IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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FEDERAL TRADE COMMISSION, **CV No. 1:25-cv-02569-RC**

Plaintiff,

v. **Washington, D.C.**
Wednesday, November 19, 2025
EDWARDS LIFESCIENCES CORPORATION **10:00 a.m.**
and JENAVALVE TECHNOLOGY, INC.,

Defendants.
- x

TRANSCRIPT OF EVIDENTIARY HEARING - DAY 2
***** MORNING SESSION *****
HELD BEFORE THE HONORABLE RUDOLPH CONTRERAS
UNITED STATES DISTRICT JUDGE

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Proceedings recorded by machine shorthand; transcript produced by computer-aided transcription.

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(Following proceedings under seal:)

[redacted]



























[redacted]

(Following proceedings in open court:)

BY MR. SHAW:

Q. Mr. Wood, you have an ongoing relationship with Edwards; right?

A. I have a consulting agreement primarily related to this litigation.

Q. And so you're being compensated for your time testifying; right?

A. I think we all are, yes.

Q. And, Mr. Wood, you're represented by Mr. Shores who's also counsel to Edwards?

A. Counsel for Edwards, and I'm here as a witness.

Q. All right.

MR. SHORES: I can represent I represent the witness, Your Honor.

MR. SHAW: Thank you.

BY MR. SHAW:

Q. And, Mr. Wood, you were deeply involved in Edwards's decision to buy both JenaValve and JC Medical; is that fair?

A. That's fair.

Q. I'd like to discuss your experience with transcatheter

aortic valve replacement. Is TAVR a common shorthand?
A. It is.
Q. And TAVR that treats aortic stenosis is called TAVR-AS; right?
A. That's correct.
Q. And TAVR to treat aortic regurgitation is called TAVR-AR; right?
A. That's correct.
Q. And you view, at least directionally, TAVR-AS as an analog to the potential for TAVR-AR; right?
A. They're different diseases, and I think the total size of the opportunity could be different, but there's a lot of similarities between the two spaces.
Q. Edwards was the first commercialized TAVR-AS in the United States; right?
A. In the United States, yes.
Q. And Edwards is currently the market leader in the United States for TAVR-AS; right?
A. That's correct.
Q. And we just discussed in closed court your estimated market share for Edwards in --
A. That's correct.
Q. And Medtronic is the next largest player?
A. That's correct.
Q. Followed by Abbott?

A. In the U.S., yes, that's correct.
Q. And Edwards is competing with Medtronic and Abbott for TAVR-AS opportunities, right?
A. That's correct.
Q. I want to look at how other competitors in the TAVR-AR space put competitive pressure on Edwards. Let's look at P-X-1271. Mr. Wood, do you have a binder up there?
A. I do.
Q. You actually won't need to turn to the binder for this one. It should appear on your screen. There are some confidential portions. We'll only put the redacted versions on the screen. But I don't think you'll need to reference it.

Let's look at the page ending --

THE DEPUTY CLERK: Counsel, this should be shown to the public, as well?

MR. SHAW: Yes. This can be shown to the public. Yes, ma'am.

BY MR. SHAW:
Q. Let's look at the page ending 003. And you should be able to see it on your screen, Mr. Wood. Mr. Wood, is it available on your screen?
A. Yes.
Q. And this is the 2025 strategic framing regarding TAVR that you've presented; right?

A. That's correct.
Q. And let's look at the page ending 013.
MR. SHAW: And, Mr. Nguyen, thank you.
BY MR. SHAW:
Q. And this slide bears the following title: While Medtronic competes with a similar playbook, other competitors may be disruptive to our premium product strategy. Did I read that right?
A. I believe so, yes.
Q. And one way Medtronic competes with a similar playbook is that Medtronic also has a high-touch service model; right?
A. Much more than that, but that's one of the things that they do.
Q. Great. And let's just take a step back. You're tracking these companies because they're Edwards's competitors in the TAVR-AS space; right?
A. Yes.
Q. And to do your job, you have to pay close attention to what Edwards's competitors are doing, right?
A. I think you pay attention to anyone who you think could be a competitor in your space.
Q. And so starting from the left, moving right, the first competitor listed is Medtronic; right?
A. That's correct.

Q. And Medtronic is a major medical device company; right?
A. I think one of the biggest, if not the biggest.
Q. Maybe the largest medical device company?
A. They're very large. Much larger than Edwards.
Q. And Abbott is another very large company with a significant medical device business; right?
A. That's correct.
Q. And the same for Boston Scientific; right?
A. That's correct.
Q. In fact, all three of these companies are larger than Edwards in absolute terms; right?
A. That's correct.
Q. Now, back to TAVR-AS. This shows that Medtronic is your primary competitor in the United States; right?
A. That's correct.
Q. And you write under the heading Medtronic, "Aggressive marketing tactics aimed at market share capture."

Did I read that right?

A. You did.
Q. And the bullet under that is, "Head-to-head trials, e.g. SMART"; correct?
A. Correct.
Q. Let's do a deeper dive on the head-to-head trial point. And if you could please look on the screen at P-X-1271 which Mr. Nguyen will put up there.

MR. SHAW: Mr. Nguyen, if we could go to P-X-1273.

BY MR. SHAW:

Q. And do you remember seeing this document in your deposition, Mr. Wood?

A. Quite possibly. We reviewed a lot of documents. So I can't remember every one, but probably.

Q. Okay. And this is a presentation you gave in 2025; right?

A. Yes.

Q. And let's look at the page ending 006. And this slide shows a timeline of Edwards's low-risk clinical trial presentations and publications; right?

A. This is just comparing Edwards to Medtronic.

Q. Right. A specific set of Edwards's presentations and publications.

A. It's comparing the low-risk trial timelines for the two companies.

Q. Right. And so that's the top half of the slide, right, is the Edwards?

A. Correct. Those are the times that we presented the different data follow-up points.

Q. And then Medtronic is the lower half of the slide; right?

A. That's correct.

Q. And so just so we understand, in March 2019, Edwards

published one-year data from a TAVR clinical trial; right?
A. That's correct.
Q. And almost simultaneously Medtronic published, as well?
A. That's correct.
Q. And then, about a year later, Edwards published its two-year data; right?
A. That's correct.
Q. And then a year after that, Medtronic published its two years' data?
A. Right.
Q. And so this is -- this slide is one example of Medtronic's aggressive marketing tactics aimed at capturing market share; right?
A. Yes. They were delaying the publication of their data by a year compared to ours, yet were going on a marketing campaign talking about data transparency.
Q. Let's turn back to -- a couple pages to the page ending 004. And these are the key takeaways from the low-risk TAVR trials; right?
A. These are key takeaways, yes.
Q. And for referring cardiologists, the key takeaway is that both EW and MDT TAVR FDA trials reinforce the safety and efficacy of TAVR; right?
A. That's correct.
Q. EW means Edwards?

A. It does.
Q. MDT means Medtronic?
A. It does.
Q. All right. Thank you. You can set that document aside.
Let's look at P-X-1270. And Mr. Nguyen will put a redacted version on the screen. In your binder there's an unredacted version, and you may want to reference it for some questions. So that's P-X-1270. Let me know when you're there.
And so, Mr. Wood, P-X-1270 starts with an email from Mr. Bobo to you and several other senior Edwards executives in May of 2025; right?
A. Yes.
Q. And Mr. Bobo was the head of corporate strategy?
A. Yes.
Q. And the subject line is, TAVR strategy session; right?
A. Yes.
Q. And Edwards is constantly reevaluating its strategy and its priorities; right?
A. We meet -- we met routinely on strategy and plans, yes.
Q. And then stepping back, you send Mr. Bobo's email to Ms. Sharma with a cover note; right?
A. Yes.
Q. But then in that same email to Ms. Sharma, you also responded to specific points in Mr. Bobo's email; is that

right?

A. That's correct.

Q. Let's look at the body of the email from Mr. Bobo. And I want to focus on the first bullet point on the second page ending 002. So the first bullet point on the second page. And this starts, "Business gets worse."

Do you see that?

A. Yep.

Q. And so, because it's a little hard to tell with the gray scale, Mr. Bobo writes, "Business gets worse over the strat plan horizon: Share, price, innovation, impact, competition. Is that the only scenario?"

That's Mr. Bobo's question; right?

A. Correct.

Q. And then let's look at closely at your response which starts, "This is the broken record."

Are you with me?

A. Yes.

Q. You write, "This is the broken record part. Are there things we could do? Yes. We sell" -- and then there's a redacted Edwards program -- "at a significant premium globally, and it's about a" -- redacted -- "dollar figure."

Are you with me?

A. Yes.

Q. And you continue, "There are a number of improvements we

could make to that platform to take share and drive adoption. We spend next to zero marketing dollars on this program. So what did we do last year? We cut all of the" -- redacted -- "programs funding."

Did I read that right?

A. You did.

Q. So Edwards had a promising program, and then Edwards cut that program because of resource constraints; right?

A. I think it was -- it's hard to get into this without getting into the redacted part. We're not talking about AS.

Q. Understood. But this program was a promising program; right?

A. It's a program, but it's not AS. So it's an adjacency.

Q. And Edwards cut that program because of resource constraints?

A. We cut marketing funding for the program primarily. We didn't spend any marketing dollars. And we cut some of the development funding, but we didn't cut it to zero. So we didn't eliminate it.

Q. In fact, this email in this bullet point references several similarly situated programs; right?

A. We're talking about another -- a number of programs here, yes.

MR. SHAW: And then if we could zoom back out, Mr. Nguyen.

BY MR. SHAW:

Q. You conclude the section "These all require investment, and last year we cut them all and slowed down two other" -- redacted -- "Edwards programs to make room for AR"; is that right?

A. That's correct.

Q. All right. You can set that document aside, Mr. Wood.

Let's discuss the market opportunity for TAVR to treat aortic regurgitation. When it comes to this TAVR-AR opportunity, Edwards's strategy is to be the leader.

