UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION,

Plaintiff(s),

v.

EDWARDS LIFESCIENCES CORPORATION, et al.,

Defendant(s).

Civil Case
No. 25-02569 RC

Washington, D.C.

November 24, 2025
Afternoon Session

EVIDENTIARY HEARING
BEFORE THE HONORABLE RUDOLPH CONTRERAS
UNITED STATES DISTRICT JUDGE

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I-N-D-E-X

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The following proceedings began at 2:12 p.m.:

(The following was heard in closed session.)

(The following was heard in open session.)

MR. NAEGELE: Do we need to do anything?

THE COURT: No.

MR. NAEGELE: Great.

BY MR. NAEGELE:

Q Mr. Sirimanne, if you look at those blue boxes, without reading anything inside of them, as we are in open session now, is it fair to describe at a high level these paragraphs describe JenaValve's FDA submission?

A I don't know whether this information was in their submission at all. It looks like it's a summary of a conversation that Mr. Russ Joseph had with Ms. Khalil.

Q And this is a conversation with Ms. Khalil in October 2024, if you go back to the first page, I believe.

A Yes.

Q All right. So that is -- if you look there, so that's after the acquisition of JC Medical?

A Yes.

Q And after the firewall was put in place?

A Yes, after the firewall.

Q Okay. And if we go to the -- if you take a look back at

page 2, do you see -- we can blow that up -- it says JenaValve had just finished -- and then it's redacted. It says, they planned to submit the results this month, October, to the FDA.

This is a discussion of JenaValve's FDA submission?

A Yes. But I don't know what part of that submission it is. It could be a pre-submission. This doesn't imply that it's a PMA submission.

Q But it does refer to some FDA submission?

A It seems like it.

Q And JenaValve's FDA submissions, you would agree, are not public information, correct?

A No, it's not.

Q All right. Now, let's go back to page 1. If we go to that email at the top, you forward this email from Mr. Joseph in the attached Microsoft Word document to Larry Wood and Finn Haley?

A Yes.

Q At the time in October 2024, Larry Wood was the head of Edwards' transcatheter heart valve division or THV group?

A Yes.

Q Finn Haley at the time was responsible for integrating J-Valve into Edwards, right?

A Yes.

Q And you forwarded this email to Mr. Wood and Mr. Haley

and proposed having a meeting to discuss the contents with them?

A Yes.

MR. NAEGELE: Thank you, Mr. Nguyen. You can take that down.

BY MR. NAEGELE:

Q Now, earlier you testified about Edwards' research and development program. Do you recall that?

A Yes.

Q Edwards doesn't fund every single R&D program they want to get funded, right?

A It does not.

Q Sometimes you need to advocate to Edwards' leadership to get funding for R&D programs that you want?

A Do I have to advocate?

Q Yes.

A Sometimes.

Q When you advocate to Edwards' leadership for funding for those R&D programs, you warn your supervisors that if they don't take your recommendations and follow them, Edwards will lose its number one spot and slip to number two in the market?

A Dylan, every engineer wants to have the best product on the market. We don't get up in the morning and say having the second-best product is good enough.

Q You want to be number one in the market, not number two?
A Not number one in the -- as an engineer, I want to have the best possible product for our patients.
Q Now, let's take a look at a document marked as PX1229.
A Which one?
Q My colleague will be passing that out.
MR. NAEGELE: Your Honor, may we approach?
THE COURT: You may.
BY MR. NAEGELE:
Q Mr. Nguyen has put a redacted version on the public screens. Please don't read any of the material contained in the blue boxes out loud. You can, of course, read it silently.
A That's fine.
Q Mr. Sirimanne, this is an email that you wrote to your supervisor, Larry Wood, on January 28, 2025?
A Yes.
Q And without reading out loud any of the material in those blue boxes, is it fair to say that this describes a scenario where Edwards does not fund an R&D program that you want to get funded?
A No. This actually does not. This is me doing my job and contingency planning. And this is saying if some of these programs don't work, that we need to have a discussion around contingency planning.

So keeping it redacted, the first program is the program that we are in a clinical study. We have already got a second program behind that as well.

And I think I can talk about the sheath. My job is to have a contingency plan. We have now a second sheath that we already got approval. There's another one that is getting filed in December. So if this doesn't work, I got two more sheaths that will be approved.

Q And in this email, when you are describing the scenario, you write at the bottom, if this comes to pass, we will be the number two company in terms of technology?

A What I am saying here is if everything we are working doesn't work, right, and my job is to come up with contingency plans, and we came up with a lot of contingency plans, so even if these don't work, there are other programs already in place.

Q Mr. Sirimanne, that was not my question.

