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 20, 2025
Afternoon Session

EVIDENTIARY HEARING
BEFORE THE HONORABLE RUDOLPH CONTRERAS
UNITED STATES DISTRICT JUDGE

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The following proceedings began at 1:56 p.m.:

THE COURT: Are we ready?

MR. SEGAL: Good afternoon, Your Honor. Will Segal for Plaintiff Federal Trade Commission.

The FTC will call Blessie Concepcion to the stand.

BLESSIE CONCEPCION

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

THE COURT: Counsel, what is your name again?

MR. SEGAL: Will Segal.

THE COURT: How do you spell the last name?

MR. SEGAL: S-E-G-A-L.

THE COURT: Okay. Out of the 20 or so names I have down here, yours is not one of them. Okay. Go ahead.

DIRECT EXAMINATION

BY MR. SEGAL:

Q Good afternoon, ma'am. My name is Will Segal. I'm an attorney for the Federal Trade Commission. Please state your name for the record.

A Blessie Concepcion.

Q Who is your current employer?

A Edwards Lifesciences.

Q What is your current position?

A Vice president of THV clinical affairs.

Q THV stands for transcatheter heart valves?

A Yes.
Q You joined Edwards three years ago?
A Yes.
Q You have held the same position since you joined Edwards, right?
A Yes.
Q You are responsible for executing clinical trials, correct?
A Yes.
Q You are leading the integration of JC Medical's clinical trials into Edwards, correct?
A No. I am only responsible for the clinical integration of JC Medical into Edwards.
Q So you are responsible for the clinical integration of JC Medical into Edwards?
A Correct.
Q Your responsibilities include integrating the J-Valve clinical trials, correct?
A Clinical trials, yes.
Q Let's turn to TAVR-AR clinical trials. I would like to introduce PX1299. The redacted version can be shown to the public.
Ma'am, an unredacted version is available in the binder in front of you.
A Okay.

Q When you turn to PX1299, you will see there's information that has a blue box around it because Edwards has deemed it confidential. The version we are displaying on the screen does not have that information shown, so please do not speak it out loud. And I am going to ask you to be very precise, yes or no with your answers. Do you understand?

A Yes.

Q In PX1299, your team was discussing expanding J-Valve's clinical sites, right?

A It's not expanding. We're -- oh, sites from 10 to 15, yes.

Q Specifically expanding clinical sites for patients with an LVAD, correct?

A Yes.

Q An LVAD is a left ventricular assist device, is that right?

A Yes.

Q Patients with an LVAD have severe heart failure, correct?

A Yes. It's end-stage heart failure.

Q Clinical sites or sites are hospitals running clinical trials, right?

A Yes.

Q Let's look at your email in the middle of the page. In

the middle of the page, you wrote, for Columbia, Piedmont, and other centers participating in the JenaValve LVAD registry, we should also ask them how do they plan to enroll patients in both competing trials.

Do you see that?

A Yes, I do.

Q JenaValve was also running a trial for patients with an LVAD, correct?

A Yes.

Q JenaValve's LVAD study would be a competing study, right?

A Yes, for the same patients.

MR. SEGAL: All right. Mr. Nguyen, we can take down that document.

BY MR. SEGAL:

Q Let's turn to your communications with physicians. In your role, you communicate with physicians who run clinical trials, right?

A Yes.

Q You communicate about the cost of medical devices with those physicians?

A Only when they ask what the research price is.

Q I would like to introduce PX1604. The redacted version can be shown to the public.

Ma'am, an unredacted version of PX1604 is in your

binder.

Ma'am, this is an email from you to Jamie Wheeler and others at Edwards, correct?

A Yes.

Q You report to Jamie Wheeler?

A Yes.

Q Ms. Wheeler is the senior vice president of transcatheter heart valve clinical affairs, correct?

A Yes.

Q Looking at your email at the top, at the end of the second line in your email, you wrote, Dr. Garcia noted that he opted out of ALIGN CAP because he wanted to focus on JOURNEY enrollment and didn't agree with their pricing strategy. Increased their price twice.

Do you see that?

A Yes, I do.

Q Dr. Garcia is a physician running clinical trials at the Christ Hospital, right?

A Yes.

Q ALIGN CAP is a program that allows patients to gain access to Trilogy pending PMA approval, right?

A Yes.

Q The reference to their pricing strategy, that means JenaValve's pricing strategy, right?

A Yes, I think so. I was merely quoting Dr. Garcia's note

to us or statement to us.

Q And in his quote, he was reporting that he disagreed with JenaValve's pricing, correct?

A Just exactly what I had written here on this email.

Q And instead, he planned to focus on JOURNEY enrollment instead, right?

A Per his statement, yes.

MR. SEGAL: Mr. Nguyen, we can please take down the document.

BY MR. SEGAL:

Q Let's continue discussing clinical strategy. I am going to introduce PX1280. The redacted version can be shown to the public.

PX1280, ma'am, is available in your binder. I am going to reemphasize that there are a lot of redactions here, so I am going to reemphasize how important it is for you to be very precise, yes or no with your answers.

On July 31, 2024, you attended an Edwards leadership team meeting on aortic regurgitation, right?

A Yes.

Q That meeting occurred a few days after Edwards acquired JC Medical and agreed to acquire JenaValve, right?

A Yes, if I recall.

Q You wrote this email the day after attending the meeting?

A These were my notes from the meeting.
Q And you wrote this email the day after the meeting?
A Sorry. Yes.
Q Okay. And as you said, these are your notes of that meeting, right?
A Yes.
Q And you sent those notes to your boss, Jamie Wheeler?
A Yes.
Q And you try to provide accurate information when you report to Ms. Wheeler, correct?
A No. These are simply my notes. Again, based on what I was hearing from the meeting, this was the first introductory meeting I had with discussions regarding JenaValve and JC Medical, so I was simply taking notes of what I thought I heard from the meeting.
Q Ma'am, I would like to repeat my question because I'm not sure you heard it.
A Okay.
Q You try to provide accurate information when you report to Ms. Wheeler, correct?
A No. I was simply writing down my notes. I can't say that these are accurate. I was simply writing down what I thought I heard from the meeting.
Q Ma'am, do you remember your deposition on September 30, 2025?

A Yes.
Q You were under oath at that deposition?
A Yes.
Q And you testified truthfully that day?
A Yes.
Q I would like to turn to a copy of your deposition, on page 18, lines 13 through 15.
You were asked, do you try to provide accurate information when you report to Ms. Wheeler?
You answered, yes.
Did I read that correct?
A Yes. But I was referring to -- I mean, generally when I try to provide information to my supervisor, I try to provide accurate information, but I can't say it applies to that specific email with my notes from the meeting.
Q Let's turn back to PX1280. You wrote to your boss, key priorities for 2024 to 2025.
Do you see that?
A Yes.
Q Let's look under those key priorities. Next to the No. 1, you wrote gen 1, JenaValve, FDA approval and commercial launch in 2025.
Do you see that?
A Yes, I do.
Q Gen 1 means JenaValve's Trilogy device, right?

A I think so based on the notes I have in my email.
Q In the next line, 1A, you wrote, not proceed with the ARTIST.
Do you see that?
A Yes, I do.
Q A key priority discussed at the Edwards leadership team meeting was not proceeding with JenaValve's ARTIST trial, correct?
A This is what I had written here in my notes. Again, this was the first time I am hearing about the ARTIST trial, and so again, I am simply writing down what I thought I heard from the meeting.
Q In the next line, next to the No. 2, you wrote JCM proceed with gen 2 over JenaValve.
Do you see that?
A Yes, I do.
Q JCM refers to JC Medical, correct?
A Yes.
MR. SEGAL: We can take down that document.
BY MR. SEGAL:
Q So that email was August 1, 2024. I am going to jump a year ahead while we are still in public session, but we will return to some topics in between those dates.
A Okay.
Q So the FTC sued to block Edwards acquiring JenaValve on

August 6, 2025, correct?

A Yes.

Q I would like to introduce PX1285. We can show the redacted document to the public.

We can turn to the third page, PX1285-003. You sent this email on August 8, 2025, correct?

A Correct.

Q Let's look at the middle of the page. You wrote, we have a meeting with LT, Larry, and Dan on Monday at 2:30 p.m. for a status update on root cause, solutions, and time lines, specifically on how we can accelerate Sojourn. This is anticipated given the news on Jena this week.

Do you see that?

A Yes, I do.

Q Larry means Larry Wood, right?

A Yes.

Q Dan is Dan Lippis?

A Yes.

Q LT stands for leadership team, right?

A Yes.

Q The JenaValve news that you are referring to here was the FTC's lawsuit, correct?

A Yes.

Q That lawsuit highlighted the urgency to restart J-Valve's clinical trials, correct?

A No. I disagree. Since the voluntary enrollment hold that we implemented on the JOURNEY trial in July of 2025, my team and I, our team, have been working to try to figure out the root cause and mitigations to try to get us back to clinic as quickly as possible.

Because when we paused the trial, we had patients that had been screened and approved to be treated in a trial, but because of the pause, right, we now had this list of patients that have not yet been treated and are waiting for treatment. So our mandate has been to try to get back to clinic as quickly as possible.

But even after the acquisition, since they won, my mandate has been to try to execute this trial as quickly as possible, to initiate the trial, to enroll the first patient in the trial as quickly as possible. So you know, yeah. So that's always been our mandate. We have always been trying to figure out how to accelerate enrollment in JOURNEY.

Q Let's turn to your deposition on September 30 on page 88.

A Can you repeat that page.

Q Page 88 of the deposition, lines 9 through 12.

You were asked, what did you mean this is anticipated given the news of Jena this week?

You answered, it just highlights the urgency, right, to get back to clinic.

Did I read that correct?

A Yes, you did.

MR. SEGAL: Your Honor, defendants have designated as confidential the remaining topics in my exam. I would like to transition to a sealed session.

THE COURT: Any objection?

MR. SHORES: Thank you.

MR. SEGAL: Fine on the FTC side.

THE COURT: Okay. Go ahead.

(The following was heard in closed session.)

(The following was heard in open session.)

MR. JOHNSON: Plaintiff calls Daniel Sun, senior director of global marketing for JenaValve, to the stand.

DANIEL SUN

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

DIRECT EXAMINATION

BY MR. JOHNSON:

Q Good afternoon, Mr.Sun. My name is Evan Johnson, and I'm an attorney at the FTC. I am going to be asking you some questions this afternoon.

To start out, could you please spell your first and last name, please.

A It's Daniel Sun, D-A-N-I-E-L, S-U-N.

Q Thank you, Mr. Sun. Let's start with some background questions. Okay?

Mr. Sun, you are the current senior director of global marketing at JenaValve, right?

A Yes.

Q You have held that role since March 2025?

A Yes.

Q And you joined JenaValve in 2021?

A Yes.

Q And prior to your current role as senior director of marketing, you held two marketing roles at JenaValve, right?

A Yes.

Q Prior to working at JenaValve, you worked at Edwards in a marketing role, right?

A Yes.

Q And specifically, you worked at Edwards from 2014 to 2021, correct?

A Correct.
Q And during your time at Edwards, you worked in marketing with respect to TAVR devices, correct?
A Correct.
Q So you have approximately over a decade of experience in the TAVR space, correct?
A Correct.
Q All right. Mr. Sun, I would like to ask you some questions about some TAVR devices.
MR. JOHNSON: Mr. Nguyen, could we please pull up PX2413 to the screen.
BY MR. JOHNSON:
Q And PX2413 is the email at the top from you to John Kilcoyne and others at JenaValve dated March 7, 2024.
Mr. Sun, you drafted the attached messaging talking points for the team to use at CRT in 2024, is that right?
A Yes.
Q And CRT is an annual cardiovascular conference, correct?
A It is -- I'm sorry, it is an annual --
Q Yes.
A Yes, correct.
Q Mr. Sun, you are responsible for tracking TAVR-AR devices that may be in development, correct?
A Yes.
Q And J-Valve is one such TAVR device in clinical trials

in the United States, correct?
A Yes.
Q And it is important for you to know the status of J-Valve's clinical trials, correct?
A Yes.
Q And J-Valve is currently owned by Edwards in the United States, correct?
A Correct.
Q Let's go to page 15 on PX2413. And let's look at the first bullet on the left under competition.
There you write, several new dedicated AR TAVR devices in development, but all are in early clinical stages and will not be available for five-plus years.
Did I read that correctly, Mr. Sun?
A Yes.
Q And then do you see there's an asterisk after AR TAVR devices? Do you see that?
A Yes.
Q And then there's a corresponding asterisk at the bottom of the left side of the page that lists Laguna Tech, Alpha Valve, Hanchor Valve, KOKA Pioneer Valve, and Ken-Valve.
Do you see those, Mr. Sun?
A Yes, I do.
Q By early clinical stages in the bullet point, you meant early clinical stages outside the United States, correct?

A I don't think I meant specifically inside or outside the United States. I think I was generally providing an update on the different AR TAVR devices in development.

Q And of the ones you listed here, Laguna Tech is the only TAVR device that you listed that's a U.S.-based valve, correct?

A Yes. Although, I think it's -- you know, some of these companies, you don't always know where they are originating from. When I build these out, I look at the program agenda, I look at what the presentation titles are, and I try to glean as much information as I can. I know that Laguna Tech is a U.S.-based company.

Q And to your awareness, the others listed there other than Laguna Tech are not a U.S.-based company, correct?

A Correct.

Q And in your message, you wanted to convey to the team on this email that they should not be concerned about these valves, correct?

A I wouldn't say that they should not be concerned about the valves. I think I just wanted to convey a general sense of the status, and I don't necessarily think that -- I wasn't being super exact in my timing when I said they are not available for five-plus years.

This was like an internal document, and it was meant to just provide general guidance to the team. This was

intended to kind of inform the team on the status of different things and what they might say if they were asked questions from physicians. So it was meant to just give them an update, I think.

Q And the status that you list here is that these are all in early clinical stages, right?

A Yes.

Q And other than J-Valve and Trilogy, you are not aware of any U.S. clinical trials for TAVR-AR, correct?

A I am not aware.

Q And J-Valve and Trilogy are the only TAVR-AR devices currently seeking FDA approval, correct?

A JenaValve Trilogy is seeking FDA approval. J-Valve, my understanding is that they are still in their clinical trial. There's an IDE study that's required. I mean, to the best of my knowledge, they have not put together a submission to the FDA for approval.

Q Fair to stay that J-Valve in their pivotal trial is ultimately seeking FDA approval?

A Yeah. Pending the outcomes of the clinical study, the goal is to have approval in the U.S., yes.

Q And so J-Valve and Trilogy are the only TAVR-AR valves currently seeking FDA approval, is that right?