A. I would hope that that would be anybody's strategy, but yes, that was ours.

Q. And if Edwards were to close on JenaValve and if JenaValve receives FDA approval, Edwards would be the first to market and would have 100 percent of the commercialized AR treatment market; is that right?

A. Well, you're starting with a hypothetical. If it can get FDA approval, which we don't know, but if it can, it would be the first device on the market. So being the first and only device on the market, it would have a 100 percent share, because that's the nature of being the first and the only one on the market.

Q. And if the Sojourn product was the second to receive FDA approval, then Edwards would still have 100 percent share of the commercial AR treatment market; right?

A. If it received approval and if it showed up, which isn't planned for many years, then -- and no one else came to the market, then Edwards would have a 100 percent share, but that's a lot of ifs.

Q. Let's talk about JC Medical and JenaValve. And if we could look at P-X-1001.

MR. SHAW: And Mr. Nguyen will -- please put this on the screen. And you can go to the second page. This -- I'm sorry, Mr. Nguyen. P-X-1001.

BY MR. SHAW:

Q. You should have it in your binder. Here we go.

Mr. Wood, do you recognize this document?

A. I --

Q. Let's start with the first email which starts in the middle of that first page. And so this is -- the subject line is, The next frontier of aortic valve disease treatment. Do you see that?

A. I do.

Q. And it's from Jackie Faulkner on behalf of Larry Wood. That's you; right?

A. The Larry Wood part, yes.

Q. And Ms. Faulkner is your assistant?

A. She was, yes.

Q. And she was sending this email on your behalf; right?

A. She did.

Q. And this is an email to your business unit; right?
A. It is.
Q. And the date is July 24th, 2004 [sic]. Do you see that?
A. I do.
Q. And that's two days after Edwards acquired JC Medical; right?
A. That's correct.
Q. And one day after Edwards would have signed the merger valve -- sorry, the JenaValve merger agreement; right?
A. I believe that's correct.
Q. Now, this was the first time that your employees were finding out about the JC Medical acquisition; right?
A. It's the first time they were finding out about both of them.
Q. Okay. You had a -- Edwards did have a press release for the JenaValve acquisition or -- right?
A. Yeah, I don't know the -- the 23rd, the 24th, the exact timing. I couldn't recall from memory. I think -- I thought we announced them both at the same time.
Q. Did -- but Edwards didn't disclose in that press release, or any press release, that it acquired JC Medical; right?
A. We didn't, as I recall.
Q. All right. Let's -- thank you. Let's look at the email. And let's start with the first line. You write,

"Today, Edwards has entered into an agreement to acquire JenaValve, a pioneer in the transcatheter treatment of aortic regurgitation."

Did I read that right?

A. You did.

Q. And you continue, "We have also closed on the deal to acquire JC Medical to develop an expanded portfolio of transcatheter solutions for treatment of AR."

Did I read that right?

A. You did.

Q. And skipping ahead to the bolded line, could you please read that for the Court.

A. Sorry. You want to go to the bold part at the bottom?

Q. The bolded part starting "JenaValve."

A. Sorry. I'm -- okay. Yes.

Q. Would you please read that?

A. "JenaValve and JC Medical are the most advanced companies in the AR space."

Q. Thank you.

And you still agree that JenaValve has the most clinical experience in the TAVR-AR space; right?

A. That's correct.

Q. And in the United States, JC Medical is the next leading TAVR-AR company; right?

A. They would have had the next most experience in the

United States.

Q. And, in fact, to your knowledge, the only specialized TAVR-AR devices in human bodies in the United States are JenaValve and JC Medical devices; right?

A. By specialized, you mean not the off-label use of other devices that are being used for AR today?

Q. I mean a TAVR device specifically designed to treat AR.

A. That's correct. They would be the two.

Q. Let's talk about Edwards's decision to buy both JC Medical and JenaValve. You were deeply involved in that decision; right?

A. I was.

Q. And if you could look at P-X-1258 which Mr. Nguyen can put on the screen. And this is a draft PowerPoint presentation. And if you look at the page -- the second page, you'll see that you're listed as a presenter. Do you see that?

A. I do.

Q. And I'd like to look at the page ending 015. And this slide is titled, "Acquisition of both dedicated AR technologies enables Edwards to lead the therapy and deliver a strong value proposition to patients. "

Did I read that right?

A. Yes.

Q. And there are two columns; right?

A. Yes.
Q. The first is labeled, "Speed to market"?
A. Correct.
Q. And that lists JenaValve; right?
A. It does.
Q. And under value proposition, the No. 1 bullet point reads, "First dedicated AR product in U.S. market"; right?
A. Correct.
Q. And then the second column is labeled, "Potential for long-term differentiation"; right?
A. Correct.
Q. And that column lists JC Medical; right?
A. Correct.
Q. Now, Mr. Wood, you give a lot of PowerPoints or at least you did when you were an Edwards executive; is that fair?
A. That is more than fair.
Q. And this -- a version of this slide appears on many of those documents, doesn't it?
A. This version of this slide is like many of them? I'm sorry?
Q. You often recycle slides; is that fair?
A. As much as humanly possible.
Q. And so I'm just saying that this slide appears on many different of your documents; right?
A. Yeah. What this slide was -- this was at an

all-employee meeting. And so we pull slides that we use in our business unit. But in your business unit you might speak for 45 minutes; in an all-employee meeting, you might speak for six, so you're just going to truncate that down to a very small summary list of things for consumption for the entire employee base of Edwards, some of which may not be interested.

Q. Let's turn back a few pages and look at the page ending 009. And this slide is titled, "We are now positioned to lead the next frontier of aortic valve disease. Acquisition of two leading AR technologies helps us lead for patients."

Did I read that right?

A. Yes.

Q. And then there's a red box in between and superimposed over the JenaValve and JC Medical logos. Do you see that?

A. Mm-hmm.

Q. And the text in the red box reads, "Funny picture of someone holding two pies. Voiceover is, 'We decided to have a bake-off and decided to buy both.'"

Did I read that right?

A. You read it correctly.

Q. And then the text continues, "Have the pie guy come up after both technology photos are up"; correct?

A. Correct.

Q. All right. Let's look at P-X-1262.

MR. SHAW: And if Mr. Nguyen could put that on the screen.

BY MR. SHAW:

Q. And if you look briefly at the cover email, you can see this is the final version of a PowerPoint presentation for your review; is that right?

A. That's what the slide -- the email says, yes.

Q. And you presented this at a town hall for the business unit you lead?

A. Well, she's sending me what she thinks her proposed final slides are. Whether I made edits to them after that or not, I couldn't tell you. But this is her proposed final slides and a link to the slide deck.

Q. Fair enough. Let's look at the page ending in 072. This -- do you remember whether you delivered this slide at the --

A. I do.

Q. This picture -- this slide shows a picture of a toddler holding two pies between and superimposed on top of the JenaValve and JC Medical logos. Is that a fair description?

A. This was intended to be a joke. In fact, I think I said, contrary to popular belief, this is actually not my baby photo. I was doing a meeting for all of my employees, and I was trying to keep them interested by doing something humorous because, otherwise, people would be on their phones

and fall asleep. So it was intended to be a joke and, as I recall, it got a big laugh.

Q. And this is the final version of the draft slide we saw on the previous exhibit; right?

A. I can't say for certain it's a final version, but it -- we presented some version of this and this is an accurate representation of that.

Q. And, Mr. Wood, I think you just alluded to this. But you told me at your deposition that you were being tongue-in-cheek in saying, "We decided we were just going to be a fat kid at the pie store and we were going to take them both"; is that fair?

A. It's what I said. It's not actually factually totally accurate, because the second pie was somebody calling me up saying, "We're going to close down this program. Would you please take this pie?" So it wasn't like we -- I had never looked at JC Medical before I got an email from Mark Turco saying that Genesis was going to close the program. So it's not like we were analyzing both companies, doing deep diligence on both companies, couldn't decide between the two, and then purchased the two. We were deep in the process with Jena, and I got a call out of the blue from Mark.

Q. But, Mr. Wood, my question was simply that you told me that you were being tongue-in-cheek and said, "We decided we

were going to be a fat kid at the pie store and we were just going to take them both." Is that what you told me?

A. I was saying it tongue-in-cheek, yes.

Q. And by "take them both," you meant the -- Edwards acquiring both JC Medical and JenaValve; right?

A. Correct.

Q. Mr. Wood, you told others at Edwards that JenaValve would facilitate speed to market; right?

A. That was the plan, yes.

Q. And you recall telling others that JC Medical has the potential for long-term differentiation; right?

A. Potential, yes.

MR. SHAW: Mr. Nguyen, you can take that slide down.

BY MR. SHAW:

Q. I'd like to unpack those concepts and look at P-X-1272. Mr. Nguyen will put a redacted version on your screen. There is an unredacted version, but I don't expect you'll need to reference it. And this is an email exchange between you and the CEO of Edwards from May of 2025; right?

A. Yes.

Q. And I want to look at the first email in the thread which starts on the page ending 002. And so -- you wrote this email to your boss; right?

