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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Also present:

Ron Huber, Videographer

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P R O C E E D I N G S

THE VIDEOGRAPHER: Today is April 15th, 2022. The time is 9:37 a.m. At this time the attorneys for the various parties, will you please introduce yourself and then the reporter will swear in the witness.

MS. ZIMMERMAN: Good morning. It's Genevieve Zimmerman. I'm one of the lawyers here for the Plaintiffs.

MR. ASSAAD: Gabriel Assaad for the Plaintiff.

MS. CAMPBELL: Tricia Campbell for the Plaintiff, and Brett Emison, who is also on via Zoom, for the Plaintiff.

MR. GORDON: Corey Gordon on behalf --

MR. FARRAR: Kyle Farrar --

MR. GORDON: Sorry, Counsel.

MR. FARRAR: -- for the Plaintiffs too on Zoom.

MR. GORDON: Any other Plaintiffs?

MS. ZIMMERMAN: I don't think so.

MR. GORDON: Corey Gordon on behalf of the Defendants and the witness.

MR. MCCAIG: Joshua McCaig for Centerpoint Medical Center and Centerpoint

Orthopaedics and Dr. Gregory Ballard in the O'Haver case.

MR. DAVIDSON: Tim Davidson for St. Luke's on the Tye case.

MR. BREER: Paul Breer here on behalf of Dr. -- Defendant Dr. Frevert and Rockhill Orthopedics, PC in the Tye case.

MR. GIVENS: Robert Givens on behalf of Dr. Bible and Anesthesia Associates of Kansas City on the O'Haver case.

MS. DAVIS: Lucy Davis on behalf of Anesthesia Associates, Kansas City, on the O'Haver case.

MR. GORDON: And that makes me realize I should have clarified that I'm here on behalf of Defendants 3M and Arizant.

THE COURT REPORTER: Okay. Sir, will you please raise your right hand?

(Witness sworn.)

ALBERT VAN DUREN,

was called as a witness and sworn to testify in the above-entitled matter.

EXAMINATION

BY MS. ZIMMERMAN:

Q Good morning, Mr. Van Duren.

A Good morning.
Q We've met a couple of times, including yesterday.
A Yes.
Q I hope you had something good to eat and a restful night?
A I did, thank you.
Q And it's unfortunately even colder today here than it was yesterday, but at least the sun is out so hopefully we're headed over this.
You had your deposition taken in January of this year. Do you recall that?
A Yes.
Q And you had some questions posed to you about sort of your habit and custom of gathering and maintaining a library of various articles. Do you recall that?
A I do.
Q And during that deposition counsel asked if you could produce sort of copies of your literature files; is that right?
A Yes.
Q And did you work with your attorneys then to provide a complete copy of your medical library?

A Yes.

Q Do you know if there was sort of -- or talk to me about the process for collecting those documents.

A The process that I used to collect documents or the process that I used to give them to attorneys?

Q Well, let's start with the attorneys part, and then I'm sort of interested in the second part as well.

A The papers -- I read the papers, annotate them, place them in folders in a physical, vertical file library, and hanging folders. And then I just made those available to 3M corporate, legal -- paralegal and they make copies of them and then give them back to me.

Q Okay. And I assume that they've done that at least one other time during the course of the --

A Done that many times.

Q All right. When have they done it before?

A During the MDL.

Q All right. So only related to the Bair Hugger litigation or anything else?

A Only related to the Bair Hugger litigation.

Q All right. And do you recall if it was once or more than once?

A It was more than once.

Q All right. So at least sometime after January of 2022, sort of recently they came and collected documents; is that fair?

A Yes.

Q And they did it at some point during the MDL, and I assume that was prior to 2017, because we had a deadline at the end of March of 2017?

A I think so.

Q Do you know if they collected documents more than once, sort of prior to the end of March of 2017?

A I don't remember exactly when those were done.

Q Okay.

A I just know that there were two recent ones to look at, the small amount of documents that have been added since the last time that those documents were made available to you.

Q Okay. And that was sort of my next question. Was the recent collection, did they go

through your entire library or did they just go through sort of what would have -- what you would have added since the last collection?

A Just the additional papers.

Q Okay. So seem fair to assume, and I know you're not responsible for providing documents to us, the Plaintiffs' lawyers, but probably if we got a new set of documents, those are all documents that you have collected since the time that 3M collected before?

A Yes.

Q Okay. Because some of them are -- the documents actually predate 2017, so I just wondered if you were collecting them new or they were just recently added to your collection?

A I'm sorry, I'm not sure exactly.

Q I think that question wasn't great.

So whatever the new production is, those are all pieces of literature or memorandums or notes that you took sometime since 2017?

A Yes. Yes.

Q So talk to me about the process that you go through in your work at 3M in terms of identifying literature. You're interested in reading, obtaining it, reviewing it, just tell me

how that works for you.

A We have -- we have -- at 3M we have a knowledge discovery and analytics group; and we have another group that came as part of our KCI acquisition, which is also a library group. I'm not sure what the title is, but they're scientific librarians. And we have a variety of table of content searches, things like that. So maybe twice or three times a week I'll get an alert from these groups that there are a number of articles that have been identified, via these sort of passive searches. And then those papers were made available either through some link or I can download them from the library. So not every one is interesting to me, but the ones that are interesting I download and read.

Q Do you have essentially saved searches?

A No.

Q Or keywords, or how do you identify what you might be interested in?

A I'm not sure precisely what search terms they use to identify these articles, but my current role is mostly aimed at advanced wound care, not temperature management. So most of my -- most of the documents that I get now are

related in some way or another to negative pressure wound therapy or advanced wound care technologies, because that's what I work on now.

But occasionally I will get an article in temperature management, or I'll look at table of content searches. Those are very unstructured; they're a list of table of contents of a journal. That's it, and it can include anything.

Q And it sounded like some of the librarians or some of the folks that helped identify some of this research, they have some sense of what your job is?

A Yes, they know exactly what my job is. Yes.

Q And so is it sometimes they're making suggestions on what they think you should be interested in, or having -- sort of knowing what your jobs are, they identify things that you've asked for?

A Well, for a specific task -- so my current role as a compliance specialist involves doing state-of-the-art searches, as well as clinical literature searches. And these are two somewhat different activities that have very specific search terms associated with them. So

when I do a specific search on a topic, I'll tell them that I need to do a state-of-an-art search on an advanced wound care topic, and they already have much of that -- much of those search terms are already stored.

And if I want to add, say, patents or something like that, they can add that to the search as well. And then they have a large number of scientific and clinical databases that they can search with exactly the same search terms. And those -- those are stored, and we keep those, especially for the work that I do now, because that's for the EU. European Union government agencies are very interested in precisely how we searched for literature on various topics that we're writing about.

Q The Bair Huggers is marketed in the EU as well, right?

A Yes.

Q And so do the same EU requirements regarding -- sort of following the literature, apply or have they applied to Bair Hugger as well?

A They do, but I don't work on it.

Q Anymore?

A Anymore.
Q Did you work on it previously though?
A Not in terms of compliance production for the EU.
Q Okay. But somebody did?
A Oh, yes.
Q And who was that?
A I don't know.
Q And is anybody doing it now?
A Oh, yes. Yeah.
Q Who's that?
A I don't know. I mean, it's a whole group of people that work on these things. And people will get assigned projects as they become -- as the deadlines approach from the EU for clinical evaluation reports. That's -- those are the items that we write clinical evaluation reports, clinical development plans, those sorts of things.

Those are on repeating deadlines. So every two years or every three years, depending on the classification of the device, they have to be updated. So if there is new literature, safety concerns, anything like that, those get put into these reports.

Q Is it reasonable to assume that these clinical evaluation reports required by the EU would have been prepared on the Bair Hugger?

A I'm sure there are some.

Q All right. And you said that they tend to be required about every two to three years?

A Something like that. Again, depending on the classification of the device.

Q All right. So it's your expectation anyways, that certainly 3M would be maintaining these clinical evaluation reports required by the EU with respect to the Bair Hugger as well?

A Oh, yes.

Q Were you ever part of the team that prepared those sort of reports or submissions?

A No.

Q Did you work with the team that was sort of getting ready to prepare those sort of reports? And I guess what I mean is, you've got an extensive library and certainly, I mean, even according to Dr. Issa, you're the most knowledgeable person on patient warming at 3M. So I wonder, is somebody coming to you and asking about your literature and that sort of thing in preparation for submission to the EU?

A No.

Q That's never happened?

A Not for the temperature management part of the business. But for the temperature monitoring, I have assisted with that particular one.

Q Okay. Do you have any idea who did prepare those submissions?

A I do not.

Q All right. Did the practice or, I guess, requirements for the EU change at any time, to your knowledge, between when 3M acquired Arizant in 2010 and today?

A They have recently changed. The requirements used to be dictated by what they call the medical devices directive. Now it's called the medical devices regulation. It went from MDD to MDR, so the requirements have changed specifically around things like benefit-risk analysis. And there are other things as well, but I mean, the basic premise of these documents is a description of the device's purpose; its safety, its efficacy, you know, what other types of products exist in the market that are similar to these, that sort of thing.

Q And these reports, sort of whatever acronym they were under, I know that the sort of letters change, but they would have included a benefit-risk analysis?

A That's a rather brand new requirement, yes.

Q All right. And do you know if one has been prepared with respect to the Bair Hugger?

A I don't know.

Q But you'd expect that that's a requirement in the EU?

A Well, at some point it will be required, yes.

Q If it hasn't been required yet?

A Yes.

Q Okay.

MR. GORDON: For what it's worth, I actually know this. It has not. It is not due until 2024 and one has not been prepared for the Bair Hugger. I actually knew --

MS. ZIMMERMAN: Okay. I appreciate that, Corey.

BY MS. ZIMMERMAN:

Q Did they have, to your knowledge, any other sort of submissions, whether to the EU or

other sort of regulatory bodies recognizing -- and I know that's not necessarily your role for Bair Hugger, but has a risk-benefit analysis been done in connection with the Blair Hugger for any government entity, be it the U.S. or somewhere else?

A I don't know.

Q Just one way or the other, you're just not aware?

A Yeah, I'm just not aware.

Q When you were talking about sort of the state-of-the-art search, is "state of the art," and I'm using that term in quotes, is that a term of art as well?

A Yes.

Q And what does it mean?

A A description of the current technological purpose and function of all of the devices in the market that would compete in that space.

Q So if you're doing a state-of-the-art, you're trying to understand sort of all the patient warming, or just convective therapy or how might that look?

A It could depend. Probably would include

all of patient warming, all types of patient warming, but it could be just specifically limited to convective, forced-air convective warming. Probably would include all though.

Q All right. And it sounds like perhaps somewhere there's some search terms saved, whether it's specific to you or sort of the librarian folks have some sense of what you might be looking for; is that fair?

