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

CASE NO. 20-md-02924-ROSENBERG

**IN RE: ZANTAC (RANITIDINE)** .  
**PRODUCTS LIABILITY** . West Palm Beach, FL  
**LITIGATION.** . May 12, 2020

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VIDEO CONFERENCING of  
STATUS CONFERENCE and SUMMARY of LAW and SCIENCE

BEFORE THE HONORABLE ROBIN L. ROSENBERG  
UNITED STATES DISTRICT JUDGE and  
THE HONORABLE BRUCE REINHART  
UNITED STATES MAGISTRATE JUDGE

Official Court Reporter: Pauline A. Stipes  
HON. ROBIN L. ROSENBERG  
Ft. Pierce/West Palm Beach, Fl  
772.467.2337

1            *THE COURT:* Okay. Good morning, everyone. I hope  
2 that all of you are as excited as I am this morning to listen  
3 and learn throughout the day. There are many participants with  
4 us today on the Zoom call/video session and for the record,  
5 everyone is appearing by Zoom due to COVID-19. Leveraging the  
6 benefit of the delay from COVID-19 and the time the parties  
7 have had to develop their understanding of the case, I have  
8 asked that today and tomorrow the parties provide a road map of  
9 the litigation, a summary of the law, the science, their vision  
10 for case management, as well as the more traditional updates on  
11 where they are in discovery and developing proposed orders for  
12 the Court to review.

13            While I intend that this will be a helpful launch pad  
14 for me in accelerating my thinking about the case, you will  
15 quickly glean that my goal is for you to have a chance to  
16 educate the others within the court who will assist me in this  
17 case, and equally important, those on each side who may not be  
18 involved in the day-to-day negotiations that have been  
19 occurring, such that this is their first opportunity to hear  
20 directly from the other side about their view of the case.

21            Having reviewed the PowerPoints that our presenters  
22 submitted to me in advance, I want to thank you for taking the  
23 time to put together such thorough presentations. I can see  
24 the great effort that has gone into this endeavor. Equally, I  
25 want to thank you on behalf of all of those joining our

1 conference today for that work, which I believe will help all  
2 of our attendees greatly appreciate and advance their  
3 understanding of this litigation.

4 Now, while we had two full days last week of  
5 interviews from very, very talented applicants and many of  
6 those applicants, in answer to some of my questions, shared  
7 with me their vision of the case generally and/or specific  
8 issues related to this litigation. I want everyone here to  
9 know that I start today with a clean slate. I have not  
10 prejudged the case in any way, or any of the issues, and I come  
11 with a completely open mind in learning about both the  
12 substantive areas of law and science and about how best to  
13 manage this case.

14 While I have issued a number of pretrial orders, I  
15 think we are up to 20 or so, and much progress has already been  
16 made to date, there is no doubt that this is a very important  
17 day for me as it is the first time that I can hear directly  
18 from the parties about the issues you have outlined on the  
19 agenda and I have very much waited for today to start to form  
20 my opinions about the litigation.

21 I value and appreciate everyone's perspective and, as  
22 one who prior to joining the bench, has had a varied career  
23 serving as a Plaintiffs' lawyer, serving as Defense counsel in  
24 a major firm, serving as general counsel, and owning my own  
25 firm and a Government attorney as well, I know how important it

1 is to be heard and to be able to communicate your own unique  
2 perspectives.

3 This is the day where the Plaintiffs' leadership and  
4 the Defense leadership teams will educate me, Judge Reinhart,  
5 and the many other attorneys, parties, and other persons who  
6 are interested in this litigation.

7 I want to point out how much I appreciated hearing at  
8 the interviews that there was a widespread sense that not only  
9 have the two sets of co-leads worked diligently, but they have  
10 worked to productively resolve the differences that have arisen  
11 over the past several months.

12 While the Court is always available to hear any  
13 dispute or motion, I very much appreciate that the parties and  
14 special master have worked to narrow those areas of  
15 disagreement and reached agreement where possible and I want to  
16 applaud them for that work and how well they have worked  
17 together so far.

18 I know that the special master has conveyed my  
19 expectations and sentiments in that regard, but I felt it was  
20 important for you to hear that from me today directly.

21 I find Special Master Dodge's insights to be helpful  
22 in my thinking, and I hope that you have as well, and she has  
23 been a helpful sounding board in your own thinking as she seems  
24 to have a very informed and at times almost intuition about  
25 this very complex litigation.

1 I believe she will not just be a great resource for  
2 all of us, but also very helpful in helping make this MDL much  
3 more efficient and in turn cost effective for all parties, so I  
4 encourage you to continue to take advantage of her as a very  
5 helpful resource.

6 I want to take this opportunity to introduce someone  
7 whom you have not yet had the opportunity to meet yet, Judge  
8 Reinhart, the magistrate judge with whom I am paired. If I  
9 could ask Judge Reinhart to turn his video on for a moment  
10 while I brag about him. He might need a cohost to turn his  
11 video on. There you go. And his audio is muted for a moment.

12 Let me say a few things about Judge Reinhart and see  
13 if there is anything he wants to say. Judge Reinhart is the  
14 magistrate assigned to the case, I am paired with him. I have  
15 another magistrate judge whom I am paired with in Ft. Pierce.  
16 I hear matters in Ft. Pierce and West Palm Beach. Judge  
17 Reinhart and I work closely together.

18 So you are aware, he watched all of the interviews  
19 last week, has read all of the submissions, and has been  
20 closely watching the case and educating himself. Judge  
21 Reinhart and I work very closely together on all cases with  
22 which we are paired. We truly have a working partnership and  
23 together we try to offer the best of our time, our knowledge,  
24 and respective roles to the parties and attorneys in the case.

25 We do share similar goals, values, and vision for how

1 to manage our cases, while recognizing that every case is  
2 different and does call upon different tools and different  
3 approaches.

4 Judge Reinhart brings a wealth of experience to the  
5 bench from his prior career in both the criminal and civil  
6 arena and, as a magistrate judge, he has become immersed in  
7 civil litigation, including complex discovery matters. He has  
8 spoken at various conferences and is as knowledgeable as anyone  
9 I've met as to the nuances of discovery and the tools that come  
10 along with complex discovery matters.

11 He is so well regarded and liked that he has a very  
12 high consent rate, meaning he has taken cases away from me.  
13 Many of the parties consent to his full jurisdiction, not only  
14 discovery matters, motion, but trial, all the way to final  
15 judgment, and he is accessible, extremely bright, hard working,  
16 curious and creative in working with parties to manage tough  
17 discovery issues.

18 Tomorrow Judge Reinhart and I will be appearing by  
19 Zoom together. I wanted you to meet him today. And I don't  
20 know if you want to say a brief hello.

21 *MAGISTRATE JUDGE REINHART:* I am not sure I should add  
22 anything to that. I go nowhere but down.

23 I want to tell the parties, I do look forward to  
24 working with you and Judge Rosenberg in this fascinating  
25 litigation. I have been starting to learn about this case. I

1 was able to watch all of the Plaintiffs' interviews, and I read  
2 the submission by the Defense and it bodes well for me and  
3 Judge Rosenberg that we have such good lawyers in the case, the  
4 expectation we will have excellent briefing and argument and  
5 issues that we need to have decided will be framed out well.

6 I share Judge Rosenberg's commitment to the values in  
7 Federal civil procedure, one to bring this case to as just,  
8 expedient and inexpensive litigation as we can. I have no  
9 background in MDL pharma courts. I do manage a lot of  
10 discovery, and we can talk about this tomorrow.

11 I am fully committed to working with you on any  
12 creative or innovative ideas you may have to frame the issues  
13 and get the information exchanged as fast as we can so the  
14 parties can do the legal work in this case.

15 With that, I thank Judge Rosenberg for giving me a few  
16 minutes, and look forward to working with you.

17 *THE COURT:* Thank you very much.

18 So, too, my law clerks are joining us, although they  
19 are not appearing by video, but they are on, rest assured.

20 I have let all of them and Judge Reinhart know that if  
21 they have any questions, they can submit them to me. As you  
22 can see, I am looking off to the right, I have various  
23 electronic tools for people to communicate with me during the  
24 presentation today, but they can submit them to me, and I will  
25 try to ask them during the Q and A portion if I think it is

1 appropriate.

2 I say that as you may see me taking notes or typing  
3 during your presentation, and it may simply be that I am  
4 coordinating with them, so you should not read too much into  
5 that. Please know, as I mentioned at the interviews, you have  
6 my undivided attention at all times. Even though my eyes are  
7 looking to the right, I am listening, I am not multitasking.  
8 Everything you are doing today, I am listening to.

9 I believe through their questions, we may get at  
10 issues that are important for our Leadership Development  
11 lawyers on the Plaintiffs' side, for retained counsel who may  
12 not be familiar with MDLs, or for the third parties who have  
13 asked to join us today who are not affiliated with either the  
14 Plaintiffs or Defense. To that end, my clerks may have  
15 question that I may know the answer to after years on the  
16 bench, but which I believe would be useful to others watching  
17 these proceedings to hear the answer to, and so I may ask those  
18 question in the question and answer session.

19 That, in turn, means you should not assume I am not  
20 familiar with the law of Daubert and the Eleventh Circuit, with  
21 choice of law in MDLs, or whatever other topic our presenters  
22 may raise. Rather, I see today as not just educating me, and I  
23 have certainly a lot to be educated about, make no mistake  
24 about that, but all of the stakeholders in this litigation. I  
25 will ask questions to the extent that I see those gaps in the

1 presentations by either side today.

2           Having been in your roles before, I know that at a  
3 first hearing there is always an instinct to try to "read" the  
4 judge, and with the stakes in this litigation, I can imagine  
5 that it would be more so. I therefore wanted to be transparent  
6 with you that the questions I ask are not the result of any  
7 ideas that I have, and instead are truly geared toward making  
8 sure that all of the stakeholders in this litigation are as  
9 well informed as possible, so that you are not drawing any  
10 mistaken inferences.

11           With that, I am excited to hear from you for the first  
12 time in person about your views of the case.

13           I would like to recognize Mr. Gilbert and McGlamry,  
14 who I believe are going to be opening up, but let me just say  
15 for the benefit of not only me, but our court reporter who is  
16 transcribing the proceedings, that if each presenter, upon the  
17 first time that you are presenting, if you would just introduce  
18 yourselves with your full name so Mrs. Stipes can take that  
19 down.

20           And with that, I will turn it over.

21           *MR. GILBERT:* May it please the Court, good morning,  
22 your Honor.

23           *THE COURT:* Good morning.

24           *MR. GILBERT:* Is my audio okay?

25           *THE COURT:* Perfect.

1           MR. GILBERT: Let me just get set here. May it please  
2 the Court, good morning, Judge Rosenberg and Judge Reinhart,  
3 and the entire court staff who have made today possible.

4           First, on behalf of the co-leads, Plaintiffs' Steering  
5 Committee -- excuse me, Judge, I ran afoul of your first  
6 request. This is Robert Gilbert speaking on behalf of the  
7 Plaintiffs. Let me start over.

8           Good morning to you, Judge Reinhart, and the entire  
9 court staff. First, on behalf of the co-leads, Plaintiffs  
10 Steering Committee, committee chairs and Leadership Development  
11 Committee, we express our gratitude and appreciation for the  
12 confidence the Court has entrusted in us. We pledge to  
13 zealously represent and advance the interests of all Plaintiffs  
14 and claimants in this MDL to the very best of our ability, to  
15 work with our Defense colleagues with professionalism and  
16 civility and to conduct ourselves before this Court with  
17 integrity, honor, and respect.

18           Second, we extend our thanks to Special Master Dodge  
19 who, as you noted, has worked tirelessly with both sides since  
20 the first days of this litigation, including fashioning today's  
21 presentations. The parties are fortunate to have Special  
22 Master Dodge involved in this MDL, and we look forward to her  
23 continued service.

24           Third, we extend our thanks to our Defense colleagues  
25 with whom we have worked over the past few months. While we

1 have extremely different views of the facts and law that will  
2 lead to the ultimate outcome of this litigation, our civil  
3 justice system cannot work without civility, collaboration, and  
4 mutual dialogue. The past few months have proven that even  
5 during one of the most disruptive periods in our nation's  
6 modern history. Lawyers on both sides of the aisle can indeed  
7 work together. We are confident the relationships we have  
8 already established with our Defense colleagues will set the  
9 stage and tone for the remainder of this litigation.

10 Your Honor, multi-district litigation holds a unique  
11 place in our civil justice system. MDLs bring together before  
12 one Federal District Court for coordinated and sometimes  
13 consolidated pretrial proceedings the claims of hundreds,  
14 thousands, or millions of people whose claims share common  
15 facts. Given the substantial number of claimants, as well as  
16 the scope and magnitude of the claims and defenses that are  
17 asserted, MDL proceedings generally look and operate  
18 differently than most civil cases, but at their core MDL  
19 proceedings share the same foundation as all civil cases,  
20 indeed all cases. Like all cases in our judicial system, MDL  
21 proceedings involve a search for the truth, albeit in a larger  
22 and more complex setting.

23 Today marks the official beginning of the search for  
24 the truth for what may ultimately be hundreds of thousands of  
25 people who were diagnosed with cancer following their use of a

1 drug marketed as a safe and efficient treatment for heartburn  
2 and stomach ulcers prior to its sudden withdrawal from the  
3 shelves a few months ago, many, many years after it was first  
4 marketed to the public.

5 Today also marks the beginning of the search for the  
6 truth for what may ultimately be several million more people  
7 who purchased and/or used this drug and have not yet been  
8 diagnosed with cancer, but who now live with the knowledge that  
9 they face an increased risk of developing cancer after taking  
10 this drug.

11 Today marks the beginning of the search for the truth  
12 for how and why we are here, how and why this drug was  
13 developed, how the companies that developed and manufactured it  
14 got the FDA to approve that it was safe, how the ingredients in  
15 this drug affect -- excuse me, how the ingredients in this drug  
16 affect humans and why thousands of people have developed cancer  
17 after taking this drug, how and why it took more than 35 years  
18 before someone other than the Defendants brought this public  
19 health crisis to the FDA's attention, and why the drug was  
20 withdrawn from the market.

21 These are just some of the questions we expect to  
22 answer in our search for the truth in this MDL.

23 I've heard judges sometimes say that civil litigation  
24 is more like a marathon than a sprint. That analogy is  
25 especially appropriate here. Today is the start of the Zantac

1 MDL marathon. The Plaintiffs leadership team has been training  
2 for months preparing to embark on what may be a 26-month or  
3 longer marathon until we reach the finish line. At the start,  
4 a gaggle of lawyers will be bunched up trying to set the pace,  
5 some wanting to push it faster than others. Others understand  
6 that it is a long race and it's not about who has the best time  
7 in the first few miles, but who has the staying power to reach  
8 the finish line.

9 I will try to make my point with a brief look back in  
10 MDL history. In 1999, American consumers began buying and  
11 using a drug approved by the FDA and marketed as a safe and  
12 revolutionary non-narcotic painkiller.

13 For years millions of people purchased and used Vioxx  
14 without fear of serious consequences, but in September 2004  
15 Vioxx was suddenly pulled from the shelves of every pharmacy in  
16 this country based on revelations that it caused heart attacks.  
17 Within days lawyers across the country began filing lawsuits  
18 seeking damages on behalf of Vioxx victims.

19 In February 2005, the JPML created the Vioxx MDL and  
20 assigned it to District Judge Eldon Fallon to preside over  
21 coordinated and consolidated pretrial proceedings. Two weeks  
22 later, Judge Fallon appointed Plaintiffs leadership and the  
23 Vioxx marathon began to move forward in earnest. In November  
24 2007, approximately 30 months after the start of the Vioxx MDL,  
25 following fulsome discovery that uncovered evidence that had

1 never before seen the light of day, extensive motion practice  
2 and bellwether trials, the parties announced a \$4.8 billion  
3 settlement for the victims of Vioxx.

4 Like Vioxx, Zantac was approved by the FDA. Like  
5 Vioxx, for years Zantac was marketed and sold to millions of  
6 people as a safe and effective drug to treat heartburn and  
7 GERD. No sane person would have taken on the risk of cancer  
8 and a possible death sentence in exchange for treating their  
9 heartburn. Like Vioxx, the makers and sellers of Zantac  
10 suddenly pulled it off the shelves in late 2019 following FDA  
11 concerns that it was unsafe.

12 Like Vioxx, civil lawsuits were filed in the days and  
13 weeks thereafter, ultimately leading the JPML in February of  
14 this year to create the Zantac MDL and transfer all cases filed  
15 in Federal Courts across the country to this Court for  
16 coordinated and consolidated pretrial proceedings.

17 Last Friday, as you noted, this Court appointed  
18 Plaintiffs leadership to prosecute the claims of all Plaintiffs  
19 and claimants for personal injury, wrongful death, medical  
20 monitoring, and economic loss arising from their purchase  
21 and/or use of Zantac.

22 Today marks the opening bell of the Zantac MDL  
23 marathon. As you noted in PTO 16, this Court directed both  
24 sides to make presentations on foundational topics and key  
25 concepts in this case to assist the Court in learning about

1 some of the factual, legal, and scientific issues the parties  
2 anticipate will be developed during the course of this MDL.  
3 Over the past weeks, as both sides prepared for today, we were  
4 reminded time and again that today is not the trial, it is  
5 merely the beginning of the Zantac MDL marathon.

6 We were directed to present opening statements, but  
7 both sides understand that these are not opening statements we  
8 will present to the people who sit in the jury box in your  
9 courtroom toward the end of the marathon. We were directed to  
10 make presentations about some of the over arching legal issues,  
11 but both sides understand that today is not about arguing  
12 motions for summary judgment, which will come much later in  
13 this legal marathon.

14 We were directed to prepare foundational science  
15 presentations, but both sides recognize that this is not the  
16 general or special causation hearings, which will come much  
17 later in this legal marathon.

18 For the next few hours, your Honors will hear both  
19 sides make these presentations on foundational topics and key  
20 concepts in this case. In just a moment my colleague, Mr.  
21 McGlamry, will help frame the Plaintiffs' position. He will  
22 present an overview of the facts, themes, and likely sources  
23 and categories of evidence from the Plaintiffs' standpoint, and  
24 touch on the personal injury and wrongful death claims we'll  
25 prosecute on behalf of individuals diagnosed with cancer as a

1 result of their usage of Zantac and Ranitidine drugs. After  
2 Mr. McGlamry, I will retake the screen to give an overview of  
3 the class claims and complete the Plaintiffs' opening  
4 statement. Then you will hear presentations from our Defense  
5 colleagues.

6 In part two you will hear about some of the over  
7 arching legal issues both sides expect to arise in this  
8 litigation. In part three, after lunch, you will hear some  
9 foundational science presentations relating to the science of  
10 Ranitidine causing cancer that both sides expect to develop  
11 during the course of this litigation.

12 Later today we will address some of the case  
13 management issues the parties have been discussing and working  
14 on over the past couple of months.

15 At this point, I will turn it over to my colleague,  
16 Mr. McGlamry.

17 *THE COURT:* Thank you.

18 *MR. McGLAMRY:* Thank you, Mr. Gilbert. While I wait  
19 for the PowerPoint to come up, your Honor, I want to thank you  
20 both this morning and Special Master Dodge and counsel for the  
21 Defendants.

22 I would like to say that MDL 2924 -- here we go -- and  
23 as I was standing here listening to Mr. Gilbert, I realized  
24 that if you added those numbers up, you get to 17, which I  
25 guess means 17 and 0 in honor of Coach Shula and the Miami

1 Dolphins.

2 Let me start. Making an opening statement at the  
3 beginning of a case is somewhat ironic and premature without  
4 discovery because we don't know all that we need to know, but  
5 it is undisputed that we do know this: That last fall we saw a  
6 dramatic turn of events that led to April 1, 2020, when the FDA  
7 announced a recall in the form of a market withdrawal of all  
8 Ranitidine containing products, or Zantac. Zantac and  
9 Ranitidine are synonymous, and for purposes of this  
10 presentation, I will generally refer to them both as Zantac.  
11 The recall covered all Zantac, prescription, over the counter,  
12 brand, generic, injection, syrup, granules, pills and capsules.

13 That was unprecedented for the FDA to issue a recall,  
14 and you have to know that with the multibillion dollar a year  
15 drug at issue and the liability that could follow, that all the  
16 lobbying industry organization pressure and scientific  
17 resources were marshaled to stop it, not just here,  
18 but worldwide.

19 On September 9, 2019, Valisure, Inc., after months of  
20 informal efforts to move the FDA to act, filed a citizen's  
21 petition calling for a recall due to their testing which  
22 confirmed exceedingly high levels of NDMA in pills. Then, less  
23 than four months later another lab, Emery Pharma, also filed a  
24 citizen's petition showing that NDMA accumulates at unsafe  
25 rates when exposed to heat during transport and storage.

1           In the meantime, the cards began to fall. Brand and  
2 generic manufacturers and retailers started recalling these  
3 products over their concerns of NDMA found in the medicine, out  
4 of a concern that it might contain a carcinogen, and because  
5 unacceptable levels of NDMA were discovered in Zantac.

6           Between September 9, 2019 and April 1, 2020, based on  
7 additional testing, studies, and reports, 43 countries and  
8 jurisdictions acted to restrict or ban Zantac products.

9           So, on April 1, 2020, the FDA acted saying that a  
10 recall was an effective method of removing or correcting  
11 defective FDA regulated products, particularly when those  
12 products present a danger to health. The FDA acted to protect  
13 the public health from products that present a risk of injury  
14 and because, quote, "the product being recalled presents a  
15 serious health risk."

16           By the end of the month, April 30th, the EMA, the  
17 European Medicines Agency, also recalled all Ranitidine  
18 medicines due to the presence of NDMA.

19           So let's think about this, Zantac -- Ranitidine is the  
20 molecule with the brand name Zantac, and it has been on the  
21 market for nearly 40 years. The FDA said it was safe and  
22 effective, now it says it is not. Now, after allowing Zantac  
23 to be sold for 40 years, the FDA has had to essentially take it  
24 back and make a monumental decision rarely seen absent an  
25 extraordinary risk.

1           So let's go back to the beginning.

2           In the late 1970's, Glaxo, a relatively small  
3 pharmaceutical company, came up with the Ranitidine molecule  
4 and branded it as Zantac. It was an effort to respond to  
5 Cimetidine, which was a molecule branded as Tagamet by  
6 SmithKline, which was then the leading product in this class of  
7 drugs.

8           Glaxo made the molecule on a computer and, boom, Glaxo  
9 was on the map. Zantac made Glaxo and so now they have  
10 everything to lose. Ultimately, and as the result of the money  
11 generated by the sale of Zantac, Glaxo bought SmithKline and  
12 now, as you know, your Honors, we have GSK.

13           Essentially, Glaxo took the Cimetidine molecule and  
14 reconstructed it by adding two compounds, nitrose, which gives  
15 us the N, and dimethylamine, which gives us the DMA. In the  
16 body they break off and join to form NDMA. Our science group  
17 will later show you this molecular design.

18           So, what is this NDMA?

19           It is a potent human carcinogen discovered as a  
20 byproduct of manufacturing jet fuel in the early 1900's. Today  
21 its only use is to induce cancerous tumors in animals as part  
22 of laboratory experiments. Its only function is to cause  
23 cancer. It has no business being in the human body, but it  
24 gets in through Zantac. It is not unlike a Trojan horse with  
25 the gift offering, the Zantac pill, but secretly exposing the

1 body to an unacceptable cancer threat.

2 Now, NDMA is found in cigarette smoke, too, at levels  
3 that have been measured between five and 43 nanograms per  
4 cigarette, which is an unquestionably small amount compared to  
5 the NDMA in one Zantac pill, and everybody knows the  
6 carcinogenic effect of cigarette smoke.

7 So, over this 40-year period, based on the information  
8 and science provided by these manufacturing Defendants, the FDA  
9 accepted an allowable daily limit of 96 nanograms of NDMA in a  
10 single dose, but now researchers have discovered over 3 million  
11 nanograms being introduced into the human body after ingestion  
12 of a single Zantac pill.

13 GSK knew about the NDMA problem long before Zantac  
14 came on the market. In 1981, in a well-known journal, The  
15 Lancet, researchers found that when Ranitidine was exposed to  
16 human gastric fluid in combination with nitrates, think red  
17 meat, the results were toxic and mutagenic effects. GSK knew  
18 at the time and indeed admitted that Ranitidine could react  
19 with nitrates in the stomach to form NDMA and that long-term  
20 use of Ranitidine could lead to elevated levels of NDMA in the  
21 human stomach.

22 Now, this is going to be a long story. It starts with  
23 Glaxo, now GSK, it passes through Pfizer, Johnson and Johnson,  
24 Boehringer Ingelheim, or BI, Sanofi, the generics, the active  
25 pharmaceutical ingredient companies, or API's, distributors and

1 retailers. We know that over most of this time GSK has had a  
2 history of malfeasance. Think of Ambien, Paxil, the Department  
3 of Justice, the FBI or the FDA. There is not enough time to go  
4 into all of that today, but we believe that this will be the  
5 latest chapter in that story, and that will come to the light  
6 of day.

7 Which leads me to emphasize where we go in this MDL,  
8 and that is to where Mr. Gilbert referenced earlier, a search  
9 for the truth. What we know now is only the very tip of the  
10 iceberg. We will be doing the discovery of the four brand  
11 manufacturers, the generic manufacturers, the API's, the  
12 distributors and the retailers, and these are the types of  
13 information and documents that will be produced by the  
14 Defendants.

15 As you can see on the screen, there are pre-clinical  
16 and nonclinical studies, animals, in vitro and vivo, you will  
17 hear more about that later, clinical trials, observational  
18 studies, post marketing reports, pharmacability vigilance,  
19 which is why I put PV in there so I don't have to pronounce it,  
20 case reports and adverse event reports.

21 In addition, and sort of more generally with regard to  
22 Defendants, we will also be looking at these categories of  
23 evidence: Company admissions, emails, memos, minutes, labeling  
24 documents, risk management documents, sales and marketing.  
25 We'll look at what they advertise, what their social media

1 looked like, their market share projections. We'll look at  
2 storage and transport and exportation. We'll look at their  
3 studies, their training manuals, their SOP's and audits and  
4 investigations.

5 We'll look at manufacturing, fabrication and  
6 production materials and documents, and we'll look at the  
7 recall. We'll look at the communications to the FDA. We'll  
8 look at the communications within the companies, and between  
9 the companies about the recall, and their studies and analysis  
10 in the investigation.

11 We will not only be looking at the parties, but third  
12 parties as well. The reason for that is pretty simple, because  
13 over time groups affiliated with the Defendants, groups that  
14 interact with the Defendants, and groups that work to support  
15 the Defendants have been involved with testing, studying,  
16 investigating, auditing, marketing, advertising, and promoting  
17 Zantac.

18 The following is an exemplar listing of these entities  
19 and individuals. You have the Governmental entities, the FDA,  
20 Department of Justice, elsewhere, looking at the recall, the  
21 regulatory issues, investigations. We'll look at Valisure and  
22 Emery Pharma. We'll look at industry groups. There are  
23 multiple industry groups that support these Defendants and  
24 support the defense of this drug. We'll look at the lobbyists.  
25 Each of these Defendants have paid lobbying firms in Washington

1 and elsewhere that are dealing with these issues, and dealing  
2 with them, I am sure, as we speak.

3 We'll look at marketing and advertising. Again, each  
4 of these companies have paid marketing and advertising firms  
5 that are working and have worked with regard to the Zantac  
6 issues, and ghost writers, those companies that write medical  
7 articles and then allow these companies to put their key  
8 opinion leaders or paid consultants as the authors of those  
9 articles. We'll look at all of that.

10 In addition, we'll look at educational and non-profit  
11 organizations, research universities, cancer institutes, as I  
12 mentioned before, key opinion leaders and consultants, journals  
13 and publications.

14 We'll also look at Johnson and Johnson because just  
15 recently in their annual report they have identified a notice  
16 of indemnification that they have received from BI and Sanofi  
17 as a result of this Zantac litigation. We'll also look at  
18 nonparty distributors, API's, wholesalers and retailers, and  
19 the industry as a whole.

20 Your Honors will hear from both sides soon enough  
21 about the legal theories, causes of action, defenses, the FDA,  
22 and science, but suffice it to say this is fundamentally a  
23 pharma products liability action on behalf of individuals who  
24 have sustained personal injuries or suffered a wrongful death  
25 as a result of having been diagnosed with cancer following

1 their use of Zantac.

2           Essentially, the personal injury and wrongful death  
3 claims will be for the defective design, manufacturing,  
4 transport, and storage of Zantac, including claims that the  
5 Defendants failed to warn of the danger and risk of NDMA and  
6 cancer. For starters, we know that none of these Defendants  
7 have ever warned of NDMA or cancer.

8           I am confident that the Court is aware from the  
9 initial census data that claims have been submitted involving  
10 multiple cancers. Why is that? That is fairly unusual.  
11 Typically in an MDL you will find that a device or a product is  
12 associated with a particular injury. So, why the numbers of  
13 cancers?

14           You will hear more in depth during the science  
15 presentations, but it is because the NDMA molecule is  
16 frighteningly small and there is nowhere in the human body it  
17 does not go. It passes through cells, the placenta, it rams  
18 into DNA, it links in with the DNA and causes mutations as it  
19 reproduces, and it causes cancers throughout the body, and  
20 causes cancers to metastasize, and it goes everywhere in the  
21 body very quickly, within just a few minutes of the pills or  
22 the drug being taken.

23           Some organs are more resilient than others. For  
24 example, the brain is a very resilient organ where the bladder  
25 is not so, and so you will see this and you will see cancers at

1 various locations in the body. With an average duration of  
2 usage among census participants of 14 years, there is a lot of  
3 exposure that we will be looking at.

4 You might wonder why from a statistical perspective  
5 that if cancer rates have, generally speaking, gone down rather  
6 than up while the Defendants have flooded the market with  
7 astronomical levels of NDMA, what is the connection? That is  
8 the red herring. We will talk about that in the science part,  
9 too. The fact is that some of these cancers have increased  
10 since Zantac was introduced into the population specifically.

11 There are other reasons why some cancer rates are  
12 down, and that has nothing to do with reducing the known  
13 carcinogens. In fact, what we think is the better question is,  
14 why don't we eliminate as a society the known carcinogens?

15 We expect at the end of the day, your Honors, when we  
16 get through the fact and expert discovery and have our general  
17 causation Daubert hearing that the Court will see the  
18 overwhelming evidence that support our claims and the cancers  
19 we will then have identified. We look forward to that day as  
20 it will lead us into the bellwether trials we need and our  
21 clients need.

22 Thank you for your consideration and your attention.

23 *THE COURT:* Thank you.

24 *MR. McGLAMRY:* Now back to Mr. Gilbert.

25 *MR. GILBERT:* Your Honor, I would like to spend just a

1 couple of minutes talking about the class claims in the Zantac  
2 MDL. Class claims are another tool in our legal tool box to  
3 help pursue justice on behalf of the Zantac victims.

4 Next slide, please.

5 While the class claims we pursue will largely be based  
6 on the same core body -- slide number 15, please. Slide number  
7 15, please.

8 *THE COURT:* Mr. Gilbert, there is a slight lag, I  
9 noticed that previously. There is a little bit of a lag. I  
10 think it is just maybe because so many people are on the  
11 system.

12 *MR. GILBERT:* Thank you. While the class claims we  
13 will pursue will largely be based on the same core body of  
14 evidence that Mr. McGlamry discussed a few moments minute ago,  
15 the Zantac victims on whose behalf we'll advance these class  
16 claims are separate and distinct from the individuals  
17 represented in the personal injury and wrongful death claims.  
18 There are two categories of claimants on whose behalf we will  
19 advance class claims.

20 First, we will advance class claims for those seeking  
21 economic losses only. These include consumers who purchased  
22 Zantac and third parties who reimbursed their members for a  
23 percentage of the cost of these purchases. Both classes will  
24 essentially seek the same relief, damages equal to the amount  
25 paid or reimbursed based on the sale of the defective product.

1           Second, we'll advance class claims on behalf of  
2 individuals seeking medical monitoring relief. These class  
3 claims will be brought on behalf of individuals who used  
4 Zantac, but have not yet been diagnosed with cancer. The  
5 relief we will seek here will be the creation of a fund to help  
6 alert these individuals to their increased risk of cancer and  
7 cover proactive medical screening and monitoring.

8           Next slide, please.

9           In a little while our colleagues, Mr. Longer and Mr.  
10 Keller, will discuss the legal claims we'll advance in these  
11 class actions. Please close the PowerPoint.

12           Your Honors, as the Court hears today's presentations,  
13 please keep in mind that the bell has just sounded and we are  
14 all just crossing the starting line of this MDL marathon.  
15 There are many miles to go.

