UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW HAMPSHIRE

IN RE: ATRIUM MEDICAL CORP. C-QUR MESH PRODUCTS LIABILITY

LITIGATION

* 1:16-md-02753-LM September 11, 2019

9:03 a.m.

REDACTED TRANSCRIPT OF MOTION TO DISMISS DAY THREE - MORNING SESSION BEFORE THE HONORABLE LANDYA B. McCAFFERTY

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Official Court Reporter

U.S. District Court 55 Pleasant Street

Concord, New Hampshire 03301

(603) 225-1442

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1 PROCEEDINGS 2 THE CLERK: The Court has before it for 3 consideration today day three in the motion to dismiss 4 hearing in In Re: Atrium Medical Corporation C-Qur Mesh Products Liability Litigation, MDL docket number 16-md-2753-LM. 6 7 THE COURT: Okay. I think it's time for the cross of Mr. Carlton. 8 9 And you were under oath, placed under oath yesterday. We don't need to do that, place you -- re --10 11 reoath you, do we? 12 THE WITNESS: No, we do not. 13 THE COURT: All right. So I'll just remind you you're under oath. 14 15 Attorney Orent. 16 MR. ORENT: Thank you, your Honor. 17 CROSS-EXAMINATION 18 BY MR. ORENT: 19 Good morning, Mr. Carlton. How are you? Q. 20 Α. Good morning, Mr. Orent. Doing well. 21 0. You clearly remember my name, so I don't need 22 to reintroduce myself, but I'm glad to talk to you 23 again. 2.4 You've been here for the last three days, 25 correct?

- 1 Yes, I have. Α.
- Okay. And you've seen all of the witnesses 2 Ο. and heard all of the testimony so far; is that right? 3
- 4 Α. Yes, I have.
- Okay. Today, one of your job titles is Q. president of Atrium Medical? 6
- 7 Α. Yes, it is.
- Okay. You would agree with me that some of 0. 8 the transactions that are involved in the sale of 9 medical devices that Atrium manufactures are complex 10 11 transactions, right?
- 12 Α. I would agree they're complex transactions, 13 yes.
- Okay. In fact, all of the sales, as you Q. 15 described yesterday and under the new contract that 16 began in 2017, all of the sales are fairly sophisticated 17 types of transactions, correct?
- 18 Α. Can -- you said a specific date there?
- Right. 19 Q.
- 20 Α. I'm sorry.
- 21 0. I was referring to the October 21st, 2017,
- 22 contract --

- 23 Α. Okay.
- 24 -- where Getinge USA replaced Maquet US Sales? Q.
- 25 Α. Yes.

Q. Okay. So let me ask this in two separate questions.

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The transaction that you discussed yesterday where Atrium produces and sterilizes its medical devices, sells it to Maquet CV LLC, who then sells it to Maquet CV US Sales, who then sells it to customers and then the profit gets returned in the way you described yesterday, that is a fairly sophisticated and complex transaction, correct?

- A. It's the transfer of funds. I think each individual transaction may not be complex. I think when you're dealing with multiple transactions, you could call that complexity.
- Q. Okay. Would you agree with me that contracts and documentation for things like that are very important?
- A. Yeah. As you -- having transactions are important, yeah. I mean, having documentation for transactions is important.
 - Q. Okay. And it wouldn't be a good thing for a medical company to sell its medical devices without a contract, correct? Through a transaction like this.
- A. You would want a -- I mean, we created contracts for that.
- Q. Okay. And there were two of them and we'll go

- 1 through that in a little bit, right? There's the one
 2 with Maquet Entities and then there's the one with
- 3 | Getinge US Sales, right?
- A. I think there's more than just one contract.
- 5 I think there's multiple contracts with different
- 6 entities globally.
- 7 Q. Right. We'll get through that in a minute.
- 8 A. All right.
- 9 Q. I also want to just, as a preliminary matter,
 10 go through -- we heard a lot of names yesterday and I
- 11 just want to make sure that I got it straight.
- 12 So Maquet, which was -- or Maquet Medical
- 13 | Systems, that's not a -- that's not an incorporated
- 14 | entity, correct?
- A. So Maquet Medical Systems, to my knowledge, is
- 16 | not. It's Maquet Holding would be what some people
- 17 refer that to. But there's a lot of Maquet -- there's a
- 18 lot of entities with the name Maquet in them.
- 19 Q. Okay. When referring to the medical systems
- 20 unit as Maquet, that's not incorporated, right?
- 21 A. Not to my knowledge, no.
- Q. Okay. And that became Acute Care Therapies, I
- 23 | think you testified to yesterday?
- A. Yeah. And for some clarity, it wasn't the
- 25 | exact structure that became Acute Care Therapies. Some

- of the businesses that were part of Maquet Medical
 Systems were no longer grouped in that grouping. So
 some of them went over to a different division within
 Getinge Group.
 - Q. Okay. But for simplicity's sake, ACT is the essential replacement of the Maquet Medical Systems group, is this unit?

- A. Yes. 75 percent, 80 percent of it, yes.
- Q. Okay. And the Getinge Group, I think you testified also, is not an incorporated entity, right?
- A. Getinge Group, as I stated, was a -- I consider it a brand name or a -- you know, for encompassing all subsidiaries, indirect and direct, of Getinge AB.
 - Q. Okay. Now, yesterday you were here when Mr. Messina was questioned about his belief and his opinion that mesh liability was known or knowable by Atrium as of sometime in 2014. Do you recall hearing that testimony?
 - A. I do recall hearing that testimony.
 - Q. Okay. Did you disagree with him?
 - A. What, that there was lawsuits on mesh? I would agree that there were lawsuits in mesh in 2014.
- Q. Okay. In fact, you were aware of substantial litigation around polypropylene mesh in 2014; isn't that

1 right?

- A. Can you clarify your definition of substantial?
- Q. Sure. You were aware that there had been some major hernia mesh litigation around Composix Kugel mesh, right?
- 7 A. Yes.
- 8 Q. All right. And you were aware that that 9 settled in around I think 2011 or '12 for about 10 \$200 million, right?
- 11 A. I don't recall exactly the figure, but I'll go 12 with you on that.
- Q. Okay. And you were also aware that there were tens of thousands of polypropylene mesh cases used for other indications in West Virginia courts against about 33 medical mesh manufacturers, right?
- A. Are you referring to the pelvic mesh?
- 18 Q. Yes.
- 19 A. I was aware of the -- the pelvic mesh 20 litigation, yes.
- Q. Okay. And Atrium had an ongoing concern
 through 2013 and '14 and even later about the uses of
 its products because of potential litigation and
 liability relating to certain uses of its devices,
- 25 | right?

- 1 A. You mean off-label uses of the device?
- 2 Q. Potentially, yeah.
- A. Yeah, there were concerns about off-label usage, yes.
- Q. Okay. And you were aware that in 2013 -2014, the first of the vaginal mesh manufacturers,
 polypropylene mesh manufacturers, settled for almost
 8 \$830 million, right?
- 9 A. I'm not sure that I was aware of that. It
 10 doesn't recall, but I may have been informed if it did
 11 occur.
- 12 Q. Would you disagree?
- 13 A. You know, in -- I wouldn't disagree that that happened.
- Q. Okay. In 2012, you were with Atrium, correct?
- 16 A. Yes.
- Q. And you were aware -- John, if I could have exhibit -- Plaintiff's 3, if we could go to the second page, and if you could zoom in on that second paragraph.
- Sorry. I just called you John. I thought
 21 John was there. Hi, Gina.
- And could we just back up and I want to get a little bit more of the whole paragraph.
- 24 Thank you.
- 25 You see here that on this date in December

- 2012, Atrium identified 629 complaint files containing
 630 complaints. One was filed with two complaints by
 accident.
 - Do you see that, in the first sentence?
 - A. So Atrium identified a total of 629 files containing 630 complaints. Is that what you --
 - Q. Right. Do you see that?
- 8 A. Yes.

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- 9 Q. Okay. And if you look at the next sentence,
 10 14 of those were specific to one type of complication,
 11 that is C-Qur infections, referenced in the FDA warning
 12 letter.
- 13 A. Uh-huh.
- 14 Q. Right?
- 15 A. Yes.
- Q. Okay. And these complaints, these 630

 complaints, had not been reported to the FDA and Atrium

 had to go through them to determine how many of those

 complaints needed to be reported to FDA through the MDR

 process, right?
- A. Yeah, they were complaints that were already reported to Atrium. It was just whether they were filed to the FDA.
- Q. Okay. And it turned out that 231 of those complaints had been determined to require reporting to

1 | the FDA, right?

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- A. That is because we managed to become more conservative in our approach to reporting.
- Q. You would agree with me that based on this letter, 231 complaints were determined to require MDR reporting?
- 7 A. Based on the method that we used to report, 8 yes.
- 9 Q. Okay. And MDR reporting is a requirement of 10 FDA, right?
- 11 A. The -- yes, you are required by the FDA to report MDRs, yes.
- Q. And just for the record, can you tell us what MDR is?
- 15 A. Medical device reporting.
- 16 Q. Thank you.
- And if we could turn to Exhibit 183 and if we could go to the bottom of page 1, paragraph A.
- Do you see there in paragraph a: The C-Qur
 family of surgical mesh devices commercially released
 and continued to be distributed without adequate
 verification of sterile package integrity or performance
 over the labeled shelf life.
- Do you see that?
- 25 A. I'm aware of that, yes.

- Q. Okay. And if we turn the page to observation number 3 on page 4. Excuse me.

 And here, Atrium -- FDA finds that the
 - And here, Atrium -- FDA finds that the procedure for corrective and preventative actions has not been adequately established. And, again, this is with specific regard to C-Qur, correct?
- 7 If you look at paragraph --
- 8 A. Yeah, I'm -- I'm trying to read the whole 9 thing.
- Can you -- can I see the next page, just to read --
- 12 Q. Absolutely.

- A. -- what it's all related to?
- Q. Would you like a paper copy?
- 15 A. That would -- actually, if you just zoom in on 16 that top part, I think it'll be all right.
- Okay. Yeah, I -- I'm aware of what that finding is related to.
- Q. Okay. And corrective and preventative actions are where nonconforming products or nonconformities in process have been identified and they need to be fixed, essentially; is that right?
- A. The -- you have identified something within
 your quality system. So we identified a CAPA. We
 identified that and, yes, the goal was to fix something.

- Yup. Okay. So I'm going to show you what 1 Q. 2 I've marked as Exhibit 241. And this is a proactive customer letter released on August -- April 29th, 2014, 3 4 and says: Proactive customer letter. There have been inquiries in regards to Atrium's polypropylene mesh and the release following announcement on FDA's website. 6 7
 - Do you see that?
 - Α. Yes, I do.

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- And essentially what Atrium is trying to do Q. here in April of 2014 is tell the world that our meshes aren't subject to this and you shouldn't be using it off-label, but for proper use, our mesh is okay. that roughly what you're trying to say?
- 14 So can I see -- where does this letter come Α. from --15
- 16 Ο. This came --
- 17 Α. -- and when was this sent?
- 18 This was a draft email, excuse me, a draft Q. 19 letter that was in -- do we have the custodial information? 20
- 21 Have you seen this document before?
 - I -- I don't know the context with it and the format of it, I'm not familiar with it. So it may have come to me, but I'm just -- I'm only seeing a certain portion of this.

- Q. Okay. Let's look at Exhibit 242. This is a newspaper article from April 30, 2014, the following day, noting that Endo agrees to a \$830 million settlement of vaginal mesh cases.
- As president of a medical device company, you would want to be up to date on competitive information, correct?
- A. I wasn't president at this time, but yes, I
 would, as president, like to be up to date on
 significant events in various industries, yes.
- Q. Okay. But even in your head, in your role in marketing, you would want to be aware of things like this, right?
 - A. Yes, very much so. Yes.

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- Q. Okay. So do you agree with me that mesh and mesh litigation was something that -- that Atrium was aware of and would be concerned about monitoring?
- A. The -- we were aware of the various items that you have identified. So, yes, we were aware of Kugel and also of vaginal mesh or pelvic mesh, as it's more known.
 - O. I'd like to turn to Exhibit 192.
- 23 And before we do that, actually, let me ask 24 you, do you know who Scott Waxler is?
- 25 A. Scott Waxler, I believe -- yes, I do. He was

- 1 the -- he's an invest -- I want to call him an
- 2 investment banker, but he's a banker of some sort to
- deal with the transactional merger. I can't remember 3
- 4 his exact title.

- And who is Eric Bielen? Ο.
- Eric Bielen is our -- he's had a couple of 7 titles recently, so I'm just trying to -- but he's in charge of our mergers and acquisitions and divestitures.
 - And he's an employee of Getinge AB? 0.
- Currently, I think -- I don't -- I can't say 10 Α.
- 11 that for sure. I think because he's based out of
- 12 Belgium, he may not be an employee of Getinge AB.
- 1.3 Q. Would you agree that at one point he was?
- 14 I know -- I would agree that he's been part of Α.
- 15 a subsidiary or an indirect subsidiary. I don't know
- 16 for sure that he was an employee of Getinge AB.
- 17 Ο. All right. Would you agree that -- well,
- let's look at Exhibit 192. 18
- 19 And Scott Walker -- excuse me --
- 20 Α. Waxler.
- 21 0. -- Waxler was involved in the project star
- 22 attempt to sell the mesh unit from -- to outside
- 23 individuals, correct?
- 2.4 Can you rephrase that, repeat that? Α.
- 25 Q. Sure. Scott Waxler was hired as an investment

1 banker to divest the hernia mesh business, correct? And, again, the investment banker -- I'm not 2 sure on the exact title, but, yes, I would agree with 3 4 you on that. 5 Yes, there you are. He's an investment banker. 6 7 Ο. All right. So I want to show you an email from Kai Trompeter to Scott Waxler dated 3/20/17. 8 9 Kai is how you produce his name. Α. Okay. And Kai was one of the interested 10 Q. 11 bidders in the mesh line, correct? 12 He has been interested on and off over a 13 number of years, yes. 14 Okay. And he says: Can you give me a brief Q. 15 update on the below? And the title of the article is 16 Ohio Woman Sues Atrium Over C-Qur Hernia Injuries. 17 18 19 20 Do you see that? 21 Α. I see that, yes. 22 Okay. And if we could look at the next email Q. 23 in the sequence, it says -- Scott forwards this to

It says: Michael, can you please provide

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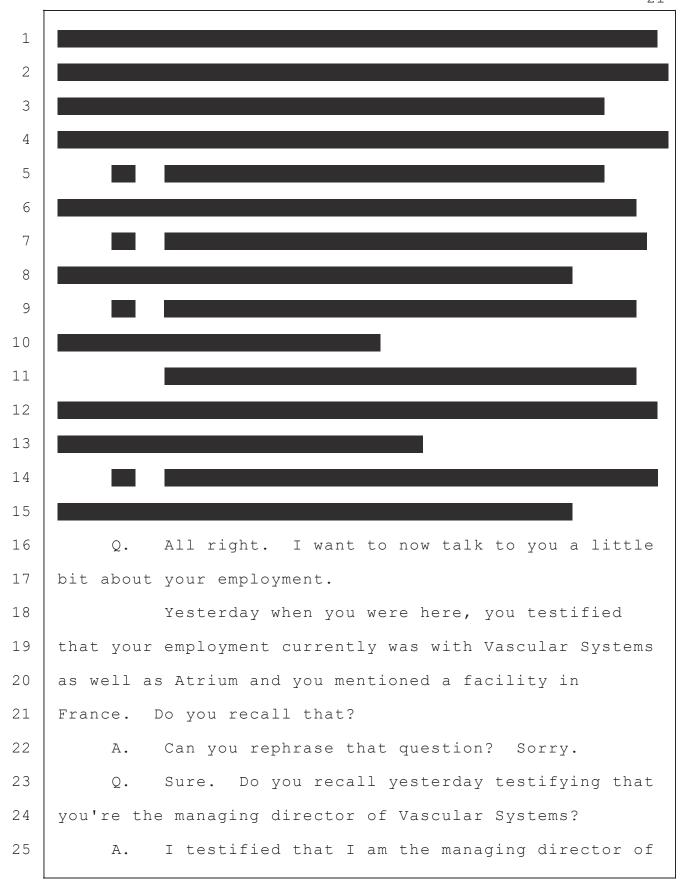
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Michael Dupont.

