

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP,  
BI-LEVEL PAP, AND MECHANICAL  
VENTILATOR PRODUCTS LIABILITY      No. 21-mc-1230  
LITIGATION.                                      MDL No. 3014

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Transcript of Status Conference proceedings held on  
Thursday, June 15, 2023, in the United States District Court,  
700 Grant Street, Pittsburgh, PA, 15219, before Senior Judge  
Joy Flowers Conti.

APPEARANCES:

For the Plaintiffs	Kelly K. Iverson, Esq. Christopher A. Seeger, Esq. Sandra L. Duggan, Esq. Steven A. Schwartz, Esq. D. Aaron Rihn, Esq. Peter St. Tienne Wolff, Esq. David R. Buchanan, Esq. Shauna Itri, Esq. Elizabeth Pollock-Avery, Esq. Charles E. Schaffer, Esq. Caleb Seeley, Esq. Joyce Chambers Reichard, Esq. Kathryn L. Harrison, Esq.
For the Philips RS North America, LLC Defendants:	Lisa C. Dykstra, Esq. Wendy West Weinstein, Esq. Colleen Gallagher, Esq. Laura Hughes McNally, Esq. Amanda B. Robinson, Esq. Ashley Gindle, Esq.
For Other Philips Defendants:	Michael H. Steinberg, Esq. William B. Monahan, Esq. Elizabeth N. Olsen, Esq. Bethany S. Labrinos, Esq.
Court Reporter:	Veronica R. Trettel, RMR, CRR U.S. Courthouse 700 Grant Street, Suite 5300 Pittsburgh, Pennsylvania 15219

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transcript produced by computer-aided transcription.

P-R-O-C-E-E-D-I-N-G-S

Thursday Morning, June 15, 2023

(In Open Court)

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4 THE COURT: This is now the time for the IN RE:  
5 Philips Recall CPAP, Bi-Level CPAP and Mechanical Ventilator  
6 Products Litigation at MDL No. 3014.

7 There has been a joint notice of those individuals  
8 who entered their appearance on the record and would be  
9 speaking on the matter before the Court.

10 If anyone else wishes to enter their appearance for  
11 purposes of the record, if you could please come forward and  
12 sign the pad of paper and we'll incorporate that to reflect  
13 your appearance at this hearing.

14 Now, moving to the joint proposed agenda, we have  
15 first a discovery update status of proceedings with the  
16 special master.

17 MS. ITRI: Good morning, Your Honor. Shauna Itri  
18 from Seeger Weiss on behalf of the plaintiffs.

19 Your Honor, so far to date, plaintiffs have received  
20 30 custodial -- about 30 custodial files consisting of emails  
21 and teams data. We're expecting about 41 more files through  
22 the end of August. Including tomorrow, we're going to be  
23 getting about 16 files that include a file from the Royal  
24 Philips executives and Netherlands-based employees.

25 We have also discussed upon Philips' review of the

1 documents, we were informed that there's certain Royal Philips  
2 executives and Netherlands-based employees that use the Dutch  
3 language. So we have negotiated the Dutch terms and we should  
4 be getting a production of Dutch language documents I think in  
5 July.

6 In terms of the noncustodial productions, we have  
7 gotten a lot of productions. We are expecting more. We are  
8 expecting about 38 more investigative reports at CAPAS and  
9 some additional complaint data.

10 Our first deposition is on June 22nd, and we are  
11 looking forward to analyzing documents and building up the  
12 deposition schedule this summer.

13 MS. McNALLY: Good afternoon, Your Honor. Laura  
14 McNally for Philips RS.

15 I agree with everything reported by my colleague  
16 Ms. Itri, and also, just to give you a sense of the scope of  
17 the discovery here that we have produced, we made about 126  
18 productions. About 2.3 million documents in total. 1.5  
19 million documents from custodians, meaning people's emails and  
20 chat messages and whatnot. Over 800,000 noncustodial  
21 documents from various Philips' systems, and we are on track  
22 to largely complete that document production in August.  
23 Right. So it's been a massive document production and we have  
24 been working cooperatively with the plaintiffs to do it as  
25 efficiently as possible.