A Well, in my case, it would be mostly for advanced wound care products. Yes, those searches are saved. I mean, we report the specific search terms to these government agencies -- well, notified bodies, and in turn government agencies.

Q And so for you, your job change, I think from your deposition you said June of 2019; is that about right?

A Somewhere, yeah. About that.

Q And now it's more on advanced wound care, but it also has included certainly, from time to time, temperature management care?

A Yes.

Q And with respect to that, do you have search terms saved with respect to temperature

management?

A No.

Q Is there a reason why no searches like that are saved for you?

A Well, that's not technically part of my job any longer, so I don't run any fixed searches or anything like that, but I mean, obviously I still passively acquire clinical documents when I run across them.

Q So that was going to be my next point. I mean, obviously in the, I don't know, 550-odd articles that we were provided after your deposition, there's a great many of them that do touch on patient warming issues or articles related to patient warming. How is it that you continue to monitor that literature?

A I'll look at table of contents. Most journals will publish a table of contents, if it's monthly or bimonthly, and I'll look to see if there is an article that is of interest to me and download it.

It's a very passive sort of process. I mean, there's no active search that provides papers to me related to temperature management.

Q Fair to say it's something that you

spent, you know, over 30 years on and so it's just something that you're still interested in?

A Yes.

Q Is it something that 3M expects you to be doing some ongoing monitoring on?

A No.

Q Despite sort of the role change, do you still have folks come to you from time to time with questions related to the Bair Hugger and other patient temperature management issues?

A Yes.

Q Is it -- do you have -- I mean, you've got librarians and sort of other folks, I assume you have access to essentially any articles that you might want or need in your role now in wound care but certainly before in Bair Hugger?

A Yes.

Q Do you still sometimes rely from time to time on experts and others to forward you something they think you might find interesting?

A Well, I mean, I don't rely on, but people will send articles to me, for sure.

Q Sure enough. Sometimes people send you unsolicited reading materials?

A Almost always unsolicited.

Q That's always helpful, right?

What -- and I apologize, I don't know the answer to this. 3M has prepared what they call a compendium with respect to temperature management. Have you seen that before?

A Yes.

Q It's 150-odd pages or so; is that right?

A I think it's about that size, yes.

Q And have you been involved in drafting that compendium in the past?

A I wasn't really involved in that. That was a marketing effort that I think mainly was -- yeah, it was a marketing group that sort of put that together.

Q Did they consult with any of the folks that had experience in sort of the design and engineering of the product, if you know?

A I don't know. I provided articles to this group for their review, and maybe -- I think I provided a list of citations to them, but I wasn't involved in the preparation of the compendium.

Q Did you provide any sort of memorandums that would have summarized various articles for their consideration?

A Well, they have access to my library. So people -- people can electronically access my library without my knowledge. You know, that's possible.

Q Okay. But in any event, the compendium itself was principally assembled or finalized by the marketing group or a marketing group of some kind?

A Yes.

Q Are you aware, are there any other products that 3M has where there's a compendium of literature related to the product?

A I don't know of any.

Q And obviously because 3M acquired Arizant sometime after 2010, the compendium started after that, or was that something that Arizant started beforehand?

A Well, actually I think there was a compendium, a small compendium that existed in 1994 that Dr. Augustine began, pretty much the same thing, a listing of various papers related to Bair Hugger and a short synopsis of what the paper said.

Q And so when Dr. Augustine did it, that was when he was with Augustine Medical?

A Yes.
Q And so some of that was probably also sort of a marketing-type piece, and my guess would be the intention was to sell the product; is that fair?
MR. GORDON: Object to the form of the question.
A Well, I mean, of course the intention is to sell product. But I think the intention of the compendium was to give customers and -- mostly customers, who are already customers of Bair Hugger, some background information in the scientific and clinical aspects of its use.
Q Sort of help them understand when the product should be used and for whom?
A Things like that, yes.
Q All right. And sort of provide some scientific support for claims that otherwise maybe might be viewed as just marketing?
A Yes.
Q And at least in your view, the compendium has sort of continued to be that as it's grown and currently exists at 3M?
A I'm sorry, you mean -- would you --
Q It's primarily a marketing piece; is that

fair?

A That's fair.

Q Do you think that it's reasonable to expect marketing pieces to be fair and accurate?

A Yes.

Q Do you think that the compendium is fair and accurate?

A Well, again, it is -- it's just a compilation of articles and a description or a synopsis or a summary of those articles. It's not -- and I think the summaries are fair and accurate, yes.

Q Do you think that the compendium reflects an accurate picture of the articles available with respect to Bair Hugger, both that are potentially critical of Bair Hugger and those that perhaps say that there is good evidence supporting its clinical application?

A Yes. There was some legal input on how we structured the articles that were included in the compendium to include both positive and negative papers.

Q So as far as you know sitting here today, the compendium includes both positive and negative articles?

A Yes.

Q Do you know if the last version of the compendium was drafted in around 2017, or is there one more recent?

A I believe the last published one was around 2017, that's correct.

Q And that's available on the Internet pretty widely; is that fair?

A Yes, it's available at the 3M website.

Q Right. Probably also available at fawfacts.com?

A Probably.

Q Are you involved or have you been involved, by the way, in maintaining or providing content for fawfacts.com?

A Not to my knowledge. But I mean, you know my papers are, again, freely available to all of the scientific affairs people, all of the nursing specialists worldwide. So they can take whatever I've written and use it for whatever purpose they deem appropriate given legal constraints and things like that.

Q Sure. Are there any other sort of tips and tricks or fonts? You still like to use the same font and maybe look if somebody has changed

it, it's not your work?

A Well, that's not the intention, but yes.

Q It's a nice hint though, right?

Let's see -- we don't have time today to go through all the articles that you prepared or produced from your library, but I do want to go through some of them. But also in your production there were a number of memos that sort of summarize articles; is that something that you do from time to time?

A Yes.

Q And then those are also available in your library to anybody who would want to access that?

A Yes.

Q How do you decide which articles to write a memo about?

A Some -- well, up until my current position, I was asked to review certain articles and provide a summary or a review of a particular article. And so, you know, I was asked by my supervisors to do that.

Q So at least some of the time, if there's a memo, it's because somebody else has asked you to review an article?

A Yes.

Q Are some of the memos that you write about articles something that you identified yourself or just sort of took it upon yourself to do?

A Occasionally.

Q When somebody was asking you -- providing you an article and saying "please summarize this," who was it?

A Well, it could be a number of people. I mean, my supervisors at the time asked me to review certain articles; but occasionally a scientific affairs person or a nursing specialist who has run across a paper, you know, where a customer has asked a question about a particular paper, they'll forward that paper to me for review and I'll review it for them.

Q All right.

A It's not an extremely formal process. It's just --

Q That's helpful.

A -- a service.

Q A favor from time to time?

A Well, more than a favor; but it's part of my role to at least look at literature, or was, and review it.

Q Then you said -- I know when your deposition was taken in January and earlier this morning, you said that you moved sort of to advanced wound care. Why did you make that transition?

A Well, I think I explained yesterday that the temperature management business at 3M is a very mature business. And the -- 3M just purchased, acquired KCI; it's a brand new business at 3M. And so a lot of attention and support, of course, is being spent on the KCI acquisition.

And so in terms of, you know, interesting things to do, that's a -- that's a business that's going to get more attention than temperature management, which, again, is a very mature business at 3M.

Q Blair Hugger sort of runs itself a little bit at this time?

A Well, it's just that less research effort will be spent on the temperature management business than will be spent on advanced wound care.

Q And why is that?

A Well, because the advanced wound care

business is not a mature business. It's still -- products are being developed, research is being conducted, you know, that sort of thing, compared to a business where it's more of a share of -- more of a fight for market share for mature technologies.

Q So I think I heard you say yesterday that there is a new Bair Hugger warmer of some kind, a cone-shaped machine; is that right?

A Yes, but that was developed a few years ago. Yes.

Q And so everything with respect to sort of developing and finalizing that product is already taken care of?

A For the warming unit? Yes.

Q All right. And did you say that was like a model 900?

A I don't remember what the number is. I should have looked that up last night, but I'm sorry, I don't know. If you need to know it, I can find it.

Q That's no problem. You said, by the way, it's a cone-shaped unit. Does the cone point down?

A No, the shorter end is at the top.

Q Okay. Is that one also that is sort of below the operating room table or is it on a pole?

A It can be placed in either way.

Q All right. Sort of like the 775?

A Yes.

Q And has that actually been brought to market yet?

A The --

Q The new version for the cone-shaped one?

A Yes. Yes.

Q And on that note, there are still 505s still in service today?

A I think there are probably model 200s in service.

Q Yeah, I got the model in the basement. That one is not in service, I promise.

A I think that you would be able to pretty much find any warming unit that Augustine Medical made in service somewhere. I have been to vet clinics that still have model 500s that they're using.

Q Well, they're actually still serviced by 3M, the 505 still?

A Well, I mean -- yes, I think they will

service them, but most of those are serviced by biomedical engineers at various clinics.

Q Do you know, by the way, 3M tends to actually still own the blower units or the heater units themselves, right, and place them in hospitals?

A In most cases in the United States.

Q All right. So most cases in the United States 3M is still the owner of the actual warming unit?

A Yes.

Q And so if it's a 505, that means you're still manufacturing or supplying filters for those products?

A I believe we're still supplying filters for them.

Q And the customers would presumably continue to obtain the filters through 3M, fair?

A Yes, I believe so.

Q They don't get the filters for a Bair Hugger from somewhere else, right?

A They may be able to, but that's not the intent. I mean, we manufacture and sell those.

Q Yeah. Filters are a big part of the business at 3M too, right?

A I really don't know how big that business is.

Q Sure. I think from somebody in Minnesota you see the signs all the time "change your filter in your house," and the like the HVAC and heating systems in your house, that kind of thing?

A Just to be clear, the filter business at 3M is in no way related to the medical business. That's a completely separate business. Yeah.

Q The advanced wound care business, that's sort of something that 3M has recently acquired so you are maybe trying to onboard the folks that are responsible for those products onto 3M?

A Well, I think it's -- I think part of the purpose of this acquisition was to gain expertise in various areas where 3M didn't have expertise. So, you know, they've -- I think many of their people have learned from us with respect to like knowledge, discovery and analytics, for example, those kinds of things, and so it's mutual.

Q How many people are in this -- is it KCI, you said?

A KCI.

Q Yeah. How many people came over with

that?

A You know, I don't know how large that business was when it was acquired.

Q Fair to say that you have a prominent role in that sort of acquisition now as well?

A I didn't understand that question.

Q You're playing sort of an important role in following the acquisition of KCI at 3M?

A No, my role is administrative really. I write reports for the European Union on compliance of -- you know, technical compliance of the products and the portfolio.

Q All right. On the -- moving sort back to Bair Hugger, I think I read in the compendium and elsewhere, that product is still used in what, 90 percent of hospitals in the United States, something like that?

A I believe that that's correct.

