

IN THE CIRCUIT COURT OF JACKSON COUNTY, MISSOURI  
AT INDEPENDENCE

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KATHERINE O'HAVER

Plaintiff,

v.

Case No.: 1816-CV30710  
Division 12

ANESTHESIA ASSOCIATES OF  
KANSAS CITY, P.C., et al.,

Defendants.  
-----

DOUGLAS TYE

Plaintiff,

v.

Case No.: 1916-CV00825  
Division 2

ST. LUKE'S ANESTHESIA SERVICES  
P.C., et al.,

Defendants.  
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CONFIDENTIAL

VIDEOTAPED DEPOSITION OF

ALBERT VAN DUREN

January 25, 2022

9:30 a.m.

Court Reporter: Rhonda Olynyk  
Stirewalt & Associates

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1 PROCEEDINGS

2 THE VIDEOGRAPHER: We are on video.

3 (Witness sworn by the reporter.)

4 ALBERT VAN DUREN,

5 called as a witness, being first duly sworn,

6 was examined and testified as follows:

7 EXAMINATION

8 BY MR. FARRAR:

9 Q. Can you introduce yourself, please, sir?

10 A. **Albert Van Duren.**

11 Q. Mr. Van Duren, my name is Kyle Farrar. You understand

12 I represent a couple plaintiffs in Missouri who have

13 brought a claim against 3M related to the Bair Hugger?

14 A. **Yes.**

15 Q. Okay. You've given, I think, four depositions before,

16 correct?

17 A. **I believe that's correct.**

18 Q. You know the rules, so I'm not going to go through it,

19 but if you need a break at any time -- this may get

20 sort of tedious. I'm going to try not to waste any

21 time, I promise. But if you need a break, that's

22 fine, just as long as you answer the question on the

23 table. Okay?

24 A. **Sure.**

25 Q. If I -- if I ask you a poor question, because you

1 probably know some if this area better than I do,

2 well, hopefully anyway, I'm joking, please ask me to

3 rephrase or just tell me that question doesn't make a

4 lot of sense. Okay?

5 A. **Okay.**

6 Q. I want to talk a little bit about what you did to

7 prepare for your deposition.

8 Did you read your old depositions?

9 A. **No.**

10 Q. Okay. Did you read your trial testimony from the

11 Gareis trial?

12 A. **No, I did not.**

13 Q. Did you review any documents?

14 A. **A few documents, a few papers.**

15 Q. Oh, like literature?

16 A. **Yes.**

17 Q. Can you tell me which ones?

18 A. **I looked at a paper by Curtis. I looked at a paper by**

19 **Oguz. I looked at a paper by McGovern. There may**

20 **have been a couple of others, but not very many.**

21 Q. Did you look at any literature that was published in,

22 say, 2018 or more recent?

23 A. **Yes. I'm not sure I did it to review for this**

24 **testimony, but just as sort of my passive collection**

25 **of those documents.**

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1 Q. As part of your job at 3M, do you keep abreast of  
 2 literature that comes out regarding products that you  
 3 are responsible for?  
 4 **A. So I don't currently have responsibility for any  
 5 products.**  
 6 Q. Okay.  
 7 **A. I'm not associated with a business within the medical  
 8 division. So I'm not associated with temperature  
 9 management, for example, not with that business.**  
 10 **My current role is a regulatory one. So I work  
 11 in the healthcare business group, which is, you know,  
 12 a large business group, and provide services to  
 13 business portfolios, including temperature management,  
 14 but not very much, mostly in advanced wound care,  
 15 vascular access, those -- those businesses.**  
 16 Q. When did you take on that role?  
 17 **A. In the summer of 2019 I left the temperature  
 18 management business and joined the evidence  
 19 development group. I worked in that group for one  
 20 year and then moved to the health economics and  
 21 outcomes research group, stayed with that group for  
 22 approximately another year, and then moved to my  
 23 current role, which is the -- which is a senior  
 24 compliance specialist in the healthcare business  
 25 group.**

Page 11

1 Q. Prior to your current role, it's my understanding you  
 2 didn't really have much responsibility for regulatory.  
 3 Is that correct?  
 4 **A. That's correct.**  
 5 Q. Okay. In the summer of 2019 when you left the  
 6 temperature control -- am I saying that right,  
 7 temperature control unit?  
 8 **A. Temperature management business.**  
 9 Q. Temperature management. Thank you.  
 10 What was the purpose for that move?  
 11 **A. I just took on another role. A role became available  
 12 in an evidence management group and expanded my role.**  
 13 Q. Who took over your job in temperature management?  
 14 **A. I don't think that job was filled by anybody.**  
 15 Q. Currently still, not to your knowledge?  
 16 **A. Not to my knowledge.**  
 17 Q. The evidence development group, what does that group  
 18 do?  
 19 **A. We collected literature, mostly clinical, some  
 20 scientific literature, and summarized it for various  
 21 business portfolios, made suggestions about sorts of  
 22 activities they could undertake to fill certain gaps  
 23 to meet regulatory requirements, things like that.**  
 24 Q. Would that include work on the Bair Hugger?  
 25 **A. There was some work with temperature management, yes.**

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1 Q. Do you remember specifically any pieces of literature  
 2 that your group summarized for anybody at temperature  
 3 management?  
 4 **A. Well, not -- not specifically.**  
 5 Q. Are you aware that since you last gave a deposition,  
 6 which was 2017, there's been new pieces of literature  
 7 that have come out regarding the Bair Hugger and its  
 8 ability to cause infections?  
 9 MR. GORDON: Object to the form of the  
 10 question.  
 11 **A. I'm aware that new literature has come out, yes --**  
 12 BY MR. FARRAR:  
 13 Q. Okay.  
 14 **A. -- related to Bair Hugger.**  
 15 Q. Is that something that in your role that you would  
 16 have looked at and summarized and evaluated?  
 17 **A. In my current role that's not part of my remit,  
 18 although I do still collect -- passively collect  
 19 literature related to the Bair Hugger, Bair Hugger  
 20 warming unit.**  
 21 Q. And if we say "Bair Hugger," we can -- if I say that  
 22 and you're thinking forced-air warming because it's  
 23 maybe about a different product, let me know, but I'm  
 24 trying to really just talk about forced-air warming,  
 25 if that's okay.

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1 **A. I'm assuming that Bair Hugger in this context means  
 2 forced-air warming --**  
 3 Q. Yeah.  
 4 **A. -- although we do have other temperature measuring  
 5 devices that are also Bair Hugger, and we have  
 6 irrigation and fluid warming devices --**  
 7 Q. Sure.  
 8 **A. -- that are Bair Hugger devices.**  
 9 Q. And I guess what I meant by that is I know there's  
 10 some literature that was comparing the Mistral with  
 11 I think it was the HotDog, I'm not sure; but if that  
 12 comes to mind, let me know. We're talking about  
 13 forced-air warming. It doesn't have to be  
 14 specifically Bair Hugger, if that's okay.  
 15 Does that make sense?  
 16 **A. Well, I think we'll make a distinction, right --**  
 17 Q. Right.  
 18 **A. -- if we're talking about Bair Hugger and maybe some  
 19 other forced-air warming devices.**  
 20 Q. When you -- up till the summer of 2019, was part of  
 21 your job in temperature management to keep abreast of  
 22 literature that affected Bair Hugger, for instance, or  
 23 forced-air warming?  
 24 **A. So I think I left that business in around June of  
 25 2019, not December.**

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1 Q. I said summer. I'm sorry.  
 2 A. **Oh, summer.**  
 3 Q. No problem.  
 4 A. **I misunderstood. So, I'm sorry, would you repeat the**  
 5 **question?**  
 6 Q. Yeah. Sure.  
 7 Your -- let me ask you this. When you left  
 8 temperature management, what was your title?  
 9 A. **It was scientific affairs and education manager.**  
 10 Q. I'm sorry. Scientific affairs and --  
 11 A. **And education manager.**  
 12 Q. Can you tell me sort of what your role was?  
 13 A. **Well, there were a number of roles, but probably the**  
 14 **largest responsibility was to collect clinical and**  
 15 **scientific data related to the business, the whole**  
 16 **business, not just forced-air warming, but temperature**  
 17 **measurement, for example, that's SpotOn or BH, Bair**  
 18 **Hugger, temperature monitoring system, which is**  
 19 **another system that we have, collect that data,**  
 20 **summarize it, critique it for our clinical managers**  
 21 **and other scientific affairs managers in the business.**  
 22 Q. When you summarized that literature, were there  
 23 written summaries that were generated?  
 24 A. **Yes.**  
 25 Q. There would have been written summaries generated

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1 after 2017 on different literature that would have  
 2 come out on forced-air warming. Fair?  
 3 A. **I believe so, yes.**  
 4 Q. When you would -- you said -- I think you said  
 5 summarize and critique?  
 6 A. **Correct.**  
 7 Q. What do you mean by "critique"?  
 8 A. **A critical analysis, making comments about the**  
 9 **materials and methods, conclusions, the manner in**  
 10 **which the data was collected, those sorts of things.**  
 11 Q. Okay. So -- and if I oversimplify this, let me know,  
 12 but basically saying whether or not you think this  
 13 study is particularly valid or has some limitations?  
 14 A. **I would -- I would make comments about limitations and**  
 15 **even, you know, in places where they had done a really**  
 16 **excellent job as well, so...**  
 17 Q. I would assume the summaries and the critiques, those  
 18 are something that 3M obviously keeps in their files,  
 19 correct?  
 20 A. **Oh, yes.**  
 21 Q. Would you look at the literature that discussed  
 22 alternatives to forced-air warming, conductive warming  
 23 or reflective blankets or things like that?  
 24 A. **If -- well, not -- not by itself, but if comparisons**  
 25 **were made between, say, the Bair Hugger forced-air**

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1 **warming system and some other method, I generally**  
 2 **would collect that information.**  
 3 Q. Whenever you would do the summaries and critiques, who  
 4 would you give them to?  
 5 A. **There were a variety of people on distribution lists,**  
 6 **but mainly the scientific affairs managers throughout**  
 7 **the world and also the clinical managers throughout**  
 8 **the world in the business, in the temperature**  
 9 **management business.**  
 10 Q. At 3M?  
 11 A. **Yes.**  
 12 Q. Okay.  
 13 A. **Only 3M.**  
 14 Q. So they were internal studies -- or internal  
 15 memorandum that were --  
 16 A. **That's correct.**  
 17 Q. -- meant only for 3M personnel?  
 18 A. **That's correct.**  
 19 Q. Sometimes would 3M send out "Dear Valued Customer"  
 20 letters that would discuss the literature?  
 21 A. **Perhaps. I'm -- I mean, I'm not aware of -- I can't**  
 22 **think of one right now. I mean, it's possible, yes.**  
 23 Q. All right. And what I'm -- I'm going to show you one,  
 24 and my real question on this, and we may come back to  
 25 it later, is just what role, if any, you would have in

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1 creating something like this, and I'll mark this as  
 2 Exhibit Number 1.  
 3 (Exhibit 1 was marked for identification.)  
 4 And, Mr. Van Duren, when I hand you an exhibit,  
 5 obviously feel free to look at any part of it that  
 6 you'd like to. For this particular one, I'm really  
 7 just going to ask you: Is this something that you  
 8 would have a hand in creating or not?  
 9 A. **Let me look at it just a minute.**  
 10 Q. It's 2013, to sort of orient you.  
 11 MR. LUCAS: Can you identify the exhibit  
 12 for the record?  
 13 MS. ZIMMERMAN: The Bates number.  
 14 MR. FARRAR: Yeah. The Bates number is  
 15 3M00597516.  
 16 MR. LUCAS: Thank you.  
 17 A. **Yeah, I do not recall working on this. So this was**  
 18 **put together by my boss. I mean, it's signed by my**  
 19 **boss. I don't know who it was put together by, but**  
 20 **it's signed by my boss, but I don't -- I don't recall**  
 21 **working on this particular document.**  
 22 BY MR. FARRAR:  
 23 Q. Okay. Is this -- whenever you talked about criticisms  
 24 or summaries, is the chart that we see sort of an  
 25 example of that?

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1 **A. The section under "Study Limitations," the row under**  
 2 **"Study Limitations" might be something that I had**  
 3 **written about at that time that was included in this**  
 4 **document, but to my recollection, I did not work on**  
 5 **this document.**  
 6 Q. Do you know if you ever did a criticisms of the Hall  
 7 or Zink articles?  
 8 **A. I may have reviewed those articles in the past and**  
 9 **written summaries about them, yes.**  
 10 Q. And I'm trying to ask specifically if you have a  
 11 recollection of a criticism or a summary of Hall and  
 12 Zink that you personally did?  
 13 **A. I don't recall if I've done one. It's certainly**  
 14 **possible that I did. I mean, those are old -- quite**  
 15 **old studies; but it's possible that I've written a**  
 16 **critique or a summary of those studies, yes.**  
 17 Q. Jay -- is it Issa?  
 18 **A. Issa.**  
 19 Q. Jay Issa was your boss in 2013?  
 20 **A. Yes.**  
 21 Q. Okay. Who did you answer to in 2000 -- I'm sorry.  
 22 Who did -- who reported to you, let's call it, in 2013  
 23 or '14?  
 24 **A. I had no direct reports.**  
 25 Q. I sort of got off-track on preparation for your

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1 deposition. So you told me you looked at a few  
 2 articles. Did you look at the article that  
 3 Dr. Elghobashi published in 2018?  
 4 **A. I've read that paper, but I didn't -- I didn't review**  
 5 **it recently.**  
 6 Q. Did you do a summary or criticism of Dr. Elghobashi's  
 7 paper?  
 8 **A. I do not recall doing one for that particular paper.**  
 9 **Normally -- that's a scientific paper more than a**  
 10 **clinical one, and I usually -- I don't believe that I**  
 11 **did very many reviews of the scientific literature,**  
 12 **more clinical.**  
 13 Q. Do you know if anybody within 3M did?  
 14 **A. I don't know.**  
 15 Q. I assume you had a chance to meet with your lawyers to  
 16 prepare for your deposition?  
 17 **A. Yes.**  
 18 Q. Okay. And I don't -- obviously, I don't get to know  
 19 what you guys talked about, but how long and when did  
 20 you meet with them?  
 21 **A. We met yesterday.**  
 22 Q. Okay. A couple hours? More?  
 23 **A. Three-quarters of the day, something like that.**  
 24 Q. Are you currently scheduled to give a deposition next  
 25 week?

Page 20

1 **A. I'm not currently scheduled.**  
 2 Q. Okay.  
 3 **A. That I know of.**  
 4 Q. There you go.  
 5 THE REPORTER: I'm sorry. One minute.  
 6 There's somebody here on Zoom.  
 7 MR. FARRAR: Sure.  
 8 THE REPORTER: Thank you. She's just  
 9 connecting.  
 10 Okay. Go ahead.  
 11 MR. FARRAR: Why don't we ask the folks  
 12 on Zoom to identify so we know who's here for our  
 13 record.  
 14 MR. ERICKSON: Mark Erickson on behalf of  
 15 the Anesthesia defendants in the Tye case.  
 16 MR. KRONAWITTER: In the O'Haver case,  
 17 Joe Kronawitter for the Anesthesia defendants,  
 18 Dr. Bible, Charles Herring, and Anesthesia Associates  
 19 of Kansas City.  
 20 MR. MCCAIG: Joshua McCaig in the O'Haver  
 21 case for Centerpoint Medical Center, Centerpoint  
 22 Orthopedics, and Dr. Gregory Ballard.  
 23 MR. MCGREVEY: Sean McGrevey in the Tye  
 24 case for St. Luke's East Hospital.  
 25 MR. LUCAS: Christopher Lucas, Tye,

Page 21

1 representing Dr. Frevert and Rockhill Orthopaedics.  
 2 MS. SCHAFFER: Haley Schaffer, in-house  
 3 counsel at 3M in the litigation group.  
 4 MS. CAMPBELL: Tricia Campbell on behalf  
 5 of both plaintiffs.  
 6 THE REPORTER: Mr. McGrevey?  
 7 I didn't hear him.  
 8 MR. MCGREVEY: Yes. Sean McGrevey on  
 9 behalf of St. Luke's East Hospital in the Tye case.  
 10 Sorry you didn't hear me.  
 11 MR. FARRAR: All right. Thanks.  
 12 MR. MCGREVEY: Did you hear me there?  
 13 MR. FARRAR: Yes, yes.  
 14 BY MR. FARRAR:  
 15 Q. Mr. Van Duren, just a little bit of background. You  
 16 went to work for Augustine Medical in 1994?  
 17 **A. Yes, that's correct.**  
 18 Q. And then Augustine Medical was acquired by Arizant.  
 19 Do you remember what year?  
 20 **A. Oh, I don't remember the precise year. I don't think**  
 21 **it was an acquisition. It was more of a change of**  
 22 **business name.**  
 23 Q. Okay. And I understand Arizant was acquired by 3M in  
 24 2010?  
 25 **A. That's correct.**

Page 22

1 Q. Would it be fair to say that -- so you -- well, let  
 2 me start -- when you started working for Augustine  
 3 Medical in 1994, you were working on the Bair Hugger  
 4 product, right?  
 5 **A. Yes.**  
 6 Q. What other products did Arizant have? I'm sorry. Let  
 7 me back that up.  
 8 What other products did Augustine Medical have?  
 9 **A. They had an airway product. They had a wound care**  
 10 **product line. And I think at that time that's pretty**  
 11 **much all that they had. So Bair Hugger forced-air**  
 12 **warming, airway, and some wound care.**  
 13 Q. Was Bair Hugger the majority of the at least revenue  
 14 or sales?  
 15 **A. I believe so, yes.**  
 16 Q. Would that be the same -- would that be true for  
 17 Arizant also?  
 18 **A. I believe so, yes.**  
 19 Q. When 3M acquired Arizant in 2010, do you remember what  
 20 products Arizant had other than the Bair Hugger?  
 21 **A. They had a fluid warming line, irrigation warming.**  
 22 **They had a temperature measuring system, at that time**  
 23 **it was known as SpotOn, which subsequently became or**  
 24 **renamed as the Bair Hugger temperature monitoring**  
 25 **system. And then they had Bair Paws, which was a gown**

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1 **platform, a warming platform; and then they had the**  
 2 **Bair Hugger forced-air warming systems.**  
 3 Q. Is it fair to say that 90 percent of Arizant's  
 4 business was Bair Hugger or forced-air warming?  
 5 **A. I don't --**  
 6 MR. GORDON: In 2010?  
 7 MR. FARRAR: In 2010, correct.  
 8 **A. I don't know. I mean, I'm in research and development**  
 9 **at the time.**  
 10 BY MR. FARRAR:  
 11 Q. Sure.  
 12 **A. I don't really know what the sales figures are.**  
 13 Q. Just from sort of your knowledge, would you agree  
 14 again that the vast majority of the business was  
 15 forced-air warming?  
 16 MR. GORDON: Object to the form of the  
 17 question.  
 18 **A. Probably.**  
 19 BY MR. FARRAR:  
 20 Q. Okay. I was just trying to be less specific than the  
 21 90 percent. I got that off an internal document, but  
 22 I don't --  
 23 **A. Yeah. I don't know.**  
 24 Q. Fair enough.  
 25 **A. But probably.**

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1 Q. Okay. Quickly on your education. You have a bachelor  
 2 of science in biology?  
 3 **A. Yes.**  
 4 Q. Not a medical doctor?  
 5 **A. I'm not.**  
 6 Q. Not a microbiologist?  
 7 **A. No.**  
 8 Q. Not an engineer?  
 9 **A. No.**  
 10 Q. But you do have a master's in physiology?  
 11 **A. That's right.**  
 12 Q. What's physiology?  
 13 **A. It's the study of the various systems of the body. So**  
 14 **in my case, I spent most of my time studying bioheat**  
 15 **transfer.**  
 16 Q. Are you currently an officer for 3M?  
 17 **A. I'm not.**  
 18 Q. Have you ever been?  
 19 **A. No.**  
 20 Q. Were you an officer at Arizant?  
 21 **A. No.**  
 22 Q. Were you an officer at Augustine Medical?  
 23 **A. No.**  
 24 Q. Do you know who -- I'm going to try not to ask this  
 25 too broad, but do you know who currently at 3M is

Page 25

1 working on the Bair Hugger and forced-air warming?  
 2 **A. I don't know.**  
 3 Q. You said that you're not aware of anybody that took  
 4 your particular role as scientific affairs and  
 5 education manager, correct?  
 6 **A. That's correct.**  
 7 Q. You don't know who's working on it in terms of  
 8 clinical or regulatory or anything?  
 9 **A. Well, what do you mean "anything"?**  
 10 Q. Well, sure. And I'm trying to sort of exclude,  
 11 obviously, the salespeople out in the field, but  
 12 people, you know, more at corporate level working on  
 13 either -- whether it's internal testing or clinical or  
 14 regulatory.  
 15 **A. No, I'm afraid I don't.**  
 16 Q. Okay. When you switched to the evidence development  
 17 group, did you still work with the folks in  
 18 temperature management?  
 19 **A. Yes, I did then.**  
 20 Q. Who were you working with?  
 21 **A. Mainly, Melissa Nelson on new product introduction.**  
 22 Q. Do you know what her position was?  
 23 **A. She was the global marketer -- or, I'm sorry, global**  
 24 **NPI or new product introduction marketer.**  
 25 Q. Okay. Is she still there?

Page 26

1 A. No.

2 Q. Is she still at 3M?

3 A. No, she's not.

4 Q. Anybody else that you can recall working with?

5 A. She was the main person in the business that I dealt

6 with.

7 Q. All right. You said that you still do some work with

8 temperature management now, correct?

9 A. I do.

10 Q. Who do you work with now?

11 A. I have really no interactions with people in the

12 business other than the global marketer occasionally.

13 Q. Who's the global marketer?

14 A. I'm -- I'm sorry, I'm blanking on her name right now.

15 I mean, these are people I've never met personally,

16 obviously, because of COVID, so -- but there's a

17 global marketer that I have interacted with on a few

18 occasions.

19 Q. When you left temperature management in the summer of

20 2019, would that have essentially stopped your work on

21 forced-air warming?

22 A. Yes. For the business? Yeah.

23 Q. Yeah.

24 So you -- I'm just trying to do the quick math.

25 You worked on basically the Bair Hugger product for --

Page 27

1 was that 23 years or so?

2 A. Yeah, about that.

3 Q. Anybody at 3M that you know worked on Bair Hugger

4 longer than you?

5 A. At 3M currently?

6 Q. Yes, sir. Yes, sir.

7 A. No.

8 Q. Do you think there's anybody at 3M more knowledgeable

9 about the Bair Hugger than you?

10 MR. GORDON: Object to the form of the

11 question.

12 A. Well, I think it -- which aspects of the product do

13 you mean?

14 BY MR. FARRAR:

15 Q. Well, that's what I'm trying to say, as overall,

16 whether it be clinical, whether literature, sales,

17 scientific, just sort of full-around grasp, knowledge

18 of the product.

19 MR. GORDON: Same objection.

20 A. I mean, there -- there probably are people in the

21 research and development group and in the legal group

22 that know quite a bit more about the product and those

23 various aspects than I do.

24 BY MR. FARRAR:

25 Q. And not the folks in the legal, but anyone else, do

Page 28

1 you know anyone by name?

2 A. In what -- I'm sorry. In which capacity?

3 Q. Well, you said -- you said in research and development

4 there may be some folks who know it better than you.

5 Do you know specifically a name?

6 A. No.

7 Q. Okay. One of your titles at one point was

8 something -- and I may be messing it up a little bit,

9 but basically director -- clinical director for

10 forced-air warming or for temperature management?

11 A. At Arizant, yes.

12 Q. Do you know if anybody has that type of role right now

13 related to the Bair Hugger?

14 A. I don't know.

15 Q. Just your knowledge of how 3M operates, would you

16 assume somebody has that position?

17 MR. GORDON: Object to the form of the

18 question, also lack of foundation.

19 A. Again, I don't know how the -- I don't know how the

20 business is currently structured.

21 BY MR. FARRAR:

22 Q. When it was Augustine Medical, do you know how many

23 folks worked there?

24 A. I don't know.

25 Q. I'm just trying to get an idea of the size. Was it --

Page 29

1 I mean, there's hundreds of people or dozens of

2 people, estimate?

3 A. Closer to hundreds, I would think.

4 Q. Would that be the same with Arizant?

5 A. Approximately so.

6 Q. When 3M acquired Arizant, did most of the folks that

7 worked at Arizant become 3M employees, or was there a

8 big turnover?

9 A. I think -- I believe initially most of the employees

10 became 3M employees, at least initially.

11 Q. When you were director of clinical affairs, was

12 that -- I don't know how to say this, for lack of a

13 better word, but was that a pretty big job position at

14 3M?

15 MR. GORDON: Object to the form of the

16 question.

17 A. Well, I don't believe I was ever director of clinical

18 affairs at 3M.

19 BY MR. FARRAR:

20 Q. Arizant. That's right.

21 A. At Arizant?

22 Q. Yes, sir.

23 A. Yes, I was there. That was my job position there.

24 Q. Was there a lot of folks ahead of you or that you had

25 to report to, or was that pretty high up on the



Page 30

1 ladder?

2 **A. I had -- I had a boss, who -- you know, head of R & D,**

3 **that I reported to.**

4 Q. What was his name?

5 **A. Gary Hansen.**

6 Q. Do you keep in touch with Mr. Hansen?

7 **A. No, I haven't.**

8 Q. Do you keep in touch with Michelle Hulse Stevens?

9 **A. I do not.**

10 Q. Do you know why she left 3M?

11 **A. I don't know why.**

12 Q. Do you know what she's doing now?

13 **A. I don't know.**

14 Q. From 2017 when you last gave a deposition till you

15 left in the summer of 2019, can you describe the type

16 of work you were doing on the Bair Hugger?

17 **A. Again, I believe my position then was scientific**

18 **affairs and education manager, so I spent a lot of**

19 **time developing talks that I gave all over the world**

20 **on temperature management and prewarming and various**

21 **topics that were relevant to temperature management.**

22 Q. I assume those talks would have PowerPoints and things

23 like that that went with them?

24 **A. Yes, they did.**

25 Q. That would be something that 3M would obviously save,

Page 31

1 correct?

2 **A. Yes.**

3 Q. Did you continue to follow the literature that was --

4 I think I may have asked you this. I'm sorry if I'm

5 being repetitive. Did you continue to follow the

6 literature that was out there regarding the product?

7 **A. Up until 2019?**

8 Q. Yes, sir.

9 **A. Yes.**

10 Q. And you continued to summarize and critique that type

11 of literature?

12 **A. Much of it, yes.**

13 Q. You said that you gave talks, and part of that would

14 include prewarming; is that right?

15 **A. Yes.**

16 Q. Is it fair to say that you're a fan of prewarming?

17 **A. I certainly believe it's an essential component of**

18 **temperature management, yes.**

19 Q. Would you agree with me there's some significant

20 advantages to prewarming versus intraoperative

21 warming?

22 MR. GORDON: Object to the form of the

23 question.

24 **A. Well, I'm not -- I mean, what do you mean by**

25 **"advantages"? Perhaps that would make it clearer.**

Page 32

1 BY MR. FARRAR:

2 Q. Fair point.

3 Would you agree with me that it is -- some

4 significant advantages are it's inexpensive?

5 MR. GORDON: Object to the form of the

6 question.

7 **A. I don't think it costs any more or less than**

8 **intraoperative warming.**

9 BY MR. FARRAR:

10 Q. A significant advantage to prewarming is it's highly

11 effective?

12 MR. GORDON: Object to the form of the

13 question.

14 **A. Well, certainly, it's an important component of the**

15 **overall temperature management of patients, yes.**

16 BY MR. FARRAR:

17 Q. Would you agree that a significant advantage to

18 prewarming is it's not associated with adverse events?

19 MR. GORDON: Object to the form of the

20 question.

21 **A. I -- again, which adverse events do you mean?**

22 **(Exhibit 2 was marked for identification.)**

23 BY MR. FARRAR:

24 Q. Mr. Van Duren, I'm going to hand you what's been

25 marked as Exhibit 2, and it is Bates number

Page 33

1 3MBH00542872.

2 **A. (Reviewed.) Okay. I read it.**

3 Q. Do you see that this is an email that you sent to Jana

4 Stender in April 3rd of 2008?

5 **A. Yes.**

6 Q. And I'm looking at the last -- second-to-last sentence

7 which starts with "Prewarming." Do you see that?

8 **A. Yes, "is inexpensive." Yes.**

9 Q. Right. So you wrote, "Prewarming is inexpensive,

10 highly effective, and not associated with...adverse

11 events."

12 Did I read that right?

13 **A. "With any adverse events," yes.**

14 Q. "With any adverse." Thank you, sir.

15 You still agree with that, right?

16 **A. It is inexpensive, it's highly effective, and not**

17 **associated with adverse events, yes.**

18 Q. Do you agree that intraoperative warming or forced-air

19 warming is largely ineffective for the first hour of

20 operation?

21 **A. Well, it depends. It can be ineffective.**

22 Q. In your email to Jana Stender, you said, "is largely

23 ineffective for the first intraoperative hour,"

24 correct?

25 **A. Well, this is a comment on a document produced -- it**

Page 34

1 looks like it was a NICE recommendation. NICE is the  
 2 UK version of the Food and Drug Administration in the  
 3 UK, and apparently they had made recommendations that  
 4 didn't have a lot of Level 1 evidence in them for the  
 5 recommendations. So I think that's what the document  
 6 is in response to.

7 Q. Were you aware that in 2016 NICE had a recommendation  
 8 specifically regarding using conductive warming over  
 9 forced-air warming?

10 MR. GORDON: Object to the form of the  
 11 question.

12 A. I'm not certain it was a recommendation over -- that  
 13 they recommended conductive over forced-air warming,  
 14 if I remember correctly. I think that was included as  
 15 a recommendation, but --

16 BY MR. FARRAR:

17 Q. We'll come back to that.

18 Would you agree with me that a significant  
 19 advantage to prewarming is it is performed before the  
 20 surgical incision, which limits the potential  
 21 contamination of the surgical site?

22 A. Well, I mean, that may be an advantage; but its  
 23 biggest advantage is that it limits the temperature  
 24 drop associated with redistribution.

25 Q. Which is why intraoperative -- or, I'm sorry,

Page 35

1 forced-air warming is not particularly effective for  
 2 the first hour of surgery; is that right?

3 A. By itself, not -- not largely effective.  
 4 (Exhibit 3 was marked for identification.)

5 Q. I'll hand you what I've marked as Exhibit 3. For the  
 6 record, Exhibit 3 is 3MBH00001873.

7 A. (Reviewed.) Okay. I've read -- I've read it.

8 Q. So, Mr. Van Duren, this is an email that you sent to  
 9 Amber Prosper on February 22nd, 2008, correct?

10 A. Yes.

11 Q. And you copied some 3M folks, Mark Scott and Jane  
 12 Eden?

13 A. Yes.

14 Q. I guess they would have been Arizant folks.

15 A. Yes, that was Arizant Healthcare at the time.

16 Q. Sure. And this was back when you were director of  
 17 clinical affairs?

18 A. Yes.

19 Q. And if you're looking at the second-to-last paragraph  
 20 in your email, it starts with "A significant advantage  
 21 to prewarming is that it is performed before the  
 22 surgical incision, which limits the potential  
 23 contamination of the surgical site."  
 24 Did I read that correctly?

25 A. Yes.

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1 Q. And that's what you wrote to a clinician, somebody at  
 2 a hospital, along with folks at Arizant, correct?

3 A. No. I only sent that to Amber Prosper and Jane Eden  
 4 and Mark Scott.

5 Q. I'm sorry.

6 A. It didn't go to a clinician.

7 Q. Amber Prosper was sort of out in the field helping to  
 8 sell the Bair Hugger?

9 A. I'm not really sure what her position is. I was  
 10 trying to find --

11 Q. Account manager?

12 A. Oh, she's an account manager, yes.

13 Q. So in sales?

14 A. In sales.

15 Q. And she had a question come up with a hospital, and  
 16 that was the response that you gave to her to tell the  
 17 folks at the hospital, right?

18 MR. GORDON: Object to the form of the  
 19 question.

20 A. I believe --

21 MR. GORDON: Object, mischaracterizes the  
 22 document.

23 MR. FARRAR: You're right. I'm thinking  
 24 of -- I've got some emails in my mind mixed up. I'll  
 25 start that question again.

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1 BY MR. FARRAR:

2 Q. Let me just ask you this. That's an email that you  
 3 wrote to folks at Arizant, and it's something you  
 4 believed at the time you wrote it, correct?

5 A. Yes.

6 Q. And you still believe that, correct?

7 A. Well, which -- which part are you talking about?

8 Q. Just that sentence, "A significant advantage to  
 9 prewarming is that it is performed before the surgical  
 10 incision, which limits the potential contamination of  
 11 the surgical site."

12 MR. GORDON: Object to the form of the  
 13 question, rule of completeness.

14 A. So this was in response to a question from a clinician  
 15 about what advantage prewarming has over  
 16 intraoperative warming.