16           Pleadings at miles one and two, document production  
17 and fact witness depositions for the next 15 to 18 miles,  
18 expert witness reports and expert depositions at miles 15  
19 through 18, general Daubert and class certification motion  
20 practice and briefing at miles 18 to 22, bellwether case  
21 selection, final pretrial discovery, and dispositive motions at  
22 miles 22 to 25, and as we turn the corner and see the finish  
23 line, bellwether trials and class trials right around mile 26.

24           Each of these points in the marathon are mutually  
25 dependent on each other. We can't reach general Daubert and

1 class classification without fulsome discovery, including a  
2 streamlined expedited process for resolution of discovery  
3 disputes. All the pieces have to compliment each other in  
4 order to enable the parties to compete fairly and finish this  
5 MDL marathon. That is part of what makes MDL litigation so  
6 interesting, there are many moving parts and they all have to  
7 fit together to make it work in the search for the truth.

8 Your Honors, we are excited to officially launch the  
9 Zantac MDL with today's initial conference. We appreciate the  
10 opportunity to give the Court a preview of what is to come as  
11 we all journey together on this MDL marathon. Thank you.

12 *THE COURT:* Thank you, Mr. Gilbert.

13 Mr. Agneshwar and Ms. Sharpe, good morning.

14 *MR. AGNESHWAR:* Good morning, your Honor. I am just  
15 sharing my screen. Hopefully it will go well. Does everyone  
16 see that?

17 *THE COURT:* We do.

18 *MR. AGNESHWAR:* Awesome. Step one accomplished.

19 Good morning, your Honor, good morning, Magistrate  
20 Judge Reinhart. It is my honor to be able to present the  
21 opening statement on behalf of the Defendants today. I  
22 represent the Sanofi Defendants in this litigation. I want to  
23 give a shout out to Special Master Dodge. I don't feel like I  
24 am at mile zero, with all the work that she has had us doing  
25 over the past few months I feel I am more at mile 10 or 12.

1           *THE COURT:* Good, I love that, so fewer more miles to  
2 go. I was going to say I don't know if I could do 26 miles  
3 anymore, it has been awhile since I ran my last marathon.

4           *MR. AGNESHWAR:* It's been seven years for me.

5           Your Honor, you have also emphasized the importance of  
6 mentoring and I really appreciate that. It is also my honor  
7 and privilege to be privileged to be copresenting this opening  
8 statement with my mentee of 12 years and my partner for four  
9 years, Paige Sharpe, who you will hear from after I talk for a  
10 little bit.

11           These are unusual circumstances and I am going to do  
12 the best I can over Zoom. My kids are safely in Zoom school, I  
13 have a homemade podium and Girl Scout cookies, and there is no  
14 one in the bathroom so hopefully there won't be a flush heard  
15 round the world.

16           *THE COURT:* You may need your kids at any point.

17           *MR. AGNESHWAR:* I already used them for the Zoom  
18 setup. Hopefully, they don't know as much about Zantac as I  
19 do.

20           With that, your Honor, I am going to launch in. We  
21 have heard a lot about what the FDA did, we have heard a lot  
22 about what Europe did. We've heard words like recall thrown  
23 around, even though it wasn't really a recall, it was a market  
24 withdrawal. We have heard a lot about NDMA, but, your Honor,  
25 my bold statement that I am going to begin with from the

1 Defendants' point of view is, in the real world there is no  
2 foundation for this litigation. There, in fact, is data on  
3 whether Zantac as used by real people in the real world creates  
4 a risk of cancer, and the answer to that, your Honor, is no.

5 What the Plaintiffs have here, and what they  
6 emphasize, is speculation built on speculation about laboratory  
7 tests involving NDMA that have resulted in inconclusive  
8 results. A litigation cannot be based on that type of  
9 speculation, your Honor.

10 Beyond that general causation issue, each Plaintiff is  
11 going to face insurmountable hurdles establishing their own  
12 case. Cancer is not a monolithic disease, so the Plaintiffs  
13 will have to have evidence on the particular cancer that they  
14 claim, and they will have to be faced with the unfortunate  
15 prevalence of cancer and the numerous other reasons why people  
16 get those diseases.

17 On top of that, your Honor, this product has been on  
18 the market nearly 40 years, it's been marketed by a number of  
19 companies over those 40 years. It is now generic and it has  
20 been generic for a long time. That is going to give Plaintiff  
21 hurdles not just on proof of use, but also on product ID,  
22 because if they can't establish that they used the branded  
23 product then they are out of court. We also have strong class  
24 action defenses that I will get into a little bit later.

25 So, let's go back to what I started with, Zantac in

1 the real word. This case is not about laboratory tests, it is  
2 about whether the use of Zantac, the way people use it gives  
3 rise to cancer. Zantac has been on the market for nearly 40  
4 years, it's been one of the first medications to treat  
5 heartburn and GERD and other ulcerative conditions.

6 What I have here is over-the-counter Zantac. What the  
7 label says is that Zantac is typically used for short term. In  
8 fact, the label says stop and ask a doctor if you need to take  
9 this product for more than 14 days or your heartburn continues  
10 to worsen.

11 That is very important, your Honor, as you look at the  
12 data because, as the label also said, heartburn can be a sign  
13 of a more serious condition. In other words, there is a big  
14 chicken and egg issue here. The very symptoms that cause  
15 people to go to the pharmacy and pick up a Zantac are also  
16 symptoms that could be early signs of stomach cancer and other  
17 GI track cancers, and that comes into play when we look at the  
18 science and you will hear about that a little later.

19 All of these regulatory authorities that you have  
20 heard about that have supposedly taken the drug off the market,  
21 why are they saying this? The European Medicines Agency which  
22 regulates pharmaceuticals in 28 European countries has said  
23 that based on comprehensive review of clinical safety data  
24 currently available, it can be concluded that there is no  
25 evidence of a causal association between Ranitidine and the

1 development of cancer in patients, no evidence of a causal  
2 association. The Food and Drug Administration, on April 1st,  
3 the same day that they announced the market withdrawal, they  
4 said, overall, the risk to individual patients potentially  
5 exposed to NDMA remains very small.

6 So, why have these agencies that have asked the  
7 companies to withdraw this drug from the market given these  
8 reassuring statements that there is no causation here? Your  
9 Honor, that is because they wear two hats. On the one hand,  
10 they wear a public health hat where they are taking action in  
11 an abundance of caution to protect the public health. On the  
12 other hand, they are scientists that also dig into the data and  
13 do it the same way that scientists do in laboratories, look at  
14 the epidemiology, look at the studies, and look at the actual  
15 risk as demonstrated to real patients. It is that lab exercise  
16 that happens in laboratories and that the FDA and EMA did in  
17 making these statements that needs to happen in the courtroom,  
18 too.

19 Your Honor said earlier today that you are very  
20 familiar with Eleventh Circuit law on Daubert and, in fact, the  
21 Eleventh Circuit law emphasizes human epidemiology as the  
22 touchstone of proving general causation. It is the most  
23 important aspect of the science in proving general causation,  
24 and that is because epidemiology looks at real people being  
25 exposed to products, or being exposed to something, and

1 comparing them to a control group. In fact, what you didn't  
2 hear from the Plaintiffs, but there is, is epidemiology on the  
3 use of Zantac in the real world and various types of cancer.

4 In fact, one study that was released just last week  
5 concluded that Ranitidine is not associated with an increased  
6 risk of GI cancers, and several cancers were studied in this  
7 one, including colorectal, liver, pancreatic, and gastric  
8 cancers, many of the types of cancers that are alleged here.  
9 Now, this is an abstract, it has not been peer reviewed and  
10 published yet, but typically abstracts, when they are presented  
11 at conferences, give rise to studies a few months or several  
12 months later, but the fact that these authors who are  
13 scientists in Cleveland saw fit to present these findings which  
14 was over a ten-year period of time is really important.

15 The other thing that is important about this new  
16 epidemiology, this brand new epidemiology, is that it confirms  
17 what we have been seeing in the real world over the past 20  
18 years in the studies that have been done.

19 As you will hear from my colleague, Mark Cheffo, later  
20 in the science presentation, there is other epidemiology on the  
21 relationship between Ranitidine and particular cancers, and it  
22 largely says no. There were also studies on the relationship  
23 between Zantac's class of drugs, H2RAs, and various cancers,  
24 and by and large the epidemiology says no.

25 There are a few positive results, but by the authors'

1 own admissions, typically those findings reflect confounding or  
2 chance or other methodological issues.

3 Here is a case in point, this was another study that  
4 came out just last week, a week ago today, where these  
5 scientists published in the British Journal of Cancer showed a  
6 modest association between PPIs and H2RAs like Zantac and  
7 gastric cancer, but they saw that risk decline the longer you  
8 took the drug, which is contrary to anything you'd expect.  
9 What they said is the chicken and egg issue. This is reverse  
10 causations. Our results revealed a marked increase in the  
11 prescription of acid suppression medications immediately before  
12 a gastric cancer diagnosis, suggesting role of reverse  
13 causation.

14 In other words, you get heartburn, for most people it  
15 is just heartburn, for some unfortunate few it is a sign of  
16 stomach cancer, but you immediately think it is heartburn and  
17 go take a Zantac and shortly thereafter end up being diagnosed  
18 with cancer. That is called reverse causation and that is what  
19 you are going to hear about later.

20 By and large, the epidemiology does not support a  
21 relationship between Ranitidine and any kind of cancer. Your  
22 Honor, that is really the end of the story on general  
23 causation, but what Plaintiffs have done is focused on NDMA, so  
24 let's talk about NDMA.

25 The NDMA theory that you heard about from the

1 Plaintiffs is really speculation built on speculation.  
2 Speculation number one is why NDMA is classified as a human  
3 carcinogen. It is actually classified as a probable human  
4 carcinogen for practical purposes only based on animal studies.  
5 There is not epidemiology on the relationship between NDMA in  
6 human beings and cancers, it is a probable, not a definite  
7 causation. So, that is one level of speculation the Plaintiffs  
8 have to get around.

9 Now, you would think from hearing the Plaintiffs'  
10 presentation that Zantac is the only thing that contains NDMA,  
11 and other than Zantac, we would not be exposed to it at all.  
12 That is not true, your Honor. NDMA is ubiquitous, it is found  
13 everywhere. It is in workplaces, the environment, in the water  
14 we drink, even in Florida water. It is in the vegetables we  
15 eat, it is in fruit, it is in mushrooms. So, you can get NDMA  
16 from a lot of different things.

17 What is also the speculation number two is, how much  
18 NDMA exposure do we need to have before we increase our cancer  
19 risk? Candidly, your Honor, nobody knows. There is  
20 speculation about that, but it is a big unknown, but the FDA  
21 set what is called an acceptable daily intake of 96 nanograms.

22 So, what are they saying when they say that is the  
23 acceptable daily intake?

24 Let me start with what they are not saying. What they  
25 are not saying is that acceptable daily intake equals a real

1 world risk. What this is, is a calculation extrapolated from  
2 animal studies that answers the following question: At what  
3 level of NDMA would a 110-pound person need to be exposed to on  
4 a daily basis for nearly their whole lives, for 70 years, in  
5 order to increase their cancer risk by one in a hundred  
6 thousand at a theoretical level? The FDA said even that one in  
7 a hundred thousand is probably understated -- I mean  
8 overstated.

9 Your Honor, when you contrast that theoretical risk to  
10 Zantac as Plaintiffs use it in the real world, you could not  
11 get any more different. Zantac has been on the market for only  
12 35 years, it has not even been on the market close to 70 years,  
13 and the longest approved OTC course without a doctor's  
14 supervision is 14 days, again, very different.

15 But even if you give Plaintiffs every benefit of the  
16 doubt and say, okay, NDMA is a human carcinogen, it is proven;  
17 okay, 96 is the level at which above that there is risk, still,  
18 when you compare that to the risks of cancer, it is apples and  
19 oranges.

20 Cancer is a terrible disease, and all of us have faced  
21 it in our own lives, either ourselves, people we are close to,  
22 family and friends, and the reason for that, your Honor, is  
23 because it is all too common. The lifetime risk of bladder  
24 cancer is two and a half percent. The lifetime risk of colon  
25 cancer is four and a half percent. Even stomach cancer is one

1 percent. And the lifetime risk of prostate cancer is  
2 13 percent in Caucasians and nearly 30 percent in  
3 African-Americans. These are high numbers, whereas the  
4 theoretical risk of being exposed to the acceptable daily  
5 intake of NDMA is one in a hundred thousand. It is a  
6 difference in magnitude of risk, your Honor.

7 Even beyond that, your Honor, the level of NDMA that  
8 is being alleged to be in Zantac has been a moving target and  
9 is still a moving target. This whole litigation started when a  
10 company called Valisure, which is an online pharmacy, submitted  
11 a citizen's petition to the FDA requesting that they  
12 withdraw Zantac from the market.

13 On the same day that Valisure filed the citizen's  
14 petition cases against these companies, my client and others,  
15 began to be filed, the very same day, suggesting some link  
16 between Valisure and the Plaintiffs Bar. Valisure purported to  
17 find levels in the millions of nanograms in tablets of Zantac,  
18 as you see on the left, and as my colleague, Mr. McGlamry,  
19 alluded to.

20 All of the complaints filed to date, as well as  
21 Plaintiffs' position statement, rely on Valisure, but Valisure  
22 and its testing methodology has been debunked, it has been  
23 debunked by the FDA. The FDA scolded Valisure that "we found  
24 that the test method you used in sampling Ranitidine for NDMA  
25 was inappropriate and contributed to or caused the levels of

1 NDMA to be artificially high."

2 What Valisure did was they exposed these products to  
3 like temperatures above the boiling point and created NDMA and  
4 then said, aha, look what we found, and the FDA said, no, that  
5 is not how you do it. We have a different better test.

6 Valisure also did another test to see if there was  
7 NDMA formed in the body as it interacts with gastric fluid,  
8 and, your Honor, here they succeeded, too, but they succeeded  
9 only when they pumped enough nitric acid into this gastric  
10 fluid, which is a compound found in smoked meats that is known  
11 to cause NDMA, in a quantity equivalent to 33 pounds of bacon  
12 and a half glass of water in a single sitting.

13 Now, I am a vegetarian so I don't eat bacon, but I  
14 doubt most people who take Zantac eat that much bacon in a  
15 single sitting to give rise to these elevated levels of NDMA.

16 So, fast forward a few months later. Mr. McGlamry  
17 also pointed to Emery Pharma, but now, months after this  
18 litigation is filed comes a different theory. Emery files a  
19 citizen's petition and says, no, no, we are not talking in the  
20 millions of nanograms, we are talking slightly above acceptable  
21 limits. We are talking like 100 to 150, and that is when it is  
22 exposed to heat.

23 So, what Emery did was they took these three samples  
24 of Zantac, some were generic and one was branded, and they  
25 exposed them to a temperature of 25 degrees Celsius, which is

1 about 80 degrees Fahrenheit, and 70 degrees Celsius, which is  
2 over 150 degrees Fahrenheit. What they found is that when you  
3 expose it to this really high temperature NDMA forms at a  
4 gradual level.

5 What Emery did was they expressed concern that maybe  
6 the product can reach these temperatures in high heat  
7 conditions, but in fact, your Honor, they cited no data on  
8 shipping conditions to make that point clear or to base it on  
9 any evidence. So, again, it is another speculation that is  
10 vastly different in magnitude and degree from what Valisure  
11 said.

12 So, what about the FDA? Well, the FDA did ask the  
13 companies to withdraw the product from the market. They did  
14 not do a recall and they specifically said they were not  
15 recalling the product.

16 What the FDA said in its press release and in its Q  
17 and A with the media was that some Zantac contained some  
18 unspecified, but elevated levels of NDMA under some conditions.  
19 But note what else the FDA said, your Honor, in this same press  
20 release. They did not find levels above acceptable daily limit  
21 in, quote unquote, "many of the samples that we tested." In  
22 another place, your Honor, they said most of the samples that  
23 they tested did not have elevated levels of NDMA. They  
24 requested withdrawal from the market, and this is a quote, "out  
25 of an abundance of caution."

1           That is a critical point, your Honor, because the  
2 Plaintiffs are basing a lot of their arguments on what the FDA  
3 did. The FDA specifically said it, your Honor, that it is not  
4 a recall because technically the products are okay, they have  
5 met all their specs and so forth. It is only when they are  
6 subjected generally to heat stress do they manifest higher  
7 levels, and that isn't what we'd expect that these products  
8 would be stored under those higher temperatures.

9           The FDA has never said Zantac causes cancer. The FDA  
10 has never said that intake above the acceptable daily intake  
11 means a real world risk of cancer. The FDA has never said that  
12 most or all of Zantac tablets contain levels above the  
13 acceptable daily intake, and certainly the FDA has never said  
14 that any particular product, any particular brand on any  
15 particular shelf contains NDMA.

16           At the end of the day, your Honor, in terms of the  
17 science of this case, which you will hear more about later, the  
18 Plaintiffs' case is based on a series of mights and maybes.  
19 There is no epidemiology now, but maybe there will be in the  
20 future.

21           Going to NDMA, do we know which packages contain NDMA?  
22 We don't. Do we know how much NDMA is in any particular  
23 package? We don't. Do we know whether any particular  
24 Plaintiff took a package with elevated levels of NDMA? We  
25 don't. Do we know what levels of NDMA can even theoretically

1 cause cancer in humans? We don't even know that, your Honor.

2 Your Honor, it is settled law that law is supposed to  
3 lag science, it's not supposed to lead it. When the science is  
4 not there, there shouldn't be a litigation. It's only if the  
5 science is there that law should then come. Your Honor, it is  
6 our position that the science is simply not there, your Honor,  
7 to link Zantac to cancer.

8 With that, I am going to turn it over to my colleague,  
9 Paige Sharpe, to pick it up.

10 *THE COURT:* Okay. Thank you very much. Welcome, Ms.  
11 Sharpe.

12 *MS. SHARPE:* Good morning, your Honors. My name is  
13 Paige Sharpe and it is a privilege to appear before you both  
14 this morning.

15 Your Honor, in my part of the presentation I am going  
16 to focus on the challenges that individual Plaintiffs are going  
17 to be facing in this litigation, challenges that we think are  
18 going to be insurmountable.

19 The first challenge has to do with a simple but  
20 fundamental fact about cancer. It is not a monolithic disease.  
21 Cancer is actually an umbrella term that encompasses all  
22 different types of cancers, each of which has its own risks and  
23 each of which has its own potential causes. As the Journal  
24 article quoted in this slide states, "It is inconceivable that  
25 a pharmaceutical agent should act as a universal carcinogen."

1 In other words, there is no single agent, no matter how  
2 carcinogenic, that can cause all types of cancer.

3 That is enormously important here because Plaintiffs  
4 haven't differentiated among types of cancers at all.

5 Thank you. This slide shows the types of cancers that  
6 are claimed just in the Complaints to date, there are some 18  
7 different types, and they claim dozens more in the census. And  
8 you will see they're claiming just about every type of cancer  
9 imaginable, not just cancers associated with the same body  
10 system as Zantac, that is the gastrointestinal tract. No, they  
11 are claiming brain cancer, breast cancer, lymphoma and myeloma.  
12 The census includes claims for thyroid cancers, for skin  
13 cancers. There is simply no limiting principles to the types  
14 of cancers that are being claimed.

15 Plaintiffs are not going to be able to bypass Daubert  
16 with these undifferentiated claims. They can't use Epi from  
17 stomach cancer, for example, to show causation in a pancreatic  
18 cancer case. They can't use Epi from a pancreatic cancer case  
19 to prove causation in a breast cancer case. They are going to  
20 need evidence for each type of cancer.

21 That is just the beginning with respect to the  
22 challenges the individual Plaintiffs will face because even if  
23 the Plaintiff could show that Zantac can cause their particular  
24 type of cancer, you are, of course, still going to have to show  
25 that Zantac actually caused their individual cancer. That is a

1 very high hurdle. First of all, they don't have Epi to show  
2 that Zantac can cause cancer at all, much less any specific  
3 cancers.

4 This isn't a case where there is a signature injury  
5 where they can say that for this particular type of cancer we  
6 know what the cause is. To the contrary, I think we all know  
7 that there are risk factors for cancer that are out there and  
8 that we are all exposed to. Some we can control, like smoking,  
9 like alcohol intake, and our diet, but others we simply can't,  
10 like our genetic makeup, and the fact that the risk of cancer  
11 increases with age.

12 Let's also not forget that Zantac, to the extent that  
13 it even contains NDMA, is far from the only source out there.

14 Now, we have been focusing on the science and  
15 causation issues, but those, of course, are not the only  
16 defenses that the Defendants are going to have in this  
17 litigation, and I want to talk about a couple of those defenses  
18 because they are going to be so important in a case like this  
19 in particular. One of those defenses concerns proof of use and  
20 product identification issues.

21 This isn't a typical product liability case or even a  
22 typical product liability MDL where you have a single product  
23 that is made by a single manufacturer. We all know, I think,  
24 that it is much more complicated than that here. The fact that  
25 you have multiple products and multiple manufacturers is

1 important for two different reasons.

2 First of all, Plaintiffs are going to have the  
3 additional burden of proving not just that they took Zantac or  
4 Ranitidine, but which Zantac or Ranitidine they took and who  
5 made it. That is a tall order for a product that has been  
6 available over the counter for so many years, where  
7 prescription records are going to be unlikely to be had, and  
8 where there have been so many generic versions available as  
9 well, as many as 75 different generics over time.

10 Second, the difference between branded use and generic  
11 use can make the difference between having a cause of action or  
12 not having one at all, and that really matters here because  
13 since it went generic -- I'm sorry, since it went over the  
14 counter several decades ago, sales of generic Ranitidine have  
15 far outstripped those of branded Zantac. That makes sense,  
16 right? Generics cost a lot less than branded. Many consumers,  
17 when they go into a drugstore, are naturally going to reach for  
18 the cheaper option.

19 Now, I understand that the census data does not  
20 comport with the data that we have on sales. The census data  
21 suggests that the majority of claimants took branded Zantac or  
22 a combination, but that is a discrepancy that Plaintiffs are  
23 going to have to grapple with over the course of this  
24 litigation because the numbers on the slide do reflect hard  
25 sales.

1           Now, I mentioned that the issue of generic use is  
2 particularly important here in determining whether a Plaintiff  
3 has a claim, and that is because of the broad rejection of the  
4 theory of innovator liability.

5           That theory of liability that a branded manufacturer  
6 can be liable for injuries caused by a generic product has been  
7 almost universally rejected by State high courts, by every  
8 Federal Court of Appeals that has considered the issue, and it  
9 has never been applied in a case like this involving an  
10 over-the-counter product.

11           So, those Plaintiffs who took generic Ranitidine are  
12 not going to have claims against the branded manufacturers, and  
13 they are also going to have problems with their claims against  
14 the generics as well because of Supreme Court precedent saying  
15 that those claims are not viable either because the generic  
16 does not control the design of the product and it doesn't  
17 control the labeling.

18           With that, your Honors, I am going to turn the  
19 presentation back to Mr. Agneshwar for final points. Thank you  
20 very much.

21           *THE COURT:* Thank you very much.

22           *MR. AGNESHWAR:* Thank you, your Honor. Just a brief  
23 note about class actions. The Plaintiffs, as Mr. Gilbert said,  
24 are going to be filing Master Complaints in class actions, they  
25 are going to be pursuing medical monitoring, they are going to

1 be pursuing consumer class actions basically saying we paid too  
2 much for this product because we didn't understand the cancer  
3 risk, and they are going to be filing what seems to be third  
4 party payor claims.

5 Just so you know, there is consistent law going back  
6 years that says that in cases like this, pharmaceutical,  
7 essentially product liability cases, classes are simply not  
8 viable, and there are good reasons for that, your Honor.

9 If you look at Rule 23, virtually none of these are  
10 satisfied, going from ascertainability all the way to  
11 superiority. Just one after another Courts have rejected this  
12 and it is no surprise why. All the defenses that we have been  
13 talking about today apply equally in class actions.

14 There is going to be myriad differences in the laws of  
15 50 states. It is going to be impossible to verify who took the  
16 drug and who is in the class. There's too many products over  
17 too much period of time, too many Defendants, there's  
18 retailers, there's branded, there's generics. There's too many  
19 cancers, each with individual proof, too many risk factors, too  
20 much individual variability. Medical monitoring itself is not  
21 accepted in the majority of states, and economic loss claims  
22 involving over-the-counter products are preempted, your Honor.

23 So, I don't see these class act allegations going far  
24 in this litigation.

25 Your Honor, we heard in the opening statements some

1 very personal allegations against some of the companies as to  
2 what they did in this case and another case, and the notice the  
3 companies supposedly had. We are confident that there is no  
4 way anybody could have known of a risk, and even today I think  
5 that is borne out by the fact that, as I have tried to  
6 demonstrate, your Honor, that the risk has not materialized  
7 even today. There just isn't such a risk.

8 Your Honor, thank you for listening. It is a pleasure  
9 to appear before you. I hope one day to do this in person. I  
10 have enjoyed working with Special Master Dodge, the Defense  
11 team, the Plaintiffs' team. I think we will work very  
12 collaboratively over this litigation and we look forward to be  
13 vindicated at the end when it comes. And there was no toilet  
14 flush, I hope.

15 *THE COURT:* No. Everything went perfectly. Thank you  
16 very much, Mr. Agneshwar and Ms. Sharpe.

17 I know on the agenda you have a break built in, and I  
18 would like to honor that agenda for the benefit of everyone,  
19 including our court reporter who is taking everything down.  
20 So, you had it from 10:30 to 10:45, and it is 10:20 now. Why  
21 don't we take a 15-minute break and we will be back at 10:35.

22 Please don't leave the meeting, it does put a great  
23 strain on those of our cohosts whom I want to thank again for  
24 helping in the administration of admitting everybody in, the  
25 liaisons and others, our special master.

1           So, don't leave the meeting, just keep yourself muted  
2 and your video off, which I will do as well. We will see  
3 everybody back at 10:35 and we will pick up with the law  
4 presentation at that point. Thank you so much.

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

6           *(Thereupon, trial reconvened after recess.)*

7           *THE COURT:* Okay, welcome back, and I'm happy to move  
8 into the next item on the agenda, which is the law  
9 presentation.

10           So, I know we have Mr. Longer, Mr. Keller, Mr.  
11 Petrosinelli and Mr. Bayman, and I turn it over to you to  
12 proceed.

13           *MR. PETROSINELLI:* Good morning, Your Honor, Joe  
14 Petrosinelli here. Your Honor, the way we have divided this, I  
15 think we provided the Court with an outline of the topics, but  
16 it is a little different format than the openings where we are  
17 going to go back and forth a little bit, give it a little  
18 collaborative feel, because the four of us did put this  
19 presentation together. Ms. Zousmer, one of our colleagues, is  
20 going to run the slides for everyone hopefully to avoid any  
21 hiccups, but if there are hiccups, we apologize in advance.

22           We have it divided into five sections of law organized  
23 in a way that we thought made sense, so unless your Honor has  
24 any questions, I will just jump right in with the first topic.

25           *THE COURT:* Perfect.

1           *MR. PETROSINELLI:* Your Honor, the first section of  
2 law we wanted to cover for the Court was the law relating --

3           *THE COURT:* Mr. Petrosinelli, just hold on one moment.  
4 I'm sorry. Just a gentle reminder, our court reporter has  
5 asked each time you go back and forth if each speaker would  
6 just, again, state your name for the record so it clearly  
7 reflects on the transcript. Okay?

8           *MR. PETROSINELLI:* Of course, we will do so.

9           Your Honor, the first topic of law is the law relating  
10 to the FDA regulatory framework that governs this case and the  
11 way we have divided this is, I will cover the pre-approval of a  
12 new drug period, and Mr. Longer, on behalf of the Plaintiffs,  
13 I'll turn it over to him and he will cover sort of the  
14 post-approval period.

15           So, let's start with just what is the source of law  
16 that relates to the approval of a new drug product in the  
17 United States, and there are really sort of two sources. One  
18 is the statutory source, which is the Federal Food Drug and  
19 Cosmetic Act. Your Honor, I think in pharmaceutical litigation  
20 you will find you are going to be inundated with acronyms and  
21 this is the first one. You will hear reference to the FDCA,  
22 and when you hear that, this is the act that folks are talking  
23 about. You see the sections there that relate to -- the  
24 portion of that act that relate to drugs and medical devices.

25           I think probably more commonly you will hear talk

1 about during the litigation the second source of law, which are  
2 the implementing regulations under the statute which are found  
3 in Title 21 of the Code of Federal Regulations. Those are the  
4 FDA implementing regulations that describe what the FDA  
5 requires to get a new drug approved, and other things, in this  
6 country.

7 And then just a final introductory acronym is the  
8 acronym CDER, C-D-E-R, that you will hear. This is the portion  
9 of the FDA, the Center for Drug Evaluation and Research that  
10 deals with and evaluates medications as opposed to, for  
11 example, there are divisions that deal with food, there are  
12 divisions that deal with medical devices. This is the division  
13 that deals with medications. So, when you hear the term CDER,  
14 that is what it is referring to.

15 The question is, what is the legal basis or the legal  
16 framework for a new medication to get approved in the United  
17 States?

18 The start of the process on the FDA side is called an  
19 investigational new drug application. If we could go to the  
20 next slide, please.

21 The so-called IND, another acronym, that is the formal  
22 way in which a manufacturer or an applicant who wants to start  
23 the process the usual way -- there are some exceptions,  
24 emergency use and so forth, but this is the usual way and  
25 certainly was the way with Zantac that a sponsor seeks approval

1 for the FDA to start the process of testing a new drug in human  
2 beings.

3 Now, importantly, it is not the start of the process  
4 from the manufacturer's side. Before you submit an IND, you  
5 will have done typically two major things; one is the discovery  
6 of the molecule. Bench scientists who are employed at  
7 pharmaceutical companies and dedicate their careers to  
8 discovering new medications that target certain diseases or  
9 cells will do what you would think of as lab experiments in  
10 test tubes and petri dishes, the kinds of things we all did in  
11 high school science class.

12 And you'll hear the term "preclinical tests," you will  
13 hear that a lot in this litigation. When you hear that term it  
14 really means two things; it means the lab tests that I have  
15 just described in test tubes and petri dishes, often referred  
16 to by the term "in vitro". So, in vitro tests, that is what  
17 those are.

18 Then, the second piece that a company will have done,  
19 and has to do before submitting an IND, is tests in animals.  
20 So, those are often called in vivo tests because they are in a  
21 live organism. And the way it will work is a company will, if  
22 it finds a molecule that seems to have efficacy in test tubes  
23 or petri dishes on a target compound, protein, enzyme, whatever  
24 is being targeted, then the company will do tests in animals,  
25 live organisms, and they will do all sorts of tests screening

1 for, among other things, efficacy and adverse events that would  
2 occur. Those data, the results of those tests have to be  
3 presented to the FDA in the IND.

4 That is one thing and it is -- one of the reasons why  
5 I point it out here is, those include carcinogenicity tests,  
6 which I will talk about in a second, but obviously that has  
7 relevance to this litigation.

8 The second thing, the main thing an IND is, you have  
9 to tell the FDA what clinical trials, meaning trials in human  
10 beings as opposed to preclinical trials, what you propose to  
11 do, how you propose to do it, and describe how you intend to do  
12 it into three phases, phase one, phase two and phase three  
13 clinical trials that I will describe in just a moment, what the  
14 difference is between those.

15 The final thing that I highlight here because it is  
16 relevant to this case based on the theories we have heard from  
17 Mr. McGlamry, for example, is you have to describe to the FDA  
18 in the IND the chemistry and manufacturing of the drug,  
19 including what methods are used to manufacture the compound to  
20 make sure that its purity and stability, two concepts that you  
21 will hear a lot about in this litigation, are true, and that  
22 the drug doesn't have impurities and doesn't have instability.  
23 You have to explain to the FDA how you have assured that and  
24 the FDA has to approve that. So, that is part of the IND  
25 package that would be submitted.

1           Once you submit an IND and the FDA gets an opportunity  
2 to review it and they approve it, you now are authorized to  
3 conduct -- by law, authorized to conduct clinical trials in  
4 actual human beings. So if we can go to the next slide.

5           This is from another part of the CFR, this is 21 CFR,  
6 Section 312.21. This is a graphic illustration of what it says  
7 in that section. These are the three types of clinical trials  
8 a company must conduct in human beings before it can get a drug  
9 approved. You see -- I won't read through it all, but  
10 generally speaking, as would make sense, it is a gradual  
11 progression. You start with smaller studies, mainly to --  
12 usually in healthy patients and mainly to figure out dose  
13 levels, like safe dose levels.

14           Then you move to what are called phase two trials,  
15 which are we are treating people with the active disease you  
16 are trying to treat. There are typically hundreds of patients,  
17 there could be more, but usually hundreds, and that takes  
18 anywhere between some months to a couple of years.

