromatograms.

6 The other big issue I would point out is that Dr.
7 Najafi and Plaintiffs here say they don't have to follow GLP,
8 GMP. They claim that they followed this arbitrary research and
9 development standard. If you actually pull up those pdf's,
10 they are titled Research and Development. So, in their
11 traditional work, research and development, this is the type of
12 report they would generate. We didn't get that here.

13 In terms of your second question, about the manual
14 integrations, there are a few things. It is important for this
15 Court to understand manual integration is an opportunity for
16 the analyst to make manipulations to the data, and so we should
17 be able to review that data and be able to ensure its
18 reliability.

19 Now, there was a comment made about expert judgment.
20 The experts on the Plaintiffs' side who did this are not put
21 forth as experts in this litigation. The only experts in this
22 litigation who can talk about the reliability of Emery's
23 processing are Defendants.

24 Now, Plaintiffs carry the burden of proving that Dr.
25 Najafi's opinions are reliable, including that they are on the

1 basis of reliable facts.

2 If they have not put forth any expert who can actually
3 come to this Court or on cross-examination explain why is their
4 chromatography reliable, there is no way for them to meet their
5 burden.

6 *THE COURT:* Thank you.

7 *MS. LUHANA:* Judge, may I raise one point about CGMP?

8 Defendants routinely do studies where they don't --
9 and experiments where they don't follow CGMP. In fact, I,
10 myself, deposed Dr. Guengerich and Dr. Lindsey. They continue
11 to raise CGMP as an issue. They have research labs where they
12 work for pharmaceutical companies 90 percent of the time, and I
13 asked them how often do they follow CGMP, and they said never.

14 They never do testing per CGMP. That is a red
15 herring. All the experiments Dr. Najafi did are research and
16 development experiments, not for drug manufacturing, and that
17 is what CGMP is for.

18 *THE COURT:* Okay. I know there has been a lot of
19 mention of that, and I want to make sure I have -- if this is
20 contained in the FDA documents. To the extent any FDA
21 documents were referenced during the question and answer part
22 of this session, I want to make sure that there can be an
23 agreement that you can get them together and give them to me.
24 That would be helpful.

25 So, on the topic of internal standards, Plaintiffs,

1 can you provide the Court with an explanation of internal
2 standards as they are used as part of chromatography? The
3 Court is interested in what internal standards can show about
4 the accuracy and validity of chromatography results and what
5 they do not show.

6 For example, can internal standards show whether the
7 method of chromatography is sufficiently separating an analyte,
8 or show whether the method might be causing NDMA to form, or
9 show anything about the accuracy of manual integration?

10 Brief answer from Plaintiffs, brief answer from
11 Defendants.

12 *MR. SELIGNAN:* Sure. The internal standard is when a
13 sample is spiked with NDMA 6, which is a chemical isotope of
14 NDMA. So, it reacts identically to the testing apparatus, and
15 so you can measure in the exact same sample how much NDMA 6 is
16 put in, and how much NDMA 6 comes out.

17 Now, importantly, NDMA 6 is not naturally occurring,
18 so as a result of that, in the exact same sample you can take a
19 pill of Ranitidine, spike it with NDMA 6, and then confirm that
20 the known spiked amount of the isotope that is put into the
21 sample also comes out, and that prevents any possibility of
22 mismeasurement of artifactual generation.

23 *THE COURT:* Okay. Defendants.

24 *MR. BOSSO:* An internal standard is like putting
25 stickers at the end of the NDMA molecule so that you can

1 identify the one that has stickers versus the NDMA molecule
2 that does not have stickers.

3 Ranitidine, if you just have a standard Ranitidine
4 molecule that artifactually generates NDMA, it is only ever
5 going to generate the naturally occurring NDMA. It is never
6 going to create the stickered version of NDMA. There is no way
7 that an internal standard could ever prove -- there is no way
8 for an internal standard to ever disprove that artifactual NDMA
9 formation is occurring. It is just not a possibility.

10 *THE COURT:* Okay. As long as you are up, I will ask
11 you this question, then I will go back to Plaintiffs.

12 Some of the internal standard chromatograms entered as
13 exhibits during Dr. Najafi's deposition show an asterisk, which
14 the Court understands from Dr. Najafi's testimony indicates
15 that manual integration was performed.

16 Why would a test and internal standard be manually
17 integrated? If a laboratory analyst is manually adjusting the
18 results, are the results still useful as a standard?

19 *MR. BOSSO:* So, why did Dr. Najafi have to manually
20 integrate his internal standard is the question, so this is
21 best answered by looking at one of the documents that we have.
22 This is part of the Court record, and I believe we mentioned it
23 in our briefing.

24 It is actually the actual SOP guidelines that Dr.
25 Najafi at one point had said we would reference those for

1 integration. Those guidelines say that if you constantly have
2 to manually integrate, it means that there is something wrong
3 with the method.

4 So, if Dr. Najafi's analysts are having to manually
5 integrate an internal standard, that is further evidence that
6 there is something wrong with the method, because they cannot
7 just have a computer get the correct value.

8 *THE COURT:* Thank you. Brief response from
9 Plaintiffs.

10 *MR. SELIGNAN:* So, the use of manual integration is a
11 standard practice in analytical chemistry and it would need to
12 be done regardless of the context of the testing, including
13 using an internal standard. The reason is because the
14 algorithm in the MassHunter software draws a line underneath
15 the curve automatically to calculate the area under the curve,
16 but the artificial intelligence doesn't yet match human
17 scientific expert judgment.

18 That issue is going to arise about the insufficiency
19 of the algorithm whether you are testing a blank, whether you
20 are testing SGF, whether you are testing a Ranitidine pill,
21 whether you are testing an internal standard. That is -- the
22 issue of integration comes up just whenever you are testing
23 anything by chromatography and mass spectrometry.

24 Now, the Defendants have suggested numerous times that
25 there is something improper about manual integration, and there

1 is not. So, manual integration is necessary precisely because
2 the artificial intelligence of the algorithms are not yet
3 perfect, and so I will quote from Dr. Steffy's declaration that
4 was attached to the opposition to the motion to strike.

5 It is a little bit of a long --

6 *THE COURT:* Just give me the Docket Entry and number.

7 *MR. SELIGNAN:* I don't have the docket number, but it
8 is paragraph 11. I will say one sentence then.

9 "An analyst reviews" --

10 *THE COURT:* Read the one sentence slowly.

11 *MR. SELIGNAN:* Sure. I apologize. I am new here.

12 *THE COURT:* You will learn quickly.

13 *MR. SELIGNAN:* Thank you your Honor, my apologies.

14 This is in paragraph 11 of Dr. Steffy's declaration,
15 and I will get you the docket entry.

16 "An analyst's review and interpretation of the native
17 data chromatography is a necessary and well accepted practice
18 in the field of analytical chemistry."

19 So, that is in the record, this is a standard
20 practice. There is nothing improper.

21 *THE COURT:* If you want to tack that on to the final
22 remarks, that would be fine. I need kind of succinct answers
23 to my questions.

24 Plaintiffs, we are talking about study controls now,
25 Dr. Najafi states in his rebuttal report that no study protocol

1 was necessary for Emery Pharma's long-term refrigeration
2 stability study because "the study was performed as a control."
3 That is at Docket Entry 5698-11 at 24.

4 Is there authority for a proposition that a study
5 intended to be a control does not need a protocol, yes or no?
6 Are you able to answer yes or no? This is what you all do to
7 deponents all the time.

8 MS. BOGDAN: I want you to understand the stability
9 study was taking the product and putting it in a refrigerator
10 at 4 degrees. That is the stability study, to verify GSK was
11 correct, that if you put the product at 4 degrees it will stop
12 NDMA formation.

13 THE COURT: I'm sorry. So, a study intended to be a
14 control does or does not need a protocol?

15 MS. BOGDAN: It depends on the study.

16 THE COURT: Did the study in this case need it?

17 MS. BOGDAN: No. It involved taking the product and
18 putting it in a refrigerator at 4 degrees.

19 THE COURT: So, no for that reason.

20 MS. BOGDAN: Yes. Yes and no, see I said both.

21 THE COURT: I am trying to think what the most
22 efficient way to do this is.

23 Let me ask a followup question. What other study was
24 the long-term refrigeration stability study a control for, or
25 what does it otherwise mean to say that the refrigeration

1 stability study was a control?

2 MS. BOGDAN: The product, when it was received, was
3 immediately put into the refrigerator. The stability study was
4 done simply to check, as GSK had represented in its root cause
5 analysis, that that would stop NDMA formation, so that the time
6 period that took place between when they received the sample
7 and when they were actually able to test the sample, that the
8 samples would have the amount of NDMA in them as of the date
9 that they were received.

10 They did it as a precaution instead of just leaving it
11 in ambient temperature, which, by the way, would be the way the
12 product was said to be stored, but they put it in the
13 refrigerator because they wanted to arrest any NDMA formation
14 that took place once they received it.

15 THE COURT: Okay. I will keep asking you, and then I
16 will ask the same questions of the Defendants. I think it's
17 easier since you are at the podium.

18 Turning to the SGF study that Emery Pharma conducted
19 with food, the Plaintiffs argue that the tests with Ranitidine
20 alone, NGSF, and with meat alone, NSGF, both of which did not
21 detect any NDMA, were controls that demonstrate the validity of
22 the testing methods. That is at Docket Entry 5914, at 22 and
23 31.

24 Can you explain to the Court how these controls
25 demonstrate method validity?

1 MS. BOGDAN: You are doing the study in a matrix,
2 which is SGF, so you want to make sure that it is the
3 combination of the meat and the drug that is causing the NDMA
4 formation. So, by doing meat alone, you make sure it is not
5 just the meat in the SGF fluid.

6 By doing the Ranitidine alone, you make sure that if
7 there was any NDMA, you would know what it is, but those are
8 controls that are done as part of the study to make sure when
9 you are contributing NDMA formation to the condition of meat
10 and Ranitidine in SGF, that it is a result of the interaction
11 between the two.

12 THE COURT: Do the controls -- don't the controls for
13 the SGF study with food demonstrate Emery Pharma's limit of
14 detection was too high, given that Dr. Najafi does not report
15 any test results where no NDMA was found in Ranitidine, and
16 given that meats such as the ones Emery Pharma used for the
17 study have been shown to contain NDMA?

18 In other words, how were the controls helpful when
19 they did not measure the NDMA that logically would have been
20 present in the Ranitidine and the meats?

21 MS. BOGDAN: They used Ranitidine with a known amount
22 of NDMA and I would have -- I don't have the protocols up here
23 in front of me, but I have a pretty good memory, but that was
24 at known, and I believe they used Ranitidine with lower values.

25 With regard to the meat itself, they tested it in the

1 SGF and showed that there was no NDMA formed, and then they
2 measured the nitrate concentration in the meat, which matched
3 FDA values.

4 *THE COURT:* Najafi states in his rebuttal report when
5 talking about the tablet bottles that he used during the
6 studies and the impact it may or may not have on NDMA formation
7 that, "in fact, the design of its experiments, DOE, analysis
8 conducted in GSK's root cause analysis, RCA, confirmed that the
9 nature of the container closure system head space issue is
10 irrelevant." Docket Entry 5698-11 at 6.

11 What GSK analysis was he referring to? Was it
12 contained in a document; and if so, where can the Court find
13 it?

14 *MS. BOGDAN:* That I would have to have the root cause
15 analysis in front of me to be able to direct the Court
16 appropriately. It is a very lengthy document.

17 *THE COURT:* It is, and I will ask you not only the
18 page, but where it is.

19 *MS. BOGDAN:* I will be happy to do that, but I can't
20 do it on the fly.

21 *THE COURT:* No problem. Okay. Defendants, same
22 questions. Do you want me to repeat them or do you get the
23 gist of what I was asking?

24 *MR. BOSSO:* What was the first question?

25 *THE COURT:* The first one was that Dr. Najafi states

1 in his rebuttal report that no study protocol was necessary. I
2 was asking the authority for the proposition that a study
3 intended to be a control does not need a protocol, and then
4 what other study was the long-term refrigeration stability
5 study a control for? What does it otherwise mean to say the
6 refrigeration stability study was a control, and then I went on
7 from there with the SGF study.

8 Really, less kind of a question, and more, did you
9 have any response to the Plaintiffs? You don't have to have a
10 response.

11 *MR. BOSSO:* Just that protocols are the basic
12 fundamental part of the scientific method, so every study needs
13 a protocol.

14 *THE COURT:* Let's move on to the topic of peer review.

15 For the Plaintiffs, you and Dr. Najafi have contended
16 that orders, and I know this was part of your presentation,
17 entered in this litigation preclude Emery Pharma's work from
18 being peer reviewed, Docket Entry 5914, at pages 29 to 30. The
19 Defendants -- and you had some presentation here today.

20 Defendants, in turn, maintain that it is not clear
21 what must be kept confidential for this litigation that would
22 prevent peer review. That is at Docket Entry 5956, at 17.

23 I want to make sure the Court is abundantly clear,
24 precisely what information and pursuant to what orders or
25 agreements do the Plaintiffs maintain must be confidential now

1 that precludes peer review of Emery Pharma's work product, and
2 did Plaintiffs ever make any request to me or Judge Reinhart to
3 lift any restriction imposed by court order, if one exists, to
4 enable peer review of Emery Pharma's work?

5 *MR. McGLAMRY:* Your Honor, I can do this one.

6 *THE COURT:* Okay. Start with introducing your name
7 for the record.

8 *MR. McGLAMRY:* Mike McGlamry for Plaintiffs.

9 *THE COURT:* Did anyone make any request of either
10 Judge Reinhart or of me to lift any restriction? Then tell me
11 precisely what the restriction is, but was any request made?

12 *MR. McGLAMRY:* No.

13 *THE COURT:* Were there any restrictions other than --
14 any purported restrictions other than those which you have put
15 on the screen? If you want to get those -- I don't know if you
16 were looking for copies of those. I am trying to understand
17 the Plaintiffs' argument on this.

18 *MR. McGLAMRY:* Sure. Like anything that you have
19 heard today, it is not as simple as just this.

20 *THE COURT:* We have to keep it simple.

21 *MR. McGLAMRY:* I am going to go not too fast.

22 *THE COURT:* Simple, but not too fast.

23 *MR. McGLAMRY:* We went through this process, to get
24 the product. You know it took a long time.

25 *THE COURT:* Yes.

1 MR. McGLAMRY: There were several components to that.
2 One are these inventory lists the Defendants provide of their
3 material.

4 THE COURT: Right. I am sorry to cut you off, but it
5 is 3:00, and we have summary judgment. I know all of that. I
6 just want to understand, just tell me what has kept the
7 Plaintiffs from being able to try to peer review.

8 Maybe Najafi didn't want to, and that is fine. I am
9 not saying he had to, but it seems like there is an argument he
10 couldn't. He wanted to, but he couldn't have. Just in a
11 nutshell.

12 MR. McGLAMRY: From our perspective, we didn't believe
13 he could, because the orders say you can't, in our opinion, and
14 it was an order prepared by the Defense that we worked with the
15 special master to put together. It says it can only be used
16 for litigation purposes, so it is not just a we had an order.
17 We did have a confidentiality order, as was referenced before,
18 and somebody could have said, well, we want to make a change to
19 that.

20 Ultimately, when it came down to the product being
21 produced to us, part of that process, it was determined that we
22 couldn't use it except in litigation, and the Court ordered
23 that.