A I mean, if you are asking me that particular question, when I hear seeking approval, I'm thinking they submitted or

are submitting a PMA for FDA approval.
Q Okay. But J-Valve and Trilogy are the only TAVR-AR valves currently in clinical trials to seek FDA approval, correct?
A In clinical trial, yeah.
MR. JOHNSON: Okay. And if we could pull that back up, Mr. Nguyen.
BY MR. JOHNSON:
Q And J-Valve is not on this list, correct?
A Well, J-Valve is in the next bullet point, but in the asterisk list, they are not.
Q That's because as of March 2024, J-Valve had begun clinical trials in the United States, is that right?
A That wouldn't not be -- I don't know if that's necessarily the reason why they wouldn't be in this list. I simply had J-Valve with separate messaging because I had additional points to make on J-Valve in particular. They were presenting at this meeting, so they had a lot of specific presentations, relevant presentations, within the sessions that I had read, so I had more to say, I guess, or I had a separate update for them. When I'm talking on the topic of, you know, quote/unquote, competition, I felt I should also mention the other players.
Q Okay. And currently, J-Valve and Trilogy are further along in their development in the United States than any

other device seeking an indication for aortic regurgitation, correct?

A I think it's a somewhat challenging answer because the development of a given device, there are a lot of parts to it during the clinical pathway. So being further along or -- you know, those are all kind of relative terms, and it's not like a specific -- so I could say that my understanding is that J-Valve has an IDE, a pivotal study, in the U.S. And obviously we've completed a pivotal study in the U.S.

Q Thank you, Mr. Sun. I appreciate that's a relative question. Let me repeat it for clarity.

So currently J-Valve and Trilogy are further along than -- in their development in the United States than any other device seeking an indication for aortic regurgitation, correct?

A In the sense that they have started their IDE or pivotal study in the U.S., yes.

Q If Edwards is allowed to buy JenaValve, it would reduce the numbers of companies currently in clinical trials in the United States for aortic regurgitation from two to one, is that right?

A Yes, because of the -- because both of these companies are in current clinical trial in the U.S.

Q And JenaValve is currently competing against J-Valve for

the development of a TAVR-AR device, correct?
A I would say JenaValve is working on a TAVR device for AR, and J-Valve is also working on a TAVR device for AR.
Q Therefore, JenaValve is currently competing against J-Valve for the development of a TAVR-AR device, is that right?
A I want to answer your question. The word I get stuck on is competing because I feel it's somewhat difficult. Like, the definition I would use for competing would be -- I work in marketing. I'm a marketer. And generally speaking, for me, competing is, like, you know, in a commercial environment. So they are both investigational devices in the U.S., both pursuing the same indication.
Q And, Mr. Sun, you testified at an investigational hearing in this matter, correct?
A Yes.
Q And you were under oath when you gave that testimony?
A Yes.
Q And to the best -- and you gave accurate and complete information at your investigational hearing, correct?
A To the best of my ability, yes.
MR. JOHNSON: All right. Mr. Nguyen, if we could pull up Mr. Sun's investigational hearing transcript and go to line 121 -- or page 121, please. That will be line 24.

BY MR. JOHNSON:

Q And, Mr. Sun, you were asked:

Is JenaValve competing against J-Valve for a development of a TAVR-AR?

And then you answered, yes.

Did I read that correctly?

A Yes.

Q All right. We can put that aside.

I want to take a look at another document. It will be PX2417. PX2417. The phone numbers have been redacted, but otherwise, everything else will be unredacted.

It's a chat message between yourself and Ryan Polzin dated February 27, 2023. Mr. Polzin is senior director of commercial operations and strategy at JenaValve, correct?

A Yes.

Q Mr. Sun, let's look at the third page.

About midway through the document, you write, they've already done 36 compassionate use cases in the U.S. Coming hot on our heels.

Do you see those messages?

A Yes.

Q You were referring to J-Valve coming hot on JenaValve's heels, correct?

A Yes. Within the context of their clinical activities yes.

Q Later on in this chat message, you text, if we wait on expanding our AR indication, we will be giving up our lead.

Do you see that, Mr. Sun?

A Yes.

Q By lead here, you are referring to JenaValve's lead relative to J-Valve, correct?

A Yes. Although, I think, you know, the important -- the context, I think, is important in that, you know, all of this is within a clinical trial within an investigational portion pre-commercial. And when I am speaking of our lead, I am talking about our lead in terms of engaging or starting or initiating a clinical study.

So, you know, I was pushing that we should initiate an indication expansion study. It's kind of a long, you know, complex reason on why that's important. But in general, it's because I think in order to treat the most patients with AR, which is in my opinion a significant unmet need, you would need to go beyond high risk. You would need to expand this treatment to low and intermediate risk. So I always felt strongly we needed to move forward with that study, which is now the ARTIST trial.

At this time, if I recall, we had not started the study yet, and I was, you know, kind of making like this impassioned plea to everyone to, like, hey, we need to start this study.

So anyway, to answer your question, I meant from a clinical study standpoint in initiating another study to achieve an additional indication, and that's what I meant by lead.

Q Got it. So as far back as February 2023, the date of this message, you thought it would be a good idea to pursue the ARTIST trial, correct?

A Yes.

Q And at least part of the reason you wanted to pursuit ARTIST even in 2023 was to maintain JenaValve's lead over J-Valve, correct?

A I think the main reason is because I felt it was the right thing to do. You know, there's other documents where I have mentioned things where I'm saying, like, we need to work on this study or we need to work on this development for this device, which is the first of its kind, a TAVR device for AR.

And joining the company, that's why I left Edwards to come to JenaValve to work on this. And there were times I felt we weren't moving forward quickly on certain things. So the reasons to pursue the study were not isolated to maintaining a so-called lead over J-Valve.

It was really because I wanted to see this potential technology reach the patients that needed it as quickly as possible.

Q And so, Mr. Sun, to make sure I understand your testimony, is it your testimony that J-Valve played no role in the -- any role in JenaValve's pursuit of the ARTIST trial?

A From my end, I do not feel that, like, it -- like, on my end, I wanted to do this irrespective of what J-Valve was doing. I used it oftentimes to kind of compel people because I felt like I was the only one with -- not the only one, but I was very urgently advocating to move more quickly.

I would often say, hey, look, J-Valve is doing things. That was kind of -- at the time there was a little frustration on my end to, like, let's move faster. We should do things.

When the opportunity came up, I would bring up J-Valve and say, look, they are doing things, they are moving things along, we should do that.

To be clear, it's not, like, a deciding factor for me wanting a larger valve or wanting to pursue the ARTIST study which would open access to more patients or to expand to more sites, things like that.

Q And, Mr. Sun, you testified at a deposition in this matter on October 2, 2025, correct?

A Yes.

Q And at that deposition, you were under oath?

A Yes.
Q And you gave truthful and accurate testimony at your deposition?
A Yes.
MR. JOHNSON: Mr. Nguyen, if we could pull up Mr. Sun's deposition transcript and go to page 202, lines 2 through 8.
BY MR. JOHNSON:
Q And there at the top, Mr. Sun, you were asked:
The context here, it was J-Valve coming hot at the heels of JenaValve.
And so at least part of the reason you wanted to pursue ARTIST even in 2023 was to maintain JenaValve's lead over J-Valve, right?
And then there was an objection.
And you answered, yes.
Did I read that correctly?
A Yes. And I think it's consistent with what I have just said because we are reading, you know, that this was part of the reason to pursue ARTIST. And I, you know, I feel that the main reason was because it's kind of in the nature of a new indication of the next step.
You know, we have completed the pivotal study which addresses high risk patients. The next step would be to engage in this indication expansion study where we

randomized a surgery where we have potentially low and intermediate risk indication afterwards.

And then part of the reason, additional reason, would be because J-Valve also is now pursuing that indication.

And also, to be honest, I don't know what came before that, so I don't know if there was additional -- I'm talking about the deposition. I don't know if there was additional context that would, I don't know, agree with kind of what of told you.

Q Thank you, Mr. Sun. I appreciate all that clarification. Again, I was just asking a simple yes or no question. I read that part of your deposition transcript correctly, yes?

A Yes.

Q Let's put that document aside. Let's turn to another document, PX2096. And let's go to the bottom of page 1 where you draft an email to Duane Pinto, Lisa Boyle, and JenaValve's CEO John Kilcoyne as well as Jane Metcalf.

You write, leadership in AR, building up walls around what we do is key to enduring success in market share dominance. We have to assume J-Valve will receive approval.

Did I read that correctly, Mr. Sun?

A Yes.

Q And so obtaining additional indications for Trilogy would help JenaValve maintain market share dominance for

TAVR-AR, correct?

A So just to be clear, the context of this is I was responding to an email from, I think, Lisa and Duane where they had put together a roadmap for future trials mapping out trials that would be in pursuit of future case indications.

So I'm kind of projecting and talking about the future and talking about in a future in which there are commercial devices on the market, in order to have a competitive advantage in that commercial landscape, you need indications and you need essentially strong clinical data.

So I think the order in which I was leading into this email is that, like, leadership in AR, meaning having indications approved, having compelling clinical evidence, is the way to build up those walls. And then, of course, yes, in a commercial setting, achieve success, achieve market dominance.

Q And I appreciate that. Obtaining additional indications for Trilogy would help JenaValve maintain market share dominance for TAVR-AR, yes?

A Yes. In the sense that if we had indications that other companies did not have or other devices did not have.

Q And specifically, having multiple indications for Trilogy is one way in which JenaValve can maintain market share dominance against J-Valve, yes?

A Yes.
Q And then you continue, so how can we ensure that customers continue to choose to keep Trilogy on the shelf when alternatives become available.
Did I read that correctly?
A Yes.
Q And by customers, you meant physicians, is that right?
A Implanting physicians, yes.
Q And then you conclude -- the next part of your email, you conclude, I'm very happy to see this vision take shape. And as Jane said, we will need to build out the pathway for XL as part of this vision.
Did I read that correctly, Mr. Sun?
A Yes.
Q XL here means JenaValve's development of larger valve sizes for Trilogy?
A Yes.
Q We can put that document aside.
I want to take a look at another document. It will be PX2041. And let's go to page 7. And the slide at the top says, proposed approach, overview of five key parts.
Mr. Sun, you were responsible primarily for creating this slide, correct?
A Yes.
Q On the very left, you list one of the key parts as

ALIGN-AR CAP. Do you see that?
A Yes.
Q ALIGN-AR is JenaValve's clinical study, correct?
A It's our high risk pivotal study, yes.
Q The CAP is the FDA's continued access program, correct?
A Yes.
Q So the CAP protocol allows JenaValve to continue offering Trilogy at clinical sites while it seeks FDA approval, is that right?
A Yes.
Q And in the text box under ALIGN-AR CAP, you wrote, the rationale is to treat high risk patients, maintain engagement with PIs and clinical sites, obstruct J-Valve IDE study enrollment.
And PIs is a reference to principal investigators?
A Yes.
Q And IDE study refers to J-Valve's pivotal clinical trial?
A Yes.
Q So one of the reasons for pursuing the ALIGN-AR CAP is to obstruct the J-Valve IDE study enrollment, correct?
A Yes. Well, I want to provide additional context here as well. I mean, I felt strong -- this is a document where I was trying to argue to initiate these various programs throughout. It's pretty consistent with what I have

testified before, that I felt that we needed to move forward on certain things.

I wanted to continue with ALIGN CAP. There was discussion around closing the CAP because it's expensive to continue to enroll. Like, we had the outcomes of the study already. We had achieved our clinical endpoints at this point. So you know, the company could decide to close the CAP and save money, but I was arguing we should continue to keep it open.

That being said, I think that context is important because I am trying to compel or trying to argue for something, so I was throwing in all these things to try to see if, you know, people could get on board.

The main and primary reason, which that's why I wanted to add this context, is that without CAP, no -- Trilogy is not being implanted anywhere. So in order to continue to treat these patients in need, you needed to have the CAP open because at this point ARTIST had not started.

One scenario if you do not continue the CAP is that no patients are treated with Trilogy. Doctors stop using Trilogy. They have multiple other devices not specific to AR devices, but they are participating in all these other trials.

So I wanted to say continue the CAP because that way we can continue to implant Trilogy in patients. PIs would

still stay top of mind. They would think about this trial and our device and keep it top of mind. They would maintain their kind of like operator skills in all these things. And then like I said, I throw in things. You know, I threw in the J-Valve study. But to be honest, I cannot testify that we genuinely -- you know, that we have an ability to obstruct enrollment in a separate study.

Q Both studies are for the same patient population of aortic regurgitation, correct?

A Yes.

Q And so one of the three rationales you write for the ALIGN-AR CAP was to obstruct J-Valve IDE study enrollment, correct?

A Yes. I mean, that's what I wrote in this text on this slide, yes.

Q And again, a patient that's eligible for both the J-Valve IDE study and the ALIGN-AR CAP study can only receive one valve at one time, correct?

A Yes.

Q If a patient meets the criteria of both studies, then JenaValve is competing with J-Valve for clinical trial patients, correct?

A I think it's a complex decision for the physician. In the end, the physician decides what device they want to use. But oftentimes, that scenario is a real one at hospitals.

PIs participate in numerous studies sometimes for the same disease, the same indication. But the two devices are very different.

So the PI or the physician may choose to use one over the other. And they might have their own reasons, like there are probably anatomical and clinical factors that would influence that decision. So on our end, whatever the physician decides is something that we are not involved in.

If they are eligible for our study and the physician wants to use our valve, assuming we agree that the patient meets the criteria of our study, we enroll them. But we don't, you know, make an attempt to, say, enroll in this study versus that study.

Q Okay. You can set that document aside.

I want to pull up another document. It will be PX2052. This is a chat between you and Devin Baerenwald on July 24, 2024. Mr. Baerenwald is director of field training at JenaValve, is that right?

A Yes.

Q Around this time, JenaValve had signed a merger agreement with Edwards, correct?

A Yeah, on this -- earlier that day.

Q Mr. Sun, let's look at page 2. Let's look at the third message from the bottom. Mr. Baerenwald writes to you, Chris got forwarded an email from an old Edwards colleague

that said Edwards had also closed the deal to acquire JC Medical which I hadn't seen anywhere online, but that would mean Edwards just bought the AR market.

Do you see that?

A Yes.

Q And Chris is a reference to a JenaValve field team employee?

A Yes.

Q And JC Medical owned J-Valve when it was acquired by Edwards, correct?

A Yes.

Q And so you understood the phrase bought the AR market refers to Edwards buying the only two TAVR-AR devices in clinical trials in the United States, correct?

A Yes.

Q We can set that document aside.

Take a look at another document. It will be PX2062. These are your text messages with Sean Kim on July 25, 2024. Mr. Kim is senior director of clinical affairs at JenaValve, correct?

A Yes.

MR. JOHNSON: Your Honor, the document contains some profanity that I would like to read aloud. Permission to do so?

THE COURT: To read the profanity?

MR. JOHNSON: Yes.

THE COURT: Sure. I assume it's relevant?

MR. JOHNSON: Yes. Not doing it for fun.

BY MR. JOHNSON:

Q Let's look on page 2, Mr. Sun. In the very first message, Mr. Kim writes to you, I don't buy this shit at all. EW is going to only keep one or the other. JC acquisition is a threat to us.

Do you see that, Mr. Sun?

A Yes

Q And EW is Edwards?

A Yes.

Q And JC acquisition is Edwards' acquisition of JC Medical?

A Yes.

Q And then you respond to Mr. Kim. You say, yes, that's what I'm saying. They will see which one is better and kill the other.

Do you see those messages?

A Yes.