17 BY MR. FARRAR:

18 Q. Sure. And -- I'm sorry. Were you finished? I didn't  
 19 mean to interrupt you.

20 A. Yes.

21 Q. Okay. And your response was a significant advantage  
 22 is that it limits potential contamination of the  
 23 surgical site, correct?

24 A. Yes.

25 Q. And that's something you stand by today, correct?

1 **A. Well, again, this was in response to a concern that a**  
 2 **clinician had at the time about the potential for**  
 3 **intraoperative warming to contaminate the surgical**  
 4 **site, and my point was addressing his concern here**  
 5 **that prewarming -- since there's no surgical site**  
 6 **during prewarming --**  
 7 Q. Sure.  
 8 **A. -- that that limits that potential.**  
 9 Q. You gave -- you gave honest and truthful information  
 10 to that particular clinician, correct?  
 11 **A. It was an honest response, yes.**  
 12 Q. Okay. And you still believe it to be an honest  
 13 response?  
 14 **A. Yes.**  
 15 Q. You would receive questions and concerns from  
 16 customers from time to time, correct?  
 17 **A. Occasionally, yes.**  
 18 Q. Is it fair to say that as far back as 1994 when you  
 19 started with Augustine Medical you were aware that  
 20 there were clinicians that were concerned that the  
 21 Bair Hugger could cause surgical -- or deep joint  
 22 infections?  
 23 **A. In 1994?**  
 24 Q. Yes, sir.  
 25 **A. I -- I mean, I'm not -- I don't recall whether I had**

1 **information back then that clinicians were concerned**  
 2 **about that. It's possible, but I don't recall.**  
 3 Q. Sure. Let me -- I'm going to show you a document that  
 4 may help refresh your recollection on that.  
 5 Mr. Van Duren, what was the last exhibit number?  
 6 **A. Oh, I'm sorry.**  
 7 Q. No, it's okay.  
 8 **A. Number 3.**  
 9 Q. Thank you.  
 10 **A. Is that what you want?**  
 11 Q. I'm going to mark Exhibit 4, which is 3MBH00554405.  
 12 (Exhibit 4 was marked for identification.)  
 13 **A. (Reviewed.) Okay. I've read it.**  
 14 Q. So before we go to this, Mr. Hansen -- I mean, I'm  
 15 sorry, Mr. Van Duren, I just want to make sure that as  
 16 your time at both -- or at least at Arizant and 3M,  
 17 you understood that there were clinicians out in the  
 18 field who were concerned about the Bair Hugger causing  
 19 deep joint infections, correct?  
 20 **A. Yes.**  
 21 Q. And you would field those, I don't know if complaints  
 22 or requests or requests for information, from time to  
 23 time, correct?  
 24 **A. That I would respond to those concerns? Is that --**  
 25 Q. Right.

1 **A. -- your question? I did respond to those.**  
 2 Q. And those type of concerns or questions came in  
 3 relatively often when you were at Arizant and then on  
 4 to 3M. Fair?  
 5 MR. GORDON: Object to the form of the  
 6 question.  
 7 **A. Actually, I don't think they came in very often.**  
 8 BY MR. FARRAR:  
 9 Q. It's fair to say that you had complaints or questions  
 10 coming in worldwide. It wasn't just in the United  
 11 States, right?  
 12 **A. I suspect that they were worldwide, yes.**  
 13 Q. Do you recall the first time that you started getting  
 14 questions or complaints regarding whether or not the  
 15 Bair Hugger can cause deep joint infections?  
 16 MR. GORDON: Object to the form of the  
 17 question.  
 18 **A. I don't recall the exact time that that occurred.**  
 19 BY MR. FARRAR:  
 20 Q. Sure. I wouldn't expect a date, but just sort of time  
 21 frame. Do you recall that?  
 22 **A. I started working at Augustine Medical in 1994, and**  
 23 **I'm pretty sure I became aware thereafter that some**  
 24 **people had concerns about that.**  
 25 Q. Okay.

1 **A. Some clinicians had concerns about it.**  
 2 Q. And does Exhibit 4, which is an email from you to Gary  
 3 Hansen dated January 12, 2012, does that sort of help  
 4 refresh your recollection that you had -- or you were  
 5 aware of clinicians being concerned as far back as  
 6 1994?  
 7 **A. Well, yeah, I think that's -- yeah, from the third**  
 8 **paragraph, it looks like I pointed out that, you know,**  
 9 **when I started in 1994 some clinicians had concerns,**  
 10 **yes, about particulates.**  
 11 Q. What did Augustine Medical do internally to test  
 12 whether or not the Bair Hugger could cause deep joint  
 13 infections?  
 14 **A. Could you clarify what you mean by "internally"?**  
 15 Q. Internal testing, whether -- you know, what tests did  
 16 they conduct, either clinical or otherwise, to  
 17 determine whether or not the Bair Hugger could cause  
 18 deep joint infections?  
 19 **A. So internally we -- we did no clinical testing**  
 20 **internally. We had no capability to do internal**  
 21 **clinical testing. There were a number of studies**  
 22 **commissioned to look at things like infection rates or**  
 23 **the number of colony-forming units in various**  
 24 **locations after the use of forced-air warming**  
 25 **products.**

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1 Q. When you say "commissioned," what do you mean by that?

2 **A. Medical companies commission investigators to conduct**

3 **clinical trials.**

4 Q. Specifically which articles or pieces of literature

5 are you referring to that Augustine Medical

6 commissioned?

7 **A. Well, I don't know right now. I mean, obviously, we**

8 **commissioned a number of studies just as a routine**

9 **course of business.**

10 Q. And I understand it's a long time ago, and I'm just

11 trying to get the best of your memory. Can you

12 specifically name any study that Augustine Medical

13 commissioned that was related to whether or not the

14 Bair Hugger could cause a deep joint infection?

15 **A. Well, specifically a deep joint infection, I can't**

16 **recall a particular study that was commissioned for**

17 **that -- to investigate that particular outcome.**

18 Q. So to be fair, Augustine Medical did not conduct any

19 internal testing or commission any external testing to

20 determine whether or not the Bair Hugger could cause a

21 deep joint infection?

22 MR. GORDON: Object to the form of the

23 question.

24 **A. Well, I just said I can't recollect whether that was**

25 **done. It may have, but I just can't recollect.**

Page 43

1 BY MR. FARRAR:

2 Q. Did Augustine Medical commission any studies to

3 determine whether or not the Bair Hugger can increase

4 particulates over the surgical site?

5 **A. I believe a study by Zink and Iaizzo was conducted to**

6 **look at that outcome.**

7 Q. All right. Zink is the study with eight, I assume,

8 sort of college-aged students who were on the

9 operating table and they put the Petri dishes around?

10 **A. Yes.**

11 Q. Okay. Your memory is Zink was commissioned by

12 Dr. Augustine -- or Augustine Medical?

13 **A. I believe so, yes.**

14 Q. Are there any other studies that you can recall that

15 Augustine Medical commissioned regarding the issue of

16 increased particulates over the surgical site?

17 **A. No, at this point I can't recall which ones were done.**

18 Q. I'm going to move to Arizant.

19 **A. Okay.**

20 Q. Do you know -- are you aware of any internal testing

21 that Arizant did to determine whether or not the Bair

22 Hugger could increase the risk of deep joint

23 infections?

24 **A. So, again, when you mean "internal," do you mean**

25 **studies conducted in the facility of Arizant**

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1 **Healthcare?**

2 Q. Yes.

3 **A. I'm not aware of any.**

4 Q. Are you aware of any studies that Arizant commissioned

5 to determine whether or not the Bair Hugger could

6 cause deep joint infections?

7 MR. GORDON: Object to the form of the

8 question.

9 **A. Again, I'm not -- I don't recollect any.**

10 BY MR. FARRAR:

11 Q. Are you aware of any internal studies that Arizant

12 did to determine whether or not the Bair Hugger could

13 cause particulates to enter the sterile field?

14 **A. Internal studies?**

15 Q. Yes, sir.

16 **A. I believe there were a couple of studies that looked**

17 **at Schlieren pictures, Schlieren images of airflow**

18 **over conductive and convective blankets --**

19 Q. Is it --

20 **A. -- and humans.**

21 Q. Is it accurate that the Schlieren studies that were

22 conducted by Arizant showed that if the pores from the

23 blanket were pointed down that they actually went up

24 because of their buoyancy?

25 MR. GORDON: Object to the form of the

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1 question.

2 **A. I don't remember what the outcome of the studies was,**

3 **just that they were conducted.**

4 BY MR. FARRAR:

5 Q. Are you aware of any studies that Arizant commissioned

6 to determine whether or not the Bair Hugger caused

7 particulates to enter the sterile field?

8 MR. GORDON: Are you talking about

9 internal testing?

10 MR. FARRAR: No. This is commissioned.

11 I'm sorry.

12 MR. GORDON: Commissioned.

13 **A. I'm sorry. Could you repeat the question?**

14 BY MR. FARRAR:

15 Q. Yeah. Sure.

16 Are you aware of any studies that Arizant

17 commissioned to determine whether or not the Bair

18 Hugger could cause particulates to enter the sterile

19 field?

20 **A. Well, I mean, I believe there were a number of studies**

21 **that looked at particulates in various locations using**

22 **Bair Hugger, yes.**

23 Q. Specifically, I'm asking, did Arizant commission any

24 of these studies?

25 **A. Yes, I believe so. Yes.**

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1 Q. Can you think of any of the names of those?  
 2 **A. Oh, there were some studies -- particulate studies**  
 3 **that were done in the Netherlands. There may have**  
 4 **been others. Those are the ones I can remember now.**  
 5 Q. In 2017 in your deposition you testified that all  
 6 testing, whether internal and external, showed  
 7 increase in particulates in the sterile field. As far  
 8 as you know, does that remain true today?  
 9 MR. GORDON: Object to the form of the  
 10 question.  
 11 **A. I'd have to see that document. I -- I don't remember**  
 12 **saying that, but I --**  
 13 BY MR. FARRAR:  
 14 Q. Sure. All right.  
 15 And just to be fair, Mr. Van Duren, I'm going to  
 16 ask you about some things you testified to, and I've  
 17 got all the testimony, so just let me know if you want  
 18 to look at it.  
 19 **A. Yes, please.**  
 20 Q. So this was in your role as a 30(b)(6), is what we  
 21 call it, sort of a --  
 22 **A. Yeah.**  
 23 Q. -- company -- a company witness.  
 24 MR. FARRAR: I have a copy if you want  
 25 it.

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1 MR. GORDON: Are you marking this as an  
 2 exhibit or --  
 3 MR. FARRAR: No, I don't think so, just a  
 4 reference.  
 5 BY MR. FARRAR:  
 6 Q. I'm going to have to find the page. Give me one  
 7 second.  
 8 I believe it's page 306. Wait. It can't be.  
 9 I'll tell you what, Mr. Van Duren, I'm on the  
 10 wrong page. Let me just -- let's take a quick break,  
 11 and I'm going to use the restroom anyway, and I'll  
 12 find the right page.  
 13 THE WITNESS: Okay.  
 14 MR. FARRAR: Sorry about that.  
 15 THE WITNESS: No problem.  
 16 THE VIDEOGRAPHER: We're off the record.  
 17 (From 10:20 a.m. to 10:32 a.m. a recess was taken.)  
 18 THE VIDEOGRAPHER: We're on the record.  
 19 BY MR. FARRAR:  
 20 Q. All right. Mr. Van Duren, I'm sorry about that. When  
 21 we took a break, it's on your 30(b)(6) deposition,  
 22 page 258, line 5 through 13, and the question was:  
 23 "Okay. Based on the data that we have today,  
 24 including the study funded by 3M as well as other  
 25 studies, every single study indicates that the Bair

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1 Hugger increases the particle count over the sterile  
 2 field, correct?"  
 3 And you answered, "In absolute numbers, yes."  
 4 It says -- the question is: "Yes. Okay. And  
 5 you have no internal studies to refute that, correct?"  
 6 The answer is: "No, we don't."  
 7 That was an accurate answer that you gave in  
 8 2017, correct?  
 9 **A. It was.**  
 10 Q. As far as you know today, is that still an accurate  
 11 answer?  
 12 **A. To my knowledge.**  
 13 Q. I want to see if there's some things that I think we  
 14 can probably agree about.  
 15 You agree that bacteria cause infections?  
 16 MR. GORDON: Object to the form of the  
 17 question.  
 18 **A. Yes.**  
 19 BY MR. FARRAR:  
 20 Q. You agree that bacteria can be transmitted through the  
 21 air?  
 22 **A. They can be.**  
 23 Q. All right. That's something I know it's different  
 24 with COVID, but we're starting to all sort of figure  
 25 that one out, right?

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1 MR. GORDON: Object to the form of the  
 2 question.  
 3 BY MR. FARRAR:  
 4 Q. You agree that bacteria ride on particles?  
 5 **A. It depends on the size, but they can.**  
 6 Q. You agree that up to 40 percent of particles have  
 7 bacteria?  
 8 MR. GORDON: Object to the form of the  
 9 question.  
 10 **A. Again, it depends on the distribution of the size of**  
 11 **the particle in a given space.**  
 12 BY MR. FARRAR:  
 13 Q. Do you know who Dr. Wenzel is?  
 14 **A. I've heard his name. I don't know him personally.**  
 15 Q. Okay. And you may not be aware. Are you aware that  
 16 3M hired Dr. Wenzel as the infectious disease expert  
 17 in this Bair Hugger litigation?  
 18 **A. I may have been aware of that; but, again, I don't**  
 19 **know him.**  
 20 Q. If he testified that up to 40 percent of particles  
 21 have bacteria, would you defer to him as an infectious  
 22 disease doctor?  
 23 MR. GORDON: Object to the form of the  
 24 question, misstates the evidence, lack of foundation.  
 25 **A. I'd want to see the context of that response and**

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1 **question, but --**  
 2 BY MR. FARRAR:  
 3 Q. Sure. And I just printed the -- I didn't print the  
 4 whole deposition, but we'll mark it as Exhibit 5.  
 5 And I'm sorry, Corey, I don't have an extra copy  
 6 for you on this one.  
 7 (Exhibit 5 was marked for identification.)  
 8 The cover page just shows Dr. Wenzel, and I'm  
 9 looking at the back of it, really just page 50, if you  
 10 want to take a look.  
 11 MR. GORDON: Let me look at it before you  
 12 answer. Oh, no, no. Go ahead and look, but I just  
 13 want to -- since there's not an extra copy.  
 14 MR. FARRAR: Yeah. Sorry about that,  
 15 Corey.  
 16 **A. So, I'm sorry, starting page 50?**  
 17 BY MR. FARRAR:  
 18 Q. Yes, sir. Really just page 50.  
 19 **A. (Reviewed.) And just page 50, is that --**  
 20 Q. Yes, sir. I was just sort of orienting you that  
 21 Dr. Wenzel testified that 40 percent of particles that  
 22 carry -- I'm sorry, 40 percent of particles can carry  
 23 bacteria.  
 24 **A. Well, he actually said that he hadn't studied that but**  
 25 **that he had read it or seen -- seen that somewhere,**

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1 **yes.**  
 2 Q. Okay. Do you have any reason to disagree with  
 3 Dr. Wenzel on this?  
 4 MR. GORDON: Object to the form of the  
 5 question, lack of foundation, misstates the evidence.  
 6 **A. I'm not an infectious disease expert or a**  
 7 **microbiologist.**  
 8 BY MR. FARRAR:  
 9 Q. That's my point. So you would defer to an infectious  
 10 disease guy who is studying the issue and specifically  
 11 prepared on the issue for a deposition, right?  
 12 MR. GORDON: Object to the form of the  
 13 question.  
 14 **A. Well, again, he's -- he's only quoting -- he's only**  
 15 **stating that he's seen that in the printed literature.**  
 16 **That's not something that he personally discovered**  
 17 **himself. He's only reporting what he believes he's**  
 18 **read in the literature.**  
 19 BY MR. FARRAR:  
 20 Q. I'll ask it this way. Do you have any information or  
 21 literature that differs from that?  
 22 MR. GORDON: Object to the form of the  
 23 question.  
 24 BY MR. FARRAR:  
 25 Q. That says that he's incorrect?

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1 **A. I'm not aware of any.**  
 2 Q. Okay. You agree that one purpose of the airflow in  
 3 an OR is to reduce the number of particles in the air?  
 4 **A. I believe that's one purpose, yes.**  
 5 Q. And that's because reducing particles will potentially  
 6 reduce the chance of infection, correct?  
 7 **A. I believe that's the theory on which that's based.**  
 8 Q. You agree that surgeons care about increased particle  
 9 count?  
 10 MR. LUCAS: Object to form, overbroad,  
 11 vague, lacks foundation.  
 12 BY MR. FARRAR:  
 13 Q. You can answer.  
 14 **A. I'm sorry. Could you repeat the question?**  
 15 Q. Sure. Do you agree that surgeons care about increased  
 16 particle count?  
 17 **A. I -- again, I don't know personally if that's true;**  
 18 **but it certainly could be.**  
 19 Q. You have communicated with surgeons in the field  
 20 regularly as your job when you were working on the  
 21 Bair Hugger, correct?  
 22 **A. No.**  
 23 Q. If you look at your 30(b)(6) deposition again, please,  
 24 page 301, and starting at line 2, the question was:  
 25 "You're aware that orthopedic surgeons do in fact care

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1 about increased particle counts, correct?"  
 2 And your answer was: "Many of them do."  
 3 "Question: And in fact some of these orthopedics  
 4 surgeons have contacted the company from time to time  
 5 about these concerns?"  
 6 And your answer is: "Yes."  
 7 Do you still stand by that answer, sir?  
 8 **A. I do.**  
 9 Q. Okay. So orthopedic surgeons, at least many of them,  
 10 care about increased particle counts, correct?  
 11 **A. But I think your first question was whether I was**  
 12 **aware of surgeons in the field, did I -- did I**  
 13 **interact with these surgeons.**  
 14 Q. The first question -- I'll just read it. Surgeons  
 15 care about increased particle count?  
 16 **A. Yes.**  
 17 Q. Okay. And that's something that you knew when you  
 18 were at Augustine Medical, Arizant, and 3M, correct?  
 19 **A. Yes.**  
 20 Q. You agree that it takes a very small amount of  
 21 bacteria to cause an infection?  
 22 MR. GORDON: Object to the form of the  
 23 question.  
 24 **A. I believe that's correct; but, again, I'm not an**  
 25 **expert in that field.**

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1 BY MR. FARRAR:  
 2 Q. You testified live at the trial in the Gareis case  
 3 to that. Would you stand by your testimony? Do you  
 4 want me to -- do you want to see it?  
 5 A. Well, I'd like to -- yeah.  
 6 Q. Sure.  
 7 A. If you're asking me a question about it, I'd like to  
 8 see it.  
 9 Q. Page 149, please. And it's line 9.  
 10 And the question is: "And your understanding  
 11 based on your education that you undertook to learn  
 12 about the Bair Hugger was that a very small amount of  
 13 bacteria are required to cause an infection in knee  
 14 and hip replacement surgery, correct?"  
 15 You answered: "Well, I don't know what the exact  
 16 amount required is."  
 17 "Question: I didn't ask exact" amount. "A very  
 18 small amount, correct, sir?"  
 19 And you said: A very small -- or I'm sorry. "A  
 20 small amount, yes."  
 21 Do you stand by that testimony, sir?  
 22 A. Yes.  
 23 Q. Okay. So again if I ask you, it takes a very small  
 24 amount of bacteria to cause an infection, that's  
 25 something you would agree with?

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1 MR. GORDON: Object to the form of the  
 2 question, misstates the testimony.  
 3 MR. LUCAS: Vague, overbroad, and an  
 4 improper hypothetical.  
 5 BY MR. FARRAR:  
 6 Q. Let me ask you a different question. Would you agree  
 7 that it takes a very small amount of bacteria to cause  
 8 an infection in a knee or hip replacement surgery?  
 9 MR. GORDON: Object to the form of the  
 10 question.  
 11 MR. LUCAS: Same prior objections.  
 12 A. I believe it's correct.  
 13 BY MR. FARRAR:  
 14 Q. And to be clear, when I said knee or hip surgery, I  
 15 mean knee or hip implant surgery.  
 16 A. Yes.  
 17 MR. GORDON: Same objections.  
 18 BY MR. FARRAR:  
 19 Q. And you understand part of the reason is, if the  
 20 bacteria gets on the implant itself and is put in  
 21 someone's body, they don't have the blood flow to  
 22 necessarily have the body's natural ability to fight  
 23 off the bacteria, correct?  
 24 MR. GORDON: Object to the form of the  
 25 question.

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1 A. I don't know what the exact mechanism is.  
 2 BY MR. FARRAR:  
 3 Q. It would be fair to say that 3M and Arizant employed  
 4 folks who would know that mechanism, correct?  
 5 A. I have -- not to my knowledge.  
 6 Q. 3M has an infectious disease department, correct?  
 7 A. I'm unaware of that.  
 8 Q. So let me ask you this question. As director of  
 9 clinical affairs for Arizant and then your positions  
 10 at 3M, is it fair to say that you have no  
 11 understanding as to why only a small number of  
 12 bacteria are required to cause an infection in a knee  
 13 or hip replacement surgery?  
 14 A. Again, I'm not an infectious disease expert, and I  
 15 suspect that the answer is multifactorial.  
 16 Q. Did you ever consult with an infectious disease expert  
 17 to understand why?  
 18 A. Not to my recollection.  
 19 Q. You know -- you understand -- I'll move on. We'll  
 20 come back to that.  
 21 Would you agree that it would be unreasonable to  
 22 intentionally increase the number of particles over a  
 23 surgical site?  
 24 MR. GORDON: Object to the form of the  
 25 question.

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1 A. I'm sorry. Would you repeat it?  
 2 BY MR. FARRAR:  
 3 Q. Would you agree that it would be unreasonable to  
 4 intentionally increase the number of particles over a  
 5 surgical site?  
 6 MR. GORDON: Same objection.  
 7 A. Well, I don't know if "unreasonable" is the correct  
 8 term there.  
 9 BY MR. FARRAR:  
 10 Q. If you'll turn to your trial testimony on page 176.  
 11 A. Of which?  
 12 Q. The trial testimony, sir. That one, yes, sir.  
 13 A. Oh, okay. 176?  
 14 Q. Yes, sir.  
 15 If you go down to 20, the question is: "Would  
 16 you agree with me that there was no reason to increase  
 17 particle loads over the surgical site from a safety  
 18 standpoint?"  
 19 And you say, "I can't think of a reason that  
 20 would be beneficial."  
 21 And the question: "In fact, it would be  
 22 unreasonable to do that, wouldn't it?"  
 23 And you say, "Well, intentionally, yes."  
 24 Have I read that correctly?  
 25 A. Yes.

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1 Q. Do you stand by that testimony, sir?

2 **A. I do.**

3 Q. And the reason it would be unreasonable is it could

4 potentially create an unsafe condition, correct?

5 **A. That's a possibility.**

6 Q. "Unsafe" meaning that it could potentially cause an

7 infection or increase the risk of infection, correct?

8 **A. Or a foreign body reaction.**

9 Q. And the same, it would be unreasonable to

10 intentionally increase the number of particles over

11 the sterile field, correct?

12 **A. I'm sorry. Would you repeat that one?**

13 Q. Yeah. It's sort of the same question just with --

14 instead of surgical site, sterile field.

15 It would be unreasonable to intentionally

16 increase the number of particles over a sterile field?

17 **A. Well, do you mean -- I mean, again, are we talking**

18 **about directly on the sterile field or well above it?**

19 **You said above the sterile field. I mean, if it's a**

20 **meter above, it probably doesn't matter.**

21 Q. In the sterile field.

22 **A. In the sterile field.**

23 Q. Yes, sir. Sorry if I was --

24 **A. So --**

25 Q. Poor wording.

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1 **A. Again?**

2 Q. Sure. I'll ask it again.

3 It would be unreasonable to intentionally

4 increase the number of particles in the sterile field?

5 **A. Yes.**

6 Q. Again, because that could potentially be unsafe?

7 **A. It could be.**

8 Q. It could potentially lead to an infection?

9 **A. Or a foreign body reaction.**

10 Q. Every single study shows that the Bair Hugger

11 increases the number of particles over the surgical

12 site, correct?

13 **A. Every study?**

14 Q. Yes, sir.

15 **A. I don't know that that's true.**

16 Q. If you would go back to your trial testimony on page

17 177 again.

18 Line 9, you're asked: "Now, you would agree that

19 every study shows that the Bair Hugger increases the

20 absolute count of particles over the sterile field;

21 correct?"

22 And your answer is: "As far as I know, in

23 absolute numbers the particulate count goes up in a

24 trivial amount, yes."

25 Did I read that correctly?

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1 **A. I did -- yes, that's correct.**

2 Q. So I may have asked the question poorly. Let me ask

3 it again.

4 Would you agree that every single study shows the

5 Bair Hugger increases the number of particles in the

6 sterile field?

7 **A. Well, again, I'm looking at my answer here. I didn't**

8 **really answer the question that was asked about every**

9 **study; and, again, I'm still uncertain about whether**

10 **every study asserts that that's true.**

11 Q. Fair.

12 **A. And so I don't know.**

13 Q. So let me ask you. Every single study that you're

14 aware of, correct?

15 MR. GORDON: Object to the form of the

16 question.

17 BY MR. FARRAR:

18 Q. I'm trying to give you the benefit, Mr. Van Duren.

19 You say, "as far as I know," which I understand you

20 can't really answer in absolutes. Maybe there's

21 something out there that you've never seen. So let me

22 just try the question again.

23 Would it be fair to say that every single study

24 that you're aware of shows that the Bair Hugger

25 increases the number of particles in the sterile

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1 field?

2 **A. So --**

3 MR. GORDON: Object to the form of the

4 question.

5 **A. Again, the "every study" is the -- I don't know that**

6 **every study shows that.**

7 BY MR. FARRAR:

8 Q. Are you aware of any studies that show the opposite,

9 that it doesn't increase?

10 **A. Well, right now I don't recollect whether that's true**

11 **either.**

12 Q. This testimony that we're reading is from May 15th of

13 2018. At that time you still had been working with

14 the Bair Hugger, correct?

15 **A. I was.**

16 Q. Okay. Would it be fair to say that you probably --

17 your memory and knowledge base of the Bair Hugger was

18 a little bit greater in 2018?

19 **A. Probably.**

20 Q. So when you testified in 2018 that as far as you know

21 in absolute numbers the particulate count goes up in a

22 trivial manner, yes, that would have been to the best

23 of your knowledge and ability accurate information

24 then, correct?

25 MR. GORDON: I think it was "trivial



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1 amount," not "trivial manner."  
 2 MR. FARRAR: Thanks, Corey.  
 3 BY MR. FARRAR:  
 4 Q. Let me rephrase that.  
 5 Would it be fair to say that when you testified  
 6 in 2018, you would agree that every study -- try it  
 7 one more time.  
 8 When you testified in 2018, as far as you know,  
 9 every study in absolute numbers the particulate count  
 10 goes up in a trivial amount, correct?  
 11 **A. No, I did not say in every study. I just said, as far**  
 12 **as I know, in absolute numbers the particulate count**  
 13 **goes up in a trivial amount.**  
 14 Q. You know some of the studies have the particulate  
 15 count up in a more than trivial amount, correct?  
 16 **A. Well, not --**  
 17 MR. GORDON: Object to the form of the  
 18 question.  
 19 **A. Not every study measured particulate counts.**  
 20 BY MR. FARRAR:  
 21 Q. No. I understand. I'm talking about the ones that  
 22 did.  
 23 Some of the studies showed a significant increase  
 24 in particulate counts, correct?  
 25 **A. Again, I'd have to see the individual study to which**

Page 63

1 **you're referring.**  
 2 Q. Are you aware that there were studies that showed a  
 3 statistically significant increase of particulate  
 4 count over the sterile field or in the sterile field  
 5 with the use of the Bair Hugger?  
 6 MR. GORDON: Object to the form of the  
 7 question.  
 8 **A. Not that I recollect.**  
 9 BY MR. FARRAR:  
 10 Q. You don't recollect -- and I understand you may not  
 11 remember the name of the study. I get that.  
 12 What I'm asking you is: Sitting here today, you  
 13 remember that there were studies that showed that,  
 14 correct?  
 15 MR. GORDON: Same objection.  
 16 **A. Significant?**  
 17 BY MR. FARRAR:  
 18 Q. Statistically significant.  
 19 **A. Statistically significant?**  
 20 Q. Yes.  
 21 **A. No, I don't recall that.**  
 22 Q. Okay. If such a study existed, would that be  
 23 something that 3M would or Arizant would want to  
 24 figure out what's going on and look at that study and  
 25 see if it's accurate?