24 It is not like, okay, now we come back and ask, can we
25 use it, and, so, in our opinion, it is very clear in the

1 context of the orders, and that is how we interpreted it when
2 we were asked to agree to it.

3 *THE COURT:* Okay. All right. And I know the screens
4 did present the different orders. Did the Defendants want to
5 be heard briefly on that issue before I move to my final -- I
6 actually have one more topic.

7 *MR. BAYMAN:* On a nontechnical one, I can handle this.

8 *THE COURT:* The history major.

9 *MR. BAYMAN:* That's right. As the Court may recall,
10 we moved the Court to unseal the Plaintiffs' expert reports,
11 including Dr. Najafi's, and the Court granted that. So, the
12 results of his testing, to the extent they are in his report,
13 they are in the public domain already, they have been unsealed.
14 And as I mentioned earlier, this can't be used for any
15 commercial purposes was because of -- for Customs reasons.

16 The product was being sent in from Mexico to -- from
17 Mexico BI to California, and we had to make it clear for
18 purposes of Customs that the Plaintiffs couldn't resell the
19 product. That is what commercial purposes means.

20 There is nothing preventing Dr. Najafi from publishing
21 the results of his testing if the -- the documents from the
22 batch records were marked as confidential, the lot numbers,
23 things like that. That doesn't prevent him from producing the
24 results of the testing and often in peer reviewed publications
25 the authors say product one, product two, product three without

1 any further description. The only thing that prevents him from
2 producing it is, it is not publishable quality, and he admitted
3 that.

4 *MR. McGLAMRY:* Your Honor, may I say one sentence?

5 *THE COURT:* You can save it. We are using the end of
6 the day as the catchall. I hope you are keeping a list of
7 everything that you wanted to say, but couldn't say, but we
8 need to get to the end of the day. Between this and that are a
9 few more questions.

10 Plaintiffs, between pages 15 and 17 of Dr. Najafi's
11 rebuttal report he cites studies by Braunstein, Aizawa, and
12 Yoku to substantiate the temperatures and levels of humidity
13 that Emery Pharma applied to Ranitidine during its simulated
14 consumer experience testing, Docket Entry 5698-11, at 17 to 19.

15 Were any of those three studies peer reviewed? That
16 is a yes or no.

17 *MS. BOGDAN:* Your Honor --

18 *THE COURT:* Or if you need to look at it and get back
19 to me.

20 *MS. BOGDAN:* I need to look at them. There is one of
21 the studies that I know was publically published and not peer
22 reviewed, but I would want to give the Court very accurate
23 information. I would prefer to be able to take the time at the
24 break and come back and tell you exactly --

25 *THE COURT:* Perfect.

1 *MS. BOGDAN:* It was a difficult thing to find
2 published information on, because we are talking about
3 temperatures in vehicles, etc. They were from Government
4 authorities and things like that.

5 *THE COURT:* Okay. So, for the Plaintiffs, page 13 of
6 the Defendants' motion and page 41 of Dr. Olsen's report
7 indicate that the maximum level of NDMA that the FDA found in a
8 150 milligram dose of Ranitidine is around 445 or 465
9 nanograms. That is coming from Docket Entry 5698 at 16.

10 Would you agree that is the maximum level of NDMA that
11 the FDA has discovered in a 150-milligram dose of Ranitidine,
12 yes or no?

13 *MR. NIGH:* I'm sorry, did you say that question was
14 for the Plaintiffs?

15 *THE COURT:* Yes.

16 *MR. NIGH:* I missed the beginning, your Honor.

17 *THE COURT:* Page 13 of the Defendants' motion and page
18 14 of Dr. Olsen's report indicate that the maximum level of
19 NDMA that the FDA found in a 150-milligram dose of Ranitidine
20 is around 445 or 465 nanograms.

21 Would you agree that is the maximum level NDMA that
22 the FDA has discovered in a 150-milligram dose of Ranitidine?

23 *MR. NIGH:* Other than the fact that the FDA has notice
24 of Sanofi's testing, the result that I put up there on the
25 screen earlier, that was 869 nanograms of NDMA, yes, I believe

1 that is accurate.

2 *THE COURT:* Okay. And then for the Plaintiffs, Dr.
3 Najafi responds on page 22 of his rebuttal report to a
4 criticism that Emery Pharma's testing of active pharmaceutical
5 ingredient, API, for NDMA is irrelevant to this litigation
6 because consumers do not ingest API. He states, "we have
7 further demonstrated that the drug product making process does
8 not influence NDMA levels," at Docket Entry 5698-11, at 24.

9 Can you tell me where in any of Dr. Najafi's reports
10 he makes this demonstration, that we have further demonstrated
11 that the drug-making process does not influence NDMA levels?
12 So he says he has demonstrated that.

13 I don't know what he meant by that or where it was.

14 *MR. SELIGNAN:* Your Honor, I will have to get back to
15 you with the exact citation of the place in Dr. Najafi's main
16 report.

17 So, Emery Pharma actually used API and then made their
18 own tablets, and they tested on both ends of that to see
19 whether the process of putting the API into a finished tablet
20 created NDMA, and through that comparison they determined
21 that the -- that is the drug-making process that he is
22 referring to in his rebuttal report. It is really the tablet
23 making process.

24 We will get that citation to you.

25 *THE COURT:* Plaintiffs and Defense have been keeping a

1 list of anything that you were going to get back to me on?
2 Okay. I have been pretty distracted up here so I have not kept
3 one.

4 So, what I would like is in your closing to give me
5 the answer -- kind of reference the question I asked that you
6 weren't able to answer and answer it. If you can't answer it,
7 just tell me that and then I can make a decision whether I want
8 anything further to be supplemented on the record. I won't
9 know that unless you tell me, you looked and you don't have the
10 answer, which is fine. I'd rather you tell me you don't have
11 the answer than something inaccurate.

12 Two more questions and then we are going to take a
13 break.

14 *MR. SELIGNAN:* Your Honor, I can quickly tell you
15 right now, it's paragraphs 262 to 264 of Dr. Najafi's main
16 report.

17 *THE COURT:* 262 to 264 of his main report?

18 *MR. SELIGNAN:* That is correct.

19 *THE COURT:* Thank you. This goes back to questions
20 that might have even been before lunch, so we have to
21 remember -- those who were talking about extrapolation and --
22 species extrapolation and dose extrapolation, can we have that
23 team back up here from the Plaintiffs.

24 Earlier today I asked you about whether you argued how
25 and why your experts conducted a species extrapolation and a

1 dose extrapolation from their animal studies. I want to
2 clarify what I was asking when I asked that question so there
3 is no confusion. This is the Court speaking.

4 There is a difference between dose response
5 relationship and a dose extrapolation as it relates to your
6 experts' reliance on animal studies. Just listen to my
7 definition here, of dose response relationship, dose
8 extrapolation, and species extrapolation and answer my
9 questions based on my definition. Hopefully they are not
10 woefully inadequate or incorrect. I am doing this so that we
11 are all thinking about the same thing when you are answering
12 the question.

13 Dose response relationship describes how changes in
14 the amount or duration of exposure to Ranitidine affects the
15 risk of disease, either by increasing or decreasing that risk.
16 That is not what I am asking about here.

17 Rather, dose extrapolation, which is what I am asking
18 about, is an inference that researchers make when drawing from
19 human beings based on the doses that were administered to the
20 animals in your experts' animal studies. In other words, the
21 question of dose extrapolation is a question of whether you
22 explained how and why your experts could draw conclusions about
23 human beings given the doses that were administered to animals
24 in those studies.

25 So, please tell me whether you explained how and why

1 your experts were able to extrapolate by dose from animal
2 studies to humans based on these definitions. So, when you
3 were answering before, tell me whether you explained how and
4 why your experts were able to extrapolate by dose from animal
5 studies to humans based on these definitions.

6 If you don't think you provided such an explanation --
7 or if you did provide such an explanation, just tell me where
8 you did that.

9 MS. LUHANA: Roopal Luhana for the Plaintiffs. Judge,
10 I believe that there is a fairly simple answer to your
11 question. Our experts do not do dose extrapolation from animal
12 data to human data.

13 I will note, though, PETO, which is the most robust
14 carcinogenicity study, is what is utilized by the FDA to set an
15 ADI for NDMA. Our experts look at the animal studies for
16 biological plausibility because they are animal studies and
17 applying it for the totality of the evidence using the
18 Bradford-Hill criteria. Our experts are not doing dose
19 extrapolation.

20 THE COURT: Okay. Similarly, species extrapolation is
21 an inference that researchers make when drawing conclusions
22 about humans based on different species. In other words, the
23 question of species extrapolation is a question of whether you
24 explained how and why your experts were able to draw
25 conclusions about human beings based on data derived from

1 different species of animals accounting for differences and
2 similarities between species.

3 Can you tell me whether you explained how and why your
4 experts were able to extrapolate by dose from animal species to
5 humans based on these definitions?

6 MS. LUHANA: Once again, Your Honor, I don't think our
7 experts extrapolate from animals to apply it to humans,
8 although the IARC does note qualitatively NDMA acts the same in
9 animals and humans. However, the metabolism in animals and
10 humans is very different and we rely on the Gombar studies to
11 look at the viability, of NDMA, but we are not extrapolating
12 and taking those numbers to apply them to humans. We
13 are relying on human epidemiological data and doses to come up
14 with our dose response calculations.

15 THE COURT: Thank you.

16 This is one lingering question on the GCMS and the
17 Matsuda, Krawczynski. So, the Defendants made the argument in
18 their remaining opinions motion that studies that use GCMS are
19 not reliable, or at least they are not reliable when they are
20 testing Ranitidine. That argument appears at Docket Entry
21 5696, at page 8.

22 That argument is premised upon the FDA's conclusion
23 that GCMS is not a reliable method to test Ranitidine for NDMA.
24 This morning, I think you conceded that GCMS is not a reliable
25 method to test Ranitidine for NDMA.

1 The Defendants have argued that the Plaintiffs have
2 not identified any reliable studies for their endogenous
3 formation argument, that is page 11 of their motion.

4 In response, the Plaintiffs have identified Matsuda
5 and Krawczynski. Those studies use GCMS. This morning when I
6 questioned Plaintiffs about GCMS and Krawczynski, the response
7 from Plaintiffs was that Krawczynski was not testing Ranitidine
8 pills, they were testing, for example, stomach fluid, and since
9 that study was testing stomach fluid, not Ranitidine pills, the
10 concerns about the reliability of GCMS did not apply.

11 What I am trying to understand is when researchers in
12 studies such as Krawczynski tested the stomach fluid, why
13 wasn't Ranitidine present in the stomach fluid, and therefore
14 in the GCMS test?

15 For example, from Dr. Le's report, at page 8, she says
16 there is "significant variability in oral bioavailability, a
17 wide range, of 39 percent, to 88 percent of Ranitidine." My
18 understanding is that she is saying that some amount of
19 Ranitidine is not metabolized prior to reaching the
20 bloodstream, so using the most conservative of her numbers, as
21 much as 61 percent, say, of Ranitidine would pass from the
22 stomach eventually into the bloodstream.

23 So, I wanted you to explain, if you could, your
24 position that the stomach fluid in these studies that use GCMS,
25 would not contain Ranitidine, meaning the GCMS was not

1 measuring Ranitidine, and reconciling your answer with your
2 expert's opinion that Ranitidine is available in the blood.

3 *MS. LUHANA:* Judge, while our experts rely on Matsuda
4 and Krawczynski, there is a bevy of scientific literature that
5 shows endogenous formation and NDMA is resulting from
6 Ranitidine, and this goes back to Mervish, Singer, Gallot. If
7 you look at those studies, that is the reason why GSK did the
8 Tanner study in 1982. In fact, the introduction of the Tanner
9 study starts out with: Ranitidine contains a dimethylamine.
10 There is concern that a dimethylamine with nitrite can form
11 NDMA.

12 *THE COURT:* I am going to get to the Tanner study. I
13 am sorry to interrupt. Are you able, though, to answer the
14 question that the stomach fluid, does it contain the Ranitidine
15 or not?

16 *MS. LUHANA:* With Matsuda, there were fasting samples
17 and they didn't have Ranitidine in them and they didn't have
18 the other H2RAs. That was when the NDMA was detected there.

19 In terms of Krawczynski, we are finding an answer for
20 you, however, if there was Ranitidine in those samples, because
21 they did those fluid tests at the end of treatment, if there
22 was Ranitidine in those samples, you would have seen a spike in
23 every single child that was tested, and there were some samples
24 that had no NDMA and there were others that had some and there
25 were others that had a lot.

1 *THE COURT:* But weren't the measurements taken after
2 the Ranitidine was added?

3 *MS. LUHANA:* No, no, it was after treatment
4 completely. So they were treated with Ranitidine for four
5 weeks, in Krawczynski, and at the end of it they tested their
6 gastric fluid to see if they found nitrosamines, and they found
7 a statistically significant increase of several nitrosamines
8 and they report that. That was at the end of treatment that it
9 was reported.

10 My point to you is, if GCMS was causing these, it
11 would cause a significant elevated spike in every single
12 child's gastric fluid samples, but that wasn't seen. There
13 were some kids that had no nitrosamines, others that had some,
14 which is indicating the testing is working to detect NDMA
15 accurately.

16 *MR. NIGH:* Your Honor, if I may, too, that 61 percent
17 from the stomach to the bloodstream for Ranitidine, that is
18 coming from Dr. Le's report, that doesn't speak to the timing
19 of how long it takes to go from the stomach to the bloodstream
20 and then empty from the bloodstream out the body.

21 The question is: Stomach to the bloodstream, would
22 there still be some retained in the stomach? I don't think
23 that that statistic from Dr. Le answers that question.

24 *THE COURT:* Do we know what is the timing from the
25 stomach to the bloodstream? Do you have record evidence of

1 that from any of the experts?

2 MS. FINKEN: Your Honor, Tracy Finken on behalf of
3 Plaintiffs. The evidence is two to three hours when Ranitidine
4 is out of the stomach, so it would not be present after
5 treatment when they took the gastric fluid samples from all of
6 the children to measure whether there were nitrosamines in the
7 stomach. I will get you a citation in the record on the two to
8 three hour range.

9 MR. NIGH: The other part of it was, as Rosemary
10 Bogdan stated earlier, there is a double -- I forget the name
11 of the wording -- heteroptic loop, which it comes back into the
12 stomach and that would be -- oh, that's for NDMA, never mind.

13 THE COURT: What about the timing of the NDMA in the
14 stomach?

15 MR. NIGH: I didn't mean to interrupt. I apologize.
16 That was for Ranitidine, it comes back into the stomach five to
17 six hours later.

18 THE COURT: How long does it stay in the stomach?

19 MR. NIGH: That is the peak, and I don't know the half
20 life thereafter. Generally when you peak, it is a couple of
21 hours thereafter that it goes back out.

22 THE COURT: So, Tanner -- studies such as Tanner,
23 which the Plaintiffs rely upon and which the Plaintiffs say
24 stands for the proposition that as much as 3 percent of
25 Ranitidine can transform into NDMA, does that mean, then, that

1 97 percent of Ranitidine would not transform and as much as
2 61 percent of that Ranitidine would not be absorbed into the
3 body?

4 So, it goes back to the question of why wouldn't there
5 be Ranitidine present in the stomach fluid at the time of
6 testing, and studies such as Krawczynski? So it is following
7 up.