My question is, at the bottom of this email, you write, if this scenario comes to pass, we will be the number two company in terms of technology. Is that right?

A We are saying if everything in this -- just to put it in context, this is basically saying if everything that we are working on absolutely doesn't work, that means we have not a single product that's going to go on the market, then we will have the number two technology because we will have all

the technology. So my job is to come up with contingency plan. We came up with contingency. Even if some of these don't work, we have new products that are coming on the market.

Q When you write number two company, that's number two relative to some other company that would be number one?

A This is in terms of technology, yes.

Q And that's relative to some other company who would be number one?

A Yes.

MR. NAEGELE: Thank you, Mr. Nguyen. You can put that down.

BY MR. NAEGELE:

Q Mr. Sirimanne, earlier today you testified about you and your team's reactions when you first learned about Edwards' proposed acquisition of JenaValve, is that correct?

A Yes.

Q I would like to show you a document, PX1232. This is a text message exchange dated February 2, 2024 between you, Sean Chow and Russ Joseph. At this time, Russ Joseph and Sean Chow both reported to you, is that correct?

A That's correct.

Q Now, if you go with me to the first message on here, you write, there is apparently a rush to close this deal ASAP.

This deal refers to Edwards' proposed acquisition of

JenaValve, correct?
A I believe so.
Q Okay. Let's go down to the third message from the bottom where it says, can we also figure out what the thickness of the porcine tissue compared to EW.
EW there, you are referring to Edwards?
A Yes.
Q Edwards valves use bovine tissue, correct?
A It is.
Q Bovine tissue, for those of us who aren't in the industry, that's tissue that comes from a cow?
A Yes.
Q And porcine tissue is tissue that comes from a pig, right?
A Yes.
Q And JenaValve's Trilogy valve uses porcine tissue, right?
A Yes.
Q Edwards does not use porcine tissue for its valves, correct?
A We don't use porcine tissue.
Q Porcine tissue is thinner than bovine tissue, correct?
A It is thinner.
Q Immediately after that message, you sent another message. And it's redacted, so please don't read the

contents of that out loud. But fair to say that it's saying that management had an expectation that you could, quote, easily, quote, incorporate some changes into JenaValve's Trilogy device?

A Give me a moment to find that.

Q Certainly.

A Is it on the first page?

Q It's on the first page. It's in the section in the blue box.

THE COURT: If you look at the one that's highlighted on the screen.

THE WITNESS: Yes.

BY MR. NAEGELE:

Q Do you see that?

A Yes. I am trying to put into context because it looks like some of the messages were at 5:00 in the evening, and others were at 11:00 at night. So there may be multiple conversations that are going on here. They may not be tied.

Q This is sent about 20 minutes after the original text message. This is about 6:00.

A Okay.

Q So is it fair to say that this is saying there's an expectation that you could, quote, easily incorporate some changes into JenaValve's Trilogy device?

A That the bovine pericardium could be incorporated.

Q Please don't read or summarize the section in the blue box. Sorry. We don't want to spill any confidential information.

Is that a fair explanation of what's said there?

A Yes.

Q If we go down below that, you wrote, Sean -- that's referring to Sean Chow?

A Yes.

Q This will be one of your projects, and then there's a laughing emoji after that. And then you wrote, seriously, you need to weigh in.

Did I read that right?

A Yes.

Q And below that, Mr. Chow responds to you, I am not excited to lead JenaValve integration is my opinion.

Did I read that right?

A Yes.

Q Mr. Chow's next text message to you answers the earlier question that we discussed about the bovine tissue, right?

And then you responded to Mr. Chow, this acquisition will be a major nightmare, is that correct?

A Correct.

MR. NAEGELE: Thank you, Mr. Nguyen. You can take that down.

BY MR. NAEGELE:

Q Now, we discussed the firewall earlier. I want to go back to that quickly and talk about sort of why that firewall was put in place.

JenaValve established the firewall after they found out about Edwards' acquisition of JC Medical, is that correct?

A Yes.

Q Okay. And let's take a look at PX1235.

MR. NAEGELE: Mr. Nguyen, would you please put that up on the screen.

BY MR. NAEGELE:

Q This is another text message exchange, this time between you and Sean Chow, dated August 2, 2024. Do you see the first text message?

A Yes.

Q And that was sent by Sean Chow?

A It seems like it.

Q All right. Sean writes, I talked to Kevin Chu just now. He says he talked to Greg. Greg says he wants to set up a firewall before we talk.

Did I read that right?

A Yes.

Q Who is Kevin Chu?

A Kevin Chu, I believe, is an engineer at JenaValve.