19           And then you get to -- if you see no adverse events of  
20 concern and there is efficacy, you get to the phase three  
21 trials. These are much larger trials, up to thousands of  
22 patients, take much longer time to do, typically several years,  
23 and the key thing about these trials is that they are  
24 typically -- not all of them have to be, but there at least  
25 several that are randomized double blind placebo-controlled

1 clinical trials, I think everyone would agree the gold standard  
2 in assessing whether or not a pharmaceutical agent causes  
3 adverse health effects in human beings.

4 And because those trials happen, and because they take  
5 a long time, they help define the warnings that would be  
6 provided in the labeling for a product because during the  
7 trial, as adverse events happen in human beings, and they  
8 happen ranging from minor to serious, they are recorded, and  
9 there is a discussion with the FDA about which of those are  
10 significant enough or prevalent enough to be put in labeling.

11 Those are the three trials that are done and, your  
12 Honor, we are talking about a many years long process, but when  
13 you get to the stage where you have done these clinical trials  
14 and all the other things, pre-clinical testing, chemical and  
15 manufacturing testing, your next stop and the sort of final  
16 stop to get a drug approved is the so-called new drug  
17 application, or NDA.

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

19 You will hear this acronym, I am confident, quite  
20 often in this litigation. The NDA is a massive -- I remember  
21 many years ago when we didn't have electronics and you had to  
22 produce NDAs in litigation, I remember being a young associate,  
23 and it filled an entire conference room of documents, and I  
24 thought this is going to be a painful document review, but this  
25 is a massive document because it contains all of these things

1 and more. I have picked out some highlights here. It must  
2 contain by law all of these things you see on the screen,  
3 including, I mentioned this earlier, in the pre-clinical test  
4 results, particularly toxicology studies on animals, there must  
5 be carcinogenicity studies. And so, the details of how that is  
6 done is sort of beyond the scope of this presentation on the  
7 law, but actually you will hear a little bit about it in the  
8 science presentations.

9           These were, of course, done on Zantac. GSK, the  
10 inventor of the drug, when it submitted its NDA had submissions  
11 on carcinogenicity tests that it had done and the FDA reviewed  
12 those and you will see what the results were those when my  
13 colleague, Mr. Cheffo, presents the science piece.

14           Of course, the results of the clinical trial, again,  
15 the information about stability and purity, and the applicant  
16 submits its own analysis, overall analysis of the summary of  
17 the data on safety and effectiveness.

18           And then, of particular note in this case because it  
19 relates to preemption -- several of these things relate to  
20 preemption issues that you will hear Mr. Bayman talk about in a  
21 second, but the sponsor or the applicant submits its proposed  
22 labeling for the drug. When I say labeling, in a prescription  
23 drug context that is typically referring to the label that goes  
24 to the prescribing doctor who can then advise his or her  
25 patient about risks and so on. In an over-the-counter context

1 it is a little different, obviously, and I will talk about that  
2 in a moment.

3 But the NDA is submitted and the FDA then gets an  
4 opportunity to review it.

5 If you could go to the next slide, please.

6 Labeling is governed very carefully and specifically  
7 and strictly by a number of provisions in the CFR. Here are  
8 three of them that relate to prescription medications, and all  
9 of these things have to -- are sections that are mandated to be  
10 in the label and, as I say, the applicant will submit its  
11 proposed wording for all these things, including warnings,  
12 precautions, adverse reactions, and the FDA will then, having  
13 had all the data now in the NDA, will then review the draft  
14 that the sponsor or applicant submits to see if they agree.

15 And that gets us to the last piece, which is the  
16 actual process of approval. If we could go to the next slide.

17 Again, there are laws in the CFR cited here that  
18 govern what the FDA does with a new drug application, and you  
19 will see, not surprisingly, the sort of standard is if the drug  
20 meets the statutory requirements for safety and effectiveness,  
21 manufacturing and controls, and labeling, the FDA will approve  
22 it.

23 Of note, you see in other sections of the CFR there  
24 are all sorts of reasons why the FDA could reject an  
25 application, to include all of the things we just talked about.

1 If they think that the data submitted about manufacturing in  
2 terms of how to ensure purity and stability is inadequate, if  
3 the clinical trial and pre-clinical trial results show some  
4 concern about safety, or if they don't like the labeling that  
5 has been proposed, they can reject the application.

6 What you will see, and certainly with Zantac, is at  
7 the end of the day, if the FDA is going to approve, there is a  
8 document called the Summary Basis of Approval in which the FDA  
9 summarizes why it is approving the product. Importantly, your  
10 Honor, when I say the FDA, CDER, the division we talked about,  
11 has itself a bunch of different offices with different medical  
12 professionals and scientists that each review sort of pieces of  
13 the application.

14 So, what do I mean by that? They have medical  
15 doctors, toxicologists, epidemiologists, biostatisticians, all  
16 sorts of scientific disciplines that are relevant to the  
17 various pieces of the application. They each do their own memo  
18 recommending whether or not they would approve based on their  
19 piece of the scientific world, and those get funneled to the  
20 leadership of CDER ultimately which then issues this Summary  
21 Basis of Approval document.

22 Your Honor, that is on the prescription drug side.  
23 So, when Zantac was originally approved as a prescription drug,  
24 that is a summary of the process. It is a little different for  
25 over the counter and generic.

1           If we could go to the next slide.

2           For an over-the-counter product, which is typically,  
3 and it certainly was in this case, a product that is a  
4 prescription product, but the manufacturer seeks  
5 over-the-counter status, that is generally done -- there are  
6 some details here that I don't think are particular relevant  
7 now, but it's generally done through a new NDA submission or  
8 what is called an abbreviated NDA or ANDA. That's another  
9 abbreviation you will hear. As you might imagine, for  
10 conversion from a prescription status to an over-the-counter  
11 status the FDA requires a large margin of safety because you  
12 are going to have consumers buying the product without --  
13 perhaps without consultation with a doctor.

14           Secondly, and importantly here, there is a very  
15 specific provision in the CFR about what exactly must be in an  
16 over-the-counter product label that sort of standardizes, no  
17 matter what you are manufacturing, if it is a drug and it's  
18 over the counter, it is going to follow the format of what is  
19 laid out in the CFR. That has all sorts of sections, like a  
20 section called stop use and ask your doctor if.

21           So, if he we go to the next slide.

22           Your Honor, just to show you, this is the sort of most  
23 recent over-the-counter labeling for Zantac 150 milligrams, and  
24 you can see on the left that format that is shown is the format  
25 that is set forth in the CFR provision I just told you about

1 that everyone has to follow.

2           And then we just highlighted -- you heard, I think,  
3 Mr. Agneshwar talk about a couple of these, like the stop use  
4 and ask your doctor if, and the issue about if you need to take  
5 the product more than 14 days. That language is talked about  
6 and negotiated with the FDA.

7           In other words, everything that is in both the  
8 prescription version label and this label will have been  
9 discussed with the FDA, gone back and forth between the company  
10 and the FDA, and the FDA will have agreed that, based on the  
11 data, that is the appropriate language to be in the label.

12           If we could go to the next slide.

13           The final thing is generic products. You have heard  
14 that in the 1990's, I think mid to late 1990's, the patent  
15 expired on Ranitidine that GSK held and that allowed generic  
16 products to enter the market. Two things to note about generic  
17 approval; it is a different pathway, it's through this ANDA,  
18 abbreviated new drug application process, where the generic has  
19 to -- the generic doesn't have to do its own clinical trials or  
20 pre-clinical testing like we saw in the brand space, but it has  
21 to show chemical equivalence and it has to show bio equivalence  
22 of a medication that has already been approved. That is one  
23 thing. It is a much more compact application.

24           Secondly, there is the so-called Doctrine of Sameness  
25 in the law, in the FDA regulatory law, which is that the

1 generic has to basically have the same of everything about the  
2 medication that has already been approved, so the same API,  
3 active pharmaceutical ingredient, Ranitidine here, strength,  
4 and so on.

5 And of special note, as you will hear in the  
6 preemption section later, the generic's labeling must be the  
7 same as the labeling that was approved by the FDA for the  
8 branded product, whether it is a prescription label or an  
9 over-the-counter label, and that the generic has no  
10 obligation -- has no ability to unilaterally change the  
11 composition of the product or the labeling of the product, it  
12 has to be the same. That, as you will hear, has implications  
13 in the case law about preemption.

14 So, your Honor, that is a broad overview of the law  
15 that relates to pre-approval of an FDA approved product, and I  
16 am going to turn it over now to my colleague for the  
17 Plaintiffs, Mr. Longer, who is going to cover the post-approval  
18 period.

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

20 Good morning, Mr. Longer.

21 *MR. LONGER:* Good morning, your Honor. I am just  
22 getting myself set up.

23 My name is Frederick Longer. This is my first  
24 appearance before the Court apart from my interview. I would  
25 just like to extend my thanks to your Honor, Magistrate Judge

1 Reinhart, and Special Master Dodge for your efforts and  
2 attention while I give my presentation.

3 I intend to address three subjects related to the  
4 post-approval period of a pharmaceutical drug. I will cover an  
5 overview of the regulatory requirements dealing with the how  
6 and why of adverse event reporting, the obligations to update  
7 the label with new safety information, and the third is FDA  
8 information about recalls or withdrawals.

9 While Mr. Petrosinelli had a number of slides to  
10 address the pre-approval process, I will do mine a little old  
11 school and just briefly explain to the Court branded and  
12 generic drug manufacturers' obligations to continue to monitor  
13 the safety of their products once they are on the market.

14 These standards are baked into the FDCA and the CFR,  
15 the Code of Federal Regulations. It is well recognized that  
16 simply because a drug has received FDA approval, the obligation  
17 to continue to study the safety of the drug does not end.  
18 Approval of marketing really is just a new beginning in drug  
19 safety. Both the act and the regulations put the obligation on  
20 the manufacturer to ensure that its product is safe and the  
21 label adequately warns of the risk of the drug, and the reason  
22 for that is simple.

23 The manufacturer is the expert about the drug it  
24 makes. The manufacturer has studied the drug and knows or  
25 should know more about its product's safety profile than any

1 other entity, including the FDA, which is why by law the  
2 manufacturer is always responsible for the drug even after it  
3 has been approved for marketing. This is true under Federal  
4 law and it is equally true under State common law.

5 The reason that the parties are addressing both the  
6 pre-market and post-market regulations is, just as Mr.  
7 Petrosinelli was mentioning, because these Federal standards  
8 could impact on whether preemption of state law duties would  
9 apply.

10 So, my brief discussion about post-marketing duties in  
11 a sense sets the stage for the next discussion to follow about  
12 preemption.

13 Since I am doing this a little old school, I would ask  
14 Ms. Zousmer if she could take down the PowerPoint because --  
15 oh, very good, thank you.

16 So, the first topic I wanted to cover, your Honor, was  
17 about regulatory requirements.

18 As your Honor saw from the presentation by Mr.  
19 Petrosinelli, pretrial clinical studies are confined to a  
20 limited population of study subjects. Some studies include  
21 less than a hundred patients. As a consequence, risk  
22 assessment during product development makes it impossible to  
23 identify all the safety concerns during the clinical trial  
24 period. Once a product is approved for marketing, however, the  
25 number of persons exposed to the agent increase significantly.

1 In the case of a very popular drug the numbers could be in the  
2 millions of persons exposed to the agent. Plus, that  
3 population now includes persons with co-morbid conditions and  
4 the potential for use of other drugs.

5 Consequently, the need for post-marketing safety data  
6 collection and risk assessment are critical to understand the  
7 product's risk profile, and what I have just described to you,  
8 your Honor, is the driving force behind pharmaco vigilance.  
9 FDA guidance defines pharmaco vigilance as all scientific and  
10 data gathering activities related to the detection, assessment,  
11 and understanding of adverse events.

12 What are adverse events? Congress defined them in the  
13 context of adverse drug experience, which means any adverse  
14 event associated with the drug -- I am sorry, with the use of a  
15 drug in humans whether or not considered drug related.

16 That covers the gamut of issues, including adverse  
17 events occurring in the use of the drug in professional  
18 practice, an adverse event occurring from an overdose of the  
19 drug, whether it's accidental or intentional, an adverse event  
20 occurring from abuse of the drug and other matters.

21 So, under the FDCA, Congress requires marketed drugs  
22 to be subject to rigorous reporting requirements. This  
23 post-marketing reporting obligation also applies equally to the  
24 ANDA holders, the generic drug manufacturer.

25 Indeed, the CFR is chock full of regulations

1     pertaining to post-marketing reporting, the contents of those  
2     reports and where the information can be observed.

3             For example, alert reports for adverse event reports  
4     must be reported as soon as possible, but no later than 15 days  
5     after the event. Also, periodic and annual adverse drug  
6     experience reports are required, mandated by the FDA.

7             This information, your Honor, is posted in what is  
8     called the FDA's Medwatch where spontaneous and voluntary  
9     reporting of cases are presented. Medwatch is the FDA's  
10    database that anyone can tap into to see if there are adverse  
11    event reports being reported for any particular drug.

12            So, that is the general picture for adverse event  
13    reporting.

14            Technical difficulties, your Honor. I am working from  
15    a new podium.

16            So, the second topic I wanted to cover, your Honor,  
17    addresses label updates. Federal law requires a manufacturer  
18    to update the label of an approved brand drug to warn of  
19    emerging risks. The Supreme Court recently stated in Albrecht,  
20    the case involving Merck and Fosamax just last year, "we also  
21    observed that through many amendments to the FDCA and to FDA  
22    regulations it has remained a central premise of Federal drug  
23    regulation that the manufacturer bears responsibility for the  
24    content of its label at all times."

25            We also learned from Wyeth that a drug manufacturer is

1 charged both with crafting an adequate label and with ensuring  
2 that its warnings remain adequate as long as the drug is on the  
3 market. "Thus, when risks to a particular drug become  
4 apparent, the manufacturer has a duty to provide a warning that  
5 adequately describes that risk."

6 So, how does a manufacturer alter its label if it  
7 finds a new risk? There are two ways. One, through the  
8 changes being effective, or CBE process; and two, through a  
9 prior approval supplement, which, as its name suggests,  
10 requires prior approval of the agency. A CBE, however, permits  
11 the manufacturer to make changes in the labeling to reflect  
12 newly acquired information without prior FDA approval when the  
13 change is to add or strengthen a contra indication, warning,  
14 precaution, or adverse reaction for which the evidence of a  
15 causal association satisfies the standard for inclusion in the  
16 label.

17 For example, in the case of warnings and precaution,  
18 the regulations recognize the need to get out important safety  
19 data fast, so, for clinically significant adverse reactions the  
20 CFR provides that the label must be revised to include a  
21 warning about a clinically significant hazard as soon as there  
22 is reasonable evidence of a causal association with the drug,  
23 but a causal relationship need not have been definitively  
24 established.

25 The post-marketing reporting obligation again becomes

1 relevant in the context of preemption which my colleague, Mr.  
2 Keller, will address as well as Mr. Bayman.

3           So, a couple of other related points, your Honor. The  
4 FDA now has authority to initiate a process to mandate label  
5 changes. Specifically, if FDA becomes aware of new safety  
6 information that FDA believes should be included in the  
7 labeling of the drug, it now has statutory authority to require  
8 new labeling, but when Congress granted FDA this authority to  
9 require new labeling it kept the responsibility of making the  
10 labeling changes on the manufacturer, which included the  
11 obligation to update the label under a CBE.

12           My second related point addresses generic  
13 manufacturers and non-prescription drugs, the ANDA holders.  
14 They have the obligation to report safety data to the FDA so  
15 that the agency can address updating the label to accurately  
16 reflect new safety data, and as Mr. Petrosinelli mentioned the  
17 duty of sameness, FDA recognized that as a result of the  
18 so-called duty of sameness, if a generic manufacturer believes  
19 that new safety information should be added to its drug's  
20 labeling, it must provide adequate supporting information to  
21 the FDA and the FDA will determine whether the labeling for the  
22 generic and the brand name drug should be revised.

23           Last, your Honor, I wanted to briefly talk about  
24 recalls and withdrawals. We heard mention of this in the  
25 opening statements of Defense counsel and I just wanted to

1 cover them as well. This is my third point.

2 Recalls and withdrawals are covered in 21 CFR, part 7.  
3 FDA's recall policy provides for removing or correcting  
4 consumer products that are in violation of laws administered by  
5 the Food and Drug Administration. The FDA prefers voluntary  
6 action by manufacturers and distributors so that they can carry  
7 out their responsibility to protect the public health and  
8 well-being from products that present a risk of injury or gross  
9 deception or are otherwise defective. Voluntary recalls are  
10 reserved for urgent situations.

11 Now, in addition to recalls, your Honor, FDA may also  
12 institute a market withdrawal, which again calls on the  
13 manufacturer who is ultimately responsible for the safety of  
14 the drug to take appropriate action and is liable for taking  
15 any actions that are inappropriate.

16 FDA recognizes that some market withdrawals may  
17 present a health hazard and can treat a market withdrawal in  
18 the same manner as a recall. The proof of that pudding is that  
19 FDA published a press release and put the recall of the  
20 Ranitidine products into the recall enterprise system that FDA  
21 uses to track recalls.

22 Last, your Honor, in this regard, FDA has enforcement  
23 authority to prevent interstate distribution of any drug that  
24 is adulterated or misbranded. In other words, if its labeling  
25 is false or misleading in any particular the FDA can prohibit

1 the sale of the drug through either recall, withdrawal, or  
2 other enforcement mechanisms.

3 So, those are the points I wanted to cover about  
4 post-marketing regulations, your Honor. With that, I yield  
5 back to Mr. Petrosinelli or Mr. Bayman for the next discussion.

6 I will put myself on stop video.

7 *MR. PETROSINELLI:* Thank you, your Honor. This is Joe  
8 Petrosinelli again for the Defendants.

9 Just one brief comment in response to Mr. Longer just  
10 to clarify one thing, and then I will turn it over to Mr.  
11 Bayman who will lead off the discussion on preemption, and that  
12 has to do with what Mr. Longer was saying right at the end  
13 about recall versus withdrawal.

14 This is important in the context of this case. When  
15 the FDA -- its action on April 1st of 2020, when it -- it asked  
16 for a withdrawal, not a recall, and that is significant, and  
17 your Honor can review the document, and it went through what  
18 the standard is for recall and what it is for withdrawal. It  
19 is significant because the standard -- as Mr. Agneshwar I think  
20 said in his opening, the standard for withdrawal is a removal  
21 or correction of a distributed product which involves a minor  
22 violation or no violation at all of FDA law.

23 So, that is the way in which the FDA chose to proceed  
24 with respect to Zantac, and I am sure there will be argument  
25 later about why they chose that as opposed to the recall

1 avenue, but I wanted to make that clear.

2 With that, I have no other comments on Mr. Longer's  
3 presentation, and I will turn it over to Mr. Bayman who is  
4 going to address preemption.

5 *THE COURT:* Thank you. Good morning, Mr. Bayman.

6 *MR. BAYMAN:* Good morning, your Honor. I am Andrew  
7 Bayman with the law firm King and Spalding and I'm counsel for  
8 Boehringer Ingelheim, or BI.

9 I am going to give the Court an overview of the  
10 Doctrine of Federal Preemption which the Defendants believe is  
11 a critically important issue in this litigation.

12 Could I have the first slide, please.

13 The Doctrine of Preemption is grounded in the  
14 supremacy clause of the Constitution, and under Supreme Court  
15 jurisprudence, this means that where state law conflicts or  
16 interferes with Federal law or standards, Federal law overrides  
17 State law. In the pharmaceutical drug context, the FDA has  
18 regulatory authority over all aspects of drug approval and  
19 sale. So, that means the FDA must approve the design of the  
20 product, the manufacture, and the labeling of the drug as part  
21 of the approval process.

22 Once the FDA approves, the manufacturers cannot change  
23 the drug itself without prior FDA approval. Once approved,  
24 manufacturers cannot make major changes to the manufacture or  
25 labeling of a drug without FDA pre-approval.

1           Preemption in this context attaches when Federal  
2 requirements conflict with what the Plaintiffs through their  
3 state law claims allege that State law requires. It is  
4 impossible to comply simultaneously with both State and Federal  
5 law.

6           The Supreme Court has recognized that Federal law can  
7 conflict with State law under different circumstances which  
8 give rise to preemption. The first is what is called express  
9 preemption. That occurs when Congress enacts a statutory  
10 provision expressly stating that the State law claims are  
11 preempted.

12           Another is the doctrine of implied preemption. Claims  
13 that are not expressly preempted can still be impliedly  
14 preempted. This occurs when State and Federal law directly  
15 conflict making it impossible to comply with both State and  
16 Federal law, but also where operation of State law poses an  
17 obstacle to achieving Congress' objectives or where Congress  
18 has taken exclusive control over an entire regulatory subject  
19 displacing impliedly all State law in that field.

20           Various Courts have recognized that claims involving  
21 pharmaceutical drugs can be preempted under a number of  
22 different circumstances. I am going to briefly address those  
23 now, your Honor.

24           Next slide.

25           I will start with express preemption. There is no

1 express preemption, your Honor, for prescription drugs.  
2 Over-the-counter drugs, however, are governed by the express  
3 preemption provision 21 U.S.C. 379r, which expressly preempts  
4 all State requirements applicable to over-the-counter  
5 manufacturers that are different, in addition to, or otherwise  
6 not identical with Federal requirements.

7 Now, 21 U.S.C. 379r contains a savings clause which  
8 does not preempt product liability claims. However, under  
9 subsection e of that same regulation, claims that are not  
10 traditional product liability claims such as claims solely for  
11 economic loss are preempted, and the Kanter case which we cite  
12 here is one example. Although there is no express preemption  
13 provision for prescription drugs, State law claims involving  
14 prescription drugs can still be preempted under the doctrine of  
15 implied preemption.

16 Because the FDA has regulatory authority over all  
17 aspects of the approval and the sale of drugs where State  
18 law -- from a State law lawsuit, or other State law cause of  
19 action, where that State law irreconcilably conflicts with the  
20 FDA's regulations and decisions preemption will attach.

21 The Courts recognize a number of specific situations  
22 where irreconcilable conflicts exist between State and Federal  
23 law with respect to claims against pharmaceutical  
24 manufacturers.

25 Next slide, please.

1           Two U.S. Supreme Court cases have held that Federal  
2 law broadly preempts claims against generic manufacturers. The  
3 first case, what is known as the Mensing case, held that  
4 warning defect claims against a generic manufacturer were  
5 preempted. In that case, the Plaintiff alleged failure to warn  
6 and claimed a generic pharmaceutical product's label was  
7 inadequate and it should have had a different warning.

8           The Supreme Court held that Federal law imposes a duty  
9 of sameness on generic drug manufacturers by requiring that the  
10 generic drug's labeling be the same as the brand name  
11 pharmaceutical product. Therefore, to adopt the Plaintiff's  
12 proposed warning the generic manufacturer could not  
13 simultaneously comply with the Federal duty of sameness and  
14 provide labeling State law allegedly demanded. The generic  
15 label, as pointed out previously, must be identical to the  
16 branded labeling. Therefore, failure to warn claims against  
17 generic manufacturers are preempted.

18           The second case from the Supreme Court, the Bartlett  
19 case, held that design defect claims against generic drug  
20 manufacturers are also preempted. Generic drugs must have the  
21 same active ingredient, the same route of administration, the  
22 same dosage form, the same strength and the same labeling as  
23 brand name pharmaceutical products. So, State law design  
24 defect claims that conflict with Federal law prohibiting a  
25 generic manufacturer from altering a drug composition are

1 preempted. Generic manufacturers cannot legally make generic  
2 drugs in another composition. The result is State law product  
3 liability claims are broadly preempted against generic  
4 manufacturers.

5 Next slide, please.

6 Certain state law claims against branded manufacturers  
7 are also impliedly preempted. Mr. Longer mentioned the changes  
8 being effected were CBE regulations which permits a  
9 manufacturer to make changes to a drug's label based on "newly  
10 acquired information" which provides reasonable evidence of a  
11 causal association of a clinically significant adverse reaction  
12 linked to a drug.

13 The regulations provide the newly acquired information  
14 must be evidence and data that was not previously submitted to  
15 the FDA or new analyses of previously submitted data if the new  
16 analyses reveal risks of a different type or a greater severity  
17 or frequency than previously included in the submissions to the  
18 FDA.

19 There are two leading cases from the United States  
20 Supreme Court, your Honor, with respect to implied preemption  
21 against branded manufacturers. They are the Wyeth versus  
22 Levine case and the Albrecht versus Merck case, which Mr.  
23 Longer briefly mentioned.

24 In Wyeth versus Levine the Court addressed whether  
25 State law failure to warn claims against brand name

1 manufacturers are preempted, it's a case from 2009, and in that  
2 case the Court held that claims in the case were not preempted  
3 because the manufacturer could have unilaterally added through  
4 the CBE regulation that you see on the screen stronger warnings  
5 about the drug in the label under the CBE regulations as  
6 allegedly required under State law without violating Federal  
7 law.

8           However, the Supreme Court did note that the FDA  
9 retains the ultimate authority to reject labeling changes made  
10 pursuant to the CBE regulation in its review of a  
11 manufacturer's supplemental application. The Supreme Court  
12 said, absent clear evidence that the FDA would not have  
13 approved the change to a drug's label, the fact that the FDA  
14 could have rejected the label change did not mean it was  
15 impossible to comply with Federal and State law from submitting  
16 a CBE supplement.

17           The second case, your Honor, Merck versus Albrecht,  
18 was decided last year, in 2019. The Court made some notable  
19 findings. First, the Court held that the question of  
20 preemption is one for the Court and not for a jury to decide.

21           The Court also in Albrecht tried to explain what the  
22 Levine clear evidence standard means. It stated, clear  
23 evidence is evidence that shows the Court the drug manufacturer  
24 fully informed the FDA of the justifications for the warning  
25 required by State law and that the FDA, in turn, informed the

1 drug manufacturer that the FDA would not approve a change to  
2 the drug's label to include the warning.

3           These cases typically arise, your Honor, in which the  
4 Plaintiff contends in his or her State law claim the warning  
5 should somehow have been different or changed and the Defendant  
6 contends that the FDA would not have approved that label  
7 change.

8           Next slide, please.

9           The next topic is preemption of State law design  
10 defect claims. Once a drug is approved, manufacturers are  
11 prohibited from making any major changes, and that would  
12 include modifying the qualitative or quantitative formulation  
13 of the drug product, without obtaining FDA's prior approval.

14           Therefore, although we have not seen the Plaintiffs'  
15 Master Complaint in this case, to the extent Plaintiffs' claims  
16 in this case will be that any changes to Zantac's design,  
17 formulation, or specifications, those would represent a major  
18 change requiring the FDA's pre-approval.

19           Any State law duty requiring unilateral action by a  
20 manufacturer that conflicts with FDA's regulations requiring  
21 FDA pre-approval results in preemption. The Court in Mensing  
22 held that the relevant inquiry for implied conflict preemption  
23 is whether a private party could independently do under Federal  
24 law what State law requires. If FDA pre-approval is required,  
25 then the claim is preempted, your Honor.

1           The Yates case recently, from 2015, in the Sixth  
2 Circuit similarly held that any claims the Defendant should  
3 have altered the formulation of the prescription medication in  
4 some way is preempted.

5           Importantly, your Honor, in the Bartlett case, which I  
6 had presented on the previous slide, which is a case involving  
7 a generic product, the Court in that case held that design  
8 defect claims are preempted as a matter of both Federal law and  
9 basic chemistry as the manufacturer could not unilaterally  
10 change the drug's composition without first obtaining the FDA's  
11 approval whether that drug was a generic or a brand name drug.  
12 So, Bartlett applies to design defect claims both for generic  
13 and brand name drugs.

14           To the extent Plaintiffs' design defect claims in this  
15 litigation are premised on a theory that Zantac should have  
16 been altered in some way to make it safer by changing its  
17 formulation, changing its manufacturing specifications, any  
18 other changes that would allegedly reduce high levels of NDMA,  
19 those claims are preempted.

20           Before concluding, your Honor, I want to briefly  
21 address two other important aspects of preemption. The first  
22 is the so-called stop selling or never sell claims.

23           In the Bartlett case, the First Circuit, before the  
24 case went to the Supreme Court, reasoned the manufacturer could  
25 comply with both Federal and State law by choosing not to make

1 the drug at all. The Supreme Court expressly rejected this  
2 logic and said that its preemption cases presume that an actor  
3 seeking to satisfy both his or her Federal and State law  
4 obligations is not required to cease acting altogether in order  
5 to avoid liability.

6 Similarly, in the Yates case from the Sixth Circuit,  
7 the Court rejected both an argument the manufacturer should  
8 have stopped selling the drug or should have never sold the  
9 drug in the first place under the same logic as Bartlett. The  
10 never selling, or never start selling rationale was rejected  
11 under the Bartlett Court's reasoning.

12 Second are claims that are so-called fraud on the FDA  
13 claims. These claims were addressed by the Supreme Court in  
14 the Buckman versus Plaintiff's Legal Committee case in 2001.  
15 The Food Drug and Cosmetic Act, which Mr. Petrosinelli  
16 described, contains no private right of action to enforce its  
17 provisions. Because of this, the Supreme Court found that  
18 certain claims seeking to enforce directly provisions of the  
19 act are impliedly preempted. In that case specifically the  
20 Court held that claims seeking to punish the alleged fraud  
21 committed on the FDA for not disclosing information during the  
22 approval process are impliedly preempted.

23 Next slide, please.

24 In sum, your Honor, depending on the way the claims  
25 are pled and developed in this case, the Defendants would

1 expect to argue that most, if not all of the claims are  
2 preempted in some way depending on the legal theory, and here  
3 you can see a summary of what I just covered in my  
4 presentation.

5 At this point, your Honor, I am going to turn it over  
6 to Mr. Keller for a rebuttal from the Plaintiffs.

7 *THE COURT:* Thank you, Mr. Bayman.

8 *MR. KELLER:* Good morning, your Honor. I will ask the  
9 obligatory questions, can you see me and hear me okay?

10 *THE COURT:* I can, thank you. Good morning.

11 *MR. KELLER:* For the court reporter, I am Ashley  
12 Keller from Keller and Lenkner. It is a great privilege to be  
13 with you this morning. I want to thank the Court and all of  
14 its staff and Special Master Dodge for doing such a superlative  
15 job of putting together the electronic means by which we are  
16 communicating today of 186 some odd participants. That cannot  
17 be easy logistically to do.

18 I am excited to talk about preemption, but before I  
19 do, I also want to thank my new friend and colleague, Ms.  
20 Zousmer, for taking over all of our screens and running the  
21 technology and shouldering that responsibility. It is a great  
22 relief for me that she has agreed to do that because that is  
23 not my area of expertise.

24 By agreement of the parties, we didn't put together  
25 rebuttal slides, so I am perfectly happy to use the Defendants'

1 slides on preemption for my remarks, so I'd ask Ms. Zousmer to  
2 go back to the first substantive slide and I will run through  
3 it from there.

4 Finally, let me offer my thanks to Mr. Bayman whose  
5 learned and cogent presentation covered a lot of the black  
6 letter law principles of preemption with which, of course, we  
7 agree, but there are some important areas of disagreement that  
8 I think are going to control all of the issues that are coming  
9 down the pike in this case. So, I do want to spend some time  
10 on those points of disagreement.

11 And I guess I will start not with a point of  
12 disagreement, but with an addition in response to an omission,  
13 which is that it is black letter law that preemption is an  
14 affirmative defense. The Supreme Court has said that multiple  
15 times, most recently in the Merck versus Albrecht case that Mr.  
16 Bayman referred to. And so always the burden of proof is  
17 relevant in a civil dispute. It is the other side's burden to  
18 carry both the factual and legal predicates of establishing  
19 preemption.

20 It is particularly important to focus on the burden  
21 with respect to implied conflict preemption and possibility  
22 preemption because the Supreme Court has said, starting in  
23 Wyeth, and again reaffirmed in Merck, that it is a demanding  
24 defense, it is quite difficult to establish.

25 The second point that I would make is a different

1 level of emphasis on the language of the supremacy clause, your  
2 Honor. Mr. Bayman focused, appropriately from his perspective,  
3 on the "shall be the supreme law of the land" language of the  
4 supremacy clause of Article 6, Paragraph 2, which is, of  
5 course, what establishes the preemptive of fact. We want to  
6 focus on a different word.

7 The supremacy clause says the Constitution and the  
8 laws, "laws of the United States which shall be made in  
9 pursuant thereof are the supreme law of the land."

10 The reason I put the accent on the word "laws" is  
11 because we are dealing here, of course, with the FDA and an  
12 agency and a regulatory body, and not all agency action carries  
13 the force of law. The Supreme Court has reiterated that the  
14 supremacy clause means what it says, it grants supreme status  
15 only to laws and agencies, in order to carry the force of law,  
16 have to go through certain hoops that administrative law  
17 principles establish. As Justice Thomas noted in his  
18 concurrence in *Albrecht*, hypothetical agency action or mere  
19 agency musings do not qualify as laws of the United States.