8 MS. LUHANA: With the Tanner study, there was a 3.1
9 yield, of NDMA that was generated, 232 micrograms, so that is
10 232,000 nanograms. I recall there was only 62 percent that was
11 recovered of NDMA, so there was still a lot of NDMA that wasn't
12 recovered from that test. It was greater than 232 micrograms.

13 Your question was specifically? I apologize.

14 THE COURT: Going back to the question, of why
15 wouldn't there be Ranitidine present in the stomach fluid at
16 the time of testing in Krawczynski.

17 MR. NIGH: Your Honor, I can address this, as well.
18 Dr. Le's figures are going to help to address this. We are
19 talking about hours for Ranitidine, how long it is in the
20 stomach. Krawczynski is four to six weeks later. It's not
21 even close.

22 THE COURT: Did Matsuda test four to six weeks later,
23 too?

24 MS. LUHANA: Matsuda tested over a period of two
25 months to three years.

1 *THE COURT:* After?

2 *MS. LUHANA:* No. It was during duration and after
3 treatment as well. We can get those specifics for you, but
4 that is why those studies are so critical, because it is
5 chronicity. You need it for a long period of time, and you
6 need to test the right population, and then you see a lot of
7 NDMA being generated there.

8 *THE COURT:* Okay. Okay, good, now we can take our
9 break. We are just a little off schedule. Why don't we take a
10 break for 15 minutes. We'll be back at 3:35, and we will start
11 our summary judgment. We will be in recess.

12 (Thereupon, a brief recess was taken.)

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

14 Okay, we have now the motions for summary judgment at
15 Docket Entry 5697. Each side had asked for 15 minutes.
16 Starting with the Defense.

17 *MS. RYDSTROM:* Thank you, your Honor, Jessica
18 Rydstrom. I am hoping to atone for going over in time this
19 morning by coming in under time, on this particular argument.
20 So much so, that if I keep that promise, with the Court's
21 indulgence, perhaps I might have a few minutes to respond to
22 what Mr. Gilbert has to say.

23 This motion, your Honor, is a bit of a palate
24 cleanser, because, in our view, it is pretty straightforward.
25 I don't think the following is ultimately disputed, that if the

1 Plaintiffs do not have expert testimony to support their
2 general causation opinion, then they cannot prove general
3 causation.

4 If they cannot produce general causation, then summary
5 judgment is, of course, appropriate on one or all of the
6 cancers for which Plaintiffs are articulating their claims.

7 Now, those summary judgments, are, of, course,
8 dependent on the Daubert rulings, that we are going to receive
9 from the Court. On this voluminous record, we submit that, as
10 you have heard over the course of the past two days,
11 Plaintiffs' experts simply do not have reliable testimony and
12 reliable opinions that are the product of those scientific
13 methodologies that Daubert and the cases tells us they have to
14 have.

15 They don't have that, your Honor, because they have
16 not shown an association between Ranitidine on the one hand and
17 an increased risk of the five designated cancers on the other
18 hand that is free from chance, bias, and confounding, and that
19 is what the Eleventh Circuit, of course, requires.

20 We know that they can't bootstrap their way into
21 general causation with any of those secondary methodologies
22 that we talked about this morning and that were the subject of
23 the Court's questions throughout this part of the day.

24 So, if the epidemiology is out, in other words, as the
25 Court knows, if it grants Defendants' motion to exclude the

1 epidemiological experts, then summary judgment is appropriate.

2 We don't know that, of course, until we receive the
3 Court's rulings, but what do we know, today? We know that as of
4 July 18th, because Plaintiffs put it in their papers to the
5 Court, that Plaintiffs' general causation theory in this
6 litigation is for long term use of Ranitidine. The claim is
7 not that Ranitidine causes cancer after one dose or even a
8 year's worth, but over many years of regular use.

9 We saw that quote in the introductions, your Honor.
10 You asked the Plaintiffs about it yesterday, can I hold you to
11 this statement, does this still hold true, and they told you,
12 your Honor, that it does.

13 Now, that doesn't meet the standard, right? Many
14 years of regular use is not a dose, it is not a duration, it is
15 not an amount. As Mr. Petrosinelli said yesterday, that is a
16 description.

17 Now, presumably Plaintiffs are going to stand up in
18 their closing and answer the question that the Court posed for
19 them today and that the Defendants have been asking since the
20 beginning of this litigation, and that is, how much is too
21 much, right? The how much is too much is the question that
22 McClain tells us Plaintiffs have to answer in this litigation.

23 We are going to respond to that. We will respond to
24 whatever it is that Plaintiffs put forth, and I suspect that we
25 are going to disagree with whatever it is that the Plaintiffs

1 say that they are able to present by way of expert testimony on
2 that question.

3 The Court is going to decide whether or not that is
4 the product of reliable scientific methodologies and whether it
5 is consistent with what they are telling the Court. We think
6 the answers to those questions are going to be no.

7 We think that the Court doesn't have to reach them, of
8 course, if it is with us on the subject of day one, that
9 epidemiological evidence, without an association that is free
10 of the risk of chance, bias, or confounding, your Honor,
11 Plaintiffs simply cannot sustain their claims, and summary
12 judgment would be appropriate.

13 Thank you.

14 *THE COURT:* You did come under, that was 4, 19.

15 And from the Plaintiffs.

16 *MR. GILBERT:* May it please the Court, Robert Gilbert,
17 co-lead counsel for the Plaintiffs. Good afternoon, your
18 Honor.

19 *THE COURT:* Good afternoon.

20 *MR. GILBERT:* The good news is I will be even briefer
21 than my colleague, Ms. Rydstrom.

22 At the time the Court established the Daubert briefing
23 process, your Honor also gave the parties the opportunity to
24 file a proforma summary judgment motion on the issue of general
25 causation. You had a specific reason in mind. We discussed

1 that at a meeting with you and the co-leads from the other
2 side.

3 Defendants indeed filed a proforma motion for summary
4 judgment as part of their road map Daubert brief, arguing that
5 Plaintiffs are unable to establish general causation because
6 all of our general causation experts must be excluded under
7 Rule 702.

8 As you know from our papers, Defendants' motion did
9 not comply with the Local Rule, 56(a)(1), which requires that a
10 statement of undisputed material facts be submitted with the
11 motion itself, and this alone is grounds for denying the
12 motion.

13 More importantly on the merits, your Honor,
14 Defendants' motion must be denied because Plaintiffs' general
15 causation experts, through their reports and sworn testimony
16 and other admissible evidence in the record, a lot of which you
17 have heard about today, but all of which you have read about
18 over the course of the summer, demonstrate conclusively that
19 Plaintiffs have satisfied our burden of showing there is
20 admissible evidence supporting claims that NDMA in Ranitidine
21 is capable of causing the five designated cancers at exposure
22 levels users might have reasonably experienced.

23 There is yet another reason for denying summary
24 judgment. As noted earlier, Defendants did not challenge one
25 of Plaintiffs' general causation experts, Dr. Errol Zeiger.

1 Like our other experts, Dr. Zeiger has unassailable
2 qualifications. He performed and directed genetic toxicology
3 testing, data analysis, and research at the FDA for seven
4 years, as well as for 24 years at the National Institute of
5 Environmental Health Sciences, an arm of NIH.

6 He served as an expert panelist during the FDA's
7 expert 2021 workshop on nitrosamines as impurities in drugs.
8 Dr. Zeiger offered multiple opinions regarding the genotoxicity
9 and carcinogenicity of NDMA which are directly applicable to
10 NDMA and Ranitidine.

11 Dr. Zeiger's opinions are unchallenged, and they
12 demonstrate that Defendants' Daubert motions should be analyzed
13 under the McClain one standard because the scientific and
14 medical community generally recognizes the toxicity of NDMA to
15 cause cancer in humans.

16 Moreover, even if the Court does not analyze this
17 Daubert challenge under the relaxed McClain one standard, Dr.
18 Zeiger's unchallenged opinions create a genuine issue of
19 material fact further supporting the denial of summary
20 judgment.

21 To be clear, this case is very different, in a very
22 different posture, your Honor, than Chapman, where the
23 Plaintiffs sought to designate new experts after the Court had
24 already ruled on Daubert.

25 Here, Plaintiffs designated Dr. Zeiger as one of our

1 general causation experts at the same time as all of our other
2 general causation experts. We provided Dr. Zeiger's expert
3 report and he was deposed by the Defendants.

4 Defendants consciously chose not to challenge Dr.
5 Zeiger under Rule 702, and therefore they forfeited this
6 evidentiary objection to his testimony at trial. Therefore,
7 Dr. Zeiger is entitled to testify in support of general
8 causation at trial.

9 For all of these reasons, as well as the record before
10 you, Defendants' motion for summary judgment must be denied.

11 Thank you.

12 *THE COURT:* Thank you. I do have questions. I know
13 you wanted a rebuttal, but maybe when you answer the question,
14 you can include any comments that you want. Let me know you
15 are doing it at that time. That goes for both sides, now that
16 you have had the benefit of each other's argument.

17 These may or may not relate to summary judgment, but I
18 needed a place to cabin them, so this is where the questions
19 arise. If you need to call a friend -- if you need to call an
20 LDC member to help you answer the question, you can do that.

21 This is for both parties. As you know, I asked you to
22 be prepared to discuss Chapman, and In Re: Abilify. Abilify
23 being at 299 F.Supp.3d 1291, Northern District of Florida,
24 2018, in which the Eleventh Circuit has drawn a distinction
25 between primary and secondary evidence.

1 So, why don't we -- let me start with the Defendant,
2 why don't you come up. I guess you need to hear the question.
3 It is about Chapman, these are Chapman related, legal questions
4 about Chapman. Whoever feels --

5 *MS. RYDSTROM:* I am calling not an LDC member, but I
6 am calling up the chain, your Honor.

7 *THE COURT:* Question number one, and state your name
8 for the record, do you agree -- again, these should be yes or
9 no, and if you need to explain, let me know you need to
10 explain.

11 Do you agree that the Eleventh Circuit in Chapman has
12 deemed epidemiology, dose response relationship, and background
13 risk of disease as three primary methodologies?

14 *MR. PETROSINELLI:* This is Joe Petrosinelli, your
15 Honor. I do.

16 *THE COURT:* Do you agree that the Eleventh Circuit in
17 Chapman has deemed animal studies and mechanistic evidence as
18 secondary methodologies?

19 *MR. PETROSINELLI:* Yes, I do.

20 *THE COURT:* And that the Court in In Re: Abilify has
21 also deemed in vitro studies secondary methodologies?

22 *MR. PETROSINELLI:* Correct. Yes.

23 *THE COURT:* This is like the perfect
24 cross-examination.

25 Do you agree that the Eleventh Circuit in Chapman has

1 held that an expert opinion that is unsupported by primary
2 evidence cannot withstand Daubert scrutiny?

3 *MR. PETROSINELLI:* I do, yes.

4 *THE COURT:* Do you agree that if I deny all three
5 motions in limine, that as a result of the denial, Defendants'
6 motion for summary judgment should be denied as well?

7 *MR. PETROSINELLI:* Correct. If they have admissible
8 general causation testimony, then our motion saying they don't
9 should be denied.

10 *THE COURT:* Do you agree that if I grant all three
11 motions in limine, that as a result of the granting,
12 Defendants' motion for summary judgment should also be granted?

13 *MR. PETROSINELLI:* Yes.

14 *THE COURT:* Do the Plaintiffs have any different
15 answers to those questions? I am happy to go through them one
16 by one if you want me to.

17 *MR. GILBERT:* No, I will join my colleague, Mr.
18 Petrosinelli here. Plaintiffs agree with all of -- the same
19 answers to all of the questions except with respect to Dr.
20 Zeiger.

21 *MR. PETROSINELLI:* That I don't agree with because Dr.
22 Zeiger did not offer a general causation opinion as to
23 Ranitidine. That is why we didn't move as to him. If his
24 testimony is admissible, that does not get them past general
25 causation of Ranitidine.

1 THE COURT: He is mechanistic, isn't he?

2 MR. PETROSINELLI: Correct.

3 THE COURT: Do Plaintiffs agree he is not a general
4 causation expert?

5 MR. GILBERT: Our position is that he is a general
6 causation expert.

7 THE COURT: How?

8 MR. GILBERT: With regard to the genotoxic effect of
9 NDMA and would -- would, together with specific causation
10 experts at trial, be able to establish general causation.

11 THE COURT: Does he say or does not say in his report
12 that he is giving a general causation opinion? I know many of
13 the experts have made it clear that they are or are not.

14 MR. GILBERT: I am going to phone a friend.

15 MS. LUHANA: Roopal Luhana for the Plaintiffs.

16 Judge, Dr. Zeiger gives the opinion that NDMA is a
17 known carcinogen and would fall -- and NDMA is in Ranitidine,
18 and we would fall under claim one, where we would go to
19 specific causation.

20 THE COURT: Okay. Walk me through the steps precisely
21 as to why you think Dr. Zeiger -- his primary evidence, that
22 his report, his testimony, his evidence is -- falls into --
23 first of all, which primary evidence, epidemiology, dose,
24 response, or background?

25 MS. LUHANA: He is a toxicologist.

1 THE COURT: So, which one?

2 MS. LUHANA: He is talking some about dose, and he has
3 mechanistic evidence as well, biological plausibility.

4 THE COURT: That is secondary.

5 MS. LUHANA: I mean, well, Abilify has said
6 specifically, I don't think you need epidemiological studies,
7 you can still get past general causation.

8 THE COURT: The Plaintiffs adopted the answers that I
9 asked of the Defendants. The second question I asked was, do
10 you agree the Eleventh Circuit in Chapman has deemed animal
11 studies and mechanistic evidence as secondary methodologies?

12 Defendants said yes and the Plaintiffs agreed with
13 that, so if I am working from that premise that mechanistic
14 evidence is secondary methodology, is Dr. Zeiger giving
15 mechanistic evidence testimony, opinions; and if so, wouldn't
16 that be secondary evidence?

17 MS. LUHANA: Plaintiffs are proffering if we fall into
18 McClain one where it is established that NDMA is a toxin at
19 issue and it is generally recognized in the medical and
20 scientific community that it can cause cancer, then we would
21 get to specific causation.

22 THE COURT: If you are not in category one, what
23 happens?

24 MS. LUHANA: If we are not in category one, I would
25 have to confer with my colleagues to see if we can get past --

1 pass muster with Dr. Zeiger's opinions.

2 *THE COURT:* Well, maybe that is something you can
3 discuss and it can be addressed in closing.

4 *MR. PETROSINELLI:* Can I phone another friend? They
5 have like three now.

6 *MR. NIGH:* It's a very quick answer. If Zeiger's
7 testimony doesn't meet McClain one in your opinion, then, no,
8 we don't get -- in other words --

9 *THE COURT:* If this is not a category one -- McClain
10 one case, Zeiger doesn't get you over the summary judgment
11 hump.

12 *MR. NIGH:* Zeiger alone.

13 *THE COURT:* Okay. Now, this is a question for the
14 Defendants. In addition to the categorization of primary and
15 secondary forms of evidence in Chapman, the Eleventh Circuit
16 has explicitly stated that an expert need not rely upon
17 epidemiology in order to pass Daubert scrutiny.