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1 MR. GORDON: Object to the form of the  
 2 question.  
 3 **A. Certainly, we would review the study to see if it had**  
 4 **limitations in the measurement techniques and methods.**  
 5 BY MR. FARRAR:  
 6 Q. Would it be reasonable to do additional investigation  
 7 to determine if that study was accurate?  
 8 **A. I suppose it depends on the consequences. If we**  
 9 **had --**  
 10 Q. Go ahead.  
 11 **A. -- clinical data that showed that that was irrelevant,**  
 12 **probably not.**  
 13 Q. You testified before that the science was not settled  
 14 on whether or not an increase in particulate count is  
 15 associated with an increased risk of infection. Do  
 16 you remember that?  
 17 **A. I do.**  
 18 Q. Do you want to change that answer now after a couple  
 19 years of additional new information?  
 20 **A. No.**  
 21 Q. You understand that the International Consensus of  
 22 Periprosthetic Joint Infection disagrees with you?  
 23 MR. GORDON: Object to the form of the  
 24 question.  
 25 **A. I'd have to see the context of that recommendation.**

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1 BY MR. FARRAR:  
 2 Q. You're familiar with ICOS, correct?  
 3 **A. Not -- not directly, no.**  
 4 Q. Okay. You know who Dr. Parvizi is?  
 5 **A. Yes.**  
 6 Q. He's well-respected?  
 7 **A. I believe so.**  
 8 Q. Well-respected by 3M even?  
 9 **A. Yes.**  
 10 Q. Okay. You know that 3M is a platinum sponsor of ICOS?  
 11 **A. No.**  
 12 Q. You didn't know that?  
 13 **A. I did not.**  
 14 Q. Did you know that 3M's attorneys were involved in  
 15 asking Dr. Mott to make additions to ICOS?  
 16 MR. GORDON: Object to the form of the  
 17 question, mischaracterizes -- or assumes facts not in  
 18 evidence.  
 19 **A. I don't know who Dr. Mott is.**  
 20 BY MR. FARRAR:  
 21 Q. Would you expect attorneys for 3M to be trying to  
 22 influence the results of ICOS?  
 23 **A. What do you mean by "influence"?**  
 24 Q. In any way.  
 25 **A. Well, I don't know.**

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1 Q. Was it your practice at either Arizant or 3M to  
 2 contact study authors?  
 3 **A. Sometimes.**  
 4 Q. What about organizations summarizing studies?  
 5 **A. I don't recall doing it, but I may have.**  
 6 Q. Have you ever requested an author change a study?  
 7 **A. What do you mean?**  
 8 Q. To make a fundamental change to the findings or the  
 9 conclusions.  
 10 MR. GORDON: Object to the form of the  
 11 question.  
 12 **A. I don't recall ever doing that.**  
 13 BY MR. FARRAR:  
 14 Q. Have you ever requested articles not be published?  
 15 **A. I don't recall ever doing that.**  
 16 Q. Ever stopped a study partway through it because it  
 17 looked like it was going to have poor results for  
 18 whatever products you're working on?  
 19 **A. Well, I haven't stopped studies.**  
 20 Q. Have you asked others to stop studies?  
 21 **A. Not that I recall.**  
 22 Q. Is it fair that at least to your knowledge 3M has  
 23 never warned orthopedic surgeons about the Bair Hugger  
 24 increasing particle count over the surgical site?  
 25 MR. GORDON: Object to the form of the

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1 question.  
 2 **A. I don't know.**  
 3 BY MR. FARRAR:  
 4 Q. Have you ever looked at the warnings on the Bair  
 5 Hugger?  
 6 **A. Not recently; but I certainly did in the past, yes.**  
 7 Q. Up until the time where you left working on the Bair  
 8 Hugger in 2019, were you ever aware of 3M warning  
 9 orthopedic surgeons that the Bair Hugger could  
 10 increase particulate count over the surgical site?  
 11 **A. I don't believe so.**  
 12 Q. Never warned hospitals or anesthesiologists also,  
 13 correct?  
 14 **A. Not to my knowledge.**  
 15 Q. Is it fair to say that a company like Arizant or 3M  
 16 needs to be aware of potential risks of medical  
 17 devices they make?  
 18 **A. Yes.**  
 19 Q. And if risks come up, whether it be through clinicians  
 20 or literature, that's something that the company has  
 21 to investigate, correct?  
 22 **A. Well, what do you mean by "has to investigate"?**  
 23 Q. Should a reasonable company investigate potential  
 24 risks that are brought to the company's attention?  
 25 **A. Well, there's an extensive risk management system, and**

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1 **all medical companies have -- all legitimate medical**  
 2 **companies have risk management systems where risks**  
 3 **are identified and then evaluated.**  
 4 Q. If risks are brought to the company's attention via  
 5 published literature or complaints from the field, is  
 6 that something that the company should investigate to  
 7 determine the validity of them?  
 8 **A. Well, again, when you say "should," are you talking**  
 9 **about some legal responsibility or a moral/ethical**  
 10 **responsibility or --**  
 11 Q. A reasonable company. Is that something a reasonable  
 12 company would do?  
 13 **A. I think so.**  
 14 Q. Patient safety is very important, correct?  
 15 **A. Yes.**  
 16 Q. Could be paramount to anything else, correct?  
 17 MR. GORDON: Object to the form of the  
 18 question.  
 19 **A. Well, patient safety is extremely important at 3M and**  
 20 **every other legitimate medical company.**  
 21 BY MR. FARRAR:  
 22 Q. Would you agree that if a medical device has no  
 23 benefit, any risk would be unreasonable?  
 24 **A. Yes.**  
 25 Q. The design of a medical device should maximize the

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1 benefit and minimize the risk. Is that fair?  
 2 **A. Yes.**  
 3 Q. The only benefit to the Bair Hugger is to keep patient  
 4 core temperature normal, correct?  
 5 **A. That is an outcome of using the Bair Hugger. It's not**  
 6 **its only benefit.**  
 7 Q. What other benefit does it have?  
 8 **A. Well, the establishment of intraoperative normothermia**  
 9 **is known to be associated with a number of good**  
 10 **post-surgical outcomes, including reduction in**  
 11 **bleeding, reduction in infections, decreasing the**  
 12 **length of postoperative stays, thermal comfort,**  
 13 **postoperative thermal comfort, those sorts of things.**  
 14 Q. Those all relate to what we call normothermia,  
 15 correct?  
 16 **A. Yes.**  
 17 Q. So the benefit is keeping normothermia. Fair enough?  
 18 **A. Well, again, the establishment of that condition of**  
 19 **normothermia produces benefits, again, that the --**  
 20 **that are recognized by the patient and clinicians.**  
 21 Q. Normothermia is defined as core temperature of over  
 22 36 degrees Celsius?  
 23 **A. That's its current clinical definition, yes.**  
 24 Q. Is it fair to say that neither 3M nor Arizant ever  
 25 conducted any internal testing to determine if the

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1 Bair Hugger causes surgical site infections?  
 2 **A. Again, "internal," you mean internal to the facility**  
 3 **where we manufacture Bair Hugger? Is that what you**  
 4 **mean by that?**  
 5 Q. Right, studies that are conducted by the folks that  
 6 work for 3M or Arizant.  
 7 **A. No, we would not conduct studies like that because we**  
 8 **didn't have personnel that were qualified to do that.**  
 9 Q. As part of your work on the Bair Hugger, I assume you  
 10 would look at competitors' products in the forced-air  
 11 warming field, right?  
 12 **A. I'm not sure what you mean by "look at."**  
 13 Q. Be familiar with them.  
 14 **A. Certainly knew that they existed, yes. You're talking**  
 15 **about me personally, right?**  
 16 Q. Sure.  
 17 One of the things -- or you tell me. Did you --  
 18 or were you familiar with the Stryker Mistral product?  
 19 **A. I know of it's existence, yes.**  
 20 Q. You know it has a blower like the Bair Hugger,  
 21 correct?  
 22 **A. Yes.**  
 23 Q. It has a hose like the Bair Hugger, correct?  
 24 **A. Yes.**  
 25 Q. It has a blanket that has perforations like the Bair

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1 Hugger, correct?  
 2 MR. GORDON: Object to the form of the  
 3 question, assumes facts not in evidence.  
 4 **A. I'm not really that familiar with the design of the**  
 5 **blanket of a Mistral.**  
 6 BY MR. FARRAR:  
 7 Q. Were you aware that it had a HEPA filter on it? Not  
 8 the blanket, but the blower?  
 9 **A. I believe I was aware of that, yes.**  
 10 Q. Are you aware that Stryker on their Mistral product  
 11 has a warning about airborne contamination?  
 12 **A. No.**  
 13 Q. You didn't know that?  
 14 **A. I did not know that, no.**  
 15 Q. Did you have any role in drafting or vetoing, or  
 16 whatever it may be, warnings on the Bair Hugger ever?  
 17 **A. I don't believe so.**  
 18 Q. Are you aware of any internal communications that --  
 19 where putting a warning on the Bair Hugger was  
 20 discussed, specifically about airborne contamination?  
 21 **A. I don't recall ever having a discussion like that.**  
 22 Q. Have you ever seen any memos or PowerPoints or  
 23 presentations, anything like that, regarding that  
 24 issue?  
 25 **A. Not that I recall.**

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1 Q. You know that the original Bair Hugger Model 200 had  
 2 a warning, correct?  
 3 **A. It had several warnings.**  
 4 Q. A warning specific to airborne contamination?  
 5 **A. I'm not aware of that, no.**  
 6 Q. You know that the Bair Hugger Model 200 was not  
 7 intended for use in the operating room, correct?  
 8 **A. Yes.**  
 9 Q. Yes, that's an accurate statement?  
 10 **A. Yes, that's an accurate statement.**  
 11 Q. Okay.  
 12 **A. And just to be clear, that was because of its**  
 13 **operating temperature.**  
 14 Q. That's the only reason is the operating temperature?  
 15 **A. To my knowledge.**  
 16 Q. It was never studied for use in the OR, correct?  
 17 **A. I'm not -- I don't -- I'm not aware of any studies**  
 18 **that were done intraoperatively with the Model 200.**  
 19 **(Exhibit 6 was marked for identification.)**  
 20 MR. FARRAR: I only have one copy of that  
 21 one. I couldn't get another one. Sorry.  
 22 BY MR. FARRAR:  
 23 Q. Before you -- before you get to that, Mr. Van Duren,  
 24 isn't it true today that the -- well, never mind.  
 25 Let's look at Exhibit 6, which is a copy of the

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1 warnings on the Bair Hugger 200.  
 2 **A. Yes.**  
 3 Q. Do you see the warning on the second page, Number 5?  
 4 **A. Yes.**  
 5 Q. Can you read that out for me, please?  
 6 **A. "Caution: This machine not intended for use in the**  
 7 **operating room."**  
 8 Q. I'm sorry. Page 2, Number --  
 9 **A. Oh, sorry.**  
 10 Q. The warning about airborne contamination.  
 11 **A. So Item Number 5 in the warnings section says, "The**  
 12 **possibility of airborne contamination should be**  
 13 **considered if patients with infected wounds are**  
 14 **treated with the Bair Hugger."**  
 15 Q. Okay. Thanks.  
 16 You can -- or, actually, if you're keeping  
 17 exhibits over there, it's perfect.  
 18 Would you agree with me that in most cases a knee  
 19 or hip replacement surgery takes about one to two  
 20 hours?  
 21 **A. I believe that's about right.**  
 22 Q. We talked a little bit about this, but just to make  
 23 sure, intraoperative warming is largely ineffective  
 24 for the first hour of an operation?  
 25 **A. In -- in maintaining core temperature, yes.**

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1 Q. When you say "in maintaining core temperature, yes,"  
 2 what is it effective for if not for maintaining core  
 3 temperature?  
 4 **A. So no form of external warming is completely effective**  
 5 **at limiting redistribution, post-induction**  
 6 **redistribution.**  
 7 Q. So -- and I apologize if I'm missing you. You sort of  
 8 put a qualifier on this question. I'll just ask --  
 9 let me ask it again.  
 10 Intraoperative warming is largely ineffective for  
 11 the first hour of an operation. That's a true  
 12 statement, correct?  
 13 **A. At minimizing the reduction in core temperature.**  
 14 Q. But that's what the Bair Hugger is meant to do,  
 15 correct?  
 16 **A. Yes.**  
 17 Q. So it's largely ineffective for doing what it's meant  
 18 to do for the first hour?  
 19 **A. It can be, yes.**  
 20 Q. All right. You knew that as far back as 2005, 2008,  
 21 correct?  
 22 **A. Probably.**  
 23 Q. It's not controversial, in other words. It's  
 24 something that's known in the community, right, the  
 25 relevant medical community?

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1 **A. Well, correct. But, again, it doesn't really matter**  
 2 **what type of intraoperative warming we're talking**  
 3 **about. As long as it's external, it's -- it's not**  
 4 **effective at limiting the drop in core temperature.**  
 5 Q. Sure. Prewarming, on the other hand, is, correct?  
 6 **A. Yes.**  
 7 Q. Okay. If a -- you know that some joint replacement  
 8 surgeons who do a lot of joint replacement surgeries  
 9 do them in less than an hour, correct?  
 10 MR. GORDON: Object to the form of the  
 11 question.  
 12 **A. I don't currently know what the median time length is**  
 13 **for a knee or a hip replacement.**  
 14 BY MR. FARRAR:  
 15 Q. You know as your role both in Arizant and at 3M that  
 16 there are orthopedic surgeons who do total knee  
 17 replacement and total hip replacement surgeries in  
 18 under an hour, though. You know that exists, right?  
 19 **A. I believe there are some who can do it in less than an**  
 20 **hour, yes.**  
 21 Q. Okay. So for those folks the use of the Bair Hugger  
 22 has no benefit, correct?  
 23 **A. No, I didn't say that. I just said it was -- it's**  
 24 **ineffective at reducing the decrease in temperature**  
 25 **due to redistribution. It's not ineffective.**

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1 Q. If you would, look at your trial testimony again,  
 2 please. Page 160, please, sir.  
 3 And starting at line 3, the question was: "And  
 4 back in 2008, you would agree that you were of the  
 5 opinion that intraoperative warming was largely  
 6 ineffective for the first intraoperative hour?"  
 7 And your answer is, "Yes, I wrote that."  
 8 And the response is, "And you would agree with  
 9 it?" The next question.  
 10 Your response, "I would agree in general that  
 11 that's true."  
 12 Do you stand by that answer, sir?  
 13 **A. Yes.**  
 14 Q. So, generally speaking, forced-air warming is largely  
 15 ineffective for the first intraoperative hour,  
 16 correct?  
 17 **A. Yes.**  
 18 Q. So if a surgery is an hour or less, use of the Bair  
 19 Hugger is largely ineffective, correct?  
 20 MR. GORDON: Objection, asked and  
 21 answered.  
 22 **A. I'm sorry. Would you repeat it again?**  
 23 BY MR. FARRAR:  
 24 Q. If a joint replacement surgery is less than an hour,  
 25 the use of the Bair Hugger is largely ineffective,

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1 correct?  
 2 **A. Yes.**  
 3 Q. And that's the benefit, is keeping you warm, correct?  
 4 **A. Yes.**  
 5 Q. I asked you earlier the question that if there's no  
 6 benefit, any risk would be unreasonable, correct?  
 7 **A. You -- yes, you did ask that.**  
 8 Q. You agreed with that?  
 9 **A. No benefit?**  
 10 Q. Right. If there's no benefit, then any risk would be  
 11 unreasonable, correct?  
 12 **A. That's correct.**  
 13 Q. Okay.  
 14 **A. And, again, but that's not what I'm saying here.**  
 15 Q. Mr. Van Duren, just so you have it, I'm going to mark  
 16 as Exhibit 7 the email where you wrote that, just so  
 17 you have the context if you'd like.  
 18 **A. Yes.**  
 19 Q. All right. So we're going to mark as Exhibit 7. This  
 20 is Bates number 3MBH01986711.  
 21 (Exhibit 7 was marked for identification.)  
 22 **A. (Reviewed.) Okay. I've read it.**  
 23 Q. Okay. And I was just orienting you, Mr. Van Duren.  
 24 If you look at the very first sentence, you say,  
 25 "Dr. Smith and his colleagues have once again

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1 demonstrated something that we all readily  
 2 acknowledge: intraoperative warming is largely  
 3 ineffective at preventing the initial decrease in core  
 4 temperature because redistribution is mostly  
 5 adiabatic." Correct?  
 6 **A. Correct.**  
 7 Q. And then you say, "The 2nd law of thermodynamics is  
 8 tough to defeat, which is why they call it a law,"  
 9 right?  
 10 **A. Correct.**  
 11 Q. This was an email that you sent to the Clinical  
 12 Research Team back in June 8 of 2008, correct?  
 13 **A. I sent to it to Jana Stender. No. Sorry. I sent**  
 14 **it -- oh, yeah, you're right, Clinical Research Team.**  
 15 Q. Who would have been on the Clinical Research Team at  
 16 the time?  
 17 **A. Dr. Bob Vosskular. And I don't think I remember any**  
 18 **of the other people. Maybe two other people.**  
 19 Q. Fair enough.  
 20 Is it true that there is evidence that a  
 21 prewarmed patient can maintain their core temperature  
 22 above 36 for 3 hours?  
 23 **A. I suspect that -- I mean, I think there's probably a**  
 24 **study that shows that, yes.**  
 25 Q. And if you would, just to refresh your recollection,

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1 on your trial testimony on page 160. Down on line 17,  
 2 the question is: "Now, in fact, as early as 2005,  
 3 wouldn't it be fair to state that you felt that you  
 4 could pre-warm a patient and that would be effective  
 5 for up to three hours?"  
 6 And your response: "There was some evidence  
 7 that" the "patients who had been prewarmed could  
 8 maintain their core temperatures above 36 for that  
 9 length of time, yes."  
 10 Do you agree with that statement, sir?  
 11 **A. Yes.**  
 12 Q. And do you stand by your testimony from that?  
 13 **A. I do.**  
 14 Q. And you're not aware of any new evidence that would  
 15 refute that, correct?  
 16 **A. No. And, again, I said there was "some evidence that**  
 17 **some patients," again.**  
 18 Q. Sure.  
 19 **A. Not all.**  
 20 Q. You know that there is much stronger evidence that  
 21 patients will stay warm for two hours if they're  
 22 prewarmed, correct?  
 23 MR. GORDON: Object to the form of the  
 24 question.  
 25 **A. I hadn't -- I hadn't considered that outcome before,**

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1 **but it's probably true.**  
 2 BY MR. FARRAR:  
 3 Q. You have been a proponent of prewarming for years,  
 4 correct?  
 5 **A. Yes.**  
 6 Q. There are some real safety advantages to prewarming  
 7 over intraoperative warming. Would you agree with  
 8 that?  
 9 MR. GORDON: Object to the form of the  
 10 question.  
 11 **A. Well, there's -- I think there may be some safety, but**  
 12 **basically it's more combining preoperative warming**  
 13 **with intraoperative warming is a very effective**  
 14 **strategy for maintaining normothermia.**  
 15 BY MR. FARRAR:  
 16 Q. If you -- if the surgery is relatively short, like an  
 17 hour- to two-hour time frame, prewarming will keep the  
 18 patient warm for that length of time, correct?  
 19 **A. Probably not for two hours.**  
 20 Q. You have submitted patent applications for air-free  
 21 warming, correct?  
 22 **A. Yes.**  
 23 Q. And that is -- as you said, can be used to keep --  
 24 used in a sterile field, right?  
 25 **A. Again, I haven't looked at those patent applications**

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1 **for quite some time, so I don't remember what the**  
 2 **introductions said.**  
 3 Q. Would you agree with me that a knee or hip replacement  
 4 surgery is a low complication -- has low complication  
 5 rates?  
 6 **A. Yes, very low.**  
 7 MR. LUCAS: Object to the form.  
 8 BY MR. FARRAR:  
 9 Q. Would you agree for surgeries with very low  
 10 complication rates the evidence for benefit of  
 11 forced-air warming is less clear and exceedingly  
 12 difficult to prove?  
 13 **A. Yes, I would say that's true.**  
 14 Q. How would you define "passive warming"?  
 15 **A. Actually, I'm not sure, but I'm sure it's**  
 16 **context-related.**  
 17 Q. Sure. I'll give you a PowerPoint.  
 18 (Exhibit 8 was marked for identification.)  
 19 Mr. Van Duren, I'm only going to ask you about  
 20 one chart on this. This is a PowerPoint that looks --  
 21 oh, you can tell me -- it looks like you created in  
 22 2016?  
 23 MR. GORDON: Is this 8?  
 24 MR. FARRAR: It is 8. Oh, I'm sorry.  
 25 Yeah, it's 8.

<p>Page 82</p> <p>1 Do you mind putting that on there for me? Here,                  2 I'll do it. Thank you.                  3 BY MR. FARRAR:                  4 Q. Do you remember this PowerPoint?                  5 <b>A. I -- no, I don't remember it.</b>                  6 Q. There's a chart on page 20, and the 20 is really small                  7 down at the bottom (indicating).                  8 <b>A. Page 20?</b>                  9 Q. Yes, sir. The Bates number on it -- on the chart ends                  10 in 687, if that's helpful.                  11 <b>A. Okay.</b>                  12 Q. All right. This is entitled "How effective is                  13 intraoperative warming." It's clearly from some                  14 published literature, correct?                  15 <b>A. It looks like a chart taken from a paper, yes.</b>                  16 Q. On the passive warming on this, do you know what that                  17 refers to in this particular article?                  18 <b>A. I don't recall what "passive warming" refers to in                  19 this article.</b>                  20 Q. Passive warming is sometimes just cotton blankets,                  21 correct?                  22 <b>A. Well, again, this chart was taken from a paper. I                  23 would have to see the paper to understand what the                  24 context is for defining passive warming.</b>                  25 Q. Sure.</p>	<p>Page 84</p> <p>1 it's warm cotton blankets that are passive, that could                  2 be a passive form of warming?                  3 <b>A. Yes.</b>                  4 Q. Okay. Understood.                  5 And those are warmed like in basically kind of an                  6 oven-type thing, right?                  7 <b>A. In all cases that I'm aware of, yes.</b>                  8 Q. Okay. What I wanted to look at was how effective is                  9 intraoperative warming, and you can see down at the                  10 bottom there's a time stamp, right?                  11 <b>A. Yes.</b>                  12 Q. Would you agree with me that at two hours both active                  13 and passive warming according to this study keep                  14 patients over 36 degrees?                  15 <b>A. Well, the core temperature did not go below                  16 36 degrees, correct.</b>                  17 Q. Sure. Even at two and a half hours, the effectiveness                  18 of active and passive warming are within the standard                  19 deviation of each other, correct?                  20 <b>A. I'm sorry. Run that by me one more?</b>                  21 Q. Yes, sir. At 150 minutes or two and a half hours, the                  22 active and passive warming are within the standard                  23 deviation of each other, correct?                  24 <b>A. Yes, as defined by these authors.</b>                  25 Q. Okay. What other types of passive warming are you</p>
<p>Page 83</p> <p>1 <b>A. I did not define that.</b>                  2 Q. And I -- and I don't mean to say that's what this is.                  3 I'm just saying, a form of passive warming is cotton                  4 blankets, correct?                  5 MR. MCGREVEY: Hello?                  6 MR. FARRAR: Yeah?                  7 MR. MCGREVEY: My screen froze.                  8 MR. FARRAR: Oh.                  9 MR. MCGREVEY: It's back.                  10 MR. FARRAR: You're back. Okay.                  11 BY MR. FARRAR:                  12 Q. Let me reask you the question.                  13 <b>A. Okay.</b>                  14 Q. Regardless of this paper, a form of passive warming is                  15 cotton blankets, correct?                  16 <b>A. I wouldn't consider that a form of passive warming.</b>                  17 Q. Let me ask you then a better question. What are some                  18 of the forms of passive warming?                  19 <b>A. Again, context-specific, it depends on the author who                  20 writes "passive warming"; but I suspect that warm                  21 cotton blankets could be a form of passive warming.</b>                  22 Q. Okay. I thought that's what I asked you. Was it the                  23 "warm" that I didn't include? I'm --                  24 <b>A. I think you just said "cotton blankets."</b>                  25 Q. Okay. I'm not trying to get into semantics. So if</p>	<p>Page 85</p> <p>1 aware of other than warm cotton blankets?                  2 <b>A. None -- none that I can think of.</b>                  3 Q. I know I asked you this, and I apologize, I don't mean                  4 to be repetitive. Do you remember the context of this                  5 PowerPoint, why it was created or who, if anybody, you                  6 gave it to?                  7 <b>A. I think there was a -- on page 2 is a list of what the                  8 goals of the presentation are.</b>                  9 Q. Yes, sir. One of the goals was, using your words, "To                  10 convince you. The company that figures out prewarming                  11 will win in the marketplace," correct?                  12 <b>A. Yes.</b>                  13 Q. You knew in 2016 that prewarming for certain type of                  14 applications like orthopedic surgery was a better                  15 option than intraoperative warming, right?                  16 MR. GORDON: Object to the form of the                  17 question.                  18 <b>A. I felt that prewarming would be a lot more attractive                  19 to orthopedic surgeons who were concerned about                  20 potential for particulate, increased particulates.</b>                  21 BY MR. FARRAR:                  22 Q. You knew it was effective, correct?                  23 MR. GORDON: Object to the form of the                  24 question.                  25 <b>A. I knew that prewarming was effective?</b></p>

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1 BY MR. FARRAR:  
 2 Q. Yes, sir. Yes, sir. I'm sorry.  
 3 **A. Yes, prewarming is effective.**  
 4 Q. Would you agree with me that periprosthetic joint  
 5 infections are a significant issue?  
 6 MR. GORDON: Object to the form of the  
 7 question.  
 8 **A. I mean, you'd have to -- what do you mean by**  
 9 **"significant"?**  
 10 BY MR. FARRAR:  
 11 Q. They can cause significant damage to folks.  
 12 MR. GORDON: Same objection.  
 13 **A. Compared to?**  
 14 BY MR. FARRAR:  
 15 Q. Not getting them?  
 16 **A. Oh, certainly.**  
 17 Q. And I didn't mean to be flip with that, but I'm  
 18 saying, some folks may hear the word "infection" and  
 19 think it's not necessarily a serious issue. A deep  
 20 joint or periprosthetic joint infection is a pretty  
 21 significant issue, correct?  
 22 **A. Yes. In that context, yes.**  
 23 Q. You wrote in 2012 that hospital infections, including  
 24 SSIs, so more broad, are the fourth-largest killer in  
 25 the U.S., claiming more U.S. lives than AIDS, breast

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1 cancer, and traffic accidents combined.  
 2 **A. I'd have to see the document --**  
 3 Q. Yeah. Sure.  
 4 **A. -- just to make sure that I did write that.**  
 5 **(Exhibit 9 was marked for identification.)**  
 6 Q. Mr. Van Duren, I think -- I'm sorry, but I think the  
 7 staple broke, so it may be a little bit loose.  
 8 **A. Okay.**  
 9 Q. But that's Exhibit 9.  
 10 **A. I'll keep it together.**  
 11 Q. Thank you.  
 12 For the -- for the record, the Bates number is  
 13 3MBH00109231, and I'm looking at the -- if you look at  
 14 the Bates number, it's 254, to sort of orient you  
 15 where I was reading from.  
 16 **A. Oh, I'm sorry.**  
 17 Q. 254. It ends in 254, yes, sir.  
 18 **A. I'm not -- oh, I see the Bates number over in the --**  
 19 **okay. I'm on the page.**  
 20 Q. Sure. And I appreciate that you may not know if  
 21 that's still accurate or not, but when you wrote that  
 22 in 2012, that was an accurate statement, correct?  
 23 **A. I'm not sure that I wrote this. This actually was a**  
 24 **presentation that was given by Dr. Hansen and I.**  
 25 Q. Okay.

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1 **A. So he may have written that part.**  
 2 Q. Sure.  
 3 Do you remember where this presentation was  
 4 given?  
 5 **A. In -- I'm sorry, I don't recall where this was given.**  
 6 Q. Do you know -- and that's okay as to the where, but  
 7 the context, was it given to outside folks, internal  
 8 folks at 3M, or do you remember?  
 9 **A. Again, sorry, I don't recall. I don't recall.**  
 10 Q. Fair enough.  
 11 Well, let me just ask you this. I mean, again,  
 12 kind of talking about infections, they're serious  
 13 issues, correct?  
 14 **A. Yes.**  
 15 Q. And we had the cause of death, but the next thing on  
 16 there was that "SSIs may result in 1 to 10 billion in  
 17 direct and indirect medical costs each year." There's  
 18 a cite to that.  
 19 Do you see that?  
 20 **A. I'm sorry. What page or what Bates?**  
 21 Q. Same page, I'm sorry, 254.  
 22 **A. Oh.**  
 23 Q. It was just the point right below it.  
 24 **A. I do see that.**  
 25 Q. You have no reason to doubt that that was accurate

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1 information that was given in this presentation,  
 2 correct?  
 3 **A. 1 to 10 billion dollars is a large range.**  
 4 Q. Sure. Well, there's a citation to it from an article  
 5 you can see.  
 6 **A. So some -- some author reported that amount, yes,**  
 7 **apparently.**  
 8 Q. Mr. Van Duren, if you go back to the -- on that same  
 9 document, sort of towards the -- well, towards the  
 10 middle. The Bates number ends in 276.  
 11 **A. Yes.**  
 12 Q. And the first point there is, it says, "There is no  
 13 published evidence that indicates forced air warming  
 14 increases microbial contamination when in use in an  
 15 OR."  
 16 Do you see that? Do you see that?  
 17 **A. I do see that.**  
 18 Q. Would you agree with me that that is no longer an  
 19 accurate statement?  
 20 **A. No, I wouldn't agree with that.**  
 21 Q. Does the McGovern article indicate that?  
 22 **A. Well, it could be interpreted for that, but even --**  
 23 **even they are not -- even the McGovern article doesn't**  
 24 **assert that forced-air warming increases wound**  
 25 **infection rates in patient populations.**

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1 Q. Didn't it determine that there was a 3.8 fold increase  
 2 in infection rates with folks who use the Bair Hugger  
 3 over --  
 4 **A. They --**  
 5 Q. -- HotDog?  
 6 **A. They observed that, yes, in a before-and-after study.**  
 7 Q. Which is what epidemiology studies are?  
 8 **A. Many of them, yes.**  
 9 Q. And epidemiology studies never actually have a  
 10 conclusion on causation, right? It's an association,  
 11 right?  
 12 **A. I believe that's correct, yes.**  
 13 Q. Have you -- you said you read Dr. Elghobashi's paper,  
 14 correct?  
 15 **A. Some time ago.**  
 16 Q. Would Dr. -- and if you don't know, that's fine, but  
 17 would you -- if you do know, would you agree that  
 18 Dr. Elghobashi's paper shows that this is no longer a  
 19 true statement?  
 20 **A. As I recall, Elghobashi's paper is a computational**  
 21 **fluid dynamics paper.**  
 22 Q. Yes, sir.  
 23 **A. So I'm not sure that the -- I'm not -- again, as I**  
 24 **recall, Elghobashi is a particulate measurement paper.**  
 25 **It has nothing to do with microbial contamination to**

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1 **my recollection.**  
 2 Q. We talked a little bit earlier that bacteria ride on  
 3 particulates, correct?  
 4 **A. It depends on the size.**  
 5 Q. Sure. So if there's more particulates of at least  
 6 sufficient size, there is more bacteria in that area,  
 7 correct?  
 8 MR. GORDON: Object to the form of the  
 9 question.  
 10 **A. I mean, that's -- again, the size of the particle**  
 11 **is critical to whether or not it is likely to be**  
 12 **populated with microorganisms.**  
 13 BY MR. FARRAR:  
 14 Q. Do you know what size particles Dr. Elghobashi used?  
 15 **A. That's a computational fluid dynamics paper, so I**  
 16 **think he -- I don't think he used actual particles to**  
 17 **do his study, but I -- again, I'm not -- I'm not**  
 18 **certain about that.**  
 19 Q. You were still in your role working with the Bair  
 20 Hugger when Dr. Elghobashi's paper was published,  
 21 correct?  
 22 **A. I may have been.**  
 23 Q. Do you recall any conversations internally at 3M  
 24 looking at that paper to determine its validity?  
 25 **A. I believe we had conversations about that paper, yes.**

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1 Q. You know that it was peer-reviewed and published,  
 2 correct?  
 3 **A. Yes.**  
 4 Q. You know that the International Consensus actually  
 5 cited it in 2018, correct?  
 6 **A. I didn't know that.**  
 7 Q. Would it surprise you, if you take my word for it?  
 8 **A. It wouldn't surprise me.**  
 9 Q. Okay. What type of conversations do you recall having  
 10 internally at 3M regarding Dr. Elghobashi's paper?  
 11 **A. I'm not sure I recall the topics that were discussed.**  
 12 **I just remember the author's name.**  
 13 Q. Who did you discuss it with, or who was having the  
 14 discussions?  
 15 **A. Again, I don't recall precisely who was involved in**  
 16 **those discussions.**  
 17 Q. Were they meetings that you would have in conference  
 18 rooms, or was this written communications? Both?  
 19 **A. I'm -- I'm certain we had discussions about it. I**  
 20 **don't recall where they occurred and with whom I had**  
 21 **them.**  
 22 Q. When you had discussions, or I guess still do, but  
 23 more specifically when you were working on the Bair  
 24 Hugger, when you had discussions were meeting minutes  
 25 kept?

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1 **A. Well, not as a matter of policy, no.**  
 2 Q. Sometimes people may jot down notes, but it wasn't  
 3 like you had somebody there who was specifically  
 4 trying to keep up?  
 5 **A. That's right.**  
 6 Q. Okay. Was there to your knowledge any actions done at  
 7 3M to determine the validity of Dr. Elghobashi's  
 8 paper?  
 9 **A. I'm -- I don't recollect doing anything to determine**  
 10 **whether his conclusions were valid.**  
 11 Q. You understand that that paper raises concerns about  
 12 the safety of Bair Hugger used in an operating room,  
 13 correct?  
 14 MR. GORDON: Object to the form of the  
 15 question.  
 16 **A. I'm sorry. Would you repeat that question?**  
 17 BY MR. FARRAR:  
 18 Q. Sure. I mean, you fundamentally understand that that  
 19 paper raises concerns about the safety of the Bair  
 20 Hugger, right?  
 21 MR. GORDON: Same objections.  
 22 **A. I'm not really sure if it does.**  
 23 BY MR. FARRAR:  
 24 Q. Let's -- and I don't want to dig deep into it, but  
 25 just look at the conclusions.



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1 **A. Okay.**  
 2 **(Exhibit 10 was marked for identification.)**  
 3 Q. So just to sort of orient you to one line, if  
 4 there's -- under "Summary and Conclusion" there's four  
 5 points, and then there's a --  
 6 **A. Is that in the back?**  
 7 Q. It's not the very end because there's some graphs and  
 8 things, but kind of close. Page 18 of 24, if you see  
 9 it up at the top.  
 10 **A. Okay. Yes.**  
 11 MR. GORDON: Is this the final published  
 12 version?  
 13 MR. FARRAR: Yes, sir.  
 14 MR. GORDON: Are there any amendments to  
 15 it or --  
 16 MR. FARRAR: Corey, I don't know.  
 17 MR. GORDON: The reason I ask is the  
 18 conflicts of interest is not that I recall.  
 19 MS. ZIMMERMAN: The requested conflicts  
 20 update that you guys got?  
 21 BY MR. FARRAR:  
 22 Q. Do you see where, the first paragraph after Number 4,  
 23 it says, "Starting with the squames"?  
 24 **A. Yes.**  
 25 Q. It says, "Starting with the squames on the floor, it

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1 **A. Well, I think that's more than a semantic difference.**  
 2 Q. Fair point.  
 3 **A. I mean, we're talking about this is a -- this is a**  
 4 **conclusion drawn from a mathematical model that**  
 5 **Dr. Elghobashi constructed.**  
 6 Q. You understand 3M has used computational fluid  
 7 dynamics to test the Bair Hugger.  
 8 **A. Of course.**  
 9 Q. Okay. So it's not that his methodology or  
 10 computational fluid dynamics is flawed for this  
 11 experiment, correct?  
 12 **A. Again, well outside my area of expertise, and there**  
 13 **are many conditions that, again, I wouldn't be able to**  
 14 **comment on. So I don't know how relevant the model is**  
 15 **to the question.**  
 16 Q. You know 3M internally did computational fluid  
 17 dynamics on the Bair Hugger, correct?  
 18 **A. I'm certain of that, yes.**  
 19 Q. Do you know who did it?  
 20 **A. I -- I -- it may have been John Stark.**  
 21 Q. Anybody else you can think of?  
 22 **A. No one else that I can think of.**  
 23 Q. Do you know what the results were?  
 24 **A. I do not.**  
 25 Q. Did you -- or are you aware whether anybody at 3M did

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1 was shown that the hot air from the blower and the  
 2 resultant thermal plumes are capable of lifting the  
 3 particles and transporting them to the side tables,  
 4 above the OT, and the surgical site."  
 5 Do you see that?  
 6 **A. I do see that.**  
 7 Q. You understand -- and I understand there's -- you may  
 8 quibble a little bit, but you understand that that is  
 9 a potential concern for the safety of patients using  
 10 the Bair Hugger, correct?  
 11 MR. GORDON: Object to the form of the  
 12 question.  
 13 **A. So this is a computational fluid dynamics paper.**  
 14 BY MR. FARRAR:  
 15 Q. Sure.  
 16 **A. This is not a clinical trial. So, first of all, I**  
 17 **probably wouldn't have -- I would have had some other**  
 18 **experts look at this. This is well outside my area of**  
 19 **expertise.**  
 20 **So this is a model that Dr. Elghobashi has used**  
 21 **to make these determinations. This is not a clinical**  
 22 **trial.**  
 23 Q. Sure. And I understand that, and that's not quite my  
 24 question. I'm not trying to get into semantics with  
 25 you too much, but you understand that --

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1 any type of criticism, summary, or review of  
 2 Dr. Elghobashi's paper?  
 3 **A. I'm not aware of it.**  
 4 Q. Is it something that when you received, you felt would  
 5 warrant some further investigation? I believe it was  
 6 published at the end of 2017.  
 7 MS. ZIMMERMAN: Early 2018.  
 8 BY MR. FARRAR:  
 9 Q. Sorry. Early 2018.  
 10 **A. Again, I don't recall alerting anyone about the**  
 11 **existence of this paper or any, you know --**  
 12 Q. Is there any reason that you didn't find it  
 13 particularly relevant to your work?  
 14 MR. GORDON: Object to the form of the  
 15 question.  
 16 **A. Well, at this point I think there was clinical**  
 17 **evidence that particulate counts were not different**  
 18 **between conductive and convective warming systems, nor**  
 19 **were there any suggestions that infection rates**  
 20 **differed.**  
 21 BY MR. FARRAR:  
 22 Q. I'm sorry. I just want to make sure I understood  
 23 exactly what you said.  
 24 Did you say there was clinical evidence that  
 25 there was no increase in particulate counts with

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1       conductive versus convective?

