IN THE CIRCUIT COURT OF JACKSON COUNTY, MISSOURI

AT INDEPENDENCE

KATHERINE O'HAVER,)
Plaintiff,)
vs.)
ANESTHESIA) Case No:
ASSOCIATES OF KANSAS) 1816-CV-30710
CITY, P.C., et al.,) Division 12
Defendants.)

DOUGLAS TYE,)
Plaintiff,)
vs.)
ST. LUKE'S EAST) Case No: 1916-CV00825
ANESTHESIA SERVICES,)
P.C., et al.)
Defendants.

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APRIL 14, 2022

VIDEOTAPED DEPOSITION OF ALBERT VAN DUREN, AS CORPORATE REPRESENTATIVE OF 3M

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P R O C E E D I N G S

THE VIDEOGRAPHER: We're on the record. The court reporter will swear in the witness.

(Witness sworn.)

ALBERT VAN DUREN,

EXAMINATION

BY MR. ASSAAD:

Q Good morning, Mr. Van Duren. Could you please state your name for the record?

A Albert P. Van Duren.

Q I premarked Exhibit No. 1, which is titled: "Second Amended Notice of Videotape Deposition of Corporate Representative of 3M Company." Do you see that in front of you?

A Yes.

MR. ASSAAD: And just for the record, I'm going to identify the topics that we believe are covered today, and I believe defense was going to make their statement as well.

Based on our understanding and the Court's ruling, topics number 1, 2, 3, 4, 8, 9, 10, 21, 26, 27, 28, 29, and 31 are to be covered today, and you've been designated as the corporate representative.

I understand there are some issues with that, and I'll leave it for the defense to make their objection and their position.

MR. GORDON: Thank you. And as we just briefly discussed before the deposition commenced, with respect to topics 2, 8, 21 and 26, we had on July 28th, 2021, objected to several topics, included those four specifically that I just mentioned.

And then on December 16th, we reiterated those objections and provided a list of topics that 3M was willing to produce a witness on, and that list, likewise, omitted topics 2, 8, 21 and 26.

The December 16th letter requested the Plaintiff identify the topics Plaintiff intended to cover besides those that were agreed to. And on December 17th, the Plaintiffs responded or Plaintiff responded to that -- to the December 16th letter identifying additional topics that were still the subject of this agreement, but did not include in that list: 2, 8, 21 or 26.

And then in the opposition to the protective order, our motion for protective order, Plaintiff specifically referenced these

letters and represented to the Court that the parties have been able to narrow the topics and/or lines of questioning.

Based on that, we construe the topics as 2, 8, 21 and 26 as abandoned, and we did not prepare Mr. Van Duren on those. As I indicated to you, to the extent there are questions that fall within this, you know, the scope of what any of these four topics cover, Mr. Van Duren may well be in possession of knowledge, and you can certainly ask him about whatever it is you want. He has not -- but because of the back and forth that I explained to you, he has not been specifically prepared on that.

And this may just be a communication error. We weren't -- we didn't object to 29; but, I guess, the 29 and 30 are so similar because they involve lobbying, that perhaps our misunderstanding was that both of those would be covered by Mr. Issa.

So again, Mr. Van Duren was not specifically prepared on 29. To the extent that he has any knowledge about anything related to it, you're certainly free to ask him about it.

MR. ASSAAD: Thank you, Mr. Gordon. I

would just like to point out that as far as I'm aware, none of the numbers that you listed: 2, 8, 21, 26, have been -- any objections have been sustained by the Court.

And 29, we understand your position, so let's just continue and you can make your objections outside the scope and we can deal with it at a later point in time whether or not they are current topics or topics that were withdrawn.

BY MR. ASSAAD:

Q Mr. Van Duren, have you seen this notice before?

A I believe I've seen this notice, yes.

Q And when have you seen this notice?

A Yesterday.

Q Yesterday was the first time that you saw the notice?

A Yes.

Q Okay. I'm going to go through the instructions. And you have been designated as a 30(b)6 witness before, which is a corporate representative. You understand that, correct?

A Yes, I do.

Q Do you understand as a corporate representative you are speaking on behalf of the

company?

A Yes.

Q And you're aware I'm going to ask you numerous questions today?

A Yes.

Q If you don't understand my question, please let me know.

A Yes.

Q If you answer the question, we will assume that you understood the question. Fair enough?

A Yes.

Q And if you want to take a break, just request a break after any pending questions have been answered.

A Okay.

Q And when I use the term "you" during my deposition, that's referring to 3M. Do you understand that?

A I do.

Q Okay. When did you first become aware that you'll be testifying as a corporate representative on behalf of 3M?

A I believe a couple of weeks ago.

Q And what did you do to prepare for your

deposition?

A I reviewed materials that were related to the topics in this notification. Do you want to know specifically what those were?

Q We'll get there; but it's my understanding that you did not know the topics until yesterday?

MR. GORDON: Object to the form of the question. Misstates his testimony.

A I only saw this notice yesterday, but had been preparing for the deposition before that time.

Q What topics were you -- was your understanding that you would be discussing at today's deposition a few weeks -- like when you first learned about this deposition?

A Well, when I initially learned about it, I thought that the topic of the deposition was going to be a discussion of my library contents.

Q Okay.

A And maybe other associated papers.

Q And that -- that was based on your last deposition, which we continued because we did not have your library contents. But with respect to the 30(b)(6) corporate representative deposition,

what was your understanding of the topics you'd be testifying on behalf of 3M?

A I didn't know precisely what they were. Two weeks or maybe -- yeah, two weeks ago.

Q When did you discover what topics you were going to testify to on behalf of 3M?

A Sometime early last week.

Q Okay. What was your understanding of the topics that you'd be discussing for your corporate -- for the corporate deposition that we're here for today?

A That they would have to do with things like engineering, specifications, clinical papers, topics that are included in this notification, for example.

Q Were you provided the actual topics that you'd be -- that you have to prepare for to discuss for today?

A I was given a copy of this notification and a list of topics, yes.

Q Well, Exhibit 1 was given to you yesterday, correct?

A I believe that was the first time I saw it, yes.

Q Okay. Prior to giving -- you receiving

Exhibit 1, which is the deposition notice, how did you become aware of what topics you would be discussing today?

A I had discussions with attorneys.

Q Which attorneys?

A Corey Gordon, Ted -- sorry, I forgot his last name.

Q Hartman?

A -- Hartman, Ted Hartman. That was it.

Q Okay. And I'm just trying to get the timeline down.

When you first were told that you were going to be designated as a corporate representative, were you told what topics you would have to prepare for for the deposition?

A Not immediately, no.

Q Okay. When were you told the topics that you would have to prepare for for the deposition?

A Sometime last week.

Q Last week, early last week?

A Yeah, early last week.

Q Okay. You were aware of the topics today, correct?

A Yes.

Q Do you feel adequately prepared to answer

questions on those topics?

A Yes.

Q Okay. In preparation for today's deposition, did you have any communications with anyone besides counsel?

A Regarding these topics?

Q Yes.

A No.

Q How much time did you spend preparing for today's deposition?

A I think probably, somewhere around 20 hours.

Q When did you begin preparing for today's deposition?

A Early last week.

Q Okay. And last week would be the week of April 10th?

A Yes.

Q Okay. So since --

A No, no, no. This is April 15th.

Q Oh, I'm sorry, the 8th?

A 7th.

Q Now you got me all confused. Let's get this correct.

MR. GORDON: Are you sure you're

celebrating Easter a week from now?

Q So last Monday was April 4th. So when do you believe that you first became aware of the topics for today's deposition?

A Sometime after that date, but during last week, early last week.

Q So Tuesday or Wednesday?

A In that -- yes, probably.

Q Okay. So April 5th or 6th, would that be fair?

A Yes, that would be fair.

Q Okay. Was it through an email or through a conversation?

A It was through conversation.

Q Okay. And you mentioned that you spent roughly around 20 hours since April 5th or 6th in preparation for today's deposition?

A About that.

Q How many of those hours were spent with counsel for 3M?

A About ten.

Q Ten hours? And the other ten hours were just you preparing on your own?

A Yes.

Q And you didn't speak with anyone

regarding any of these topics in preparation for the deposition?

A No, I did not.

Q Okay. Did you have any conversations with -- withdraw that.

Did you review any documents in preparation for today's deposition?

A Yes.

Q What documents did you review?

A I reviewed a number of engineering documents. I reviewed sales training documents. I reviewed regulatory documents. I reviewed a number of letters from attorneys. I reviewed some corporate structure documents, personnel structure documents; some clinical documents related to bibliographies, that type of thing.

Q Letters from attorneys. Can you elaborate more on that, please?

A I reviewed a number of documents that were written by attorneys for Dr. Augustine. And also documents that were written in response to those documents from David Westlund, people like that; and other attorneys, Randy Benham. You know, I don't remember precisely every one of them, but I did review them.

Q Where were -- how did you obtain those documents?

A Through my attorneys.

Q Can you -- what were the subject matter of those documents, the ones from the attorneys to Scott Augustine?

A Well, they were all related in one way or another to assertions that Dr. Augustine had made about the operating room contamination associated with the Bair Hugger system.

Q And that -- you're talking about the assertions back in around 2000 -- after he left Arizant, correct?

A Yes. Yes, all after.

Q So the dates of all of those letters were after Arizant, correct?

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

A Well, they weren't all after Arizant. I think some of them were written -- some of them were written by personnel at Arizant Healthcare in response to letters sent by either Dr. Augustine or his attorneys.

Q I understand. But all the -- the date of the letters were after Scott Augustine left

Arizant?

A Yes. They were all after 2003, which I think is the date, roughly. I don't remember the exact month, but I think he left in 2003.

Q Okay. And what assertions are you talking about?

A Dr. Augustine was asserting that there were design flaws and lack of follow-up. I mean, a number of assertions related to the existence of contamination in the Bair Hugger system.

Q And you would agree with me that's not the first time -- these assertions or these ideas of airborne contamination in the operating room, that was not the first time Arizant was aware of that, correct?

A No, they were aware of these assertions much earlier than that.

Q How early?

A Well, I got -- I began working at Augustine Medical in 1994; and before that time, there had been -- Dr. Augustine was concerned about these matters then, and had commissioned research studies to investigate that problem or that assertion.

Q When you say Dr. Augustine was concerned

about these issues, we're talking about airborne contamination in the operating room, correct?

A Yes. Yes.

Q Okay. So when Arizant got these letters from Augustine or Augustine's attorneys, those assertions were nothing new to them?

A That's correct.

Q Okay. And in fact, when 3M bought Arizant Care for 810 million, 3M was aware of these assertions, correct?

A Certainly. Yes, they were.

Q So the issue of airborne contamination or the -- was known to Augustine before you arrive in 1994?

MR. GORDON: Object to the form of the question; also lack of foundation.

A I'm sorry, would you repeat that?

Q So there's no dispute that the issue of airborne contamination in an operating room was known to Augustine before 1994?

MR. GORDON: Same objection.

A You mean as a result of using forced-air warming or?

Q Yes.

A There were assertions from certain

customers that that could be a problem, yes.

Q Do you know how early those assertions were by certain customers?

A I don't know precisely when they began, but certainly between 1987 and 1994.

Q Well, you mentioned two studies that were commissioned by or studies that were commissioned by Augustine to look at this issue of airborne contamination, correct?

A I mentioned that he had commissioned studies, yes.

Q And that would be the Zink study, correct?

A That would be one of them, yes.

Q And Zink was 1993, correct?

A I don't remember the precise date, but probably.

Q Okay. I'll represent to you that it's 1993, and I can bring a copy at the next break.

A I think that sounds about right.

Q And also Hall and Teenier, correct?

A Yes.

Q And that was 1991 -- a poster in 1991, correct?

A Earlier than Zink, yes. I recall that.

Q And Hall and Teenier was the only two studies that were commissioned by Augustine to look into the issue of airborne contamination, correct?

MR. GORDON: You mean Hall and Zink? You said Hall and Teenier.

MR. ASSAAD: Correct. It's because Hall and Teenier is two names as well.

BY MR. ASSAAD:

Q Withdraw that question.

The two studies of Zink and Hall and Tenier were the only two studies commissioned by Augustine to look into the issue of airborne contamination in the operating room, correct?

A Prior to what date?

Q Prior to your arriving.

A Oh, I believe that's correct.

Q Are there any other studies that Arizant or Augustine Medical did to look into the airborne contamination that you're aware of?

A At any time?

Q Yeah.

A I mean, right now I don't recall specifically any studies that were done to look into that -- that Augustine Medical commissioned

to study that issue. I am aware of other studies that were done independently, but not commissioned by Augustine Medical.

Q Okay. Well, so would it be fair to say or accurate to say that the only two studies commissioned by Augustine Medical to look into airborne contamination in the operating room was the Zink study and the Hall and Teenier study?

A To my recollection, that's correct.

Q When you say "to my recollection," you're talking about 3M's recollection?

A Yes.

Q I kind of went off my outline here, so I'm going to go back a little bit.

So the letters that you reviewed, would it be accurate that they were involving the assertions, all the letters were regarding the letters by Dr. Augustine regarding airborne contamination in the operating room?

A Well, they were either -- they were either letters written by him or on his behalf regarding this issue and then responses to them.

Q Okay. Did you review any of the Bair Hugger manuals in preparation for today's deposition?

A Yes.
Q Which ones?
A A number of them. Early models of the model 200, Model 250, model 500 and its variant 500 OR, 505, 750.
Q 775?
A And 775, yes.
Q Is that the last Bair Hugger model designed was a 775 for inoperative warming?
A Well, there's a -- I don't recall the current model of the one that 3M developed after the acquisition, but I didn't review that particular manual. Also a model 600.
Q Okay. But to your knowledge, is there any model that came after the 775?
A Yes.
Q Which model?
A I don't remember the number. But -- yeah, I'm sorry, I don't recall the number, but it's a completely -- it was developed entirely at 3M.
Q Okay. What's the difference between the one made by 3M and the ones made by Arizant?
A It's smaller, has a completely different shape. It's a cone-shaped, rather than a

rectangular or roughly cuboid shape.

Q Do you use the same blankets?

A Yes. Yes.

Q Same output temperature?

A Yes.

Q 43 degrees on high, 43 degree celsius?

A Yes.

Q And in fact, all of the Bair Hugger models were set at 43 degrees celsius at the high temperature, correct?

A That's correct, although they did not all have the same tolerance.

Q Okay.

A But the setpoint temperatures, the high setpoint temperature is on all models were 43, with the exception of the Model 200 and 250. Those had higher temperatures.

Q What were the temperatures of those?

A Those are 40 -- I believe that the Model 200 was around 40 -- could reach temperatures around 46.

Q Within the tolerance, correct?

A No, that was a setpoint temperature. It might have been -- it might have been 44 or 46, I don't remember precisely, but it was higher than

43.

Q Okay. And that would be in the manual, correct?

A Yes.

Q Okay. And the Model 200 and 250, they were not to be used in an operating room, correct?

A That's right.

Q Because of airborne contamination, right?

A No, because of the high temperature setting.

Q Okay. Do you recall 3M or Arizant mentioning at any point that they did not use the 200 series in the operating room because of airborne contamination?

A I don't remember anybody stating that. That was not the reason.

Q Okay. So if -- well, okay. We'll get to that.

So you reviewed the manuals, correct?

A Yes.

Q All the manuals? Did you notice any inaccuracies or incorrect statements in the manuals?

A Not that I recall.

Q Okay. I mean, the manuals are reviewed by Augustine Medical, Arizant or 3M, you know, to make sure that they're accurate, correct?

A Yes.

Q Okay. And they're also reviewed by regulatory, correct?

A Yes.

Q Okay. To make sure that there's not any inaccurate statements, correct?

A That's the purpose of the review, yes.

Q And the manuals would consider any contradictions or warnings, correct? In the manuals will be the contradictions for the use of the Bair Hugger or any warnings?

A The contraindications?

Q Yeah, you're right. Contraindications, I'm sorry.

A So I'm sorry, state it again?

Q The manual contained contraindications, correct?

A And -- yes.

Q And warnings, correct?

A Yes, and cautions.

Q And cautions, okay. And to the best of 3M's knowledge, the manuals are accurate?

A To the best of our knowledge.

Q Okay. Because when you sell a medical device you should be -- you should have accurate statements in the manuals, correct?

A Yes.

Q It's very important, correct?

A Yes.

Q You don't want to mislead the customers with inaccurate statements in the manual, correct?

A We do our best not to mislead people, yes.

Q Okay. The documents that you reviewed in preparation for today's deposition, were they all provided to you by counsel?

A Not every one of them, no.

Q Okay. What documents were provided to you by counsel?

A The manuals, corporate structure documents, regulatory documents, legal documents, a number of categories of documents. I've got a bibliography that was produced by Dr. Augustine, for example. Things of that nature.

Q Okay. And what documents did you look up yourself or review yourself that were not given

to you by counsel?

A I reviewed a number of documents in my library. I don't remember precisely which ones they were, but they were documents related to the activities that were conducted in the late 1990s and 2000s, just to refresh my memory.

Q What type of documents, activities?

A Clinical papers.

Q Clinical papers? So articles?

A Yes.

Q So besides the clinical papers or articles, did you review any other documents that were not provided to you by counsel?

A No.

Q Okay. You've spent most of your life working in forced-air warming, correct?

A A large percentage of it, yes.

Q Since 1994?

A Yes.

Q And recently you have left the patient-warming division of 3M, correct?

A I did.

Q What year was that again?

A 2018.

Q Okay. But even afterwards you still

wrote articles on patient warming or papers on patient warming?

A Well, I wrote review documents, yes. Is that what you meant?

Q Yeah. And do you plan on retiring anytime soon?

A Within a couple of years.

Q Your departure from the patient-warming business at 3M, was that your decision or 3M's decision?

A That was my decision.

Q Why?

A Well, other opportunities had presented themselves with some new clinical research departments. And the patient-warming business is a very mature business at 3M, and so the investment in that business is somewhat less now than it was, and more significant investment is being made; the KCI business that 3M acquired.

Q What's KCI?

A It's a company, Kinetic Concepts Incorporated that they purchased.

Q Does it have anything to do with warming?

A There are aspects of that that include warming, or that include temperature management,

how about that?

Q Okay. What aspects?

A The KCI business is an advanced wound care technology. And the components of that therapy can be used to infuse and withdraw fluids from abdominal cavities, for example, so that's a heat and mass transfer problem. It's not primarily temperature management, however.

Q While you were -- I'll get back to it real quick. But has 3M considered getting into conductive heat warming instead of convective heat warming while you were there in the patient warming business?

A Yes.

Q Okay. And do you know whether or not they plan to come out with a conductive warming blanket?

A To my knowledge, no.

Q Okay. At one time they were involved with VitaHEAT, correct?

A Yes.

Q And that was a conductive blanket, correct?

A Yes, it was.

Q And that only lasted for about a year?

A In that -- yes, something like that.
Q Do you know why that terminated, their relationship?
A Well, I don't know precisely why it terminated, but the sales were terrible of that product, so probably related to the fact that we couldn't sell it.
Q Okay. Do you know whether or not there was any research and development by 3M with respect to inventing or creating a conductive warming device?
A I missed part of that.
Q Inventing or creating a conductive warming device?
A Not to my knowledge, other than VitaHEAT.
Q Okay. And you were one of the people that actually looked into VitaHEAT, correct?
A Yes.
Q Okay. And you believe it was a good product?
A No.
Q No? I mean, there were studies -- you agree that there were studies that show that it warmed patients effectively?
A There may have been, yeah.

Q Okay.

A I think there was a -- at the time I looked into the product, there was not very much clinical information regarding its performance.

Q Now, I just want to get -- just to understand the -- I like the term "genealogy" of the Bair Hugger. Like the beginning of the models and stuff, this is what I have, my understanding. The first Bair Hugger to be marketed was the 200 series, correct?

A Yes.

Q Okay. And that was -- the predicate medical device for the 200 was an Aircast warmer, correct?

A Yes.

Q The Sweetwater Aircast warmer that came out -- the pan came out in 1984?

A That was the predicate in the 510k submission to the FDA.

Q Okay. And this is before you, Mr. Van Duren, arrived at Augustine?

A Yes, this was in 1987.

Q Okay. And then 250 came out, correct?

A Yes.

Q Okay. And both of those were not to be

used in the operating room, correct?

A That's correct.

Q Okay. Then the 500 came out, correct?

A Yes.

Q What year did the 500 came out?

A I don't know what year that came out.

Q Okay. And then the 500 OR?

A That's right.

Q Okay. The 500 was not supposed to be used in an operating room as well, correct?

A Yes, that's correct.

Q It was not to be used in that operating room, correct?

A That's correct.

Q Okay. The 500 OR was the first Bair Hugger device to be used in an operating room, correct?

A Yes.

Q And then after that came the 505?

A I actually think there was a 502 --

Q Okay.

A -- that came after 500 OR and then the 505.

Q Okay. Was the 502 to be used in the operating room?

A Yes.

Q Okay. And just going back, the 200 and 250 series, they were primarily made to be used in the PACU?

A Yes.

Q Okay. And, in fact, that was the initial purpose of the formation of Augustine is to create a warming device to be used in the PACU?

A Yes, the whole purpose was to rewarm patients --

Q Okay.

A -- in the PACU.

Q Was the 500 -- withdraw the question.

So then after the 505 was the 750, correct?

A Yes.

Q And then after that was a 775?

A Yes.

Q And there was also a new one out by 3M that we don't know what the number is?

A Yeah, I'm sorry, I can't remember the number.

Q Does it have a name?

A No, they're all numbered.

Q Okay. And then there's a 600 series?

A There was.
Q Okay.
A That was a cooling device.
Q A cooling device? Okay. So besides the -- I've listed all the warming devices from the 200 to the 775, and then the new 3M -- I'm just going to call it the cone device.
A Okay.
Q Fair enough?
A Yes.
Q I'm sure we can look it up on the Internet. Is it to market already?
A Yes.
Q Okay. And you reviewed all the manuals that we've discussed?
A I did not review the 600 manual. I did review the 502 manual.
Q Okay. Who designed the original 200 series of Bair Hugger?
A I believe Scott and Doug Augustine.
Q Well, Scott Augustine is not an engineer, correct?
A No, he isn't.
Q Was -- did he hire an engineer? Was it a third-party company?

A I believe he put it together himself.
Q He put the 200 together himself?
A I believe so, and his dad, Doug Augustine.
Q Okay. And then started the company?
A Yes.
Q Okay. And my understanding is that he made it in his garage?
A Yes, that's right.
Q Kind of like the first PC, wasn't that made in the garage?
A I think a lot of inventions were made in garages.
Q Have you made anything in your garage, inventions?
A I have.
MR. GORDON: I've made a mess.
Q And just to be clear, in preparation for today's deposition, especially specific topic number one, which is the original design of the Bair Hugger warming system, you've had no conversations with Dr. Augustine to prepare for today's deposition?
A No.
Q When was the last time that you have seen

Dr. Augustine or had any conversations with him?

A Somewhere between 2003 and 2005.

Q Okay. Going back to the knowledge of 3M, and when I say "3M" I'm including 3M, Arizant, Augustine, all the companies. The issue of airborne contamination, do you know how early the issue was raised with Augustine Medical, like what year?

A I don't know precisely when that was raised. It had to have been somewhere between 1987 and 1994.

Q Okay. And when you joined Augustine Medical in 1994, that was after the Zink and Hall and Teenier studies, correct?

A Yes, they were before 1994.

Q Okay. Okay. Do you recall what, if anything, Augustine Medical or Arizant or 3M did to determine whether any of these issues of airborne contamination were actually true or not?

A I'm not aware of any activities that were done to confirm the suspicions that there were problems associated with that.

Q Were there any activities to confirm that the opposite is true, that there is no airborne contamination?

A I'm not aware of any activities that were done to confirm the opposite.

Q Okay. And when you say "you," you mean 3M, correct?

A 3M.

Q Okay. So as far as you know, until today there is no activities done by 3M, Arizant or Augustine to confirm that the Bair Hugger does not cause airborne contamination in the operating room?

A Well --

MR. GORDON: You're talking about internal?

MR. ASSAAD: Yes.

A Internal activities?

Q Yes.

A I'm not aware of any internal activities.

Q Okay. When you say "activities," you're referring to testing, correct?

A Testing, clinical trials.

Q CFD?

A There was some CFD activity looking at particulates. Not contamination, but particulates.

Q And you've seen the results of those

CFDs?

A I've read those papers.

Q The internal CFD?

A I'm not sure I've read those internal ones.

Q We're talking about internally. So internally 3M, Arizant, or Augustine did not perform any CFD analysis on the Bair Hugger to determine whether or not it can cause airborne contamination in the operating room?

A I think all of the CFD work was commissioned outside of 3M.

Q Okay. I'm just going to go through a list. We're going to create a list together about what 3M, Augustine and Arizant did internally to resolve the issue of whether or not the Bair Hugger causes airborne contamination in the operating room. Fair enough?

A Sure.

Q Okay. So we have two studies that were commissioned by Augustine which was Zink and Hall, correct?

A Yes. Yes.

Q Okay.

A Out of order, but yes.

Q Okay. Hall was 1991?
A Yeah.
Q And Zink was 1993?
A I think that's correct, yes.
Q What else?
A By Augustine?
Q By Augustine, Arizant or 3M.
A So are we talking particulate -- particulates or?
Q Anything to deal with airborne contamination in an operating room.
A So that --
Q Particulates, bacteria, calculation, engineering calculations, heat transfer, anything.
MR. GORDON: Are you talking about just what they did internally?
MR. ASSAAD: Internally.
MR. GORDON: Because, I mean, even Hall and --
MR. ASSAAD: Or they commissioned.
MR. GORDON: That's why I was asking.
A So I'm probably more familiar with the later activities. 3M commissioned some CFD work by Professor John Abraham.

BY MR. ASSAAD:

Q And that would have been in 2015, correct?

A I think that was the date that he did that work.

Q And that was a result of a lawsuit being filed?

A I don't know what prompted that work, but I'm sure it was related to lawsuits, yeah.

Q Okay. Let's -- okay. Let's start off before any lawsuit was filed, which I'll represent was in 2013, and then we'll go to what 3M did after the lawsuit was filed, okay? So prior to 2013 we have Hall and Zink. What else?

A Prior to 2013? It's a little difficult for me to remember precisely the order in which the contaminate papers appear. I mean, I'm just going to try to remember the ones that I can. I mean, I can think of one by Avadon, Michael Avadon.

Q That wasn't commissioned by 3M though, was it?

A No, that was an independent study.

Q We're talking about what 3M actually did or Arizant or Augustine.

A I'm -- again, I don't recall -- I don't recall papers or I don't recall any activity before 2013. Before -- yeah, that would be before -- I'm sorry, I don't recall any of the activities that occurred before 2013 related to this subject.

Q Well, we can agree, and I think you testified to this in the past, that as far as what 3M or Arizant did with internal testing, they did no internal testing to determine whether or not the Bair Hugger causes airborne contamination, correct?

A Well, those are -- those are activities that Arizant -- Augustine Medical or Arizant didn't have the capability of doing those kinds of studies internally.

The design of the forced-air warming unit was such that the specifications for the filters were used as the justification or explanation for the size of particles that would be excluded from the internal circuitry of the warming unit.

Q I'm going to restate my question again. I just need an answer to this.

With respect to internal tests, studies, activities, 3M and Arizant and Augustine

performed no internal tests, activities, calculations to determine whether or not the Bair Hugger causes airborne contamination in the operating room, correct?

A Those types of studies were commissioned outside of the companies.

Q And the only two studies that were commissioned outside of Arizant, Augustine Medical were the Zink and Hall study?

A Well, there was a study at, I believe, the University of -- or perhaps the Cleveland clinic or University of Minnesota by Curtis that was commissioned. I mean --

Q Regarding airborne contamination?

A Well, regarding perhaps the effects of airborne contamination. Comparing infection rates between HEPA filters and non HEPA filters. That would be the Curtis study.

Q Is the Curtis study the one at the Cleveland Clinic?

A I think it's the Cleveland Clinic.

Q Comparing the Mistral to the Bair Hugger, correct?

A Correct.

Q I got that. And that was commissioned by

3M?

A Yes.

Q Okay. But there was still forced-air warming against forced-air warming, it only changes like the filter, correct?

A Yes.

Q Okay. My question is this: Besides Zink and Hall, did 3M, Arizant or Augustine perform any internal tests or commissioned any test to determine whether or not forced-air warming increases particulates over the sterile field?

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

A Well, there were -- there was some studies done by Olmsted and Sessler that looked at particulate levels in an actual operating room with forced-air warming.

Q So now we have the Sessler-Olmsted study, the Zink study and the Hall study. Any other stuff that was done internally or commissioned by 3M, Arizant, or Augustine?

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

A Well, again, off the top of my head, I don't -- it's hard for me to remember which

studies were commissioned by 3M and which ones were conducted independently.

Q Let's take away studies for now.

A Okay.

Q Take away studies that were commissioned. Let's talk about internally; and I'll break this up even more.

The Bair Hugger produces heat, correct?

A Produces heated air, yes.

Q Heated air. And you agree with me that between 80 and 90 percent of the heated air is released into the environment?

A Well, I think all of it is released into the environment. 100 percent.

Q But some of it is absorbed by the body?

A No, none of the air is absorbed by the body.

Q Okay. None of the heat is absorbed by the body?

A The heat it, but not the air.

Q Okay. Okay. Let me rephrase. 80 to 90 percent of the heat is absorbed by the body -- is released into the air?

A I don't think it's quite that high, especially for the later models of the --

Q Okay. Do you recall giving a presentation regarding the waste heat with respect to the Bair Hugger?

A Do I?

Q Mmm-hmm.

A That's -- I may have; but no, I don't recall giving one.

Q Well, heat is released into the environment, correct?

A From?

Q From the Bair Hugger.

A Yes.

Q Okay. Did 3M ever look at the effect of the heat in an operating room environment internally?

A We did -- yeah, we did Schlieren photography studies, I think around 2011, maybe it was 2010.

Q Are you sure it wasn't 2015?

A I think it was earlier than that, but it could have been that late. It's possible.

Q Okay. What else?

A Well, again, so you were talking about internal studies related to particulates.

Q Related to the effect of the Bair Hugger

in an operating room environment. Let me back up. Let's back up. I'm going to start all over again. Okay.

The Bair Hugger was designed, correct, to be used in an operating room, correct?

A No, it was not. It was originally designed to be used in a PACU.

Q The 500 OR was designed to be used in an operating room?

A Yes.

Q And that was the first device to be used in an operating room, correct?

A Yes.

Q Okay. And that's the environments of use or one of the environments of use for a 500 OR is to be used in the operating room?

A Yes.

Q That's why the OR is there, correct?

A Yes.

Q Okay. And 3M, or Arizant or Augustine is aware that the OR is designed to remove particulates away from the sterile field, correct?

A That's one of the design considerations, yes.