18 In Rider they said "it is well settled that while
19 epidemiological studies may be powerful, evidence of causation,
20 the lack thereof is not fatal to a Plaintiff's case." Rider
21 versus Sandoz Pharmaceutical Corporation, 295 F.3d, 1194, at
22 1198, Eleventh Circuit, 2002.

23 Given the Eleventh Circuit's jurisprudence regarding
24 primary evidence and epidemiology, I want to understand the
25 Defendants' position that -- I think I heard it a number of

1 times -- that if Plaintiffs' epidemiology is found
2 inadmissible, that their experts must be stricken.

3 In your motion for summary judgment the Defendants
4 state, "to the extent the Court grants Defendants' epidemiology
5 motion, it need not go further because Plaintiffs cannot
6 proceed without reliable and admissible expert testimony that
7 Ranitidine causes the cancers they allege." Docket Entry 5697
8 at 6.

9 How do you reconcile this statement in your summary
10 judgment motion with the Eleventh Circuit case law outlined in
11 Chapman, Rider, and Abilify?

12 What I mean by that is, three forms of primary
13 evidence, epidemiology, dose response relationship, and
14 background risk, I am reading the motion thinking you are
15 arguing if epidemiology is gone, the case is over for the
16 Plaintiffs. I want to understand that.

17 *MR. PETROSINELLI:* The reason is, because the
18 epidemiology is what they are using to try to meet the Daubert
19 standard and the epidemiology is what they are using to try to
20 establish, in one expert's case, that is Dr. Salmon, a dose
21 response relationship.

22 *THE COURT:* You are the Plaintiffs' position, as
23 articulated through everything they have presented, including
24 their response, that the only primary evidence they are relying
25 upon is epidemiology and not background risk and not dose

1 response relationship?

2 MR. PETROSINELLI: They are relying on epidemiology to
3 prove -- that is why they have two epidemiologists as their
4 main experts, but their other experts, like Dr. Salmon, who is
5 not an epidemiologist, in trying to calculate a dose response
6 relationship, he is relying on epidemiology, which we will talk
7 about in closing when we get to it.

8 So, whether you look at it as proceeding under
9 epidemiology via their main experts, or trying to establish a
10 dose response relationship through epidemiology, if the
11 epidemiology fails, then everything fails.

12 THE COURT: Okay. My next question for the Plaintiffs
13 might help clear this up. This one is for the Plaintiffs.

14 So, yesterday in your slides you provided a checklist
15 of primary evidence, which included epidemiology, background
16 risk of disease, and dose response relationship. It appeared
17 on slide 31 of slide deck named intro deck one, 9/20/22.

18 On the slide you stated that your experts relied on
19 all three forms of primary evidence, epidemiological studies,
20 dose response relationship, background risk of disease.

21 I guess, what I would like you to do is respond to
22 what the Defendants just said about your dose response
23 relationship as far as primary evidence, and maybe you agree
24 that the way the Plaintiffs are trying to get to dose response
25 is through your epidemiological, so maybe that are one in the

1 same.

2 I would like you to explain that to me, but in any
3 event, where, if at all, you have relied upon background risk
4 of disease as one form of primary evidence. I don't think I
5 saw that anywhere in your papers, but you have it checked off
6 on slide 31.

7 *MR. NIGH:* I am going to address the first part of
8 that, not the second part. Maybe my colleagues will address
9 the second part. The first part, I have a clear answer, and
10 that is, no, those wagons are not tied together, dose response
11 and epidemiology are not -- the Eleventh Circuit makes it clear
12 that it is any one of those.

13 Our way that we attempted that question did not tie
14 those wagons together. To say that an expert relies on
15 epidemiology to do a dose response is not the same thing in
16 terms of challenges of reliable epidemiology opinions. Those
17 are two different things.

18 *THE COURT:* I suppose if a dose response relationship
19 expert relies on his or her -- on an epidemiology study that
20 has been stricken, hypothetically, and that is the input or the
21 data or basis on which the expert -- the dose response
22 relationship, maybe the toxicologist expert forms his or her
23 opinion, that might be a different scenario.

24 *MR. NIGH:* That could be a different scenario.

25 *THE COURT:* But you are not talking about that

1 scenario.

2 MR. NIGH: Right. That would depend on the logistics
3 of why the epidemiology study was stricken for the purpose of
4 the dose response, but that is a different statement than if
5 the epidemiology as a whole opinion is reliable compared to the
6 dose response opinion. That is all.

7 THE COURT: Okay. And the background risk question.

8 MR. HEINZ: Noah Heinz for the Plaintiff. I think a
9 useful thing to think about as far as what background risk
10 means and how it can be contradistinguished from epidemiology
11 is to read the descriptions of background risk in Chapman and
12 McClain. I don't have the exact quotations in front of me, but
13 it talks about the increased risks for people exposed versus
14 the general population.

15 A useful context to think about that is the use versus
16 nonuse studies, so if the Court were to conclude, for example,
17 that looking at epidemiology by itself, maybe the active
18 comparator studies are better epidemiology, for example, we
19 would submit that you could still look at the use versus nonuse
20 epidemiology for purposes of the background risk primary --

21 THE COURT: Did you make that argument in your papers?

22 MR. HEINZ: We may have mentioned it briefly in the
23 context of describing background risk, but I don't think we
24 articulated it in this fashion.

25 THE COURT: I would need to know where you think you

1 mentioned it as a form of primary evidence that you are relying
2 upon to put forth your general causation theory.

3 I know you spoke at length about why use versus nonuse
4 studies have certain relevance and why comparators at times
5 don't, but you are making a very specific statement. You are
6 making an argument that I don't think I saw. I want to know
7 whether I missed it or whether that is a new argument.

8 I don't remember seeing background risk anywhere, so I
9 want to be sure.

10 *MR. NIGH:* Your Honor, background risk, there is a
11 whole section in Dr. McTiernan's expert report. We do have
12 arguments in the briefing, to rely on that we have background
13 risk. It has never been opposed by the Defendants, but we have
14 put in our motions that we have background risk.

15 *THE COURT:* In your motions or in your response?

16 *MR. NIGH:* In our response to their motion.

17 *THE COURT:* Can you let me know where, if you could
18 take a moment to look, so I know what you are relying upon so I
19 can go back and look at that.

20 *MR. NIGH:* We will get you where it is in McTiernan's
21 expert report, which in and of itself, we believe would be
22 enough for the record, but we will also look for it in the
23 motion.

24 *THE COURT:* Yes.

25 *MR. NIGH:* We may need to give that to you after the

1 break.

2 *THE COURT:* From the Defendant, any response, on --
3 you seem to take issue with how they characterized dose
4 response, that it is a separate wagon, and then also the
5 background risk issue.

6 *MR. PETROSINELLI:* I will hit the background risk
7 first. They never argued this. In their opposition brief they
8 argued that epidemiology is what they were relying on to defeat
9 our Daubert, motion. There is nowhere in their opposition
10 where they say we are proceeding under the background risk
11 prong of Chapman and McClain and so on. So, I think your Honor
12 is absolutely correct about that.

13 Secondly, in terms of the dose response, your Honor
14 hit the nail on the head. We just heard from them in
15 connection with the argument about animal studies, they said, I
16 think it was Ms. Luhana, we are not relying on animal studies
17 for our dose response. We are relying on the epidemiology.

18 We will get to this, but Dr. Salmon is relying on the
19 Hidajat study and the NDMA dietary studies, epidemiology, NMA
20 epidemiology, which is the problem. Your Honor is absolutely
21 right, if you find that it is unreliable to rely on those
22 studies, his whole dose response opinion falls apart.

23 Rider, which your Honor cited about, which says you
24 don't need epidemiology, but when you have epidemiology, right,
25 in all the other cases that is what the Plaintiffs rely on and

1 that is what the Plaintiffs did here.

2 *THE COURT:* Okay. To help Plaintiffs out, we did a
3 word search of background and we didn't find it in the
4 motion -- in the response other than factual background, the
5 word background. And then we seem to -- we could be wrong. We
6 looked at it in the expert reports, too. I do need
7 clarification on that.

8 Okay. So, maybe some of these are repetitive, because
9 we have been talking about dose response, but let's go through
10 these questions that I have here.

11 This is now on dose response for Plaintiffs.
12 Yesterday -- let me make sure I haven't already asked it. Let
13 me read it, and then we'll see.

14 Yesterday, during the hearing when you were here you
15 stated that some of your experts specifically looked at studies
16 with the intent to analyze dose response, but those study
17 authors stated that their study did not have data on dose
18 response. You states that your experts' consideration of dose
19 response in those studies, even though the studies turned out
20 not to have any data on dose response, was sufficient to
21 satisfy the primary methodology of dose response.

22 Can you confirm whether my understanding of what you
23 said yesterday is correct? And if not, then can you correct
24 me? But if it is, can you give me any support for that?

25 Looking at studies with the intent -- that your

1 experts looked at studies with the intent to analyze dose
2 response, but that the study authors stated that their study
3 did not have data on dose response.

4 MR. HEINZ: I am sorry, would you please repeat the
5 question one more time?

6 THE COURT: Yesterday, during the hearing -- and I
7 don't have access to the transcript, it's the best I could to
8 write it down. I thought it was stated that some of your
9 experts specifically looked at studies with the intent to
10 analyze dose response, but that those study authors stated that
11 their study did not have data on dose response.

12 You stated that your experts' consideration of dose
13 response in those studies was sufficient, even though the
14 studies turned out not to have any data on dose response.

15 Did I hear it correctly? And are you -- if I did, are
16 you saying that is sufficient to satisfy primary methodology of
17 dose response when an expert relies upon a study to analyze a
18 dose response, but the authors of the study say they don't have
19 data on dose response?

20 MR. HEINZ: The answer to would be no, that would not
21 be sufficient. I believe, if I remember correctly, the point
22 that I or Mr. Ronca was trying to make is that the Defendants
23 said that a number of the Ranitidine studies disproved the
24 notion of dose response.

25 For example, in the Norgaard study comparing two

1 prescriptions to ten prescriptions, there was a chart that said
2 the does response actually went down. The point was mainly to
3 say that sub analyses on dose response were not informative,
4 largely because the doses were so low that the change within
5 them would not be expected to identify a dose response effect.

6 The methodology of dose response that does satisfy the
7 burden, were instead based on different studies that did show
8 an effect. For example, for bladder cancer, that would be the
9 Cardwell study which did find a dose response effect, and a
10 number of dietary studies for each cancer, then the Hidajat
11 occupational study for a number of cancers.

12 That would be the basis of the dose response, primary
13 methodology and those studies are appropriately cited in the
14 respective sections of each expert's report.

15 I also do have the background risk, answer if your
16 Honor would like that.

17 This ran together a bit in my head, and you are
18 correct that the background risk citation does not appear in
19 the opposition. My colleague tells me that it does appear in
20 the Moorman report at pages 12, and 13, and in the McTiernan
21 report at pages 28, 32, 64, 161, 213, and 219.

22 The thing I was thinking of is in the quotation from
23 McClain, for example, on what background risk is, is actually
24 in our reply in support to our motion to exclude the
25 Defendants' experts which has a section addressing this. I

1 believe it is on page 11, but it has a block quote, and makes
2 the same type of inference that I stated earlier.

3 You are correct, that it does not appear in the
4 response in opposition.

5 *THE COURT:* What were the pages, in Moorman and
6 McTiernan again? State them slowly.

7 *MR. HEINZ:* In the Moorman report it is on pages 12
8 and 13. Then in the McTiernan report on pages 28, 32, 64, 161,
9 213, and 219. And Mr. Gilbert reminds me, they did not raise
10 the point in their affirmative motion regarding background
11 risk, and that is one reason we did not oppose on that specific
12 basis.

13 *THE COURT:* Okay. Yesterday, during the hearing
14 Plaintiffs stated that an opinion that exposure to one
15 Ranitidine pill is not sufficient to get over what you
16 described as the general causation hump for minimum dose, and
17 Plaintiffs characterized exposure to one pill of Ranitidine as
18 something like a one in one billion likelihood of developing
19 cancer, which you stated would not be sufficient to meet the
20 preponderance of the evidence standard.

21 Can you explain to the Court what exposure is enough
22 to get over the general causation hump for dose?

23 *MR. HEINZ:* If I can ask a clarifying question. Is
24 the question what particular doses of Ranitidine or sort of a
25 more conceptual legal question of what number if it is, not one

1 in a billion?

2 *THE COURT:* I am just picking up on a comment the
3 Plaintiffs made, exposure to one Ranitidine pill. You all were
4 talking about Ranitidine and Ranitidine pill, and the general
5 causation hump.

6 I wanted to know what exposure of Ranitidine pills is
7 enough to get over the general causation hump.

8 *MR. HEINZ:* I think the conceptual answer -- and I
9 will get to the practical answer quickly -- has to be something
10 that would be sufficient for a jury to find by a preponderance
11 of the evidence that it could be a cause under the relevant
12 state law causation standards. That might be substantial
13 contributing factor, for example.

14 In the context of Ranitidine, there are a number of
15 estimates for what that dose might be. Your Honor has heard
16 that Plaintiffs' position is that we do not need to specify a
17 minimum dose, but if you disagree, the places to look for that
18 would be especially the Salmon report, which does calculate
19 cumulative amounts, the Panigraphy report which also calculates
20 an amount.

21 We would also say, even though it is not precisely
22 quantified, that the Moorman and McTiernan reports sufficiently
23 do say that a dose would be sufficient, maybe something like
24 three years, especially for bladder cancer, for example, stated
25 in the dose response sections on that.

1 Those would be the answers.

2 *THE COURT:* Okay. Let's see what else you said
3 yesterday. Also yesterday, during the hearing, Plaintiffs
4 stated that they were required to show that a realistic dose
5 can cause cancer. These are words the Plaintiffs used, counsel
6 used, and then you explain that a realistic dose is a dose that
7 a person can get from taking Zantac.

8 Can you clarify whether a realistic dose referred to a
9 realistic dose of Ranitidine or a realistic dose of NDMA?

10 *MR. HEINZ:* I suppose it would be a realistic dose of
11 NDMA in Ranitidine, so that would have to be a realistic number
12 of pills and at an at least possible or plausible testing
13 amount of the NDMA within the pills as well.

14 *THE COURT:* When you refer to realistic dose, what
15 does that term generally mean and what does doses of -- what
16 doses of Ranitidine and NDMA constitute realistic doses? Is
17 there an approximate number, a range of numbers of what doses
18 of Ranitidine and NDMA are considered realistic doses?

19 *MR. HEINZ:* I believe when I said that, and said
20 something like, well, a thousand doses would be ridiculous,
21 something like that, conceptually that way we would say the
22 question should work is think about the highest plausible dose
23 that one -- a Plaintiff in the pool could take. That's the way
24 Judge Chhabria framed the question in *In Re: Roundup*.

25 So, we would say a realistic number could be two pills

1 a day for 30 or more years, something like that, is at least a
2 realistic dose as far as the Plaintiffs in this litigation.

3 *THE COURT:* Where does that come from, two pills a day
4 for 30 years?

5 *MR. HEINZ:* I suppose it comes from, you know, comes
6 from -- part of it comes from what people have said in the
7 registry as far as -- we did say in our papers that I think
8 60 percent of Plaintiffs used it for at least ten years, and
9 there are indications for Ranitidine maintenance use, for
10 example, in which that amount is permitted, one pill a day, two
11 pills a day, higher for some conditions, and it is just not an
12 outlandish number.