1 THE COURT: Thank you.

2 MS. POLLOCK-AVERY: Elizabeth Pollock-Avery for the  
3 plaintiffs. I just wanted to update the Court on plaintiffs'  
4 production so far.

5 THE COURT: Okay.

6 MS. POLLOCK-AVERY: For all the plaintiffs, including  
7 both class plaintiffs and the PI plaintiffs, we produced about  
8 57,000 documents.

9 THE COURT: Are you listed on the joint notice?

10 MS. POLLOCK-AVERY: My apologies. I can enter my  
11 appearance if I'm not.

12 THE COURT: Yes. I don't see you.

13 MS. IVERSON: I think that's my fault. I took  
14 Ms. Avery off the last conference because she was in Italy  
15 enjoying herself and I forgot to put her back on for this one.

16 THE COURT: Okay. So you'll just have to sign the  
17 paper so you can be identified with the client.

18 MS. POLLOCK-AVERY: Yes, Your Honor.

19 THE COURT: Thank you.

20 MS. POLLOCK-AVERY: So just to quickly provide the  
21 update to Your Honor, the plaintiffs, including personal  
22 injury plaintiffs and class plaintiffs have produced about  
23 57,000 documents, including 285,000 pages of documents, and  
24 these include medical billing records and injuries, support  
25 documents for the PI plaintiffs, as well as insurance

1 documents, receipts, credit cards statements, prescriptions,  
2 user manuals and documents related to the recall for the class  
3 plaintiffs for both medical monitoring and e-com, (sic).

4 THE COURT: Thank you.

5 MS. POLLOCK-AVERY: Thank you.

6 THE COURT: I did receive something today about the  
7 Trilogy devices. It was a protocol.

8 MR. MONAHAN: That's going to be for Philips  
9 Respironics. Do you want to cover that now, Your Honor?

10 THE COURT: It's not on the list here. I did sign  
11 it. I just want to get a record here that they are no longer  
12 making the Trilogy devices, is that correct?

13 MS. DYKSTRA: I'm sorry, Your Honor. You are  
14 correct, we're no longer making --

15 THE COURT REPORTER: I'm sorry, ma'am, could you  
16 state your name?

17 MS. DYKSTRA: Lisa Dykstra for Philips RS.

18 I'm sorry, Your Honor, what was your question?

19 THE COURT: About the Trilogy. I just entered the  
20 order that you have requested about the protocol for  
21 preservation, and it appears from my reading of that, that  
22 Philips is no longer marketing the Trilogy devices, but it's  
23 doing some kind of remedial work?

24 MS. DYKSTRA: That's correct, Your Honor.

25 THE COURT: Okay, for those devices. And then

1 there's a way to -- some of the devices can be returned to you  
2 to be preserved. And so this is an arrangement to assist in  
3 that process. They can still function, but have some  
4 protections.

5 MS. DYKSTRA: That is correct. We get those devices  
6 back and we replace the foam and then we ship them back out,  
7 but we don't have new devices being marketed.

8 THE COURT: Thank you.

9 MS. DYKSTRA: Yes, Your Honor.

10 THE COURT: Okay. Now the update on personal  
11 jurisdiction. So we want to move this hearing -- from what  
12 you are saying, there's still some discovery underway, and it  
13 would be -- you wouldn't have time for adequate preparation if  
14 we had the meeting then.

15 So when I look into July, the date that I would have,  
16 we have -- you'll be busy on the 10th and the 11th with  
17 arguments on motions to dismiss. So then I have other things  
18 scheduled.

19 We do have the 20th where we have available -- we  
20 have hearings in the morning, just status conferences. It's  
21 possible you could do it that afternoon. I have criminal  
22 matters the day before. So that would not make it helpful  
23 for me. Or we could come in on the 25th and do it on the  
24 25th.