Q And so you agreed with Mr. Kim's assessment that Edwards was only going to keep either Trilogy or J-Valve, correct?

A So to add context to this, I think, you know, this is a text message exchange. We were -- this was the day of the announcement of the Edwards' acquisition of JenaValve. And

then separately from this, we found out through those back channels you mentioned that Edwards had acquired JC Medical as well. So it was shocking news to us.

And it's essentially like, you know, this kind of pessimistic, you know, doomist back and forth between Sean and I in a very, like, informal kind of off the cuff type of way. I don't know what Edwards will do with the devices.

Here I confirm that that's what I say in that text, but you know, I wanted to add that there's no, like, time frame I'm referring to. I'm not saying, like, I don't believe that Edwards bought one of the devices to kill it. Like, I don't believe that to be true. I think perhaps I was thinking in the future if they have conducted clinical trials and they have determined one device performs better than the other and -- you know, there's so much undetermined, but I do admit that's what it says in the text.

Q And simply -- I'm just simply asking you, you are agreeing with Mr. Kim's assessment that it was going to only keep Trilogy or J-Valve in this message, correct?

A Can you say that one more time.

Q I am simply asking, you agreed with Mr. Kim's assessment that Edwards was only going to keep either Trilogy or J-Valve, yes?

A At this moment in time, I was responding that way. And

perhaps in that mind-set, I was agreeing. But I can't say realistically or honestly that I honestly believe this now or that I know what Edwards will do with either company or product.

MR. JOHNSON: Okay. No further questions at this time, Your Honor.

THE COURT: All right.

MR. MUSALLAM: Good afternoon, Your Honor.

CROSS EXAMINATION

BY MR. MUSALLAM:

Q Good afternoon, Mr. Sun. Let's start with those text messages. And those were sent on the day of the announcement of both JenaValve's acquisition by Edwards as well as JC Medical's acquisition by Edwards. And how were you feeling that day when you found out that news?

A So there was a lot of shock. It was specifically to the acquisition of JC Medical or the J-Valve. There was a lot of shock on our end. We didn't know that was happening.

I think there was probably a little bit of resentment too because obviously we work for a company and we are proud of the work and we have been spending our time and energy and efforts in driving forward this device.

So there was, I think, frustration and shock and resentment throughout a lot of the company. I can't speak for everybody, but you know, I can certainly speak for

myself. I think that's how I felt.

Q How would you describe the text exchanges with Mr. Kim and Mr. Baerenwald?

A I mean, so we are colleagues, but we are also comfortable with each other. I guess you could say we are friends. We are friends. So there's this kind of like in -- I mean, they are text messages, right? Like, to be honest, we all just speak openly in text messages. It's, like, from your brain to your fingers, and you just tap it out.

I would describe those text messages as kind of like off the cuff stream of consciousness kind of, you know, I don't want to say word vomit, but you are just blurting things out. And I think we were being a little bit like -- you know, we were commiserating a little bit. We were kind of like being pessimistic about everything.

Q What, if any, involvement did you have in negotiating the proposed transaction with Edwards?

A None.

Q Did anyone ask for your input regarding the terms of the agreement?

A No.

Q Did you provide any input to Mr. Kilcoyne or the board about the proposed transaction?

A No.

Q Did you have any involvement in the transaction at all?
A No.
Q And what visibility do you have into Edwards' plans for either JenaValve or J-Valve?
A I don't have any visibility.
Q And what personal knowledge do you have of Edwards' plans for Trilogy or J-Valve?
A I have no knowledge.
Q Okay. And, Mr. Sun, in your position as the senior director of global marketing, are you part of the senior leadership team at JenaValve?
A No.
Q Do you sit on any corporate committees?
A No.
Q Did you make any board-level decisions regarding trials, budgets, or corporate strategy?
A No.
Q Who do you report to?
A I report to Pete Spadaro, our chief commercial officer.
Q Who does he report to?
A He reports to Mr. Kilcoyne, the CEO.
Q Who does Mr. Kilcoyne report to?
A He reports through the board of directors.
Q Thank you.
Mr. Sun, counsel showed you some documents discussing, I

think it was, market share dominance. What is JenaValve's market share in TAVR-AR devices in the U.S. today?

A There's no market for TAVR-AR. There's no approved devices. There are devices in clinical study. They are investigational devices.

Q What will JenaValve's market share be if Trilogy doesn't receive FDA approval?

A Then there will be no market. There's no market share to speak of.

Q All right. Now I want to turn to clinical trial competition. We have heard that kind of concept being thrown. What does that mean to you?

A I think we use, like, the word competition, for lack of a better term, but we are talking about investigational devices. When we say clinical trial competition, we are speaking of clinical trials that are similar to other clinical trials or clinical trials that have the same indication as another.

So in the investigational phase, there are just all these steps. And, you know, I don't work in clinical affairs. I'm not an expert in trial design or trial protocols and things like that. But there's so much to be done. And those little steps that go on, you know, I track those.

So when I speak of competition, I don't know if I use

that term to describe the companies in the clinical trial phase, but if I did, it would be speaking to, like, their point in that research phase of a given device.

Q So they are both trying to get approval?

A Yes.

Q And, Mr. Sun, in your experience, how common is it for a TAVR center to run more than one clinical trial?

A Most -- all sites that I am aware of have multiple clinical trials.

Q And you know, there are clinical sites today that run both clinical trials for J-Valve as well as JenaValve, is that right?

A Yes.

Q And you have already given us description of how the physicians choose which patient to enroll, but is there anything you can do to incentivize a physician to pick one device over another in a clinical setting?

A No. This is a research activity, so it's important that the physician has the decision to choose what patients to use which device for.

Q And what role, if any, does pricing play in this clinical setting?

A None.

Q Has JenaValve ever used pricing or discounts to incentivize a physician to enroll Trilogy over J-Valve?

A No.
Q Do you charge for Trilogy in the clinical trial setting?
A We do.
Q And why is that?
A It's simply just to offset some of the costs of a clinical trial. These trials are very expensive, and we -- the company loses money. We don't generate any revenue from a clinical trial. You lose money. So it offsets some of those costs.
Q Thank you. And then counsel showed you some documents discussing J-Valve coming hot at our heels. You had mentioned that there was some frustration that you were feeling. Can you tell us a little bit about that frustration while you have been at JenaValve.
A Yeah. Yes, I can. So, you know, I left Edwards to join JenaValve, and I thought it was a unique opportunity to develop a device focused specifically on this disease where none existed. I was passionate about working on this device and addressing this unmet need.

I mean, patients are untreated. They are under diagnosed. There is a need for some type of TAVR solution for these patients. So I wanted to work on that.

And coming over, I felt that there were times where it seemed like we were moving slowly, or you know, it wasn't a conscious decision, but it was like things would happen that

I felt were just, like, setbacks. Setbacks would occur.

And you know, obviously, going from a big, publicly traded company to a smaller, privately funded company, there are financial decisions to make.

So in general, I think, joining in 2021, those first few years, it felt that we needed to do more. And there was frustration resulting from that inability to do more, whether it was, you know, distractions in the vision of the company or financial restraints or, like, you know, we couldn't do the things we needed to do. So there were, like, production issues, things like that. Those were all things that made me feel we took one step forward and, like, two steps back.

Q Thank you.

I want to show you PX2413. This is a document that counsel showed you. This is the one, the talk track document. I want to focus. What is the date of this document?

A March 7, 2024.

Q If you can turn to page 15, please, Mr. Sun.

All right. And you noted that several of these new dedicated AR TAVR devices won't be available for five-plus years, so probably like 2029 is what you are estimating here?

A Somewhat, yeah. I mean, like, it was a rough estimate,

but yes.
Q All right. And how do you typically learn about the development or the progress of, you know, another company's TAVR device?
A So the only -- I mean, sometimes you might hear about things from doctors that are working on multiple studies, but for the most part, it's through a presentation in a, you know, in a medical conference. They would present something on the podium and then present new research.
Q And just on the asterisk on the bottom there, there are a couple of them named Laguna Tech, Alpha Valve, Hanchor Valve, KOKA Pioneer Valve, Ken-Valve. Since the date that this document was prepared, have any of those companies presented clinical data at conferences?
A This document was prepared prior to CRT of that year, so CRT 2024. So at that conference, Laguna Tech presented data. The other companies have presented since then, so Hanchor Valve presented recently, actually, at TCT, which was in October. And Ken-Valve also presented at TCT, which was in October, in the same session, actually.
Q What is the significance of presenting clinical data?
A I mean, these are academic meetings. It's to inform the cardiology community or the interventional cardiology community of research that's going on. And they always -- you know, the goal is to present results from different

studies that would be during that clinical phase. So it's to educate and inform and provide updates on development.

Q Are you aware of others who are developing TAVR-AR devices or other devices to treat aortic regurgitation?

A Yes. So there's a few other companies that I didn't list here, but like there's a device called the Cusper device which is intended to treat aortic regurgitation, but they have presented pretty consistently. They have presented, that I am aware of, most recently at Europe PCR this past May.

And there are -- another pathway is that you have a TAVR device that has an AS indication, and if you can prove that device also works on AR, then you can feasibly achieve an indication for that. So there are companies with studies on AS devices, TAVR devices designed for AS where they are -- the hypothesis is whether or not that device would also work in an AR population.

Q Do you monitor these companies even though they are not in clinical trials in the U.S.?

A Yes.

Q Why is that?

A It's -- you know, it's like a global -- you know, it's a global community, so it's very common for companies to run trials in other regions. And you know, we are a global company, so we just try to keep track -- like, things aren't

isolated to one region, you know. Things move, so we track everything.

Q Okay. Thank you.

MR. JOHNSON: Nothing further, Your Honor.

Thank you, Mr. Sun.

THE COURT: Thank you, Mr. Sun.

MR. SHORES: Your Honor, it's 3:35. Would now be a good time for a break?

THE COURT: If you want it to be, sure. We will take a 15-minute break.

(A recess was taken at 3:36 p.m.)

MR. ANDERSON: May I proceed, Your Honor?

THE COURT: Yes.

MR. ANDERSON: Plaintiff calls Dr. Duane Pinto to the stand.

DUANE PINTO

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

DIRECT EXAMINATION

BY MR. ANDERSON:

Q Good afternoon, sir.

A Good afternoon. How are you?

Q I'm well. How are you?

A Not too bad.

Q Could you please state your name for the record.

A Duane Pinto.
Q Dr. Pinto, at the present time, you are the chief medical officer of JenaValve Technology?
A I am.
Q You have been CMO since October 2022?
A I have.
Q In your role as CMO, you helped design and oversee JenaValve's clinical trials for the Trilogy product, correct?
A I did.
Q Fair to say that you are familiar with FDA requirements for clinical trials supporting approval of medical devices in the United States?
A I am.
Q One of those FDA requirements is called an IDE?
A It is.
Q Another FDA requirement for clinical trials is that 50 percent or more of your data has to be from the United States?
A That's correct.
Q I would like to ask you a little bit about JenaValve's clinical trials. ALIGN-AR was JenaValve's pivotal trial for high risk SSAR patient population, is that correct?
A Yes.
Q When did ALIGN-AR begin?

A ALIGN-AR began in June of 2018.
Q And when was it completed?
A August 29, 2022.
Q How many patients did JenaValve enroll in ALIGN-AR over the course of the trial?
A 180.
Q In 2024, is it fair that JenaValve enrolled another 220 patients in the continued access protocol?
A I'm not sure the exact number. Approximately, yes.
Q In the first six months of 2025, it enrolled an additional about 150 patients in CAP?
A Yes.
Q Do you know how many more have been enrolled in CAP since the first sixth months of 2025?
A Right now in total, we are at 780, 782, so that minus what you told me.
Q Is that CAP and ALIGN-AR together or just CAP?
A CAP and ALIGN-AR together.
Q It's fair to say that JenaValve's cadence of enrolling patients in CAP is increasing?
A Yes.
Q It's increasing because, in your opinion, doctors are becoming more aware of the unmet need for AR patients?
A That's correct.
Q JenaValve has another clinical trial for intermediate

and low risk SSAR patients called the ARTIST trial, correct?
A Yes. Those patients don't always have to be symptomatic. So the first S of the SSAR is symptomatic. But there are indications for patients who are asymptomatic to have aortic valve replacement, but largely, yes.
Q So it would be fair to say that is the intermediate and low risk AR population?
A Yes.
Q If successful, ARTIST would expand the FDA approved indication for Trilogy so it could treat more of the total addressable market?
A Yes.
Q JenaValve's goal is to enroll 1,000 patients in ARTIST?
A Yes, approximately.
Q Without saying the specific number which has been marked confidential, it is fair to say that JenaValve has started enrolling patients in ARTIST?
A It has.
Q A third ongoing JenaValve clinical trial is called JENA-VAD?
A Correct.
Q And that is aimed at patients who have a VAD or ventricular assist device?
A That's correct.
Q Do you know approximately how many patients JenaValve

has enrolled in JENA-VAD?
A Around 16 out of 50.
Q It's also true that JenaValve provides Trilogy to AR patients under compassionate use and emergency use protocols?
A That's correct.
Q Those protocols require separate FDA approval, correct?
A Yes.
Q Do you know how many Trilogy valves JenaValve has provided under the compassionate use and emergency use protocols?
A Approximately 50.
Q Do you know how many AR patients have received Trilogy valves in the United States as of today in all?
A As I mentioned, 780 in PMA and CAP, another 15 or 16, like I said, for JENA-VAD, and the compassionate use cases, so let's say approximately 850.
Q 850. Dr. Pinto, it's fair that even more AR patients have received a Trilogy valve outside the United States?
A Yeah.
Q I would like to talk to you about Europe for a moment. Trilogy is right now the only TAVR-AR valve approved for commercial sale in Europe, correct?
A Yes.
Q In fact, just this past Monday of this week, JenaValve

announced that it had treated its 1,000th commercial patient in Europe, correct?

A You are correct.

Q In your words, in Europe more and more patients are being referred that would not have historically been identified as a candidate for treatment or even diagnosed?

A That's right.

Q This milestone speaks to the vast unmet need for patients suffering from AR, correct?

A That's right.

Q Dr. Pinto, you are aware of another TAVR-AR device called the J-Valve, correct?

A I am.

Q The J-Valve is in the United States?

A Yes.

Q And it's owned by Edwards?

A It is.

Q Trilogy is the first mover in the AR space, correct?

A Yes.

Q J-Valve would be the second mover?

A I'm not sure what you mean by second mover. In what domain?

Q It's the second mover in the TAVR-AR space in the United States?

A As an approved device or for sale or investigation?

Q It's the second mover in the TAVR-AR space in the United States that has been implanted in humans in the United States?
A Correct.
Q Sorry. That's correct?
A Yeah.
Q Now, you have previously compared Trilogy to a Benz and J-Valve to a Prius, correct?
A Yes.
Q Dr. Pinto, you have been part of internal JenaValve discussions about J-Valve's development?
A Not in particular.
Q I would like to introduce a document, PX2195. Let's look at the top -- excuse me. Let's start with the email on the bottom, which is from Mr. John Kilcoyne.
Mr. Kilcoyne was the CEO of JenaValve as of the date of this email, March 21, 2023?
A Yes.
Q And the subject of this email is forward J-Valve. That refers to the J-Valve TAVR-AR device?
A Yes.
Q It's fair to say that in May of 2023, J-Valve was not yet owned by Edwards?
A Yes, that's correct.
Q Mr. Kilcoyne writes to you, Mr. Pinto. He says, look

forward to your thoughts re: clinical outcomes.

