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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. . April 29, 2022

MOTION TO STRIKE PROCEEDINGS (through Zoom)
BEFORE THE HONORABLE ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE

FOR THE PLAINTIFFS: **TRACY A. FINKEN, ESQ.**
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Official Court Reporter: Pauline A. Stipes
HON. ROBIN L. ROSENBERG
West Palm Beach/Ft. Pierce, Fl
561-803-3434

13:02:10 1 *THE COURT:* All right. Good afternoon, everyone. We
13:02:14 2 are here in the matter of In Re: Zantac Products Liability
13:02:20 3 Litigation, it's MDL 2924, and we are here for a hearing by
13:02:27 4 Zoom in light of the ongoing COVID pandemic on the brand
13:02:31 5 Defendants' expedited motion to strike rebuttal expert report
13:02:37 6 by Mira M., H-I-D-A-J-A-T, Hidajat, Ph.D., and motion for
13:02:46 7 approval of expedited briefing schedule, Docket Entry 5460, the
13:02:54 8 Plaintiffs' opposition to the motion at Docket Entry 5470, and
13:02:58 9 the reply in support of the motion at Docket Entry 5493.

13:03:00 10 Could we please have counsel who are arguing the
13:03:03 11 motion state your appearance for the record. And feel free to
13:03:06 12 turn your videos on as well.

13:03:10 13 *MS. HORN:* Good afternoon, your Honor, I am Elaine
13:03:11 14 Horn from Williams & Connelly, I represent Pfizer, but I am
13:03:14 15 arguing today on behalf of the brand Defendants.

13:03:19 16 *THE COURT:* Good afternoon.

13:03:20 17 *MS. FINKEN:* Good afternoon, your Honor, Tracy Finken
13:03:22 18 on behalf of Plaintiffs.

13:03:24 19 *THE COURT:* Good afternoon. I understand that there
13:03:24 20 has been agreement that the parties wanted 20 minutes each, and
13:03:31 21 that the Defense perhaps was going to reserve a certain amount
13:03:36 22 of that 20 minutes.

13:03:37 23 Is that correct, and have you decided how much time
13:03:40 24 you wanted to reserve for any rebuttal?

13:03:44 25 *MS. HORN:* Yes, five minutes, please.

13:03:46 1 *THE COURT:* Okay. All right. And so, 20 minutes
13:03:52 2 each, five minutes rebuttal for the Defense, and I guess we can
13:03:57 3 get started. I will keep track of the time, as I am sure you
13:04:01 4 will or someone assisting you.

13:04:04 5 Are you all ready to get started at this time?

13:04:09 6 *MS. HORN:* Yes, your Honor.

13:04:10 7 *THE COURT:* I will let you know, of course, that I
13:04:11 8 have read everything, including the report, but look forward to
13:04:16 9 your presentation and, you know, may have a question, but may
13:04:21 10 not, so I will see how it goes.

13:04:24 11 With that, you may proceed.

13:04:27 12 *MS. HORN:* Okay. So, your Honor, as you stated, we
13:04:29 13 are here on our motion to strike and the crux of this dispute
13:04:34 14 concerns the parties' expert epidemiologist. Plaintiffs have
13:04:38 15 designated two epidemiologists, Dr. Anne McTiernan and Dr.
13:04:44 16 Patricia Moorman, and as part of their work those experts
13:04:50 17 reviewed the current scientific literature on Ranitidine, as
13:04:54 18 well as NDMA, and provided an opinion that they thought that
13:04:58 19 the current scientific literature supported finding a general
13:05:02 20 causation.

13:05:02 21 As part of that, they looked at specifically data
13:05:06 22 concerning occupational exposure to NDMA, so these are not
13:05:12 23 people who took Ranitidine, they are people who were in a
13:05:15 24 workplace where they were exposed to NDMA. In the case of Dr.
13:05:19 25 Hidajat's work it was U.K. rubber workers.

13:05:24 1 So, both of them looked at the work, they analyzed it,
13:05:24 2 and they reached a conclusion that it helped support their
13:05:30 3 general causation opinions. As part of reviewing and analyzing
13:05:34 4 that work both of them went through it and identified certain
13:05:38 5 limitations, and notwithstanding those limitations, they both
13:05:39 6 reached the conclusion that it supported their work and they
13:05:43 7 relied on that.

13:05:45 8 It is the limitations that are key here. Both of
13:05:49 9 those experts independently identified limitations and
13:05:55 10 weaknesses; some of them overlapped, some of them didn't. For
13:05:58 11 Dr. McTiernan, she identified the inability to deal
13:06:03 12 with confounding factors, that there was not an establishment
13:06:07 13 of the dose of NDMA exposure, that there was an inability to
13:06:12 14 prove that any individual worker was exposed to any specific,
13:06:17 15 you know, level of exposure of NDMA, that there is a difficulty
13:06:21 16 in correlating occupational exposures, whether it is by skin or
13:06:28 17 breathing, to medication exposures, and that there is a failure
13:06:32 18 to adjust for the presence of other known carcinogens in a
13:06:36 19 rubber works workplace.

13:06:37 20 Similarly, Dr. Patricia Moorman, she also cited the
13:06:42 21 inability to control for confounding factors, specifically
13:06:42 22 smoking, that there is -- occupational exposures to NDMA may
13:06:46 23 not track the same type of route that medication exposure
13:06:51 24 would, and that workers within the occupational rubber works
13:06:56 25 field are often exposed to many carcinogens and not just NDMA.

13:07:05 1 At the appropriate time, the Defendants designated
13:07:07 2 their own experts, including epidemiologists, who addressed the
13:07:11 3 points that were raised by those two Plaintiffs' experts. They
13:07:18 4 also looked at the scientific literature and they specifically
13:07:19 5 looked at the Hidajat research, the rubber works research,
13:07:22 6 because it was relied upon by Plaintiffs' experts.