Q And more than 50,000 times a day, fair estimate?

A Yeah, I think that's correct.

Q Do you know, by the way, if the 750 is also still in service in the field?

A Yes, it is.

Q And that's something that 3M continues to

service for its customers?

A Yes.

Q Same is true with the 775?

A Yes.

Q And then is this new product that's apparently been finalized -- and I apologize, I don't know the number either, has that actually just started to roll out to customers now?

A It has been, yes.

Q Do you know when that first started?

A I don't know when it was first commercialized, but certainly sometime after 2010.

Q Fair enough. Before the time that you switched over to the advanced wound care?

A Yes.

Q All right. So sometime in the sort of 2010 to 2019 timeframe?

A Yes.

Q Turning back briefly to the compendium, and I want to go through some of these articles. You agree that it's reasonable to expect that even a marketing document like the compendium be fair and accurate; is that right?

A I mean, our code of conduct requires all

of our communications to be fair and accurate.

Q And that would certainly be your expectation with respect to marketing documents as well, right?

A I would expect that.

Q And you'd expect that your customers are going to rely on your representations, even from the marketing department, to be fair and accurate?

A I do.

Q And do they from time to time ask questions from you with respect to various articles? It sounds like they were accessing some of, or at least could have access to some of, the articles that you maintained and memos that you prepare about those articles?

A So are you talking about for the compendium?

Q Yes.

A I think that was all done pretty much independently by the medical writers. I don't recall having any input into the summarizing of articles for the compendium.

Q Do you know what kind of training medical writers have? Any specific medical --

A I think it varies.
Q Some of them may have actually scientific or medical training?
A Yes, I know some do.
Q And some probably, like me, have a political science major or something like that?
A I really don't know. But many of them do have a scientific background. I know there are at least two Ph.D.s in that group so...
Q And so as you'd expect consistent with the 3M code of conduct that marketing documents also be fair and accurate, part of that is because safety of patients is paramount to 3M, right?
A Well, I mean --
MR. GORDON: Object to the form of the question.
A I'm sorry, the reason? Could you just state it again?
Q Sure. One of the reasons that the code of conduct at 3M requires even marketing documents to be fair and accurate, is that you know your customers are going to rely on the representations that the company makes, right?
A Yes.

Q And certainly 3M agrees that patients' safety is very important, fair?

A Extremely important, yes.

Q Can you think of anything that is more to 3M than patient safety?

A Well, I know we had this discussion before about patient safety being paramount, but the fact is when a product is designed, what is paramount is the benefit-to-risk ratio in a medical product. We maximum the benefit and minimize the risk. There are lots of medical products, for example, that are extremely risky, but they provide a benefit that you would not be able to get without taking on that risk.

And so yes, of course, patient safety is extremely important. We work very hard to minimize every risk that we encounter to the lowest possible amount that it can be reduced.

Q All right. And you certainly would agree and have agreed in the past that if there's no benefit to a product, then there's no reason to use it, fair?

A Yes.

Q And in that risk-benefit analysis, you have to do the weighing of risks and benefits,

and the benefit has to outweigh the risk, right?

A That's correct.

Q As 3M was preparing this sort of new model for the Bair Hugger, the cone-shaped one, did they do a risk-benefit analysis for that Bair Hugger?

A So the product development process has an entire risk mitigation -- risk identification and mitigation process associated with it. So the benefit of temperature management, of course, is creation of and maintaining normothermia in surgical patients. And so the risks by themselves get evaluated sort of without -- without regard to any benefit. So again, we already know the -- we already know there is benefit. What we try to do is minimize the risks.

Q When a product development team is looking to come up with a new Bair Hugger like this, is the benefit assumed or does the product development team go back and look at whether or not there is adequate evidence supporting a benefit?

A Well, there is a clinical evaluation of the benefit of the product or the condition

that's going to be produced by the product. So these product development teams are quite large. They include engineers, clinicians, scientists, regulatory people. You know, all sorts of people that have different inputs on how to evaluate and reduce risks associated with the use of the product.

Q Fair to say as 3M is developing new machines, new Bair Hugger or other new therapies, that the product development team is going to evaluate whether there is evidence of a benefit and not assume a benefit?

A The -- so in the way that the product development teams are structured, marketers develop an understanding of what it is they want to produce based on clinical evidence, for example. You know, existing -- experience from existing products, that sort of thing. All of that is taken into account when the products are developed.

Q And there is always -- people are learning new things all the time, including in medicine, and including in medical product design, fair?

A Yes.

Q So, for example -- well, one of the things in your library is there are articles about the heater-cooler problems. Do you recall those?

A Yes.

Q And so you would agree that those studies, it's a series of studies, identified medical equipment in the operating room can be a source of nosocomial infection, right?

A Yes.

Q And prior to that research on the heater-coolers, that had not been appreciated with respect to those particular pieces of medical equipment, fair?

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

A Under those conditions, yes.

Q Right. You know, prior to the research that initiated or originated -- I'm sorry, in sort of Germany and Switzerland, probably anybody in the operating room looked at that heater-cooler device as sort of benign, right?

MR. GORDON: Object, lack of foundation.

Q With respect to a -- from an infection perspective anyhow.

A I don't know.
Q Okay.
A Again, yes, it's true that this particular device was implicated and causing infections, but I don't know how people viewed it prior to the --
Q That's fair enough. Yeah, you don't know what everybody is sort of thinking about the device.
A Correct.
Q But there were a series of maybe 12 or 14 articles, scientific papers that were published regarding the heater-cooler devices and you read at least some of those, right?
A I have read some of them.
Q And you read some of the HCPCS meeting notes from the CDC; is that fair?
A I did.
Q And so you know then that the folks that were gathered together to sort of evaluate the evidence about the heater-cooler devices, had not appreciated that the heater-cooler may be a source of nosocomial transmission of pathogens prior to that research being conducted; is that right?

A At least some of them on the committee.

Q Okay. And you know that there were at least two different problems identified in the heater-cooler? One of the manufacturers actually had a point source contamination. So where they manufactured the facilities, germs got on the machine before they were shipped out. You know that?

A I wasn't aware of that.

Q And do you know that one of the other, I guess, discoveries in that research was that the water tray inside the heater-cooler is manufactured by multiple, different brands, could host and grow bacteria, specifically mycobacteria chimaera?

A Yes, I did know that.

Q And then what they discovered in that research was that those water trays, there was a fan in the machine as well and essentially the fan blew past the water tray and that bacteria became aerosolized, right?

A Yes.

Q And the bacteria in the heater-cooler device, anyhow, because of the fan, because of the blowing air, traveled through the air, right?

A Yes.
Q And those researchers, anyways, discovered and determined down to a DNA level that the bacteria from those heater-cooler devices were traveling from the machine and into a patient's open wound during heart surgery, right?
A Yes.
Q And as a result of that, various researchers and ultimately a panel of folks at the CDC made a recommendation that nothing that blows air should be in an operating room if possible. Do you recall reading that?
MR. GORDON: Object to the form of the question.
A I do remember reading that.
Q And certainly as somebody who has been involved with a medical device that does blow air in an operating room, that was something that you paid attention to as you were reading the articles, fair?
MR. GORDON: Object to the form of the question.
A I read the article. I did pay attention, yes.

Q Did you think it was relevant?

A Well, again, this is an advisory committee, and these are sort of unstructured comments from a group of people sitting around a table making comments. People can say things at times that, taken out of context, may not seem correct. And I think that in the case of this advisory committee, the idea that anything that blows air shouldn't be in an operating room is incorrect. There are many, many things that blow air in an operating room. I mean, most of them have no filters at all, like this device that you're talking about, the heater-cooler unit.

Q So -- and I apologize, that wasn't quite my question. When you're reading about the HCPCS CDC minutes, did it occur to you that the findings in the heater-cooler context might be applicable to the Bair Hugger context?

A No.

Q Did you talk about it with anybody at 3M?

A I had discussions with people at 3M about it.

Q And did they agree with you that it wasn't applicable at all to the Bair Hugger?

A Yes.

Q And what was the basis for your determination there?

A Well, that water was involved and no filtering.

Q And you would agree that the Bair Hugger itself, bacteria can be cultured inside the machine, fair?

A Bacteria can be cultured from the inside, yes.

Q And has been in many published studies, fair?

A Yes.

Q The bacteria can also be cultured from the inside of the hose, fair?

A Yes, it's not sterile.

Q Absolutely. And both the inside of the blower unit itself and the hose are past the point of the filter in the Bair Hugger, right?

A Yes.

Q So the filter has already happened and so if there is something on the inside of either the blower or the hose, that's bacteria that got past the filter, fair?

A Could be, yes.

Q And you've seen internal testing

documents that show that that bacteria then will continue to grow on the inside of the machine, right?

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

A I don't believe that I've seen any documents that bacteria continue to grow on the inside of the machine.

Q Do you recall any of the testing that done with, I think it's Ion-Armor looking at the inside of the hose in particular?

A No.

Q Do you recall testing where 3M was considering essentially a microbial lining or spray on the inside of the hose to prevent the growth of bacteria?

A I don't recall that.

Q Fair.

A I wasn't involved in those, yeah.

Q All right. But sort of like what they learned in the heater-cooler where bacteria landed in and grew in the water tray, 3M knows that there's bacteria inside the heater and the hose of the bacteria -- pardon me, of the blower unit, fair?

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

A Well, I think you're talking about two different things here.

Q Absolutely.

A So the mycobacterium that grew in the heater-cooler unit actually grew -- I mean, these are big colonies of mycobacterium that were blown out of an unfiltered airstream in a relatively dirty piece of equipment. That's not the same thing as a Bair Hugger, where there is really -- there's no substrate in the Bair Hugger for bacteria or even mycobacteria to grow.

Yes, it's not sterile. You know, I mean, we've labeled it not sterile from the beginning.

Q So let me stop you there. What I'm trying to get to, anyways, is that with the heater-cooler we know that from a series of studies, one of which followed the next, so they would identify a question and then they go to try to answer the question that was identified in the study beforehand, right?

A Yes. It's been a while since I reviewed that literature, but yes.

Q Right. And we know ultimately that very

-- mycobacterium chimaera is a very hearty bacteria, right?

A Yes.

Q Slow growing, for example?

A All the mycobacterium are very hearty.

Q And perhaps you recall from reading those papers that one -- that the researchers who originally identified this piece of medical equipment as potentially problematic in an operating room, the reason they figured it out was that -- normally a mycobacterium is like a tuberculosis, right? You have an infection in your lungs?

A Well, tuberculosis is a mycobacterium, yes.

Q And do you know if the infection would normally present itself in your lungs -- in a patient's lungs?

A Most times, yes.

Q Hopefully not yours.

A In the United States.

Q Yes. But with the heater-cooler patients, you may recall the infection itself presented in the patient's heart tissues. Do you recall that?

A Around them, yes.

