IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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FEDERAL TRADE COMMISSION,

Plaintiff,

v.

EDWARDS LIFESCIENCES CORPORATION and JENAVALVE TECHNOLOGY, INC.,

Defendants.

- x

CV No. 1:25-cv-02569-RC

Washington, D.C.
Friday, November 21, 2025
10:00 a.m.

TRANSCRIPT OF EVIDENTIARY HEARING - DAY 4
*** MORNING SESSION ***
HELD BEFORE THE HONORABLE RUDOLPH CONTRERAS
UNITED STATES DISTRICT JUDGE

APPEARANCES:

For the Plaintiff: Laura Hall, Esq.
Barrett J. Anderson, Esq.
James R. Weiss, Esq.
Jay Tymkovich, Esq.
Lisa DeMarchi Sleigh, Esq.
Jordan Andrew, Esq.
FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, NW
Washington, DC 20580
(202) 326-3282

For the Defendants: Ryan A. Shores, Esq.
Jacob Coate, Esq.
CLEARY GOTTLIEB STEEN & HAMILTON LLP
2112 Pennsylvania Avenue, NW
Washington, DC 20037
(202) 974-1876

Joshua Lipton, Esq.
Jamie E. France, Esq.
GIBSON, DUNN & CRUTCHER, LLP
1050 Connecticut Avenue, NW
Washington, DC 20036
(202) 955-8226

APPEARANCES CONTINUED:

For the Defendants: Samer M. Musallam, Esq.
Matthew L. McGinnis, Esq.
Elizabeth T. McInerney, Esq.
Sandra Masselink, Esq.
ROPES & GRAY LLP
2099 Pennsylvania Avenue, NW
Washington, DC 20006
(202) 508-4850

Court Reporter: Timothy R. Miller, RPR, CRR, NJ-CCR
Official Court Reporter
U.S. Courthouse, Room 6722
333 Constitution Avenue, NW
Washington, DC 20001
(202) 354-3111

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P R O C E E D I N G S

MR. HALL: Good morning, Your Honor.

THE COURT: Good morning.

MR. HALL: Just a few housekeeping points.

So today, as we went over yesterday, we'll have Dr. Vahl, Dr. Turco, Dr. Kesselheim, and then we're going to try to play two videos. We'll see where we end up on time. And so we may switch them depending upon what the amount of time is left.

And we checked. Our designations, plus their counter-designations, we think would be about two hours to read. So I do think there's a time savings to submitting those on paper.

And, I think -- you also had some scheduling.

MR. SHORES: Yeah. So Your Honor, in terms of next week, we are trying to figure out our best how to finish up on Tuesday. It will require us not using our entire allotted hours, but we're going to work through that. One request I was going to ask of the Court is if it would be possible to start at 9:30 on Monday and Tuesday. I think that might help us get there. And then we've had a great conversation about, maybe, ways that we could work together in order to do that Monday and Tuesday, but just wanted to see if that's an option.

THE COURT: All right. Tanya, 9:30?

THE DEPUTY CLERK: (Indicating.)

THE COURT: Tim?

THE COURT REPORTER: (Indicating.)

THE COURT: All right. 9:30 for both days.

MR. SHORES: Thank you so much.

THE COURT: There should be less traffic next week.

MR. SHORES: Thank you so much.

MR. HALL: And, Your Honor, just one last thing. Since, obviously, that would put any closings off the schedule, we just wanted to check whether Your Honor would like to provide us questions to answer in our written submissions on the 10th or we'd add 10 pages of summation or anything that would be helpful along those lines.

THE COURT: Whatever you think is helpful. It's a pretty straightforward case thus far.

MR. HALL: Okay. Thank you very much.

MR. ANDERSON: Okay. We'll begin with Dr. Pinto.

(Duane Pinto resumes the stand.)

DIRECT EXAMINATION

BY MR. ANDERSON:

Q. Good morning, Dr. Pinto.

A. Good morning.

Q. Let's get right to it. Dr. Pinto, we were talking about the ARTIST trial yesterday afternoon. Do you recall that?

A. I do.
Q. And that's a trial for intermediate and low-risk AR patients; correct?
A. That's correct.
Q. It's fair to say that these patients have options besides a Trilogy valve; correct?
A. That's correct.
Q. They are eligible for surgery, for example?
A. Yes.
Q. JenaValve is implanting Trilogy in these low- and intermediate-risk surgical patients today under the ARTIST trial?
A. That's correct.
Q. Dr. Pinto, it wouldn't be medically ethical to implant Trilogy in these intermediate- and low-risk patients if there was any doubt about Trilogy's safety; correct?
A. Correct.
Q. It wouldn't be medically ethical to implant Trilogy in these intermediate- and low-risk patients if there was any doubt about Trilogy's durability; correct?
A. We don't know Trilogy's durability beyond two years. We have a handful of patients at -- about 100 patients at three years, 50 at four years, and 20 at five years. So that's not enough to really make claims in that regard, but the early signs are that we are durable. So that was enough to

make a best guess that, yes, we could do this trial because -- but I can't promise that the durability will be the same. That's why it's one of the endpoints that we measure in this 10-year study.

Q. Dr. Pinto, it's fair that if you, sitting here today, had doubts about the durability of the device, it wouldn't be medically ethical to put it in a human.

A. That's correct.

Q. Dr. Pinto, yesterday afternoon, we talked about -- excuse me -- you talked with your counsel about a number of TAVR-AR devices made by Chinese companies, including the Pioneer valve, the Hanchor valve, the Ken-Valve, and the DOCS VALVE [ph]. Do you recall that?

A. Correct.

Q. You're not aware of any U.S. offices for the Chinese companies that make those valves; correct?

A. No, I'm not.

Q. You're not aware of any plans by those Chinese companies to conduct a clinical trial that would be accepted by the U.S. Food and Drug Administration?

A. Correct.

Q. And you're not aware of any plans by those Chinese companies to enter the U.S. market for TAVR-AR devices?

A. I'm not aware of any.

Q. Dr. Pinto, another thing that you said yesterday

afternoon was that Trilogy was modified from a transapical to a transfemoral device starting in 2014, correct?

A. I estimated that was about the time, yes.

Q. Okay. Fair that you didn't start working at JenaValve until 2022; correct?

A. That's right.

Q. So it's fair to say you don't have any firsthand -- you don't have any firsthand knowledge of JenaValve's efforts to redesign Trilogy; correct?

A. Correct.

Q. Dr. Pinto, you'd agree that if a device is materially resigned, FDA rules would require that the company obtain new data to support its safety and efficacy before it could be implanted in humans?

A. Yes. For example, say our device were approved and we were to make a second generation device. There would need to be a study looking at safety and efficacy, but the burden of that trial would be different than the initial IDE that we talked about because you can leverage your early preclinical testing and all those other modules, and it's really about the clinical data. So it's an abbreviated version of what we're in the process of doing now. But yes, you can't just have a new valve and then start putting it into people.

Q. Dr. Pinto, you were asked a series of questions about

what resources that you believe Edwards might be able to provide to JenaValve. Do you recall those questions?
A. Yes.
Q. You're not involved in any integration planning related to the proposed acquisition; correct?
A. I'm not.
Q. You don't know anything about Edwards's plans for JenaValve if the proposed acquisition closes?
A. I don't.
Q. So no one at Edwards has made any promises about money or employees, about how they would provide that or if they would provide that to JenaValve?
A. I don't think anybody would or have made promises to me since I'm a small fry, but no one's talked to me about that.
Q. Okay. And no one's made any promises that Edwards would develop the next generation Trilogy or continue the large valve program; correct?
A. It would stand to reason that the deficiencies that we have in our current product would need to be ameliorated.
Q. But no one's made any promises that Edwards would continue to develop a next generation Trilogy or continue the large valve program; correct?
A. Correct.
Q. Dr. Pinto, you were also asked about Trilogy's price. I'd like to ask you just a few questions about that. You're

aware of a time when one of the ALIGN-AR hospital sites declined to agree with a Trilogy price increase; correct?

A. Yes.

Q. Okay. I'd like to introduce P-X-2201. P-X-2201. Here we go. Let's start with Page No. 2 of this document, Dr. Pinto. If we look at the email starting in the middle of the page -- this is from Ms. Boyle who, I believe, we heard from you -- worked for you at this point in time; is that correct?

A. That's right.

Q. And this is Tuesday, November 26th, 2024. And this is -- in the "to" line is to a series of names, the first of which is Rebecca Harper. Rebecca Harper works at the Christ Hospital; correct?

A. Yes, sir.

Q. And the Christ Hospital is one of the sites where both J-Valve and Trilogy were available in November of 2024?

A. Yes.

Q. I'd like to look at the third paragraph of this document. And without saying the price that you see in those red boxes, can you confirm, yes or no, that JenaValve raised the price of Trilogy that it was charging Christ Hospital by the amount shown in that sentence?

A. We did.

Q. Okay. Let's flip up to Page 1 of the document. There's

a response at the bottom of the page from Ms. Harper dated November 27th, 2024 to Ms. Boyle. And looking at the body, Ms. Harper writes, "I have consulted with Dr. Garcia and Dr. Kereiakes, both copied on this email, on the JENA-VAD trial and, at this time, we are choosing not to move forward with this trial. The device cost is not something we can agree to."

Dr. Pinto, fair to say that Christ Hospital told JenaValve it would not move forward with the JENA-VAD clinical site because of the price increase?

A. That's right.

Q. She continues, "Additionally, if JenaValve determines that they will increase the price of the device cost in the ALIGN trial, we will not plan to continue enrollment."

Fair to say Christ also told JenaValve it would discontinue enrollment in an ongoing trial because of the price increase?

A. That's right.

Q. Her last paragraph, "It is unfortunate, but given the cost issue and other viable device options available to us, it's the best decision for our organization."

Dr. Pinto, at the time of this email exchange, Christ Hospital had access to the J-Valve; correct?

A. They had access to the J-Valve. I don't know what they refer to when they mean [sic] a viable device option,

though.

MR. ANDERSON: Nothing further.

MR. MCGINNIS: Your Honor, just a couple of questions for Dr. Pinto.

CROSS-EXAMINATION

BY MR. MCGINNIS:

Q. Good morning, Dr. Pinto.

A. Good morning.

Q. You were asked a few questions this morning about some of the other companies that are conducting research on TAVR-AR devices, including companies in China. Do you recall that?

A. Yes.

Q. And have you observed recently clinical research or reports of clinical research or clinical data from some of those companies at conferences?

A. I have.

Q. Why are you interested in these companies' clinical research and data?

A. Well, this is an understudied, undertreated population, TAVR for aortic regurgitation. So any data is important data to learn about this population. As we talked about, as opposed to TAVR aortic stenosis where thousands and thousands of patients have been studied, in the AR, there hasn't. So I like to know, how are patients doing? What

are the characteristics of the patients? How does the device perform? And learn from that, and -- so that can inform our next trials, how we treat our patients, and perhaps differences in how people are treated outside the United States that can be used to improve our treatment in the United States.

Q. And so do you think that data also helps you and JenaValve innovate Trilogy?

A. Of course.

Q. Dr. Pinto, do you want the -- you understand that we're here today about a transaction involving Edwards and JenaValve?

A. Yeah.

Q. Do you want this transaction to close?

A. I do.

Q. Why?

A. Well, I mean, just starting with that, I helped publish this data on 700 patients, which means I know about the complications. I know about what our valve can and can't do and where we need to get better. Right now, I can't do anything about it. Our three or four engineers that are working on the valve -- we have more engineers. Some of them are working on the sheaths and stuff like that. But they are not working on the large valve. They're not working on -- we don't even have a way to get to our next

valve to make these improvements that I know we need to make because, for example, they're dealing with communications with the FDA, et cetera. So they don't -- there's no, kind of, pathway for me to fix things.

The next thing that bothers me is that, as we spoke about earlier, we can't get the valve to the people that need it because we can't manufacture at scale and we can't get the people there to train the sites. There are entire parts of the country that I get calls from my colleagues nearly daily saying, "When is this coming? When do I get the valve? I have a patient."

MR. MCGINNIS: Thank you, Dr. Pinto.

MR. ANDERSON: Nothing further.

THE COURT: All right. Thank you, Dr. Pinto.

THE WITNESS: Thank you.

(Witness steps down.)

MS. FRANCE: Good morning, Your Honor. Jamie France on behalf of Edwards. We are calling Dr. Vahl out of time in defendants' case, given his schedule. So defendants call Dr. Torsten Vahl.

TORSTEN VAHL, WITNESS FOR THE DEFENDANT, SWORN

DIRECT EXAMINATION

BY MS. FRANCE:

Q. Good morning, Dr. Vahl.

A. Good morning.

Q. Who is your current employer?
A. Columbia University Medical Center.
Q. And what is your current role or position at Columbia University?
A. I'm an attending physician there in cardiology -- interventional cardiology.
Q. Could you explain, please, for the Court what is the specialty of interventional cardiology?
A. We perform minimally invasive procedures to help patients with coronary artery disease or structural heart and valve disease. And we implant devices to alleviate their disorders.
Q. And does your current practice include transcatheter aortic valve replacement, or TAVR?
A. Yes.
Q. Doctor, could you please just briefly describe your medical training and your current practice to the extent that you haven't already.
A. So I'm trained in internal medicine, cardiology and interventional cardiology. In addition, I did a special fellowship in structural heart and valve disease at Columbia University.
Q. Now, without saying exact numbers, because they've been designated confidential, could you give us an approximation of how many TAVR procedures you've performed over the course

of your career?
A. In the order of 1 to 2,000.
Q. And did that include TAVR for AS, or aortic stenosis?
A. The vast majority of those procedures were for aortic stenosis.
Q. Have you done procedures for aortic regurgitation, as well?
A. Yes, about 100.
Q. Are you familiar with the company Edwards Lifesciences?
A. Yes.
Q. And how are you familiar with Edwards?
A. Edwards Lifesciences provides heart valves to us, TAVR devices, the Edwards SAPIEN family that's been commercially approved in the U.S., and it's one of the devices that I implant frequently.
Q. Are you familiar with the company JenaValve Technologies?
A. Yes.
Q. How are you familiar with JenaValve?
A. I performed the initial animal testing in the U.S. that was the -- that was the backbone to, then, perform the early feasibility study for this investigational device to treat patients with aortic regurgitation.
Q. And have you participated in any clinical trials related to dedicated TAVR devices for AR?

A. Yes, it was -- I'm the principal investigator of the ALIGN-AR trial, which is a dedicated AR trial in the United States that was completed.

Q. What does it mean to be the principal investigator for that trial?

A. Every clinical trial has a leadership committee and, for TAVR trials, there's usually a surgical principal investigator and an interventional principal investigator. I'm the interventional principal investigator. In that role, I was involved in the trial design, but also looking at the trial data. And the final trial data was published with me as the first author.

Q. Have you had any involvement in the ARTIST trial?

A. Yes, I'm also one of the principal investigators on the ARTIST trial.

Q. And as a principal investigator involved in the ALIGN-AR and ARTIST trials, have you had any interactions with JenaValve executives or employees?

A. Yes.

Q. Could you please describe the nature of those interactions?

A. Well, we have the steering committee calls on a weekly or biweekly basis for the ALIGN-AR trial and now, in -- in the more recent time, also for the ARTIST trial.

Q. Now, you mentioned earlier you've performed procedures

using the JenaValve Trilogy valve. And could you remind us approximately how many of those procedures have you performed using the Trilogy valve?

A. About 100.

Q. And that was to treat patients with AR?

A. Predominantly. In -- early on, in the ALIGN-AR trial -- in the early feasibility study, I should say, patients with aortic stenosis were also allowed, but ultimately, the company gave up on the aortic stenosis trial because they didn't have enough resources to run both an AS and an AR trial. But in Europe, the device is actually approved for both aortic stenosis and aortic regurgitation. So in addition to the AR patients that we've treated at Columbia, we've also treated about a dozen patient with aortic stenosis with the device.