13:07:24 7 They were not independently bringing it to the table.
13:07:26 8 The only reason they were looking at it was because Plaintiffs'
13:07:32 9 experts relied upon it. As part of their review, they also
13:07:34 10 went through the limitations and weaknesses, but they reached
13:07:37 11 contrary conclusions than the ones reached by Plaintiffs'
13:07:41 12 experts.

13:07:43 13 So, that brings us to Dr. Hidajat. So, at the time of
13:07:49 14 the date in the scheduling order to serve rebuttal experts, the
13:07:54 15 slate that the Plaintiffs served included a brand new expert,
13:07:58 16 and it was Dr. Hidajat herself, who was the lead author of two
13:08:04 17 of the studies that were analyzing the U.K. rubber works data.

13:08:11 18 In her report there is one sentence that references
13:08:14 19 the Defendants' experts, but otherwise it is basically a
13:08:16 20 summary of the work that she and her team did previously, and
13:08:21 21 there is an expansion of it providing more detail, but it is
13:08:26 22 not actually rebutting anything that the Defendants brought to
13:08:29 23 the table.

13:08:29 24 In fact, she notes that the limitations that everyone
13:08:34 25 has discussed, but reached different conclusions, that those

13:08:38 1 are known limitations, that they are acknowledged to some
13:08:40 2 extent in the publications themselves, that it came up in the
13:08:44 3 peer review process, so this is not new.

13:08:49 4 And to designate her report as a rebuttal report turns
13:08:53 5 the concept of rebuttal on its head. These are issues that
13:08:58 6 were brought to the table for analysis by the Plaintiffs'
13:09:01 7 experts. We responded and you don't turn around and then bring
13:09:04 8 a third expert to amplify what your first two experts said and
13:09:10 9 call that rebuttal.

13:09:12 10 Both parties cite a range of cases, and if you look at
13:09:15 11 those cases, generally, when you are providing rebuttal
13:09:19 12 evidence you are rebutting some issue or new material or new
13:09:23 13 information that was affirmatively brought to the table by your
13:09:27 14 opposing party, and that is not what is going on here.

13:09:31 15 This report was something that could easily have been
13:09:34 16 served with the January reports. As I said, if you just took a
13:09:37 17 pen and struck through the sentence that references the
13:09:40 18 Defendants and change the date, it would be perfectly agreed,
13:09:43 19 just like the other reports that were served in January.

13:09:46 20 We know from her report that Dr. Hidajat was retained
13:09:50 21 had in November 2020, so well before the expert deadline. The
13:09:53 22 opinions that she presents, they closely track the opinions
13:09:58 23 that are already in the original slate of experts, Dr.
13:10:03 24 McTiernan and Dr. Moorman, and none of the limitations or
13:10:07 25 weaknesses that she is addressing were unknown.

13:10:12 1 This untimely submission, because it is untimely, it
13:10:16 2 prejudices the Defendants. As you know, today is April 29th,
13:10:21 3 the cutoff for expert discovery is May 31st, just a month away,
13:10:26 4 and between now and then the parties have to depose, between
13:10:31 5 both two sides, over 21 experts. Seven of those experts are
13:10:39 6 going to be deposed over two days, and at this point, we are
13:10:41 7 double tracking and in some instances triple tracking
13:10:46 8 depositions.

13:10:47 9 It is just unfair to inject at this late stage an
13:10:47 10 entirely new expert. We have a scheduling order that was
13:10:50 11 agreed to by both of the parties and approved by the Court, and
13:10:55 12 it should not be derailed at this 11th hour, so we are asking
13:11:00 13 that you strike the Dr. Hidajat report.

13:11:04 14 Thank you.

13:11:05 15 *THE COURT:* Okay, thank you. You didn't even come
13:11:07 16 close to using all of your time. That was six minutes and 35
13:11:12 17 seconds so you will have time to rebut if you need it.

13:11:17 18 Okay. With that, then, let me hear the response from
13:11:20 19 Plaintiff, from Ms. Finken.

13:11:24 20 *MS. FINKEN:* Thank you, your Honor, Tracy Finken on
13:11:27 21 behalf of Plaintiffs. I hope not to take my entire 20 minutes
13:11:32 22 as well, I will try to be brief.

13:11:34 23 Plaintiffs respectfully request that your Honor deny
13:11:37 24 Defendants' motion to strike. Rule 26 allows for the parties
13:11:41 25 to submit rebuttal expert reports as long as they directly

13:11:45 1 address the -- or contradict or rebut the evidence on the same
13:11:51 2 subject matter identified by another party's designated expert.

13:11:54 3 PTO 65 in this case allowed for rebuttal expert
13:11:58 4 reports, they were due on March 28th, and Plaintiffs timely
13:12:02 5 submitted Dr. Hidajat's rebuttal report on that date, and I
13:12:06 6 don't think that that issue is in dispute.

13:12:10 7 Dr. Hidajat is the lead author on a study that was
13:12:16 8 attached as Exhibit 1 to Plaintiffs' opposition to the brief,
13:12:21 9 and on page three of her report, which is attached as Exhibit
13:12:25 10 2, Dr. Hidajat directly addresses the criticisms of her study
13:12:30 11 and the methodologies that she used in her study that were
13:12:34 12 raised by the Defense experts, Dr. Terry, Dr. Witte, Dr. Chan,
13:12:40 13 and Dr. Wang, and it is in relation to five specific categories
13:12:45 14 that relate to the methodology that she used within her study.

13:12:49 15 Dr. Hidajat's opinions in her rebuttal report are
13:12:52 16 limited to the four corners of her study, they do not go beyond
13:13:00 17 the boundaries of the four corners of her study, and they
13:13:03 18 relate to the methodologies and the qualifications of the
13:13:07 19 individuals that were involved in that study.