Q And the reason that the researchers in the heater-cooler found that peculiar and required additional research is that you wouldn't normally expect to find mycobacterium chimaera infections in the tissues surrounding the heart, fair?

A Correct.

Q And what happened was there were, I think, two patients that had the similar presentation of this very strange, rare bacteria in a very rare infection in the heart, and the thing that they had in common was that they both had open heart surgery in the same operating room a few months before, right?

A Yes. I think it was a cluster of unusual cases that initially drew the investigators' attention to the problem.

Q So what happened with those investigators is, they said, Jeez, the only thing that is in common with the patient with the very strange bug and this very strange infection is that they were in the same operating room. The bug must be coming from inside the operating room, right?

A Yes, I think that was the logical

conclusion.

Q And so they pursued that, right?

A Yes.

Q And they went to follow up and ultimately identified it did come from the heater-cooler device that was in the operating room at the time of these heart surgeries, fair?

A Yes.

Q And so one of the important takeaways, if you follow the series of those articles and then ultimately the HCPCS meeting from the CDC, was really the mechanism of aerosolization of bacteria in an operating room potentially causing -- well, actually causing infection in patients, right?

A Yes.

Q And that's what HCPCS from the CDC was talking about when they met in 2015. Do you recall that?

A Yes.

Q And actually, 3M had representatives present at those meetings, right?

A They did.

Q And those aren't meetings of just sort of, you know, poly-sci majors like me. Those are

experts in their field, fair?

A Well, the clinicians, yes.

Q And representatives from the industry that are sort of trained to study and investigate these issues; is that right?

A Yes.

Q And that's sort of what HCPCS did for the CDC; is that right?

A I believe so.

Q And they identified this medical equipment in the operating room caused aerosolization of bacteria and infection in patients, right?

A Yes.

Q And turning to the Bair Hugger, we know that the blower unit itself is sold as not sterile, right?

A Correct.

Q There are series of peer reviewed published articles identifying that swabs are taken of the inside of the machine and the inside of the hose, and that bacteria is cultured from the inside of those machines, right?

A Yes.

Q There is no distal-end filter at the end

of the hose, right?

A Well, other than the blanket.

Q The blanket isn't considered a filter by the company, correct?

A Correct.

Q And at no point has the company claimed that the blanket acted as a filter, fair?

A No, but there's a number of clinical papers that demonstrate that when the blanket is attached to the end of the hose, that the air beneath it is sterile or you cannot culture bacteria beneath the blanket.

Q Are you talking about Hall and Zink?

A No, I'm talking about Michael Avadon, Mike Reed and his group did some work where they tried to culture bacteria beneath a blanket, and were unable to do that.

Q And so it's your position, as you sit here today, that the blanket is a filter for the Bair Hugger?

A Well, it can act as one.

Q It may --

A We don't make that claim.

Q Sure.

A But I'm just saying that the blanket

plays a role in decelerating the airflow. It has electrostatic properties. It changes the momentum, you know, of the air or any particles that happen to be in it. So there are many things that the blanket does to the airflow that apparently, at least in these studies that I'm referring to, makes it unlikely that you'll be able to culture viable organisms.

Q So the fact that the bacteria that -- first off, there is bacteria in the machine and in the hose, and it will be expelled from the machine and the hose as air is blowing out of it; is that fair?

A Well, I don't know. The bacteria may be adhered to the service. Yes, it's certainly possible to take a swab and remove bacteria -- remove bacteria and then culture it. But I don't know that necessarily, that the bacteria are able to blow off of the surfaces of the warming unit.

Q And after 30 years working in the product, you still don't have an answer to that question?

A Well, we have lots of clinical evidence that suggests that the device doesn't cause an increase -- or increased risk of infections.

Q Fair to say that 3M has never done a test internally to see if bacteria comes out of the Bair Hugger machine?

A Not to my knowledge.

Q And that's despite the fact that there are these ongoing concerns that bacteria -- culture from the machine may be putting the patients in the OR at an increased risk of infection, right?

A Well, and also there's competing clinical evidence that it doesn't increase risk of infection.

Q But the question, I guess, respectfully, Mr. Van Duren, is that 3M has not done any bacteriology studies itself to study whether or not the bacteria we know that is in the machine comes out of the machine?

MR. GORDON: I'll object on foundation grounds.

Counsel, I understand it's kind of hard to make the switch after several hours yesterday of 30(b)(6) deposition, but now he's here today in his individual capacity to talk about his library; and we've gone almost an hour and I don't think you really talked about any specific

things from his library.

I'm letting -- go ahead and continue to ask these questions, but I just, you know, this really feels like it's a continuation of yesterday.

Q Well, Mr. Gordon makes an accurate point that you are here in your personal capacity today; and I don't mean as I'm saying "you" today, I should have gone through the instructions again.

A No, I understand.

Q Thank you, Mr. Van Duren. I'm not trying to trick you.

A I know.

Q But as you sit here today, as someone who worked on this for 30 years and who maintains a large library, both sort of electronically and certainly in your head walking around every day, you don't know about any study that 3M did to show there is no bacteria that comes out of that machine in an operating room, right?

A Again, I'm not aware of any.

Q And there's no claims that you or 3M make that the filter -- pardon me, that the blanket acts as a filter?

A No, we don't make that claim.
Q And that would be an inappropriate claim to make?
A Well, we don't have FDA approval to make that claim, for one thing.
Q Recognizing that we also sort of have some limited time here this morning and your library is significant, you'd agree that, at least what was produced sort of recently, a lot of it has to do with sort of wound care articles?
A Yes.
Q Makes some sense because your job has changed. Lots of articles about preventing and treating infection in central lines?
A Yes.
Q That's something that I think you spent, I would gather having reviewed it, spent a lot of your time on right now?
A I did, yes.
Q Are you not doing that anymore?
A No, I'm actually working on negative wound care pressure therapy right now.
Q How long were you working on sort of the PKC line?
A About a year.

Q And you're sort of out of that area now?
A Yes.
Q Has that been a welcome change or fun to learn something new?
A I prefer advanced wound care.
Q All right. But each of these lines, whether it was Bair Hugger or sort of the central line infection prevention and now wound care, you've certainly been involved with or monitoring issues related to infection for 30-plus years at this point, right?
A Well, it wasn't my primary interest or responsibility, but I have, yes.
Q And that -- it's fair to say that there continues to be a great deal of research, frankly, in all three areas, whether you're talking about Bair Hugger and patient warming and the risk of infection, preventing infection in folks that have a central line placement, and sort of how to treat infected wounds. That's something -- ongoing research in all areas, fair?
A Yes.
Q And so the, you know, the production that we were provided, some 500 articles since your last production, reflects that there are still

areas worthy of research in each of those areas; is that fair?

A Well, I suspect the largest percentage had to do with negative pressure wound therapy given that is where my -- the activities my current role take me. I mean, I think the lion's share of these papers are going to be negative pressure wound therapy, if I'm not mistaken. But yes, infection is a big part of that.

Q Would you agree that there is no valid, current scientific evidence supporting the notion that normothermia will prevent surgical site infection?

A No, I don't agree.

Q Have you -- you've been presented before the excerpts of the depositions of both Dr. Sessler and Dr. Kurz? Maybe?

A Maybe.

Q Sure. It's been a minute.

A How long ago was that?

Q Well, I think your last deposition was also five years ago and the MDL was in March of 2017?

A I may have seen portions of depositions by those two individuals, but I don't really

recall for sure.

Q So you don't recall if they said that sort of in modern standards there's no basis to claim that normothermia will prevent surgical site infection?

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

A So I don't think we've ever said that normothermia prevents surgical site infections. What we have -- I believe what we claim is that the existence of normothermia reduces the risk of developing a surgical site infection.

I mean, we -- people still get surgical site infections. They take antibiotics, they will do everything right and still get a surgical site infection. So all of the -- all of the treatments that are spent on keeping patients well don't always prevent them from getting a surgical site infection, including normothermia.

Q Certainly. But sort of like seatbelts have prevented both a number of injuries and deaths in traffic accidents over the last 30 years, in medical device design there are improvements all the time, right?

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

A Well, medical device has improved over time yes, generally.

Q And even if you can't prevent every sort of traffic fatality by using seatbelts, it prevents some and that's a laudable goal, right?

A Yes.

Q And that's why we hopefully wear our seatbelts when we drive, fair?

A That and it's a law.

Q Well, that helps too.

And so with respect to preventing surgical site infection, you think that it would be reasonable, even if it can't be completely eliminated, that we should reduce surgical site infection to the extent that we're able, fair?

A Yes.

Q And that's certainly a goal of 3M?

A Yes.

Q And part of achieving that sort of goal is to stay up-to-date on the literature preventing normothermia and potential risks associated with using the Bair Hugger, right?

A I don't know that my keeping up with the

literature is going to have an affect on patients' risk of surgical site infection, but it's part of my job to keep up with the scientific literature, yes.

Q So -- and again, because it's in your library, I'm going to get back to the heater-cooler example. What did 3M do, if anything, to assure the company that the mechanism of risk to patients presented by the heater-cooler was not likewise presented by the Bair Hugger?

MR. GORDON: I'll object on foundation grounds.

Q That you know about, I apologize.

A Well, that I know about? I don't know what was done. There were certainly discussions about the differences that were apparent in the heater-cooler unit and Bair Hugger. There are very large differences that did not make these comparable.

Q But as you sit here today, in terms of any kind of testing that 3M may have done to assure the company and its customers and patients it serves, you're unaware of any testing that was done in response to the heater-cooler problem?

A Not in response to the heater-cooler problem.

Q Do you know if -- is the heater-cooler part of the compendium at all, any of those articles?

A I don't know. Only if a Bair Hugger was involved in some way would they be included in the compendium. The compendium is not a state-of-the-art analysis, it's a Bair Hugger analysis or Bair Hugger compendium.

Q All right. Do you remember Dr. Parvizi?

A Yes.

Q Do you know him personally?

A Yes.

Q Are you aware of the article that he had published as sort of a Letter to the Editor shortly after the beginning of COVID?

A Well, you'll have to tell me what the subject was.

Q I apologize, he publishes fairly a lot?

A Well, I read a lot so...

Q Sure. Is he also the head of the International Consensus for prevention of periprosthetic infection?

A I believe so.

Q And sometimes we call that ICOS?
A Umm-hmm.
Q And he's, I think, on the board or was on the board of 3M infection prevention division as well, right?
A On the speaker's bureau?
Q Maybe that's right. Is he a key opinion leader for 3M?
A He was. I don't know if he is currently.
Q All right. Do you know if he has raised concerns in the last couple of years in published papers about the risk forced-air warming units pose with respect to nosocomial transmission of pathogens; so bacteria to patients in the operating room?
A I don't recall reading any of those papers, if they exist.
Q Why don't we take a quick break and I'll get it for you.
A Sure.
THE VIDEOGRAPHER: Off the record.
(Whereupon, a break was taken from 10:43 a.m. until 10:56 a.m., after which, the following transpired.)
THE VIDEOGRAPHER: We're on the record.