Q Okay. And then Greg is Greg Mirigian, JenaValve's vice

president of R&D?
A Yes.
Q And then you write back to Mr. Chow, fair enough.
Did I read that right?
A Yes.
Q And the reason it's fair enough is that you have competing AR technology and the deal has not closed yet, is that correct?
A Yes. I'm just saying that if Greg wanted to have a firewall and not want to talk to Sean Chow, that that is a right they have.
Q And your explanation that you sent to Sean Chow in the text message sent at 1:51 is, the deal hasn't closed yet and we have a competing AR technology.
Did I read that correctly?
A Yes.
Q Now, let's break that down. The deal hasn't closed yet. That's a reference to Edwards' proposed acquisition of JenaValve?
A It is.
Q And we refers to Edwards Lifesciences?
A Yes.
Q And the competing AR technology, that's J-Valve, correct?
A It is J-Valve.

MR. NAEGELE: All right. Thank you, Mr. Nguyen. You can take that down.

Your Honor, no further questions.

MS. PEARL: Hi, Your Honor. Just a few questions.

REDIRECT EXAMINATION

BY MS. PEARL:

Q Hi again, Mr. Sirimanne. Sorry that I'm back.

You discussed the firewall that JenaValve put up between itself and Edwards after the deal with the FTC's counsel. Do you recall that conversation?

A Yes.

Q And you discussed the clean team that was set up as part of this firewall, correct?

A Correct.

Q And you understand that the firewall is important, right, Mr. Sirimanne?

A Yes, I do.

Q And as a result of this firewall, as you discussed, you and your team don't have access to JenaValve's device right now, right?

A We don't have access to any devices.

Q And did you have any responsibilities for setting up this firewall?

A No, I did not.

Q Who did?

A So our Edwards lawyers set it up with JenaValve lawyers.
Q And who else was involved with the firewall from your team?
A Russ Joseph, I believe, had access.
Q And do you have any responsibilities for establishing what's in or out of the clean room?
A No, I don't. It's -- the lawyers decide that.
Q And do you know JenaValve's approach to classifying something as in or out of the clean room?
A No, I don't.
Q Now, we talk -- you talked about a document with information that you received from Mr. Joseph. If you received information from Mr. Joseph about JenaValve, what is your understanding as to whether that information would be clean or not?
A Yeah, so I look at it as our Edwards -- Russ Joseph was working with Edwards' lawyers around what should be in the firewall, within the firewall, and what is not. I was not involved in any of that. So if Mr. Joseph sends me this document, then I take it as that he has the approval and this is not a document that needs to be in the clean room, that he is able to send it to me.
Q And we discussed -- and I know this is during closed session, so I won't go into detail. But we did discuss some of the JenaValve information you received during that due

diligence, right?
A Yes.
Q And some of that information was not public, right?
A It was not public.
Q So in the case of the document that you reviewed with the FTC's counsel, do you have any reason to believe that the clean team process wasn't working properly?
A I had no reason to think that the clean team process was not working.
Q So you also spoke about a conversation or, I guess, a text chain with Mr. Chow. It's PX1232. You don't need to bring it back up. We can just talk about it quickly.
So, Mr. Sirimanne, are you excited about having these two products?
A I am very excited about having both products.
Q So what was being discussed here about the integration being not as something that you were as excited about?
A Sean and I are engineers. We are total nerds. We love this technology. We think we could improve on it. We can come up with multiple generations. But integrating a 150-person company, that is not going to be an easy task. There's human resources issues. There are facility issues. Integration is not easy, and it's not really in our wheelhouse.
Having said that, Sean and I -- you know, there are a

lot of aspects of my job that's really exciting. But there are things that we have to do that's not exciting. And if we were asked to do the integration, we would do it. But we prefer to work on the technology and not on integrating companies.

Q Thank you. Thank you, Mr. Sirimanne. No further questions.

THE COURT: Thank you.

Okay. Thank you.

MR. NAEGELE: No further questions from the FTC.

Thank you, Mr. Sirimanne.

THE COURT: Thank you, sir.

MR. SHORES: Your Honor, we have one more live witness today. Would Your Honor, in terms of the videos, prefer a thumb drive or something emailed, or should I work that out separately?

THE COURT: Either way. It doesn't make a difference to us.

MR. SHORES: Okay.

MR. COATE: Your Honor, defendants would like to call Ms. Sharma.

POOJA SHARMA

Having been first duly sworn on oath, was examined and testified as follows:

THE COURT: I assume you are not related to the judge

in this building.

THE WITNESS: No, I'm not.

MR. COATE: I didn't check.

THE WITNESS: I don't think so. Thank you.

MR. COATE: May I proceed, Your Honor?