A. I did.

Q. And let's look at the last full paragraph. You're giving him an update on the JC Medical integration; right?
A. Correct.
Q. And you write "Feedback from the doctors who have used Jena and JC is that JC is clearly the better platform. There are Jena loyalists" -- and then you list some doctors' names -- "but none of them have used JC yet. It is becoming increasingly clear we have a next generation AR platform."
Did I read that right?
A. You did.
Q. And that's a reference to the JC Medical legacy platform; right?
A. It's certainly what I believed at the time that I wrote that.
Q. And that used to be called J-Valve; right?
A. Correct.
Q. And now Edwards calls it Sojourn; right?
A. That's correct.
Q. Mr. Wood, let's talk about the FDA approval process for a device like a TAVR. And you can set that document aside.
You are familiar with the FDA approval process; correct?
A. Extremely, yes.
Q. And you would agree that the FDA has a higher bar to get approval in the United States compared to other regulatory

bodies in the rest of the world; right?
A. For commercial approval, that is true.
Q. Let's walk through the necessary steps to get approval for TAVR devices for U.S. patients. When Edwards seeks FDA approval for a complex medical device in the United States, it starts with development work, including in vitro testing and animal testing; right?
A. That's correct.
Q. And then the typical next step is to move to an early feasibility study; right?
A. I think that's typical.
Q. And you think that's the smartest next step; right?
A. We did that for what?
Q. The smartest next step? The early feasibility study.
A. We do those for what? I'm sorry. I apologize. I don't understand.
Q. So you just testified that the typical next step is to move to an early feasibility study?
A. That's -- it's not required, but it's typical.
Q. And I was just saying that you believe that is the smartest next step; right?
A. If you don't have other clinical experience outside the United States or from somewhere, you have to have some data to power your pivotal clinical trial so that you can make sure that that trial's going to be successful. So you have

to get -- you should get clinical experience from somewhere. You don't have to, but I think it's prudent to do that before you enter into a pivotal clinical trial.

Q. And -- but we're talking about an early feasibility study still.

A. Right. An early feasibility would be how you would get the first-in-human experience if you wanted to do it in the United States.

Q. And so you need an investigational device exemption, or an IDE, from the FDA for an early feasibility study; right?

A. That's correct.

Q. And then you need to contract for your clinical sites; right?

A. That's correct.

Q. And that requires either approval from the Centers for Medicare and Medicaid Services, which saves money, or paying out of one's own pocket, which saves time; right?

A. Correct. You can either reimburse the sites for the entire cost or you can wait and get CMS approval and then the sites get reimbursed, which would reduce the contract for the clinical trial sites.

Q. And for each site, you need sign-off from the institution, including their institutional review board; right?

A. Yeah, it's two separate things. The institution has to

sign a contract with you for the research, but then their institutional review board has to review the clinical trial and find that it meets their ethical and research standards.

Q. And then, after you've done all of that, that's when you can do your first-in-human case; right?

A. Again, if you're doing it in the United States, which you're not required to do.

Q. And if that first-in-human case goes well, you get a new investigational device exemption from the FDA for your pivotal study or trial; right?

A. If that series of cases go well and you decide the device is ready for a pivotal trial and you have enough clinical performance data to design the clinical trial, then the next logical step would be to do your pivotal trial.

Q. And when Edwards acquired JC Medical, it was in position to start its pivotal trial; right?

A. They had completed, I believe it was, a 15-patient EFS trial, along with some other compassionate patients, and they were moving towards starting a pivotal trial, but they had not started yet.

Q. And so when you start a pivotal trial, you have to enroll patients; right?

A. That's correct.

Q. And that requires going through the same contracting process all over again; right?

A. Yeah, if you have an early feasibility trial, usually, if you're going to that same site again, it's easier to get the pivotal trial approved because you've already established reimbursement levels, you've already established a lot of things. So the second contract normally goes faster.

Q. But it can still take a significant amount of time; right?

A. It certainly can, depending on the site.

Q. And then once all the patients are enrolled in the pivotal trial, you have to wait until the endpoint is reached; right?

A. That's correct.

Q. And for TAVR-AS and TAVR-AR, those are typically one-year endpoints; right?

A. Depends on the trial. Some of our trials for AS were two-year endpoints, but I'd say the majority of the trials have a one-year endpoint.

Q. And then once the last patient reaches his or her endpoint and you have collected all the data, then that data forms the basis of approval for your premarket approval, or PMA application; right?

A. Assuming the trial is successful, you would correlate all of that data and you would submit it to FDA, along with all your in vitro testing, and seek approval.

Q. And when Edwards signed its merger agreement with JenaValve, JenaValve was at or about at the PMA application point; right?

A. They were deep in the PMA application process at that time.

Q. And the FDA has 180 days to review a PMA application?

A. That's the statutory requirement, yes.

Q. But the FDA doesn't have to approve it.

A. That's correct.

Q. And the FDA doesn't have to make a final decision with that 180 days; right?

A. They don't have to be the final what?

Q. Final decision.

A. Well, FDA is ultimately the final decision.

Q. But I'm saying the 180-day clock can be restarted if the FDA has questions that you can't answer based on the data you already collected.

A. Yeah, they can have an unlimited number of reviews if you can't satisfy their questions.

Q. And so, given this process, it isn't uncommon for FDA approval to take years to obtain.

A. It can.

Q. Let's look at P-X-1267. I want to look at the landscape of TAVR-AR devices. And Mr. Nguyen can put the redacted version on the screen. There is an unredacted version in

your binder, but I don't expect you'll need to reference it.
A. Okay.
Q. Now, P-X-1267 is an email with an attachment from Patrick Bohan to several people, including you, from April of 2025. Do you see that?
A. I do.
Q. And the line is, "Competitive clinical trials, April 2025."
Do you see that?
A. I do.
Q. Now, this would be during the pendency of the FTC merger investigation; right?
A. Yes. This -- these are routinely done. These are done probably quarterly.
Q. Okay. And you routinely receive them; right?
A. I'm listed here on the list. So I'm sure I did.
Q. Let's look at the page ending 006. And this slide is titled, "Aortic competitive snapshot, VIV-AR." VIV stands for valve-in-valve; right?
A. That's correct.
Q. And that's another Edwards product; right?
A. No, that's a procedure technique. It's not limited to Edwards.
Q. Thank you for that clarification.
And the AR is aortic regurgitation; right?

A. That's correct.
Q. And so the far left-hand side of this are a list of TAVR and, I guess, other valve systems; right?
A. There are, but it's, obviously, incomplete because it's missing Jena.
Q. Well, we'll get to that in a moment.
And then across the top, there are columns -- categories for Aortic Surgical VIV, Aortic Transcatheter VIV-AR, and Other; right?
A. Correct.
Q. And so this chart is tracking what is known or publicly available across those different categories; right?
A. Sorry. These are just the different indications under each one of those categories.
Q. Right. And it's tracking the -- what is in the left-hand column -- it's tracking that across what is the top row.
A. Based on what's publicly available.
Q. So let's look at the AR column. Do you see that?
A. I do.
Q. And underneath, it shows FDA, CE, and Other; right?
A. Correct.
Q. And FDA is the Food and Drug Administration?
A. FDA is the Food and Drug Administration, yes.
Q. And for practical purposes, CE is the European

equivalent?
A. For practical purposes.
Q. And "Other" would be any other regulatory body in the world; right?
A. Yeah. Primarily Japan or China, but yes.
Q. Now, if we look back at the far left-hand side of the slide, you see J-Valve EW; right?
A. Yes.
Q. And that's the Edwards Sojourn product?
A. Yes.
Q. The one that you purchased as part of the JC Medical acquisition; right?
A. Yes.
Q. And so this chart shows that there are pathways to approval for Sojourn in the United States; right?
A. Well, it doesn't say that. It gives a status of where they are, and it's saying that it has a study ongoing. That doesn't mean that there's a pathway. If the study's not successful, it will never get approved.
Q. But the study is an important step towards ultimate approval?
A. Boston Scientific just ran a 1,600-patient study and they failed their trial and didn't get approved and withdrew the product from the market. So the study is a milestone, but if your study isn't successful, then you never get

approval.
Q. But the study is a necessary step towards approval.
A. You can't get approved without a study, but having a study doesn't guarantee you'll get approved.
Q. Understood. And then, similarly, it shows that a study is planned or approval -- seeking approval is planned in Europe and in Japan; is that right?
A. Correct. Again, this is all based on what's publicly available. So the accuracy of it's based on what's publicly available. If somebody's working on a program in secret, we'd have no knowledge of it.
Q. Now, the only other valve showing the markings in the AR column is J-Valve Genesis. Do you see that?
A. I do.
Q. And Edwards bought JC Medical from Genesis; right?
A. That's correct.
Q. But Genesis retained the rights to the J-Valve for China; is that right?
A. That's correct.
Q. But, contractually, J-Valve Genesis could never enter the United States; right?
A. I believe that that's true.
Q. All right. Let's turn to the next page ending 007. And this slide is titled, "AR TAVR;" right?
A. Yes.

Q. And this section is tracking, again, what Edwards knows about different valves in the AR TAVR space; right?
A. That's -- it's tracking what's publicly available that we are aware of, yes.
Q. And so this slide lists three TAVR systems. And the first is JenaValve?
A. Correct.
Q. And if you look in the notes, it shows that an FDA AR indication expected. Do you see that?
A. Yes.
Q. And the note also, then, says, "Breakthrough device designation, FDA."

Do you see that?

A. I do.
Q. And breakthrough designation by the FDA means that the FDA recognizes that the device treats a disease or a condition for which there isn't already an approved device; right?
A. That's their definition, yes.
Q. And the FDA is supposed to pay special attention to that device; right?
A. I think that was the intent, but in practicality, I haven't seen breakthrough designation actually accelerate someone's pathway to market.
Q. The second TAVR system listed is JC Medical EW

subsidiary; right?
A. Yes.
Q. And the notes for that column flag two things; right? First, in 2023 [sic], Edwards acquired J-Valve.
A. Yes.
Q. And in 2023, J-Valve also received breakthrough device designation; right?
A. That's correct. I think any device that came into the U.S. for AR would receive breakthrough designation because there's currently no approved product for AR.
Q. The third is Genesis MedTech; right?
A. Yes.
Q. And this represents the China-only rights that Genesis retained for the J-Valve, right?
A. That's correct.
Q. And it's transapical. Do you see that in the features?
A. I do.
Q. And that's different from transfemoral; right?
A. It's different.
Q. And transfemoral is preferred in the United States; right?
A. I think transfemoral is preferred.
Q. Now, let's look at the next two slides, 08 and 09.
MR. SHAW: And I'm going to ask Mr. Nguyen if he can put both of these on the screen at the same time and

we'll treat them together.
BY MR. SHAW:
Q. This slide is titled, "Other AR TAVR players."
Both of them are. Do you see that?
A. I do.
Q. And this is a continuation of the previous slide; right?
A. I believe so, yes.
Q. And so the first one on the list is Laguna Tech Alpha and Zeta. Do you see that?
A. I do.
Q. And the notes for both say, "No U.S. studies."
Did I read that right?
A. I see the note. I see off to the right where they have EFS is planned, or they're noted out here, but it -- to date, we were not aware of any U.S. studies. But it's important to note IDEs are not -- FDA does not disclose approval of IDEs, only commercial approvals. So someone could have an IDE and actually be doing research in the United States and we could have no knowledge of it.
Q. But you have no knowledge of Laguna Tech --
A. Have no knowledge of it, no, but that doesn't mean that it didn't occur.
Q. And Laguna Tech doesn't have breakthrough device designation, does it?
A. I wouldn't know.