BY MS. ZIMMERMAN:

Q Thank you, Mr. Van Duren. Are you ready to get started again?

A Yes.

Q And I understand we have gone a little more than an hour, so not too much longer to go. Obviously we could talk about these issues for a long time.

But before the break we were talking about a publication by Dr. Parvizi. And you know Dr. Parvizi, and he's been sort of a consultant for 3M from time to time over the years?

A Yes.

Q And do you know whether he may have been an author in the study of arthoplasty that recommended forced-air warming systems be used with caution as they may increase the distribution of aerosolized particles during a surgery?

A He may have written that. Again, I don't recall reading that exact phrase.

Q Okay. And I am going to hand you -- I highlighted it to make it a little easier for him. This is Exhibit 32.

(Whereupon, Exhibit 32 was marked for identification.)

BY MS. ZIMMERMAN:

Q Mr. Van Duren, do you know if you have this paper in your clinical library?

A I don't know for a fact. I can tell you for a fact that this did not come from my library because it doesn't have a library tag on it.

Q That's correct. And you see the last listed article there is Javad Parvizi? And I'm not sure if I pronounced his first name right.

A Yes, I see that.

Q And it was published in the Journal of Arthoplasty in 2020?

A Yes.

Q I tried to highlight that. It looks like it's available online on April 22nd of 2020?

A Yes, I saw that.

Q And they are talking -- of course, that was about two months into the COVID epidemic; is that right?

A Yeah, in 2020? Around that.

Q Yeah. And so they -- if you turn to the sort of third page of the article, they talk about the prevention of spread in the air?

A Yes.

Q And at the bottom there's a table one saying: "Common steps for the surgical procedure and recommendations for decreasing the potential viral load for each step," right?

A Yes.

Q Do you see that?

A Mmm-hmm.

Q And to be clear, viruses and bacteria are two different types of pathogens, right?

A Yes.

Q But both viruses and bacteria can ride on particles, correct?

A Yes.

Q And you can see in table one that there is a surgical step listed for forced-air warming? I tried to highlight it just to facilitate your review, but you're welcome to look at it if you'd like.

A I see it.

Q And you can see that Dr. Parvizi and other authors there, their suggested action with respect to forced-air warming systems is: "These devices should be used with caution, as they may increase the distribution of aerosolized

particles during the case. Blankets may be more effective at decreasing particulate generation and distribution." Did I read that right?

A Yes.

Q And do you know, and by you I mean Mr. Van Duren, do you know if 3M took any action with respect to these comments published by Dr. Parvizi and others with respect to the aerosolization of and airborne transmission of pathogens?

A I don't know. I doubt it. This is a speculation on Dr. -- well, on these authors' part. It doesn't say that "it does," it says "it may" increase.

Q All right. But that is certainly identification of a potential risk of airborne transmission of pathogens, right?

A Well, in the context of -- I think this is a paper having to do with COVID-19 virus particle transfer, right?

Q Right.

A I haven't read this paper. I mean, if you want me to read the paper, I could read it and understand it completely. But just looking at the table, again, this is just an appeal to

logic. This isn't a research finding or anything like that. This is just his opinion.

Q Okay. Well, it certainly got -- it's six different authors at the top of this peer-reviewed paper?

A Yes.

Q And you'd agree that the Journal of Arthoplasty is a peer-reviewed paper and well regarded by folks in the field?

A Yes, the Journal of Arthoplasty is a good journal.

Q And you, and certainly 3M has, from time to time hired and consulted with Dr. Parvizi and considers him an expert on a number of different things, fair?

A We have.

Q And I think you just characterized this as an appeal to logic? You agree that this is, in fact, an appeal to logic?

A I'm just saying that the statement that you highlighted here is an appeal to logic.

Q Right.

A It's not based on results of a study that was conducted.

Q Okay. Do you recall a paper in your

library from a Dr. Uggen?

A I don't remember the name. If you can show me the paper, I can review it.

(Whereupon, Exhibit 33 was marked for identification.)

BY MS. ZIMMERMAN:

Q And I will represent to you that the sort of square highlighting, that's mine, it's not yours. It's not inadvertent to hand it to you. I just thought I would try to speed things up.

This is a paper that you have in your library as well?

A It looks like it. It's got a number on it that would seem like it would be about right for a paper of this year.

Q And so that would be -- it looks like it's dated 2019, and it is in the arthroscopy, the Journal of Arthroscopic and Related Surgery. Do you see that?

A Yes.

Q It looks actually like February of 2020. And so that was an article that you had in your library?

A I'm pretty sure this is in my library, yes.

Q And Dr. Christopher Uggen -- I apologize to him, whoever he is, if I mispronounce that -- he's a doctor and on the editorial board of this journal. Is that what it seems from the beginning?

A Yes.

Q And he notes in the first page of the article in the section that I highlighted, that -- and he's talking about active warming devices. It says, "Including forced-air warmers and resistive heating devices. Although known to improve the ability to maintain the ability to maintain normothermia, do not eliminate the instance of hypothermia."

And the rest of the highlighted part says, "also the use of these devices carry some risk to patients, including burns and pressure sores. More importantly, several articles have raised concerns surrounding possible increased risk of deep surgical site infection of forced-air warming devices" and puts in "(Bair Hugger)." Did I read that correctly?

A Yes.

Q It says, "Some studies suggest these devices can create convection currents,

disrupting laminar flow and mobilizing floor air into the surgical site." Did I read that sentence correctly as well?

A That's correct.

Q And then he says, "Other studies have shown that potentially pathogenic organisms grow in the hoses and filters of the forced-air warming devices." Did I read that correctly as well?

A Yes.

Q So Dr. Uggen is identifying in this paper that there are at least other papers that raise these particular concerns, both with respect to airflow disruption caused by the Bair Hugger and pathogenic organisms growing inside of the machines; is that right?

A That's correct.

Q And he sort of talks about whether or not -- on the next page, whether or not warming is necessarily indicated, correct?

A I haven't read it. May I read it?

Q You may.

A Okay.

Q And Dr. Uggen is sort of -- obviously this is a short editorial commentary, but he

raises sort of at a high level the potential concerns some articles have identified with respect to both an airflow disruption danger to patients associated with Bair Hugger, and also with respect to the pathogenic organisms that grow inside the machine itself, right?

A He has cited that, yes.

Q And would you agree that Dr. Uggen, in this particular editorial piece, says that the possibility of -- "concern regarding possible increased risk of surgical site contamination with forced-air warmers warrants further study."

It's right at the top and, in fact, it's sort of in the middle of the abstract. He says it also in the second to last sentence of the editorial commentary.

A Yes, I see that.

Q And so Dr. Uggen, anyways, identifies that the concern regarding potential increased risk of surgical site contamination with forced-air warmers warrants further study, right?

A He does say that.

Q And that "warrants further study" was sort of a refrain that you have seen raised by a number of different articles, particularly over

the past five years; is that right?

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

A Virtually every clinical trial ends with the same phrase, "warrants further study," regardless of the outcome.

This is an opinion from Dr. Uggen. You know, and he also states in the last paragraph that it's unlikely that in -- and he's talking about arthroscopic surgery here that the risk is very significant. He says something like, in orthopedic surgery with arthroscopic that it's unlikely to be a significant factor; but anyway, this is an opinion.

Q Is one of the reasons that he thinks that it may be particularly or potentially irrelevant in arthroscopic procedures the fact that most of those surgeries lasts only 30 minutes and therefore the patients aren't warmed?

MR. GORDON: I'll object, lack of foundation.

A Well, actually I think what he's suggesting since this surgery only last 30 minutes, they don't need to be warmed at all.

Q Correct.

A That's what he's suggesting. That's not true, but that's what he's suggesting.

Q So at any rate, if Dr. Uggen is assuming that for those surgeries lasting less than 60 minutes, no warming is required and, therefore, arthroscopic surgery patients would not be exposed to the potential risks that he identifies in this editorial piece, potentially associated with Bair Hugger. That is sort of the recommendation that he's making, right? That maybe this isn't relevant to arthroscopic surgery patients because you doctors aren't even really using warmers because the surgeries are short; is that right?

MR. GORDON: Objection, lack of foundation.

A Well, I don't know the basis of his opinion, but my guess is that the risk of surgical site infection from an arthroscopic procedure is very, very low; primarily because the puncture site is very small and it's easily controlled, it doesn't normally get infected.

So, you know, for all of the reasons that arthroscopic surgery is --

Q Lower risk?

A -- is a lower risk surgery. Those patients do better with respect to surgical site infection.

Q But some of those reasons also include, one, that there is not typically an implant in an arthroscopic surgery procedure, right?

A Typically not.

Q And that means that those patients are not at the sort of increased risk that the total joint or a total knee or total hip would be at, fair?

A Well, again, total knee and total hip surgeries are extremely low-risk surgeries for surgical site infection, as are arthroscopic surgeries. They're all very low risk.

Q But you would agree that any implant surgery is at a higher risk than a non-implant surgery given the potential for biofilm?

A No, I don't think I would agree. I think -- do you mean the incidents of surgical site infection is higher?

Q No, and I apologize if I'm not asking a good question. I apologize.

When an implant is involved in a surgery, that patient is at higher risk than a patient

that is having a surgery without an implant?

A No, I don't think so. I think implant surgery is an exceedingly low risk surgery.

Q Lower risk. It doesn't happen often, but because the body has a more difficult time fighting off infection when an implant is involved, and because a lower dose of bacteria is required to create a deep joint infection when an implant is involved, those patients are at higher risk, fair?

A Well, I think you're conflating the severity of the risk with the actual incidents. So the incidents, the likelihood of an adverse consequence is low in implant surgery, very low, it's among the lowest that exist.

Yes, it's true if patients with an implant get a deep joint infection, that's a devastating, terrible, adverse consequence; but the incidents of those failures is exceedingly low in the United States.

Q And I apologize, again, I'm sorry, maybe I'm asking a bad question. To the extent that the infectious disease doctors, and I'll focus on Dr. Wenzel, the expert author by 3M, to the extent that he has said that implant surgery

patients, particularly total hip and total knee, are at increased risk of infection, deep joint infection because it takes a smaller bacterial load to create a deep joint infection, you would defer to the infectious disease doctor; is that fair?

A Yes. Of course, Dr. Wenzel knows a lot more about this topic than I do. But the question was, are these patients at higher risk? And I don't believe that the answer is yes; it's no. Orthopedic joint surgeries are among the lowest risk surgeries for surgical site infections and deep joint infections.

Q Right. And you certainly agree that deep joint infections is one of the top concerns of an orthopod doing a total hip or total knee surgery because other things are sort of --

A Well, I would say it's probably one of the top things that they would like to avoid.

Q Okay. And some of the potential risk to those patients has to do with the dose of bacteria required to create an infection; would you agree with that?