It's fair to say he was asking for your thoughts on data from J-Valve's EFS study?

A That's correct.

Q Now I would like to look at the top email. And this email, Dr. Pinto, is from your JenaValve work account also dated May 21, 2023. And this has 18 bullet points of your thoughts on J-Valve's EFS results, correct?

A It does.

Q I would like to look at just a few of them.

Let's start with the third bullet. It says, they enrolled moderate to severe, also helps us with FDA.

They there refers to the J-Valve EFS study, correct?

A That's correct.

Q It's fair to say that the J-Valve EFS protocol enrolled moderate to severe AR SSAR patients, is that correct?

A Yes.

Q And in your opinion, J-Valve's EFS protocol copied Trilogy's protocol, right?

A I don't know the details of their protocol. I haven't seen it. But I'm sure it's very similar.

Q And this EFS study showed to you that the FDA would accept protocols that enrolled moderate to severe AR patients, correct?

A Correct.

Q I would like to look at bullet No. 8. You write here, I thought they treat to 100 millimeter, but they go from 57 to 109 millimeter, maximum diameter 33 millimeter.

Is this a reference to J-Valve's valve-sizing matrix?

A Yes. I don't really track it, so this was news to me, what they really were treating.

Q So you learned the sizing matrix from the EFS data on J-Valve, correct?

A That's correct.

Q I would like to look now at bullet point No. 15.

This says, I like 13 percent pacer rate given our rate was 13 percent in the last year.

In this bullet, you are looking at something called the pacemaker rate. And what is the pacemaker rate?

A So between the right coronary cusp and the noncoronary cusp is the wiring of the heart. When you put a TAVR valve in, you can, I don't know what the technical term is, smoosh the electrical system and require -- the patient would require a pacemaker.

Q It's fair to say that the pacemaker rate measures the rate of AR patients who must receive a pacemaker after they get a TAVR-AR valve?

A Yes.

Q A lower pacemaker rate is preferrable, correct?

A Depends on what you mean by preferrable. There's no

hazard of getting a pacemaker. It's a little bit longer time in the hospital, but certainly I don't want my patients to suffer a complication.

Q If you got to choose, Dr. Pinto, you wouldn't want your patients to get a pacemaker, is that right?

A I would want them to get the valve so they wouldn't die, but if that was the price of not dying, then it's better to be alive with a pacemaker.

Q Choosing between two equal worlds, a pacemaker is not something you would prefer a patient have who has received a TAVR valve. Is that fair?

A I don't live in a world of equal worlds. There's tradeoffs for everything.

Q Okay. Let's look at bullet point No. 16. This bullet says, their sheath size goes up as the size of the valve goes up, I presume. So that means that only 3 of the 27 use the really big valve, 10 percent.

This bullet is comparing sheath sizes used by J-Valve with the sheath sizes of the Trilogy product, correct?

A Yes, it does.

Q And it's fair that a sheath is the tube that goes into a patient's leg and through which a TAVR-AR valve is delivered to the heart?

A That's correct.

Q The smaller the sheath, the smaller the incision needed

in the patient's leg, correct?
A Yeah. We don't really make an incision in the leg. You are largely correct, though. It's the hole you make in the artery to put the sheath in.
Q The smaller the hole in the leg, the fewer the complications that may arise from the procedure, correct?
A Not really, actually. So, for example, in our data, we had 35 patients out of 700 that had a vascular complication. That's actually lower than the TAVR-AS valves that have smaller sheath sizes, so...
Q Dr. Pinto, is your testimony that the smaller hole does not mean fewer complications for the patients?
A It depends. Yes and no. Because there are a number of factors. The size of the hole that you make, or in other words, the size of the sheath, but also the tortuosity or twists and turns the leg artery makes, calcification, whether there's disease, whether they have been treated before, what the body mass index of the patient. There are people who have more complications. So it's not a single factor, it's multiple factors that lead to vascular complications.
Q But it's one factor that could lead to complications the size of the hole, correct?
A Correct.
Q This sentence continues, this means our 20 versus their

18 for many cases. Sheath size is measured in something call French, correct?

A It is.

Q So this would refer to 20 French and 18 French?

A Yes. So the difference is .33 millimeters per French so it's a little over half a millimeter difference.

Q In this, the 20 French refers to size of Trilogy's sheath, is that correct?

A So it's -- it's a little confusing because a sheath has an inner diameter. Ours is 20 French. But an 18 French sheath has an outer diameter that's similar to ours. I don't know if that's too detailed. Sorry.

Q Dr. Pinto, I am referring to the words you wrote on this page. You wrote our 20, so you were referring Trilogy is 20, correct?

A Correct.

Q And the 18 here refers to J-Valve's 18 French sheath size, correct?

A I mean, the reason I said that is at that time, it's not the case now, J-Valve used off the shelf 18 French sheaths which the outer diameter of those sheaths is exactly the same as the outer diameter of our 20 sheath -- 20 French sheath.

Q Thank you, Dr. Pinto. Directing you back to my question, you wrote 18 here, and that refers to J-Valve's 18

French, correct?

A Yes. Sorry

Q We will come back to valve sizes, pacemaker rates, and sheath size in just a moment. First I would like to talk to you a little bit more about clinical data.

It's fair that you have reported about J-Valve's clinical data to the JenaValve's board of directors?

A Not that I'm aware.

Q I would like to look at PX2109.

Dr. Pinto, let's look at the top box here. This is an email from your work account dated August 31, 2023.

Fair to say this was before the acquisition of J-Valve by Edwards, correct?

A Yes.

Q And you see in the to line there, you recognize those names as the JenaValve board of directors?

A Yes.

Q And the subject line of your email is recent interesting papers.

A Yes.

Q I would like to look at the body. It says, dear board members, I wanted to draw your attention to some very interesting information that was just published in JACC cardiovascular interventions as part of an AR spotlight issue.

Then in the fourth paragraph, Dr. Pinto, you write, furthermore, the compassionate use experience for J-Valve was also reported in another paper in the same issue with results that did not compare favorably to the Trilogy valve.

Do you see that?

A I do.

Q I would like to look at the paper you are referring to in the body of this email. If we could flip to page 005.

This is the first page of the paper that you are referring to, is that correct?

A Yes.

Q Now, I would like to flip to 06 in that paper, so the next page. And you see here a chart in the middle. Do you recall looking at this chart during our deposition together, Dr. Pinto?

A I do.

Q You will see here three valves. I would like to walk through them one by one. The valve on the left is the Pantheon valve. That is a TAVR-AS valve, correct?

A So the Pantheon is a registry. So that's why you see pictures of two valves. One is a SAPIEN valve, and one is the Evolut valve. So it's a registry, Pantheon, so you are partly right.

Q It's referring to the Evolut valve, which is a TAVR-AR valve?

A And the SAPIEN valve. Both are in the picture there. The left one is the SAPIEN valve. The right one is the Evolut valve.

Q The SAPIEN valve is the TAVR-AS valve made by Edwards, correct?

A That's right.

Q And the Evolut valve is the TAVR-AS valve made by Medtronic?

A That's correct.

Q And this column shows the results for when a TAVR-AS valve was used off label to treat AR patients?

A That's right.

Q You would agree that the outcomes in this column are bad?

A Well, they are not great.

Q Okay.

A Yeah.

Q So the middle column is for J-Valve, and the right column is for Trilogy.

At the time of this paper, Dr. Pinto, the only two TAVR-AR products approved by the FDA for compassionate use cases were J-Valve and JenaValve, correct?

A Yes.

Q I would like to look at the chart then, the rows where it compares J-Valve and Trilogy.

So the fourth row down says, technical success. Do you see that?
A Yes.
Q J-Valve's is 81 percent to Trilogy's 100 percent?
A That's right.
Q So Trilogy's technical success is better than J-Valve's?
A Can't get better than a hundred percent.
Q Looking at the next row, device success, J-Valve's is 81 percent, Trilogy's is 98 percent?
A Yes.
Q Trilogy's is better?
A Uh-huh, yes.
Q And looking at the seventh row, transcatheter, migration, or embolization. Dr. Pinto, migration or embolization are possible complications that arise from implanting a TAVR-AR valve, correct?
A They are.
Q Migration is when a valve moves from where it was originally implanted?
A That's right.
Q Embolization is when a valve fully dislodges from where it was implanted?
A That's correct.
Q J-Valve's rate for migration or embolization is 14.8 percent, and Trilogy's was 0 percent, correct?

A That's correct.
Q Trilogy's migration or embolization rates are better?
A Can't get lower than zero percent.
Q Looking at the eighth row, a need for second valve. An AR patient would only need a second valve when the first valve doesn't work, correct?
A Yeah. So if the valve translocates, like you said, embolizes, either you stop or you put another valve in.
Q So J-Valve's rate here is 11.1 percent, and Trilogy's was 0 percent. Again, Trilogy's second valve rate is better, correct?
A Correct.
Q These are the numbers you were referring to in your letter to the JenaValve board?
A Indeed.
Q I would like to look at the 11th row, which says, new pacemaker implantation rate. Do you see that row?
A I do.
Q We talked about pacemaker rates a little bit ago. Here you have J-Valve at 13 percent, Trilogy's nearly 20 percent. Dr. Pinto, it's fair to say that when it comes to pacemaker rates, this comparison suggests that J-Valve's outcomes are better than Trilogy's?
A That's not knowable from these numbers because the numbers are so small. One or two pacemakers changes the

pacemaker rate a lot on both, and in fact, all three. There's only 200 in the left-hand column, 27 in the middle column, and in the right-hand column, it's only 58, actually, that Dr. Adams wrote about. These are interesting data, but I don't think we can draw definitive conclusions because, I don't know, statistically we can say confidence intervals are wide.

Q Dr. Pinto, you have compared the other data favorably for Trilogy, correct?

A When you are talking about zero and a hundred, that's easy to compare. When you are talking about 16 and 13 or 19 and 13, that's not easy to compare.

Q Okay. We can put that document to the side.

Dr. Pinto, let's go back to talking about valve sizes for a moment. I would like to introduce a document, PX2916.

Dr. Pinto, this is a text message conversation dated March 11, 2023. If you look at the names on that row in the middle of the page, you will see Daniel Sun, Peter Spadaro, Ryan Polzin. Those are all JenaValve employees, correct?

A That's correct.

Q I would like to look to page No. 2. Let's look at the text message you sent at 7:35 p.m. to this chain.

The first sentence here says, just got off the phone with Joao. I'm going to pronounce that wrong because it's a Brazilian name. Is that correct, Dr. Pinto?

A You are better than in the deposition.
Q I need to get better, clearly. Joao is Dr. Joao Cavalcante, a cardiologist at the Minneapolis Heart Institute, correct?
A Yes, sir.
Q Dr. Cavalcante specializes in cardiac MRI and noninvasive imaging?
A He does.
Q You continue on in your test message, they're going to be in the EFS for J-Valve.
Fair to stay Dr. Cavalcante told you that the Minneapolis Heart Institute was going to participate in the J-Valve early feasibility study?
A Correct.
Q The third sentence, the talking points are lower pacemaker rate, shorter frame, and larger sizing matrix larger.
Dr. Cavalcante also passed on to you what J-Valve representatives were saying about why J-Valve is preferred over Trilogy, correct?
A Yes.
Q One of the reasons was that J-Valve had better pacemaker rates, correct?
A Correct.
Q Another was J-Valve's larger sizing matrix was larger,

correct?
A That's right.
Q Looking down on this page, you see Mr. Polzin sent a message at 7:38 p.m., the body of which appears on the top of page 3, so it's the very bottom message on this page.
A Yes.
Q And Mr. Polzin writes at 7:38 p.m., before or if they hit the market, we need to larger valve and DS.
DS here means delivery system, correct?
A That's right.
Q And he continues in a message at 7:39 and writes, J-Valve, that is.
He was clarifying he was talking about J-Valve, right?
A Yes.
Q The next text message is a response from you and actually appears to be an emphasis. You emphasized Mr. Polzin's message, before, if they hit the market, we need that larger valve and yes. Is that correct?
A Yes. We need the larger valve tomorrow. I would agree with that.
Q It's fair you agreed with Mr. Polzin's comment that you need a larger valve size?
A If the implication is there's causality, we have needed the larger valve since the first time that a patient was screened out for their perimeter being too big for our

sizing matrix.

Q Dr. Pinto, I was not asking you to imply anything. My question was simple. You were agreeing with Mr. Polzin that you need a larger valve size?

A I gave a thumbs up, likely it is that we would need a larger valve.

Q Dr. Pinto, principal investigators who work with JenaValve have talked with you about J-Valve's larger sizing matrix, correct?

A Yes.

Q We can put this document down. I would like to introduce PX2132.

Dr. Pinto, this is an email from your JenaValve account dated June 27, 2024. So now we are about a year after these text messages we looked at where you exchanged with Mr. Polzin, is that fair to say?

A Yes.

Q In looking at that date, Dr. Pinto, this is about a month before JenaValve announced the proposed transaction with Edwards, correct?

A Approximately, yes.

Q So you sent this message to Mr. Kilcoyne with the subject line LMK, which stands for let me know, is that right?

A Yes.

Q And you write to Mr. Kilcoyne, if you have some time to debrief some time today, No. 1 says steering committee.

Dr. Pinto, the steering committee is you, Mr. Kilcoyne, and the ALIGN-AR principal investigators, is that right?

A Yes.

Q This bullet point continues, ML fired up about large valve.

I'll say that again. ML fired up about large valve. ML is a reference to Dr. Martin Leon?

A It is.

Q Dr. Leon is an interventional cardiologist who has worked with JenaValve for many years to develop Trilogy?

A That's right.

Q He's a major part of the ALIGN-AR trial?

A He is.

Q The bullet point continues, comes from a place where we all are. He is worried J-Valve is gaining too much of a foothold and two years to develop too long.

Dr. Pinto, in June 2024, when you sent this email, J-Valve was available in the United States with larger valve sizes than Trilogy?

A I believe they were still in their EFS and had not started their pivotal trial, but yes, they were implanting valves in the United States.

Q At this steering committee meeting, Dr. Leon said that

he didn't want to wait two years for a larger valve size for Trilogy, correct?

A Yeah. Marty had been talking about a large valve for years. And, frankly, JenaValve had not done anything about it. And when I told him that it was probably going to take another couple of years with the number of engineers that we have, he was not happy.

Q It's fair to say that JenaValve is developing a larger valve size for Trilogy called Trilogy XL?

A I don't know if that's going to be the name, but yeah.

Q Is that the project name right now?

A I don't know what the name is. Yeah, we are making a bigger valve.

Q If we looked at documents that refer to Trilogy XL, it would be referring to the larger valve program?

A I would know what you are talking about.

Q Fair to say, Dr. Pinto, that JenaValve plans to launch Trilogy XL in the future?

A Yeah. We plan on making a large valve.