1 answer to me on Kai's question below. Have a great 2 weekend. PS, the issue that this question represents 3 seems to be representative of forward deal momentum. 4 Do you see that? 5 Α. Yes. Okay. If we turn the page. 6 Q. 7 And Eric Bielen responds to this and says: 8 Dear Scott, 9 10 11 12 13 14 Do you see that? 15 Α. Insightra. 16 Q. Insightra. Do you see that? 17 Α. Yes, I do. Okay. And he is -- Eric Bielen is -- his 18 Q. 19 address is in Göteborg, Sweden, on this document, 20 correct? 21 He has a Getinge -- I mean, he has a Göteborg, 22 Sweden, address, but I know he lives in Belgium. 23 Well, at least as of 2017, buyers were Q. 24 concerned about liability for hernia mesh litigation 25 from Atrium's devices, correct?

1 Yes, they were. Α. Okay. I'm going to show you Plaintiff's 2 Ο. Exhibit 200, please. Excuse me, 120. 3 4 And would you agree with me that this is a 5 Zurich insurance policy that Getinge AB purchased? It says policyholder, Getinge AB with Zurich. 6 7 An insurance policy, yes. Okay. And if we could look down, this is 8 0. products liability for mesh products? Products liability for mesh products, yes. 10 Α. Okay. And who's the policyholder? 11 Ο. 12 Α. Getinge AB. 13 And who's the insured? Q. 14 It says the insured is Getinge AB, including Α. its subsidiaries in the USA. 15 16 Ο. And what is the insured business? 17 Α. Manufacturing, marketing, and sales of mesh 18 implants. 19 Okay. And what is the limit of liability? Q. 20 Α. It says 21 Okay. And if you would turn to Exhibit 122. 22 Q. 23 And if we could pull that up, Gina. 24

| 1 | A. |
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| 2 | |
| 3 | Q. Okay. And if you would go to the "whereas" |
| 4 | paragraph, does this appear to be for mesh product |
| 5 | liability insurance? |
| 6 | A. So it says: Whereas the mesh products is |
| 7 | covered under the insurance policies. |
| 8 | Yes. |
| 9 | Q. And if you would read out loud into the record |
| 10 | the next line, beginning with "the parties have." |
| 11 | A. |
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Q. And you were asked a question yesterday, can you explain why this agreement -- and if we could bring up Exhibit 7?

You were asked: Can you explain why this agreement was with Getinge Group instead of with Atrium Medical?

Do you recall that question?

- A. Yes.
- Q. And I believe your answer was essentially that
 you were managing director of Vascular Systems at the
 time, so you also oversaw La Ciotat.

Do you recall that, approximately?

- A. I don't recall that that's what I responded on this particular document.
- 16 Q. Let me ask you --
- 17 A. I responded on the next document that we reviewed.
- Q. Let me ask you, this agreement is made on November 1st, 2016, by and between Getinge Group and Chad Carlton, right?
- 22 A. That is correct.
- Q. And Getinge Group's not a legal entity, is it?
- A. No, it is not.
- 25 Q. Okay. So you signed a contract with a

1 | nonlegal entity, right?

A. Yes.

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Okay. And if we look at your positions and 3 0. 4 duties -- Position and Duties. Executive shall serve as managing director of Hudson/Merrimack and as president of Atrium Medical Corporation. Executive shall be based 6 7 in Merrimack, New Hampshire, reporting to Jens Viebke, president, Acute Care Therapies, and shall have such 8 9 responsibilities and duties consistent with such 10 position. Executive acknowledges that Getinge may 11 reassign him to a different position in the company 12 based on business requirements.

Do you see that?

- 14 A. Yes, I do.
 - Q. Did I read that correctly?
- 16 A. Yes, you did.
- Q. Okay. And you testified earlier today that
 Acute Care Therapies is not a legal entity, correct?
- 19 A. Correct.
- Q. All right. So Jens Viebke is president of an entity that is not a legal entity, right?
 - A. Correct.
- Q. All right. And Getinge, an entity which is not a legal entity, may reassign you to a different position in the company based upon its requirements,

right?

A. Correct.

Q. Okay. And let's scroll down to the

Compensation.

In consideration of the agreements made by

executive herein and the performance by executive of

obligations under, during the employment term, Geting

agrees to pay executive pursuant to Getinge normal and

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executive herein and the performance by executive of his obligations under, during the employment term, Getinge agrees to pay executive pursuant to Getinge normal and customary payroll procedures a base salary equivalent to -- and I'm not going to say it because I don't know that this needs to be in the record. The base salary shall be subject to annual review, although any determination to increase the base salary shall be

Do you see that?

within Getinge's sole discretion.

A. Yes, I do.

Q. Okay. So in consideration of the agreements, the executive -- and that's you -- and the performance of you under the employment agreement with a nonlegal entity, Getinge, that nonlegal entity is agreeing to pay you; right?

- A. Yeah.
- 23 Q. Okay.
- A. And they still do.
- 25 Q. Okay. And they -- the nonlegal entities

- 1 reviews your base salary and adjusts it at its 2 discretion, correct?
 - A. Technically my boss does, yes.
- Q. And, in addition, if we go down to the bottom,
 under Standard Benefits: During the employment term,
 executive shall be eligible to participate in the
 employee benefits plans currently or hereafter
 maintained by Getinge of general applicability to other
 like executives of Getinge.
 - So here, this paragraph, they're saying that the executive -- you can participate in plans maintained by an entity that's not a legal entity, right?
- 13 A. It -- it's plans they've created as a group,
 14 yeah.
- Q. Okay. It's not a legal entity.
- And to other executives of Getinge, which isn't a legal entity, right?
- 18 A. Right.

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- 19 Q. Okay. Let's turn the page.
- Getinge's group medical, dental, vision,
 disability, life insurance, and flexible spending
- 22 account plans are available to you, correct?
- 23 A. Yes.
- Q. Okay. And so a nonlegal entity is binding itself to provide you medical, dental, vision,

- disability, and life insurance under this contract,
- 2 | correct?
- A. And I happen to get life insurance, dental,
- 4 | vision, all that.
- 5 Q. Okay. And the Getinge executive vehicle
- 6 program, you're entitled to a Getinge executive vehicle
- 7 | under this agreement, correct?
- 8 A. Yes, but I don't utilize one.
- 9 Q. Okay. But you are entitled to one
- 10 | nonetheless?
- 11 A. Yes, I am.
- 12 Q. Okay. And so a -- a nonlegal entity is
- 13 | binding itself to giving you the option of using an
- 14 executive vehicle, right, under your contract?
- 15 A. As -- yes.
- 16 Q. Okay. Executive life and disability program,
- 17 | here Getinge is offering you eligibility to participate
- 18 | in their executive life and disability program, correct?
- 19 A. Yes, it is.
- Q. Okay. And, again, this is a nonlegal entity
- 21 | that's binding itself to giving you executive life and
- 22 | disability, correct?
- 23 A. Yes.
- Q. And if we turn to the back of this agreement,
- 25 on page 7, we see that this is signed by Jens Viebke,

- 1 | president of Acute Care Therapies. Do you see that?
- 2 A. Yes, I do.
- Q. Okay. And, again, Acute Care Therapies is not a legal entity, right?
- A. Correct.
- 6 Q. Okay. And it's also signed by Thomas
- 7 | Marschal, vice-president human resources, Acute Care
- 8 | Therapies; correct?
- A. Correct.
- 10 Q. Again, not a legal entity, right?
- 11 A. Correct.
- Q. Okay. So these two gentlemen are signing and
- 13 | binding a non- -- an entity that is -- that doesn't
- 14 | exist?
- 15 A. Yes.
- 16 Q. Okay. I'd like to turn to Exhibit 41.
- And this is the indemnity agreement that you
- 18 | spoke about yesterday. If we could zoom in on the front
- 19 part.
- 20 Now, yesterday you testified, and I think a
- 21 | moment ago you testified, that La Ciotat facility is a
- 22 | separate entity and I think that's the explanation you
- 23 offered as to why Getinge was offering the
- 24 | indemnification; is that right?
- 25 A. Yes. La Ciotat is Intervascular SAS.

- Okay. So if we look at this indemnity 1 Q. 2 agreement in the first paragraph: Whereas the Getinge Group, acting through its parent company, Getinge AB, 3 4 together with Atrium Medical Corporation, collectively Getinge, desires Chad Carlton to serve as an officer and director of Atrium Medical Corporation and Getinge 6 7 further desires to indemnify executive in accordance with the terms and conditions of this indemnification 8 9 agreement.
- 10 Do you see that?
- 11 A. Yes, I do.

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- Q. And so if I understand, your testimony is and from yesterday -- well, strike that.
 - I don't see La Ciotat in that first sentence:
 Whereas the Getinge Group, acting through its parent
 company, Getinge AB, and together with Atrium Medical
 Corporation, desires Chad Carlton to serve as officer
 and director of Atrium Medical Corporation.
 - Do you see the word La Ciotat in there?
- 20 A. No, because that's a city.
- Q. Okay. Do you see the name of the -- the vascular entity, the company?
- 23 A. No.
- Q. Okay. In fact, it's nowhere in this indemnification agreement, is it?

- 1 A. No, it's not.
- Q. Okay. So what this agreement says within the four corners of the agreement is that Getinge AB,
- 4 | together with Atrium Medical Corporation, desires
- 5 Chad Carlton to serve as an officer and director of
- 6 Atrium Medical, right?
- 7 A. Yes.
- 8 Q. Okay. It doesn't make any mention of any
 9 other facilities, right?
- 10 A. Not the La Ciotat, nor the Wayne facility --
- 11 Q. Okay.
- 12 A. -- that I have products I oversee.
- 13 Q. So we have no proof other than your word that
- 14 | this indemnification agreement is for anything other
- 15 than your job at Atrium, right? We have no documented
- 16 proof.
- 17 A. It's my indemnification agreement. I know why
- 18 | I had it created.
- 19 Q. I'm not questioning that, sir, but I'm asking
- 20 | within the four corners of the document, we have no
- 21 | documentation to suggest that this is for what you've
- 22 | said it was for.
- 23 A. Except for my word.
- Q. Okay. We talked a little bit ago about
- 25 | contracts and the importance of contracts. Do you

1 recall that testimony? 2 The contracts -- are you meaning with selling medical devices? 3 Right. That's all --4 Q. Α. Is that what you're referring back to? Do you recall that? Q. 6 7 Α. Yes, I do. And it's important when you're selling medical 8 Ο. devices, excuse me, when you're doing contracts that 9 10 they be accurate, right? 11 I -- I've learned that you always want to be 12 accurate, but I often find that contracts are not always 1.3 accurate. 14 Okay. Well, I'm going to hand you or show Q. 15 you -- and maybe I should hand you for the purposes of 16 this a paper copy because of the size of this exhibit. 17 Your Honor, may I approach the witness? THE COURT: Yes. 18 19 Thank you. Α. 20 Q. Sure. 21 Okay. So this is a distributorship agreement 22 that has been testified to as being the agreement that 23 sets out the deal that you have set forth on that easel;

A. That easel is a general piece of the

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is that right?

1 | high-level standpoint. It is not the specific piece --

- Q. Right. But this --
- A. -- of transactions that take place, yeah.
- Q. I understand. But this is the distributorship agreement --
 - A. Yes.

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- Q. -- that governs --
- A. Let me review before --

This is an agreement between Atrium and Maquet Medical Systems. I'm not sure that I see -- and I'm not completely familiar, I didn't read through this whole document, but I don't see Maquet Cardiovascular LLC on this.

Q. Well, that's because they're not on there.

This is the only distribution agreement prior to the Getinge USA agreement that we'll get to that later that was produced in this litigation and several witnesses have testified about this agreement as being the operative agreement. Do you disagree with those witnesses?

- A. If they are more familiar with the contract than I am, I -- I don't know who those witnesses are specifically.
- Q. All right. So let me ask you, looking at this, you would agree with me that if we look at the

- 1 first paragraph, Atrium Medical Corporation, a Delaware
- 2 | corporation and part of the Maquet Getinge Group,
- 3 | hereinafter referred to as Maquet, and Maquet Medical
- 4 | Systems USA, established at 45 Barbour Pond Drive,
- 5 | hereafter Maquet SSU, hereby enter into the following
- 6 agreement.
- 7 Do you see that?
- 8 A. Yes, I do.
- 9 Q. Okay. And you would agree with me that this
- 10 | legal entity is -- excuse me, this is not a legal entity
- 11 | entering into this contract, true?
- 12 A. If it's Maquet Medical Systems USA, is it
- 13 | USA -- is this the USA Sales that we say, Maquet Medical
- 14 | Systems USA Sales LLC.
- 15 Q. Medical Systems isn't a -- isn't a legal
- 16 | entity, correct?
- 17 A. No, but the -- in terms of Maquet Medical
- 18 | Systems USA, maybe. I don't know. This is from
- 19 December 31st, 2012, so -- whereas that relationship
- 20 occurred in January of 2014.
- 21 So I'm just trying to -- I'm trying to mesh
- 22 this right now.
- Q. All right. Well, there is no agreement from
- 24 2014.
- 25 A. Okay.

- 1 Q. Have you ever seen an agreement from 2014?
 - A. I wasn't responsible in that area in 2014.
 - Q. Well, you testified about this relationship yesterday, right?
 - A. Yes, I did.

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- Q. Okay. Can you show me anywhere in this document where the profit of 50 percent going back to Atrium is?
- A. And, by the way, that's an approximate profit that comes back and it depends -- I believe I said yesterday it depends on the product line.
- Q. But can you show me anywhere where that
 document -- or this document shows those approximate
 product profit lines?
- 15 A. I don't know that there's any prices 16 associated with this document.
 - Q. Okay. And if we look at the agreement, I want you to turn to the signature page, on page 14. Do you see this is dated December 31st, 2012?
- 20 A. Yes, I do.
 - Q. And what I want to do is I want to pull down the bottom of this page, the document. How is it that this document was created on April 17th, 2013, it is dated and signed December 31st, 2012. Do you have an answer for that?

- 1 A. I do not have an answer for that.
- Q. Okay. I'd like to turn to page 8. Excuse me,
- 3 | page 7.
- A. So, by the way, I did notice that it says
- 5 | Maquet Cardiovascular LLC on the document that you kind
- 6 of showed down there.
- 7 Q. On page 8?
- 8 A. Down at the bottom --
- 9 Q. You can flip through it.
- 10 A. -- that you just showed me.
- 11 Q. Yes. Yes, it does, which is one of the
- 12 | entities there.
- 13 A. Yeah, that's the first --
- Q. And that doesn't match up with the entity that
- 15 | is the signatory, correct?
- 16 A. Again, I don't know if there was any
- 17 | transition or change. This was in 2012 versus 2013 or
- 18 | '14.
- 19 Q. All right. Can we look at page 7, your
- 20 | applicable law and jurisdiction.
- 21 So presuming it's Maquet Medical, a nonlegal
- 22 | entity, this agreement is to be construed and governed
- 23 | in accordance with the laws of state of Delaware.
- Do you see that?
- 25 A. I'm sorry. Page 7 where?