Q. Was that in the United States?

A. Yes, at Columbia.

Q. Doctor, have you ever performed a procedure using the J-Valve or -- also known as Sojourn, which is now owned by Edwards?

A. Not in humans. Only in animals.

Q. And approximately how many of those have you implanted?

A. I think four or five animals.

Q. Now, we've been talking about some of the clinical trials involving the Trilogy device. Approximately how many

other clinical trials have you participated in throughout the course of your career?

A. 40, 50.

Q. And could you give us a sense of what devices or what types of devices those trials involved?

A. Many of these have been related to aortic stenosis, TAVR devices in aortic stenosis, but we're also participating in trials that involve transcatheter treatments, both repair and replacement for mitral and tricuspid.

Q. And have you participated in any clinical trials involving any Edwards valves or devices?

A. Yes.

Q. In what disease areas?

A. All of the above. So aortic stenosis, mitral regurgitation, and tricuspid regurgitation.

Q. Dr. Vahl, I'd like to ask you a few questions about the Trilogy and the J-Valve TAVR-AR devices. Based on your experience, are there any differences between Trilogy and J-Valve?

A. There are differences in, A, the sizing matrix. So J-Valve spans a bigger span of sizes, covering an aortic annulus perimeter from the mid-50s to 100 and -- 304 [sic], I believe, and JenaValve covers from 66 to 90 millimeters perimeter. So more annulus sizes can be treated with the J-Valve, in theory, if it ever completes a clinical trial.

Q. Are there any other differences between Trilogy and J-Valve apart from the sizing matrix?
A. Yeah, the deployment mechanism is different. In the preliminary data that we have so far, it appears that the pacemaker rates are lower with J-Valve than with JenaValve.
Q. Could you please explain for the Court, what is the significance of the pacemaker rate of one of these devices?
A. So in a perfect world, we would want to only implant the TAVR device and not have to give the patient a permanent pacemaker afterwards, but the electrical conduction system runs very close to where the valve is. And so TAVR, even in AS, is frequently associated with worsening of the conduction system which, then, requires the patient to get a permanent pacemaker.
Q. So what does it mean for a valve to have a lower pacemaker rate?
A. It makes it better, in theory. That's one aspect that would be better.
Q. Is either valve, the Trilogy or the J-Valve, limited by a patient's aortic angle?
A. Yes. So in the ALIGN-AR trial, JenaValve required that patients with an aortic angle of greater than 70 degrees were supposed to be excluded. Now, in the ARTIST trial, they're saying the device has not the exact same number qualification anymore. Also, in Europe, and also, for us,

for compassionate use cases, we have implanted patients with higher angles. So in clinical practice, I'm not sure that it will ultimately be limited as much by the aortic angle. But in -- from a trial basis, J-Valve did not have this angle requirement, but JenaValve did.

Q. So based on your knowledge of the differences between the Trilogy and the J-Valve devices, is there an opportunity to treat a different set of patients with J-Valve than with Trilogy?

A. There probably is. I think we will, as clinicians, need a little bit more experience to understand which device will suit which patient best.

Q. Dr. Vahl, do you have any familiarity with the FDA approval process for medical devices?

A. Yes.

Q. And how are you familiar with the FDA approval process for medical devices?

A. Through my work as an investigator in some of these clinical studies.

Q. Could you please describe for -- at a high level for the Court the steps in the FDA approval process for medical devices like the Trilogy or J-Valve.

A. Yeah. In -- as a first step, animal studies are required that demonstrate that the components that are used in the device are considered medically safe. In addition,

they have to show that it's feasible to implant the device, and then, after the animal studies, we move on to what's called early feasibility studies where usually somewhere between 15 to 30 patients will be implanted. Safety data mostly is looked at at that point, not necessarily long-term outcomes are evaluated. And if it's shown that the device has good 30-day safety data, then the FDA will typically allow that now a pivotal trial is conducted which has the goal to get commercial approval for the device.

Q. In your experience, is there any uncertainty associated with the FDA approval process for medical devices?

A. There never is a guarantee.

Q. And why is there never a guarantee?

A. Because none of us can predict. If we could, we wouldn't have to do as many studies. None of us can predict whatever the clinical outcomes will be. And even after we get approval sometimes for these devices in trials, they're often still recalled or terminated afterwards because the small number of patients that are implanted do not necessarily give us full information about the full clinical picture later on.

Q. Are you aware of any structural heart devices that have received FDA approval but then were taken off the market?

A. Yeah, a number of them. Like, in the TAVR world, the Lotus device had been implanted over 10,000 times worldwide,

and then was withdrawn from the market because there were issues with the delivery system. More recently, ACCURATE neo, also a Boston device, was taken from the market after over 50,000 implants.

Q. And going back to the approval process, in your experience, can the FDA approval process take longer than expected?

A. Yeah. If someone would have told me that -- in 2018, when we started this study, that, in 2025, we still wouldn't have approval for a study that was only supposed to enroll 180 patients, I would have been very disappointed.

Q. And more generally, can you please describe the types of setbacks or challenges that you've seen devices face in clinical trials?

A. Well, there are often unforeseen complications, sometimes with the delivery system, sometimes with the valve itself, that require companies to go back and make redesigns. That can take the engineers sometimes a good amount of time.

Q. Have you ever seen setbacks in the FDA approval process related to the safety profile of a device?

A. Yes. So if, for instance, a device has issues with frame fractures, which is -- has occurred with some aortic and mitral devices, then often the trial will be put on hold and an investigation will be performed by the engineers.

They have to come up with new constructions to figure out how to prevent that in the future. That would be one example.

Q. And in your experience, how common is it for medical devices to fail clinical trials?

A. I don't have a percentage, but my clinical experience and experience within the research that I've conducted is that more devices fail than get approved.

Q. And new experience, is it the case that after the first medical device in a particular treatment area receives FDA approval, it may be faster for subsequent devices to go through that FDA approval timeline?

A. Generally speaking, that is true. I mean, the ALIGN-AR trial is an example for that. To get the FDA to agree to only enrolling 180 patients, to give this device approval for a new indication is built on the fact that the FDA felt comfortable that, overall, many thousand TAVR implants had been performed for aortic stenosis and there are enough similarities that they felt comfortable to give it a faster pathway with respect to lower numbers.

Q. Does physician awareness play any role in helping subsequent devices shorten their FDA approval timeline?

A. Yes. So when you embark on the new indication for a disease that's previously not treated with transcatheter therapies, the referral process needs to be taught and put

in place. So early on, our clinics did not have any patients with aortic regurgitation when we started the ALIGN-AR trial, for instance, or, similarly, very recently, we've seen this in the tricuspid field for patients with tricuspid regurgitation. No one referred us these patients because there were no transcatheter treatments. Now that they are more aware, a lot more patients are being referred.

Q. And that helps enrollment figures for the trials?

A. Yeah, and it certainly makes enrollment and future trials faster because we already have an established patient base.

Q. Now, Dr. Vahl, we've been talking about the Trilogy and J-Valve devices. Are you aware of any other TAVR-AR devices in development around the world?

A. Yes, most of these are currently developed in China. I was just last week at London Valves, and trial data was presented from the Ken-Valve. Over 100 patients had been treated there, in China, with that dedicated AR device with a similar safety profile and similarly good efficacy profile. The Hanchor valve is another Chinese device that's not self-expanding, but balloon-expandable. It's also been published this year. Over 120 patients have been treated with that device in a clinical trial. And there's a number of other ones that are not as far along right now in clinical trials, but conceptually have been developed.

Q. Based on your experience with TAVR devices and with the FDA approval process, do you think it would be possible for a TAVR-AR device developed outside the U.S. to enter the U.S.?

A. Well, J-Valve has just proven that that's possible.

Q. Can you explain what you mean by that?

A. Well, J-Valve was developed outside the U.S., in China, and is currently commercially approved in China and is now under clinical investigation here in the JOURNEY trial in the U.S., which happens to be on hold, but they transferred over from China to the U.S.

Q. In your experience, have you seen medical devices that are seeking FDA approval in the United States use clinical trial data from outside the U.S. to shorten the FDA approval process?

A. Well, it's naturally -- the short answer is yes, but it's naturally shorter because all the initial steps that we discussed, like the preclinical data -- typically, the FDA will still ask the company to do preclinical studies in the United States. But everything has been worked out and if you have human implants already outside of the United States, then all these processes and timelines are much faster. When you normally start with a new device and you start a preclinical study, that can take several years. But if you already have completed preclinical studies and

clinical studies outside of the U.S., performance of the preclinical studies in the U.S. now usually only takes five months because the FDA always asks us for 150-day data. So you can, then, very much predict that you can deliver that in the five-month time frame, and then also enrollment in the studies -- in the clinical studies in patients will go faster.

Q. Dr. Vahl, we talked earlier about how part of your practice involves treating patients with AS. And I think you told us earlier you've participated in a number of clinical trials for TAVR-AS devices; is that right?

A. That's correct.

Q. Who was the first manufacturer to develop and commercialize a TAVR device to treat aortic stenosis in the United States?

A. Edwards.

Q. And do you know the name of Edwards's TAVR device to treat AS?

A. Well, the initial device was named the SAPIEN valve. That was then followed by iterations that happened over the following years, the SAPIEN XT and SAPIEN 3 devices.

Q. And in your experience, has Edwards continued to make improvements to the SAPIEN platform over time?

A. Yeah, the SAPIEN 3 is a major improvement over the SAPIEN XT which was an improvement over SAPIEN. Initially,

the -- access was a big issue for us. We weren't able to treat patients with small arteries. They were able to make the devices smaller so we could treat patients with smaller arteries, but also the valves themselves became better over time, addressed questions like paravalvular leak that were a big issue at the beginning.

Q. In your view, does Edwards have a track record of innovation in the structural heart space and in the TAVR space specifically?

A. Yeah, they definitely do in the TAVR space, but I would say, in the overall structural heart space, they are running multiple programs in the aortic space, but also in the mitral and tricuspid space.

Q. Have you seen Edwards develop more than one approach simultaneously in terms of a particular program?

A. Yes, while they were developing the balloon-expanding platform, SAPIEN, and worked on the iterations, SAPIEN XT and SAPIEN 3, they also worked on a self-expanding platform called CENTERA. The outcomes with that device weren't as expected, so that line was put to rest.

Q. When you say the outcomes with that device weren't as expected, could you please explain what you mean by that?

A. So the safety profile of the Edwards balloon-expandable valve is excellent. And the CENTERA valve was not able to meet the same safety profile. There were some vascular

complications, there were some malpositions, and so the company decided not to proceed any longer with that.

Q. And based on that track record that you just described of Edwards having of -- of innovating in the structural heart space, would you expect Edwards to invest in developing a successful TAVR-AR device, as well?

A. I would expect them to do that, and I would hope they would do it.

MS. FRANCE: Your Honor, I would ask at this time that we close the courtroom. The remainder of my questions for Dr. Vahl are about information designated confidential.

THE COURT: Okay. Any objection from the FTC?

MS. SANCHEZ: No, Your Honor.

THE COURT: All right. Let's close the courtroom, then.

MR. SHORES: Can everybody except counsel for the parties please --

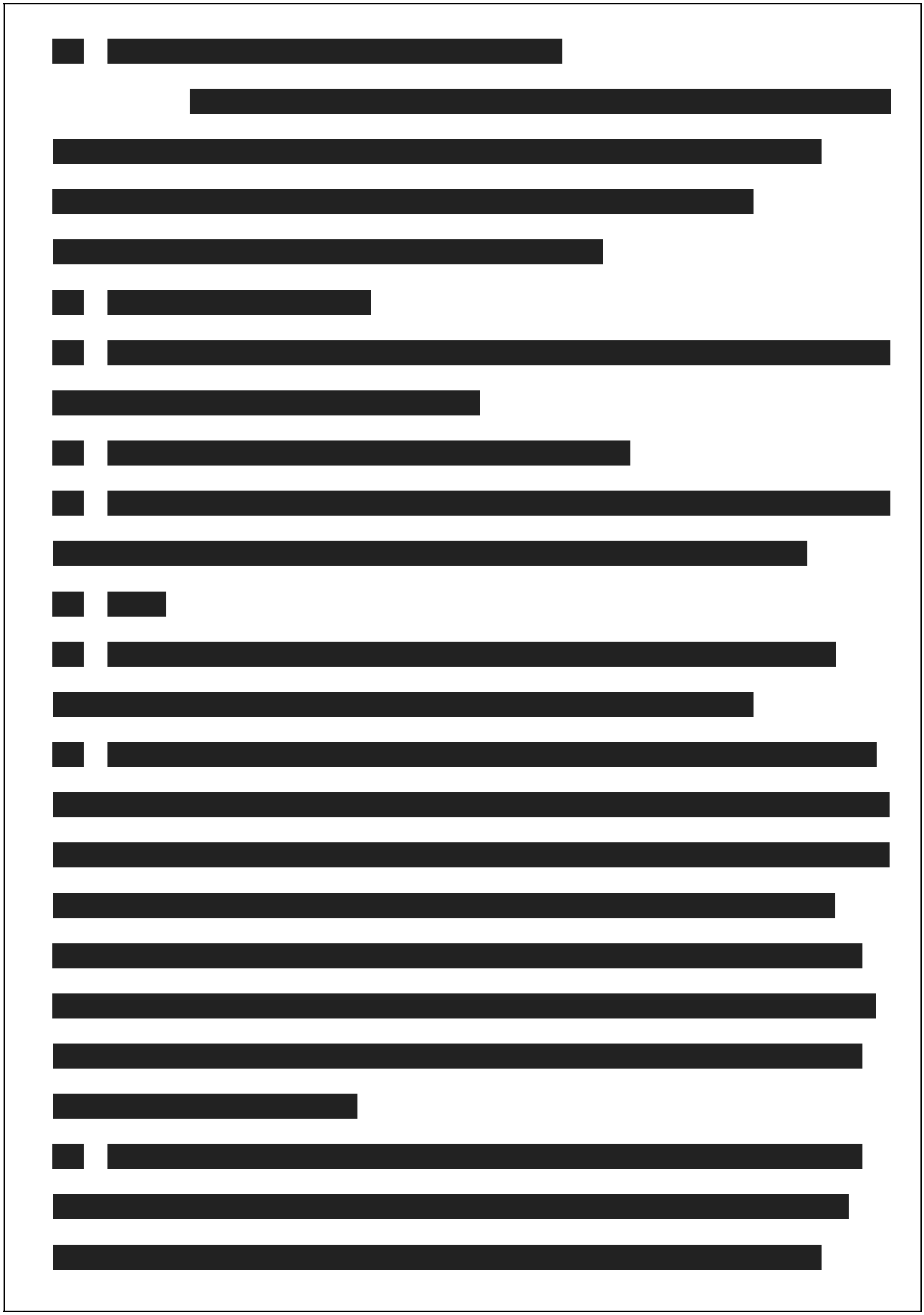
MS. FRANCE: And I'll just note Dr. Vahl's counsel is here. So he'll remain in the courtroom, as well.