2       **A. Yes.**

3       Q. What evidence -- what clinical evidence suggests that?

4       **A. There's a paper by Oliver Kimberger. I think it's**

5       **published by Oguz, is the first author of that paper,**

6       **where they showed similar levels of contamination on**

7       **various parts of the operating room.**

8       Q. Anything other than Oguz?

9       **A. Oh. Not that I recall at this time.**

10      Q. You know that there was clinical evidence that showed

11      there was an increase in particles with forced-air

12      warming over conductive, correct?

13      **A. I'm sorry. Would you repeat that again?**

14      Q. Yeah. You're aware that there is also clinical

15      evidence to indicate that there is an increase in

16      particulate count with forced-air warming versus

17      conductive, correct?

18      **A. Sorry. Are you referring to the studies that were**

19      **conducted in the Netherlands?**

20      Q. By McGovern?

21      **A. Oh, by McGovern.**

22             MR. GORDON: Object to the form of the

23      question.

24      **A. I'm aware of the McGovern study, yes.**

25      BY MR. FARRAR:

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1       Q. Okay. And you would agree with me that that is

2       clinical evidence that there is an increase in

3       particulates when forced-air -- forced-air warming is

4       used over conductive warming, correct?

5             MR. GORDON: Are you talking about the

6       McGovern 2011 paper with Reed or some other McGovern

7       paper?

8             MR. FARRAR: I'm asking him.

9       **A. I think I'm more familiar with the 2000 -- the later**

10      **McGovern paper where they looked at infection rates,**

11      **and there was a number of things that they did in that**

12      **study that were both particulate and infection rate**

13      **counting.**

14      BY MR. FARRAR:

15      Q. There are multiple studies that looked at particulate

16      levels, correct?

17      **A. Yes.**

18      Q. And we agreed that all of them -- to your knowledge,

19      all the ones that you're aware of show some amount of

20      increased rate of particulates, correct?

21      **A. Well, I don't recall every -- every single one of**

22      **them, but -- so I can't confirm that they all show**

23      **that, no.**

24      Q. McGovern looked at actual infection rates, correct?

25      **A. They did.**

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1       Q. And it showed an increase in infection rates of

2       3.8 percent with the Bair Hugger versus conductive

3       warming, correct?

4             MR. GORDON: Object to the form of the

5       question.

6       BY MR. FARRAR:

7       Q. 3.8 fold.

8       **A. So that was a conclusion they drew from their data,**

9       **yes.**

10      Q. So that is a 380 percent increased risk. That's what

11      3.8 fold means, correct?

12      **A. Well, 3.8 times, yes.**

13      Q. Okay.

14      **A. And I should just point out that as I recall the**

15      **McGovern paper has some significant limitations with**

16      **respect to patient populations and other factors that**

17      **occurred after the introduction of their conductive**

18      **warming system.**

19      Q. Is there any other study on actual people that shows

20      McGovern is not accurate, measuring actual infection

21      rates?

22      **A. There's a -- well, are you talking about comparing**

23      **conductive to convective warming?**

24      Q. I am. I am. Thanks for the clarification.

25      **A. I'm not currently aware of any or I can't recollect.**

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1       Q. Have you ever read the deposition of the authors of

2       the McGovern article?

3       **A. I don't recall doing it, don't remember.**

4       Q. Okay. Are you aware that they all stand by their work

5       on that paper?

6             MR. GORDON: Object to the form of the

7       question, misstates the -- mischaracterizes the

8       evidence, assumes facts not in evidence.

9       **A. I don't know that.**

10      BY MR. FARRAR:

11      Q. Would you agree -- would you agree that 3M never

12      really evaluated the risks associated with use of Bair

13      Hugger in total knee or total hip surgeries?

14      **A. No, I would not agree with that.**

15      Q. Would you turn in your 30(b)(6) deposition, please?

16      It's the --

17      **A. Is it this one?**

18      Q. Dated March 7th on the front top left page.

19      **A. March 7th. Yep.**

20             MR. GORDON: What page?

21             MR. FARRAR: 304, please.

22      BY MR. FARRAR:

23      Q. I'm looking at line 6. The question --

24      **A. On 304?**

25      Q. On 304, yes, sir.

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1 The question is: "All right. And you'd agree  
 2 that 3M" -- excuse me -- "you'd agree that 3M never  
 3 really evaluated the risks associated with use of  
 4 Bair Hugger in total knee or total hip surgeries;  
 5 correct?"  
 6 And your answer is: "Not specifically in that  
 7 type of surgery."  
 8 That's what you testified to in 2017, correct?  
 9 **A. Yes, I did say that.**  
 10 Q. That was truthful, honest information when you gave  
 11 that testimony, correct?  
 12 **A. Yes.**  
 13 Q. You understand when you took -- when you gave that  
 14 deposition you weren't actually acting as Al Van  
 15 Duren, you were speaking for the company?  
 16 **A. Yes, I am.**  
 17 Q. Are you aware of something that has happened since  
 18 then that would make that answer no longer accurate?  
 19 **A. There was a study conducted at the Cleveland Clinic, I**  
 20 **don't remember what year, it may have been 2017, I**  
 21 **don't recall the year, by Curtis or Gannon that**  
 22 **compared joint infection rates between two types of**  
 23 **convective warming systems.**  
 24 Q. What were the two types? Do you know?  
 25 **A. One was Bair Hugger. I believe the other one was**

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1 **Stryker.**  
 2 Q. Do you remember the results?  
 3 **A. There was no difference in infection -- deep joint**  
 4 **infection rates.**  
 5 Q. Was 3M a sponsor of that article or study?  
 6 **A. They sponsored the study, yes.**  
 7 THE WITNESS: Could we break for --  
 8 MR. FARRAR: Yeah.  
 9 THE WITNESS: -- the bathroom?  
 10 MR. FARRAR: Sure.  
 11 THE VIDEOGRAPHER: We're off the record.  
 12 (From 11:41 a.m. to 11:57 a.m. a recess was taken.)  
 13 THE VIDEOGRAPHER: We're on the record.  
 14 BY MR. FARRAR:  
 15 Q. Mr. Van Duren, I want to ask you a slightly different  
 16 question than what we ended with.  
 17 Would you agree with this: Neither Arizant nor  
 18 3M has ever evaluated the risks associated with the  
 19 use of Bair Hugger versus conductive heating in total  
 20 knee or total hip surgeries?  
 21 MR. GORDON: Object to the form of the  
 22 question.  
 23 **A. I mean, we have certainly looked at the clinical**  
 24 **evidence regarding periprosthetic joint infections**  
 25 **occurring when conductive or convective warming is**

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1 **used.**  
 2 BY MR. FARRAR:  
 3 Q. Let me -- let me tell you where I'm getting the  
 4 question. If we look back to 304 in your 30(b)(6)  
 5 deposition.  
 6 **A. From March 7th?**  
 7 Q. Yes, sir.  
 8 **A. Yeah.**  
 9 Q. This is the question we just sort of ended with on  
 10 page 304, line 6. And the question was: "All right.  
 11 And you'd agree that 3M never really evaluated the  
 12 risks associated with use of Bair Hugger in total knee  
 13 or total hip surgeries; correct?"  
 14 And your answer was: No. "Not -- not  
 15 specifically in that type of surgery."  
 16 And then you told me that since then there is  
 17 something from the Cleveland Clinic with Gannon and  
 18 Curtis; is that right?  
 19 **A. I believe those are the authors, yes.**  
 20 Q. That evaluated two different types of forced-air  
 21 warming, correct?  
 22 **A. That's correct.**  
 23 Q. So the question is: Have you ever evaluated the risks  
 24 associated with use of Bair Hugger versus conductive  
 25 warming in total knee or total hip surgeries? That

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1 would be an accurate statement, correct?  
 2 **A. That would be -- that's accurate.**  
 3 Q. Okay. You understand that the allegations in -- I  
 4 guess in the case are that there's contamination of  
 5 the sterile field on two different mechanisms. Do you  
 6 sort of fundamentally understand that? And I'll  
 7 explain it. Both by disruption of the laminar flow  
 8 and also microbes being in the Bair Hugger actually  
 9 blown out.  
 10 You understand those are sort of the two  
 11 allegations. I'm not asking you to agree with them,  
 12 but you understand that's the allegations of how the  
 13 Bair Hugger increases the risk of infections?  
 14 **A. I understand that those are the allegations.**  
 15 Q. You're aware that both of those type of allegations,  
 16 or not allegations, at least questions, have been  
 17 coming into Arizant, Augustine Medical, and 3M for  
 18 decades really, right?  
 19 MR. GORDON: Object to the form of the  
 20 question.  
 21 **A. I mean, I don't know if those questions have been**  
 22 **coming in to -- to Augustine, Arizant, 3M.**  
 23 BY MR. FARRAR:  
 24 Q. If you look at -- I think it's Exhibit 4. It's this  
 25 one that starts with "Wow! Crazy Town." We talked a

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1 little bit about it, but didn't really sort of delve  
 2 in. I wanted to get a little bit more into specifics.  
 3 In that fourth paragraph, the one that's sort  
 4 of at issue, I guess, you say, "Dr. Augustine and  
 5 others made it clear to me when I started here in 1994  
 6 that some clinicians had concerns about particulates  
 7 as causes of wound infection."  
 8 Do you see that?  
 9 **A. Yes.**  
 10 Q. And that was true when you wrote it, true today,  
 11 correct?  
 12 **A. I believe it was in 1994, yes.**  
 13 Q. Sure.  
 14 Do you know who the "and others" refers to? Do  
 15 you remember anybody else?  
 16 **A. I mean, I don't know to whom I was referring in that**  
 17 **statement.**  
 18 Q. Okay. And you discuss an air-free heating system that  
 19 you submitted patents for in 1994, 2002, and then  
 20 again in 2011, correct?  
 21 **A. In this document?**  
 22 Q. Yes, sir. You say, just the next sentence, "As a  
 23 result of those conversations, I submitted invention  
 24 disclosures for joule heating devices."  
 25 **A. Yes.**

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1 Q. And I'll just read it all. "December, 1994, May,  
 2 2002, that specifically addressed the advantage of  
 3 using RF heating as an air-free alternative to warming  
 4 patients in a sterile environment."  
 5 Did I read that right?  
 6 **A. Yes.**  
 7 Q. What did you mean by "in a sterile environment"?  
 8 **A. I was probably referring to the area surrounding the**  
 9 **sterile field in a surgical patient.**  
 10 Q. Okay. And RF heating, that's sort of like a microwave  
 11 kind of thing, right?  
 12 **A. Yes.**  
 13 Q. All right. The advantages of using air-free to warm  
 14 patients in a sterile field is there's not the risk of  
 15 contaminating the sterile field, correct?  
 16 **A. I -- well, I didn't say what the advantages were here,**  
 17 **so I'm not really sure precisely what I was referring**  
 18 **to, although it could have been, you know, the**  
 19 **advantages of making it attractive to people who were**  
 20 **concerned about particulates.**  
 21 Q. You don't recall what your advantages were sitting  
 22 here today?  
 23 **A. I do not. I would have to look at those invention**  
 24 **disclosures and patent applications.**  
 25 **(Exhibit 11 was marked for identification.)**

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1 Q. I'm going to hand you what I've marked as Exhibit 11,  
 2 and it's -- you can sort of tell it's an email and  
 3 there's an attachment, and then this is the  
 4 attachment. So it's two documents.  
 5 MR. FARRAR: And, I'm sorry, Corey, I  
 6 somehow don't have an extra copy.  
 7 MR. GORDON: What is this, the Bates?  
 8 MR. FARRAR: Yeah. The Bates number is  
 9 3MBH02160847, the first page.  
 10 MR. GORDON: Is this two separate things?  
 11 THE WITNESS: It's an email with the  
 12 attachment.  
 13 MR. FARRAR: It's the email with the  
 14 attachment.  
 15 MR. GORDON: Okay.  
 16 MR. FARRAR: It's just the next page.  
 17 Just for the record, the document goes through  
 18 3MBH02160849 -- 850, actually.  
 19 **A. Oh, sorry.**  
 20 **(Reviewed.) Okay. I've read those.**  
 21 BY MR. FARRAR:  
 22 Q. So this is an email from you to John Rock in December  
 23 of 2011, but you're attaching an invention disclosure  
 24 that was back from December of 1994, correct?  
 25 **A. Yes.**

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1 Q. And that invention disclosure was the RF technology  
 2 that we saw in Exhibit 4, the email from you to Gary  
 3 Hansen, correct? It's down in the fourth paragraph.  
 4 **A. Oh, okay. Let me just --**  
 5 Q. "As a result of those conversations."  
 6 **A. Yes, I believe so.**  
 7 Q. Okay. So if we look at the new patent -- the  
 8 invention disclosure --  
 9 **A. Yeah.**  
 10 Q. -- you talk about some of the advantages of this type  
 11 of technology of heating, of RF heating, correct?  
 12 **A. Yes.**  
 13 Q. And the second advantage you have is "No air is  
 14 required to move the thermal energy from the energy  
 15 producing device to the patient, so it might be  
 16 possible to use the device in a sterile environment."  
 17 I read that correctly, right?  
 18 **A. Yes.**  
 19 Q. At the time, in 1994, the Bair Hugger was not used  
 20 inside the OR, correct?  
 21 **A. I'm not certain about that.**  
 22 Q. Do you know when the -- which model moved the Bair  
 23 Hugger from outside the OR to inside the OR?  
 24 **A. I believe it was the 500 OR unit.**  
 25 Q. Do you remember when the 500 OR was approved for sale

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1 in the United States?  
 2 **A. I don't.**  
 3 Q. You know the 200 was specifically prohibited from  
 4 being used inside the OR, correct?  
 5 **A. Well, its warning -- it had warnings on it not to use**  
 6 **in the operating room. I don't think it was**  
 7 **prohibited by the government, but --**  
 8 Q. Sure.  
 9 **A. Or the FDA. But, yes.**  
 10 Q. Fair point. It was the -- anyway.  
 11 The RF does not use any type of air technology,  
 12 right? There's no air movement.  
 13 **A. Correct.**  
 14 Q. All right. So when you say that there is no air  
 15 required to move the thermal energy from the energy  
 16 producing device to the patient, so it might be  
 17 possible to use the device in a sterile environment,  
 18 what do you mean by that?  
 19 **A. Well, this is back in 1994. I'm not entirely certain**  
 20 **what I meant by that, to be honest.**  
 21 Q. Well, let's look at your email from 2011. You say,  
 22 "I pointed out back then that Joule heating was air  
 23 free and could be used instead of Bair Hugger warming  
 24 in a sterile environment," correct?  
 25 **A. Wait a minute. Is this the right -- just a second.**

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1 **I'm sorry.**  
 2 Q. I don't believe you have the right one, sir.  
 3 **A. Okay.**  
 4 Q. That's it right there. It's the back side of that  
 5 one. In your right hand. Right there.  
 6 **A. Oh, this one. Okay. Got it.**  
 7 **(Reviewed.) Yes.**  
 8 Q. So it's fair to say that you recognize an issue with  
 9 respect to air and contamination of the sterile  
 10 environment in 1994, correct?  
 11 MR. GORDON: Object to the form of the  
 12 question.  
 13 **A. Again, I'm not entirely certain why I wrote could be**  
 14 **used in a sterile environment.**  
 15 BY MR. FARRAR:  
 16 Q. Do you think it's because moving air is a possible  
 17 contamination of the sterile environment?  
 18 MR. GORDON: Object to the form of the  
 19 question.  
 20 **A. Again, I'm not entirely certain why I wrote "sterile**  
 21 **environment" there.**  
 22 BY MR. FARRAR:  
 23 Q. And I understand you're not entirely certain, but I'm  
 24 asking you, sir: Does it stand likely, more likely  
 25 than not, stand to reason, if you will, the reason you

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1 said that is you knew that moving air could possibly  
 2 contaminate the sterile field?  
 3 MR. GORDON: Object to the form of the  
 4 question.  
 5 **A. I think it's more likely that I was thinking that we**  
 6 **had customers who objected to that and that this was a**  
 7 **way to satisfy their objections to using Bair Hugger**  
 8 **technology.**  
 9 BY MR. FARRAR:  
 10 Q. Pathogens, including bacteria, can travel through the  
 11 air, correct?  
 12 **A. They can.**  
 13 Q. That wasn't controversial even back in 1994. That was  
 14 things that we knew, correct, the medical community?  
 15 MR. GORDON: Object to the form of the  
 16 question.  
 17 **A. It's known that viable microorganisms can travel**  
 18 **through the air.**  
 19 BY MR. FARRAR:  
 20 Q. Organisms that can cause infections if they get inside  
 21 the human body, correct?  
 22 **A. They can.**  
 23 Q. Arizant knew that, Dr. Augustine knew that, Augustine  
 24 Medical knew that, correct?  
 25 MR. GORDON: Object to the form of the

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1 question.  
 2 **A. I don't know what Dr. Augustine knows.**  
 3 BY MR. FARRAR:  
 4 Q. Folks at Augustine Medical knew that.  
 5 **A. Again, I don't know what they know.**  
 6 Q. Back in 1994 surgeons used masks and PPE and things  
 7 like that just like we do now, correct?  
 8 **A. Yes.**  
 9 Q. Because we knew that bacteria can move through the air  
 10 and cause infections, correct?  
 11 **A. That's the theory.**  
 12 Q. Well, it's not a theory. It's just proven science.  
 13 Bacteria through the air can cause infections,  
 14 correct?  
 15 **A. I don't --**  
 16 MR. GORDON: Object to the form of the  
 17 question.  
 18 **A. To my knowledge, operating room masks have never been**  
 19 **shown to be effective.**  
 20 BY MR. FARRAR:  
 21 Q. Fair. And I apologize if my question was sloppy.  
 22 Bacteria moving through the air can cause  
 23 infections. That is a known fact, correct?  
 24 **A. Well, just moving through the air, no, they can't**  
 25 **cause infections. They have to --**

1 BY MR. FARRAR:  
2 Q. Fair point.  
3 Bacteria moving through the air that ends up in  
4 the human body can cause infections, correct?  
5 **A. It can.**  
6 Q. And that piece of medical knowledge was known in 1994,  
7 correct?  
8 **A. Yes.**  
9 Q. One of the things that you testified to in other  
10 depositions and we sort of hit on a little bit here  
11 today is, is there a correlation between the number of  
12 bacteria and the probability or possibility of a  
13 surgical site infection, correct? You remember that  
14 discussion, right?  
15 **A. Yes.**  
16 Q. Do you doubt that that is actually a fact?  
17 **A. I'm not -- I'm not convinced today that there is a**  
18 **fixed relationship between the number of bacteria in a**  
19 **surgical site and the likelihood or risk of developing**  
20 **a postoperative infection.**  
21 Q. You know that the International Consensus disagrees  
22 with that, correct?  
23 MR. GORDON: Object to the form of the  
24 question.  
25 **A. I don't know specifically --**

1 BY MR. FARRAR:  
2 Q. Sure.  
3 **A. -- that they disagree with that.**  
4 **(Exhibit 12 was marked for identification.)**  
5 Q. I'll hand you what I've marked as Exhibit 12.  
6 **A. Was there a part that you wanted me to read --**  
7 Q. Yeah, actually --  
8 **A. -- in specific -- specifically?**  
9 Q. I do appreciate that, because I don't -- we don't have  
10 to see it all.  
11 Let me ask you just generally. Have you -- do  
12 you keep up with the International Consensus and their  
13 findings?  
14 **A. No.**  
15 Q. Okay. Have you ever? I asked you a bad question  
16 because I know you're in a different role now.  
17 **A. I've read their -- I've read their findings, yes.**  
18 **I've read their paper.**  
19 Q. So you -- when this came out in -- this is the 2014,  
20 you can see at the top, consensus. This is something  
21 that you would have taken a look at, correct?  
22 **A. Probably.**  
23 Q. As part of your job duties at 3M?  
24 **A. Yes.**  
25 Q. So Question Number 1 is the one I'm interested --

1 actually, 1 and 2. 1 is: "Do numbers of bacteria  
2 arriving in the surgical wound correlate directly with  
3 the probability of surgical site infection?"  
4 The Consensus is: "We recognize that the  
5 probability of SSI correlates directly with the  
6 quantity of bacteria that reach the wound.  
7 Accordingly we support strategies to lower particulate  
8 and bacterial counts at surgical wounds."  
9 Did I read that correctly?  
10 **A. Yes.**  
11 Q. The delegate vote is 97 percent agree, correct?  
12 **A. Yes.**  
13 Q. You disagree with that statement?  
14 **A. So what they're -- what they recognize is that there's**  
15 **a -- that the postoperative probability of a surgical**  
16 **site infection correlates in some way with the**  
17 **quantity of bacteria. I mean, it's certainly true**  
18 **that very large amounts of bacteria in a surgical**  
19 **wound most likely will lead to a postoperative**  
20 **infection, but it's multivariate. And, again, this is**  
21 **a consensus document. This isn't a clinical study.**  
22 **This is the opinion of experts in the field.**  
23 Q. Sure. Opinions of experts who are reviewing the  
24 clinical data and research, correct?  
25 **A. Well, I'm not sure that they reviewed it. It's just**

1 **simply a vote. They vote on whether or not they agree**  
2 **with the statements.**  
3 Q. You don't believe that they, in determining what their  
4 vote is going to be, review the medical and clinical  
5 data?  
6 **A. I just don't know if they've done it. I can't --**  
7 Q. I understand that you may not know for sure, but it  
8 stands to reason that if these guys are going to vote  
9 on important issues like keeping patients safe they're  
10 doing the research, if they're the ones being chose to  
11 make these votes, right?  
12 **A. There's no way for me to know that.**  
13 MR. GORDON: Object to the form of the  
14 question.  
15 BY MR. FARRAR:  
16 Q. All right. You won't agree that the people who are  
17 voting, like Dr. Parvizi, for instance -- and, again,  
18 you know, 3M is the platinum sponsor of ICOS, right?  
19 You don't agree that these folks are doing their  
20 homework before they cast these votes?  
21 MR. GORDON: Object to the form of the  
22 question.  
23 **A. There's no way that I can know if they've done their**  
24 **homework.**  
25 BY MR. FARRAR:

1 Q. Okay. And you said -- you said the number of  
 2 bacteria -- you said what they said -- let me try this  
 3 again. If I understand you, that the number of  
 4 bacteria correlates somehow. But that's not what they  
 5 said. It says, "correlates directly with the quantity  
 6 of bacteria that reach the wound," correct?  
 7 **A. That's what they said.**  
 8 Q. Okay. And I want to ask you again because I don't  
 9 think you quite answered the question. Do you  
 10 disagree with this -- their consensus?  
 11 MR. GORDON: Object to the form of the  
 12 question.  
 13 **A. Well, again, this is a qualitative statement. So,  
 14 yes, qualitatively I agree with it. Quantitatively,  
 15 there's no quantitative data here to decide whether  
 16 numbers of bacteria directly correlate with the risk.**  
 17 BY MR. FARRAR:  
 18 Q. When you say "here," do you mean in this ICOS paper?  
 19 **A. In this statement right here, there's no quantitative  
 20 data to make a decision about what this statement  
 21 means.**  
 22 Q. Do you know that there are studies that do  
 23 quantitatively make that connection?  
 24 **A. I mean, I suspect there are, yes.**  
 25 Q. You're familiar with the study from a man named

1 Mr. Darouiche?  
 2 **A. I've -- I may be.  
 3 12 was the last one I have.**  
 4 Q. Thank you, sir.  
 5 (Exhibit 13 was marked for identification.)  
 6 I'm going to hand you this study from 2017 from  
 7 Dr. Darouiche. And take your time to familiarize.  
 8 I'll tell you the point I'm looking at.  
 9 **A. (Reviewed.) Okay.**  
 10 Q. So if you look a couple pages in, sir, there's a --  
 11 I'll just show you the graph down here just to sort of  
 12 orient you, and up above that under "CFU and  
 13 Particulate Densities and Infection."  
 14 Do you see that?  
 15 **A. I'm sorry. Is it Table 1 that we're looking at?**  
 16 Q. No, sir. I'm looking at the -- I'm looking at the  
 17 actual text.  
 18 **A. Oh, the text.**  
 19 Q. Yes, sir.  
 20 **A. On page 4? "CFU and Particulate Densities and  
 21 Infection"?**  
 22 Q. Yes, sir.  
 23 **A. Yes.**  
 24 Q. And I just wanted to look at the first two sentences  
 25 there, and it says, "CFU density" -- and just for the

1 record, "CFU" is colony-forming units, correct?  
 2 **A. Yes.**  
 3 Q. So that is an amount of bacteria that will cause an  
 4 infection. Is that a fair way to define that?  
 5 **A. No. CFU is a statistical -- or is a technique used by  
 6 microbiologists to determine generally that a single  
 7 infectious particle produces an area of growth on a  
 8 plate.**  
 9 Q. Okay. It says, "CFU density at incision sites was  
 10 significantly related to incidence of implant  
 11 infection, but not of incisional infection. Every  
 12 10 colony-forming units per meter cubed increase in  
 13 median CFU density approximately doubled the  
 14 probability of implant infection."  
 15 Do you see that?  
 16 **A. I do.**  
 17 Q. Okay. So this is somebody quantifying the risk that  
 18 for every 10 CFUs you get in a meter cubed, you're  
 19 going to double the chance of an actual implant  
 20 infection. Fair?  
 21 **A. That's what they state there, yes.**  
 22 Q. So this was done in 2000 -- just to make sure I'm  
 23 right, '17, I believe, but -- yeah, so it was  
 24 published in 2017. So you would have still been  
 25 working on the Bair Hugger at this time, right?

1 **A. In 2017 I would have been, yeah.**  
 2 Q. Do you recall receiving this and reviewing it when  
 3 you were working on the Bair Hugger?  
 4 **A. I don't recall this exact paper, no; but that's why  
 5 I'm just -- if I may read this --**  
 6 Q. Sure.  
 7 **A. -- just one more time, make --**  
 8 Q. Sure.  
 9 **A. -- sure I can --**  
 10 Q. Tell me when you're ready.  
 11 **A. (Reviewed.) Okay. I'm -- I probably have reviewed  
 12 this paper.**  
 13 Q. Do you remember if you did a critique or summary of  
 14 it?  
 15 **A. I don't recall.**  
 16 Q. Okay. Are you aware of any studies that 3M has done  
 17 internally to answer the question of, if there are  
 18 more CFUs above a surgical site, does that actually  
 19 increase the risk of a joint infection?  
 20 **A. I'm not aware of any.**  
 21 MR. FARRAR: I'm going to sort of be  
 22 shifting gears a little bit. I think it's probably a  
 23 good time if we want to take a lunch break real quick,  
 24 if that's all right. I know we weren't on real long  
 25 there. Sorry.

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1 THE VIDEOGRAPHER: Okay. We're off the  
 2 record.  
 3 (From 12:22 p.m. to 1:02 p.m. a recess was taken.)  
 4 THE VIDEOGRAPHER: We're back on the  
 5 record.  
 6 BY MR. FARRAR:  
 7 Q. Mr. Van Duren, a couple questions at the beginning I  
 8 didn't ask. Are you being paid anything extra over  
 9 and above your normal salary for testifying here  
 10 today?  
 11 A. No.  
 12 Q. Do you have any plans for retiring in the sort of near  
 13 future?  
 14 A. Probably in a year and a half.  
 15 Q. Okay. Is that sort of in motion or just --  
 16 A. No.  
 17 Q. Gotcha.  
 18 When you retire, will you have stock options at  
 19 3M?  
 20 A. Yes.  
 21 Q. Okay. So it's been part of your compensation is stock  
 22 options through time?  
 23 A. Yes.  
 24 Q. Okay. Are you currently working remotely?  
 25 A. Yes.

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1 Q. Have you been since really the pandemic started?  
 2 A. Yes.  
 3 Q. Okay. At any time at your work at 3M, were you tasked  
 4 with sort of monitoring or keeping up with the  
 5 litigation that was happening regarding the Bair  
 6 Hugger?  
 7 A. No.  
 8 Q. Sure. I mean, I know you've testified, but, I mean,  
 9 outside of --  
 10 A. Yeah, I was wondering how -- to what extent do you  
 11 mean.  
 12 Q. Yeah, just -- and I don't really -- and I don't really  
 13 know how to phrase it other than just sort of  
 14 monitoring it and reporting to folks at 3M, not that  
 15 it --  
 16 A. No, I had no involvement in that.  
 17 Q. Did you ever have any involvement with monitoring the  
 18 activities of Dr. Augustine?  
 19 A. No.  
 20 Q. Okay. Do you keep up with him at all?  
 21 A. No.  
 22 Q. Sort of shifting gears, just so not out of total left  
 23 field.  
 24 Do you agree that there's no study on orthopedic  
 25 joint replacement surgeries that demonstrates

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1 normothermia has any benefits?  
 2 MR. GORDON: Object to the form of the  
 3 question.  
 4 A. I would -- I'm sorry. Could you rephrase it again?  
 5 BY MR. FARRAR:  
 6 Q. Sure.  
 7 A. Or restate it? Sorry.  
 8 Q. Yeah. Do you agree that there is no study on  
 9 orthopedic joint replacement surgeries that  
 10 demonstrates normothermia has any benefits?  
 11 A. I believe there's a study that shows a decrease in  
 12 bleeding in orthopedic surgery from normothermic  
 13 patients.  
 14 Q. Do you know the name of that, by chance?  
 15 A. I'm sorry, I do not.  
 16 Q. That's okay.  
 17 Do you know -- can you give me any details where  
 18 it was conducted or general year, anything like that?  
 19 A. It's old.  
 20 Q. Okay. Older than Kurz, or do you know?  
 21 A. In that era.  
 22 Q. So mid-90s maybe?  
 23 A. Yes.  
 24 Q. Do you know where it's published, by chance?  
 25 A. I'm sorry, I do not.

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1 Q. Would you agree there's no study on orthopedic joint  
 2 replacement surgeries that demonstrates normothermia  
 3 helps prevent infections?  
 4 A. I'm sorry. Restate it.  
 5 Q. Yep. Agree that there's no study on orthopedic joint  
 6 replacement surgeries that demonstrates normothermia  
 7 helps reduce infections?  
 8 A. I believe that's correct.  
 9 Q. Is that study you're talking about Melling?  
 10 A. No.  
 11 Q. If you would look at Exhibit 12, which is the  
 12 International Consensus from 2014.  
 13 A. Yes.  
 14 Q. And the question I'm interested in is Question 14, a  
 15 couple pages in. And the question is: "Does patient  
 16 normothermia have an essential role in preventing  
 17 infectious complications?"  
 18 The Consensus: "We recognize the significance of  
 19 patient normothermia and the data from non-orthopedic  
 20 procedures. We support general recommendations from  
 21 the general surgery literature and identify this as a  
 22 field that requires further research."  
 23 Did I read that correctly?  
 24 A. Yes.  
 25 Q. This is something when it came out in 2014 or '15 you



1 would have been aware of, right?

2 **A. I believe so.**

3 Q. And at that time you had been one of the persons --

4 people at 3M that would be able to do further study on

5 this topic, right, in other words, either commission

6 it or have it done internally?

7 MR. GORDON: Object to the form of the

8 question.

9 **A. So in 2018? What was this? 2014.**

10 BY MR. FARRAR:

11 Q. This came out in 2014, sir.

12 **A. No, I would not have had -- played a role in**

13 **commissioning clinical research.**

14 Q. You were in the clinical department at 3M, correct?

15 **A. No. I was in the infection prevention division.**

16 Q. Okay. You would have -- if you were monitoring this,

17 there's people at 3M you could have gone to and said,

18 "There's a request for further study. Maybe we should

19 look into this," correct?