Q Of an OR, correct?
A Yes.
Q I mean, that's the main purpose of an OR is to try to keep the area over the surgical site as sterile as possible, correct?
MR. GORDON: Object to the form of the question, lack of foundation, outside the scope.
A I think that's a major concern of a design consideration, yes, for an operating room.
Q Is to have a sterile environment, or try to get as much --
A No.
Q -- as close to sterile as possible?
A No, not sterile.
Q Try to remove as many particulates away from the sterile field?
A Well, and to evacuate gases and stuff like that that are toxic. I mean, there are a number of things that go into designing an operating room. That's one of them.
Q Okay. And that was known back in the 1980s and 1990s, correct?
A I'm sorry, what was?
Q That one of the purposes of an operating room is to remove particulates from the sterile

field?

A Well, I think one of the -- it doesn't remove particles from the sterile field. No operating room does that.

Q What does it do then?

A Well, it may reduce the population of particles in the air, but it can't remove them from the sterile field.

Q So you want to use the word "reduction"; is that better? Reduce particles over the sterile field?

A Over the sterile field?

Q Yeah.

A Yeah.

Q Okay. Let's use that then. So one of the purposes of the OR is to reduce the particles over the sterile field?

A Well, within the environment in the operating room, not just the sterile field, the entire operating room.

Q Yes, fair enough. So reduces particles from the operating room?

A Yes.

Q And that's why they have filtered air coming in from the vents and exhaust vents to

remove the air area, correct?

A Yes.

Q Okay. And 3M, Arizant and Augustine were aware that that is one of the purposes of an OR is to reduce particulates over the sterile fields?

A Yes.

Q In the operating room?

A Yep.

Q Because particulates carry bacteria?

MR. GORDON: Object to the form.

A They can.

Q Okay. And that was known to 3M, Arizant and Augustine, correct?

A Well, I think that's universally known.

Q Yes. I mean, that's why we have operating rooms instead of doing operations outside nowadays, correct?

A One reason, yes.

Q Is to control the environment?

A Yes.

Q Okay. And millions and millions of dollars are spent on operating room designs?

A Probably, yes.

Q Okay. This is not new science?

A No.

Q Okay. And Augustine, who is an anesthesiologist, and Arizant and 3M were aware of one of the functions of the operating room is to reduce particulates, correct?

A Yes.

Q Okay. What did Augustine do, Dr. Augustine do to determine whether or not the Bair Hugger in any way affected the ability of an operating room to reduce particulates over the sterile field?

A I'm sorry, would you repeat that question?

Q And I'm going to go by company by company.

A Okay.

Q What did Augustine Medical do, when they existed, to determine whether or not the 500 OR had any affect on the ability of an operating room to reduce particulates over the sterile field?

A I don't know that anything was done to investigate that.

Q Augustine Medical was aware that heat from the Bair Hugger blanket was being released

into the environment of the OR around the operating room table, correct?

A Well, I mean heat, heat is a form of energy that is absorbed by matter. It doesn't -- it's not, it doesn't exist in like an ether. I mean, it exists as a property of matter.

Q Yes.

A I mean, I'm not --

Q We could get technical on it. You and I have done it before, but I'm trying to keep it simple, okay? We can go into the law of thermodynamics, the second law of thermodynamics, heat transfer and all of that stuff. I'm just trying to keep it simple.

So energy, let's do energy, is being released around the operating room table?

A So heated air could be released around the operating room table, yes.

Q And Augustine was aware of that?

A Certainly.

Q Okay. With respect to -- and heated air is energy, correct? Heat is energy?

A That's right.

Q Okay. It's going to have an affect on the environment?

A It will.

Q Okay. What did Augustine Medical do to determine the affect of the heat that's being exhausted by the Bair Hugger, or emitted by the Bair Hugger on the environment of the operating room?

A Well, primarily investigations were made looking at the temperature management of patients under those conditions. So the application of heated air to patients under anesthesia, the amount by which their core temperature changed under those conditions was investigated in response to being warmed by the Bair Hugger.

Q So energy is being emitted, in a general sense -- let's just call it heat because it just makes it easier. Heat is being emitted by the Bair Hugger, okay? Some of that is being absorbed by the patient to warm the patient, correct?

A Mmm-hmm.

Q Yes?

A Yes.

Q Okay. And the rest of that heat, which is not absorbed by the patient, is being released into the OR environment, correct?

A Yes.

Q Okay. What did Augustine Medical do to determine the effect of that excess heat that is not absorbed by the human, its affect on the operating room environment?

A There were -- I think back in the '90s, I did some calculations to determine the effect of heated air on the temperature of the operating room. And, of course, back then most operating rooms were conventionally ventilated, not laminar-airflow ventilated. So I used standard design calculations to figure out if a forced-air warming unit had an additional load on the HVAC system of operating rooms.

Q And do you know what year that was?

A I don't know, but it's in my -- it's in my library.

Q Is that 1998?

A It -- yeah, it could have been in that era.

Q Is that whether or not the flow underneath the blanket was laminar or not laminar?

A No, no, no, this was -- this was a heating load calculation that was done.

Q Okay. And you performed the calculation?
A Yes.
Q Did you have any assistance?
A I don't believe so.
Q Okay. And you believe it was sometime in the '90s?
A It was in the '90s, yes.
Q Okay.
A But the question was whether -- the questions that customers had was, did the -- does the Bair Hugger add an additional heat load that cannot be compensated by the HVAC system in their operating room.
Q And was your analysis testing done in an operating room or calculations?
A All calculations.
Q All calculations. And in your calculations, did you take into account objects such as people, lights, and a patient and their heat loads?
A I think it was a very simplified model that looked at mass airflow from the HVAC system in the operating room combined with the mass airflow from the Bair Hugger systems.
Q So you didn't take into account any of

the other heat sources or obstructions in the operating room?

A Correct. It was merely the additional heat load from the warming system.

Q Okay. And what exactly were you trying to solve?

A Whether the Bair Hugger would overpower conventional HVAC systems in operating rooms.

Q When you say "overpower," what do you mean?

A Make it so that the room temperature could not be controlled, because it was adding so much additional heat that the air-conditioning couldn't compensate.

Q Okay. Did you look at the airflow, the affect of airflow in your calculations?

A Certainly, yes.

Q Okay. So you actually looked at airflow and whether or not there's a change in the airflow or any buoyancy?

A No, not buoyancy.

Q Okay. And for an operating room, did you look at an operating room size? You just looked at the HVAC load?

A No, I looked at different sizes. I

picked a size. There's a whole -- there's a whole manual on operating room design from either the --

Q ASHRE?

A Yeah, it's ASHRE. ASHRE has a whole manual on operating room design. I used their basic design calculations for airflow and size of the rooms.

Q You have a degree in physiology, correct?

A Yes.

Q And a minor in chemistry?

A A minor in biology.

Q Biology, I'm sorry. Well, according to your CV, you have a master's in physiology, correct?

A Yes.

Q A bachelor's in biology?

A Yes.

Q And a minor in chemistry?

A A minor in chemistry.

MS. ZIMMERMAN: Much more employable than my poly-sci.

Q Okay. You have no engineering degree, correct?

A My physiology degree, I did half of it in

the school of mechanical engineering at the University of Minnesota.

Q And so you took the law of -- you took heat transfer?

A I did.

Q Okay. And thermodynamics?

A Yes.

Q And fluid transfer, fluid dynamics?

A Fluid mechanics?

Q Yes.

A Yes.

Q But you don't hold yourself out as an expert in HVAC systems, do you?

A No.

Q And you don't hold yourself out as an expert as an engineer, correct?

A No.

Q Okay. Did -- why were you the one doing the calculations on the affect of the Bair Hugger instead of someone that is actually skilled in the art of engineering or HVAC?

A I think at the time we didn't have any mechanical engineers and it was of interest to me.

Q So it was something that -- you took it

upon yourself?

A Yes.

Q Okay. That makes sense.

Did you share your results with anybody?

A Yes. Yeah.

Q Who?

A I mean, this was some time ago. I don't recall who got a report or a response. I'm sure there was an email response sent to a person who asked about it.

Q Well, did someone ask you to do the testing or was -- you said you took it upon yourself?

A Someone asked me the question and I did the calculations. This was a common response to the role that I had at the time at Arizant.

Q Were there many institutions or hospitals that were asking for this information, the affect of the Bair Hugger on the HVAC system?

A No.

Q You said someone mentioned it or someone asked the question?

A Someone sent an email to me and asked the question.

Q Okay.

A I didn't know the answer, so I did this.

Q Okay. So my understanding is -- and we'll go get your notes in a second -- you did a laminar-flow calculation, correct? Regarding the Bair Hugger, whether or not it affects the laminar flow in an operating room?

A Oh, yes.

Q And you also did whether or not the heat load of a Bair Hugger affects the cooling -- the HVAC system in an operating room, correct?

A Mmm-hmm.

Q Okay.

MR. GORDON: You have to answer "yes" or "no."

A Yes. Sorry.

MR. ASSAAD: Thank you, Corey.

Q With respect to -- let's just take a break.

I'm going to go find your notes and so we can talk about it intelligently.

THE VIDEOGRAPHER: Off the record.

(Whereupon, a short recess was taken at 10:40 a.m.)

THE VIDEOGRAPHER: We're on the record.

MR. ASSAAD: Gabriel Assaad on behalf of

the Plaintiffs.

MS. ZIMMERMAN: Genevieve Zimmerman also on behalf of Plaintiffs.

MS. CAMPBELL: Tricia Campbell, and I believe Brett Emison is on by Zoom, with Langdon & Emison, on behalf of the Plaintiffs.

MR. FARRAR: Kyle Farrar on Zoom on behalf of Plaintiffs.

MR. GORDON: Corey Gordon and Charmaine Harris on behalf of 3M and the witness.

MR. MCCAIG: Joshua McCaig for Centerpoint Medical Center, Centerpoint Orthopedics and Dr. Gregory Ballard.

MR. KRONAWITTER: Joe Kronawitter for the Anesthesia Defendants on O'Haver.

MS. DAVIS: Lucy Davis for Kansas City Anesthesia, Defendants in O'Haver.

MR. BREER: Paul Breer here on behalf of Dr. Frevert and Rockhill Orthopaedics, PC appearing via Zoom.

MR. MCGREVEY: Sean McGrevey for St. Luke's East Hospital in the Tye case.

MR. ASSAAD: Is that everybody? I guess so.

BY MR. ASSAAD:

Q Going back to your calculations on the affect of heat on the HVAC system. Just to be clear, you did one calculation with one set of assumptions for a model OR; is that fair?

A I believe that's correct, yes.

Q You didn't look at any other sizes or any different ORs, you just used one OR?

A I believe I used the dimensions that were relayed to me by the person asking the question of the operating room.

Q Who was asking the question?

A I don't remember.

Q Okay.

A A salesperson.

Q To put it another way: You didn't do calculations for all ORs in the United States, you just used one OR?

A No, just one.

Q And you believe with respect to determining that question of the affect of the heat on the Bair Hugger and HVAC system, that it would be reasonable to use just one OR?

A Well, to answer the specific question, yes. It was not meant to be a general solution, it was meant to answer a question that I believe

the salesperson had about whether a HVAC system would be overwhelmed by a Bair Hugger.

Q Okay. But the conditions of the OR that you used, was that provided to you by the sales rep or by ASHRE?

A The dimensions were provided by the sales rep and then ASHRE provided a number of the other factors like flow rates and air exchanges per hour, that kind of thing.

Q So you did a calculation to answer the general question of whether or not the Bair Hugger's heat has an affect on the HVAC system in an OR?

A Yes.

Q I would like to go through the design process, which is one of the topics. And I think the best way I'm going to do it is just to go through the history, the genealogy of the Bair Hugger system; fair enough?

A Yeah, sure.

Q Okay. And just to go through the design process, it would be fair to say that Dr. Augustine identified a problem with patients, rewarming patients, and created a product to rewarm patients in the PACU, correct?

A That's correct.

Q Okay. And so he identified the problem and he designed the solution for the problem, correct?

A Yes.

Q Okay. And that's -- the design process, you identify a problem and you design a solution for the problem?

A In this case.

Q Okay. And part of designing a product, one of the key factors to look at is the environment of use, correct?

A Yes.

Q Okay. In designing a medical device, for example the Model 200, the environment of use was in the PACU, correct?

A Yes.

Q And you need to look at the PACU in the design process to determine what factors and what issues are there in the PACU in designing a medical device for the PACU, correct?

A Yes.

Q Okay. And the same thing with the design. When Augustine decides to design a forced-air warming unit for the operating room,

you have to look at the operating room's environment of use, correct?

A Yes.

Q Okay. And that's different than the PACU, correct?

A Well, I'm not certain what Dr. Augustine considered in the design phases; but in general, yes, the conditions that exist where you're going to operate the device must be considered.

Q So, for example -- withdraw that.

When Augustine Medical made the decision to design a forced-air warming device for the operating room, changes had to be made to the Model 200 because of the environment of use at the operating room instead of a PACU, correct?

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

A Well, the Model 200 or the Model 250, neither of those were modified to operate in the operating room. A brand new design was considered.

Q I understand that. But the premise design of a blower, a heating element, both consist in the 200 series and the series that was going to be used in the operating room, correct?

A Yes.

Q Okay. But certain considerations had to be made as part of the design process with respect to having a medical device in an operating room as compared to a PACU?

A Yes.

Q Okay. The intended use for the Model 200 or 250 was in the PACU?

A That's correct. The site of intended use was the PACU.

Q Okay. And the site of the intended use for the Model 500 was in the PACU?

A For the?

Q Model 500.

A Yes.

Q The intended use for the 500 OR was for the operating room?

A The site of intended use was in the operating room, yes, in the 500 OR.

Q Okay. And as part of the design process you have to take, as part of your design considerations, the environment of use, where the device is going to be used?

A Yes.

Q Okay. And in fact, under 3M's code of

conduct it states under "Product safety: As part of our mission to improve every life, 3M will provide our customers with quality products that are safe for their intended use." Correct?

A That is correct. However, 3M had nothing whatsoever to do with the 500 OR.

Q I understand that. But they bought the company, they bought Arizant, correct?

A Yes.

Q To meet their code of conduct, the company, 3M, Arizant, or Augustine needs to know the location of the intended use, correct? The site of the intended use?

A So the code of conduct at Arizant differs from the code of conduct at 3M, and I don't recall precisely what the code of conduct was at Arizant, but it's not the same as the one at 3M.

Q Well, I would assume that Arizant and Augustine had a code of conduct that promoted product safety?

A Yes.

Q Okay. And I assume both had a code of conduct to design products that are safe for the intended use?

A Yes.

Q Okay. And also safe for the environment of use?

A I'm not entirely certain what you mean by that.

Q Well, they have to be aware of its intended use, and, for example, the 500 OR the intended use is for use in an operating room?

A So intended use is a specific technical term that the FDA uses to decide whether to clear a product for use.

Q Let's not get -- I don't really want to get into the FDA. I'm talking about general design --

A But when you use the term "intended use," that is a specific term used by the FDA.

Q But it also has its ordinary meaning as well, correct?

A Well, I guess it depends on how you want to use it. For a person who works in a medical device industry, intended use has a very specific meaning, and especially to the FDA.

Q The environment of use must be taken into consideration in the design process of a medical device, correct?

A Yes.

Q Okay. And you would agree that with designing a medical device that's to be used in an operating room, that environment of use must be taken into consideration in designing that medical device?

A Yes.

Q Okay. And as part of the design for the 500 OR, the first forced-air warming device by Augustine to be used in an operating room, as part of the design process the fact that it would be used in an operating room, that environment of use must be taken into consideration in the design process?

A Yes, as well as the condition of patients in that environment.

Q There's many different factors, but that's one condition, is the environment of use?

A Yes.

Q Okay. And the reason why you take into consideration the environment of use is in the consideration of whether or not the medical device would be safe for that particular environment of use?

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

A So that's one consideration, yes.

Q For example, 3M, Arizant or Augustine, the company in general, was aware that the model 200, the 250 and the 500 was going to be used in an operating room -- strike that.

The Model 200, 250 and 500 was not safe to be used in an operating room?

A That's correct.

Q Okay. What changed between the model -- what changed between the devices that were not intended for use in the operating room and the 505 to make it suitable to be used in an operating room? I'm sorry, the 500 OR. I'm sorry.

A The nozzle temperature was lowered because it was understood that insensate patients would not be able to respond to very high temperatures that existed with the 200, the 250, and the 500 warming units. Those were acceptable for use when patients were in the PACU, but those were not acceptable for patients who were under anesthesia.

Q Anything else?

A A filter was added.

Q Well, there was a filter on the 200, 250

--

A A different filter was added.

Q What was the change in filter?

A I believe that at the time it was a 0.2 micron filter in the 500 OR warming unit.

Q What was used before in the 200, the 250 and the 500?

A I believe it was a 2 micron, 2.0 micron filter.

Q So in the 200, model 200, it was a 2 micron filter?

A Yes.

Q And the model 250 it was a 2 micron filter?

A Yes.

Q In the model of 500 it was a 2 micron filter?

A Yes.

Q And then the model 500 OR changed to a .2 micron filter, correct?

A Yes.

Q Okay. And what was the nozzle temperature in the Model 200?

A Something less than 46 degrees celsius or thereabouts.

Q And what about the Model 250?
A Same.
Q And what about the model 500?
A I believe the same there as well.
Q And when you're talking about the nozzle temperature, you're talking about the temperature of the air exiting the end of the nozzle?
A Yes.
Q Okay. And then what was the 500 OR, the temperature at the end?
A 43 degree celsius.
Q And would it be fair that every other model after the 500 OR was 43 degrees celsius?
A Yes. The high temperature subpoint was limited to 43 degree celsius.
Q Okay. So my understanding that one of the reasons the temperature was reduced from 46 degrees celsius to 43 degrees celsius, according to 3M, was that anesthestized patients, the higher temperature would affect them differently?
A They would not be able to respond by alerting a clinician that they were getting too hot, because they're under anesthesia.
MS. ZIMMERMAN: So if the anesthesia is working, they can't talk.

A Correct, they're insensate.
Q Okay. And that would be to prevent a thermal injury?
A That or just making them too hot. Hyperthermia.
Q Hyperthermia?
A Hyperthermia.
Q Okay. What studies were done or tests to support that the temperature setting for the OR needed to be reduced from 46 degrees -- or the temperature setting for the Bair Hugger that's used in an OR, that the output temperature needed to be reduced from 46 degrees to 43 degrees?
A I'm not sure that any studies were conducted to set that temperature. That temperature was the result of numerous studies that were conducted around World War II in airmen to determine burn thresholds, mainly for pilots in aircraft cockpits to decide when they got burned. So those were used as -- those were used to inform the decision to lower the temperature of the nozzle to prevent burns.
Q Okay. But those airmen were not anesthestized, correct?
A Correct.

Q Okay. Okay. Was there any clinical studies or scientific studies to show that for anesthestized patients, a company needs to reduce the output temperature from 46 degrees to 43 degrees?

A There were clinical studies conducted on volunteer soldiers to establish what the threshold limit was for burns in skin. These tests were done right after World War II and determined that burns, burns are the result of an accumulation of energy in the tissue. And after World War II, it was possible to make measurements of that and also burn people to determine where that occurred.

Now, these tests, of course, can no longer be conducted because it would be unethical, because we now know where the threshold occurs.

Q Was there any concern with respect to using the 200 series, the 200 to 250 -- withdraw the question.

Was there any concern with respect to the 200 that using the 200 in an operating room environment would cause airborne contamination?

A I don't know. But the main reason was

its temperature.

Q I understand the main reason, but there are many factors that go into a design process. One is the warming of the patient, the temperature, correct?

A Correct.

Q Another factor that should go into the design of a medical device that is used in an OR is whether or not it would cause any type of airborne contamination, correct?

A Yes.

Q Okay. Was that considered -- was there any discussion -- strike that.

Was airborne contamination one of the reasons why the Model 200 should not be used in an operating room?

A I don't believe that was a consideration because the Model 200 was never intended to be used in an operating room.

Q I understand that. But was one of the considerations or one of the reasons why it should not be used in an operating room is because it could cause airborne contamination?

A I don't believe so. Again, the model 200 and 250 were designed never to be used in an

operating room, primarily because of their temperatures.

Q Do you know whether or not 3M warned clinicians that the Model 200 or 250 should not be used in an operating room because it may cause airborne contamination?

A Well, 3M did not develop or sell the Model 200 or 250. That was done by Augustine Medical.

Q Okay. When I say 3M, I mean 3M and the companies that they have bought, which is Arizant, that bought Augustine. So if I use "the company," would that be better for you?

A Well, I guess my point is that the Model 200 and 250 were obsoleted devices long before 3M bought Arizant Healthcare.

Q I understand. I'm going through the design process.

I would assume that when, you know, you take what you learn from one device when you make a new device, especially with forced-air warming, correct?

A Mmm-hmm, yes.

Q Okay. So did -- and when I say "you," I want to be referring to all the companies, okay?

So did you take into account -- strike that.

Did you warn to the clinicians that the use of the 200 and 250 were prohibited in the operating room?

A We did warn that.

Q Did you warn clinicians that the model 200 and 250 may cause airborne contamination and therefore do not use in an operating room?

A Not for that reason.

Q So the answer to my question is "no"?

A No.

Q Okay. If the company warned about airborne contamination for use of the Model 200 or 250 in the operating room, would you know what the basis of that warning would be coming from?

MR. GORDON: Object to the form of the question, assumes facts not in evidence.

A I'm sorry, would you repeat that question?

Q Let me withdraw that question.

Were there any tests done on the 200 or 250 to determine whether or not it could cause airborne contamination?

A Not to my knowledge.

Q I would like to show what's been marked as Exhibit 1.

MR. GORDON: Exhibit 2?

MR. ASSAAD: Exhibit 2, I'm sorry.

(Whereupon, Exhibit 2 was marked for identification.)

BY MR. ASSAAD:

Q What's been marked as Exhibit 2 is a patent filed March 27, 1934, but issued on July 5, 1938, by E.J. Sweetland. Are you familiar with this document?

A I believe I've seen this before.

Q And this is a predicate device for -- provided to the FDA for the clearance of the Model 200, correct?

A I believe this is one of the predicate devices. I think there is another one.

Q Okay. And the Sweetland device is a cast warmer, correct?

A A cast dryer.

Q Cast dryer. Did you review this document in preparation for today's deposition?

A No.

Q But you've seen this document before?

A I have.

Q Okay. Do you know whether or not this is where the company got the idea to create a forced-air warming device for patients?

A I don't know that this is where Dr. Augustine got the idea.

Q Okay. But you're aware that this is one of the devices used to support their 510k FDA clearance?

A As a substantially equivalent predicate device, yes.

Q And the environment for use of the Sweetland drying apparatus is outside of an operating room, correct?

A Apparently so.

Q Okay. It's the same environment of use as say, for example, the Model 200?

A Well, again, 1938, I'm just going by the diagram here, it looks to me like the device is intended to be used in a patient room, it looks like a bed, so not even in a PACU.

Q Well, we could agree it's outside the operating room?

A Well, I mean, yes.

Q Okay.

A By the diagram.

Q Okay.

A I haven't read the patent in quite some time.

Q Do you know whether or not the Sweetland device ever went to production?

A I have no idea.

Q That's all I was going to ask you on that. Unless you feel like reading it just for fun.

A Oh, I was just going to see if they had a preferred location of operation.

(Whereupon, Exhibit 3 was marked for identification.)

Q What's been marked as Exhibit Number 3 is -- well, going back to the Sweetland patent, you were looking to determine whether or not location was listed in the patent --

A Yes.

Q -- where it should be used? Is that something that is usually listed in a patent?

A I doubt it in 1938.

Q Okay. What about now?

A It could be now.

Q It's basically up to the patent inventor as well as the examiner as to whether that

information is needed in the patent, correct?

A That's correct. But patents are a good bit more sophisticated now than they were in 1938.

Q I understand.

What's been marked as Exhibit 3 is the Model 200, 250 Operation Manual. Are you familiar with this document?

A Yes.

Q And I believe this document was published in 1988?

A I don't see a date on it, but it would have to be around that time because --

Q If you go to page --

A Oh, yes. Copyright 1988, Augustine Medical, Inc.

Q And you're familiar with this document, correct?

A Yes.

Q Okay. I want to go over a few things with this document. First of all, under the introduction it talks about its intended use to treat the common problem of post-operative hypothermia, correct? First paragraph under "Introduction."

A Well, again, intended use is a very specific, technical term used by the FDA. I'm not sure that that fits the description of what this describes.

Q Well, I guess there's -- I'm just -- I'm using "intended use" as to what the device was intended to be used for. Do you want me to use a different word? Is there a better word that you could use? I'm not speaking about regulatory.

Let me ask it this way: The Bair Hugger 250 system was to be used in a -- for post-operative hypothermia, correct?

A And the significant discomfort that occurs in patients that are cold after surgery; so two things.

Q Okay.

A And can be used to treat shivering, so actually three things.

Q But it was meant to be used in the post-operative period of patients that went through surgery?

A Yes, that's correct.

Q Okay. And so the Model 250, just so we can list it out to be clear, one use was for post-operative hypothermia, correct?

A Yes.

Q The second use was for significant discomfort that occurs in patients that are cold after surgery?

A Yes.

Q And the third use is that the Model 250 can be used to treat shivering and tremors?

A Yes.

Q All related to being cold after surgery?

A Mmm-hmm, that's correct.

Q Okay. Going back to one of the warnings, I want to point you to warning number four. It says, "The possibility of airborne contamination should be considered if patients with infected wounds are treated with the Bair Hugger." Did I read that correctly?

A Yes.

Q So that's one of the warnings that -- on the device of Model 200 and 250 is the possibility of airborne contamination should be considered if patients with infected wounds are treated with the Bair Hugger?

A Yes, that's a warning.

Q Okay. And what was the basis of this warning?

A I have no idea where it originated. Given that this is the first type of this device, probably was an appeal to logic.

Q Can you elaborate a little bit more on that?

A Well, since there was no -- there were no existing forced-air warming devices at the time, my guess is that the design team conducted a risk analysis of the device and came up with these warnings to address risks that were identified during the risk mitigation process.

Q Okay. So the design team at the time was Dr. Scott Augustine and his dad Doug Augustine, correct?

A Well, there may have been a couple of others as well, yes.

Q Okay. Do you know anyone else?

A Randy Arnold.

Q Anyone else?

A Not by name, no. Sorry.

Q Okay. And based on the risk analysis and the fact that the Bair Hugger blows air, one of the warnings they gave is the potential for airborne contamination?

MR. GORDON: Object to the form of the

question, incomplete.

A In patients with infected wounds.

Q Okay. So with a patient with an infected wound, the Bair Hugger might spread any bacteria in an infected wound in the environment?

A Well, again, the warning actually says, "the possibility of airborne contamination should be considered." It doesn't say that it will occur, it just says "should be considered."

Q Okay.

A That's the warning.

Q Should be considered if patients with infected wounds are treated with the Bair Hugger, correct?

A Yes.

Q And when treated with the Bair Hugger, you're treated with warm air blowing over your body?

A Yes.

Q And as a result of warm air blowing over your body, one of the concerns and what they warned for is that if you have an infected wound bacteria, that the possibility of airborne contamination should be considered?

A In the case of a patient with an infected

wound, yes.

Q And that's airborne contamination in the PACU?

A Yes.

Q Okay. Because bacteria could move through the air, correct?

A Again, that's what the warning is suggesting, that it should be considered.

Q Okay. Because bacteria can move through the air?

A Yes.

Q Okay. And bacteria is what causes infections?

A It's what causes bacterial infections. It doesn't cause viral infections.

Q Viruses cause viral infections?

A Correct.

Q Okay. Viruses and bacteria can travel through the air?

A I'm sorry?

Q Viruses and bacteria can travel through the air?

A Yes.

Q Okay. And that's probably more understood now with the whole COVID pandemic than

ever before?

MR. GORDON: Object to the form of the question, lack of foundation, vague.

A I'm not an expert in microbiology. I don't know if it's understood now more by clinicians than it was in the past.

Q The general public.

MR. GORDON: Same objection.

A Again, I don't know what the general public knows about transmission of microorganisms in an operating room.

Q Okay. Well, I'm talking about in general. Like everyone is wearing masks because of COVID, you know. People are aware that COVID travels through the air.

A There still seems to be some controversy about the effectiveness of those devices.

Q I want to go to page 5. And Dr. Augustine started his company, I believe, in 1987, correct?

A I think '87 was the first commercial product introduction, yes.

Q Okay. Which was the 200?

A Yes.

Q Let's look at the average temperature of

air surrounding the patient. It says the temperature settings here, "heat off, ambient temperature, low" -- we'll use celsius -- "33 degrees celsius, medium 37.6 degrees celsius, and high 43.1 degree celsius," correct?

A That's correct.

Q And I read that correctly, correct?

A You did read that correctly.

Q And so in the Model 200 the air coming out of the air nozzle is 43 degree celsius, correct?

A No, that's not what table says. It says, "Average temperature of air surrounding the patient." So this is an average of the air completely surrounding the patient in operation.

Q Okay. So this is what it estimates surrounding the patient?

A They may have estimated it.

Q Okay.

A It says "average," so I'm assuming that was a measurement.

Q Okay. Do you know how they came up with this number?

A No, I was not working there then.

Q Okay.

A I don't know.

Q All right. And then after the Model 200, I want to show you what the Model 500 is.

Let's mark this as Exhibit Number 4.

(Whereupon, Exhibit No. 4 was marked for identification.)

BY MR. ASSAAD:

Q What's been marked as Exhibit Number 4 is the Model 500, 500 E and 500 J. Have you seen this document before?

A Yes.

Q What is it?

A It's a service manual for the Model 500 warming system.

Q And do you know what year the Model 500 came out?

A I don't know what year it was introduced. Let's see, this manual probably has a copyright date. It looks like -- well, that can't be right. August of '78 would not be right. Oh, it's an Augustine numbering system. I don't know what year it came out.

Q Okay.

A It would have been before 1994.

Q Okay.

A That I know for certain.

Q If you look under the warnings on page 2, it has a similar warning as the Model 200. It says, "Due to the possibility of airborne contamination, the Bair Hugger warming cover should not be applied to services with open, infected wounds." Did I read that correctly?

A Yes.

Q And that's the same warning as the Model 200 and 250, correct?

A No, I believe it's different. I believe this one says "open, infected wounds." I don't think the previous one said "open."

Q You're right. That's correct. So they changed the warning to state "open, infected wounds"?

A Yes.

Q Do you know why the warning was changed?

A Again, most likely because a risk mitigation analysis determined that the real risk occurred when there were infected wounds that were open covered with the warming system.

Q A risk to who?

A Well, it could be a risk to the patient, it could be a risk to the clinicians. I don't

know -- again, I don't have that risk mitigation document, but I'm guessing just based on the difference in language.

Q But that would be part of the design process to look at the potential risks of a device, correct?

A Well, yes, it's part of the design process. But it's a separate process where the risks of the device are analyzed separately from the design of it.

Q I understand that. But the design process would include evaluating the device for potential risks?

A It does.

Q Okay. And in preparation for today's deposition, did you review any documents or have any discussions as to the source of data used to put these warnings in for the Model 200, 250 and the 500?

A No.

Q Okay. But you were aware of these warnings previously, correct?

A Yes.

Q Okay. And the reason behind the warning was that blowing air over an open, infected wound

could be a source of bacteria that could cause airborne contamination, correct?

A The reason for the warning was a mitigation due to a risk that was identified during the risk mitigation process.