Q. And so, again, as of April 2025 when this was made, Edwards, as a company, wasn't aware of any U.S. studies; right?
A. We were not aware.
Q. And, in fact, as of your deposition on September 26th, 2025, you weren't aware of any U.S. studies; right?
A. I was not aware.
Q. All right. The third one listed here is Shanghai Kindly. Do you see that?
A. I do.
Q. And that's a Chinese-based company?
A. It is.
Q. And the notes state that it was submitted for approval in China; right?
A. That's correct.
Q. And then if we could look at the next slide, this also lists three systems; right?
A. Correct.
Q. And neither of these slides mention anything for any of these devices regarding FDA approval status; right?
A. Yeah, there's nothing about FDA on these.
Q. And other than Laguna Tech, all are manufacturers based in China; right?
A. That's correct.
Q. And valves made in China cannot be commercialized in the

United States; is that right?
A. You would need to move the manufacturing outside of China.
Q. And that's because the FDA won't send its employees to China to inspect medical device manufacturing facilities located there; right?
A. I don't know that they've ever publicly stated that, but I believe that's the -- that's the feedback I received from Mark Turco when we had discussions about J-Valve.
Q. Great. Mr. Wood, I'd like to talk about Edwards's plans for innovating with what it acquires from JenaValve if the transaction closes. Edwards plans to commercialize JenaValve as soon as it receives FDA approval; right?
A. That's correct.
Q. And then, longer term, Edwards plans to create a Gen 2 TAVR-AR product; right?
A. That was correct.
Q. And Gen 2 simply means another improved iteration down the road; right?
A. Correct.
Q. But Edwards doesn't have enough information to know yet what a Gen 2 design would look like; right?
A. We -- we don't because we don't have approval of Jena and we don't have Jena in our possession, and JC is too early to know what things we'd be solving for. So we're

committing that we would invest in the next generation, and probably a generation beyond that, but until you know what you're solving for, it's hard to design the next generation product.

Q. And so you can't know until Edwards actually owns JenaValve; right?

A. We can work on concepts, but to know whether those will be the final version of the next gen, you'd want more information just because of the timeline and the expense of bringing a next-generation product to market.

Q. And finally, let's talk about what it would take for Edwards to bring JenaValve to market. Edwards can't make concrete integration plans for JenaValve until Edwards owns it; right?

A. They have a product today that you could begin selling. The problem is they can't manufacture this product at scale. And so you would have to go in and improve their manufacturing process to be able to manufacture the process at scale so you could make enough products to have a thorough commercialization. And until we own them, you're not able to go in and figure out how to fix their manufacturing process, because I'm sure there's a lot of trade secrets and other things in there that no one's going to disclose until after the transaction's completed.

Q. So that means, assuming FDA approval and assuming the

transaction closes and assuming that JenaValve's methodology is safe and reasonable, Edwards will go to market, essentially, with what JenaValve already has ready to go?

A. Yeah, they would -- you can only deviate so much from what was studied in the clinical trial before FDA might say it's a new product. So if we found out that the problem was people didn't have the selling experience and Edwards has more selling expertise, then you could just improve the quality by just doing what they currently do better. But if there's a design issue that you need to implement, that would have to be reviewed by FDA, and FDA would have to agree that the design change didn't invalidate the clinical data.

Q. And Edwards has no way of knowing what is needed on that front until it actually closes the JenaValve transaction; right?

A. You can't be specific until you have the opportunity to go in there and see all of their processes and knowing what needs to be changed.

Q. Thank you.

MR. SHAW: That's all the questions I have for right now.

MR. SHORES: Your Honor, just a housekeeping note. I think, for confidentiality purposes, we're not even going to need to use the binders. It will all come up on the

screen. I just wanted to flag that to make it easier on yourself and the witness.

THE COURT: All right.

MR. SHORES: But if we need to, we can go into the binders. May I proceed, Your Honor?

THE COURT: You may.

MR. SHORES: Okay.

CROSS-EXAMINATION

BY MR. SHORES:

Q. Good morning, Mr. Wood.

A. Good morning.

Q. Thank you for being here with us.

Mr. Wood, where did you grow up?

A. Medford, Oregon. Outside of Medford Oregon, small town.

Q. Did you go to college?

A. Not immediately, but eventually, yeah.

Q. Okay. Did you get any degrees?

A. I have two degrees, yeah.

Q. Okay. Did you work during college?

A. Yeah, I started Edwards Lifesciences in 2019 and I did -- or, sorry, in 1985, and I did both my degrees while I was working full time.

Q. Okay. And when you started at Edwards, what was your job, Mr. Wood?

A. I was a mechanical assembler 3.

Q. How much did you make?
A. 6.36 an hour.
Q. You make more today?
A. I do better, thankfully.
Q. Okay. After you had this role, what other roles did you have at Edwards?
A. I moved up through manufacturing and operations. I transitioned to regulatory, spent some time in quality, and then came back to regulatory and clinical. Then I transitioned over to marketing where I did clinical marketing which is, like, med affairs. Then in 1999, I started working on transcatheter valves. We acquired PVT in 2004, I believe. And I was the general manager of that program until the time I left Edwards when I was group president.
Q. Okay. And we're going to come back to PVT and some of those concepts, but can you just explain for the judge, what does regulatory mean within the business? What does that function do?
A. Yeah. Regulatory and clinical is the process of doing the human clinical trials, but then all of the reports and interactions with FDA to actually get approval.
Q. So you -- fair to say you've had a lot of interaction with the FDA?
A. Yes.

Q. Okay. What was your role when you left Edwards?
A. Group president of transcatheter heart valves and surgical.
Q. Okay. So did you oversee the entire transcatheter heart valve business at Edwards?
A. I did.
Q. Okay. How many years of experience do you have with transcatheter heart valves?
A. I started in 1999 and was doing it until I left.
Q. Who took over for you in the TAVR business?
A. Dan Lippis.
Q. Is Mr. Lippis experienced in TAVR?
A. Extremely.
Q. Okay. How do you think he's going to do in your job?
A. I think he's going to do great.
Q. Okay. And why did you leave Edwards?
A. I joined the board of another company called PROCEPT BioRobotics about 18 months before, and during my time on the board, I fell in love with the technology that they had. And the board asked me if I would be willing to step off the board and take on the role of CEO. And I initially said no, because I loved Edwards and I loved structural heart, but they came back again, and the more I thought about the opportunity, the more I thought it was about something that I needed to do because the technology needed a different

approach to be able to maximize it.

Q. Okay. Thank you, Mr. Wood.

I'm going to transition a little bit and talk about pivotal trials. Okay?

A. Okay.

Q. Before a company receives premarket approval from the FDA, is it allowed to market its device in the United States?

A. No, that is illegal.

Q. Okay. What happens if you do that?

A. You get fitted with an orange jumpsuit.

Q. Okay. And tell us -- there's been a lot of talk about pivotal trials. But I think it would be helpful for the judge to hear, what is a pivotal trial?

A. A pivotal trial is the fundamental trial that shows that your device meets the standard of safety and efficacy. So you design a trial, and you have to predict what the clinical outcomes are going to be compared to either historical control, which means you know what the data is that you have to beat, or an active control, which means you're randomized against another therapy, and you have to show that you're either non-inferior to the existing therapy, basically equivalent, or you have show that you're superior to the existing therapy, which shows that you're better, and you have to predesign what the endpoints are and

what the expectations are, and then you have to achieve those endpoints to be able to submit that for an approval.

Q. Okay. And are these pivotal trials conducted at hospitals?

A. They are.

Q. And sometimes those are called sites?

A. Yes.

Q. Okay. And sometimes are there overlapping trials at these sites when Edwards would be conducting trials, as well?

A. There can be, yes.

Q. And sometimes there would be the same doctors doing multiple trials; is that right?

A. There can be. You try to avoid that, if you can.

Q. Okay. Has ever -- Edwards ever struggled to find enough hospitals to do clinical trials?

A. No, we have the opposite problem. There's -- you're -- if you're doing a 200-patient trial, for example, you don't want to have 100 sites all doing two cases. So you want to make sure you have the learning -- that people are learning and getting through the learning curve, and so you might say we have 30 sites, but there's literally hundreds of people that want to be involved with clinical research. And so you end up telling a lot more people no than you tell yes.

Q. Approximately how many hospitals can conduct pivotal

trials for a TAVR device?
A. Oh, at least a couple of hundred.
Q. Does Edwards make money on pivotal trials?
A. We charge for the devices, but you don't make money. The cost of the clinical research far exceeds the revenue that you get for the valve and the trial.
Q. Well, how do you set your price in a pivotal trial?
A. You try to approximate what you think the eventual commercial pricing will be.
Q. Are you, in a pivotal trial, trying to sell as many devices as you can?
A. No. What you want to -- the pivotal trial is all about getting your device to a commercial approval. So you want to make sure you have enough patients that you can demonstrate safety and efficacy. But if you could do that with 800 patients, you wouldn't want to enroll 2,000 because that would delay your time to getting commercially approved because you have to complete that enrollment. So you're trying to figure out, what's the minimum number of patients that I need, plus a little bit of a margin for safety, and then that's going to be the fastest path to the market.
Q. So the number of devices or enrollees depends on the need for FDA approval; is that fair?
A. It depends on the statistics of the trial, yes.
Q. Okay. Mr. Wood, I would like to transition and talk

about TAVR-AS. You were asked some questions about that by the Government's counsel. Do you remember that?