THE COURT: You may.

DIRECT EXAMINATION

BY MR. COATE:

Q Good afternoon, almost evening, Ms. Sharma.

A Good afternoon.

Q I would like to start with just a little bit of your background for the judge. Where do you live?

A Palo Alto, California.

Q Where did you go to college?

A University of Southern California in Los Angeles.

Q What did you study?

A Biomedical engineering.

Q What did you do after you graduated?

A I joined Edwards as an engineer immediately after I graduated.

Q And after you worked as an engineer, did you work through any other roles?

A I did. I joined marketing for the TAVR business unit, held various different roles in marketing on the commercial side, on the upstream side, and ultimately became the senior

vice president of strategy and marketing for TAVR.

THE COURT: One second. What is your name again?

MR. COATE: Jacob Coate.

BY MR. COATE:

Q Just at a high level, what were your responsibilities as the senior vice president for strategy and marketing?

A I supported the business unit in strategic planning, understanding how we were going to transform care with TAVR. And on the marketing side, I was responsible for things like patient education. My team did customer training as well as understanding voice of the customer from physicians to inform our next generation products.

Q All right. And, Ms. Sharma, do you still work at Edwards?

A I do not, no.

Q When did you leave?

A Very recently. My last day was November 3.

Q Why did you leave?

A My family and I decided to relocate to the Bay area.

Q Any concerns with Edwards' business or its strategy when you left?

A No, not at all. It's a great company.

Q Where do you work now?

A PROCEPT BioRobotics.

Q What is your position?

A I'M the chief strategy and marketing officer for PROCEPT.
Q Any familiar faces there at PROCEPT?
A Yes. I report to the CEO of PROCEPT, Larry Wood, who was also my boss as president of TAVR at Edwards.
Q I would like to shift topics to the way Edwards approaches competition and TAVR. Okay?
A Sure.
Q Was Edwards the first company to offer a commercial TAVR-AS device in the United States?
A Yes, we were.
Q And when did that device receive FDA premarket approval?
A 2011.
Q All right. And after Edwards received FDA premarket approval, was it good to go, or did it have to build the market?
A No. We had to invest heavily in market development.
Q How did you go about doing that?
A We invested in three main areas. One is around technology evolution, so making sure that we were consistently improving the product for patients.
The second was around clinical evidence, so you know, building data and evidence around the platform and also expanding indications.
And the third is around education. So physician

education for those who were actually implanting the heart valve, but also, of course, as time went on, patient education and education of the referrers who are managing these patients with severe aortic stenosis.

Q Why is patient education important?

A So it's a really deadly disease, but patients in general are quite intervention avoidant. And as you can imagine, there's a lot of fear of getting your heart valve replaced. So it's really important. There's so many people who go untreated with severe aortic stenosis. So that was important to make sure patients were educated about the disease and the urgency of treatment as well as the options that were available to them.

Q Okay. Let's pull up DX0220. And this is an email from a Pooja Sharma to a Pooja Sharma. Is that you?

A Yes, that's right.

Q This is from April 8, 2025. Let's go to page 2.

This is the title slide of the attachment. It's entitled advancing structural heart innovations by Pooja Sharma.

Are you familiar with this document?

A Yes, I am.

Q What is it?

A This is a presentation that I gave to customers who were visiting Edwards, physicians who were visiting Edwards.

Q This was earlier this year?
A That's right, in April 2025.
Q Let's go to page 6. And I think the court has seen various versions of this, so we will move through it quickly. But the title of this slide is five generations of valves and 10,000-plus patients in marquis clinical trials.
There are a series of images across the top. What are those images representing, Ms. Sharma?
A They are representing the various evolutions of our Sapien platform through our portfolio.
Q Did each of these generations represent a major innovation in the technology?
A Yes, each was a significant innovation for patients.
Q And at the beginning of this process, could Edwards have planned out what each generation was going to be in advance?
A No. It would have been very difficult to do that.
Q Why is that?
A So it's a very data driven company, and we go where the data takes us. So understanding the evidence from clinical trials as well as our customer experience in the market as we scale is really important to inform where the portfolio should go and where we should make sure that we make improvements.
Q Let's take a couple of examples. If we look at the top, Edwards began with Sapien, what drove the advancement from

Sapien to Sapien XT, which is the next device?

A At the time, for example, we found in the data that patients who had, for example, a lot of bleeding in their access site at the femoral artery because the size of the device was large, for example, that patients who had what's call the vascular complications, which is that bleeding there, they died more often.

It was really important for us to reduce the size of the device as it entered the femoral artery, and that's an example of how Sapien XT was born.