25 MR. SCHWARTZ: Your Honor, Mr. Dundon is not

1 available on the 20th. So that does not work, at least as  
2 things stand for us.

3 THE COURT: How about the 25th?

4 MR. SCHWARTZ: The 25th --

5 MR. MONAHAN: I'm going to be out-of-town.

6 THE COURT: You're out-of-town. Okay. Then I go on  
7 vacation. What's the dates people are available?

8 MR. SCHWARTZ: In July?

9 THE COURT: Yes. I have -- I don't think the week of  
10 the 4th of July is very good to have it.

11 MR. MONAHAN: Anything earlier than the week of the  
12 17th, Your Honor, that would work for you or for Mr. Dundon,  
13 and then we would have my partner come in from California and  
14 come in for that one week.

15 THE COURT: I could try to move something. I have  
16 some hearings on the 18th. Is the 18th a good day?

17 MR. MONAHAN: No, that won't work, I'm sorry, Your  
18 Honor.

19 THE COURT: Okay.

20 MR. SCHWARTZ: There's a big conference going on.  
21 It's going to be ending the 18th, which may impact the  
22 plaintiffs' side.

23 THE COURT: Okay.

24 MR. MONAHAN: The week before?

25 THE COURT: I have a couple of criminal things on the

1 19th. I could try to move those to the 20th. Does the 19th  
2 work?

3 MR. MONAHAN: No, Your Honor, I'm sorry.

4 THE COURT: All right. So what about the week of the  
5 24th? You can't do the 25th.

6 MR. MONAHAN: That's my vacation week, Your Honor.

7 THE COURT: Okay. So that's out. And I'm out the  
8 next week. So we're looking at the week of August the 7th. I  
9 have a couple of things on the 8th. We could do it on the 8th  
10 if I move those matters.

11 MR. SCHWARTZ: That may work, if it works for the  
12 rest of our team. I don't have experts schedules that extend  
13 out that there, but I can certainly find out pretty quickly,  
14 and my hope would be that they would have availability with  
15 that much lead time.

16 MR. MONAHAN: August 8th works for us, Your Honor.

17 THE COURT: Okay. So let's set it for August the  
18 8th. That way you all can come in on the 7th, and we'll have  
19 the hearing, we'll start at 10 a.m. Okay. You expect -- how  
20 long do you expect that hearing to be?

21 MR. SCHWARTZ: Well, we need a fully-developed  
22 record, as Your Honor mentioned earlier in the SoClean status.  
23 So it's unclear, and it's unclear in part because we have made  
24 progress, but the shape of the field is changing a little bit.

25 We did just take Ms. Ruse deposition, KPNV's witness

1 yesterday, and that was helpful. We were pleased with that  
2 from our perspective. She answered some of our questions, but  
3 she also raised additional questions. There's going to be  
4 some additional documents which she identified, including  
5 documents she relied on that we asked Philips for, and  
6 hopefully we will get them.

7 So we have some document issues to work through, and  
8 they're probably going to be some additional documents, but I  
9 think with the August 8th deadline for the hearing, I think  
10 there's enough time to work through those things, work through  
11 our experts.

12 THE COURT: What I'm going to ask is that on the 2nd  
13 of August, you submit a proposed agenda for the hearing. So  
14 if there's going -- so we have on the 8th -- we can have those  
15 matters on the 8th.

16 On the 2nd, you'll submit a proposed agenda, and if  
17 there's witnesses, you'll list who is going to be called and  
18 in what order.

19 If it's just going to be argument, you can break the  
20 argument by whatever issues you are raising, and then have  
21 identified the timing and who is going to be speaking and that  
22 kind of thing.

23 MR. MONAHAN: Sounds good, Your Honor.

24 MR. SCHWARTZ: We could do that.

25 THE COURT: I know there's been some exhibits already

1 provided. Are there additional exhibits that are going to  
2 come in? Maybe we should just have a clean set of exhibits  
3 that are going to be used for the hearing and you can submit  
4 that on the 2nd as a joint exhibit.