A. I do.

Q. Okay. And just for definitional purposes or explanation, can you explain aortic stenosis versus aortic regurgitation?

A. So your aortic valve sits at the exit of the left ventricle and it is the primary valve that allows blood to flow out to the rest of your body from the heart. What happens gradually over time is your heart valve narrows, the leaflets begin to thicken and get stiffer, and it's happening to all of us actually while we're sitting here but very slowly. As your valve gets narrower and narrower over time, it's not a problem to a point, but at a point, it finally reaches where not enough blood can move forward. Your blood -- your body doesn't receive the amount of blood that it needs to oxygenate your brain and to fill your extremities, and that's when you start to develop symptoms and you start to have problems. And your heart has to work harder and harder to overcome that narrowing. And if not treated, it eventually leads to heart failure and death.

Q. Okay. And for aortic stenosis, does Edwards have a valve to treat aortic stenosis?

A. We have multiple valves.

Q. Okay. And is one of them called SAPIEN?

A. Yes.
Q. Okay. And did Edwards buy a company called PVT? I think you mentioned this earlier.
A. They did.
Q. Okay. And was that part of your development efforts related to aortic stenosis?
A. Yes.
Q. When did that happen?
A. We entered into the agreement in late 2023 and -- or, sorry, 2003, and we closed in 2004.
Q. How many employees did PVT have at the time?
A. 17, I believe.
Q. And what was the status of their development efforts?
A. They had completed, I think, around eight or nine cases in their total experience. Most of them had been done in France and, I believe, one case -- a compassionate case had been attempted in the United States.
Q. And was Edwards also working on TAVR-AS development at the time it purchased PVT?
A. Yes.
Q. All right. And what happened with respect to your research after you bought PVT?
A. Well, I took the team from -- the team was primarily located in Israel. I took the team from Israel, my team in Irvine, I combined the two teams together and made --

created one team, and then we pursued the project from there.

Q. Okay. And what was the net result of combining the teams?

A. Well, we were able to massively accelerate the development.

Q. Do you think PVT would have gotten FDA approval without Edwards?

A. I don't believe they would have, and certainly not in the same time frame.

Q. Are you aware of any other companies that pursued PVT when Edwards bought them?

A. No. Medtronic, Boston Scientific, and J&J were all on the board of PVT, but when we put in an offer, no one outbid us and we were able to acquire PVT.

Q. And, Mr. Wood, you mentioned risk-taking. I think risk-taking was asked about in the Government's case. Do you remember that?

A. Yeah.

Q. Okay. Was this a risk to the company to acquire PVT and go into AS?

A. It was a huge risk at the time. Edwards was pretty small. I think it was about a year's worth of cash flow for us. So it was almost a "bet the company," sort of, decision.

Q. And was anybody else willing to take that risk?
A. Well, J&J, Boston, and Medtronic were on the board and they didn't outbid us, so no.
Q. What year did SAPIEN become approved in the United States?
A. 2011.
Q. How much money was spent prior to 2011 on development of AS?
A. We spent over a billion dollars before we sold the first commercial product in the U.S.
Q. So let's just -- time frame-wise, 2011, the product is approved in the U.S. Are you with me?
A. Yes.
Q. Okay. So did hospitals just start buying it from a catalog at that point, Mr. Wood?
A. No, it doesn't work that way. The transcatheter heart valve was a totally new class of products. And so nobody had learned how to use transcatheter heart valves in medical school or in their training, outside of the few clinical trial sites we had. So every site that wanted to start a transcatheter valve program had to be trained on how to use the product.
Q. And what did that entail?
A. Well, we actually developed full simulators that could simulate the implantation of a transcatheter heart valve.

But we would take two surgeons, two interventional cardiologists, usually an imaging person, and a nurse practitioner, for a total of six, and we would bring them to one of our training facilities. They would do -- spend a day on the simulators. They would spend another day doing complications, but also case observations where they would actually watch cases. Then they would have to submit five cases to us for review. We would have to deem them to be acceptable. And then we would send a trained proctor to their site who would train them for a minimum of two cases, but really an unlimited number of cases, until the proctor signed off and said they were ready to be independent.

Q. And we're going to talk about aortic regurgitation in just a minute. But is there going to have to be a training process with respect to doctors and hospitals on the aortic regurgitation side, as well?

A. There will.

Q. Did you do anything to educate patients around aortic stenosis?

A. We did. We did a lot of education, a lot of work to educate patients, but also general cardiologists and general practitioners as well so that they were aware that there's a new therapy available.

Q. And why did you have to make them aware that there was a new therapy?

A. Well, the traditional treater of aortic stenosis was a surgeon, and the typical person who uses a transcatheter heart valve is an interventional cardiologist. So the referral patterns would generally have somebody referring to a surgeon, because that was the only treatment option. And if a patient got referred to a surgeon, a surgeon would just operate on them. So they would never tell them that TAVR even existed. So we needed to make sure that patients knew what questions to ask and that they would get referred to a heart team that had surgeons and cardiologists that offered both therapies so they could choose which therapy they wanted of the available therapies.

Q. And with respect to AR, is there going to have to be a similar education effort?

A. There will.

Q. What about manufacturing? Did you set up manufacturing for TAVR-AS?

A. We did.

Q. And what did that entail?

A. Well, PVT couldn't manufacture their own valve. So they had a small contract manufacturer, but they were also using a tissue material that no one had ever used in a commercial heart valve before. They used equine pericardial tissue, so pericardial tissue from a horse. We never believed that that would be scalable to the volumes that we would need.

So we switched over to our bovine pericardial tissue and brought all of the manufacturing in-house at Edwards.

Q. Okay. And can you just describe today how many people are in the supply chain for AS?

A. We have thousands of people in the supply chain.

Q. Okay. Mr. Wood, so is it fair to say that Edwards built the TAVR-AS market?

A. I think that's fair.

Q. And after you did that, after you started building it, did you stop your innovation efforts?

A. No, absolutely not. The only -- the one certainty in med-tech is you are going to be obsoleted. You have a choice: Either you obsolete yourself or someone else will obsolete you.

Q. Let's look at --

MR. SHORES: If we could pull up Exhibit-D X-220, please. And we can start with the next slide, the cover page.

BY MR. SHORES:

Q. This is entitled, "Advancing structural heart innovations."

Do you see that?

A. I do.

Q. Okay.

MR. SHORES: And if we could, let's go to Slide 5.

BY MR. SHORES:

Q. All right. Mr. Wood, the title of this slide is "Five generations of valves and 10,000-plus patients in marquee clinical trials."

Do you see that?

A. I do.

Q. Are the five generations of valves represented below this title?

A. Yeah. It's SAPIEN through SAPIEN 3 Ultra RESILIA.

Q. And all of these represent different innovations by Edwards?

A. They do.

Q. All right. Let's look at the timeline at the bottom. You see it starts in 2007?

A. Yes.

Q. Okay. Was Edwards doing any innovation in TAVR-AS before 2007?

A. Oh, yes.

Q. Okay. So has it been over 20 years that Edwards has been doing innovation for TAVR-AS?

A. Yeah -- well, we completed the acquisition of PVT in 2004. I had been working on the program since 1999. So it goes back -- that time frame.

Q. Okay. And above 2007, you see where it says, inoperable, high risk, and there's other categories there?

A. That's correct.
Q. Okay. Are those different patient populations?
A. They are.
Q. Okay. And the word "risk," what is -- risk relative to what?
A. Relative to open-heart surgery.
Q. Okay. And are these different risk populations called an indication?
A. They are.
Q. And can you just explain for the judge the purpose of an indication.
A. When you get your device approved, it -- the FDA approves it. They give you a specific indication. So they say -- like, the original SAPIEN valve was approved for patients who were deemed inoperable by two cardiac surgeons for open-heart surgical replacement of their aortic valve, and so that would have been our first approval. But that indication is really important because that's what you're able to legally market and promote, and that's also what CMS will cover and pay for.
Q. And there are some arrows pointing to the right on this chart. Do you see that, Mr. Wood?
A. Yes.
Q. All right. And I'm counting 10 of those. You can check my math, if you want. But were you involved in all 10 of

these pivotal trials?
A. I was deeply involved in all of those trials.
Q. Okay. And did Edwards use these pivotal trials to expand the indications of patients that they could offer TAVR-AS to?
A. That's correct. It was the advancement of the device technology, but combined with the evidence generation of multiple clinical trials.
Q. Okay. And when was your first competitor approved for sale in the U.S. of an alternative TAVR-AS device?
A. That would have been Medtronic with CoreValve, which, I think, happened in 2014, 2015, right around in that ballpark.
Q. And were you doing any innovation before they came to the U.S.?
A. Oh, absolutely.
Q. And is that reflected on this chart here?
A. Yeah. When they were showing up, we were just getting approval for our XT valve which is our second generation product.
Q. Okay. And were there any products approved in Europe at the time?
A. Yeah. CoreValve -- Medtronic -- well, Medtronic didn't own them at the time, but CoreValve was actually approved in Europe before we were. We were both approved in 2007, but

Medtronic -- or CoreValve was actually approved before Edwards in 2007.

Q. And were you tracking what CoreValve was doing in Europe?

A. Oh, yes.

Q. And why?

A. Well, we were both tracking each other. It was -- we were both racing to be first and we were tracking each other because you always track competitors in the space, but we would have tracked these even if we didn't have a transcatheter program, because we have a surgical business and these would have been disruptive to our surgical business, as well.