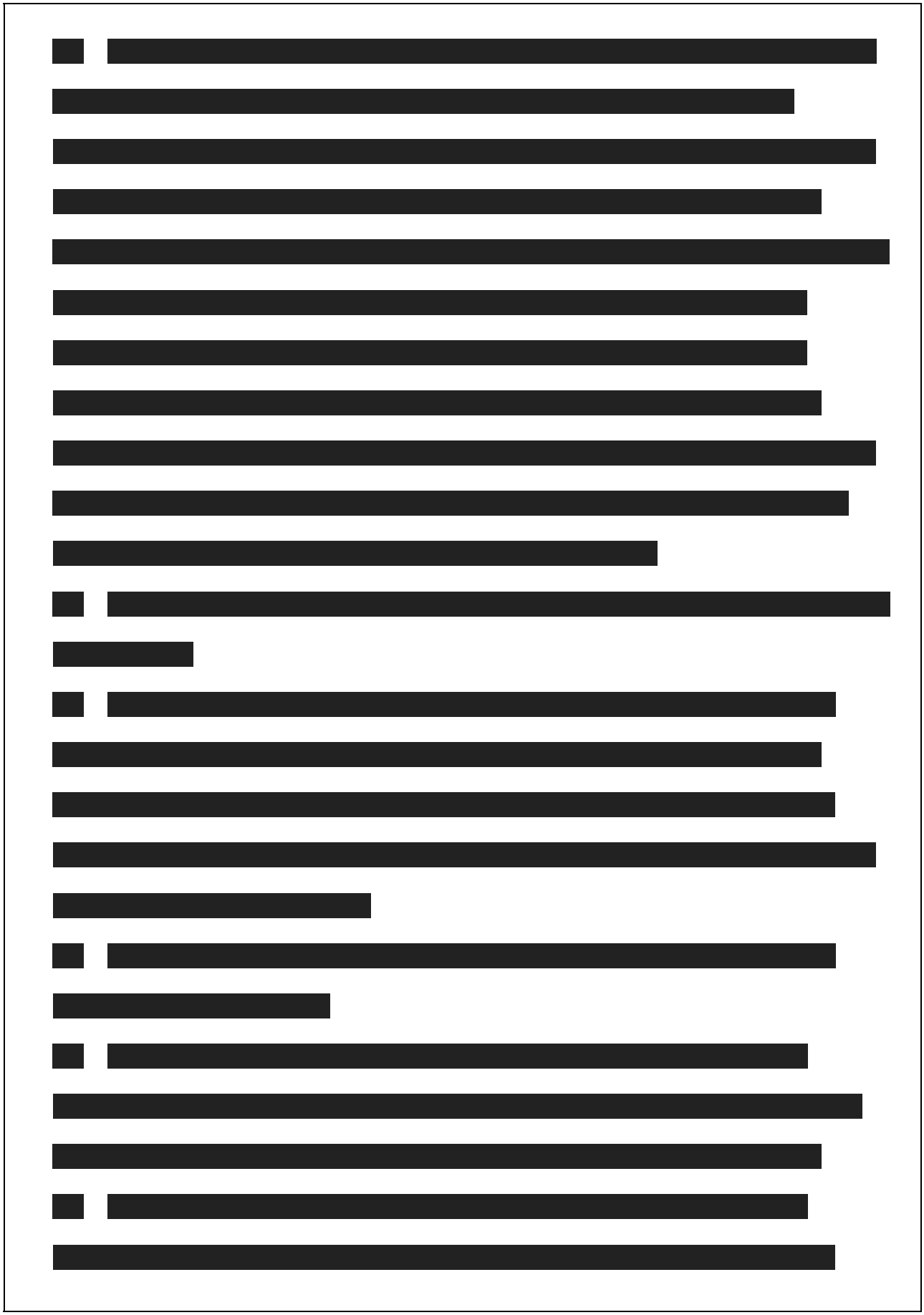
(Following proceedings under seal:)

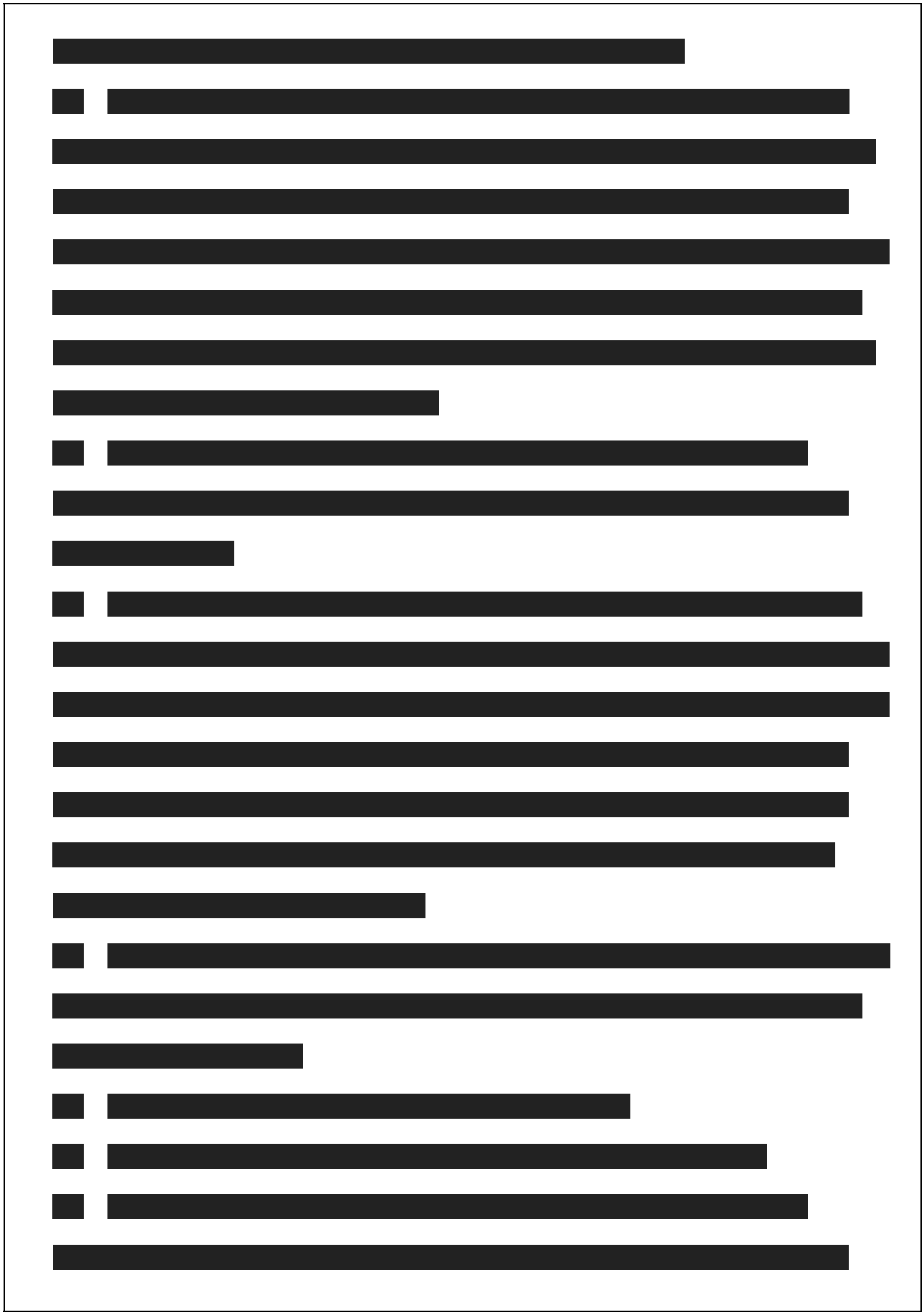
[redacted]