5 MR. MONAHAN: One question, Your Honor. So I think  
6 that's great. I think that one set of joint exhibits --

7 THE COURT: Plaintiffs letters. Defendants numbers.

8 MR. MONAHAN: Plaintiffs letters. Defendants  
9 numbers.

10 THE COURT: Um-hum.

11 MR. MONAHAN: One question, Your Honor, there's going  
12 to be hopefully a small number, but probably some, we have  
13 narrowed it, of objections on exhibits. Right.

14 So both sides have reserved all objections on  
15 relevancy. We think most of what they are trying to do is  
16 totally irrelevant to day-to-day control, which is the  
17 standard.

18 But leaving aside relevancy, there's actually some  
19 other objections, and right now, we have on calendar the June  
20 27th date. Of course, it's up to Your Honor. We were  
21 thinking that that could stay on calendar for now so that we  
22 have some objections already identified on documents and we  
23 could argue those to Your Honor to try to deal with this a  
24 little bit piecemeal. If Your Honor doesn't want to deal with  
25 it piecemeal and wants to set another date for dealing with

1 those objections, that's, of course, fine, but that's another  
2 item we need to consider.

3 THE COURT: Normally what I do is, okay, if you file  
4 something -- we have to move it back then a little bit. I  
5 would have you file your proposed plan on the 26th of  
6 August -- I mean of July, and then if things are disputed, you  
7 should have the responsive briefing for any objections to the  
8 exhibits because you'll identify what the exhibits are, and if  
9 they are disputed, the movant of that exhibit would have to  
10 set forth a brief, brief summary what authority you are  
11 relying on for the admissibility of those documents, and then  
12 the response to that would come in on the 2nd. Okay. Then  
13 we'll have the hearing on those exhibits on the -- at 10 a.m.  
14 on 8th.

15 I just have to have time to look through these  
16 things, and I'm only returning -- I'll only be back here that  
17 week of the 7th. I need to be able to look through and  
18 respond appropriately.

19 MR. MONAHAN: Sounds good, Your Honor. Hopefully we  
20 will not be giving you many documents with objections.

21 THE COURT: Right. It's usually pretty clear, at  
22 least to me, when I look through them what the issue is, and  
23 since it's just a judge hearing, I can always admit them  
24 subject to my later determination that it's not to be  
25 considered.

1           MR. MONAHAN: That's largely why we deferred on the  
2 relevancy objections. So you would have August 8th, we'll  
3 start at 10 a.m. dealing with the objections, and then we'll  
4 get into the rest?

5           THE COURT: Right, go right into the hearing.

6           MR. SCHWARTZ: Thank you very much, Your Honor.

7           MR. MONAHAN: Thank you, Your Honor.

8           THE COURT: Okay. Update on the census registry.

9           MS. WEST FEINSTEIN: Wendy West Feinstein for  
10 Philips RS.

11           As of yesterday, June 14th, we had 48,601 registries  
12 in the census registry. And just by way of further  
13 information, there's been a recent kind of uptake in the  
14 filings of the short-form complaints, too. I'm sure the Court  
15 has seen that on its docket. We think that's likely because  
16 we're coming up on the -- or we have been coming up on the two  
17 year anniversary of the recall. So that's the update. Very  
18 brief.

19           MS. REICHARD: Good afternoon, Your Honor, Joyce  
20 Reichard on behalf of plaintiffs.

21           I did want to just note that last month during our  
22 status conference, you asked if we were expecting new  
23 registrants to participate, and I would just recognize that  
24 there were 2,937 new participants between last month and this  
25 month.

1 THE COURT: Okay.

2 MS. REICHARD: Thank you.

3 THE COURT: Thank you all.

4 MS. WEST FEINSTEIN: And just moving into this State  
5 Court --

6 THE COURT: The State Court litigation?

7 MS. WEST FEINSTEIN: Yes. If you don't mind, Your  
8 Honor, just briefly, really no new update. We are still  
9 waiting for Judge Barry Smith to issue an order lifting the  
10 stay, if he is so inclined to do that.