Q. Okay. So even though a company is in Europe, you're still tracking them relative to your business in the United States?

A. We track anybody on the globe if we know where they are.

Q. These pivotal trials, Mr. Wood, can they take a long time?

A. Yes.

Q. Okay. And how does that affect your innovation strategy?

A. Well, you're investing in the clinical trials, but you're not getting any revenue because you can't sell until you get the commercial approval. So the longer it goes, the

more expensive it is until you get that commercial approval.
Q. And have you heard the word "development cycle" before?
A. Yes.
Q. Okay. What's a development cycle?
A. The development cycle is basically the time from the time you come up with a new concept until the time that you have a new valve approved. And, like, that process can take a long time. It can take five years, seven years. That's why it's so important that you always have the innovations working, because, if you wait for a competitor to show up, you can't catch them.
Q. Have you seen any examples of competitors who have not innovated and waited for somebody else to show up?
A. Yeah, I mean, probably the most famous example is J&J. They were -- had the first commercial coronary stent. They had the first commercial drug-eluting stent. But they never invested in a next generation stent. And Boston Scientific showed up and, I think, took 40 share points out of them in 40 days, and now J&J doesn't even sell a coronary stent anymore.
Q. All right. Let's, if we could, look at D-X-282. Do you recognize this document, Mr. Wood?
A. I do.
Q. Your name's on it?
A. It is.

Q. What is it?
A. It's a strategic plan from 2015.
Q. And why -- what was the purpose of this presentation?
A. We have an annual process where we do a strategic plan which gives us usually a seven-year look at what we predict the future to look like.
Q. Okay. So we're in 2015, and I want to ask you about Slide 18. And the title of this slide is "Expanded indication is the single biggest driver of growth in the U.S. over the plan period."
Do you see that?
A. I do.
Q. And as -- we talked about indications before; is that a same reference here?
A. It is a same reference. There's one other note here. When we expanded the number of valve sizes, it also leaded -- left us to treat more patients because our indication is specific to the size of the patients that you can treat.
Q. Thank you for that.
On the left-hand side, it says 2015. Do you see that?
A. I do.
Q. And there's 1.9 billion under it. Do you see that?
A. I do.

Q. And what does that mean?
A. That means we estimated the total market to be about 1.9 billion in 2015.
Q. Okay. And if you look at over at 2021 -- do you see that?
A. I do.
Q. And it says 4 to 8 billion?
A. I do -- yes.
Q. And what does that mean?
A. It means we were projecting that in 2021 that the market would be worth 4 to 8 billion.
Q. And how much is the market worth today?
A. I think a little over 6 billion.
Q. Okay. And has indication expansion played a role in that?
A. It's the single biggest driver. It played a massive role.
Q. All right. What about expanding valve sizes. Do you see that?
A. Yes.
Q. What does that mean?
A. Originally, when we started, we only had a 23- and a 26-millimeter valve, but we were screening out about 20 percent of our patients who were too large for our 26-millimeter. So we added a 29-millimeter valve which

allowed us to capture 20 percent more people than we would have before. We also added a 20-millimeter valve, which is a smaller segment, but it's probably about 3 to 5 percent of the market, but we thought it would be more important outside the U.S. in certain geographies.

Q. So does expanding valve size allow you to sell your device to a new patient population?

A. Yeah, we can treat more patients we couldn't treat without it.

Q. All right. What about "Increasing Awareness"? Do you see that box?

A. Yes.

Q. What does that mean?

A. Well, aortic stenosis is vastly undertreated. Only about 13 out of 100 people with severe aortic stenosis actually get therapy. And a lot of people think the disease is benign and that, as long as you can tolerate the symptoms, it's okay. But we ran a trial that showed that waiting is not winning for these patients and there's actually bad things that happen to them while they're waiting. So we have to make people aware of that, that they need to focus on the disease, not just on their symptoms.

Q. All right. And does that education process going to happen -- have to happen with respect to aortic regurgitation, as well?

A. Absolutely.

MR. SHORES: You can take that slide down.

BY MR. SHORES:

Q. So I just want to pause on the AS space. So just to wrap up, how much has -- money has Edwards invested in developing the TAVR-AS device portfolio that we saw from the beginning?

A. Billions of dollars. Probably, I don't know, 3-1/2 to 4, probably. I mean, we spent a billion before we sold the first one, and it's much more than that now.

Q. Do you have any sense of, since 2019, the last six years?

A. I mean, my annual budget was probably close to a billion for -- spending for sales and marketing and R&D. So we were spending a lot.

Q. How many patients has Edwards served in the AS space?

A. When I left, it was about 1.2 million patients.

Q. Okay. And do you believe that Edwards saved lives in those patients?

A. Absolutely.

Q. Do you know how many people work today for Edwards in the sales and marketing group in AS?

A. Well over 500.

Q. And what about with respect to field specialists that assist the doctors with training? How many folks do you

have doing that?
A. They would be part of the 500. They're part of the commercial team if they do commercial sales. We also have a clinical group that does that function under the clinical umbrella.
Q. And what about R&D? How many people within your group, when you left, were doing R&D?
A. Oh, between research and development and clinical, it was probably close to 1,000.
Q. All right. I want to transition now and talk about AR. And we talked about AS. Can you just give the judge a sense of the relationship between the two diseases.
A. Sure. Well, you're going to the same aortic valve. So as it relates to the delivery system and being able to deliver a transcatheter valve to that location, there's a lot of similarities. But where your aortic valve is getting -- the leaflets are getting thicker and they're getting calcified and narrow, in regurgitation, sometimes the leaflets won't have any calcification or thickening at all, but the leaflets don't meet up and collapse properly. And when that happens, the blood flows backwards back into the heart. So your ventricle is trying to eject blood out, but when the valve closes, some amount of the blood starts moving backward. And it has the same effect to the patient. You're not getting enough forward flow of blood, whether you

have regurgitation or whether you have stenosis. So the symptoms can be similar, but the damage that's being done to the heart, the mechanism is different.

Q. And Edwards wants to go into the AR space; is that right, Mr. Wood?

A. That's correct.

Q. And how would Edwards use its experience in the AS space to inform its business and its strategy in the AR space?

A. Well, I think one of the big learnings that we had in the aortic stenosis patients is -- like, there was a view that there weren't a lot of inoperable people, and we thought that surgery did a good job of treating almost everybody with the disease. But what we learned was, once we had a transcatheter option, there were a lot of patients who weren't well served from surgery. And there were a lot of patients, even if they were surgical candidates, some patients would rather die than have open-heart surgery. So when we developed a transcatheter option, it greatly expanded the number of people that could get this deadly disease treated.

Q. And do you think you'll be able to leverage your clinical learnings from AS in any way in the AR space?

A. Well -- 100 percent. You're working with the same clinicians. You're working with the same societies. You're working with the same group. And you're going to the same

exact valve. It's just the disease is different.
Q. When did Edwards become interested in developing a TAVR-AR device?
A. Well, we actually ran a feasibility program some time ago where we used our SAPIEN product with a docking mechanism and actually treated, I think, around 10 AR patients, but this was probably well over a decade ago. And the device actually worked. We demonstrated proof of concept. But at the time, there was so much focus on AS, no one was paying any attention to AR, and I think it took us about 10 months to a year to -- just to enroll those 10 patients. So it just didn't seem like something the market was ready for at that time.
Q. So when did you start thinking about acquiring JenaValve?
A. I think the biggest thing that happened was in 2023, they presented the data from their pivotal trial at TCT, and that's when I started talking to a lot of clinicians. And by then, TAVR for AS has gotten pretty mature. I think doctors were looking for other ways to treat patients. And more AR patients seemed to be showing up and, I think, the trial itself made people aware that there was a catheter-based treatment option, and the fact that they were able to enroll that trial, the results looked solid for the patients they were treating, and they were able to continue

to enroll in continued access, which seemed to mean there were enough patients there. So I think that's when I got personally interested in taking another look at Jena.

Q. Okay. And just so we're clear on the time frames, that was in the fall of 2023?

A. That was in the fall of 2023.

Q. All right. And did you do due diligence on JenaValve?

A. We did.

Q. Okay. And was that in 2024?

A. I believe so, yes.

Q. Okay. At a high level, without going into details -- we'll have to close the courtroom to get to that -- what did you find in due diligence?

A. A number of issues in product development and in manufacturing.

Q. Okay. And did you agree to acquire JenaValve in 2024 -- July of 2024?

A. We did.

Q. Now, while you were in discussions with JenaValve, did you get approached by another company about possibly selling a TAVR-AR device to you?

A. Yes. Mark Turco called me out of the blue, and I know he was running JC Medical, and he said that the parent company, Genesis, had decided they didn't want to move the program forward, there was too much risk and it was too

expensive, and they were going to close the program, but they gave Mark the opportunity to try to sell it if anyone would buy it. And so Mark called me and said, "Look, I think this would fit great in your portfolio and I think you can get it -- pick it up really, really cheap. So would you be interested?" And so I said I'd take a look at it.

MR. SHORES: And if we could, let's pull up D-X-78.

BY MR. SHORES:

Q. And this is an email exchange between you and Mr. Turco. Is it Dr. Turco?

A. It is Dr. Turco.

Q. Okay. And that's February 8th of 2024. Do you see that?

A. I do.

Q. And the email notes, "Thanks for the time yesterday."

Do you see that?

A. I do.

Q. Is that the conversation you had with Dr. Turco?

A. Yes.

Q. Had you had -- I'm sorry. Go ahead.

A. Yeah, he's following up the day after.

Q. Okay. And you had had no conversations with Dr. Turco prior to February 8th; is that right?

A. I mean, I know Mark. I've known him for a long time.

He was an interventional cardiologist and he worked for Medtronic for a while. So I've known him. But we had no conversations about JC Medical.