20 So, I hope the Court will indulge me for a moment  
21 while I go through some basic principles, a primer, if you  
22 will, on some agency law precedent from the Supreme Court which  
23 I think is eventually going to be important for the issues that  
24 the parties disagree with each other on in this case.

25 So, I will start with the seminal case of *Chevron*

1 versus NRDC. I think that it still claims the status as one of  
2 the five most cited Supreme Court precedents of all time. What  
3 Chevron says is -- in the wake of the New Deal Congress wanted  
4 to entrust expert agencies and regulatory bodies with the  
5 authority to make policy, and so they have wide latitude to  
6 interpret the statutes they administer.

7           And so the famous statement from Chevron is that if  
8 Congress has spoken to the precise question at issue in the  
9 statute in question, here the Food Drug and Cosmetic Act, then  
10 Courts don't have any latitude to defer to the agency, they  
11 have to enforce the statute according to its terms; however, if  
12 there is more than one reasonable interpretation of a statute,  
13 the agency gets leeway to decide which interpretation to  
14 embrace, and under certain circumstances, that interpretation,  
15 through the CFR, through the regulations, can carry the force  
16 of law and thus trigger the supremacy clause and preemption if  
17 there is a conflict with State law.

18           Since Chevron was decided the Supreme Court has added  
19 some important provisos that I want to flag for the Court. The  
20 first is a case called United States versus Mead, 533 U.S. 218,  
21 where the Supreme Court said, look, if Congress is going to  
22 delegate lawmaking power to an agency, which is still with  
23 experts, but they're unelected, they have to jump through  
24 certain formal procedural hoops before Courts are going to  
25 afford their pronouncements the force of law.

1           For example, if an agency like the FDA promulgates  
2 rules through notice and comment rule making which allows all  
3 the different stakeholders to provide their perspective and  
4 then considers those different points and promulgates a  
5 reasonable interpretation of the statute through regulation,  
6 that will carry the force of law.

7           If an agency engages in formal adjudication, acting  
8 very much like a court with a trial, with cross-examination,  
9 with witnesses, with evidence, and then issues a reasoned  
10 opinion interpreting statutory language which is susceptible to  
11 more than one interpretation, that can carry the force of law.

12           But mere informal action, publishing something on a  
13 website, a letter, a statement, an email from a regulator at  
14 the FDA, Courts can look at that, they can take into account  
15 that there are experts at the agency who chose to make that  
16 informal statement, but those do not carry the force of law  
17 under United States versus Mead.

18           Another important concept is when an agency is not  
19 issuing a rule, but is interpreting a prior rule that the  
20 agency promulgated, and there is a case called Hour (phon) that  
21 says agency interpretations of its own rules do not carry the  
22 force of law, but they are entitled to deference under certain  
23 circumstances. And importantly, the Supreme Court clarified  
24 just last term in a case called Wilkie, 139 Supreme Court 2400,  
25 where the question presented was, should the Court overturn

1 Hour deference altogether, the Court narrowly, in a five to  
2 four decision, said no, we are going to retain Hour deference,  
3 and agencies still can receive deference when they are  
4 interpreting their own regulations, but the office of the Hour  
5 doctrine was constricted by Wilkie.

6 What the Supreme Court said was, first, a regulation  
7 has to be genuinely ambiguous before we are going to give the  
8 agency any deference in interpreting it. The Supreme Court  
9 even said, "when we say ambiguous, we mean it." Courts are not  
10 allowed to just fly the white flag of surrender and say this  
11 regulation is kind of impenetrable, it's really tough to read,  
12 we are just going to let the expert agency decide what it means  
13 and move along. No. Courts have to conduct a much more  
14 thorough analysis when they interpret their regulations if they  
15 are going to get deference. There must be legitimate  
16 ambiguity.

17 Moreover, even if there is legitimate ambiguity, if  
18 the policy rationale behind the implementing statute that  
19 Congress passed doesn't support deference, Courts don't have to  
20 give deference. So, Hour deference still exists, but it exists  
21 in a much more narrow sphere in the wake of Wilkie from just  
22 last term.

23 The final administrative law point that I want to make  
24 to your Honor, which is important and I think stems directly  
25 from the logic of Chevron, comes from a case called Brand X,

1 545 U.S. 981, where the Supreme Court said agencies are allowed  
2 to and frequently do change their minds. If they change their  
3 mind by moving from one reasonable interpretation of a statute  
4 or a regulation to another reasonable interpretation of a  
5 statute or regulation, that choice must be respected. And  
6 indeed, Chevron itself was a case where the agency was moving  
7 from a previous interpretation with a new administration to a  
8 different interpretation of the statute, and Brand X makes  
9 clear that agencies are entitled to do that.

10 One of the things that Brand X flags as a reason to no  
11 longer necessarily afford the same level of deference to a  
12 prior interpretation of a statute or regulation is a change of  
13 administration. A different FDA is entitled to view the  
14 complete corpus of its regulations in a different way with  
15 different expertise and different reasonable interpretations  
16 brought to bear on that entire body of regulatory law.

17 So, with those basic principles firmly in view, let me  
18 move on in the order that Mr. Bayman did just talking about  
19 preemption for over-the-counter, generic, and then branded  
20 pharmaceutical manufacturers.

21 Ms. Zousmer, if you could move to the next slide,  
22 please. Sorry, one previously. There we go. The OTC  
23 manufacturers.

24 So, I am not sure whether there is disagreement here,  
25 your Honor, but I just wanted to state our position for

1 completeness because there might be.

2 We, of course, agree that Section 379r is an express  
3 preemption provision that applies to OTC manufacturers, and we,  
4 of course, agree that subsection e creates a savings clause  
5 that says the preemptive effect of 379r will not have any  
6 application to products liability cases.

7 Where there may be some disagreement is with respect  
8 to the Kanter case that is cited in this slide, and I think the  
9 proposition of law that Mr. Bayman articulated was that the  
10 product liability law exception to preemption does not allow  
11 any recovery of economic losses.

12 We agree that that is what the Kanter case says, but  
13 we do not agree that that applies across the board. What  
14 Kanter was saying -- it's an intermediate California Court of  
15 Appeals case and it says that, under California law, products  
16 liability law does not allow recovery for economic losses.

17 So, to the extent that your Honor, in considering  
18 California cases in the future where California law applies,  
19 believes that Kanter is a good prediction of what the  
20 California Supreme Court would say, we agree that that is  
21 relevant authority that you could consult, but Kanter does not  
22 purport to speak for the law of the other 49 sovereign states  
23 who have every right to define the metes and bounds of their  
24 own products liability law, and have every right to say that  
25 products liability law can allow recovery for economic losses.

1           For that proposition of law, in a case that actually  
2 cites Kanter, I would commend to the Court's attention Carter  
3 versus Novartis, 582 F.Supp.2d 1271, from the Central District  
4 of California in 2008. That is a case that actually goes  
5 against us on preemption, but it very clearly notes that Kanter  
6 is only speaking for California and that the law of every other  
7 state is entitled to encompass whatever it wants with respect  
8 to products liability and recovery.

9           So, the other point of disagreement that may exist  
10 between us here is about the express preemption clause. We  
11 agree again that subsection e allows products liability claims,  
12 but the express preemption clause doesn't foreclose every other  
13 type of State law claim. What it forecloses are claims that  
14 are different, or in addition to, or not identical with the  
15 Federal requirements. If there is a State regime that doesn't  
16 sound in products liability law, but exactly mirrors the  
17 Federal statute or regulations that are entitled to the force  
18 of law, those claims are also not preempted, and for that  
19 proposition of law I cite to your Honor Canale versus Colgate  
20 Palmolive, 258 F.Supp.3d 312, from the Southern District of New  
21 York, 2017.

22           We will, of course, have many more citations when we  
23 get to the briefing on these issues, but I at least wanted to  
24 give your Honor a couple of cases that you could look to that  
25 we think clearly establish the principles I have just

1 articulated.

2 So, that, I think, covers the scope of our potential  
3 respectful disagreements with respect to the OTC manufacturers.

4 Now let's turn, please, Ms. Zousmer, to the next slide  
5 on the generic manufacturers. And this is going to be, as your  
6 Honor could no doubt predict, an important point of focus  
7 between the parties. It is going to control a lot of the  
8 claims for a lot of Plaintiffs and certain Defendant  
9 manufacturers, so it is worth spending a few moments on this  
10 slide. I am going to focus most on the left most part of the  
11 slide in Mensing because I don't think that Bartlett adds that  
12 much other than to simply apply Mensing faithfully. So,  
13 Mensing is, I think, where the action is and it's the seminal  
14 case with respect to generic manufacturers.

15 We agree with a lot of what Mr. Bayman said about the  
16 case, but there are some important differences that I will get  
17 into now.

18 So, Mensing rests on two basic principles, first, as  
19 already articulated, the duty of sameness. The FDA regulations  
20 do indeed require that ANDA holders have the same label as the  
21 branded manufacturer.

22 The second principle of Mensing, though, which is more  
23 controversial and I think, in light of the principles I  
24 previously articulated, more open to question is that ANDA  
25 holders are not allowed to invoke the CBE process, the change

1 being effected process, that the branded manufacturers are to  
2 change their label unilaterally and then see if the FDA chooses  
3 to pull them back.

4 The reason that's more controversial, your Honor, is  
5 that in *Mensing* the Supreme Court, through Justice Thomas, gave  
6 deference under *Hour* to the FDA's then interpretation of its  
7 own regulations. There is not a regulation that says that the  
8 ANDA holders are not allowed to implement a change unilaterally  
9 through the CBE process. It was the FDA's interpretation of  
10 its own regulations that led the Court under *Hour* to that  
11 conclusion.

12 Obviously, we have a different FDA today, and your  
13 Honor will be allowed at the appropriate time to solicit the  
14 opinion of the FDA to see if they still adhere to the view that  
15 the previous FDA did, and I believe your Honor is going to be  
16 obligated under the *Wilkie* precedent to do a more searching  
17 analysis of whether the regulations are genuinely ambiguous.  
18 The Court in *Mensing* did not do that, it simply cited *Hour* and  
19 moved on. Interestingly, Justice Thomas now believes that *Hour*  
20 should be overturned, so the lineup of the Court on this  
21 question is different. But let's put a pin in that.

22 I believe that even if you take *Mensing* on its own  
23 terms, Mr. Bayman's statement of the law is a little bit too  
24 broad. *Mensing* does not say that generic manufacturers cannot  
25 be held liable for their storage conditions, for the

1 manufacturing conditions, if they store the drugs at too high a  
2 temperature and that produces NDMA, if the manufacturing API  
3 partners that they have selected are introducing NDMA in the  
4 manufacturing process. There is no regulation in Mensing or  
5 that anybody has pointed to that would preclude Plaintiffs from  
6 recovering under those sorts of theories. So, Mensing does not  
7 speak to that.

8 Similarly, I don't even think that Mensing speaks to a  
9 broad prohibition on duty to warn claims. Quite to the  
10 contrary, Mensing embraces the FDA's position that there can be  
11 duty to warn claims, it just can't be duty to warn through the  
12 label. So, let me unpack that for a moment, your Honor.

13 There are many states, including California, that have  
14 said our common law duty to warn includes the duty to warn  
15 third parties such as the FDA if that is the most effective  
16 means of disseminating important safety and efficacy  
17 information to doctors, consumers, and patients. And through a  
18 case called Coleman versus Medtronic, 223 Cal.F4th 413, the  
19 California intermediate Court of Appeals expressly said parties  
20 subject to the FDCA have a duty to warn the FDA if they become  
21 aware of no risks.

22 So, in this context, under California law, and the law  
23 of other states when we get to the area analysis that we will  
24 present to your Honor, there can be a duty by the generic to  
25 inform the FDA of adverse events, of new risks that they have

1 discovered, and invite the FDA to change the label. You don't  
2 have to look any further than Mensing itself and the FDA's own  
3 position in that case to see that this is true.

4           What the FDA told the Court in Mensing was there is no  
5 preemption because the generics have an obligation to come to  
6 us with new information so that we can try and change the  
7 product label, and they were quoting 57 Federal Regulation  
8 17950-01, paragraph 40, and the Supreme Court agreed with that.  
9 They said, we'll agree that the FDA is right that the generics  
10 have a duty to come to us so that we, the FDA, can change the  
11 label, but the problem in that case was the theory of recovery  
12 for the Plaintiff was failure to change the label. The Federal  
13 regulations prohibited the generic from unilaterally changing  
14 the label so there could be no recovery.

15           If the theory of recovery under the State common law  
16 is, you didn't warn, generics, the FDA to allow the FDA to  
17 implement the label change, that is not preempted, and there is  
18 a persuasive authority from the Ninth Circuit in a case called  
19 Stengel versus Medtronic, 704 F.3d aa 1224, it was an en banc  
20 decision by Judge Fletcher that embraces this theory of  
21 recovery and says that if that is what the State common law  
22 warning regime requires, there is no preemption under the FDCA  
23 or any FDA regulations that are entitled to the force of law.

24           Let me just briefly cover Bartlett on this slide, your  
25 Honor, because, as I mentioned, I don't think it adds very much

1 to the Mensing analysis. The warning defect claim, as the top  
2 bullet under Mensing, and the design defect claim under  
3 Bartlett makes it seem like all sorts of different types  
4 of claims are preempted, but it was basically the same theory  
5 of recovery. Under New Hampshire law in Bartlett, it is a  
6 design defect if you don't have a proper warning on your  
7 product. So, the Plaintiffs were trying to just shift from one  
8 theory of recovery to another, and the Supreme Court said, no,  
9 I don't care what you style the theory, what you name the tort,  
10 if you are trying to make the generic unilaterally change the  
11 label, Mensing says you can't do that, and so it is preempted.

12 We agree with Mr. Bayman that Bartlett clearly held  
13 that a stop selling theory is not actionable, and so that is, I  
14 think, the gloss that Bartlett provides for Mensing.

15 Could you turn to the next slide, please. Thank you.

16 I am going to be very brief with respect to the  
17 branded manufacturers because, very respectfully to my learned  
18 colleagues on the other side, I don't think that this is really  
19 a close call. The Wyeth case, I would commend it to the Court,  
20 it is crystal clear that it is extremely difficult for a  
21 branded manufacturer to invoke implied impossibility preemption  
22 because of the CBE regulations.

23 The only thing that I would point out on the slide,  
24 your Honor, that I believe is -- I won't say misleading, but  
25 incomplete is the Celexa case, which essentially makes it seem

1 like if you already have the data in your possession when you  
2 first went to the FDA that can't be a basis for invoking the  
3 CBE process. That was roundly rejected in Wyeth, 555 U.S. at  
4 569, and I'll just read directly from the opinion.

5 "Newly acquired information is not limited, not  
6 limited to new data. The rule accounts for the fact" -- the  
7 FDA rule that is. "The rule accounts for the fact that risk  
8 information accumulates over time and that the same data may  
9 take on a different meaning in light of subsequent  
10 developments."

11 And so, the notion that the data has to be new is  
12 again squarely at odds with the Supreme Court's binding  
13 pronouncement in Wyeth. So, the only way that the branded  
14 manufacturers are going to be able to invoke the very difficult  
15 defense of preemption in this case is to say that they  
16 presented everything that the Plaintiffs are eventually going  
17 to present to you, your Honor, and ultimately on remand to the  
18 jury, about what happened here, what the risks were associated  
19 with these drugs. They are going to have to say that they  
20 presented that to the FDA, and had they done so, the FDA would  
21 have said, no, we are reversing your label change. You invoked  
22 the CBE process improperly, you have to go back to the old  
23 label.

24 I think it is going to be exceedingly difficult for  
25 the brands to meet that heavy burden given that we don't have

1 to deal in the realm of hypotheticals. We know what the FDA  
2 actually did here when presented with a scintilla of the  
3 information that we are ultimately going to present at trial,  
4 it took the products off the market entirely. It didn't say  
5 change the label; it just said stop taking these drugs. So, I  
6 think that the affirmative defense of preemption for the  
7 branded manufacturers is going to be a very tough one to  
8 surmount, very respectfully.

9 If we can go to the last slide -- you can skip this  
10 slide and go to the last slide, please.

11 I will conclude where I began, which is that  
12 preemption is an affirmative defense and a very difficult one  
13 to surmount when it comes to implied impossibility preemption.  
14 I think this concluding chart makes it seem like we have a  
15 tightrope to walk in order to succeed on preemption, but it is  
16 actually the other way around.

17 I would just conclude by saying that the final two  
18 points, the stop selling point and the fraud on the FDA point,  
19 we agree with that, but I would characterize those bullets as  
20 truthful irrelevancies. No Plaintiff is bringing a stop  
21 selling or fraud on the FDA claim. So, while those are correct  
22 propositions of law, I am not sure that they have any salience  
23 with respect to the claims that the Plaintiffs are bringing.

24 With that, your Honor, unless you have any questions  
25 at this time, I am happy to turn the Zoom presentation back

1 over to my friend, Mr. Longer.

2           *THE COURT:* Okay, thank you. Thank you, Mr. Keller.  
3 We are going to have Mr. Longer come back on.

4           There you are.

5           *MR. LONGER:* Thank you, your Honor. I tried to get  
6 over my technical difficulty before. Fred Longer for the  
7 record.

8           I was asked to explain the theories of the case as we  
9 anticipate filing of a Master Complaint. While we were, and  
10 still are, investigating matters without the benefit of formal  
11 discovery, we have learned a great deal about Zantac and  
12 Ranitidine containing products. Obviously, our investigation  
13 is ongoing, but I hope this discussion provides the framework  
14 within which Plaintiffs perceive our theories of the case.

15           What I will describe is that there are basically three  
16 components to the framework. Those include, one, the  
17 responsible Defendants; the second is the mechanism by which  
18 injury occurs; and the third are the legal theories we will  
19 likely be pursuing in the Master Complaint against any  
20 particular Defendant.

21           So, as you see on the screen, your Honor, the first  
22 tier there is the identification of the different types of  
23 Defendants. So, I would like to begin in the middle actually  
24 with the active pharmaceutical ingredient manufacturers, we  
25 call them API manufacturers for short. They sell API to finish

1 dose manufacturers, who then sell the Ranitidine containing  
2 products to distributors who then distribute it and sell the  
3 product to retailers, including but not limited to pharmacies,  
4 drug stores, grocery stores, etc. to dispense them to patients  
5 who are our Plaintiffs. The API Defendants have not been  
6 named, but our investigation suggests they may be responsible  
7 parties, and their liability is noted in this flow chart.

8 Just as an example, your Honor, Dr. Reddy, which is an  
9 India -- an Indian company, has subsidiaries here in the United  
10 States and would be an example of an active pharmaceutical  
11 ingredient manufacturer.

12 The next type of Defendant is the brand manufacturer,  
13 they are the finish dose manufacturer. These include the GSK  
14 Defendants, the Boehringer Ingelheim Defendants, Pfizer, the  
15 Sanofi Defendants.

16 Next is the generic manufacturer, generic  
17 manufacturers are also finish dose manufacturers. These  
18 include current and former and abbreviated new drug application  
19 holders, and examples of them, you may recognize the Apotex  
20 Corporation which is situated in Weston, Florida, there are  
21 others.

22 The next type of Defendant is the distributor, this  
23 will include the big three, which is Cardinal Health,  
24 AmerisourceBergen and McKesson.

25 Finally, there are retailers, pharmacies like CVS,

1 Walgreens. Some of these companies actually are involved in  
2 distribution as well, but generically, those are the types of  
3 Defendants -- I'm sorry, retailers that will be named.

4 So, if we could advance the slide, thank you, to the  
5 next level, which is the method of injury. And by the way, I  
6 owe a debt of gratitude to Ms. Zousmer as well because this is  
7 terrific to have the assistance.

8 The method of injury is the overarching contentions in  
9 this litigation which my co-counsel will later explain in the  
10 science presentation about Ranitidine being an unstable  
11 molecule. It's susceptible of forming NDMA in three discrete  
12 ways. So, the first way we describe is that NDMA forms in the  
13 body. The way the human body digests Ranitidine results in the  
14 molecule breaking down into NDMA.

15 The next concern is that NDMA increases through the  
16 manufacturing process. So, through the manufacturing process,  
17 use of solvents and other procedures, NDMA is created in the  
18 Ranitidine product itself.

19 The last, as we found out from many of the studies  
20 that have been done by the FDA, NDMA increases through storage  
21 and transport. This method was confirmed by the FDA and other  
22 independent laboratories who found extraordinarily high  
23 quantities of NDMA in Ranitidine products which was associated  
24 with storage and transport and exacerbated by heat and time.

25 So, following up, if we could advance the slide once

1 more, please. Thank you.

2 So, from those theories the claims being asserted  
3 against the various Defendants flow. We are going to have  
4 strict liability failure to warn claims, we will have strict  
5 liability design defect claims, and we will have strict  
6 liability manufacturing defect claims against the various  
7 Defendants as identified here.

8 We will also have negligence claims, we will have  
9 fraud based claims like negligent misrepresentation. We will  
10 have supply chain defect claims which address the liability for  
11 heat and time. We will have warranty claims, express and  
12 implied warranty claims. We will also be asserting equitable  
13 remedies, such as unjust enrichment.

14 Now, as these cases present themselves in this court  
15 through diversity jurisdiction choice of law determinations  
16 will result in different state laws being applied depending on  
17 the citizenship of each Plaintiff and other factors.

18 That, in essence, describes the theories of the case  
19 and where we intend for the litigation to proceed.

20 The next point of discussion, your Honor, is related  
21 to a procedural point regarding Lexecon, which is an issue that  
22 is unique to multi-district litigation.

23 In the Lexecon case, the Supreme Court curtailed the  
24 longstanding practice of transferee Courts to self transfer  
25 within the MDL in order to preside over a trial of foreign or a

1 transferred action.

2 The Supreme Court's ruling was based on a literal  
3 interpretation of Section 1407, which requires that any action  
4 transferred for consolidated proceedings shall be remanded by  
5 the panel at or before the conclusion of such pretrial  
6 proceeding to the District Court from which it was transferred  
7 unless it shall have been previously terminated.

8 Following the Supreme Court's ruling, MDL Courts have  
9 observed different practices to obtain the end of preserving  
10 their ability to conduct representative trials that remain  
11 within their authority. Either the MDL Court tries cases that  
12 were originally filed in the transferee forum, or the Court  
13 evokes a waiver of each party's right to a Lexecon remand so  
14 that the trial may occur in the MDL court.

15 The conduct of bellwether trials, your Honor, is  
16 essential to afford the parties and the Court information and  
17 jury feedback regarding both the merits of the claims and  
18 defenses and the efficacy of witness testimony and evidence  
19 presentation. Such trials also require a commitment of both  
20 judicial and litigant resources.

21 For those reasons, it is recognized in MDL proceedings  
22 that the results of bellwether trials are only valuable to the  
23 extent they are instructive, and every effort should be made to  
24 select and try bellwether cases which are truly representative  
25 of the entire census of cases filed in the MDL.

1           In some instances, one or both parties refused to  
2 provide a Lexecon waiver. Typically, a Plaintiff who prefers  
3 the convenience and availability of local witnesses, doctors,  
4 for example, refused to waive their right to a trial in the  
5 transfer order forum.

6           However, there are occasions where Defendants, for  
7 tactical purposes, refused to waive their Lexecon rights.  
8 Whereas there are a multitude of Plaintiffs in MDLs who are  
9 willing to waive their Lexecon rights and participate in the  
10 bellwether process, there are a more finite number of  
11 Defendants, and should the Defendants refuse to waive their  
12 Lexecon rights here, we believe the Court -- the Court and  
13 Plaintiffs' leadership should be informed early on in the  
14 litigation to permit the development of alternative bellwether  
15 trial plans.

16           Just by way of example, Your Honor, this was a recent  
17 experience of mine in the Xarelto litigation where we were --  
18 Judge Fallon presided over that MDL, and he sits, of course, in  
19 New Orleans, in the Eastern District of Louisiana, and the  
20 Defendants in that case refused to waive their Lexecon rights,  
21 so the Court was restricted to trying cases that were basically  
22 filed in Louisiana or Mississippi because there were no Texas  
23 Plaintiffs that Plaintiffs could try.

24           So, it became very restrictive, and obviously not very  
25 representative of all of the different claims across the United

1 States because we were limited to Louisiana or Mississippi law  
2 to determine Plaintiffs' rights.

3 So, that refusal to waive Lexecon in that instance was  
4 known early on, and it directed and channeled the parties  
5 regarding how they proceeded through the bellwether process,  
6 but it is certainly something that we think we should know  
7 early on in the litigation so that we, when we get to the  
8 bellwether selection process, are very prepared as to how to  
9 proceed.

10 Unless the Court has any further questions, that is my  
11 conclusion and I would turn it over to counsel opposite.

12 *THE COURT:* Okay. No, no questions at this time. I  
13 want to make sure everyone has an opportunity.

14 Who are we going to next?

15 *MR. PETROSINELLI:* Your Honor, this is Joe  
16 Petrosinelli. I think we have fallen a little behind in time  
17 after that rebuttal on preemption, so let me just save some  
18 time here and say, in terms of what Mr. Longer just said, I  
19 don't have much to say about the Plaintiffs' claims. Those  
20 arrows made me a little dizzy, but I think whenever we see the  
21 master complaint we will be able to talk about what claims  
22 there actually are.

23 With respect to Lexecon waivers, in my experience, we  
24 are way, way too early in this litigation to be talking about  
25 that. I am sure we will have that discussion somewhere down

1 the road. In my experience, just as often Plaintiffs don't  
2 waive as Defendants, but whatever it is, when we get the census  
3 data and so on I think we will be able to have an intelligent  
4 discussion about that, so I don't have any particular comment  
5 about that right now.

6 To keep us going, I will turn it over to Mr. Keller  
7 who is going to speak on the innovator liability theory.

8 *THE COURT:* Okay. Let me just let you know that I am  
9 willing to forego the 15 minutes I had allotted for Q and A  
10 before we break for lunch. I don't want you to feel rushed,  
11 Mr. Petrosinelli, so if you had something more you wanted to  
12 say now, feel free to say it and then you'll have an  
13 opportunity to respond to Mr. Keller afterwards.

14 I do want to just, obviously, remind everyone that  
15 there is going to be ample time throughout this litigation to  
16 have full briefing. I am very mindful that this is broad  
17 strokes, this is an overview, and I don't want anyone to feel  
18 concerned in not being able to present everything that you  
19 might otherwise do when it is time for a full briefing.

20 *MR. PETROSINELLI:* Thank you, your Honor. I don't  
21 have any further comments. I will turn it over to Mr. Keller  
22 who is going to explain Plaintiffs' innovator liability theory.

23 *THE COURT:* Okay. Mr. Keller, so coming up on the  
24 lunch hour.

25 *MR. KELLER:* Thank you, your Honor. Ashley Keller

1 again for the Plaintiffs. I will now adhere to Polonius' maxim  
2 that brevity is the soul of wit and move through innovator  
3 liability much more quickly.

4 So, let me confess that I allowed innovator liability  
5 to be the title of this slide because it is commonly referred  
6 to that way, but with a little bit of reluctance because  
7 innovator liability is not the name of the tort in any state,  
8 it is just common law negligence that is being applied, and the  
9 office of this tort of common law negligence and this theory  
10 really only applies with respect to folks who only took an  
11 exclusively generic version of the drug.

12 The theory of liability here, again applying common  
13 law negligence principles under the law of certain states, is  
14 that the branded manufacturer can be held liable because the  
15 label for the brand is being put on the generic product for  
16 generic sales. This stems from the regulatory environments  
17 that we were talking about previously with the duty of sameness  
18 and the fact that the generic and the holder has to use the  
19 brand's label.

20 What certain State Supreme Courts have said is that  
21 the brand thus foresees that if they don't take their  
22 responsibility seriously and use the CBE process appropriately  
23 to change their labels that any generic sales are going to also  
24 fail to warn. So, it is appropriate as a matter of state  
25 public policy to hold the brand accountable for those generic

1 sales.

2           So, the leading case in this regard comes from the  
3 California Supreme Court, it's TH versus Novartis, 4 Cal.5th  
4 145. To very quickly talk about the policy rationale behind  
5 this theory of recovery, after going through the common law  
6 negligence principles, it's the same elements of negligence,  
7 duty, breach, causation, and damages. What the California  
8 Supreme Court said is that as a matter of public policy, if the  
9 brands are not held accountable for the generic sales when  
10 there is a failure to warn it will actually encourage consumers  
11 to buy only the branded product because that is the only way  
12 they will get to recover for a failure to warn.

13           On the margin, as an economic proposition, that runs  
14 directly counter to the policies of California and to the  
15 policies of the United States which is to lower prescription  
16 drug prices by encouraging consumers to take a generic version  
17 of the product after a brand loses brand exclusivity and  
18 patents expire or what have you. So, once they are no longer  
19 charging the monopoly price we want consumers to buy the  
20 cheaper version of a drug, and this is a good way to ensure  
21 that they do so, by imposing a duty on the brand that they  
22 should foresee given their responsibilities and the unique  
23 regulatory framework of prescription drugs.

24           Just very quickly, there are some variations on the  
25 California version of this theory. For example, Massachusetts,

1 in Rafferty versus Merck, 479 Mass. 141, from 2018, said we  
2 want to balance the policy considerations. On the one hand we  
3 agree the brands should be held accountable when they really  
4 misbehave, but on the other, it is a big thing to hold them  
5 accountable for a different manufacturer of sales, so we're  
6 going to raise the level of misconduct to gross negligence as  
7 opposed to mere negligence.

8           There are some State Supreme Courts, admittedly, that  
9 have rejected the theory. The West Virginia Supreme Court did  
10 so last year. Different Federal Courts have made different  
11 predictions of what State Supreme Courts would do under the  
12 Erie Doctrine, and your Honor is going to have to engage with  
13 that issue as well because most states have not said one way or  
14 the other certainly through their state highest court whether  
15 they would embrace this common law theory of negligence, but  
16 that is the theory in a nutshell.

17           Unless you have questions, I am happy to leave it  
18 there.

19           *THE COURT:* Okay, thank you.

20           *MR. BAYMAN:* Your Honor, Andy Bayman again. Just in  
21 the interest of time, I am not going to do a rebuttal other  
22 than to say Ms. Sharpe pointed out some of our contentions in  
23 her opening. I would note that every Federal Circuit Court of  
24 Appeals that has considered this question has rejected  
25 innovator liability, as well as the highest Courts of the State

1 Legislatures in four states, and Florida has also, as well as  
2 the Eleventh Circuit rejected it. I have nothing further in  
3 the interest of time, your Honor.

4 *THE COURT:* Okay. Were there any other presenters in  
5 the law presentation?

6 *MR. PETROSINELLI:* Yes, your Honor, the next thing is  
7 that Mr. Longer will present on the medical monitoring cause of  
8 action of the Plaintiffs.

9 *MR. LONGER:* Back again, your Honor, thank you. Fred  
10 Longer for the record.

11 Because so many people were exposed to NDMA in the  
12 Zantac or Ranitidine containing products they consumed, they  
13 are now at risk of contracting a latent disease of cancer. For  
14 every harm there is a remedy and medical monitoring fits that  
15 maxim, your Honor.

16 The theory of the claim itself, the thinking behind  
17 the monitoring, I think is best explained in a case just around  
18 the corner here from where I used to live in Paoli, the Paoli  
19 Railroad Yard case, Judge Becker. In that opinion the Court  
20 said that medical monitoring is a legal theory by which  
21 Plaintiffs seek to recover the costs of periodic medical  
22 examinations that they contend are medically necessary to  
23 protect against the exacerbation of latent diseases brought  
24 about by exposure to a harmful substance.

25 So, that is the essence of the claim. There are

1 choice of law concerns that arise in that because there are so  
2 many Plaintiffs in this litigation.

3           Since the seminal case of Friends For All Children,  
4 which was out of the D.C. Circuit, a large number of Courts  
5 around the country recognize the validity of approving some  
6 form of medical monitoring to persons seeking equitable or  
7 legal relief. State Supreme Courts recognize that medical  
8 monitoring claims are available in Arizona, California,  
9 Florida, Maryland, Massachusetts, Nevada, Pennsylvania, Utah,  
10 and West Virginia.

11           Now, Mr. Agneshwar earlier said that medical  
12 monitoring is not accepted in the majority of the states. We  
13 disagree, in fact, we see it just the opposite, but that issue  
14 will present itself at a more appropriate time.

15           Meanwhile, we submit that most jurisdictions authorize  
16 medical monitoring theories of recovery.

17           There are differences in how states treat medical  
18 monitoring theories, they exist, but the variances are often  
19 minor and groupings of claims can be employed to manage any  
20 differences amongst those variations.