- 1 Q. I'm sorry. At the bottom, section 11.
- 2 A. Section 11. Okay.
- 3 Yes.
- Q. Okay. And it lists a place of jurisdiction and it lists that the adjudication will be in Delaware, right, and depositions to occur in New Jersey?
- 7 A. Yes, it does.
 - Q. Okay. And then if we turn to page 8, on the section 14, first paragraph, we see Maquet agreeing to be bound by and adhere to the laws of the United States, right?
- 12 A. Yup.

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- Q. Okay. If we turn to page 19, we see Medical
 Systems Internal Guide and Getinge Corporate Manual.
- 15 Maquet acknowledges receipt and acceptance of the terms 16 contained in the documents referenced below.
- And these are the Medical Systems documents, right, the Medical Systems group?
- A. Again, I'm not familiar with these, but I'll take your word for it.
- Q. Okay. So if you never saw a contract, how
 were you able to describe that transaction yesterday?
 Was that based on practice?
- 24 A. That was through discussions with Gary Sufat.
- 25 Q. Okay. So you have no personal knowledge of

1 | that?

- A. He signed this contract, but that's his explanation to me.
 - Q. Okay. And when your brother testified, he said: I wouldn't say it was an agreement. It was their integration plan. And they would -- they would pace out what their SSUs, take over sales, so it just started with one or two SSUs and then kept going. And so there was -- it was an overall plan on when -- when the Atrium teams would be -- would be handing off sales responsibilities to the Maquet SSU.

And that's at page 207, lines 10 through 25 of his deposition.

So would you agree with me that the knowledge -- you're not professing to have more knowledge than your brother, who was president at the time, correct?

- A. I -- I was aware in certain discussions in terms of integration plans of various SSUs and the time point. I think you probably found that in some of my documents.
- Q. When your brother says -- so as president of Atrium business unit, did you have any involvement in the discussions as to the terms of the distribution agreement between Atrium and Maquet, page 213, line 16

- 1 through 214 line 6, when he says: I don't recall, but I
- 2 | don't think there were ever negotiations. I think it
- 3 | was an agreement that was just required to properly
- 4 transfer the product.
- 5 Question: So when you say there weren't any
- 6 | negotiations, is it your understanding that this is
- 7 | something that Maquet put in place so that the products
- 8 | could be transferred from Atrium to Maquet and then sold
- 9 by Maquet?
- 10 Answer: That would be my assumption.
- 11 You don't disagree with your brother, do you?
- 12 A. I disagree that we had no input on it. We set
- 13 transfer prices.
- Q. Do you have personal knowledge of that?
- 15 A. That we set transfer prices?
- 16 Q. No. Do you have personal knowledge of the
- 17 | negotiation of the contract?
- 18 A. Of the negotiation contract, no, but I have --
- 19 Q. Okay.
- 20 A. -- knowledge that we set transfer prices.
- 21 Q. Now, if we go back to Exhibit 2, that sales
- 22 agreement, there's -- there's nothing attached here that
- 23 | is a price list.
- 24 A. I -- I stated that, yes.
- 25 Q. Okay. All right. Now, hopefully we can go --

we're going to look at Exhibit 66 now, which is the agreement that is in effect now, I believe.

You testified yesterday that as of October 1st, 2017, Atrium was now setting -- selling through, ultimately, Getinge USA Sales; is that correct?

- A. Through Maquet Cardiovascular LLC and then through Getinge USA Sales.
- Q. Okay. And if we look on the first paragraph here on the first page, we see that this agreement is effective October 1st, 2017, commencement date. And that's consistent with what you testified to yesterday, right?
 - A. That is correct.

Q. And it's consistent because you would want to make sure that you had an agreement at the time -- you don't want to sell a product -- strike that.

It's consistent and you wouldn't want to sell a product without a contract, right, as president?

- A. As -- as you're aware, they transitioned in terms of their piece to another piece, so we were putting a contract into place to reflect that.
- Q. Okay. What I'd like to do is I'd like to turn to the signature page. Your signature is -- can be found on Bates ending 2732.
- Okay. If we could zoom in, Chad Carlton, and

- 1 | that's dated 06 July, 2018, right?
- 2 A. Yes, it is.
- 3 Q. And you wrote that?
- 4 A. Yes, I did.
- Q. So there's no contract from October 1st, 2017, the commencement date, signed through to 6 July, 2018, right?
- 8 A. There's no signed contract, no.
- 9 Q. Okay. So we can't find -- of the two sales
 10 agreements, we can't find an accurate agreement that was
 11 written without errors, can we?
- A. I -- as I stated, and I think this probably

 occurs in many different companies that what you want

 and put in place may not always seem clear and concise.

 We try our best.
 - Q. All right. Now, I want to now talk about the sales service agreements. And I think you testified that Atrium participates and receives some services under these agreements, correct?
- 20 A. Yes.

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- 21 Q. If we could turn to Exhibit 87, please.
- A. Hang on one second.
- Okay. Thank you.
- Q. Okay. So if we look at the first page, this is an agreement between Getinge AB and Atrium Medical

Corporation, correct?

A. Yes, it is.

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- Q. Okay. And Getinge AB here is called the provider, right?
 - A. Yes, it is.
 - Q. Okay. And then it says where is -- whereas, excuse me -- provider and its affiliated companies constitute a multinational group of enterprises and recipient is a member of this group.

10 Do you see that?

- 11 A. Yes.
- Q. And then it goes on to say: All companies of the group have a continuing need for advice and assistance in various areas, including finance, information technology, human resources and management, as set out in Annex 1.

Do you see that?

- 18 A. Yes, I do.
 - Q. Okay. And the service departments of provider are staffed with highly experienced personnel and form a valuable resource which can provide and coordinate a variety of useful and beneficial services in the above-mentioned areas to other companies of the group by drawing on its own resources as well as on those available from other companies in the group or from

1 third parties. Do you see that? 2 3 Α. Yes, I do. 4 Q. And then it says provider is willing to render to recipient -- so, in this case, it's Getinge AB -- is willing to render to recipient -- and recipient being 6 Atrium -- and Atrium desires to use such services. 7 That's what this agreement says, right? 8 That's -- you've read it correctly, yes. 9 Α. Okay. Engagement of Provider. Recipient, 10 Q. 11 that would be Atrium, hereby engages provider, that'd be 12 Getinge AB, right --1.3 Α. Yes. 14 -- okay -- to carry out such of the functions Q. 15 as set in Annex 1 for the company as the recipient may 16 reasonably request and the provider shall agree to 17 perform from time to time. 18 Do you see that? 19 Α. From time to time, yes. 20 Q. Okay. And these fees -- excuse me.

And we heard earlier, and I think we saw, that there were fees associated with the services, correct?

Yeah, there are fees associated with the services.

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Okay. And if we look at Terms and Termination 25 Q.

- on page 5, we can see that this agreement shall be 1 effective as of November 4th, 2011, right? 2
 - Α. Yes.

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- Q. And that makes sense, because that's the time of the closing of the acquisition by Getinge AB, right?
- Yes, it does. Α. 6
- 7 Okay. What I'd like to do is turn the page Q. now and I'd like to zoom in on the signature and the 8 9 date.
- 10 So it appears that this agreement was 11 backdated by about two years, correct?
- 12 Well, I think he signed it on that date and it 13 reflected the contract earlier, yes.
- 14 Okay. Thank you. You can put that aside. Q. I'd like to look at Plaintiff's 89. 15
- 16 Okay. So this is a replacement contract that 17 came in and this one, again, is between Getinge AB and the parties listed in Annex 1. And Atrium is a party listed in Annex 1, right?
- 20 Α. Yes, it is. I would believe it is, yes.
 - 0. Okay. At this time, Atrium -- excuse me --Getinge refers to itself as a pass-through entity, right?
- 24 Α. Yes.
- 25 Q. Otherwise, the process is roughly the same;

- 1 Atrium -- excuse me, Getinge coordinates services for 2 the benefit of the recipients, right?
 - A. So -- right. Repeat that again. I'm sorry.
 - Q. So, otherwise, despite the name change from provider to pass-through entity, the terms of this agreement are basically the same.
 - A. I'm not familiar enough with the original agreement and this agreement to compare them side by side. The concept is the same, I would agree with you, that they provide services and they serve as a -- as Peter stated in his testimony, as kind of -- they would collect the different invoices and charge that down to us, depending on where it was.
 - Q. They also acted like a general contractor almost, right, coordinating the services?
 - A. I -- I haven't worked with general contractors enough to state if that's how they behave.
 - Q. All right. If you look at the last sentence on the page: Pass-through entity shall provide the services on a continuing basis without any further specific request or whenever recipient places an order for them with any of the group internal service providers.
 - Do you see that?

25 A. Pass-through entity will, through the Getinge

- 1 internal services provider, render the services to
- 2 recipients throughout the term of this agreement.
- 3 | Pass-through entity shall provide the services on a
- 4 continuing basis without any further specific request.
- 5 So it's meaning it will continue on without
- 6 having to do multiple requests, yes.
- 7 Q. Okay. All right. And if we turn to page 4,
- 8 | this agreement was signed on behalf of pass-through
- 9 entity by Joacim Lindoff on 3/1/2017. Do you see that?
- 10 A. Joacim, yes.
- 11 Q. Okay. If we turn the page, we see just a
- 12 | little bit later, on 6 April, 2017, Steve Emery signs
- 13 | for Atrium.
- Do you see that?
- 15 A. Yes.
- 16 Q. And if we turn to page 12, we see: Acute Care
- 17 | Therapies business support services include, but not
- 18 | limited to, the following services.
- So would you agree with me that these are the
- 20 | types of services that Acute Care Therapies' businesses
- 21 | would be able to receive?
- 22 A. Give me a second. Sorry.
- Okay. I'm familiar -- yeah, they can provide
- 24 | some of these, yes, different entities, including our
- 25 | entity, yeah.

- Q. Okay. And so they provide market analysis, right?
- 3 A. Yeah, we do that as well.
- Q. Okay. They provide some global solutions management, right?
- A. Yeah.

- 7 Q. Commercial operations?
- 8 A. Okay. Yes.
 - Q. Okay. Finance and PMO?
- 10 A. Yeah. We do a lot of that internally, though.
- 11 Q. But you do receive some support, right?
- 12 A. Yeah, but it's local, so it's kind of a different transaction.
- Q. And you receive quality and regulatory compliance assistance, correct?
- A. Well, that -- again, that's internal, so there
 may be things like some audits that we may get from
 other individuals that would be crossed, but a lot of
 those things are actually done internally to us.
- Q. Okay. So both internal and external on those?
- 21 A. Yes.
- Q. Okay. Going back now to page 4, again, just to reorient us, this was signed on 3/1/2017, right?
- A. By Joacim.
- 25 Q. Okay. I want to turn back to page 3.

- And this agreement is effective 1 January,
 2 2016, about a year and two months earlier, right?
 - Q. Okay. So we've now looked at four documents that appear to be backdated today, right?
 - A. They're -- I just want to be careful with the term backdating. They are -- they are dated and they were in effect before that. Backdating has a very negative connotation that you can't do in the medical device industry.
- 11 Q. The dates on the documents were signed after 12 the effective date began?
- 13 A. Yes.

Α.

Yes.

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- Q. All right. Now, you also talk about -- talked about the organizational structure of Atrium. I want to hand -- look at Plaintiff's 1, page 2.
 - This is the last org chart that I have been provided with in the discovery in this case. I believe this is from 2017. We used this in --
- 20 A. It's somewhat outdated.
- 21 Q. Right. I understand that, but --
- 22 A. Okay.
- Q. -- I'm going to ask you, as of 2017,
- 24 | Jens Viebke was president of Acute Care Therapies?
- 25 A. Correct.

- 1 Q. And he was the boss, right?
- 2 A. Yes.
- 3 Q. Okay. And then there was you, Chad Carlton,
- 4 | managing director, president, Atrium Medical
- 5 | Corporation, right?
- 6 A. Correct.
- 7 Q. Okay. And then we see there's a -- if you
- 8 look at the bottom there, there are three little stars,
- 9 and they say not Atrium QMS, not on-site, right?
- 10 A. Correct.
- 11 Q. Okay. And we see that for chief commercial
- 12 officer, Acute Care Therapies, marketing, Ajey Atre.
- Do you see that?
- 14 A. Correct.
- 15 Q. All right. And I just want to stop there for
- 16 | a minute.
- So Ajey's off-site and not an Atrium employee,
- 18 | right?
- 19 A. Ajey is off-site and not an Atrium employee,
- 20 | correct.
- 21 Q. Okay. Now, we talked earlier about Acute Care
- 22 | Therapies, right?
- A. (Nods head.)
- Q. So Acute Care Therapies -- we've now seen that
- 25 | Acute Care Therapies has a president, right --

- 1 A. Yes. 2 Q. -- J
 - Q. -- Jens Viebke?
- 3 A. Uh-huh.
- 4 Q. They have Thomas Marschal, vice-president of
- 5 | HR, right?
- A. You're referring to at this time, correct?
- 7 Q. At this time.
- 8 A. So at this time there was the creation of 9 that, yes.
- 10 Q. Okay. There's a chief commercial officer in
- 11 | Ajey Atre, right?
- 12 A. Yes.
- Q. Okay. And Gary Sufat was actually made the CFO of Acute Care Therapies, right?
- A. And he was also -- I believe at this time -- I would have to know when Alistair was made CFO. But he,
- 17 | I believe, was also CFO of Atrium at that time, too.
- 18 Q. Okay.
- 19 A. He had joint roles.
- Q. Okay. But he held the position of CFO of
- 21 | Acute Care Therapies, correct?
- 22 A. Correct.
- Q. Okay. So Atrium -- so Acute Care Therapies,
- 24 | though it's not a legal entity, we saw that it has
- 25 | contracts, right? It signs contracts?

- 1 A. Okay. Yes.
- Q. Okay. And we saw that it has officers, right?
- 3 A. Yes.
- Q. Okay. And we saw that the Getinge Group also
- 5 | has officers, the GET team, right?
- A. Yes.
- 7 Q. Okay. And we saw that the Getinge Group has
- 8 | contracts like your agreement, right?
- 9 A. Yes.
- 10 Q. Okay. And you get paid pursuant to that
- 11 | agreement, right?
- 12 A. I get paid by Atrium Medical, yes.
- Q. You get paid pursuant to that agreement?
- 14 A. Yes.
- 15 Q. Okay. All right. Focusing back on Exhibit
- 16 | 2 -- excuse me, Exhibit 1 -- want to turn the page,
- 17 | please?
- And here this is HR, again back in 2007. So
- 19 | we see -- I think this is -- '17, excuse me.
- 20 This is indicative of, I think, the -- the
- 21 | shared services agreement.
- We see Thomas Marschal, George Sanders,
- 23 | Andreas Fagher, those three individuals. And Andreas
- 24 Fagher, if we could highlight.
- So George Sanders not on-site, not an employee

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of Atrium, correct?
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             Correct.
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         Α.
              Okay. And that's the top of the HR food
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         Ο.
4
    chain, right?
             George Sanders at this time --
5
         Α.
             At this time.
 6
         Q.
7
         Α.
             -- yes.
             Okay. And underneath him was Andreas Fagher,
8
         Ο.
    right?
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             Correct.
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         Α.
11
         Ο.
             Okay. And that's vice-president, human
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    resources, supply chain function, right?
1.3
             Correct.
         Α.
14
             Okay. And that was -- again, that person's
         Q.
15
    not on-site, right?
16
         Α.
             Correct.
             Matt Kelly, manufacturing consumables director
17
         Q.
    of HR, that person is on-site, right?
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19
         Α.
              That is correct.
20
         Q.
              Okay. So Matt Kelly's boss was -- that's a
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    direct line, solid-line report, right?
         A. You also have other people who are on-site in
22
23
    this piece.
24
         Q. Right, I understand. I'm focusing just on the
25
    Matt Kelly-Andreas Fagher relationship. That's a direct
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- 1 | solid-line report, right?
- A. At that time, that was a solid line and he had a dotted line to me, correct.
- Q. Okay. Solid-line means that that person is the boss; they do their year-end reviews, that sort of thing, right?
- 7 A. Yeah. Oftentimes on a dotted line I may have 8 some contribution to that.
- 9 Q. Okay. Thomas Marschal -- at this time, okay,
 10 and today -- not an Atrium employee, not on-site, right?
- 11 A. Correct.
- Q. And Nancy Michael, director of HR, Acute Care
 Therapies, not on-site, right?
- A. She's not on-site, no.
- Q. Okay. Let's turn the page to information technology.
- Okay. And here we see two different chains

 here, but we see Ludovic Batal, vice-president, group IT

 operations, and Matthias Gelsok, chief information

 officer.
- Do you see those two individuals?
- 22 A. Yes, I do.
- Q. Okay. Both not on-site and not Atrium employees, right?
- 25 A. Correct.