11 The parties in the Massachusetts state court action  
12 and the defendants continue to discuss protective order and  
13 deposition protocol when that stay is lifted, and we had hoped  
14 to coordinate with the plaintiffs there the depositions in the  
15 MDL, but as you know, there's a deposition next week, and  
16 we're going to proceed and hopefully bring them in as soon as  
17 we can so that, you know, it's more efficient and we don't  
18 have duplicative questioning of these witnesses.

19 Thank you, Your Honor.

20 THE COURT: Okay.

21 MR. BUCHANAN: Briefly, Your Honor. I'm advised --  
22 as of the last conference, I was not as well informed of the  
23 status of those proceedings.

24 I'm advised from counsel there they have yet to  
25 receive document productions or, if they have, it's happened

1 in the last couple of weeks. It's going to be very difficult  
2 for them to be on the same type of track as we are with the  
3 schedule that we have in the cases, but obviously the  
4 defendants will do what they do and those litigants will be  
5 coordinated. We're happy to be cooperative, but we just have  
6 a schedule to be mindful of here. Thank you.

7 THE COURT: Okay. Thank you.

8 For the leadership development.

9 MS. HARRISON: Good afternoon, Your Honor. Kathryn  
10 Harrison representing the leadership development committee  
11 today. And, Your Honor, it's me again today and for good  
12 reason. I think many members of the LDC on plaintiffs' side  
13 are involved in significant case matters this week. And so  
14 I'm here to represent us once again.

15 Your Honor, I thought today I would mention a benefit  
16 of the LDC that you likely anticipated and that I've really  
17 been reflecting on, and that is the networking that the  
18 members of the LDC have become for one another.

19 We're a very collegial group, and I personally have  
20 learned so much from the other attorneys in the leadership  
21 development committee. We are in weekly, if not sometimes  
22 daily communication with one other, not just related to this  
23 litigation, but also on our thought process about these types  
24 of matters going forward and how we can be involved in other  
25 litigations.

1           Your Honor, I know you are always interested in what  
2 we're working on. We have been working on discovery matters.  
3 I myself am on online briefing and will be helping with the  
4 preparation for the oral arguments in front of Judge Vanaskie,  
5 which are coming up and I am very honored to be a part of  
6 that.

7           Your Honor, finally, if you would indulge me, I would  
8 like to mention one other very positive aspect of my  
9 participation on the LDC.

10           We have a summer law clerk in our office, Kyle  
11 Bobeck. Kyle is a rising third year at Pitt Law and was able  
12 to join me today. I think he's back underneath the clock.  
13 And I'm happy to say that Kyle is also able to be around this  
14 litigation and to experience this aspect of our practice.  
15 He's very, very talented and I'm hoping this will be a great  
16 learning experience for him as well.

17           THE COURT: Thank you.

18           MS. HARRISON: Thank you.

19           MS. GINDLE: Hi. Good afternoon, Your Honor. Ashley  
20 Gindle here on behalf of Philips RS and my colleagues from  
21 Morgan, Lewis.

22           First, I'm really thankful to be here today. I have  
23 been practicing for less than a year. So it's absolutely  
24 surreal to be looking at you and speaking before you today.  
25 So just thank you for encouraging young attorneys in our

1 professional development. I know we really appreciate it.

2 So as for the work, I've been really lucky to work  
3 with and very closely with a lot of the partners on our team.  
4 I'm involved in a variety of work streams. So with that, I  
5 have had a lot of opportunities in document collection and  
6 production; specifically design history file records for the  
7 devices. I've also been involved in written discovery and  
8 plenty of document reviews, I'm sure you can understand.

9 So these opportunities, of course, have afforded me  
10 the opportunity to work with who I think are some very  
11 brilliant people -- the partners in the team, my fellow  
12 associates, paralegals, and importantly, obviously, the  
13 client, which has been a great experience.