21           Finally, how do Courts treat medical monitoring? Some  
22 Courts, depending on the jurisdiction, recognize medical  
23 monitoring as a distinct cause of action for which damages are  
24 recoverable. That is certainly the case here where I live, in  
25 Pennsylvania. The Supreme Court here in the Redland Soccer

1 case found that to be the case. Other Courts simply find  
2 medical monitoring is available as a form of damages. That is  
3 the case in California, Potter versus Firestone. And still  
4 even other Courts recognize medical monitoring in the form of  
5 an equitable trust. That goes back to the Friends For All  
6 Children case.

7 This theory is particularly apt for the class actions  
8 which we will be discussing, but it is a widely recognized  
9 theory of recovery either in tort or in damages.

10 I believe Mr. Petrosinelli may have some comments  
11 based upon what I said, but I will leave it up to him.

12 *THE COURT:* Thank you, Mr. Longer.

13 *MR. PETROSINELLI:* Thank you, your Honor, Joe  
14 Petrosinelli again for the Defendants. I have the next two  
15 sections which will be quick. We're coming up near to the end  
16 here.

17 One of my sort of rebuttal on medical monitoring is,  
18 your Honor will just have to see the case law and if you want,  
19 we can submit you the states, but by our count there are 16  
20 states out of the 50 that recognize medical monitoring either  
21 as a cause of action, that is seven states, Florida happens to  
22 be one, and then, or as a remedy for a traditional tort claim  
23 like a negligence claim, that is nine. We think it is 16  
24 states, which is important because, as Mr. Longer says, when we  
25 talk about the class actions related to medical monitoring it

1 presents a problem, we think, for class certification, the  
2 difference in state law. Anyway, that is all I will say about  
3 medical monitoring. I'm sure, as we get into it, we can talk  
4 to the Court about our respective views on which states  
5 recognize it and which states don't.

6           The next section we have is a few selected defenses  
7 that the Court is likely to encounter in the case beyond  
8 preemption. The first one is Statutes of Repose. Because this  
9 product was on the market for so long, many states have -- 19  
10 by our count have a Statute of Repose, Florida included, that  
11 applies in products liability actions.

12           Typically -- there's a little variation in the state  
13 laws, but typically from the point at which the Defendant sold  
14 and delivered the product until -- and then you count the years  
15 forward, most states it's ten years, some states it's 12, some  
16 states it's 20, but those are the states, the 14 states that  
17 have statutes that bar product liability claims a set number of  
18 years, as I say, typically ten after the product is sold or  
19 delivered.

20           There is an asterisk next to Alabama because that  
21 actually is not a statute, but it's common law in Alabama.

22           Then there are five states listed there where it  
23 doesn't create an absolute bar, like a traditional Statute of  
24 Repose normally does, but a rebuttal of presumption that the  
25 product was not defective if the injury took place that much

1 longer after the Defendant sold and delivered the product.

2 So, that is a defense that will be -- you see a lot of  
3 big large states in there where I expect we are going to have a  
4 lot of claimants from the census. That will be in play. There  
5 are obviously exceptions under certain state statutes that will  
6 have to be dealt with, but just in terms of a core defense,  
7 that is one of them.

8 The next one I was going to talk about before I turn  
9 it over to Mr. Bayman is -- next slide, please.

10 There are also a number of states, Florida also  
11 included, that create statutory defenses for products that  
12 comply with Government standards. Some of them, like the  
13 Florida law, are general to all Government standards, or some  
14 states, like Michigan you see there, for example, it is  
15 actually specific to FDA approved products, and again,  
16 depending on the state -- and these are only three states,  
17 there are other states that have statutes like this -- either  
18 it is a bar to recovery, or it is more commonly a rebuttal of  
19 presumption of non-defectiveness, or you see New Jersey, that  
20 the label is adequate.

21 Those are two defenses that you are likely to see come  
22 up in the context of this litigation, and I will turn it to Mr.  
23 Bayman to talk about one or two more.

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

25 *MR. BAYMAN:* Thank you, your Honor. I will be quick

1 with the lunch hour coming up, and Ms. Sharpe covered this  
2 briefly in her opening.

3 But Plaintiffs have the burden of proof in this  
4 litigation to demonstrate the particular claimant consumed  
5 Ranitidine, whether branded or generic, that the Plaintiff also  
6 has the burden of identifying which manufacturer's Ranitidine  
7 was consumed, and the Plaintiff also has the burden of  
8 demonstrating that harmful levels of Ranitidine were consumed.

9 In *Levine versus Wyeth*, not the same case as the  
10 Supreme Court case we talked about, and I would commend that  
11 decision to your Honor, the Court dismissed claims against  
12 branded manufacturers where the Plaintiff's testimony was that  
13 he ingested only a generic form of the drug and the Court does  
14 an analysis about the need for proof of use and for product  
15 identification because a manufacturer does not owe a duty to a  
16 Plaintiff who did not consume its product.

17 This is a key issue in this litigation, your Honor,  
18 because, according to the initial census data, more than half  
19 the claimants have reported using more than one medication.

20 Finally, your Honor, for me, there are issues of  
21 personal jurisdiction in the case. I just want to highlight  
22 for your Honor, I am not going to get into those in any detail,  
23 but several cases in this MDL have named the foreign, that is  
24 non U.S. parent companies of GlaxoSmithKline and Sanofi, these  
25 companies never held the NDA for Zantac, and for manufacture or

1 distributor promoted Zantac in the United States and they will  
2 be asserting personal jurisdictional claims. Because of their  
3 foreign status, general jurisdiction does not apply, and the  
4 analysis would be a specific jurisdiction analysis.

5 Next slide, please, Ms. Zousmer.

6 The test in the Eleventh Circuit is the Waite case.  
7 You see that the Plaintiffs have to establish the first two  
8 elements, that their claims arise out of or relate to at least  
9 one of the Defendant's contacts with the forum, and that,  
10 importantly, that the Defendants purposely availed themselves  
11 of the privilege of conducting activities in the forum.

12 The Takata case, which was an MDL also in the Southern  
13 District of Florida, holds that generalized and conclusory  
14 allegations that a foreign Defendant designed, developed,  
15 manufactured, marketed, sold, or advertised the product are  
16 insufficient to confer jurisdiction.

17 I just wanted to highlight that for your Honor. These  
18 defenses are going to be asserted in much more detail by some  
19 of the Defendants in the litigation.

20 Thank you, your Honor.

21 *THE COURT:* Thank you.

22 *MR. LONGER:* Fred Longer. My thought was I would turn  
23 on my video now, but I do believe that Mr. Keller will address  
24 the earlier arguments by Mr. Petrosinelli and some by Mr.  
25 Bayman, and then I was just going to address the last dealing

1 with personal jurisdiction.

2 *THE COURT:* Okay.

3 *MR. KELLER:* If that pleases the Court, Ashley Keller  
4 again for the Plaintiffs. I will be extremely brief.

5 We are in agreement with the Defendants that of course  
6 they get to raise their affirmative defenses, whether it is  
7 Statute of Repose or otherwise. Most of those issues are  
8 questions of fact. I'm sure I could cite to your Honor chapter  
9 and verse and you have read already chapter and verse that that  
10 is true. And so, there are going to be factual issues  
11 associated with that. There are going to be choice of law  
12 issues associated with that.

13 Imagine a Plaintiff who took a drug starting in  
14 Tennessee, and then moves to Florida and continued taking the  
15 drug, and then moved to West Virginia and discovered her  
16 injuries there. Each state might have a competing interest in  
17 having its own law applied, so that is going to be a thorny  
18 question. Obviously, they get to raise these issues and they  
19 may apply in certain fact specific circumstances. And  
20 similarly, with respect to evidence, of course we have to  
21 establish causation. To the extent that they are trying to say  
22 that the normal rules of evidence don't apply, we don't agree  
23 with that.

24 A Plaintiff who has taken a pharmaceutical product  
25 for, on average, 14 years is competent to testify as to which

1 product they took as the way to identify it and establish  
2 causation, and they can put in place whatever rebuttal or  
3 challenge the memory that they want, but again, those will be  
4 fact specific issues. We have no quibble, of course, with  
5 their ability to raise the panoply of defenses that they  
6 mentioned in the previous slides, and I will close my remarks  
7 there.

8 *THE COURT:* Thank you.

9 *MR. LONGER:* Your honor, I just wanted to address the  
10 personal jurisdiction presentation. I heard about Polonius  
11 just a moment ago, brevity being the soul of wit. Let me try  
12 to keep it very short.

13 Personal jurisdiction, to the extent it is a defense,  
14 it raises a lot of factual questions and there is no discovery  
15 yet. Typically, within the Eleventh Circuit case law  
16 recognizes that where discovery would be appropriate, it should  
17 be granted so that the defense can be met. That would be my  
18 one position as to the personal jurisdiction.

19 And the last is, whether or not the Defendants  
20 intended to raise it or not, it is possible that they meant to  
21 include a BMS argument as addressed to class actions which you  
22 have on the screen right here, and there is ample authority to  
23 suggest that, under Federalism, Rule 23 has not yet been  
24 superseded, and that a national class action can still be  
25 permitted absent -- or despite the BMS ruling.

1           So, to the extent that is at issue, I don't know that  
2 it was intended in Mr. Bayman's argument, but to the extent it  
3 was embedded therein, we will have an opposition to that  
4 position.

5           If you have no further questions on that, your Honor,  
6 I would speak to you very briefly about class actions. I know  
7 that the lunch hour is coming up and we are into your Q and A  
8 period.

9           So, as Mr. Gilbert started out our discussion earlier  
10 this morning, we are going to be presenting consumer class  
11 actions and third party payor class actions. The consumer  
12 class actions will involve individual Plaintiffs and putative  
13 class members who purchased Zantac or Ranitidine containing  
14 products based on representations of the Defendants that their  
15 products were safe and effective when in fact they were exposed  
16 to products that contained dangerously unsafe levels of the  
17 known carcinogen NDMA.

18           Had the Plaintiffs and putative class members known of  
19 these risks posed by these products, they would not have used  
20 the products. That is the essence of the theory. There is  
21 going to be a whole host of claims presented to address those  
22 issues. Mr. Gilbert alluded to them earlier in consumer  
23 claims. We are going to have nationwide and state classes,  
24 presenting Federal RICO claims, Magnus and Moss Warranty Act  
25 claims, unjust enrichment claims, fraudulent and negligent

1 misrepresentations and omissions, negligence and negligence per  
2 se claims, state consumer protection statute claims, express  
3 and implied warranty, fraudulent concealment, and as we just  
4 talked about a moment ago, medical monitoring claims, and  
5 theories of recovery which will address those states where the  
6 theory is recognized and available.

7           So, that is all that I wanted to say about where we  
8 are going with class actions in the brief amount of time that I  
9 have, your Honor, unless you have other questions.

10           *THE COURT:* No, no questions. Thank you.

11           *MR. PETROSINELLI:* Your Honor, this is Joe  
12 Petrosinelli. We'll just make our 12:30 deadline.

13           I think all I will say on the class action piece is, I  
14 will echo what you might remember Mr. Agneshwar said in the  
15 opening, which is the fact of the matter is in pharmaceutical  
16 litigation consumer classes, proposed consumer classes and  
17 proposed third party payor classes are -- almost always  
18 certification is denied. You can look at all sorts of cases,  
19 MDL cases, non-MDL cases, but generally on predominance  
20 grounds, or lack of predominance grounds because there are so  
21 many individual issues with respect to -- you heard Mr. Longer  
22 describe the claims.

23           They are sort of grounded in fraud type claims,  
24 warranty and fraud claims, and those cases in the  
25 pharmaceutical context almost always result in certification

1 being denied. I looked for the last couple of pharmaceutical  
2 MDL opinions on this. In the testosterone replacement therapy  
3 litigation, Judge Kenelli (phon) in Illinois recently denied  
4 class certification of a third party payor class in that  
5 litigation.

6 There are many, many MDL opinions where, because of  
7 differences in state law, individual questions that predominate  
8 over common ones, and ascertainability questions, one issue --  
9 your Honor may not deal with a lot of class actions, but in  
10 over-the-counter cases, not so much prescription cases, trying  
11 to define or ascertain what the class is, there's a bunch of  
12 Eleventh Circuit and Southern District of Florida case law  
13 denying class certification of proposed classes relating to  
14 over-the-counter products because of inability to ascertain the  
15 class in a reasonable manner.

16 So, we are a ways away from a class certification  
17 motion, but there are plenty of cases that repeatedly -- the  
18 cases repeatedly reject class certification in the  
19 pharmaceutical context for those reasons, so I won't say more  
20 than that now.

21 That is the last piece of our law presentation and I  
22 look at my clock and it is 12:30.

23 *THE COURT:* Perfect. Okay. So, we are right on  
24 schedule. We just excised the Q and A out, but the  
25 presentations were so thorough I don't need to utilize those 15

1 minutes and certainly not now. Thank you, everyone, this  
2 morning for giving such a comprehensive, collaborative and  
3 informative presentation. I can't tell you how much I  
4 appreciate it.

5           The technology worked beautifully. You crystallized  
6 the issues for the Court, and I recognize you are just  
7 scratching the surface, but it is incredibly helpful for the  
8 Court and for all of the other participants to just sort of  
9 hear the highlights of the legal issues that will be presented  
10 in this case, so I can't thank you enough.

11           With that, I am going to call a lunch break until  
12 1:30, one hour, just as we have on the agenda. We will pick up  
13 with the science presentation. Again I ask, if you intend to  
14 be here this afternoon, not to leave the meeting, just keep  
15 your video off, your mute on, so our cohosts don't need to  
16 readmit you and it saves time.

17           We will begin as promptly as possible at 1:30. Have a  
18 nice lunch, and we will see you back.

19           *(Thereupon, a luncheon recess was taken.)*

20           *THE COURT:* Welcome back, everybody. I hope you had a  
21 nice lunch. I did want to say from the outset that I am going  
22 to give up my Q and A session at 2:45. I hope that that gives  
23 the presenters a little more latitude. I don't want anyone to  
24 feel rushed, and I think that is all I really wanted to say. I  
25 will put everybody at ease so you don't feel rushed.

1           With that, if we could have our science presenters.

2           *MS. FINKEN:* Good afternoon, your Honor. Can you hear  
3 me okay?

4           *THE COURT:* Yes. Good afternoon.

5           *MS. LEONE:* Before we get started, could I just ask  
6 that my colleague, Jonathan Tam, be able to screen share since  
7 he is running a number of these slides for us.

8           *THE COURT:* Absolutely. There is a slide on the  
9 screen right now, so maybe he has already begun.

10          *MS. LEONE:* Perfect. Are we ready?

11          *THE COURT:* Yes. For the benefit of our court  
12 reporter, if you are all going to be on together, the first  
13 time you speak if you would say your name for the record so it  
14 is very clear who is speaking.

15          *MS. LEONE:* Good morning, your Honors, Judge  
16 Rosenberg, Judge Reinhart. My name is Judy Leone and I  
17 represent GSK.

18                 To start off the science section of the presentations  
19 I will be speaking on behalf of the Defendants and Daniel Nigh  
20 on behalf of the Plaintiffs, but this is intended to be a joint  
21 presentation, one on which we will be collaborating and passing  
22 the baton back and forth to cover our slides.

23                 We are going to present for you a brief timeline of,  
24 one, the regulatory approvals for Ranitidine and the  
25 indications for which it was approved; two, the changes in

1 ownership for OTC Zantac over time; and three, the timeline for  
2 the arrival of generic forms of Ranitidine, both prescription  
3 and OTC, over the counter. Sorry.

4 To begin with, Glaxo first discovered Ranitidine in  
5 1976, and in 1977 the first tests on Ranitidine began.  
6 Following extensive toxicity tests in animals, clinical trials  
7 began in 1978, and in 1979, GSK submitted the initial IND for  
8 Zantac tablets to the U.S. FDA, and that is the investigational  
9 new drug application that Mr. Petrosinelli spoke about this  
10 morning.

11 We can move to the next slide.

12 Zantac was first approved late in June of 1981, and  
13 GSK began marketing the product in that country. Shortly  
14 thereafter, in 1982, GSK submitted the original NDA for  
15 prescription Zantac tablets to the U.S. Food and Drug  
16 Administration.

17 Following numerous discussions with GSK, the FDA  
18 approved Zantac for prescription use as a histamine 2H2 blocker  
19 in June of 1983. At this time, Zantac was a prescription  
20 medication indicated for the short-term treatment of active  
21 duodenal ulcers and the treatment of pathological  
22 hypersecretory conditions such as Zollinger-Ellison syndrome,  
23 which is a condition in which gastric tumors cause the stomach  
24 to produce too much acid. The recommended adult dosage at that  
25 time was two 150-milligram tablets daily.

1           Go to the next one.

2           The FDA reviewed this medication frequently over the  
3 ensuing years, approving Zantac for a number of additional  
4 indications. In 1985, the FDA approved Zantac for short-term  
5 treatment of active benign gastric ulcers, and then later that  
6 year, FDA approved Zantac 300-milligram tablets for duodenal  
7 ulcers.

8           In 1986, FDA approved Zantac for maintenance therapy  
9 of duodenal ulcers as well as for gastroesophageal reflux  
10 disease, which most of us know as GERD. So, Zantac for  
11 duodenal ulcers for maintenance therapy, Zantac could now be  
12 given for maintenance therapy for duodenal secretions at a  
13 reduced dosage after the healing of the acute ulcers.

14           In 1992, the FDA approved Zantac for the treatment of  
15 endoscopically diagnosed erosive esophagitis, and that was a  
16 recommended adult dosage of 150 milligrams four times a day.  
17 Then in 1994, FDA approved Zantac for maintenance therapy for  
18 the healing of erosive esophagitis.

19           Finally, in 1995, the FDA approved Zantac for  
20 maintenance therapy for the healing of gastric ulcers. For  
21 this condition Zantac could be prescribed at a reduced dosage  
22 after the acute ulcers had healed.

23           Now I am going to turn the microphone over to Daniel  
24 for the over-the-counter discussion.

25           *MR. NIGH:* Good afternoon, your Honors, Daniel Nigh

1 for the Plaintiffs. I am going to talk about when  
2 over-the-counter Zantac became available. This would obviously  
3 be the time at which you could purchase Zantac over the counter  
4 and not need a physician's prescription.

5 First, it starts in approximately July of 1993, GSK  
6 and Warner Lambert entered into a partnership contract under  
7 which GSK and its affiliates would manufacture over-the-counter  
8 Zantac products for the partnership. GSK submitted the  
9 original NDA for over-the-counter approval of Zantac  
10 75-milligram tablets in September of 1994. In December of  
11 1995, the FDA approved over-the-counter Zantac for the  
12 treatment of heartburn, acid indigestion, and sour stomach.  
13 Over-the-counter Zantac launched in April of 1996, and was  
14 first available in 75-milligram dosage.

15 Next slide, please.

16 On December 18, 1998, the partnership between GSK and  
17 Warner Lambert formally dissolved. Warner Lambert retained the  
18 exclusive rights to sell over-the-counter Zantac 75-milligram  
19 in the U.S. GSK retained the rights to sell prescription  
20 Zantac in the U.S. In 2000, Pfizer acquired Warner Lambert and  
21 became the NDA holder for over-the-counter Zantac  
22 75 milligrams.

23 In August 2004, FDA approved over-the-counter Zantac  
24 150-milligram tablets. In 2006, Boehringer Ingelheim acquired  
25 rights to over-the-counter Zantac and became the NDA holder.

1 In 2017, Sanofi acquired the rights to over-the-counter Zantac  
2 and became the NDA holder.

3 *MS. LEONE:* This is Judy Leone again.

4 As you will see, the FDA approved several different  
5 forms of Zantac over the years, including injection and  
6 injection pre-mixed which were used in hospital settings,  
7 syrup, GELdose, which are gel capsules, and EFFERdose tablets  
8 and granules which are dissolvable. As you see on the slide,  
9 these different forms of Zantac were transferred to other  
10 companies or discontinued, the first two transferred to Covis  
11 Pharma in 2011, and the next group, syrup and EFFERdose,  
12 discontinued at various times from 1994 up through, for syrup,  
13 2013.

14 Although the generic version of prescription  
15 Ranitidine came on the market in 1997, GSK continued to sell  
16 prescription Zantac 150-milligram tablets until 2017, and  
17 300-milligram tablets until 2018. The very last batch of  
18 prescription Zantac expired in early 2019.

19 *MR. NIGH:* Next slide, please. This is Daniel Nigh  
20 for the Plaintiffs.

21 In terms of generic Ranitidine -- again, Ranitidine is  
22 the generic form name of the medication Zantac. In 1997,  
23 prescription generic Ranitidine became available. Generic  
24 over-the-counter Ranitidine manufacturers were able to seek FDA  
25 approval for their products beginning in June of 1998. Ms.

1 Leone and I have been trying to figure out exactly when the  
2 first generic over-the-counter Ranitidine was sold, but we  
3 believe it was sometime in 1998, 1999, and then approximately  
4 75 companies have likely sold generic prescription or generic  
5 over the counter. That concludes our joint presentation.

6 *THE COURT:* Thank you very much. As I understand it,  
7 you are going to divide up 30 minutes for each side. As I  
8 said, I am going to give up the Q and A, so you have a little  
9 latitude there to make sure everybody has enough time to say  
10 what you want to say.

11 *MS. FINKEN:* Thank you. Good afternoon, your Honors.  
12 This is Tracy Finken on behalf of Plaintiff, and I am going to  
13 be joined by Daniel Nigh and Brent Wisner to provide a basic  
14 primer on the preliminary science that is involved in this  
15 case. We are going to be moving at a very quick pace so if you  
16 need us to slow down at all, please let us know. Thank you.

17 *THE COURT:* Everyone feel free to just take your time,  
18 especially with some of the terminology and this and that. I  
19 have a perfectionist of a court reporter. And Pauline, just  
20 feel free to put your hand up if you want me to have something  
21 repeated. Thank you.

22 *MS. FINKEN:* If we are moving too quickly and you need  
23 me to slow down, please just let me know, but we have a lot to  
24 cover in a short period of time so we are going to try to move  
25 through it as quickly as we can.

1           To get started, Mr. McGlamry talked a bit about the  
2 timeline of regulatory action that has occurred from September  
3 2019 until the recent FDA product recall request. I have a  
4 timeline up on the screen for your Honor.

5           As you are aware, the story began with the Citizen's  
6 Petition that was filed by Valisure in September 2019, putting  
7 the FDA on notice that they had tested batches of Zantac and  
8 found extremely high levels of NDMA, a known carcinogen.  
9 Subsequently, the FDA did its own testing and also found NDMA  
10 in all test samples, many of which had unacceptable levels.

11           In December, and this is an important point, the FDA  
12 notified consumers that there was evidence that when ingested  
13 Zantac could form NDMA if nitrates were also present in the  
14 human body. The FDA advised Zantac users to limit the intake  
15 of nitrate containing foods such as processed meats to reduce  
16 the risk of NDMA forming when Zantac reacted with nitrates in  
17 the stomach. Next slide, please.

18           In January 2020, Emery Pharma filed a Citizen's  
19 Petition requesting a full Zantac product recall, and raising  
20 the concern that Zantac generates a significant amount of NDMA  
21 under elevated temperatures such that could occur during  
22 storage or transport.

23           If you fast forward then to April 1st, the FDA  
24 responds to Emery, and in the response cites to 1978  
25 International Agency for Research and Cancer Guidelines that

1 NDMA should be regarded as carcinogenic to humans. These same  
2 guidelines from 1978 noted that NDMA is carcinogenic in all  
3 animal species tested, that it induces tumors in various organs  
4 in various species, including the liver, kidneys, and  
5 respiratory tract, and that a dose response relationship had  
6 been established, meaning that the more exposure, the higher  
7 the risk of developing cancer. So, as of 1978, it had already  
8 been well established within the international medical  
9 community that NDMA was a toxin. Next slide.

10 The FDA then requested that all U.S. Ranitidine  
11 containing products be recalled and all consumers should stop  
12 taking it, and the FDA noted that its testing demonstrated  
13 three things that I would like to point out.

14 One, that NDMA levels in Zantac increased to  
15 unacceptable levels even stored at room temperature; two, that  
16 elevated levels of NDMA were found in all products after two  
17 weeks; and three, that the agency was no longer confident that  
18 any Ranitidine product would remain stable or free of NDMA  
19 through its label expiration date.

20 The FDA recalls were followed by multiple foreign  
21 regulatory bodies removing all Ranitidine products from the  
22 global markets, and with that being said, your Honor, I am  
23 going to turn the floor over to Brent Wisner, who is going to  
24 talk to you a little bit about the science.

25 *THE COURT:* Thank you.

1           *MR. WISNER:* Good morning -- good afternoon, your  
2 Honor. It's morning for me. Can you see me?

3           *THE COURT:* I can.

4           *MR. WISNER:* Great. I am going to be talking to you  
5 about cancer and specifically what causes it. Now, before you  
6 can talk about what is a carcinogen, you first have to  
7 understand what cancer is. Cancer is a particularly vicious  
8 disease, it does not operate the way traditional diseases work  
9 with a pathogen or an underlying medical condition, but it's  
10 actually turning one's own cells against you to become lethal.

11           To get to that point there are a lot of steps in the  
12 process. You first have a healthy human cell, it gets  
13 initiated by exposure either to a carcinogen or to a natural  
14 genetic predisposition. Once that cell is initiated, it then  
15 can be promoted and then proliferated, ultimately leading to  
16 what we consider a tumor or a malignancy.

17           Now, each one of these steps, your Honor, actually is  
18 part of the causal chain in causing cancer, so any substance  
19 that affects any aspect of this chain is considered a  
20 carcinogen.

21           For example, substances that may not initiate a cell,  
22 but ultimately promote cancer toward the latter end of a  
23 person's treatment or condition, they are considered  
24 carcinogens just as much because they play a substantial role  
25 in contributing to the development of a malignancy.

1           What is really underlying this, your Honor, is  
2 fundamentally an understanding that cancer is multi factoid.  
3 Right? People have certain predispositions and other people  
4 don't. Somebody can smoke three packs of cigarettes every day  
5 for 30 years and not get lung cancer, and another person can  
6 smoke half a pack for five years and get lung cancer. Those  
7 differences are what we call sort of genetic (inaudible) --  
8 there are various predispositions that make them more or less  
9 vulnerable to a particular carcinogen.

10           What this case is trying to focus on and what --

11           *THE COURT:* Hold on one second, Mr. Wisner. Mr.  
12 Wisner, do you have a volume button you can turn up? You do  
13 fade out.

14           *MR. WISNER:* Sure. I can speak up, too. Is that  
15 better?

16           *THE COURT:* Yes. Start that last point again so we  
17 get the full thought.

18           *MR. WISNER:* Sure. So, what this litigation is  
19 ultimately about is the interplay of the genetics or  
20 predisposition of an individual and their exposures to various  
21 aspects of carcinogens in the environment. The overlapping  
22 form of cancer, that is really where this case derives. This  
23 is really important in understanding concepts like dose  
24 response, right, because what dose is needed to cause an  
25 individual's cancer is going to vary by definition by

1 individual. Now, there are studies that look at these issues  
2 and we are going to go over that --

3 *THE COURT:* I'm sorry. I just put the volume up on my  
4 computer. Maybe that will help.

5 *MR. WISNER:* I just changed microphones. Is that  
6 better?

7 *THE COURT:* Much better, yes.

8 *MR. WISNER:* I will use this one. I am sorry, your  
9 Honor.

10 *THE COURT:* That's okay. Just maybe say that last  
11 thought because we cut you off.

12 *MR. WISNER:* Thank you, your Honor. So, when it comes  
13 to issues of dose response, this is really important because  
14 the dose that might affect one individual may change based upon  
15 their particular medical conditions and underlying genetics.  
16 There are studies that go into this. We will get into that,  
17 obviously, as part of our scientific analysis in the process of  
18 developing this case, but I think it is really important to  
19 understand that the dose issue is largely how it affects a  
20 specific individual. We will get into that a little later  
21 towards the end of the presentation.

22 In the realm of cancer science there are really three  
23 pillars, and these three pillars are well recognized in every  
24 scientific regulatory agency and every scientific body. These  
25 various aspects of the cancer science pillars, as we like to

1 call them, reflect the various types of data that we have.

2 To say that one of these is more important than the  
3 other I think is very problematic. Indeed, a lot of substances  
4 are deemed carcinogens just based on animal studies, a lot of  
5 substances are called carcinogens based on cell studies, and,  
6 of course, many are based on epidemiology.

7 At the end of the day, it is really important not to  
8 itemize the science. You have to look at all of the data, and  
9 look at it holistically, and that is something that I will  
10 bring together at the end of this presentation when we talk  
11 about general causation.

12 Animal studies have a benefit over, for example,  
13 epidemiology studies. They are highly controlled. The exact  
14 dose, temperature, food, everything is controlled in a sort of  
15 hermetically sealed environment, so you can really tease out  
16 just what effect is being caused by the compound, the agent  
17 here, versus what is being caused by the natural background  
18 rate. You are looking for replication of tumors, rare tumors,  
19 seeing it across species. For example, your Honor, when it  
20 comes to NDMA, it has caused tumors in every animal it has ever  
21 been tested in. Hard stop.

22 Similarly, cell studies are very informative as well.  
23 They take us down to the cellular level and see what is  
24 happening with a chemical compound on a homogenic level. You  
25 can actually see it causing genetic damage in these types of

1 experiments. Now, they are done, obviously, in living  
2 creatures, in vivo, as well as in vitro, but this data,  
3 combined with the animal data and the epidemiology, help us  
4 create a picture both relating to what causes cancer, but also  
5 how it causes cancer and the way it goes about affecting  
6 individuals.

7           These types of studies are really important in  
8 understanding what sort of genes are being impacted by a  
9 chemical.

10           That leads us to epidemiology. Obviously your Honor  
11 is going to hear more about epidemiology from my colleagues and  
12 you are going to hear more about it from the Defendants. I  
13 have a feeling it is going to be an important story in this  
14 litigation as it unfolds. I am not going to get into too much  
15 detail about what epidemiology is, it's a broad subject, but  
16 basically there are two broad types of studies that we're  
17 really interested in. Right?

18           One study follows individuals --

19           *(Background conversation.)*

20           *THE COURT:* I am not sure if that is somebody on the  
21 screen -- do you have something going on in the background?

22           *MR. WISNER:* Not me.

23           *THE COURT:* If any participants have their audio on  
24 inadvertently, just go ahead and turn it off.

25           You are being tested, Mr. Wisner. All of our

1 technological challenges are revealing themselves, so we will  
2 see how you navigate them. You have navigated them very well.  
3 So, carry on.

4 MR. WISNER: All right, your Honor. So, we have two  
5 types of epidemiology studies that we're primarily interested  
6 in. One follows different groups of people, those exposed and  
7 unexposed over time, to see how their cancer outcomes are. The  
8 other one takes people who have cancer today and compares them  
9 with people who don't have cancer today and makes sure they're  
10 similar enough, and then looks back in time to see, okay, who  
11 of those individuals were exposed to the agent at issue.

12 Now, I can get into the nuances of epidemiology, we  
13 don't have time for that. I could do a two-hour presentation  
14 of just the facts and ways to do epidemiology. I think what is  
15 really important for this presentation, really to set the  
16 stage, is how to read epidemiology.

17 Typically epidemiology is represented this way. You  
18 have a point estimate which tells you what the data shows. So  
19 here 2.2 would mean that twice, or 2.2 times as many  
20 individuals in the exposed group are getting the cancer from  
21 people who are unexposed. Another way of saying this is it is  
22 more than doubling the risk, 2.2 odds ratio, or relative risk,  
23 or it multiplies the risk by 220 percent. All of those sort of  
24 capture that same idea.

25 But that number is just what that data shows, and what

1 you are trying to find out is, is that data, that point  
2 estimate a fair representation of the rest of the world, and  
3 that is where statistical significance tries to come in, tries  
4 to tell us is that result that we are seeing just the product  
5 of statistical anomalies or is it a real risk, okay, and that  
6 is what the confidence interval is. It is often expressed as a  
7 95 percent confidence interval.

8 Now, it is very common for certain scientists who want  
9 to see a result to just disregard non-statistically significant  
10 results, but this has largely been rejected in the scientific  
11 community as just bad science. Just last year 800  
12 epidemiologists published an article in Nature condemning the  
13 use of significance testing altogether because it can obscure  
14 risks.

15 But what this number actually shows -- and this is  
16 typically, by the way, your Honor, how we plot out an odds  
17 ratio on a graph. Right? We have an increased risk to the  
18 right of one, and the decreased risk to the left of one.  
19 Anything to the right of the blue line is considered elevated,  
20 and anything to the left of it is considered protected, and the  
21 question is, what is the range? Does that range cross one?