Q So a risk was identified that blowing warm air over an open, infected wound may cause airborne contamination?

A Most likely, yes.

Q Okay. And they were concerned that the fact of possible airborne contamination could cause -- could be a source of bacteria that could cause harm to either the patient or other people in the PACU?

A I suspect that was the risk that was trying to be mitigated, yes.

Q Because they were concerned that the device can aerosolize bacteria from a wound and contaminate the area around the patient?

A Not just any wound, it says "an open, infected wound."

Q Okay. For the Model 500?

A Yep.

Q Okay. An open infected wound could aerosolize the bacteria that is on the open,

infected wound and cause harm to other people, including the patient?

A Yes.

Q Okay. Therefore, at this time, and the time of the 500, the company was aware that the Bair Hugger device can blow bacteria into the environment?

A Again, I don't know if it was aware. It identified as a potential risk the possibility that the device could blow bacteria from an open, infected wound.

Q And I understand that. They identified the risk that the Bair Hugger can blow bacteria from a patient into the environment?

A From an open, infected wound.

Q Okay. Well, when you say "open, infected wound," that means there's bacteria in the wound, correct?

A Yes.

Q Okay. But there is also bacteria on the patient's skin, correct?

A Yes.

Q Are you saying that the Bair Hugger is going to distinguish between the bacteria on the patient's skin and the bacteria in an open wound

and decide to just blow the bacteria and the open wound into the environment and not on the skin?

A No. What I'm saying is that the designers of this system identified this as a potential risk and used this warning to mitigate it.

Q And maybe I can simplify this a little bit. The warning here states -- they identify an open, infected wound as a source of bacteria, correct?

A They did.

Q Okay. So the concern is, there's a source of bacteria and there's a possibility that when the Bair Hugger blower blows over that source of bacteria, that it could cause -- it may cause airborne contamination, correct?

A That appears to be the concern.

Q Okay. And it was a risk identified as early as 1988?

A Yes.

Q Okay. And part of the design process -- and let me know if you agree with me -- is you identify a problem, correct, a potential problem?

A Well, go ahead and continue.

Q I just want to go step-by-step.

A Okay.
Q You identify a potential problem, correct?
A That can be part of the design process, yes.
Q You try to design around the problem or to solve the problem, potential problem, correct?
A Yes.
Q And if you can't design around it, you provide a warning?
A So we're talking about two different things here. So the design process is the process involved in developing a product. Risk mitigation is the process that is used to minimize the risks caused by the product.
Q And you're way more accurate than I am. But the risk mitigation is kind of a part of the design, overall design process?
A Well, it's included as part of the design process.
Q Okay.
A But risk mitigation is a strictly controlled, managed process that the FDA is very concerned about.
Q We'll forget about the FDA. I don't want

to talk about the FDA, but any medical device manufacturer.

A Well, the risk mitigation process is approved by the FDA and the standards promulgating bodies and we follow that.

Q I understand that. But regardless of the FDA, 3M's code of ethics wants to provide safe products, correct?

A Of course.

Q And whether or not it's the FDA requiring you to do it or internally, it's good business practice to identify risks of your product and to try to design -- design a solution or to warn about it, correct?

A Yes.

Q Okay. And in this situation, do you know whether or not the company tried to design out -- to make a design to avoid the possibility of airborne contamination regarding the Bair Hugger warming cover when applied to surfaces with open, infected wounds?

A Well, they attempted to mitigate it by using a warning.

Q Okay. And you agree with me that the warning should only -- should be used if you

cannot design a solution to design out a solution, correct -- to design out of a problem?

A The goal of the design process is to try and find an engineering solution; and if you can't do that, then mitigate it by instructions, labeling, warnings.

Q And based on the fact that there is a warning in Exhibit Number 4, that would mean that the company could not design out a solution for this possible risk?

A Well, at the time they couldn't design it out and mitigated it by a warning.

Q Okay. In other words, if there is a warning, the risk could not be eliminated through a design?

A At that time.

Q At that time. At the time, do you know what was done to try to design out or eliminate the risk through engineering design?

A I'm not aware of any engineering activity that went into mitigating this. I think it was mitigated by warning about it.

Q Okay. I would like to show you what's been marked -- what will be marked as Exhibit Number 5.

(Whereupon, Exhibit 5 was marked for identification.)

BY MR. ASSAAD:

Q Have you seen Exhibit Number 5 before?

A I've seen this hose card before, yes.

Q And I don't know the exact date of this, but I assume it does not apply to the Model 200 series. So it's either the 500 -- 500 OR or something past it?

A I'm sorry, say that one more time?

Q Do you know -- withdraw the question.

Based on looking at this document, do you know when this document was created?

A Well, it says, "Do not use 200 series warming units in the operating room." So I'm assuming that it had to be at least somewhere between 1987 and relatively recent times.

Q Okay.

A Since it's warning about using a product that existed in 1987.

Q And it specifically states: "Do not use the 200 series" -- "Do not use the 200 series warming units in the OR. Thermal injury and airborne contamination may result." Did I read that correctly?

A Yes.

Q So is it fair to say that one of the reasons that -- one of the warnings that the company is giving with respect to the 200 series is that thermal injury and airborne contamination may result if you use the Model 200 in the operating room?

A Yes.

Q Okay. When was the Model 200 phased out, if you know?

A I don't know when its manufacturing was terminated. I don't know.

Q Was it terminated before or after the introduction of the 500?

A Probably about the same time.

Q Okay. So when the manufacturing of the 500 began, they stopped manufacturing the 200 around the same time?

A I think that's correct.

Q Okay. Now, as you can see here on this warning -- withdraw that question.

The warning has two aspects, thermal injury and airborne contamination, correct?

A Yes.

Q Okay. Thermal injury as a result of the

200 has a higher temperature that may cause thermal injury?

A Yes.

Q Okay. The airborne contamination is a result of the 200 blowing air in the operating room?

A Yes.

Q Okay.

MR. GORDON: Are you done with 5?

MR. ASSAAD: Yes, I think -- am I done with 5?

MS. ZIMMERMAN: Yes. I mean, you never know.

(Whereupon, Exhibit 6 was marked for identification.)

BY MR. ASSAAD:

Q What's been marked as Exhibit 6 is a document titled -- I gave you the wrong one because I wrote on it.

"Bair Hugger Sales Training Manual, dated August 22-24, 1995." Do you see this?

A Yes.

Q Have you seen this document before?

A Yes.

Q Are you familiar with this document?

A I've scanned parts of this document this week.

Q Okay. I'm sorry to do this to you. I do have one more question on Exhibit Number 5. This is me.

We can agree, if you look at the second page on Exhibit 5, the copyright date is 1994, correct?

A Where is it?

Q The bottom under it says, "printed on 100 percent recycled paper," the line below it.

A I see date of issue, 12/1/94.

Q Yes.

A Is that right?

Q Yes, so 1994?

A So December 1st, 1994.

Q That talks about actually the patent number. The date of issue is 12/1/94.

A Oh.

Q Does that give you an idea of what device -- is it referring to the blanket?

A This is a Model 560 full surgical blanket.

MR. GORDON: Gabe, I can see they're sequentially numbered, but are these the same

document?

MS. ZIMMERMAN: I believe so.

MR. ASSAAD: Yes. 237, 238.

MR. GORDON: Okay.

A So this is a hose card.

BY MR. ASSAAD:

Q Yes.

A This looks to me like a package insert.

Q Okay.

A Unrelated.

Q To the hose card?

A It's unrelated to the hose card.

Q But it's still part of the whole package?

A No. This is actually part of the -- this is the mechanical part of the blanket that allows it to connect to the nozzle.

I think this looks like instructions that were included -- instructions for use that were included with the blanket, and it's for a Model 560.

Q Blanket?

A Yep.

Q Okay. So it's after 1994?

A Well, since the issue date -- oh, that was the patent date. Yeah, 1994 or after.

Q Okay. And the Model 560, is that a whole body blanket?

A It's a whole body surgical blanket, yes.

Q Okay. The 500 series blankets are surgical blankets, correct?

A All of -- yes, I believe that's correct. Yes.

Q And the 300 series blankets are for PACU, nonsurgical?

A Correct, full body, nonsurgical.

Q So if it's for a surgical blanket, it's for use in the operating room?

A Yes, which is another reason it warns against not using a Model 200.

Q Okay. Exhibit No. 6 is the "Bair Hugger Sales Training Manual." Just give me a second while I pull it up on my computer.

A Before you ask your next question, could I take a break?

MR. ASSAAD: Sure, let's take a break.

THE VIDEOGRAPHER: Off the record.

(Whereupon, a short recess was taken from 12:08 p.m. until 12:23 p.m., after which, the following transpired.)

THE VIDEOGRAPHER: On the record.

BY MR. ASSAAD:

Q Mr. Van Duren, just to be clear, the company was aware that blowing air can cause bacteria to aerosolize?

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

A Again, the risk mitigation determined that blowing air on an infected open wound could conceivably blow bacteria, yes.

Q In an operating room?

A In an operating room. Well, I think probably in any location because it was a warning on the Model 200, which was not permitted in an operating room.

Q And the reason to not use the Model 200 was because it could cause airborne contamination in the operating room?

A No. The reason not to use it was because the temperature was too high to use on insensate patients.

Q Well, in Exhibit 5 it says, "Do not use 200 series warming units in the OR. Thermal injury and airborne contamination may result."

A Okay. Perhaps both were considered.

Q Thermal injury would be a result of the

temperature as we discussed before, correct? The increased temperature of the Model 200, correct?

A Yes.

Q And then the other warning was airborne contamination?

A Yes.

Q Okay. In an OR?

A In an operating room, yes.

Q Okay. And I just want to clarify and try to simplify it a little bit. An open, infected wound has bacteria, correct?

A By definition.

Q Okay. So blowing air over the -- blowing the air can aerosolize the bacteria into the operating room?

A Well, that was the -- that was the risk that was identified, yes.

Q Okay. So the company identified that risk as early as the early 1990s?

A Perhaps even before.

Q Okay. Going back to Exhibit No. 6, you're familiar with this document, correct?

A Yes.

Q I would like you to turn to page -- it's page 3, but there's multiple 3s, but page 18 of

the whole document?

A The Bates number?

Q The Bates number is 7046.

Now, I just want to clarify something. You mentioned before that the Model 500 used a 2 micron filter. But here it states "The Model 500 and the 500 OR warming units use a .2 micron filter." Do you see that?

A I do see that.

Q Do you want to correct a previous statement or is the document incorrect?

A I may have been incorrect about the Model 500. The Model 200 and Model 250 had an extremely different type of air filter than was used later, so it's possible that the 500 and 500 OR used the 0.2 micron filter.

Q But the 500 was not supposed to be used in an operating room, correct?

A That is correct.

Q What was the difference between the 500 and the 500 OR?

A Well, they were mechanically different. The filters were different; the filter sizes were different. I believe the airflow was different. Like if you think there's a comparison table in

this document somewhere that compares the airflow of a 500 and a 500 OR. I'd have to hunt that down, but right now I can only find a table for operating room versions for the warming units.

Q Maybe as we go through the document you'll see it, and you can raise it if you see it.

A Okay.

Q That's not a big deal at this point.

So it goes on, under "Air filter," it says, "The Model 500 and 500 warming units use a .2 micron filter. This grade of filtration is identical to the laminar flow systems in operating rooms." Did I read that correctly?

A Yes.

Q Okay. A .2 micron filter is not a HEPA filter, correct?

A No.

Q It goes on, it says, "It is important to note that the Model 200 and 250 units have a reduced filtration level, more porous filter, and, therefore, should never be used in the operating room." Did I read that correctly?

A Yes.

Q Okay. What is it -- is the only reason

that the Model 200 and 250 -- or one of the reasons why a Model 200 and 250 should never be used in an operating room is because of the filter being used?

A According to this document, yes.

Q Okay. And according to the company?

A Yes.

Q Okay.

MR. GORDON: I'm sorry, did you say --

MR. ASSAAD: According to the company.

MR. GORDON: No, no, did you say that was the only reason?

THE WITNESS: No, one of.

MR. GORDON: One of, okay. I misheard.

BY MR. ASSAAD:

Q What studies were done to support this statement that the air filter used by the Model 200 and 250 was inadequate and therefore should never be used in an operating room?

MR. GORDON: Object to the form of the question, mischaracterizes the document.

A I don't know that studies were done to develop that warning.

Q Okay. So why was the warning in there -- why -- this is what is being taught to the sales

reps, correct?

A Yes.

Q Okay. So the sales reps are told, "It's important to note that the Model 200 and 250 warming units have a reduced filtration level, more porous filter, and therefore, should never be used in the operating room." I read that correctly, right?

A Yes.

Q So in layman's terms, because of the reduced filtration level, that made the Model 200 and 250 unacceptable to be used in an operating room environment, correct?

A Well, according to the paragraph, it looks like the purpose was to maintain the same level of filtration that existed in the HVAC system in the operating room with that of the warming unit.

Q Okay. I understand that's what the statement says before. What was it about -- what tests were done or analysis to support the statement that because the 250 and 200 have a more porous filter, that it should never be used in an operating room?

A Again, I don't know that any testing was

done; but the point here, according to this paragraph, is to maintain similar filtration levels to what already exists in an operating room.

Q Okay. Any other reason that you're aware of?

A Well, the temperature was elevated in the 200 and 250 units.

Q I understand. We're talking about filtration here --

A Oh, okay.

Q -- filter.

A I'm sorry, so what was the --

Q Any other reason besides maintaining the level of -- the same filtration as what occurs in the operating room?

A Well, not according to this paragraph, no.

Q Okay. Were any analysis -- I'm going to use an analysis, it can be studies, calculations, any type of scientific analysis -- withdraw that question.

The concern here about the filter is to avoid any type of airborne contamination with respect to the 200 and 250, correct?

A Again, the concern from this paragraph looks like the point here is to try and maintain the filtration level similar to what exists in the operating room.

Q Okay. Why did the company want to maintain the same level of filtration that is used in an operating room for the Bair Hugger device?

A I'm assuming it was an appeal to logic. You certainly didn't want to make it worse.

Q Okay. But if the air is already filtered in the operating room -- the air is already filtered by the HVAC system, correct?

A Correct.

Q So all the air in the operating room is filtered, correct?

A Yes.

Q Okay. So why would you want -- what was the purpose of maintaining that filtration for the Bair Hugger device that is just going to draw from that filtered air?

A Well, again, I don't know precisely the reason, but it's possible that contaminates could be introduced into the room that were not filtered by the HVAC system in that room. And

they didn't want to have filtration systems that had lower efficacy than those that had already exited in the room.

Q So there are contaminates in the operating room?

A Yeah.

Q Such as personnel?

A Well, the people in the operating room have bacteria on their skin and microorganisms, yes.

Q Okay. So one of the concerns was you wanted to filter the contaminants from the -- the added contaminants in the operating room from people through the Bair Hugger system so it wouldn't reintroduce those contaminants into the environment, correct?

A I think that's a likely explanation. But again, the reason is that they didn't want to have filtration levels that were lower than that that had already existed in the HVAC system.

Q Well, do you know what the filtration levels are in the other devices that filter air in the operating room, such as the anesthesia machine or the -- any of the other --

A Some of them don't have any filters on

them.

Q Okay. So the purpose of the filtration was to prevent airborne contamination. One of the purposes is to use the filtration to prevent airborne contamination in the operating room?

A Again, I think that's a likely reason that it was done. But the stated reason was to make sure that it wasn't worse than what already existed in the operating room.

Q Okay. And that would only filter -- withdraw that question.

MS. ZIMMERMAN: Do you mind if we take a quick break?

THE VIDEOGRAPHER: Off the record.

(Whereupon, a short recess was had.)

THE VIDEOGRAPHER: We're on the record.

BY MR. ASSAAD:

Q During the design process of the Bair Hugger devices, 3M was aware that the bioburn in an operating room increases as a result of personnel being in the operating room shedding squamous and bacteria?

A Yes.

Q Okay. And they were aware that in most operating rooms the bioburn would be directed

towards the ground and out the vents, correct?

A Yes.

Q And they're also aware that the Bair Hugger would be -- the intake manifold of the Bair Hugger, which draws in the air, is going to be where much of the bacteria and bioburn is directed towards the ground?

A It can be.

Q And one of the purposes of the filter was to filter any added contaminants that came from the personnel that would be brought in by the suction of the Bair Hugger and out into the patient?

A Yes.

Q Okay. And 3M was aware that heat rises?

A No, we're not aware of that.

Q The company wasn't aware that heat is less buoyant and rises?

A Heat is a form of energy, so heated air rises, yes. But heat itself only goes from an area of high energy to lower energy, regardless of direction.

Q Warm air rises, correct?

A Well, it's the cold air actually pushing down that makes the warm air appear to rise.

Q That's technically correct. We can go down that route.

Cold air is -- goes down and force the hot air to rise, correct?

A Correct.

Q And there's something called thermal plumes, correct?

A Yes.

Q And the company was aware of thermal plumes?

A Yes.

Q Okay. As early as the 1990s?

A Yes, I believe so.

Q And, in fact, even before the 1990s, I mean, this is not new science that hot air -- cold air goes down and hot air rises, correct?

A Thermal plumes have been visualized since the 1920s.

Q And thermal plumes can carry bacteria, and 3M was aware of that?

A They can.

Q Okay. And the company was aware of that?

A Yes.

Q Okay. And in fact, the company did Schlieren tests that showed the thermal plumes

coming off the Bair Hugger device?

A Well, we did Schlieren photography. I'm not sure I would call them tests; but we experimented with Schlieren devices to see if we could visualize these plumes, yes.

Q And you did visualize these plumes?

A Yes.

Q And you did Schlieren photography with the Bair Hugger under drapes?

A Yes.

Q Surgical drapes?

A Yes.

Q And thermal plumes were evident in the photography, correct?

A Correct.

Q And the thermal plumes would be seen going up, correct?

A Correct.

Q Because cold air is more dense and it goes down and the thermal plumes forms with the hot air and go up, correct?

A Yes.

Q And they carry bacteria up, correct?

A They can.

Q Okay. And you could see that -- you

could see the thermal plumes in the Schlieren photography?

A That we did internally?

Q Yes.

A Yes.

Q Okay. And in fact, the Schlieren photography just confirmed what science already knew regarding the affects of hot air in an environment?

A In certain environments, yes.

Q Okay. I mean, in any environment in the world, hot air is always going to be less dense than cold air?

A That's true, but that doesn't always mean that thermal plumes always exists.

Q I get that, that's why I asked the question that I did. Okay?

A And I wanted to make it clear --

Q Okay.

A -- that the conditions under which we visualized Schlieren photography were not those that exist in an operating room.

Q Okay. But thermal plumes did exist in the Schlieren photography as we've discussed before?

A Yes.
Q Okay. And the Schlieren photography was never done in an OR?
A Not by anybody at Arizant or 3M.
Q Okay. Anyone?
A I don't believe so.
Q Okay. And in fact, 3M is aware that in a non-OR environment, a Bair Hugger covered with a surgical drape will form thermal plumes, correct?
A Yes.
Q Okay. They have no evidence of what would occur because they never tested the thermal plumes that would form in an OR environment as a result of the Bair Hugger?
A I'm sorry, would you repeat that one?
Q They never did any studies to determine the thermal plume -- the effect of the Bair Hugger creating thermal plumes in an OR?
A When you said "we never did," you mean we never -- internally or?
Q Internally.
A We did not do that internally.
Q So therefore, internally there's no evidence as to whether or not thermal plumes would form or not form in an operating room

environment?

A There are a couple of studies that show the effect of conventional and laminar airflow ventilation in an operating room and their ability to suppress thermal plumes, both generated by human beings and also warmed patients.

Q Okay. A human being generates approximately 100 watts, correct?

A Usually a little more than that if they're awake and sitting up or standing. About 150 watts.

Q The Bair Hugger generates about 850 watts?

A Perhaps a little less than that.

Q 800?

A You know, I don't know precisely what it is.

Q My point is, it's on a scale of three to four times more energy producing than a human being standing?

A Power.

Q Power?

A Producing, yes.

Q Okay. Power is energy?

A No, power is the rate of energy utilization.

Q So the rate of energy produced by a Bair Hugger is three to four times more than a human being?

A In that range.

Q Okay. And 3M clearly saw thermal plumes outside the OR environment doing Schlieren photography, correct?

A Yes.

Q 3M -- or the company has no evidence of the size of the thermal plumes or if any exists of the Bair Hugger device being used in an operating room?

A We do have clinical data that show the effect of thermal plumes being generated by human beings in an operating room setting, being suppressed or being reversed by laminar and conventional airflow.

Q Well, we're talking about the Bair Hugger here, which has three to four times more --

A Yes.

Q -- power than a human, correct?

A Yes.

Q Okay. Same question: 3M has no evidence

of the plumes that are generated and the effect of those plumes in an operating room because no study was done in an operating room with respect to the plume formation of a Bair Hugger device?

A No, that's incorrect. There is a study that shows the suppression of thermal plumes using a Bair Hugger in an operating room.

Q Is that the Settles?

A No, it's by Shirozu.

Q The CFD study by Shirozu?

A No, this is a -- this is an array that was placed, that he built, placed over the operating room table that measured air velocities in three directions.

Q Okay. We're talking about internally here though. 3M did not perform any Schlieren studies to show the thermal plumes -- did not perform any studies internally to show that thermal plumes created by the Bair Hugger in an operating room?

A Well, we don't have an operating room so we would not have been able to conduct those kind of studies. And Schlieren, it's not a quantitative study, it's qualitative.

Q Okay. And nothing was ever done in

operating room internally by 3M?

A We don't have --

Q Either commissioned or --

A Correct.

Q Okay. 3M has access to operating rooms though, correct?

A Human operating rooms?

Q Yes.

A No, not to my knowledge.

Q Well, when Dr. Abraham wanted access to an operating room to do a CFD study and to take measurements, 3M got access for him, correct?

A Not on the 3M property or campus.

Q No, but they have access. I didn't say access on campus, but they have access. If they wanted to use an operating room to do an analysis, 3M has the ability to have access to operating rooms in the country?

A I don't know. Maybe.

Q Well, they have in the past. I mean, the Abraham study was done in Southdale.

A Well, I don't know how he was able to gain access to an operating room. I mean, he might have done that himself.

Q Well, Augustine had access to an

operating room when he commissioned studies, correct?

A Yes.

Q Okay.

A But he was a practicing physician at the time.

Q And have you been to the fawfacts.com website anytime recently?

A No.

Q You've been during the past, correct?

A Years ago, yes.

Q There was videos of testing done in an operating room with 3M personnel in the videos, correct?

A Yes, I believe so. Yes.

Q So clearly they have access to operating rooms?

A Those people who did the studies did, yes.

Q Now, prior to the Schlieren study on the effects of the Bair Hugger heat generation on the thermal plumes and in an operating room, what studies internally did the company perform to determine the effects of the energy generated by the Bair Hugger system on the operating room

environment?

A There was some computational fluid dynamics studies conducted. I mean, internal studies, is that what you're getting at?

Q Yes.

A I mean, to my knowledge, that might have been it. The computational, the CFD models.

Q Well, let's back up a little bit. During the design process, the company was aware that heat was going to be generated and released into the environment, correct?

A Yes.

Q They were aware that heat was going to be generated and released into an operating room environment, correct?

A Yes.

Q They were aware that the heat was going to have an affect on the environment?

A Yes.

Q The company was aware that hot air is less dense than cold air, and the cold air would lower and the hot air would rise, correct?

A Yes.

Q Okay. They were aware that the hot air that rises would be carrying particles and

bacteria?

A It could be, yes.

Q Okay. The company was aware that the increase of bacteria over a surgical site would increase the risk of infection?

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

A So the relationship between recovering bacteria above or around a surgical site and its relationship to the subsequent development of a post-surgical infection has not been well established.

Q I understand that maybe the quantitative amount has not been established. But I think most surgeons would agree that the more bacteria you have over a surgical site, the increase of a likelihood of infection that could occur?

MR. GORDON: Object to the form of the statement, I guess. Are you asking him to agree with you?

Q You're aware of the International Consensus of Orthopedic Surgeons?

A Yes, I'm aware.

Q ICOS. And they -- one of their statements is that they want to reduce the risk

of infection by reducing the amount of bacteria over the surgical site?

A Yes.

Q You don't disagree with that?

A Well, I don't disagree with that recommendation, no.

Q Okay.

A I do not disagree that that is a recommendation they make.

Q Okay. You're aware that most surgeons want to minimize the amount of bacteria over the surgical site?

A Yes.

Q In fact, all surgeons probably want to do that?

A I think it's a concern that surgeons have, yes.

Q Statistically speaking, the more bacteria that is over the surgical site, the higher the chances of an infection of the surgical site?

A I think that many surgeons believe that, yes.

Q Okay. And 3M was aware of that?

A Yes.

Q The company was aware of that?

A Yes.

Q And the company was aware that the Bair Hugger was generating heat, hot air; that hot air is going to rise and form thermal plumes; that the hot air was going to -- can carry particles and bacteria; and that surgeons wanted to reduce bacteria over the surgical site, correct?

A Yes, we're generally aware of all of that. Yes.

Q And 3M or the company performed no studies internally before putting the products on the market, the 500, the 500 OR, the 505 or the 750, did no internal studies to determine whether or not the plumes generated by the Bair Hugger device would carry bacteria onto the surgical site?

A Internal studies, no. But we were aware of thermal-hydraulic studies, and operating room airflow studies that showed that the air in a conventionally ventilated operating room had enough momentum to reverse or suppress the thermal plumes that arose from the blanket or from humans standing near the patient.

Q From humans and the patient, but not a Bair Hugger system, correct?

A Well, we looked at both, both human beings, patient and the Bair Hugger.

Q What study, internal study are you referring to with respect to the Bair Hugger?

A It's not an internal study. These are studies where people looked at the suppression of thermal plumes in a conventionally ventilated operating room.

Q Okay. With the Bair Hugger?

A With a warming device. I'm not sure if it was Bair Hugger.

Q Okay. And you stated in your last 30(b)(6) deposition that we did in the MDL, that every single study performed, looking at particles over the surgical site, showed an increase on the amount of particles when the Bair Hugger is used as compared to when the Bair Hugger is not used?

A In absolute numbers, yes.

Q Okay. And the International Consensus of Orthopedic Surgeons recommends or statements states that to reduce bacteria over the surgical site, that one should reduce the amount of particles over the surgical site?

A I think there's a statement to that

effect, yes.

Q Okay. Because particles carry bacteria?

A They can.

Q And according to Dr. Wenzel, the expert hired by 3M, Dr. Wenzel, 40 percent of particles carry bacteria?

MR. GORDON: Object to the form of the question, mischaracterizes Dr. Wenzel's testimony, also outside the scope of 30(b)(6) deposition, and also lack of foundation.

Q You may answer.

A I'm sorry, would you repeat it?

Q You understand that 3M was aware of Dr. Wenzel's testimony in the multi-district litigation?

A Yes.

Q Have you read his testimony?

A No.

Q You're aware that 3M retained Dr. Wenzel as an expert in infectious disease?

A Yes.

Q And Dr. Wenzel is more knowledgeable than probably anyone in the patient-warming business at 3M on infectious disease?

MR. GORDON: Same objections.

A He's a recognized world expert in infectious disease.

Q Okay. Now, with respect to the 505 OR and we'll get to the manual. During the design process, you will agree with me that the company did absolutely no testing or no analysis to determine whether or not the 505 OR model would increase particles over the surgical site before it was marketed?

A So not to be overly technical, but there is no such thing as a 505 OR model.

Q My fault. The 500 OR.

A Okay.

Q The first model to be used in the operating room.

A Okay.

Q You agree with me that the company did no analysis of whether or not putting a Bair Hugger device in the operating room would or would not increase particles in the surgical site?

A To my knowledge, no study like that was conducted.

Q Okay. Even though it was a concern as early as 1991, that the Bair Hugger may increase particles over the surgical site?

A And again, this was the reason for selecting a filter media that had at least the same level of filtration as the HVAC system in the operating room.

Q Yes, but that's only one source, one mechanism to increase particulates over the surgical site was the filter, correct?

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

A It is a mechanism.

Q Another mechanism is the heat generation and thermal plumes?

MR. GORDON: Same objection.

A They could be.

Q It's a mechanism that could raise particles from a lower point -- or raise them over the surgical table, correct?

A They could.

Q Okay. And the company never looked at that issue?

A To my knowledge, no.

Q Okay.

MR. ASSAAD: Let's take a five-minute break.

THE VIDEOGRAPHER: Off the record.

(Whereupon, a recess was taken at 1:05 p.m. until 1:42 p.m., after which, the following transpired.)

THE VIDEOGRAPHER: We're on the record.

BY MR. ASSAAD:

Q Are you ready to continue, Mr. Van Duren?

A Yes.

Q Okay. During the design process, one of the goals is to identify potential risks of the device?

A Yes.

Q And one of the -- and in an operating room, one of the risks, a risk of a device could be causing airborne contamination?

A Could be.

Q Yes. And the company was aware that surgeons do not want devices that could increase particulates over the sterile field?

A I mean, I would say that we assumed that that was true, yes.

Q I mean, Dr. Augustine was an anesthesiologist. He understands the sterile field and the concept of maintaining a sterile field?

A Right, but you said "surgeons."

Q Okay. Well, surgeons as well, International Consensus of Orthopedic Surgeons --

A Yep.

Q -- do not want to increase particulates over the sterile field?

A I assume that that's true.

Q Okay. Especially orthopedic surgeons?

A Yes.

Q Okay. Because orthopedic surgeons are aware that it takes a very minimal amount of bacteria to cause a deep joint infection?

A It can, yes.

Q Yes. Okay. And 3M is aware that every single study that looked at this issue shows an increase of particulates in absolute numbers when the Bair Hugger is used, correct?

A Yes.

Q Okay. Until this day, 3M does not warn that the Bair Hugger may increase the amount of particulates over the sterile field, correct?

A That's correct.

Q Okay. With respect to the Bair Hugger devices before the 500 OR that were not intended to be used in an operating room environment, 3M was aware that blowing air over a patient may

aerosolize bacteria?

A I think it was -- again, the risk management program determined that blowing air over an open, infected wound could aerosolize bacteria.

Q Because there's bacteria on the open wound, we discussed this already.

A Right.

Q But there's also bacteria on the patient's skin, correct?

A Yes.

Q And for the same reasons why it might aerosolize the bacteria on an infected wound, the same reasons would occur with bacteria on a patient's skin, correct?

A Well, I believe that the risk management team recognized that there was a large difference between those two conditions and warned against the latter.

Q I understand what the risk management team did, but from a science standpoint, from a design standpoint, 3M -- or the company was aware that there was bacteria on a patient's skin?

MR. GORDON: Object, asked and answered.

A Yes, we recognize that.

Q And for the same mechanism that bacteria can be aerosolized that are on open, infected wounds, the same could happen for the bacteria that is on a patient's skin?

A I don't know that the mechanism is identical.

Q Okay. 3M was aware that -- the company was aware that bacteria in an operating room, one of the main sources of bacteria are from the people that are in the operating room, the patient and the staff?

A Those are sources of bacteria in the operating room, yes.