13:13:09 20 So, there are Courts in this district, your Honor,
13:13:13 21 that find it permissible to use a rebuttal expert who has
13:13:17 22 specialized knowledge to rebut assumptions of another expert.
13:13:22 23 You can find that in Ohio State Troopers, which Plaintiffs cite
13:13:26 24 in Footnote 9 on page five of their opposition brief, and that
13:13:32 25 is precisely, precisely what Dr. Hidajat is in this case.

13:13:36 1 She has specialized knowledge about her study, and she
13:13:39 2 has been brought in as a rebuttal expert to rebut the
13:13:43 3 assumptions that Defendants' expert epidemiologists have made
13:13:48 4 about her studying the methodologies that were used in her
13:13:54 5 study. Like I said, her opinions are limited to the four
13:13:57 6 corners of her report.

13:13:59 7 The reality is, your honor, that the Defendants take
13:14:02 8 issue with one -- one sentence in Dr. Hidajat's report, and
13:14:06 9 that is the last sentence, which is on page 28 of her report
13:14:09 10 where she states her opinion that NDMA can cause cancer. This
13:14:14 11 opinion is based on the findings in her study which, as I said,
13:14:18 12 was attached as Exhibit 1.

13:14:20 13 I direct your Honor's attention specifically to page
13:14:22 14 257 and 258 of Exhibit 1, her study, where Dr. Hidajat and her
13:14:29 15 colleagues found a linear exposure response, otherwise known as
13:14:34 16 a dose response, association of NDMA with an increased risk of
13:14:39 17 mortality from cancers of the bladder, liver, stomach, among
13:14:43 18 others.

13:14:44 19 Despite this one single offending sentence, Defendants
13:14:47 20 seek to strike Dr. Hidajat's report in its entirety, and this
13:14:52 21 is improper. Moreover, your honor, it would be highly, highly
13:14:55 22 prejudicial to Plaintiffs to grant this motion.

13:14:58 23 Plaintiffs' experts -- and your Honor has the expert
13:15:01 24 reports so you are well aware -- rely on many, many studies to
13:15:08 25 support their conclusions that the NDMA found in Ranitidine can

13:15:10 1 cause stomach, esophageal, bladder, liver, and pancreatic
13:15:16 2 cancers. Plaintiffs could not possibly anticipate what
13:15:19 3 arguments or criticisms that the Defense experts would raise in
13:15:23 4 relation to that large volume of literature that Plaintiffs'
13:15:27 5 experts rely on which demonstrates and supports their opinions.

13:15:32 6 For example, Dr. Panigrahy, he cited to 530 peer
13:15:38 7 reviewed publications to support his conclusions that NDMA
13:15:43 8 causes the five cancers at issue here. Dr. Moorman cited to
13:15:44 9 276 peer reviewed publications to support her conclusions that
13:15:50 10 NDMA and Ranitidine cause the five cancers here, and Dr.
13:15:54 11 Salmon, another example, cites to 274 peer reviewed
13:15:57 12 publications to support his conclusions.

13:16:01 13 It is unreasonable to suggest that Plaintiffs should
13:16:04 14 anticipate exactly which publications Defendants would target
13:16:09 15 as a primary focus in their defense.

13:16:14 16 However, your Honor, after receipt of Defendants'
13:16:16 17 expert reports, it is clear that they have targeted Dr.
13:16:21 18 Hidajat's methodologies and her study as a significant part of
13:16:24 19 the defense of this case. In fact, a prime example, beyond the
13:16:28 20 opinions of the Defendants' experts that criticize the Hidajat
13:16:33 21 study with no support, the Defense has spent considerable time
13:16:37 22 attacking aggressively Defense -- the Plaintiffs' experts at
13:16:42 23 deposition about the methodologies in the Hidajat study.

13:16:48 24 For example, on Monday and Tuesday of this week
13:16:52 25 Defense took the deposition of expert Dr. Dipak Panigrahy, one

13:16:57 1 of Plaintiffs biocancer research experts, and even though Dr.
13:16:59 2 Panigrahy's opinions and methodology regarding NDMA's ability
13:17:06 3 to cause human cancers have already been deemed reliable by
13:17:12 4 Judge Kugler in the District Court of New Jersey, Defense
13:17:17 5 counsel cross-examined Dr. Panigrahy for ten hours on the
13:17:20 6 record and specifically asked over 120 questions related to the
13:17:23 7 methodologies in the Hidajat study. Many of the issues
13:17:28 8 that Defense counsel cross-examined Dr. Panigrahy about
13:17:29 9 centered on the issues that Dr. Hidajat addresses in her
13:17:33 10 rebuttal report.

13:17:35 11 The significance of Dr. Hidajat's report and study to
13:17:38 12 this case is telling given the great lengths Defendants are
13:17:43 13 going to in an attempt to strike Dr. Hidajat as an expert.
13:17:45 14 Rather than pose these questions directly to the author of the
13:17:50 15 study herself, she is the lead author on that study, they would
13:17:56 16 rather spend their time moving to strike that and posing over
13:18:00 17 120 questions to other Plaintiffs' experts in the case about
13:18:04 18 the methodology in that particular study.

13:18:08 19 Just moving on, your Honor, if you should agree with
13:18:11 20 the Defendants that the rebuttal report should have been
13:18:13 21 submitted on January 24th in Plaintiffs case in chief, it is
13:18:18 22 certainly within the Court's discretion whether to permit it at
13:18:23 23 this juncture.

13:18:23 24 As I said, respectfully, it would be extremely
13:18:31 25 prejudicial to Plaintiffs to strike Dr. Hidajat's report in its

13:18:32 1 entirety given the Defense attack on the Hidajat study is a
13:18:35 2 primary part of their defense, and especially since a trial
13:18:39 3 date has not even been set in this case.