20 **A. Well, I don't think they requested it. It's not a**

21 **request for further study.**

22 Q. Sure. That's a bad question.

23 You could have said, "There's a consensus of

24 folks that have identified an area that requires

25 further research," correct?

1 **A. And, I'm sorry, what would I have done with that?**

2 Q. Yeah, let me just ask you that question. Did you do

3 anything with that?

4 **A. I think -- no.**

5 Q. Do you know if anybody at 3M took them up on this

6 field that requires further research?

7 **A. Well, as I pointed out before, there were some studies**

8 **commissioned, like the one from Gannon or Curtis at**

9 **the Cleveland Clinic, where HEPA and non-HEPA**

10 **filtration systems were compared in forced-air warming**

11 **systems.**

12 Q. Does that really answer the question if normothermia

13 has an essential role in preventing infectious

14 complications?

15 **A. Well, the consensus doesn't mention infections.**

16 Q. In the question, sir.

17 **A. The question does, but --**

18 Q. Yeah.

19 **A. -- the consensus is that they recognize data from**

20 **nonorthopedic procedures.**

21 Q. Would you agree that the Kurz and Sessler study was

22 the only random controlled trial regarding patient

23 warming?

24 **A. No. There have been a number of randomized clinical**

25 **trials in patient warming.**

1 Q. I'm sorry. Regarding the benefits of normothermia.

2 **A. No.**

3 Q. What else?

4 **A. There have been a number having to do with bleeding,**

5 **length of stay, thermal comfort, postoperative thermal**

6 **comfort, troponin levels, a number of them.**

7 Q. Any of them in orthopedic surgery that you're aware

8 of?

9 **A. Not to my knowledge.**

10 Q. Does 3M still point to the Sessler-Kurz study as

11 evidence that there is a benefit to normothermia in

12 orthopedic surgery?

13 **A. Well, I'm not sure what you mean by "point to."**

14 Q. Reference as a source.

15 **A. In -- in patient -- or in customer-facing brochures**

16 **or --**

17 Q. Well, just as a company. I mean, does 3M to your

18 knowledge and your work there use the Sessler -- the

19 Sessler-Kurz study as evidence that normothermia has a

20 benefit in orthopedic surgeries?

21 **A. Well, I haven't been in that division -- or I haven't**

22 **been in that business for over two years, so I'm not**

23 **sure what they're using currently.**

24 Q. When you left.

25 **A. It was certainly cited in some customer-facing**

1 **literature, yes.**

2 Q. Do you think it is reliable?

3 **A. Yes.**

4 Q. Do you think it's reliable to extrapolate to

5 orthopedic surgery?

6 **A. I'm not an expert in that -- in that area.**

7 Q. Do you know that that study was funded by

8 Dr. Augustine or Augustine Medical?

9 **A. Yes. And I believe that's disclosed in the study as**

10 **well.**

11 Q. That doesn't disqualify the study for 3M, correct?

12 **A. No. I mean -- no.**

13 Q. Okay. Just for that study, the fact that it was

14 funded by Dr. Augustine doesn't change its

15 reliability?

16 **A. No.**

17 Q. We talked -- do you agree there's a difference between

18 a clean surgery and a dirty surgery?

19 **A. Yes.**

20 Q. What's the difference?

21 **A. Well, there are -- there are really, I think, three**

22 **classes of surgery. Clean surgeries are where organ**

23 **spaces are not entered. Then there's clean**

24 **contaminated surgeries where organ spaces are invaded**

25 **during a surgical incision, and then dirty surgeries**

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1 **are where the surgical field is contaminated with**  
 2 **either abdominal contents or organ contents during the**  
 3 **surgery.**  
 4 Q. You're aware that the Kurz-Sessler study was done on  
 5 colorectal surgery?  
 6 **A. Yes.**  
 7 Q. That would be considered a dirty surgery?  
 8 **A. Or clean contaminated, yes.**  
 9 Q. Okay. The study concluded that there was a benefit to  
 10 normothermia in colorectal surgery, which is either  
 11 dirty or clean contaminated?  
 12 **A. Yes.**  
 13 Q. Joint replacement is always a clean surgery, correct?  
 14 **A. Yes.**  
 15 Q. Oftentimes in an ultra-clean environment?  
 16 **A. Yes.**  
 17 Q. The risk of infection is different in a dirty surgery  
 18 versus an ultra-clean surgery. Fair?  
 19 **A. Yes.**  
 20 **(Exhibit 17 was marked for identification.)**  
 21 Q. I want to hand you what I've marked as Exhibit 17.  
 22 You're familiar with the NICE guidelines?  
 23 **A. I have read them.**  
 24 Q. Okay. They are guidelines sort of for best practices  
 25 in the UK. Is that fair?

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1 Q. Do you have any personal understanding as to what it  
 2 means by forced-air warming device being unsuitable?  
 3 **A. Not in this context.**  
 4 Q. Did you personally do any research to determine what  
 5 the NICE folks meant when they said "forced-air  
 6 warming device is unsuitable"?  
 7 **A. Not that I recall.**  
 8 Q. Do you know if that meant in joint replacement  
 9 surgeries?  
 10 **A. Again, it's not clear what's meant by that phrase.**  
 11 Q. Did, to your knowledge, anybody at 3M try to figure  
 12 out what that meant?  
 13 **A. I do not recall.**  
 14 Q. Fair enough.  
 15 So sitting here today, you don't know what it  
 16 means?  
 17 **A. There does not seem to be any context around that**  
 18 **statement to help understand what is meant by it.**  
 19 Q. Mr. Van Duren, I agree there's not any context.  
 20 That's sort of why I'm asking you if somebody at 3M  
 21 tried to put some context on it.  
 22 You don't have any knowledge of that happening?  
 23 **A. I don't.**  
 24 Q. Okay. If you go a couple more pages in, page 13, and  
 25 this section is entitled "Recommendations for

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1 MR. GORDON: What number is this?  
 2 MR. FARRAR: 17.  
 3 **A. A list of recommendations, yes, of practice guideline**  
 4 **recommendations.**  
 5 BY MR. FARRAR:  
 6 Q. And if you look down at the very bottom, it's really  
 7 faint, but it says, "Page 8 of 18," is where I'm  
 8 looking. It sort of starts on 7. There's an  
 9 intraoperative phase, and on the next page there's a  
 10 comment about forced-air warming I wanted to ask you  
 11 about.  
 12 **A. On page 8?**  
 13 Q. Yes, sir.  
 14 **A. Okay.**  
 15 Q. At the top it says, "Consider a resistive heating  
 16 mattress or resistive heating blanket if a forced-air  
 17 warming device is unsuitable."  
 18 Do you see that?  
 19 **A. Yes.**  
 20 Q. Were you aware of this guideline that came out in  
 21 2016?  
 22 **A. I'm certain I read it in 2016.**  
 23 Q. Do you know if anybody at 3M contacted NICE to ask,  
 24 "What does that mean?"  
 25 **A. I'm not aware of that.**

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1 research." Do you see that?  
 2 **A. Yeah.**  
 3 Q. And then down at the end there is, "Forced-air warming  
 4 compared with conductive fabric warming in laminar  
 5 flow theatre." Do you see that?  
 6 **A. Yes.**  
 7 Q. And the next page it says, Why is this important?  
 8 **A. Yes.**  
 9 Q. And you can see "new 2016." So this is a new area of  
 10 study that the NICE folks were recommending in 2016.  
 11 You agree with that?  
 12 **A. That it's new? Yes. It's new in 2016, yes.**  
 13 Q. Okay. And what they -- and I'll let you read it to  
 14 yourself so you will be familiar with it.  
 15 **A. (Reviewed.) Okay.**  
 16 Q. The second sentence in that says, "Research suggests  
 17 that conductive warming devices are less likely to  
 18 cause surgical site infection because the disruption  
 19 to air flow is less than that caused by forced-air  
 20 warming."  
 21 Do you agree that there's research that suggests  
 22 that?  
 23 **A. There is research that suggests that.**  
 24 Q. Would you agree that conductive warming devices don't  
 25 have the same type of disruption to airflow as

Page 134

1 forced-air warming?

2 **A. No, I would not agree.**

3 Q. What would you point to to support your proposition

4 that you do not agree to that?

5 **A. Schlieren photography that we conducted at 3M as well**

6 **as in other places that show that the disruption**

7 **caused by the heated devices is essentially the same**

8 **regardless of the method used to heat the device.**

9 Q. Do you know who did that Schlieren study?

10 **A. No, I don't know who personally was involved in that**

11 **study.**

12 Q. Was it internal done at 3M or external or both?

13 **A. I think both, some internal and some external.**

14 Q. Do you know approximately when?

15 **A. Oh, in about the 2010-2011 time frame.**

16 Q. The work that would have been done internal would be

17 saved in memorandums or test reports or things like

18 this?

19 **A. Test reports.**

20 Q. Okay. And that would be something that should still

21 be at 3M?

22 **A. It should.**

23 Q. Okay. Do you see where it says, "RCTs"? That stands

24 for randomized control trials, correct?

25 **A. Or randomized clinical trial, yes.**

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1 Q. "RCTs should be carried out to compare forced-air

2 warming with conductive warming in laminar flow

3 theatre."

4 Do you see that?

5 **A. Yes.**

6 Q. "The RCTs should be sufficiently powered to show

7 clinically significant differences"?

8 **A. Yes.**

9 Q. And that "Primary outcomes should be surgical site

10 infection and core temperature at the end of surgery,"

11 correct?

12 **A. Yes.**

13 Q. So basically, and let me see if you'd agree with this,

14 what NICE is suggesting is that RCTs be done and

15 determine two things, core temperatures at the end of

16 surgery and infection rates, correct?

17 **A. Yes.**

18 Q. You agree that RCT is sort of the gold standard of

19 clinical testing?

20 **A. Yes.**

21 Q. 3M would have received this particular recommendation

22 from NICE back whenever it was published in 2016,

23 correct?

24 **A. Yes.**

25 Q. Did you set forth or commission an RCT to test these

Page 136

1 theories?

2 **A. I did not.**

3 Q. Did anybody at 3M?

4 **A. Not to my knowledge.**

5 Q. Do you know why not?

6 **A. Well, a number of reasons. Primarily, the number of**

7 **subjects or of participants required in a trial is so**

8 **enormous as to make it logistically impossible to**

9 **conduct, and this is because the adverse event rate in**

10 **joint replacement surgery is so low to begin with.**

11 Q. At one point I saw a document, and I think I've heard

12 testimony, that 3M sells about 50,000 Bair Huggers a

13 day, correct?

14 **A. I don't know how many it is.**

15 Q. Is it your testimony, Mr. Van Duren, that cost was the

16 reason that 3M didn't do the RCT that was recommended

17 by NICE?

18 **A. No, it's not my understanding.**

19 Q. When you say it's too many people, that's a cost

20 issue, right?

21 **A. No. It's a -- it's more of a logistical. I mean,**

22 **cost certainly factors into it, but it's more of a**

23 **logistical hurdle that has to be overcome. When you**

24 **recruit that many subjects into a trial, it has to be**

25 **done in a multicenter configuration. These are very,**

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1 **very difficult and long trials to carry out.**

2 Q. It could be done, correct?

3 **A. Could be done? It could be.**

4 Q. Not cost-prohibitive to 3M to do it. Is that fair?

5 MR. GORDON: Object to the form of the

6 question.

7 **A. Well, I'm not -- I'm not sure what you mean by**

8 **"cost-prohibitive." I mean --**

9 BY MR. FARRAR:

10 Q. Sure. I'm saying, 3M could afford to do the study?

11 MR. GORDON: Object to the form of the

12 question.

13 **A. I don't know how expensive the study would be, so**

14 **I can't answer that question.**

15 BY MR. FARRAR:

16 Q. That would put this issue to bed as to whether or not

17 forced-air warming causes deep joint infections,

18 correct?

19 **A. Not --**

20 MR. GORDON: Object to form of the

21 question, lack of foundation.

22 **A. There would be some questions still if this study**

23 **were -- a single study were conducted. There would**

24 **still be a question, because studies -- randomized**

25 **clinical trials, studies, are powered to give a likely**

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1 **correct answer, but that doesn't mean that the answer**  
 2 **is correct. It just means that it's likely correct.**  
 3 BY MR. FARRAR:  
 4 Q. This is an issue that has been discussed both in the  
 5 medical community and within the company since 1994,  
 6 correct?  
 7 MR. GORDON: Object to the form of the  
 8 question.  
 9 **A. Which issue?**  
 10 BY MR. FARRAR:  
 11 Q. Whether or not that forced-air warming causes or  
 12 contributes to deep joint infections.  
 13 **A. There have been -- there have been clinicians who have**  
 14 **had that concern, yes.**  
 15 Q. For 28-plus years now, right?  
 16 **A. Yes.**  
 17 Q. At some point doesn't the company have a  
 18 responsibility -- a reasonable company have a  
 19 responsibility to run the trial to figure out if  
 20 there's any validity to that allegation?  
 21 MR. GORDON: Object to the form of the  
 22 question.  
 23 **A. Infection rate data would suggest that Bair Hugger**  
 24 **doesn't increase the infection rate. There are many**  
 25 **other factors that are well-known to increase**

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1 **infection rates in these patients.**  
 2 BY MR. FARRAR:  
 3 Q. Is it true that the infection rates for patients in  
 4 the United States has been going up since the early  
 5 2000s?  
 6 MR. GORDON: Object to the form of the  
 7 question.  
 8 **A. I'm not really -- I do not know what that rate is**  
 9 **right now.**  
 10 BY MR. FARRAR:  
 11 Q. Back when you left your position in 2019, did you  
 12 know?  
 13 **A. Yes.**  
 14 Q. Is it accurate that they have been going up for the  
 15 last -- for the ten years before that?  
 16 MR. GORDON: Object to the form of the  
 17 question.  
 18 **A. I don't believe that the rate of infection has been**  
 19 **going up, but certainly the number of patients**  
 20 **receiving joint replacement therapy has been going up.**  
 21 **(Exhibit 14 was marked for identification.)**  
 22 BY MR. FARRAR:  
 23 Q. I'll hand you what I've marked as Exhibit 14.  
 24 **A. (Reviewed.) Yes, I've read it.**  
 25 Q. You have in fact considered a randomized control study

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1 for the Bair Hugger before, correct?  
 2 **A. I -- this is an email I sent back to a -- I believe it**  
 3 **was a sales representative where I responded to a**  
 4 **question about whether a study could be conducted.**  
 5 Q. That's my point. In 2006 you sent an email where you  
 6 discussed the possibility of a randomized clinical  
 7 trial to study the safety of Bair Hugger, correct?  
 8 **A. Yes.**  
 9 MR. GORDON: Object to the form of the  
 10 question.  
 11 BY MR. FARRAR:  
 12 Q. Okay. And at the time you thought it would cost  
 13 approximately 6 million dollars, correct?  
 14 **A. I did.**  
 15 Q. Do you remember how much money 3M paid for Arizant?  
 16 **A. In round figures, around 300 million dollars, I**  
 17 **believe.**  
 18 **I also pointed out in this paragraph, by the way,**  
 19 **that -- just what I told you before, that this is not**  
 20 **a conclusive study, that there -- if we powered it at**  
 21 **an 80 percent level, we would still have questions**  
 22 **about the results of the study, and even in the case**  
 23 **we would -- whether there wasn't a difference, we**  
 24 **would still conclude that there was one 5 percent of**  
 25 **the time. So it's not just cost.**

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1 Q. There was a concern of a false-positive, right?  
 2 **A. Yes.**  
 3 Q. And that that would affect sales negatively, right?  
 4 **A. It doesn't say that here.**  
 5 Q. You know a false-positive would have negatively  
 6 affected sales, right?  
 7 **A. No, I don't know that.**  
 8 Q. When you said, "I don't think that promoting a study  
 9 like this would be a good career move for me," you  
 10 meant a false-positive would be -- or a false-positive  
 11 would be a problem for you, right?  
 12 **A. No. I think what I meant here was that spending**  
 13 **6 million dollars on something that was inconclusive**  
 14 **would not be a good career move.**  
 15 Q. Would spending 6 million dollars to ensure that the  
 16 product that you're selling 50,000 of a day doesn't  
 17 hurt people be a good career move?  
 18 MR. GORDON: Object to the form of the  
 19 question.  
 20 **A. I'm not sure what you mean by that.**  
 21 BY MR. FARRAR:  
 22 Q. Well, you know there's been allegations for almost  
 23 30 years that the device causes deep joint infections,  
 24 and the company, and by "the company" I mean Augustine  
 25 Medical, Arizant, and 3M, have never done an RCT to

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1 figure out if that's an accurate statement, correct?

2 **A. And primarily because conducting an RCT to answer that**

3 **question is logistically impossible.**

4 Q. So the folks at NICE who recommended one of those

5 be done have no idea that that would be logistically

6 impossible?

7 **A. They're not biostatisticians. I'm sure they did not**

8 **do a power analysis.**

9 Q. And I don't mean this insulting. You're not a

10 biostatistician either, right?

11 **A. No, I'm not.**

12 Q. Okay. No offense.

13 **A. I'm not an expert --**

14 Q. We are what we are, right?

15 **A. I'm not an expert in that field.**

16 Q. Dr. Sessler is considered a key opinion leader for

17 Bair Hugger with 3M -- by 3M, correct?

18 **A. Yes.**

19 Q. Let me ask you before I go there, would you agree with

20 me that -- that there were conscious decisions to not

21 pursue clinical research on Bair Hugger due to ongoing

22 legal issues?

23 **A. Would you restate that? I'm sorry.**

24 Q. Yeah. Would you agree with me that there were

25 decisions at the highest level of 3M to not pursue

Page 143

1 clinical research on Bair Hugger due to ongoing legal

2 issues?

3 **A. Oh, there's no way I would know that.**

4 Q. Would that surprise you?

5 **A. Again, I have no way of knowing whether it's true or**

6 **not.**

7 Q. Do you know who Mark Morken is?

8 **A. Yes.**

9 Q. Who is he?

10 **A. He currently works in the healthcare business group**

11 **and in the -- a regulatory capacity like mine.**

12 Q. And Michelle Hulse Stevens, what was her position?

13 **A. She was the medical director.**

14 **(Exhibit 15 was marked for identification.)**

15 Q. I'm handing you Exhibit 15 which is Bates marked

16 3MBH01330587.

17 **A. Is there a part of it you want me to --**

18 Q. There is. It's actually the very top email. I can

19 sort of orient you. The very first email would be

20 on --

21 **A. Yeah.**

22 Q. Back to your other way. I'm sorry.

23 **A. I was just looking to see -- I wanted to see what the**

24 **whole thing -- go ahead.**

25 Q. Sure, sure. The very last email on it where it starts

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1 "Hi Scott."

2 **A. Yes.**

3 Q. And I'll let you read that, and then I'll ask you

4 questions about it.

5 **A. (Reviewed.) Okay. I read the top email.**

6 Q. Okay. And the subject line you can see is "Message to

7 address safety and efficacy of forced air warming,"

8 correct?

9 **A. Yes.**

10 Q. Do you see where Mr. Morken says, "Given the ongoing

11 legal situation, decisions were made previously (at a

12 high level) not to pursue clinical research work on

13 this topic"? Do you see that?

14 **A. I do see that.**

15 Q. Were you aware that there were decisions made at high

16 levels to not do clinical research due to ongoing

17 legal situations with forced-air warming?

18 **A. I was not.**

19 Q. Okay. Do you remember times where Dr. Sessler wanted

20 specific studies done that 3M didn't conduct?

21 **A. I'm aware that Dr. Sessler recommended studies that we**

22 **elected not to pursue or fund.**

23 Q. Specifically bacterial sampling studies?

24 **A. I believe there were some like that, yes.**

25 **(Exhibit 16 was marked for identification.)**

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1 Q. I hand you Exhibit 16, Mr. Van Duren. This is Bates

2 labeled 3MBH00107719.

3 **A. (Reviewed.) Okay. I've read it.**

4 Q. You see where Dr. Sessler in April of 2013 is

5 recommending a bacterial sampling study?

6 **A. Well, his attachment isn't included here, but it**

7 **looks like that's what he's suggesting.**

8 Q. And he says, "It could have been done by now," with

9 dot dot dot after that, right?

10 **A. Yes.**

11 Q. Now, you said in your email, "I have strongly resisted

12 conducting a study of this type for reasons I can

13 discuss with you or the group during our meeting."

14 Do you remember why you strongly resisted

15 conducting a study like this?

16 **A. Because the results would be inconclusive.**

17 Q. Is it that you were worried that the results would be

18 bad for Bair Hugger?

19 **A. No, just inconclusive.**

20 Q. Why would inconclusive hurt you?

21 **A. We have a finite amount of money that we can spend on**

22 **clinical trials, and to do one that you know is going**

23 **to be inconclusive would be counterproductive.**

24 Q. Dr. Sessler is somebody 3M relies upon as a key

25 opinion leader in this field, right?

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1 **A. Yes.**  
 2 MR. GORDON: Object to the form --  
 3 BY MR. FARRAR:  
 4 Q. Why did you --  
 5 MR. GORDON: -- of the question.  
 6 MR. FARRAR: Sorry, Corey.  
 7 BY MR. FARRAR:  
 8 Q. Why did you disagree with him that the study was  
 9 needed? Let me ask you a better question.  
 10 It's clear from the email that he thought the  
 11 study was needed and would be conclusive. Fair?  
 12 MR. GORDON: Object to the form of the  
 13 question, lack of foundation.  
 14 **A. I agree that he thinks the study would be needed. I'm**  
 15 **not sure he would have thought of it conclusive.**  
 16 BY MR. FARRAR:  
 17 Q. You don't think Dr. Sessler would want to do a study  
 18 that he knew would be inconclusive, would you?  
 19 MR. GORDON: Same objection.  
 20 **A. I think it would be inappropriate to do -- conduct any**  
 21 **trial that you already knew the answer to.**  
 22 BY MR. FARRAR:  
 23 Q. So clearly if Dr. Sessler wants to do the trial, he  
 24 doesn't think we already know the answer, right?  
 25 MR. GORDON: Object to the form of the

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1 question.  
 2 **A. I'm sorry. Would you repeat it?**  
 3 BY MR. FARRAR:  
 4 Q. Clearly Dr. Sessler didn't think we already knew the  
 5 answer if he's the one wanting to do the trial, right?  
 6 **A. Well, again, it's hard for me to know precisely what**  
 7 **Dr. Sessler was thinking from this email.**  
 8 Q. If you already knew the results of the study, you  
 9 would never have to do a study, right? I mean, the  
 10 point of the study is to see what the results are.  
 11 **A. Well, at this point we knew bacterial sampling was not**  
 12 **very -- was not related to the risk of developing deep**  
 13 **joint infections.**  
 14 Q. Didn't Zink do bacterial sampling?  
 15 **A. I believe so, yes.**  
 16 Q. And 3M relied on Zink to show that the Bair Hugger  
 17 doesn't increase the risk of surgical site infections,  
 18 right?  
 19 **A. It suggested that, yes.**  
 20 Q. And still does. 3M still does that, right?  
 21 **A. I don't know.**  
 22 Q. Okay. They did when you left the department in 2019?  
 23 **A. Again, I'm not -- I don't know. I'm not certain.**  
 24 Q. But you believe that bacterial sampling does not -- is  
 25 ineffective at determining the risk of surgical site

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1 infections?  
 2 **A. It's not conclusive.**  
 3 Q. What do you mean by "conclusive"?  
 4 **A. The development of a perioperative joint infection is**  
 5 **the result of a number of factors, one of which is the**  
 6 **dose of bacteria, only one of which is the dose of**  
 7 **bacteria. There are many other factors that are**  
 8 **related to the development of a postoperative joint**  
 9 **infection.**  
 10 Q. The number of bacteria -- the increase in the number  
 11 of bacteria increase the risk, right?  
 12 **A. It may.**  
 13 Q. Okay. If there's no bacteria, there's no risk at all,  
 14 right?  
 15 **A. No, that's not true.**  
 16 Q. You can have an infection with no bacteria?  
 17 **A. No, that's not true.**  
 18 Q. That was too many negatives. I'm going to try it  
 19 again.  
 20 Can you have an infection with no bacteria?  
 21 **A. No.**  
 22 Q. Okay. So the number of bacteria clearly has some  
 23 correlation to the risk of infection, right?  
 24 **A. Well, I think your original question had to do with**  
 25 **the source of the bacteria. So many -- bacterial**

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1 **infections can come from endogenous sources as well.**  
 2 Q. Okay. I don't think I was asking about sources.  
 3 **A. Okay.**  
 4 Q. So I apologize if I did.  
 5 I guess the only point is, bacteria are required  
 6 for an infection, right?  
 7 **A. Yes.**  
 8 Q. Okay. And the more bacteria, the increased likelihood  
 9 of an infection?  
 10 **A. Within limits, yes.**  
 11 Q. Okay. You agree one of the -- one of the primary  
 12 duties of the folks in the OR is to try to limit the  
 13 amount of bacteria, right, or amount of particles?  
 14 MR. LUCAS: Object to form, calls for  
 15 speculation, lacks proper foundation.  
 16 **A. I'm sorry. Would you repeat the question?**  
 17 BY MR. FARRAR:  
 18 Q. Let me ask you a different one.  
 19 Would you agree that the folks in the operating  
 20 room do what they can to minimize the bacteria in the  
 21 OR?  
 22 MR. GORDON: Object to the form of the  
 23 question.  
 24 **A. I mean, not all of them are concerned with that, no.**  
 25 **No, I guess I would not agree with that.**

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1 BY MR. FARRAR:  
 2 Q. Would you agree that one of the primary  
 3 responsibilities of a hospital or OR personnel is to  
 4 mitigate the possibility of deep joint infections?  
 5 **A. It depends on the remit of that person involved.**  
 6 Q. If you'd take a look at your trial testimony, sir.  
 7 It's the one that has your -- yeah, that's it. On  
 8 page 149. I'm looking at 16.  
 9 "And in an operating room, you would agree, would  
 10 you not, that the intent is to mitigate the potential  
 11 for a surgical site infection to the greatest degree  
 12 possible?"  
 13 And you say: "Yes."  
 14 And then the question: "That the hospital and  
 15 the operating room personnel have that as one of their  
 16 primary responsibilities?"  
 17 And you say: "Absolutely, yes."  
 18 Do you stand by that, sir?  
 19 **A. Yes.**  
 20 Q. Okay.  
 21 **A. Just to note that the question was: "That the**  
 22 **hospital and the operating room personnel have that as**  
 23 **one of their primary responsibilities?"**  
 24 Q. Okay. I think the question I asked you -- and let me  
 25 go back to the original. Would you agree that one of

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1 the primary responsibilities of a hospital and OR  
 2 personnel is to mitigate the possibility of a deep  
 3 joint infection?  
 4 **A. Yes.**  
 5 Q. I mean, that's everybody from the nurses,  
 6 anesthesiologists, surgeons. That's something that  
 7 they're all concerned with, correct?  
 8 MR. LUCAS: Object to the form, lacks  
 9 proper foundation, calls for speculation, and  
 10 potentially calls for a medical opinion on behalf of  
 11 this witness.  
 12 MR. KRONAWITTER: And join. It's also an  
 13 incomplete hypothetical.  
 14 MR. MCCAIG: This is Josh.  
 15 Can we get an agreement that one objection  
 16 suffices for everyone?  
 17 MR. FARRAR: Sure.  
 18 MR. MCCAIG: Thank you.  
 19 BY MR. FARRAR:  
 20 Q. Would you agree with me that the folks in the OR rely  
 21 on the medical device company to supply them with  
 22 materials regarding risks and benefits of the  
 23 products?  
 24 MR. GORDON: Object to the form of the  
 25 question.

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1 **A. Would you restate that?**  
 2 BY MR. FARRAR:  
 3 Q. Yeah. Would you agree that the people in the hospital  
 4 rely on medical device manufacturers to tell them  
 5 about the risks and benefits of the products they  
 6 manufacture?  
 7 MR. GORDON: Object to the form of the  
 8 question, also lack of foundation.  
 9 **A. I think that the risks and benefits are part of the**  
 10 **instructions for use that -- the labeling of the**  
 11 **product, yes.**  
 12 BY MR. FARRAR:  
 13 Q. Sure.  
 14 **A. Approved by the FDA.**  
 15 Q. And you agree it's reasonable for the hospitals or  
 16 medical folks to rely on the manufacturers to give  
 17 them truthful and honest information?  
 18 **A. Yes.**  
 19 Q. Would you agree that 3M knows more about the Bair  
 20 Hugger than anybody else, the folks at 3M?  
 21 **A. Regarding what?**  
 22 Q. Really everything, the safety, the history, the  
 23 efficacy. I mean, they're the ones selling it 50,000  
 24 times a day and monitoring it constantly, correct?  
 25 MR. GORDON: Object to the form of the

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1 question.  
 2 **A. Well, there's a lot there. Sorry.**  
 3 BY MR. FARRAR:  
 4 Q. It was a little broad. I'm sorry. I'll do better.  
 5 Would you agree that the folks at 3M know about  
 6 the risks and benefits of the Bair Hugger better than  
 7 anybody else?  
 8 MR. GORDON: Object to the form of the  
 9 question.  
 10 **A. It's -- it's hard for me to know "better than anybody**  
 11 **else" part of the answer, of the --**  
 12 BY MR. FARRAR:  
 13 Q. How about as good or better than anybody else?  
 14 **A. Probably.**  
 15 Q. To your knowledge, has 3M ever told doctors or  
 16 hospitals that the machine itself harbors bacteria?  
 17 **A. I don't know that 3M has ever done that.**  
 18 Q. It is a fact that it does harbor bacteria, correct?  
 19 MR. GORDON: Object to the form of the  
 20 question.  
 21 **A. Well, bacteria can be cultured from it, yes.**  
 22 BY MR. FARRAR:  
 23 Q. Okay. So it does harbor and grow bacteria or at least  
 24 potentially can?  
 25 MR. GORDON: Object to the form of the

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1 question.

2 **A. Well, I don't know about "grow"; but bacteria can be**

3 **cultured from it, yes.**

4 BY MR. FARRAR:

5 Q. That is true both in the machine and as well as in the

6 hose, the distal hose, correct?

7 MR. GORDON: Same objection.

8 **A. Bacteria can be cultured from inside the hose.**

9 BY MR. FARRAR:

10 Q. 3M has known about that for a significant amount of

11 time, correct, decades, 3M or Arizant?

12 **A. Well, the device is not sold as a sterile device.**

13 Q. Right. And it has a filter on it, correct?

14 **A. Yes.**

15 Q. The filter isn't -- its purpose was to protect the

16 motor. Fair?

17 **A. No.**

18 Q. What's the purpose of the filter?

19 **A. To prevent internal fouling of the fan and heater from**

20 **particles.**

21 Q. Was the concern that the particles would be blown onto

22 the patients, or was the concern that they would sort

23 of muck up the inner workings of the blower?

24 **A. I believe it was both, but we'd have to look at the**

25 **risk management documents for that.**

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1 Q. The filter on the 505 wasn't airtight, right?

2 **A. To my knowledge, no.**

3 Q. The filter on the 750 changed efficiencies and made it

4 a less efficient filter, correct?

5 **A. I'm not certain of that.**

6 Q. You have seen studies where the filter efficiency is

7 67 percent on the 750?

8 **A. Well, it depends on the particle size, of course; but**

9 **I'm sure I've looked at numerous studies where filter**

10 **efficiencies were evaluated.**

11 Q. Would you agree that 3M and Arizant did not do any

12 testing with respect to whether or not contamination

13 inside the machine could ultimately migrate to the

14 surgical field?

15 **A. I'm not -- I'm not certain whether specific studies**

16 **were done to look at that question.**

17 Q. In your 30(b)(6) you testified, "To my knowledge, we

18 did not conduct studies like that." It's page 306.

19 **A. Okay.**

20 Q. And, again, this is the testimony of you in your role

21 as the company, not Mr. Van Duren, correct?

22 **A. I understand. Yes.**

23 Q. Okay. 306, line 16, the question is: "All right.

24 Would you agree that 3M didn't -- did not and Arizant

25 did not do any testing with respect to whether or not

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1 contaminants inside the machine could ultimately

2 migrate to the surgical field?"

3 Your answer: "To my knowledge, we did not

4 conduct studies like that."

5 Do you still agree with that?

6 **A. Yes.**

7 Q. Are you aware of any studies since you gave this

8 deposition that would look at that issue?

9 **A. I'm not aware of any.**

10 **(Exhibit 18 was marked for identification.)**

11 Q. Mr. Van Duren, I'm handing you Exhibit 18, which is

12 Bates labeled 3M00580475.

13 **A. (Reviewed.) Okay. I've read it.**

14 Q. Okay. Michelle Hulse Stevens was the medical

15 director, correct?

16 **A. For the --**

17 Q. Infection disease division?

18 **A. Correct.**

19 Q. Were you aware that she sat in on the International

20 Consensus, their meetings?

21 **A. I may have known that, but I -- I didn't recall it.**

22 Q. Sure.

23 This is an email she sent in August of 2013, and

24 she says, "There is amazing concern about" the

25 "particulates in the air during joint replacement

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1 surgery and almost uniform comment that FAW" -- which

2 is forced-air warming, correct?