- Q. Okay. And they have direct-line reports. So the first person we see that appears to be on-site is Tom McDonnell?
 - A. Yes.

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- Q. Okay. And he's VP of IT Operations for the Americas, so he's on-site, but he also has off-site responsibilities at this time, right?
- A. Correct. So when we talk about shared services, he's able -- some of his team contracts out and sends some things to other sites as well as here, so --
- Q. Right. So when we talk about contacts under
 the -- the -- those two contracts, the shared services
 agreement, Atrium is both a recipient of services, but
 then it also provides services back through the
 contract, through Getinge AB, to other companies in the
 organization, right?
 - A. That is correct.
- 19 Q. Okay. So, here, Tom McDonnell would be an 20 example of that, right?
- 21 A. Yes, he would.
 - Q. All right. Now, I want to look at Shen Lu, vice-president, IS SSC Getinge, and at this point in time, the next person down is an open position, right?
- 25 A. That's what it appears, yes.

- Q. Okay. All right. Let's now go to accounting and finance.
- All right. So Gary Sufat, chief financial

 officer of Acute Care Therapies and was supervising

 through a solid line Stephen Emery, right?
 - A. Yes.

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- Q. Okay. Now, we see over to the right,

 Lena Hagman, EVP Quality -- group quality regulatory

 compliance, and she's off-site, right?
- 10 A. Yes, she is. It's --
- 11 Q. She's a GET team member, right?
- 12 A. She is a GET team member, correct.

this time it may have been also to Lena.

- 13 Q. Okay.
- A. So that's -- she's on this because

 Alistair Ryan not only reports to Stephen Emery, but

 also reports out elsewhere within the organization. And

 I believe at -- I don't know for sure, but I believe at
- Q. Okay. Colleen Hargove, director of finance, budget analysis, also not on-site, not an Atrium employee, correct?
- 22 A. Correct.
- Q. Okay. And those two individuals have

 functions related to remediation of the Atrium facility

 and performance under the consent decree, correct? In

- 1 terms of budgeting for that, on this.
- 2 A. Colleen does? I -- I don't recall Colleen
- 3 being involved in that. Alistair would.
 - Q. Okay. Alistair, too, not on-site?
 - A. No, Alistair is on-site.
- 6 Q. All right. Okay. We're done with this
- 7 exhibit.

- Gina, can I have Exhibit 174. If we could
- 9 turn to page 4.
- 10 Earlier today when we were talking about mesh
- 11 | liabilities and mesh lawsuits, I forgot to ask you this
- 12 question.
- 13 | Atrium was aware -- Atrium had received a
- 14 letter in March of 2009, hadn't it -- and you can see
- 15 | there's a lot of deposition testimony on this from
- 16 | Mr. McNamara, so I'll represent to you that this letter
- 17 | found its way to Atrium.
- 18 From LyondellBasell -- and LyondellBasell,
- 19 just for the Court, is the manufacturer of the
- 20 | polypropylene used in the -- the C-Qur devices, is it
- 21 | not?
- 22 A. To my -- it's the -- we usually say Basell,
- 23 | but if it's Basell, I don't know the -- the right
- 24 terminology.
- 25 Q. Okay. And the manufacturer data sheet that

- comes with -- the safety data sheet, rather, that comes
 with the polypropylene actually warns and has warned for
 some time not to put in humans, correct?
 - A. The original data sheet said -- did not say that.
 - Q. Okay. Well, in 2004 and 2005, individuals from Atrium actually called the manufacturer and were told not to use this in medical devices, were they not?
 - A. That part, I don't -- I'm not aware of.
 - Q. Okay. Well, I'm going to show you and we're going to skip to it because I just brought this document with me. This is a March 6th document from 2009.
 - And Atrium got this letter and we have a lot of testimony. And it says: I'm writing this letter on behalf of Basell, or Basell USA, a member of the LyondellBasell Industries group of companies, because it has come to our attention that certain users of Basell's Pro-fax 6523 polypropylene resin -- and that's the resin we just talked about that's in C-Qur, right?
 - A. It's the resin used for all of our polypropylene.
 - Q. Okay.

23 That they may be utilizing this material in 24 implantable medical devices. Basell's very clear 25 policy, as expressed in our product data sheets -- and

- 1 that's the one I was just referring to, right? 2 I -- I haven't seen the exact ones, but I'll take your word for it. 3 4 Q. Okay. Is that our materials, including but not limited to Pro-fax 6523, are never to be used in FDA 6 7 Class III medical devices and may only be used in FDA Class II medical devices with Basell's prior written 8 approval. 9 10 Do you see that? 11 Α. Yes. 12 Ο. Okay. And then it goes on to say: In 13 addition, it has been our long-standing policy that our 14 materials are not -- not -- to be used in implantable 15 medical devices, regardless of their FDA classification. 16 Atrium knows this as of 2009 the latest, 17 right? 18 According to this letter, that's -- that's the Α. 19 case.
- 20 Q. Okay. All right. I'm going to move on from 21 there.
 - All right. Yesterday your counsel asked you some questions about the consent decree. Do you recall those questions?
- 25 A. Yes, I do.

23

1 Q. I'd like to bring up Exhibit 209.

And we see that this is from the consent decree. You can see the case here, Atrium Medical Corp. vs. Maquet BV Holdings, Maquet Cardiovascular, et cetera, and this is an unopposed motion to remove Gail Christie from the caption of the consent decree and

Do you see that?

A. Yes, I do.

substitute Lena Hagman.

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- Q. Have you read this document before?
- 11 A. I don't know that I have read that document.
 - Q. Okay. Well, I want to look at the bottom of the first page. It says: Ms. Christie has ceased to be employed by or act on behalf of any of the corporate defendants. So -- and substitute a new individual defendant to the caption, Lena Hagman.

Do you see that?

- A. I see that.
- Q. Were you aware that Gail Christie represented and was responsible for oversight of the consent decree for all of the corporate defendants?
- A. She -- yeah, the -- from a quality
 perspective, yeah, her name was on the consent decree,
 yes.
- 25 Q. Okay. So if we turn the page, I want to focus

1 on paragraph 4.

2.4

Paragraph 30 of the consent decree provides as follows, and I'm not going to read the whole thing. I'm going to start midway through the bottom of the paragraph, kind of in the middle, right here.

An individual defendant shall notify FDA within 30 days after said defendant ceases to be employed by or act on behalf of all the corporate defendants.

So what this is saying is that Gail Christie should notify FDA within 30 days after she ceases to be employed by or act on behalf of all of the companies that are listed on the front. Is that your understanding as well?

- A. That's -- my understanding is that the FDA required that.
 - Q. Okay.

Once an individual defendant ceases to be employed or otherwise act for all of the corporate defendant entities, corporate defendants shall petition the court to formally remove that individual's name from the caption of this decree and the United States will not oppose such motion, so long as -- so long as -- FDA has sufficient evidence or information that the individual defendant to be removed is no longer directly

or indirectly working with or in any way -- this goes 1 2 onto the next page -- influencing corporate defendant entities. 3

Do you see that?

Α. Yes, I see that.

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Okay. It then goes on to say, starting here: United States will not oppose such motion so long as FDA has sufficient evidence or information that the Christie substitute defendant is vested with responsibility for all quality system functions as described in paragraph 12.

So this is saying that -- that all of the quality system functions have to be vested in this replacement personal defendant, right?

- Α. That is the case, yes.
- Ο. Okay. Let's turn to page 4, paragraph 9.

Lena Hagman is now the individual vested with responsibility for all quality systems for the corporate defendants.

And that is a defined term, right? That means all of the corporate defendants, including Atrium, right? Correct?

- 22
 - Α. Correct.
- 24 Q. Okay.
- 25 As described in paragraph 12 of the consent

1 decree. Accordingly, and solely -- solely -- because 2 she has that responsibility by reason of her position as executive vice-president for quality regulatory 3 4 compliance, the corporate defendants hereby petition the court to substitute Gail Christie with Lena Hagman, whose substitution will satisfy both the Christie 6 7 substitute defendant and substitute individual defendant provisions of paragraph 30 of the consent decree. 8 Do you see that? 10 Α. Yes, I do. 11 Okay. And I want to look at the last 0. 12 paragraph -- the last sentence of paragraph 10. 13 THE COURT: We're going to take our break 14 after you --15 MR. ORENT: Absolutely. 16 THE COURT: -- finish this. 17 Ο. And do you see where it says Ms. Hagman 18 consents to giving this court personal jurisdiction over her? 19 20 Α. Yes, I see that. 21 0. Okay. And I want to just scroll to the 22 caption page here. If we could go to just the front 23 page, please, Gina, and scroll up here. 2.4 What court is that?

United States District Court of New Hampshire.

25

Α.

- Q. And where are we today?
- 2 A. United States District Court. I mean United 3 States District Court, District of New Hampshire.
- MR. ORENT: Okay. Your Honor, now's a good time for that break.
- 6 THE COURT: Okay. Good. We'll take our
- 7 | break. We'll be back --

- 8 MR. ORENT: Thank you.
- 9 THE COURT: -- at close to 10:30.
- 10 (Recess taken from 10:20 a.m. until 10:38 a.m.)
- 11 THE COURT: Go ahead, Attorney Orent.
- 12 Q. Mr. Carlton, yesterday you were asked some
- 13 questions by your counsel and I'm just going to
- 14 | paraphrase briefly, but I believe you testified roughly
- 15 | that Atrium is responsible for the production of the
- 16 | C-Qur mesh devices; is that right?
- 17 A. Yes, it is.
- Q. I believe that you testified that Atrium is
- 19 | the one that is responsible for the design of the C-Qur
- 20 devices, right?
- 21 A. Yes, we are.
- 22 Q. And I believe you testified that you were
- 23 | responsible for the -- you being Atrium -- were
- 24 responsible for the quality systems related to the C-Qur
- 25 devices, right?

A. Yes, we are.

- Q. And also the packaging of the C-Qur mesh devices, correct?
 - A. That is correct.
 - Q. Okay. What I'd like to do is I'd like to turn to Exhibit 184. And, again, this is a copy of the consent decree.

And if you look on page 5, it says here:

Specifically, defendants shall take the following

actions, among others; number one, establish and

maintain procedures to control defendants' devices'

designs in order to ensure the specified design

requirements are met.

Would you agree that establishing and maintaining procedures to control the design of C-Qur in order to ensure that the specified design requirements are met is part of the design of the device?

- A. Can you repeat that question for me?
- Q. Sure.
- A. Sorry.
- Q. If you look at paragraph -- the first paragraph there, would you agree that establishing and maintaining procedures to control design in order to ensure that specified design requirements are met is an obligation of a medical device manufacturer?

A. So we -- we are required to maintain the design procedures and -- yes, we are -- that is something we are required to do.

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- Q. Okay. And would you agree with me under the consent decree that Lena Hagman is personally, in her official capacity, responsible to make sure that defendants establish and maintain procedures to control defendants' devices' designs in order to ensure that specified design requirements are met?
- 10 A. I believe she gave that responsibility to me locally.
- 12 Q. Do you see anywhere in the consent decree 13 where she can assign away that responsibility?
 - A. I would have to read through further, but I believe she has the power to do that through regulations in terms of creating a local designate.
- Q. Let's quickly move to -- you'd be a local designate, not the ultimate responsible party, true?
- A. I am the management with authority and within the FDA that has a specific connotation associated with it.
- Q. All right. Let's -- let's turn to paragraph

 23 | 12.
- Corporate defendants shall vest responsibility

 for all quality system functions, as designed -- as

- 1 defined in 21 C.F.R. 8020.3(v)(sic) in the specified and
- 2 | additional facilities an individual who shall be
- 3 | authorized and responsible for all quality system
- 4 functions at the specified and additional facilities,
- 5 | including establishing, implementing, and maintaining a
- 6 | comprehensive written program -- quality program -- to
- 7 | ensure defendants' continuous compliance with this
- 8 decree, the Act, and the QS, CR, and MDR regulations.
 - As you sit here today, you understand that
- 10 | Lena Hagman is that individual, correct?
- 11 A. She has the overall responsibility and she has
- 12 | vested -- she has provided that responsibility to me
- 13 | locally, yes.
- Q. Okay. But it's her name that's on the
- 15 | caption?

- 16 A. Huh?
- 17 Q. Her name is the one that we looked at on the
- 18 | caption.
- 19 A. Well, on this particular one she's not, but on
- 20 the other one she is.
- 21 Q. Right. And that document -- and we can look
- 22 | back at Exhibit 209 -- that document says that she's
- 23 | being substituted in place of Gail Christie, right?
- 24 | That's what we saw.
- 25 A. Correct.

- Q. Okay. So this document doesn't say your name, does it?
 - A. It does not have my name, no.
 - Q. Okay. Document 209 does not have your name?
 - A. No, it does not.

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22

- Q. Okay. Your name has not been submitted by
 Lena Hagman for approval to the FDA for substitution of
 her, has it?
- 9 A. No, it's -- it's documented locally that I am
 10 the management with responsibility, though.
- Q. You are the local management responsibility,
 but ultimately she is the party on the consent decree.

 You agree with that?
- 14 A. She is a party on the consent decree.
- 15 Q. Okay.
- 16 A. And Atrium Medical is as well.
- 17 Q. All right. Let's go back to page 6.

Do you agree with me that a manufacturer of medical devices has an obligation to ensure that all devices meet requirements for design, development, and planning? Do you agree with me that?

- A. We -- yes.
- Q. And would you agree with me that a medical device manufacturer in the design process has design planning as part of it?

- 1 A. Are you meaning the next bullet or --
- 2 Q. No, I'm asking you a question.
- 3 A. Okay.

- Q. Would you agree with me that part of the design process is design development and planning?
- 6 A. Design -- can you elaborate planning?
 - Q. In the way the FDA uses it.
- A. So it -- in terms of design, design and validate the product, yes, absolutely.
- Q. Okay. Design inputs, design outputs, design review, those are all functions that a medical device manufacturer has obligations for under MDR regulations, correct?
- A. Absolutely.
- 15 Q. Okay. Design verification, a medical device 16 manufacturer has to do that, right?
- 17 A. Yes.
- 18 Q. Okay. Design validation, a medical device
 19 manufacturer has to do that, correct?
- 20 A. Yes.
- Q. Design change, design transfer, those are things that medical device companies have to do, correct?
- 24 A. Yes, they do.
- Q. And as well as maintain a design history file,

- 1 correct?
- 2 A. That's correct.
- 3 Q. And Atrium -- strike that.
- 4 All of this work has been done for the C-Qur
- 5 device, correct?
- 6 A. Correct.
- Q. Okay. And Lena Hagman, via the consent
 decree, has personal responsibility for each of those
 under this decree; isn't that right?
- 10 A. She has personal responsibility for that -- I
 11 think that would be a stretch.
- Q. Well, don't you see here it says:

 Specifically, defendants shall take the following

 actions, right?
- 15 A. And Atrium is one of those defendants.
- Q. Right. But that's plural, right? If we look back -- let's go back to page 1.
- The term defendants is a defined term and if
 we look here, we can see it. We can see that it's both
 the corporate defendants and the individual defendants,
 right?
- 22 A. Yes.
- Q. Okay. So if we go back to page 5, the way a defined term works is that another way to say that would be specifically the corporate defendants and the

individual defendants shall take the following actions,
among others.