Q Okay. And with respect to the warnings of possibility of airborne contamination on the air blowing from the Bair Hugger over an open, infected wound may cause airborne contamination, the changing of a filter does not address that risk of changing of a filter?

A Not likely.

Q Okay. Because the generation of the airborne contamination, the possibility of airborne contamination is from the bacteria that's on the patient, not what's being drawn in from the Bair Hugger device, correct?

MR. GORDON: Object to the form of the question, lack of foundation also.

A Again, based on the language of the warning, that would suggest that that's true.

Q Okay. The 500 device also contained a warning regarding the possibility of airborne contamination, correct? You can look at Exhibit 4 if you need to.

A Yeah, I think we saw that. That's the one where it said "open contaminated wounds," "open, infected wounds." Yes.

Q Okay. The 500 device had a .02 micron filter, correct?

A .2, I believe.

Q Well, if you look at page 7675 of Exhibit 4, Bates number 7675, it says, "filter system .02 micron filter." Left-hand column, third from the bottom?

A Yes, I see that.

Q Okay. So according to the Model 500 service manual, Exhibit 4, the Model 500 had a .02 micron filter, correct?

A That's what is written there. I'm not sure that that is correct.

Q Okay. But what do you think it is?

A I think it's probably .2.
Q Okay. .2, which is the same filter that is used in the 505, correct?
A Yes.
Q And the same filter that is used in the 750, correct?
A Yes.
Q And the same filter that is used in the 775, correct?
A Yes.
Q Okay. So even with the point -- just say it's incorrect as a .2 micron filter, the company warned about the possibility of airborne contamination?
A They did.
Q Okay. And that is because the filter -- the mechanism of airborne contamination addressed in the 500, the filter -- the filter issue doesn't address that mechanism of blowing hot air over the open, infected wound, correct?
A That's correct.
Q Okay. And you were aware of other manufacturers of forced-air warming devices, correct?
A Yes.

Q And other manufacturers also warn about -- currently warn about the potential of airborne contamination?

A I don't know for a fact that they do that. It wouldn't surprise me to find out that they do.

Q Why wouldn't it surprise you?

A They all follow what we do.

Q Well, you currently don't warn about airborne contamination in the 505, and the 750 and the 775, correct?

A I don't believe that there's a warning there about that.

Q Okay. So they're not following what you do currently, because you don't warn about it currently, correct?

MR. GORDON: Object to the form of the question, it's argumentative.

A Again, to my knowledge, we don't currently do it.

Q Okay. But other manufacturers such as Mistral or Stryker warn about airborne contamination such as the Mistral device?

A They may. I have not looked at their manual in some time.

Q And that wouldn't surprise you?
A That wouldn't surprise me.
Q Why not?
A Because virtually every manufacturer copied us and perhaps they haven't removed that warning yet.
Q Okay. You're familiar with the Stryker Mistral, correct?
A Yes.
Q Do you know when that device came out?
A No, I don't know what year that came out.
Q For the purposes of this next couple of questions, let's just assume that the Stryker Mistral came out after the 505.
A Okay.
Q Okay? And you agree with me that the 505 device does not warn about airborne contamination?
A I can't say completely for certain, but I'll -- for the purposes of argument, I'll take your word for it.
Q I'll pull it up at the next break, but I think -- I'm 99.9 percent sure that it does not warn about airborne contamination.
So assuming that the Mistral came

after -- the forced-air warming device came after the 505, and I'm just trying to address the fact that you mentioned that they probably were copying what 3M was doing. 3M wasn't warning about airborne contamination, then they wouldn't be copying 3M on any of the warnings, correct, on the airborne contamination?

MR. GORDON: A couple of objections. First of all, lack of foundation. Secondly, I've let you go on and on about Mistral, but this is really way outside of the scope of 30(b)06 topics.

MR. ASSAAD: Let me bring it in and maybe I can bring it in just to correct your objection.

BY MR. ASSAAD:

Q As part of the design process, you look at your competitors to see what they're doing and what is out in the field, as an engineer would, to determine the best way to design something?

A That would be one way, yes.

Q Okay.

A Yep.

Q And the company keeps track of what other competitors are doing?

A Yes.

Q Okay. And the advantages and disadvantages of their devices as compared to the company's device?

A Yes.

Q And actually it's -- a lot of it is also in the sales material given to the sales reps to distinguish the Bair Hugger from other devices?

A Yes.

Q Okay. And the company is aware that Stryker Mistral warns about airborne contamination?

MR. GORDON: Object, lack of foundation.

A Again, I don't recall looking at their manual, but it wouldn't surprise me if they do.

Q Okay.

A They could have looked at earlier versions of our operating manual and just copied the warnings directly from there as a possibility. I just don't know.

Q Okay. But what we do know is that they currently warn for airborne contamination?

MR. GORDON: Same objection.

A I'd have to see the actual warning in their manual.

Q Okay. It is what it is, right?

A Well, I'd have to see it.

Q Okay. Between the 505 -- the 500 and the 500 OR, the company removed the warning regarding the possibility of airborne contamination, correct?

A Yes.

Q What studies were conducted prior to the marketing of the 500 OR to determine that the warning about the possibility of airborne contamination was not needed in the manual?

A I'm unaware of any studies that were conducted. But a risk mitigation process certainly was undertaken, and the warning would have been removed as a result of the determination that it was no longer necessary.

Q Okay. So the company -- the company's position that the warning regarding airborne contamination that was in the 500 was not needed in the 500 OR based on their risk assessment?

A Yes.

Q And that was not based on any internal studies that you're aware of sitting here today?

A That I'm aware of, no.

Q Okay. And it was not based on any external studies that you're aware of today prior

to the marketing of the 500 OR?

A None that I can recall.

Q What was the basis or the reasoning behind the termination that the warning for the possibility of airborne contamination was not needed for the 500 OR?

A Well, I haven't seen the risk management document, so I don't know precisely why that was removed. But labeling is one of the things that is strictly controlled by the ECO system once a product is released; so there had to have been a risk management process supplied to that labeling.

Q Sitting here today, you have not -- you don't have an explanation as to why that warning was removed from the 500 OR?

A Only that it would have been removed as a result of the risk mitigation process.

Q But you don't know what occurred during the risk mitigation process?

A I don't.

Q Okay. But the removal of the warning was not based on any tests that you're aware of?

A None that I'm aware of.

Q Okay. And you're assuming that there was

a scientific basis for the removal of the warning from the 500 OR device?

A Well, I'm assuming that there was a logical basis for its removal that depended on evidence to overturn the justification for its existence in the first place, which could have been an appeal to reason.

The existence of a warning based on a proposed risk may not have had any basis and scientific fact. It might have just been someone thought that was a good idea.

Q Sitting here today, the company doesn't know?

A That's correct.

Q And at the time when the 500 OR was marketed, the company was aware that hospitals and surgeons would not want devices that caused airborne contamination in the operating room, correct?

A Well, we're certainly aware that the desire among surgeons in the operating room is to minimize particulates and contamination, yes.

Q Because the medical community is of the opinion that if you increase particulates, you increase the risk of infection?

A Yes.

Q And as a result of your admission that every single study that looked at the increase of particles as a result of the Bair Hugger, you would agree that there is going to be a risk of infection as a result of the Bair Hugger?

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

A I wouldn't agree to that.

Q Okay. You would agree that surgeons, especially orthopedic surgeons, would opine that if you increase particles over the surgical site you increase the risk of infection?

MR. GORDON: Object to the form of the question, also lack of foundation.

A I would agree.

Q Does 3M take a different position as to the science and the opinions of the orthopedic community with respect to particles and the risk of infection?

MR. GORDON: Object to the form of the question, also lack of foundation.

A Well, I'm not sure what you mean by a different opinion. Do we believe that bacteria cause infections? Is that the question?

Q Would orthopedic surgeons want to minimize the amount of particles over the surgical site? Correct?

A Yes.

Q Orthopedic surgeons believe that there is a correlation between the amount of particles and the risk of a deep joint infection in orthopedic surgery?

MR. GORDON: I'm going to object, lack of foundation.

A I believe that's true.

Q Okay. 3M is aware of what the medical community, especially the orthopedic surgeons' opinion on between the correlation of particles and deep joint infections?

A Yes, we're aware of their opinion.

Q Okay. Does 3M disagree with the medical community and orthopedic surgeons that increasing particles over the surgical site increases the risk of a deep joint infection in orthopedic surgery?

MR. GORDON: Same objections.

A Well, in a qualitative way we agree with that.

Q Okay. The company is aware that the Bair

Hugger increases particles over the surgical site?

A We know from some studies that particle counts are increased over the surgical site when Bair Hugger is used.

Q Which, in turn, means that the Bair Hugger has an affect on the airflow of an operating room system, correct?

A Those are two different things.

Q Well --

A One does not derive from another.

Q Let's back up a little bit. You know when Bair Hugger is used particles increase over the surgical site?

A They can, yes.

Q Okay. And there's a correlation between the Bair Hugger use and particles over the surgical site?

A Yes.

Q Okay. And through the laws of physics, there has to be something that the Bair Hugger does to increase particles over the surgical site, correct?

A I'm trying to understand what you mean by "through the laws of physics."

Q Well, there's a cause and effect. The Bair Hugger blows hot air, correct?

A Yes.

Q And as a result, the Bair Hugger blows in hot air, there's an increase in particles over the surgical site?

A Yes.

Q Okay. So I don't want to go into all the physics and the science, but would you agree with me that when the Bair Hugger is off, there's less particles over the surgical site?

MR. GORDON: Object to the form of the question, also incomplete hypothetical.

A I would agree that in certain studies that that is the case, yes.

Q And that is because the operating room ventilation system, which is designed to reduce particles over the surgical site, is not being affected by the Bair Hugger?

A So that's a probable explanation, but I don't know the exact mechanism for the increase.

Q But it's the most likely explanation?

A It's an explanation.

Q What other explanations would there be?

A Well, I don't know. I'm just saying that

it's a possible explanation of the mechanism, yeah.

Q Okay. Well, it's a probable explanation?

A Okay, probable.

Q I mean, you have the studies that were done, you have the Bair Hugger, everything is the same except the Bair Hugger is on and the Bair Hugger is off, correct? You have the control, okay, like everything is constant except one thing changes, the Bair Hugger, correct?

A Yes.

Q The studies that we're referring to. Therefore, one could conclude, more likely than not, that the Bair Hugger is increasing particles over the surgical site?

A Or that -- yeah, the increase is related to the use of the Bair Hugger. Yep.

Q And as a result of the Bair Hugger is reducing the effect of the operating room ventilation system to reduce particles over the surgical site?

A Well, again, I don't know -- well, the effect, yes. Yep.

Q Okay. The company is aware that the medical community is of the opinion that the

increase of particulates over the surgical site increases the risk of a surgical site infection?

MR. GORDON: Object to the form of the question; also, lack of foundation.

A Well, I think there are quantitative thresholds that that is the case, yes.

Q Okay. And with respect to the quantitative thresholds, 3M has never performed a study to determine whether or not the increase in particles that are over the surgical site caused by the Bair Hugger, has a -- increases the risk of a deep joint infection in orthopedic surgery?

A Well, I think the study by Curtis would suggest that the difference in particulate counts, assuming that HEPA filtration reduces those, makes no difference.

Q Curtis evaluated the filters, correct?

A Well, the whole systems.

Q Okay. But the filter, the main difference -- the Curtis study dealt with the HEPA -- the question was: Does the HEPA filter make a difference with deep joint infections?

A Yes.

Q That was the question presented in that study, correct? They're both forced-air warming

units, correct?

A Yes.

Q Okay. They both blow hot air, correct?

A Yes.

Q Okay. And what we're talking about here is the increase in particulates as a result of the hot air -- the increase of particulates over the surgical site as a result of the hot air over-generated by the Bair Hugger machine?

A Well, again, I don't know that the increase is caused by the hot air. It could just be caused by the air. It may not have to be hot.

Q Okay. 3M is unaware of whether or not -- strike that.

3M does not know whether the increase of particulates over the sterile field caused by the Bair Hugger has any affect on patients with respect to infection rates. That was a bad question. Let me rephrase it.

You mentioned the qualitative versus quantitative issue about the particles, correct?

A Yes.

Q Okay. We can all agree that 3M is aware that the Bair Hugger increases particles over the surgical site?

A In absolute numbers, yes.

Q 3M is unaware of whether or not that increase of particles increases the risk of a deep joint infection in orthopedic surgeries, correct?

A Well, again, taking the data from Curtis would suggest that if HEPA filtration produces lower particle counts, then there's no difference.

Q But Curtis didn't measure particle counts?

A Right. They measured the actual outcome of --

Q Of infection rates?

A Yep.

Q Of infection rates?

A Correct.

Q Curtis did not measure whether or not the particle generation over the surgical site was different than the Bair Hugger than the Mistral, right?

A I am assuming though, based on the design of the experiment, that the particulate counts are lower with the HEPA filter.

Q You don't know one way or another?

A I don't know.
Q You're assuming?
A I'm assuming.
Q Okay. During the risk mitigation process, during the design process, I would assume that the company relies on medical personnel or doctors and surgeons to help evaluate any of the risks associated with a device?
A Is that a question --
Q Yes.
A -- I'm not sure. So the risk mitigation process includes a variety of disciplines. Some could be medical doctors.
Q Has 3M or the company ever consulted with any orthopedic surgeons, such as Parvizi or Dr. Mont, and informed them this device increases particles over the surgical site, would you consider that a risk factor for orthopedic surgeries?
A I don't know that that information has been presented exactly like that to them.
Q So even though 3M is aware that the Bair Hugger, through whatever mechanism we don't know, okay? Whether it's the filter or the hot air,

whatever, but what we do know is that the Bair Hugger increases particles over the surgical site, the company has not consulted with any orthopedic surgeons to determine whether or not that is a risk for deep joint infections in orthopedic surgeries?

A I am not aware of consultations with any of those orthopedic surgeons.

Q Okay. And with respect to the issues of particles over the surgical site and its correlation with a deep joint infection, the company would agree that there are surgeons or scientists out on the field that are better or more knowledgeable about the actual risk factors than 3M?

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

A I'm sorry, would you rephrase or restate the question?

Q It wasn't clear. When it comes to the risk of particles over the surgical site and the risk of a deep joint infection, there are experts in the field in the medical community that are more knowledgeable than 3M regarding the correlation between particles and infections?

A I suspect that's true.

Q And the company has never consulted any of these experts and told them, "studies are showing that the Bair Hugger increases particles over the surgical site, should we be concerned about this?"

A I don't know that we presented data in exactly that format to orthopedic surgeons or infectious disease specialists.

Q Or in other words, we are aware that Bair Hugger increases particles over the surgical site, you know, should we put a warning on this to warn physicians? Was that ever discussed with any of the experts in periprosthetic joint infection?

A I don't know. Those notes would appear in the risk mitigation process.

Q 3M is a platinum member of the International Consensus of Orthopedic Surgeons, a donor, correct?

A Yes.

Q And they were involved in the last one, correct? They attended the meetings?

A Yes.

Q During the issue of forced-air warming,

did they tell the doctors, "Hey, all the studies here indicate that there is an increase of particles over the surgical site when the Bair Hugger is used." You know, "that is information that you should use before conducting your vote." Was that ever done by 3M?

A No, but again, those are experts at those meetings. They're well aware of the research.

Q Well, you assume that they're well aware of the research?

A Well, they're experts.

Q Okay. At those meetings did 3M inform those experts that based on strong, scientific evidence and all the studies that have been conducted, that Bair Hugger increases particles over the surgical site?

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

A No.

MR. ASSAAD: Okay. Let's take a break.

THE VIDEOGRAPHER: Off the record.

(Whereupon, a break was taken from 2:22 p.m. until 2:37 p.m., after which, the following transpired.)

THE VIDEOGRAPHER: We're on the record.

BY MS. ASSAAD:

Q When the 500 OR was discussed, came out, they removed the warning about airborne contamination, correct?

A I believe so, yes.

Q Okay. And roughly that was the early '90s, correct?

A It was, yes.

Q It was before you got there?

A Yes.

Q Okay. And as time passed by from the 1994 to the present, there have been studies regarding the Bair Hugger increasing airborne particulates over the sterile field, correct?

A There have been.

Q Okay. At any time during the period from the 500 OR to the present, were there any discussions at 3M regarding adding back a warning about airborne contamination?

A Not that I recall.

Q To the present?

A Yeah, to the present.

Q Even until today?

A Not that I recall.

Q Well, as part of the design process

there's also the label, correct?

A Yes.

Q Okay. And you're here today as a 30(b)6 witness, you know, to discuss 3M's knowledge regarding the design process, which includes the label, correct?

A Yes.

Q And when you say "not to my knowledge," are you saying there's been no discussions, you being 3M --

A Yep.

Q -- regarding changing the label to add airborne contamination?

A Again, I don't recall any discussions having to do with changing the label in response to concerns about particulates.

Q What about adding information regarding airborne contamination in the label?

A Again, not that I recall.

Q Was there anyone that 3M is aware of in the company that suggested that a warning regarding airborne contamination should be added to the label?

A I don't believe so.

Q Okay. And the purpose of the label is to

educate customers and to warn customers about the product, correct?

A Yes. One of its purposes.

Q And 3M understands its customers rely on 3M to provide clear instructions for use, correct?

A Yes.

Q And for contraindications, correct?

A Well, warnings and cautions.

Q And contraindications?

A Yes, I think that can be one as well.

Q Actually on the label it says, "contraindicated for aorta clamp"?

A Yes.

Q Okay. And 3M has been, the company, Augustine, Arizant and 3M, have been in the forced-air warming business longer than any other company?

A Yeah, I think so.

Q Okay. And therefore, when it comes to forced-air warming, they're -- I don't want to say they're the most knowledgeable, but there probably is no one more knowledgeable than forced-air warming devices than the company?

A Probably.

Q And 3M is more knowledgeable with respect to any of the studies, externally and internally, that are done on forced-air warming devices, the Bair Hugger, than any other person in the world?

A The company is more knowledgeable --

Q Yeah.

A The question is: Is the company more knowledgeable than any person in the world?

Q Yeah.

A Oh, I mean, there certainly could be some experts who know more than the company.

Q Who knows more about the Bair Hugger than you?

A Oh, I would think, you know, Professor Sessler, probably, you know, at least its therapeutic applications.

Q I'm talking about the overall Bair Hugger, its risk, its design, its -- you know, about the studies that are out there?

A Yeah, probably me.

Q Okay. And that was your -- one of your main roles was to keep up-to-date on all the literature regarding the Bair Hugger devices, correct?

A Yes.

Q Okay.
A As well as other warming devices.
Q Have you ever suggested adding a warning to the Bair Hugger device?
A I don't believe I have.
Q Did you ever raise a -- I mean, you informed 3M at some point that this issue about particles over the sterile field was something that was discussed back in the '90s?
A I'm sorry, what was the question?
Q You informed 3M that this issue -- when the issue arose when Augustine was sending his letters, you informed 3M that this is nothing new, we've been discussing this since I joined the company in 1994?
A Well, actually, I don't think I was responsible for transmitting that knowledge. I mean, I think there was a whole team of people involved in business development who transferred that information to 3M.
Q An I'm not talking about during the purchase. I'm talking about when Augustine was sending letters regarding the affect on airflow that the Bair Hugger has or increasing particles over the surgical site, that wasn't something

that was new to you in 2012?

MR. GORDON: Object to the form of the question, misstates and mischaracterizes the timeline.

A So it wasn't new to me, but I did not see most of those letters.

Q Do you remember informing Gary Hansen in 2012 with respect to the Scott Augustine issue, and you said, "The following point I want to emphasize is that Scott did not just have a recent epiphany concerning forced-air warming and particulates. Clinicians had expressed concerns about this very issue even while Scott was at Augustine Medical"?

A Yes, that sounds like something I wrote.

Q So it wasn't something new to you regarding particulates over the surgical site when you -- when Scott Augustine started sending letters to 3M?

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

A Well -- I'm sorry, could you restate it?

Q You have known since 1994 there was an issue with particulates over the surgical site caused by the Bair Hugger?

A Well, I've known that customers had perceptions about whether that was appropriate or not.

Q Okay. And with respect to the issue of determining whether or not the Bair Hugger increases particles over the surgical site, no testing was done by 3M except for Hall and Zink until 2013, correct?

A Regarding particles or regarding bacteria or infection?

Q Particles or bacteria.

A Well, two different things.

Q Okay.

A So are we talking about --

Q Let's talk about particles. Okay, let's start this way: 3M never conducted any particle tests with respect to the Bair Hugger in an operating room until they commissioned this test done by Sessler and Olmsted, correct?

A That's correct.

Q With respect to bacteria, the only test done with bacteria by 3M or the company was Zink and Hall?

A Well, I mean, there were studies that looked at infection rates. Like Oguz, for

example, looked like at the difference between infectious particle-forming units or colony-forming units in operating rooms with and without forced-air warming.

Q Okay. So you have Oguz and that was in 2016, '17, '15?

A It might have been. I'm not sure about the year.

Q But internally or commissioned by 3M or the company looking at bacteria, it was only Zink and Hall, correct?

A Well, I mean, I'd have to confirm in my library, but that's probably correct.

Q So from Zink, which was 2003 to the present, no tests were done with respect to bacteria counts over the surgical site that were either done or commissioned by the company?

A No, but there were studies done. I mean, Michael Avadon's study, for example.

Q I'm saying commissioned or done by the company.

A Well, again, I'd have to confirm by looking at my library, but I think that's right.

Q Okay. And with respect to the Sessler-Olmsted study on particles, when you

looked at the absolute number of particles, there's always an increase when the Bair Hugger was used on average, correct?

A Yes.

Q Okay. And in fact, 3M personnel were actually involved in that study and actually went to the Netherlands to help conduct the study, correct?

A They were not involved in the study, they went to observe.

Q Were you one of the people that went to observe?

A Yes.

Q Okay. And just to be clear, no studies were done by 3M prior to the Sessler-Olmsted study with respect to the particles?

A Not to my recollection.

Q Now, you mentioned other studies, CFD was done internally at 3M?

A There was -- I'm trying to recall. Well, part of what year again are we talking about?

Q Prior to the litigation.

A So --

Q 2013?

A -- '13. I think there was some work done

by Memarzadeh. I'm not sure that we -- I don't think we commissioned him to do it.

Q But with respect to 3M or the company, they did not -- was there any CFD performed internally --

A Before 2013, I don't believe so.

Q Okay. What about after 2013?

A There may have been some done, but I'm not entirely certain about that either. At that point there were external investigators that were doing that work.

Q What other studies were performed prior to 2013 -- or strike that.

What other internal studies were done by 3M or the company with respect to bacteria at any time?

A Internal studies?

Q Yeah.

A None that I know of.

Q What about with respect to particulates, besides Sessler and Olmsted? I'm just trying to get a list of everything that was done internally by 3M.

A Well, with respect to particles, I don't think there were any.

Q By the way, just to clarify something with respect to the Sessler-Olmsted study on particles, 3M was involved in the editing of the manuscript, correct?

A I think we got to see the manuscript. I don't believe I made any edits to that manuscript.

Q What about Gary Hansen?

A He might have.

Q Changing gears a little bit. We've been talking about the risks of particle and bacteria over the surgical site. You would agree with me that for certain operations, such as orthopedic implants, the risk of increased particles is greater than for maybe some other surgeries such as colorectal?

A No, I wouldn't agree with that.

Q Okay. In marketing the Bair Hugger 500 OR and beyond, for all the Bair Huggers that are listed in the OR, 3M did not distinguish or determine the type of benefit for different type of surgeries that the Bair Hugger may be used in, correct?

A 3M didn't, no.

Q Okay. And they did not commission a

study with respect to, for example, the benefits of forced-air warming for orthopedic implant surgeries?

A No.

Q And in fact, with respect to hip and knee implant surgeries, there's no scientific evidence that forced-air warming -- intraoperative forced-air warming has any benefit for those surgeries?

MR. GORDON: Object to the form of the question; also outside of the scope of the 30(b)(6).

You can answer.

A So I'm aware of at least one study that I can think of, and that was a study by Scott at -- and I've forgotten the institution where it was conducted, a composite outcome of surgical site infections plus post-operative infections was reduced by intraoperative warming.

Q But that was for all surgeries, which included orthopedic surgery.

A It included orthopedic surgery, yeah.

Q But other studies, such as Frisch, showed that there's no benefit for maintaining normothermia for orthopedic surgeries, correct?

A The study by Frisch did show that. But, again, small study and the infection rates in orthopedic implant surgeries are exceedingly low; and therefore, to have appropriate power to detect differences, the studies have to be enormous.

Q Let me put this way: When 3M marketed and designed the Bair Hugger for intraoperative warming, there were no studies conducted by 3M to identify benefits, if any, for the different type of surgeries that the Bair Hugger could be used for?

A Well, the benefits to maintaining normothermia are not exclusive to particular kinds of surgery. They're related to the physiology of human beings under anesthesia.

Q Was there a study done with respect to the benefits of using the forced -- the Bair Hugger in orthopedic hip and knee implants prior to using them in orthopedic surgeries?

A No. I'm sure that forced-air warming was used in lots of hip and knee implant surgeries before any studies were done.

Q With respect to -- with respect to the studies on forced-air warming and infection risk,

3M relies on the Sessler study of 1996, Curt Sessler study, correct?

A One of.

Q And that was a dirty surgery, correct?

A Yes.

Q Okay. And based on that study, 3M marketed the Bair Hugger, used that to support the Bair Hugger to be used in all surgeries?

A Well, that wasn't the only surgical study that showed benefit to intraoperative normothermia. There were several studies that looked at things like bleeding, transfusion rates, you know, a number of -- a number of outcomes other than infections to demonstrate that intraoperative normothermia was beneficial.

Q But my question is with respect to orthopedic surgery and knee and hip surgeries. There were no studies to evaluate the risk-benefit analysis for orthopedic surgeries such as hip and knee by 3M or the company?

A That's correct.

Q Okay. You agree with me that a deep joint infection is a serious complication of hip and knee surgeries, correct?

A Very serious.

Q Okay. And that risk would outweigh any of the benefits provided by forced-air warming of hip and knee patients during intraoperative forced-air warming, correct?

MR. GORDON: Object to the form of the question, incomplete hypothetical, lack of foundation and outside the scope.

A So other than death, other than the prevention of death, probably there aren't other outcomes that are more important than a deep joint infection.

Q Let me ask it this way, make it simple. Assuming that the Bair Hugger device significantly increases the risk of deep joint infection, that assumption, you would agree that that risk would outweigh any benefits for the use of forced-air warming during hip and knee surgeries?

A No. The prevention of death would be more important than the increased risk of surgical site infection.

Q Are you saying that forced-air warming prevents death?

A I'm just saying that if -- when you look at the study by Scott, for example, 30-day

all-cause mortality is reduced in patients, in the group of patients assigned to intraoperative warming and normothermia.

So I'm not saying that Bair Hugger reduces death, but I am saying that normothermia, intraoperative normothermia, which is reduced with all-cause mortality, 30-day mortality.

Q And you're relying on the Scott study?

A Among -- yeah, yeah.

Q Scott study?

A Hmm?

Q That's what you're relying on, the Scott study?

A Yes. And I believe there are a couple by P.J. Devereux in Canada as well that showed -- had similar outcomes.

Q With respect to -- with respect to the change in the device between the 500 and the 500 OR, besides the filter and the temperature, were there any other changes done?

A Well, the whole device is different.

Q Let me rephrase that. I understand that the shape of the device and everything, but with the air flow coming out and the temperature and the filter, were there any output changes of the

device?

A I don't believe any substantial ones. There may have been some airflow changes.

Q Do you know if the airflow changed between the 500?

A I think it went from 28 to 33. I was just reading that in the manual here.

Q Okay. So besides the physical -- I mean, the real changes we look at between the devices are going to be the filter, and the airflow and the temperature output, correct?

A Yes.

Q Okay. Whether the device is smaller or bigger, that's irrelevant for the function of the device?

A For those characteristics, yes.

Q I mean, the characteristics that matter for warming are -- is the temperature coming out of a nozzle and the airflow coming out of the nozzle, correct?

A Yes.

Q And filtration deals with whether or not what particles are coming out of the nozzle, correct?

A Yes.

Q Okay. But we agree inside the hose there are particles and bacteria?

A It's not sterile, that's correct.

Q Okay. So whether or not it prevents additional particles coming in through the bottom of the machine or through the filter, there would be bacteria or particles coming out of the hose because the hose is usually contaminated with bacteria and particles?

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

A I'm sorry, would you restate that?

Q The filter is not going to prevent particles and bacteria coming out of the end of the hose because particles and bacteria are inside the hose?

MR. GORDON: I'll object to the form of the question.

A Again, it's not sterile; so yeah, I would expect.

Q And 3M is aware that on many studies that have done microbiological tests on the inside of the hose, that there is usually bacteria that is found inside the hose?

A Yes.

Q Okay.

A But we're also aware that studies where a blanket is put at the end of the hose are generally sterile, have sterile conditions under the blanket.

Q Are you talking about Avadon?

A Avadon is one, yeah.

Q But not Oguz? Oguz found --

A Not Oguz. That was a multi-site sampling study.

Q Okay.

A And I think also Mike Reed and his colleagues also found that doing essentially what Michael Avadon did, that they were unable to recover bacteria from beneath the blanket.

Q On a published study?

A No.

Q Okay. You're aware that the published study came out of Stanford recently?

A Yes.

Q Okay. That found bacteria coming out of the blanket, correct?

A Well, I think it was out at the end of the nose nozzle, if I remember correctly.

Q So between the 500 and the 500 OR, the

change of temperature to 43 degrees celsius in 500 OR increased the airflow, correct?

A By a small amount, yes.

Q To 33. And put a .2 micron filter?

A Yes.

Q Okay. The 505 has a .2 micron filter?

A Yes.

Q Same temperature as the 500?

A Yes.

Q And the same airflow?

A Well, the same upper limit temperature.

Q Upper limit temperature?

A Yep.

Q And the same airflow?

A I'm not entirely certain that it's exactly the same, but it's roughly the same.

Q Okay. And then the 705, same temperature?

A 750?

Q 750. Same temperature?

A Yes.

Q 43 degrees?

A Yes.

Q Increased airflow?

A Substantially higher airflow.

Q What was the airflow?
A I don't recall the exact number. 48 CFM, I believe, but it could be even more.
Q And the same filter?
A The same filter material, yes.
Q Okay. And then the 775, I kind of counted as a combination between the 505 and the 750, correct?
A Well, I think it's -- it mainly has a fan switch that lowers the fan speed.
Q To the same, that would be for the 505 and then the high speed would be like the 750?
A Yes.
Q The same temperature, 43 degrees?
A Same temperatures.
Q And same filter?
A And same filter.
Q Okay. And I understand there's some other design changes, like the 750 had the temperature sensor at the end of the hose as compared to inside the machine, like the 505?
A That's right.
Q Okay. And during the generations of the 500 OR to the present, it's 3M's testimony that they never considered adding a warning regarding

like airborne contamination?

A Not to my recollection did we ever consider that.

Q Okay. And with respect to studies, the only epidemiology study conducted regarding infection rates and Bair Hugger is the McGovern study, correct?

A I'm sorry, would you restate it?

Q The only epidemiology study conducted between -- any relationship between the Bair Hugger and deep joint infections is the McGovern study?