Q Okay. If we look at the second bullet, let's start at the sentence that's highlighted here, Dr. Pinto. It says, better not to antagonize Raj or Dave Daniels restricting cases or with an inefficient CRV process as they will jump to J-Valve.

I want to define some of the terms and names in this

bullet. Raj refers to Dr. Raj Makkar?
A It does.
Q He's a principal investigator for ALIGN-AR, which is JenaValve's trial, is that correct?
A He is the local principal investigator at Cedar Sinai Hospital, yes.
Q And Cedar Sinai is in Los Angeles?
A It is.
Q Dave Daniels is also a PI for ALIGN-AR?
A He is.
Q And he's located at the California Pacific Hospital in San Francisco?
A Yes.
Q And the reference here to CRB refers to case review board?
A It does.
Q Case review board is the group that reviews and accepts AR patients for Trilogy valves, correct?
A That's correct.
Q As a result of this conversation that you had with your PIs, you streamlined JenaValve's CRB process, correct?
A Yeah. When I joined JenaValve, the CRB process was certainly an outlier compared to what I had experience with. It took weeks, if not months, to get a patient through the process, which is required to enroll a patient in the trial,

making slides, getting stuff back from the Core Lab. And people were getting frustrated because we were taking longer than in my own experience what it took to get a patient enrolled in a trial. And so, you know, that's not something that we want to do.

Q Dr. Pinto, you actually dropped that CRB process all the way down to one to two weeks, correct?

A It doesn't always work out that way, but we have tried to get it such that, at least for ARTIST, that when someone submits a patient, that we through-put it within a couple weeks.

Q And one of the reasons you were concerned that they wanted an efficient CRB process is because they would jump to J-Valve, is that right?

A No. I mean, it is one concern. It's probably number ten on the list. The most important thing is to get the patients treated. You know, with the 25 percent mortality of the year, if we take two months to get someone through, a proportion of patients are going to get sick.

Q What you reference in this bullet point here to Mr. Kilcoyne is the concern that they will jump to J-Valve, right?

A Well, it's a concern that any other physician would have. If you are waiting two months for a sick patient to get treated, you are going to go with however you can get

them treated. It doesn't matter whether it's J-Valve or anything. An inefficient process for us is an inefficient process, not fair to the patients.

Q Dr. Pinto, it's fair to say that June 27, 2024, a month before the proposed acquisition, the only other option was J-Valve?

A The sites that we are at number at five or six, so if they are finding a patient that is for our study, that number of maybe 15 patients in totality over a year, I guess they could treat them. But a proportion of those wouldn't be able to treat anyways because they have a bigger size matrix and we don't.

Q Directing you back to my question. For Raj or Dave Daniels, the alternative to Trilogy was J-Valve?

A Not for Dave Daniels or Raj because they are not J-Valve sites.

Q Dr. Pinto, You wrote in this message to Mr. Kilcoyne that you did not want to antagonize them because they would jump to J-Valve from, is that correct?

A I didn't want to antagonize them for a variety of reasons. Probably the least important is one that they can't do, which is treat someone with a J-Valve when they are not a J-Valve investigational site.

Q Dr. Pinto, yes or no, you wrote in this message to Mr. Kilcoyne that you wanted to streamline the CRB process

in order to prevent your PIs from jumping to J-Valve?
A Yes, that's what those words say. Whether that's practical or possible is a different matter.
Q Thank you, Dr. Pinto.
I would like to talk to you about sheath size.
Let's pull up PX2120. I would like to go to page No. 3 first. This is an email from Daniel Sun dated January 6, 2023. So this is before the proposed acquisition, is that correct?
A It is.
Q And he sent this email to a group of JenaValve employees including yourself with the subject line J-Valve at CRT.
Dr. Pinto, CRT is the annual conference in Washington, D.C., correct?
A That's right.
Q Mr. Sun writes to you, our friend Dr. Kereiakes is presenting J-Valve at CRT.
Dr. Kereiakes is an interventional cardiologist at Christ Hospital in Cincinnati, Ohio, correct?
A He is.
Q I would like to flip to page 2.
A Can you remind me, please, which one we are on.
Q PX2120. I will also display it on the screen for you.
THE COURT: It's not in mine, so it may not be in yours either.

MR. ANDERSON: Apologies, Your Honor. We have copies right here.

Permission to approach?

THE COURT: Of course.

THE WITNESS: Thank you.

BY MR. ANDERSON:

Q Dr. Pinto, now that you have the document in front of you, let's go back to page No. 3 really quick just to confirm what we were looking at.

Fair to say this is the email from Mr. Sun, January 6, related to Dr. Kereiakes presenting J-Valve at CRT, is that right?

A Yes.

Q And we were just talking about Dr. Kereiakes. He's an interventional cardiologist at Christ Hospital in Cincinnati, Ohio?

A He is.

Q I would like to flip to page No. 2.

In the middle of the page, Dr. Pinto, this is an email from you, January 7, 2023.

You write back to the same group of JenaValve employees, hopefully their marketing guys are effective as Daniel, Ryan, and Cory.

Daniel, Ryan, and Cory are JenaValve marketing employees, correct?

A Cory is no longer with the company, but at that time, yes.
Q You continue to write, with our runway, superior product, and implementation strategy, it's like having extra free employees?
A Yes.
Q Let's look at the email response at the top of this page from an employee named Bassam Alansari. That's actually -- it starts at the bottom of page 1, continues on to the top of page 2. Do you see that?
A Yes.
Q Okay. Mr. Alansari, he was a JenaValve employee at the time?
A Yes, he was.
Q He was in charge of field clinical specialists that support Trilogy procedures, correct?
A That's correct.
Q He responds to you, wow, it's a Saturday morning love fest. They are truly an inferior product compared to JV hands down.
JV there is JenaValve's Trilogy product?
A Yes.
Q Pacemaker rate is higher. Gradients are considerably higher. They had three deaths in 11 compassionate cases. We are easier to implant. They are 16 French is the only

advantage.

We talked about French before, Dr. Pinto. Mr. Alansari is referring to sheath size here?

A Yes.

Q Let's flip up to the top of the page. You respond January 7 at 3:46 with a picture of what is the Soup Nazi from Seinfeld, correct?

A It is.

Q And the meme here, I believe, is no socks for you. That's a reference to sheath size, correct?

A Not exactly. One of Bassam's hot-button items are the coverings -- see the coverings on the Trilogy valve and the locaters? Those are called socks. He didn't think they were necessary, so he's always complaining that we should take them off, so take off your socks.

Q And isn't it fair, Dr. Pinto, that one of the reasons that socks became an issue is because they may have required a larger hole in the leg in order to implement a TAVR-AR device?

A Well, as it turns out, I asked our R&D vice president about this, and apparently it doesn't matter. We still need the same sheath size.

Q Dr. Pinto, at the time when you sent this meme, you were investigating whether removing socks from the Trilogy product would result in a lower sheath size and a smaller

hole in the leg of patients?
A If investigating means asking whether it does any good or not, yes, I did ask him.
Q This meme related to sheath size, correct?
A No. It's related to the socks and whether we need them or not. But I guess tangentially that's related to sheath size.
Q We can put that document to the side.
Dr. Pinto --
A Should I put it in here?
Q You can leave it right there on the table. Thank you.
Dr. Pinto, let's talk about site selection now. Part of your job as CMO is to help select sites for clinical trials, correct.
A It is.
Q Okay. One annual conference that you have attended in the field is called London Valves?
A It is.
Q Let's introduce PX2104.
I would like to start with the email in the middle. Dr. Pinto, this is from your JenaValve work account dated Tuesday, November 21, 2023. So we are still before the proposed acquisition, correct?
A It is, yes.
Q Lisa Boyle, she's a JenaValve employee that reports to

you?
A She's no longer with the company. She's the interim CEO of Veranex.
Q At this time, Dr. Pinto, she was reporting to you at JenaValve?
A Yes.
Q The subject is LV update. That refers to London Valves, correct?
A It does.
Q I would like to look at bullet No. 3. It says, LVAD registry. LVAD relates to the ventricular assist devices we talked about before?
A Yes.
Q And you write here, got some collateral from Mike Reardon that he has suggested that J-Valve put a registry for LVAD in their IDE.
Mike Reardon is an interventional cardiologist at Houston Methodist, isn't that correct?
A He's a cardiac surgeon at Houston Methodist.
Q Fair to say that at this time, he was working with J-Valve?
A I don't know whether he was working with J-Valve. I know he was involved with their trial.
Q This bullet continues, that tells me that IDE not finalized and that it will be good for us to get them boxed

out of this by getting something up and running Q1 2024.

When you went to London Valves this year, J-Valve's IDE had not been finalized yet, correct?

A I didn't know that. I was surmising that based on what Mike was saying.

Q Based on what Dr. Reardon told you, you thought it would be a good idea to have JenaValve start an LVAD registry?

A Mike told me that they weren't listening to him and he thought it was a very important group to study. He does a lot of LVADs. They are surgically implanted. He sees a lot of the complications, so he was pushing me to do something of that sort.

Q You thought it would be a good idea to start an LVAD registry to help maintain JenaValve's leadership position with LVAD patients?

A Yeah. I think it's very important for us -- these are some of the sickest people that we treat. They don't have any options. It's actually the most common reason that we get requests for compassionate use. So of the 50 cases or so that I mentioned to you, 25 of them that we have done are for compassionate emergency use.

The problem with doing them that way is when you do compassionate use, emergency use cases, they can't be used for indication. So we are basically doing that and throwing away the data. So I wanted to get them into a protocol

where we can either get it into our IFU, instructions for use, or actually have it as a specific indication for the JenaValve.

Q Dr. Pinto, you wanted to start an LVAD registry in part because you didn't want J-Valve to usurp that leadership position?

A I wanted to start a registry for VAD patients not only because I wanted to make it easier for them to be treated because the compassionate use protocol is very demanding to get a patient through the FDA approval process, the FDA had asked us to do this registry for several years before this, and we didn't have the resources to do it. But now that we had finished enrolling in ALIGN-AR, we had the capacity to enroll these 50 patients in, and so we did.

Q Is it fair to say -- excuse me. I just want to clarify your testimony, Dr. Pinto. Is it your testimony that you did not start LVAD registry in part to prevent J-Valve or any other competitor that would come along from usurping JenaValve's leadership position with LVAD patients?

A I, indeed, want to maintain JenaValve as the leader in AR.

Q That's a yes to my question? You didn't want J-Valve to usurp your leadership position, correct?

A I didn't want any valve, including J-Valve, to usurp our leadership position, whether it be in VAD or anything.

Q Dr. Pinto, JenaValve did start an LVAD registry, correct?
A We have, yes.
Q I would like to look up to bullet point No. 2. Discussion with Marty that it is time critical and mission critical to get our ARTIST sites buttoned up ASAP. Concerned about J-Valve.
ARTIST sites refers to the hospitals that JenaValve was recruiting to take part in the ARTIST trial, correct?
A If you could clarify recruiting at that time in 2023, because we didn't have an approved protocol and we didn't start recruiting sites until about six months ago.
Q Dr. Pinto, here you are referring to buttoning up ARTIST sites, so it's fair that you were considering sites for ARTIST at this time?
A We were planning ARTIST. We hadn't actually done anything yet.
Q Marty, in this message, refers to Dr. Leon again?
A It does.
Q You talked with Dr. Leon at the London Valves conference about ARTIST sites?
A I talked with him about the trial. As you mentioned, he's a very important person in our ALIGN-AR trial. He's also the study chair for ARTIST. So obviously we would talk about the planning phase of the trial.

Q Fair to say that Dr. Leon had conveyed to you that he was concerned about J-Valve?
A He has been concerned about J-Valve, yes.
Q Your response to Dr. Leon is in this next sentence, and you told him that we are already on this, correct?
A Yes.
Q Dr. Pinto, about a month after this London Valves conference in 2023, you passed another message to Dr. Leon letting him know that you were on it for sure selection to lock out J-Valve, correct?
We can put the document to the side.
A I don't recall. If you can show me that.
Q Would it refresh your recollection to look at text messages in which you passed a message to Dr. Leon letting him know that you were on it for sure selection to lock out J-Valve?
A Yeah, it would help.
MR. ANDERSON: This contains redacted material, Your Honor, so may I approach to provide a written copy?
THE COURT: You may.
THE WITNESS: Thanks.
BY MR. ANDERSON:
Q Dr. Pinto, this is a text message chain, December 14, 2023, between you and Mr. Kilcoyne.
If you could, read the text messages on page 2. Look up

at me when you are done. Don't say them out loud.
A Wait. Say that again.
Q Don't read the information out loud. Just read the text messages and look up when you are done.
A Okay.
Yeah.
Q Does that refresh your recollection about passing a message to Dr. Leon about being for sure selection to lock out J-Valve?
A So I think this text message is to John Kilcoyne.
Q Dr. Pinto, you were telling Mr. Kilcoyne to pass a message to Dr. Leon, correct?
A I'm sorry. Could you repeat the question.
Q You were telling Mr. Kilcoyne to pass a message to Dr. Leon saying that you had for sure selection to lock out J-Valve, correct?
A Yes. Sorry. I misunderstood you.
Q That is what you passed on to Dr. Leon?
A I passed on information about a conversation I had with Marty, yes.
Q And you said the words for sure selection to lock out J-Valve, correct?
A Yes.
Q You can put that document to the side.
Dr. Pinto, we have talked about J-Valve's EFS, but you

are also familiar with J-Valve's pivotal clinical trial JOURNEY, correct?

A I am.

Q I would like to introduce a document, PX2194.

Dr. Pinto, this is another text message exchange, September 25, 2024, between you, Lisa Boyle, Peter Spadaro. I would like to look at page 2, the top message, which is from you at 4:57 p.m. You write, Yoshi at Wash U is surgical PI for J-Valve pivotal.

Do you see that?

A Yes.

Q Yoshi is Yoshi Kaneko, the head of cardiac surgery at Washington University in St. Louis?

A He is.

Q Mr. Spadaro replies a few messages below saying, makes me very much less interested for ARTIST.

Do you see that?

A Yes.

Q Ms. Boyle then writes, okay. So we slow roll Wash U and get our next list of sites going.

Then, Dr. Pinto -- excuse me. Mr. Spadaro then writes, I am aligned with that thinking.

Do you see that series of text messages?

A Yes.

Q You follow Mr. Spadaro's message with a message of your

own at 4:59, a picture of Tony Soprano and then a text message after that saying, feeling Sicilian this morning, correct?

A Yes.

Q By feeling Sicilian, you meant that it's okay to not be friendly to a clinical site?

A You know, it's a little bit of a back and forth that I have with my Sicilian friend Mr. Spadaro who threatens to put me in the trunk of his Cadillac every once in a while.

Really, Peter doesn't have any role in whether we -- whether or not we select clinical trial sites. And I already had not a huge amount of interest in Washington University because in the entire course of ALIGN-AR, they had at that time enrolled less than six patients.

So for ARTIST, which is a randomized trial, again, surgery versus our device, I very much prefer sites that have experience using our valve. So at that point, as I mentioned, we have done now over 800 cases. They would account for less than 1 percent of our cases.