14 Overall, I feel like I have grown a ton in the past  
15 nine months of practice. I've improved my skills in  
16 communication, analysis, teamwork, and then, of course, today  
17 speaking, which is great. So thanks so much for the  
18 opportunity. Thank you.

19 THE COURT: You're welcome.

20 MS. WEST FEINSTEIN: Your Honor, if I could, Wendy  
21 West Feinstein again on behalf of Philips RS.

22 Before we move on with the LDC, I just wanted to  
23 introduce Your Honor to a summer associate at the Morgan,  
24 Lewis office, Daniel McTiernan, who is here today observing  
25 his first Federal Court hearing. So thank you for allowing

1 folks to come in and observe. We appreciate it.

2 THE COURT: Thank you.

3 So onto the test results.

4 MS. DYKSTRA: Onto the test results. Thank you, Your  
5 Honor. Lisa Dykstra for Philips RS.

6 We are going to set up a slideshow for you and I have  
7 a deck and hard copy.

8 MR. SEEGER: Can I interrupt? Judge, I think I have  
9 a sense and didn't know before now, and now I do know, but I'm  
10 right, about the presentation Ms. Dykstra is about to do for  
11 the Court. I really think it's inappropriate. It's not for a  
12 case management conference.

13 THE COURT: Yeah, see this -- you know, when I see  
14 this on here, I'm assuming that you both agreed on it.

15 MR. SEEGER: No. I thought she was going to come up  
16 and tell you about maybe some new published article. This is  
17 science for hire. This is what the lawyers put together.

18 I can't sit here and have them use this court for  
19 propaganda for the press in the back. It's just unfair to the  
20 plaintiffs and it's unfair to you, Your Honor.

21 I don't think this should be presented in a case  
22 management. I should be able to challenge this in a hearing.

23 MS. DYKSTRA: So, Your Honor, this is an update on  
24 what we recently provided to the FDA. We have been giving the  
25 Court updates on the 518(a) order and what we have been

1 providing.

2           What we're providing today we have shown plaintiffs  
3 previously and we did put it on the agenda. So I thought that  
4 they were aware and agreed to the agenda. It's not going to  
5 be too long. It will give you an update of what we provided  
6 to the FDA, what's also been produced to plaintiffs and would,  
7 I think, be helpful, and we are certainly not using it to  
8 build the case.

9           THE COURT: Why don't you just give me a summary of  
10 it, rather than going through the slides.

11           MR. STEINBERG: We haven't even gotten -- what's been  
12 produced is that, the summary, the conclusions. We don't have  
13 the testing data. We don't have any of this, and we're in the  
14 middle of discovery. And to do a PR presentation in court I  
15 just don't think is appropriate.

16           Even her conclusions, we have the right to challenge  
17 and look -- X-Pryonix (phonetic) is a company that is hired by  
18 companies like BP and Exxon Mobile to provide what looked like  
19 scientific conclusions.

20           THE COURT: All I need to know today is you submitted  
21 some new tests that you had run and you submitted those to the  
22 FDA.

23           MS. DYKSTRA: That's correct, Your Honor.

24           THE COURT: Okay. Now, why are you submitting them  
25 to the FDA?

1 MS. DYKSTRA: So 518(a) order that the FDA put  
2 forward requires us to put forward to plaintiffs, healthcare  
3 providers and the public information around the data and  
4 information around the foam and any degradation studies that  
5 we have done.

6 As we have talked about previously, the pre-recall  
7 data was based on a very limited set of information of one or  
8 two studies with one or two devices. And so post-recall, the  
9 FDA has required us to give them updates on that information  
10 and we have made it public.

11 So there's two basic pieces to that. Well, three.  
12 One, we have retained five independent laboratories to do  
13 studies, and we committed to FDA, and we produced almost all  
14 of this to plaintiff -- but Mr. Seeger is right, not all, and  
15 I'll get to that in a moment -- to produce to the FDA  
16 summaries of those studies and, also, to produce to the FDA if  
17 they want them, all of the underlying data, which is extremely  
18 voluminous. Sometimes the FDA says, yes, we want it all.  
19 Sometimes they just want summaries, et cetera.