MR. GORDON: I'll object to the form of the question and assumes facts not in evidence.

How are you defining epidemiology study?

MR. ASSAAD: As everyone else would define it.

MR. GORDON: Why did you exclude Augustine then?

A So I'm sorry, would you restate it once more?

BY MR. ASSAAD:

Q With respect to epidemiology studies looking at Bair Hugger and deep joint infections, what studies are out there?

A Well, I think Curtis is one, Scott is one; not strictly limited to deep joint, but orthopedic procedures.

Q Let me rephrase my question: With respect to an epidemiological study determining if there was a correlation between forced-air warming and deep joint infection rates, what studies are out there?

A Well, I mean, I think I did an epidemiological study that was internal that looked at a number of Bair Hugger warming units versus reported infection rates from the -- I think it was AHRQ or CDC, I don't remember, one of those, so that one was done.

Q McGovern?

A The McGovern.

Q Okay. What else?

A I mean, I'm sorry, I am just not recalling any epidemiological studies.

Q Now, would you agree with me that the epidemiological study that you did was not published?

A Oh, yeah, it was not published.

Q And it was not peer reviewed?

A No.

Q Would you agree with me that the only peer reviewed, epidemiological study that looked at forced-air warming and periprosthetic joint infections is the McGovern-Reed study?

MR. GORDON: I object to the form of the question.

And Gabe, you're an officer of the Court. How can you ask that question? You know that Augustine has a peer reviewed, published epidemiological study that does exactly what you said. I don't know why --

MR. ASSAAD: Peer reviewed?

MR. GORDON: Yes, peer reviewed, published study. And I do know why you want to avoid mentioning it, but when you frame the question that way. I thought you were --

MR. ASSAAD: Do you want him to step out so you can make your objection? But I don't like you coaching the witness.

MR. GORDON: I don't like you -- I mean, you know, that that's not -- the McGovern is not the only study.

MR. ASSAAD: I'm asking for peer review.

MR. GORDON: Yeah. That's why I tried to clarify, because I didn't know what you're

talking about.

As you defined it, you know that Augustine meets that criteria. I understand why you don't want to talk about it, but you can't make believe that it doesn't exist.

MR. ASSAAD: Are you representing that the Augustine paper, I assume the one that you're referring to is 2017 --

MR. GORDON: That's right.

MR. ASSAAD: -- is peer reviewed?

MR. GORDON: It is peer reviewed, published, and it is completely fraudulent.

MR. ASSAAD: Well, that wasn't my question. You agree that it's peer reviewed?

MR. GORDON: Absolutely.

MR. ASSAAD: Okay.

BY MR. ASSAAD:

Q Let me ask it this way: Is 3M aware of any epidemiological study that states that there is no correlation between forced-air warming and deep joint infections?

A I don't believe so.

Q Since the application -- withdraw the question.

The McGovern study was published prior to

the 775 being released into the market, correct?

A Yes, I think so. Yes.

Q And I can't remember the year the 750 was released into the market. Was it 2012 or before then?

A It was -- oh, it was before that.

Q Okay.

A Yeah.

Q So the 775. So when the McGovern study came out and prior to the marketing of the 775, were there any discussions by 3M to warn about the risk of the Bair Hugger device in orthopedic surgeries?

A I don't believe so.

Q And Michael Reed is a paid consultant for 3M currently, correct?

A I don't believe so.

Q At any point?

A A paid consultant?

Q Yes.

A I don't think so.

Q Was he ever doing research on behalf or receive any grants from 3M?

A Well, unintentionally, yes. He was hired by a group of researchers to help them continue a

study, yes. This was after the study was commissioned. I assume you're referring to the Rio study, right?

Q Yeah.

A Yeah.

Q And Michael Reed headed one of the issues in the International Consensus of the Orthopedic Surgeons meetings, right?

A He what?

Q He headed one of the issues, one of the questions regarding forced-air warming in the meeting of the International Consensus?

A Yes.

MR. GORDON: 2018, right? That's what you're asking about?

MR. ASSAAD: Yeah.

BY MR. ASSAAD:

Q And 3M has had meetings with Michael Reed regarding or Mr. Reed regarding his studies on forced-air warming?

A Not to my knowledge.

Q You're not aware of any meetings back in, like, 2012 or 2013?

A Unaware of any.

Q Okay. You understand that Mr. Reed is

one of the authors of the McGovern study?

A Yes.

Q Okay. And you read his depo -- deposition in the multi-districtal litigation?

A Not recently, but I did read it prior to the first deposition.

Q After the McGovern study came out and prior to the 775, were there any discussions at 3M to conduct a study to determine whether or not there is a correlation between forced-air warming and deep joint infections?

A Well, I think we had -- we had discussions about the pragmatic issues regarding the studies of that size. We certainly had discussions about the McGovern study.

Q I'm aware of those. I'm wondering -- there's a McGovern study that correlates or is in association between forced-air warming and deep joint infections.

Did 3M have any discussions regarding performing a study to determine whether or not that it's actually true or not? Or even putting a warning identifying what was in the study to its customers?

MR. GORDON: Object to the form of the

question, compound.

A So I think the McGovern study came out before the acquisition by 3M, so that would have been Arizant, I think? What year was that study?

Q 2011.

A Oh, right after. I don't recall any -- I don't recall any discussions about whether we should do a study, because we thought that the McGovern study had some substantial flaws.

Q Well, as we've discussed before, every study has limitations, correct?

A Yes.

Q Okay. And you rely on Zink and Hall and Teenier, which have significant limitations in your marketing material to your consumers, correct?

A Well, again, I was talking about the McGovern study that there were --

Q I understand that. But there's articles that 3M relies upon to market their devices, and those articles have limitations as well, correct?

A Yes.

Q Okay. I don't know if you recall, but I used the term "flaws" and you said "limitations" but now you're using the term "flaws." So are we

going to use the term flaws or limitations?
A Limitations is good.
Q Limitation is a more correct response?
A Yes.
Q Okay. So assuming that the McGovern has limitations, but every study that 3M uses to promote the Bair Hugger product has limitations as well, correct?
A I'm sure that you could find limitations in every study, yes; but not every limitations are equivalent.
Q I understand that. You would agree that the Zink study has significant limitations?
A I mean, it's quite old, yes.
Q And it was eight patients?
A Yes.
Q Okay. I mean, it's a very, very, very, very, very, very weak study. Do you agree?
A Very small.
Q A very weak study?
A Okay, yeah.
Q If you look at the McGovern study compared to the Zink study, the McGovern study is a much stronger study than the Zink study?
A Well, it recruited more subjects. I get

we could argue about whether it's stronger.

Q And then you rely upon the Hall and Teenier study in many of your marketing materials, correct?

A I don't think we rely on those materials any longer for modern marketing materials.

Q Okay. But you have in the past?

A Yeah.

Q Up until recently, I think, until like maybe 2015, 2016, I've seen it.

A It's possible, but we don't any longer.

Q Okay. And that's a study that's not even published, correct?

A Which study?

Q Hall and Teenier.

A Right, it's a poster.

Q It's a poster.

MR. ASSAAD: Let's mark this as Exhibit Number 7.

(Whereupon, Exhibit Number 7 was marked for identification.)

BY MR. ASSAAD:

Q In fact, I would like to point out about this poster on the second page, the study which 3M has relied upon in numerous marketing

materials and publications under "discussion" states: "The device may cause alteration of air movements within the OR, and it is unknown if this results in increased contamination of the surgical field or operating instruments."

Do you see where it says that under "discussion"?

A Yeah, I do see this.

Q Okay. So this study that 3M relies upon -- and I think if you even want to look at Exhibit Number 6, it identifies these two studies. The device -- it states, "The device may cause alteration of air movements within the OR, and it is unknown if this result is increased contamination of the surgical field or operating instruments," correct?

A I see that, yes.

Q Okay. So number one, the device may cause alteration of air movements within the OR, correct?

A Right. I mean, they acknowledge it may cause.

Q This is 1991, correct?

A Yes.

Q Okay. And 3M has conducted no study --

or the company has conducted no study to determine whether the statement is accurate or not, correct?

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

A Well, again, there are numerous studies of the use of Bair Hugger in the operating room that look at microbial contamination in the operating room. Now, we may not have funded those studies, but there are studies.

Q Well, this study was commissioned by Augustine, correct?

A Yes.

Q Okay. And based on the knowledge back then, the authors here said "the device may cause alteration of air movement in the OR"?

A May.

Q Okay, "may." Which means air movements within the OR is caused by blowing air in the OR, correct?

A That's --

MR. GORDON: Object to the form of the question and also lack of foundation.

Q I mean, you're not going to alter air movement within the OR by the type of filter that

you're using on the device, correct?

A Well, no, that would be the air being exhausted from the unit.

Q So the effect, when it says "the device may cause alteration of air movements within the OR," that is as a result of the heated air being blown out of the Bair Hugger device?

A Well, I don't think it necessarily has to be heated, but I think that's what they're getting at is that the movement of air from the device.

Q Okay. And "it is unknown if this results in increased contamination of the surgical field or operating instruments." I read that correctly?

A Yes.

Q So the study is saying that as of 1991, according to the study commissioned by Augustine, it is unknown if it's going to be an increased contamination of the surgical field, correct?

MR. GORDON: Object to the form of the question. Totally mischaracterizes. That's what the study was about. They're setting up what the study is about. Go on to the next page where they answer the question.

MR. ASSAAD: I'm going to get there. I'm going to get there.

BY MR. ASSAAD:

Q "It is unknown if this results in increased contamination of the surgical field," correct? That's what it says?

A That's what it says.

Q Okay. "Or operating instruments," correct?

A Yes.

Q So you don't want to contaminate -- a surgeon doesn't want to contaminate the surgical field or the operating instruments, correct?

A That's true.

Q Okay. If you want to go to the conclusions, the last paragraph, it says: "The risks of this method of thermal maintenance --" can we agree thermal maintenance is blowing hot air, right?

A Bair Hugger, yes.

Q "The risk of this method of thermal maintenance" -- "the risks of this method of thermal maintenance," which means the risk of using the Bair Hugger, correct?

A Right, not just infection risk.

Q Is not completely known. That's the conclusion, right?

MR. GORDON: Object to the form of the question, incomplete --

A This study of bacterial contamination in six locations reveals that the Bair Hugger does not increase the rate of contamination.

Q So the six locations that they use in the Hall and Teenier study did not increase bacterial -- did not show increased bacterial levels on the dishes, right?

A That's correct.

Q Okay. And you agree with me that none of the locations are on the surgical site, correct? Diagram one.

A Yeah, I was looking to see whether they actually -- oh, okay. Yeah. It doesn't look like they put any on the surgical site.

Q And actually all of them, all the dishes were on the floor?

A Yes.

Q Okay. None of them were on instrument tables, correct?

A I don't know if five or six, were they -- they may have all been placed on the floor. I

don't know.

Q Okay. Well, I don't see -- I mean, you have the anesthesia machine, you have the anesthesia cart, you have the table. You don't see any of the dishes on the table, the OR table or any other table in the room, correct?

A Yeah, I was just looking to see what their method section had to say about that.

Q And, in fact, as we've discussed before, we're talking about the risk of this method of thermal maintenance, which is using hot air, okay? Hot air we discussed is going to bring the contaminants up and mix with the air above it, not below it, correct, where the air is coming out of?

A I'm sorry, would you restate it?

Q As the hot air comes out of the Bair Hugger --

A Yes.

Q -- the Bair Hugger is on the operating room table. These, I believe, are dental -- dental patients?

A Yes.

Q Okay. So the Bair Hugger is on them, correct?

A Yes.
Q On their legs?
A Mmm-hmm.
Q Blowing hot air down, correct? The hot air is less dense than the cold air, correct?
A Yes.
Q So it's going to cause an upward flow, correct?
A Yes.
Q Okay. So putting the dishes --
A Assuming that it's not counteracted by the conventional ventilation in the operating room.
Q Okay. So putting the Apgar dishes on the ground really doesn't show you the effect of the Bair Hugger on the surgical site or on the instrument tables, correct?
A That's fair.
Q Okay. So you would agree with me that the Hall study does not answer the question of whether or not the Bair Hugger increases bacteria on the surgical site or the instruments that are on an instrument table?
A That's correct.
Q Thank you. Going back to Hall, it's the

last paragraph, says: "The risks of this method of thermal maintenance are not completely known."

When did 3M become aware of whether or not thermal maintenance such as the Bair Hugger was a risk or not a risk with respect to contamination of the surgical site?

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

Q Well, as you said. I'll withdraw the question.

Hall didn't answer the question of whether or not the Bair Hugger increases bacteria over the surgical site or on the instrument tables as you stated previously, correct?

A Yes.

Q Okay. When was there conclusive evidence that the Bair Hugger did not increase bacteria over the surgical site or the operating -- or the table in which the operating instruments were on?

A Well --

Q If it ever did.

A Well, I mean, the outcome of interest, of course, is surgical site infection. And at least in the case of Kurz' 1995 paper, it was a reduction in surgical site infection in patients

with the Bair Hugger who had higher temperatures, higher core temperatures.

Q I'm not talking about outcomes. I'm talking about --

A Right. But that's -- the particulate measures are just surrogates for the actual outcome of interest, which is a decrease in surgical site infection.

Q Or increase?

A Or increase.

Q More particles, may mean more increase, correct?

A Maybe. But what we really care about is the reduction in surgical site infection.

Q Okay. Well, there is absolutely no evidence that forced-air warming reduces the incident of deep joint infections, correct?

A No. I think the Scott -- Scott's paper, the orthopedic -- there is a group of orthopedic patients in there that had a composite outcome that was --

Q Scott refers to SSIs.

A I'm sorry?

Q Scott refers to SSIs.

A Yes, right.

Q We don't know whether or not Scott was deep joint -- superficial or deep joint, correct?
A We don't, yeah.
Q Okay. So the question I have is: There is no evidence, conclusive evidence, randomized control style -- study, observational, retrospective, that forced-air warming reduces the incident of deep joint infections, correct?
A To my knowledge, there hasn't been a study large enough to show that, yeah.
Q So what we have, is what we do know, according to orthopedic surgeons, particulates -- an increase in particulates and bacteria increases the risk of deep joint infections for hip and knee implant surgeries?
MR. GORDON: Object to the form of the question.
A That's what most of them believe.
Q That's well-settled in the orthopedic science world, correct?
MR. GORDON: Same objection.
Q And the study of De Ruge (phonetic) supports that, correct?
A Yes.
Q So okay. So what we can look at, because

you're right, doing a large enough study on deep joint infections might be impossible to do, correct?

A It might be.

Q Okay. So we can look at the second best thing of whether or not the Bair Hugger increases bacteria over the surgical site, correct?

A Well, not really. Because, again, that's a surrogate for surgical site infection. We don't know the relationship. While it's true that many surgeons believe that an increase in bacteria or particles over the surgical site can increase infection risk, it's not settled completely.

There is a not a fixed relationship between an increased measurement of particles or bacteria at the surgical site and a subsequent increase in surgical site infection.

Q Maybe I'll just ask it this way. Maybe we can agree on something.

There is no study out there that -- there is no study that a forced-air warming device does not increase the bacterial load over the surgical site?

A I'm sorry? State it one more time.

Q That forced-air warming does not increase the bacterial load over the surgical site?

A Well, I mean, there are studies that show that it increases the particulate load. That's different than the --

Q I'm saying the opposite here. There is no study that indicates that the Bair Hugger does not increase the bacterial load over the surgical site?

A Okay. Yeah, that's true.

Q Okay. There's no study that concludes that the Bair Hugger does not increase the risk of deep joint infection for hip and knee implants?

A I'm sorry? Say it one more time.

Q There's no study that concludes that the Bair Hugger does not increase the risk for a deep joint infection in hip and knee implants?

A That does not increase it?

Q Yeah.

A I don't believe there is one.

Q Okay. 3M has never eliminated the possibility that Bair Hugger can cause airborne contamination?

A Well, I mean, the Bair Hugger system has

filters and the blankets also form a portion of a system that reduces particulates. So, I mean, I'm not exactly sure what you're asking me to agree to.

Q There is no study that 3M is aware of that concludes that Bair Hugger does not cause airborne contamination over the surgical site in an operating room?

A That eliminates Bair Hugger as a cause of bacterial contamination?

Q Yeah, or particulates.

A Or particulates.

Q Airborne contamination in general.

A Well, again, I can't think of a study that would directly speak to that.

Q Okay. In other words, if 3M wanted to make a statement that the Bair Hugger does not contaminate the sterile field, they would not have any study to support that statement, correct?

A Well, they may not, but that's not the critical outcome. The critical outcome is the development of a post-surgical site infection. That's the outcome that we're interested in.

Q I understand that.

A Particulates are merely a surrogate.
Q Let's break it up then, okay? 3M cannot scientifically state that the Bair Hugger does not increase particles over the sterile field, correct?
A That it does not?
Q Yeah.
A Well, we have evidence that it does.
Q Okay. So they can't state that, correct?
A Well, we wouldn't.
Q Okay. 3M cannot state that the Bair Hugger does not increase bacterial contamination over the sterile field, correct?
A I'm sorry, say it one more time?
Q 3M cannot state that the Bair Hugger does not increase bacterial contamination over the sterile field.
A Well, again, I don't think we have evidence to that.
Q Okay. What we do have evidence is that it increases particles over the sterile field, correct?
A We do have a study that shows that.
Q And we do have evidence --
A Small amounts.

Q In an operating room a significant number of particles are squamous, correct?

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

A They can be, yes.

Q Well, you're aware of the amount of squamous that are generated during an operation by the personnel in the patient in the operating room, correct?

A Yes.

Q In the order of millions?

A Yes.

Q Okay. And you're aware of studies or literature that indicates that the majority of particles generated in an operating room is from the personnel in the operating room?

A Yes.

Q Okay. And you agree that there is a significant amount of the squamous that are generated can carry bacteria?

A Yes.

Q Okay. And according to 3M's own expert, he estimated about 40 percent of the squamous in the operating room carry bacteria?

MR. GORDON: Object to the form of the

question, mischaracterizes the evidence, misstates the evidence, lack of foundation and also way beyond the scope of the 30(b)(6) deposition.

A Is this Angalingous (phonetic)?

Q Wenzel.

A Oh, Wenzel. So I'm sorry, would you state it one more time?

Q Bacteria travel on squamous, correct?

A Among other things.

Q And everyone has bacteria on them, correct?

A Yes.

Q Okay. A lot of bacteria, to be quite honest?

A Yes.

Q So much we don't even think about it?

A Correct.

Q And --

A Well, we don't know it.

Q -- and we can agree that a significant number of the squamous that are in an operating room contain bacteria?

A Yes.

Q Okay. And some say up to 40 percent of

the squamous carry bacteria?

A I'll assume that that's correct.

Q And 3M agrees to that?

MR. GORDON: Object to the form of the question and beyond the scope.

A I mean, if Professor Wenzel said that that's the number, then that's probably correct, but that doesn't have anything to do with Bair Hugger.

Q And with respect to the environment of use and designing, for example, the 775, this is information that 3M is aware of, you know, that there's squamous in the operating room, correct?

A Yeah, particles.

Q That squamous carry bacteria?

A Yeah.

Q Okay. That physicians want to reduce particles over the surgical site?

A Yes.

Q They want to reduce bacteria over the surgical site?

A Yes.

Q Okay. That 3M was aware that the Bair Hugger increases particles over the surgical site?

A Yes.
Q Therefore increasing the bacteria load of the surgical site?
A Well, again, particles are not bacteria.
Q I understand that. But if a certain percentage of particles carry bacteria, if you increase the particles, logic would mean that you would increase the bacteria?
MR. GORDON: Object to the form of the question.
A Well, I mean --
Q Statistics.
A Okay.
Q I mean, if you increase -- if you have a million particles and 40 percent of them carry bacteria, and you take that and you increase that load of particles over the surgical site, some of those particles will have bacteria on them, right?
MR. GORDON: Object to the form of the question, incomplete hypothetical, lack of foundation, and beyond the scope of this deposition, 30(b)(6).
A I mean, that makes mathematical sense, yes.

Q And logical sense, correct?

MR. GORDON: Same objections.

A Yes.

Q Okay. And therefore -- withdraw that question.

3M, with all of this knowledge, chose not to warn physicians or hospitals regarding this increased load -- or increase in bacteria over the surgical site -- over the surgical site as a result of the Bair Hugger, correct?

MR. GORDON: Object to the form of the question, assumes facts not in evidence, incomplete hypothetical, and beyond the scope of 30(b)(6).

A So I'm not seeing the relationship between the skin squamous and the Bair Hugger. What does one have to do with the other? I don't understand that connection.

Q Forget about the skin squamous for now. The mere fact that the Bair Hugger increases particles over the surgical site you agree, correct?

A It can, yes.

Q It does. Not it can, it does.

A Okay.

Q In every study it showed that, correct?
A Well, in the studies that we know of, the particulate counts went up over the surgical site.
Q We only know what we know because of science and a lot of this is through peer reviewed studies, correct?
A Yes.
Q Are you aware of studies that Bair Hugger does not increase particles over the surgical site?
A I am not.
Q Okay. So we know that increased particles of surgical site, therefore, it is going to increase the bacterial load over the surgical site, agree?
MR. GORDON: Object to the form of the question.
A It may increase the bacterial load over the surgical site. I don't know where those bacteria end up landing. Obviously there's a lot of complex airflow that can sweep them away.
Q As someone that's been in the medical device community for 30 years, you would agree that orthopedic surgeons -- that information

would want to be known to orthopedic surgeons that do hip and knee implant surgeries, correct?

MR. GORDON: Object to the form of the question, lack of foundation, outside the scope of this deposition.

A I suspect that some would want to know that, yes.

Q Okay. And 3M was aware of that information?

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

A Well, in fact, this was published in a top tier journal.

Q I understand that. But --

A There's no attempt to hide it.

Q Huh?

A There was no attempt to hide it.

Q 3M chose not to put any warnings in their manuals regarding the increase of particles as a result of the Bair Hugger over the surgical site, correct?

A Because there is no evidence that it increases the risk of surgical site infection.

Q And there's no evidence that it doesn't either?

A But there's no evidence that it does.

Q Okay. But there is evidence that 3M is aware that many orthopedic surgeons are of the opinion that increased particles over the surgical site increases the risk of a deep joint infection?

MR. GORDON: Objection, asked and answered several times.

A Well, I think we know from the International Consensus Committee that they do believe that.

Q Okay. So the orthopedic surgeons know it or believe it. 3M is aware of the increased particles, but 3M chooses not to add a warning or add any caution regarding orthopedic surgeries or hip and knee implant surgeries in their manual, correct?

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

A Well, again, the International Consensus Committee reviewed these papers and chose not to restrict the use of forced-air warming in orthopedic surgeries. They know all of this information.

So yes, it's true, many orthopedic

surgeons believe that this could be a problem, but they as a group decided, based on the evidence that we're talking about, that it didn't -- it didn't -- it wasn't enough of a reason to restrict its use.

Q The International Consensus didn't have any internal documents that 3M had or all the information that 3M had, correct?

A Well, I think they have all of the publicly available science that we have.

Q They didn't have the Schlieren testing that 3M had, correct?

A Yeah, but that's a qualitative.

Q They didn't have the CFD studies that 3M had?

A Well, first of all, Schlieren doesn't show particulates.

Q I understand that, but it shows thermal plumes.

A They are all completely aware of that. It's hard to find an orthopedic textbook that doesn't have a Schlieren picture in it.

Q My question is: Let's talk about what the International Consensus had. They had published studies, correct?

A Yes.
Q They didn't have --
A Plus the experience of their researchers.
Q They didn't have the knowledge that 3M -- all the knowledge that 3M has, correct?
MR. GORDON: Object to the form of the question, lack of foundation, beyond the scope.
A Well, what knowledge do you mean?
Q Well, do you know whether or not any of the voting members of the International Consensus was aware of the fact that every single study that looked at particulates over the surgical site showed an increase over the surgical site of particulates when the Bair Hugger was used?
A Well, I'm not aware of whether they are aware of that. But again, they are experts whose professional careers are dependent on being aware of the literature.
Q Let me ask you: Does a corporation such as 3M rely on consensus statements to formulate warnings for their medical devices?
A Among other things.
Q Okay. I mean, you're not sitting here today, 3M, and saying we're only going to put warning devices when an orthopedic surgeon or a

consensus tells us to put a warning on our labels, correct?

A In fact, we put warnings on based on a probability of an adverse outcome.

Q There was nothing preventing 3M from putting in the cautions or in the manual that the Bair Hugger increases particulates over the sterile field?

A Well, there's nothing preventing it. But again, the people on the risk mitigation committee obviously didn't perceive that risk as being high enough to justify that label warning.

Q But nothing prevented 3M from adding that risk?

A Well, I don't know. Prevented us, you mean legally prevented us?

Q There's nothing false about that statement?

A Well, it may not be false, but it also may not have -- it may not rise to the level of probability to make it justifiable to put on there.

Q Well, when every single study shows increased particles over the sterile field, the probability is very high that the Bair Hugger is

going to increase particles over the sterile field?

A That may be, but the probability that it increases surgical site infection is not.

Q That's fair. But that would be something for the surgeons to decide of whether or not they want to use the Bair Hugger device for hip and knee implant and not for 3M to decide, correct?

MR. GORDON: Object to the form of the question, lack of foundation, argumentative, outside the scope of the 30(b)(6) deposition.

Q Let me ask you this: 3M is aware of this information. Has 3M come out publicly in any media, convention, conference, Dear Dr. Letter that said, "Hey, surgeons, we want you to know this. We have conclusive evidence that the Bair Hugger increases particles over the surgical site"?

A No, we have not.

MR. ASSAAD: That's all I have. Genevieve is going to be next.

MS. ZIMMERMAN: We're going to take a break.

MR. GORDON: What do you mean Genevieve is going to be next?

MR. ASSAAD: For the other topics. I only dealt with engineering and design.

THE VIDEOGRAPHER: Should we go off the record?

MR. ASSAAD: Yes.

THE VIDEOGRAPHER: Off the record.

(Whereupon, a break was taken from 3:53 p.m. until 4:07 p.m., after which, the following transpired.)

THE VIDEOGRAPHER: We're on the record.

EXAMINATION

BY MS. ZIMMERMAN:

Q All right. Good afternoon, Mr. Van Duren.

A Hi.

Q I'm Genevieve Zimmerman. We've met once or twice in this litigation and I know you've been deposed before. And I'm going to ask you about some other topics about Exhibit 1 that was in front of you.

To start with, number 9 asks about "Defendants' internal tests conducted to determine the benefits and efficacies of preoperative warming." Do you see that?

A Yes.

Q And that is something that you are prepared to testify about today?

A Yes.

Q All right. What internal tests did 3M or Arizant or Augustine conduct to determine the benefits and efficacy of preoperative warming?

A So we did some testing in 2006, I believe -- yeah, 2006, where we looked at the effect of extremity directed warming. So heating the arms and legs and hands and feet as opposed to heating the central part of the body to see which one happened to be more effective at prewarming.

Q And so that would have been directing warming to just one particular part of the body at a time?

A Yes, so heating only the central region of the body or heating the extremities of the body.

Q Was that specific to forced-air warming or other patient modalities?

A So it was forced-air warming for the central part and it was conductive warming for the extremities.

Q What kind of conductive warming?

A It was heated towels.
Q Something like a cotton blanket that is put in a little --
A Yeah, a heated cotton blanket. Exactly.
Q And do you consider heated cotton blankets conductive?
A Yes.
Q And that was 2006. Who was involved in that testing?
A I was.
Q Anyone else?
A My assistant at the time, Tracy Pownell.
Q And what were the results of your tests?
A That there -- that there wasn't any substantive difference due to the fact that the warm cotton blankets didn't really have a lot of energy. They were warmed up in an oven, put on the subjects that we looked at, core temperatures, things like that.
Q And so was the aim of the tests to figure out if both were effective at preserving patient normothermia?
A The hypothesis was that the extremity one would be more effective. Initially we were going to use forced-air warming for that, but the

device that we had anticipated using was not FDA approved at the time, so that's why we moved to warm cotton blankets or towels.

Q And that was -- 2006, that was during your time at Arizant?

A Yes.

Q After Dr. Augustine left and before 3M acquired the company?

A Correct.

Q All right. What type of forced-air warming was used in that study?

A Bair Hugger.

Q Okay. The model 600 or?

A It was -- it was a 750 with a full-body blanket.

Q And what about that configuration --

A I beg your pardon, that's not right. It was a gown. A gown with, whatever the 850, I think, is the gown warming device.

Q And so when you say "gown," you mean the Bair Paws device?

A Bair Paws.

Q Was it called Bair Paws then already?

A Yeah, I think it was called that.

Q And when, by the way, did the Bair Paws

come to be?

A Oh, well, I think the first one was still -- Dr. Augustine was still there, so 2003-ish.

Q And I'm sorry, so this device wasn't approved for this use by the FDA at the time?

A Correct. We never did get FDA approval on that.

Q And why was that?

A We didn't pursue it.

Q Did you submit an application and withdraw it?

A No. We -- I don't think we -- we just never pursued it. We didn't think that there would be much of a market for it.

Q And by "it" you mean?

A The extremity-directed warming.

Q All right. So it was the --

A We already had a Bair Paws gown at the time. This was kind of superfluous and we didn't think that people would buy it.

Q All right. That's sort of a cotton blanket or towels that go on the extremities?

A Yes.

Q All right.

A Well, that's what we used in place of.
Q In place of?
A Of the device that we didn't seek approval on.
Q So there -- and did you not seek approval of the device because of the results of this particular test that sort of --
A Nope. We just didn't because the Bair Paws gown was doing well, we didn't think there would be much market for this.
Q All right. And the Bair Paws gown was invented anyway somewhere around when Dr. Augustine was still involved with the company?
A Right about the same time, yes.
Q Right around 2003?
A Somewhere in that timeframe.
Q And is that about when the company changed name from Augustine to Arizant?
A Very shortly thereafter.
Q All right. And was Dr. Augustine involved in the design of the Bair Paws?
A I don't -- I don't know. I think that was actually designed by -- well, I'd have to look at the patent. I don't know.

Q Okay.
A There were a number of people involved in the design of the Bair Paws gown.
Q Is the Bair Paws gown approved by the FDA for use in the operating room?
A Yes.
Q And when did that approval take place?
A Well, whenever it was first commercialized.
Q Was that shortly after when it was invented, around 2003?
A Yes.
Q Well, what other testing did you do or were you involved in? And by "you" I mean 3M, to determine the benefits and efficacy of pre-operative warming?
A Internally? Internal testing, is that what you mean?
Q Yes, sir.
A That was about what the extent of what we did internally; so, yeah.
Q And is it fair to say that that test was limited, for the most part, for efficacy of the warming product?
A Yes.

Q Was there any focus in that test that you did about safety of the product?

A Only insofar as that it didn't heat tissue to higher than 43 degrees.

Q Fair to say it was not a thermal sort of injury, sort of a concern?

A No, we had no concerns about thermal injury.

Q Were there any other risks that you were concerned about with respect to prewarming the patient this way?

A No.

Q Have you come to learn of any other risks associated with prewarming a patient?

A No, we have not.

Q So fair to say that prewarming a patient is safe?