Q Let's take one more example here. What drove Sapien 3 Ultra Risilia, which is further down in the chart?

A Risilia is an advanced tissue designed to enhance long-term durability. Durability is important. Obviously valve durability is important for all patients. But specifically, as we went down the risk spectrum to patients who were lower risk and oftentimes younger, especially for that patient population, durability is of great importance.

Q And is that because for lower risk patients, the device needs to last longer?

A Yeah. So often those patients have less comorbidities, and they can sometimes be younger. So they have a longer life expectancy, so durability is a particularly important concern to those patients.

Q You were just talking about the risk spectrum. Let's

take a look at the left-hand side of the chart. At the bottom it says inoperable and high risk, intermediate risk, low risk. Is this the risk spectrum that you were talking about?

A Yes, that's what I was referring to.

Q What is that risk in reference to?

A It's actually referencing the risk of a patient having severe complication with open heart surgery for their valve replacement.

Q So at least for the inoperable through the low risk categories, these are in reference to the surgical risk?

A That's correct.

Q And why would it be in comparison to surgery if this is a TAVR device?

A Yeah, so surgery was a very well-established therapy at the time. And you know, it was a lifesaving therapy for patients with severe aortic stenosis. So the intent, especially in those early trials, was to demonstrate that TAVR could be at least as good as surgery because it was such a well-established alternative treatment for these patients.

Q And is that what Edwards did in the trials that are reflected in the arrows in the middle of the chart?

A That's right. So, for example, the high risk, intermediate risk, and low risk trials, we had to compare

TAVR to the established alternative, which was surgery.
Q So in these clinical trials, Edwards is essentially competing against surgery to establish that the TAVR device is superior or at least as good?
A That's right.
Q Looking at the chart as a whole, both the innovations along the top and the growth in patient indications in the middle, how does this fit into Edwards' commercial strategy?
A For us, the biggest competitor for us is the disease. This is a very, very deadly disease. And there are enormous number of patients who just go untreated. And so, you know, as we were able to evolve the technology so more patients could have access but also the indications, ultimately that unlocked the market and drove market growth, which, of course, was good for our revenue.
Q And when you were senior vice president at Edwards, how much of your focus and budget was focused on growing the market?
A Vast majority of my budget.
Q All right. Now, you previously testified, I think, that Sapien first received premarket approval in 2011 for inoperable, is that right?
A Yes, that's right.
Q And that was the first TAVR device in the U.S. market?
A That is correct.

Q What was the second device?
A The second TAVR device in the market was the Medtronic CoreValve device.
Q When was the Medtronic -- when did the Medtronic CoreValve device receive FDA approval?
A In June of 2014.
Q So let's take a look at the time between when Edwards first received FDA premarket approval and when Medtronic entered with CoreValve.
When did Sapien expand from inoperable patients to high risk patients?
A In 2012 we received an indication for high risk.
Q And when did Sapien XT receive FDA approval?
A Also in June of 2014.
Q All right. So by the time that Medtronic entered with their device, Edwards had already expanded patient indications and introduced a new generation of technology?
A That's correct.
Q And during that time, there were no other companies that had commercially approved devices?
A That is correct.
Q Let's also look at early TAVR trial, which is an arrow on the right-hand side.
What was the early TAVR trial?
A So the early TAVR trial intended to establish the

benefits and impact of TAVR in a patient population that still had severe aortic stenosis but had not yet developed symptoms. So they were called asymptomatic. Early TAVR is a trial for TAVR in an asymptomatic severe aortic stenosis patient.

Q And when did the early TAVR trial start?

A Approximately 2018.

Q In 2018, to your knowledge, were any other companies working to expand indications into asymptomatic patients?

A No. In 2018, not to my knowledge, nobody else was working on it at the time.

Q And did Edwards ultimately successfully complete this trial and receive an indication for asymptomatic patients?

A We did. We received FDA approval for an asymptomatic indication in March of this year, 2025.

Q And at this time, is there still any other company that is even working on an asymptomatic indication?

A No other company has an asymptomatic indication. I believe that Medtronic did start an asymptomatic trial in 2020, but they seem to have paused that shortly thereafter.

Q Ms. Sharma, why is Edwards working on these indications or these generations even when other companies or competitors are not?

A So again, we really sort of go with where the disease takes us. So each of these trials has had the opportunity

to unlock additional indications and, therefore, grow the market, which, of course, has a positive impact on our revenue.

Q And so does Edwards have an incentive to innovate regardless of what its competitors are doing?

A Yes, very much so.

Q Let's pull up DX0140. This is a couple of emails. I will ask about the second one in the chain from the top, which is an email from you to Meridith Zia on July 20, 2023. Do you see that?