Would you agree with that?

- A. Specifically the defendants shall take the following actions, among others.
- Q. Right. And in place of the defined term, defendants, we could use the individual definitions that were given; we could say specifically the corporate defendants and the individual defendants shall take the following actions, among others. Isn't that right?
- 11 A. I guess so, yes.

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- Q. Okay. Now, if we go to number 2, excuse me,
 number 3: Conduct design evaluations of all marketed
 devices to ensure that current designs have been
 properly validated and transferred into appropriate
 product specifications.
 - That's something that a manufacturer of medical devices has to do, correct?
- 19 A. Yes. Yes.
- Q. In fact, that's -- that was done with C-Qur, correct?
- 22 A. Yes, it was.
 - Q. And under the consent decree it was redone to make sure that you were compliant with the consent decree, right?

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A. I -- I think it was redone prior to the consent decree.

Q. Okay. Through the regulatory process, the
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A. Yes.

483 process?

6 Q. Okay.

4

- 7 A. The 483 process?
- Q. You understand that there were a series -9 strike that.
- 10 All right. Let's go on to the next sentence.
- Number 4, can we bring that back up, Gina?
- 12 Validate processes whose results cannot be
- 13 | fully tested by subsequent inspection testing. Still on
- 14 page 6. Right here. Right there. Thank you.
- Do you see that?
- 16 A. Yes, I see that.
- Q. And that's a responsibility of a medical device manufacturer, correct?
- 19 A. Yes, it is.
- Q. And it was placed in here as a -- something
 that needed to be done under the consent decree as well,
 correct?
- 23 A. Yes.
- Q. Okay. If we go down here to number 5, develop, conduct, control, and monitor production

- 1 processes, ensure the devices conform to their specifications. 2 3 That is a -- something that needs to be done 4 with medical devices, correct? Α. That is something in the regulations, yes. Okay. And Atrium has done that? 6 Q. 7 Α. Yes, it has. Ο. Okay. And it's been done with regard to the 8 C-Qur device, correct? Yes, it has. 10 Α. 11 Ο. Okay. And that is part of manufacture, 12 correct? 13 Α. That is part of -- part of the whole process of design and developing and manufacturing a product, 14 15 yes. 16 Okay. 6, establish and implement adequate Ο. 17 written procedures to control devices that do not 18 conform to specified requirements. 19 Do you see that? 20 Α. Yes, I do. 21 0. That's a requirement of all medical device 22 manufacturers, correct?
- Q. Atrium did that with regard to the C-Qur device, correct?

Α.

Correct.

1 A. Yes, it has.

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- Q. And it was required under the consent decree, correct?
 - A. It's required of the -- they're referring to the C.F.R. earlier in this and, yes, it's part of the regulations and it's part of the consent decree, yes.
 - Q. Okay. 7: Establish and maintain adequate written procedures for corrective and preventative actions, documenting those activities.

That is a requirement of medical device
manufacturers, correct?

- 12 A. That is a requirement of the medical device
 13 manufacturers, yes.
- Q. It was done for the C-Qur devices, correct?
- 15 A. Yes.
- 16 Q. And it's in the consent decree, correct?
- 17 A. Yes.
- Q. Okay. 8: Maintain accurate and complete
 complaint files and establish and implement adequate
 written procedures receiving, reviewing, and evaluating
 complaints.
- Do you see that?
- 23 A. Yes, I do.
- Q. That's a requirement of medical device manufacturers, correct?

- 1 A. As mentioned earlier, yes.
- Q. Okay. That was done for C-Qur, correct?
- 3 A. Yes, it was.
- Q. And it's required under the consent decree,
- 5 | correct?
- 6 A. Yes, it is.
- Q. Okay. Number 9: Develop and implement
 adequate written MDR procedures in compliance with
 21 C.F.R. part 803, including but not limited to
 adequate procedures for management review and ensure
 that employees are trained on, understand, and properly
- Do you see that?
- 14 A. Yes.

Q. And that's required of medical device manufacturers, correct?

implement the MDR requirements and procedures.

- 17 | A. Yes, it is.
- 18 Q. It was done with C-Qur, correct?
- 19 A. Yes, it was.
- Q. And it's required under the consent decree,
- 21 | correct?
- 22 A. Yes, it is.
- Q. Okay. Gina -- okay. If we could bring up
 page 125 from yesterday and focus on line 6 through 14,
- 25 | please.

1 Yesterday --MS. ARMSTRONG: I'm sorry. What is this 2 3 document? 4 MR. ORENT: This is the transcript from 5 yesterday. MS. ARMSTRONG: Okay. 6 7 Yesterday you were asked: Is it unusual to distribute retained earnings to a shareholder? 8 9 And you stated: No. In fact, when Atrium existed -- when Atrium existed, they sent earnings to 10 shareholders as well. 11 12 Then your counsel went back and said: When you say Atrium existed, you mean prior to the --13 14 And you said: Oh, I'm sorry. Let me correct 15 that. When Atrium was a privately held company, they 16 did the same thing. 17 That was your testimony yesterday, correct? Yeah. It was an error. 18 Α. 19 Let's go to Exhibit 238 and let's scroll in Q. 20 under Maquet Vascular Systems. 21 This is your CV, correct? 22 Α. Yes. We reviewed this quite extensively 23 during my deposition. 2.4 Okay. And I want to focus right here on your Q.

description of Maquet Vascular Systems. You said it's

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1
    formally Atrium Medical Corporation on your resume, did
2
    you not?
 3
         Α.
              Yeah, and we discussed this at length.
 4
              MR. ORENT: I have no further questions.
              Thank you, your Honor.
              THE COURT: Okay.
 6
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              MR. ORENT: Thank you.
              MS. ARMSTRONG: Give me just a minute to get
8
    organized and find the pages --
9
              THE COURT: That's fine.
10
11
              MS. ARMSTRONG: -- in the consent decree that
12
    he was referring to.
13
              MR. ORENT: Your Honor, if I may, just one
14
    housekeeping item.
15
              Formally move in Exhibits 239 through 242 and
    237 and 238 and 243.
16
17
              THE COURT: Okay. I don't know what those
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    exhibits are, but do defendants have any objection to
19
    them?
20
              MR. CHABOT: Your Honor, provided we have the
21
    opportunity to address them on the exhibit list so that
22
    they can be subject to the stipulation that Attorney
23
    Orent read at the beginning of the hearing --
2.4
              THE COURT: Okay.
25
              MR. CHABOT: -- I think that would be fine.
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              THE COURT: All right.
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              MR. ORENT: Thank you, your Honor.
3
              THE COURT: So with that qualification, they
4
    are full exhibits. 239, 242 --
5
              MR. GLASSER: Do you want to read those to her
6
    again, Jon?
7
              MR. ORENT: Yes.
              THE COURT: -- as well as 237, 238 and 243.
8
              MR. ORENT: Correct. 239 through 42, 237,
9
    238, and 243.
10
              THE COURT: 237 to 243.
11
12
          (Plaintiffs' Exhibits No. 237-243 admitted.)
13
              MR. CHABOT: Counsel, if you'll provide an
14
    exhibit list so that we can make any objections and
    we'll have them --
15
16
              MS. ARMSTRONG: Your Honor, I just -- Mr. --
17
    Mr. Orent was going through the consent decree pretty
18
    fast. Can I just get him to point me to the pages,
19
    actual pages, in the paper copy that he was reading
20
    from?
21
              THE COURT: Absolutely.
22
              MS. ARMSTRONG: Just show me. I was reading
23
    on the screen.
24
              MR. ORENT: It's starting on 5 and then 6.
25
              MS. ARMSTRONG: Thank you.
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1 MR. ORENT: You're welcome. REDIRECT EXAMINATION 2 BY MS. ARMSTRONG: 3 4 Q. Good morning, Mr. Carlton. Good morning, Ms. Armstrong. Α. Do you remember Mr. Orent just now asking you 6 Q. 7 some questions about pelvic mesh litigation? Yes, I do. 8 Α. And he threw out some very, very big numbers 9 Q. that have been in the news, right? 10 11 Α. Yes. 12 Ο. Was Atrium's products, surgical mesh products, 13 were they ever marketed for pelvic use? 14 No, they were not. Α. 15 Is that a very different use than hernia --Q. 16 than use in hernia surgery? 17 Α. Yes, it was. 18 Q. Is it one of the indications for your surgical 19 mesh products? 20 Α. No, it is not. 21 0. Do you -- do you know how many -- how many 22 pending litigations you have that involve the -- the use 23 of one of your surgical mesh products in a pelvic 24 application? 25 Α. I don't know the exact number, but it's --

- 1 it's less than probably two percent or one percent of
- 2 | the total --
- 3 Q. Okay.
- A. -- litigation, of the lawsuits that are out
- 5 there. Sorry.

- 6 Q. Do you have any idea -- I'll stop there.
- You were also shown an email from Scott Waxler
 in February of 2017. Do you recall that?
 - A. I recall seeing that here, yes.
- 10 Q. And who is he --
- 11 A. I had not seen it before.
- 12 O. Who is he with?
- 13 A. He is with LockeBridge.
- Q. And it was concerning the mesh litigation; it was a question about the mesh litigation, correct?
- 16 A. There was a question on the mesh litigation, 17 yes.
- Q. And it was -- I believe that the document was dated February 2017. Do you recall that?
- 20 A. Yes, I do.
- 21 Q. Do you know when the C-Qur MDL was created?
- 22 A. It was just prior to that time, I believe.
- Q. Okay. You were also shown a response to -- or
 I think it was an interim response to the FDA regarding
 your complaint review procedure and whether or not some

should have been reported as MDRs, correct?

- A. That is correct.
- Q. Okay. You -- you told us yesterday about your postmarket surveillance and you said it included review of complaints, right?
 - A. Yes.

2.4

- Q. Do you review complaints for postmarket surveillance regardless of their status as MDRs or not?
- A. Absolutely. We -- we had filed -- so -- so within that particular item related to the -- the 483, we had actually had all of those complaints. We looked and the particular auditor had a different viewpoint on filing and there is some differences, not only within interpretation of the regulations, but different medical device manufacturers will report things in different ways.
- Q. Okay. Have -- had you already included those complaints -- whether reported as MDRs or not, have they already been reported in your risk analysis for the product?
- A. Yes, they are also part of our complaint system. They were part of things that we analyzed. It was just not something that was submitted and filed with the FDA.
- 25 Q. And -- and -- and did your risk analysis

- change because some then were reported to the FDA as MDRs?
 - A. No, it's not -- when we do our analysis, it's not related specifically to that MDR versus not MDR.
 - Q. And had you noticed anything unusual in complaint reporting patterns that created any kind of alert to you about concerns about your surgical mesh products or specifically the C-Qur products?
 - A. No.

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- Q. Mr. Orent asked you if you were covered by some of the group insurance plans. Do you recall that?
- 12 A. Yes, I do.
 - Q. Is there a reason why an organization would try to get coverage -- group insurance on the largest scale possible?
- 16 A. Yeah, it -- it's less expensive typically.
- Q. Would you explain again what your role is as
 the managing director -- I think I'm -- I may be
 misstating your title, so correct me if I'm wrong, but
 would you explain your role again as the director of
 Vascular Products?
 - A. You mean in my history?
- Q. No, just describe what your responsibilities are, please.
- 25 A. Oh, from -- as managing director of Vascular

- Systems. So I oversee the -- you know, the design, 1
- 2 development, production of not only the Atrium, but also
- look to the -- from a marketing perspective and the 3
- 4 strategic side, the three- to five-year plan for all the
- vascular products.
- And I oversee La Ciotat, where those vascular 6 7 products are manufactured as well.
- And is it a product line responsibility or is 8 Ο. it -- is it primarily a product line responsibility or 9 is it a site responsibility? 10
- 11 So primarily it's a product line 12 responsibility overseeing those. I mean, I do have the 13 managing director of La Ciotat who reports in to me.
- 14 Do they make any products other than vascular Q. products? 15
- 16 No, they do not. Α.
- 17 0. So you -- but you also -- vascular -- you said also the vascular products were made by another entity, 18
- 19 right?
- 20 Cardiovascular LLC -- Maquet Cardiovascular 21
- LLC down in Wayne, New Jersey, yes.
- 22 Ο. Do they make -- do they make other products?
- 23 They make many other products, yes. Α.
- 24 Do you have any responsibility for them, other Q. 25 than for the vascular products?

1 No, I do not, and I do not oversee any of the Α. individuals there. 2 3 So when Getinge AB undertook to indemnify you, 0. 4 was that in part because of your role for this product line? 5 Yes. It extended to multiple entities, yup. 6 7 Ο. Can we pull up Exhibit 122 for a minute? Maybe more than a minute, but let's pull up 122. 8 9 Are you familiar with this document? I was not --10 Α. Can we blow it up a little bit? 11 Ο. 12 Are you familiar with this document? 13 Α. I was not familiar with it prior to -- to this 14 litigation, no. 15 16 17 18 19 Is Atrium Medical Corporation a party to this 0. 20 agreement? 21 Α. No, it is not. To your knowledge, does Atrium Medical 22 Q. 23 Corporation have any ability to enforce this agreement 24 or to go to Getinge AB and do anything with respect to 25 this agreement?

1 Α. No. 2 3 4 5 6 7 8 9 10 Q. Has Getinge AB ever agreed with Atrium AB that it's going to indemnify you, Atrium AB, for the -- I 11 12 mean Getinge. Has Getinge AB ever agreed that it's 13 going to indemnify Atrium for these liabilities in this 14 litigation? 15 Α. No. 16 Ο. Mr. Orent asked you about the fact that your 17 employment agreement is with Getinge Group. That's not 18 technically a legal -- you don't disagree that it's not 19 a legal entity? 20 Α. No, I don't disagree with that. 21 Q. You get a paycheck every -- periodically? 22 I have learned that agreements are much more 23

about trusting the person and interacting with a person

that you're involved with there for employment

24

25

agreements. So --

- 1 Q. How often do you get a paycheck?
- 2 A. I get a paycheck, I believe, every two weeks.
- 3 Q. And who issues that paycheck?
- 4 A. Atrium Medical Corporation.
- Q. And what is your understanding of who your employer is?
- 7 A. Atrium Medical Corporation.
- 8 Q. Are there occasions -- you're pretty busy in 9 your work, aren't you?
- 10 A. I am, and being here for three days has taken
 11 me away from a lot of that, yes.
- Q. And all of your managing directors and your direct reports are pretty busy, right?
- 14 A. Yes, they are.
- Q. Is it -- is it not necessarily ideal, but is it unusual where transactions get ahead of the
- 17 | paperwork?
- 18 A. It -- it happens more frequently than I would
 19 like. But, yes, it happens frequently, yeah.
- Q. And when you do create a contract that represents a transaction that's been going on for a while --
- 23 A. Uh-huh.
- Q. -- and that contract references an effective date, what is the effective date?