13 *MR. NIGH:* I wanted to add, Daniel Nigh, 37 years is
14 the time that Ranitidine was approved and sold in the market in
15 the United States. In addition to that, even some users could
16 have had Ranitidine as part of a clinical trial before it was
17 approved in the U.S. Clinical trials started, I believe, five
18 years before approval, so it could be up to 42 years.

19 The second question is, what is the highest dose the
20 Plaintiffs could have? Dr. Le answers that question in her --
21 she gives information on the prescribing and what people would
22 take these doses for. For most, it is 300 milligrams a day, up
23 to 300 milligrams. There are certain conditions, and I forget
24 the names of some of the conditions, but some it is
25 600 milligrams a day, and so that is actually four times

1 150-milligram pills.

2 There are actually some conditions that are fairly
3 rare, but they could be prescribed and they have been approved
4 for prescription purposes to have up to 6 grams a day, so that
5 would be much more Ranitidine, so those people could actually
6 have a lot more dose.

7 *THE COURT:* Okay. Any response on any of those issues
8 from the Defense?

9 *MR. PETROSINELLI:* Yes, your Honor, Joe Petrosinelli.
10 This is the legal questioning we flagged in the opening, which
11 is, what is the standard in the Eleventh Circuit as to what has
12 to be proven at the general causation stage on dose? What you
13 just heard again, which is the highest possible dose that any
14 Plaintiff in the MDL could experience, is completely and
15 utterly inconsistent with Eleventh Circuit precedent.

16 The Eleventh Circuit, in McClain, in Chapman, in all
17 the District Court cases on products MDLs afterwards, Judge
18 Altonaga in the Fixodent case, Judge Moody in Accutane, Judge
19 Rodgers, in Deepwater Horizon, they all say -- I'll quote
20 McClain and Chapman, to provide a reliable general causation
21 opinion in a toxic tort case you have to prove the dose that
22 can be hazardous to humans generally, by which they mean the
23 threshold dose, what we have been calling.

24 The cases say it over and over again. I know Judge
25 Chhabria said something different, and he interpreted Ninth

1 Circuit law as being different. That is not the Eleventh
2 Circuit, it is the complete opposite of what you just heard.

3 They have to have reliable -- we're on Daubert, they
4 have to have reliable expert evidence in considering -- in
5 giving a causation opinion of the threshold dose. To quote
6 McClain, the dose at which the compound, whatever it is, can be
7 hazardous or cause the effect, here cancer, five cancers, in
8 humans generally. That means the dose at which the person who
9 could be a Plaintiff realistically had the lowest dose.

10 That only makes sense at the general causation stage
11 because if they have that dose, whatever it is -- I still
12 haven't heard what it is, which is a huge problem, but whatever
13 it is, then it is specific causation. The Plaintiff has to
14 prove I had more than that dose, and then they have proven
15 general causation, and then the jury has to decide whether
16 there is specific causation, and all the things that would go
17 into specific causation.

18 That is the law and that is the fundamental defect in
19 their -- whether you view it as them proceeding under the dose
20 response relationship primary method or epidemiology which
21 informs the dose response relationship primary method, they
22 can't meet it. They haven't met it, either because -- for all
23 of their experts but for -- all their experts who offer a
24 general causation opinion, but for Dr. Salmon, explicitly say
25 we can't say.

1 Dr. Salmon attempts to say it, and you have heard the
2 motion on Dr. Salmon, and I have some more comments about him
3 the appropriate time. That is the reason they can't pursue it.

4 *THE COURT:* I think this would be a good time, we can
5 proceed into final statements. It looks like each side has
6 asked for a half hour. I don't know if you need a break, first
7 or whether we should go into them and take a break. I do want
8 to get -- the lingering questions that I have put out there, I
9 would like for you to put on the record what the answer is, if
10 you found it, or if you haven't found it, that you haven't
11 found it, so we know if there should be any followup post
12 hearing. I do want to get everything on the record.

13 Are you okay to proceed?

14 *MR. CHEFFO:* We are, but if we are going to take a
15 break, it makes sense to take a break now.

16 *THE COURT:* When did we come in? Are you okay,
17 Pauline?

18 *THE COURT REPORTER:* I am okay.

19 *THE COURT:* We can proceed.

20 *MR. CHEFFO:* Thank you, your Honor. I am going to
21 divide this with Mr. Petrosinelli.

22 At the outset, it is kind of unclear whether the
23 Plaintiffs are going to offer any calculations. If they do, we
24 would like an opportunity after this to come back. You will be
25 the judge of that, obviously, your Honor.

1 First let me thank the Court again for the time and
2 effort. A lot of words and documents have been put at your
3 Honor.

4 I think there is a few themes throughout the last day
5 and a half. The first, is that the Plaintiff -- this may have
6 been lost in the way this has been presented, but the
7 Plaintiffs have the burden of proof here, right, and they spend
8 virtually all of their time trying to essentially poke holes at
9 the peer reviewed Ranitidine data.

10 The second theme is that Plaintiffs have still and
11 continue to fail to provide answers to dose and dose response,
12 notwithstanding your Honor's multiple questions, and I think
13 the time for that, frankly, was not even today, that was at the
14 time when the expert reports were due.

15 The third is that there has really has been no dispute
16 that no one other than the Plaintiffs' experts and their
17 counsel have held these positions here on general causation,
18 literally no one else.

19 The fourth is Plaintiffs are essentially asking the
20 Court to speculate about what science might be or could be, if
21 we just waited a little more time, or saw a curve, a change or
22 looked at things, law lagging science.

23 And the final thing, is, you have heard a number of
24 full-throated arguments, frankly, from day one of this
25 litigation when the Plaintiffs basically said that there were

1 dozens of cancers, and hundreds of thousands of people who
2 filed claims based on those. We now went to ten, and then
3 there's eight, and now there is five. The reality is, the same
4 studies, the same epidemiological studies that address the
5 cancers were conceded govern the five.

6 It would be unprecedented, your Honor, respectfully,
7 to allow Plaintiffs' experts to testify about a product causing
8 cancer when literally the world's scientific community has a
9 different view.

10 Next slide, please.

11 As your Honor may recall, the world kind of best and
12 brightest looked at this issue and they spoke to this issue,
13 and they spoke loudly.

14 Next slide.

15 And, you know, we heard, and I agree, Ms. Luhana said
16 earlier today that we shouldn't look behind what the authors
17 say, right, that would be inappropriate, yet, what we have only
18 seen are data points from some of these studies, kind of we say
19 cherry picking situational science. There hasn't been a lot of
20 this what the authors actually said.

21 We went through that, so I am not going to do that,
22 but you have read these studies, and you know not one of these
23 authors say that you should read our data points as finding an
24 association or causation. No one has said that, and both the
25 case law, and what we have heard is that following what the

1 authors say in these peer reviewed studies is the appropriate
2 methodology.

3 Next slide.

4 Okay. Again, you could search and study and you will
5 not find anyone -- if this was so prolific, that literally
6 millions of people over 30 years were subjected to this
7 genotoxin, as the Plaintiffs say, could it be that it wouldn't
8 be picked up in the evidence? That is just not the way science
9 works.

10 Next slide.

11 Widespread acceptance is a critical factor. That is
12 why we spent a fair amount of time talking about it. What is
13 generally accepted is not just the conclusions of the authors,
14 which is generally accepted, we have seen that from the EMA and
15 the FDA, we haven't have seen anything new about that.

16 It is also the fact that the way these studies were
17 conducted and the way they went about them, so using an active
18 comparator, that is generally accepted. That is the way the
19 scientific community addressed this.

20 Looking at Ranitidine data, not occupational data, not
21 dietary data, that is generally accepted. No one else has done
22 that, no one, except a few of the Plaintiffs' experts. Looking
23 at statistically significant findings in order to make
24 conclusions, that is what the world's community has done, so
25 that is generally accepted. Looking at world use, and relying

1 on what the authors say, those are all generally accepted.

2 The Plaintiffs essentially have two main attacks on
3 why your Honor should disregard or minimize the importance.
4 They first talk about statistical significance.

5 Next slide.

6 You don't really need to look at the significance.,
7 maybe the Defendants spent too much time talking about it. We
8 can look at trends, but as your Honor may recall from the
9 presentation on Dr. McTiernan, that is not the way she has
10 approached kind of her life's work outside of this courtroom.
11 When she looks at the same data points in this litigation, it
12 is increased risk, but everywhere else she says it is no
13 association. That is the epitome of situational science.

14 Next slide, please.

15 Some of the Plaintiffs' briefs, Defendants argue that
16 if the confidence interval study includes one, there no
17 statistical association between the exposure and the disease.
18 This flawed but repeated view is pseudoscience. Well, their
19 basically expert says when the confidence interval includes
20 one, you interpret the finding as no statistical association.

21 It is not the point of whether it is of statistical
22 significance or not, the pint here is saying there is no
23 association if it includes one. I don't think that is
24 pseudoscience, and I don't think Dr. Le in this regard is
25 practicing pseudoscience.

1 Next slide.

2 You have seen the slides about Dr. Salmon. He also
3 recognizes the importance of statistical significance outside
4 this litigation.

5 Next slide.

6 The next issue is followup time. The Plaintiffs
7 basically say, well, a lot of these studies, you can't really
8 rely on them because they don't capture -- cancer takes a long
9 time. I heard that a lot before this hearing.

10 We put up yesterday a slide saying, well, what Dr.
11 McTiernan is doing here is different than what she has done
12 outside the courtroom. The Plaintiff said, well, wait a
13 minute, there's 400 studies, you can't really rely on it. We
14 are cherry pecking, so here is what we did.

15 Next slide.

16 We went back and looked at those 400 studies, and
17 there are actually 20 studies that deal with medication and
18 cancer, two of them are case controls, which would not have a
19 followup, but of the cohorts, all of the cohorts studies, you
20 can see many of them are less than the one -- the examples we
21 used, but they are all less than the followup that we have seen
22 has occurred in connection with the Ranitidine data, the epi
23 data.

24 So, when the Plaintiffs say, oh my gosh, that is not
25 reliable, their own expert, in connection with her own science

1 outside the courtroom, relies on followup that is substantially
2 less than the peer reviewed literature we have been talking
3 about, that is situational science and cherry picking.

4 Similarly, Dr. Panigraphy says you see a measurable
5 effect within a period of four years. Again, we dispute that,
6 but to the extent that is true, then that is squarely within
7 the followup times of most of the studies that we have put
8 forward and the world's scientific community has put forward as
9 the reliable epidemiological data. Plaintiffs can't have it
10 both ways here.

11 Next slide, please.

12 And this also highlights the point. Mr Petrosinelli
13 is going to talk a little bit about this, maybe at some length,
14 but if we take this as true, right, and it is accurate, at
15 least as I understand, this, the Plaintiffs are saying the
16 column on the right is the real world use, this is what happens
17 in the real world, and people who have gastric cancer, they can
18 experience cancer diagnosis at a year and a half, esophagus,
19 1.8, bladder almost 4, pancreas, liver.

20 Putting aside the fact that we don't think these are
21 methodologically sound, you can't have it both ways. You can't
22 say the reasons why I am disregarding epidemiological peer
23 reviewed data is because of statistical significance when your
24 experts rely on -- use statistical significance in different
25 ways, you can't also say, well, gosh, those are not long enough

1 studies when your own data is saying we would expect to see
2 cancers within this period of time based on it.

3 You can't have it both ways, so this is kind of the
4 epitome of situational science, and I think what this
5 highlights -- and I will turn it over to Mr. Petrosinelli -- is
6 that when you look at the totality of the world's literature,
7 when you look at what the EPA, the EMA, and all the scientists
8 outside this courtroom have found, there is no support for
9 general causation, and that is a methodology issue.

10 Thank you, your Honor.

11 *THE COURT:* Thank you.

12 *MR. PETROSINELLI:* Joe Petrosinelli here, you Honor.
13 I will try to bring this home for us.

14 Next slide, please.

15 This is one more piece of situational science that Mr.
16 Cheffo was talking about with Dr. McTiernan where she gave less
17 weight to relative risks that were not greater than one, more
18 weight to risks that were greater than one, which she does not
19 do in her peer review publications.

20 Next slide, please.

21 You remember Mr. Brown showed this slide about Dr.
22 Moorman, and I won't go through explaining it, here, but again,
23 she set forth criteria, which you are supposed to do under
24 Daubert if you are going to perform a Bradford-Hill analysis,
25 she set forth criteria as to how she weighed the studies. That

1 is okay.

2 But as I said in my opening and as the case law shows,
3 then the way that you do it has to have some reliable method.
4 It has to be based on principles of science, and when you look
5 at the studies that she gave little weight to versus strong
6 weight to on the criteria that she herself said she was
7 applying, it doesn't make any sense. It is completely random.

8 Next slide, please. Next slide.

9 Again, we made this point that the Plaintiffs in their
10 briefing are relying on the Habel study, and their own experts
11 say don't rely on the Habel study.

12 Next slide, please. Next slide. Skip that one.

13 Okay. So this gets to my piece on dose. You have
14 saved me some time, your Honor, because I was going to do the
15 McClain and Chapman cases that we just talked about.

16 Next slide, please.

17 One of the things I would say is, Judge Rodgers'
18 opinion in Deepwater Horizon, super critical on this point.
19 The chemical at issue in Deepwater Horizon was arsenic. They
20 sprayed the oil dispersants in the air containing, among other
21 things, arsenic, and the residents claimed that it floated onto
22 shore and caused them injury.

23 Arsenic is a Class I carcinogen, human carcinogen
24 under the IARC classification system, so much more than NDMA.
25 The Plaintiffs said it is a Class I carcinogen, what is the

1 problem with general causation? Judge Rodgers said, no, it is
2 about dose the eleventh Circuit case law tells us to get past
3 general causation you have to have reliable evidence of dose,
4 meaning exposure level and duration.

5 One of the reasons why she excluded a very highly
6 qualified -- she says almost wistfully at the end of the
7 opinion, I feel bad doing this, because I am not saying this
8 person didn't honestly believe this, but in the Eleventh
9 Circuit, you can't come in and say, oh, it is a known
10 carcinogen and so it must be general causation, and that was
11 the biggest problem in Deepwater Horizon.

12 The same thing here, except you don't actually have a
13 Class I human carcinogen, you have a lesser under the
14 classification system.

15 Next slide.

16 This is the quote that we have been talking about that
17 we are still waiting for an answer. The Plaintiffs agree that,
18 as a general causation matter, they are not claiming a year's
19 worth of use could cause an increased risk of cancer. Many
20 years of regular use does not satisfy the Eleventh Circuit
21 standard.

22 So where does that leave us? Where I would say is
23 sort of what I just alluded to, which is, if you think about
24 the experts on the Plaintiffs' side who have offered general
25 causation opinions on Ranitidine, you have Drs. McTiernan,

1 Moorman, Le, and Michaels, the four of them don't offer any
2 opinion on threshold dose, what it is. They say they are not
3 going to do it, and they don't have an opinion on it, and they
4 offer no opinion on what is the dose response relationship, if
5 there is one, between Ranitidine use and any of the five
6 cancers.

7 You would have to provide it for each of the five.
8 One would think, with different target organs, you couldn't
9 can't have the same threshold dose and the response
10 relationship for with five entirely different cancers. They
11 haven't done it for any of them.

12 Their methodologies, which in the Eleventh Circuit it
13 says if you are going to give a general causation opinion it
14 must have a reliable analysis of threshold dose and dose
15 response, they don't have it, they are excluded.