22 What that is really reflecting here, your Honor, is a  
23 probability curve. So, we know based on our data that the most  
24 likely probabilistic outcome is 2.2. Now, we want to be  
25 confident that 95 percent of those probable outcomes are

1 captured, that is what is under the curve. Those are the  
2 probabilistic possibilities of what the risk is outside of our  
3 data set, and this confidence interval is supposed to capture  
4 that. We're leaving two and a half percent on each side of the  
5 curve out saying we are not concerned about those outliers, we  
6 are just focusing on 95 percent. Draw a line between them and  
7 that gives us what we call a confidence interval. Most of the  
8 time odds ratios are represented this way.

9 Now, it is really important that you consider this  
10 also in the context of non-statistically significant results.  
11 So here we have a 1.3, so it's an elevated risk, the data is  
12 showing a 30 percent increased risk, but the confidence  
13 interval spans from .8 to 2.3. Now, if you draw the curve  
14 underneath it, just like we did above, you will see that over  
15 90 percent of the area under the curve falls to the right of 1,  
16 only a small percentage falls to the left of 1.

17 So, if you were to disregard this result and say,  
18 well, it doesn't tell us anything, then you would be  
19 disregarding 90 percent of what this is telling you, which is  
20 one of the reasons why epidemiologists like to look at  
21 everything and consider is there a holistic trend in the data  
22 we're seeing, specifically, are they all basically to the right  
23 of 1, because you can change the width of a confidence interval  
24 with sheer data. Just add more numbers and it will decrease it  
25 as the function of statistical laws.

1           This, your Honor, is interesting, and I want to pass  
2 it over now to Mr. Nigh, who is going to talk about NDMA, but  
3 you know, earlier in the presentation Defense counsel said to  
4 you that there was no epidemiology related to morbidity, and  
5 that is just not true.

6           These results are actually real data. This is the  
7 risks of invasive breast cancer for women. For current  
8 Ranitidine users, that's 2.2, statistically significant result,  
9 and the 1.3 shows for invasive breast cancers for users who  
10 used Ranitidine for longer than two years.

11           With that, I hand it off to Mr. Nigh.

12           *THE COURT:* Thank you very much. Mr. Nigh.

13           *MR. NIGH:* Thank you, your Honor. This is David Nigh  
14 for the Plaintiffs. I am going to be discussing a few things  
15 during my topic. I am going to talk about how NDMA causes  
16 cancer and then I'm going to talk -- NDMA, the carcinogen  
17 itself. Then I'm going to discuss how Zantac breaks down into  
18 high amounts of NDMA and the multiple ways that it does so, and  
19 ergo, therefore Zantac causes cancer. But after me, Ms. Finken  
20 is going to discuss the different ways -- or the epidemiology  
21 that shows Ranitidine itself, Zantac, causes cancer.

22           Next slide.

23           I am just going to hit some of the highlights here  
24 because we have talked about some of it already, but every  
25 health authority that has looked at this issue, or nearly every

1 health authority that has looked at this issue, they all agree  
2 that NDMA is likely a carcinogen.

3 Next slide.

4 A few things I want to point out here, I won't get  
5 into all of this because Mr. McGlamry touched on it in his  
6 opening statement.

7 I want to point out first that NDMA is in the family  
8 of nitrosamines, but it has been pointed out that NDMA is the  
9 most potent in that family. When trace amounts of NDMA are  
10 found in the water Governmental agencies can spend hundreds of  
11 millions of dollars to minimize the amounts of NDMA in drinking  
12 water. NDMA is found in foods like bacon, cured meats, and  
13 salted fish, but these industries have spent lots of money to  
14 try to minimize the amount of NDMA in those foods because they  
15 have recognized, and they have done many studies that shows  
16 just low levels of NDMA in these foods can cause a significant  
17 increase in the risk of multiple types of cancers.

18 Next slide, please.

19 Next, NDMA is a genotoxic carcinogen. What that means  
20 is the toxicity of genotoxic carcinogens is referred to as  
21 being "non-threshold," meaning there is essentially no level of  
22 exposure that does not pose some probability of producing a  
23 carcinogenic response. Therefore, no dose of NDMA can be  
24 considered to be risk free.

25 Now, the EPA had calculated an oral slope factor for

1 the risk, and they have shown it 51 milligrams per kilogram per  
2 day, converted here into the U.S., as you heard earlier, that  
3 would be 96 nanograms for somebody who weighs 110 pounds.

4 Now, I will tell you the risk and that association  
5 would mean you have one in 100,000 people at that weight who  
6 would get cancer. I can tell you that slope factor at 110  
7 pounds, that is not indicative of me, clearly, because I  
8 obviously weigh more than 110 pounds, and a lot of people weigh  
9 more than that, especially in the American population as  
10 compared to the European population.

11 Another thing that is important to understand is that  
12 the dietary studies showed that with higher concentrations of  
13 NDMA the oral slope factor increases significantly. So, this  
14 slope factor is calculated at 96 nanograms per day to get you  
15 to 100,000, but as your concentration increases, this slope  
16 factor is not linear, it is exponential. So, the slope as to  
17 your cancer risk as its concentration increases will increase  
18 significantly as well.

19 Also, this slope factor is based on animal studies.  
20 In vivo studies in human s have shown that NDMA is much more  
21 reactive in the human tissue compared to the animal tissue.

22 Next slide, please.

23 NDMA's only practical purpose today is to induce  
24 tumors in laboratory animals for the purpose of studying cancer  
25 and the treatments of cancer. NDMA, when they want to study

1 cancer and the treatments of cancer, is often the toxin ala  
2 choice that scientists will use because they recognize they can  
3 induce a tumor at any cancer site unlike most carcinogens.  
4 Substances that induce tumors in animals are considered as  
5 presumed or suspected human carcinogens until convincing  
6 evidence to the contrary is presented. This is a basic  
7 toxicological principle.

8 Next slide.

9 I am not going to go into a lot of detail on  
10 mechanistically how NDMA causes cancer. Mr. Wisner showed you  
11 some of the different steps. I will advise that NDMA can  
12 initiate a cancer from a single cell. It can also promote a  
13 cancer once the initial cell has formed.

14 Next slide.

15 But I think most importantly, and something that is  
16 important to understand when it comes to latency, is that NDMA  
17 and a lot of the cutting research over the last ten years on  
18 tumors themselves is that the introduction of NDMA can cause  
19 clinical cancer diagnoses very quickly.

20 To describe this, a lot of the new literature shows  
21 that most of the people in the population, that we actually  
22 have tumors inside of us. So, what that means -- it sounds  
23 very odd to just hear that, that most of us have tumors,  
24 probably most of us in this panel have tumors at multiple organ  
25 sites. The reason we know this is that when people pass away

1 in a car accident they will do autopsies, people that have  
2 donated their body to science, they will do autopsies of them  
3 and they will see that for people who were never diagnosed with  
4 cancer, weren't aware of it at all, they will see tumors at  
5 multiple sites, often times smaller tumors, and those tumors  
6 have become dormant in multiple different ways, as the slide  
7 previously shows. They have been dormant as a result of our  
8 immune response. They have been dormant as a -- because of  
9 cellular dormancy, and multiple of these different ways.

10 What happens with NDMA, and what is important, is that  
11 NDMA can disturb every single one of these types of dormancies.  
12 The important key is now, in terms of cancer, when does it go  
13 from subclinical to a clinical manifestation of the tumors?  
14 And so we can see that NDMA very often times will initiate a  
15 subclinical dormant tumor that may have never been a problem in  
16 that person's life to a clinical manifestation of those tumors.

17 This has been discussed in multiple other litigations,  
18 these -- and those reports have occurred also in other  
19 litigations.

20 Next slide.

21 Now, I want to talk about how we know that cancer is  
22 caused by NDMA in humans. There are multiple different things  
23 that we can rely upon. As I said before, Ms. Finken is going  
24 to talk about the Zantac Ranitidine specific episodes.

25 The other things that we look at, though, are dietary

1 NDMA studies. We have heard multiple times that, yes, bacon,  
2 salted foods, those types of things do have NDMA, but what we  
3 have found is that actually diets are very explanatory of many  
4 of the cancers that people have here in the U.S., absolutely.  
5 It has been pointed out numerous times that a person's diet can  
6 be one of the most indicative things as to why they got cancer.  
7 People have become aware that red meats can be bad for you,  
8 your doctor tells you that. Your doctor does not tell you that  
9 your medication that you are taking for GERD can give you  
10 cancer.

11 Now, in terms of dietary studies, diets that consist  
12 of 79 nanograms of NDMA per day, 79 nanograms of NDMA per day,  
13 can lead to a 66 percent increase in stomach cancer. There are  
14 dietary studies that show that just those low levels can have a  
15 very significant increase in your cancer risk.

16 There are many NDMA dietary studies that show that  
17 your diet, at these type of low levels, can lead to a  
18 significant risk of stomach cancer, pancreatic cancer, breast  
19 cancer, prostate cancer, liver cancer, and I am not surprised,  
20 as you saw in that graph of the cases that are filed, that most  
21 of the cases that are filed are precisely those kinds of cases.

22 The other thing I will talk about is occupational  
23 exposure studies. The dye industry is one of these types of  
24 occupational exposure studies where people have been exposed to  
25 low levels of NDMA for a long period of time. Those studies

1 have also shown that they have an increased risk of those same  
2 cancers, stomach cancer, pancreatic cancer, breast cancer,  
3 prostate cancer, liver cancer, and many other types of cancers.  
4 We talked about animal studies and in vitro studies. I won't  
5 go further into that other than to say there is a plethora of  
6 data in terms of NDMA causing cancer.

7 Next slide.

8 Next I want to show you the Ranitidine molecule and  
9 the NDMA molecule, and explain how Ranitidine breaks down in  
10 NDMA. You can see the entire Ranitidine molecule on the left  
11 side and you can see the entire NDMA molecule on the right  
12 side.

13 The odd thing is that every piece of ingredient that  
14 you need to get NDMA is wholly contained in the Ranitidine  
15 molecule, and this is precisely what makes the Ranitidine  
16 molecule so unstable, is that the two edges of the molecule are  
17 sheared off the molecule to formulate NDMA.

18 Next slide.

19 Now, because Ranitidine is so unstable, it breaks down  
20 in NDMA in multiple ways, not just one or the other, and every  
21 one of these ways is additive and/or multiplicative in terms of  
22 the amount of NDMA that a person is going to get.

23 The first way that people will formulate NDMA, as  
24 shown by the Valisure study, is that if you have a high nitrite  
25 diet in your stomach at the same time that you are taking

1 Zantac or Ranitidine it is going to formulate high levels of  
2 NDMA that are going to be broken off or sheared off because the  
3 nitrites in the stomach will shear off the NDMA -- or the  
4 Ranitidine molecule will shear off the parts of the NDMA and  
5 they will form in the stomach.

6 Second, shipping and storage. We have seen from the  
7 Emery Pharma that when you ship or you store, even at room  
8 temperatures, but obviously the higher the heat, the higher the  
9 amount of NDMA that is going to break down, that is in addition  
10 to what is breaking down in the body.

11 Finally, and really the base level, is the API  
12 manufacturing because we have seen in Valsartan, and we will  
13 see it here again, we can tell by the numbers already, that  
14 when they are manufacturing the active pharmaceutical  
15 ingredient over in India and China they get sloppy. They reuse  
16 solvents and their manufacturing process makes an unstable  
17 Ranitidine molecule very susceptible to NDMA.

18 We can already see it in the results and I will show  
19 how we can see a base line of NDMA that is already in each one  
20 of these products just in the API manufacturing alone.

21 Next slide.

22 Finally, I will show the amounts of NDMA. First, this  
23 is the Valisure study, I won't go into details again other than  
24 to show Valisure started this out by testing it under the  
25 standard FDA testing protocol, that protocol involved using

1 heat, and they found about 2.6 million nanograms of NDMA per  
2 pill. We certainly don't need those kinds of levels to  
3 establish a cancer being caused by NDMA.

4 The most important thing about this testing is to show  
5 that while this is the standard protocol testing for every  
6 other drug, it couldn't be for Zantac or Ranitidine where it  
7 created this high level of NDMA because the molecule is so  
8 unstable.

9 Next slide.

10 Let's go ahead and highlight it in red. This is early  
11 on, this is several months ago that this testing was done by  
12 the FDA. This is before the April 1st announcement by the FDA  
13 withdrawing all medications. This testing, all of these in red  
14 have excessive amounts of NDMA, and they were recalled by each  
15 of the manufacturers numerous months ago. These levels likely  
16 represent the underlying amount of NDMA being introduced as a  
17 result of the API manufacturing process, and some of the  
18 negligence that was done during those processes.

19 We know that by the varying levels of NDMA, for  
20 example Sanofi. Now, how do we calculate NDMA? We simply  
21 multiply the 2.38 times the 150 milligrams and that will give  
22 us the amount in nanograms. That leads to 357 nanograms,  
23 significantly higher than the 96 nanogram level threshold set  
24 by the FDA and EPA. You can also take a look at the Navidea,  
25 855 nanograms, significantly higher than the 96 nanograms.

1 That is just the starting point. That is the base line.

2 From there, it becomes additive as a result of  
3 shipping and storage, and as a result of breaking down inside  
4 of the body.

5 Next slide.

6 We can see this additive multiplicative process in the  
7 Emery study. Emery is another fully accredited laboratory.  
8 Let's take a look at the results on the next slide.

9 This is a petition that was filed in January to the  
10 FDA where Emery looked at what is the effect of heat on  
11 Ranitidine, and they chose 70 degrees Celsius because they  
12 actually were informed that this is the temperature that a lot  
13 of these products were stored and a lot of these products were  
14 shipped.

15 So, just in looking at 70 degrees, all they wanted to  
16 do is go for two weeks and see how much NDMA is established.  
17 At less than 12 days 150 nanograms had broken down from a  
18 Ranitidine product that at zero days that you see on the graph  
19 there for that red line, at zero days its baseline level was  
20 approximately only 20 nanograms.

21 The FDA agreed with Emery Pharma that these drugs  
22 break down over time and form significant levels of NDMA. This  
23 is in addition for multiplicity to the NDMA created during the  
24 API manufacturing process and in addition to the NDMA broken  
25 down in the stomach.

1           You can see just in this process in 12 days the amount  
2 of NDMA that has formed at this temperature has been multiplied  
3 sixfold when it only started with 20. So, imagine how much  
4 NDMA is going to build that starts at 855 nanograms and then is  
5 multiplied sixfold under heat conditions.

6           Finally, I want to talk about the mixed study because  
7 several years ago Stanford investigators designed a simple  
8 study that gave multiple volunteers Zantac. After only 24  
9 hours they compared the NDMA levels in the urine for the  
10 volunteers that ingested Zantac versus the volunteers who did  
11 not ingest Zantac. Stanford investigators found astonishingly  
12 significantly higher levels of NDMA in the urine of the  
13 volunteers who ingested Zantac. This study cannot be  
14 replicated now as it would be inhumane to give humans Zantac, a  
15 known carcinogen now.

16           What this shows is that the Ranitidine product clearly  
17 breaks down into significantly high levels of NDMA in the human  
18 body.

19           With that, Ms. Finken is going to discuss the  
20 epidemiology of a few cancers.

21           *THE COURT:* Thank you, Mr. Nigh. Ms. Finken.

22           *MS. FINKEN:* Thank you. Your Honor, I am going to now  
23 go over a very brief sampling of epidemiological data showing  
24 an increased risk of certain cancers associated with Zantac.  
25 This is not exhaustive, but just meant to give your Honor a

1 glimpse of the available data that we already have before  
2 Zantac -- before discovery has even begun that demonstrates a  
3 doubling of the risk of certain types of cancers with Zantac  
4 and which also demonstrates evidence of a dose response  
5 relationship with exposure to NDMA and these same types of  
6 cancers.

7 I can only assume, based upon the opening statements,  
8 that counsel for Sanofi, Mr. Agneshwar and Ms. Sharpe, do not  
9 have these studies, but I am happy to provide them with copies  
10 of these studies after the conclusion of these conferences.

11 Looking at the first slide, this is a study from a  
12 2019 meta analysis conducted that looked at the link between  
13 H2RAs as a class and pancreatic cancer. H2RAs is the class of  
14 medication that Zantac is in and it includes Tagamet, Pepcid,  
15 and others. A meta analysis is a statistical analysis that  
16 combines the results of multiple scientific studies.

17 None of the studies contained in this meta analysis  
18 looked at Zantac specifically, but they looked at the class of  
19 medications as a whole and found that there was a combined  
20 overall odds ratio of 1.26. That was statistically  
21 significant. This means that there was a 26 percent increased  
22 odds of developing pancreatic cancer after exposure to H2RAs.

23 Next slide.

24 However, when looking at Zantac specifically in a  
25 cohort study from 2000 comparing Zantac to Tagamet, which is

1 another medication in the class, as well as compared against  
2 non H2RA users, it was found that Zantac specifically had a  
3 relative risk of 2.6. That was a statistically significant,  
4 more than doubling of the risk of pancreatic cancer with  
5 ingestion of Zantac compared to nonusers. Tagamet did not  
6 demonstrate an increased risk of pancreatic cancer.

7 This data that you're looking at on the screen now is  
8 from a study looking at a population with occupational exposure  
9 to NDMA and the risk of pancreatic cancer. That is one of the  
10 types of studies that Mr. Nigh just discussed.

11 This study demonstrated a statistically significant  
12 increased risk of death from pancreatic cancer in people who  
13 were exposed to NDMA in the workplace which ranged from 1.59 to  
14 2.6. These findings are similar to the risk of pancreatic  
15 cancer found in the Zantac exposed population and they show  
16 consistent findings between NDMA epidemiological studies and  
17 Zantac specific epidemiological studies.

18 Last, this study also shows a dose response  
19 relationship, meaning that the greater the exposure was  
20 associated with the higher risk of pancreatic cancer.

21 Okay, this next slide, this is data from a study  
22 looking at dietary exposure and the risk of pancreatic cancer.  
23 As you may recall, Mr. Nigh pointed out that dietary exposure  
24 to NDMA can occur through items like red meat, tobacco smoke,  
25 beer, and smoked meats, and as you can see here, consumption of

1 red meat was associated with a relative risk of pancreatic  
2 cancer ranging from 1.1 to 2.4. Again, this is showing a  
3 similar risk as the prior occupational exposure and Zantac  
4 exposure studies, which were 2.6, 2.6, and now we are at 2.4.

5 Next slide.

6 This is from the same dietary study and shows more  
7 than a doubling of the risk and sometimes more than a tripling  
8 of the risk of pancreatic cancer associated with exposure to  
9 cigarette smoke or beer, both known to contain NDMA. Again,  
10 this is showing consistency among the studies and the dose  
11 response relationship in that the risk increased as the  
12 exposure increased.

13 As you can see, your Honor, all three studies  
14 demonstrate more than a doubling of the risk of pancreatic  
15 cancer when exposed to NDMA whether the Trojan horse that was  
16 carrying the NDMA was Zantac, or tobacco smoke, or dietary  
17 consumption, or workplace exposure, so it is consistent.

18 Now I am going to show you a similar analysis with  
19 prostate cancer. So, we have a Zantac specific study that  
20 demonstrated a statistically significant increased risk of  
21 prostate cancer in Zantac users compared to Tagamet users,  
22 which showed no association. The overall relative risk was  
23 1.57. However, this study also demonstrated a statistically  
24 significant and a substantial risk, over five times the risk of  
25 prostate cancer for Zantac users who were 59 or younger. The

1 relative risk was 5.33.

2 This study also demonstrated more than a doubling of  
3 the risk of prostate cancer in Zantac users between the ages of  
4 60 and 69, and this was compared against the general population  
5 as well as against Tagamet users.

6 Again, this is the same occupational exposure study  
7 that I went over previously. This time it shows a risk of  
8 death from prostate cancer after exposure to NDMA in the  
9 workplace. The hazard ratio ranges from 2.32 in the lower  
10 quartile to 5.36 in the higher quartile. Again, the risk was  
11 statistically significant and demonstrated a dose response  
12 relationship, as well as consistency between the studies  
13 whether the exposure was from NDMA in Zantac or from NDMA  
14 exposure in the workplace.

15 The data that I just presented is a small snapshot of  
16 the science that is out there. The science in this case is  
17 still developing, but epidemiological evidence already exists  
18 demonstrating more than a doubling of the risk of certain types  
19 of cancers with Zantac use and a dose response relationship.

20 In addition, there is unanimous consensus in the  
21 scientific and medical communities that NDMA is toxic and a  
22 carcinogen that causes cancer in multiple organs. This  
23 statement holds true whether the Trojan horse delivering the  
24 NDMA is Zantac or tobacco smoke or through occupational  
25 exposure.

1           When you look at the weight of the evidence thus far  
2 you can see a picture beginning to appear even though we are  
3 only seeing the tip of the iceberg. We believe discovery will  
4 only add to the weight of the evidence demonstrating that the  
5 NDMA in Zantac causes certain cancers within the human body.

6           In fact, you can see how much it has changed in the  
7 last few weeks with the national recall. Last week a study was  
8 published in the British Journal of Cancer, the study that Mr.  
9 Agneshwar discussed in his opening. This study evaluated the  
10 class of H2RAs and gastric cancer and the authors stated that  
11 they found some evidence of the associations between PPI and  
12 H2RA use and gastric cancer risk. Those authors recognize the  
13 possibility of reverse causality, which Mr. Agneshwar noted,  
14 but what he did not tell you was that they adjusted for this  
15 possibility when they analyzed the study results.

16           When they examined the data in relation to Zantac  
17 specifically there was an increased risk of gastric cancer  
18 compared to non-Zantac users with fully adjusted odds ratios  
19 ranging from 1.42 to 1.17 with varying statistical  
20 significance. So, it was simply incorrect to state that the  
21 authors found no increased risk.

22           In addition, two posters were published at an industry  
23 sponsored convention last week regarding Zantac and cancer. We  
24 don't have the complete data or the full publications, but one  
25 poster indicated that the overall incidence of cancer was 26.4

1 percent in the Zantac exposed population compared to 13 percent  
2 in the general population, again a doubling of the percentage  
3 of incidents of cancer found in Zantac exposed population  
4 compared to the general population.

5 And the second poster was the Kim poster which Mr.  
6 Agneshwar also discussed in his opening. Kim noted that NDMA  
7 is a carcinogen and known to cause various malignancies.  
8 Again, I will preface this by saying we do not have the  
9 underlying data or the full publication, but the poster  
10 indicated that the authors only examined the risk of gastric  
11 cancer with Zantac versus two other drugs. Zantac was not  
12 evaluated against the general population.

13 The authors further noted that there was no increased  
14 risk compared to the other two drugs, but that the Zantac group  
15 had less risk factors for gastric cancer overall compared to  
16 the other two groups, and that may have affected the results.

17 Again, I bring these points up to demonstrate that the  
18 science is still developing and I suspect as we get into full  
19 discovery we will find further scientific evidence to support  
20 that the NDMA in Zantac leads to an increased risk of certain  
21 types of cancers.

22 Next slide.

23 Last, your Honor, this slide is a visual aid to show  
24 the increase in cancer incident rates over the ten years after  
25 Zantac was approved in the U.S. This data demonstrates the

1 incident rates when you plug in the top ten cancers that the  
2 Plaintiffs listed in the registry census data. As you can see,  
3 taking the ten most commonly listed cancers in the census and  
4 plugging them into the National Cancer Institute's database to  
5 track incident rates over time, it shows a very dramatic  
6 increase from 1983, when Zantac was approved, onward, and so  
7 the red line represents when Zantac was approved.

8 This next slide that just came up is a graph that is  
9 similar to the last graph, however, this time we plugged in the  
10 six types of cancers where there is epidemiological data  
11 showing an increased risk of cancer with Zantac. Again, you  
12 can see a rather dramatic increase in these cancer incident  
13 rates during the ten years after Zantac entered the market.

14 The last slide, we did the same analysis, but we only  
15 plugged in the breast cancer. As you recall, your Honor, Mr.  
16 Wisner mentioned the Mathes study from 2008, which demonstrated  
17 a 2.2 to 2.4 statistically significant relative risk of ductal  
18 carcinoma breast cancer in Zantac users compared to Cimetidine,  
19 which is Tagamet, Tagamet users. Again, you can see a really  
20 dramatic increase in the ten years after the product was  
21 approved for use in 1983. You see bumps up -- it spikes up  
22 again when Zantac over-the-counter 75 milligrams became  
23 available in 1995, and again when Zantac over-the-counter  
24 150 milligrams became available in 2004, you can see the trends  
25 going up.

1           You start to see a drop right after the time that  
2 Prilosec goes generic and Nexium hits the market at right  
3 around 2001, and both of those products -- that situation that  
4 occurred in 2001 significantly affected the Zantac market  
5 share. They were direct competitors of Zantac, a different  
6 class of medications not associated with breast cancer, and you  
7 can see there is a little bit of a leveling out of the big  
8 spike in breast cancer rates that had occurred.

9           Your Honor, with that, I will conclude. I thank you  
10 for your time and consideration. I am going to turn the floor  
11 over to Mr. Wisner to conclude our science presentation for  
12 today. Thank you.

13           *THE COURT:* Thank you.

14           I just want to assure the Defense that you will be  
15 given ample time because, again, I am not going to be going  
16 with my Q and A from 2:45 to 3:00 because I do see we are at  
17 2:30.

18           *MR. WISNER:* Thank you, your Honor. I apologize for  
19 us taking so long. We have a big burden of proof in this case  
20 and we are trying to lay out the basics as much as we can early  
21 on in the case.

22           What I am going to talk to you about for the last next  
23 few minutes here is, okay, look at all of this stuff we have  
24 seen about science, how the heck do you actually prove that in  
25 a court of law? That is sort of what I have done in my work as

1 a trial lawyer and working on how to prove cancer, and I kind  
2 of want to walk you through that process.

3 We obviously start with the jury instructions. I  
4 pulled the Florida jury instruction as well as the California  
5 jury instruction. Many states, not all, but many states follow  
6 a similar standard of causation. It is not that it has to be  
7 the only cause, that the substance has to be the only cause of  
8 the cancer, but a substantial contributing factor.

9 Well, what does that mean? I think the way you do  
10 that is you look at the process through which oncologists and  
11 physicians actually go about examining this question. They do  
12 something called a differential etiology or often referred to  
13 as a differential diagnosis.

14 The first thing you do is you make a list of known  
15 risk factors. For here I will give a hypothetical example,  
16 we'll say prostate cancer. I am not saying these are the risk  
17 factors for prostate cancer, but just for purposes of this  
18 exercise I am going to walk you through that.

19 You list all those risk factors. As you can see there  
20 at the bottom, NDMA exposure is one of the risk factors for  
21 prostate cancer. Determining that list of risk factors  
22 requires examining genealogy and science, and very often these  
23 risk factors are largely agreed to in the scientific community.  
24 For example, we know HIV is a known risk factor for lymphoma.  
25 There is no dispute about that.

1           Once you have the list of known risk factors, you then  
2 have to look at the individual client and ask yourself which of  
3 these known risk factors actually apply to this person, the  
4 person in front of you, the patient. You go through them all  
5 and you cross out the ones that just don't apply, and you move  
6 over the ones that do. For example, this hypothetical  
7 individual, their age was a potential contributor, they also  
8 had some Agent Orange exposure back in Vietnam, and they had  
9 NDMA exposure. Now you have gone through the known risk  
10 factors, the potential contributors for this specific  
11 individual.

12           Now comes the last step. That last step actually  
13 examines -- has you look at the specific potential contributors  
14 and decide which ones of them were substantial. And how you  
15 define "substantial" means more probably -- it's a  
16 probabilistic determination, it's similar to the weight of  
17 evidence that we have in a court of law, to show was it is a  
18 substantial contributing causal factor in that person's cancer.

19           So here, for example, the person's age, they were very  
20 elderly, and it's a disease highly associated with age, so age  
21 ends up then being a substantial contributing factor. The  
22 Agent Orange exposure that we identified originally, it turns  
23 out he was exposed only once back 45 years ago, there's no way  
24 that that itself could have caused it.

25           Then, of course, we have NDMA exposure. Here we have

1 a significant amount of NDMA exposure so they both are  
2 substantial contributors. Now, at this point, your Honor, we  
3 have actually proven our case because we have now shown maybe  
4 it wasn't the only cause, but it was a substantial contributing  
5 cause, and that is what is required by the law.

6 There is also an instance, your Honor, where you get  
7 to the end of it, and you have nothing left on the list. You  
8 crossed out all the potential contributors, and there are just  
9 no substantial contributing factors. Well, that's called  
10 idiopathic.

11 Something caused the cancer, we just don't know what  
12 it was. So, when you can't figure it out, we call it  
13 idiopathic. I think it's really important to keep that in  
14 context because very often someone will say, well, you haven't  
15 ruled out idiopathic causes. Well, the phrase idiopathic cause  
16 is itself incoherent because idiopathic means an unknown cause.

17 In any event, I think as we look at the general  
18 context of what we are doing here in discovery, first list, the  
19 known risk factors, that's general causation. The question you  
20 are trying to answer is: Is NDMA found in or created by  
21 Ranitidine capable of causing a particular type of cancer? We  
22 fully agree with the Defendants that we are going to have to do  
23 it on a cancer-by-cancer basis, but this is the question we are  
24 trying to resolve for the most part.

25 And then you go to the specific causation: Did the

1 NDMA exposure caused by ingesting Ranitidine substantially  
2 contribute to the development of that Plaintiff's cancer?

3 These two questions are what get you ultimately to a  
4 conclusion by a jury one way or the other whether or not  
5 Ranitidine caused that person's cancer.

6 Your Honor, I know we are way over time here and I  
7 apologize, I am trying to rush through this. The last point,  
8 it is really important, and that is how we untangle association  
9 and causation.

10 This is one of the core problematic things that we  
11 deal with in the science area, particularly epidemiologists  
12 deal with. This exact point was addressed by Sir Bradford  
13 Hill. He was a researcher, in 1965 he published an article  
14 titled The Environment and Disease: Association or Causation.

15 What he did is he outlined the various factors that  
16 you should consider when you see an association to determine if  
17 that association is in fact causal. These Bradford Hill  
18 factors are uniformly accepted in every regulatory agency, it's  
19 accepted in every scientific institution like IARC, part of the  
20 World Health Organization, and it is what Courts routinely  
21 consider in assessing whether or not general causation exists.

22 These are the factors, I will not get into them today,  
23 your Honor, this will be the subject of significant Daubert  
24 briefings and discussions later on, but I just wanted to give  
25 this as sort of template, the factors that we are going to go

1 through about the associations we're seeing that NDMA cancer  
2 are in fact causal.

3           Finally, the reference manual discusses this at  
4 length, I'm sure your Honor has studied this, and it says very  
5 clearly that this analysis, this Bradford Hill analysis, this  
6 is a function of judgment, that you have to look at it,  
7 consider it, is it realistic. And although these factors, none  
8 of them by themselves get you there, not having one of them  
9 also doesn't get you there. So, they are just things to  
10 consider and whether or not that methodology, which is reliable  
11 and acceptable, an appropriate way of doing it.

12           With that, thank you, your Honors, for your time. I  
13 know it has been a marathon and we turn it over to the  
14 Defendants.

15           *THE COURT:* Thank you from the Plaintiffs' team, and I  
16 look forward to hearing from the Defense team.

17           *MR. CHEFFO:* Good morning, your Honor, Mark Cheffo.  
18 For this presentation it is a team of one. Mr. Tam actually  
19 was good enough to get it up for me.

20           So, I am Mark Cheffo, your Honor, and I represent  
21 GlaxoSmithKline, and I am going to be doing the presentation on  
22 behalf of GSK as well as Boehringer Ingelheim, BI, Sanofi and  
23 Pfizer.

24           Let me first start by echoing what you have heard a  
25 lot of the last day or so, which is thank you. Thank you for

1 all of the work that you have done and the magistrate judge,  
2 special master, your staff and your team in getting us to this  
3 point and it's certainly well noticed.

4 The other thing that has really been impressive is  
5 that, notwithstanding all the challenges that we've faced, we  
6 have been so collegial about how you encouraged us to move  
7 forward, and we thank you for that, and also certainly thank  
8 you for the opportunity to present this science because not  
9 only is this my first Zoom Federal Court science presentation,  
10 it is probably the first time that I've actually had an  
11 opportunity, on behalf of my colleagues, to speak with a  
12 Federal Court Judge, probably any judge, this early in the  
13 litigation about the science issues. So we really do  
14 appreciate that.