3 **A. Um-hmm.**

4 Q. -- "increases particulates in the air."

5 Did I read that correctly?

6 **A. Yes.**

7 Q. Okay. So that's her take-away from sitting in at this

8 meeting that there's almost a uniform consensus of

9 that issue, right?

10 MR. GORDON: Object to the form of the

11 question, also lack of foundation.

12 **A. So this is a -- appears to be a small group of the**

13 **entire consensus group. So this is a subgroup, yes.**

14 BY MR. FARRAR:

15 Q. Sure. Okay.

16 That subgroup, anyway, said there's -- or her

17 take-away, anyway, Ms. Hulse Stevens, is: "There is

18 amazing concern about any particulates in the air

19 during joint replacement surgery and almost uniform

20 comment that forced-air warming increases particulates

21 in the air."

22 That's her take-away from that meeting, correct?

23 MR. GORDON: Same objections.

24 **A. That's what she wrote.**

25 BY MR. FARRAR:



1 Q. And she goes on to say, "They equate particulates with  
2 bacteria in the air and cite studies (do not have the  
3 citations) that support this."  
4 You're aware that there are studies that equate  
5 particulates with bacteria, correct?  
6 MR. GORDON: Object to the form of the  
7 question.  
8 **A. I'm -- I'm -- I've seen studies that discuss the**  
9 **number of bacteria on various size particulates, yes.**  
10 BY MR. FARRAR:  
11 Q. And you know that researchers use particulates as a  
12 proxy for bacteria in some studies that they do,  
13 right?  
14 MR. GORDON: Object to the form of the  
15 question.  
16 **A. Some have.**  
17 BY MR. FARRAR:  
18 Q. And another way to say it is, particulate count is a  
19 surrogate for bacterial load, correct?  
20 MR. GORDON: Same objection.  
21 BY MR. FARRAR:  
22 Q. Bacterial load.  
23 **A. It has been proposed to be such, yes.**  
24 Q. If you look at the end of the second paragraph,  
25 Ms. Hulse Stevens says, "I mention this now so that if

1 **A. I'm not sure what's -- I'm sure there were several**  
2 **proposed. I'm not sure which one you're talking**  
3 **about.**  
4 Q. Sure. Let me give you the email chain talking about  
5 it.  
6 (Exhibit 19 was marked for identification.)  
7 This is Exhibit 19, and it begins with  
8 3MBH01300869.  
9 **A. Which one? Which part of it do you want me --**  
10 Q. Actually, you probably need to read it all to get the  
11 context.  
12 **A. Oh, okay.**  
13 Q. Start from the back and come forward.  
14 **A. Okay. (Reviewed.) Okay.**  
15 Q. All right. So I just wanted to ask you a few  
16 questions.  
17 Were you aware of a protocol for a proposed trial  
18 that Dr. Harper sent to 3M in mid-2016?  
19 **A. I believe so.**  
20 Q. And from sort of reviewing this and from your memory,  
21 was the topic comparing FAW versus RFW regarding  
22 differences in SSI reductions?  
23 **A. And there was -- there was another outcome too. Yes,**  
24 **infection was one outcome.**  
25 Q. Okay. What was the other outcome?

1 an aerobiology study needs to be considered for 2014  
2 to lay this concern to rest the budget and rationale  
3 can be included in the 2014 budgeting planning."  
4 Do you see that?  
5 **A. I do.**  
6 Q. Do you know if that study was conducted at 3M?  
7 **A. I don't know if an aerobiology study was conducted.**  
8 **It may have been, but I don't know.**  
9 Q. Okay. At least in 2013 Ms. Hulse Stevens is saying,  
10 we could lay the concern to rest and that the budget  
11 and the money is there for that, correct?  
12 **A. Yes.**  
13 Q. Okay. Were you aware of -- do you know who Dr. Harper  
14 is? In the UK.  
15 **A. C. Mark Harper?**  
16 Q. Correct.  
17 **A. Yes, I know who he is.**  
18 Q. Were you aware that he wanted to do a study comparing  
19 forced-air warming with RFW regarding differences in  
20 SSI reductions?  
21 **A. I believe so, yes.**  
22 Q. And you know that that study was also never done,  
23 correct?  
24 **A. No, I don't know that it wasn't done.**  
25 Q. Do you know if it was done?

1 **A. It looked like quality of life. They were considering**  
2 **quality of life issues.**  
3 Q. Is "RFW" reflective?  
4 **A. I think it's resistive -- resistive fiber warming.**  
5 Q. What would be an example?  
6 **A. The Bair -- sorry. The Augustine Medical blanket,**  
7 **the --**  
8 Q. HotDog?  
9 **A. The HotDog, LMA, a couple of them.**  
10 Q. VitaHEAT?  
11 **A. VitaHEAT would be one, yes.**  
12 Q. Okay. And if you look at this, there's sort of folks  
13 from different areas at 3M, for instance, Mark Morken  
14 we talked about. He was in infection prevention  
15 division, correct?  
16 **A. Yes, he was clinical research manager at that point.**  
17 Q. And then Christine Bongards, she is in healthcare  
18 business group?  
19 **A. She -- then she was -- yeah. She was a clinical**  
20 **research manager as well, um-hmm.**  
21 Q. And then Steve Foster, and he is a health economics  
22 manager, correct?  
23 **A. Yes.**  
24 Q. What does the health -- what does that division do?  
25 **A. Health economics is a study of the costs associated**

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1 **with producing various outcomes in medicine.**  
 2 Q. Okay. I want to focus on Steve Foster's email, and he  
 3 says: "Thanks for sending the protocol through. This  
 4 is certainly an ambitious study and not without its  
 5 risks. I would imagine that if there is a definitive  
 6 and differential outcome it will be very good for one  
 7 product and very bad for the other."  
 8 Would you agree with that, that there is a  
 9 definitive and differential outcome that's going to  
 10 hurt one of the products, forced-air warming or  
 11 HotDog, and help the other one?  
 12 **A. Let me just -- let me just read that one more time.**  
 13 Q. Sure.  
 14 **A. Where was that one, by the way?**  
 15 Q. I'm sorry. Really on the first page, on the -- there  
 16 you go. Right in the middle of the very first  
 17 paragraph, where it begins with "Hi Christine and  
 18 Mark."  
 19 **A. Oh, yes. Okay.**  
 20 **(Reviewed.) Okay. I've read it. Sorry.**  
 21 Q. All right. And this is where Mr. Foster says this  
 22 type of study sounds risky to him, right?  
 23 **A. Yes.**  
 24 Q. Clearly the risk that he is concerned with is there's  
 25 a better outcome with HotDog than forced-air warming,

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1 correct?  
 2 MR. GORDON: Object to the form of the  
 3 question, lack of foundation.  
 4 **A. In this context it's hard for me to understand or know**  
 5 **what he was considering as risks.**  
 6 BY MR. FARRAR:  
 7 Q. Well, he says, "I would imagine that if there is a  
 8 definitive and differential outcome it will be very  
 9 good for one product and very bad for the other."  
 10 Do you see that?  
 11 **A. I do see that.**  
 12 Q. Okay. So if there's a definitive and differential  
 13 outcome, that will either hurt or help forced-air  
 14 warming and then also hurt or help RFW, correct?  
 15 **A. I'm sorry. What was the question?**  
 16 Q. Well, let me ask you this way. You can't agree with  
 17 Mr. Foster, right, that if a study comes out that is  
 18 very definitive and differential that one of them  
 19 really reduces the incident of SSI and the other  
 20 doesn't, that's going to hurt one of the product's  
 21 sales, correct?  
 22 **A. It could.**  
 23 Q. And it's probably going to help the other company's  
 24 sales, right?  
 25 **A. It may.**

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1 Q. Okay. So the point is, the risk that Mr. Foster is  
 2 concerned about is that this study does not end up  
 3 favorable for forced-air warming, correct?  
 4 MR. GORDON: Object to the form of the  
 5 question, also lack of foundation.  
 6 **A. Well, again, he says "risks," plural --**  
 7 BY MR. FARRAR:  
 8 Q. Okay.  
 9 **A. -- and defines one of them. There could be many other**  
 10 **risks associated with the conduct of this trial.**  
 11 Q. Just curiosity, what other risks are you -- do you  
 12 have in mind?  
 13 **A. Well, again, if this is a study that looks at**  
 14 **infection rates in joint arthroplasty, the adverse**  
 15 **event rates are so low that the study is likely to be**  
 16 **inconclusive.**  
 17 Q. Do you know if Dr. Harper was requesting funding from  
 18 3M?  
 19 **A. I don't know.**  
 20 Q. Do you know if the study was ever done?  
 21 **A. I -- again, with the information that I have in front**  
 22 **of me, I don't really know what study is being**  
 23 **referred to here.**  
 24 Q. If this study would have been done, you would have  
 25 known about it in your position at 3M up until

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1 mid-2019, right?  
 2 **A. Likely.**  
 3 MR. GORDON: Object to the form of the  
 4 question.  
 5 BY MR. FARRAR:  
 6 Q. I'm sorry, your answer got stepped on.  
 7 **A. It's likely, yes.**  
 8 Q. Okay. And in fact I think you told me right at the  
 9 very beginning that even though you're not really  
 10 working with forced-air warming anymore you're still  
 11 sort of tracking the literature for your own personal  
 12 edification. Fair?  
 13 **A. Yes.**  
 14 Q. I mean, you worked on the product for almost 30 years.  
 15 You've got to be interested in it, right?  
 16 **A. Yes.**  
 17 Q. Okay. Fair to say, I mean, nobody has worked in  
 18 forced-air warming longer than you?  
 19 **A. Well, I -- maybe at 3M that's true, yes.**  
 20 Q. Okay. Well, probably, frankly, in the world, really.  
 21 I mean, you started out with the inventor of it,  
 22 right?  
 23 **A. Oh, no. That was Dr. Augustine.**  
 24 Q. No. I said, you started out with working with him.  
 25 **A. Oh, yes.**

1 Q. Yeah, yeah.  
 2 And he doesn't work in forced-air warming  
 3 anymore, right?  
 4 **A. Not to my knowledge.**  
 5 Q. That's my point. You're probably the longest tenured  
 6 ever person to work on forced-air warming. Fair  
 7 enough?  
 8 **A. It's possible, yeah.**  
 9 Q. Do you -- so to just sort of close that loop, and I  
 10 apologize, you're not aware if that study was ever  
 11 conducted, correct?  
 12 MR. GORDON: Object to the form of the  
 13 question.  
 14 **A. I'm not certain what study is being referred to here.**  
 15 **It's not identified.**  
 16 BY MR. FARRAR:  
 17 Q. Okay. You're not aware of a study being conducted  
 18 that seems to be consistent with the emails that we  
 19 see in Exhibit 18, correct?  
 20 MR. GORDON: Same objection.  
 21 **A. Again, it's not identified. It's difficult for me to**  
 22 **know. Investigators suggest lots of studies, so I**  
 23 **don't know.**  
 24 BY MR. FARRAR:  
 25 Q. You don't have any information one way or other if the

1 **A. I believe -- I believe so.**  
 2 Q. Do you know what the results are?  
 3 **A. Again, I'm not -- right at -- right now I don't recall**  
 4 **exactly what the results were.**  
 5 Q. Okay. Do you know who any of the co-authors were, by  
 6 chance?  
 7 **A. Well, I think there was a study -- Mike Reed might**  
 8 **have been a co-author on the study that I'm aware of.**  
 9 Q. Are you familiar with ECRI, Enhanced Recovery After  
 10 Surgery Society?  
 11 **A. So ECRI is the --**  
 12 Q. I'm sorry. You're right. ERAS is what I meant. I  
 13 apologize.  
 14 **A. ERAS.**  
 15 Q. Let me reask you the question. Are you familiar with  
 16 ERAS?  
 17 **A. I am.**  
 18 Q. Are you familiar with their consensus statement  
 19 regarding use of Bair Hugger in joint replacement  
 20 surgery?  
 21 MR. GORDON: Did you say "consistent" or  
 22 "consensus"?  
 23 MR. FARRAR: Consensus statement. Sorry.  
 24 **A. I'm not -- I'm not sure I'm aware of a consensus**  
 25 **statement from ERAS.**

1 study was conducted?  
 2 **A. Again, I don't know --**  
 3 MR. GORDON: Same objection.  
 4 **A. -- what study is being referred to here.**  
 5 BY MR. FARRAR:  
 6 Q. If Dr. Harper would have published a study on the  
 7 topic of comparing FAW versus RFW regarding  
 8 differences in SSI reductions, that's something you  
 9 think you would know exists, correct?  
 10 **A. I would probably.**  
 11 Q. Okay. And don't know of any such study?  
 12 **A. I just don't know what is being referred to in this**  
 13 **email chain.**  
 14 Q. Let me ask you slightly different. Are you aware of  
 15 any study published where Dr. Harper is an author on  
 16 the topic comparing FAW versus RFW regarding  
 17 differences in SSI reductions?  
 18 **A. I believe there was a study conducted like that.**  
 19 Q. Has it been published?  
 20 **A. I believe so, yes.**  
 21 Q. That Dr. Harper is authoring?  
 22 **A. Yes, I believe so.**  
 23 Q. Okay. Do you know where it was published or when?  
 24 **A. I don't know where it was published, no.**  
 25 Q. This email chain is in 2016. Was it after that?

1 BY MR. FARRAR:  
 2 Q. You mentioned Mike Reed. Mike Reed is a  
 3 well-respected researcher in the UK. Fair?  
 4 **A. I don't know.**  
 5 Q. Have you ever talked or had any communications with  
 6 Dr. Reed?  
 7 **A. I don't believe I've ever met him.**  
 8 Q. Have you had any communications, telephone, email,  
 9 anything like that?  
 10 **A. Not to -- not that I remember.**  
 11 Q. Okay. You're familiar with some of his work, correct?  
 12 **A. Yes.**  
 13 Q. You know he's an author on the McGovern paper?  
 14 **A. Yes.**  
 15 Q. You know he's part of ICOS?  
 16 **A. Yes.**  
 17 Q. You know 3M has hired him before to do research for  
 18 3M, correct?  
 19 **A. I may have known that, yes.**  
 20 Q. If 3M hires someone to do research, you would expect  
 21 they're sort of top-notch researchers, correct?  
 22 **A. I wasn't involved in any sort of decision regarding**  
 23 **Dr. Reed, so I just don't know.**  
 24 Q. You would hope if 3M is hiring someone to do research  
 25 for them that they're a top-notch researcher, correct?

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1 **A. Researchers get vetted to make sure that they meet**  
 2 **certain requirements for their capabilities to conduct**  
 3 **particular kinds of research.**  
 4 Q. Have you hired researchers to do research for  
 5 different topics that you've had?  
 6 **A. Not at 3M.**  
 7 Q. At Arizant?  
 8 **A. Yes.**  
 9 Q. Okay. And you took pride in who you hired to make  
 10 sure they were going to do a good job, right?  
 11 **A. Yes.**  
 12 **(Exhibit 20 was marked for identification.)**  
 13 Q. Okay. I want to hand you Exhibit 20.  
 14 MR. FARRAR: I'm sorry, Corey, I only  
 15 have one of these.  
 16 MS. ZIMMERMAN: I think there's two.  
 17 MR. FARRAR: I don't think so.  
 18 MS. ZIMMERMAN: Are you sure?  
 19 MR. FARRAR: Yeah.  
 20 MR. GORDON: You don't have the latest  
 21 version of this?  
 22 MR. FARRAR: I don't. I have the  
 23 October 30th, 2019.  
 24 MR. GORDON: So you don't have the  
 25 amendment to it.

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1 MR. FARRAR: I do not.  
 2 BY MR. FARRAR:  
 3 Q. Can you tell me about ERAS? What do you know about  
 4 them?  
 5 **A. It's a group of mostly physicians worldwide divided up**  
 6 **by surgical specialty, and they develop consensus**  
 7 **statements and operative guidelines or practice**  
 8 **guidelines for various types of surgical specialties.**  
 9 Q. Is it something that you would have kept up with in  
 10 your job duties and work on the Bair Hugger?  
 11 **A. Yes.**  
 12 Q. Okay. If you would look at -- it's page 10. The  
 13 numbers are sort of in the top left corner.  
 14 **A. I'm sorry. Page 10?**  
 15 Q. Yes, sir.  
 16 **A. Okay.**  
 17 Q. And then do you see the section called "Maintaining  
 18 normothermia"?  
 19 **A. Yes.**  
 20 Q. I'll let you take a -- read through that note and then  
 21 ask you a couple questions.  
 22 **A. (Reviewed.) Okay. I've read it.**  
 23 Q. There's a sentence about two-thirds of the way down  
 24 that says, "However, the use of forced air warming is  
 25 not recommended as there is evidence that this is

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1 associated with an increased risk of infection."  
 2 Do you see that part?  
 3 **A. I do see it.**  
 4 Q. Now, I appreciate that you sort of left Bair Hugger at  
 5 this time. I think in October 2019 you would have  
 6 been in the evidence development group?  
 7 **A. Yes.**  
 8 Q. Okay. Were you aware that this statement came out by  
 9 ERAS?  
 10 MR. GORDON: Object to the form of the  
 11 question, assumes facts not in evidence, misstates the  
 12 evidence, and best evidence rule, also lack of  
 13 foundation.  
 14 **A. I suspect I have seen this.**  
 15 BY MR. FARRAR:  
 16 Q. Okay.  
 17 **A. Yeah.**  
 18 Q. Do you know whether you or anybody else at 3M took any  
 19 action when this came out?  
 20 **A. I'm pretty certain that I did not take any action.**  
 21 Q. Do you know if anybody else took any action when it  
 22 came out?  
 23 **A. I don't know.**  
 24 Q. Do you know if 3M's attorneys took any action when  
 25 that came out?

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1 **A. I don't know.**  
 2 Q. Okay. Were you involved in any conversations about  
 3 this statement that's in this ERAS consensus  
 4 statement?  
 5 **A. Not that I recall.**  
 6 Q. I mean, other than you and me talking about it, do you  
 7 recall talking about it with anybody?  
 8 **A. I don't -- I don't recall talking about this to**  
 9 **anybody.**  
 10 Q. Did you see any other communications or presentations  
 11 at 3M regarding it?  
 12 **A. Not that I recall.**  
 13 Q. So one of the articles that's cited by ERAS is Koc,  
 14 K-O-C. Do you see that?  
 15 **A. I do.**  
 16 Q. Have you read that article, sir?  
 17 **A. I don't remember if I've read it.**  
 18 Q. It's short. I'm going to give you the abstract.  
 19 (Exhibit 21 was marked for identification.)  
 20 This is Exhibit 21. I'm really just going to  
 21 focus on the "Background" part.  
 22 **A. (Reviewed.) Oh, okay. I've read it.**  
 23 Q. Under the "Background" do you see where it says,  
 24 "Commonly, forced air warming devices are used  
 25 intraoperatively to maintain body temperature in

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1 patients undergoing surgery," and it says, "However,  
 2 it is believed that these convective warming systems  
 3 could increase the risk of deep surgical site  
 4 infections due to disruption of unidirectional  
 5 downward" laminal -- "laminar airflow. Conductive  
 6 warming devices have no noticeable effect on  
 7 ventilation airflow."  
 8 Do you see that?  
 9 **A. I do.**  
 10 Q. Do you agree with that last sentence that "Conductive  
 11 warming devices have no noticeable effect on  
 12 ventilation airflow"?  
 13 **A. No.**  
 14 Q. Has 3M ever conducted any internal testing to  
 15 determine whether or not conductive warming devices  
 16 have a noticeable effect on ventilation airflow?  
 17 **A. Yes.**  
 18 Q. What studies?  
 19 **A. We've looked at Schlieren photography --**  
 20 Q. That's right.  
 21 **A. -- of conductive and convective warming systems.**  
 22 Q. Other than the Schlieren studies, is there anything  
 23 else that 3M has done to research that issue?  
 24 **A. I don't recall now whether there has been a comparison**  
 25 **study done between those two devices to look at the**

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1 "Background" the authors say, "One of the main  
 2 concerns with forced air devices is that they may  
 3 increase bacterial contamination in the surgical field  
 4 before and during surgery. Recently, conductive  
 5 heating systems have been developed and used to  
 6 address these concerns. While these devices do not  
 7 disrupt airflow at the surgical site, their efficacy  
 8 versus forced-air devices has been called into  
 9 question."  
 10 Do you see that part?  
 11 **A. I do.**  
 12 Q. Do you agree -- I guess you disagree with these  
 13 authors also when they say that these devices, meaning  
 14 conductive heating, do not disrupt airflow at the  
 15 surgical site?  
 16 **A. I disagree.**  
 17 Q. Okay. Do you see that their conclusion, what they  
 18 did -- they did 50 patients, half using a Bair Hugger  
 19 and half using VitaHEAT, correct?  
 20 **A. I did see that.**  
 21 Q. And their conclusion was there was no difference  
 22 between intraoperative and recovery room temperatures  
 23 between patients using either forced-air device or  
 24 conductive heating device, correct?  
 25 **A. That was their conclusion.**

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1 **effect on ventilation airflow.**  
 2 Q. Do you agree that conductive warming is as effective  
 3 as forced-air warming in maintaining normothermia?  
 4 **A. No.**  
 5 Q. What studies do you rely on for that?  
 6 **A. There are a number of them. Moretti is probably the**  
 7 **best one.**  
 8 Q. Are you aware of recent studies that have come out  
 9 that says that they're equivalent?  
 10 **A. Yes.**  
 11 Q. The study specifically in orthopedic surgeries in 2018  
 12 comparing the Bair Hugger and VitaHEAT, are you  
 13 familiar with that?  
 14 **A. I'm certain I've read it. I don't recall the actual**  
 15 **results, but I'm sure I've seen that one.**  
 16 **(Exhibit 22 was marked for identification.)**  
 17 Q. I'll hand you what I've marked as Exhibit 2, which is  
 18 the study I was referencing.  
 19 MR. GORDON: Exhibit 22?  
 20 MR. FARRAR: 22. I'm sorry.  
 21 MR. GORDON: Thank you.  
 22 **A. (Reviewed.) Okay. I've looked at most of it.**  
 23 BY MR. FARRAR:  
 24 Q. Okay. And I'm just going to read from the language in  
 25 here, but just to short-circuit it, in the

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1 Q. Okay. Do you discredit their conclusion?  
 2 MR. GORDON: Object to the form of the  
 3 question.  
 4 **A. The measurements they made I think are probably**  
 5 **correct, but what they failed to understand is that**  
 6 **the dominant cause of intraoperative hypothermia is**  
 7 **redistribution, and intraoperative warming doesn't**  
 8 **have a large effect on reducing that at this time**  
 9 **scale.**  
 10 BY MR. FARRAR:  
 11 Q. What was their time scale?  
 12 **A. (Reviewed.) They reported in their abstract that they**  
 13 **measured temperature every 15 minutes. So I'm**  
 14 **assuming that -- well, I'm not sure what to assume.**  
 15 **So they concluded that there was no difference**  
 16 **between intraoperative and recovery room temperatures,**  
 17 **but they have a histogram here that shows**  
 18 **intraoperative mean temperatures. So I'm assuming,**  
 19 **again, that that's an average, you know, that's what**  
 20 **they report, in recovery room mean temperatures. So**  
 21 **they've averaged the core temperatures that they**  
 22 **measured, I think, with a tympanic membrane device.**  
 23 Q. Mr. Van Duren, I think you said originally you  
 24 disagreed with the authors because of the short time  
 25 scale, right?

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1 **A. Correct.**  
 2 Q. But fair enough that you don't know what the actual  
 3 time scale is?  
 4 **A. I don't know precisely how long it is, and I don't**  
 5 **think they report it either.**  
 6 Q. Okay.  
 7 **A. However, this is an average temperature.**  
 8 Q. You would have still been in temperature management  
 9 when this was published in February of 2018, correct?  
 10 **A. Yes.**  
 11 Q. All right. Did you do a summary or criticism of this  
 12 article, do you recall?  
 13 **A. The author's name sounds familiar to me. I probably**  
 14 **did.**  
 15 Q. Okay. That would be something that's still at the  
 16 files at 3M presumably, correct?  
 17 **A. Yes.**  
 18 MR. FARRAR: Okay. Why don't we take a  
 19 break. We've been going about an hour and a half.  
 20 THE VIDEOGRAPHER: We're off the record.  
 21 (From 2:20 p.m. to 2:40 p.m. a recess was taken.)  
 22 (Exhibit 23 was marked for identification.)  
 23 THE VIDEOGRAPHER: We're on video. We're  
 24 on the record.  
 25 BY MR. FARRAR:

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1 Q. Mr. Van Duren, I've handed you another exhibit,  
 2 Number 23. That is an October 22nd, 2018, study,  
 3 again, looking at heat transfer effectiveness between  
 4 forced-air warming and conductive.  
 5 Are you familiar with this study?  
 6 **A. I don't recall reading it, but I know Professor**  
 7 **Yamakage.**  
 8 Q. Okay. Remind me, in October of 2018 were you out  
 9 of --  
 10 **A. No.**  
 11 Q. Or you were still -- yeah, you're still there.  
 12 Do you remember if you did a summary or any type  
 13 of criticisms of this article?  
 14 **A. I don't remember if I did one or not. It's possible.**  
 15 Q. You're aware that the results of this study show the  
 16 CFW, which is the convective warming, showed a  
 17 significantly higher patient warming rates than  
 18 forced-air warming, correct?  
 19 MR. GORDON: Well --  
 20 **A. Well, I need to read it --**  
 21 BY MR. FARRAR:  
 22 Q. Sure.  
 23 **A. -- first just a minute.**  
 24 Q. Yeah, take your time.  
 25 MR. GORDON: You're not representing that

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1 this has anything to do with Bair Hugger, are you?  
 2 MR. FARRAR: It's forced-air warming.  
 3 **A. (Reviewed.) Okay. I've read the abstract.**  
 4 BY MR. FARRAR:  
 5 Q. Okay. I was looking at the -- under "Results." It's  
 6 really on page -- this page with the graph. If you  
 7 want to look at the abstract too, we can.  
 8 **A. Yes.**  
 9 Q. Right under that graph, that paragraph, and if you go  
 10 about halfway down, it says, "under these controlled  
 11 conditions, the clinical heat transfer effectiveness  
 12 of CFW (HotDog) system is significantly greater than  
 13 FAW (Warm Touch) system. There were no adverse events  
 14 to patients in either group."  
 15 Do you see that?  
 16 **A. I do.**  
 17 Q. Were you familiar with this study when you were  
 18 working in temperature management?  
 19 **A. I may have been. I don't recall this precise study,**  
 20 **particular study.**  
 21 Q. Okay. Is there any criticisms that you recall having  
 22 of it or have of it right now?  
 23 **A. Well, I just read it. I mean, I just read the**  
 24 **abstract.**  
 25 Q. Sure.

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1 **A. And this is really not a -- this is not a fair**  
 2 **comparison. First of all, the conductive fabric**  
 3 **electric warming group had a full-body underbody**  
 4 **blanket plus a -- it looks like it's either an upper**  
 5 **body or a lower -- or lower body blanket, plus an**  
 6 **underbody heated mattress. The forced-air warming**  
 7 **group only had an upper or lower body blanket only,**  
 8 **and they operated it at 39 degrees. So this is --**  
 9 **this is not a fair comparison of the performance of**  
 10 **the two devices.**  
 11 Q. It is peer-reviewed and published, correct?  
 12 MR. GORDON: Object to the form of the  
 13 question, lack of foundation.  
 14 **A. This is an Open Access journal. I don't know if it's**  
 15 **peer-reviewed.**  
 16 BY MR. FARRAR:  
 17 Q. Okay.  
 18 **A. It might have been.**  
 19 Q. There's a paragraph a little bit further over that  
 20 starts -- on your right side, on the right-hand  
 21 column --  
 22 **A. Okay.**  
 23 Q. -- that says, "There is another issue." Do you see  
 24 that?  
 25 **A. I'm sorry. How does the paragraph start?**

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1 Q. "There is another issue that underscores the  
 2 importance."  
 3 **A. Oh, "There is" -- yeah. Okay.**  
 4 Q. It says, "There is another issue that underscores the  
 5 importance of finding an effective alternative to  
 6 forced-air warming." It goes on to say, "Forced-air  
 7 warming systems have been shown to produce an  
 8 unintended consequence of disrupting operating room  
 9 airflow and contaminating the surgical field."  
 10 Do you see that?  
 11 **A. I do.**  
 12 Q. It talks about the clinical concern. It says, "The  
 13 U.S. Centers for Disease Control and Prevention  
 14 recently issued a warning: 'Nothing that blows air  
 15 should be in an operating theater, if possible.'"  
 16 You're aware of that statement from the CDC?  
 17 **A. Yes.**  
 18 Q. Do you agree with it?  
 19 MR. GORDON: Object to the form of the --  
 20 object to the form of the question, assumes facts not  
 21 in evidence, mischaracterizes the -- actually makes it  
 22 up.  
 23 MR. FARRAR: I wasn't laughing at you,  
 24 Mr. Gordon. I was laughing at sort of the --  
 25 MR. GORDON: Well, you --

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1 MR. GORDON: With the statement that  
 2 somebody made or with the fact that Michelle Hulse  
 3 Stevens participated?  
 4 BY MR. FARRAR:  
 5 Q. With the statement that nothing that blows air should  
 6 be in an operating theater, if possible.  
 7 **A. Well, I agree that they made that statement, yes.**  
 8 Q. I'm trying to ask you a different question.  
 9 Do you agree with the statement?  
 10 **A. Well, I'm not -- so, no, I don't agree with that.**  
 11 Q. Okay. You believe that there should be things in  
 12 the OR that blow air?  
 13 **A. Well, I'm just saying that in an operating room you  
 14 have human beings walking around that are breathing.  
 15 That's blowing air. You have equipment on the  
 16 physiologic monitoring systems. Those all have fans  
 17 and blowers in them. They're blowing air. So, I  
 18 mean, there are numerous pieces of equipment within a  
 19 modern operating room that blow air.**  
 20 Q. Sure. And there's a statement "if possible," right?  
 21 So we need people to do the surgeries, correct? So  
 22 it's not possible not to have them for the most part,  
 23 right?  
 24 **A. Right.**  
 25 Q. Right. So, I mean, the statement is "Nothing that

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1 MR. FARRAR: It's okay.  
 2 MR. GORDON: You kind of zinged it by me.  
 3 The FDA never said that, and you know the FDA never  
 4 said that.  
 5 MR. FARRAR: CDC. I'm sorry. If I said  
 6 FDA, I mean CDC.  
 7 MR. GORDON: The CDC never said it, and  
 8 you know that.  
 9 BY MR. FARRAR:  
 10 Q. You know there's a statement from at least somebody at  
 11 the CDC that says nothing that blows air should be  
 12 in the operating room, correct?  
 13 **A. I think that was an advisory panel empaneled by the  
 14 CDC that made that statement. I am aware of that  
 15 statement.**  
 16 Q. Okay. So an advisory panel for the CDC, and I'll just  
 17 quote it directly, said, quote: "Nothing that blows  
 18 air should be in an operating theater, if possible."  
 19 You're aware of that statement, guideline? How  
 20 would you like to characterize it?  
 21 **A. A statement.**  
 22 Q. All right. You know that Michelle Hulse Stevens  
 23 participated in those CDC meetings, correct?  
 24 **A. I believe I was aware of that, yes.**  
 25 Q. Do you agree with it or disagree with it?

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1 blows air should be in an operating theater, if  
 2 possible."  
 3 **A. Well, this statement is taken out of context. This is  
 4 referring to a special type of heater/cooler unit  
 5 that's used for cardiac surgery.**  
 6 Q. Well, to be fair, the statement doesn't say,  
 7 "Specialized heater/cooler units used for cardiac  
 8 surgery cannot be" --  
 9 **A. The statement here doesn't say that.**  
 10 Q. Sure.  
 11 **A. But that's what the -- that's what the advisory panel  
 12 was empowered to look at.**  
 13 Q. Oh, no question that's what they were looking at, but  
 14 the statement goes broader than that, right?  
 15 MR. GORDON: Object to the form of the  
 16 question, also lack of foundation.  
 17 BY MR. FARRAR:  
 18 Q. Let me -- let me ask you this question. Do you agree  
 19 with the basic proposition that we should try to  
 20 minimize the risks of infection in an operating room?  
 21 **A. Yes.**  
 22 Q. Do you agree with the statement that part of  
 23 minimizing that risk would be reducing the amount of  
 24 airborne turbulence?  
 25 **A. No.**

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1 Q. What do you rely on for the proposition that reducing  
 2 airborne -- or air turbulence would not reduce the  
 3 rate of infection?  
 4 **A. Well, there are a number of studies that look at  
 5 laminar airflow, for example, and show that it  
 6 increases the risk of joint infection, in patients  
 7 undergoing joint infection. These are studies out of  
 8 Australia and Germany that looked at this question.**  
 9 Q. Do you agree that research into the heater/cooler was  
 10 important because it found there was a piece of  
 11 equipment that was originally thought to be risk-free  
 12 was proven to be -- was proven to cause infections?  
 13 MR. GORDON: Object to the form of the  
 14 question.  
 15 **A. Well, I have no idea if it was thought to be  
 16 risk-free. I -- I kind of doubt it.**  
 17 BY MR. FARRAR:  
 18 Q. So, I guess, a different way to say it is: Would you  
 19 agree it's important to determine if a machine in the  
 20 operating room poses a risk that was previously  
 21 unknown?  
 22 **A. I'm sorry. State that again.**  
 23 Q. Sure. It would be -- it's important to find out if a  
 24 medical device in an operating room possesses a risk  
 25 that was previously unknown?