Q Dr. Pinto, my question was, when you said feeling Sicilian, you meant that it's okay to not be friendly to a site, yes or no?

A I do not mean we should not be friendly to sites. These are my colleagues. These are people treating patients. And being unfriendly is just not what I do.

Q Okay. You remember being deposed in this case, Dr. Pinto?
A I do.
Q Do you remember that I took your deposition?
A It was memorable.
Q And you remember being under oath for that?
A Yes.
Q I would like to look at the first page of your deposition, your personal deposition. This is dated September 23, 2025. You remember this is your transcript of your deposition?
A Yes.
Q I would like to turn to page 210, lines 8 through 12.

Dr. Pinto, read silently to yourself while I read aloud.

Question, why were you feeling Sicilian? What does that mean?

Answer, I think that the idea is that when we talked about sites and preferences and such, it's okay to not be friendly to a site.

I read that correctly, didn't I, Dr. Pinto?
A Yes.
Q Dr. Pinto -- we can put that down.

As JenaValve signed up ARTIST sites you negotiated agreements with each site, correct?
A Correct.

Q Let's look at PX2119. Let's start on page No. 2.

This is an email from Sean Kim, JenaValve's director of clinical affairs. And he writes, on February 12, 2025, hi, Duane. Just an FYI. The specific language in the ARTIST contract is creating an issue for a site.

You recall that he was writing to you about a noncompete clause in the ARTIST trial, correct?

A I do.

Q And it related to whether PIs can serve in trials for competing devices?

A Correct.

Q Let's flip to page 1, the bottom email, from your email account, February 12, 2025. You write back to Mr. Kim, yes, we should remove this. Any J-Valve site such as Methodist, Piedmont, Christ, et cetera, site will not agree.

Methodist, Piedmont, and Christ are hospitals that are participating in both the ARTIST trial for Trilogy and the JOURNEY trial for J-Valve?

A That's correct.

Q You continue in the email, you can point out that this does not apply to ARTIST since it is not a high risk trial like JOURNEY so technically there is no competition. But regardless, since there is no competing device besides them, the point is moot, but that may change during the ten-year follow-up.

Do you see that?
A Yes.
Q When you wrote there is no competing device besides them, you were referring to the J-Valve device?
A I was referring to J-Valve that there's not competition for ARTIST since they are totally different patient populations. But if somebody thinks that there's competition, that they are being restricted, they may think they cannot participate in JOURNEY, which is a noncompeting trial. But I didn't want -- I still think it's wrong to have this noncompete thing in there in the first place.
Q Dr. Pinto, it's fair to say that the phrase no competing device was referring to J-Valve, yes?
A Correct.
Q And it's fair to say that Methodist, Piedmont, Christ are enrolled in the ALIGN CAP program?
A They are.
Q That is the same patient population as JOURNEY?
A It is.
Q You can put that document to the side.
Dr. Pinto, it's fair to say that J-Valve is a TAVR-AR device that competes with Trilogy?
A I don't believe they compete.
Q Okay. Let's look at PX2187. Let start on page 2, the email at the bottom from Devin Baerenwald.

Mr. Baerenwald is JenaValve's senior manager of professional education, correct?

A Yes.

Q This is dated April 12, 2024?

A Yes.

Q And he writes in the second paragraph, I realize there's a substantial amount of effort being applied to minimize inventory challenges globally over the next few months, but I just wanted to bring an update on the Christ Hospital to your attention.

Christ Hospital was one of those enrolled in both ALIGN-AR and JOURNEY, correct?

A It is.

Q It seems that the gap between the J-Valve EFS and IDE has led to a push toward JVT yielding about a half-dozen screening submissions in the last couple weeks alone.

Do you see that?

A Yes.

Q Push towards JVT refers to JenaValve Technology?

A Yes.

Q He continues, I don't have much in the way of patient details and I know we have gone back and forth on how to manage them, but they are hounding Chris about implant dates and this is nearing Cedar's volume.

Fair to say Christ Hospital was asking for more implant

dates for Trilogy valves?
A Yes.
Q Cedars is the largest implant site for Trilogy in the United States?
A It is.
Q Let's look at the email starting on the bottom of page 1 and continuing on to the top of page 2. This is dated April 12, 2024.
And you write, this is a great demonstration of success in the AR market. I think I will create a slide of future J-Valve site and the increase in volume submitted to CAP because we are going to crush them.
Dr. Pinto, the them in this sentence that you are going to crush refers to J-Valve, correct?
A Yes.
Q And you continue, it is fine to show that Methodist, Christ, and Piedmont have all reawakened.
Those are the three sites we discussed that have both Trilogy and J-Valve, correct?
A Yes.
Q Now that our field team, Pete, and Duane involved, we will take advantage of all these as well as our current sites strategically.
Now, Dr. Pinto, you sent this email at 7:00 a.m., correct?

A Yes.
Q You could not stop thinking about this Christ Hospital update, is that right?
A I'm not sure what you mean stop thinking about it.
Q Dr. Pinto, let's look at the email right above that. You replied to your own email to the same group of people at 10:00 am, three hours later, correct?
A Yes.
Q And you sent a YouTube video, didn't you?
A I did.
Q Do you remember watching that YouTube video in the deposition?
A I do.
MR. ANDERSON: I would like to play it for the court. Mr. Nguyen, would you please play it.
(The videotape was played.)
BY MR. ANDERSON:
Q Dr. Pinto, that is the video you meant to send?
A That is the video I sent.
Q You sent that video in reference to you and JenaValve's field team crushing J-Valve?
A I think I sent it as a moment of levity to lighten the mood with my buddies.
Q Dr. Pinto, you sent that in reference to crushing J-Valve?

A I sent it in reference to maintaining our leadership position and being the best. You have shown me the inferior outcomes, so I think it's inevitable that we are going to maintain our status as the leader in AR.

Q Dr. Pinto, let's go to your deposition, page 218, lines 22 through 25.

A I'm sorry. Can you tell me which one this is again, please.

Q Your deposition, page 218, lines 22 through 25. And Mr. Nguyen will be putting that on the screen here.

Please read silently while I read aloud.

Question, you sent that in reference to crushing J-Valve?

Answer, yes.

Okay. I read that correctly, right, Dr. Pinto?

A One second. Which page? I'm sorry.

Q It's on the screen in front of you, but it was page 218.

A Sorry. There are two 218s.

Q We are looking at your personal deposition, Dr. Pinto.

A Yes.

Q Okay. You can put that to the side.

Dr. Pinto, let's shift gears and talk about the proposed acquisition of JenaValve by Edwards. It's fair that you learned about that proposed transaction in July of 2024, a week or two before it was announced to the public?

A Yes.
Q You did not know at the time that Edwards was also negotiating to acquire J-Valve?
A I did not.
Q You found out about the J-Valve acquisition when you got a text message at the same time that Mr. Kilcoyne was announcing the proposed acquisition to JenaValve, the company?
A That's right.
Q You were annoyed to learn that Edwards had bought J-Valve, correct?
A That's correct.
Q Let's talk about how the proposed transaction has impacted JenaValve. You recall a time in early 2025 when JenaValve had to send certain ARTIST agreements to Edwards for its review, correct?
A Correct.
Q Let's look at PX2204. Let's start on page No. 3.

If we look at the email in the middle, this is an email Mr. Kilcoyne sent you July 30, 2025. He writes, Duane, give the revised ARTIST corp goal enrollment number a look and let me know what you think.

Dr. Pinto, the ARTIST corporate goal was the proportion of the 1,000 AR patients that you aimed to enroll in ARTIST by the end of 2025, correct?

A No. We aimed to enroll these patients by the end of 2027.

Q So this revised corporate goal --

A No. I'm sorry. The corporate goal was how many by 2025. The entire trial, by 2027. Sorry.

Q JenaValve was revising this number because the chances of the company hitting its original 2025 goal had gone down as of this date, correct?

A Correct.

Q Let's look at why. If we look to the middle of page 1, there's an email from your JenaValve account dated July 31, 2025, subject re: urgent ARTIST enrollment.

You sent this to a group of JenaValve employees. I would like to look at the second sentence.

I'm trying to balance what we have said. Three months' delay to contracting which will decrease prior 203 estimate and would be a 25 percent reduction which would put us at 150.

So there was a three-month delay for ARTIST trial agreements, correct?

A Yes.

Q And the 203 estimate, that was the original goal in 2025?

A Yes.

Q I would like to look down a little further in this

paragraph where it says, balancing with what is achievable with no new resources from Edwards.

Dr. Pinto, as of July 31, 2025, JenaValve had not received any new resources from Edwards to support the ARTIST trial, correct?

A Correct.

Q Let's look at the top email. It's from your email account, August 1.

You write, after talking it over with Lisa, I think we should revise down to 90.

Fair to say that you recommended revising the corporate goal in 2025 from 203 patients to 90 patients?

A Correct.

Q Okay. Let's take a look at those ARTIST agreements that we talked about for a moment. If we could look at PX2227. That's PX2227.

Okay. Let's look at page 2, the middle email from someone named Steve Sloan to your JenaValve work account. Mr. Sloan is currently the interim CFO of JenaValve, correct?

A Yes.

Q This is dated March 18, 2025. The subject is ARTIST trial agreements. Do you see that?

A Yes.

Q He writes, Duane, thanks for the call on the ARTIST

trial agreement status. And then these three names of the agreements are redacted, but it's fair to say he identifies three different agreements related to the ARTIST trial that had been sent to Edwards for review, correct?

A That's correct.

Q Each of those three agreements is necessary for the ARTIST trial to proceed, correct?

A Correct.

Q Let's look at the email on page 1.

You write -- it's dated Tuesday March 18, 2025. You write back to Mr. Sloan and cc Mr. Kilcoyne. You say, hi, Steve. This is a major problem. We cannot meet our company goals with these delays. I cannot, of course, enroll in the trial without these agreements.

Dr. Pinto, you were unable to start enrolling patients in the ARTIST trial until you had gotten these ARTIST agreements signed, correct?

A Correct.

Q The next sentence that crosses onto the next page says, obviously it is a major benefit to the company if we enroll prior to our presentation at the late breaker at the ACC.

The ACC is the American College of Cardiology?

A It is.

Q And that conference was at the end of March 2025, correct?

A It was.
Q Just about two weeks after this email?
A Yes.
Q Fair to say you didn't enroll any patients by the late breaker at ACC, correct?
A We would not have been able to even if those contracts were signed at that time, yeah.
Q Okay. The remainder of your email reads, we will never recover this momentum, but we understand the realities of the requirements we have. Just wish we were independent so that we could make normal progress as we have and get our trial under way. We are under significant duress with the sites asking me why we can't enroll.
Dr. Pinto, the we in these sentences refers to JenaValve?
A Yes.
Q And when you wrote just wish we were independent, you meant you wished that JenaValve was independent in its decision making, correct?
A Correct.
MR. ANDERSON: Nothing further at this time.
THE COURT: This is a much thinner binder.
MR. McGINNIS: I sense some optimism, Your Honor. I will do my best to meet it, but I cannot promise. We will try.

CROSS EXAMINATION

BY MR. McGINNIS:

Q Good late afternoon, Dr. Pinto. Matt McGinnis of Ropes & Gray.

I want to start with Conan the Barbarian. Why did you send that video to your colleagues?

A As I mentioned, I deal with, in general, dire situations in the hospital for many years, and I like to use humor to lighten the mood when people are stressed or anxious, and I like to use memes. We have seen more than one today. So that's how I lighten the mood. It was a joke.

Q Have you sent the Conan video to other people before?

A I have.

Q Have you sent other memes to other people before?

A I have.

Q Let's step back for a moment. I want to go back to the beginning. You are the chief medical officer of JenaValve, correct?

A I am.

Q How long have you been there?

A Since October 2022.

Q What did you do before that?

A I am an interventional cardiologist. I was the chief of the interventional section at Beth Israel Deaconess Medical Center, Harvard Medical School in Boston.

Q How long have you been an interventional cardiologist, Dr. Pinto?
A I finished my training in 2003.
Q Can you tell us a little bit about your educational background, please.
A I went to Dartmouth College for undergrad and then came here to Washington, D.C. and went to Georgetown Medical School. I went from there to Boston for my internship, as I mentioned. At the BI Harvard training hospital is where I did my residency, chief residency, general cardiology fellowship, interventional cardiology fellowship, and then I stayed on staff in 2003. And then I got a master's in public health in clinical design, biostatistics, and epidemiology in 2009.
Q And what is an interventional cardiologist?
A An interventional cardiologist is a cardiologist that does interventions, sorry, and we use catheter-based devices to repair defects in the heart.
Q Very basic question. Is that something different than a heart surgeon?
A Yes. We aim to avoid heart surgery, which involves opening the chest, being put on cardiopulmonary bypass in open heart surgery.
Q Apologies if I missed this in one of your prior answers, but do you have an affiliation with Harvard Medical School

too?
A Yes. I was an associate professor at Harvard Medical School.
Q For how long?
A I think -- some years.
Q A long time, fair to say?
A Yeah.
Q Okay. And in your career as an interventional cardiologist, have you participated in clinical trials?
A Yes. I mean, since I was in training that involved my research, I enrolled patients in trials. I was a local principal investigator, then an investigator on a more leadership basis, and then more recently, designing the protocols, running the trials, and all the subaspects of trials like clinical events committees, DSMVs, et cetera.
Q Do you have any publications, Dr. Pinto?
A I do.
Q Approximately how many?
A A couple hundred.
Q So why did you, after your career as an interventional cardiologist, join JenaValve?
A Don't put me out to pasture yet. I am still doing procedures. I am on call this weekend. I had basically come to a point in my career where I had accomplished new things. There were no new things for me to really

accomplish. I had done a lot of procedures. I trained my replacements. And this good opportunity came along.

I had always been involved in innovation. And, frankly, the hand-to-hand combat of doing one-to-one procedures, I still loved the patients, but I really wanted to make an impact and change the field, and this was the opportunity to do it.

Q Dr. Pinto, there's been a lot of testimony in this case about TAVR procedures, but are there other ways other than a TAVR procedure to treat aortic regurgitation or AR?

A Yeah. I mean, there's aortic valve repair. There's a device that's being developed for that, a placation device to kind of pull the defective leaflets together. And other than that, valve replacement is the primary treatment.

Q By valve replacement, we have been talking about TAVR, but is there a different type of valve replacement as well?

A Yeah. There's open heart surgery, of course, which we have talked about, and that's called SAFR, surgical aortic valve replacement.

Q And in your experience, sir, what are the benefits, if any, of a TAVR procedure as opposed to open heart surgery?

A Let's hope there are benefits because, otherwise, I am out of business. Those benefits are quicker recovery for the patient. They are up and ambulating faster. They can go home faster. They can rehab better.

And so there's obviously, in the short term and medium term, there's an improved quality of life. When it comes to a high risk population where they don't have an option, one of the most important benefits is avoidance of death.

Q And just on that last point, you mentioned, I think, that for some patients, open heart surgery is not an option, correct?

A That's correct.

Q Can you describe briefly what you mean by that.

A A number of patients are just too sick to withstand the open heart surgery. They may be frail. They may have advanced cancer. They may be on immunosuppressives. They may have some dementia where being on the heart-lung bypass is a not good idea for them. There's a whole host of reasons.