1 A. The effective date is when that contract 2 states.

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- Q. Or does it -- does the effective -- when the activities predate the actual creation of the paper contract, what does the effective date represent?
 - A. It is the date that those activities started.
- Q. And when you sign it, do you sign it as of the effective date or do you sign it on the date that you actually sign it?
- 10 A. I always sign on the date that I am signing.
 11 I never backdate.
- Q. What is your understanding of what backdating means?
 - A. Backdating is when you actually write down a date of a prior date than the day that you're actually signing something. And that is an extreme no-no in our business.
 - Q. In any of the documents that you've seen while you've been here these past three days, have you seen any documents that were backdated?
 - A. No, they were not backdated. They took -- they were signed after the effective date.
- Q. Can we put up Exhibit 174, please, Plaintiff's Exhibit 174.
- This was the email about the Basell resin; is

```
1
    that correct?
2
              I was not shown this earlier portion, so I --
3
             Can we scroll to the part that the witness was
         Ο.
4
    shown?
5
              Jon, do you remember what page it was?
              MR. ORENT: I believe it's page 4.
 6
7
              MS. ARMSTRONG: Page 4.
              MR. ORENT: 4, I believe. It's the next page.
8
    There it is.
9
             Okay. Is this what you were shown by
10
         Q.
    Mr. Orent?
11
12
         Α.
             Yes, it was.
13
         Q.
             Has Atrium done its own testing to determine
    the appropriate materials to use in its products?
14
15
         A. Yes, just -- that is one of the key things
16
    that we do when we're selecting suppliers, and we will
17
    do our testing on the different materials that we
18
    receive.
19
              And did Atrium satisfy itself that the resin
         Q.
20
    that it was using was the appropriate resin to be used?
21
         Α.
              Yes, we did.
22
         Q.
              And that was done by Atrium or by Getinge AB?
23
              That was done by Atrium.
         Α.
24
              Okay. You can put this document away.
         Q.
```

Is Atrium part of Acute Care Therapies?

- A. Atrium is, yeah, one of the businesses that are within Acute Care Therapies.
 - Q. You explained that to us yesterday.
- 4 A. Yup.

- Q. Does Acute Care Therapies have officers?
- A. It -- it does. It has a president. It also has a chief marketing officer, technology officer, and chief operating officer.
- 9 Q. Are those officers -- Acute Care Therapies is 10 not a legal entity, correct?
- 11 A. Correct.
- Q. Are those officers employed by other legal entities within the Getinge group of companies?
- 14 A. Yes, they are.
- 15 Q. Are they -- are those officers employed by 16 Getinge AB?
- A. Not to my knowledge, no.
- Q. The org charts that Mr. Orent showed you, are those consistent with the fact that there's this layer of Acute Care Therapies?
- 21 A. The org chart that he showed, no.
- 22 Q. Okay.
- 23 | A. I mean -- wait.
- Q. Did he show you org charts that showed other people above Atrium on the org charts?

- 1 Α. Yes.
- Were they generally officers of Acute Care 2 Ο. Therapies? 3
- 4 Α. He showed a couple of different charts. The -- Jens is the -- he was an officer; Ajey was an officer. The other individuals that they stated were 6 7 not officers of ACT, to my knowledge.
 - 0. Okay.

10

11

12

14

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16

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22

23

24

- Α. Yup.
- Okay. But does anything on the org charts 0. that he showed you change anything that you testified to yesterday about who manages and directs the day-to-day operations of the company? 13
 - Α. Not at all.
 - And, in fact, yesterday you explained -- would Q. you explain -- I think you told us about the reporting structure for regulatory. Would you -- regulatory and quality. Would you explain that again?
 - So we have a director of quality who reports Α. in to John Costello, who is the vice-president of corporate compliance and -- sorry, corporate quality and compliance.
 - And then you have a senior manager on-site who reports up to the director of regulatory and -- the director of regulatory in Maquet Cardiovascular LLC.

- O. And tell us again when that structure came 1 2 into play?
- Α. So that structure came into place essentially -- it was prior to my taking over as president, but it occurred after the consent decree in the roughly late 2015, early 2016 time frame. 6
 - Ο. And -- and why is that structure created?
 - Α. So part of it was as the consent decree, but it also provided greater oversight.
 - But in terms of the day-to-day operations that Q. you described managing -- reporting MDRs to the FDA, preparing 510(k) applications to the FDA, how were those managed by Atrium?
- 14 That's still managed internally locally at Α. Atrium. 15
 - And is anything in the org charts that Ο. Mr. Orent showed you today inconsistent with what you testified to yesterday about the regulatory structure?
 - No, not at all. Α.

4

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18

- 20 Q. Can we put up 1 -- Plaintiff's Exhibit 184, 21 the consent decree.
- 22 This is the consent decree, correct?
- 23 Α. Yes, it is, to my knowledge.
- 24 Is Getinge AB a party to this consent decree? Q.
- 25 Α. Getinge AB, no, it is not.

- There are -- there are four corporate 1 Q. 2 defendants, correct?
 - Α. Yes, there are.
- 4 Q. So there's Atrium Medical Corporation, Maquet Holding BV and Company KG, Maquet Cardiovascular LLC and Maguet Cardiopulmonary AG; is that correct? 6
 - Α. Yes, it is.

7

- 0. Can we turn to page 5, please, paragraph 5A. 8 Actually, paragraph -- let's look at paragraph 5. 9
- 10 It says: Except as provided in paragraphs 6 11 and 11, defendants and each and all of their directors, 12 officers, et cetera -- and it goes on to list some 13 responsibilities for defendants, correct?
- 14 Yes, it does. Α.
- And Atrium was a defendant to this consent 15 Ο. 16 decree, correct?
- 17 Α. Yes, it was.
- 18 And does Atrium have responsibilities pursuant Q. 19 to this consent decree?
- 20 Α. Yes, it very much does.
- 0. Now, I think Mr. Orent suggested to you that 22 by use of the term defendants here, the FDA intended 23 that all of the defendants would be responsible for all 2.4 of these activities at all of the sites covered by the 25 consent decree. Is that consistent with your

1 understanding? I -- as I said to you earlier, I think Atrium 2 is a defendant and it's responsible for its entity. 3 4 Q. Well, for example, do you think the FDA 5 intended Atrium to be responsible for the design of products in Rastatt, Germany? 6 7 Α. No, it did not. Do you think that's what it intended by the 8 0. word defendants? No, it did not. 10 Α. 11 Do you think it intended Atrium to be 0. 12 responsible for Atrium's activities? 1.3 Α. Yes, it did. 14 Did the Atrium -- did the FDA insist that Q. 15 there be a -- because there were multiple sites 16 involved, did the FDA insist there be an individual or 17 individuals named in the complaint that would have overall oversight responsibility? 18 19 Α. Yes. 20 MR. ORENT: Objection, personal knowledge. 21 Ο. Do you have personal knowledge of the consent 22 decree and how it's been implemented? 23 I do. Α. 2.4 Q. Okay.

THE COURT: Okay. Overruled.

- 1 A. I have -- would you like me to elaborate?
- 2 Q. So I just want -- no, you don't have to.
- 3 A. Okay.

5

- Q. Did the -- the FDA insist that there be an individual or individuals that have to have oversight responsibility because there were multiple sites?
- 7 A. Yes.
- Q. Okay. And were -- did those individual or individuals delegate responsibility to you for the Atrium sites?
- 11 A. Did they delegate to me for -- repeat that 12 question. I'm sorry.
- Q. Okay. Did those individuals -- were you delegated responsibility for the Atrium sites?
- 15 A. Yes.
- Q. And was that consistent with the consent decree?
- 18 A. Yes, it is.
- Q. Was it consistent with the federal regulations governing the medical device manufacturers?
- 21 A. Yes.
- 22 Q. And I think we saw yesterday that you were 23 named the managing director of the Atrium sites with 24 full executive authority.
- 25 A. Correct.

```
Q. Can we pull up Exhibit 166. I'm sorry,
1
2
    Exhibit 66. I apologize.
              That's not it. The Exhibit 66 that was used
3
4
    by Mr. Orcutt (sic) just now. It's Defendant's Exhibit
    66.
5
              What is this document?
7
              This is the distributor agreement between
    Atrium Medical, Maquet Cardiovascular LLC, and Getinge
8
9
    USA Sales.
10
             Okay. Now, this has three entities in it,
         Ο.
    correct?
11
12
         Α.
             Yes, it does.
13
         Q.
              And you're familiar with this structure and
14
    this distribution arrangement, correct?
15
         Α.
             Yes, I am.
16
              Now, if we substituted -- now, yesterday I was
         Ο.
17
    asking you questions that were limited to 2014 through
    2017, correct?
18
19
             Uh-huh.
         Α.
20
         Ο.
              If we substituted Getinge USA Sales for Maquet
21
    Cardiovascular US -- USA Sales in that chart, would that
    be the current structure?
22
```

And that's your understanding of how the

23

24

25

Α.

0.

structure is?

That is, yes.

- A. Yeah. And I -- as I stated, if an agreement doesn't fully outline it, I know how the structure actually works.
 - Q. Okay. And is it your understanding that prior to Getinge USA Sales that point in the chart was occupied by Maquet Cardiovascular USA Sales?
- 7 A. Yes.

- Q. Now, you said you spoke to Gary Sufat about that. Do you have a general understanding of how the distribution works?
- 11 A. Yes, I know where my products go. I know the 12 bases and where we ship them, yes.
- Q. As the president of the company, you have a general understanding of this?
- 15 A. Yes.
- 16 Q. Why did you speak to Mr. Sufat?
- A. I wanted to just get a greater understanding

 of the -- the financial transactions going back and

 forth. I -- I had the general overview and I wanted to

 make sure that I was correct with -- with my statements.
- Q. Are you aware that Mr. Sufat has given an affidavit in this litigation?
- 23 A. I am aware, yes.
- Q. Can we put up Mr. Sufat's affidavit?

 And if we look at paragraph 9, please, it

```
1
    says: Since January 1, 2014, Atrium has transferred its
2
    products to Maquet Cardiovascular LLC, a distribution
    center, at standard cost. Maquet -- MCV LLC is an
3
4
    indirect wholly owned subsidiary of Getinge AB.
5
              Have I read that correctly?
              Yes, you have.
 6
         Α.
7
         Ο.
              Is that consistent with your understanding?
         Α.
              That is my understanding, yes.
8
              Have you heard any testimony from a fact
9
         Q.
10
    witness in either the depositions that were played or
11
    any other -- any fact witness testimony in this
12
    litigation -- not Mr. Messina's, but any fact witness
13
    testimony in this litigation that contradicts
14
    Mr. Sufat's testimony?
15
         Α.
              No.
16
         Ο.
             And he would know?
17
         Α.
              Yes.
18
              Let's look at paragraph 10.
         Q.
19
              From January 1, 2014, through September 30th,
    2017, MCV LLC then sold --
20
21
              MR. ORENT: Your Honor, I'd like to object
    that this is hearsay. This is an available witness.
22
23
              THE COURT: I'm going to overrule --
2.4
              MS. ARMSTRONG: It's redirect, your Honor.
                                                            Не
```

was crossed about this.

Q. From January 1st, 2014, through September 30, 1 2 2017, MCV LLC then sold to Atrium products at a markup to Maquet Cardiovascular US Sales LLC, MCV US Sales, 3 4 at -- a sales entity. MCV US Sales is an indirect 5 wholly owned subsidiary of Getinge AB. Have I read that correctly? 6 7 Α. Yes, you have. And are you aware of any facts that have been 8 0. presented in this -- in this hearing that contradict 9 this? 10 11 No, it's consistent with what I discussed 12 with -- with Gary, yes. 13 Q. And is it consistent with your general understanding as the president of the company? 14 15 Α. Yes. 16 Paragraph 11: From October 1 through 2017, 0. 17 MCV LLC then sold the Atrium products at a markup to 18 Getinge USA Sales LLC, a sales entity. Getinge USA 19 Sales LLC is an indirect wholly owned subsidiary of 20 Getinge AB. 21 Have I read that correctly? 22

- Yes, you have. Α.
- 23 And, again, is that consistent your with Q. 24 understanding as the president of the company?
- 25 Α. Yes, it is.

And have you heard anything in the hearing so 1 Q. far that contradicts Mr. Sufat's personal knowledge of 2 3 this? 4 Α. No, nothing. Q. And then in paragraph 12, it says: The distribution center MCV LLC earns approximately half of 6 7 the margin and the sales entity MCV US Sales, now 8 Getinge USA Sales LLC instead of MCV US Sales, earns approximately half the margin. 10 Have I read that correctly? 11 Α. Yes, you have. 12 And, again, is that consistent with your Q. 13 general understanding as the president of the company? 14 Yes, it is. Α. 15 And have you heard anything that contradicts 0. 16 that in this hearing? 17 Α. No, I have not. 18 And is it consistent with the chart you Q. 19 presented the other day? 20 Α. Yes, it is. 21 MS. ARMSTRONG: Your Honor, that's all I have. 22 THE COURT: All right. Excellent. 23 MR. ORENT: Can we have that for a moment?

MS. ARMSTRONG: The affidavit?

MR. ORENT: Yeah, the affidavit.

2.4

```
1
              MS. ARMSTRONG: Sure.
2
              MR. ORENT: Okay.
              THE COURT: Is Mr. Carlton free to leave?
3
 4
                       RECROSS-EXAMINATION
5
    BY MR. ORENT:
              Just on that one point, if we could zoom in on
 6
7
    that same paragraph there. I believe it was paragraph
    15.
8
              MR. GLASSER: 12.
              MR. ORENT: 12. Sorry.
10
11
             Mr. Carlton, the distribution center, MCV LLC,
         Ο.
12
    earns approximately half of the margin, right? That's
13
    what that says, right? And the sales entity, MCV US
14
    Sales, earns approximately half the margin.
15
              That does not say that Atrium gets half the
16
    margin, does it?
17
         Α.
              The distribution center earns half of the
18
    margin and the sales entity earns approximately half the
19
    margin.
20
              Can I see the rest of the piece, because
21
    that's --
22
              If you go down, number 14: Margin returned to
         0.
23
    Atrium is reflected in the profit and loss statement.
24
              Right. So -- so then the margin is returned
         Α.
25
    through Maquet.
```

- So if you read 13, 13 says: The margin earned by the distribution center, MCV LLC, is returned to Atrium on a monthly basis.
 - Q. You're aware of the profit and loss statements in this case, correct?
 - A. Yes.

7

8

- Q. How do you explain how the cost of goods sold exceeds the sale price?
- The -- the -- the transaction that is taking 9 Α. place is that we are selling from Atrium to Maquet 10 11 Cardiovascular at what is known as standard cost 12 initially. So that standard cost has some fluctuations 13 and particularly in those years that we've looked at, 14 there have been extraordinary circumstances where our 15 costs at the -- what we estimated for the cost at the 16 beginning of the year versus the costs that have 17 occurred during the course of the year have been much 18 higher. And there were multiple reasons and I can go 19 into those for each year, if you'd like.
 - MR. ORENT: Thank you.
- No further questions.
- 22 THE COURT: All right. Done with this witness
- 23 | then?