16 Dr. Salmon is the only one who offers a general
17 causation opinion as to Ranitidine, not Dr. Panigraphy or Dr.
18 Zeiger. They don't offer general causation opinions as to
19 Ranitidine. He is the only one, and these are the charts that
20 the Plaintiffs have presented.

21 I am not going to repeat. You heard from Mr. Holian
22 yesterday all the methodological flaws in these two charts if
23 you remember, these are the charts on pages 221 and 223 of his
24 report.

25 So, starting at the top where he gets the dose, look

1 at what he relied on. For bladder, pancreatic and liver cancer
2 to calculate the threshold dose of an increased risk, he relied
3 on the Hidajat study, an occupational rubber, worker inhalation
4 of chemicals study, completely, totally unwarranted to any
5 scientific method.

6 Esophageal, cancer, you might remember the Keszei
7 study. That dose that he put in there and the relative risk he
8 calculates, it is for males only, not females, and squamous
9 cell esophageal cancer, not adenoma carcinoma esophageal
10 cancer, which, by the way, is the more common one, the
11 definition of cherry picking, pick one gender and not the
12 other, and pick one sub type of the cancer and not the other,
13 those are unreliable.

14 Of course, the other, De Stefani, is an NDMA dietary
15 study, and you know our position on relying on that. That is
16 chart number one.

17 Then, to get to chart number two, the duration, right,
18 you carry down the numbers. You see those milligrams of NDMA
19 in the first column of the chart at the top, they are now in
20 the first column of the chart at the bottom. This assumes that
21 someone is taking a 300-milligram dose every single day for
22 these number of years and that every single dose has the same
23 level of NDMA in it, which is totally contrary to Plaintiffs'
24 theory that there are variations in levels because it is about
25 heat and humidity.

1 It is just completely untethered to any science or
2 even their theory of the case. As Mr. Cheffo pointed out, I am
3 still not sure what column they are relying on to say what the
4 dose is. I think Mr. Nigh said today the right-hand column,
5 because of course those have the fewest number of years, but
6 that runs into two problems.

7 That is dependent on the admissibility of the Emery
8 test, because those numbers are based on the levels found by
9 Emery in their tests. So, if those are inadmissible, they
10 can't rely on that column, nor can they rely on that other
11 column that says Emery overall average. That is one problem.

12 The second problem, is what Mr. Cheffo identified. If
13 these were methodologically sound and that is the number of
14 years in which you would see an increased risk of cancer, then
15 they run headlong into the Ranitidine epidemiological studies,
16 all of which have a longer followup period than anything that
17 is there.

18 It is a Daubert mess. There is no possible way they
19 can rely -- Dr. Salmon can reliably offer opinions about these
20 numbers to support a general causation opinion.

21 Next slide, please.

22 Finally -- click it one more time. Thank you.

23 Finally, I just want to mention one thing that was
24 mentioned yesterday by the Plaintiffs. We have this all star
25 lineup of MDL judges who have handled these pharmaceutical

1 MDLs, all of whom have excluded opinions under Daubert with
2 qualified experts who offered Bradford-Hill analyses. The
3 Plaintiffs haven't disputed that that was the holding in these
4 cases and these three things are indeed features of these
5 cases.

6 What they said was, if you look at the Eleventh
7 Circuit cases, like McClain and Chapman, the experts there
8 didn't offer any epidemiology, it just wasn't a close call for
9 the Court. It is true that in those cases the experts didn't
10 offer epidemiology, or very little epidemiology, although in
11 other Eleventh Circuit cases like Allison they did.

12 If you look at these decisions, and I was involved in
13 some of these cases, the experts were qualified epidemiologists
14 who presented an abundance of human epidemiological studies, of
15 varying significance and the whole fight in those cases is the
16 exact same fight that we have here.

17 In the Viagra, Cialis litigation, in the Zolofit
18 litigation that Judge Rufe handled, Plaintiffs had
19 statistically significant multiple -- like a dozen
20 epidemiologic studies showing an association between the drug
21 itself, the studies were of the drug, and the outcome in
22 question, and for various reasons -- in the cases, the judges
23 carefully went through it and said that is -- the fact that
24 there are some statistically significant studies showing
25 increased risk doesn't get you past Daubert and it doesn't get

1 you into a Bradford-Hill analysis, or if it does, you have to
2 do it reliably, and those Courts excluded those opinions.

3 It is not like this is some unique situation where
4 Drs. Moorman and McTiernan have found things that no other
5 epidemiologists have found in these other cases. These cases
6 had evidence that was much more powerful, on its face at least,
7 than what Dr. Moorman and Dr. McTiernan present here.

8 Next slide, please.

9 We talked about Abilify. If you want to know what a
10 case looks like in the Eleventh Circuit, a pharmaceutical case
11 where someone can get past Daubert on general causation, look
12 at Abilify for the reasons we talked about in my opening.
13 There was only one epidemiologic study and uncontradicted in
14 the literature, and look at the statistically significant
15 increased risk, massive.

16 Nothing like that, in this case and the broad
17 scientific consensus in the regulatory and scientific
18 community, which I need hardly say is not this case. It is
19 just the opposite in this case.

20 Next slide.

21 Finally, Judge, to pick up on Mr. Cheffo's statement
22 about law lagging science, if you look at the Eleventh Circuit
23 cases, one thing you find in these pharmaceutical cases that
24 have excluded expert -- or products cases I should say, Allison
25 is a silicone implant case. In these toxic tort cases, there

1 is this theme that runs through it, which is that -- as you see
2 in Allison and Rider, which is that, look, maybe some day in
3 the future, when there is longer -- to the Plaintiffs saying
4 there is longer followup in Ranitidine studies, or there is
5 other data, maybe the Plaintiffs' opinions will be proven to be
6 true, but the quote in Rider, says it all, you have to judge
7 the science as it is today.

8 The Plaintiffs brought these lawsuits, they have to go
9 with the science as it is today. As Judge Seibel said, I
10 showed this in opening, it is not that anyone is saying these
11 experts are insincere, or they don't honestly believe in their
12 own minds that they have concluded this, but that doesn't get
13 you past Daubert.

14 When the entire scientific community, having studied
15 the question, is against you, the law can't wait until -- as we
16 have heard from the Plaintiffs, well, what if the studies had a
17 longer followup period, or what if higher dose, what if this or
18 that, what if this abstract that they showed from May, 2022,
19 that is not in record, for reasons we have talked about, what
20 if that gets published and there is better data.

21 That is not how we deal with our motions, and these
22 Eleventh Circuit cases, and in almost every one of the MDLs I
23 showed, on the prior slide, that is what the judges said, that
24 as we sit here today, based on the science, based on the
25 consensus in the scientific community, these opinions are not

1 accepted, and they are not based on reliable methodology, and
2 that fundamentally is what we have in this case and why we seek
3 exclusion here.

4 Thank you, your Honor.

5 *THE COURT:* Okay, thank you very much.

6 Okay, from the Plaintiffs, closing.

7 *MR. GILBERT:* Your Honor, would you give me a warning
8 at five minutes and at one minute?

9 *THE COURT:* For the full 30 minutes?

10 *MR. GILBERT:* Please.

11 *THE COURT:* Okay.

12 *MR. GILBERT:* May it please the Court, Robert Gilbert
13 on behalf of the Plaintiffs.

14 Before I begin, on behalf of our entire Plaintiffs
15 team, I, too, would like to thank the Court, your staff, and
16 especially Ms. Stipes for your critical roles in connection
17 with our Daubert proceedings it has been going on for quite
18 awhile, there have been a lot of hearings related to it,
19 culminating in the past two days, and we appreciate everybody's
20 support and cooperation.

21 Let's start with the basics. After four decades,
22 Zantac was pulled from the market. That was because there is
23 no dispute that it degrades into NDMA, particularly when
24 subjected to heat and humidity. And it is also undisputed that
25 NDMA is a known carcinogen.

1 With those undisputed facts in mind, I am going to
2 discuss three topics, the general causation question, the
3 Court's role in deciding Daubert motions, and third, I will
4 discuss each of our experts who have been challenged.

5 First, on the general causation question, I ask the
6 Court to imagine a Plaintiff, like many of those in the
7 registry, who took a 300-milligram Zantac tablet every day for
8 two decades and stored that Zantac in her medicine cabinet
9 subject to daily heat and humidity and developed one of the
10 five cancers. If the Court grants Defendants' Daubert motions,
11 that Plaintiff will never try her case to a jury. That can't
12 be right, and as I will discuss over the next few minutes, that
13 isn't right.

14 The reason it isn't right is because it violates the
15 fundamental principles of Daubert.

16 We have heard a lot of talk by my esteemed colleagues
17 on the other side about Judge Chhabria's decisions in Roundup,
18 and as Judge Chhabria explained in that case, it is black
19 letter law that a Court's 702 inquiry focuses on expert
20 methodology -- methodologies, not conclusions.

21 As applied to the question of general causation here,
22 Judge Chhabria's opinion framed the relevant inquiry this way:
23 Whether Plaintiffs' experts utilized accepted methods to
24 conclude that NDMA exposure from Ranitidine can cause any of
25 the designated cancers for any Plaintiff based on the highest

1 dose a Plaintiff might have experienced.

2 Once again, that is our Plaintiff who consumed
3 300-milligram Zantac tablets every day for two decades.

4 The Defendants run from this legal standard in the
5 hopes that your Honor will reach your own scientific
6 conclusions. My colleague, Mr. Petrosinelli, tried to tell the
7 Court that Judge Chhabria's decision wouldn't be good law in
8 this circuit. He went on to say in his opening that if Judge
9 Chhabria were here he would tell you that, too. I am confident
10 that if Judge Chhabria were here, he would prove Mr.
11 Petrosinelli wrong.

12 We don't have to speculate about this. Judge
13 Chhabria's Daubert decision was appealed to Monsanto to the
14 Ninth Circuit and the Ninth Circuit affirmed that decision and
15 expressly rejected Judge Chhabria's assumption that the Daubert
16 standard differs between the Eleventh and Ninth Circuits.

17 This is precisely what the Ninth Circuit said: "To
18 the extent the District Court relied on In Re: Zolof and
19 McClain" -- and I am omitting the cites -- "those cases do not
20 reveal a more flexible Daubert in this circuit," meaning the
21 Ninth Circuit.

22 The Court went on: "Despite its incorrect assumption
23 that this Court is more permissive than others in admitting
24 Daubert testimony, the District Court still employed the
25 correct legal standard for reliability when it

1 admitted Hardeman's expert testimony."

2 Judge Chhabria framed the general causation question
3 properly for us, too, whether NDMA exposure from Ranitidine can
4 cause any of the five designated cancers for any Plaintiff
5 based on the highest dose a Plaintiff might have experienced.

6 That framing is consistent with McClain, which defines
7 general causation as the, quote, "general question of whether
8 the drug or chemical can cause the harm Plaintiff alleges,"
9 unquote. That is McClain, at page 1239.

10 A drug can cause a given harm, if it could possibly
11 cause it for any Plaintiff. Judge Chhabria's formulation
12 follows directly from that basic definition in any MDL with
13 thousands of Plaintiffs all with different usage facts. Even
14 though the Ninth Circuit made it clear that the standard is the
15 same under both Eleventh and Ninth Circuit law, my colleague,
16 Mr. Petrosinelli, continued to try to reshape the law of this
17 circuit to fit Defendants' preferred outcome.

18 You heard him claim multiple times that Plaintiffs
19 must identify the minimum, in fact he did it today again,
20 Plaintiffs must identify the minimum threshold dose or we lose
21 on general causation. Not a single case says Plaintiffs must
22 identify the minimum threshold dose, not precisely, not in a
23 range, not at all.

24 The closest the Eleventh Circuit cases come simply
25 restate what Plaintiffs -- what we already agree with, dose

1 response is important to analyze. Defendants say this about
2 McClain, quote, "As the Eleventh Circuit has explained, an
3 opinion that exposure to a toxin at any level is too much
4 conflicts with the importance of individual responses to
5 toxins." That is found at DE 5696, at pages, 20 and 21.

6 Plaintiffs, of course, agree with that. We do not
7 argue that any Plaintiff can prevail by saying he or she took
8 Zantac a single time and then developed cancer. But nothing in
9 that quote from McClain ever says that Plaintiffs' experts get
10 excluded if they don't identify the minimum threshold dose
11 after they have shown that many Plaintiffs exceed any realistic
12 threshold.

13 Of course, this makes perfect sense. There is a world
14 of difference between saying causation cannot be shown if no
15 Plaintiff has enough of a drug to cause harm, versus
16 saying causation cannot be shown even though many are above any
17 plausible threshold, which is not precisely stated.

18 Defendants also try to include Mr. Petrosinelli's
19 rewrite of the law in a footnote to the reply to the
20 epidemiology motion, Docket Entry 5958, at footnote 48.
21 Footnote 48 claims that Chapman says satisfies, and I quote,
22 "To carry the burden in a toxic tort case a Plaintiff must
23 demonstrate the levels of exposure that are hazardous to human
24 beings generally, as well as the Plaintiff's actual level of
25 exposure to the Defendants' toxic substance before he or she

1 may recover," unquote.

2 Your Honor, that quote does not appear in Chapman,
3 nowhere. It is not off by a little bit, it is not in the
4 Eleventh Circuit's opinion. It is instead a quote from McClain
5 taken out of context noting a case where Plaintiffs did not
6 offer any opinion about the specific Plaintiff's exposure.
7 There is no authority, none, none, none, that converts the
8 importance of identifying a dose response relationship into a
9 requirement to identify a minimum threshold dose.

10 Defendants are pushing the boundaries of zealous
11 advocacy to claim that the law in the Eleventh Circuit embraces
12 the role they advocated yesterday and again just now.

13 As we will show your Honor, and have shown through our
14 evidence, forfeiture aside, misstatements aside, our experts do
15 identify thresholds that create increased risk.

16 Specifically, Plaintiffs' experts provide three
17 proposed answers. From Dr. Salmon, cumulative lifetime doses,
18 as stated in the chart on page 233 of his report.

19 From Dr. Panigraphy, 7.5 years of daily use for
20 stomach, bladder, esophageal and pancreatic cancer, and 14.3
21 years of daily use for liver cancer.

22 From Drs. McTiernan and Moorman, a more qualitative
23 dose of approximately three years, as I will explain in a
24 moment.

25 Next, let's remind ourselves of this Court's role

1 under Daubert. It is, as I know you know, a limited
2 gatekeeping role.

3 Shaky and strong evidence alike pass through. Only a
4 wholly unreliable -- only wholly unreliable evidence can be
5 excluded.

6 *THE COURT:* Can I have you repeat what you said a
7 minute ago about the three sources. Can you say that again?

8 *MR. GILBERT:* Sure. Dr. Salmon, cumulative lifetime
9 doses, as stated in the chart on page 233 of his report.

10 From Panigraphy, 7.5 years of daily use for stomach,
11 bladder, esophageal, and pancreatic cancer, and 14.3 years of
12 daily use for liver cancer.

13 From Drs. McTiernan and Moorman, a more qualitative
14 dose of approximately three years.

15 Second, to remind ourselves of the Court's role under
16 Daubert, a limited gatekeeping role. Both shaky and strong
17 evidence alike passes through. Only wholly unreliable evidence
18 is excluded.