A Perhaps.

Q In any event, getting back to Dr. Uggen's

editorial piece, he is identifying that these sort of concerns about forced-air warmer devices, like the Bair Hugger, creating an increased risk of surgical site contamination both through what I'll call the dirty machine theory, the facts that bugs can grow in a swab from the inside, and also because they disrupt the airflow in an operating room, he identifies that as areas warranting further study, right?

A Yes.

Q And you certainly have seen other articles that have requested additional study on these issues?

A Virtually every clinical paper at the end says "require further study," regardless of the result.

Q Sure. For example, the International Consensus on prevention of periprosthetic joint infection, when they got together in 2014, you know from your research and following the issues that ICOS identified or noted the agreement with the theoretical risk associated with use of forced-air warming intraoperatively, and identified that as an area that required additional research?

A I believe that's correct.
Q And as you sit here today, do you know whether 3M has done the additional research that the International Consensus called for in 2014?
A Well, since 2014?
Q Yes.
A I mean, 3M has done research looking at, for example, comparing infection rate differences between patients who are warmed with a device or the HEPA filter and ones that were not. I mean, that's an example of additional research in that area.
Q And that was the one comparing Bair Hugger to the Stryker Mistral?
A Yes.
Q Were there any other studies that you're aware of?
A Well, there may be others. I mean, I can't recall right now. But again, this is an opinion piece.
Q Sure. Do you recall the study -- and it's in your library, I did not bring the copy that's in your library, but I can get it if we need, from a group of researchers associated with Stanford last year?

A Brock-Utne?
Q Yes, absolutely.
A I recall that paper.
Q Do you know Dr. Brock-Utne or any of his --
A No, I've never met him.
Q But you recall reading the article?
A I did read it.
Q And you understand that those are -- it's a group of anesthesiologists working at Stanford University?
A Yes.
Q And you know from their paper that they also sampled bacteria from the inside of both the Bair Hugger and the hose?
A I don't recall specifically the details of the paper. I do recall reading it; but yes.
Q Do you recall that they concluded that the Bair Hugger patient-warming device could be a source of airborne microbial contamination in an operating room?
A It wouldn't surprise me to find out that they said it could be.
Q All right. And so that would have been April of 2021. Is that consistent with your

recollection?

A I believe so, yes. Yes, it's a recent paper. Yes, relatively.

Q And do you know -- do you, Mr. Van Duren, know as you sit here today, know whether 3M has done -- has contacted these authors?

A I don't know.

Q Do you know if 3M has done anything to sort of follow up on the research that the Stanford University folks did identifying Bair Hugger as a potential source of bacterial contamination in the operating room?

A Well, again, I don't know. But I am not associated with that business anymore; so they may well have, I just don't know.

Q Right. And I'm asking because I know the paper is in your library and maybe --

A I'm sure it's in many people's library at 3M.

Q Sure. Sure. And so at any rate, if they have recommended also to do some additional study, as far as you know that hasn't started since April of 2021?

A Not to my knowledge.

Q All right. Do you know if there are any

follow-up studies at all that these folks are conducting?

A I don't know.

Q As you reviewed various papers related to diagnoses of periprosthetic joint infection, would you agree that likely the rate of periprosthetic joint infection is underreported?

A I think it's unlikely that the rate of deep joint periprosthetic joint infection is underreported. It could be, but it seems unlikely. It's such a devastating outcome that it almost certainly is going to get reported.

Q Sure. As you've done sort of research, and I know you have some pieces from the Department of Health and Human Services on definitions of deep joint infection and sort of timing of those, you'd agree that, for example, the majority of deep joint infections that are diagnosed within two years of surgery are believed to be from bacteria that was inoculated during the time the surgical wound was open in the operating room?

MR. GORDON: I'm going to object to lack of foundation.

Q If you know.

MR. GORDON: Also form.

A Again, I'm not a microbiologist, so I'm not an expert in this field. But that's certainly one possible route of infection for sure.

Q And do you know, as you sit here today, that whether sort of the belief in the infectious disease and orthopedic community, is that if a deep joint infection is diagnosed within two years of an operation, that the presumption is that the bacteria that caused that infection was introduced during the time of the surgery? If you don't know, it's all right.

A Well, again, I think there is some controversy about the source of this bacteria. It could be endemic from, you know, bad dentition, multiple internal sources, pneumonias and things like that are frequently thought to be sources of the infection, especially late ones that occur two years after the surgery. But yes, it's true that inoculation during the surgery is also thought to be a cause.

Q And it's thought to be the cause of most of the periprosthetic joint infections, right?

A I don't know that for a fact.

Q Okay. You have, from time to time, been involved in drafted various marketing-related pieces, including with respect to patient temperature management; is that right?

A Drafting?

Q Yeah.

A The whole piece, marketing piece? No.

Q Okay. But it would certainly be your expectation and practice that the marketing pieces would be accurate and fair, fair?

A Yes.

(Whereupon, Exhibit 34 was marked for identification.)

BY MS. ZIMMERMAN:

Q Do you recognize this document, Mr. Van Duren?

A I do.

Q Is this a document that you wrote?

A I did.

Q And if you flip to the very last page, it has sort of a revision history. It says the first draft was created on November 14th of 2018; is that right?

A Yes.

Q And then on November 26th of 2018, it

says "added citations"?

A Yes, I see that.

Q And then December 6th of 2018, it says, "Legal, regulatory and professional services revisions," right?

A Yes.

Q But the author is confirmed here to be yourself?

A Yes.

Q This is an eight-page document; is that right?

A Yes.

Q And the very first page includes the 3M logo and it says "temperature management business. Fast facts for sales rep," right?

A It does, yes.

Q This is an internal document that you prepared at 3M?

A Yes.

Q And you also -- it's called a "technical brief" at the top?

A I think that's what it was titled, yes.

Q And so you would certainly be endeavoring to provide correct and accurate information to the sales rep so they can provide fair and

accurate information to the customers purchasing temperature management products, fair?

A Or giving them information, yes.

Q All right. And if you flip to, I guess, what's page 2 of 8, at the beginning it's titled: "Patient Warming Essentials. A Quick Reference Quide," right?

A Yes.

Q Towards the back, you even have read terms defined in a glossary at the end of your memo. Actually, the glossary starts on page 4.

A Okay, yes.

Q Okay. But the real, sort of, crux of the memo itself appears on page 2 and 3; is that right?

A Yes.

Q And essentially you have, it looks like 18 numbered, I don't know if you call them facts or I guess you call them "patient warming essentials"; is that right?

So it starts out number one: "The patient warming has three distinct goals: Increase preoperative mean body temperature; maintenance or restoration of intraoperative core body temperature in the normal thermic range

between 36 to 37.5 degrees celsius; and post-operative thermal comfort and normothermia"; is that right?

A Yes.

Q And you got an end note there number one?

A Yes.

Q I would like to focus your attention on number 2 here. It says, "The purpose of patient warming is the reduction of risk of the following post-operative consequences."

You list: "Surgical wound infection, increased length of hospital stay, transfusion requirement, intraoperative blood loss, cardiac erythremias, myocardial injury, protein utilization, extended duration of neuromuscular blockade, increased PACU time, adrenergic activation" --

A Adrenergic.

Q "Adrenergic." "-- post-operative shiver, and thermal discomfort."

And you say: "Each one of the adverse consequences listed here had at least one randomized control trial that demonstrates increased risk associated with intraoperative hyperthermia"; is that right?

A That's right.

Q And so you are instructing the sales reps that each one of these potential conditions is associated with hypo -- intraoperative hypothermia, and that there is an RTC that proves that, right?

A Yes.

Q And then you list -- there's again a footnote number one. And if you go to the back, reference number one is Sessler from 2016, "perioperative thermal regulation and heat balance." That's the citation that you have with respect to each of those potential problems following intraoperative hypothermia; is that right?

A Yes.

Q So the full basis for the claim that you're instructing the sales reps about with respect to potential problems associated with intraoperative hypothermia is addressed by that Sessler paper, right?

A Well, except that I would not call it a claim. Claims have specific meaning, FDA terminology, so we wouldn't make it a claim. This is just an assertion that each of these

adverse consequences has a randomized control trial that associates intraoperative hypothermia with an adverse outcome.

Q All right. As you were preparing and finalizing this memo in 2018, you were instructing the sales representatives that each of these morbidities is associated with intraoperative hypothermia?

A Yes.

Q And that that is all demonstrated by the Sessler article from 2016?

A Well, it contains a much lengthier explanation of it than this one paragraph, yes.

Q So do you know, is the Sessler paper actually an RCT itself or does it list --

A No, it's a review.

Q It's a review paper?

A Yes.

Q All right. So it's a series of potentially RCTs that justify this assertion that intraoperative hypothermia helps patients, right?

A That's -- the paper that I'm citing here is the --

Q Basis for your claim?

A Exactly.

Q Basis for your assertion?
A Yes.
Q Flipping to the next page, page 3 of 8. It looks like you have responses to customer objections or questions there. Do you see that?
A I see it.
Q And the one that I'll direct you to is highlighted in yellow there. It says, in quotations -- and I assume that this is a customer question or objection that is received by the field from time to time; is that fair?
A Yes.
Q And that question is quote: "Forced-air warming contaminates the sterile field and leads to increased risk of surgical infection", right?
A Yes.
Q And that's because this particular question had been raised basically throughout your time at both Augustine, Arizant, and ongoing at 3M, fair?
A Yes.
Q And the response that you instruct the sales representatives to provide says, "There is now substantial clinical, scientific, microbiological, engineering, and epidemiological

evidence that forced-air warming systems do not increase the risk of surgical site infection in either laminar or conventionally-vented operating rooms. Normothermia provides substantial clinical benefits, including a reduction in surgical infection risk."

You cite to number 26, and then you say, "see fawfacts.com for more details." Do you see that?

A I do, yes.

Q Did I read that correctly?

A Yes.

Q And what is your basis for your instruction to the sales representative that there is substantial clinical evidence, excluding forced-air warming as a potential for increasing the risk of surgical site infection?

A Well, I cited a paper by Scott and a number of other authors, which is a randomized control trial that looked at outcomes associated with the use of forced-air warming in hospital patients, at a large hospital system.

Q And Scott's an RCT?

A Yes.

Q And did it address each of the issues

that you list in your response to customer objections or questions?

A I think there's a partial review of each of those within that paper. That's a very long paper. I don't remember every detail about that paper, but it addresses those.

Q What specifically is the microbiological evidence that you point to that eliminates Bair Hugger as increasing the risk of surgical infection?

A Well, I wouldn't say completely eliminates, but evidence suggests, in clinical medicine anyway, and I mean papers like Avadon, for example, or the activities that were done by Mike Reed and his colleagues, where the -- you know, where they were unable to culture bacteria from beneath a blanket, from a forced-air warming system with a blanket, for example, compared to, you know, systems where they didn't have a blanket.