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1 **A. Yes.**  
 2 Q. And this particular risk with the heater/cooler was  
 3 unknown before a couple cases and then -- and then  
 4 study into it, correct?  
 5 **A. To my knowledge.**  
 6 Q. Okay. And it gave a mechanism -- mechanistic way  
 7 for an infection to occur in an operating room,  
 8 specifically blowing air, right?  
 9 MR. GORDON: Object to the form of the  
 10 question, incomplete hypothetical, lack of foundation.  
 11 **A. I believe what the investigators discovered was  
 12 that the chiller system of this heater/cooler unit had  
 13 water in it that was -- that had the same -- had the  
 14 same microbes in it as the patients who were used --  
 15 who were in -- exposed to it in that operating room.**  
 16 BY MR. FARRAR:  
 17 Q. So the heater/cooler harbored bacteria.  
 18 MR. GORDON: Object to the form of the  
 19 question.  
 20 **A. Well, they were able to culture bacteria from the  
 21 heater/cooler unit, yes.**  
 22 BY MR. FARRAR:  
 23 Q. And that bacteria was a real rare kind, so whenever it  
 24 got in somebody's body and created an infection, it  
 25 was easy to trace back to the heater/cooler, right?

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1 MR. GORDON: Object to the form of the  
 2 question.  
 3 **A. Yes.**  
 4 BY MR. FARRAR:  
 5 Q. It got into the heart tissue, I think, right?  
 6 **A. I believe so.**  
 7 Q. So it gave a mechanistic way for that to get inside  
 8 the body via blowing air, right?  
 9 **A. Well, I think that was supposition on the part of  
 10 the authors of this paper; but, I mean, yes, that's  
 11 what -- that was their proposal.**  
 12 Q. Okay. So the ultimate conclusion reached was there  
 13 were bacteria in the unit that got into the person  
 14 through blown air, correct?  
 15 **A. Well, that was part of the mechanism. The other part  
 16 was that the chiller unit in this heater/cooler unit  
 17 had a reservoir filled with water that was  
 18 contaminated with this particular kind of bacteria.**  
 19 Q. Right. That's what I was saying. There was -- the  
 20 machine itself harbored bacteria, and the bacteria got  
 21 into the patient via blowing air, right?  
 22 MR. GORDON: Object to the form of the  
 23 question.  
 24 **A. Well, again, I don't -- I'm not sure that the authors  
 25 of this investigation actually discovered that, but**

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1 **that's what they presume.**  
 2 BY MR. FARRAR:  
 3 Q. Well, that's a fair presumption because there's no  
 4 other real way it could have got from inside the  
 5 machine into someone's heart, right, other than being  
 6 blown there?  
 7 MR. GORDON: Object to the form of the  
 8 question, also lack of foundation.  
 9 **A. Again, I don't know. There may be other pathways.**  
 10 BY MR. FARRAR:  
 11 Q. In your knowledge, education, and experience, do you  
 12 not agree, sir, that that bacteria got to these folks'  
 13 hearts more likely than not via being blown through  
 14 the air?  
 15 MR. GORDON: Same objections.  
 16 **A. Well, I mean, I'd have to speculate. I don't know how  
 17 it got there.**  
 18 BY MR. FARRAR:  
 19 Q. You know that's what the researchers determined,  
 20 correct?  
 21 **A. Yes.**  
 22 MR. GORDON: Object to the form of the  
 23 question.  
 24 BY MR. FARRAR:  
 25 Q. You don't have any reason to disagree with them. You



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1 just haven't done the work on it, right?

2 **A. I'm not aware of -- yeah, I haven't done any work.**

3 Q. Okay. Clinicians in the field have from time to time

4 come to 3M, and specifically you've handled some of

5 those results or complaints or discussions regarding

6 the Bair Hugger harboring bacteria, correct?

7 MR. GORDON: Object to the form of the

8 question.

9 **A. I'm aware of complaints had been made, yes.**

10 **(Exhibit 24 was marked for identification.)**

11 BY MR. FARRAR:

12 Q. I hand you Exhibit 24, which is Bates labeled

13 3MBH01945219.

14 **A. (Reviewed.) Okay. I've read it.**

15 Q. This was, you would agree with me, complaints from

16 New Zealand coming in about contamination issues,

17 correct?

18 **A. I believe it was New Zealand, yes.**

19 Q. Okay. And the concern was the infection risk due to

20 infiltration, correct?

21 **A. That was the -- yes, that's the -- yeah, that's the**

22 **concern.**

23 Q. All right. And you agree with me that inside of the

24 Bair Hugger has bacteria, correct?

25 MR. GORDON: Objection, asked and

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1 answered.

2 **A. Yes.**

3 BY MR. FARRAR:

4 Q. The same with the hose. There's bacteria that can be

5 cultured from there, right?

6 **A. In most cases, yes.**

7 Q. To your knowledge, did Arizant or 3M ever notify

8 doctors that the inside of the Bair Hugger can harbor

9 bacteria?

10 **A. Not to my knowledge; but, again, in the labeling it's**

11 **not sterile.**

12 Q. To your knowledge, did 3M or Arizant ever notify

13 physicians or hospitals that the hose of the Bair

14 Hugger can contain bacteria, it can harbor bacteria?

15 **A. Not to my knowledge.**

16 **(Exhibit 25 was marked for identification.)**

17 Q. I'm going to hand you what I've marked as Exhibit 25,

18 sir. It is Bates labeled 3MBH01592941.

19 **A. (Reviewed.) Okay. I've read it.**

20 Q. The MHRA, that's the UK's version of the FDA, correct?

21 **A. Yes.**

22 Q. And who is ECRI?

23 **A. ECRI is a private company that does safety analyses of**

24 **medical devices.**

25 Q. They are a nonprofit, right?

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1 **A. I believe they are.**

2 Q. This is clearly regarding a meeting in 2011 on

3 March 9th with some ECRI folks and some folks from 3M,

4 correct?

5 MR. GORDON: Object to the form of the

6 question, also lack of foundation.

7 **A. The last part of the email is a note about a meeting**

8 **that's being set up to meet with the folks at ECRI,**

9 **yes.**

10 BY MR. FARRAR:

11 Q. Okay. And it looks like the folks at 3M were going

12 to bring Dr. Sessler and Dr. Olmstead with them?

13 MR. GORDON: Same objections.

14 **A. It looks like that, yes.**

15 BY MR. FARRAR:

16 Q. Were you aware of this meeting?

17 **A. I don't believe I was at the time.**

18 Q. I just want to ask you a couple questions on "What

19 topics do they want us to address," and the first

20 one, "Bacterial contamination of forced air warmer

21 systems - internal contamination," and the question,

22 "I would be interested in decontamination and

23 maintenance protocols."

24 Was there ever any decontamination protocol for

25 the Bair Hugger?

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1 **A. I believe in the instructions for use there are**

2 **instructions for decontaminating the Bair Hugger.**

3 Q. The outside, right?

4 **A. Correct.**

5 Q. Not the inside?

6 **A. Other than replacing the filter, no.**

7 Q. Replacing the filter wouldn't decontaminate the inside

8 of the Bair Hugger, correct?

9 **A. Well, no; but it would remove any contamination that**

10 **happened to exist on the intake of the Bair Hugger,**

11 **yes.**

12 Q. It wouldn't affect any contamination in the hose,

13 correct?

14 **A. Not contamination that was already there.**

15 Q. Okay. A couple points down, "Forced air warming

16 systems potential contribution to surgical site

17 infections - air movement plus bacteria?" That's the

18 disruption to laminar flow we've been talking about,

19 correct?

20 MR. GORDON: Object to the form of the

21 question, also lack of foundation.

22 **A. Well, I think the next point has to do with laminar**

23 **flow interruptions. I think this one has to do just**

24 **with its direct potential contribution.**

25 BY MR. FARRAR:

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1 Q. Did you provide any information regarding any of the  
 2 topics that ECRI wanted to talk to 3M about?  
 3 MR. GORDON: Object to the form of the  
 4 question.  
 5 **A. I don't remember preparing for this meeting in 2011.**  
 6 BY MR. FARRAR:  
 7 Q. A couple down it says, "Have you reported incidents to  
 8 the FDA and what criteria do you use?" Were you ever  
 9 responsible for reporting adverse events to the FDA?  
 10 **A. No.**  
 11 Q. Were you ever involved in it at all?  
 12 **A. No.**  
 13 Q. Do you know if 3M reported adverse events,  
 14 specifically infections, connected to the Bair Hugger  
 15 to the FDA?  
 16 **A. There's a -- there's a group that did report or at**  
 17 **least collected data from the MAUDE database where**  
 18 **clinicians report suspected adverse events.**  
 19 Q. Are you aware of the FDA ever reporting adverse events  
 20 to the F -- I'm sorry.  
 21 Are you aware of 3M ever reporting adverse events  
 22 to the FDA regarding infection in the Bair Hugger?  
 23 **A. I'm not aware personally.**  
 24 Q. You know that both clinicians and manufacturers report  
 25 to the MAUDE database?

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1 **A. Anybody can report to the MAUDE database. You don't**  
 2 **have to be a manufacturer or a clinician.**  
 3 Q. That's an actual obligation on the part of the  
 4 manufacturer if they have information, correct?  
 5 MR. GORDON: Object to the form of the  
 6 question.  
 7 **A. I'm sorry. Could you repeat it?**  
 8 BY MR. FARRAR:  
 9 Q. Yeah. It's a -- it's an obligation on the  
 10 manufacturer to report adverse events that are  
 11 connected to a medical device, correct?  
 12 **A. It depends on what type they are.**  
 13 Q. What do you mean?  
 14 **A. A death has to be reported within, I believe, 24**  
 15 **hours. They're graded, so --**  
 16 Q. Sure.  
 17 **A. A serious adverse event has to be reported within a**  
 18 **different time frame. I don't remember precisely what**  
 19 **the time frames are. Again, that's a regulatory group**  
 20 **responsibility.**  
 21 **(Exhibit 26 was marked for identification.)**  
 22 Q. I want to hand you what I've marked as Exhibit 26,  
 23 which is Bates labeled 3MBH01485746.  
 24 **A. (Reviewed.) Okay. I've read it.**  
 25 Q. Linda Johnsen, it looks like this is an email from

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1 her, the middle one, an email from her to you. She  
 2 was in regulatory affairs, correct?  
 3 **A. Yes.**  
 4 Q. And what she's telling you is that she's received a  
 5 number of complaints alleging infections, and it seems  
 6 to me that she's wanting some data to indicate that  
 7 it's not from the Bair Hugger. Is that fair?  
 8 MR. GORDON: I'll object, lack of  
 9 foundation.  
 10 **A. (Reviewed.) I'm still trying to -- I'm not sure the**  
 11 **entire chain is here, so it's hard for me to --**  
 12 BY MR. FARRAR:  
 13 Q. Yeah, let me --  
 14 **A. This looks like her response to something that I sent**  
 15 **to her.**  
 16 Q. Okay. And what she says is, "To be brief," and then  
 17 there's one -- there's two bullet points and then a  
 18 third down below. Bullet point number 1, "Received a  
 19 number of complaints alleging infections," correct?  
 20 **A. Yes.**  
 21 Q. Bullet point number 2, "Within the MDR reporting  
 22 requirements you are exempt from reporting" and then  
 23 "(Bold Emphasis Mine) based on CFR803.20 (C)(2)."  
 24 Do you see that?  
 25 **A. I do.**

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1 Q. She goes down what that means. And then she says,  
 2 "In summary, Looking for a qualified person article,  
 3 study or letter that would support decision as noted  
 4 above."  
 5 Do you see that?  
 6 **A. Yes.**  
 7 Q. And that would be noted being that you're exempt from  
 8 reporting, correct?  
 9 MR. GORDON: Object, lack of foundation.  
 10 **A. Well, so in bullet point 2 she says, "you are exempt**  
 11 **from reporting," yeah.**  
 12 BY MR. FARRAR:  
 13 Q. Right. Meaning 3M?  
 14 **A. I believe so.**  
 15 Q. Okay. This was in 2015. I forgot to make that point.  
 16 Right?  
 17 **A. Yes.**  
 18 Q. Okay. You attached some articles. They are something  
 19 from Anesthesia. I'm not sure what the rest of that  
 20 is. The Hall -- what is the first article, by the  
 21 way? Do you know?  
 22 **A. I'm not sure what article it is, but it's in**  
 23 **Anesthesia & Analgesia.**  
 24 Q. You don't know what the name of that article is --  
 25 **A. I don't.**

1 Q. -- from 2011?

2 **A. Not just from that citation.**

3 Q. The Hall presentation; the Memarzadeh; MHRA, I guess,

4 letters; Olmsted Poster; some other references.

5 Correct?

6 **A. Yes, it looks like that.**

7 Q. You knew at this time there was evidence to support

8 the contention that Bair Hugger causes infections,

9 correct?

10 MR. GORDON: Object to the form of the

11 question.

12 **A. I knew there were complaints.**

13 BY MR. FARRAR:

14 Q. You knew there was evidence, right, by 2015?

15 MR. GORDON: Object to the form of the

16 question.

17 **A. So -- I'm sorry. Would you repeat it again?**

18 BY MR. FARRAR:

19 Q. You knew by actually 2010 that there was evidence that

20 forced-air warming causes infections, correct?

21 MR. GORDON: Object to the form of the

22 question.

23 **A. Well, I knew that there were -- I knew that**

24 **clinicians, some clinicians had the opinion that that**

25 **was the case; and, yes, that is evidence.**

1 **(Exhibit 27 was marked for identification.)**

2 BY MR. FARRAR:

3 Q. I'm handing you Exhibit 27, which is Bates labeled

4 3MBH00001336.

5 **A. Yes.**

6 Q. You've seen this document before, correct?

7 **A. Yes.**

8 Q. Is this something you reviewed to prepare for your

9 deposition?

10 **A. No.**

11 Q. Okay. There is a -- at the very first there's a

12 position paper. This is still Arizant, correct?

13 **A. In 2010, June, yes.**

14 Q. Okay.

15 **A. Arizant.**

16 Q. And there's a position, "Our position," and it begins,

17 "There is no evidence that forced-air warming

18 increases risk of surgical site infections."

19 And you have a comment to that, the "no

20 evidence," correct?

21 **A. Yes.**

22 Q. Your comment says, "Actually, there is evidence that

23 forced-air warming use increases risk. This evidence

24 was the motivation for Dr. Memarzadeh's work."

25 Have I read that correctly?

1 **A. Yes.**

2 Q. So you knew in 2010 that there is evidence that

3 forced-air warming use increases risk, right?

4 **A. And, again, I knew in 2010 that there were experts who**

5 **had opinions that forced-air warming increased the**

6 **risk of surgical site infections, which is a form of**

7 **evidence.**

8 Q. Okay. Is that the only evidence that you're aware of

9 at that time?

10 **A. In 20 -- yes, I think so.**

11 Q. In 2015 you knew that there were published studies

12 that indicated the use of forced-air warming increased

13 the risk of surgical site infections, correct?

14 **A. The conclusions of some of them, yes.**

15 Q. That's not something you included in this email for

16 the FDA, the exhibit right before that, Number 26,

17 correct?

18 **A. Well, this isn't for the FDA. This is for an internal**

19 **person.**

20 Q. Who is providing the information -- or at least using

21 the information to make rationale to not report to the

22 FDA complaints of infections, correct?

23 **A. Well, they're two different things. So in this one**

24 **she's asking for articles -- "Looking for a qualified**

25 **person article, study or letter that would support the**

1 **decision as noted above."**

2 Q. Don't you think it would have been fair, Mr. Van

3 Duren, that if you had information that linked Bair

4 Hugger to surgical site infection you would give the

5 full body of evidence?

6 MR. GORDON: Object to the form of the

7 question.

8 **A. That's not what this person asked for. This is an**

9 **internal communication.**

10 BY MR. FARRAR:

11 Q. You would agree that it's an internal communication

12 designed to figure out a way to not report infections

13 to the FDA, correct?

14 MR. GORDON: Object to the form of the

15 question, lack of foundation.

16 **A. No. I mean, she's asking for an article I think to**

17 **identify a qualified person.**

18 BY MR. FARRAR:

19 Q. To identify a qualified person to call and talk to

20 about these particular complaints?

21 **A. Well, I think there are three things: a qualified**

22 **person, article, study, or letter. So she's looking**

23 **for four things to justify the decision.**

24 Q. The decision to not report to the FDA?

25 **A. I believe so.**

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1 Q. Don't you think it would be reasonable, Mr. Van Duren,  
 2 to respond to her and say, "Well, here are some  
 3 articles you want, but there's some evidence on the  
 4 other side that you should be aware of also"?

5 MR. GORDON: Object to the form of the  
 6 question.

7 **A. In this context, no. She was asking for a specific  
 8 justification, which I sent.**

9 BY MR. FARRAR:  
 10 Q. Do you know if she knew that there was evidence on the  
 11 other side?

12 **A. Well, I think she had complaints.**

13 Q. That would be evidence that it causes infections, the  
 14 Bair Hugger, correct?

15 MR. GORDON: Object to the form of the  
 16 question, lack of foundation, assumes facts not in  
 17 evidence. You haven't established the nature of the  
 18 complaints that we're talking about, and you know as  
 19 well as I do that they were all coming from Scott  
 20 Augustine.

21 **A. So the answer -- my answer is that in clinical  
 22 medicine we think of opinion as representing a low  
 23 form of evidence.**

24 BY MR. FARRAR:  
 25 Q. You had published, peer-reviewed studies in 2015

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1 showing that the Bair Hugger had a 3.8 times increased  
 2 risk of infection over conductive warming, correct?

3 MR. GORDON: Object to the form of the --  
 4 object to the form of the question, misstates and  
 5 mischaracterizes the evidence, assumes facts not in  
 6 evidence.

7 **A. Are you referring to the McGovern article?**

8 BY MR. FARRAR:  
 9 Q. Yes, sir, I am.

10 **A. So, I mean, that article has some substantial  
 11 limitations which even the authors of the article  
 12 acknowledge.**

13 Q. That wasn't the question. It was a peer-reviewed,  
 14 published article, correct?

15 **A. I don't know if it's peer-reviewed.**

16 MR. GORDON: Object to the form of the  
 17 question.

18 **A. Published, yes.**

19 MR. GORDON: And move to strike counsel's  
 20 prelude.

21 BY MR. FARRAR:  
 22 Q. The fact that you didn't agree with McGovern doesn't  
 23 mean it didn't exist, right?

24 MR. GORDON: Object to the form of the  
 25 question.

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1 **A. Well, I mean, of course it exists.**

2 BY MR. FARRAR:  
 3 Q. Can you name one other epidemiology study that refutes  
 4 McGovern?

5 **A. An epidemiological study?**

6 Q. Yes, sir.

7 **A. Not off the top of my head.**

8 Q. Are you aware that 3M from time to time has said that  
 9 the blankets themselves provide extra filtration?

10 **A. I believe I know we've asserted that at times, yes.**

11 Q. You would agree with me that the Bair Hugger blankets  
 12 were at no time designed specifically for the purpose  
 13 of filtering air coming out of the unit, correct?

14 **A. I joined Augustine Medical after the blankets were  
 15 already designed, so I'm not certain what all of the  
 16 design criteria for the blankets are.**

17 Q. I'm going to show you a different deposition than  
 18 we've talked about today. This is your deposition  
 19 from November 7th, 2016. And if you would, go to page  
 20 181, please.

21 **A. 181?**

22 Q. Yes, sir. 181, line 25, right at the end.  
 23 The question was: "Were the Bair Hugger blankets  
 24 at any point in time designed specifically for the  
 25 purposes of filtering air coming from the Bair Hugger

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1 unit?"

2 You said, "Not specifically."  
 3 Do you stand by that?

4 MR. GORDON: What page? What page are  
 5 you on?

6 **A. I don't see that on 181.**

7 BY MR. FARRAR:  
 8 Q. 181, line 25?

9 **A. Oh. Oh, yeah. Okay. Sorry.**

10 Q. Sorry.

11 **A. I didn't go far enough.**

12 Q. No, no. That's fine.

13 **A. It's on page 182 as well. Okay.**

14 Q. Yes, sir. I'll ask the question again.  
 15 181, line 25, the question was: "Were the Bair  
 16 Hugger blankets at any point in time designed  
 17 specifically for the purposes of filtering air coming  
 18 from the Bair Hugger unit?"  
 19 And you responded, "Not specifically."  
 20 Correct?

21 **A. Yes.**

22 Q. Do you stand by that answer?

23 **A. To my knowledge.**

24 Q. Sure.  
 25 Next question: "Okay. And in fact you didn't do

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1 any internal testing either at Arizant or to date at  
 2 3M relating to the specific filtering efficiencies of  
 3 those blankets, if any, correct, sir?"  
 4 And your response is: "Not that I recall."  
 5 Is that still accurate?  
 6 **A. Yes.**  
 7 Q. Okay. So, in short, the blankets were neither  
 8 designed for nor tested to determine their filtration  
 9 efficiencies, correct?  
 10 **A. I believe the study by Avidan provided some testing of**  
 11 **that theory.**  
 12 Q. You know there's case reports of soot coming out of  
 13 the Bair Hugger blanket, correct?  
 14 **A. I may have been aware of a failure of a warming unit**  
 15 **that caused soot to come out, yes.**  
 16 Q. From MD Anderson?  
 17 **A. Yeah, I don't remember.**  
 18 Q. Okay. If soot is coming out of the perforations of  
 19 the blanket, it's not filtering out microbes. Fair  
 20 enough?  
 21 MR. GORDON: Object to the form of the  
 22 question, lack of foundation, misstates the evidence,  
 23 mischaracterizes the evidence, and assumes facts not  
 24 in evidence.  
 25 **A. So, again, I don't know what the particulate size of**

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1 **A. Growing?**  
 2 Q. Yes, sir.  
 3 **A. I'm not aware of any studies like that.**  
 4 Q. Did you ever consult a microbiologist regarding  
 5 contamination issues with the Bair Hugger?  
 6 **A. No.**  
 7 Q. Never instructed anyone else to do so also, right?  
 8 **A. Not -- not that I recall.**  
 9 Q. You would agree with me that there are multiple  
 10 different ways to warm a patient for surgery?  
 11 **A. Yes.**  
 12 Q. Obviously, we've been talking about conductive, and  
 13 that would be like a HotDog or heating blanket, for  
 14 better word, correct?  
 15 **A. Yes.**  
 16 Q. Convective, which is forced-air warming, correct?  
 17 **A. Yes.**  
 18 Q. Reflective blankets?  
 19 **A. Not actively warming, no.**  
 20 Q. Okay. There is passive warming, hot cotton blankets,  
 21 warm cotton blankets, correct?  
 22 **A. Yes.**  
 23 Q. And prewarming, which is something that you've written  
 24 rather extensively about. Fair enough?  
 25 **A. Yes.**

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1 **soot is compared to the particles that are being**  
 2 **retained by the blanket.**  
 3 BY MR. FARRAR:  
 4 Q. Well, you can see soot. You can't see particles that  
 5 carry bacteria, right?  
 6 MR. GORDON: Object to the form of the  
 7 question, lack of foundation, assumes facts not in  
 8 evidence, and mischaracterizes the evidence.  
 9 **A. I'm sorry. Restate.**  
 10 BY MR. FARRAR:  
 11 Q. Is it your testimony that you believe soot particles  
 12 could be larger than particles that carry bacteria?  
 13 **A. I don't know.**  
 14 Q. Are you familiar with the article I'm talking about?  
 15 I think it's -- I don't know how to spell it -- or say  
 16 it, but it's T-S-A-I.  
 17 MR. FARRAR: How do you say that? "Say"?  
 18 MS. ZIMMERMAN: I think it's "Si."  
 19 MR. FARRAR: "Si."  
 20 **A. Not off the top of my head, no.**  
 21 BY MR. FARRAR:  
 22 Q. Is it fair that you're not aware of any studies at any  
 23 point in time by either Arizant or 3M to determine  
 24 whether there could be bacteria growing inside the  
 25 Bair Hugger?

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1 Q. Okay. 3M used to have the exclusive distributing  
 2 right for the VitaHEAT, which was a conductive  
 3 warming, correct?  
 4 **A. Yes.**  
 5 Q. Do you know if they still do?  
 6 **A. I don't know if they still do.**  
 7 Q. When you left the temperature management, did they?  
 8 **A. I don't know if that agreement is still in place or**  
 9 **not.**  
 10 Q. When you were in temperature management, that's  
 11 something that you would have known, right?  
 12 **A. Not necessarily. That would be a business decision.**  
 13 Q. Whether or not that you would have responsibility over  
 14 it? What do you mean it would be a business decision?  
 15 **A. I think you asked me if we had an exclusive**  
 16 **distributorship of that product. I don't know if that**  
 17 **still exists.**  
 18 Q. Do you have any distributing rights of the product?  
 19 **A. I don't know.**  
 20 Q. Did you when you left the temperature management  
 21 section?  
 22 **A. I don't know.**  
 23 Q. Is that not something you would have been working  
 24 on --  
 25 **A. No.**

1 Q. -- in temperature management?  
 2 Why not?  
 3 **A. Because that's a business decision.**  
 4 Q. And that's what I'm trying to figure out. Like a  
 5 business decision to be assigned to a different  
 6 person, you're saying?  
 7 **A. Well, it wasn't -- it didn't -- there was no**  
 8 **scientific involvement at that time for me with that**  
 9 **product.**  
 10 Q. Were you aware of any sort of falling-out with the  
 11 manufacturer of VitaHEAT and 3M?  
 12 **A. I was aware of that.**  
 13 Q. What was that about? Tell me what you know.  
 14 **A. I --**  
 15 MR. GORDON: Object to the form of the  
 16 question.  
 17 **A. There was some disagreement about the number of sales**  
 18 **of the device with 3M. That's really the extent of my**  
 19 **knowledge.**  
 20 BY MR. FARRAR:  
 21 Q. Who did you talk with about that?  
 22 **A. You know, I don't recall which person I spoke to about**  
 23 **that.**  
 24 Q. Do you know who was in charge of VitaHEAT at 3M?  
 25 **A. No, I do not.**

1 Q. On any -- whether it be regulatory or scientific or  
 2 any areas?  
 3 **A. I don't know.**  
 4 Q. I want to talk to you about prewarming, and I know we  
 5 sort of touched on it earlier, but get a little bit  
 6 back into that. Okay?  
 7 **A. Okay.**  
 8 Q. And I showed you the documents, but to sort of orient,  
 9 you think there's some advantages to prewarming, that  
 10 inexpensive, highly effective, not associated with  
 11 adverse events. Something that you wrote, correct?  
 12 **A. Yes.**  
 13 Q. You also wrote that there's a significant advantage in  
 14 that prewarming is done before the surgical incision,  
 15 which limits the potential contamination of the  
 16 surgical site.  
 17 Do you remember writing that?  
 18 **A. I remember reading it this morning, yes.**  
 19 Q. Okay. And you did significant work when you were at  
 20 both -- I guess starting at Arizant, or was it -- and  
 21 3M on prewarming?  
 22 **A. For most of my career, yes.**  
 23 Q. I won't mark this, but this is a "Prewarming for  
 24 future generations." Do you remember that picture?  
 25 **A. I do.**

1 Q. All right. That's you in there?  
 2 **A. Yes, it is.**  
 3 Q. All right. I'll just say the Bates number for the --  
 4 but my point being, Mr. Van Duren, is: This was near  
 5 and dear to your heart and something you really  
 6 believed in, right?  
 7 **A. Yes.**  
 8 Q. The Bates number of that picture is 3MBH00983123.  
 9 Do you agree that prewarming has been shown to  
 10 reduce the postoperative surgical wound infections by  
 11 a significant amount in large, randomized control  
 12 studies?  
 13 **A. I'm not -- I'm not certain if a study was conducted to**  
 14 **show simply prewarming reduced postoperative adverse**  
 15 **outcomes.**  
 16 Q. When you say "simply prewarming," you mean?  
 17 **A. Only.**  
 18 Q. Okay.  
 19 **A. Solely.**  
 20 Q. Gotcha.  
 21 (Exhibit 28 was marked for identification.)  
 22 Mr. Van Duren, I'm going to hand you what I've  
 23 marked Exhibit 28. This has got the last page torn  
 24 off. I'm sorry. I mean, it's on there. It's just  
 25 not stapled.

1 **A. (Reviewed.)**  
 2 Q. You ready?  
 3 **A. Yes.**  
 4 Q. I'm sorry. I was giving you a second. It was a  
 5 little bit long.  
 6 **A. Oh, I reviewed it.**  
 7 Q. Sure.  
 8 This is something you wrote in January 2005?  
 9 **A. It appears to be, yes.**  
 10 Q. Okay. Did you review this for your deposition today?  
 11 **A. No.**  
 12 Q. Have you reviewed it in the last couple years?  
 13 **A. No.**  
 14 Q. Okay. If you go to page 9 is the question I just  
 15 asked you. I just want to make sure I read it right.  
 16 The very bottom last paragraph on page 9, it  
 17 says, "Prewarming has been shown to reduce the  
 18 incidence of postoperative surgical wound infections  
 19 by a significant amount in a large, randomized control  
 20 study."  
 21 And that's the one you said you just don't know  
 22 if it was prewarming alone or both?  
 23 **A. Correct.**  
 24 Q. If you look at the cite on 69, does that help you?  
 25 **A. So as I recall, the Melling study was both pre and**

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1 **intraoperative warming.**  
 2 Q. Okay.  
 3 **A. It combined both. There were -- I mean, there were a**  
 4 **number of studies done by Andy Melling, so I'm not**  
 5 **sure precisely which one this is. Oh, this was one**  
 6 **that was in the Lancet. I think that included**  
 7 **intraoperative warming as well.**  
 8 Q. Okay. We can look it up, and it either does or  
 9 doesn't, right?  
 10 **A. Yeah.**  
 11 Q. I want to go to page 1, second paragraph. It says,  
 12 "Several devices and techniques are used to augment  
 13 heat gain or minimize heat loss in surgical patients."  
 14 Do you see that?  
 15 **A. Yes.**  
 16 Q. And that's what we talked about, there's different  
 17 ways, convective, conductive, even passive or  
 18 reflective, things of this nature, right?  
 19 **A. Correct.**  
 20 Q. You talk about convective first. That's forced-air  
 21 warming, correct?  
 22 **A. Yes.**  
 23 Q. And you say, "The few drawbacks to the use of  
 24 convective warming blankets include inadequate time to  
 25 deploy the systems in shorter duration cases,

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1 going to dominant the market or something like that.  
 2 Do you recall that?  
 3 MR. GORDON: Object to the form of the  
 4 question.  
 5 BY MR. FARRAR:  
 6 Q. Yeah, let's just find it. It's Exhibit 8. You can  
 7 just read off mine, if you'd like.  
 8 You say, "My goals - To convince you. The  
 9 company that figures out prewarming will win in the  
 10 marketplace." Correct?  
 11 **A. Yes. Okay.**  
 12 Q. So that was 2016. So this is eleven years before that  
 13 you're writing about the advantages of prewarming,  
 14 right?  
 15 **A. Yes.**  
 16 Q. And you're really comparing it to forced-air warming  
 17 for the most part. Is that fair?  
 18 **A. I'm not sure I'm comparing it to anything.**  
 19 Q. Well, if you do like a pros and cons, it's clearly why  
 20 it's better than something else or why it's worse than  
 21 something else, right?  
 22 **A. Well, I think I even said, "When performed correctly,**  
 23 **prewarming alone is capable of preventing significant**  
 24 **surgical hypothermia."**  
 25 Q. Right. Meaning you don't have to do intraoperative

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1 inaccessibility of patient skin surface area because  
 2 of surgical requirements, limited effectiveness during  
 3 the first hour of anesthesia, burn risks during aortic  
 4 cross-clamping or in patients with poor tissue  
 5 perfusion," and then last, "and unwillingness to use  
 6 forced air systems in ultra-clean surgeries such as  
 7 orthopedic cases."  
 8 That unwillingness came from clinicians' fear of  
 9 infection risks. Is that what you're referring to?  
 10 **A. Yes.**  
 11 Q. Okay. The next paragraph down, I'm not going to read  
 12 the whole thing, but right in the middle, it says,  
 13 "When performed correctly," and you're talking about  
 14 prewarming, you say, "prewarming alone is capable of  
 15 preventing significant surgical hypothermia for up to  
 16 3 hours in suitable individuals." Correct?  
 17 **A. Yes.**  
 18 Q. And that's something you still know here today, right?  
 19 **A. Yes.**  
 20 Q. Do you remember what the purpose of this -- what the  
 21 purpose of this paper was?  
 22 **A. I don't -- I don't recall why I wrote it.**  
 23 Q. That presentation, we looked at it earlier, you said  
 24 one of the goals of the presentation was to convince  
 25 readers that whoever figures out prewarming first is

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1 warming?  
 2 **A. In special cases, yeah.**  
 3 Q. Shorter cases, for instance?  
 4 **A. Well, in specially selected individuals, in shorter**  
 5 **cases, a number of things --**  
 6 Q. Okay.  
 7 **A. -- up to a line.**  
 8 Q. Sure. But in two hours prewarming is as effective as  
 9 intraoperative warming in maintaining normothermia.  
 10 Fair?  
 11 **A. No. It depends on how well it's conducted.**  
 12 Q. I want to look at page 11. You have a pros and cons  
 13 list related to convective prewarming, correct?  
 14 **A. Yes.**  
 15 Q. One of them is "Can be used when intraoperative  
 16 warming is contraindicated (aortic cross clamp," and  
 17 "orthopedic cases)." Correct?  
 18 **A. Yes.**  
 19 Q. And you talked about at page 1 aortic cross clamp  
 20 there is a risk of burn, correct?  
 21 **A. Yes.**  
 22 Q. Define "contraindicated."  
 23 **A. It means not indicated, indicated against.**  
 24 Q. Okay. So you're talking -- when you're talking about  
 25 orthopedic cases, you're talking about intraoperative

1 warming being not indicated or indicated against for  
2 those cases, correct?  
3 **A. That's what the statement means, yes.**  
4 Q. It means dangerous to use, right?  
5 **A. Well, it doesn't say "dangerous."**  
6 Q. Well, but you contraindicate things that are  
7 dangerous, right?  
8 MR. GORDON: Object to the form of the  
9 question.  
10 **A. Or ineffective.**  
11 BY MR. FARRAR:  
12 Q. Okay. Ineffective. So if it doesn't have any  
13 benefit -- we talked about that earlier. If there's  
14 no benefit, any risk would be unreasonable, right?  
15 MR. GORDON: Object to the form of the  
16 question.  
17 **A. Yes.**  
18 BY MR. FARRAR:  
19 Q. Okay. So what you said here is intraoperative  
20 warming, which would be forced-air warming, is  
21 contraindicated in orthopedic cases, correct?  
22 MR. GORDON: Object to the form of the  
23 question.  
24 **A. Well, it says "when intraoperative warming is**  
25 **contraindicated."**

1 BY MR. FARRAR:  
2 Q. Well, the two are examples, right?  
3 **A. They're examples.**  
4 Q. Okay. So orthopedic case is an example of when  
5 intraoperative warming would have been contra -- or is  
6 contraindicated, as you wrote in 2005?  
7 **A. Well, in the context of this document, again, I think**  
8 **you'll see that what I'm referring to is the notion**  
9 **that some clinicians were concerned that orthopedic**  
10 **warming with forced-air warming was hazardous.**  
11 Q. Clinicians being concerned doesn't contraindicate  
12 something, correct?  
13 **A. That's true.**  
14 Q. Okay. So your word -- I'm just using your words. You  
15 said intraoperative warming is contraindicated in  
16 orthopedic cases in the paper that you wrote in 2005,  
17 correct?  
18 MR. GORDON: Object to the form. Object  
19 to the form of the question, misstates the document.  
20 **A. So I did write that. This is a draft. It's not -- it**  
21 **was never published anywhere. I'm not even sure it**  
22 **was ever used internally.**  
23 BY MR. FARRAR:  
24 Q. Was it -- I know you said you don't remember exactly  
25 what it was for, but it was used for internal use. Is

1 that your understanding?  
2 **A. I'm not sure it ever was used internally.**  
3 Q. The purpose of it. When you were sitting down to  
4 write it, do you know if it was meant for internal use  
5 or external use?  
6 **A. I don't know what the purpose -- I don't remember why**  
7 **I wrote this.**  
8 Q. If you don't remember why you wrote it, how do you  
9 know it wasn't used?  
10 **A. It was never published internally. It was never**  
11 **published externally.**  
12 Q. I don't know what "published internally" means. Can  
13 you help me with that?  
14 **A. It was never made available to people internally to my**  
15 **recollection.**  
16 Q. How would something like this be made available to  
17 people internally in 2005?  
18 **A. A database.**  
19 Q. I'm sorry?  
20 **A. A database.**  
21 Q. Can I -- do you mind if I see your copy real quick?  
22 **A. Oh, sure.**  
23 Q. At the very top of yours, it's not on mine, but it  
24 says, "Clinical Research Library 1553." What does  
25 that mean?