- MS. ARMSTRONG: Yes, your Honor.
- 25 THE COURT: All right. Mr. Carlton, you are

```
1
    free to go.
                        (Witness excused.)
2
3
              THE COURT: And you may call your next
4
    witness.
5
              MR. CHEFFO: Thank you.
 6
              THE COURT: Thank you.
7
              THE WITNESS: I'm not sure what to do with
    this.
8
9
              THE COURT: I would hand that back to Counsel.
10
              He has a couple of exhibits.
11
              MS. ARMSTRONG: Your Honor, if I may approach,
12
    I'll grab the exhibits.
13
              MR. CHEFFO: We're going to call, your
14
    Honor -- we're going to call Mr. Alex Fernandez, your
15
    Honor, and just for the -- you may recall, Mr. Fernandez
16
    and then Professor Orcutt and then I think that'll be
    our witnesses.
17
18
              THE COURT: So Mr. Fernandez will go first?
19
              MR. CHEFFO: Yes, your Honor.
20
              THE COURT: He is the gentlemen for whom there
21
    is a sealed portion?
22
              MR. CHEFFO: There is, and I -- we're going to
23
    try to not seal it --
24
              THE COURT: Okay.
25
              MR. CHEFFO: -- but I --
```

```
1
              THE COURT: Excellent.
              MR. CHEFFO: But thank you for being
2
3
    considerate about that. We're trying to do it at a high
4
    enough level that it doesn't really implicate these
    issues.
5
              THE COURT: Okay.
 6
7
              MR. ORENT: Your Honor, at this point, a
    housekeeping item.
8
9
              As the parties have planned to do these
    closing presentations this afternoon, Mr. Glasser's
10
11
    going to be handling the final witnesses. I'd like to
12
    be excused to prepare that argument.
1.3
              THE COURT: That's fine.
14
              Do you have any objection?
15
              MR. CHEFFO: No, of course not, your Honor.
16
    As much as I love Mr. Orcutt -- Orcutt -- Mr. Orent --
17
              MR. ORENT: You know, everybody does that to
18
    me.
19
              MR. CHEFFO: -- I'm -- professor -- you're not
20
    the professor yet.
21
              My only question, while we're talking about
22
    this, we have talked about it and obviously to the
23
    extent that the Court would find closings helpful,
24
    certainly we're happy to do that. And we also think
25
    what might be helpful is some type of posthearing
```

```
submission -- again, not a hundred pages, but, you know,
1
2
    something within a reasonable period of time to tie some
    of it together.
3
 4
              I -- I think we've both been -- both sides
    have been very optimistic about -- you know, and there's
    no fault; I've done it, too. I think I told them
 6
7
    yesterday I was going to be an hour and it took longer.
    I think, you know, Mr. Orent thought it would be 45
8
    minutes and obviously it took a little longer.
9
10
              So I'm only raising this because by the time
11
    we get through here, you know, I'm not sure I'm going
12
    to -- maybe I'll finish, hopefully, by around
1.3
    lunchtime --
14
              THE COURT: We'll break at noon.
15
              MR. CHEFFO: Right. So I'm not sure I'll be
16
    done exactly then and then obviously they'll have some
17
    questions and then we'll have, you know, Professor
18
    Orcutt, you know.
19
20
```

So to the extent, obviously, we have time and your Honor has the inclination to hear some -- you know, some 20, 30 minutes of closings each, obviously we'd be happy to do that, but in lieu of that, we certainly can submit or even in addition to that.

21

22

23

24

25

So that all -- obviously whatever your Honor thinks is best.