A It is safe.

Q It's effective?

A It can be effective, yes.

Q Agree that it's also inexpensive?

A It's the same cost as intraoperative warming, yes.

Q And there are a number of different ways that prewarming can be accomplished, correct?

A Yes.
Q And that's true for intraoperative warming as well, right?
A Yes.
Q Different products that can accomplish the same goal?
A Yes.
Q And that's something that you have paid attention to throughout your role both at Augustine, then at Arizant, and also at 3M; fair?
A Yes.
Q There have been other alternatives to achieving patient normothermia throughout your duration of these companies?
A They can work, yes. They're not all as -- they have different efficacies; but yes, the goal is the same.
Q And there are other products that also achieve this goal as well; is that fair?
A Yes.
Q Prewarming is something that you have been studying in your role at both Augustine, Arizant and now at 3M, for 20 years; is that fair?
A Almost 30.

Q Almost 30. All right.

And it's fair to say that you've kept abreast of the litigation -- litigation, pardon me -- the literature about prewarming?

A Yes.

Q That was one of the responsibilities that you had at all three iterations at the company?

A Yes, not only that but --

Q One of your responsibilities?

A Portion, yep.

Q And you prepared some memos from time to time about the efficacy of prewarming, right?

A Yeah, reports and memos. Yes.

Q Would you agree that prewarming is also not associated with any adverse events?

A Well, I mean, what we always are concerned about with any sort of warming is the creation of a burn. So we always worry about that, and that's certainly a risk. We don't want to -- we would never -- we don't want to operate the warming system at a temperature high enough to cause a burn. That's a big risk, so we are concerned about that.

Q And do you avoid that risk by setting the maximum temperature of the machine at 43 degrees

celsius?

A Yes.

Q Are you aware of any thermal burns to patients caused by prewarming?

A Not by prewarming.

Q Are you aware of thermal burns to patients caused by other prewarming?

A Yes, by conductive warming.

Q Tell me about that.

A Some electric mattress devices can -- have caused burns in the past.

Q In the prewarming context as well?

A I'm pretty sure they were during prewarming, yes. And in veterinary applications as well.

Q And you keep abreast of also the literature in the veterinary field as well?

A Yes, we sell into that market as well.

Q Quite a bit, I think. Vets use quite a bit of Bair Paws and Bair Hugger blankets?

A We do.

Q We love our animals here for sure in the United States and take good care of them.

A Yes.

Q Would you agree that a significant

advantage of prewarming is that it is done before the surgical incision is made?

A Well, it's true it's done before the surgical incision. I'm not sure that it's an advantage. I'm not sure what you mean by an advantage, necessarily.

Q And you're not sure if it is an advantage?

A Well, I don't know what you mean by that being an advantage.

Q Okay. Would you agree that prewarming has been shown to reduce post-operative surgical wound infections?

A At present I don't think that there are any prewarming-only studies that show a reduction in post-operative wound infections.

Q When you studied prewarming, is your literature focused on prewarming only or prewarming in addition to intraoperative warming?

A Both.

Q Is some of the literature focused only on prewarming?

A Very little.

(Whereupon, Exhibit No. 8 was marked for identification.)

MS. ZIMMERMAN: What number are we on?

THE REPORTER: 8.

MS. ZIMMERMAN: And Corey, the cover page is just our document service. It has nothing to do with you guys.

BY MS. ZIMMERMAN:

Q Mr. Van Duren, do you recognize this document?

A Yes.

Q What is it?

A Oh, it's a report that I wrote back in 2005 about prewarming.

Q And the Bates number at the bottom starts with 3MBH_00834864; is that right?

A Yes.

Q And it looks like there's a clinical research library notation at the top right-hand, it says number 1553; is that right?

A Yes.

Q Is that your numbering system?

A That's my numbering system for my library.

Q And is that something that you maintain throughout the time that you have worked both at Augustine, then Arizant and now at 3M?

A Yes.

Q And that's part of the documents that were produced after the last time that we sat down for a deposition; is that right?

A Same group, yes.

Q Okay.

MR. GORDON: This one wasn't though, was it?

MS. ZIMMERMAN: I don't know that this specific one was, or it's in the collection of documents.

MR. GORDON: But I mean, it was produced a long time ago.

MS. ZIMMERMAN: It may have been.

A This is a very low number, so I'm sure it was produced a long time ago. The library has been copied at least once, maybe more than once.

BY MR. ZIMMERMAN:

Q Fair to say that you haven't been asked any questions about the memos that you wrote about prewarming in any of the depositions that you've had so far; is that right?

A I don't believe so.

Q And this, again, is a memo that you wrote in January of 2005; is that correct?

A Yes.

Q And you're talking specifically about prewarming of patients for surgeries; is that right?

A Yes.

Q On page 2 of 14, you've got a chart there that sort of documents a growth of outpatient procedures and hospitals; is that right?

A Yes.

Q And the basic notion is that there are getting to be more and more surgeries, particularly outpatient surgeries as the time has gone forward; is that right?

A That's correct.

Q And you would expect that that growth is going to continue, fair?

A Yes.

Q For the most part, it's been your experience and your understanding that doctors like to get their patients in and out of the hospital as quickly as safely as possible, fair?

A And through surgery as fast as possible.

Q Right.

A Yes.

Q And throughout the course of this 14-page

memo, you go through with some precision sort of how a body absorbs heat, how to measure body temperature, the physiology of thermal regulation. Fair to say that you pay pretty close attention to the work that you do and you try to be careful about that, right?

A Yes.

Q And that's been your practice throughout the time that you worked, whether with Dr. Augustine at Augustine Medical, for Arizant, and continuing to this day at 3M; fair?

A My approach has been similar at every place that I've worked.

Q You've always taken pride in what you do, right?

A I try to, yes.

Q And by the way, who asked you to prepare this document?

A I don't think anybody asked me to do this. This was -- I think this was conceived as a -- maybe a white paper or something like that for customers at the time.

Q All right. So you think that at some point that -- it's sort of an intended audience was likely to be a customer of the company?

A I think so. I think that was the point at the time. I'm not sure that we ever published it --

Q Sure.

A -- but that was what the intent was.

Q And part of that was because you, Augustine, Arizant and 3M, were selling prewarming products; is that fair?

A Yes.

Q And so from time to time you would get customer questions about whether or not the product that you were selling had any evidence supporting its clinical use; is that fair?

A Well, and also more how it worked.

Q Sure. And both of those things would be questions that you would get from time to time?

A Yes.

Q At the beginning or the top of page 7 of 14, you have included at figure 2 the three phases of anesthetic-induced hypothermia. Do you see that?

A Yes.

Q And basically you're plotting on a graph or whoever -- you didn't create this graph, I assume?

A No, this came from Andrea Kurz and Dan Sessler.

Q Okay. So this is Kurz and Sessler work. And their chart, anyway, shows that there is three different phases of anesthetic-induced hypothermia; is that right?

A Yes. This is a graph that shows core body temperature in response to anesthesia in nude, anesthetized men.

Q Okay. Pretty specific subset?

A Yes.

Q Was it specific to any particular type of surgical procedure?

A There was no surgical procedure involved. These were just --

Q Volunteers?

A -- volunteers who volunteered to be anesthetized.

Q Okay. That's an interesting hobby. I guess we're all grateful that they do that but...

So fair to say that Dr. Sessler in his chart here sort of documents that over the course of the first, is it six hours of anesthetic, basically time under anesthesia, the patient will lose somewhere between zero, and it looks like

about three-and-a-half degrees celsius?

A Something like that, yes.

Q All right. And would you agree that according to Dr. Sessler's chart, that at least for the first hour the expected heat loss for sort of phase one is just shy of one-and-a-half degrees celsius; is that about fair?

A So I just want to get -- not to be too technical, but it's not heat loss.

Q Okay.

A So that's the really critical thing about prewarming. It has almost nothing to do with heat loss.

What happens in -- after the induction of anesthesia is that the heat in the body mixes. So the heat that is in the central part of the body moves to the external areas, and the cold blood that is in the external areas moves to the central part, so there's a mixing. That's what causes this initial decrease. It has nothing to do with heat loss.

Q All right. But at least for this chart, is this specific to patients that have been prewarmed or is this just a chart about volunteers that --

A No.

Q -- have agreed to be anesthetized?

A Right. These are unprewarmed, nude male volunteers.

Q So those folks that are not prewarmed, according to this chart anyway, drop their core temperature somewhere around one-and-a-half degree celsius inside that first hour; is that about right?

A That's correct.

Q And then through, it looks like, about the two-hour mark it's a little over two-and-a-half degrees celsius change in core temperature; is that fair?

A Yes.

Q And then it goes down yet a little bit more during phase three, which occurs between, say, two-and-a-half hours of elapsed time and six hours; is that fair?

A That's fair. Yeah, that's correct.

Q Now, with the charts on the next page, 8 of 14, both of those are actually cited to be from Sessler and -- is it Moayeri?

A Mmm-hmm.

Q The one on page 7 doesn't actually have

the same cite, but it comes from the same place?

A Yes.

Q Okay.

A Yeah. I think this is probably -- this is a draft, so I would have gone back and put in the citation for that chart.

The chart is unusual because the data comes from one paper and the graph comes from another one.

Q And you have a number of citations you can see in the last couple of pages of your memo, it looks like 74 different citations?

A Mmm-hmm.

Q Obviously sort of trying to show where you got this information from and the support for that?

A Right.

Q What, by the way, Mr. Van Duren, tells you that this is a draft of this document?

A Well, I mean, just the format. It's not in any sort of Arizant or 3M-brochure style.

Q Okay.

A This is a draft as I would have typed it.

Q Okay. And presumably then the sort of results of the memo that you put together would

be something that you would discuss with the folks at Augustine or Arizant, and that's where you were at the time, right?

A Yes.

Q So at the sort of bottom part of page 10, if you can flip over to the next page, you've got a paragraph that's titled "summary"; is that fair?

A Yes.

Q And you, again, you say that "the maintenance of normothermia during anesthesia and surgery improves clinical outcomes." But you sort of note that only a fraction of surgical patients receive perioperative warming, so before surgery warming, right?

A Perioperative means that any time during the surgical procedure, before, during or after.

Q And that's how you meant in that particular --

A Mmm-hmm.

Q And it includes, for sure, intraoperative as well?

A Yes.

Q Okay. But only a fraction of surgical patients are actually warmed at some point; is

that fair?

A Right.

Q And this was in 2005, I think; is that right?

A All right. Yes.

Q About -- let's see, halfway down the paragraph you say, "A commonly cited reason for failing to provide warming is that it interferes with the preoperative workflow once the patient is actually in the operating room." Do you see that?

A Yes.

Q And it says, "One solution to this problem is prewarm the patient prior to arrival in the operating room"; is that right?

A Yes.

Q So basically make sure that they're warm before they get to the operating room and then there's not going to be any sort of interference for the staff inside the OR; is that fair?

A Yeah, that's the theory. Yes.

Q And you go on to say, "The goal of prewarming is to raise the mean body temperature to its maximum tolerable level as rapidly as possible without provoking a compensatory,

thermal, regulatory response." That's sweating, right?

A Yes.

Q And then you say that "current research suggests that 30 minutes of prewarming with existing convective warming blankets provides protection against hypothermia for approximately one hour in most cases"; is that right?

A Yes.

Q And what that means is that if you warm a patient for 30 minutes, there's not going to be hypothermia for at least the first hour; is that fair?

A In selected patients.

Q Does it say "selected" in your summary here?

A Well, it says again --

Q It says in most cases, to be fair?

A Most cases.

Q All right. And then you say "the barriers to prewarming are --" you note two -- "one, the additional time spent in the preinduction area"; is that right?

A Yes.

Q And then "two, the autonomic responses

that resist additional heat in the body"?

A Yes.

Q Some people just don't get warm as easily?

A Well, the human body resists being made warmer than its setpoint.

Q Needs to be?

A Yeah.

Q Okay. And then you say at the conclusion of the sort of summary paragraph: "Future research should focus on methods to minimize the amount of time required to prewarm patients requiring anesthesia by exploiting high intensity focal warming on areas of the bodies that are insensitive to the rate of temperature change."

And that's sort of a lot in that sentence. Is that sort of like warming up the extremities that you were talking about?

A Well, it turns out the extremities are extremely sensitive to the rate of temperature change. So that's kind of one thing that we learned in the --

Q Study in 2006?

A -- the study that I was discussing, yeah, after this.

Q I remember, you know, I was a cross-country skier in high school and college and they'd say if you got hot, take off your hat or gloves and it would cool down your whole body pretty quickly, right?

A That's probably true. Yeah.

Q Is that what you saw in the study in 2006?

A We saw that the patients who got the extremity directed warming developed thermal -- thermal comfort much more rapidly than the patients who got central warming.

Q And did it ultimately impact their mean core temperature?

A No, it didn't.

Q They just felt more comfortable?

A They felt more comfortable, but it didn't have any effect on their mean core temperature.

Q Have you done any research on warming patients that way after surgery? For example, warming their hands or warming their feet. Does that make a difference with shivering, for example?

A No, I have not.

Q Okay. And then so the next page you have

prepared a chart and it is called: "Table One, Pros and Cons of Convective Prewarming." Is this a chart that you drafted?

A Yes.

Q And again, you tried to be detailed and careful as you prepared this?

A Yes.

Q And the top it says, "The following table lists several pros and cons related to the use of convective prewarming," right?

A Mmm-hmm.

Q And "convective" means with forced-air warming, for example?

A Yes.

Q All right. So the pros on the left-hand side, warming somebody with convective technology before the surgery, prewarming, is inexpensive, correct?

A Yes.

Q You also found that it's safe, right?

A Yes.

Q You found that it can be used when intraoperative warming is contraindicated. And the two examples that you provide are aorta cross clamp and orthopedic cases, right?

A Yes.

Q You note next, "It permits unrestricted intraoperative patient access"?

A Correct.

Q So easy for the team to access the part of the patient that they need to get to during the surgery; is that right?

A That's right. Well, it doesn't prevent intraoperative access. So once you've prewarmed the patient, you have intraoperative access to the patient.

Q And that's because you don't need to warm them intraoperatively, correct?

A Well, in some cases you don't. But in many cases you can prewarm patients and use heat, preservation methods to prevent them from getting cold again.

Q So sometimes healthcare providers decide to both prewarm and warm intraoperatively; is that right?

A Yes.

Q But the research in this memo also suggests that prewarming alone for a half an hour can be effective at eliminating hypothermia for at least an hour in most cases; is that fair?

A Yes. Again, in some patients, and as long as the prewarming occurs right up until the point of induction.

Q All right.

A So there are restrictions. It's not unlimited.

Q Sure. But if that happens, if the prewarming has been done correctly, that would permit unrestricted intraoperative patient access, as you note as a pro in this column, right?

A Yes.

Q Okay. The next one you list is that: "The use of convective or forced-air warming in the prewarming setting does not contaminate the sterile field"; is that fair?

A Yes.

Q Because it's not used in the operation room, right?

A That's right.

Q Next, you say that "the use of forced-air warming in the prewarming context does not interfere with OR equipment," correct?

A Yes. So at the time in 2005, whenever this was --

Q Yeah.
A -- or prior.
Q 2005.
A The control circuitry in all forced-air warming systems switched the electric heater in the blower unit all as a complete load, one complete load, usually about a thousand watts. And when it did that, it caused the lights in the operating room to flicker so surgeons hated that. So if you don't use forced-air warming in the operating room, you don't have that problem. So that's what it's referring to.
Q Okay. And the Bair Hugger, if it's a thousand watts, it's a pretty powerful -- it requires a large amount of energy inside the operating room, right?
A It does. And it's not just Bair Hugger, it's all of the forced-air warming devices.
Q Sure. Oh, and I didn't mean to make that specific. Because this chart is intended to be summarizing the pros and cons of using convective prewarming as compared to convective intraoperative warming, fair?
A Well, I'm not sure it's a comparison, it's just the pros and cons of doing it.

Q Okay. The next one on your pros list, it has: "Convective prewarming through a forced-air warmer is generally well tolerated and comfortable"; is that right?

A Yes.

Q Patients sort of like it while they're waiting to get ready for surgery?

A They can generally tolerate it if it doesn't last too long.

Q By the way, were there other convective prewarming products on the market besides the Bair Paws at this time?

A There were products that could be used to convectively prewarm, yes.

Q Do you remember which ones?

A Well, any of the ones that had full-body blankets.

Q Okay. And were they generally used, do you know?

A No. Prewarming is really not something that is widely practiced anywhere well, in the world, frankly. It wasn't then and it's not much now.

Q Is it fair to say that sometimes people get set in their ways, the way they're trained to

do things?

A No, it's more because it interferes with the work flow is in the operating room. So any -- any disruption of getting patients into an operating room is something that is to be avoided at all costs.

An operating room in the United States costs about a dollar a second. The PACU cost about a dollar a minute. Preoperative is even less than that, I don't recall what it is. But if you can spend the money in the preoperative area and in the post-op -- the PACU, it's better than doing it in the operating room. But the problem is that prewarming patients in the pre-operative area completely halts their entry into an operating room. And so the operating room is sitting there with no patient sitting in it, so that's very, very expensive. So -- and so that's one major reason why it's not widely practiced.

Q Okay, but one of the issues there are proper scheduling of the operating room, right?

A Which is a virtual impossibility. And people have spent entire careers working on schemes to schedule operating rooms. I mean,

there's a whole academic literature on operating room scheduling and queue theory, and all kinds of points on distributions. It's very complicated stuff, believe it or not. And nobody has really figured out a very good way to handle it. Because the first time there's a delay in an operating room, it throws all the scheduling off.

And so yeah, I mean, people understand the consequences, but trying to schedule it appropriately is very, very difficult.

Q And yet, despite the difficulty, it's something that the people that research those sorts of issues, they continue to do the research and make suggestions about how they might do it better; is that fair?

A They do.

Q All right. The next point that you make in your pros and cons chart is that "preoperative warming with convective therapy is effective during at least the first post-induction hours"; is that right?

A Yes.

Q And that's what we just talked about. The end of your summary was if you prewarm somebody effectively for 30 minutes, it's going

to prevent intraoperative hypothermia, sort of post-induction for the first hour; is that right?

A It can in selected patients as long as the prewarming occurs right up to the point of induction.

Q Well, it may be selected cases, but the way you summarized it on the previous page was "most cases"; is that fair?

A It's fair; but again, this is a draft.

Q Sure. The next pro that you list is that it "Reduces the incidents of surgical site infection to use convective prewarming therapy." Do you see that?

A Yes.

Q And that's accurate or was at least when you wrote it?

A It was based on the idea that intraoperative normothermia reduces the risk of surgical site infection in many kinds of surgeries.

Q So this particular pro is based essentially on Sessler and Kurz's work?

A And others that looked at surgical site infections during normothermic surgeries, yes.

Q All right. So anyways, this particular

pro is related to -- at least the theory, and we can debate it, but I won't right now, about normothermia providing a benefit of avoiding surgical site infection; is that right?

A Yes.

Q So then we move on from there to the next pro. You also note that it "reduces the potential for nosocomial transition of pathogens by eliminating the need of intraoperative warming." That's what happens if you use forced-air warming in a prewarming setting, right?

A It's what many of our customers had been complaining about, yes.

Q And that's sort of some of what we've been talking about today and the other times that we've done your deposition?

A Absolutely.

(Reporter interruption.)

Q And then, of course, Mr. Van Duren, you know, this is a topic that we've talked about from time to time, both with you and with other witnesses for 3M, but the notion of this pro is that by not having intraoperative warming with a forced-air warming unit, that there is less of a

chance that pathogens are going to get into that surgical site during an operation, right?

A Well, again, this was -- this was put in there for customers who had that perception that that's -- that was a problem. So this is a way that they could get around that.

Q Right. This particular pro sort of eliminates concerns that people may have, fair?

A By the customers, yes.

Q All right. And certainly that's something that you had heard about from time to time throughout the course of the time that you've worked both for Augustine, Arizant and 3M, fair?

A Especially by 2005, yes.

Q Right. The next pro that you list is that: "Preoperative warming blanket may be used in surgery and the PACU."

So that means that that forced-air warming, convective prewarming blanket, they can take it right into the operating room with them, right?

A That's right.

Q And perhaps that means that it may shorten the time that the surgical team needs to

drape and otherwise get the patient ready for surgery; is that right?

A Well, more importantly it just reduces the cost associated with intraoperative warming and post-operative warming. You don't have to use three different devices, you can use one device.

Q All right. Sort of brings the cost down and eliminates extra disposables; is that right?

A Yes.

Q Okay. And then the last pro that you have on this chart is: "Insensate patients can control degree of heating."

Basically because they're still awake when they're prewarmed, they can say if they want more or less warmth"; is that right?

A It's true. It turns out that's not correct though.

Q Really?

A Yes. It turns out that -- yeah, when I put that there, that's what I believed. But it turns out that patients, in fact, all human beings, when they can they adjust their external temperature environment so they're thermal neutral. That they don't -- that they don't

absorb any excess heat.

And so while, you know, this was something that Dr. Augustine thought was great with the Bair Paws that you could control the temperature of the prewarming, but it turns out that it doesn't work because the minute that you let someone control the temperature to which they're exposed, they turn it down so that they don't absorb any heat.

Q They don't want to be hot?

A They don't want to, yeah.

Q Okay.

A So that is incorrect.

Q All right. And you didn't say that is incorrect for any of the other pros that we went through on this list?

A Well, the -- I mean, they're not -- it's not that they're incorrect. But I mean, for example, "it does not contaminate the sterile field" was put there to appeal to the customers who have been complaining about the fact that they were worried at this point, because I think Dr. Augustine had already started his "Blowing Air is Risky" campaign by 2005, I'm pretty sure. And you know, we had people call us and

complaining about, you know, what do we do?

Q Well, certainly you were told, even when you started in 1994, that there were already concerns by various clinicians about the potential risk of airborne contamination causing wound infections, right?

A It was a very, a very small number of complaints -- or not even complaints, but questions at the time; but in 2005, it was quite a bit more.

Q But to the extent that it may have been characterized, perhaps, in this litigation or in some other place that there was a newfound concern once Dr. Augustine left the company, that would be incorrect, fair?

A I'm sorry, I misunderstood. Can you say that again?

Q Sure. So when you started at the company in 1994, you were already told that there were customers calling in with either questions or complaints about the potential risk of wound infection coming from airborne contamination associated with the Bair Hugger?

MR. GORDON: Object to the form of the question, compound.

A So there was some questions about it, yes, in 1994.

Q And that was -- those questions were made clear to you when you started at the company in 1994, fair?

A Well, soon after.

Q Okay. And that those questions were, that clinicians had concerns about particulates as causes of wound infection, right?

A Yes.

Q And they were deemed to be significant enough that as a result of those conversations, you, Mr. Van Duren, submitted invention disclosures for dual-heating devices in December of '94 and in May of 2002, that specifically addressed the advantage of using RF heating as an air-free alternative to warming patients in a sterile environment. Do you remember that?

A Yes.

Q The disclosures were then resubmitted in the 3M patent system in 2011, fair?

A I guess. Not by me, but it sounds right.

Q Somebody submitted them anyways?

A Yes.

Q And that would be consistent with your --

sort of your recollection, right?

A Yes.

Q And you were emailing Mr. Hansen about that in 2012. Is that generally consistent with your recollection?

A Yes.

Q So to the extent that you were including in the list of pros of convective prewarming, this sort of potential -- that it reduces the potential for nosocomial transmission of pathogens by eliminating the need of intraoperative warming, to the extent that that was done to appease ongoing complaints that you and the company had received, those weren't brand new complaints based on Augustine, those -- perhaps they grew, but it was the same complaint that you had been advised about starting even in 1994; is that fair?

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

A Again, it was a concern by some customers, and by 2005 was probably more than just a concern. I mean, there was -- it was a campaign on at that time to draw attention to it by Dr. Augustine. So...

Q Which campaign are you referring to?

A I think it was called the "Blowing Air is Risky" campaign.

Q Do you know or recall as you sit here when that started?

A I -- well, let's see, he left in 2003, so maybe around 2000 -- maybe 2007, somewhere around there. So this is -- this precedes that, but again, there were, you know, there were questions, concerns.

Q And is it fair to say that that was sort of an ongoing question -- questions and concerns you received on an ongoing basis from when you started in '94, at least through the time of this memo in 2005?

A Ongoing? Yes.

Q You list a couple of cons on the right side of your chart, the table one. It says that "convective prewarming" -- obviously with a Bair Paws-type device -- "interferes with current workflow practices"?

A Yes.

Q Does that sort of have to do with the OR scheduling issue that we were just talking about?

A Yes.

Q You also said a con is that "the current therapy adds at least 30 minutes of pre-surgical time." Is that because it takes 30 minutes to prewarm a patient?

A It did then, yes.

Q Does it take less time now?

A No. To do properly, it still takes about 30 minutes.

Q Is there some research out there that says that prewarming for as little as ten minutes is also effective?

A Yes.

Q Okay. An additional con that you have on your chart is that "convective prewarming interferes with the preoperative access to the patient."

A Yes. If you prewarm with a full-body blanket, for example, you may have a difficult time placing ECG electrodes or IVs, access, that type of thing. Those are generally things that are done preoperatively.

Q All right. And I assume that the nursing and other medical care team manage to sort of navigate their way around that to some extent?

A They try.

Q Okay. Another con it says that "prewarming with convective therapy adds minor costs to short-duration surgery." Do you see that?

A Yes.

Q Does that mean because it's adding essentially another disposable?

A Yes, that's right. There was -- there was a view then and still exists that short-duration surgeries don't need any sort of temperature maintenance, which is not true, but adding any additional costs in particular to an outpatient surgical procedure is something to be avoided.

Q All right. Is it fair to say that the costs associated with these short-duration surgeries, blankets are less than $20.00 a piece; is that about right?

A They're less than $5.00 a piece.

Q All right. So that's the minor cost that you're talking about?

A Yes.

Q And then the last con of convective prewarming therapy is that "it is ineffective that the patient begins to sweat"; is that right?

A Yes.

Q And so when you say "short-duration surgery," by the way, is that less than an hour, less than two, less than three?

A Well, back in 2005, that was considered a surgery that was less than an hour.

Q Okay. Has the definition changed?

A A lot of surgeries nowadays can be around a half an hour of anesthesia time.

Q So it can be even shorter?

A It could be very short. And that's a goal.

Q Right. And by the way, I apologize, I sometimes talk too fast and sometimes I think I know where you're going, and I'm so happy to be back to depositions in person, I'll do my best to not run you over with my questions.

And so this is a memo that you drafted, and do you recall who you discussed this memo with in 2005?

A Probably Gary Hansen, my boss.

Q Anyone else that you can remember discussing it with?

A I don't remember discussing it with anyone else at the time, but Gary Hansen would

have been a person that I discussed it with.

Q So you would have discussed it with Gary Hansen in 2005. Have you discussed it with anybody else since?

A I think it was -- I think it was largely used in another paper, but I don't remember what the -- I don't remember -- it may have been an invention disclosure.

Q Okay.

A I don't recall, but I don't think I discussed it with anybody else.

Q All right. I assume you discussed it with the lawyers at some point, but I'm not asking about that.

Generally when you did a memo like this, is this something that would get sort of filed away in your office or circulated someplace that people could find it?

A Both.

Q Where would somebody access that particular memo?

A Well, this is in my library.

Q Yep.

A My library is all online. So all of the scientific affairs managers, clinical support

specialists, they all have access to my library. And medical writers, they all have access to my library.

Q And was that true in 2005 as well?

A No, not then, but now they all have access to it.

Q Who would have had access to this in 2005?

A Probably no one. Not electronically anyway.

Q Okay. Would there be -- I mean, you said that you discussed it with Gary Hansen at the time. Would there have been somebody else that sort of you routinely checked in with in terms of these white papers that you were drafting?

A No. Gary Hansen was my boss, so I discussed it with him.

Q And obviously, I guess -- I would guess that it's something that took a fair bit of time and attention on your part. 74 citations, that's a pretty thorough piece of research?

A Yeah, I'm sure it took a few days.

Q That was your goal anyways?

A Yep.

(Whereupon, Exhibit 9 was marked for identification.)

BY MS. ZIMMERMAN:

Q I've handed you what's been marked as Exhibit 9. Do you recognize that, Mr. Van Duren?

A Yeah, I recognize the format. Let me just take a quick peak at what this is.

Q Sure thing.

MR. GORDON: I assume the highlighting was yours?

MS. ZIMMERMAN: Mine and I'm happy to --

MR. GORDON: No, I just was --

MR. ZIMMERMAN: Yep, and not inadvertently given to you.

BY MS. ZIMMERMAN:

Q Does the front page of Exhibit 9 say that this is a protocol? It looks like the protocol revision date is September 6 of 2007, and the author is you, Mr. Van Duren?

A Yes.

Q And it looks like the title, there's an Arizant sort of logo at the top, and the title of the protocol is: "The effect of prewarming by a Bair Paws gown on redistribution hypothermia in patients undergoing total joint replacement or

colorectal surgery"; is that right?

A Yes.

Q And it looks like you were potentially working with an investigator at Forest Hills Hospital in New York; is that right?

A Yes.

Q And again, this was about prewarming in both total joint replacement and in colorectal surgery; is that right?

A Yeah, that's what the title says. Yes.

Q All right. Now, this document is a little bit longer than the one that we just went through. This one is 19 pages instead of 14. But it's got a cover page on it, and sort of as you flip through it, does much of it look sort of familiar to you?

A Well, this is largely a derive from that original document, yes.

Q So probably Exhibit Number 8 is sort of the predecessor to Exhibit Number 9?

A Yes.

Q So -- or one of the predecessors, there may have been more than one; is that fair?

A Yes.

Q And again, you're talking about

prewarming of patients, both in colorectal and total joint replacement surgery, right?

A Yes.

Q Turning to page 3 of 19, sort of in the middle, and I highlighted it sort of hoping that you can see where I'm going to. It says, "When performed correctly, prewarming alone is capable of preventing significant surgical hypothermia for up to three hours in suitable individuals." Do you see that?

A I do.

Q And that is, again, part of the protocol that you drafted?

A Yes, it is.

Q Turning to the next page, 4 of 19, again you sort of have a graph here, showing the growth of outpatient procedures in hospitals. Does this also come from Sessler, if you recall?

A I don't know. I don't know where that graph derived. I'm not really -- I don't think it came from Sessler. It actually looks like something that I put together.

Q Okay.

A I may have gotten this -- I suspect I got this data from the CDC. The CDC maintains a

database with this sort of data, so I probably got it from there.

Q And again, this is documenting that there is, at least a point, a demonstration of an increased number of both total surgeries, but also especially outpatient procedures between 1981 and 2004 on this chart, right?

A And a decrease of inpatient, yes.

Q And incidentally, Mr. Van Duren, I sort of asked you before that hospitals try to get patients out just as quickly as they can, if that's possible, right? As quickly as they safely can?

A Yes.

Q And you also said that surgeons also try to conclude surgeries as quickly as they safely can, correct?

A Right, because the complication rates are much lower the faster they can get patients in and out of the operating room.

Q All right. And would you agree that one of the complications that surgeons are trying to avoid by having a shorter duration surgery is potential nosocomial acquisition of bacteria resulting in infection?