Q So with respect to the statement that -- the instruction that you're providing to the sales force confirming that there is substantial microbiological evidence that forced-air warming systems do not increase the risk of surgical site

infection, you're pointing to Avadon and Reed. Anything else?

MR. GORDON: Object to form of the question.

A Oguz is an example.

Q Anything else? No internal studies, right?

A No, no internal studies.

Q And you agree that even with respect to this microbiological evidence, that the potential for risk has not been completely eliminated even with the citations that you've listed today?

A Well --

MR. GORDON: Object to form of the question.

A -- the purpose of evidence is to justify the acceptance of a particular perspective or point of view. It doesn't mean that it's impossible, but it suggests that the use of this device is not associated with an increased risk in infection.

Q Does the statement that you provide to the sales reps and how to respond to questions or objections from customers say there is evidence to suggest that there is no risk of surgical site

infection? Or does it say that these systems do not increase the risk of surgical site infection?

A I'm sorry, state again?

Q So I heard you to say that the issue here is, you know, that these different papers, you use them as evidence to suggest, you know, Reed didn't culture bacteria coming out of the blanket and that means there's microbiological evidence to suggest forced-air warming does not increase the rate of surgical site infection; is that right?

A As an example, yes.

Q That's the example that you provided. And so -- but the language that you actually chose to write in instructing these sales representatives is not, well, the evidence suggests that there is not a problem, there's not an increased risk of surgical site infection. You said: "Forced-air warming systems do not increase the risk of surgical site infection," right?

A Well, I said there's evidence.

MR. GORDON: Object to form of the question.

Q And this whole article, by the way, Scott

is comparing forced-air warming to no forced-air warming or what is he comparing, do you know?

A Well, it's patients who were warmed according to the SKIP protocol, either with forced-air warming.

Q Or something else?

A Or some other method.

Q Right.

A What Scott demonstrates is that the vast majority of the patients in that paper were warmed with forced-air warming; some were not, but the vast majority were. And other patients did not get warmed according to the SKIP protocol, so that's what he's comparing.

Q He's comparing -- but he's not comparing forced-air warming patients to other warmed patients?

A No, he's comparing patients who are normothermic to patients who are not normothermic.

Q All right.

A I'm also referring them to the fawfacts.com for more details.

Q Do you know if his results were clinically significant? For wound infection, I'm

sorry.

A Well, so for a composite, so what Scott did was he combined several adverse outcomes into a single outcome. And that outcome was significantly less in the normothermic group. So I think it was a composite of surgical site infection, plus things like -- infections, like pneumonias and bladder infections and things like that, and one other thing that I can't recall right now.

Q So he's looking at a lot of different sort of issues. He's comparing warmed patients and non-warmed patients?

A Well, I'm not describing it very well probably. But he compared -- he compared the same outcomes in two different groups of patients. One group of patients that was essentially hypothermic or had not been treated according to the SKIP protocol, to a group of patients who were normothermic and had been treated to the SKIP protocol.

And he showed, interestingly enough, that whether you follow the SKIP protocol or measure temperature, core temperature, that you got roughly the same result.

Q Fair to say that the Scott paper isn't looking specifically at deep joint infection, fair?

A No, it's looking at a number of surgical types.

Q Right. And at any rate, in your instruction here in this memo to sales representatives, you're not identifying something specific or special training to, for example, the sales reps that deal with orthopedic surgery or orthopedic surgeons, those sort of different patients, right?

A This is a general statement.

Q This is a general statement. And your instruction to those sales reps is that there is substantial clinical, scientific, microbiological, engineering and epidemiological evidence that forced-air warming systems do not increase the risk of surgical site infection, right?

A Yes.

Q You don't say anything in here that there are a number of different researchers that are calling for additional study on this, correct?

A No, I did not say that.

Q And there is no differentiation here saying that there may be certain patient populations where the healthcare provider team should take another look, fair?

A I did not say that.

Q And you certainly knew by the time that you were writing this in 2018, that the International Consensus, for which 3M is a platinum sponsor, has raised and requested additional study into the safety of forced-air warming in orthopedic joint replacement surgery be done, fair?

A Well, I'm aware that there was an opinion piece by one of the people in that group that suggested that, yes.

Q You know that in the 2014, sort of questions and answers from the consensus, that they agreed with the theoretical risk presented by forced-air warming and identified that as an area that needed more study, right?

A Well, I believe that the vast majority also agreed that it wasn't a cause of additional risk.

Q Fair to say that as we sit here today, you don't know what the International Consensus

was specifically considering beyond sort of what the citations they list publicly, right?

A Correct, I don't know.

Q And they certainly didn't have any internal 3M documents, right?

A Not to my knowledge.

Q All right. So you and I have more information as we sit here today in 2022 than those folks did in 2014 about the potential risk associated with forced-air warming in total joint replacement patients, fair?

MR. GORDON: Objection, lack of foundation.

A I have no way of knowing that.

Q And you and I may probably come down differently on what that risk may be. But we both have significantly more information about what the company knew, what the company did, and the various companies did to study this issue and this risk across the years, fair?

MR. GORDON: Same objection.

A Again, I don't know that. I mean, there are a lot of researchers at the International Consensus meeting who actively studied this area, so they may have more information.

Q But as you sit here you don't know?
A I don't know.
Q Fair to say you would expect that they do not have any internal, confidential 3M documents?
A Well, they absolutely would not have any confidential 3M documents.
Q Right. And this again, this was a memo that you prepared for distribution to the sales representatives and authored at the end of 2018; is that right?
A Yes.
Q And again you, as would be your practice personally and would be your expectation for 3M, the information provided there should be fair and accurate and reliable for your customers, right?
A Correct. And just to reiterate, it also went through a legal, regulatory and professional services review, in addition to my statement, in order to make certain that it was compliant with our code of conduct.
Q All right.
A Among other things.
Q And you -- that would be the code of conduct that you sort of expected of yourself, whether 3M imposed it or not --

A Yes.
Q -- I think that's fair.
I'm going to hand you what's going to be marked as 35, when I stop talking.
(Whereupon, Exhibit Number 35 was marked for identification.)
BY MS. ZIMMERMAN:
Q Do you recognize this document, Mr. Van Duren?
A I do recognize it.
Q And this is a document that you authored that is dated October 10th of 2019, right?
A Yes.
Q And the title here, again it bears the 3M logo at the top. The title on your document is: "The review of optimized management of patient normothermia health economics tool." Do you see that?
A I do.
Q At this point it lists your name, it says you're the global evidence development manager in the 3M healthcare business group, right?
A Correct.
Q Again, this is a technical report. And as is your practice and would be the expectation

at 3M, this is to be an accurate memorandum; is that fair?

A Yes.

Q And I know you take pride in the work that you do throughout your career, and that has continued to be the case at 3M; is that right?

A Yes.

Q This is a short document. It's only five pages, including the title sheet and the last page 4 and 5 are really references. Do you see that?

A Yes.

Q It looks like 29 different citations you have here?

A Yes.

Q So your executive summary, you say, "Some of the evidence used to develop this HE tool --" so "HE" is health economics?

A Yes.

Q Is that sort of how a hospital or a customer saves money?

A Well, health economics is the study of the costs associated with the delivering healthcare mainly.

Q All right. And so it says: "Some of the

evidence used to develop this HE tools derives from the NICE systemic review, which is now 11 years old. Much of the evidence used by the NICE systematic review is relatively weak, over twenty years old, and is not relevant to clinical practices of today. I believe that you will encounter resistance from customers if you try to base economic estimates on this old data." Did I read that correctly?

A Yes.

Q And you're sort of -- you're saying that the health economics data was based on NICE, and NICE is based on old information, right?

A Yes.

Q And customers are going to be suspicious, reluctant, something like that, to hear you sort of rely on that old, outdated data, fair?

A Yes, that was my opinion.

Q Okay. You say, "One major difference between older and newer trials relates to the practice of dichotomizing core temperature to identify hypothermic from normothermic patients. While the hypothermia threshold is typically established at 36 degrees, the mean core of patients in the under 36 degree celsius group

tends to be substantially lower in older studies than what we see today"; is that right?

A Yes.

Q Incidentally, you've been involved in the 3M product where the actual temperature of the patient is monitored; is that right?

A Yes, I'm the inventor of that.

Q Oh, you're the inventor of that. What's that product called?

A Well, it was called Spot On.

Q That's what I thought.

A Now it's called the Bair Hugger Temperature Monitoring System.

Q And there are a number of articles in your library that indicate that the accuracy of the temperature measured by that can be off, plus or minus, a full degree celsius; is that right?

A It can be, yes.

Q There are, at least, I think three or four articles alone that focus on that potential variation?

A Yes.

Q And you'd agree, by the way, if the temperature -- the device that takes the patient's temperature is inaccurate, you may have

inaccurate information about whether the patient is normothermic or hypothermic, right?

A It's true, but all thermometers have inaccuracies, not just the BHTMS.

Q Do you know if folks that -- or healthcare facilities that use the Bair Hugger blankets tend also to use, sort of the Spot On and the Bair Hugger Temperature Monitoring System?

A Many fewer. I mean, it's not a widely purchased product.

Q Okay. All right. And you go on in your executive summary here to say: "Due to the age and study conditions, the effect sizes reported by many of these older trials are unjustifiably large and could lead to unreasonable estimates of the economic benefits from patient-warming interventions in a modern clinical environment. I would not use this tool as the basis of a risk-sharing agreement." Did I read that correctly?

A Yes.

Q So basically some of these older trials are not reliable for sort of the purposes we maybe relied on them in the past for; is that

right?

A That was my opinion.

Q Okay. You go on and say: "Additionally several review papers are cited as primary evidence for various effect sizes. Review papers are not acceptable sources of primary data for health economic analysis tools." Did I read that right?

A Yes.

Q You agree with that? Review papers are not acceptable sources of primary data for health economic analysis tools?

A That's my opinion.

Q Do you think that clinicians feel the same way about review papers with respect to decisions about treating their patients, not just with respect to health economic decisions?

A Not all of them.

Q Not all of them but some?

A Some do.

Q All right. You say: "Please site and use the original papers for these tools. Also, while the evidentiary quality of newer trials may be lower than some older trials, please use the more modern estimates of effect sizes for this

tool."

You say: "Thermal discomfort is difficult but not impossible to monetize. Please review some willingness to pay and welfare economics papers that describe how to monetize this outcome."

Is that because part of the focus of this paper is sort of how to continue to sell patient normothermia as a revenue generator for the company?

A The point here is to try and establish that the effects produced by using Bair Hugger or maintaining normothermia are at least as great as the cost of producing it. Yeah, at least as great as the cost of producing normothermia. That's kind of the goal of this activity.

Q So the benefits sort of justify investing in the technology?

A Correct.

Q All right. And that's monetizing is getting money either for the hospital or the company or both?