15 We spent a lot of time, frankly, cutting down our  
16 presentation trying to get within -- I will tell you, I think  
17 we are going to keep it within what we understood we were  
18 supposed to be doing, but I also heard your Honor saying that  
19 if I need a few minutes, that you are not going to --

20 *THE COURT:* I just want to be clear, I want you to  
21 take the time that you need. I really have been liberal with  
22 time, but it was not intended to be to the detriment of any  
23 party. When we have more formal proceedings and trials, you  
24 know, I am very time sensitive because there are a lot of  
25 moving parts, including jurors and witnesses, and things of

1 that nature, but I feel my time -- I am available to hear  
2 everything you have to say, so I don't want you to feel that  
3 you have to stick within your time limit.

4 If we have to go over a little bit and it  
5 encroaches -- I know we have a break coming up -- we are fine.  
6 So, don't feel pressure to stick within. I've tried to afford  
7 a little bit of leniency here today with everyone.

8 *MR. CHEFFO:* And I appreciate that. Thank you, your  
9 Honor.

10 With that, let me just see if I can jump into it.  
11 Irrespective of time, today is not the day to cover every  
12 single issue we have, or address every single allegation, but  
13 certainly we would like to highlight for your Honor the main  
14 themes and issues that we think are important for your Honor to  
15 consider, and obviously, we will try to address many of the  
16 Plaintiffs' points that they have raised to the extent that we  
17 think it is appropriate at this point.

18 Just to give your Honor a quick road map of where we  
19 are going to go, there are maybe five themes that I think you  
20 will hear in this presentation today.

21 First, and I don't think this is controversial, is  
22 that we believe that well-established scientific principles and  
23 methods should be applied by your Honor, just like they would  
24 be by scientists and experts and researches outside the Court.  
25 As I said, I don't think that is controversial.

1           Second, general causation is a threshold issue, and we  
2 will talk a little bit about that.

3           Third, and this is very important, particularly based  
4 on what you have heard for the last 50, 60 minutes, Ranitidine  
5 is not NDMA. Data and science about Ranitidine, not NDMA or  
6 other products, or red meat or other exposures, are what we  
7 respectfully submit should actually drive the Court's inquiry.  
8 As you will hear, that is not hard to do because this is a  
9 product that's been on the market for a long time, and there  
10 actually is epidemiological data, even though I'm not sure that  
11 you heard that much about it from the Plaintiffs' perspective.

12           Fourth is that cancer is not a monolithic disease. I  
13 think there is actually some fair agreement on this one. It is  
14 a heterogenous disease, it's not homogenous, and I think we  
15 need to kind of evaluate the different types of cancers just as  
16 they would be evaluated in the real world.

17           Finally, we believe that when you look at the reliable  
18 scientific epidemiological and other data, there really is no  
19 causal connection between Zantac and any of the cancer disease  
20 end points that the Plaintiffs have alleged in this lawsuit.

21           That is particularly highlighted when you look at the  
22 regulatory actions of both the FDA and EMA, which is  
23 essentially the European FDA, because what their actions  
24 actually involved were not a determination of causality in any  
25 regard and we will talk a little bit about that.

1           So, that is kind of a broad road map. With that, your  
2 Honor, I am going to jump right into the slides here.

3           So, again, you have heard that Zantac is the brand  
4 name for a medication that is generically known as Ranitidine.  
5 It is in a class of medications called H2RAs, and what they do  
6 is they reduce stomach acid and they are effective in treating  
7 ulcers, reflux, and damage caused to the esophagus that is  
8 caused by reflux.

9           What you may not have heard or been aware of before  
10 is, we have all probably heard of Zantac in our normal lives,  
11 and think of it as a heartburn medicine, and in fact it is used  
12 for heartburn, but what I think is also important is that at  
13 the time that Zantac was actually approved it was a very  
14 important medicine because it was only the second nonsurgical  
15 treatment for ulcers at the time. So, obviously that gave  
16 patients and physicians a much broader range of optionality in  
17 terms of how to treat what could be potentially very serious  
18 ulcers that required surgery prior to that.

19           So, again, with the caveats, your Honor, that you  
20 certainly have probably dealt with causation, you have probably  
21 dealt with that as a practitioner, so I am going to only gently  
22 or generally touch upon these.

23           You will see a few things. One is, what we tried --  
24 if you look on the bottom of our slides, we sourced, where it  
25 is appropriate, the actual citations, and you will also see

1 many of our the citations come from things like the reference  
2 manual. So, hopefully that will make it easier for your Honor  
3 if you care to kind of check any of the sources or followup, if  
4 you will. With that, general causation and specific causation,  
5 two important points.

6 One is, it is the Plaintiffs' burden, I don't think  
7 there is any dispute about this, to prove both general, and if  
8 they get there, specific causation. It is not our burden to  
9 disprove any of them.

10 General causation, the way I think about it is  
11 examining whether an agent can cause an illness or injury in  
12 the general population, can it cause the injury. And then  
13 specific is, to the extent you determine that it can as a  
14 general matter, did it or does it in a particular individual.  
15 That is specific causation.

16 I said earlier, your Honor, that general causation is  
17 a threshold issue. The reason why I said that, one, it is from  
18 the manual, but it is also important that to the extent that  
19 the Court determines as we, again, respectfully submit that it  
20 can and should, that there is no -- the Plaintiffs have not met  
21 their burden on general causation, essentially it is do not  
22 pass go, full stop, we do not get to specific causation. In  
23 that regard, if it can't cause it from a population based  
24 perspective, then it certainly can't cause disease in any  
25 individual.

1           So, we've tried to, I think, objectively identify kind  
2 of what the question is that your Honor might ask yourself or  
3 might ask us to answer, really, at the general causation stage,  
4 and that is: Does the scientific evidence reliably demonstrate  
5 that therapeutic doses of Ranitidine, the actual medicine here,  
6 cause the specific cancers alleged?

7           There are a few components to this particular  
8 question, but I would like to first focus on the specificity of  
9 the exposure, and by that I mean Ranitidine and Zantac, because  
10 this case is about -- this MDL is not about red meat or  
11 occupational exposures to NDMA or anything else; it is about  
12 Ranitidine and about Zantac.

13           The Plaintiffs have kind of classified the, you know,  
14 the medicine as a pernicious carcinogen, and I don't think the  
15 Court should be left with the misinterpretation or  
16 misapprehension that, in fact, Ranitidine is some rare toxin  
17 with a signature injury. In fact, it is really just the  
18 opposite.

19           You have seen a similar slide to this, and I actually  
20 ask your Honor to look at a few points of this.

21           Before we kind of get there, we've heard a number of  
22 things. I think earlier in the opening we heard from Mr.  
23 McGlamry that NDMA has no business in the body. I think we  
24 heard a few times that this is a Trojan horse. We have seen  
25 that Trojan horse slide. This is like all the Trojans are

1 outside the horse because, in fact, this is levels in kind of  
2 everyday food at 3.5 ounces.

3 So, just taking beer that many of us might have a beer  
4 a day, or whenever it is, if you look at 3.5 ounces, it is 202,  
5 that translates to about a 12-ounce beer being 700 nanograms  
6 per day, which is seven times more than the actual FDA  
7 limitations that you heard about earlier today and I will talk  
8 a little bit about. Combine that with a sausage sandwich and  
9 some other things and you are obviously well over these daily  
10 limits.

11 There is a study that we cite here also that talks  
12 about dietary intakes, a recent study reporting up to 600  
13 nanograms a day for human beings.

14 So, let's talk about this 96 nanogram per day kind of  
15 FDA daily living. Mr. Agneshwar talked a little bit about this  
16 earlier, but I think it's worth highlighting just what this is  
17 and really how it -- it can't be overstated or oversold.

18 So, let me start from the beginning. It is not our  
19 point on any of this that this should be ignored, or the FDA  
20 does not have any right to set regulatory limits, of course  
21 not. The other side of this is that this is not a causation  
22 standard, this is not if you go -- if you have 97 nanograms a  
23 day somehow it is going to cause cancer. In fact, what the FDA  
24 has said is if you use this limit and you take it for 70 years,  
25 it is not expected to have an increased risk of cancer.

1           They characterize this as a theoretical calculated  
2 level. We know that this was used in, I believe, rat or mice  
3 studies, not human beings. So, this is a guide point, this is  
4 a regulatory limit that obviously the FDA has every right to  
5 set, but it is not a causation standard.

6           We also know that the FDA recently did some testing of  
7 samples of Zantac and determined that some of them actually  
8 exceeded the 96 nanogram per day limit, but others didn't, and  
9 what I don't think you saw in the Plaintiffs' presentation is  
10 the ultimate conclusion from this market withdrawal, which is  
11 that overall the risks to individual patients potentially  
12 exposed to nitrosamines in any drug product remain very small.

13           Again, the FDA has a right to do that, all the  
14 companies, to my knowledge, involved in this litigation have  
15 withdrawn their products, but the FDA did not come out and say  
16 that there is a causation between these issues, between cancers  
17 and Zantac, just the opposite.

18           Similarly, the EMA, again, the European FDA, said in  
19 probably even stronger language, available safety data do not  
20 show that Ranitidine increases the risk of cancer and any  
21 possible risk is likely to be very low.

22           We have heard a lot about the recent action, but I  
23 think it is hard to not focus on the actual statements and  
24 conclusions by the agencies that are instigating those actions,  
25 and just without taking that context of really what the

1 agencies have told us.

2 Your Honor, we know -- I think we have seen this, the  
3 Rider case cited perhaps by both sides, but I think it is  
4 important. As I said, what the FDA has done, it is a risk  
5 utility analysis and they are fully within their rights to do  
6 it. But I think many Courts, including the Eleventh Circuit,  
7 have said that the FDA's risk utility analysis involves a much  
8 lower standard than that which is demanded by a court of law.  
9 A regulatory agency such as the FDA may choose to err on the  
10 side of caution.

11 We believe that is what they did. Again, appropriate  
12 for them to do that, but as you read on in this, it basically  
13 says the standard that you are ultimately going to be judging  
14 general and specific causation under Daubert are very different  
15 in both the real world and before your Honor's courtroom.

16 So, if all of those things that I have been talking  
17 about are not ways to determine causation, how is it that we  
18 should look at the question of causation?

19 I apologize, this slide is a little bit busy, but let  
20 me see if it hopefully helps your Honor in thinking about some  
21 of these issues.

22 So, I would say that these are -- there are  
23 methodologies that are absolutely generally accepted and  
24 procedures and ways that scientists both, frankly, inside and  
25 outside the courtroom look at the questions of causation, and

1 it is largely a four-step process.

2 The first is possible association, is there  
3 association.

4 I will turn in a few minutes to the question of  
5 whether people look at Epi data or not, but I would submit that  
6 the vast majority, if not everyone other than outliers, would  
7 suggest that determining a possible association requires human  
8 epidemiological data that shows some type of positive  
9 association. So, that is the first.

10 But like most things in the world, and certainly in  
11 science, scientists don't take just a specific point estimate  
12 or a confidence interval or a dot on a chart at face value and  
13 just say, ah-hah, this causes cancer, this doesn't cause  
14 cancer. Frankly, if that was the way it worked, any of us  
15 could do it.

16 What they do is they use possible association data  
17 from epidemiology studies and then they go a few steps further.  
18 They then say, okay, is it possible that that finding is the  
19 result of what is called chance, bias, or confounding, because  
20 we have to rule out each of those. And these are very common  
21 concepts among scientists and researchers and peer review  
22 studies.

23 Then if, and only if, you actually get past the  
24 association, step one, chance, bias, and confounding, step two,  
25 do you then move to the Bradford Hill factors. Mr. Wisner

1 talked a little bit about those, and I agree that those are  
2 standard factors. I think if you were to read the literature  
3 on it, what it would tell us is that you don't have to apply --  
4 every one of them doesn't have to be a check the box, but  
5 typically the strength of the association must be kind of  
6 satisfied in terms of Bradford Hill, and then once you apply  
7 all the Bradford Hill factors, then you could actually make a  
8 considered decision based on causation or lack of causation.

9           So, there is absolutely a hierarchy of evidence, of  
10 scientific evidence. I think this might be an area where we  
11 kind of agree and respectfully disagree. We agree that there  
12 is human data, there's in vivo, animal data, and there's test  
13 tube data, but certainly having three pillars and kind of  
14 representing that they are all the same level of importance and  
15 hierarchy, we would kind of strenuously disagree. I think that  
16 is inconsistent with what you would find kind of in the real  
17 world with respect to scientific evidence.

18           Human Epi data is kind of the gold standard. It is at  
19 the top of the food chain, if you will, the hierarchy. I am  
20 going to talk about animal and test tube data. We are not  
21 suggesting that they are useless or that they don't have a  
22 point or they should be ignored, just the opposite.

23           Typically, what in vitro and in vivo data are used for  
24 are hypothesis generating to find out is there something  
25 potentially there, can you rule it out, and typically the way

1 science works and medicine and even the formation and approval  
2 of medicines require human epidemiological data to make sure  
3 that these findings can be replicated and are consistent in  
4 human beings.

5 So, remember in my little chart, the first is, is  
6 there association, right? And again, this is from the manual,  
7 your Honor. An association is the degree of statistical  
8 relationship between two or more events or variables, but  
9 because there are steps two, three, and four, association does  
10 not necessarily imply causation.

11 Then in step two we talked about, based on what the  
12 science tells us, and obviously this is validated by the  
13 manual -- let's take a step back.

14 I think a lot of what the point estimates -- and not  
15 being critical, I know there was a limited amount of time, but  
16 you saw a lot in the Plaintiffs' presentation just about charts  
17 and about all the point estimates and kind of trends. I think  
18 it would be helpful for the Court to also know that the story  
19 actually continues.

20 You have to then look at is there chance, bias, and  
21 confounding, because just because you have a positive  
22 association doesn't necessarily mean that it is a true or valid  
23 association; it could be false.

24 So, this is such a mockup of -- you probably heard a  
25 little bit about this, and you'll forgive me, your Honor, if it

1 is something that you are very familiar with, but I am going to  
2 spend a minute or two just to give some background.

3 This is a forest plot and we took some kind of  
4 hypothetical end points to just show the role of chance. That  
5 is one of the first, the chance, bias, and confounding.

6 The way scientists typically look at whether there is  
7 chance is that they look at whether there is statistical  
8 significance. I always hate to kind of overstate it, but the  
9 idea that you could have all these non-statistically  
10 significant findings and actually get a drug approved, that  
11 would probably be surprising. In other words, in the real  
12 world, statistical significance is very important, it is what  
13 epidemiology looks at, and it is what statisticians look at.

14 What this end point first shows is that you have a  
15 positive association. You can see that little purple circle to  
16 the right, and I agree with Mr. Wisner, he said that there was  
17 proof of an elevated risk or a protected risk. So, you have a  
18 positive association, but because the purple line, the  
19 confidence interval, crosses one, which is the center line,  
20 that means it is not statistically significant.

21 The second is a negative association, which again is  
22 not statistically significant. You can't rule out chance.

23 The third and fourth show findings that are  
24 statistically significant, right? One is a positive  
25 association, the other is a negative. That is statistically

1 significant because neither one of those in the confidence  
2 intervals -- if you look, it's CI, on the last one it's 0.9 to  
3 0.32. It doesn't include the number one, so that means that it  
4 is statistically significant. But even if you have a  
5 statistically significant finding it doesn't mean you have  
6 ruled out chance, but more importantly, it doesn't mean game  
7 over because you now have to kind of -- oops, sorry, I think I  
8 dropped here.

9 Excuse me, your Honor, technical problems.

10 *THE COURT:* Take your time, that is fine.

11 *MR. CHEFFO:* Your Honor, I apologize, this is a  
12 problem I never had in a courtroom before, place a screen  
13 behind a book.

14 So, let me just give you kind of an example. The way  
15 I typically think about this is, is something else going on?  
16 There's obviously scientific explanations for it. Confounding  
17 occurs when other causal factors confuse the relationship  
18 between the agent of interest and the outcome of interest. I  
19 wonder why my team picked this example from the manual, but for  
20 example, researchers may conduct a study that finds individuals  
21 with gray hair have a higher rate of death than those with hair  
22 of another color. Instead of hair color having an impact on  
23 death, the result might be explained by the confounding factor  
24 of age.

25 Again, in the real world, if you were to do a study

1 and you were to say we are going to look at people who have  
2 gray hair and then do a point estimate and determine that, in  
3 fact, it showed that it was relatively high that gray hair was  
4 a factor or caused death, it would be confounded by age.  
5 That's why you can't just look at the specific numbers, you  
6 have to actually look at is something else going on,  
7 essentially.

8 We talked about bias as well, this is protopathic  
9 bias, and for ease of memory, and certainly for me not to  
10 butcher the word, most people talk about this as reverse  
11 causation. I think you may have heard about this earlier, but  
12 let me just give you an example why this is so important,  
13 because not only do I think it is something your Honor will be  
14 presented with throughout this litigation, but in the real  
15 world studies that I am going to be talking about in a few  
16 minutes, the authors explain some of their findings, not me, in  
17 terms of reverse causation.

18 So, kind of a perfect example of this is that if  
19 someone were, unfortunately, to have stomach cancer that had  
20 not been diagnosed, they would likely have or they may have  
21 heartburn, right, and they don't know why they have heartburn,  
22 and then they go and they might take Zantac for the heartburn.

23 If someone were then to say, oh, within four months  
24 later that person went to the doctor and got diagnosed with  
25 stomach cancer, there would be a finding that they were taking

1 Zantac and they were diagnosed with stomach cancer, but clearly  
2 that is reverse causation because it's not that the Zantac  
3 caused the stomach cancer, it is that there was an underlying  
4 cancer that actually had a symptom that was treated by the  
5 medicine, so that is reverse causation. As you can imagine, in  
6 this kind of forum and these types of medicines and these  
7 diseases this is kind of a very common issue.

8 Now, the manual also tells us that you need  
9 replication and consistency and often, as things with science  
10 and, frankly, the law, things make sense, so you want to have  
11 replication and consistency. In order to do that, if we are  
12 going to say that something is a toxin or a carcinogen, we want  
13 to make sure that we actually can replicate the findings, that  
14 we have looked at it under similar situations, that the  
15 findings, the procedures are consistent, so we don't have the  
16 bias, and confounding, and the chance issues.

17 I would respectfully submit that picking a finding  
18 from occupational exposure, or red meat, or NDMA, or H2RAs,  
19 that is not what the science or the manual is talking about  
20 when they talk about replication or consistency.

21 If you have an actual disease causing agent and you  
22 look at a forest plot, you see multiple studies on the positive  
23 side with statistical significance with meta analyses. That's  
24 how you determine causation, when you have replication and  
25 consistency. As I am going to show your Honor in a few

1 minutes, when you actually look at the actual data for  
2 Ranitidine you do not see that.

3 So, taking our same question, your Honor, and just  
4 focusing briefly on another component, which is the specific  
5 cancers alleged -- you know, in some regards, many of us have  
6 been doing this for a pretty long time, your Honor, but having  
7 said that, we are always a little surprised, and I think many  
8 of us were surprised to see the panoply of cancers that were  
9 alleged. It seems every body system above the thigh, the  
10 Plaintiffs are alleging that Zantac caused those cancers. And,  
11 you know, again, respectfully, we don't think that that is the  
12 way, you know, carcinogens or toxins work.

13 Cancer is not a monolithic disease, it's not  
14 heterogenous. It has different biology, as your Honor can see  
15 on the screen, prognosis and progressions, different inductions  
16 and latency periods, different symptoms, etiologies, causes and  
17 risk factors. I won't belabor the point because, as Anand said  
18 earlier, unfortunately, probably all of us have been impacted  
19 one way or the other with cancer. I should have said at the  
20 beginning no one is minimizing, obviously, any of these  
21 diseases, they are very serious. The question here today is,  
22 is there a causal connection.

23 The fact is, if you went into a doctor's office and  
24 said, I have cancer, that really wouldn't tell anyone very  
25 much. You would have to know how you treat it, what the cause

1 is, what the risk factors, what the potential for spread is.  
2 All of those would depend on all the different factors and the  
3 differences between how the cancer spread, was caused, and how  
4 you treat it. So, they are very different, and that is why  
5 even within oncology we know doctors and specialists will often  
6 focus on very specific cancer end points.

7 And we also know, not from us, but from the American  
8 Cancer Society that even the strongest carcinogens don't raise  
9 the risk of all types of cancer.

10 If you looked at -- our colleagues on the other side  
11 are great lawyers, right, and they are going to be zealous  
12 advocates, and they already are, but what I would say is, if  
13 you looked at a lot of the discussion about even NDMA, it is a  
14 possible carcinogen, it is maybe, or it is linked, or we should  
15 make an assumption.

16 So, again, this case is not about whether NDMA causes  
17 cancer -- or Zantac, but even with respect to NDMA, it is  
18 certainly not the strongest carcinogen. Even if it was, the  
19 American Cancer Society tells us we would not expect it to be a  
20 complete body system cancer pill.

21 Now, the scientific evidence, your Honor, that is what  
22 we're going to focus on, the Zantac, Ranitidine specific data,  
23 and just a few words on that. You will see some actual human  
24 data.

25 In many regards this is unlike a lot of different

1 substances where we don't have a track record or there is no  
2 data, but here there actually is, and as you've heard, this  
3 product has been on the market, this medicine, for almost 40  
4 years. I am going to talk about the human data and I'm also  
5 going to talk about the others. You shouldn't be left with,  
6 hopefully, the implication or the impression that we are in any  
7 way trying to kind of run from or hide from the animal or test  
8 tube data, just the opposite.

9 We are trying to essentially be honest with ourselves  
10 and your Honor about how science works and focus on what  
11 scientists do, which is to look at the human data, but of  
12 course we will also talk briefly about the animal and test tube  
13 data.

14 So, this is that -- again, a little bit of an eye  
15 chart, we recognize that, your Honor, but this is a forest  
16 plot. We wanted to be super clear with our colleagues on the  
17 other side and with your Honor, this is a forest plot that has  
18 the main top level findings of specific cancers. There are  
19 other sub group analyses and smaller studies, and for a number  
20 of reasons, including time, but also, frankly, the reliability  
21 of those data, if we were to look at some of these sub group  
22 analyses, we would see findings from positive or negative.

23 But looking at kind of the reported out top level  
24 findings, what you see is a picture that does not say  
25 causation. In fact, if we kind of group these, and you look at

1 these different -- even within breast cancer, you heard a  
2 little bit about that earlier, if you look at the top, that is  
3 a non-statistically significant finding which trends negative,  
4 then you have non-statistically significant findings -- you  
5 have heard about the Mathes study, but in his overall study it  
6 is basically not a statistically significant finding with a  
7 minor positive trend and the same thing from the second breast  
8 cancer finding.

9 As you can see when you go down -- and we are not  
10 ignoring, your Honor, the three that are not highlighted now,  
11 but I just wanted to highlight these first.

12 You see, basically, the vast majority of the actual  
13 human Ranitidine data, which we think your Honor should be  
14 focusing on, and the Plaintiffs have not, is actually what  
15 tells the story here, that this is not a picture of a causal  
16 agent, much less the cancer pill that the Plaintiffs seem to be  
17 alleging in this litigation.

18 So, let's talk about the two findings. You will see  
19 that these are nominally statistically significant, meaning  
20 that they are positive findings, and that they are to the right  
21 of the axis.

22 Actually, can we go back for a minute to the last  
23 slide. Just a quick point I wanted to raise, your Honor, I am  
24 sorry about that.

25 You heard that, you know, we should be looking at the

1 data, even if the end point, that little dot, is to the right,  
2 we should -- you know, it could send us information or send  
3 signals, and I don't think any of us are suggesting that you  
4 just ignore data, that is not the point.

5           Could you imagine if you looked at all the dots on the  
6 left-hand side and we were saying, well, because it is trending  
7 negative, we think we should treat people with colorectal  
8 cancer, or esophageal cancer, or lymphoma, melanoma, ovarian  
9 cancer and uterine cancer with Ranitidine because there is a  
10 negative association, meaning you are less likely if you are  
11 using according to those studies? The answer would be  
12 absolutely not. That is not the way science works.

13           No doctor would look at that, or scientist, and say,  
14 oh, because it is trending negative, but it is not a  
15 statistically significant finding that this is somehow a cure  
16 for it. Similarly, if it is a positive association that is not  
17 statistically significant where you can't rule out chance or  
18 other factors, that also doesn't establish causation.

19           So, back to these, your Honor, apologies.

20           You have these three findings, and these authors, we  
21 are going to show you in a minute, they did exactly what you  
22 would expect because that is what happens when you go and you  
23 have a peer review study.

24           This is what Habel, the author -- I can't read the  
25 small print, I believe it is a she. Basically what she

1 found -- remember, there is only three in that whole study --  
2 that elevation of cancer risk might reflect the use of  
3 Ranitidine for early symptoms of cancer. In other words, we  
4 are seeing people diagnosed with cancer, but we think they  
5 actually had the underlying disease and were taking the  
6 medicine for that.

7 And she also, and her colleagues, also said that  
8 information was not available on known factors other than age  
9 and gender for specific cancers and our estimates may be  
10 confounded, meaning we really couldn't rule out here whether  
11 there were other things going on that also could have and  
12 perhaps likely contributed to those issues. You don't see the  
13 author saying, ah-hah, we think that this causes cancer,  
14 actually just the opposite.

15 And Habel basically, that same author, your Honor,  
16 published a textbook or was an author in a textbook and  
17 continued even eight years later to say that looking back at 11  
18 observational studies that looked at PPI and H2RAs for more  
19 than five years, what the author determined was that this  
20 review could not exclude reverse causation, and no data were  
21 available on underlying gastric conditions.

22 The same author that had those one or two findings  
23 basically says reverse causation, confounding, both then and  
24 eight years later.

25 You heard a lot about this, your Honor, but I think

1 this is a pretty interesting study in a lot of ways. One is,  
2 if we want to know what the author thinks the data said, not  
3 what the lawyers think, you have to look at what the author  
4 said. What the author said was these associations were  
5 sensitive to the duration of lag time used in the analysis.  
6 "Our results revealed a marked increase in the prescription of  
7 acid-suppression medications immediately before gastric cancer  
8 diagnosis suggesting the role of reverse causation."

9 Let me just see if I can break that down because I  
10 have had the benefit of reading that five times and the first  
11 time I read it, it wasn't a hundred percent clear to me.

12 What the author said, if you look back at that forest  
13 plot you would see three separate findings under Liu. One of  
14 them was statistically significant, the second two were not  
15 statistically significant. The first one that was  
16 statistically significant actually was within a year -- they  
17 looked at people who were a year of discontinuing Zantac, and  
18 they had a statistically significant elevated association  
19 between the cancer, I think it was stomach in that case and  
20 esophageal, and the Zantac.

21 The author said, well, that doesn't really make sense  
22 because the more -- you have heard about dose response.  
23 Cancers take a long time to develop, and it should be the more  
24 you actually take a medicine if it is actually a carcinogen,  
25 the greater the likelihood would be that you actually would

1 develop it.

2           What happened here is the people who only took it for  
3 a short period of time, there was a statistical association.  
4 When they looked at years two and three, that statistical  
5 significant association went away. So the authors, not us,  
6 concluded that there is confounding here, and this is the thing  
7 we talked about, the people actually had the cancer to begin  
8 with, took the medicine and then there was a finding, as  
9 opposed to the medicine causing the cancer.

10           Very briefly, your Honor, you saw the -- I think there  
11 was a fair amount of time spent by the Plaintiffs, or some time  
12 on the Mathes study. I showed you the top level findings on  
13 the forest plot, but what I think is important to understand  
14 also, in the concept of chance I think the numbers are, if you  
15 run -- in these studies, if you run 20 separate tests, for  
16 every 20, one of them will likely be the result of chance,  
17 either positive or negative. That is why when you see some of  
18 these studies that have 300 or 400, nothing is wrong with  
19 authors looking at it or doing it, but what they also recognize  
20 is that the more studies you run, the more likely from a  
21 statistical perspective you are likely to get certain findings  
22 of chance.

23           What this author said is that he recognized that -- he  
24 ran multiple testing, 82, and four of them would be subject to  
25 chance alone. So, we can look at the point estimate that you

1 were shown earlier, but when you actually look at what the  
2 author said, he said we cannot rule out that this observed  
3 increase risk in breast cancer among Ranitidine users "is a  
4 chance finding due to the number of statistical tests we did."  
5 That is what the author said, not what we are saying.

6 And again for completeness, but hopefully some level  
7 of brevity, as I said with the animal and test data, your  
8 Honor, we are not running away from it because we think it is  
9 not helpful. In fact, we don't think it really changes the  
10 equation. It is just a matter if you really want to find out  
11 if Zantac causes a cancer, you don't need look at red meat, and  
12 occupational exposure, and H2RAs, you look at the data from  
13 Ranitidine. But if you were to look at the H2RA class data,  
14 what you would find is that it does not actually support a  
15 finding of causation.

16 So, La Vecchia concluded that epidemiological data are  
17 consistent with the absence, with the absence -- you see that  
18 underlined -- of the causal association. Ahn could not rule  
19 out protopathic bias for reverse causation. Liu that we talked  
20 about just told us that the data suggests reverse causation  
21 because Liu actually dealt with H2RA data.

22 And then there is a very recent study, you know, you  
23 saw some information on pancreatic cancer in one of the slides,  
24 and obviously people talked about how that was a confounding  
25 and bias issue, but also this study looking at meta-analyses,

1 recent study, said "H2RAs were not associated with an increased  
2 risk of pancreatic cancer after the exclusion of a study with  
3 extreme results. In conclusion, there is no strong association  
4 between PPI and H2RA and the risk of pancreatic cancer."

5 So, while the data are actually evolving, they are not  
6 evolving in a way that shows causation.

7 Very briefly, your Honor, I am just going to talk  
8 about the animal data and test tube data, and then I will rap  
9 it up for you and your court reporter who has been so gracious.

10 To the extent that there was a question of the animal  
11 data, it is one of these examples of kind of hidden in plain  
12 sight. This is from the label, and in fact there was animal  
13 testing as you might imagine. You heard Mr. Petrosinelli talk  
14 about there was a truckload of information for MDAs. All of  
15 that was looked at. They didn't see any tumorigenic or  
16 carcinogenic effects when they were looking at this. They  
17 didn't see any mutagenic effects, which is an impact on  
18 mutations of the DNA. So, all of that was studied early on, it  
19 is in the label. The FDA approved it.

20 In terms of the bench science, just briefly, Mr.  
21 McGlamry talked about a Lancet article in his initial comments,  
22 and basically, I think the implication was that the study came  
23 out and that Glaxo either ignored it or was on notice.

24 Let me just put some color as to what actually  
25 happened. What Glaxo did was they analyzed that study. If it

1 was published in Lancet, it is obviously very well known, so it  
2 is hard to believe any regulatory agency would not have seen an  
3 article published in Lancet, but nonetheless, they looked at  
4 it. They shared the underlying studies and Glaxo's actions  
5 with the FDA. That study used NDMA at 20,000 times the dose of  
6 a fasting human gastric fluid and then they wrote to the FDA  
7 basically saying they have evaluated, they didn't think that  
8 there was any issues based on what they have done in this  
9 study.

10 What did the FDA do after that, having the study,  
11 having the data? They actually approved the product,  
12 Ranitidine, Zantac then for sale.

13 So, your Honor, everything we have talked about at  
14 every level of the hierarchy, there really is no reliable  
15 evidence of causation when you look at it the way,  
16 respectfully, we think scientists and your Honor will both  
17 inside and outside the courtroom.

18 Now, this was covered a little bit, but just very  
19 briefly in terms of specific causation, you know, it is  
20 obviously a differential diagnosis, and we agree that that  
21 would be the way to look at this to the extent your Honor got  
22 this far.

23 Also, we agree -- I think Paige talked about this a  
24 little bit earlier -- that in order to rule out all of these  
25 other -- you have heard about them even from the Plaintiffs,

1 how complicated this is with genetics, environmental factors,  
2 idiopathic, occupational exposures. A doctor would have to, he  
3 or she, if she got past the general causation, determine that  
4 it was Zantac that was a fact substantial contributing factor,  
5 whatever the specific law might be in that case.

6 I think, your Honor, that kind of brings me to the  
7 end. If you will indulge me maybe 30 more seconds, I would be  
8 remiss if I didn't kind of conclude with one quick point  
9 because I have been tasked to do the science today.

10 There were a number of claims and somewhat colorful  
11 rhetoric about the companies, and I think there will be a time  
12 and a place to address that and now is probably not that time,  
13 but I would just also suggest that we have people and companies  
14 who work pretty hard and they are trying to develop things like  
15 cures for COVID and get us all back to work, people who mean  
16 well, just like the Plaintiffs, and I would just suggest, just  
17 as I think there is a level of cordiality and collegiality and  
18 professionalism between the lawyers, as there is, I would  
19 suggest that we make sure that also extends to the clients on  
20 both sides, your Honor.

21 *THE COURT:* Okay, thank you very much, Mr. Cheffo.

22 Are you the last presenter for the science session?

23 *MR. CHEFFO:* Mercifully, yes, your Honor.

24 *THE COURT:* Okay. Thank you so much, I really  
25 appreciate it.