Q. Okay. Yeah, that was a poor question. I meant about JC Medical. Thank you for clarifying.

Let's go down into the email, if we could. And it says -- I want to go down to the paragraph that starts, "We have a good deal of data," and focus on the next sentence. It says, "We completed or" -- I think that means our, O-U-R -- "EFS in January and plan to present 15 patients to 30 days at CRT."

Do you see that?

A. I do.

Q. And -- so the 15 patients, is that a lot, Mr. Wood?

A. No.

Q. Okay. Can you give us a sense of that?

A. Well, Boston Scientific's trial, they just completed it -- they failed -- was 1,600 patients. I think my early TAVR trial was probably around 1,000. So 15 is a very -- it's a very small number. But it's an early feasibility study. This is basically, like, doing first-in-man research, trying to demonstrate proof of concept.

Q. Okay. And then if you go down, it says, "We have good feedback from the FDA on our pivotal trial and hope to initiate in May of this year."

Do you see that?

A. I do.

Q. So at this point, they had not entered into a pivotal trial; is that correct?

A. They had not, and they did not have an IDE approval either.

Q. And then, if you turn to the last paragraph, there's a reference to 34 millimeters. I won't read the whole thing. But do you see it? It says 34 millimeters in the next paragraph?

A. I do.

Q. Can you just explain what that's a reference to?

A. Yeah. This whole sentence is about patients that they believe they can treat that JenaValve can't treat. The first is a reference to horizontal aortas. There's questions about whether Jena can treat patients with a certain anatomical aorta positioning.

But the second part is that they have a 34-millimeter valve, which is much larger than anything Jena has, and so they can treat patients outside of the range that Jena can treat.

Q. Okay. So --

MR. SHORES: You can take this document down.

BY MR. SHORES:

Q. So Mr. Wood, did you also agree to acquire JC Medical in

July of 2024 along with JenaValve?
A. Edwards agreed to, yes.
Q. Edwards. And at the time, did you believe that Edwards had bought the market for TAVR-AR?
A. There is no market.
Q. Did you believe that Edwards had bought all of the competitors for TAVR-AR?
A. Absolutely not.
Q. Did you tell anybody on your team, "Hey, guys, we bought the TAVR market"?
A. I told them the exact opposite.
Q. Do you remember the two pies -- the slide showed with the two pies?
A. I do.
Q. Is there more pie out there, Mr. Wood?
A. There's a lot more pie.
Q. Let's look what you actually did tell your team. Let's look at D-X-114. So Mr. Wood, this is an email from May of 2024 sent at 9:22 p.m. Do you see that?
A. I do.
Q. So you're working late?
A. That was pretty normal, but yeah.
Q. And who are the people in the "to" line?
A. The majority of my leadership team.
Q. So this was -- when you say "my leadership team," what

are you referring to?

A. The THV leadership team.

Q. Okay. And --

MR. SHORES: Could you zoom out on the email, please, sir?

BY MR. SHORES:

Q. This is a long email, Mr. Wood?

A. It is.

Q. Did you put thought into this email?

A. I did.

Q. Okay.

MR. SHORES: If we could go down to the paragraph that starts, "The challenges with X4." Thank you.

BY MR. SHORES:

Q. And I want to start with the language "When we make these acquisitions."

Do you see that?

A. I do.

Q. It says, "When we make these acquisitions, it will be a massive signal to the world that the leader in THV thinks AR is an enormous opportunity."

Do you see that?

A. I do.

Q. What do you mean by that?

A. Well, I mean, JenaValve had been sitting out there for a

long time, and I think everyone had looked at it and no one had made the decision to acquire it. You know, Mark was trying to unload JC Medical to anybody who would take it and get any money back for that that he could. So clearly, a lot of people didn't believe that AR was a big opportunity.

Once Edwards, as we were the leaders in transcatheter AS -- once we decided that we were going to acquire these, it would be sending a signal to everyone, all the competitors, that we believe AR is a meaningful opportunity.

Q. Let me just ask you this, Mr. Wood. And, I'm sorry, I should have asked you this before. You talked about your market share in AS. Do you remember that?

A. I do.

Q. How have you maintained that market share?

A. We've out-innovated everyone and stayed ahead on technology, and then we backed it up by having the best clinical trials and the most extensive evidence that shows our product is better than anyone else's.

Q. Returning to the email, sir, it says, "Last time they all waited on the sideline to see if THV was real. They will not make that mistake again."

Do you see that?

A. I do.

Q. What does that mean?

A. Well, you had Johnson & Johnson, Medtronic, and Boston, who were all on the board of PVT. They let Edwards buy it. They said it's too early, it's too risky. And we innovated it. And then once we demonstrated that it really was a real opportunity, then they've all been trying to play catch-up ever since. And they gave us a big lead. They're not going to make that mistake again. They're -- now that they know it's a big opportunity, they're going to turn on their innovation engines and try to do everything they can to catch us or pass us.

Q. And the next sentence says, "They will race to be number two and try to attain leadership."

Is that what you were just referring to, Mr. Wood?

A. Yes.

Q. All right. And you say, "It will be a competition with multiple players."

Is that your belief, sitting here today, sir?

A. 100 percent.

Q. And then it says, "If we don't move at best speed, we will waste the first mover advantage and this all will be for nothing."

Do you see that?

A. I do.

Q. What do you mean by best speed?

A. If we don't take risks and move quickly and keep our

team incredibly driven on this, we will lose the first mover advantage because this is going to attract a lot of other sharks, and if we spend all this money on these acquisitions and we're not first and we're not leaders, that would be bad.

Q. And does best speed have anything to do with innovation?

A. It has everything to do with innovation.

Q. Why do you say that?

A. Well, it's always making sure that you're having the best device, but even when problems come up, you know, you have to be able to attack those problems quickly and iterate your device and move very quickly so that you stay ahead. If every time you had an issue or had a bad case, you paused for six months, other companies are going to move at a pace faster than you and they're going to pass you and then they're going to be in first. So we have to keep the team very driven and very focused to keep it moving.

Q. Okay. And, Mr. Wood, just, again, to frame our timing here, this email is from May of 2024; is that right?

A. That's correct.

Q. Okay. I want to go to the next month. And let's look at D-X-118. All right. And this is an email chain from June of -- June 13th, 2024, between yourself and Pooja Sharma. Do you see that?

A. I do.

Q. Who's Pooja Sharma?
A. She was my head of strategy and marketing.
Q. Okay. And I want to go down to the last paragraph here, the next to last one. It starts, "The two critical things."
Do you see that?
A. Yes.
Q. Okay. And then there's a sentence that says, "How do we get AR moving on a path to $500 million within the plan horizon" --
A. I do.
Q. -- do you see that? What did you mean by that?
A. Well, how do we get, you know -- during a plan horizon -- this was when we were doing the strategy planning process, so it was, sort of, in the next five to seven years. How do we get AR commercially approved and on a pathway to $500 million of revenue within that plan horizon?
Q. Okay. And your next sentence says, "How do we defend against increasing competition from all sides?"
Do you see that?
A. I do.
Q. Why were you asking Ms. Sharma that in June of 2024?
A. Well, because I believe there's going to be multiple competitors coming. And so how do we stay ahead from innovation and clinical evidence against all these competitors that are going to be showing up?

Q. Mr. Wood, both of these emails that we just went through, they were before Edwards acquired these companies; is that right?
A. Yes.
Q. Okay.
A. That's true.
Q. Mr. Wood, I want to talk a little bit about the competition. And I want to go to, actually, the document that counsel showed you on your original examination. Is that okay?
A. Sure.
Q. Okay. And that's D-X-228. All right. And this is "Competitive Clinical Trials." Do you see that?
A. I do.
Q. All right. And it says April 2025?
A. Yes.
Q. Does Edwards create more of these competitive clinical trials?
A. Yes. I think these are done probably quarterly.
Q. All right. And you have your team do these?
A. Patrick is also on the -- is actually on the clinical team working for Jamie, but yeah, my team would work on these.
Q. Okay. Thank you for that clarification. So this actually goes to the people doing the innovation and

research at Edwards; is that right?
A. The clinical team is the group that monitors it, but they send it out to the broad leadership team.
Q. Okay. And look under, if you could with me, "Aortic." Do you see that in this email?
A. I do.
Q. All right. And I'm looking at a reference to -- the first one says FPI EFS. Do you see that?
A. I do.
Q. Why are you tracking companies in the EFS stage?
A. Anybody who's -- anybody who has a device, no matter how early stage it is, is a potential competitor over the long run.
Q. And I also see down in here, the last bullet has FIH. Do you see that?
A. Yes.
Q. What is FIH?
A. First-in-human.
Q. So do you track companies that are first-in-human, doing their first-in-human studies?
A. Yes.
Q. Why?
A. We track anybody that we're aware of anywhere because any of these things can be disruptive.
Q. Above that, you see the reference to Canada?

A. Yes.
Q. And there's a reference to China?
A. Yes.
Q. Do you track companies' development efforts in other countries?
A. We track anybody on the globe. Anything that we're aware of, we try to track.
Q. And are you always aware of what development efforts are going on?
A. No.
Q. Why not?
A. Well, because development is confidential. And even doing an IDE is confidential. There's no requirement to publicly disclose those things. And so companies can keep things in secret for a long time.
Q. So these are just -- just to be clear, these are just the development efforts you even know about?
A. That's correct. Abbott, for example, just announced that they have a balloon-expandable TAVR that they're going to move into a pivotal clinical trial, I think, this year. And we had no idea that it was under development. And they presented, like, their first seven patients earlier this year.
Q. Okay. Mr. Wood, I'd like to look at some of the slides. And actually, let's look at the same slides you were shown

previously.

MR. SHORES: Could we pull up Slides 8 and 9?

BY MR. SHORES:

Q. And these are the other TAVR players. Do you see that, Mr. Wood?

A. I do.

Q. And there's a column that says "Features."

A. Yes.

Q. Why does Edwards track the features of other devices?

A. Well, we're trying to see how they're going to try to differentiate themselves. And then we always want to know, how do we compete based on what their perceived differentiation strategy is?