A Yes.

Q The shorter amount of time that somebody's wound is open, the better for the patient, fair?

A Well, everything else being equal. I mean, you can be fast and so sloppy and still have problems.

Q Yeah.

A But in general, the -- in general, faster surgeons have fewer complication rates.

Q All right. And one of the complication rates that we're talking about is potential infection, fair?

A Yes.

Q And that's another reason that hospitals and the healthcare providers within the hospitals like to get the patients out of the hospital quickly, right?

A Right. They're less exposed to other people who have infectious diseases.

Q All right. Now, you go on through part of this memo again talking about sort of how anesthesia works and how patients absorb heat. We have the same chart on page 8 of 19 that talks about the three phases of anesthetic-induced

hyperthermia?

A Um-hmm.

Q Is that again from Dr. Sessler's work?

A Yes.

Q Okay. Moving on then to page 9 of 19, you start to talk about prewarming in the middle of the page; is that right?

A Yes.

Q And then you have some charts here. Figure 3 and figure 4 talk about "core temperature decrease during preinduction warming with several types of warming units." So this is new to this memo, at least as compared to Exhibit 8; is that fair?

A No, it's in that one.

Q I think we might be looking at different charts.

A You said --

Q On 9 of 19?

A -- page 9 of 19.

Q Okay. Yeah, I guess we are looking at the same one, and that's in the 2005 memo as well?

A Yep, that was included.

Q And it includes comparisons, it says,

"Bair on the low, medium and high"; is that right?

A Yeah, the point of this graph or this chart is that the higher the heat transfer rate from an external warming system, the lower the core temperature becomes. That's a compensatory change and it can be used to detect how efficacious a prewarming system is.

Q All right. And when you're measuring this, on figure 3, this is talking about, again, prewarming, right? And it shows -- is this a surgery that lasts up to about 35 minutes or is that how long the prewarming takes place?

A I believe, again, this is an older study in 1990. I think this was done in volunteers --

Q Okay.

A -- who were anesthestized. Or maybe they not anesthetized -- no, they weren't anesthestized. This is done in volunteers and they measured core temperature while they prewarmed them.

Q And the four ways -- pardon me, the six ways that they're being warmed on the chart, they show three of them are Bair, I assume it's a Bair Hugger if it's 1990?

A Yeah.
Q And they're tracking both low, medium and high settings there, right?
A Yes.
Q And then there's infrared lamps, that's one of the ways that you can prewarm a patient?
A Yeah.
Q At least in 1990?
A Well, that was one that was tested. Yes.
Q Okay. And then there's something they call "thermal sealing"; is that right?
A Yes.
Q And they list water blanket as well, right? Fair?
A Yes.
Q And none of them listed here are just warm cotton blankets. Do you know why?
A Because those are not generally considered active warming. All of these are active. These actively transfer heat.
Warm cotton blankets, they begin warm but they cool off very fast and they don't transfer a lot of heat. These are continuously transferring heat.
Q So you would say that warmed cotton

blankets are passive-conductive warming blankets?

A Yes.

Q Okay. Moving on to figure 4, you talk about, again sort of, a graph, I guess. Again, this is from Sessler?

A Yes.

Q The comparison of core temperatures in both pre and unwarmed volunteers before and during general anesthesia. So this is -- they're being anesthestized but they don't have an actual surgery; is that right?

A Yeah, but they were anesthestized.

Q Okay. And if they are prewarmed, it looks like at least for the first 60 minutes they stay above 36 degrees celsius in their core temperature; is that right?

A Yes, this group of subjects did. And again, these are --

Q Nonsurgical patients?

A Not only that, but they're medical school students so they're fit, young men.

Q Okay. That's sort of similar with the Zink study. Those were volunteers, not actual surgical patients?

A Correct.

Q And that's a distinction that you think merits some remarks?

A Well, only that when I'm talking about prewarming selected patients that these don't really represent typical surgical patients in the real world.

Q Okay.

A But the physiology is correct.

Q And you draw some conclusions based on sort of what test was done even on these, perhaps, better than average patients about how and whether this particular therapy can be delivered to patients more broadly, correct?

A Yes. Well, the point of this graph really is that in the patients who were warmed preinduction, the core temperature decreases during the warming, which is -- which is not what most people think happen. Most people think that core temperature goes up when patients are warm, but it's not true. Their core temperature goes down. The fastest way to decrease core temperature is to cool people.

Q Right. Moving to page 12 of 19 of your -- what is this called, a protocol?

MR. GORDON: I'm sorry, what page?

MS. ZIMMERMAN: The bottom says 12 of 19.
BY MS. ZIMMERMAN:
Q Again, this is a summary, and then you include, again, the chart that you drafted, which is listed as table one. Do you see that?
A Mmm-hmm.
Q So again, the summary in sort of the middle it says -- let's see, "Most of the hypothermia observed within the first hour following induction of anesthesia is a result of primary adiabatic redistribution of heat within the body and is not amenable to any form of externally applied heat. The improvement of surgical instruments and technique has led to a steady decline in operative time that has rendered intraoperative warming during the first hour after anesthetic induction a relatively ineffective therapy"; is that right?
A Yes.
Q And that sentence goes on, it says, "Since redistribution tends to increase the peripheral cutaneous temperature and reduce the temperature difference between the skin and the warming surface." Did I read that correctly?
A That's correct.

Q And so as you were preparing -- I keep wanting to call it a protocol. It is a protocol.

A It is a protocol.

Q Good. You would agree and wrote down here that essentially intraoperative warming during the first hour is largely ineffective, fair?

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

A I'm --

MR. GORDON: It misstates -- you didn't read it correctly, Genevieve.

MS. ZIMMERMAN: I read the middle part of it.

So let me start again so I can clear my foundation objection.

MR. GORDON: You actually changed a word.

MS. ZIMMERMAN: Okay. I don't want to trick your witness and I would like to have a clear record.

MR. GORDON: I know, that's why I'm saying this.

BY MS. ZIMMERMAN:

Q In your protocol it says, "The steady decline in operative time that has rendered

intraoperative warming during the first hour after anesthetic induction a relatively ineffective therapy," right?

A Well, I mean, that's not the way the sentence reads.

Q The sentence -- there's some sort of before and there's some sort of after.

A Yeah, okay. I just want to make sure.

Q Fair enough.

A Okay. Yes. What you read is correct.

Q And those are your words, right?

A Yes.

Q And you go on and say, "One solution to the problem is to prewarm a patient prior to arrival in the operating room." Do you see that sentence? I highlighted the first part of it so hopefully you could find it quicker.

A Yep.

Q And then, again, you prepare and include the chart or the table that lists "advantages and disadvantages related to the use of convective prewarming," fair?

A Yes.

Q And why don't you compare table one in Exhibit Number 9 with table one in Exhibit Number

8? They seem to be identical.

A The advantages seem to be identical.

Q All right.

A And the word "con" was changed to "disadvantages."

Q Okay. Yeah, advantages and disadvantages used to be pros and cons; is that right?

A Yes.

Q All right.

A Okay. Yeah, the internal part of the tables are the same.

Q And just to be clear, Mr. Van Duren, pros and cons, advantages and disadvantages, this is all part of a system you might call risk-benefit analysis, fair?

A Well, no, not really. Risk-benefit or benefit-risk analysis is an analysis that -- well, in the best of cases can provide a number that indicates, you know, a level of benefit that exceeds risk. This is more the sorts of things that customers might experience when using the device.

Q So in an ideal risk-benefit analysis we'd have numbers so we can sort of quantify?

A That would be the ideal setting, yes.

Q All right. And sometimes we have to operate in less than ideal settings; is that fair?

A Yes.

Q That's certainly been your experience throughout your tenure working on forced-air warming; is that right?

A Well, up until recently most benefit-risk analyses were done on a narrative approach, not a numerical one.

Q All right. And so as you were preparing this protocol for Forest Hill Hospital as part of your work with Arizant, again, you listed the advantages and disadvantages of using convective prewarming therapy such as the Bair Paws, fair?

A Yes.

Q And that's identical to the memo, or this chart anyways is identical to the memo that you prepared in 2005, right?

A Yes.

Q And so at no point during 2005 and 2007 had you, at least eliminated in your mind in terms of a potential advantage, the idea that prewarming convective therapy reduces the potential for nosocomial transmission of

pathogens by eliminating the need for intraoperative warming, fair?

A I'm sorry, that I hadn't eliminated that item?

Q Correct, sir.

A I had not eliminated it.

Q All right. That would continue be to a question that you would get from time to time from various orthopedic surgeons and other healthcare professionals in the field, true?

A Well, I don't know if that's true, but the document resided in my library until I worked on this protocol.

Q All right. And in any event, there had been no sort of testing or other sort of work that you had done internally at 3M that would eliminate that as a potential concern; is that fair?

A By -- no, not by 2007.

Q And you were, or 3M, I should say Arizant at the time, was at that time contacted periodically, regularly, with questions about the potential nosocomial transmission of pathogens by forced-air warming intraoperatively, fair?

MR. GORDON: Object to the form of the

question.

A Well, I think if you go back and look at our complaint logs, you'll probably find logs of customers who called in with questions like that, and I'm certain that I answered questions like that at the time.

Q Absolutely. And you had been doing so for decades; is that fair?

A Well --

Q By 2007?

A Yes, a little more than a decade.

Q And then sort of the new portion of this protocol includes pages -- starting at page 13 of 19, you've got "risks and benefits of the potential therapy." Do you see that?

A Mmm-hmm.

Q You talk about the dosage, the compliant statement, the study population. You're designing a protocol; is that fair?

A Yes.

Q And you sent this out for the hospital in New York to consider, fair?

A Well, I may have. I don't recall doing it, but it's certainly very likely.

(Whereupon, Exhibit No. 10 was marked for identification.)

BY MS. ZIMMERMAN:

Q I'm showing you what's been marked as Exhibit 10. Do you recognize that?

A Yes.

Q And it's an email from you to a Miss Cindy Quint dated November 1st of 2007; is that right?

A Yes.

Q And it says that "the attachment is the Bair Paws prewarming trial protocol draft B"; is that right?

A Yes.

Q And in your email you say, it says, "Hi, Cindy. Here is a draft protocol that I'm shopping around. Let me know if this interests you. Thanks, Al."

So you provided this outside of 3M; is that fair?

A Well, in 2007, it would have been Arizant, right?

Q Yes. I appreciate the clarification.

Fair to say, Mr. Van Duren, that there's nothing trade-secreted in this document?

A I'm sure this was reviewed by a number of people before I sent that out, yes.

Q Sure. And so there's no trade secret inside of the document at Exhibit 9; is that fair?

A Not that I've seen.

Q All right. Who is Cindy Quint, by the way?

A Well, let's see, so she's apparently an employee at the hospital in U of M, I don't know.

Q When you say "U of M"?

A I'm just looking at her email address, UofMHospital.org.

Q And I hate to guess at this sort of thing, but on the bottom of the second page of Exhibit 10, it looks like it says, "forwarded by Cindy Quint," and then it says "/Underwood Memorial Hospital." Do you see that?

A Oh, yes, I see that.

Q Does that sort of ring a bell? Maybe that's the "UM," Underwood Memorial?

A Yeah, probably that's it. Yeah, honestly I don't remember this.

Q It was a minute ago.

A But it is something that I clearly sent.

Q It was a minute ago.

And I'll represent to you -- I believe they were produced sequentially, but I believe that it is Exhibit 9 was attached to Exhibit 10.

So anyways, you were shopping this protocol around. Do you know if you sent it to anyone besides Ms. Quint?

A I don't know.

Q It's not fair that lawyers come back and ask you questions from so long ago, I know.

A But I mean, I really, honestly don't recall. I didn't recall this document until you showed it to me.

Q Absolutely, makes total sense.

Turning to page 14 of 19, back on Exhibit 19 -- 9. Letter H says "assessment of safety." I highlighted it in yellow hoping to make it sort of easier to find.

A I'm sorry, what page again?

Q 14 of 19, I'm sorry, sir. Do you see that highlighted part?

A Yes.

Q It says that "Bair Paws warming system is a fully-released medical product that has undergone important safety evaluation."

We talked about the sort of testing that you did in 2006, and that had to do with sort of the effect of Bair Paws and sort of extremity-directing warming. What other safety evaluation was done with respect to the Bair Paws?

MR. GORDON: Object to the extent that this it is beyond the scope of 30(b)(6).

A Well, again, this is a medical product that has a rigid risk management process applied to it before it's released and before the FDA clears it.

So again, I don't know precisely what is included in the risk management process, but it's a systematic approach to identifying and reducing all of the risks that are identified in the product. All I know at this point is that when I say "fully released," that means that the FDA has --

Q Cleared it.

A -- cleared the device.

Q So it's cleared for marketing. And that's not a decision about safety, fair?

MR. GORDON: Objection, calls for a legal conclusion.

Q If you know.

A So the FDA looks at safety and efficacy of product before they clear them. But in this case, it's a 510k, so this would have largely been cleared on the basis of it being substantially equivalent to a predicate device.

Q Right. And that's what the 510k process sort of evaluates, right?

A Yes, but it does look at safety and efficacy.

Q And so to the extent that Mr. Gordon objected that this is beyond sort of the scope of the 30(b)6, topic number nine does say: "Defendants' internal tests conducted to determine the benefit/efficacy of preoperative warming."

So to the extent that letter H on Exhibit 9 is talking about the extensive safety evaluation, I'm asking you, what has the Defendant, Arizant or Augustine, done to ensure that it's done an extensive safety evaluation? Is it limited to the tests that we talked about before that you did in 2006?

A Oh, no, this is completely unrelated to that. This would be part of a product

development process. So there would be a very systematic approach to identifying risks, mitigating them to the lowest possible level that can be done.

And I mean, we have extensive paperwork on risk mitigation for all of our products, so I am sure those have been made available to you.

Q What were the risks associated with the Bair Paws?

MR. GORDON: In any context or just prewarming?

MS. ZIMMERMAN: That's all that Bair Paws is used for, right?

MR. GORDON: No.

A No, Bair Paws can be used intraoperatively as well.

BY MS. ZIMMERMAN:

Q Okay. What are the risks associated with the use of Bair Paws in a prewarming setting?

A Well, I'm not sure that I know exhaustively. But the thing that concerns us most off the top of -- right off the bat is the temperature, burns. That's a big one.

Q Okay.

A The Bair Paws gown has attachment --

Q Ties?

A -- ties on it. So we want to make sure that people don't get choked with those when, you know, they're in bed and they're not aware. We don't want them to get tangled up with that.

I mean, there are a number of risks associated with a device that get evaluated, assessed, and mitigated.

Q So the risks associated with Bair Paws used preoperatively for prewarming of patients that you can recall as you sit here right now are potentially thermal injury, including burns and choking from the ties. Are there any others?

A Yeah, we did an extensive amount of dermal sensitivity testing on the material to make sure that it didn't cause any sort of allergic reactions, so that's one.

I mean, again, there's a whole -- it's a big process conducted by a large group of people; and you know, it includes engineers, scientists, clinicians. That's how that's done. It's not just one person.

Q I sort of figured that. And I apologize for, you know, for not being sure, but as one of the lawyers representing the Plaintiffs here, we

have to ask you, as the company sitting here today, what are the internal tests that were done by Augustine, by Arizant, by 3M to determine the benefits or efficacy of preoperative warming?

And as you talk about the risks, it seems that the three that were identified with sort of Bair Paws used preoperatively are: Potential thermal-related burns, that sort of thing; choking, if someone is not fully conscious or otherwise able, may be at risk from the ties on the actual robe; or perhaps they have an allergic sort of skin reaction to the material.

Were there other risks that were identified?

A Tripping. I remember tripping was one of the hazards. I mean, again, I'm sure there are others. I know these are extensive documents, but right now those are the only ones that I can recall.

Q All right. And you were prepared to testify about what the internal tests were as you came here today, fair?

A Correct. You mean, the ones that I already testified to?

Q Yes, absolutely.

A And point of fact, this protocol was never executed; I'm not really sure why. It was sent to an account to evaluate. They elected not to conduct it, and that's as far as I recall.

Q And that's happened with respect to lots of studies that you've actually proposed concerning various forced-air Bair Hugger products; is that right?

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

A Well, I don't know if it's a lot. But part of my job is, you know, being director of clinical affairs was to develop protocols and find people who would -- who wanted to conduct them, because they would answer questions that we had an interest in.

Q All right. Do you know if the reason that this particular protocol did not turn into a full-blown study was because Arizant didn't want to proceed or because the hospital didn't want to proceed or some other reason?

A I don't know the reason.

Q You don't recall as you sit here today?

A I don't.

Q Ad so it says the investigators

institution is Forest Hills Hospital in Forest Hills, New York. It seems that that's maybe different than the email address that we had for Ms. Quint. Are those two different hospitals, if you know?

In the last email to you it appears as Exhibit 10?

A Yes, I see that was forwarded by Cindy Quint.

Q And she says, "This weekend I fly to Missouri to defend my paper." I don't know if that helps at all in sort of understanding where this Underwood Memorial Hospital is, but it seems likely that it's not the same as Forest Hills Hospital; is that right?

A It probably isn't.

Q Is it fair to assume that you probably shopped this protocol around to more than one hospital?

A More than likely.

Q Do you recall that specifically?

A No, I don't.

Q Fair enough.

Turning back to page 12 of 19 in Exhibit 9, the chart of advantages and disadvantages of

convective prewarming.

You note again that it's inexpensive and safe to do prewarming with convective therapy like the Bair Paws.

And the third advantage in your chart is that it can be used when intraoperative warming is contraindicated. And the two examples that you provide in your chart are aortic cross clap and orthopedic cases; is that right?

A Yes.

Q You'd agree that the Bair Hugger has a warning on it that use of the Bair Hugger is contraindicated for use in aortic cross-clamp surgeries?

A Yes.

Q You agree that there is no contraindication on the Bair Hugger with respect to use of the Bair Hugger intraoperatively for orthopedic cases?

A I would agree. However, in 2007, whenever this was done, yeah.

Q Yes.

A In 2007, there were orthopedic surgeons who would not allow Bair Hugger to be used in orthopedic cases. So in a sense, they were

contraindicated by the surgeons in these hospitals.

Q So certainly by both 2005 when you first drafted this, and then again in 2007, you knew that various orthopedic surgeons and perhaps entire hospitals or practices believed that the Bair Hugger was contraindicated for use in orthopedic surgery, fair?

A That there were surgeons who would not allow it to be used, yes.

Q All right. But that was not a contraindication that Arizant ever placed on either the machine itself or any of the instructions for use; is that fair?

A That's correct.

Q You'd agree that communicating clearly any contraindications for products is a responsibility of a product manufacturer?

A Yes.

Q The only way one of your customers can use your product safely and correctly is if you provide them adequate instructions for use; is that fair?

A That's correct, and we would do that.

Q Right. And that's what your customers

expect of you, fair?

A Yes.

Q But, of course, this information that it may be contraindicated was not communicated by Arizant at the time; is that fair?

A Well, I think it's poor choice on my part. Contraindicated in the sense that a physician would not allow the device to be used because of concerns about contamination.

Q Well, contraindication has a specific meaning in the medical device industry, fair?

A It does.

Q There's a difference between a contraindication and a warning and a precaution, fair?

A Well, yes, that's true.

Q It's fair to say that each of those has a specific meaning for folks like you that work in the medical device industry?

A Yeah.

Q And fair to say that orthopedic surgeons, anesthesiologists, other healthcare providers understand those words to have a specific meaning as well, fair?

A They do.

Q Just like "intended use"?

A Yes. And in the sense that a surgeon would prohibit the use of a device, then it is contraindicated by that particular surgeon.

Q But in your chart here, table one, you note "aorta cross clamp," which is a contraindication that was actually placed on a machine and in the instructions for use both by Augustine and by Arizant, fair?

MR. GORDON: Object to the form of the question, argumentative.

A Yes. And again, you know, this is a careless use of wording here on my part.

Q Okay. Well, but the contraindication anyways -- and that, by the way, remains the case right now while 3M markets the device; is that right?

A The aortic cross clamp?

Q Correct.

A Yes.

Q And to this date there are still no warning, either warning or precaution or contraindication with respect to using the Bair Hugger intraoperatively for orthopedic cases, fair?

A That's correct.

Q And that's despite the fact that you know that orthopedic surgeons, some of them think it's contraindicated altogether, right?

A Some of them do.

Q And that particular Exhibit 9, by the way, you shared that, I assume, with Mr. Hansen as well?

A I would have at least told him that I was sending it out for consideration by people who might want to conduct it.

Q Right. And when you're getting ready to send out a protocol, particularly for review by potential partners, hospitals, that sort of thing for work on essentially a clinical trial -- not quite a clinical trial, I know that's different, but for work on a project like this research --

A Well, this would have been a clinical trial.

Q It would have been a clinical trial, okay.

A Mmm-hmm.

Q When you send out a proposed clinical trial protocol to a hospital, it's certainly your practice to be as precise and thorough in your

research and your drafting of the proposal as possible, right?

A I try to be, yes.

Q All right.

A I just want to note, it does say, "I'm sending a draft protocol." So this was in no way intended to be a final product. This was --

Q It is seeking input from potential collaborators?

A Not only that, but, you know, they may have modified a protocol.

Q Fair enough. But at least from your perspective as you sent it out, it was a final proposal worthy of consideration, fair?

A Yes. It's worthy of consideration, yes.

Q And that was what you were requesting, in fact, from the folks you sent it to?

A Yes.

Q Since the time of the sort of the test that you talked about doing in 2006, about sort of the effect or sort of efficacy of warming sort of the core of the body as compared to the extremities of the body, have you -- and by "you" I mean Arizant and 3M, conducted any other testing internally to determine the benefits or

efficacy of preoperative warming?

A No.

Q So that was the only one?

A That was the only one.

Q All right. It's fair to say that you're a proponent of prewarming?

A I am.

Q And you have been for a long time?

A Yes.

Q You think it's a good thing for patients?

A I do.

Q And you've said from time to time that you think that that's sort of the future of patient temperature management, fair?

A I probably have said that, yes. Yeah, wouldn't surprise me to find that written in an email.

Q In your experience, by the way, do most healthcare facilities sort of pick a brand? So if they're using the Bair Paws to warm somebody, prewarming, they're sort of more likely to sit with the Bair Hugger intraoperatively and so on? They don't switch back and forth, for example, either the Stryker product or VitaHEAT or some other product intraoperatively?

A Well, again, I'm not in sales. My observation is that most healthcare facilities are on contracts, and these contracts generally last for two years or three years. So once they pick a product, they stick with it for two or three years, and then at the end of that period, they renegotiate contracts with companies like 3M or Stryker or Mallinckrodt, you know, or Medtronic, whoever, for the best price that they can negotiate.

Q What's the Medtronic product, by the way?

A Well, they make a number of implantable pacemakers.

Q I was thinking you meant patient warming.

A Maybe that's not -- that may not have been a good example. But for companies that make products that are used all over healthcare systems, they're all on contract.

Q Okay.

A And so once they make a decision, it's difficult for them to change unless there's some breach of contract or something like that.

Q And you'd agree you've seen emails and received emails over a number of years where perhaps because the orthopedic surgeons became

concerned about the potential risk associated with Bair Hugger intraoperatively, that sales representatives were worried that they would lose the whole hospital for Bair Hugger products; is that fair?

A I've seen a couple emails like that.

Q All right.

(Whereupon, Exhibit No. 11 was marked for identification.)

BY MS. ZIMMERMAN:

Q Mr. Van Duren, do you recognize -- we just handed you Exhibit Number 11. Do you recognize that? You've probably written a lot of PowerPoints over the years.

A Yes, I think this is a PowerPoint that I put together.

Q And that was one of the things that you did sort of regularly, both -- maybe even at Augustine, but certainly at Arizant and 3M?

A Yes.

Q And this one has to do with "human thermal regulation principles and practices"?

A Yes.

Q And it looks like it's printed with sort of the presenter's notes at the bottom. Is that

consistent with your experience?

A Well, that's the way this is printed, yes.

Q So in PowerPoint you can do that, you can sort of see your internal notes when you're giving a presentation if you want?

A Yes.

Q And then your bio is on page 2 of the PowerPoint, just in case you had some sort of question about whose it was.

A No, this looks like mine.

Q All right. And is this a recent PowerPoint that you put together, do you know?

A Well, it's since 2011, because it's a 3M PowerPoint, so we were acquired by 3M in 2010.

Q Late 2010.

A So it has to be at least 2011.

Q Okay.

A I don't know what date it was.

Q And I would ask you to move forward to page 7 of your PowerPoint, which is 7 at the bottom of both the slide and then right about the Bates range.

And the slide says "Intraoperative Warming, How Effective?" Do you see that?

A Yes.

Q And again, it looks like your notes here are talking about -- at least talking about the slide says, "Here is another example of the difficulty of warming adult patients intraoperatively."

You'd agree that it is difficult to warm patients intraoperatively; is that right?

A Yes.

Q And in fact, prewarming is the most effective way to warm patients?

A Well, the combination is probably the most effective, but --

Q But if you're going to pick one or the other, prewarming is more effective than intraoperative warming, fair?

A If you can do it.

Q But if you have to pick between one or the other, prewarming is more effective than intraoperative warming, correct?

A Well, both are challenging for different reasons.

Q Sure.

A But from a thermal-dynamic perspective, prewarming is more effective. But you can't

discount the pragmatic reasons that it's very difficult for customers to prewarm. Regardless of how effective it is, customers find it extremely difficult from a pragmatic perspective to do it, even if it is very effective.

Q All right.

A And so both are really important.

Q All right. And that's sort of part of what you tried to demonstrate with your chart about both advantages and disadvantages, right, of convective prewarming of a patient?

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

A Well, no, that chart really was more the disadvantages and advantages of just prewarming.

Q Right.

A Not related to intraoperative warming.

Q Okay. And then I'd ask you to move forward to page 11 of your presentation. Do you see at the top is says: "How long must patients be prewarmed?"

A Yes.

Q And I tried to print this in color so we could all read it. I apologize for the small font, this is how it was produced to us.

But fair to say that you're citing to a trial conducted by Just and colleagues?

A Wait a minute. I'm looking at the wrong one. I thought it was Horn.

Q I'm sorry. It looks like at bottom of page 11 and --

A Horn. This is a study by Horn.

Q Are we looking at the same document?

MR. GORDON: I think so.

A The study was conducted by --

Q Oh, wow, you can read that?

A I'm referring to used --

Q In your presenter's comments?

A Now, I understand.

Q And I'm sorry. And I'm sorry to the court reporter.

In your presenter's comments, you say "Although the trial conducted by --" is it "Just and colleagues" --

A Yes.

Q -- "showed 90 minutes of prewarming was able to minimize the effect of redistribution, that practically delayed every surgery and that made it sort of impossible," right?

A Yes.

Q "And for that reason, several studies have been conducted to determine the minimum length of time that provides effective prewarming."

And then you go on to actually say, "This study by Horn and colleagues compares post-induction core temperatures in groups of patients who have been prewarmed for zero, 10, 20 and 30 minutes." Do you see that?

A Yes.

Q And as you note in your presenter comments and in the chart, there's essentially no difference in core temperature between patients who were prewarmed even for as few as ten minutes, right?

A That's correct.

Q They all do better than the patients that weren't prewarmed at all, fair?

A Yes.

Q And the prewarming is largely successful in preventing intraoperative hypothermia, fair?

A Right. As I recall, these patients were also intraoperatively warmed as well.

Q They were?

A Yes.

Q Does that say that in your chart?

A It doesn't say that in the chart.

Q Okay. Moving on to page 14 of your PowerPoint. The top says: "The 3M Bair Hugger normothermia system." And here you say, "30 years of temperature management experience with the 3M Bair Hugger temperature management system, empowering healthcare professionals to advance quality of care, optimize quality utilization, streamline workflow, implement evidence-based protocols and strengthen patient satisfaction." Did I read that correctly?

A Yes.

Q You're presenting this to potential customers; is that fair? If you recall?

A I'm sorry?

Q If you recall?

A Well, first of all, I don't recall -- I'm wondering if someone took my presentation and added this. This doesn't look like something that I would write.

Q Okay.

A But go ahead and ask your question. I mean, I'm not sure that I wrote this. I'm virtually certain I did not write this.

Q And I would like to say that I am reading this correctly, but the copyright in the bottom left of the actual PowerPoint slide, I don't know if you can see it, it says, "C3M" and then "2022"?

A Yes, probably because it was printed out.

Q And that was my question.

A And PowerPoint updates the slide copyright every time you print it.

Q You might imagine that presents difficulty for lawyers that are trying to date things.

A I hate it.

MR. GORDON: A recent production?

MS. ZIMMERMAN: I presume so, yeah. I assume it was some time in the last four months, right?

MR. GORDON: That's what's kind of throwing me too. Because obviously that he wouldn't have done this.

MS. ZIMMERMAN: It's obvious to you, it's not obvious to me.

A It's obvious to me that this is something that I wouldn't have produced.

This starting at the page 13 -- or sorry,

ending at page 13. That clearly isn't my work. This is somebody else's.

BY MS. ZIMMERMAN:

Q So starting at 14 is someone else's work?

A Yeah, but I can still answer questions about it.

Q At any rate, whoever has added these slides on now says on slide 14, that "more than 300 million patients in the world have benefited from Bair Hugger therapy, the industry's first forced-air warming system." Do you see that?

A Yes.

Q Do you think that that's fair and accurate?

A Yes. I mean, I think that's correct, around 300 million patients at the time. I recall there was a company announcement that 300 million patients had been warmed at some point during my --

Q Sort of like the McDonald's sign about burgers served?

A Yeah, like that.

Q Yeah. And then it goes on to say, "more than 170 studies document Bair Hugger forced-air warmings clinical benefits efficacy and safety."

Do you see that?

A I see that.

Q Do you think that's a fair statement?

A Well, I think that might be a stretch; but again, there are probably that many studies that report on clinical benefits of using Bair Hugger for a variety of -- in a variety of clinical trials.

Q Fair to say that probably there's 170 studies where at least Bair Hugger was one of the things that was in the study, whether in an operating room or a PACU or something like that? Does that seem fair?

A Probably a lot more if you included that sort of casual mention, but...

Q And 3M prepares and provides, even on the Internet today, a compendium of literature supporting Bair Hugger; is that fair?

A Yes.

Q By the way, did you talk to Mr. -- or Dr. -- I'm sorry -- Issa about his deposition?

A Well, only that he was giving one.

Q And we went through sort of the compendium with him. Have you reviewed his deposition at all?

A No, I have not seen his deposition.

Q And then this slide says that "nine of the top ten hospitals in the United States use Bair Hugger temperature management." Is that fair and accurate?

A Again, this is a marketing thing. It's probably true. I mean, I can't imagine that we would lie about something like that. But I mean, I can't unequivocally state that it's true. And maybe it was true when it was written, I don't know.

Q Sure.

A I just don't know.

Q And you would agree, Mr. Van Duren, that even marketing pieces should be fair and accurate?

A Yes.

Q I was going to ask you about the cost of the blanket, but I think we already covered that.

By the way, do you know if any of these slides -- is this your work or someone else's work, sort of after that page 14, if you even know?

It looks like there's -- one says "A temperature management partner," one says

"potential costs of a hypothermic patient"?