1 **A. It means I filed it in my library.**  
2 Q. So that library is only for you and not for other  
3 folks?  
4 **A. Correct.**  
5 Q. It wouldn't be in the database that has access to  
6 other folks?  
7 **A. There is a database also that contains this.**  
8 Q. You said you don't remember drafting this, right? Or  
9 writing it?  
10 **A. No, I remember writing it. I just don't remember the**  
11 **reason for writing it.**  
12 Q. How do you know it's a draft?  
13 **A. Well, again, I don't believe I ever sent this to**  
14 **anyone. It certainly wasn't published in a -- in a**  
15 **journal.**  
16 Q. When you say "published in a journal," you mean  
17 externally?  
18 **A. Yes.**  
19 Q. There's 74 references on there, correct?  
20 **A. Yes.**  
21 Q. This took some time --  
22 **A. Yes.**  
23 Q. -- and effort and deliberate thought, correct?  
24 **A. Yes.**  
25 Q. I mean, this was -- you took pride in your work. So



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1 if you were going to write something like this,  
 2 presumably it was meant for other people, correct?  
 3 MR. GORDON: Object to the form of the  
 4 question.  
 5 **A. Again, I don't remember the reason that this was**  
 6 **written.**  
 7 BY MR. FARRAR:  
 8 Q. You would have written things to the best of your  
 9 knowledge and understanding and experience and  
 10 education at the time, correct?  
 11 **A. Yes.**  
 12 Q. So when you wrote, "Can be used when intraoperative  
 13 warming is contraindicated (aortic cross clamp," and  
 14 "orthopedic cases)," that was the best of your  
 15 information and knowledge at the time, correct?  
 16 MR. GORDON: Object to the form of the  
 17 question, mischaracterizes the document,  
 18 mischaracterizes his prior testimony, misstates his  
 19 prior testimony.  
 20 MR. FARRAR: For the record, I wasn't  
 21 stating his prior testimony at all, and I read the  
 22 words verbatim off the page.  
 23 BY MR. FARRAR:  
 24 Q. But you can answer.  
 25 **A. So this is a table that lists the pros and cons of**

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1 **the -- of convective warming.**  
 2 Q. Sure.  
 3 **A. And I'm listing to the best of my ability the sorts of**  
 4 **reasons why, you know, convective prewarming is**  
 5 **desirable.**  
 6 Q. Sure. And you're using all your knowledge and  
 7 resources available to do that. So that's my only  
 8 point, right? I mean, you're careful when you're  
 9 doing this?  
 10 **A. I hope so.**  
 11 Q. Okay. Some of the other pros, "Does not contaminate  
 12 sterile field." That's because it's not on when the  
 13 incision is made, correct?  
 14 **A. That's right.**  
 15 Q. If you go down a couple more, "Reduces the incidence  
 16 of surgical site infection." That could both be  
 17 because of normothermia and also it's not on when the  
 18 incision is on, correct? Or the incision has been  
 19 made.  
 20 MR. GORDON: Object to the form of the  
 21 question.  
 22 **A. It could be.**  
 23 BY MR. FARRAR:  
 24 Q. Okay. The next one, "Reduces the potential for  
 25 nosocomial transmission of pathogens by eliminating

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1 the need for intraoperative warming."  
 2 Did I read that correctly?  
 3 **A. Yes.**  
 4 Q. What is a nosocomial transmission of pathogens?  
 5 **A. That means caused by a clinician.**  
 6 Q. Okay. So if you're reducing the potential for that by  
 7 eliminating the need for intraoperative warming,  
 8 that's because, again, the warming isn't happening  
 9 while the incision is open, correct?  
 10 **A. Well, again, it's the potential for nosocomial**  
 11 **transmission.**  
 12 Q. Meaning there is a potential for nosocomial  
 13 transmission with intraoperative warming, correct?  
 14 **A. As perceived by some clinicians, yes.**  
 15 Q. There's no "as perceived by some clinicians" in your  
 16 document, right?  
 17 **A. Well, again, this is a draft.**  
 18 MR. GORDON: Object to the form of the  
 19 question.  
 20 BY MR. FARRAR:  
 21 Q. Nowhere on this document does it say the word "draft,"  
 22 correct?  
 23 **A. True.**  
 24 Q. And, in fact, there's a reference library number on  
 25 top of it, correct?

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1 **A. My personal reference library. That's not available**  
 2 **to anyone else.**  
 3 Q. You're telling me that -- I don't know if Mr. Hansen  
 4 was -- well, I guess he was -- Mr. Hansen was never  
 5 your boss when you went to 3M, correct?  
 6 **A. He may have been briefly.**  
 7 Q. In 2000 -- well, this is 2005. So this is at Arizant.  
 8 **A. This is -- this is at Arizant.**  
 9 Q. Okay. You're telling me Mr. Hansen didn't have access  
 10 to this document?  
 11 **A. I don't think he did. He did not have access to my**  
 12 **personal library.**  
 13 Q. Do you know if 3M has ever seen this document, folks  
 14 at 3M?  
 15 MR. GORDON: Outside of the context of  
 16 litigation?  
 17 MR. FARRAR: Yes, sir.  
 18 **A. I have no way of knowing.**  
 19 BY MR. FARRAR:  
 20 Q. Would it have -- would it have been something that  
 21 3M would have looked at in evaluating the acquisition  
 22 of Arizant?  
 23 **A. I don't know.**  
 24 Q. When Arizant purchased -- I'm sorry. When 3M  
 25 purchased Arizant, were you requested to give them

1 documents on the products that you were working on?  
 2 **A. I wasn't aware of the acquisition.**  
 3 Q. You didn't know it was happening when it happened?  
 4 **A. I did not.**  
 5 Q. How did you find out?  
 6 **A. There was a companywide meeting the morning of the**  
 7 **acquisition to let all the employees know.**  
 8 Q. Did you personally find this document through your own  
 9 search as the litigation unfolded?  
 10 **A. You mean in prior depositions?**  
 11 Q. Have you been asked about the document in other  
 12 depositions?  
 13 **A. I may have.**  
 14 Q. Okay. My question was something different.  
 15 Whenever 3M first was sued for allegations  
 16 related to the Bair Hugger, did you go in your files  
 17 and find this document, or was it found some other way  
 18 that you don't know?  
 19 **A. My entire library was taken out of the building and**  
 20 **recorded during, you know, discovery, and so I'm**  
 21 **assuming that that's where it was located.**  
 22 Q. Was it electronic or hard copy? Do you know?  
 23 **A. Well, they took my entire library physically.**  
 24 Q. Okay.  
 25 **A. So I don't know where it's stored, but likely it's**

1 BY MR. FARRAR:  
 2 Q. My point being is, you continued your work on  
 3 prewarming, correct?  
 4 **A. I'm not sure what you meant by "continued my work."**  
 5 Q. Well, 2005 you have this memo regarding prewarming and  
 6 talk about the pros and cons. That wasn't it. I  
 7 mean, you didn't stop studying prewarming at that  
 8 point, right?  
 9 **A. No.**  
 10 **(Exhibit 29 was marked for identification.)**  
 11 Q. Okay. I'll hand you what I've marked as Exhibit 29.  
 12 It's Bates labeled 3MBH00982867.  
 13 **A. (Reviewed.) Okay. I've reviewed it.**  
 14 Q. I'm looking at page 12 of 19. That's a chart that's  
 15 really similar to the one we saw before, but before we  
 16 do that, on page 1, this is September 6 of 2007. So  
 17 we're talking about two and a half years or so later,  
 18 correct?  
 19 **A. Later than the article was written, yes.**  
 20 Q. Later than the last --  
 21 **A. Version of this article?**  
 22 Q. Yes, sir.  
 23 **A. The prewarming article? Yes.**  
 24 Q. You got it.  
 25 And this -- again, you're the author of this?

1 **electronic.**  
 2 Q. Do you know how many different memos such as this were  
 3 in your personal library?  
 4 **A. No, I don't know.**  
 5 Q. If this one is 1553, does it mean there's at least  
 6 1,553, or did you have a different numbering system?  
 7 **A. Oh, you mean the total number of documents in my**  
 8 **library.**  
 9 Q. Yes, sir.  
 10 **A. It's around 5,000 now.**  
 11 Q. And there -- just so I understand what's in there, is  
 12 it things like this that are memos or research  
 13 projects about different products that either Arizant  
 14 or 3M was manufacturing?  
 15 **A. No -- no email memoranda or anything like that.**  
 16 **They're all clinical or -- clinical articles,**  
 17 **scientific articles only.**  
 18 Q. Scientific by other folks or by you?  
 19 **A. By other people, yeah.**  
 20 Q. Okay. You appreciate that this isn't the only time  
 21 that you listed pros for convective prewarming that  
 22 are similar to this, correct?  
 23 MR. GORDON: Object to the form of the  
 24 question.  
 25 **A. I mean, I don't know off the top of my head.**

1 **A. Yes.**  
 2 Q. Okay. And on page 12 of 19 is an advantages and  
 3 disadvantages chart. It's similar but a little bit  
 4 different, but under advantages of convective  
 5 prewarming you again say, "Can be used when  
 6 intraoperative warming is contraindicated (aortic  
 7 cross clamp," and "orthopedic cases)." Correct?  
 8 **A. Yes.**  
 9 Q. So, again, your words saying orthopedic cases  
 10 intraoperative warming is contraindicated, correct?  
 11 **A. Yes.**  
 12 Q. You also say, "Reduces the incidence of surgical site  
 13 infection," correct?  
 14 **A. Yes.**  
 15 Q. And I skipped "Does not contaminate sterile field."  
 16 Correct?  
 17 **A. I'm sorry. Where was that?**  
 18 Q. I'm sorry, I skipped one. If you go back up a few,  
 19 "Does not contaminate sterile field"?  
 20 **A. Oh, yes.**  
 21 Q. And then last, "Reduces the potential for nosocomial  
 22 transmission of pathogens by eliminating the need for  
 23 intraoperative warming." Correct?  
 24 **A. Yes.**  
 25 Q. So you're acknowledging that intraoperative warming

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1 has a potential for nosocomial transmission of  
 2 pathogens, correct?  
 3 MR. GORDON: Object to the form of the  
 4 question.  
 5 **A. In the minds of some clinicians, yes.**  
 6 BY MR. FARRAR:  
 7 Q. Nowhere in here does it say "in the minds of some  
 8 clinicians," right? These are your words saying it,  
 9 correct?  
 10 **A. That's correct.**  
 11 Q. Do you remember going to Paris in 2012 with  
 12 Dr. Sessler, Andrea Kurz, and some other folks on an  
 13 advisory meeting board?  
 14 Let me back up before.  
 15 **A. Okay.**  
 16 Q. I'm going to do one more thing before I forget.  
 17 **A. Okay.**  
 18 Q. The documents, the 2005 and the 2007 memo that we were  
 19 just talking about --  
 20 **A. Um-hmm.**  
 21 Q. -- did you ever send those to anybody outside of the  
 22 company?  
 23 **A. I don't know, but this is labeled "Draft." So I don't**  
 24 **know that it ever went any farther than my desk.**  
 25 Q. Do you know a Geraldine Desmond at Forest Hills

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1 Hospital?  
 2 **A. I don't remember who that is, no.**  
 3 Q. Do you recall sending any documents -- any of these  
 4 documents to someone at the Forest Hills Hospital?  
 5 **A. I don't remember doing it, no.**  
 6 Q. Do you remember seeing -- do you know a person named  
 7 Cindy Quest at -- Clint, I'm sorry, at Underwood  
 8 Memorial Hospital?  
 9 **A. I don't think I remember that person.**  
 10 Q. If there are emails showing that you sent these  
 11 documents to those folks, would you have any reason to  
 12 dispute it?  
 13 **A. No.**  
 14 MR. GORDON: Object to the form of the  
 15 question.  
 16 BY MR. FARRAR:  
 17 Q. Do you know Julie Powell?  
 18 **A. Yes.**  
 19 Q. And Jamie Collin? Collins?  
 20 **A. Yes.**  
 21 Q. Do you know if you circulated these drafts to either  
 22 of those folks?  
 23 **A. It's possible. I don't remember.**  
 24 MR. FARRAR: I'll tell you what. We've  
 25 been going a bit. Let's take a quick break.

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1 THE WITNESS: Okay.  
 2 THE VIDEOGRAPHER: We're off the record.  
 3 (Exhibit 30 was marked for identification.)  
 4 THE VIDEOGRAPHER: We're on the record.  
 5 BY MR. FARRAR:  
 6 Q. Mr. Van Duren, I've handed you what's marked as  
 7 Exhibit 30. It's 3MBH01242427, and this relates to a  
 8 patient warming globally -- global advisory board  
 9 meeting in June of 2012 in Paris.  
 10 Do you see that?  
 11 **A. Yes.**  
 12 Q. Do you remember attending this event?  
 13 **A. Yes.**  
 14 Q. Do you know who typed up this document?  
 15 **A. No. I was surprised to see it.**  
 16 Q. Okay. I've looked through it. It doesn't seem to  
 17 indicate who typed it, but I thought maybe you would  
 18 know.  
 19 If you look at the front, it has everybody's  
 20 initials. So Dan Sessler was there, Andrea Kurz was  
 21 there, Gary Hansen, Bob Buehler, Michelle Hulse  
 22 Stevens, and yourself and some other folks, correct?  
 23 **A. Yes.**  
 24 Q. These are either folks that worked at 3M, or I guess  
 25 Dan Sessler's a key opinion leader for 3M, correct?

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1 **A. Some private physicians, and the rest were employees**  
 2 **at 3M.**  
 3 Q. Okay. There's really only one page I wanted to ask  
 4 you about. I'll give you the Bates number. It ends  
 5 in 438.  
 6 **A. Okay.**  
 7 Q. And you see the first "DS," which is Dan Sessler,  
 8 correct?  
 9 **A. I believe so.**  
 10 Q. If you look at the cover page --  
 11 **A. Yeah, yeah.**  
 12 Q. -- it gives a -- and Mr. -- or Dr. Sessler, he writes,  
 13 I guess isn't accurate, but he's attributed to the  
 14 statement of "Need to pick an outcome. Not bleeding,  
 15 that's already established. So SSI or cardiac  
 16 events."  
 17 Do you see that?  
 18 **A. Yes.**  
 19 Q. Do you remember Dr. Sessler saying, "We need to pick  
 20 an outcome for the use of forced-air warming"?  
 21 **A. Well, I think this relates to the introduction of a**  
 22 **thermometric device called SpotOn at the time.**  
 23 Q. Okay.  
 24 **A. So this is not really forced-air warming. This is**  
 25 **zero heat flux thermometry --**

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1 Q. Okay.

2 **A. -- that's being discussed.**

3 Q. Let me ask you --

4 **A. I believe.**

5 Q. Sure.

6 And do you remember this advisory meeting

7 discussing forced-air warming at all?

8 **A. Well, no, I don't remember precisely what was**

9 **discussed. I'm going on these notes.**

10 Q. Okay. Wasn't SpotOn used to just measure temperature

11 intraoperatively, just a measuring device?

12 **A. Yes. It estimates core temperature.**

13 Q. Okay. So it doesn't actually help prevent

14 hypothermia, right?

15 MR. GORDON: Object to the form of the

16 question.

17 **A. No. It's a thermometer.**

18 BY MR. FARRAR:

19 Q. Right.

20 Two of the folks that were at this was Dan

21 Sessler and Andrea Kurz, right?

22 **A. Yes.**

23 Q. They're the folks who wrote the colorectal surgery

24 paper back in 1996?

25 **A. Yes.**

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1 Q. Okay. That same sentence, it says, "There have been

2 no outcomes studies on this since 1996 - no one has

3 looked at this since Frank. Frank was a very weak

4 study. They only looked at results after one day,

5 most within 1 to 2 hours after surgery."

6 Do you know what "Frank" refers to?

7 **A. I believe it refers to Steven Frank.**

8 Q. Was he an author in the Kurz-Sessler?

9 **A. No, I don't believe so.**

10 Q. Do you know what study this is referring to?

11 **A. Morbid cardiac events, I'm pretty sure, around the**

12 **same time frame.**

13 Q. Do you know what that study related to?

14 **A. Dr. Frank demonstrated that patients with hypothermia**

15 **had morbid cardiac events at a rate much higher**

16 **than -- I'm sorry, that hypothermic patients had**

17 **morbid cardiac events at a higher rate than**

18 **normothermic ones.**

19 Q. Okay. If we look down a little bit further, there's a

20 sentence in italics that says, "DS." Do you see that?

21 It begins with "DS argued."

22 **A. I'm sorry. What page?**

23 Q. Same page. I'm sorry. The one that had -- the same

24 as the need to pick an outcome part.

25 **A. Oh, okay.**

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1 Q. And there's a sentence in italics that begins with

2 "DS argued."

3 **A. I see it.**

4 Q. It says, "DS argued the case that the current evidence

5 base to support warming is too weak, with more

6 evidence needed to justify larger spending on patient

7 warming."

8 Do you see that?

9 **A. I see that.**

10 Q. Do you know what that was in reference to, any

11 specific type of surgery?

12 **A. Well, I'd have to read the whole document to see what**

13 **the context is, but I suspect it could apply to any**

14 **number of surgeries other than colorectal.**

15 Q. Okay. And you testified that in low complication

16 surgeries there's not much evidence for warming or the

17 evidence is pretty weak, correct?

18 **A. I believe I argued that doing studies in those low**

19 **event rate surgeries would -- would be very difficult.**

20 Q. Okay. That's all I have on that one.

21 I want to show you one more exhibit. Our court

22 reporter laughs at me.

23 MR. GORDON: We all do inwardly --

24 MR. FARRAR: Fair enough.

25 MR. GORDON: -- because we've all done it

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1 too.

2 MR. FARRAR: It's the dreaded "I only

3 have one more question, Your Honor."

4 MR. GORDON: Exactly.

5 (Exhibit 31 was marked for identification.)

6 BY MR. FARRAR:

7 Q. And so this will be marked as Exhibit 31. I'm not

8 going to ask you anything about the substance. I'm

9 just going to ask you who the folks are, so to sort of

10 save you time from reading it, if you'd like.

11 So this is Bates labeled Wagner00000013. Tell me

12 when you're ready.

13 **A. (Reviewed.)**

14 MS. ZIMMERMAN: It's a third-party

15 production from MDA. I believe Jennifer Wagner is her

16 name.

17 MR. GORDON: Oh, Jennifer.

18 MS. YOUNG: Oh, yes. I could not place

19 that. Thanks.

20 MR. GORDON: Yeah. Thanks.

21 **A. Okay. I've reviewed it.**

22 BY MR. FARRAR:

23 Q. So, Mr. Van Duren, in just sort of cursory, this looks

24 like it's discussing a CFD analysis done with the

25 Model 750 Bair Hugger, correct?

1 **A. No. It looks to me like this is a Schlieren**  
2 **photography protocol.**  
3 Q. Do you see on page 1, it says, "Introduction"? So let  
4 me -- I'll start again. It says, "Introduction:  
5 Computational fluid dynamic analysis" --  
6 **A. Okay.**  
7 Q. -- "and experimental flow visualization were used to  
8 study a plume of air effusing from the upper body Bair  
9 Hugger blanket as an independent component and  
10 integrated into a 'non-laminar' operating room."  
11 Do you see that?  
12 **A. Yes.**  
13 Q. Have you ever seen this document before today?  
14 **A. Not to my knowledge.**  
15 Q. Okay. The date is October 15, 2015?  
16 **A. It is.**  
17 Q. All right. Do you know who Dave Eaton is?  
18 **A. No.**  
19 Q. Do you know who James Endle is?  
20 **A. No.**  
21 Q. Do you know who Andrew Chen is?  
22 **A. No.**  
23 Q. Okay. If you look down at the bottom of the page,  
24 Andrew Chen looks like a design engineering services  
25 at 3M. Does that ring a bell, or no?

1 **A. I still don't know who he is. I mean, obviously he's**  
2 **a 3M employee.**  
3 Q. Sure.  
4 **A. Um-hmm.**  
5 Q. Before sitting here today, you don't have any  
6 recollection of ever seeing this document?  
7 **A. I'm pretty sure I've not seen this document before.**  
8 Q. Okay. It is titled "Internal Correspondence 3M  
9 Confidential Document," correct? Just at the very  
10 top?  
11 **A. Yes.**  
12 Q. And you testified earlier that you know that 3M has  
13 done internal CFD analysis, correct?  
14 **A. I believe they have, yes.**  
15 Q. Are you aware of the results?  
16 **A. No, I'm not.**  
17 Q. Have you ever seen them?  
18 **A. Not to my knowledge.**  
19 Q. All right. So it's not a situation where you saw them  
20 and can't remember them. You just don't remember ever  
21 actually seeing them?  
22 **A. I don't remember ever seeing any.**  
23 Q. I'm shifting gears a little bit.  
24 Something you said earlier, you talked about  
25 with the Model 200 it couldn't be used in the OR

1 because of the amount of heat?  
2 **A. High temperature.**  
3 Q. Okay. What was done to change that so that the Model  
4 500 could go into the OR?  
5 **A. Lower the temperature.**  
6 Q. Do you know how much it was lowered?  
7 **A. I believe that the upper limit threshold was around**  
8 **43 degrees plus or minus 2 degrees Celsius.**  
9 Q. With the 200 or the --  
10 **A. With the -- with the OR, with the 500 OR warming unit.**  
11 Q. How much of a change was that?  
12 **A. I believe that the Model 200 went up to 48 degrees**  
13 **Celsius.**  
14 Q. Do you know what testing was done to justify that  
15 reduction in temperature to where it was now safe for  
16 use in the OR?  
17 **A. No.**  
18 Q. Do you know when it was done?  
19 **A. No.**  
20 Q. One quick question on 31. The Schlieren testing that  
21 you looked at, is that the Schlieren testing that you  
22 were talking about earlier to justify the proposition  
23 that conductive blankets disturb airflow just as much  
24 as convective?  
25 **A. Again, I've never seen this -- to my knowledge, I've**

1 **never seen this document before. And, actually, I**  
2 **don't think I've even -- to my knowledge, I've never**  
3 **seen this facility --**  
4 Q. Okay.  
5 **A. -- that's described here in the document.**  
6 Q. And I could be wrong in this, but I believe you told  
7 me that the Schlieren testing that you were referring  
8 to was maybe 2010 or 2011. Does that seem right?  
9 **A. I believe there were discussions about doing it then,**  
10 **yes.**  
11 Q. Okay. So this may just be a different set of testing?  
12 **A. It could be.**  
13 Q. Fair enough.  
14 Are you aware that the FDA issued a letter in  
15 August of 2017 regarding clinicians' use of Bair  
16 Hugger?  
17 **A. I'd have to see the subject just to -- I'd have to see**  
18 **the letter. I mean, FDA issues lots of letters.**  
19 Q. I don't have a copy. I could probably take a break  
20 and grab one, but I guess I'll just ask you. Do you  
21 have a specific recollection of working with anybody  
22 at 3M to get the FDA information about a letter that  
23 they were going to submit to healthcare providers  
24 regarding use of forced-air warming or Bair Hugger?  
25 **A. No.**

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1 Q. So just your recollection is don't remember getting  
 2 any -- gathering any information or anything like that  
 3 for the FDA?  
 4 **A. I don't remember doing that.**  
 5 Q. Do you ever remember any work gathering information  
 6 for a law firm in Washington, D.C., to get information  
 7 to the FDA?  
 8 **A. About what topic? About what -- when?**  
 9 Q. Safety and efficacy of the Bair Hugger. And I'm  
 10 talking about specific in the 2017 time frame.  
 11 **A. Not that I recall.**  
 12 Q. I want to run through a few conductive systems and  
 13 just see if you're familiar with them and if they're  
 14 still on the market to your knowledge. Okay?  
 15 **A. Okay.**  
 16 Q. Are you familiar with the Cincinnati Sub-Zero surface  
 17 temp?  
 18 **A. Not -- not specifically.**  
 19 Q. Do you know if it's on the market or not?  
 20 **A. I don't know.**  
 21 Q. Okay. Obviously, the Augustine HotDog?  
 22 **A. Yes.**  
 23 Q. Okay. VitaHEAT?  
 24 **A. I don't believe that's on the market.**  
 25 Q. The BARRIER EasyWarm?

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1 **A. I'm aware of it. I don't know if it's still on the**  
 2 **market.**  
 3 Q. The Medline PerfecTemp?  
 4 **A. I'm not familiar with that one.**  
 5 Q. The Printler Medical -- Pintler. Sorry. Pintler,  
 6 P-I-N-T-L-E-R.  
 7 **A. I've heard of it.**  
 8 Q. Okay. These are all alternatives to forced-air  
 9 warming. Is that fair?  
 10 **A. Yes.**  
 11 Q. Okay. And we've seen some documents that -- well,  
 12 I'll scrap that.  
 13 I guess it suffices to say that there are  
 14 multiple ways to warm a patient for surgery. Fair?  
 15 **A. Yes.**  
 16 Q. Okay. And multiple effective ways, correct?  
 17 **A. No, I wouldn't agree with that.**  
 18 Q. Would you not agree that prewarming is effective?  
 19 **A. Prewarming is effective.**  
 20 Q. Do you think conductive is effective?  
 21 **A. It can be.**  
 22 Q. Okay. So that's what I'm saying. There are -- there  
 23 are options other than forced-air warming to warm a  
 24 patient intraoperatively. Fair?  
 25 **A. Yes.**

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1 MR. FARRAR: Okay. Mr. Van Duren, I  
 2 don't think I have any more questions for you today.  
 3 THE WITNESS: Okay.  
 4 MR. FARRAR: I appreciate it.  
 5 MR. GORDON: A couple things. Let me  
 6 just note that we'll have this transcript be  
 7 confidential just until we can review it and see if  
 8 there was anything. I suspect there wasn't, but in an  
 9 abundance of caution, we'll declare it confidential  
 10 under the protective order.  
 11 And I just want to note that we didn't in any way  
 12 restrict you to post-2017 questions, and rough  
 13 estimate here, I would say 90 percent or more of what  
 14 was asked was all pre-2017 anyway, but we didn't limit  
 15 in it in any way, so...  
 16 MR. FARRAR: I don't know if anybody on  
 17 the Zoom has any questions.  
 18 MR. GORDON: Good point. I'm sorry.  
 19 Anyone on Zoom?  
 20 MR. ERICKSON: Mark Erickson. No  
 21 questions from me.  
 22 MR. MCGREVEY: Sean McGrevey. No  
 23 questions.  
 24 MR. MCCAIG: Josh McCaig. No questions.  
 25 MR. KRONAWITTER: Joe Kronawitter. No

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1 questions.  
 2 MR. LUCAS: Chris Lucas. No questions.  
 3 MR. FARRAR: Is that it?  
 4 THE REPORTER: That's it.  
 5 THE VIDEOGRAPHER: Okay. We're going to  
 6 go off the record.  
 7 MR. GORDON: Yeah. And we'll read and  
 8 sign.  
 9 (Proceedings concluded at 4:26 p.m.)  
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1 CERTIFICATE OF REPORTER  
 2 STATE OF MINNESOTA  
 3 COUNTY OF SCOTT  
 4 Be it known that I took the foregoing videotaped  
 5 deposition of ALBERT VAN DUREN;  
 6 That I was then and there a Notary Public in and  
 7 for the County of Scott, Minnesota;  
 8 That by virtue thereof I was duly authorized to  
 9 administer an oath;  
 10 That the witness was by me first duly sworn to  
 11 testify the truth concerning the matter in controversy  
 12 aforesaid;  
 13 That the reading and signing of the deposition by  
 14 the witness was reserved;  
 15 That I am not related to nor an employee of any  
 16 of the parties hereto, nor a relative nor employee of  
 17 any party or counsel employed by the parties hereto,  
 18 nor interested in the outcome of the action.  
 19 WITNESS MY HAND AND SEAL this 1st day of February  
 20 2022.  
 21 \_\_\_\_\_  
 22  
 23 Rhonda Olynyk  
 Notary Public, Scott County  
 24  
 25

1 ERRATA SHEET  
 2  
 3 I, ALBERT VAN DUREN, certify that I have read  
 4 and examined the typewritten transcript of the  
 5 deposition taken of me in the matter referenced on  
 6 the first page on January 25, 2022, consisting of the  
 7 preceding pages, and find the same to be true and  
 8 correct.  
 9 (Except as follows):  
 10 PAGE:LINE CORRECTION REASON  
 11 : \_\_\_\_\_  
 12 : \_\_\_\_\_  
 13 : \_\_\_\_\_  
 14 : \_\_\_\_\_  
 15 : \_\_\_\_\_  
 16 : \_\_\_\_\_  
 17 : \_\_\_\_\_  
 18 : \_\_\_\_\_  
 19  
 20 Dated this \_\_\_\_ day of \_\_\_\_\_, 2022.  
 21  
 22  
 23 \_\_\_\_\_  
 ALBERT VAN DUREN  
 24  
 25

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