13:18:41 4 The rebuttal report was served before any
13:18:45 5 Plaintiffs -- sorry, any expert depositions had been taken at
13:18:50 6 all, and when it was served we had a meet and confer about
13:18:57 7 this, and Plaintiffs concede that the deposition of Dr. Hidajat
13:19:02 8 is appropriate. We also discussed the possibility of Defense
13:19:07 9 experts being able to file a rebuttal to Dr. Hidajat's
13:19:11 10 rebuttal. Defendants declined to do that. Instead, they filed
13:19:17 11 a motion to strike, and here we are one month later, and the
13:19:21 12 time, you know, has passed.

13:19:25 13 We -- it is our position that there is no prejudice to
13:19:28 14 Defendants to allow Dr. Hidajat opinions and her report to go
13:19:36 15 forward. There are more than seven large law firms
13:19:40 16 representing the Defendants in this case, many of whom we see
13:19:43 17 on every conference, and there is more than a month left to
13:19:46 18 take a single deposition of one rebuttal witness that has a
13:19:52 19 very narrow area of focus concerning the four corners of her
13:19:58 20 study.

13:19:59 21 Given the extraordinary amount of time that Defense
13:20:03 22 counsel spent cross-examining Dr. Panigrahy, it is abundantly
13:20:08 23 clear that Defendants are adequately prepared to take that
13:20:11 24 deposition, and it is simply disingenuous at best for
13:20:16 25 Defendants to say that they cannot get that done within the

13:20:19 1 confines of the expert deadlines in this case.

13:20:24 2 I say that, your Honor, because we have been having
13:20:25 3 multiple expert depositions this week. We had a two-day
13:20:29 4 deposition of Dr. Panigrahy. There were more than five lawyers
13:20:35 5 for Sanofi on that deposition, there were more than three
13:20:39 6 lawyers for GSK on that deposition, and similarly, we have the
13:20:44 7 deposition going forward yesterday and today for Dr. McTiernan,
13:20:48 8 there are more than seven or eight Defense lawyers on that
13:20:51 9 deposition.

13:20:51 10 Surely they can spare a single lawyer, or even two, to
13:20:54 11 take a single narrowly focused deposition of Dr. Hidajat within
13:20:59 12 the next month, and Plaintiffs are certainly willing to work
13:21:03 13 with the Defendants to make sure that that deposition can
13:21:06 14 occur.

13:21:07 15 With that being said, your Honor, we believe that the
13:21:11 16 Defendants' motion should be denied, and we should proceed with
13:21:14 17 the scheduling of Dr. Hidajat's deposition, and I am certainly
13:21:20 18 happy to answer any questions that Your Honor might have.

13:21:24 19 *THE COURT:* Thank you, that was about 9:59.

13:21:27 20 Let me hear any rebuttal, and then I will see if I
13:21:29 21 have any questions. Thanks so much.

13:21:32 22 *MS. HORN:* Thank you, your Honor. Ms. Finken
13:21:35 23 referenced the voluminous number of citations that her other
13:21:40 24 experts relied on in their report and that it would be
13:21:42 25 unreasonable to anticipate what types of attacks could come to

13:21:47 1 those particular other study authors. The thing is, here they
13:21:50 2 obviously did anticipate the issue of Dr. Hidajat's research
13:21:55 3 because they retained her in November 2020. So, it was not a
13:22:00 4 surprise that someone was going to criticize her work, they
13:22:02 5 were anticipating that. Why they did not submit a report from
13:22:08 6 her in accordance with the actual schedule is unknown.

13:22:12 7 Plaintiffs say that the -- basically, Dr. Hidajat's
13:22:17 8 rebuttal report is limited to the four corners of her study,
13:22:23 9 which is the -- there's two parts, I'm sure which publication
13:22:24 10 that specifically she is referencing, but regardless, they are
13:22:30 11 all from 2019.

13:22:31 12 If that is the case, that same report has already been
13:22:35 13 analyzed and reviewed and discussed by Plaintiffs' other
13:22:39 14 epidemiologists. Again, the criticisms about the methodology,
13:22:45 15 those were already noted in large part by Plaintiffs' own
13:22:48 16 experts. They are noted to some extent -- or preemptively
13:22:52 17 addressed in the publication and Dr. Hidajat noted that these
13:22:57 18 same types of questions came up during the peer review process.

13:23:03 19 None of this is new, none of this is new, and
13:23:05 20 Defendants are entitled to rely upon the schedule that is in
13:23:10 21 place, and so they are entitled to, you know, work with the
13:23:14 22 schedule that we have, schedule in the experts that are already
13:23:18 23 in existence.

13:23:20 24 The Defense attorneys are not interchangeable. I
13:23:25 25 cannot speak to the specific identity of the people that

13:23:28 1 Ms. Finken referenced, but I am sure some of them may have been
13:23:31 2 associates who were learning about depositions. It could have
13:23:32 3 been a wide range of things, but again, these are people who
13:23:36 4 are not interchangeable.

13:23:36 5 There are some people who are focused on epidemiology,
13:23:41 6 which is not new, not news, that's what happens. There are
13:23:44 7 some people that are focused on other topics, but the people
13:23:48 8 who are focused on these issues, they are booked up, as I said,
13:23:51 9 through the end of May. We all planned ahead and everything
13:23:55 10 has been scheduled through the end of May, so it would be very
13:23:58 11 unfair to now throw in this completely curve ball new expert.

13:24:08 12 Ms. Finken referenced the fact that Dr. Hidajat --
13:24:10 13 that we take issue with Dr. Hidajat's conclusion that NDMA
13:24:15 14 causes cancer. Of course, many of Plaintiffs' experts reach
13:24:19 15 that conclusion. That is not something that is novel or new,
13:24:22 16 and that is not the reason that we want to strike her report.

13:24:26 17 We want to strike her report because it is out of time
13:24:29 18 and it is new. The report itself is new, not that particular
13:24:34 19 conclusion.