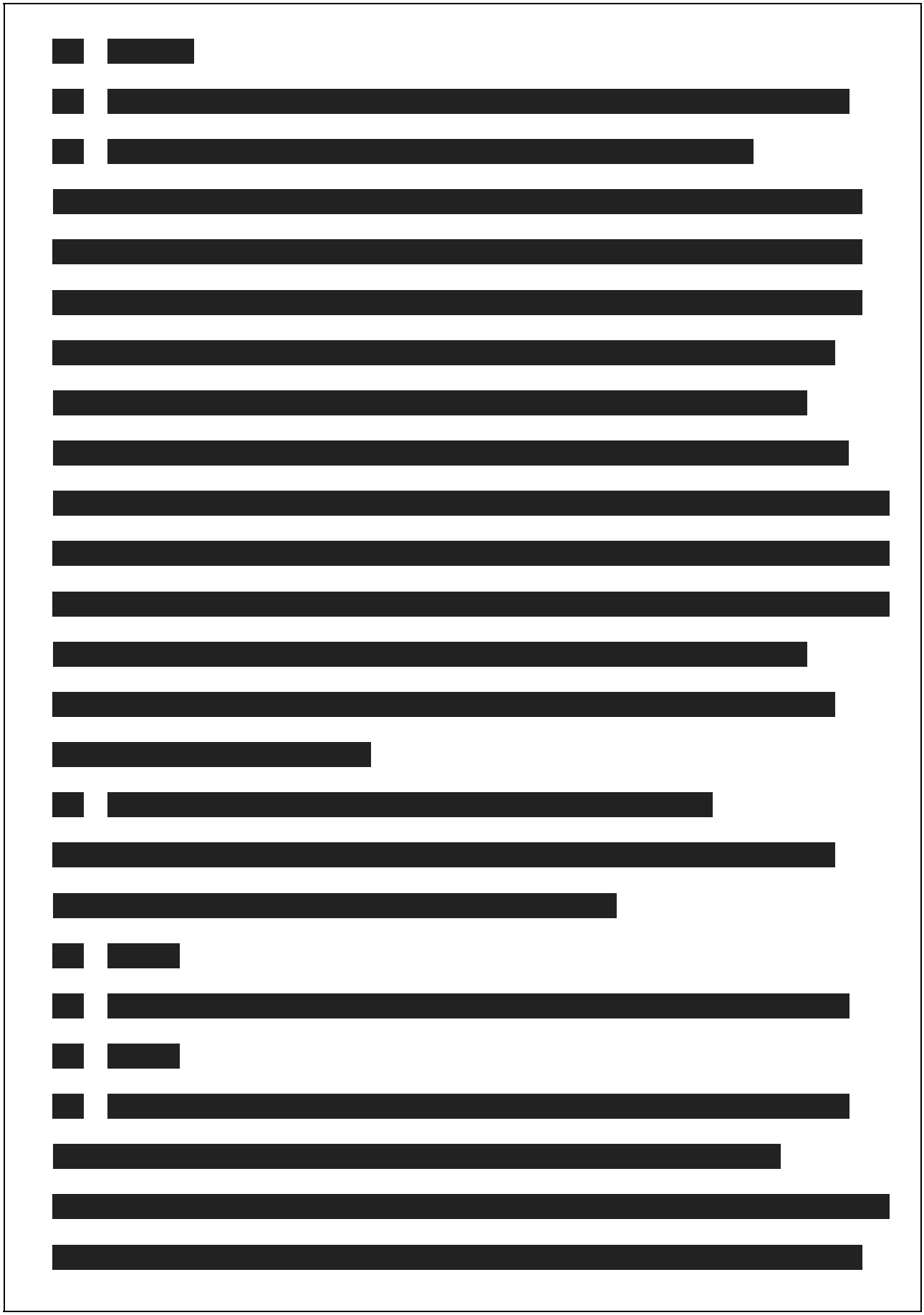




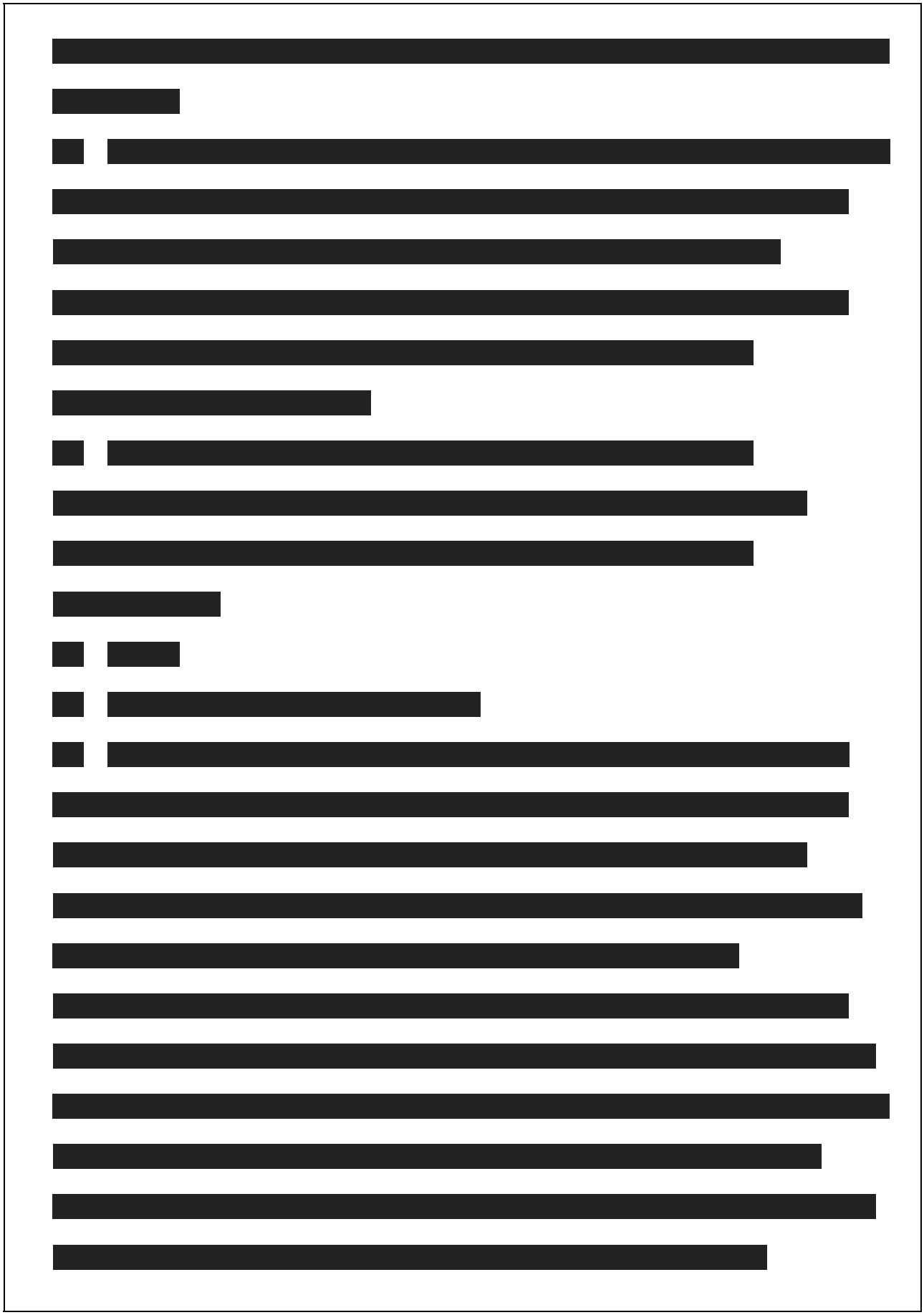




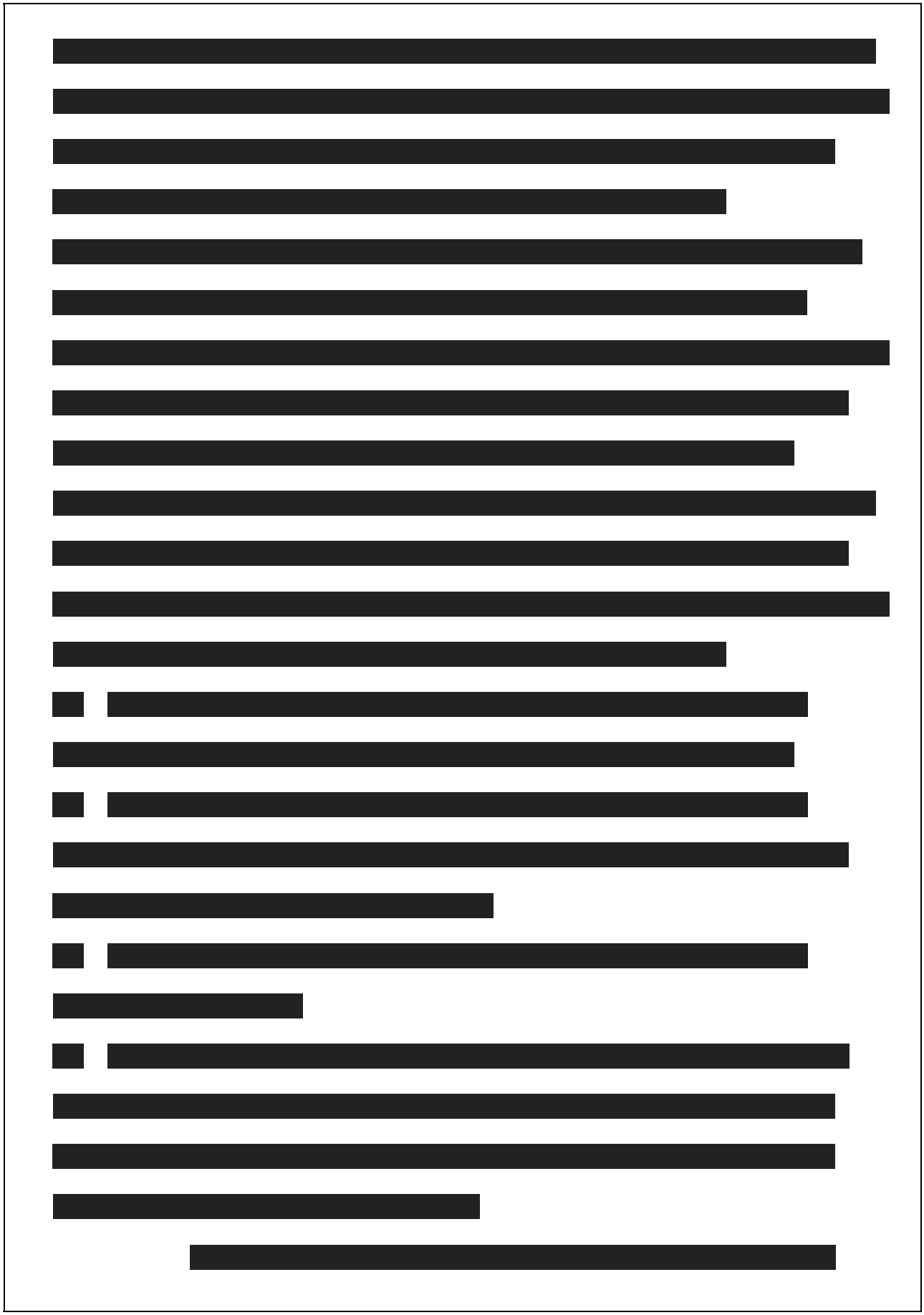






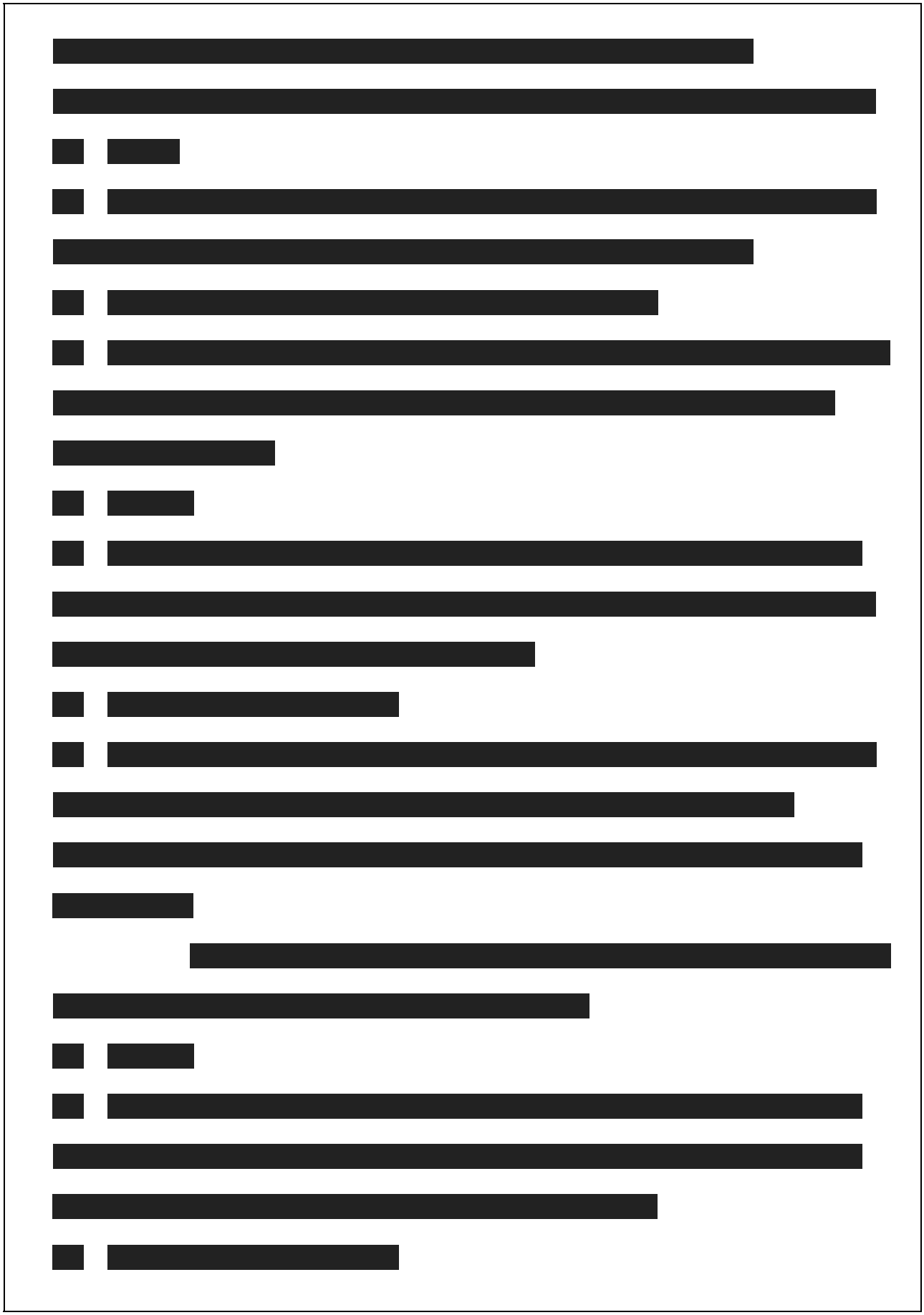
















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(Following proceedings in open court:)

THE WITNESS: Can I just make one clarification?

BY MS. SANCHEZ:

Q. There's no question pending right now, Dr. Vahl.

A. Okay.

Q. If defendants want to ask some follow-up questions, they can.

A. Okay.

MS. SANCHEZ: May I begin?

THE COURT: (Indicates affirmatively.)

BY MS. SANCHEZ:

Q. Dr. Vahl, you've been an attending physician at Columbia University's faculty since 2014; correct?
A. Yes.
Q. Your specialty is in interventional cardiology?
A. Yes.
Q. You don't have any surgical training; correct?
A. No.
Q. If you have a patient that requires surgery, you refer that patient to a surgeon; correct?
A. We have a heart team that evaluates all patients with valvular heart disease. That heart team includes cardiac surgeons. So we frequently or -- as a default, see these patients not just as an interventional cardiologist but with a heart team that also has a cardiac surgeon. After that, we decide what's best -- what the best treatment strategy is for a given patient.
Q. So when a patient -- it's been determined that a patient needs surgery, that patient is referred to a cardiac surgeon for that surgery; correct?
A. Yes, yes.
Q. You've never been employed by a medical device company; correct?
A. Only as a consultant, but not directly as an employee.
Q. You've never been employed by Edwards; correct?
A. No.

Q. You also were never employed by JC Medical before it was acquired by Edwards; correct?
A. No.
Q. You've never been employed by JenaValve?
A. Correct.
Q. You've never served on the management team of either JenaValve or Edwards; correct?
A. Correct.
Q. You've never served on the strategy teams of either company; correct?
A. Correct.
Q. You've never served on the pricing teams of either company?
A. I did not.
Q. You don't know how pricing decisions are made at Edwards, correct?
A. I do not.
Q. You do not know how pricing decisions are made at JenaValve; correct?
A. I do not.
Q. Defendants' counsel asked you some questions about what might happen if Edwards acquires JenaValve, and I'd like to follow up on a few of those questions.
To be clear, you've never had any communications with anyone at Edwards about the proposed transaction;

correct?
A. I did not.
Q. And you don't have any contacts at Edwards; correct?
A. No, I do not.
Q. More specifically, you have not had any communications with anyone at Edwards about their plans for Trilogy if the proposed transaction closes, correct?
A. That's also correct.
Q. You do not know how much money Edwards plans to devote to the continued development of JenaValve's Trilogy; correct?
A. Correct.
Q. You do not know what Edwards's plans are for manufacturing Trilogy if the proposed transaction closes; correct?
A. Correct.
Q. You also do not know what Edwards's plans are for commercializing Trilogy if the proposed transaction with JenaValve closes; correct?
A. Correct.
Q. And you do not know anything about what Edwards's plans are for JenaValve's ARTIST trial if the proposed transaction closes; correct?
A. Correct.
Q. Shifting gears a little bit, I want to ask you a few

questions about your knowledge regarding JenaValve's plans if the transaction does not go forward. You've not had any communications with anyone associated with JenaValve about the company's plans if the proposed transaction does not close; correct?

A. Correct.

Q. You do not have any awareness of what JenaValve's commercialization plans are for Trilogy; correct?

A. Correct.

Q. You do not know about potential additional funding that might become available to JenaValve if the transaction does not close; correct?

A. Correct.

Q. You spoke about a PTFE shortage that occurred a few years ago during your direct examination with defendants. And I want to ask you a few follow-ups on that.

It was your understanding that the delay in obtaining Trilogy devices at that time was caused by a third-party PTFE supplier that JenaValve was working with; correct?

A. Yes, that was required to make the sheath. Yeah.

Q. Ultimately, JenaValve resolved the issue caused by the PTFE supplier; correct?

A. Yes, eventually it became available again. Yes.

Q. And following the resolution of that issue, you resumed

enrolling patients in JenaValve's ALIGN-AR trial; correct?
A. Yes.
Q. And today, you continue to enroll patients through the ALIGN-AR continued access protocol; correct?
A. Yes.
Q. And notwithstanding the supply incidents in the ALIGN-AR trial, you signed on to another JenaValve pivotal clinical trial, studying the same Trilogy device in a different population; correct?
A. What do you mean by notwithstanding?
Q. You signed on to another JenaValve pivotal clinical trial studying the same Trilogy device in a different population; correct?
A. Yes.
Q. And you signed on to do that after those supply issues occurred; correct?
A. That is correct, because it's the only option we have.
Q. And the trial that we're talking about here is JenaValve's ARTIST trial; correct?
A. Yes.
Q. And not only did you sign on to be a clinical trial site PI, but you're -- you've agreed to be one of the national principal investigators for that study; correct?
A. Yes.
Q. You are actively enrolling patients in JenaValve's

ARTIST trial; correct?

A. Yes.

Q. Defendant's counsel asked you some questions about the European experience with JenaValve. Do you recall that?

A. Yes.

Q. You're not employed by any clinical sites in Europe; correct?

A. That's correct.

Q. There are different principal investigators that handle the European sites; correct?

A. Yes.

Q. And the information you have about the European experience is what the European physicians have told you; correct?

A. Yes.

Q. Is it fair to say those physicians can speak more directly to the experience with Trilogy in Europe than you can; correct?

A. Fair.

Q. Shifting topics again, I want to follow up on some questions defendants' counsel asked you about field support teams.

And I believe you testified that in its current state, you didn't believe JenaValve could support rolling out to all the sites that implant TAVR-AS today; correct?

A. Yes.
Q. But today, JenaValve does not have a device that it can commercially sell to all those sites; correct?
A. Correct.
Q. So even if JenaValve wanted to, it would not be permitted to go out and sell Trilogy commercially to all the hospitals that perform TAVR for AS today; correct?
A. Correct.
Q. You testified earlier that you don't know anything about JenaValve's plans for commercialization; correct?
A. That's correct.
Q. So you would not know what plans JenaValve may or may not have to build out its field team once it's permitted to commercially sell Trilogy; correct?
A. That's correct.
Q. Defendants' counsel asked you some questions about your expectation about Edwards's ability to support the rollout of Trilogy. And I want to ask you a few questions on that.
You're not aware of whether Edwards has any field representatives that are currently trained on Trilogy; correct?
A. Correct.
Q. You don't know if Edwards plans to use any of its existing field representatives to support Trilogy if the proposed transaction closes; correct?

A. Also correct.
Q. You also don't know how many field representatives Edwards has assigned to its own TAVR-AR device, J-Valve; correct?
A. Correct.
Q. And you do not know whether Edwards plans to use the same field representatives for Trilogy as it uses for its other products; correct?
A. Correct.
Q. And earlier, you testified about your personal expectations about Edwards's ability to address issues you face with JenaValve. Do you recall that?
A. Mm-hmm.
Q. Is that a "yes"?
A. Yes. Yes.
Q. That testimony is not based on any information that came directly from Edwards; correct?
A. No.
Q. No, that's correct, or --
A. It's correct, yes. It's not based on any direct information.
Q. Now, earlier, you testified about Edwards's history of developing platforms, and one of the platforms you had mentioned was CENTERA. Am I recalling that correctly?
A. Yes, CENTERA. Yes.

Q. And CENTERA was a developmental TAVR for AS, correct?
A. Yes, it reached the E-mark approval in Europe but not in the U.S., yes.
Q. And Edwards ran that clinical trial while it was also developing SAPIEN 3; correct?
A. Yes.
Q. Edwards did not continue CENTERA past the clinical trial stage; correct?
A. That's correct.
Q. You were not privy to Edwards's internal decision-making process for CENTERA; correct?
A. That's also correct. Yes.
Q. So you do not know why Edwards decided not to move forward with CENTERA, correct?
A. Well, I only know what's written publicly. And the statements from the company were that they didn't move forward because they weren't happy with the overall safety profile. It was commercialized in Europe, but it never reached commercialization in the U.S.
Q. But you were not privy to Edwards's internal decision-making on --
A. No, no, just public information.
Q. Now, earlier, defendants' counsel asked you some questions about TAVR devices -- TAVR-AR devices that are currently in development. I want to ask you some additional

questions on that, as well.

I'd like to introduce P-X-6006. It's in your binder, in paper, or it's going to show up on your screen. So whichever's easier for you, Dr. Vahl. You've seen P-X-6006 before; correct?

A. Yes.

Q. P-X-6006 is an article co-authored by you that was published in March/April 2024 issue of Cardiac Interventions Today; correct?

A. Yes.

Q. And the title of the article is, "Current and future TAVR devices for aortic insufficiency"; correct?

A. Yes.

Q. And just to clarify, aortic insufficiency is the same thing as aortic regurgitation; correct?

A. Yes, yes.

Q. Now, if you look directly underneath the main title, you wrote, "An outline of current experience with off-label TAVR for aortic insufficiency, as well as an overview of emerging dedicated TAVR devices for aortic insufficiency."

Do you see that?

A. Yes.

Q. Off-label TAVR referred to the use of TAVR-AS devices to treat AR; correct?

A. Yes.

Q. Now, emerging dedicated TAVR devices for aortic insufficiency refers to TAVR-AR devices that are under development; correct?
A. Yes.
Q. Now, one of the things you discuss in this article is the clinical experience with using TAVR-AS devices in AR patients; correct?
A. Yes.
Q. And you've described the use of TAVR-AS devices to treat AR as a horrible idea.
A. Yes.
Q. And using TAVR-AS devices to treat AR is associated with really high risk of complications; correct?
A. Yes.
Q. The off-label use of TAVR-AS devices does not provide you with acceptable clinical outcomes for your patients; correct?
A. Yes.
Q. If we could go to Page 2 of 6006. Do you see the heading "Dedicated TAVR devices for aortic insufficiency"?
A. Yes.
Q. And here in this section, you discuss the dedicated TAVR devices for AR that are currently in development in the United States; correct?
A. Yes.