Q Sir, is there any research into the mortality rate associated with aortic regurgitation?

A Yes. Left untreated, patients with severe symptomatic aortic regurgitation or SSAR have an estimated one-year mortality of about 25 percent.

Q Now, I believe you had testified previously that there are -- I don't want to misspeak for you, but are there -- let me withdraw and ask that again.

Are there any valves currently available to treat AR that have been approved by the FDA in the United States?

A No.
Q Historically, then, in the United States, how have patients with AR been treated?
A Well, they have been treated with three things: Nothing because they were too sick for surgery, patients were treated with surgery, or they have been treated with off-label devices like -- you saw the CoreValve and the SAPIEN valve. Those valves for aortic stenosis have been repurposed and used with inferior outcomes in AR.
Q The court has also heard of a couple terms, transapical and transfemoral. Could you briefly describe what a transapical TAVR is, please.
A Yes. Transapical TAVR is opening the chest here with an incision, inserting the catheter in antegrade fashion through the apex of the heart, transapical, and then advancing the wire past the valve and deploying the valve in this direction into the aortic valve.
Q How does that compare to a transfemoral device?
A Transfemoral device would go through the leg and then go retrograde. This way the wire goes across and we deploy the valve this direction.
Q Mr. Anderson had asked you some questions about Trilogy, which is JenaValve's AR device, is that right?
A Yes.
Q Is Trilogy today a transfemoral device?

A It is.
Q Was it previously a transapical device?
A It was.
Q And was it modified at some point?
A Yes.
Q And do you know approximately when?
A I think in around 2014.
Q And do you know approximately how long that process of modification took?
A Approximately a year and a half.
Q All right. So, Dr. Pinto, you are the chief medical officer. What exactly does that mean? What do you do?
A Good question. So as has been said, I am responsible for the clinical trial development process. And along that, it's site selection. It also means I'm the editor of manuscripts. I am a resource to the field team when they have complicated cases. I field calls from physicians like I did right before here asking about compassionate use cases.

I am also a resource to the people in the company who may have medical questions since I'm one of the few people who have actually done a TAVR in the company.
Q You mentioned, I think, that you work with and communicate with physicians in the field. Is that right?
A I do.

Q Let's look at DX241. It should be in the binder in front of you.
A DX?
Q I'm sorry. Dr. Pinto, there should be -- do you have --
MR. McGINNIS: Did we forget to give the witness a binder?
May I approach, Your Honor?
THE WITNESS: Thanks.
BY MR. McGINNIS:
Q Now that you have the correct binder, please turn to DX241.
A Okay.
Q Are you there, sir?
A I am.
Q What is this document?
A So this is a printed out PowerPoint of a presentation made at St. Francis Hospital.
Q And why -- did you present this to St. Francis?
A I did.
Q Why did you do that?
A So this is a site that we on-boarded in ALIGN-AR recently that was starting to do cases and this was a presentation to educate them on the disease state, disease process, and the procedure.
Q Please turn to page 3 of the presentation.

A Yes.

Q It's also on your screen, sir. What does this slide show?

A So this slide is derived from the OxVALVE study, which was screening patients in Oxfordshire, England. They looked at 2,500 patients who were over 65 years old and looked at whether those echocardiograms could diagnose valvular heart disease or not.

And in this case, the blue represents the people who had known valvular heart disease. And the red are those that had unknown valvular heart disease and the echocardiogram picked it up. The slope in the arrow represents the increase in population over time.

The primary reason for valvular heart disease in the western population is aging and degeneration of the valve. So this is an expanding population. And this paper came out in 2016, I think. And since then, it's been recapitulated in many populations including last month in the United States.

Q Just so this was clear, what is the red part of the chart?

A The red part are the undiagnosed people. This is the unmet need. This is the work we need to do. We need to get these people off the sideline so that they are at least in the blue, we know about them. Now, whether we treat them or

not -- because, of course, we are not treating everybody who needs it.

Q Let's turn to page 15.

A Got it.

Q Directing your attention, sir, to the chart on the left side of this page, what does that pie chart show?

A So that pie chart shows, of patients, the pie is how many people who have AR. And the 25 percent are the people who get treated, a quarter of them. So 75 percent of the people aren't being treated after their diagnosis of aortic regurgitation after a year.

Q Thank you. You can put that away, sir.

Now, you were asked a number of questions by Mr. Anderson about J-Valve. Do you recall that?

A I do.

Q Do you know of other companies that are developing valves to treat AR?

A Yes.

Q What companies are you aware are?

A There are a number of companies. The names of the valves are the Pioneer Valve, the Hanchor Valve, the Ken-Valve, the DOC Valve. There are in various stages of development and have done either their EFS or pivotal trials.

Q You mentioned DOC Valve. When did you learn about DOC

Valve?

A A few weeks ago.

Q Okay. And how did you learn about DOC Valve and that they were developing an AR valve?

A It was presented at a conference.

Q What conference?

A The London Valves conference that you heard of a few minutes ago, but the 2025 version.

Q And what exactly was presented at the conference as far as you understand?

A Their data on pivotal trial results for their valve in aortic regurgitation.

Q Now, a number of the companies that I believe you referred to there, they are based in China, is that right?

A That's right.

Q Do you have an understanding as to why there are so many Chinese companies that appear to be focused on developing TAVR-AR devices?

A Yeah. It's an interesting thing. In the western world, the proportion of aortic regurgitation that is all aortic disease is about to 10 percent. But in China it represents 50 percent or more. Those physicians with, you know, their population and the fact that it's a larger proportion see that disease all the time.

Q Now, these companies that you just listed off, do you

know if any of them have data from clinical trials?
A Yes.
Q And when you, Dr. Pinto, look at the landscape of AR development or TAVR-AR development out there, do you place any particular significance on whether an AR company has an office in the United States?
A No.
Q Do you place any significance on whether the company has a presence in the U.S. more generally?
A No.
Q Why not?
A Well, you know, my interest in these devices is do they work. You know, are they helping patients or not. Because if they do, they are going to have an unmet need. And if they solve an unmeet need, then they are going to be brought to the patients regardless of where they originated.
Q Now, it's fair to say, sir, that these foreign-based companies that you identified, none of them ever received FDA approval for their devices today? Is that fair?
A That's correct.
Q Do you know whether they are conducting or have completed clinical trials outside the United States?
A They have.
Q Are you familiar with something called an IDE?
A I am.

Q What is an IDE?
A An IDE is an exemption given by the FDA that allows you to study unapproved devices in the United States.
Q I believe Mr. Anderson had mentioned something called an early feasibility study or an EFS in some of these questions. Do you recall that?
A I don't recall specifically. Sorry.
Q Fair enough. It's been a long afternoon.
Are you familiar with what an EFS or an early feasibility study is?
A I am.
Q Once a device obtains IDE, can it skip the EFS and go straight to a pivotal trial in the United States?
A It can.
Q And based on your experience, can companies submit data gathered in trials outside the United States to obtain an IDE in the United States?
A Yes.
Q Okay. And how long does the FDA have to respond to an IDE application?
A In their own guidance documents, they propose to respond within 30 days.
Q One more question, I think, on J-Valve for the time. Mr. Anderson had asked you about PX2195.
MR. McGINNIS: Could we maybe put PX2195 up briefly.

BY MR. McGINNIS:

Q Do you recall being asked about this email? It's on the screen now.

A Yeah.

Q This is in the big binder but also on the screen.

A Yes.

Q And in the interest of time, I promise I am not going to ask any detailed questions about it.

A Okay.

Q This is an email where you were summarizing your assessment of some clinical findings with respect to J-Valve, is that right?

A Yes.

Q Why did you send this email?

A I sent it because Lisa didn't attend the conference, and I wanted to debrief with her.

Q I want to make sure we are talking about the same document, sir. This is an email that you sent to John Kilcoyne and Greg --

A I'm sorry. I am talking about a different one.

Q Take your time. I did not mean to rush you.

A Which one is this one?

Q It is PX2195 in the large binder, sir.

A Okay. I got it. Okay. I see it.

Q Why did you send this email?

A Yes. This was -- John had sent me the manuscript for a J-Valve study and asked me to summarize what my thoughts were about it.

Q Do you from time to time comment or summarize findings or analyses that you might have of clinical studies in the field?

A Reading about scientific advancement has been my job since I have been in medical school.

Q Shifting -- you can put that to the side, sir.

Shifting gears for a moment, I want to talk a little bit about your time as a practicing physician, which I will not misstate again in suggesting it is over, sir.

Are you familiar with any of the valves that Edwards makes to treat aortic stenosis?

A I am.

Q And what valves are you familiar with?

A I am familiar with the array of SAPIEN valves over time and most recently the EVOQUE Valve, the valve that has recently been approved for treatment of the tricuspid valve.

Q Are these valves approved for treatment in the United States by the FDA?

A They are.

Q Have you performed TAVR procedures with these valves?

A I have.

Q Approximately how many times roughly?

A I have done hundreds of these. I don't keep track, frankly.
Q Why do you use -- let's take the SAPIEN valve. Why do you use the SAPIEN valve for some procedures?
A I use the SAPIEN valve for the majority of my procedures because it's the most studied valve on the planet. It has the best data. I have had great support from the team. I have done cases with Alex and Sal for years, and I know that it's a predictable device that is reliable.

And I know the five-year outcomes. So given the variation of patients, I don't want to have a lot of variation in the device. And other devices are a little less predictable with, for example, deployment. So that's my preference.
Q One thing you mentioned was the support you receive in connection with the implants. Can you describe for the court what sort of support is provided in connection with a valve implant by Edwards?
A Yes. So for every case that we do, when I come into the control booth, the representative of, in this case, Edwards is there. They have reviewed the imaging of the patient. They have gone over the sizing. We discuss that. We talk about watchouts. And then the case starts when the patient is on the table.

They begin preparing valve. I start with a patient.

And when it comes to a critical portion of the procedure, for example, positioning the valve in the aortic annulus, whether it's too high or too low, I will take a pause, make sure everybody in the room is comfortable, what do you think.

And, frankly, I may have done hundreds of cases, but those guys have done thousands of cases. They go to every hospital. So I really rely upon their set of eyes as an additional kind of check for me to make sure I'm doing the best that I can.

Q Thank you. Excuse me. Shifting gears, you were asked some questions about JenaValve's clinical trials and the ALIGN-AR trial. What was the ALIGN-AR trial again just to keep our terminology straight?

A The ALIGN-AR trial is our pivotal trial to obtain FDA approval for patients with symptomatic severe aortic regurgitation who are high risk for surgery.

Q Was this the first pivotal trial for such a device and such an indication in the United States?

A Yes.

Q In your experience, are there any challenges associated with designing and running the first pivotal trial for a device of that type?

A Well, there are incredible challenges to do the first thing, which is why it's exciting. But the first is to get

people trained to develop the pipeline of patients. You know, obviously, if you aren't developing the referral pattern from the general cardiologist, then you don't have any patients to enroll. So that's, you know, kind of what kills a clinical trial is slow enrollment. And you have heard me say that. But those are the challenges.

And then there are obviously the unforeseen challenges. Supply chain problems. There have been a number of problems that we have not had enough valves. We haven't had enough delivery systems. We haven't had enough sheaths. So we have to slow down enrollment.

Then there are things like something happens with the device. There's a safety concern. You have to stop, make sure you investigate that. That's unfortunately happening right now with J-Valve. It did happen with us. It's the nature of device development.

Q Once the first pivotal trial is run for a device, can that be used in any way to expedite other pivotal trials for other devices?

A Yeah, of course. I mean, all the infrastructure that's needed to run a trial, but also all the -- I don't want to throw around the term precedent here, but once you have set the precedent of what the protocol is, what the definitions are, how many patients you need to study, what the stats are, all of these things, we publish that. And then the

next person can take that and help develop their own work and move the field forward.

Q Dr. Pinto, how many clinical sites or hospitals did JenaValve work with for the ALIGN-AR trial?

A Well, we worked with 30 sites in the ALIGN-AR pivotal trial, 20 of them enrolled patients.

Q And how many TAVR sites are there in the United States approximately?

A There are over 800.

Q How do you decide which sites or hospitals to work with for a particular clinical trial?

A Well, in the terms of ALIGN-AR, I didn't decide. The trial was already enrolling by the time I joined the company.

But when I do decide, what I look at is what is the expertise of the implanting team. Are they good at it. And that in part is familiarity with the device. And then do they have a pipeline where they are going to be treating patients so that the trial enrolls. And then do they do a good job at data collection. That can be something that meets regulatory standards; otherwise, it's for naught.

Q Dr. Pinto, just to be clear, do you ever or have you ever targeted clinical sites for participation in JenaValve's trials to block J-Valve from accessing those sites?

A No.
Q Can you explain.
A Well, we had a very simple algorithm for how we selected our sites for ARTIST, and that was are you an ALIGN-AR site that's enrolling patients. Because without a commercial device, we can't train new sites on how to use the device, and thus, they don't have a pipeline to bring these patients who haven't been referred historically, as we went over. So it was pretty simple. We just invited all the ALIGN-AR sites.
Q I want to pull up PX2194, which Mr. Anderson had asked you about as well, very briefly if we could.
And this is -- you will have this in the large binder, Dr. Pinto. This is the series of messages that, I think, concerned Washington University. Do you recall that?
A Yes.
Q And Mr. Anderson had asked you some questions about it, but I just wanted to ask about the current status of Washington University. Is Washington University enrolled in JenaValve trials today?
A Yes. They are part of -- they are onboarding for ARTIST, and they are onboarding for JENA-VAD, and they are an ALIGN-AR site.
Q Why is that? Why are they enrolling now?
A Because they know how to use the device. They are not

necessarily a priority, like I said, because they have enrolled seven patients in their entire experience. So I would like for them to do more so that when we go up against what's tried and true and been done for 40 years, SAFR, that they are ready to have outcomes that don't actually -- that compare favorably with surgery.

MR. McGINNIS: Thank you. We can take that down.

BY MR. McGINNIS:

Q Dr. Pinto, a few questions about ARTIST, the ARTIST trial, which Mr. Anderson had also asked you about.

I take it from your testimony, sir, that enrollment is behind where you would like it to be in ARTIST. Is that fair?

A It is.

Q I don't want to talk about specific numbers or anything like that, but just why is enrollment behind for ARTIST?

A Well, I mean, it takes a lot to get a clinical trial up and running. And I have six people helping me. If it was a clinical trial in an appropriately resourced company, a trial like this would probably have a couple hundred people. I am, as mentioned, dotting the Is, crossing the Ts myself. I have been down at the loading dock putting labels on boxes to get them mailed out.

I and everybody else has to do things just to get things done. It's difficult, and it takes a lot to run a

thousand-patient randomized trial. A trial this scale hasn't been run by an independent organization like us, a small company, ever.

Q You mentioned the size of the team that's supporting you on this. Can you just tell a little bit about how the size of that team impacts your ability to achieve the enrollment that you want for ARTIST?

A As you can imagine, just getting the paperwork done to contract with sites, dealing with their ethics review boards, getting them the documentation that they need, that takes a certain amount of effort administratively. We have one person working on contracting, so we have to process in series rather than in parallel.