A I do, yes.

Q Let's go to the bottom paragraph, and specifically the last parenthetical at the end of that paragraph, which is kind of a long parenthetical. We will read it together. You wrote, remember our penetration rate in SAS before the advent of TAVR was 6 out of 100, and surgeons thought they were treating everyone. 12 years later, we are still low at 12 out of 100, but it has doubled and volume of patients now coming into the system is up significantly.

Do you see that sentence?

A I do, yes.

Q Let's pause there for a moment. What did you mean by this?

A Yeah, so before 2011 when TAVR was introduced, out of every 100 patients that have severe aortic stenosis in the

U.S., only six of them were treated with any aortic valve replacement, which at the time, the only option was surgical valve replacement where the patient's chest was cracked open and their heart was stopped.

If you fast-forward 12 years later, the number of patients who receive any aortic valve replacement in the U.S. has nearly doubled, but the adoption rate, the penetration rate, is still very low at 12 out of a hundred patients who receive any therapy for aortic valve replacement including surgery or any transcatheter heart valve.

Q And this was a couple years ago. What is the number today?

A 13 out of a hundred.

Q So only 13 percent of patients with severe aortic stenosis receive any form of therapy at all?

A That is correct.

Q The last sentence reads, so sometimes technology itself unlocks the opportunity.

What did you mean by that?

A As I mentioned earlier, patients are often very intervention avoidant. You can imagine when the only option for intervention is someone's chest being cracked open and their heart being stopped, you know, a lot of patients just don't want to get any intervention. And so the introduction

of a minimally invasive option where someone can get their heart valve replaced on a beating heart, that was ultimately, you know, a real opportunity to unlock the patient population so more patients were open to receiving any treatment.

Q How does the fact that only 13 percent of patients receive any treatment today play into Edwards' incentive to grow the market?

A So again, I think this just underscores why the disease is our competitor, because there are so many patients who just don't receive any treatment. And severe aortic stenosis in particular is an incredibly deadly disease. So for us, we were incentivized to make sure that patients were well educated about their options and that referrers actually sent these patients for any treatment.

Q Let's set that aside and pull up PX1512. I am going to ask you about a different topic now.

This is an email from -- actually, if we zoom out, you will see your signature on here, but not in the to, from line. But this is an email from you to several folks including Larry Wood on August 1, 2024. Do you see this?

A I do see that, yes.

Q Are you familiar with this document?

A Yes, I am.

Q Let's take a look at the bottom half of this email and

both of the bold sections.

Let's start with the bottom bolded language. You wrote, the following programs will be stopped. And stopped is in all caps. Do you see that?

A I do see that.

Q Any reason you chose all caps for stopped?

A No. I think I was trying to get people to pay attention to it.

Q There are several bullets under that. I am going to ask you about the last one. Your wrote, JenaValve ARTIST intermediate and low risk U.S. IDE.

Do you see that?

A I do see that, yes.

Q Let's take a step back for a moment. Did JenaValve conduct a pivotal trial for inoperable and high risk patients?

A Yes, they did. That trial is called ALIGN-AR.

Q When did that trial end?

A I believe 2023.

Q ALIGN-AR, that's different from the ARTIST trial that's on the page here, right?

A That's right. The ARTIST trial is in lower risk patients.

Q Has JenaValve received FDA approval for inoperable and high risk patients yet?

A No, they have not.
Q All right. So just to explain again, ARTIST was for intermediate and low risk patients?
A That's right.
Q That's further down on the risk spectrum?
A That's correct.
Q So were there -- were you involved in due diligence with JenaValve?
A Yes, I was.
Q Were there issues that you identified during due diligence that would have impacted your recommendation here?
A There were a couple of issues raised during diligence, one being concerns around manufacturing and scalability of the device, so just the ability to provide the product to customers at scale. And then the second was raised around some AWT durability testing failures.
Q Ms. Sharma, earlier you told the court that it was an important part of Edwards' strategy to expand patient indication, right?
A Yes.
Q So why were you writing that ARTIST, which was designated for intermediate and low risk patients, should be stopped?
A Yes, indication expansion is an important part of market development, but doing it thoughtfully is really, really

important, and especially as you are building a market, which was our experience with TAVR-AS. It's important that you get great outcomes, a great customer experience, and then very methodically and thoughtfully step down the risk spectrum.

Q Do intermediate and low risk patients have more surgical options than high risk and inoperable?

A Going back to when we say intermediate and low risk, this is the patient's risk of having a severe complication from open heart surgery. And so by nature, these patients typically have fewer comorbidities, a longer life expectancy, and can sometimes be younger.