Q. And the only two devices that you discuss here are JenaValve's Trilogy and Edwards's J-Valve; correct?
A. I'm not sure if it was Edwards's J-Valve at the time, but yes. The J-Valve, yes.
Q. And you understand that Edwards currently owns J-Valve?
A. Yes.
Q. If Edwards is permitted to acquire JenaValve, Edwards would own the only two TAVR-AR devices currently under clinical investigation in the United States; correct?
A. In the United States, yes.
Q. Now, defendants' counsel asked you some questions about the differences between Trilogy and J-Valve. And I'd like to ask you some questions about their similarities which is -- you discuss in this article.

Now, both J-Valve and Trilogy are designed to attach to the native leaflets; correct?
A. Yes.
Q. And that means both device -- those devices do not require the calcifications that are present in aortic stenosis; correct?
A. Yes.
Q. Another similarity is that both J-Valve and Trilogy devices that are currently being studied in the United States use what's called a transfemoral approach; is that correct?

A. Yes.
Q. And that's different from what's referred to as a transapical approach; correct?
A. Yes.
Q. A transfemoral approach does not require making major incisions in the patient; correct?
A. Small incision in the groin, yes.
Q. A transapical approach, on the other hand, requires a surgical incision and surgical access to the heart; correct?
A. Yes.
Q. Transapical procedures involve a spreading of the ribs?
A. Depends on the surgeon. There are a number of surgeons that can do it without rib spreading, but generally speaking, it may be required, yes.
Q. In most patients, transapical procedures lead to prolonged recoveries compared to transfemoral procedures; correct?
A. Yes.
Q. Generally, the outcomes are better in patients that undergo transfemoral procedures versus those that undergo a transapical procedures, correct?
A. We know that for TAVR-AS. It's not been studied comparatively for TAVR-AR. But your statement is correct for TAVR-AS, and we would all assume that it holds true for TAVR-AR.

Q. And just looking at the entire article that you co-authored, Dr. Vahl, the only two TAVR-AR devices that you discuss here are JenaValve's Trilogy and Edwards's J-Valve; correct?
A. At that time, yes.
Q. Okay. And just a few weeks ago, you presented at the annual TCT conference; correct?
A. Yes.
Q. TCT is one of the major conferences in your field?
A. Yes.
Q. You presented on the subject of TAVR-AR at that conference; correct?
A. Yes.
Q. The title of your presentation was "Contemporary transcatheter options for AR: Where do we stand"; correct?
A. Yes.
Q. There, you discussed TAVR-AR devices under development, correct?
A. Yes.
Q. And the only two devices you mentioned in your presentation from just a few weeks ago were JenaValve's Trilogy and Edwards's J-Valve; correct?
A. Correct.
Q. Now, defendants' counsel asked you some questions about devices that might be in development outside the United

States. Do you recall that?
A. Yes.
Q. You are not aware of any TAVR-AR devices other than J-Valve and Trilogy that are currently in development in the United States; correct?
A. Correct.
Q. And your understanding is that most of the devices that are being developed outside the United States are being mostly studied in China?
A. That's correct as well.
Q. You don't have any personal experience with any of those devices; correct?
A. I do not.
Q. You don't know the details of any of those devices; correct?
A. You mean from personal experience? I know the data. I'm aware of the data. The data was just presented at London Valves two, three days ago. So I'm aware of the data of these other devices, but I have no personal experience with them.
Q. At your deposition just over a month ago, you did not know the names of any of the devices that were being developed outside of the United States; correct?
A. I told you that some of the devices, at that point, were not published, and I didn't feel comfortable naming the

devices that were not published. Because, again, if the -- if we --

Q. Doctor --

A. Yeah. Okay.

Q. Dr. Vahl, at that time, you did not specify that you were aware of the names and that you just weren't sharing them; correct? You didn't testify to that in your deposition; right?

A. No, I think if you look at the deposition, I said that -- I was asked the question at some point, "Do you recall any of the devices that you reviewed, for instance, and articles?" And I said those articles have not been published so, therefore, I'm not going to name the devices.

Q. Is it your testimony that you did not testify that "I don't have the names and I'm sure -- I'm not sure I may know these"? Is that your testimony?

A. I'm not sure. I think I was asked that question in multiple different ways. At some point, I was asked about articles that I had reviewed and, I think, in that context I said if -- because the articles weren't published on Ken-Valve, for instance, that I wouldn't name them, yeah.

Q. Can we pull up -- if you would take a look at your deposition --

A. Sure.

Q. -- on Page 179, Lines 1 through 7. And what --

Question: "And what devices are you aware of that are being studied outside of the U.S.?"

Answer: "I don't have the names and I'm not sure I may know these. As far as I understand it, these review processes are confidential and there's no published literature on it currently."

Did I read that correctly?

A. Right.

Q. All right. I'd like to shift topics and talk about the ARTIST trial.

MS. SANCHEZ: If we could pull up P-X-3072.

BY MS. SANCHEZ:

Q. Dr. Vahl, you've seen this document before, correct?

A. Yes.

Q. Your name appears on the title slide?

A. Yes.

Q. This is a presentation you gave at the New York Valves conference earlier this year; correct?

A. Yes.

Q. The title of the presentation is, "Building the case for an all-comers RCT in AR: Surgery versus transcatheter replacement."

Do you see that?

A. Yes.

Q. This presentation discusses JenaValve's ARTIST trial;

correct?

A. Yes.

Q. JenaValve's ARTIST trial is the first randomized controlled trial comparing TAVR-AR to SAVR in non-high-risk patients that have symptomatic aortic regurgitation; correct?

A. Yes.

Q. And in the ARTIST trial, half of the trial patients will be randomized to be implanted with Trilogy and the other half will be randomized to SAVR; correct?

A. Yes.

Q. In your experience with randomized TAVR trials, sometimes patients that are randomized as surgery may not show up for surgery; correct?

A. Yes.

Q. And you believe that happens because those patients are terrified at the thought of having someone take a saw and open their chest; correct?

A. Yes.

Q. In your own practice, Dr. Vahl, you've had AR patients who were low to medium risk for surgery but simply declined surgical intervention to treat their AR; correct?

A. Yes.

Q. And your understanding of why some of those patients declined surgical intervention is because there is a

subgroup of patients that have a hard time accepting the thought of open-heart surgery; correct?

A. Yes.

MS. SANCHEZ: If we can turn to Page 23 of P-X-3072.

BY MS. SANCHEZ:

Q. It's the summary slide of your presentation.

In the first bullet, you write, "The ARTIST trial is a rigorous, randomized study that is an important milestone in our endeavor to find a transcatheter treatment for patients with aortic regurgitation."

Do you see that?

A. Yes.

Q. In order to provide non-high-risk AR patients with a less invasive therapy than surgery, you need randomized clinical trial; correct?

A. Yes.

Q. And that's the kind of data that will be generated in the JenaValve's ARTIST trial; correct?

A. Yes.

Q. And that means, from JenaValve's ARTIST -- that means the data from JenaValve's ARTIST trial is an important milestone towards potentially providing a less invasive option to non-high-risk patients; correct?

A. Yes.

Q. In your experience, patients are hoping for less invasive treatment than open-heart surgery; correct?
A. Yes.
Q. Your view, it would be desirable for AR patients not at high risk for surgery to have a TAVR option; correct?
A. Well, I think I stated that the last time, too, assuming that this trial shows that TAVR is non-inferior in that patient population, then yes. I would not want to offer an inferior TAVR procedure to someone who would -- if the trial shows that surgical AVR is better, then my recommendation is not going to be to any patient, that is low or intermediate risk, to have TAVR.
Q. And, Dr. Vahl, my question was, in your view, it would be desirable for patients not at high risk to have TAVR as an option; correct?
A. Yes.
Q. If you can go to the second bullet, it reads, "The clinical evidence that this trial will generate is critically needed."
Do you see that?
A. Yes.
Q. And you shared this view with your colleagues at the New York Valves conference; correct?
A. Yes.
Q. You agree with that statement; correct?

A. Yes.
Q. It's fair to say you think the ARTIST trial is an important clinical study to undertake; correct?
A. Yes.
Q. And it's your hope that the ARTIST trial reaches completion; correct?
A. Yes.
MS. SANCHEZ: Those are all my questions. Thank you for your time, Dr. Vahl. I really appreciate it.
THE WITNESS: Thank you.

REDIRECT EXAMINATION

BY MS. FRANCE:
Q. Just one question, Dr. Vahl. You were asked some questions by counsel for the FTC about referring patients to other clinical trial sites, and you'd wanted the opportunity to provide a clarification?
A. Yes, I recall that I've submitted one -- sent one patient to a practice in New Jersey, and that was related to insurance coverage. Our hospital did not accept the patient's insurance, so we couldn't enroll them in the trial at our site. But they accepted that patient at Robert Wood Johnson because they're partnering with the insurance.
MS. FRANCE: Thank you, Dr. Vahl. No further questions.
THE COURT: Thank you.

Thank you, Doctor.

THE WITNESS: Thank you.

(Witness steps down.)

THE COURT: We'll take a five-minute break -- 10-minute break.

(Brief recess taken.)

MR. TYMKOVICH: Good morning, Your Honor. Jay Tymkovich for the Federal Trade Commission.

Plaintiff calls Dr. Mark Turco to the stand.

MARK TURCO, WITNESS FOR THE PLAINTIFF, SWORN

MR. TYMKOVICH: Your Honor, may I proceed?

THE COURT: You may.

DIRECT EXAMINATION

BY MR. TYMKOVICH:

Q. Please state your name for the record.

A. Mark A. Turco.

Q. Are you represented today by Gibson Dunn?

A. I am.

Q. Is Edwards paying for your representation today?

A. Yes.

Q. Without divulging any privileged information, did counsel for Edwards help you prepare for today's hearing?

A. Yes.

Q. Where are you currently employed?

A. Rhode Island, at the Rhode Island Life Science Hub.

It's a quasi-public organization through the state of Rhode Island.

Q. You were a paid consultant for Edwards from July 2024 to December 2024; is that right?

A. That is correct.

Q. And you were the CEO of JC Medical from May 2023 to July 2024; right?

A. Yes.

Q. When you became CEO, Genesis MedTech was the owner of JC Medical; right?

A. Yes.

Q. Genesis owned 100 percent of JC Medical at that time?

A. Yes.

Q. Edwards acquired JC Medical in July 2024; right?

A. Yes.

Q. I want to briefly discuss JC Medical's business strategy. Let's start with a document, P-X-1037.

This is a PowerPoint presentation titled, "Structural heart upstream meeting" from April 2023. Do you see that?

A. Yes.

Q. Please turn to Page 16. This slide is titled, "Updates on JenaValve, our closest competitor in USA TAVR-AR market."

Do you see that?

A. Yes.

Q. Let's look at the box on the right labeled, "Key insights." At the bottom at point 3, it says, "Now our clinical performance has to match or be superior to JenaValve's."

Do you see that?

A. Yes.

Q. And point 4 says, "We need to start U.S. pivotal trial before Trilogy is approved. Estimate Q3 2024."

Do you see that?

A. Yes.

Q. We can set this document aside and turn to P-X-1049. P-X-1049 is a January 25, 2024 email attaching a file titled, "U.S. JCM valuation, 25 Jan 2024"; right?

A. Yes.

Q. Let's go to Page 1 of the attachment. It's titled, "U.S. TAVR market and JCM valuation"; correct?

A. Yes.

Q. This presentation was shared with the Genesis Board of Directors; right?

A. I cannot be sure about that since I don't present to the Genesis Board of Directors.

Q. So it's your testimony that you don't know whether this presentation was presented with the Genesis Board of Directors?

A. That is correct.

Q. Dr. Turco, you sat for an investigational hearing on July 14th, 2025; correct? Like a deposition?
A. Can you repeat the date of that?
Q. July 14, 2025.
A. Yes.
Q. And you were under oath?
A. Yes.
Q. Let's turn to the investigational hearing transcript at Page 115, Line 19 to 22.

"QUESTION: Okay. So the market model contained in this attachment you and Ms. Pang [ph] developed to share with the Genesis board and potential investors?

"ANSWER: That is correct."

Did I read that right?

A. That is correct.
Q. Let's go to Page 10. This slide is titled, "USA TAVR-AR case volumes and JCM revenue projections."

Do you see that?

A. Yes.
Q. On the left of the page are three bar graphs with JC Medical's projections for the bull, base, and bear case for TAVR-AR case volumes in the United States; is that right?
A. Correct.
Q. And these bar graphs depict TAVR-AR market share from

2024 to 2035; is that accurate?
A. Yes.
Q. There's a key at the top showing that J-Valve's market share is depicted in blue and JenaValve's market share is depicted in the gray; right?
A. Yes.
Q. So in all three of these bar graphs, JenaValve has 100 percent market share up to 2026; right?
A. Yes.
Q. Once J-Valve gets FDA approval in each of these graphs, J-Valve starts obtaining TAVR-AR market share; right?
A. That is correct.
Q. And J-Valve is depicted taking market share from JenaValve; right?
A. Yes.
Q. Let's focus on the base case graph in the middle. In 2027, JC Medical obtains FDA approval and has 3 percent market share; right?
A. Yes.
Q. And JenaValve has the remainder; is that correct?
A. That's what's projected here in this model.
Q. And in 2028, JC Medical's share grows to 8 percent; is that right?
A. That's what's shown here in this model.
Q. And in 2029, what's shown in this model is that

JC Medical's TAVR-AR market share grows to 13 percent?
A. Yes.
Q. And JC Medical continues taking market share from JenaValve through to 2035; right?
A. Yes.
Q. In 2035, this graph projects that JC Medical would have 37 percent of the U.S. TAVR-AR market share?
A. Of a base case model. Correct.
Q. And JenaValve would have the remainder in 2035?
A. Yes.
THE COURT: Counsel, let me ask this question. I see the red line around the graph. Is the courtroom supposed to closed?
MR. TYMKOVICH: No, Your Honor. This document came with a red box. It confused me as well initially when I looked at this document.
THE COURT: Okay.
BY MR. TYMKOVICH:
Q. So Dr. Turco, according to this document, from 2024 through 2035, there are no other providers of TAVR-AR case volumes besides JC Medical and JenaValve; correct?
A. This model is built on two players in the market, J-Valve and JenaValve. But there are a lot of assumptions that go into building models, and there's even assumptions in regulatory timelines that go into -- when you build a

model. So as you can see, we were assuming that JenaValve would have FDA approval at a certain time frame and, as you well know, JenaValve still, to this day, doesn't have FDA approval. So this model would not have been accurate in predicting, you know, true market share because if we could have truly launched in the first half of '27 with FDA approval and JenaValve wasn't on market, we would have had 100 percent of market share at that time.

Q. Dr. Turco, understanding that the model is based on assumptions, this model shows that there are no other providers of TAVR-AR case volumes besides JC Medical and JenaValve through to 2035; is that correct?

A. They -- that's how this model was created with two players in the market at that time.

Q. So the answer is yes?

A. Yes.

Q. So these market share projections do not anticipate any entrants other than JC Medical and JenaValve for U.S. TAVR-AR?

A. Again, for this particular model, yes. Obviously, we were quite aware that there were many other players, including other strategics that were working on aortic regurgitation technology. So this was a base case model that we put together to try to evaluate the revenue and the market share that we could obtain in the out years once we

launched.

Q. And no other competitors, other than JenaValve and JC Medical, are depicted in this model; correct?

A. They are not -- can you repeat the question? They are or are not?

Q. No other competitors are depicted in this model?

A. That is correct.

Q. Thank you.

We can set this document aside.

I'd like to shift gears and discuss JC Medical's background before it was acquired.

MR. TYMKOVICH: Let's pull up P-X-1048.

BY MR. TYMKOVICH:

Q. This is a February 26th, 2024 email from yourself to Medtronic, attaching a file titled, "JC Medical and J-Valve for Medtronic"; is that correct?