And just training the sites, we have site initiation visits. We have training. We have simulated training. And all of these things are necessary to get a trial -- a trial site ready. We have to talk with the surgeons, and then we also have to let people know that the trial exists so that referring physicians can send their patients to the investigators to be enrolled in the trial.

Q Now, you understand, Dr. Pinto, that J-Valve is running a pivotal trial called JOURNEY?

A Yes.

Q How does the ARTIST trial compare to the JOURNEY trial?

A I mean, a number of things are different. First of all,

the scale. There are a couple hundred patients in a single-arm study of JOURNEY versus over a thousand patients. It's fewer sites. We have approval from the FDA to enroll up to 60 sites. It's an international study. We have approval to do up to 30 sites outside of the United States.

Most importantly, they are totally different patient populations. One is a group of patients that have options, ARTIST, where they can get surgery, and we are showing that we are hopefully not any worse than surgery, and we are giving people an option that's less invasive compared with what they have.

As mentioned, JOURNEY is for people who can't get surgery, so that's different.

Q You were asked some questions, Dr. Pinto, about something called the LVAD registry. Do you recall that?

A Yes.

Q And I believe you had referred to in your responses to something called a compassionate use case?

A That's right.

Q Could you describe for the court, what is a compassionate use case?

A So a compassionate use case is a patient who doesn't meet the inclusion/exclusion criteria of a trial, which are often very restrictive. So the call I got earlier today was for a patient with metastatic cancer who can't get his

chemotherapy because he has a leaky valve. That person, because his prognosis is less than 24 months, can't be treated in the protocol.

So a hospital calls me and says can I get this valve for compassionate use for this patient, and then we have to apply to the FDA saying that this patient is in need, they don't qualify for the trial and the IDE, can we get this valve to a person in this case. The person is not at one of our sites, so then we now have to get that person to one of our sites.

Q Now, if the person was at one of your sites, could you handle that person through the LVAD registry?

A Yes.

Q I believe you had mentioned earlier that the FDA had asked you to handle these compassionate use cases through LVAD. Is that right?

A Yes, because they have to review each and every one of these cases, and then they review the outcome of it. And they know that it was happening so often that they preferred, and we preferred for the reasons I mentioned, that we would be able to treat these people comprehensively and collect their data in a rigorous fashion so that it wasn't just these one-off cases.

Q Dr. Pinto, in your experience as a physician, when you were looking to treat a particular patient with a device,

how do you select what device to use?

A Well, there are a number of factors. I start with the device-related factors. Firstly, I want to make sure that that device works. That is based on review of the data and my knowledge of what has been published about that.

Then the next is can I use it myself appropriately, have I been trained in how to do this, and is that device actually in my hands going to be able to reflect the outcomes that were in the published outcomes, so that, you know, kind of learning is necessary.

Then I look at the patient and say does this patient have any specific characteristics that I have to watch out for, what makes them different from what was studied. Then I apply all of those things and say this is the right device for the right patient at the right time.

Q In your experience as a physician, does the price of a device impact whether you recommend that device for a particular patient or procedure?

A Not particularly because I don't pay for the device. The hospital pays for the device. I make the best decisions and try to get the best outcomes for my patients, which ultimately benefits not only the patients, but the hospital as well because they have good outcomes and more patients come.

MR. McGINNIS: Your Honor, I am aware it is 5:30.

THE COURT: How much longer do you think you have?

MR. McGINNIS: I had a feeling that was the question. Probably 15 to 20.

THE COURT: You got 15 minutes.

MR. McGINNIS: Thank you, Your Honor.

BY MR. McGINNIS:

Q Shifting to a new topic, Dr. Pinto, I would like to discuss briefly JenaValve's efforts to meet the demand at the sites. I think you referred to this earlier.

As you sit here today, does JenaValve have the resources required to support all of the implant requests it receives?

A No.

Q Why not?

A Well, we are a small organization. We have had a number of challenges. I mentioned the supply chain problems where we don't have the devices to get to the patients, but we also don't have the staff in many cases. We have somewhere around six to ten field team people depending on training and such. We send two of them two each case, one to load the valve, one to support the case. And those people are meant to cover the entire country.

So they are flying all over the place. And as such, we can support approximately 20 cases a month right now.

Q I think you said two JenaValve employees are at each case, is that right, at each implant?

A Correct.
Q How many valves have to be at each case?
A So we have to have two systems; valves, sheaths, loading tools, et cetera, because if something falls on the floor or somebody touches something and it's not sterile anymore, we need to be able to treat that patient. If we embolize the valve, you need a second valve, you need a second valve. And that's multiplied if there's more than one case. For example, sometimes hospitals have two cases in a day.
Q All right. Let's take a look at another, DX37, which will be in the small binder, Dr. Pinto.
Just starting at the top of the document, this is from February of '23. Who is Bassam Alansari? I think we heard his name earlier.
A He was the director of the field team.
Q Let's drop to the very bottom email on the document, sir, which is from a gentleman by the name of Dean Kereiakes on February 9, 2023. Do you see that?
A Yes.
Q Who is Dr. Kereiakes?
A As we heard earlier, he's an interventional cardiologist in Cincinnati, Christ Hospital.
Q Looking at the email in front of you on the screen -- actually, sorry.
MR. McGINNIS: Can we please -- can we drop to the

bottom email. I am sorry. At the bottom of the document. Thank you.

There we go.

BY MR. McGINNIS:

Q Now that we've got that there, Dr. Pinto, why was Dr. Kereiakes reaching out to you?

A Well, Dean was upset that it was taking a long time for us to get his patient through-putted in the case review process, which I described in what was probably excruciating detail to you earlier.

Q And what were the challenges that JenaValve was facing in meeting Dr. Kereiakes's request in this email?

A Well, there were a number of challenges. At this time we did not have sheaths available to us, so we had to restrict the number of cases that we could do. We have one person handling the CRB process, so we do two calls a month in order -- eight patients each call in order to get the patients on-boarded for the trial. So we have limited slots. So what he was upset about was that his patient had to wait several weeks to get presented.

Q Do you get emails like this a lot, Dr. Pinto?

A I get them all the time.

Q Why is that?

A Well, there's simply not enough. We don't have enough people. We don't have enough valves. We don't have enough

to get all the stuff done that we need to do.
Q You previously talked about your experience as a physician implanting valves. Did you ever have to send emails like this to any of the device companies that you worked with?
A I have never.
Q Based on your experience, including with Edwards, do you think that Edwards has the resources to help address the supply chain and other issues that you were just testifying about?
A I do. As mentioned, I reliably walk into the cath lab, and I know that those field team people are going to be there. I know the devices are going to be there. I know the device is going to work. I just get to worry about the patient.
Q We have been talking about the clinical cases that you support. I want to talk with commercialization for a moment as well.
Does JenaValve have a plan to commercialize Trilogy?
A Yes.
Q Do you have the money to support that plan to commercialize Trilogy?
A No.
Q Can you expand on that what you mean by that?
A Well, to commercialize appropriately, we need to go

beyond the 30 sites that we are at and cover the sites in places that we are not at. As you mentioned, there is over 800 sites. But more importantly, we are not in large swaths of the country. For example, we don't have anywhere in North Carolina where we can do a case. Indiana, no. Nevada, no. Obviously the patients are distributed where patients are.

In order to expand effectively upon commercial approval by the FDA, we need to get to where the patients are, and right now we can't do that.

Q So I asked you about money. How about employees? Does JenaValve have the employee team in place that can -- to actually commercialize based on the plan that JenaValve would like to do?

A No. I mean, from the mail room to the shipping dock to the field team, we just don't have enough people to get the devices where they need to go and the people to support the cases. It takes about six months to train somebody to be at that level I was talking about where they can be a resource rather than a hindrance to the doctor. That is, you know, just not practical to go from zero today to be able to support, you know, more than a handful more of sites than we are doing right now.

Q Speaking of the device in particular, has JenaValve done any work towards developing a next generation version of

Trilogy?
A No.
Q Why not?
A Well, we are just consumed with surviving and getting to the next thing, which is doing our 20 cases a month, getting FDA approval, and a number of things that are required in order to get there. We respond to complaints from the field about the device, and the same group of people that are obtaining FDA approval are the same group of people that are trying to run clinical trials.
Q Mr. Anderson had asked you if you have a plan for large valve or Trilogy XL. Do you recall that?
A Yes.
Q Do you have funding for that plan?
A No.
Q Is any work happening on that plan right now?
A No.
Q Earlier today, Dr. Pinto, you had testified about some of the research you have done on the effectiveness of Trilogy. Do you recall that?
A I do.
Q Let's look at the final document in your binder, DX297.
A Is it the small one?
Yes.
Q I apologize to everyone for the small font of the

document, but we do have it on the screen as well.

What is this document, sir?

A This is a manuscript detailing the results of ALIGN-AR in 700 patients.

Q When was it published?

A November 16 of this year.

Q So earlier this week?

A Yes.

Q And where was it published?

A It was published in the Lancet.

Q What's the Lancet?

A The Lancet is arguably the number one journal on the planet.

Q And you will see there in red ital there's a number of authors identified for this article.

A Yes.

Q You are an author, sir?

A I am.

Q And is Dr. Makkar an author?

A He is.

Q Is Dr. Thourani an author?

A He is.

Q Is Dr. Chetcuti an author?

A Yes.

Q Is Dr. McCabe an author?

A He is.
Q At a very basic level, what does this article -- what sort of research does this report on?
A This reports on 700 patients and the safety outcomes associated with those patients and in 500 patients who have reached one year what the efficacy outcome is.
Q What clinical sites were used for this study?
A The ALIGN-AR sides.
Q Are those the same 30 sites you testified about earlier?
A Yes.
Q All in the United States?
A Correct.
Q Let's turn to page 6 of the document.
MR. McGINNIS: If we can blow up figure 1 on page 6.
BY MR. McGINNIS:
Q What does this show, Dr. Pinto?
A So figure 1 is a so-called CONSORT diagram, which is the flow of patients through a trial.
Q Can you describe what that means, the flow of patients through the trial.
A Yeah. So you can see that at the top, 1352 patients were screened to enroll 700 patients. That means that 652 were ineligible.
Q And these are patients that were screened for the trial and were excluded from participating, is that fair?

A That's correct.
Q And when did this trial begin?
A This trial began, as we talked about earlier, in 2018.
Q Okay. Looking two lines down under the ineligible category, there's a reference there to 129 aortic annulus perimeter outside device sizing range. Do you see that?
A I do.
Q What does that refer to?
A These are the patients whose annulus, the perimeter of their aortic valve, was too big in the vast majority of cases for us to treat because we can only treat between 66 and 90 millimeters.
Q And so are these the sorts of patients that would benefit from the large valve project that you testified about earlier?
A Yes.
Q Let's go ahead and turn to page 8 in the document, sir. And here we have table 2. What does table 2 show?
A So table 2 shows two important things. The first row is the primary safety outcome at 30 days, and the last row is the primary efficacy outcome, which is the one-year mortality rate.
Q So the one-year mortality rate, that's the 25 percent in the second column in the bottom there?
A No. Actually, the one-year mortality rate is 7.7

percent in the population. The performance goal is the anticipated death rate for patients left untreated.

Q So what does this mean for the efficacy of patients who benefit from a Trilogy implant?

A So what this means is that if you get the treatment, your chances of dying is somewhere around 7, 8 percent of the year. And if you -- that's against the performance goal of 25 percent, which we talked about earlier.

Q And so based on your experience, what impact would increasing the number of Trilogy implants have on the number of Americans or others in the United States who suffer from aortic regurgitation?

A So that difference of 17 percent translates into, if a thousand patients are treated, then we save 170 lives.

Q Thank you. No further questions.

THE COURT: All right. That will be a good time to stop.

How long do you expect your redirect to be tomorrow?

MR. ANDERSON: 15 to 20 minutes, Your Honor.

THE COURT: All right. We will pause for the night.

Thank you, Doctor.

THE WITNESS: No problem. Thank you.

THE COURT: You said that there was a change in tomorrow's schedule, that you were dropping someone?

MS. HALL: Yes, Your Honor. Dr. McCabe, who had been

planned to be after Dr. Vahl, I believe. And he had been by Zoom, so we are going to turn that into designations.

THE COURT: Okay. So of the ones that remain on your schedule, what do you think we realistically will get through tomorrow?

MS. HALL: I think we expect to be able to get through Dr. Kesselheim and two videos tomorrow. So replacing Dr. McCabe with one video, and then we should have time to do another video. We have two roughly 45-minute videos, and then that would leave us with just one witness for Monday.

THE COURT: Which is?

MS. HALL: Dr. Wilson, our economist.

THE COURT: All right.

MR. SHORES: Could I have a moment to confer, Your Honor?

THE COURT: Sure.

You can step down.

THE WITNESS: All right. Thanks.

MS. HALL: I was told not to make any timing promises, so we are redoing the math as well to see what we can see.

THE COURT: Okay. But tomorrow you expect to get through Dr. Kereiakes, who is a video?

MS. HALL: Yes.

THE COURT: Dr. Vahl in person?

MS. HALL: He's on defendants' list. I believe he is coming in person, yes.

MR. SHORES: Yes, he is.

THE COURT: Okay. Dr. Turco?

MS. HALL: Yes.

THE COURT: In person?

MS. HALL: Yes.

THE COURT: Gilbert Madrid?

MS. HALL: Right. That's the other video.

THE COURT: Okay. And then you think Dr. Kesselheim will not be until Monday?

MS. HALL: The hope is to get Dr. Kesselheim on and off on Friday, and then it will be Dr. Wilson on Monday. We will probably put Dr. Kesselheim on before running any videos. He would probably be irritated to be stuck for the weekend because of a video.

THE COURT: All right. I will see you tomorrow at 10:00.

(The hearing adjourned at 5:47 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.

12/21/25

s/ Tammy Nestor
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MR. ANDERSON: [7] 71/12 71/14 98/1 106/18 115/14 121/21 156/19
MR. JOHNSON: [11] 38/14 38/19 40/10 44/6 46/22 51/5 59/22 60/1 60/3 62/5 71/4
MR. McGINNIS: [9] 121/23 129/5 134/25 142/7 146/25 147/2 147/5 148/25 154/14
MR. MUSALLAM: [1] 62/8
MR. SEGAL: [10] 4/3 4/10 4/12 7/13 9/8 12/19 15/3 15/8 29/6 38/11
MR. SHORES: [6] 15/7 21/6 21/8 71/7 157/15 158/4
MS. HALL: [10] 156/25 157/6 157/13 157/20 157/25 158/2 158/6 158/8 158/10 158/13
MS. PEARL: [5] 21/9 32/12 32/20 32/24 38/9
THE COURT: [38] 4/2 4/9 4/11 4/13 15/6 15/9 21/4 29/8 32/18 32/23 38/12 38/17 59/25 60/2 62/7 71/6 71/9 71/13 97/24 98/4 106/20 121/22 147/1 147/4 156/16 156/20 156/23 157/3 157/12 157/14 157/17 157/23 158/1 158/5 158/7 158/9 158/11 158/18
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