13:24:39 20 So, your Honor, we again would ask that our motion be
13:24:43 21 granted, but if it is not granted, we don't believe that it
13:24:47 22 would be fair to try to schedule in both the additional
13:24:52 23 deposition of Dr. Hidajat before May 31st, and as Ms. Finken
13:24:57 24 noted, we believe for some of our experts we need to file
13:25:00 25 rebuttal reports as well. Given the fact that everything has

13:25:06 1 been planned out and we are completely booked, it would not be
13:25:11 2 reasonable to try to get that all done before May 31st, so we
13:25:14 3 ask that you grant our motion and strike the report.

13:25:18 4 Thank you.

13:25:19 5 *THE COURT:* Okay, thank you very much.

13:25:24 6 So, from the Plaintiffs, why wasn't Hidajat named as a
13:25:29 7 primary expert if she is so important and her report and her
13:25:33 8 study or studies are so important, and she is the subject at
13:25:37 9 least in part of the McTiernan and Moorman, and I guess she --
13:25:43 10 coupled with that question, she offers at the very end of her
13:25:47 11 report on page 28 -- she says: Taken together, based on the
13:25:52 12 totality of the evidence, it is my professional opinion within
13:25:56 13 a reasonable degree of scientific certainty that NDMA can cause
13:26:01 14 cancer.

13:26:02 15 Then earlier up on that page in the conclusion she
13:26:06 16 says: There were other statistically significant findings for
13:26:14 17 cancer mortality for which we -- I am sorry -- which we did not
13:26:19 18 conduct sensitivity analysis on. That was not as relevant to
13:26:25 19 my question.

13:26:26 20 So, I guess just to recap, why was she not named
13:26:30 21 initially given, I am sensing from Plaintiff, they consider her
13:26:36 22 study to be very important? It is not that it is important
13:26:39 23 because the Defendants have necessarily attacked it, but I am
13:26:43 24 presuming the Plaintiffs feel her study is important, and in
13:26:47 25 fact, two of your primary general causation experts, at least

13:26:50 1 two, rely upon her, and then she makes this -- she offers this
13:26:56 2 opinion that within scientific certainty that NDMA causes
13:27:03 3 cancer, which is what the Plaintiffs are trying to establish,
13:27:06 4 and there certainly is a body of case law that speaks about the
13:27:13 5 burden is on the Plaintiff in that regard and so that should be
13:27:18 6 put forth in -- that is something that is put forth in the case
13:27:21 7 in chief for the Plaintiff.

13:27:22 8 So, I guess that is one question I have for
13:27:25 9 Plaintiffs, for Ms. Finken.

13:27:29 10 *MS. FINKEN:* Certainly, your Honor. First, Dr.
13:27:29 11 Hidajat was retained as a consulting expert, she is not giving
13:27:36 12 a general causation opinion because, obviously, we want to be
13:27:38 13 offering up a general causation opinion based on one singular
13:27:42 14 epidemiological study. That is all she addresses in her
13:27:48 15 report, and her conclusion at the end of her rebuttal report is
13:27:50 16 related to her findings within the study itself.

13:27:55 17 Plaintiffs did not intend to put Dr. Hidajat up as an
13:27:59 18 expert at all. We were using her as a consulting expert, but
13:28:04 19 given the assumptions that were made and criticizing
13:28:08 20 the methodology of Dr. Hidajat's study, we felt that we had no
13:28:12 21 choice but to do that in a rebuttal manner.

13:28:15 22 One of the things, your Honor, to be frank, we could
13:28:18 23 have easily offered the information about the methodology and
13:28:22 24 the assumptions that were made in an affidavit as a fact
13:28:26 25 witness and attached it to the Daubert briefing. Defendants

13:28:30 1 would have cried foul that they didn't have the opportunity to
13:28:34 2 depose her, so we wanted to be transparent and offer her up as
13:28:38 3 a rebuttal expert witness so they could actually depose her,
13:28:43 4 thoroughly ask her about her methodologies and the assumptions
13:28:47 5 that were made and be transparent about the situation.

13:28:50 6 I mean, we had weighed whether or not it just made
13:28:53 7 sense to address those assumptions in an affidavit and call her
13:28:58 8 as a fact witness.

13:28:59 9 We are trying to be transparent and offering her as a
13:29:03 10 rebuttal witness so that the Defendants can thoroughly explore
13:29:07 11 her opinions about her study and the methodologies that were
13:29:08 12 undertaken for that study. She is certainly not offering a
13:29:13 13 general causation opinion. That particular sentence pertains
13:29:16 14 to the findings that she made in her study.

13:29:20 15 However, your Honor, I would submit that if your Honor
13:29:22 16 was inclined to strike anything, it would be that particular
13:29:27 17 sentence, and not the entirety of Dr. Hidajat's report if you
13:29:32 18 think that that particular sentence in the report is improper
13:29:36 19 as a rebuttal opinion.

13:29:43 20 *THE COURT:* Okay, thank you. Just a general question.
13:29:51 21 It sounds like you have your depo schedule already in place.
13:29:56 22 Maybe you shared it with me, but I don't have the answer here.
13:30:02 23 Can you tell me when Drs. Chan, Terry, Witte, and Wang's depositions
13:30:04 24 are set?

13:30:08 25 *MS. FINKEN:* Your Honor, they are set the last week of

13:30:10 1 May, May 26th, May 27th, May 30th, May 31st. Those four are
13:30:21 2 set for the very last days of this expert discovery schedule,
13:30:25 3 with Dr. Terry being the last one on May 31st.

13:30:44 4 *THE COURT:* Why aren't McTiernan and Moorman, why
13:30:46 5 aren't their rebuttal reports sufficient to address any
13:30:49 6 criticisms that Chan, Terry, Witte, and Wang have lodged
13:30:55 7 against Hidajat's study and her methodology and, you know, the
13:31:07 8 various things that kind of are summarized with the five bullet
13:31:10 9 points on page three of the report and then expanded upon
13:31:14 10 throughout the study -- throughout her report itself?