20 So we recently in March of 2023, provided to the FDA  
21 a 141-page report, which consolidated all of the data, which  
22 tested both the VOCs and the particulates and the degradation  
23 of particulates, and evaluated all of that data under a worse-  
24 case scenario saying assuming you, patient, ingested or  
25 inhaled 100 percent of the foam, what would be your risk, if

1 any?

2 And the conclusion of the laboratories, the five  
3 independent laboratories that are all accredited laboratories,  
4 summarized in the report by our expert Exponent, concluded  
5 that there is no -- there's no appreciable risk to health,  
6 period, across the board based on either VOCs or particulates.

7 THE COURT: Is this the same summary of how you  
8 published it?

9 MS. DYKSTRA: We published it. The 141-page report  
10 the plaintiffs do have. Most of the data, but not all, they  
11 also have.

12 It's interesting that Mr. Seeger says this because  
13 the day we published this data -- and there's hundreds of  
14 studies in this summary report provided to FDA. The day we  
15 published that report, less than eight hours after we  
16 published it -- and, again, they didn't have all of the data,  
17 but they came out in the press and criticized the data and  
18 said it was unreliable, which in our mind is very unfortunate  
19 because we are absolutely willing to engage in a discussion  
20 around the science. We are absolutely willing to take  
21 questions from the plaintiffs around the science and engage  
22 fully in a debate about it, but not to come out and criticize  
23 it before you have read it.

24 MR. SEEGER: Do it at a hearing. That's all we are  
25 saying.

1 MS. DYKSTRA: So in any case, the big picture for  
2 Your Honor is that the studies have been provided to the FDA,  
3 the five laboratory studies and the summary report for all of  
4 them. The 141-page report goes through the VOC risks, the  
5 particulate risks, and the FDA evaluating that data.

6 THE COURT: So it's before the FDA now.

7 MS. DYKSTRA: Um-hum.

8 THE COURT: And you published to the public that  
9 you've done this? How did you publish to the public?

10 MS. DYKSTRA: Yes. There's a 45-page summary which  
11 is more digestible for the public and that Philips put onto  
12 the website, and then there's going to be updates kind of to  
13 help healthcare providers get through all of this data,  
14 because --

15 THE COURT: How do the healthcare providers have to  
16 access the website?

17 MS. DYKSTRA: Well, there's a couple ways. We're  
18 trying to put out some press releases and information directly  
19 to providers, put it through website, and also publicize it as  
20 well through other experts, both in Netherlands and here,  
21 globally because this is obviously a global issue. And the  
22 data is complicated and complex. So we're trying to make it  
23 more user friendly.

24 But the bottom line is that neither of the VOCs or  
25 the particulates caused any appreciable risk to harm,

1 including using the FDA required standards. So the FDA  
2 threshold for evaluating cancer risk is 1 and 100,000. So  
3 basically 1 and 100,000 times somebody would not get cancer.  
4 That's their threshold.

5 I like to think of it like getting struck by  
6 lightning is 1 and 15,300. So it's a much, much higher  
7 standard, but that's the level, that's the threshold that we  
8 use in these studies.

9 THE COURT: So that's what the results were. I'm  
10 understanding you are going to contest --

11 MR. SEEGER: Judge, Ms. Dykstra knows that there's a  
12 lot of controversy surrounding this, including emails that  
13 have been produced that she's on. I'm not going to go into  
14 them right now. I would rather save it for a hearing.

15 But the data results are suspect, but interestingly,  
16 they do conclude that the off-gassing and the particulate are  
17 cytotoxic and genotoxic and that there were 12 times the  
18 amount of formaldehyde in their own testing that they paid  
19 this company Exponent to do for them. But having that said,  
20 you see why I don't think it's appropriate --

21 THE COURT: Well, I just think it's just information  
22 for the Court at this time.

23 MS. DYKSTRA: Yes.

24 THE COURT: There have been studies done since our  
25 last science day, and these studies have come out, and they

1 have been published to the public. So it's not like it's --

2 MR. SEEGER: The conclusions. Not the data.

3 THE COURT: The conclusions have been published to  
4 the public. So they can say what the conclusions are, and I  
5 understand that the plaintiffs do dispute those.