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1
              THE COURT: Okay. We'll cross that bridge
    when we get there this afternoon. And I'm happy to hear
2
    arguments if counsel would like if we have time.
3
4
              MR. CHEFFO: Great.
5
              MR. ORENT: Thank you, your Honor.
              THE COURT: All right.
 6
7
              THE CLERK: Mr. Fernandez, would you please
    rise and raise your right hand.
8
9
              ALEX FERNANDEZ, having been first duly sworn,
    testified as follows:
10
11
              THE CLERK: Thank you. Please state your full
12
    name and spell your last name for the record.
1.3
              THE WITNESS: Alex Fernandez,
14
    F-e-r-n-a-n-d-e-z.
15
              THE CLERK: Thank you very much. Please be
16
    seated.
17
                        DIRECT EXAMINATION
    BY MR. CHEFFO:
18
19
              It's still morning, Mr. Fernandez. Good
         Q.
20
    morning.
21
         Α.
             Good morning.
22
              Were you asked to prepare a report in
         Q.
23
    connection with this litigation?
24
             Yes, I was.
         Α.
25
         Q.
             And would you please tell the Court what --
```

- the general scope of what you were asked to do in terms of what you were asked to address?
 - A. I was asked to address the solvency of the company as well as the company's ability to meet its operating needs and its obligations.
 - Q. And did you work with us and ask us to assist you in preparing some slides that would assist and facilitate your testimony here today?
 - A. I did.

- Q. So one of those slides, in order to try and move this along, we've prepared a summary of your professional experience and education. Would you be good enough to just explain for the Court and take the Court through some of your experience and education.
- A. Certainly. I have a bachelor's degree in accounting from the University of Florida, minor studies in economics.

I spent the first five years of my career with Coopers & Lybrand, where I had the responsibilities of performing multiple audits of multinational corporations, including addressing their ability to continue as a going concern in each and every case.

I then spent the next approximately five years with Deloitte, where I ran -- I was a manager of their litigation service group, which primarily focused on

- 1 evaluations and due diligence work as well as
- 2 investigative audits and assessment of damages.
- 3 Subsequent to that, I started what is now AFC
- 4 Group. I'm the managing director. It's a specialized
- 5 | firm that focuses on those services as I was performing
- 6 | at Deloitte.
- 7 I'm a certified public accountant. Obviously
- 8 you need to be that in order to be able to opine on the
- 9 fair value of financial statements with these firms.
- In addition to that, I'm also a certified
- 11 | fraud examiner, which is a certain level of experience
- 12 | and education and continuing education relating to the
- 13 | identification of fraud.
- And I'm a certified valuation analyst, which
- 15 | focuses on the valuation of companies and allows you to
- 16 | issue certified valuation reports on companies.
- Q. All right. Are the types of issues, albeit a
- 18 | narrow issue, that you've been asked to render an
- 19 opinion on here today consistent with your professional
- 20 | training, your work experience, and your education?
- 21 A. Yes, they are.
- 22 Q. Is this the first time you've testified in
- 23 | court?
- A. No, it is not.
- 25 Q. Would you give us just a general overview of

- the types of cases that you've testified in and some of
 the -- the clients, the government entities that you've
 testified on behalf of?

 A. Certainly. I've been retained by the federal
 - A. Certainly. I've been retained by the federal government, U.S. Government, U.S. Attorney's Office, been retained by the SEC, FDIC, RTC. I was the expert for the Committee of Commerce in the review of financial institutions during the financial institution crisis.

I have been retained by foreign governments to review complex financial transactions. I've been also retained by multiple multinational companies in performing either investigative audits, valuation work, or doing assessment of damages in litigation.

- Q. We don't need to run through all of them, but is it fair to say that in addition to what we've talked about, you've also been a member of several professional associations and affiliations?
 - A. Yes, I have.
- MR. CHEFFO: Your Honor, I'd move
- 20 Mr. Fernandez as an expert in solvency and accounting.
- 21 MR. GLASSER: No -- no objection.
- 22 THE COURT: All right. Motion granted.
- MR. CHEFFO: Thank you, your Honor.
- Q. You are being compensated for your time?
- 25 A. Yes, I am.

6

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- 1 Q. And what is your hourly rate?
- 2 A. It's 475 an hour.
- Q. And prior to your work in this case, have you ever done work for Atrium Medical?
 - A. No, I have not.
- 6 Q. Have you ever worked with me before?
- 7 A. No, I have not.
 - Q. Have you ever worked with Getinge AB?
- 9 A. No, sir.
- 10 Q. Any Getinge-related company or entity?
- 11 A. No, sir.
- Q. And am I correct you have no financial interest or affiliation with any of the Getinge group of
- 14 | companies?
- 15 A. That is correct.
- Q. Now, before we get into the details, would you provide just a brief summary of your opinion in this
- 18 case?

- 19 A. I have concluded that as of December 31, 2017,
- 20 | that Atrium was, in fact, solvent. It had adequate
- 21 | capital, it had sufficient liquidity to meet its
- 22 operating needs and its obligations. That held true for
- 23 | 2015 and 2016 as well.
- Q. Now, let's talk a little bit about some basic
- 25 accounting principles that are, you know, commonplace to

1 you, but may not be commonplace to many of us who are 2 not CPAs.

But what are the types of general accounting principles that are used by businesses? What are they called?

A. Clearly in the United States we're obligated to report under general accepted accounting principles that provides uniformity in the way companies report and classify assets in their financial statements.

Internationally, they use the -- very comparable rules, a set of rules that are referred to as International Financial Reporting Standards.

There's a lot of overlap where they are similar, if not identical, but there are some distinct differences as well.

- Q. And is one of the -- one of the goals of these rules to try and have some uniformity about how -- how financials are recorded and interpreted?
- A. Certainly. You know, if not, you would have the wild west out there in how people report revenues, report expenses, you know, how they treat their balance sheet and income statements. So it -- it provides a standardized methodology and a process from which to report.
 - Q. Is it fair to say you're very familiar with

1 | these rules?

standards.

- 2 A. Yes, I am.
- Q. And they're essentially your stock-in-trade;
 they're the way you have been operating when you've been
 an accountant?
- A. Certainly. As a CPA, when you issue an opinion, you're basically attesting to the fact that the financial statements are presented fairly in conformity with either domestic standards or international
- 11 Q. Now, Getinge AB, you know, is a foreign 12 company, a Swedish company, correct?
- 13 A. That's correct.
- Q. What -- what are the standards that govern 6. Getinge?
- 16 A. They're required to report under international financial reporting standards.
- Q. And for your benefit and the Court's benefit,

 I may not say Getinge AB all the time, but that's what
- 20 I'm going to be referring to when I say Getinge. Okay,
- 21 Mr. Fernandez?
- 22 A. That's okay.
- Q. Now, what types of accounting standards apply,
- 24 | if any, to Atrium?
- 25 A. Well, Atrium does not issue a separate

- financial statement, so they're not obligated to report
 under either GAAP or International Standards. Their
 reports are prepared for internal consumption, to assist
 management in the running of the company as well as to
 assist the shareholders, owners of the company, in
 gauging the performance of the company.
 - Q. So is that -- would it be different if they were a listed company on NASDAQ or the Stock Exchange?
 - A. Well, they can maintain their statements for internal purposes the way they do, but once they issue a formal report, it would be presented in accordance with those standards.
- Q. And because they're not, they don't have to follow those, the GAAP standards?
 - A. That's correct.

- Q. Now, what is a consolidated financial statement?
- A. Again, if you have a parent company with multiple subsidiaries, they are, in fact, required to consolidate those subsidiaries into one financial statement, one income statement, one balance sheet, one cash flow statement, one set of footnote disclosures.
- Q. So the IFRS, which -- by which -- which binds Getinge AB, requires Getinge AB to compile consolidated financials; is that right?

- A. That's correct. Any wholly owned subsidiary or subsidiary where they have a -- control is defined by the regulations would need to be consolidated and rolled into their financials.
- Q. But you know, and we've seen throughout the last few days and more so in the discovery, that Atrium does maintain financial records, correct?
 - A. They certainly do.

1.3

2.0

2.4

- Q. And why do they do that?
- A. As a separate entity, they need to be able to measure -- first of all, they need to have the tools to be able to manage the company. Financial statements provide that tool to the managers. The owners of the company need to have a way to measure their performance. So it's necessary from multiple standpoints.
- Q. Now, do -- because Atrium doesn't -- is not required to follow GAAP and uses its -- its financials for internal purposes, does that mean that they're somewhat inaccurate or improper or -- or somehow not useful?
- 21 A. Not at all.
 - Q. And in connection with your work and your evaluation and your deep dive into some of these financial issues, have you found any issues that lead you to believe that the Atrium financial statements are

1 not reliable or inaccurate? 2 Α. No, I have not. 3 Ο. And that's not a basis of your testimony here 4 today, is it? I'm sorry? Α. That -- that -- that's not part of your Ο. 7 opinion or your testimony today, correct? While I did not perform an independent audit Α. 8 of the statements, I have no reason to believe that the 10 numbers were not fairly presented. I perhaps took 11 issues with a couple of classifications just for 12 purposes of determining solvency, but that's more of a 13 tool than it is a result of the way they managed their internal records. 14 15 In determining solvency -- and we'll talk a 16 little bit about this later, but in determining 17 solvency, you -- you found it was important to apply the GAAP standards, correct? 18 19 There's -- there's certain measurements --Α. 20 there are certain measurements --21 MR. GLASSER: Now that we're getting into the 22 opinion, I'd object to leading, like to the exact 23 opinion. 24 THE COURT: Okay.

MR. CHEFFO: I'll try and do better, your

1 Honor. THE COURT: Okay. Go ahead. 2 In connection with your -- your -- your 3 Ο. 4 analysis and your opinion with respect to solvency, how, if at all, did GAAP come into play? Well, to the extent that, you know, 30 7 years -- 38 years of applying and analyzing financial statements, I'm used to seeing them represented in 8 accordance with GAAP. I usually try to get them to that 9 same standard in order to be able to properly analyze 10 11 them. 12 But more specifically, when you're looking at 13 specific items such as gross profits and gross margins 14 and current ratios, you want to make sure that you're 15 considering the right accounts for those measurements 16 tools. 17 Ο. Okay. Now, Getinge AB's financial statements 18 are audited, correct? 19 Yes, they are. Α. 20 Q. Do you know who audits them? 21 Α. I believe PricewaterhouseCoopers is their

- 22 auditors.
 - A large, very prominent organization, right? Q.
 - One of the final fours. Α.

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25 Q. And are Atrium's financial statements audited, to the extent that you know?

- A. Well, they would be subjected to the same procedures as the parent company. They're not audited on a separate company basis, but they are subjected to audit procedures based on the parent company's audit.
 - Q. Okay. Thank you.

Now, as a general matter, what is solvency?

- A. In the most general way to look at it, solvency is when you have assets in excess of liabilities. That's generally the first thing that you look at.
- However, you also want to go beyond that and look at the company's ability to meet its current operating needs as far as do they have sufficient liquidity to meet those operating needs and that they can meet their financial obligations as well. And normally we use the term foreseeable period, but that's usually defined as within the next 12 months.
 - Q. Okay. And what is adequate capitalization?
- A. Again, it goes part and parcel with the entity's ability to meet its operating needs; does the entity has sufficient capital to meet its operating needs and its obligations.
- Q. And when you are undertaking the task or the assignment of evaluating a company's solvency, how do

you go about doing that?

A. You start off by going and doing an analytical review of the financial statements, look at the income statement, analyze the income statement, try to identify what the key metrics are, whether the company is a net contributor to capital in each and every year or whether they're actually drawing on capital as a result of operating losses. If there are operating losses to be considered, you want to find out why they're losing money; is this a recurring issue, is this a nonrecurring issue.

So you want to be able to do a -- a very close look at the income statement as well as the balance sheet, which will tell you the assets that are available that may be convertible into cash, the liabilities that are going to become due over the next 12 months, does the company have the ability to meet those obligations.

- Q. Okay. And we'll talk a little more about it, but in addition to looking at -- at the documents, the balance sheet, the income statement, did you also -- in connection with your assignment in this case, did you speak with anyone? Did you look at any other materials?
- A. Well, certainly. It's not enough to read the statements. You have to have an understanding of how the different accounts are presented, what's captured

within the individual accounts, what is the substance of that account, and how would you consider that in a solvency analysis.

- So I did have interviews with both the tax director and the CFO of the company. In a multinational, you have all the transfer pricing issues, which are primarily tax-related issues or regulated by the tax bodies, I should say. So you have to have an understanding of how that -- how those transfer pricing adjustments are being recorded and are they, in fact, a fair value as required by the taxing authorities, are they in compliance with the various authorities, whether it's European authorities, UK authorities, U.S. authorities.
 - Q. Particularly with a company that's a subsidiary that is not required to follow the GAAP rules, that's not audited, is there anything untoward or improper or nefarious about actually talking to the CFO, the head of tax, and the CEO in order to just understand how the business operates and how the policies and procedures are being implemented?
 - A. I don't see how you can do that without those discussions.
 - Q. And do you believe that the information that you were provided and that you reviewed was sufficient

to enable you to assess Atrium's solvency and capitalization through December 31st, 2017?

A. Certainly.

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- Q. And would you give the Court just a general overview or as much as you need to to explain what steps you took in order to determine whether the company was solvent up to December 31st, 2017.
- A. I started by analyzing the income statement.

 I was trying to make two basic determinations from reviewing the income statement; does the company generate a profit from the sale of the units that it is manufacturing, a gross profit, and does the company generate an operating -- operating income or an operating loss from the total results from operation.

If the company is reflecting a loss or reflecting a negative number in any of those categories, then you want to make sure you understand why it is reflecting that negative number and that's where the inquiries and the consultations are important.

- Q. And that's what you were talking about earlier. To the extent that you have a question about either a positive or a negative number that may need some explanation, that's when you would talk to some of the professionals?
 - A. Each one of those observations may require you

1 to dig deeper. You know, you don't necessarily accept
2 it at face value. You want to know why.

So, for example, if a company is reflecting a negative gross profit number, you want to understand why. If the company's losing money every time it sells a product, the more they sell, the more they're going to lose, that's obviously a critical concern in a solvency analysis.

If the company's net result, its net income, is a negative number, obviously you want to make sure that the company has sufficient capital to absorb those losses for a foreseeable period or until the point that they can actually turn that around.

- Q. And, similarly, you don't -- am I correct you don't take at face value something that somebody tells you from the company if it's inconsistent with your professional experience or documentary evidence, right?
- A. Well, certainly. I mean, you go in there with your understanding of how it's supposed to be done, how the companies typically do it, and that's the way you pursue your discussions.
- Q. Now, you indicated that you reviewed Atrium's income statements for 2015 to 2017, right?
 - A. That's correct.
 - Q. And would you just explain for us what an

income statement is?

- A. The income statement in this case is capturing all the transactional data of the company for the prior 12 months, so from December -- the 12 months prior to December 31, 2017, 2016, and 2015. It ends up being a scorecard of how it performed that year. It reflects the revenues that they realized, the expenses that they incurred, and any unusual or nonrecurring items that should be further considered.
- Q. And how is -- what can you determine from an income statement and how is it a component in connection with a solvency analysis?
- A. Well, again, that's -- part of your task is to determine whether the company has the ability to meet its current operating needs. So, therefore, you want to know whether their performance is indicating a drawdown of capital or an augmentation of capital. And then when you look at the balance sheet, you make the determination whether that capital is there for it.

So you look at each and every year historically to try to understand what to expect over the next 12 months.

Q. Now, this is -- and I apologize to you and to the Court. These are, admittedly, some small numbers, but we tried to call out the areas that I think we'll be

- 1 focusing on. 2 Do you recognize this document? Yes. These are the internal statements that 3 Α. 4 are produced by Atrium. Q. Okay. And this is a document that you reviewed, correct? 6 7 Α. That's correct. Now, in your report, you prepared something as 8 Exhibit A. 9 So -- before we do that, so the -- the -- your 10 11 Honor, this isn't that much better, but it -- I don't --12 you know, I'm not going to go into great detail. 13 you'd like a copy at any time, obviously just let me 14 know. 15 THE COURT: Okay. 16 MR. CHEFFO: All right. Thank you. 17 Ο. So this starts '15 -- I think we'll see this 18 just from a format purpose. I was a little confused 19 initially, right, sometimes when we're used to seeing 20 things left to right, but this is '15, '16, '17 starts 21 on the right, right? 22 Α. That's correct.
 - Q. Okay. Now, I want to take a minute just to have you explain what this is and why you went about
- 25 | creating Exhibit A to your report.

- A. Well, primarily when you're dealing with a multinational company that has transactions with an affiliated company, you have transfer pricing rules that -- that they are obligated to follow in accordance to the tax instructions and according --
 - Q. Let's just stop there.

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- A. -- to the regulatory bodies.
- Q. Just briefly, when you transfer pricing, just tell us what that generally means.
- A. If two companies that are part of a group or two affiliates have companies within each other, the rules require those transactions at the end of the day be reflected at fair value. Those rules are critical because without that a company can manipulate its earnings and allocate earnings.

Many of the taxing authorities realized that this was a common tool being done about 10, 15 years ago, where multinationals would allocate costs to the high-taxing districts and revenues to the low-taxing districts so they can maximize or pay the least amount of taxes possible.

Transfer pricing rules basically came back and said, no, you have to be able to demonstrate to the authorities that those transactions are being valued at fair value. And you -- that obligation is the entity's

obligation, the reporting company's obligation.

So companies would generally have studies done, generally have agreements, generally have, you know, the -- the documentation to suffice their allocation of revenues and costs at a fair value to the taxing authorities and to the regulatory authorities.

Q. Okay. And let's just be clear about what it is Exhibit A is and what it is not.

So did you do this to manipulate any of the numbers or the -- the values in -- in the statements?

A. No, this -- this was simply done to recast the two line items that pick up the part of the sales revenues that are not reflected in the internal and external sales categories.

So to properly reflect a hundred percent of the revenues derived from the sale of the product, we needed to reclassify or to group the transfer pricing adjustments in with the sales.

- Q. So all the numbers are the same, right?
- A. The numbers are exactly the same. The net results for the company, as you can see, the \$527,000 loss in 2017, was, in fact, what they reflected on their internal. All this is is basically recharacterizing or grouping all the revenue items for the sale of the product within one group so they can properly be

measured against the cost of goods sold.

- Q. And you did that so that they would be in accordance with what you understand the GAAP regulations to be?
- A. Yeah. GAAP basically requires all your revenues to be reflected together if they're derived from the sale of the same product in the same process.
- Q. So it's all the same numbers, you only focused on two areas that you believed needed to be -- I think you said reclassified in order to make them consistent with the GAAP rules; is that what you did?
- A. Without -- without going through that process, on first blush it would appear that the company's actually losing money from the sale of the units. And that's because the company is initially recording the sale at a standard costing process from the originating entity, Atrium, to the distribution center. That does not reflect the total revenues that the company benefitted from. That revenue isn't realized until the sale is completed at the sales affiliate and then transferred back to Atrium through these two accounts through the transfer pricing adjustments.

MR. CHEFFO: Okay. May I just approach the -- that board there for a minute? I'm going to go a little bit off script.

Q. I don't know if you can even see it from back there, but just while we're on this topic, am I generally understanding -- you heard earlier that there was an initial transfer of funds at this stage, correct, when -- when basically the -- the company sent it to the distribution center, correct?

- A. The first step is Atrium sends the product to the distribution center. At that point, Atrium is recording a profit at standard cost. So it's only recording a portion of the revenues that are being derived from the sale of that profit.
- Q. So -- so -- so it wouldn't be accurate to just only look at this amount of money that the company received, right, because ultimately we saw the chain.

 Once it's actually sold to the customers, there's additional funds that get transferred up through the chain back to the company, correct?
- A. Certainly. The -- the final sales price to the end user is not determined until the sale is closed by the sales entity. So that would be your -- your third circle down. At that point, then there's a true-up, which is basically the -- a determination of here's how much money we made on the sale of the product and we're going to allocate those profits based on their internal agreements, which I believe is approximately 50

1 percent.

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- Q. Right. So if we were to just look at this transaction and say -- and pretend like this didn't exist, right, it would look like the company's getting a lot less than it ultimately is, correct?
- A. Certainly. It doesn't include the full sales that's being realized by Atrium.
 - Q. So what you tried to do was to basically capture the reality of the situation, correct?
- 10 A. Correct.
 - Q. And basically not just look at the amount of money that comes at this stage, but figure out exactly the real real-life impact, which is when there's a sale, they actually get 50 percent -- approximately 50 percent of the profits, correct?
 - A. So they're actually deriving revenues at two different stages; the first stage on transfer, the final on the -- on the sale to the end user.
- MR. GLASSER: I object to the leading. I
 think the witness should be asked a -- some questions
 that he can answer.
- THE COURT: Okay. Overruled.
- Go ahead.
- Q. Now -- excuse me, your Honor. I think I just covered some of my outline, so I'm just going to skip

1 through it.

So let's -- let me just ask you, what is -- what does this slide represent?

- A. It highlights the two accounts that are reflected within the income statement of Atrium that are part of the sales proceeds that are being derived by Atrium. So I'm basically including them at the top part of the statement so that I can properly analyze the gross profit from the sale of the units.
- Q. So when it says above the line and below the line, can you just explain what that means?
 - A. Well, above the -- the line basically is, you know, what is the gross profit that the company's making from the sale of each individual unit. So, therefore, we have to consider not only the standard cost in the first stage of revenues that they realize, but also the final sale proceeds that they share or they benefit from.

So what this does is it allows me to consider the full revenues that are being realized by the company and comparing it to the cost to manufacture those products and conclude that they are, in fact, being manufactured and sold at a profit.

Q. So -- and that's just what we talked about, right, in the sense of how the transaction actually

1 | works?

- 2 A. That's correct.
- 3 | O. And --
 - A. This is the mechanics of that chart, I quess.
 - Q. And that's -- am I correct that that's all you did in terms of using the same numbers and you just focused on that aspect of the balance sheet and then created Exhibit A?
 - A. Yeah, it would be inconsistent with generally accepted standards to analyze gross profit without analyzing all the revenues derived from the sale of the product.
 - Q. And because -- by virtue of the fact that you looked at these in the way that you did and created Exhibit A, does that mean that Atrium's books are unreliable or inaccurate or somehow should be disregarded?
 - A. No, I didn't change any of the numbers. I mean, these are their numbers. Management is well aware of what items need to be included when analyzing gross profit. I -- I had detailed discussions with their CFO regarding this and he said, of course you have to include those line items in order to analyze gross profit.
- So, no, it's -- it's just easier for me to

- reflect that calculation after I make these two
 adjustments rather than doing a separate, set-aside
 calculation.
 - Q. And you were asked to perform a solvency analysis, correct?
 - A. Correct. I mean, gross profit from the sale of your product is an important metric to look at in a solvency analysis.
 - Q. And the -- the way the books and records and financial information that's maintained by the company, that has many purposes, right?
- 12 A. That's correct.
 - Q. Now, for solvency analysis, are we concerned with gross profit?
- 15 A. Certainly.

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- Q. Would you please tell us why?
- 17 If a company can't make money, if a company 18 can't cover its costs to manufacture a product from the 19 sales price that it derives from it, then you've got an 20 issue. So you've got to -- you know, you've got to do a 21 lot more digging and understanding to find out how it is 22 that they're going to overcome that significant problem. 23 I mean, you could sell a product at a loss for a 24 short-term period of time, but you cannot indefinitely 25 sell a product at a loss.

- Q. You had an opportunity to hear Mr. Messina testify yesterday?
 - A. I did.
 - Q. And you've read his reports?
 - A. I have.

- Q. How does what you've done differ from what Mr. Messina did with respect to these issues and would you explain for the Court why you think, if you think, that his view was -- was not the right way to look at this?
- A. He ignores the transfer pricing adjustments that are reflected in green on this schedule. So he ignores a significant portion of the revenues derived from the sale of the product to conclude that the company is, in fact, losing money on the sale of each and every product. It's just an incomplete assessment.
- Q. Now, were you able to identify any nonrecurring extraordinary expenses from your review of the income statement?
- 20 A. I was.
 - Q. And why don't you just tell us, what are nonrecurring extraordinary expenses?
- A. Well, again, you're analyzing the income

 statement for purposes of trying to figure out whether

 the company's going to be using capital over the next 12

months or contributing capital. If there are items that are nonrecurring, then you can exclude that from your analysis just when you're thinking about are they likely to need capital or lose capital.

If a company is reflecting a net loss, but that net loss is the result of a nonrecurring extraordinary item, you have to consider that in your cash flow demands.

- Q. So just as an example, that might be, you know, storm damage, correct, or litigation that's a one-time deal; is that the type of thing --
- A. As long as it's determined that it is a one-time deal and not a recurring event.
 - Q. Now, based on your analysis, your discussions, your experience, your looking at all the information, your analysis of the transfer pricing issues, taking into account Mr. Messina's views and opinions, what opinion did you form from conducting your review of all of that?
 - A. Well, we would have to continue to go beyond the income statement. The income statement showed me that the company did have a drawdown in capital for the three years that I analyzed, but that a large portion of that drawdown in capital resulted from nonrecurring events. But, still, if you anticipate a drawdown in

capital, if there's sufficient resources that are reflected on the balance sheet to absorb that drawdown.

So the next step would be then to analyze what are the sources of capital, the sources of cash and liquidity available to the company as of that measurement date, December 31, 2017.

- Q. Okay. And could you just tell us what a balance sheet typically is and what this represents, slide 12, which is Plaintiff's Exhibit 31?
- A. I mean, these are the real accounts as opposed to the nominal accounts as of a specific point in time. So we are measuring the accounts of the company as of December 31, 2015, '16, and '17. It tells us what assets are convertible to cash within the next 12 months, what liabilities are likely to be paid or obligated to be paid within the next 12 months. It'll alert you to any deficiency in that calculation and to see whether there are other sources of -- of assets that can be converted into current assets or liabilities that are convertible into long-term liability that will assist you in meeting your current obligations.

And it also tells you what the net worth or the capital position of the capital -- of the company is at a specific point in time.

Q. Okay. Now, let's look at this next slide.

This is Atrium's internal balance sheet, correct?

- A. That's correct.
- Q. And how, if at all, did these balance sheets or this balance sheet factor into your analysis?
- A. Well, the first thing it tells you is if you go to the total equity number as of December 31, 2017, the company had in assets in excess of liabilities.
 - Q. Can I just stop you for a minute?
- A. Certainly.

- MR. CHEFFO: I had a little trouble. I just want the Court to -- just to orient your Honor that -- so we're pulling out, obviously, a section from this, which is line 21-10.
 - Q. I'm sorry, Mr. Fernandez. Please go ahead.
- A. Okay. So this roughly -- the total equity line item represents the net assets of the company over its liabilities. So the company has assets on a historical basis in excess of the total liabilities that are reflected in the company's books and records.

So that is an early, quick look that you -that you want to get comfortable with; what is the
capital position, the net worth of the company, the
equity of the company, at these various measurement
dates.

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              Even from a lay --
         Q.
              It's a starting point, though, not a finishing
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         Α.
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    point.
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         Q.
             Understood. But even from a layperson's
    perspective, this is basically saying they have more
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    assets than liabilities, right?
             Right. Which, you know, is, in the simplest
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         Α.
    form, solvency.
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         Q.
              Now --
              THE COURT: Attorney Cheffo, we're going to
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11
    take --
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              MR. CHEFFO: Oh.
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              THE COURT: -- our lunch break. Is that --
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              MR. CHEFFO: No, that's perfect, your Honor.
              THE COURT: All right. Good. We'll be back
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16
    then around one o'clock.
              MR. CHEFFO: Thank you.
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              (Lunch recess taken at 12:00 p.m.)
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CERTIFICATE

I, Liza W. Dubois, do hereby certify that the foregoing transcript is a true and accurate transcription of the within proceedings, to the best of my knowledge, skill, ability and belief.

Submitted: 9/27/19

/s/ Liza W. Dubois
LIZA W. DUBOIS, RMR, CRR

I certify that the foregoing is a true and correct copy of the transcript originally filed with the Clerk of Court on September 27, 2019, and incorporating redactions of personal identifiers requested by the Honorable Landya B. McCafferty in accordance with Judicial Conference policy. Redacted characters appear as a black box in the original transcript and blank lines in the copies.

Dated: 10/28/19

/s/ Liza W. Dubois
LIZA W. DUBOIS, LCR, CRR