19 That is what Abilify explains, and I quote, "This
20 weight of the evidence approach to analyzing causation can be
21 considered reliable provided the expert considers all available
22 evidence carefully and explains how the relative weight of the
23 various pieces of evidence led to his conclusion." That is
24 Abilify at page 1311.

25 Here is what Schultz from the Seventh Circuit says,

1 quote, "Rule 702 did not require or even permit the District
2 Court to choose between those two studies at the gatekeeping
3 stage. Both experts were entitled to present their views and
4 the merits and demerits of each study can be explored at
5 trial," Schultz at 433.

6 Your Honor, for the gatekeeping role to be limited.
7 It really has to mean something, that Daubert is about
8 methodology, not conclusions. It has to mean something, that
9 the Court is not permitted to assess an expert's credibility or
10 a particular study's persuasiveness.

11 Focusing on methods, Plaintiffs' experts'
12 methodologies are beyond reproach. Our experts opine that
13 Zantac can cause cancer using the Bradford-Hill criteria and a
14 weight of all of the evidence approach. That, as the Court
15 knows, is a widely accepted methodology that scientists
16 routinely employ. For that reason, the weight of the evidence
17 approach is routinely viewed as reliable, noted in Abilify,
18 Bear Hugger, Milward, and even in the Reference Manual on
19 Scientific Evidence.

20 Plaintiffs' experts reviewed and weighed Ranitidine
21 specific epidemiology, dose response relationship for NDMA, and
22 the background risk of disease. As Judge Rodgers noted in
23 Abilify, echoing the Eleventh Circuit, any one of those sources
24 of evidence suffices to show general causation.

25 We did and urge the Court to do a control F of the

1 Defendants' motions, as the Court indicated earlier with regard
2 to our opposition. Should the Court do that, the Court will
3 confirm that the Defendants never moved to exclude the opinions
4 of Drs. Moorman and McTiernan on background risk, so, of
5 course, we don't oppose in our opposition an unraised argument.

6 Their background risk opinions are unchallenged, and
7 that alone means that we prevail.

8 Defendants know that they have a problem. There is
9 ample evidence in the peer reviewed literature that Ranitidine
10 is associated with each of the five designated cancers, that
11 NDMA is associated with cancer, and that Ranitidine degrades
12 into NDMA.

13 That is more than enough for a qualified expert,
14 applying reliable methodologies, to conclude that Zantac causes
15 certain cancers. It is far, far more evidence that the
16 Plaintiffs had in Roundup where Judge Chhabria, applying the
17 same standard, permitted Plaintiffs' experts to testify.

18 So, how did Defendants attempt to overcome this
19 problem? They go to the familiar playbook when the Plaintiffs'
20 evidence is this strong, they invite this Court to go beyond
21 the limited inquiry into whether Plaintiff's experts used
22 reliable methods.

23 While they pay lip service to that standard, it is
24 obvious that what they really want you to do is pick and choose
25 which studies are better and which are less credible.

1 You could be perfectly sure that is what the
2 Defendants really want because they don't even try to say that
3 Plaintiffs' experts did not carefully review all the relevant
4 scientific literature.

5 They don't even try to argue that the factors
6 Plaintiffs' experts identified as strengths, such as long
7 followup periods, really are strengths, and factors identified
8 as weaknesses, such as not accounting for cancer risk factors,
9 really are weaknesses. They skip right over them and debate
10 the merits of each study, telling you why the ones they like
11 are probative and the ones they don't are irrelevant.

12 That is fundamentally a disagreement with the experts'
13 conclusions, not their methods.

14 So, Mr. Cheffo told you yesterday that the conclusions
15 are so out of whack that they are akin to opining that two plus
16 two equals five. They threw that Hail Mary because Defendants
17 know full well that Courts cannot focus on conclusions unless
18 they are utterly divorced from a valid scientific method, and
19 that is their only way to try to get the Court to accept only
20 the studies that are good for Defendants, tempting your Honor
21 to agree with them that those studies represent the scientific
22 consensus.

23 They will quote, as Mr. Cheffo called it, the loud
24 chorus from the respectable science that Ranitidine is safe
25 according to Defendants.

1 Mr. Cheffo put his ask to the Court on full
2 display when he discussed the Ranitidine epidemiologist's
3 forest plots and systematically crossed out various studies
4 from it. From one study to another, Mr. Cheffo said not
5 persuasive, not persuasive, not persuasive, exactly what
6 Abilify, Quiet Tech, and Schultz expressly warn Courts may not
7 do in deciding Daubert. That is over the line of gatekeeping,
8 it is asking this Court to enter the arena.

9 First, Mr. Cheffo summarily rejected the NDMA dietary
10 studies as flawed and irrelevant, but he made no effort to
11 explain how Plaintiffs' experts weigh them, much less how
12 considering that evidence rendered their methodology
13 unreliable.

14 Mr. Cheffo similarly rejected the occupational
15 exposure study because of his concerns about rubber dust.
16 Again, he failed to address this concern in terms of the
17 experts' actual consideration of the evidence and methodology.

18 As another example, Mr. Cheffo summarily rejected all
19 non-statistically significant results. Apparently Defendants
20 don't care for this form of evidence, which is a position they
21 are certainly free to take at trial, but what they can't do is
22 argue here that it was an unreliable method for an expert to
23 consider non-statistically significant results in the context
24 of all the available evidence, which is what epidemiologists do
25 each and every day.

1 In the end, all that remained were the studies that
2 the Defendants like, but each time that Mr. Cheffo asked you to
3 eliminate from your consideration a particular study, he was
4 effectively asking you to weigh the evidence, asking you to
5 evaluate persuasiveness, asking the Court ultimately to play
6 the role of a juror.

7 This Court should reject that invitation. Mr.
8 Cheffo's arguments might make for a great closing statement or
9 cross-examination, but they have no place in the Daubert
10 analysis.

11 With that foundation in the law, let's talk about Dr.
12 McTiernan's and Dr. Moorman's methodology. You heard from Mr.
13 Ronca and Mr. Heinz that each of these experts considered all
14 the scientific literature, Ranitidine studies, dietary studies,
15 occupational studies, animal studies, tissue studies, and so
16 forth, and Defendants agree -- let me say it again, Defendants
17 agree that both of these experts considered all the relevant
18 evidence.

19 Next you heard that both experts carefully and
20 consistently evaluated each study based on criteria that
21 epidemiologists routinely employ. They identified potential
22 biases, accounted for dose and followup, examined each study's
23 design, and a few other factors. Based on those consistent
24 factors, they weighed each study.

25 Once again, Defendants agree that both epidemiology

1 experts properly identified relevant factors.

2 Last, after according each study due weight, they
3 applied Bradford-Hill factors and exercised scientific judgment
4 to conclude that Zantac can cause each of the five cancers.
5 That is what they are supposed to do.

6 Defendants' criticisms all go to the weight.
7 Defendants argue that the dietary studies receive too much
8 weight. Rather than the moderate to little weight they
9 received, Defendants demand a weight of zero, but even
10 Defendants' case law, Burst and Hendrickson, agree that
11 evidence about the toxin, there Benzene, here NDMA, is relevant
12 and worth considering.

13 The FDA and the EMA considered NDMA evidence. Giving
14 that evidence some weight is not even close to unreliable and
15 was carefully explained across dozens of pages.

16 Defendants also argue that the active comparator
17 studies should be weighted double, but Drs. McTiernan and
18 Moorman disagreed. The issue is not active comparator studies
19 at large, but these active comparator studies, which have low
20 dose information, short followup, misclassification, and no
21 information about confounders.

22 Any one of these would be a sufficient reason to
23 discount a study. Together, they persuasively explain why
24 neither of these experts weighted studies like Iwagami,
25 Norgaard, and Adami highly. Again, that explanation does not

1 have to be persuasive to the Court, though Plaintiffs believe
2 it is highly persuasive.

3 It is enough that the explanation is based on valid,
4 consistently applied judgment from qualified experts. That a
5 different expert would give more or less weight to those
6 studies is irrelevant under Daubert.

7 The Court asked for a factual dose calculation. Drs.
8 McTiernan and Moorman did not supply a mathematically precise
9 minimum dose, though they plainly opine that high doses, many
10 years of use, could cause cancer. Their qualitative doses
11 estimates are on pages 34 to 47 for Moorman, and 291 through 98
12 for McTiernan.

13 Cancer specific analyses for Dr. Moorman on pages 110,
14 134 through 35, 162 through 63, 190 through 92 --

15 *THE COURT:* Wait, wait, wait, you lost me. Can you
16 start from the beginning where you started to quote page
17 numbers.

18 *MR. GILBERT:* Pages 110 --

19 *THE COURT:* Go back to --

20 *MR. GILBERT:* I'm sorry. Pages 34 through 47 for
21 Moorman, and 291 through 98 for McTiernan. Cancer specific
22 analyses for Moorman on pages 110, 134 through 35, 162, through
23 63, 190nine on through 92, and 222 through 24. And for Dr.
24 McTiernan, on pages 203, 222, 236, 254, 283.

25 McClain, the case Defendants rely on incorrectly to

1 require a minimum dose, says this in footnote 6, and I quote,
2 "One should not conclude from this analysis that to pass
3 Daubert muster an expert must give precise numbers," unquote.

4 Drs. Moorman and McTiernan clearly identified an
5 increased risk starting with regular users of Ranitidine after
6 three years of bladder cancer. No study for any other cancer
7 analyzed three years of dose, but Drs. Moorman and McTiernan
8 found NDMA analyses to be comparable.

9 Plaintiffs' position is that three years of daily use
10 would certainly be sufficient based on this analysis. Maybe
11 less could be enough, but certainly three years is a sufficient
12 dose.

13 As Schultz explains, an inability to precisely
14 quantify an even lower bound is not required, and that comes
15 from Schultz, at page 432.

16 Plaintiffs' epidemiology experts should sail through
17 Daubert, your Honor, and the same is true for Drs. Michael and
18 Le. Defendants did not even bother to present oral argument --

19 *THE COURT:* You have five minutes left.

20 *MR. GILBERT:* Defendants did not even bother to
21 present oral argument against them and their arguments in the
22 papers barely give any reason to exclude them.

23 Now it is to Dr. Salmon. Defendants' briefing
24 differed dramatically from what you heard over the last two
25 days. Dr. Salmon explained in detail how to convert

1 occupational inhalation exposure of NDMA into the equivalent
2 dose for a dietary exposure using a well-understood formula.
3 Defendants did not challenge this calculation.

4 Dr. Salmon also conducted intensive calculations based
5 on statistically significant findings in the dietary and
6 occupational studies. Had he used non-statistically
7 significant associations, he would have found even higher
8 numbers, but his conservative assumptions allowed him to
9 construct a cumulative dose chart showing how much Ranitidine
10 would be sufficient to cause the same levels of risk.

11 Dr. Salmon calculated this cumulative dose using four
12 different alternative assumptions about the amount of NDMA in
13 Ranitidine.

14 Defendants protest, but wrongly, that Dr. Salmon
15 picked the highest possible NDMA levels, and the highest
16 possible associations, but in fact he repeatedly used
17 conservative assumptions and calculated using alternative
18 assumptions so the Court can see how different premises affect
19 the analysis.

20 Your Honor specifically asked for a factual answer on
21 the minimum dose. Plaintiffs' answer remains that a minimum
22 dose is not required, but if it is, minimums are provided from
23 Dr. Salmon's chart on page 223 of his report. That chart lists
24 the number of years necessary to reach a given risk for each of
25 the five designated cancers.

1 So, if Dr. Najafi is permitted to testify, the far
2 right column would apply. That means that an increased risk of
3 gastric cancer would arise after one year and five months of
4 daily use, or a longer period for less regular use.

5 For esophageal, cancer, one year and ten months. For
6 bladder, three years and ten months. For pancreatic, three
7 years and ten months, and for liver cancer, six years and eight
8 months.

9 But even if the Court were to exclude Dr. Najafi, it
10 could use one of the other columns, each of which suffices to
11 show a minimum dose.

12 Something you heard almost nothing about at this
13 hearing is Dr. Dipak Panigraphy. He also calculated a minimum
14 dose, which is Plaintiffs' third answer. On pages 195 through
15 99 of his report, and 12 through 16 of his rebuttal report, Dr.
16 Panigraphy calculates minimum doses of 7.5 years of daily use
17 for stomach, bladder, esophageal, bladder, and pancreatic
18 cancer, and 14 years for liver cancer.

19 Defendants challenged two of his opinions, and only
20 two, both in the catchall brief. Those were his supposed use
21 of FDA's ADI and no threshold opinion, nothing at all about his
22 dose calculation. That is for good reason. Dr. Panigraphy
23 himself, using this identical methodology, was allowed through
24 Daubert in the Valsartan, MDL, yet Defense counsel did not
25 repeat their failed argument against him here.

1 Today you heard a lot about Dr. Najafi's testing. I
2 am not going to repeat that now based on the amount of time
3 left.

4 *THE COURT:* That is one minute.

5 *MR. GILBERT:* Thank you. Defendants' Daubert argument
6 is that Dr. Najafi is lying, he is lying about validation, he
7 is lying about internal standards, he is lying about
8 recordkeeping. These attacks are false. These attacks are
9 really not with unreliable science or methods, but Defendants'
10 contention that Dr. Najafi is an unreliable witness, but
11 Daubert is not about credibility of that sort.

12 Your Honor, you also heard a little bit about
13 endogenous formation. These opinions mostly go to the amount
14 of NDMA exposure. Again, Defendants attack interpretations of
15 the studies and seek to demonstrate certain studies are more
16 persuasive than others. Not a Daubert issue.

17 Let me close. Early next year, your Honor, juries in
18 this district should be able to learn about what these
19 companies did and what thousands of Plaintiffs went through.
20 Many of those Plaintiffs took Zantac, meaning they consumed
21 NDMA for decades at high doses, and suffered devastating
22 cancers.

23 Thanks to the FDA in 2019, that won't happen again,
24 but that forward looking relief is cold comfort to the
25 thousands of cancer victims.

1 Plaintiffs' experts offer reliable opinions about why
2 Zantac was the cause of those cancers. Juries should be able
3 to decide whether the studies they relied on are persuasive,
4 whether they are credible, and ultimately whether Zantac caused
5 these people's cancer.

6 Thank you.

7 *THE COURT:* Thank you.

8 So, the remaining loose ends that we were going to tie
9 up. How about Plaintiffs, do you have your list, and can you
10 give me a report on that?

11 *MS. FINKEN:* Tracy Finken on behalf of Plaintiffs.

12 Your Honor, I have many of the citations, that you
13 requested. I will try to go slowly because they are numbers.

14 You asked for the citation from Dr. Le on
15 bioavailability. That is on page 46 to 49 of her report. You
16 asked for citations to where Plaintiffs discuss the Gombar
17 case -- the Gombar study. In Dr. Le's report, it is on pages
18 46 to 48; on Dr. Marletta's report, pages 35 and 47; in Dr.
19 Michaels' report, it's pages 34 to 35; Dr. Najafi's report,
20 pages 25 to 27; Dr. Panigraphy's report, pages 187 to 188; Dr.
21 Salmon's report, pages 30 to 31.

22 You asked for the citation for the length of time that
23 Ranitidine can remain in the gut, and those can be found in Dr.
24 Panigraphy's report on page 88; Dr. Le's report on page 8,
25 paragraph 13.