6 MR. SEEGER: Yes.

7 MS. DYKSTRA: The only point I would add, Your Honor,  
8 is that the pre and post-recall difference is one of the  
9 things we have been stressing with the FDA and the pre-recall  
10 studies were based on testing of two devices. The post-recall  
11 studies, there's hundreds of studies that uniformly conclude,  
12 uniformly that they pass all of the relevant standards.

13 MR. SEEGER: By a company that was paid.

14 THE COURT: I understand. I understand the position  
15 of both sides.

16 MR. SEEGER: Just aside from that, we are going to  
17 have to raise some new issues that come up with this probably  
18 with Ms. Katz because a lot of these documents are marked  
19 attorney-client privilege --

20 MS. DYKSTRA: There's two things --

21 MR. SEEGER: Well, I don't know that --

22 THE COURT REPORTER: Can we please talk one at a  
23 time.

24 MS. DYKSTRA: Yeah, I'm sorry. All of the testing  
25 data from all of the five labs, and we have discussed this at

1 length with Ms. Katz, all of the testing data from all of the  
2 five independent labs have been produced. Period. Whether  
3 it's marked privileged or not, we have gone through it with a  
4 fine-tooth comb, and it has been produced.

5 There was one report that Exponent drafted. It's a  
6 141-page report that kind of consolidates everything. But in  
7 the technical term, it's what's called a self-contained  
8 report.

9 So that report includes assumptions, methodologies,  
10 protocols, and all of the data to reach the conclusions, and  
11 that report basically could be -- they could take that report  
12 and replicate the studies themselves.

13 Plaintiffs did challenge that. And we produced that  
14 report. We gave it to the FDA. Gave it to the plaintiffs.  
15 Plaintiffs recently had a challenge to underlying privileged  
16 documents, attorney-client privilege and work-product  
17 documents that Ms. Katz addressed and that is no longer in  
18 dispute.

19 MR. BUCHANAN: The contention that all the data has  
20 been produced is not accurate. I think Ms. Dykstra would  
21 correct that. There's at least 150 studies or more --

22 THE COURT: I just need to know this is in dispute.  
23 But I do have the information that there's been new tests and  
24 there's a new expert report, and the parties are discussing  
25 this. The plaintiffs dispute the analysis --

1           MR. SEEGER: The take -- I'm sorry. I didn't mean to  
2 cut you off.

3           THE COURT: Go ahead.

4           MR. SEEGER: The takeaway is that this is an  
5 independent testing done in peer-reviewed medical literature.  
6 It's done for litigation and we would like to address it in  
7 the context of this.

8           THE COURT: Sure. And you will have a right to do  
9 so.

10          MR. BUCHANAN: It's done by their consulting expert.  
11 Thank you.

12          MS. DYKSTRA: Thank you, Your Honor.

13          THE COURT: I'm sure we'll be having this at Daubert  
14 hearings.

15          MS. DYKSTRA: I'm sure we will. We looked forward to  
16 that.

17          THE COURT: Is there anything else to come before the  
18 Court? Okay. Then I guess we'll be back here at the  
19 arguments before the special master for the motions to  
20 dismiss. Thank you.

21          MR. MONAHAN: Thank you, Your Honor.

22          MR. CABRAL: Thank you, Your Honor.

23                                 - - -

24                                 (The hearing concluded.)

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C E R T I F I C A T E

I, VERONICA R. TRETTEL, RMR, CRR, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled case.

\s\ Veronica R. Trettel  
VERONICA R. TRETTEL, RMR, CRR  
Official Court Reporter

06/17/2023  
Date of Certification

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