13:31:19 11 *MS. FINKEN:* And that is very -- that is a great
13:31:22 12 question, your Honor, and the reason is that Dr. Hidajat has
13:31:26 13 specialized knowledge about the analysis and the methodology
13:31:29 14 that was undertaken that Dr. McTiernan and Dr. Moorman would
13:31:37 15 not be able to necessarily glean just from a publication.

13:31:40 16 Dr. Hidajat is the only one who has the entirety of
13:31:43 17 the body of knowledge about the methodology, the peer review
13:31:47 18 process, and everything that was undertaken for purposes of
13:31:50 19 this study and the multiple publications that came out of this
13:31:55 20 study, and she is in the best position to support that
13:31:57 21 methodology in the study.

13:32:00 22 She is the one who has the specialized knowledge about
13:32:02 23 it, and the experts that she is rebutting have made criticisms
13:32:07 24 of her report that are unsupported based on assumptions, and
13:32:15 25 those assumptions can only properly be addressed by the study

13:32:19 1 author herself, who is the only one who has the entirety of the
13:32:21 2 body of knowledge to address those criticisms that, like I
13:32:25 3 said, are based on assumptions and there are no references as
13:32:29 4 to why they are criticizing those reports for those reasons.

13:32:35 5 Drs. McTiernan and Moorman would not necessary have
13:32:40 6 access to some of that information. It is not only Drs.
13:32:45 7 McTiernan and Moorman who are at issue here. Like I said, Dr.
13:32:45 8 Panigrahy was questioned for a significant amount of time on
13:32:50 9 Tuesday, over 120 questions about specifically the methodology
13:32:54 10 in Dr. Hidajat's report.

13:32:58 11 *THE COURT:* Could that expert answer the questions?

13:33:02 12 *MS. FINKEN:* Some of them he could, but only what was
13:33:04 13 contained within the publication. If it is not within the body
13:33:07 14 of the publication itself, it is not something that he would be
13:33:10 15 able to answer.

13:33:12 16 *THE COURT:* Sorry to interrupt. That is really a
13:33:14 17 question I have. There are some things that only she knows
13:33:17 18 because it is in her brain, it is in her mind. It is, as you
13:33:22 19 call it, her own specialized knowledge.

13:33:25 20 So, I think you are acknowledging that there are
13:33:31 21 aspects of what is in her report that were not and could not
13:33:35 22 have been in McTiernan's or Moorman's report, and so even
13:33:43 23 though some -- either none, some, or all, that is where the
13:33:50 24 dispute lies in terms of kind of the -- is it substantially
13:33:56 25 sort of the same subject matter. There were attacks lodged at

13:34:02 1 methodologies. Surely McTiernan and Moorman had to understand
13:34:07 2 methodologies to be able to rely upon it and come to their own
13:34:12 3 conclusion.

13:34:13 4 So one would presume a certain level of comfort that
13:34:18 5 they must have had in relying upon the report in the ways that
13:34:21 6 they did, but in introducing a specialized knowledge in a
13:34:25 7 rebuttal report that I think you are saying has never been
13:34:28 8 disclosed before, so it is brand new -- not the methodology,
13:34:35 9 not the limitations, not necessarily the conclusions, but the
13:34:37 10 specialized knowledge brought to the table by Hidajat is anew,
13:34:42 11 and really, shouldn't rebuttal reports not be bringing
13:34:48 12 something to the table anew? I mean, doesn't that run counter
13:34:52 13 to a rebuttal report?

13:34:57 14 *MS. FINKEN:* Your Honor, there is actually authority
13:34:59 15 that suggests that if a rebuttal expert has specialized
13:35:04 16 knowledge to rebut assumptions that are being made by another
13:35:08 17 expert, that that is proper rebuttal testimony.

13:35:10 18 As I stated, you can find that in Ohio State Troopers,
13:35:14 19 which is cited in Footnote 9 of Plaintiffs' opposition and that
13:35:19 20 is expressly stated here.

13:35:23 21 I want to make this really clear.

13:35:25 22 *THE COURT:* In that case, I am sorry, was the
13:35:26 23 specialized knowledge brought up initially? Was it out there
13:35:31 24 initially, and then it comes back again also in the rebuttal,
13:35:36 25 or was it brought up for the first time in the rebuttal?

13:35:40 1 MS. FINKEN: It was brought up initially, but here it
13:35:42 2 was brought up initially, too. Dr. Hidajat's study was
13:35:46 3 discussed I think in every expert report in this case. Where
13:35:54 4 it becomes problematic is that Defendants attack the
13:35:55 5 Plaintiffs' experts for relying on Hidajat because they are
13:35:59 6 talking about what they believe is an improper methodology or a
13:36:02 7 failure to consider certain conditions, and the only person who
13:36:07 8 can truly support the methodology that was used in that study
13:36:11 9 are the study investigators and the study authors.

13:36:16 10 It is not an epidemiologist's role to assess the
13:36:23 11 specific methodologies of every single study that they rely on.
13:36:28 12 I mean they certainly look at the strengths and the limitations
13:36:32 13 of the study and look at the methods, but unless they are in
13:36:35 14 the investigator's shoes, they can't answer all of those
13:36:38 15 specific questions.

13:36:39 16 There were assumptions being made by the Defense
13:36:42 17 experts, and just ipse dixit attack of the methodology in Dr.
13:36:51 18 Hidajat's report.

13:36:53 19 It is certainly not new information. It was used to
13:36:54 20 rebut the assumptions being made by the Defense experts and
13:36:59 21 that is all. It is limited to the four corners of her study,
13:37:02 22 it is a very targeted rebuttal report, and under the case law
13:37:05 23 that is out there, it is Plaintiffs' contention that it is
13:37:09 24 proper.