Q When did Edwards receive FDA approval to treat inoperable patients?

A November of 2011.

Q When did Edwards begin its trial for low risk patients?

A I believe in 2016.

Q So to do a little math, how many years was it from the time Edwards received FDA approval for inoperable patients before it began its trial for low risk patients?

A Approximately five years.

Q And today, JenaValve still doesn't have approval even for inoperable patients?

A That is correct.

MR. COATE: We can take that document down.

Let's pull up DX0114.

BY MR. COATE:

Q It's an email from Larry Wood to several folks including you on May 24, 2024. Are you familiar with this document?

A Yes, I am.

Q Let's go down to the second to last paragraph.

All right. And I am going to -- I'm not going to ask you to count, but I am going to go to the sixth sentence, I think, here in this paragraph that begins with when we make these acquisitions. Do you see that?

A Yes.

Q Larry wrote, when we make these acquisitions, it will be a massive signal to the world that the leader in THV thinks AR is an enormous opportunity. Last time they all waited on the sideline to see if THV was real. They will not make that mistake again. They will race to be number two and try to obtain leadership. It will be a competition with multiple players. If we don't move at best speed, we will waste the first mover advantage, and this will all be for nothing.

Do you see that, Ms. Sharma?

A I do, yes.

Q At the time that Larry sent you this email in May 2024, were you aware that Edwards was buying JenaValve and JC Medical?

A Yes, I was aware.
Q So were you surprised that Larry was telling you that Edwards was going to face, quote, competition with multiple players?
A No, I wasn't surprised at all.
Q Why not?
A I think it reflected our experience in TAVR-AS and, you know, when Edwards invested in market development of TAVR-AS. And we did it really thoughtfully, and we had fantastic patient outcomes and a really deep trust with our customers. It attracted other players to the market.
Q And who were some of those other players?
A Medtronic as an example, Abbott, Boston Scientific, just to name a few of the strategics.
Q Could companies like Medtronic, Abbott, or Boston Scientific acquire one of the companies working on a TAVR-AR device to enter the market?
A Yes, I would imagine they could.
Q Is that what Edwards did with JC Medical?
A Yes, it is.
Q And are other companies currently working on TAVR-AR devices?
A Yes, I believe they are.
Q Let me ask you about one that the court's heard about before. Are you familiar with a company called Jenscare?

A I am, yes.
Q Where are they based?
A In China.
Q Does Jenscare have a TAVR-AR device commercially approved in China today?
A Yes, my understanding is they do.
Q Is that device used transapically?
A Yes, it is.
Q I want to make sure we are clear about this terminology. So what does it mean for a TAVR device to be transapical?
A So that refers to the access route. So at the bottom of the heart, sort of if you look at the heart like this, there's a pointy area called the apex, and transapical device means you are approaching the diseased valve from the apex of the heart.
Q And what does it mean for a TAVR device to be transfemoral?
A Transfemoral would refer to another access route, which is in the leg via the femoral artery.
Q Are transapical and transfemoral devices both transcatheter devices?
A Yes, they are both transcatheter devices.
Q If they were used to treat AR, would they both be a TAVR-AR device?
A Yes, that's right.

Q The difference just refers to the entry point in the heart?
A Yes, correct. There are multiple entry points. You can go transapical, transfemoral. Some devices come transcorotid as an example.
Q Could the same valve be used transapically or transfemorally in certain circumstances?
A It could be, yes.
Q Do you have any examples?
A Yes. Sapien was used both transapically and transfemorally.
Q That's Edwards' TAVR-AS device?
A That's correct.
Q Are you aware of any situation where a company began using a TAVR device transapically and then shifted to transfemoral?
A Yes. JC Medical did that.
Q When Edwards purchased JC Medical, was its device being used both transapically and transfemorally?
A Yes, it was.
Q And when Edwards purchased JC Medical, did it look at both the transapical data and the transfemoral data?
A Yes. We considered all data.
Q Was a large part of this data developed in China?
A Yes, it was.

Q So is your team, back when you worked at Edwards still, anticipating that Jenscare could be a potential entrant into the U.S. with a TAVR-AR device?
A Yes, we did anticipate that when I was there.
Q And to your knowledge, does Jenscare have any experience navigating the U.S. regulatory field?
A Yes. My understanding is that Jenscare has a tricuspid valve transcatheter device, tricuspid valve is just another valve in the heart, and that they are pursuing early feasibility work in the United States.
MR. COATE: Okay. Let go back to DX0220.
BY MR. COATE:
Q I promise this is the last time I am going to ask you about this document.
Let's go to page 22. And just to reorient everyone, this was the presentation that you gave to physicians earlier this year, is that right?
A Yes, that's correct.
Q The title of this slide is our structural valve expertise with new complementary technologies positions us to bring early therapies to patients.
Do you see that?
A Yes, I do.
Q There is a picture of the J-Valve technology and a picture of the JenaValve technology?