A. Yes.

Q. Let's look at Page 1 of the attachment. This is a pitch deck that JC Medical prepared; correct?

A. That is correct.

Q. Let's go to Page 7. This slide is titled, "Key milestones"; is that right?

A. Yes.

Q. And this appears to be a timeline of JC Medical's history; is that correct?

A. Yes.
Q. So JC Medical was founded in 2007 in Burlingame, California; right?
A. That's when work started in JC Medical and, obviously, that predated -- well predated my time with the company, but that's what this timeline does show.
Q. Let's go to Page 6. The slide is titled, "JC Medical company overview"; right?
A. Yes.
Q. And there's a map depicted here. According to the map, JC Medical has operations in the United States and China; correct?
A. JC Medical, as we spoke to at the outset, is owned by Genesis MedTech. Genesis MedTech has operations in those particular regions.
Q. And JC Medical, as a subsidiary of Genesis, had operations in the United States and China?
A. Yes.
Q. JC Medical was based in Burlingame, California, is that correct?
A. Our United States headquarters was in Burlingame, California.
Q. Let's look at the text under the USA bubble. So JC Medical had R&D, clinical activities, and corporate operations located in the United States?

A. That is correct.

THE COURT: Where was your office?

THE WITNESS: In Burlingame. I was based on the East Coast, but spent a good portion of the month time, 15 days a month usually, in the West Coast in Burlingame.

THE COURT: Okay.

BY MR. TYMKOVICH:

Q. Let's return to Page 7. Looking at the third entry on the timeline, in 2018, JC Medical began implanting J-Valves in U.S. patients; right?

A. Yes.

Q. You became CEO of JC Medical in 2023?

A. In May of 2023.

Q. JC Medical's FDA-approved early feasibility study began in 2023; right?

A. Yes.

Q. So it took 16 years from JC Medical's founding in 2007 to start -- to the start of its early feasibility study in 2023; is that correct?

A. From this timeline, that is correct.

Q. In February 2024, JC Medical completed enrollment in its early feasibility study; right? It may not be depicted on this slide.

A. We completed enrollment sometime in Q3/Q4 of 2024 -- I'm sorry, 2023 is -- I think it was October of 2023 that we

completed enrollment in the early feasibility study.
Q. Okay. JC Medical submitted its application to the FDA for an investigational device exemption, or IDE, in April 2024 for a pivotal trial; is that correct?
A. That is correct.
Q. And the FDA granted JC Medical's IDE in May 2024, allowing JC Medical to commence its pivotal JOURNEY trial; is that correct?
A. Yes.
Q. And JC Medical received the IDE before Edwards acquired it in July 2024?
A. Yes.
Q. Let's talk now about the process of selling JC Medical in early 2024. Genesis told you in early 2024 that it did not want to spend the money to move forward with a J-Valve pivotal trial; right?
A. That I would need to raise the money outside of what Genesis could provide to be able to move forward with the pivotal trial IDE in the United States.
Q. So by February 2024, Genesis told you to find outside investments or a buyer for the U.S. J-Valve business?
A. Yes, it was probably closer to mid-January that I had that discussion with the president and CEO of Genesis MedTech, Warren Wang, in his office in Shanghai.
Q. You did not conduct a formal sales process for

JC Medical; is that correct?
A. That is not correct.
Q. Well, you didn't hire an investment bank to assist with the sale; is that correct?
A. Why would we need to hire an investment bank?
Q. My question is whether you hired an investment bank --
A. I did not hire an investment banker.
Q. You relied on your personal relationships with strategics to execute the sale of JC Medical?
A. Yes.
Q. You started the outreach process to strategics in early 2024; right?
A. As soon as I had spoken to Warren Wang, because we needed to change gears and either raise money to do the clinical trial or find a strategic to acquire JC Medical.
MR. TYMKOVICH: Your Honor, I've prepared a demonstrative to help talk through Dr. Turco's outreach process.
Could we pull up P-D-X-8.
BY MR. TYMKOVICH:
Q. Looking at P-D-X-8 on your screen, once you decided to try to sell JC Medical, you sent a pitch deck to Edwards first; right?
A. That is correct, because that was the first company that I had made contact with.

Q. Mm-hmm. You sent a pitch deck to Edwards in early February 2024; right?

A. Yes.

THE COURT: Just so you understand, this is not an exhibit. This is something counsel put together. So don't rely on those dates for accuracy.

THE WITNESS: Thank you, Judge.

THE COURT: Unless you have independent knowledge.

BY MR. TYMKOVICH:

Q. So as shown in the demonstrative, you didn't begin discussions with other strategic buyers besides Edwards until about two weeks later; is that accurate?

A. It's hard to recall the exact dates, but that is probably not accurate because what I did was, as soon as I had the message -- was communicate with each of the strategics that we would want to try to get involved in a possible acquisition. So just as I, probably in early February, spoke with the business development folks and leaders at Edwards, I did the same with Medtronic, Boston Scientific, Abbott, and Johnson & Johnson.

Q. Okay. Perhaps being a bit more precise, the second potential buyer you sent a pitch deck to was Abbott in late February?

A. I don't recall the exact date, and I would not think that this is a good understanding of how we would do

outreach, because a pitch deck may be something that is sent much later in the game where there's other conversations that are -- that occur with the leaders and the business development individuals and venture partners at the big strategics. So I don't recall exactly when I sent a pitch deck to Medtronic, Abbott, Boston Scientific, but I can assure you that conversations with each of those companies, including Johnson & Johnson, occurred in that late January/very early February time frame.

Q. Dr. Turco, we already looked at the pitch deck you sent to Medtronic. That was sent on February 26th; correct?

A. Again, if that is -- was the date on the previous pitch deck, that -- then that's accurate. I don't recall offhand the exact date that I would have sent the pitch deck to Medtronic.

THE COURT: Hold on a second. Let me ask a question. Did a witness just walk into the courtroom?

MR. HALL: Your Honor, this is our FDA regulatory expert, Dr. Aaron Kesselheim.

THE COURT: Okay.

BY MR. TYMKOVICH:

Q. So, Dr. Turco, in April 2024, you sent JC Medical's pitch deck to Johnson & Johnson; correct?

A. I don't recall the exact date that I sent the pitch deck to J&J.

Q. In the middle of all this outreach to potential strategic buyers, you also reached out to a venture capital fund called Vensana; correct?
A. Yes.
Q. You discussed a financing arrangement with Vensana; correct?
A. I discussed with Vensana their possible interest in investing and looking for creative ways to fund the clinical trial to keep JC Medical moving down the path toward FDA approval and ultimate commercialization.
Q. Focusing back on strategics, you had discussions with all of these companies in the February, March, April 2024 timeline?
A. Yes.
Q. On April 21, Edwards sent you a term sheet; correct?
A. If that is the date. I don't recall offhand the exact date that we received the term sheet, but that is likely -- sometime in April we received the term sheet from Edwards.
Q. That date seems roughly correct?
A. In the ballpark, yes.
Q. That term sheet from Edwards included an exclusivity provision; is that correct?
A. Yes.
Q. After JC Medical received Edwards's term sheet, you re-engaged with the other large medical device companies;

right?
A. I'm not sure whether it was re-engaged. I let the other companies know that we had an existing term sheet so that we could, then, turn the conversations off with those other companies, given the existing exclusivity.
Q. What did you mean by turn conversations off?
A. Well, once we had begun to work with Edwards, then, in the term sheet, it was important for us to let Johnson & Johnson, Boston Scientific, and Abbott, as well as Medtronic, know that we were in -- we had received a term sheet and in formal negotiations with Edwards Lifesciences.
Q. So you reached out to Abbott, Medtronic, Johnson & Johnson to let them know that you had a term sheet?
A. Yes. And Boston Scientific.
Q. You told them that you had a term sheet and that they would need to show greater urgency; is that correct?
A. Usually, what happens in an M&A, you do want to try to get two buyers to the table so that there can be some competition around the valuation of the company. So usually, in -- the process is to let other strategics in this case know that we were in formal negotiations, and if they did want to move forward, they would need to move forward before our process with Edwards got further down the line.
Q. J&J responded to your outreach that this timeline was

too fast for them; correct?

A. Among other things. J&J did not have true interest. It wasn't just the timeline issue. It was a matter of them really not being sure what their strategy was in the structural heart space. So that was only -- the timeline was only one issue.

MR. TYMKOVICH: Let's turn to D-X-0104. Let's go to the bottom of Page 2.

BY MR. TYMKOVICH:

Q. This email is dated April 25. You sent it to Johnson & Johnson. In the second sentence, you write, "Late last week, we received a term sheet for consideration and we are currently reviewing the terms internally with the engaged party. In the near future, we will likely be moving towards an exclusivity period."

Did I read that right?

A. Yes.

Q. In the last paragraph, you said, "We would need to move quickly"; is that correct?

A. Yes.

Q. On Page 1 in the middle of the page, Johnson & Johnson responds, "Thanks, Mark. Appreciate the situation. This would come too soon on our end since there is a degree of strategy alignment and asset selection still to be done"; correct?

A. Yes.
Q. You can set this document aside.
So you sent similar emails urging Medtronic to move quickly, as well?
A. Yes.
Q. So after you told Johnson & Johnson and Medtronic about your term sheet, that's when they passed on the sale of JC Medical; is that accurate?
A. The -- Johnson & Johnson passed. I went back to Medtronic and had a number of conversations with both Sean Salmon, Nina Goodheart, and the head of strategy and business development, and it was clear that Medtronic had no interest in moving forward with an acquisition of JC Medical. Medtronic's comment -- and I -- they were a company that we approached very seriously, one, because of relationships; but, two, because of the fit being very good for Medtronic and giving them a play in the field of aortic regurgitation. Medtronic was very clear with me that the market was unclear, the size of the market was unclear for them to engage in the field of aortic regurgitation. And, in addition, the amount of dollars that would need to be spent for market development were beyond what they were willing to commit. And so those conversations occurred, and I do believe there was an email back from their business development team stating things along those same lines.

Q. Dr. Turco, I guess, my question was simpler than that. But after you told Medtronic that you had a term sheet and would have to move quickly before exclusivity attached, that's when they passed?
A. I don't remember the exact date when they passed, so I don't know whether it was before or after, but, as I mentioned to you, there were multiple conversations with Medtronic that occurred over email, by voice, and other means with their leadership because, again, my job as CEO of JC Medical and as a person running this process was to bring as many players as possible to the table.
Q. In any event, in 2024, you signed a term sheet with Edwards in mid-May; correct?
A. I don't remember the exact date that we signed the term sheet, but that sounds in the neighborhood.
Q. And on July 22, you signed an agreement to be acquired by Edwards; correct?
A. It was either -- if July 22 -- it was either July 22 or July 24. I don't recall the exact date. But in that ballpark.
Q. We have a handy demonstrative.
A. There you go. That's great.
Q. The next day, Edwards signed the JenaValve deal; right?
A. Yes.
Q. Let's turn to P-X-1160. At the bottom of Page 2,

there's an email from Mike Kramer of Vensana on July 24th, which is the day after the JenaValve deal; correct?

A. Yes.

Q. And Vensana, as we discussed, was the venture capital firm you were in discussions with before you entered exclusivity with Edwards?

A. Can you repeat the question, please?

Q. Sure. Vensana was the venture capital firm you were in discussions with before you entered exclusivity with Edwards?

A. Vensana was one of the venture capital firms. I must have gone to probably 20 different venture capital firms over the period to try to, again, develop out a creative financing arrangement, with or without a strategic involved. And we were talking to Vensana around developing out a syndicate, and they were very interested in possibly doing a syndicate, especially if a strategic was at the table. And I believe, after -- on this email of July 24, Mr. Kramer is responding back to me because of the prior discussions that we had had around building a syndicate.

Q. Right. So Vensana writes to you, "Given today's EW news, I wanted to reach out to see if you may be in the market for financing again."

Did I read that right?

A. Yes.

Q. The news he's referring to here being the JenaValve acquisition?
A. I would assume that's the case. I don't -- I can't speak for him.
Q. So on July 24, the day Edwards announced the JenaValve acquisition, Vensana Capital reached out to you to ask if you were in the market for financing again; right?
A. That's what this email says, yes.
Q. Let's look at your response. You told them that they were too late because Edwards acquired both J-Valve and Jena, both platforms; right?
A. Yes.
Q. We can set this document aside.

I have one more topic for you, Dr. Turco. It's about the negotiations between JC Medical and Edwards. You were involved in negotiating the sale of JC Medical to Edwards; right?
A. I was one of several people involved in that.
Q. And you wanted to negotiate the highest acquisition price possible for JC Medical; is that true?
A. As a person responsible for fiduciary responsibility for the company, yes, that's the process.
Q. Let's turn to P-X-1039. This is an email from yourself to Sean Zhang and Warren Wang with the subject line "Alps" dated April 22nd, 2024. Alps in the subject line refers to

the code name for the sale of JC Medical; right?
A. Yes.
Q. You mentioned that Warren Wang is the CEO of JC Medical -- or Genesis?
A. Warren Wang is the CEO of Genesis MedTech.
Q. And Sean Zhang ws the head of business development for Genesis?
A. Yes.
Q. You write to Mr. Wang and Mr. Zhang, "I spent some time today speaking to many folks in a very generic sense to get a better idea of the HRS component."
Did I read that right?
A. Yes, and obviously, that's a typo. It should be HSR.
Q. Right. And HSR is short for Hart Scott Rodino; is that correct?
A. Correct.
Q. Under the HSR Act, acquisitions above a certain dollar value threshold must be reported to the FTC and Department of Justice; correct?
A. Yes.
Q. You continued in this exhibit, "From what I sent you from analyst report, it does seem like the HRS concern is real and not something for EW to hide behind as a negotiating ploy."
EW refers to Edwards; correct?

A. Yes.
Q. You continue, "We will speak soon prior to the Don call, but my suggestion, as we all agreed, was to listen to Don and understand a bit more his thinking."
Don is Don Bobo, corporate vice president of Edwards; right?
A. Yes.
Q. You continue, "If the HSR component is a no-go for the deal structure, my suggestion is the following" -- and what follows is a deal structure you suggested to Genesis leadership; right?
A. Yes.
Q. Let's look at that proposed structure. You write, "No. 1, the 115M up front"; right?
A. Yes.
Q. And then skipping to No. 4, "The gap of 10M to 35M (125 to 150) be made up by an investment into Genesis similar to others you have that would be outside of this deal and not impacting HSR, but helpful to Genesis from a strategic and monetary standpoint."
So you proposed that Edwards would pay $115 million up front in this deal?
A. That's what their term sheet had suggested. So that is what Edwards had proposed, yes.
Q. Okay. And 115 million was below the HSR filing

threshold of 119 million; correct?
A. That is correct.
Q. And looking at item 4, you propose that Edwards close the valuation gap by making an investment into Genesis; right?
A. That's correct, but the thinking here was, again -- and I've stressed this in prior depositions -- that the company itself was in a financial situation that we needed to do a sign and close. Otherwise, we were in a situation where we were going to need to furlough employees and probably really reduce the valuation of JC Medical and the company. And so we did want to keep it under the threshold of HSR so that we can do a formal sign and close and see if we can find a creative way to do a second deal where investment was coming from Edwards into Genesis. So these were never attached. The 115 million up front and the subsequent line that you have here highlighted in No. 4, the gap of 10 to 35 million, it was never meant to basically skirt around HSR requirements or filing. They were two separate -- two separate deal structures here that were set forth to try to get us to a number that was going to work for the Genesis board as well as Edwards and allow us to sign and close so that we can keep the company moving.
Q. So this investment in Genesis, that would increase the monetary value that Genesis would get from the sale of

JC Medical; correct?
A. My wording of that would be that investment would be coming from Edwards into Genesis. It has nothing to do with increasing the monetary value of this deal. Genesis would, basically, be achieving a strategic investor, like an Edwards Lifesciences, into a company like Genesis MedTech, which would be a big positive for Genesis MedTech that had future acquisitions. But it was never a matter of looking at the 115 and then adding on whatever that other additional dollar amount to describe it as one complete monetary value. It was two separate concepts here to allow Genesis to also be able to work with Edwards in other particular matters.
Q. The JC Medical sale did, in fact, close for $115 million; right?
A. Yes.
Q. Edwards did, in fact, make an investment into Genesis of $25 million; right?
A. Yes.
Q. JC Medical did not make an HSR filing with the FTC; correct?
A. To my knowledge, no, they did not.
Q. And the transaction was intentionally structured to avoid reporting it under the HSR laws; right?
A. No.
Q. Let's turn to P-X-1479. This is a text message from

yourself to Don Bobo of Edwards dated April 26th, 2024. We'll explore the substance of the message in a second, but before we do that, the message makes reference to several people by their first names, Nick, Jeff, Sean, and Warren. Just so we're all clear, those are all executives at Edwards and Genesis; correct?