13:37:10 25 I just lost my train --

13:37:13 1 *THE COURT:* Does that open the door -- I think Defense
13:37:15 2 made this point, and it is not as if you have done it with
13:37:19 3 other studies, but is it the Plaintiffs' position that if a
13:37:23 4 study that is relied upon by a primary expert is attacked by
13:37:28 5 way of methodology, which seems to be a common attack on
13:37:33 6 experts, you know, their qualifications or their methodologies,
13:37:38 7 you know, which covers really a whole range of things, that you
13:37:42 8 just bring in the author of the study to rebut because that
13:37:49 9 author is the only person who has the specialized knowledge?

13:37:54 10 *MS. FINKEN:* Your Honor, I think that -- that is a
13:37:59 11 good question. Honestly, I don't know. I can tell you,
13:38:02 12 though, that we had Dr. Hidajat already as a consulting expert,
13:38:06 13 which is why we did it. We certainly didn't reach out to every
13:38:10 14 study that they criticized the methodology to provide a
13:38:16 15 rebuttal expert report.

13:38:18 16 The one thing I do want to point out -- and it just
13:38:20 17 came to me where I had lost my train of thought -- is it is not
13:38:21 18 just Drs. Moorman and McTiernan who rely on Dr. Hidajat's
13:38:25 19 study, Dr. Hidajat's study is relied upon by Dr. Panigrahy and
13:38:31 20 Dr. Salmon, and in particular, in relation to dose of NDMA that
13:38:36 21 would provide certain cancers.

13:38:38 22 So, to exclude her ability to justify the methodology
13:38:43 23 and criteria and some of the confounders that were taken into
13:38:49 24 effect during that study, like I said, we believe would be
13:38:53 25 highly prejudicial to Plaintiffs. Since there is no prejudice

13:38:57 1 to Defendants for this disclosure, they have the ability to
13:39:00 2 take the deposition, they have the ability to rebut it if
13:39:03 3 necessary, Plaintiffs would submit that it would be appropriate
13:39:06 4 to allow her to testify in this case.

13:39:26 5 *THE COURT:* Okay. Well, I appreciate it.

13:39:29 6 Let me make sure I don't have any more questions. Let
13:39:32 7 me look at my notes real quick.

13:39:56 8 *MS. FINKEN:* Respectfully, your Honor, one last point
13:39:58 9 to make. Ms. Horn has actually stated herself during her
13:40:04 10 argument that there is nothing new that Dr. Hidajat -- it is
13:40:08 11 not new evidence that she is discussing. So, I just wanted to
13:40:12 12 point that out in response to your Honor's question on whether
13:40:16 13 this is new or novel and should not -- would not be appropriate
13:40:19 14 for rebuttal testimony.

13:40:22 15 *MS. HORN:* Can I speak to that, your Honor?

13:40:24 16 *THE COURT:* Yes. I know that the Defendants -- on
13:40:27 17 page seven of your motion you say in the first full paragraph
13:40:35 18 that the doctor offers novel opinions on the studies that are
13:40:38 19 entirely absent from the opening reports submitted by the other
13:40:43 20 general causation experts, and then you go through a litany of
13:40:47 21 what those are with citations to her study.

13:40:51 22 *MS. HORN:* Correct. My reference, though, is to the
13:40:53 23 limitations and weaknesses that we are criticizing, that those
13:41:00 24 criticisms were already known well before Defendants ever filed
13:41:05 25 their particular expert reports.

13:41:08 1 *THE COURT:* What did you mean by the novel opinions on
13:41:12 2 page seven?

13:41:15 3 *MS. HORN:* That's referencing the same types of
13:41:19 4 information that Ms. Finken is referencing, basically adding in
13:41:24 5 new information or details about how certain things were
13:41:29 6 considered.

13:41:30 7 *THE COURT:* Specialized knowledge? In other words,
13:41:31 8 you are calling novel opinions what Ms. Finken is calling the
13:41:37 9 specialized knowledge?

13:41:39 10 *MS. HORN:* Correct. Just to carry on from that, it is
13:41:40 11 also important to note that presumably when Plaintiffs' other
13:41:44 12 experts, like Dr. McTiernan, when they relied upon Dr.
13:41:51 13 Hidajat's work, or the publications, they didn't have all of
13:41:55 14 this extra little detail that Dr. Hidajat is apparently wanting
13:42:01 15 to bring in now.

13:42:03 16 They were relying on the four corners, as she says, of
13:42:05 17 the publications, and it's -- they were relying on it, our
13:42:12 18 experts were criticizing their reliance because of these
13:42:15 19 issues. The fact that they are able to potentially address
13:42:19 20 those issues doesn't change the fact that their original
13:42:23 21 experts were willing to rely on the studies without having
13:42:27 22 those issues addressed.

13:42:29 23 That calls into question the conclusions reached by
13:42:33 24 their original experts.

13:42:35 25 *MS. FINKEN:* Your Honor, can I respond to that?

13:42:36 1 *THE COURT:* The Defendants can make that argument
13:42:38 2 regardless, whether she is offered as an expert or not. If her
13:42:43 3 -- if they weren't privy to this kind of detail of her
13:42:50 4 methodology, and your experts say that is a problem, I mean,
13:42:55 5 wouldn't that still be fair game for the Defendants to
13:43:01 6 cross-examine or seek to impeach, at least her conclusions?

13:43:07 7 Now Plaintiffs are fighting for a chance to have the
13:43:12 8 author herself in a separate conversation, sort of say how she
13:43:17 9 did things and maybe why they weren't flawed in the way that
13:43:23 10 the Defendants are saying they are, although the Plaintiffs'
13:43:28 11 experts note the limitations as well.

13:43:31 12 *MS. FINKEN:* Your Honor, can I respond to that
13:43:32 13 briefly? Because I think that this is a really critical
13:43:36 14 distinction.