1 And you asked questions about the study which
2 demonstrates human cells are considerably more active than
3 animals in stimulating mutagenic response to NDMA. This is
4 discussed in Dr. Panigraphy's report on pages 164 and 165, and
5 Dr. Salmon's report on page 50.

6 And then Ms. Bogdan has some answers for you on the
7 peer reviewed publications, your Honor.

8 *THE COURT:* Okay, great.

9 *MS. BOGDAN:* You had asked a question, if I remember
10 correctly, with regard to a cite in Najafi's rebuttal report
11 with regard to head space in the containers, and what he is
12 referring to there is the DOE, which is the design of
13 experiment section of the GSK root cause analysis where they
14 assess a statistical study to assess stress, which can be found
15 on page 19, and also referring to page 79 through 82 of the
16 root cause analysis where they do their tablet study in vials
17 that are open which would have unlimited head space.

18 With regard to the studies that the Court inquired
19 about, one of the studies is a U.S. Department of Agriculture
20 report with regard to the heat that cars can reach. To what I
21 can discern --

22 *THE COURT:* I am sorry, back to the root cause, was
23 there a Docket Entry number for that one?

24 *MS. BOGDAN:* I would have to look for the Docket
25 Entry. I went to the actual 93 or 5 page.

1 *THE COURT:* Maybe if one of your colleagues can look.
2 The Docket Entry would be helpful. I interrupted.

3 *MS. BOGDAN:* That's okay. We will get that for you.

4 *THE COURT:* Okay.

5 *MS. BOGDAN:* With regard to the studies, one is a U.S.
6 Department of Agriculture Report.

7 *THE COURT:* Tell me what studies these are.

8 *MS. BOGDAN:* These are the studies that you inquired
9 about with regard to the references for the temperatures in the
10 cars that are relied on by Dr. Najafi in his report, and there
11 is one that is a publication of the U.S. Department of
12 Agriculture. I don't see that that is peer reviewed, but it is
13 published by the U.S. Department.

14 The Vanos study is peer reviewed in the medical
15 physiological journal, which is Taylor and Francis online. The
16 Grundstein is peer reviewed, which is in the International
17 Journal of Bio -- I am getting the pinpoint cite for the Court.
18 I have a friend here who is giving me Exhibit 43.

19 *MR. HEINZ:* Plaintiffs' response in opposition to the
20 motion, Exhibit 43, the root cause analysis.

21 *THE COURT:* Exhibit 43 to the Plaintiffs' opposition?

22 *MR. HEINZ:* Correct. I believe it is the Finken
23 declaration.

24 *THE COURT:* The Finken declaration is --

25 *MR. HEINZ:* Exhibit 43 to the Finken declaration.

1 *THE COURT:* Where is it in here? Is it an attachment?
2 I don't have it in front of me.

3 *MS. BOGDAN:* I think it is its own docketed document.

4 *THE COURT:* Do you know what the Docket Entry number
5 is?

6 *MR. HEINZ:* I don't, I can get it.

7 *THE COURT:* What you are saying, is Exhibit 43 to the
8 Finken declaration, because the Finken declaration I think is
9 very long, so just if you have that Docket Entry. You can
10 search. Were there any others?

11 *MS. BOGDAN:* The Vanos study is peer reviewed,
12 V-A-N-O-S. I believe I started where the Grundstein study,
13 which is also peer reviewed in a journal. And then there is
14 the Yohoo, Y-O-H-O-O, which is a publication of a university in
15 Japan and it is a research paper that is published on Research
16 Gate, which does not appear to be peer reviewed.

17 *THE COURT:* Okay. What about the Aizawa?

18 *MS. BOGDAN:* Aizawa and Yohoo are coauthors.

19 *THE COURT:* So it's one in the same?

20 *MS. BOGDAN:* Yes.

21 *THE COURT:* I am going trust your laundry list, other
22 than we are looking for the Docket Entry for the
23 Finken declaration.

24 *MS. FINKEN:* There is one more. Your Honor had asked
25 about criticisms of the timing of the dosing of Ranitidine in

1 the Florian study, and what our experts indicate would be a
2 more optimal time to take Ranitidine, to assess results. I
3 wanted your Honor to note that Dr. Najafi discusses this on
4 page 105, of his report; Dr. Le, in her report on page 45; Dr.
5 Marletta discusses it on page 55.

6 They discuss several reasons why it is problematic,
7 because taken Ranitidine on an empty stomach is not have the
8 labeling instructs, so it doesn't reflect how patients take it
9 in the real world.

10 The labeling states to take it before bed time or with
11 an evening meal, the point being you would not take it on a
12 completely empty stomach, like they did with Florian. The
13 fasting stomach will have little nitrates and the addition of
14 food on a fasting stomach will immediately affect the PH, which
15 is an important factor in NFDMA formation from Ranitidine.

16 The criticism of Florian is also in the published
17 literature. The White article in JAMA in 2021 criticizes
18 Florian, and you can find the citations to White in Plaintiffs'
19 expert reports, particularly in Dr. Marletta's report on page
20 55, where he discusses the limitations with the Florian study.

21 *THE COURT:* Okay, thank you.

22 Were Defendants going to followup, something on the
23 FDA policies? Then we will circle back to Plaintiffs if there
24 is anything more.

25 *MR. BOSSO:* For the FDA guidance document, we were

1 discussing about validation, that is not part of the record,
2 and we didn't rely on that in briefing. The only reason we
3 brought it up was because it was in Plaintiffs' slides today.
4 We could file it if you want us to. They call it USB,
5 Guidelines.

6 *THE COURT:* You need to talk into the microphone.

7 *MR. BOSSO:* A screen shot of the guidance on method
8 validation.

9 *THE COURT:* To the extent the Plaintiffs have used it
10 min their presentation and it is an FDA document, ids there any
11 objection to there being sort of a joint filing, notice of
12 filing whatever the official name of this document is. It
13 sounds like the Defendants are willing to.

14 Are the Plaintiffs willing to?

15 *MR. NIGH:* Yes.

16 *THE COURT:* If you could followup with that.

17 *MS. FINKEN:* Tracy Finken for Plaintiffs. Would it be
18 permissible for us to file it with your order for the September
19 30th completion of the record? We can file it as part of that
20 filing.

21 *THE COURT:* Right. That is the certification that
22 everything you have provided to me already is part of the
23 record, or if something is not part of the record that you have
24 provided to me, you will file it and certify that.

25 *MS. FINKEN:* Yes, your Honor.

1 THE COURT: Okay, that is fine. That is fine.

2 MR. HEINZ: Your Honor, on the root cause analysis.

3 THE COURT: Yes.

4 MR. HEINZ: I believe it was the sealed filing that
5 was noticed at Docket 5947. The actual Docket Entry would be
6 on the sealed docket, and I wasn't able to identify it, but it
7 is Exhibit 43 of the Nigh declaration, but I couldn't find the
8 precise Docket Entry.

9 THE COURT: Okay. It looks like we found it. Okay.

10 All right. Hard to believe that it has come to an
11 end. Are we happy about that or sad about that?

12 It looks like you are exhausted and you can't answer
13 the question.

14 Okay. I want to again thank everyone. I think it was
15 an amazing amount of information that you conveyed in a very
16 organized and methodical and well thought out, well prepared
17 way. You divided your time, you kept to your time. The only
18 reason that we are over is probably my fault because of
19 injecting my questions and stealing a little time here and
20 there, but even with that, we are only over by an hour.

21 I hope we haven't caused anybody to miss any flights,
22 that would be terrible. So it is 5:30. To the extent that
23 there are flights to be had this evening, I am going to cut
24 this really short and really just say thank you. I appreciate
25 all of the hard work and effort and patience that everyone has

1 shown, the professionalism, the collegiality.

2 I will look forward to seeing some of you back,
3 whoever is arguing next week, on Friday, September 30th, I
4 believe it is for the Plaintiffs' motions on that day.

5 Let me confirm. Yes, September 30th.

6 Safe travels, be well, everyone, and we will see you
7 again shortly. Thank you.

8 That concludes our hearings.

9 (Thereupon, the hearing was concluded.)

10 * * *

11 I certify that the foregoing is a correct transcript
12 from the record of proceedings in the above matter.

13
14 Date: September 27, 2022

15 /s/ Pauline A. Stipes, Official Federal Reporter

16 Signature of Court Reporter
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Pauline A. Stipes, Official Federal Reporter

<p>MR. BAYMAN: [6] 91/1 107/3 127/13 138/1 174/6 174/8 MR. BOSSO: [18] 138/12 138/17 138/24 139/4 139/8 141/22 142/13 151/5 152/15 155/1 155/11 160/24 163/23 164/18 170/23 171/10 252/24 253/6 MR. CHEFFO: [4] 4/16 4/20 214/13 214/19 MR. GILBERT: [14] 190/15 190/19 195/16 196/4 196/7 196/13 230/6 230/9 230/11 236/7 243/17 243/19 244/19 247/4 MR. HEINZ: [17] 27/4 202/7 202/21 206/3 206/19 208/6 208/22 209/7 210/9 210/18 211/4 250/18 250/21 250/24 251/5 254/1 254/3 MR. HOLIAN: [1] 28/3 MR. McGLAMRY: [9] 172/4 172/7 172/11 172/17 172/20 172/22 172/25 173/11 175/3 MR. NIGH: [53] 17/19 18/2 21/22 22/1 22/7 22/10 22/13 22/19 22/22 23/3 23/13 23/21 24/3 24/9 24/13 24/16 25/1 25/12 25/17 25/24 26/8 78/8 78/12 108/11 108/14 108/17 124/6 124/8 124/11 127/2 142/16 143/2 143/9 145/5 176/12 176/15 176/22 184/15 185/8 185/14 185/18 186/16 198/5 198/11 201/6 201/23 202/1 203/9 203/15 203/19 203/24 211/12 253/14 MR. PETROSINELLI: [14] 194/13 194/18 194/21 195/2 195/6 195/12 195/20 196/1 198/3 199/16 200/1 204/5 212/8 221/11 MR. RONCA: [7] 19/6 19/8 19/12 19/16 20/3 20/7 20/24 MR. SACHSE: [16] 4/23 6/11 6/13 6/15 6/18 6/23 7/2 7/7 7/10 7/14 10/7 12/17 13/25 14/17 15/2 15/8 MR. SELIGNAN: [20] 132/16 133/21 133/23 135/1 135/6 136/10 137/13 137/20 143/15 143/22 144/5 146/23 163/11 165/9 166/6 166/10 166/12 177/13 178/13 178/17 MS. BOGDAN: [75] 53/21 54/1 54/16 55/2 55/7 56/5 56/8 57/21 58/2 58/7 60/23 63/3 63/10 64/1 67/14 68/8 76/14 76/23 77/7 78/3 78/23 80/3 80/23 81/2 81/11 82/4 82/18 83/17 83/20 84/7 84/10 84/14 85/4 86/13 88/4 88/18 146/25 147/9 147/15 147/20 150/7 150/11 151/20 153/16 153/19 153/24 156/7 156/17 156/20 157/13 158/7 159/3 160/5</p>	<p>160/9 167/7 167/14 167/16 167/19 168/1 168/25 169/20 170/13 170/18 175/16 175/19 175/25 249/8 249/23 250/2 250/4 250/7 251/2 251/10 251/17 251/19 MS. FINKEN: [5] 185/1 248/10 251/23 253/16 253/24 MS. LUHANA: [51] 7/4 15/5 15/12 15/14 40/12 40/16 50/7 52/16 53/10 53/17 58/14 58/17 59/13 60/10 60/24 61/16 69/13 69/20 70/18 71/4 71/19 72/1 72/17 72/20 73/18 74/11 74/21 75/4 75/8 76/6 79/13 79/24 81/25 85/13 85/23 160/16 162/6 180/8 181/5 183/2 183/15 184/2 186/7 186/23 187/1 196/14 196/24 197/1 197/4 197/16 197/23 MS. RYDSTROM: [9] 29/11 39/23 64/18 64/24 67/18 86/12 88/21 187/16 194/4 THE COURT REPORTER: [1] 214/17 THE COURT: [313]</p> <p>'</p> <p>'84 [1] 8/16</p> <p>.</p> <p>.0378 [2] 67/6 67/10 .04 [1] 14/11 .1 [1] 37/1 .13 [1] 50/9 .2 [2] 64/7 67/14 .2 pounds [1] 64/7 .32 [3] 10/24 10/25 12/23 .467 [1] 66/15 .467 milligrams [1] 66/15 .5 [2] 149/13 149/13 .73 [1] 123/19</p> <p>/</p> <p>/s [1] 255/15</p> <p>0</p> <p>0.2 [1] 63/21 02924 [1] 4/7</p> <p>1</p> <p>1,000 [1] 149/4 1,150 milligrams [1] 66/8 1,975 [1] 48/15 1.16 [1] 23/8 1.2 [1] 44/19 1.23 [1] 149/25 1.42 [1] 22/15 1.5 [2] 53/13 59/7 1.8 [1] 220/19 1.81 [1] 22/15 1.96 [1] 23/5 10 [11] 131/22 137/10 137/11 146/3 146/18 146/25 147/18 149/14 149/14 152/4 153/12 10 millimoles [1] 44/17 100 [6] 37/1 60/22 60/24</p>	<p>110/11 110/15 136/20 100-page [1] 110/16 10016 [1] 2/2 10036 [1] 2/23 103 [1] 20/18 105 [3] 52/4 57/19 252/4 1095 [1] 2/22 10:00 [1] 29/10 10:15 [1] 50/21 10:30 [2] 50/22 51/8 11 [11] 21/1 21/2 132/2 166/8 166/14 167/3 170/10 175/14 177/8 182/3 208/1 11,000 [1] 44/19 110 [3] 243/13 243/18 243/22 1100 [1] 1/21 1113 [1] 2/3 1130 [1] 1/15 1180 [1] 2/5 1194 [1] 198/21 1198 [1] 198/22 12 [6] 78/18 124/5 124/11 207/20 208/7 246/15 12,420 [1] 17/2 121 milliliters [2] 67/10 67/11 1239 [1] 233/9 127 [1] 20/18 1291 [1] 193/23 12:00 [2] 90/18 90/20 12:08 [1] 107/25 12th [3] 2/2 2/12 2/15 13 [9] 1/14 76/5 132/2 160/13 176/5 176/17 207/20 208/8 248/25 13 grams [3] 61/10 63/15 64/6 1300 [1] 1/24 1311 [1] 236/24 134 [3] 123/1 243/14 243/22 135 [1] 123/2 14 [4] 76/5 76/20 176/18 246/18 14.3 [2] 235/20 236/11 1440 [1] 124/14 15 [12] 29/11 39/23 40/9 72/8 72/12 72/13 112/24 112/25 150/22 175/10 187/10 187/15 15 millimoles [1] 62/9 15-minute [2] 51/7 51/13 150 [6] 5/18 46/18 125/3 125/14 125/15 176/8 150 milligrams [1] 124/14 150-milligram [5] 46/3 176/11 176/19 176/22 212/1 155 [1] 39/5 16 [7] 20/8 40/10 66/25 132/10 137/7 176/9 246/15 1600 [2] 1/14 2/5 161 [2] 207/21 208/8 162 [2] 243/14 243/22 164 [1] 249/4 165 [1] 249/4 1650 [1] 2/18 167 [4] 131/23 146/3 146/25 147/19 168 [2] 146/18 153/13</p>
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