A. Yes.

Q. Dr. Turco, could you please read the text message on the right side of the page aloud.

A. "Hi, and good morning again. Wanted to reach out once again and see if we might find 15 minutes today to review and align on some final business items, allowing the teams to, then, get at it. We are very close. Productive call yesterday with Nick, Jeff, and antitrust folks on both sides. Post-call, I spent time with Sean and Warren. And we are all aligned in avoiding HSR. Would like to present to you thoughts as to where we landed. Please let me know what might be best. Thank you. Mark."

MR. TYMKOVICH: Thank you, Dr. Turco. I have no further questions right now.

CROSS-EXAMINATION

BY MR. LIPTON:

Q. Good afternoon, Dr. Turco.

A. Good afternoon.

Q. I'd like to start. Briefly, you gave some of your

background -- I'd like to start briefly with a little bit more of your background. You were trained as a physician; is that correct?

A. Yes.

Q. And when you were practicing as a physician, what was your specialty?

A. Interventional cardiology.

Q. And how long did you practice as an interventional cardiologist?

A. Around 14 to 15 years.

Q. And you were eventually recruited to be the chief medical officer for a company called Covidien; is that correct?

A. Yes.

Q. Covidien was subsequently acquired by another company; is that correct?

A. Yes.

Q. And what company acquired Covidien?

A. Medtronic.

Q. And approximately when was that?

A. That was, I believe, in 2017.

Q. And did you work at Medtronic for some period of time?

A. Yes, I did.

Q. And what was your role at Medtronic?

A. I was the chief medical officer over their cardiac,

vascular, and neuro product lines.
Q. Okay. And how long did you work at Medtronic?
A. About two years. A little over two years.
Q. And after a few other roles, you became CEO of JC Medical; is that correct?
A. Yes.
Q. During what period of time were you the CEO at JC Medical?
A. In May 2023 until Edwards's acquisition in July of 2024.
Q. Okay. And after the acquisition by Edwards, did you become an Edwards employee?
A. I did not. I was a contractor for Edwards for a period of six months to help with technology transfer of the JC Medical into Edwards, as well as an integration of my JC Medical team into the team at Edwards.
Q. Okay. And what role did you take after you left that consulting role with Edwards?
A. I then became president and CEO of the Rhode Island Life Science Hub, which is a quasi-public organization, driving life science development in the state of Rhode Island.
Q. And who do you report to in that position?
A. The Governor of Rhode Island, Governor McKee.
Q. And let's go back to your time at JC Medical. And let me -- I want to make sure we get terms and corporate entities right. Was there a JC Medical U.S. entity and a

JC Medical China entity during the time where you were at JC Medical?

A. There is a -- certainly, a JC Medical China entity that was totally separate and not a structure that I was involved in. And then there was JC Medical outside of China that I was involved in. So it wasn't just the United States. It was North America, as well as possibilities of looking for opportunity in other Asian countries or Europe itself.

Q. Okay. And which JC Medical entity was sold to Edwards?

A. Edwards acquired JC Medical rights and technology outside of China. So the rest of the world outside of Mainland China and some of the small neighboring and -- Hong Kong is included in that and Taiwan.

Q. Okay. And is there still today a JC Medical entity operating in China that's separate from Edwards?

A. Yes.

Q. Okay. Is that -- to your knowledge, is that still owned by Genesis MedTech?

A. That is correct.

Q. Okay. Who is Genesis MedTech?

A. Genesis MedTech is a Singapore-based company that has a number of different technologies, but -- in the structural heart space, as well in the minimally invasive surgical field, and currently has sales in Mainland China as well as Japan.

Q. And at the time when you started at JC Medical -- and I'll -- when I'm referring to your -- the JC Medical that you were affiliated with, will you understand I'm talking about the JC Medical outside of China?

A. Okay.

Q. When you started at JC Medical, how many employees did JC Medical have at that time?

A. I think it was roughly six or eight employees.

Q. Okay. Was JC Medical working on a TAVR-AR treatment at the time?

A. Yes.

Q. And what was the name of JC Medical's TAVR-AR treatment?

A. The J-Valve.

Q. Okay. And can you describe for us the attributes of the J-Valve?

A. The J-Valve is a very low-profile transcatheter heart valve that has a unique anchoring mechanism for treatment of patients with aortic regurgitation. It is a self-expanding system, and its low profile as well as larger sizes, to be able to treat larger aortic annular dimensions, were some of the key attributes that we felt were important and physicians that were working with us felt were very important.

Q. And when you started working at the company in May of 2023, did JC Medical have approval to conduct clinical

trials in the United States?
A. They did not.
Q. Okay. At that time, had JC Medical -- either the global entity or the China entity -- been doing clinical studies in patients outside the United States?
A. Yes, in China.
Q. Okay. And at the time when you started at the company, what was the status of JC Medical's clinical trials in China with the J-Valve?
A. They were beginning to enroll in their transfemoral trial. And they had a commercial product in a transapical J-Valve at the time that I started.
Q. And did -- did the J-Valve start as a transapical or a transfemoral product?
A. It started as a transapical product.
Q. And then JC Medical converted the transapical to a transfemoral device?
A. Well, I wouldn't say convert, but there was a lot of research and development that went into, then, developing out a transfemoral system for the delivery of the J-Valve.
Q. Okay. And switching from transapical to transfemoral, is that primarily changing the delivery system or is it primarily changes in the valve?
A. There are some subtle changes in the valve and differences, very subtle, between the transapical J-Valve

and the transfemoral J-Valve. It is mainly in the delivery system. And, obviously, market trends outside of certain geographies dictate that one needs to have a transfemoral system to be commercially viable.

Q. Okay. And today, does JC Medical China have approval to sell the J-Valve commercially in China?

A. They received China FDA approval a month or so ago and they are working on their commercial launch as we speak.

Q. Is that the transfemoral or transapical?

A. For the transfemoral.

Q. Transfemoral is commercially approved in China?

A. As of a month or two ago. Correct.

Q. Okay. Let's go back to JC Medical, the U.S. entity -- or the global entity when you started at the company in May of 2023. What can you tell us about JC Medical's clinical and regulatory strategy in the United States when you started at the company?

A. Unfortunately, and one of the reasons that Mr. Wang had asked me to come in, was because they were pretty dead in the water with their clinical and regulatory strategies. And the company was relatively dormant at that time, in May of 2023. There was an outstanding deficiency letter from the FDA with multiple deficiencies that were never really being answered by the prior leadership team at JC Medical. So -- and there was no chance of FDA regulatory approvals

for either a feasibility study or beyond until that deficiency letter was answered.

Q. And do you know approximately when JC Medical received that deficiency letter?

A. It was prior to COVID. I believe in the 2019 time frame or so.

Q. So from roughly 2019 to when you started at 2023, there was an outstanding deficiency letter and, I believe, you said, no one was doing anything to respond to it; is that correct?

A. Yes. The company's approach at that time, which was not something that the FDA took kindly on, was to basically just try to do compassionate use cases in the United States, and there were a few cases done in Canada, and then use that compassionate use data to bypass an early feasibility trial and go directly to a pivotal trial. That clinical strategy was not going to work with the FDA, and when I started, I had received calls from FDA leadership that we needed to close down the compassionate use pathway and move toward a more normal submission process and, certainly, get at answering the deficiencies that were existing from the FDA.

Q. And so what did you do?

A. So we moved forward and attacked each of the deficiencies through our engineering and process -- engineering and R&D teams. And we, then, were able to

ultimately respond back to the FDA. We received breakthrough device designation once we submitted and corrected our deficiencies as well as, then, an IDE approval for a feasibility study to be done in North America.

Q. And do you recall approximately when you received that approval to conduct the feasibility study in the U.S.?

A. I believe it was late summertime. Probably in July of 2023 or so. Somewhere in that time frame.

Q. So it took you roughly two months to answer all the questions and get approval for the --

A. Two to three months.

Q. Okay. And then did you conduct the feasibility study?

A. We did.

Q. And do you recall approximately when you completed the feasibility study?

A. It was sometime in that late Q3 or early Q4 time frame. Off the top of my head, it may have been October of 2023. We enrolled 15 patients very, very quickly due to the pent-up demand and the need for patients to have a dedicated device for treatment of this pathophysiology. So yeah, I believe it was October of '23 that we completed the EFS.

Q. Okay. We're all still within the first -- within the first year that you were at the company; correct?

A. Yes.

Q. And did you receive approval from the -- did you receive

authorization from the FDA to begin a pivotal trial in the United States for J-Valve?

A. Yes, but that was -- once we compiled our data and our 30-day endpoint, we needed to respond to the FDA. And we submitted our formal IDE -- I believe it was early in 20 -- or it may have been late in 2023, and then ultimately received -- we received our PMA -- our IDE approval for our pivotal trial in, I believe it was, March of 20 -- March/April time frame of '24.

Q. So a little less than a year to go from dormant, an IDE letter that no one was responding, to completing a feasibility study, to getting FDA authorization to conduct a pivotal trial? Is that about, you know, roughly the timeline?

A. Yes.

Q. And you testified earlier, in response to FTC counsel's questioning, that there was a time when you worked on the sale -- the sale -- of JC Medical U.S.; is that correct?

A. Yes.

Q. And when did that process begin?

A. That process began pretty short -- shortly after speaking with Mr. Wang in Shanghai, China -- so I believe that was sometime mid-January time frame, maybe January 15 -- when I was informed that the board had made a decision not to continue to fund JC Medical outside of

China, as Genesis wanted to continue their work within China and really concentrate. And Mr. Wang was told by his board that he needed to be profitable as he moved into the next fiscal year. So as soon as Mr. Wang mentioned that to me, I got busy trying to either fundraise or look for a partner to acquire the company.

Q. And just so we're clear, did Genesis tell you either way whether they would fund the pivotal trial or not?

A. Genesis said that they would not fund the clinical trial.

Q. Okay. So let's turn, if we could, to D-X-123, please, Dr. Turco. And you could either look on the screen or you have a binder, either way. And let's look at -- this is an email exchange between you and individuals -- I'll do my best with pronunciation -- Xiaobo Zhu [ph], Sean Zhang, and Warren Wang; is that correct?

A. Yes, among others.

Q. Oh, yes. Thank you.

And who were those individuals?

A. Xiaobo Zhu [ph] was the chief financial officer for Genesis MedTech. Sean Zhang was the head of business development and strategy for Genesis MedTech. Warren Wang was the president and CEO of Genesis MedTech. And then there are also some -- Gabrielle Yap is the head of human resources.

Q. Thank you.

And if we go down to -- in this email in bullets 3 and 4, there's a reference to Project Alps. What was Project Alps?

A. That was our internal code name for looking to find either a sale or a way to help fund our existing gap that we needed to move forward with our United States pivotal trial.

Q. And in the first bullet in that email, you reference a $6.8 million budget. Was that your budget for JC Medical U.S. for 2024?

A. Yes.

Q. And then in the second bullet, you say, "The $6.8 million budget was agreed with a close-down of the company, JCM U.S., by May 31, 2024, with communication to employees (notice period) of one month, with communication to occur by April 30, 2024."

Did you write that, Dr. Turco?

A. Yes.

Q. Were you instructed by Genesis MedTech to shut down JC Medical's U.S. operations if you were not able to complete a sale of the company?

A. Unfortunately, yes.

Q. Let's go to the second page of the document, please. There's an email from you at the bottom of the page to the same individuals. And in there -- and this is dated

June 18th, 2024. And you write, "$6.8 million operating budget at burn rates gets us to end of August."

So does that indicate you were able to stretch your budget through August?

A. Yes. The strategy here was to try to stretch the budget so that we could find an investor or an acquirer before, again, we would need to furlough employees. And, obviously, we were very careful with these numbers because we wanted to be sure that we had cash on hand to cover all of our legal liabilities.

Q. And lower down in that email, you write "If deal does not close and we move to a full shutdown, then there will be -- additional liabilities will need to be covered beyond employee cash needs."

Do you see that?

A. Yes.

Q. And when you say, "If deal does not close," which deal were you referring to?

A. The deal between JC Medical and Edwards Lifesciences.

Q. And if the sale to Edwards had not closed when it did, what would you have done with JC Medical U.S.?

A. We would have closed the company down.

Q. And how quickly would you have had to lay off employees?

A. Immediately.

Q. You testified earlier, Dr. Turco, about your efforts to

sell JC Medical to strategic buyers. Do you recall that?
A. Yes.
Q. Okay. And remind me, please, which strategic buyers you reached out to.
A. The strategic buyers were Medtronic, Abbott, Boston Scientific, and Johnson & Johnson as well as, obviously, Edwards.
Q. Let's start with your outreach to Edwards. Who did you reach out to at Edwards about potentially acquiring JC Medical?
A. I placed a call to Don Bobo.
Q. And do you recall approximately when you reached out to Mr. Bobo?
A. I believe it was either very late January or the first week in February.
Q. And what was Mr. Bobo's reaction to your outreach?
A. That he was very interested in putting what he termed a tiger team on the evaluation of JC Medical, and that I should speak with Larry Wood and move the process along.
Q. And did Edwards conduct diligence on JC Medical?
A. Very detailed diligence, correct.
Q. And do you -- just -- I don't need every detail, but at a high level, what sort of diligence do you recall?
A. Well, they did diligence, obviously, on the valve itself, but they sent a very large contingent team to

Suzhou, China, which is where the valve was -- valve and delivery system was being manufactured at the time. And -- actually, several trips to China. And then came to Burlingame on a number of occasions. And I also spoke extensively with their Israel R&D team that is very involved in the development and R&D of all of Edwards's valve technologies. And so it was a very extensive process.

Q. And did that process ultimately result in the sale of JC Medical to --

A. Yes.

Q. Other than Edwards, were any of the other strategic purchasers interested in buying JC Medical?

A. They were not.

Q. And other than Edwards, did all of the other strategics pass on the acquisition opportunity?

A. Yes.

Q. Okay. I'd like to explore one of the other strategics, but I'll need to do it in a closed session that we'll do at the end because of that company applying confidentiality. So we'll come back to that, Dr. Turco.

Other than the strategic medical device companies, did you reach out to other buyers or investors?

A. Yes, I reached out to a number of venture capitalists, as well as some private equity groups, to see whether there was interest, again, in creating a syndicate or other

avenues for investment and creative financing to allow us to keep the company going beyond the June time frame, if we were not able to close the deal with Edwards.

Q. And you mentioned earlier in your testimony about a venture capital firm named Vensana that you said was interested in a syndicate. Do you recall that?

A. Yes.

Q. Obviously, that did not come to fruition. But -- why did that not come to fruition?

A. Because then we -- the deal with Edwards closed and we were fully engaged with Edwards on the process for a full-out acquisition. What we were thinking about with Vensana was a concept of, can we do a build-to-buy type of process where we would have a strategic involved, like an Edwards, as well as then a venture capital firm, and allow the company to continue its research and development and engineering and clinical trial and regulatory work, and then ultimately, at the end of that process, at an agreed-upon milestone, the strategic would acquire that company.

Q. And was Vensana interested in -- you mentioned it was a syndicate. So was Vensana interested in funding and doing this all on its own?