13:43:37 15 Plaintiffs' experts point out the limitations in the
13:43:40 16 study, the body of the study, and the strengths, strengths and
13:43:45 17 limitations, like they do with all of the epidemiology studies
13:43:50 18 that are out there.

13:43:51 19 The Defense experts criticize the Plaintiffs'
13:43:55 20 methodology for how they approach the study because the Defense
13:43:59 21 experts, their methodology is unreliable because they are
13:44:04 22 making assumptions that they don't know, assumptions about the
13:44:07 23 Hidajat study that they are citing in the report that are
13:44:11 24 completely unfounded and unsupported.

13:44:14 25 *THE COURT:* But they wouldn't know otherwise, right?

13:44:17 1 There was nothing, presumably, put before the
13:44:20 2 Defendants to -- you know, I am not taking sides one way or the
13:44:24 3 other, but if it this was never put forward as to how the study
13:44:30 4 was conducted, the methodology, you know, I guess they could
13:44:36 5 just not address it at all, or you make assumptions.

13:44:39 6 You are saying the assumptions are wrong, your
13:44:42 7 assumptions are wrong, but they had -- they didn't have
13:44:49 8 anything, presumably. Nothing that was put forth by the
13:44:52 9 Plaintiffs, are you saying, that would have given them a reason
13:44:55 10 to reach a conclusion one way or the other, so they shouldn't
13:44:58 11 have drawn any assumptions?

13:44:59 12 Or now that they have drawn assumptions and they are
13:45:04 13 wrong, we want to come back with something new in terms of like
13:45:07 14 the specialized knowledge, or the novel opinion, however we
13:45:08 15 want to call it, we are all agreeing -- I guess the parties are
13:45:10 16 agreeing, you know, that part is new, and so now it is coming
13:45:16 17 forward.

13:45:17 18 So now they are saying, oh, okay, well, we didn't have
13:45:20 19 that before, maybe we would have come up with a different
13:45:25 20 assumption or a different conclusion even. Is that fair?

13:45:31 21 *MS. FINKEN:* Well, your Honor, I think the thing that
13:45:34 22 is critical to make the point is that they could have relied on
13:45:39 23 the limitations and the strengths and the information contained
13:45:44 24 in the study report, but they went one step further, they made
13:45:48 25 assumptions that they have no grounds or nothing supporting

13:45:53 1 those assumptions, and used it to attack our Plaintiffs'
13:45:59 2 experts in the case in chief.

13:46:00 3 So Dr. Hidajat's singular role is to provide a
13:46:05 4 rebuttal report to correct and rebut those assumptions. That
13:46:09 5 is all she is doing here. She is not providing a general
13:46:12 6 causation expert report. It was improper for the Defendants to
13:46:16 7 attack the methodology and make assumptions based on no
13:46:20 8 supporting evidence whatsoever.

13:46:24 9 *THE COURT:* Did the Plaintiffs' rebuttal expert
13:46:27 10 reports -- I don't have everything at my fingertips -- by
13:46:32 11 McTiernan and Moorman point out that the Defendants -- the four
13:46:37 12 Defendants' experts, Chan and Terry and Witte and Wang, had no
13:46:44 13 basis to make those assumptions, they are just out of left
13:46:48 14 field? There is no basis, no foundation on which they can --
13:46:52 15 there is no scientific methodology, there is nothing reasonable
13:46:58 16 about the Defendants' experts making those assumptions, did
13:47:03 17 they point that out in their rebuttal reports?

13:47:07 18 *MS. FINKEN:* Your Honor, I would have to check. I
13:47:09 19 know that they rebutted some experts, and off the top of my
13:47:12 20 head -- I would have to go pull them up, but some of the
13:47:16 21 experts did provide rebuttals to some of the Defense experts,
13:47:21 22 those four Defense experts.

13:47:21 23 Whether they spoke specifically to assumptions made by
13:47:24 24 them on the Hidajat study, I am uncertain as I sit here today
13:47:30 25 in all honesty. I would have to go and check.

13:47:39 1 *THE COURT:* Ms. Horn, do you know offhand?

13:47:40 2 *MS. HORN:* I don't actually. The people who know this
13:47:41 3 particular point, the vast are actually in a deposition right
13:47:45 4 now. I don't have that specific level of detail.

13:47:50 5 *THE COURT:* That is fine. That is fine.

13:47:51 6 Was there one other thing, Ms. Finken, you wanted to
13:47:54 7 say?

13:47:55 8 *MS. FINKEN:* No, your Honor. I just want to stress
13:47:55 9 that Plaintiffs could have just, as I said previously,
13:48:02 10 submitted the information as an affidavit and had Dr. Hidajat
13:48:06 11 as a fact witness to basically attack the assumptions that were
13:48:09 12 being made in her study; however, we chose to be transparent,
13:48:17 13 give the Defendants the opportunity to depose her as an expert,
13:48:20 14 discuss her methodologies in detail, and we gave them plenty of
13:48:22 15 time to do that.

13:48:24 16 It has been a month since those reports were served.
13:48:26 17 We could have had a deposition by now. We are willing to work
13:48:28 18 with them to make sure that happens within the confines of the
13:48:31 19 expert discovery deadline that is in place today. Thank you.

13:48:35 20 *THE COURT:* Thank you both very much. Nice to see
13:48:37 21 both of you.

13:48:38 22 *MS. FINKEN:* Good to see you as well, have a great
13:48:42 23 weekend.

13:48:43 24 *THE COURT:* You, too, take care, bye-bye.

13:48:45 25 (Thereupon, the hearing concluded.)

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I certify that the foregoing is a correct transcript
from the record of proceedings in the above matter.

Date: April 29, 2022

/s/ Pauline A. Stipes, Official Federal Reporter

Signature of Court Reporter

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