A Yes, I see that.
Q At the time that you left Edwards as the senior vice president for strategy and marketing, was it the strategy if the acquisition went through to proceed with both of these technologies?
A Yes, it was.
Q Do you note at the top that these are complementary technologies. What did you mean by that?
A Aortic regurgitation is a complex disease. You have a lot of complexity in the patients, the size of their native valve, you know, how technology can approach their valve, how a system could approach it, the height of their coronary arteries, so it would be very feasible that doing right by those patients might require a toolbox approach. And that's what I was referring to with regards to complementary technologies.
Q And these devices differ in several ways?
A Yes, they do.
Q Let's turn to page 23.
Here you wrote, we expect the aortic regurgitation JOURNEY to be similar to TAVR.
Do you see that?
A I do, yes.
Q And there's some boxes along the side. What do those boxes show?

A As I mentioned earlier, you know, when we are looking at market development, there are three key areas that we invest in and we take really seriously. One is technology iteration, making sure that we get better and better with the products and how they serve patients.

The second listed here is clinical evidence generation, so really generating clinical data and doing the indication expansion.

And then the third is around education and training, which includes targeted towards the customers who are actually implanting our valves, but also patient education and education for their managing providers.

Q And is that how Edwards built the market in TAVR-AS?

A Yes.

Q And then there's some devices off to the right. Are these the devices that we saw earlier?

A Yes.

Q Was the plan when you left Edwards to proceed with TAVR-AR the same way that Edwards proceeded with TAVR-AS?

A Yes, it was.

Q And in TAVR-AS, did Edwards experience competitors following it into the market?

A Yes, we did.

Q And were you anticipating that the same thing would happen here?

A Yes, we were.
Q Thank you, Ms. Sharma.
A Thank you.
MS. SHIMSHONI: Good afternoon, Your Honor. Hilla Shimshoni on behalf of the Federal Trade Commission.
May I proceed, Your Honor?
THE COURT: You may.

CROSS EXAMINATION

BY MS. SHIMSHONI:
Q Good afternoon, Ms. Sharma.
A Hi.
Q I have a few preliminary questions for you. I believe you testified you are no longer employed by Edwards. Is that right?
A That's correct.
Q You testified in connection with -- in a deposition in connection with this litigation on October 10, 2025. Do you recall that?
A I do, yes.
Q At the time, you were still an Edwards employee, is that right?
A Yes, that's right.
Q And today you are represented by Edwards' legal counsel?
A I am represented by Cleary, yes.
Q Legal counsel for Edwards?

A Yes.
Q And Edwards is paying your legal counsel?
A I believe so, yes.
Q Okay. And I believe you said you now work at PROCEPT BioRobotics?
A That's right.
Q So you are no longer responsible for Edwards' business strategy?
A That's correct.
Q All right. And to be clear, you are not a JenaValve employee?
A I am not, no.
Q You have never been a JenaValve employee?
A No, I have not.
Q You are not a JenaValve board member?
A No, I am not.
Q And you have never been a JenaValve board member?
A No, I have not.
Q Turning back to your time at Edwards, you were not responsible for regulatory approval of products in the THV business unit, correct?
A That is correct.
Q All right. That would be Scott Beggins?
A That's right.
Q And you were not responsible for research and

development either, is that right?
A That's correct.
Q That would be Mr. Laksen Sirimanne, who we just saw, is that right?
A That's right.
Q You were not responsible for clinical affairs, is that right?
A That's correct.
Q That would be Jamie Wheeler?
A Yes.
Q Okay. And switching to the proposed transaction with JenaValve, you were not on the team responsible for conducting financial diligence of JenaValve, is that right?
A That's correct.
Q And you were not on the team responsible for clinical due diligence?
A I was part of the diligence team, but I was not responsible for clinical due diligence.
Q Or technical due diligence?
A That's correct.
Q Or medical due diligence?
A That's correct.
Q Or regulatory due diligence?
A That is correct.
Q All right.

MS. SHIMSHONI: Your Honor, I request that we move to a closed session given the defendant's confidential designations for the next part.

THE COURT: Any objection?

MR. COATE: No, Your Honor.

(The following was heard in closed session.)

(The hearing adjourned at 5:46 p.m.)

- - -

C E R T I F I C A T E

I hereby certify that the foregoing is an accurate transcription of the proceedings in the above-entitled matter.

11/24/25

s/ Tammy Nestor
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