A. No.

Q. And what sort of a syndicate were they looking for?

A. They were looking for a strategic investor to come along

and possibly put a specific term sheet at the back end so that, if certain milestones were met, then there was a guaranteed exit for that -- JC Medical. And the venture capital firm, then, would have an exit as -- and it would be a process that is pretty common in today's world of med-tech.

Q. Were you able to get another strategic interested in being a part of that syndicate?

A. I was not.

Q. Okay. And did that cause the syndicate idea to fall apart?

A. Yes.

Q. And, I believe, you mentioned -- did you try to get Genesis MedTech to invest more in JC Medical U.S.?

A. I tried very hard to do such.

Q. And what was their response?

A. No.

Q. So if not for the sale to Edwards, what would you have done with JC Medical?

A. We would have had to close the company down.

Q. Okay.

MR. LIPTON: I'd like to pull up, please, if we could, P-X-1049.

BY MR. LIPTON:

Q. And this is a document that FTC counsel showed to you,

Dr. Turco. And this is a document -- it looks like it was created -- the cover email is January 25th, 2024. Do you see that?

A. Yes.

Q. Was your process to try to sell the company already underway at that time?

A. Yes.

Q. So why did you create the projections that are contained in this document?

A. Because one of the biggest issues with us in this new space of valvular treatments for a totally new field was to, really, assess the market size, and what we kept hearing and I kept hearing from strategics was it was unclear how big the market was for the treatment of patients with aortic regurgitation. So it was important for us to try to develop out a market size that would, then, allow us to have a reasonable valuation for the company as well, as we moved through the M&A process.

Q. Did these projections have any ordinary course business purpose or was it purely to provide to potential buyers of JC Medical?

A. Yeah, so it was purely to provide to those who were interested in trying to understand the market size. And, really, it gets to the revenue projections in these models that are critically important, as most large strategics are

not going to take the time and energy to engage in an M&A process, if the ultimate revenue projections are not at a level that would allow such a process to be worth its time.

Q. Okay. And you may have already answered this, and I apologize if you have, but are there certain aspects of these projections that you were expecting buyers to be focused on?

A. I think revenue -- ultimately, revenue was one, and then, to some extent, market share, you know, was another and, you know -- they're the main ones.

Q. Okay. And what about the market size projections?

A. And the market size. It was probably one of the most, if not most, important numbers outside of revenue.

Q. Okay. And counsel asked you to look at -- counsel asked you questions before about Page 10 of this document which showed the market share charts.

MR. LIPTON: Thank you for pulling that up, Mr. McCloud.

BY MR. LIPTON:

Q. And do you see these projections here?

A. Yes.

Q. And these projections show market share projections out to 2035; is that correct?

A. Yes.

Q. At the time you created this document, you'd already

been told by Genesis that you would have to sell the company or wind up operations, is that correct?

A. Yes.

Q. Okay. When you made these projections, were you making an affirmative prediction that there would only be two TAVR-AR competitors, JC Medical and JenaValve, all the way up to 2035?

A. Absolutely not.

Q. Okay. Did you do any research or analysis to support these market share projections?

A. We did. We did market share analysis, and we had a lot of individuals look at this, as well as some independent eyes, to try to validate our market size.

Q. And, maybe, I mixed up -- maybe we were talking past each other. That analysis and research that you did, was that on the market size analysis or was that on the market share analysis?

A. The market size, so to speak. The market share is less important of an indicator because there are so many variables that can go into market share and, as you suggested, there may be other players, and certainly were other players, that one would take into account. So it's the market size that is -- and the revenue projections that really are key. It's looking at that total addressable market and then, ultimately, the market that we can obtain

in that larger pool of what the total addressable market is.
Q. Did you expect any buyer to rely on these market share projections in their analysis of JC Medical?
A. No. Quite honestly, we put these together -- and I've been in this for a long time. Each strategic company is going to do their own market model themselves. They're not really going to depend on the market model that we put together. They're going to put together their own market models. But this is a model that helps set the stage for conversation as we move forward in the M&A process.
Q. Okay. Thank you. We can set that aside.
One more question about that. If you were told that someone was relying on these market share projections to say that JC Medical believed there would be no entry by anyone else into TAVR-AR in the United States by any other supplier until 2035, if you were told that, how would you respond to that?
A. That's a very naive way to think about what this is supposed to project.
Q. Okay. Thank you. We can set that aside.
I'd like to talk about -- you said earlier that you worked as a consultant with Edwards for about six months after the transaction; is that correct?
A. Yes.
Q. Okay. I'd like to talk about what you observed at

Edwards after the sale of JC Medical to Edwards. We talked -- I guess, let me just ask an, you know, open-ended question. What did you observe at Edwards after they took over the JC Medical business?

A. There was incredible energy on the part of Edwards with the acquisition of JC Medical. And, you know, I spent an awful lot of time in Irvine, California, the headquarters of Edwards, and working with the teams and the integration teams in transitioning what we had, as JC Medical, into the larger Edwards. And the thing that was really outstanding, from my mind, was that we would never have been able to do some of the things that ultimately were done pretty early into the course of acquisition because of resources within a small company.

And so the example that I would give you is that when the R&D folks began to look at the valve and the delivery system, they were already thinking very early into what a generation 1.5, what a generation 2.0 to that system would look like. And for me, as a CEO of a small startup company, it would have been impossible for us to resource those programs, yet we had very similar mindsets as to where we needed to go with the next generation technologies. So from an R&D standpoint, from an operations and manufacturing standpoint, from a clinical and regulatory standpoint, Edwards, as far as I'm concerned, put the A-team on the work

that needed to be done, and resourced it exceedingly well, especially given -- with many of the other competing priorities that Edwards had on their plate.

Q. And you mentioned earlier that you had authorization at JC Medical to conduct a pivotal trial for J-Valve. Did Edwards move forward with that pivotal trial?

A. They did.

Q. And was that the JOURNEY trial?

A. The JOURNEY trial.

Q. And do you recall when Edwards enrolled the first patients in the JOURNEY trial?

A. It was -- I don't remember the exact date, but somewhere in the summertime of '24.

Q. Okay. Thank you.

I'd like to now -- apologize for jumping around in time. I'd like to go back to your time at JC Medical and talk a little bit about -- well, let me ask it this way. Was it part of your job responsibility at JC Medical to be aware of other companies that were working on TAVR-AR treatments?

A. As part of -- as CEO of a structural heart company, I need to be aware of everybody that's working in the space, and so, obviously, I keep a close tab on that and, you know, there's information, obviously, that is not available in public, but it -- we do try to obtain as much information

about competitors and others working in the space as possible.

Q. Okay.

MR. LIPTON: I'd like to look, if we could, at D-X-0068. Can we pull that up, please, Mr. McCloud?

BY MR. LIPTON:

Q. And this is an email exchange from January 2004 [sic] between you and Warren Wang of Genesis MedTech. Let's look at Page 2 of the document, if we could, please. And to the bottom email in the chain. On January 4, 2024, you wrote an email, Dr. Turco, that says, "FYI." Do you see that?

A. Yes.

Q. And to that email, you attached the article that's on the next page of the document.

MR. LIPTON: If we could see that, please, Mr. McCloud.

BY MR. LIPTON:

Q. And that -- the article you attached is titled, "Laguna Tech USA announces site record number of transcatheter heart valves implanted at single center on same day in first-in-human clinical trial."

Do you see that?

A. Yes.

Q. Why did you forward that article to Mr. Wang?

A. Again, it was important for Mr. Wang to know the state

of the players in the field of aortic regurgitation, and Laguna was, at that time, an aggressively -- an aggressive startup company that was developing technology for treatment of patients with aortic regurgitation.

And as far as our strategy, we were comfortable, to some extent, to be that fast follower to JenaValve, realizing that JenaValve had completed their pivotal trial and was approaching the FDA for their PMA approval which, today, is still not present, but, you know, once we get beyond being that initial fast follower, we don't want to be that third, fourth, fifth to market. So it's important to know all of the other technologies in this space.

Q. Thank you.

And let's go back to the email. So the -- Mr. Wang responded to you. Mr. Wang responded "I noticed this news a few days ago. We need to accelerate our EFS enrollment."

Do you see that?

A. Yes.

Q. And what did he mean by "accelerate our EFS enrollment"?

A. That -- he was directing me to try to move as quick as possible to complete our early feasibility trial, again, so that we do not fall behind, and we were going at a record pace and moving as fast as we could, but he was being a good CEO and pushing me, as the CEO of one of his portfolio

companies, to try to accelerate the work that we're doing.

Q. And you responded to Mr. Wang and then he responded back to you on the --

MR. LIPTON: Let's go to the first page of the email and see Mr. Wang's response there in the middle of the page, please.

BY MR. LIPTON:

Q. And Mr. Wang said to you "If we can finish the enrollment by January 15th for EFS, that will put us ahead of the game compared to many other startups. I heard many Chinese structure heart companies want to come to the U.S., K-clip, Jenscare for tricuspid, et cetera. Let's continue to stay ahead of them."

Do you see that?

A. Yes.

Q. And what did you understand Mr. Wang to mean there?

A. Again, I think he's trying to be sure that we try to stay ahead of the competition in the space for dedicated valves for the treatment of aortic regurgitation and pushing me to keep my eye on the ball here to complete our early feasibility.

Q. Okay. Thank you. We can set that aside.

And I want to now go forward in time to more recently. Did you attend the recent TCT conference in San Francisco?

A. I did.
Q. And what is TCT?
A. TCT is one of the largest medical device meetings that occurs, and it is a meeting put on by the Cardiovascular Research Foundation based out of New York City and associated with Columbia University, and the meeting this year was in San Francisco.
Q. And when did that take place, roughly?
A. I'm losing track of time. About a month ago.
Q. Okay. And were you on a panel at that meeting about innovations in the TAVR-AR space?
A. I was.
Q. Did companies developing TAVR-AR devices present their clinical results during that panel that you were on?
A. They did.
Q. And which companies presented clinical results during that panel?
A. I believe it was Jenscare and the -- and a China company that has a valve called the Hancock valve.
Q. And did JC Medical also present --
A. And JC Medical presented, as well.
Q. And what can you tell us about the presentation that you saw from Jenscare?
A. That they are aggressively moving forward with their timeline and they currently have a transapical version of

their technology, and it was clearly stated that they are moving forward with a transfemoral product, which is what they would need for the United States market. And -- so between them and between Hancock and between a company called Cuspa, there are a number of other companies out there in the valve space that are looking at avenues to treat aortic regurgitation.

Q. So to make sure I understand this clearly, Jenscare stated during their presentation that they're working on a transfemoral implantation method for their AR device?

A. Yes.

Q. And what does that indicate to you about Jenscare's plans in relation to the United States?

A. That they realize they can't enter the United States market with a transapical product, and so they're going to accelerate the development of the transfemoral technology to try to obtain U.S. regulatory approval.

Q. And if Jenscare were acquired by or partnered with a company that already has transfemoral delivery technology, would that accelerate Jenscare's move to the United States?

A. I can't say for sure, but, certainly, the resources, as I've mentioned before, of a large strategic company and the expertise of research and development teams and engineering teams at the large strategic companies would certainly accelerate the development over what a startup company can

do.

MR. LIPTON: Thank you, Dr. Turco. My remaining questions are in a brief closed session, if that's all right, Your Honor.

THE COURT: How long do you think that closed session will go?

MR. LIPTON: I would hope five minutes or less.

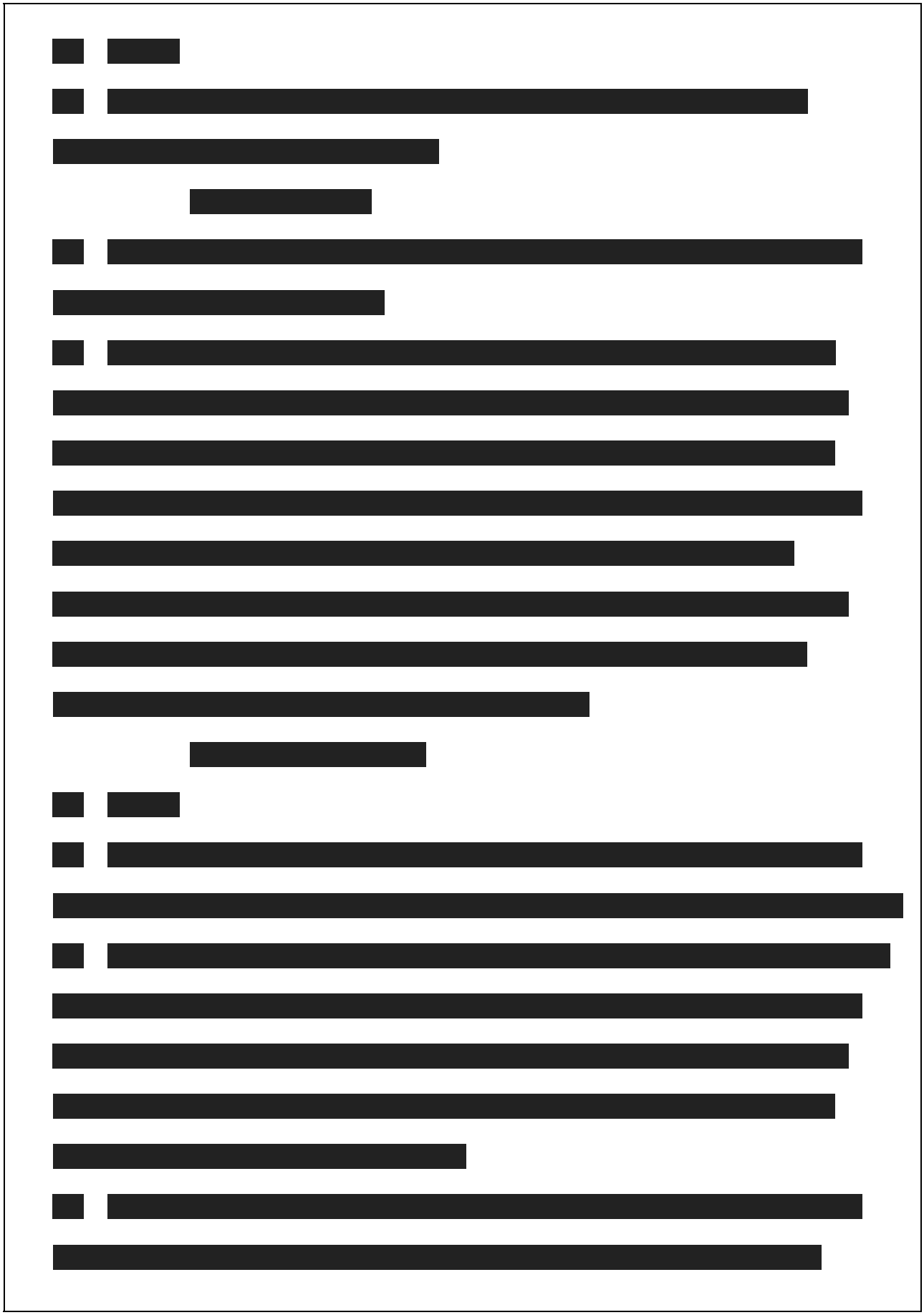
THE COURT: Okay. Let's close the courtroom.

MR. LIPTON: Thank you, Your Honor.

MR. SHORES: Could everybody except counsel for the parties please exit.

(Following proceedings under seal:)

[redacted]



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CERTIFICATE OF OFFICIAL COURT REPORTER

I, TIMOTHY R. MILLER, RPR, CRR, NJ-CCR, do hereby certify that the above and foregoing constitutes a true and accurate transcript of my stenographic notes and is a full, true and complete transcript of the proceedings to the best of my ability, dated this 21st day of November 2025.

/s/Timothy R. Miller, RPR, CRR, NJ-CCR
Official Court Reporter
United States Courthouse
Room 6722

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Washington, DC 20001

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