1           MR. CHEFFO: Thank you, your Honor.

2           THE COURT: So, we are going to take a little break.  
3 I recognize we are just off, but I would say we are doing  
4 pretty well given there is a lot of information packed into the  
5 day. If we are off by a few minutes it doesn't bother me. I  
6 hope it doesn't bother any of you.

7           It is 3:20, we are going to take a 15-minute break and  
8 we will be back at 3:35, and at that point, we will pick up  
9 with the case management issues, and I know you have allotted  
10 an hour for that, so let's try to keep that within an hour.  
11 We'll look to conclude by 4:30ish as opposed to 4:15. Quite  
12 frankly, actually I had us concluding at 4:30, so I think we  
13 are right on the mark. Without taking any more of our break  
14 time, we will see you back at 3:35.

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

16           THE COURT: Okay, we are back and now we are moving  
17 into the case management issues, agreed case scheduling  
18 proposal, and I turn it over to our presenters for this  
19 session.

20           MR. AGNESHWAR: Good afternoon, your Honor. I am  
21 Anand Agneshwar from Arnold & Porter on behalf of Sanofi.  
22 Welcome to the home stretch, at least for today.

23           THE COURT: What mile are we at? I want to know.

24           MR. AGNESHWAR: I think we are at about 26.1, because  
25 as long as your Honor likes what I am going to tell you, and

1 what we're all going to tell you, I think this should be a  
2 relatively short session that might even get us out of here a  
3 little bit early tonight.

4 *THE COURT:* Okay.

5 *MR. AGNESHWAR:* As your Honor has heard throughout the  
6 day, I think one thing that is clear from today is that the  
7 parties have diametrically different views about this case,  
8 about the science in the case, about culpability in the case,  
9 about really the whole shebang. Candidly, your Honor, that is  
10 where negotiations on how a case is going to be litigated often  
11 break down in an MDL, and that is structural, what is going to  
12 go first, what is going to go second, what is going to go  
13 third, how are things going to be organized. So, in this case,  
14 I mean, it is no different.

15 Because of these different views, back to the marathon  
16 analogy, it is clear from today we see this, general cause, as  
17 being the big issue in this case, and we see that as really the  
18 be all and end all, so we kind of see it as maybe a 5K or even  
19 a sprint in the litigation. Plaintiffs, obviously they are  
20 goading to get to trial, they want to go the whole shebang,  
21 they see general cause as kind of a nuisance along the way, and  
22 they are looking at it more as a marathon.

23 Notwithstanding those differences, over the past  
24 several weeks Joe Petrosinelli and I and Bobby and Mike on the  
25 other side -- I hope it is okay that I refer to them by first

1 names, we have been spending a lot of time together over these  
2 last couple of months -- have rolled up our sleeves to see if  
3 we can break through that and figure out a way to minimize the  
4 work on your Honor and on the Magistrate Judge and present to  
5 you a structure that we think is going to work for this case.

6 After all these meetings, after a lot of internal  
7 stuff we have had to do on our side and with our clients, and I  
8 am sure there has been a lot of sheep herding on the other side  
9 as well to sort of get all the ducks in a row, I am pleased to  
10 report that, with the assistance of Special Master Dodge, we  
11 have an agreement for a framework of this case.

12 *THE COURT:* Wonderful.

13 *MR. AGNESHWAR:* We haven't put it to writing yet, but  
14 we will do that, but right now I will let you know what the  
15 outline of that is.

16 *THE COURT:* Okay.

17 *MR. AGNESHWAR:* Basically, in a nutshell it is this:  
18 General causation, Daubert briefing, and that decision on  
19 general causation is going to precede the selection of  
20 bellwether and individual case workup.

21 The agreement is that we will file our Daubert motions  
22 18 months from June 1st, which will be about December 1st,  
23 2021. Hopefully we will be out of quarantine by then. That  
24 will be the first brief that we file and will trigger  
25 opposition briefs, replies, ultimately a hearing on this issue.

1           Between now and then, we will engage in non-bifurcated  
2 discovery. In other words, we, the Defendants, have agreed not  
3 to insist on case discovery or bifurcated discovery such that  
4 only general causation discovery will go first. We will agree  
5 that all discovery against the Defendants will happen within  
6 that 18-month period. That was important to the Plaintiffs  
7 because for them, if they prevail on some or all of the general  
8 causation hearing, they want to get right to it in working up  
9 individual cases for trial.

10           We have also agreed that, depending on how things  
11 shake out over the next 18 months and in the Daubert hearing,  
12 then we will at a later time, particularly when your Honor  
13 rules on general causation and we know if there is anything  
14 left in this case, or if it is one cancer or if it is two  
15 cancers and how that matches up with the census, we will have a  
16 better idea what the case workup is going to be like, are these  
17 all going to be people that have a 30-year history or is it  
18 going to be shorter term use, and that is going to inform what  
19 the time frame will be if the Plaintiffs survive general  
20 causation for case specific discovery and trial.

21           We have agreed to revisit that at that point in time.

22           In the meantime, we have also agreed that class  
23 certification will be done on the same track as Daubert so that  
24 first briefs to -- motions to certify class, however many  
25 classes the Plaintiffs feel they want, those motions will also

1 be filed on December 1st, 2021.

2 So what that means is, your Honor, that we have a lot  
3 of work to do over the next 18 months, but we know your Honor  
4 wants to keep things going, so there will be a Master Complaint  
5 that will be filed in the personal injury cases, there will be  
6 Master Complaints that will be filed in the class cases. There  
7 will be motions, I'm sure, but there will also be negotiations  
8 on discovery. You have a lot of companies here, so the  
9 Plaintiffs will have to tell us what they want and we will be  
10 negotiating things like search terms, custodians, how many  
11 depositions.

12 Similar on the class side, I think the Plaintiffs have  
13 told us that there is going to be approximately a hundred class  
14 representatives, so that is going to give rise to medical  
15 record collection and depositions of some number, if not all of  
16 them.

17 We think -- because we have been working  
18 collaboratively and we have come this far, I think this is kind  
19 of the big enchilada, reaching an agreement on the structure.  
20 We believe that if we start right now and roll up our sleeves  
21 and start negotiating that we will be able to do that.

22 That's essentially how we see the case going forward.

23 I think Mr. Gilbert wanted to talk a little bit about  
24 our vision for the next case management conference and what the  
25 immediate next steps will be with your Honor. With that,

1 unless your Honor has any questions about the schedule, I can  
2 turn it over to him.

3 *THE COURT:* No. I just want to reiterate my great  
4 appreciation for the hard work and the collaboration. I can  
5 only imagine that was not necessarily an easy consensus to  
6 reach on such critical issues in the case to both sides for  
7 different reasons.

8 Did you have to negotiate that you were the one able  
9 to actually make that announcement to the Court? I think that  
10 would have --

11 *MR. AGNESHWAR:* We talked about that at about  
12 8:00 o'clock last night, and that was the consensus decision as  
13 well.

14 *THE COURT:* Good. That is terrific. I want to  
15 express my gratitude, thank you.

16 *MR. AGNESHWAR:* Thank you, your Honor.

17 *THE COURT:* Okay. Mr. Gilbert, you wanted to address  
18 some other issues.

19 *MR. GILBERT:* Yes, I would like to just respond to my  
20 colleague, Mr. Agneshwar. Before I do so, let me, on behalf of  
21 all of us, and I know I speak on his behalf and on behalf of  
22 our Defense colleagues, but specifically on behalf of the  
23 Plaintiffs' leadership, I thank the Court, thank your Honor,  
24 thank Judge Reinhart, thank your staff and the Court Reporter  
25 for your attention today.

1 I'm sure you recognize how much work went into putting  
2 this day on from our standpoint, and we in turn recognize how  
3 much time and effort it took on the Court's part to get ready  
4 for it and to hold it, and we are all very appreciative. That  
5 is number one.

6 Number two, with regard to what my colleague, Mr.  
7 Agneshwar, just announced, in principle we have the same  
8 understanding. There are a couple of tweaks that, maybe just  
9 in hearing it, I didn't hear it exactly the way I understood  
10 it, but I don't think it is going to be an issue.

11 There are four orders that we discussed yesterday that  
12 are foundational, what we call foundational discovery orders,  
13 that we need to have in order to make a schedule like this  
14 work. In order to start discovery on day one and finish it by  
15 month 18 so that those motions can be filed everything has to  
16 be set and ready to go on the day the discovery date opens.

17 There are four orders that Mr. McGlamry and I  
18 discussed with Mr. Agneshwar and Mr. Petrosinelli yesterday  
19 that have been the subject of ongoing negotiations, and we hope  
20 will be resolved very shortly, that need to be in place on the  
21 day discovery opens, and that is the preservation order, the  
22 privilege order, the confidentiality order, and the ESI order.

23 You will hear more about those tomorrow. I am  
24 cautiously optimistic, as the Court knows I generally am, that  
25 we are going to reach agreement on either all or most of those

1 orders shortly.

2           What we discussed yesterday with our colleagues on the  
3 Defense side is that in the event we are unable to reach  
4 agreement and submit them to the Court by June 1st, which is  
5 our projected start date for discovery, and if any of those  
6 orders have not yet been resolved, that the unresolved orders,  
7 we notify the Court about those, and the Court can schedule a  
8 followup case management conference for sometime in the middle  
9 of June, and hear from both sides about our respective  
10 differences with respect to whichever of those orders haven't  
11 been resolved, and then make a decision and decide, okay, I am  
12 entering the ESI order based on this or based on that.

13           When the fourth of those orders are entered, that  
14 would become the official start date, the opening gate of  
15 discovery.

16           That was the only small nit, if you will, that I  
17 heard, a slight difference with my colleague, Mr. Agneshwar,  
18 about, but in principle, yes, from the start date of discovery  
19 we would go 18 months on full discovery, no bifurcation, no  
20 phasing. At the end of that 18-month period, they would file  
21 their general causation motions on Daubert in the PI cases, we  
22 file our motions for class certification.

23           The four of us expect to be able to put the dates and  
24 details on the key events and deadlines that need to take place  
25 between the opening of the discovery gate and the briefing on

1 those motions and be able to submit that comprehensive  
2 scheduling order to your Honor by June 1st as well, and we  
3 discussed that yesterday.

4 The last thing that is a joint issue that we discussed  
5 is that we plan to file our Master Personal Injury Complaint  
6 and our Master Class Complaints no later than 45 days from the  
7 date of the leadership appointment, which would come out on  
8 Monday, June 22nd. If we can get them filed sooner than that,  
9 we would love to, but we don't want to ask the Court for more  
10 time, so we have settled on the idea of 45 days, which comes  
11 out to Monday, June 22nd. And it is my understanding from our  
12 prior discussions that our colleagues on the Defense side have  
13 no objection to that as well.

14 So, that is where we are and I am hoping that Mr.  
15 Agneshwar will confirm that my slight tweak to his presentation  
16 is accurate, and assuming he does, we have one more Plaintiff  
17 side issue to discuss and I believe the Defense, Mr.  
18 Petrosinelli, has one more side issue to discuss.

19 *MR. AGNESHWAR:* Yes, your Honor, that is right. I did  
20 not mention that June 15th date because that is a date that  
21 happens only if we don't reach agreement on these initial  
22 orders. It was my understanding that Mr. Gilbert was going to  
23 handle that. I didn't view that as my responsibility to raise  
24 that issue, but all of that is correct. It is also correct, if  
25 this sounds acceptable to your Honor, then we will try to fill

1 in these dates over the next couple of weeks and hopefully  
2 submit yet another agreed upon order.

3 *THE COURT:* Okay. No, that sounds good.

4 Did I hear you, Mr. Gilbert, propose that there be a  
5 scheduled date for a conference, or shall we wait and see if  
6 you work things out so that I don't set it and then have to  
7 cancel it?

8 You all have worked so well together, I am like  
9 99.9 percent sure you are going to work it out because you have  
10 done that with a hundred percent of everything so far.

11 *MR. GILBERT:* We are in agreement that we don't want  
12 you to set it and have to cancel it if we work it out.

13 I confirmed to my friends on the other side that if we  
14 are unable to reach agreement and submit all the agreed orders  
15 by June 1st to the Court, we'll notify the Court that we need  
16 the conference, and then we'd ask the Court to set it sometime  
17 at the Court's convenience in the middle of June.

18 *THE COURT:* I will make myself available, so I think,  
19 consistent with the theme we heard last week and today, in many  
20 ways things are much more difficult because we are dealing with  
21 things remotely, but then again, in many cases things are  
22 easier. I can send you a Zoom link, and we could meet  
23 tomorrow.

24 And, you know, to be quite honest, there is a lot that  
25 is not happening in the courthouses these days because of COVID

1 and other things can go on. Fortunately, at this stage of the  
2 MDL right now, we can go on.

3 I guess that is a long way of saying I am available,  
4 so I don't want you to work out of fear that if we don't get  
5 to her and we don't work it out -- I do want you to work it  
6 out, or at least try to, so I take that back, but I am  
7 available, and with the ease of Zoom, we are like pros now  
8 after all of these sessions we've had. I am very accessible.

9 *MR. GILBERT:* We appreciate that. We can all tell our  
10 kids we are pros now even if they don't believe that.

11 Yes, obviously lawyers work well with deadlines. We  
12 don't need to have the Court set a hearing yet. We've agreed  
13 internally between our two sides that June 1st is that  
14 deadline, if you will, to get these agreed orders submitted or  
15 to say we couldn't reach agreement on one of them or two of  
16 them, and to so advise the Court.

17 So we have agreed on the deadline of June 22nd,  
18 subject to the Court's approval of it, for the filing of the  
19 Master PI Complaint and the Master Class Complaints, and we  
20 have agreed that we are going to submit the proposed scheduling  
21 order to the Court that Mr. Agneshwar announced. It will take  
22 us through Daubert, general causation Daubert, and to class  
23 certification by June 1st as well. With the cooperative spirit  
24 that has already developed and that you have recognized, I am  
25 extremely confident that we will be able to accomplish all

1 those goals and hopefully won't even need a mid June hearing.

2           The one last thing I actually forgot to say is that,  
3 assuming we don't need the mid June hearing, Mr. Agneshwar and  
4 Mr. Petrosinelli suggested that it would be a good idea to get  
5 a case management conference on the books for about -- I think  
6 they said about a week or ten days after the filing of the  
7 Master PI and Master Class Complaints, and that would give  
8 everyone an opportunity to have looked at them, reviewed them  
9 preliminarily, and there might be some peripheral discussion  
10 with the Court at that time to talk about how we are dealing  
11 with those particular matters.

12           *THE COURT:* I think that makes sense if Defense  
13 agrees. I had thought, short of there being issues that  
14 couldn't be resolved that you needed the Court for, and  
15 anticipating that you were going to propose a filing date of  
16 the Master Complaint that was within a very reasonable period  
17 of time -- okay so it's not 30 days, but we will take 45 --  
18 that it would seem to make sense to have the status conference  
19 following that.

20           So, I am very amenable to the week to ten days. What  
21 if I do this? What if I speak with Special Master Dodge, and  
22 she can coordinate with you to make sure your calendars are  
23 free, maybe you are not as available as I am, but coordinate so  
24 that we don't interfere with any outstanding obligations and we  
25 will set a date and a time consistent with that seven days to

1 ten days following the filing of the Master Complaints.

2 *MR. GILBERT:* That sounds great from our perspective,  
3 Judge.

4 *MR. AGNESHWAR:* And ours, your Honor, and I think at  
5 that case management conference we will also have a  
6 recommendation to your Honor as to how often we should have  
7 these management conferences over the next 18 months of this  
8 litigation.

9 *THE COURT:* That would be great. I had thought about  
10 do we want to lock ourselves in today or even tomorrow. I have  
11 looked at a lot of case management orders from many judges, and  
12 it would be easy to sort of pull one and say, okay, we are  
13 going to meet every month on the first Thursday of the month,  
14 but let's think about it and what makes the most sense, and at  
15 least for right now, I'm very available.

16 You have the time to mull that over and see how often  
17 you want to meet on a regular basis, but nothing precludes the  
18 parties from reaching out and saying we need something out of  
19 the ordinary, something has come up and we want to get off  
20 schedule for this month, and that is fine, too.

21 *MR. AGNESHWAR:* Understood, your Honor, we appreciate  
22 that and thank you.

23 *MR. GILBERT:* Thank you, your Honor. Do we need to  
24 submit anything to you now with respect to the June 22nd date  
25 or will the Court memorialize it --

1           *THE COURT:* Sorry to interrupt.

2           I think it would be -- again, we can develop what our  
3 approach -- mutual approach will be that works best for  
4 everyone. On a going forward basis, as you know, I like to be  
5 prepared and plan, so certainly before conferences having  
6 proposed agendas would be highly helpful. So we can maybe  
7 start thinking about how far in advance, how you want to submit  
8 them, what has worked well in other MDLs for you. It is not to  
9 say that an unexpected issue that may come up between the time  
10 you submit the agenda and the status conference is off limits,  
11 although I don't want to unfairly prejudice the other side by  
12 not having notice, so it is as long as everybody is okay with  
13 it.

14           But I would like as much advance planning, I am not a  
15 seat of the pants kind of person, although I recognize in some  
16 instances you need to be, but I do like to be prepared.

17           That's a long way of answering your question that  
18 before case management conferences I would like to have  
19 proposed agendas and you can think about how far in advance you  
20 are comfortable doing that, and then following each status  
21 conference I think it would behoove the parties and it would be  
22 helpful to the Court if the parties could submit a proposed  
23 order that memorializes that which we accomplished during the  
24 status conference.

25           If there is disagreement between the parties about

1 that, I can ultimately be the one -- obviously I will be the  
2 one to enter the final order, but I think that that -- you  
3 know, you can put the wording that you think works best.

4 So, to that end, if you would submit a proposed order  
5 following the status conference that memorializes, even if it  
6 is just these few points, I would be prepared to enter it.

7 Any time you do that, I would like it in Word format.  
8 You submit it to the Zantac email. I would like the other side  
9 to be copied and there be a representation in the email that  
10 leadership on both sides have reviewed and agreed with this  
11 order.

12 *MR. GILBERT:* Of course. We will work with Mr.  
13 Agneshwar and we will prepare it and get it in to the Court in  
14 the next couple of days.

15 *THE COURT:* For little things, you are spending so  
16 much time on big issues, not every order has to be taking a lot  
17 of your time. So far, Master Complaints on June 22nd and  
18 proposed scheduling order on June 1st, and any other dates,  
19 projected start date for discovery, June 1st, things of that  
20 nature, so it can be very short and simple, because there will  
21 be plenty of times when we will have more detailed orders that  
22 will require much more time on everyone's part.

23 *MR. GILBERT:* Of course. Thank you.

24 *MR. YOO:* Your Honor, this is Thomas Yoo. May I be  
25 heard for a moment on behalf of the generics?

1           *THE COURT:* Yes, absolutely. Do you want to put your  
2 video on so you can be seen as well?

3           *MR. YOO:* I am trying, but I am being blocked.

4           *THE COURT:* I think one of the cohosts will let you  
5 in. Let's just be patient a moment. I know that has happened  
6 in the past where it takes a moment for the video.

7           There you are. With you on, Mr. Yoo -- and I was  
8 going to -- actually when Mr. Petrosinelli was going to  
9 address, I think, the next section, I was going to call upon  
10 you, and also Ms. Johnston. If she wants to come on as well  
11 now, that is fine.

12           *MR. YOO:* Than you, your Honor. I don't want to cause  
13 any friction with how smoothly today has gone, and on behalf of  
14 the generics, we do appreciate all of the presentations. As  
15 your Honor knows, Mr. Petrosinelli has worked with me and my  
16 colleague, Rick Barnes, on behalf of the generics, and he has  
17 done a very diligent job of keeping us in the loop, but there  
18 are a lot of different cooks in the kitchen cooking up a lot of  
19 different things.

20           We felt it was necessary for us to just make one point  
21 with regard to the last agenda item regarding the case  
22 management plan as it relates to discovery.

23           This is the first the generics are hearing about this  
24 particular plan. We wanted to note for your Honor, and for  
25 everyone else on the call, the generics have not had an

1 opportunity to consider things like a start date, June 1st, for  
2 discovery, I heard the expression full discovery. We have not  
3 had a chance to speak with Plaintiffs about any specific  
4 proposal or what else they may have in mind with regard to the  
5 generics concerning the discovery.

6 I will also add on behalf of the generics that, as  
7 your Honor saw in the presentations today, preemption is going  
8 to be a particularly important issue for the generics. We as a  
9 group believe that preemption is a totally dispositive issue  
10 for our group.

11 So, we would like, certainly, to be considered on  
12 appropriate motions to dismiss once we see the Master  
13 Complaint, but we would also like an opportunity to speak with  
14 your Honor, Special Master Dodge, and the Plaintiffs, we have  
15 not had a meet and confer with the Plaintiffs yet, about  
16 holding discovery in abeyance as to the generics until the  
17 preemption issue is decided, or otherwise limiting initial  
18 discovery, but the idea of full discovery starting on June 1 is  
19 both a foreign concept to us and one that we think raises some  
20 important issues for our group.

21 *MR. PETROSINELLI:* May I respond, your Honor?

22 *THE COURT:* Yes. And did Ms. Johnston want to come on  
23 the video as well for the retailers? There she is.

24 Let me just ask, Ms. Johnston, did you want to say  
25 anything at this time before I turn it over to Mr. Gilbert?

1           *MS. JOHNSTON:* No, your Honor. Thank you.

2           *THE COURT:* There you are.

3           *MR. GILBERT:* My colleague, Mr. McGlamry, is on as  
4 well as you can see.

5           I am a little surprised to hear the presentation on  
6 behalf of generics only because it was my understanding that  
7 the Defense had been coordinating the discussions that we were  
8 having regarding the opening of discovery gates and the  
9 18-month plan with all of the different buckets of Defendants.  
10 Perhaps I misunderstood, but I will ask my colleague, Mr.  
11 McGlamry, to chime in here.

12           Obviously, discovery is discovery is discovery. If we  
13 are going to move forward in this case with discovery along the  
14 lines that we discussed, we intend to move forward with this  
15 discovery against all the buckets of Defendants, not select  
16 buckets of Defendants.

17           So, I'd ask Mr. McGlamry just to chime in to make sure  
18 that I didn't mishear what I thought the representation that  
19 had been made to us was, and let's see where it takes us.

20           *THE COURT:* What I will say is tomorrow is called the  
21 discovery conference, so this is the centerpiece of tomorrow's  
22 conference, and so, while I don't think that it is a bad idea  
23 that perhaps there are some -- there is some alert now to maybe  
24 some possible -- I don't want to say misunderstanding, but need  
25 to further clarify among the group that has worked so well

1 together, I will let Mr. McGlamry respond.

2 I am not going to make any ruling, I can tell you  
3 right now, about holding any kind of discovery in abeyance for  
4 any party at this very moment.

5 Now, while I appreciate hearing from Mr. Yoo, I do  
6 think that the issues for discovery are better suited for  
7 tomorrow. I would just say that, in light of Mr. Yoo's  
8 comment, that perhaps there can be some more discussions  
9 following the conference today as we move into tomorrow and  
10 certainly we can flush some of these issues out in greater  
11 detail.

12 *MR. McGLAMRY:* Thank you, your Honor. I feel like Joe  
13 and I are seconds at a duel and we are here to make sure that  
14 Bobby and Anand are doing this correctly. Let me respond, your  
15 Honor, because you are correct, tomorrow is our discovery day,  
16 and we will go through most of this tomorrow, but I will say  
17 this:

18 It is my understanding as we work through these  
19 various discovery orders, ESI, confidentiality, privilege,  
20 preservation, all of that has been on behalf of all Defendants,  
21 not just the four brand manufacturers, and they have included  
22 the generics and the retailers in that.

23 So, I find it hard to kind of appreciate that the  
24 generics would not understand that discovery would start like  
25 everybody else as the result of the work with these orders.

1           I do believe that we have had discussions, I have not  
2 personally, but others in our group with retailers, with  
3 Ms. Johnston about discovery beginning here as we get started,  
4 and so, obviously, we can talk about all of that tomorrow. Our  
5 goal, as it has been in our discussions with Joe and with Anand  
6 over the past several weeks with regard to this issue, that it  
7 is a full open discovery with all hands on deck from all  
8 parties. Thank you, your Honor.

9           *THE COURT:* Why don't I hear from Mr. Petrosinelli.

10           *MR. PETROSINELLI:* Yes, your Honor, I just was going  
11 to echo what you said, which is the issue that Mr. Yoo raises  
12 is really an issue for tomorrow.

13           One of the things I think your Honor has asked us is  
14 to consider a leadership structure on the Defense side. One of  
15 the things that relates to that is -- as Mr. Yoo said, I have  
16 been keeping the generics and the retailers, we have had weekly  
17 calls, up to date, and generally we have been able to submit a  
18 unified position to Mr. Gilbert, Mr. McGlamry, and the  
19 Plaintiffs, for example, on discovery orders we have and have  
20 been circulating those to the generics and retailers, but there  
21 are times when the generics and retailers raise issues that  
22 are, quite properly, unique to them. I can't speak for them on  
23 behalf of those and they are entitled to speak for themselves  
24 on behalf of those.

25           If they have an issue, as Mr. Yoo said, about

1 discovery or wanting to hold it in abeyance upon filing of  
2 preemption motions, that is their right to raise, in my view.  
3 It is not my right to say anything about that. But that is a  
4 tomorrow issue, I think, not a today issue.

5 *THE COURT:* Just following up on your point about  
6 leadership structure, can you speak as to what structure you  
7 believe has worked well, would work well on a going forward  
8 basis? I know that in one of my prior PTOs the Defense  
9 leadership team was put in place on an interim basis, and then  
10 we have the liaison counsel as well on an interim basis.

11 What process might you suggest for converting interim  
12 to permanent?

13 *MR. PETROSINELLI:* Yes, your Honor, we have to address  
14 that. We have -- since your Honor entered interim leadership  
15 appointments and liaison appointments, we have talked about  
16 this subject, talked about it with Mr. Yoo, Ms. Johnston, Mr.  
17 Barnes, and we actually have a consensus, and obviously they  
18 can speak for themselves, that the current structure has worked  
19 well, and at least at this stage of the litigation, given the  
20 Defendants, meaning the buckets of Defendants now are the brand  
21 Defendants, the generic Defendants and the retailers, we think  
22 that the way it has worked so far with the interim lead  
23 appointments essentially of the lead counsel for the four  
24 brands, then Mr. Yoo and Mr. Barnes as the liaison counsel for  
25 the generics, and Ms. Johnston as the liaison counsel for the

1     retailers, seems to have worked well.

2             We considered alternative structures, but we thought,  
3     given how well things have been working and given the current  
4     state of the litigation, that we would ask the Court to make  
5     those appointments permanent. They are always subject to being  
6     revisited if the nature and shape of the litigation changes,  
7     for example, if more Defendants in different categories are  
8     added, and so on. At least at this point, we thought we would  
9     ask your Honor to make these appointments permanent.

10            In terms of the process for that, I take guidance from  
11    the Court, but I assume that the Court would -- it is sort of  
12    an agreed slate in a sense, so it's a little bit different than  
13    the Plaintiffs' side, but if your Honor wanted short  
14    applications and conflict disclosures as you did on the  
15    Plaintiffs' side, because it is sort of an agreed slate, I feel  
16    confident we could do that in relatively short order.

17            *THE COURT:* Okay. What do you mean by short order?

18            *MR. PETROSINELLI:* Maybe about a week.

19            *THE COURT:* Okay. May I turn to Mr. Yoo and  
20    Ms. Johnston to see whether you are in agreement or have a  
21    different idea about leadership structure for the Defense.

22            *MR. YOO:* I am in agreement, your Honor, and I know  
23    Mr. Barnes is as well on behalf of the generics.

24            *MS. JOHNSTON:* Yes, your Honor, I am also in agreement  
25    for the retailers. It is something that we discussed as a

1 group and I think the structure as it seems works well.

2 *THE COURT:* Thank you so much.

3 Were there other issues, Mr. Petrosinelli, that you  
4 wanted to discuss other than leadership structure?

5 *MR. PETROSINELLI:* Just one other issue on the defense  
6 case management side. I think your Honor asked us particularly  
7 with respect to the census to consider and propose a cost  
8 sharing order. I don't have anything to report on that other  
9 than we are having productive discussions about that. I don't  
10 think there is anything to talk about today. There are no  
11 costs that have been incurred yet from the census vendors, and  
12 so we will continue to talk about that on our side and  
13 hopefully come to an agreed order on that.

14 *THE COURT:* Okay. Let me just ask as to everyone, as  
15 perhaps a final issue, or close to final issue, thus far  
16 between the Special Master and the Magistrate Judge, who will  
17 play a more active role tomorrow, Judge Reinhart, do you feel  
18 that you have adequate resources available to you, whether it  
19 be from the Court or from Special Master Dodge, or is there  
20 anything else that you need?

21 *MR. PETROSINELLI:* I was going to say, I think I speak  
22 for Anand as well, not at all. The help that we have gotten  
23 from Special Master Dodge, who seems to have boundless energy  
24 and has been able to really facilitate discussions on case  
25 management issues and the census, for sure, I think has been

1     incredibly helpful to us, and I don't think -- in fact, I think  
2     it might be even worse if we added another resource at this  
3     time because I think she has been so involved in the back and  
4     forth. So, from our perspective, it has been working perfectly  
5     well and we would like it to continue.

6             *MR. AGNESHWAR:* If I could say, your Honor, I don't  
7     want to jinx things, but I am amazed at how seamlessly this  
8     process has gone over the past month or two and I do believe  
9     that Special Master Dodge has done a great job in facilitating  
10    that and the parties have worked well together. We have now  
11    gone about seven and a half hours on a Zoom call and it has  
12    gone much more seamlessly than I thought it would, so I am  
13    finding the whole thing very impressive.

14            *THE COURT:* That is probably a good note to end on  
15    lest we do jinx something.

16            *MR. GILBERT:* From our perspective, your Honor, we  
17    completely agree. Special Master Dodge, as Anand and Joe have  
18    said, is just an incredible resource to both sides and we very  
19    much hope that she will continue in this role. Between her  
20    continued service and being able to have the opportunity to  
21    work with Judge Reinhart on the areas of his expertise starting  
22    tomorrow, we don't see any need right now for an additional  
23    appointment.

24            We have one small housekeeping thing. I meant to  
25    bring it up before.

1           *THE COURT:* Okay.

2           *MR. GILBERT:* We had previously submitted to you a  
3 proposed common benefit order. It was not -- now that we have  
4 formal leadership appointed, we would like to update that order  
5 and submit a final proposed common benefit order to you. It  
6 probably won't take us until June 1st, but since we have set  
7 June 1st as the deadline for everything else, I would just as  
8 soon set that and keep the deadline the same, but if we can get  
9 that in sooner, we certainly will, so the Court can enter it,  
10 assuming the Court is in agreement, and then we can move  
11 forward in that regard as well.

12           *THE COURT:* Yes, I am aware that I have been sitting  
13 on that insofar as you submitted it, it was intentional, it  
14 wasn't an oversight. I felt it was appropriate that leadership  
15 be put in place before an order of that nature be entered. It  
16 sounds like that was wise because you may want to update it or  
17 change it, or at least get the benefit of others who are now  
18 part of the leadership team.

19           You can include that in the deadlines that we have  
20 discussed here today, and June 1st would be acceptable.

21           I suspect coming out of tomorrow's hearing there may  
22 be other matters, so whether it is one combined order that  
23 includes what we just discussed today -- and I know Mr. Yoo  
24 still wants to have some discussions with Defense. And again,  
25 no order is going to be entered until I know that there is

1 agreement from everybody or I feel that there needs to be  
2 further discussion on the issue.

3 I look forward to seeing everybody tomorrow, tomorrow  
4 morning at nine o'clock, and following the agenda that you have  
5 laid out for me. It looks like it is a bit of a shorter day  
6 tomorrow, so that should maybe be a welcome relief for  
7 everybody.

8 MR. PETROSINELLI: Yes, thank you, your Honor.

9 THE COURT: With that, thank you so much, everybody,  
10 our presenters and all of the participants who are hiding  
11 behind the video. I can't see you, but I appreciate your  
12 attentiveness and wanting to learn more about the case. I hope  
13 you did. I certainly did, and wish everybody a nice evening  
14 and see you tomorrow morning.

15 MR. GILBERT: Thank you, Judge.

16 MR. PETROSINELLI: Thank you, your Honor.

17 *(Thereupon, the hearing was concluded.)*

18 \* \* \*

19 I certify that the foregoing is a correct transcript  
20 from the record of proceedings in the above matter.

21  
22 Date: May 24, 2020

23 /s/ Pauline A. Stipes, Official Federal Reporter

24 Signature of Court Reporter

25  
Pauline A. Stipes, Official Federal Reporter

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