A So the way that I can tell my slides is that I always use Gill Sans as my presentation font. And if it's not Gill Sans, it's not me.

Q It's not you. All right.

A I would never use Helvetia, which is what this is.

Q I appreciate that sort of dedication to font selection.

A I hate Helvetia, so it sticks out like a sore thumb.

Q There are some awful ones. I hate Courier. And I want to like Garamond, but I can't.

Do you know if the rest of this is sort of in your font that would suggest that this is your work?

A This is not my work.

Q Okay.

MS. ZIMMERMAN: So I'll represent to you, Corey, that he is the custodian on the document that was produced to us.

A I'm sure in my library. It has my library stamp on it, but this was -- the last -- I mean, I'd be happy to answer questions about

it, if you want to ask.

Q I don't think I have a ton more, maybe just one more. The last two slides at 26 and 27, it talks about ERAS. Are you familiar with ERAS?

A Yes.

Q Enhanced Recovery After Surgery; is that right?

A Yes.

Q And it is -- it looks, it is really hard to read, but at the bottom of slide number 37 -- 27, it's citing to ERAS, it looks like 2008?

A Yes, I wrote a paper on ERAS.

Q All right. And you know that in 2018, in the initial draft of the ERAS sort of best practices recommendation, they suggested not using forced-air warming anymore, fair?

A So ERAS is a group of surgical specialties, and I think they're up to about, I don't know, 16 of them now, something like that; so orthopedics, cardiac, gynecological, breasts, neuro. And each one of those surgical specialties writes its own ERAS protocol. So there's no such thing as an ERAS protocol; there are numerous ERAS protocols.

And so whenever I present on ERAS, I have

a comprehensive chart that shows which surgical specialty recommends the use of warming. So, for example, bariatric surgery, they don't recommend any warming at all.

Q Okay. Is that because it's a dirty surgery or what?

A No, it's because obese people don't get cold in surgery, so obesity is protected from hypothermia.

But then, you know, almost all of the other specialties -- I think there's one other specialty that doesn't recommend it. But all of the other ERAS surgical specialities, the vast majority of them recommend warming and forced-air warming.

Q In previous depositions you've testified that the benefit of the Bair Hugger is warming a patient, fair?

A That's a benefit, yes.

Q And we can debate whether or not there are benefits that flow from warming, but the thing that the Bair Hugger does is warm a patient, right?

A Yes.

Q There aren't any -- there are no other

potential benefits that the Bair Hugger provides in, for example, the operating room?

A Well, I guess we normally think of normothermia as a condition that leads to certain benefits: Reduction in certain risks of cardiac events, surgical site infection, bleeding, length of stay. On a number of outcomes, those are the things that are -- that we think of as the benefits.

Q The outcomes are different than the actual benefit or the therapy provided by the device; is that fair?

A Well, the condition -- the condition provided by Bair Hugger is normothermia, at least that's what we attempt to do.

Q Well, but the service or the function of the Bair Hugger is simply warming a patient, right? And that may or may not be effective in achieving normothermia?

A Well, correct. But, for example, in prewarming, prewarming does not change the core temperature of a patient, so it's very difficult to consider that warming. Yes, it does increase the mean body temperature, but it doesn't increase the core temperature.

Q The core temperature? Right.
A So I guess that's the distinction that I want to make.
Q It's not something -- it doesn't provide, for example, nutrition to a patient?
A No.
Q And the only thing that the Bair Hugger does, and we can debate about whether it's important or not clinically, but the only thing that the Bair Hugger does is warm a patient?
A Yes.
Q So if obese patients don't get cold, is there a warning or a precaution on the Bair Hugger at all saying you don't need to use this with obese patients?
A No.
Q Why is that?
A Well, it's not contraindicated. It's just not indicated, because it's not necessary.
Q So it's providing no benefit to those patients?
A For obese patients. And again, we always recommend, regardless, that patients have their core temperature monitored throughout a procedure. So if they have absolutely normal

core temperature intraoperatively, there would be no reason to warm them.

Q All right.

A And that's pretty typical of an obese patient.

Q But also if the patient isn't going to become cold because they are obese, there's also no benefit to using the Bair Hugger, fair?

A Yes, I would agree with that.

Q Do you know, by the way, who -- you don't know, this isn't your font of the ERAS compliant normothermia protocol?

A I don't know who did this.

Q All right. And it looks like there's sort of a small version of maybe an internal memo. And it's got a 3M Bair Hugger logo on the right-hand side of the slide 27.

It looks like it says: "An evidence-based warming protocol compliant with ERAS society guidelines recommendations for perioperative normothermia"?

A Yes, I wrote that.

Q You wrote that memo?

A Yes.

Q Okay.

A It's a white paper.

Q And do you recall when you wrote it? Sometime after ERAS came out in 2018, I assume?

A Again, ERAS has been -- ERAS has been around for quite some time. I don't remember when I wrote this paper, but it would have been -- I wrote it when I was at 3M, so it would have to have been after 2010. I'm pretty sure I wrote it -- oh, I wrote it when Lisa Pfeifer was my boss, so whenever that was.

Q Okay. And it looks like the footnote that's dropped -- and it seems like it's quoting your paper, it says, "An evidence-based warming protocol complaint with ERAS society guidelines recommendation for perioperative normothermia version nine, 3M technical document, 3M" -- does it say -- "public identification 3M 20 --" 18 or 19? I can't tell.

A I can't read it.

Q And I feel I can get the driver's license renewed if that all was accurate.

Do you know if you had more than one memo that you wrote about ERAS protocols?

A Well, the reason that there are more than -- the reason there is more than one version has

to do with the fact that the surgical specialties within ERAS kept updating their own protocols. So I updated this every time that I got a new surgical specialty update for the ERAS protocol.

Q Okay.

A And, again, there is no such thing as a single ERAS protocol. There are numerous ERAS protocols all built around surgical specialties.

Q And do you recall if the last ERAS protocol with respect to orthopedic surgery recommended against warming patients with convective therapy intraoperatively?

A No, I believe it recommended for. The only ones that I recall for sure were bariatric and cardiac.

Q Is it possible that there may have been more than one version of the last ERAS with respect to orthopedic surgery?

A It's possible. I haven't updated this -- I mean, I haven't been in this group since 2018, so I don't know who is updating it now.

Q Okay. And you don't know if anybody is updating it right now?

A I don't know.

MS. ZIMMERMAN: Why don't we take a short

break and figure out how much time we have left and where we go from here.

THE VIDEOGRAPHER: We're off the record.

(Whereupon, a break was taken from 5:59 p.m. until 6:06 p.m.)

THE VIDEOGRAPHER: We're on the record.

BY MS. ZIMMERMAN:

Q All right. We took a short break. Are you ready to continue, Mr. Van Duren?

A Yes.

Q And I appreciate your patience today. We're trying to be as efficient as we can; and as you know, the issues are complicated and the documents are sort of voluminous.

You've talked a little bit today about sort of a risk mitigation team. Who is on the risk mitigation team?

A There are a number of people that are on those teams. They generally have some engineers; marketing people can be on them, clinicians. It's usually people in the product development group that are assigned to that team. They have training that allows them to identify and grade different risks.

Q Does the risk mitigation team typically

include lawyers, do you know?

A Well, I don't think typically, no.

Q Has it, in your experience?

A Very rarely.

Q With respect to either the Bair Hugger -- well, with respect to the Bair Hugger, has it included lawyers?

A I don't recall -- I don't recall an attorney ever being present during a Bair Hugger risk management meeting.

Q All right. And were you part of the risk management team for Bair Hugger?

A I've been on a couple of them.

Q During what times?

A At Augustine Medical. Not at 3M.

Q Okay. At Arizant at all?

A Not on Bair Hugger. On the temperature monitoring system I was, but not on Bair Hugger.

Q All right. And was it the practice when you were at Augustine that the risk management or mitigation team would document its activities?

A Oh, yes, very much so.

Q Do you know if those have been produced in this litigation?

A I don't know.

Q All right. And have you reviewed any risk mitigation team memos?

A No, none.

Q So to the extent today that you've testified that sort of a risk mitigation team would have considered something, that sort of -- it's your expectation that should have happened, but as you sit here today, you don't have any evidence or memos that it did happen; is that fair?

A That's right. But it's my experience that just given the way that the product development process works and our quality management system, that's part of it. There's just no way that you can develop a product without having a risk analysis team, a risk mitigation.

Q And in any event, as you sit here today, you can't speak to the substance of whatever discussions or decisions may have or may not have been made by the risk mitigation team?

A No. No, I can't.

Q Okay.

MR. GORDON: Specifically about infections? Or anything to do -- I mean, because

he's talked about a whole bunch of dermal risks.

MS. ZIMMERMAN: Sure. It's not a secret. What I don't want to have happen is that we're going to go to trial in Missouri in September and all of a sudden we're going to have memos or sort of a recollection of events that says, "Oh, that's right. We talked about that explicitly in this meeting and we assured ourselves this wasn't a risk in the following ways."

Q Because my chance to ask you that question is today, and as you sit here today, 3M is unaware of what those discussion meetings would be, fair?

A I'm completely unaware.

Q Okay.

A Only that they did occur.

Q All right.

MR. GORDON: But we did produce the risk mitigation files.

MS. ZIMMERMAN: And Mr. Van Duren -- in preparation for today?

MR. GORDON: Yeah.

MS. ZIMMERMAN: The witness seems sort of surprised by that.

MR. GORDON: I know we inundated him with

stuff.

THE WITNESS: Maybe I've forgotten the risk mitigation. I'm sorry, I just do not recall the risk mitigation files, but okay.

MR. GORDON: Ted actually -- if you think of what Ted was working with you on.

THE WITNESS: Okay. It was quite a bit in the last two days.

MR. GORDON: Those were part of the risk --

MS. ZIMMERMAN: Corey, I would ask that to the extent that those have been provided to the witness and he was prepared to answer them before he got here today but is not prepared to answer right now, perhaps he re-review those tonight and we'll reconvene that limited portion in the morning. We're going to be here anyways, but it is part of the topic that we're supposed to be talking about.

MR. GORDON: No, I understand.

MS. ZIMMERMAN: Okay. I'm not trying to be a jerk.

MR. GORDON: He has talked about risk mitigation. But if you -- so rather -- instead of just broadly what risk mitigation, if you want

to ask him specific questions.

MS. ZIMMERMAN: Well, my question is sort of specifically what was done; and I think the answer is "not sure."

MR. GORDON: Well, it depends on what product, what time period, what risk. I mean, all risks? I mean, risks --

MS. ZIMMERMAN: The witness has just said that he doesn't remember looking at the risk mitigation memos, so I'm going to take him at his word at that. If you guys have prepared and produced something to him, and he was prepared to do it today, I would ask that he be re-prepared to talk about that briefly tomorrow.

You also said that -- and one of the notices was the Failure Mode Effects Analysis conducted regarding the Bair Hugger warming system.

And Corey, you had sort of said that he wasn't prepared to talk about that, but we can ask a question.

MR. GORDON: Yeah, we don't understand it, but you can ask questions and to the extent that he knows, that's fine.

MS. ZIMMERMAN: Sure.

BY MS. ZIMMERMAN:

Q Well, Mr. Van Duren, do you know what a FMEA or a Failure Mode Effects Analysis is?

A Yes.

Q And do you know if they were conducted regarding the Bair Hugger warming system?

A I believe FMEA was conducted.

Q Do you know by whom?

A Again, a large group of people that are involved with sort of risk identification mitigation.

Q And would that be done prior to, essentially, during the design phase of a product?

A Well, it certainly would be done around the time, closer to the end of the product development than the beginning.

Q Is it done again as in the event of or as complaints or other problems arise with a product, for example?

A So it's actually done continuously in a way. After the project is kicked off, risk mitigation begins.

Q All right.

A And it is continuously updated.

Q And the idea behind a Failure-Mode Effects Analysis is to identify potential failure modes, fair?

A Yes.

Q To identify the effect of that failure; is that right?

A That's right.

Q To identify the cause of the failure?

A Yes.

Q To prioritize the risk?

A Yes.

Q And then also to make a recommendation with respect to corrective action and status; is that right?

A Yes.

Q And, you know or you believe that that was done with respect to the Bair Hugger machines at various times?

A Oh, yes, that's been done numerous times.

Q You'd expect certainly in sort of the design phase or late in the design phase for each of the different models in the Bair Hugger?

A Yes.

Q Do you know if in doing a Failure-Mode Effects Analysis on the Model 500 to be used in

the operating room the potential for airborne contamination of the operating room was considered?

A I don't know if that was done. I would have to consult that document.

Q All right. Would you expect that it should have been done if it was not?

A I just don't know. It may have been, I don't know.

Q Right. Given that there was a warning on the Model 200 about the potential risk of airborne contamination, would it make sense that the potential risk of airborne contamination should likewise have been considered with respect to the Model 500 OR?

A In the event that the label warning was removed, there almost certainly will be a risk mitigation activity associated with it, because you wouldn't -- no one would remove a labeling warning without an evaluation like that.

Q And whether you know if it actually happened or not, you would agree that it should have happened --

A Yes.

Q -- fair?

I'm going to switch gears to number 27 -- well, actually 26 on Exhibit 1. That's "Claims, notices of claims, lawsuits or other notices of claims of operative site infection alleged to have been caused by the Bair Hugger warming system."

Is that something that Augustine tracked?

MR. GORDON: Just for the record, that's one that he's not -- he wasn't prepared on, but again, to the extent that he can answer.

MS. ZIMMERMAN: Right.

A Sorry, say it again?

BY MS. ZIMMERMAN:

Q Were these sort of claims or notices of claims or lawsuits, is that something that was tracked by Augustine Medical while you were working there?

A Well, there was a -- complaints were tracked, yes. Yes, there was a complaint tracking system.

Q All right. And did that continue then when you were at Arizant?

A Yes, that's a requirement of a quality system for medical products.

Q And that continues to be a requirement at

3M?

A Yes.

Q And to your knowledge, that's been provided to counsel and produced to us?

A As far as I know. There's a whole department associated with that activity.

Q All right. And you're not in that department?

A No.

Q Probably thankfully.

Moving on to, hopefully sort of briefly, number 27 that is, "Other patient warming systems including, but not limited to, passive warming, convective warming and conductive warming."

Mr. Van Duren, you would agree that there are a number of different ways to warm patients; is that fair?

A Yes.

Q And a number of the different options available to healthcare providers are safe. Would you agree with that?

A Well, I would agree that they have different levels of safety and efficacy. They're not the same. They're not equivalent.

Q Sure. Would you agree that there are a

number, though, of alternatives that are safe, for example?

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

A Well, again, the safety of some devices is not equivalent to the safety of forced-air warming. Forced-air warming happens to be extraordinarily safe; conductive warming, less so.

Q Would you agree that cotton blankets are safer than forced-air warming?

A Yes, but not very effective.

Q All right. And then so the next question: There are additional products or alternatives available that are effective besides just forced-air warming, fair?

A Yes.

Q There are alternative products that are easy for healthcare providers to use; is that right?

A Easier than forced-air warming?

Q Yes.

A Hard for me to imagine another product easier to use than forced-air warming.

Q Okay. You agree that there's clinical

evidence supporting the use of alternative patient warming modalities besides just Bair Hugger, fair?

A Yes. But again, not equivalent.

Q You'd agree that there are other alternatives for patient warming that are cost-effective?

A Meaning that the purchase and operating price is essentially the same as forced-air warming or lower?

Q Sure.

A Yes.

Q And some of those alternative forced-air warming products include the Stryker Mistral, right?

A I don't know that it's less. I don't know that it's more cost-effective.

Q And I apologize if my question was sort of suggesting one was more cost-effective. I'm going to go through a list, hopefully quickly, of --

A Oh, okay.

Q -- other alternative warming therapies out there.

The Stryker Mistral is one alternative

available?

A Yes.

Q It has a HEPA filter on it, which is different than the Bair Hugger, fair?

A I believe the most modern warming system has a HEPA filter, yes.

Q Okay. Smiths Medical makes a product called the Snuggle Warm or EQUATOR; is that right?

A Yes.

Q That could be used for patient warming as well?

A Yes.

Q That's a forced-air warming product?

A Yes.

Q Covidien makes a product called the WarmTouch System?

A Yes.

Q Alternative to the forced-air warming that is made by 3M, right?

A Yes.

Q Cincinnati Sub-Zero makes the FilteredFlo and Warm Air; is that right?

A Yes.

Q There's a company called Care Essentials

that makes a product called the Cocoon; is that right?

A I think it is Care Essentials, yes.

Q Okay. And then there's one more forced-air warming product made by BS MedTech called Calima or Calima, maybe? Calima, I bet, I like climate; if you're aware?

A Maybe. I'm not sure I heard of that one.

Q And then there is the passive-conductive option, which is a heated cotton blanket, fair?

A Yes.

Q And you would agree that those are safe?

A Safe but not very effective.

Q All right. They're easy to use?

A Yes.

Q They don't make any noise?

A Well, you have to get them out of an oven.

Q Fair enough. Easy to maintain?

A No, not particularly.

Q All right. Are they comparatively speaking actually less expensive than the Bair Hugger?

A Well, I think we've done cost-utility analyses of warm cotton blankets and they

actually cost quite a bit. Usually about the same or more.

Q All right. And then with respect to conductive patient warming technologies, there are products made by, and I'm going to -- are you aware of a product by Kimberly-Clark called the K-C System M1000?

A I'm not familiar with that one.

Q Are you aware of the Cincinnati Sub-Zero which makes something called the Surface Temp?

A Yes.

Q Inditherm, I think is the name of the company and the product. You're familiar with that?

A Yes.

Q Is it Molnlycke?

A Molnlycke.

Q Molnlycke makes a Barrier EasyWarm?

A Yes, I'm familiar with that.

Q VitaHEAT Medical, you're familiar with the VitaHEAT product?

A Yes, but I think they are out of business.

Q Are they out of business? Okay.

Obviously you're familiar with the

Augustine, who makes the HotDog?

A Yes.

Q A company called MedLine makes something called the PerfecTemp?

A Yes.

Q And Pintler Medical makes a product called Pintler; is that right?

A Yes, but I believe that's a fluid warm air.

Q Okay. And in any event, there are a number of potential options for a healthcare provider trying to decide, if they choose to warm, there are options available to the healthcare provider and how to warm the patient?

A Yes.

Q With respect to -- and I'm going to jump ahead actually to number 31, which is the due diligence that was conducted on Arizant before purchasing the company.

You were prepared to talk about that today, Mr. Van Duren?

A Yes.

Q And the company did, 3M did, in fact, conduct due diligence on Arizant prior to purchasing the company for $810 million; is that

right?

A Yes.

Q You want to sort of kick the tires before you make a purchase like that?

A Yes.

Q Are you aware of what kind of due diligence was conducted?

A Well, there was a business development team that I think coordinated efforts from a number of departments in the company: Legal, regulatory, engineering, sales and marketing, people like that. There were, you know, there were obviously legal evaluations related to the allegations made by Scott Augustine.

Q And that's really sort of where I was getting, Mr. Van Duren, and I don't mean to jump over you.

A No, that's all right.

Q But certainly the allegations or the sort of concern about particulates as potential causes of surgical site infection and particularly deep joint infection, that was something that was known to you or you were informed of in 1994 when you started --

A Yes.

Q -- with Augustine?

And that was certainly -- that issue was something that was absolutely communicated to 3M when it did the due diligence of Arizant, fair?

A Absolutely.

Q Not a secret to 3M at all?

A No.

Q And throughout the due diligence process, would you agree that 3M did a thorough investigation of those potential allegations?

A Yes.

Q Do you know, as part of that due diligence, whether 3M commissioned any studies?

A I don't think any studies were commissioned at that time.

Q As you sit here today --

A Maybe because of the confidentiality issues.

Q All right. And I'm sorry, what do you mean with respect to confidentiality issues?

A The potential purchase of another company is a -- because of stock issues and things like that, it's done under strict confidence. And so those kinds of activities would not have been pursued before the acquisition of a company.

Q So it would not have been pursued by Arizant?

A Well, they might have been pursued by Arizant, they would not have been pursued by 3M. I thought you were asking about the due diligence conducted by 3M.

Q Well, right. And what I would like to understand is what did 3M do to assure itself and ultimately the shareholders that there was no risk or what that risk was with respect to the clinicians' concerns about potential for infection, particularly in orthopedic surgery?

A It was thoroughly reviewed by a team of attorneys at 3M.

Q And so when you say "thoroughly reviewed," provide for me, if you would, a list of what was considered.

A Well, certainly the allegations from Scott Augustine and letters that he had written, letters from his attorneys, those kinds of communications to both the management of Arizant but also to customers. So all of that information was made available to 3M for review.

Q Fair to say that the 3M lawyers would have reviewed, for example, the complaints

database?

A Oh, yes.

Q Fair to say that the 3M lawyers or whoever was doing the due diligence would have reviewed your memos about the Bair Paws and prewarming?

A It's -- that level of detail I don't know. It's possible, but I kind of doubt it.

Q You certainly would have made that available to them?

A Oh, yeah, it's all available. Yes, of course.

Q What else do you know --

(Phone alarm.)

MR. GORDON: The time is out, but if you have one or two quick follow-ups.

Q I just want a list of what the due diligence required.

A Well, I mean, the companies' structure; you know, the way in which the company was managed from the senior management on down; the sales and marketing figures; projections of sales, products; clinical activities that were underway or proposed. All of the important aspects concerning the company that would have a

material effect on its value.

Q All right. Let me see if I can ask, sort of, I hope three sort of real succinct questions. Fair to say that all the sort of -- or the general nature, anyways, of the allegations that Bair Hugger may interfere with airflow and be contaminated and sort of through those mechanisms contribute to deep joint infection, that was known to 3M when they purchased Arizant, fair?

A Yes, in more than just a general sense.

Q All right. In a specific sense?

A Yes.

Q Fair to say that Augustine, who he was, all of the stuff that happened in 2003 with respect to Medicare fraud, his criminal trial, the outcome of all of that, all of that was known to 3M when they did the due diligence as well, fair?

A Yes.

Q And 3M continues to this day to rely on the Augustine-funded Kurz and Sessler studies, correct?

A Well, Augustine Medical, not Dr. Augustine personally.

Q Okay. But still relies on the Augustine

Medical funded study from Kurz and Sessler, right?

A Well, when you say relied on it, we cite it in our references, yes.

Q And promote it regularly as one of the reasons that Bair Hugger is safe, effective and a good idea?

A Yes.

Q And at least as you sit here today, as the corporate representative for 3M, you're confident that any and all questions that 3M had during the due diligence phase were answered to 3M's satisfaction in that process, fair?

A Yes.

MR. GORDON: I just want to make sure that nobody on the line has any questions? Is anybody still --

MS. ZIMMERMAN: Wake up.

MR. KRONAWITTER: No.

MS. DAVIS: No.

MR. MCCAIG: No.

MR. GORDON: I actually have about three questions.

MS. ZIMMERMAN: Do you want me to move?

MR. GORDON: You know what? No. Let's

not move.

Al, do me this favor. If you could ignore the fact that I'm talking to your left and answer to the camera. Is that okay? It's a little bit --

MR. ASSAAD: Pretend he's the camera.

EXAMINATION

BY MR. GORDON:

Q Yes. If you can pull out Exhibit 8, I just want to ask you a couple of questions about that.

A Exhibit A?

Q Exhibit 8.

A Oh, 8. I thought they were numbered.

Q If you turn to page 11 of 14.

A 11 of 14? Yes.

Q And this is the chart that you were asked questions about both in -- the same chart essentially that appears in Exhibit 8 and Exhibit 9, correct?

A Yes.

Q Okay. And Exhibit 8 was 2005, and Exhibit 9 was -- you used that chart in 2007, right?

A Yes, that's correct.

Q And my first question is: In 2005, when you wrote -- when you drafted this memo, was it your belief that intraoperative warming was contraindicated in orthopedic cases?

MS. ZIMMERMAN: Object to form.

A No, I did not believe it was contraindicated.

Q Did you believe that in 2007 when you used this same chart in this memo in Exhibit 9?

A No, it was not contraindicated.

Q Has 3M, Arizant or Augustine Medical ever believed that intraoperative warming was contraindicated in orthopedic cases?

MS. ZIMMERMAN: Object to form.

A No, they did not.

Q Why did you phrase it this way?

A Careless wording. Because a few orthopedic surgeons at this time had prohibited the use of Bair Hugger in the operating room while they were preparing patients for orthopedic surgery. So in that sense it was contraindicated by an individual surgeon.

Q Okay. And in the same chart that you used the phrase "does not contaminate the sterile field" -- "does not contaminate sterile field,"

when you wrote this in 2005, was it your belief that intraoperative warming with the Bair Hugger contaminated the sterile field?

MS. ZIMMERMAN: Object to form.

A No.

Q Was it your belief when you wrote that in the memo in 2007, Exhibit 9?

A No.

Q Is it your belief today?

A No.

Q Is it 3M's belief that use of the Bair Hugger contaminates the sterile field?

MS. ZIMMERMAN: Object to form.

A No.

Q Okay. Going back to Exhibit 8, in the chart you said under "Pros: Reduces the potential for nosocomial transmission of pathogens by the need for intraoperative warming." Do you see that?

A Yes.

Q When you wrote that, was it your belief that the use of the Bair Hugger had created a potential for nosocomial transmission for pathogens?

Let me state that question again because

it sounded like I was going to continue.

When you wrote this in 2005, was it your belief that the intraoperative warming with the Bair Hugger increased the potential for nosocomial transmission of pathogens?

MS. ZIMMERMAN: Object to form.

A No, but many physicians did. Many surgeons did.

Q Okay. Did you believe that -- strike that.

Did you believe that when you wrote it in 2007?

A No.

Q Okay. Does 3M believe that the use of the Bair Hugger warming system for intraoperative warming increases the risk of nosocomial transmission of pathogens?

MS. ZIMMERMAN: Object to form.

A No.

Q And you -- in your 2009 -- excuse me. Exhibit 9, your 2007 version of the memo, same page where that chart is, but in the summary text, you referred to intraoperative warming as "relatively ineffective therapy." Do you remember that?

A Yes.
Q What did you mean by "relatively ineffective"?
A That in the initial part of warming after the induction of anesthesia, it's very difficult to transfer enough heat to raise the patient's temperature.
Q And so when you said relatively ineffective, relative to what?
A Well, relative to prewarming.
Q Okay. So is it your view, your view personally, that prewarming is all you need to prevent hypothermia or maintain normothermia for surgery?
MS. ZIMMERMAN: Object to form.
A In some select cases that can work, but that's very unusual for a number of reasons, mainly for pragmatic ones, but in most cases both are required to maintain normothermia.
Q And is it 3M's position that prewarming is adequate to prevent hypothermia and that intraoperative warming is unnecessary?
A No.
Q Would you ever personally have general anesthetic surgery without intraoperative

warming?

MS. ZIMMERMAN: Object to form. 3M is not going to have surgery.

A No, and I've had intraoperative warming while I've had surgery.

Q And even though you're a strong advocate of prewarming, you still had intraoperative warming?

A I had both.

Q Okay.

MR. GORDON: Nothing further. Thanks.

MS. ZIMMERMAN: Do people on the phone have questions? Otherwise I have a couple of follow-ups.

I assume nobody has questions. Are they shaking their head? Are they even awake? Bueller?

MS. DAVIS: No questions.

EXAMINATION

BY MS. ZIMMERMAN:

Q Mr. Van Duren, with respect to a series of questions now that Mr. Gordon respectfully asked you about these charts that you've prepared in the 2005 and 2007 memos, you'd agree that the answers that you're giving to Mr. Gordon would

change the plain meaning of the chart in each of those memos, fair?

MR. GORDON: Object to form.

A Well, not the contraindicated. Like I mentioned, in that case it was contraindicated by the surgeon, so that's not -- that is the plain meaning of that word.

Q All right. But "does not contaminate the sterile field." That's pretty plain in its language, fair?

A It's fair. But again, this is a draft and I'm capturing my thoughts here, so it's not fully worked. But it addresses the concern that many surgeons had at the time, and still do, about forced-air warming contaminating the sterile field.

Q Mr. Van Duren, is it fair to say that both of these charts in 2005 and 2007 do not provide good factual testimony for your current employer?

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

A I'm not sure exactly what you mean by that.

Q So to the extent that in 2005 and 2007,

you wrote and were careful in drafting a protocol and sending it out to hospitals for consideration, that you wrote potential pros and cons or advantages and disadvantages to the use of prewarming convective therapy. To the extent that you called it potentially contraindicated in orthopedic surgery, that's not a good fact for 3M today, correct? Assuming that's true, that's not a good fact for 3M, right?

A Well, it's a reflection of the fact that there are surgeons who are concerned about that issue.

Q Right. And it certainly confirms that you and 3M were aware of those issues in 2005 and 2007, fair?

A Yes, which we admit, fully admit. Yes.

Q All right. And similarly to the extent that your memos in 2005 and 2007 say that "convective prewarming reduces the potential for nosocomial transmission of pathogens by eliminating the need for intraoperative warming," to the extent that that's true and the plain meaning carries, that's not a good fact for 3M in facing these lawsuits; is that fair?

MR. GORDON: Same objection.

A Well, it needs an explanation. And again, in both cases, if you look at emails that went with these, these are drafts, they're not fully completed.

So the thought there was that we are addressing concerns that our customers have regarding the use of this device in an operating room, and they're concerned that it might contaminate the sterile field.

Q Right. And those were concerns that continue to be brought up to you as you worked at all three of these different companies; is that fair?

A Yes.

Q And in looking at these memos, obviously any of us looking at an email that is almost -- a memo that is almost 20 years old or 15 years old, we have the benefit of hindsight; is that right?

A We do.

Q All right. And we also now, you were trying to prepare a thorough and complete and accurate work product at the time, right?

A I was.

Q Right. And now we're viewing these through the lens of potentially 6,000 or more

lawsuits, fair?

MR. GORDON: Object to the form.

A I suppose, yes.

Q All right. And at any rate, we've gone through with your testimony today that there is not a specific internal test that 3M has done that eliminates the Bair Hugger as a potential contributor to deep joint infection when used in the operating room; is that fair?

A An internal test? No.

Q Yes.

A No, we have not done an internal test.

MS. ZIMMERMAN: That's all I've got.

THE VIDEOGRAPHER: We're off the record.

(Whereupon, the deposition concluded at 6:43 p.m.)

CERTIFICATE

I, Amy C. Lundgren, RPR, hereby certify that I am qualified as a verbatim shorthand reporter; that I took in stenographic shorthand the testimony of ALBERT VAN DUREN, at the time and place aforesaid; and that the foregoing transcript consisting of 346 pages is a true and correct, full and complete transcription of said shorthand notes, to the best of my ability.

Dated at Baxter, Minnesota, this 22nd of April, 2022.

AMY C. LUNDGREN

Notary Public

S I G N A T U R E P A G E

I, ALBERT VAN DUREN, the deponent, hereby certify that I have read the foregoing transcript, consisting of 346 pages, and that said transcript is a true and correct, full and complete transcription of my deposition, except per the attached corrections, if any.

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Date Signature of Witness

WITNESS MY HAND AND SEAL this_____ day of _____, 2022.

(ACL) _____