A Monetizing these outcomes is necessary because you have to compare -- you have to compare the cost of the thing to the value

produced by the condition. And so you have to convert these to something, money is the easiest thing to do; but you can use other quantities as well, but money is usually the easiest one to do.

Q Fair to say also for a medical device company that is in the business of selling devices, that identifying new potential applications is going to monetize that technology for the company?

MR. GORDON: Object to form of the question.

A Well, the purpose of this is not to find new applications. The purpose of this is to just justify whether it's worth doing.

Q For the hospital or for 3M or for both?

A For the hospital.

Q All right. You then say: "If this is a customer-facing document, please pick uniform format for citations." That's just sort of housekeeping as you're finalizing this memo?

A Correct. Yeah.

Q And so the review of major topics, you won't be surprised is the part I'm interested in. It says: "Risk of surgical site infection in morbid cardiac events. Although the metaanalysis

used to compute much of the economic burden of complications from hypothermia are relatively new, the underlying data is quite old and was collected during a time when very large differences existed between normothermic and hypothermic patients. This large difference has the effect of accentuating the effect size associated with intervention. In fact, the authors, Kurz and Frank, of the two most important randomized-controlled trials have concluded the estimate of the benefit computed originally are likely too great now, and that now that surgical patients are not permitted to become as cold, regardless of what the warming intervention is.

"There are now at least ten retrospective studies that have detected no significant differences in surgical infection rates between normothermic and hypothermic patients."

Did I read that paragraph correctly?

A Yes.

Q So you're noting for, at least the intended audience of this memorandum, that as research has continued, that the dataset upon which -- well, certainly 3M, relied to claim that

normothermia is going to result in a decrease or a difference in surgical infection rates, is no longer reliable; is that right?

A That was my opinion.

Q And there's a number of studies that followed the Kurz and the Frank papers that concurred with and supported your opinion; is that right?

A Yes, much lower evidence value; but yes, that's true.

Q And so at the time that you were writing this anyways, it was your belief that claiming that a difference in surgical infection rates based on normothermia was no longer supported by the literature; is that fair?

A Not that it wasn't supported, it's just that the -- trying to quantify the effects might not be appropriate now given the fact that patients are no longer ever permitted to get that cold.

Q There is a big difference in the sort of normothermic and hypothermic patients in Kurz, for example?

A My opinion was that the papers, the earlier papers, the conditions that the patients

were exposed to in the earlier papers are not the same conditions that patients are exposed to now.

Q And the authors agreed with that when we took their depositions as well.

But the ten retrospective studies you point to concurred with your opinion that essentially new data didn't support the claims about a decreased risk of surgical site infection between normothermic and hypothermic patients, right?

A Right --

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

A Correct, but those are much lower evidence levels than randomized controlled trials.

Q And so that was sort of what you're summarizing for those folks.

You go on to say: "Although Frank did not know it at the time, the rate of morbid cardiac events he detected was far too low and many investigators no longer cite this study for that reason"; is that right?

A Correct.

Q So to the extent that perhaps

investigators used to cite Frank for the proposition that there was fewer heart attacks if you maintain normothermia, that is no longer -- that paper is generally not cited for that proposition anymore, right?

A Well, it's not cited for the reason that I cited there; and that is that the rate of morbid cardiac events that he detected was obviously way too low.

Q Okay. And you say, "For example, a very large retrospective study by Frank and colleagues showed no significant difference in wound infection or myocardial infraction between groups of patients who were normothermic and those that were hypothermic," right?

A Correct.

Q Do you know, though, that in forced-air warming facts and in some of the marketing materials were some of the claims that 3M and Augustine and Arizant made about the benefit of normothermia, a decreased risk of surgical site infection and a decreased risk of myocardial infraction?

A Were they? Yes.

Q Yes. And so in this memo you're saying

that evidence may not be good?

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

MS. ZIMMERMAN: It's his memo.

A Again, I just want to make it clear that we have never claimed that the use of Bair Hugger reduces the risk of myocardial infraction or even surgical site infection. We never make that claim.

Q And so if somebody stood up in court and said that using Bair Hugger reduces the risk of surgical site infection, that would be false, right?

A Well, it may not be false, but we would never make that claim.

MR. GORDON: I think we're past the two-hour mark.

THE VIDEOGRAPHER: We're at two hours and two minutes.

MR. GORDON: And that concludes.

MS. ZIMMERMAN: Well, you can sort of let me finish this and we can go to the Court if we need to with the 500 things that were produced late. Or you can see --

MR. GORDON: We agreed to two hours.

I've given you more than two hours.

MS. ZIMMERMAN: Well, in fairness, though, you agreed to two hours before we got 500 and some odd articles.

MR. GORDON: As you acknowledge, the vast majority of which have nothing to do with patient warming. So I mean, there were probably what, a dozen articles, two dozen articles at most that had something to do with patient warming.

And that's fine. Do you have one or two more questions?

MS. ZIMMERMAN: I'm going to finish this memo at least.

MR. GORDON: I'll let you ask, you know -- I'll give you two more minutes.

MS. ZIMMERMAN: You let me know. I have got plenty more questions.

MR. GORDON: I have no doubt, but we agreed to a time limit.

MS. ZIMMERMAN: Before you produced the documents.

I mean, just so we're all aware, and we're likely to see each other again. We've got other cases going. There's been subsequent productions just from Mr. Van Duren. There

certainly hasn't been a production from 3M besides the voluntary production here.

MR. GORDON: Counsel, I'm letting you ask a couple more questions, so why don't you take advantage of that.

MS. ZIMMERMAN: All right. Well, I mean, I just -- I think that the transcript will preserve our objection to your ending of the deposition for the Court and the Court can rule on it when we get there.

MR. GORDON: Well, I ended it more than two hours of time. And now I'm giving you a couple more minutes even after the extra time, so that's what the record will reflect.

MS. ZIMMERMAN: All right. Understood. We missed each other, didn't we, Corey?

BY MS. ZIMMERMAN:

Q Similarly, Mr. Van Duren, you have a notation in this memo, the major topics, the need for mechanical ventilation. And you note that there are two studies that are used to provide a relative risk assessment for essentially a difference in mean core temperature differences between normothermic and hypothermic patients.

And then you say, "In neither study was

the need for mechanical ventilation significantly different between the groups; and in the metaanalysis, the confidence interval was .96 to 2.61, which is also nonsignificant," right?

A Yes.

Q And so in your opinion, as you were writing this memo, it would be inappropriate to claim that keeping a patient normothermic may prevent the need for mechanical ventilation. That's what you're trying to say here, right?

A Based on this evidence, yes.

Q Right. Moving on, you talk -- the next sort of topic is that there -- is regarding the need for blood transfusion.

You say in your memo: "The NICE analysis for blood transfusion included six studies conducted 1994, 1996, 1997, 1999, 2000 and 2002?"

You say, "The transfusion thresholds were substantially different in the era during which these studies were conducted. Moreover, in two subsequent analyses in which cell saver and overlap studies were excluded, there were no significant differences between the groups."

Fair to say that you're saying in this memo that any claim that normothermia may prevent

a need for blood transfusion would be inappropriate?

A Based on these studies, yes.

Q All right. Similarly, you go on, the next topic is the extra length of stay in the recovery group. And you say, "Except for the study by Smith, all the studies included in the metaanalysis were conducted in 1990s. So the core temperature difference is tended to be substantially larger than those seen today.

"In the study by Lenhardt, et al, for example, the mean intraoperative core temperatures in the control groups was 34.8 degree celsius, and the core temperature difference was purposefully maintained at 2.0 degrees celsius between the warmed and unwarmed patients.

"In the trial by Smith, patients in the control group received --" it looks like -- "saline. And no patient was warmed intra or postoperatively.

"Interestingly, the most recent study included in the metaanalysis found no difference in ICU time between the groups, although there was a substantial increase in cost in the

treatment group."

This sort of section of your paper is to suggest that any claims, that if you don't keep a patient normothermic, they may end up with an extra long stay in the PACU would be inappropriate or false, right?

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

Q Unsupported by the literature you're citing.

A Exactly.

Q Is that a better answer?

A Yes.

Q The next topic you identify is increase in mortality. You know that there have been claims at various points that maintaining normothermia intraoperatively may result in a decrease in mortality, right?

A We have never made that claim.

Q And it would be inappropriate for somebody to do so, correct?

A But we would never make that claim.

Q All right. But you've identified that as a claim that somebody perhaps may make. And here you say, essentially, that that would not be a

claim justified by the literature you cite to?

MR. GORDON: Object to the form of the question, also mischaracterizes the document which speaks for itself.

Q And you have two other ones. One is post-operative shiver and one is thermal discomfort.

In post-operative shiver, you sort of again, you say that the papers that are cited are from sort of the mid-90s and practices were very different. The only one of the papers cited is a trial, the other is a review. "Review papers should not be used as a primary reference for health economic tools," right?

A My opinion.

Q Yep. So you're saying with respect to post-operative shiver anyways, the data that you're citing to and reviewing doesn't suggest that is a benefit of maintaining normothermia, right?

A Correct.

Q And then the last sort of claim that you identify here is thermal discomfort. Your memo says, "While it's true patients dislike thermal discomfort, the paper cited in the tool is a

review and does not describe a method to monetize this outcome. Please review some willingness to pay in welfare economic papers that describe how to monetize this outcome," and you cite some papers, right?

A Yes.

Q Based on this memo are you making a recommendation on whether it's appropriate to claim patient thermal discomfort is an adequate -- or pardon me, an appropriate health objective to achieve through the Bair Hugger?

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

A It's absolutely an important health outcome for virtually all surgical patients, yes.

Q Patients don't like to be cold; is that fair?

A Right. And I was making a recommendation about how they could monetize the outcome to do this analysis.

Q Reasonable to say that patients that are anesthestized in an operating room are not aware whether they're cold or warm?

A Not during surgery, but certainly they are afterward.

MR. GORDON: You've gone through the end of this document.

We're ending the deposition and I've given you quite a bit of extra time.

MS. ZIMMERMAN: Corey, you don't have to storm out. I understand your position. I'm just going to put on the record that it is our position that the two-hour limitation was offered and we appreciate that. It was offered though prior to producing 500 and some articles, a large majority of which do touch on normothermia and Bair Hugger-related issues. They're not just on wound infection, wound therapy or PKC line infection prevention, which I did read as well.

I appreciate that you produced the witness. And I don't mean any offense to you at all, Mr. Van Duren. I expect we'll see each other again probably at some point; whether with respect to the documents in this library and some of the memos that you wrote, or some of the other documents that we expect to be produced sometime later.

So I hope you both have a nice weekend.

MR. GORDON: We'll read and sign.

THE VIDEOGRAPHER: We're off the record.

(Whereupon, the deposition adjourned at 12:01 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 123 pages is a true and correct, full and complete transcription of said shorthand notes, to the best of my ability.

Dated at Crosby, 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 123 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) _____