Q. Okay. And let's look at a couple of these. So let's look at Hanchor. Do you see that? It's at the bottom on the left-hand side.

A. I do.

Q. All right. And then there is a "Study" section. Do you see that?

A. I do.

Q. And just to orient us, if you look, there's an N equals in a couple of places there. Do you see that? N equals 128?

A. I do.

Q. Can you explain for the Court what the N means?

A. That's the sample size of their clinical trial. So that's the number of patients they treated in that clinical trial.

Q. Okay. And they have a -- so they did 128; is that right?

A. 128. And then something else down below for another 27. So their total experience would be in the 150s.

Q. Okay. And then let's go over to Ken-Valve on the next slide. And under "Studies," do you see their N number?

A. I do.

Q. What is that?

A. That's the number of patients they treated in that study.

Q. All right. And let's go down to MicroPort. Do you see that?

A. I do.

Q. All right. And what is their -- what is the number of patients that they have treated in their study?

A. 120 in the top, and then another 100 in the one below that.

Q. So just stepping back for a second, how do these numbers compare to the number of patients that J-Valve had treated when you acquired J-Valve?

A. These are all more.

Q. Did these companies have more clinical data, according

to this chart, than JC Medical had when Edwards acquired JC Medical?

A. Yeah, I think JC had about 15 patients in their EFS trial and they had another, I don't know, maybe, 15 or 20 that they had done compassionate use, if memory serves. So their experience would have been in the 30s. And these have much larger experiences, many of them.

Q. Mr. Wood, what does the term "IDE" mean?

A. Investigational device exemption. It's what you have to have before you can put a nonapproved device in a human in the United States.

Q. And how difficult is it to get an IDE for, let's say, an EFS study in the United States?

A. Actually, FDA has made that process much simpler. It used to be more difficult. But FDA went on a very dedicated path to try to bring early research back to the United States. So they've actually made it quite easy for people to get EFS IDEs approved in the U.S. to do research here.

Q. Have you ever gotten a device approved that you've worked on while [sic] your time at Edwards without getting and an IDE?

A. Yes.

Q. And can you explain that?

A. Yeah. I had a surgical heart valve, our mitral pericardial valve, model 6900, and I was able to take data

from France and from Canada and we were able to put it together and submit it to FDA and get an approval even though we had never done an IDE or studied that valve in the United States.

Q. Mr. Wood, I'd like to transition and talk about your plans for the -- for Sojourn and Trilogy. And, again, from your time when you were at Edwards. Okay?

A. Okay.

Q. All right. Let's introduce D-X-116. And, Mr. Wood, this is an email from May 31st of 2024 at 2:37 p.m. Do you see that?

A. I do.

Q. And it's to Don Bobo, Bernard Zovighian, and others. Do you see that?

A. I do.

Q. Are they important people at Edwards?

A. Well, Bernard was my boss, so he was certainly important. But Don is a colleague who ran strategy. So yes.

Q. Okay. And the title of this email is, "TAVR strat plan portfolio."

Do you see that subject matter?

A. I do.

Q. All right. And there's an AR down this email. Do you see that?

A. I do.
Q. And does this reflect your thoughts on what would happen with respect to the platforms that you were acquiring upon the acquisition?
A. Yeah. There's still a lot of work to be done regarding how these two platforms fit together. We don't know how complementary they are, and we know JC has larger sizes; Jena has smaller sizes. So what would we need to treat the entire market was still unknown.
Q. Okay. And -- but you did -- did you have any plans with respect to these two platforms?
A. Yeah, yeah. We -- well, I mean, JC, we, you know -- once we acquired it, we could implement all of the plans. I mean, this was before the acquisition, but once we acquired it, we could implement everything. Jena, we had to wait until the acquisition closed before we could implement, but we had plans and we had designated people that would be ready to go once the acquisition closed.
Q. And can you just describe for the Court, who are some of those people that were going to be ready to go?
A. Well, we had people in manufacturing and ops. We had identified, I think, Andrew Walls to be the heavyweight team leader for the operations side of it. But we had R&D people that -- a lot of the same people that worked on the diligence would have been the same people that would have

been expected to go in once we closed the acquisition.

Q. And I want to go down under AR, and No. 1 says, "The first priority would be to shore up the Jena platform and bring it to the U.S. as quickly as possible."

Do you see that?

A. I do.

Q. What does that mean?

A. That means the, you know -- we thought that FDA approval would be imminent, and so, if it was imminent, we wanted to be able to bring that product to market as quickly as possible.

Q. And the next sentence says, "This will be a heavy operations and R&D lift."

Do you see that?

A. I do.

Q. And what does that mean?

A. Well, we know that they can't manufacture it in volume, and we know their manufacturing costs are very high. So we needed to get our operations people in there -- and it was probably going to take people from R&D as well -- to figure out, how do we make this device more manufacturable, how do we improve yields, how can we produce this thing at scale, and how can we produce it at a better cost structure?

Q. And would that happen immediately upon the acquisition's closing?

A. I expect the day after the acquisition, we would have sent a team of people in.

Q. No. 2 says "Make the JenaValve [sic] manufacturable and reduce the prep and improve margins."

Do you see that?

A. I do.

Q. What does that mean?

A. Well, right now, to prep a JenaValve in the clinic, in the cath lab, takes two engineers, and it's a very tedious process which -- that, in and of itself, would not be scalable. And so we needed to figure out how to make that -- the prep in the cath lab much simpler, but then also improving the cost structure of the product.

Q. Okay. And --

MR. SHORES: I'm going to wait until closed session on that, Your Honor. I withdraw.

Can we go down to 3, please.

BY MR. SHORES:

Q. It says, "Decide on what the true Gen 2 product looks like."

Do you see that?

A. I do.

Q. All right. And if you go further down, it says, "The optimal device may be a combination of the two concepts."

Do you see that?

A. I do.
Q. Why do you say it may be a combination of the two concepts?
A. Well, I mean, the answer's a little bit up above. You know, we, kind of, knew what Trilogy was, and it's run its clinical trial. So we know what issues it has and what we would need to improve on.

JC has larger valve sizes. So we know that's something that would be important that we would need. But the clinical experience is so short and the delivery system is crude. So I don't really know what I have in either product at this point, because neither one of them's reached that FDA approval milestone yet.
Q. And what would you want to know if this transaction closed about JenaValve in order to develop your strategy of next-generation development?
A. Well, I mean, I have to know that it can pass all of the required compendium testing. And I also have to know that I can manufacture it at scale and get yields improved and do all those things that have to be done. But it also has things like a high pacemaker rate and other things that would need to be improved, I believe, to expand indications.
Q. All right.

MR. SHORES: You can take that document down and let's pull up D-X-0160.

BY MR. SHORES:

Q. And this is a September 11, 2024, Board of Directors strategy session that you presented, Mr. Wood; is that right?

A. That's correct.

Q. So you presented this to the Board of Directors?

A. I did.

Q. Okay. Let's turn to Slide 28. And then at the -- it says -- there's aortic regurgitation portfolio strategy. Do you see that?

A. I do.

Q. And under that it says, "Speed to market. Bring Gen 1 JenaValve Trilogy to U.S. market ASAP."

Do you see that?

A. I do.

Q. Okay. So you presented that to the Board of Directors?

A. I did.

Q. And what was their reaction?

A. I think they were, overall, supportive of the entire AR strategy and plan.

Q. Okay. And were you confident you'd be able to get the resources in order to effectuate the plans that you set out to the board?

A. Absolutely.

Q. All right. Let's turn to Slide 27. This slide is

entitled, "As the pioneers and global leaders in TAVR, we are best positioned to bring these technologies to patients in a high-quality way."

Do you see that?

A. I do.

Q. And then below that it says, "Now the hard work begins."

Do you see that?

A. Yes.

Q. What did you mean by that?

A. Well, I mean, you have a company in JenaValve that we know has a number of problems that have to be corrected before we could make it commercially successful, and it still didn't have its FDA approval so there was going to be heavy lifting that had to be done there. But JC Medical is very early stage with a crude delivery system and, you know, we were going to have to get that through a clinical trial successfully and get it on a pathway to approval. So you know, the acquisition's the easy part. The hard part is making these things real.

Q. And the next part down says, "We expect this journey to be like TAVR-AS."

In what way?

A. Well, it's going to be a combination of technology iteration, clinical evidence, and then training. The other part about this is you can have a great device, but if you

don't train your doctors on how to use it properly and they make mistakes or they have problems because they're not properly educated, you can kill a market before it even gets started.

So you know, one of the big successes of the transcatheter valve journey is we invested so heavily in training that everybody -- you know, people had great results. And we had a national registry where the results were all tracked. And the fact that the commercial data was actually better in many ways than the clinical trial data was a testament to that training investment and success of that program.

Q. And then there's, looks like, six valves listed here next to "We expect this journey to be like AS"?

A. Yes.

Q. And why picture those valves?

A. Well, this is the iteration process. Each one of these reflects a meaningful innovation over the previous generation that either improved outcomes or expanded indications or both.

Q. And could you tell, when the SAPIEN device first came on the market, what SAPIEN X4 would be like, Mr. Wood?

A. No. I don't think the Wright brothers knew what a 747 was going to look like either. I think you -- it's through the learning process you figure out where the weaknesses of

your device are that you try to correct with the next generation of the device. And you can't fix everything, but you fix as many things as you can to try to bring a next iteration as quickly as you can.

MR. SHORES: All right. Your Honor, I'm going to transition to some questions that I think should be in closed session. So I'd ask, respectfully, if we could clear the courtroom at this time.

THE COURT: Okay. We'll clear the courtroom and take a 10-minute break.

MR. SHORES: Thank you.

(Brief recess taken.)

MR. SHORES: Thank you, Your Honor. May I just confirm nobody else but counsel is here in the courtroom.

THE COURT: Sure.

(Brief pause.)

(Following proceedings under seal:)

[redacted]











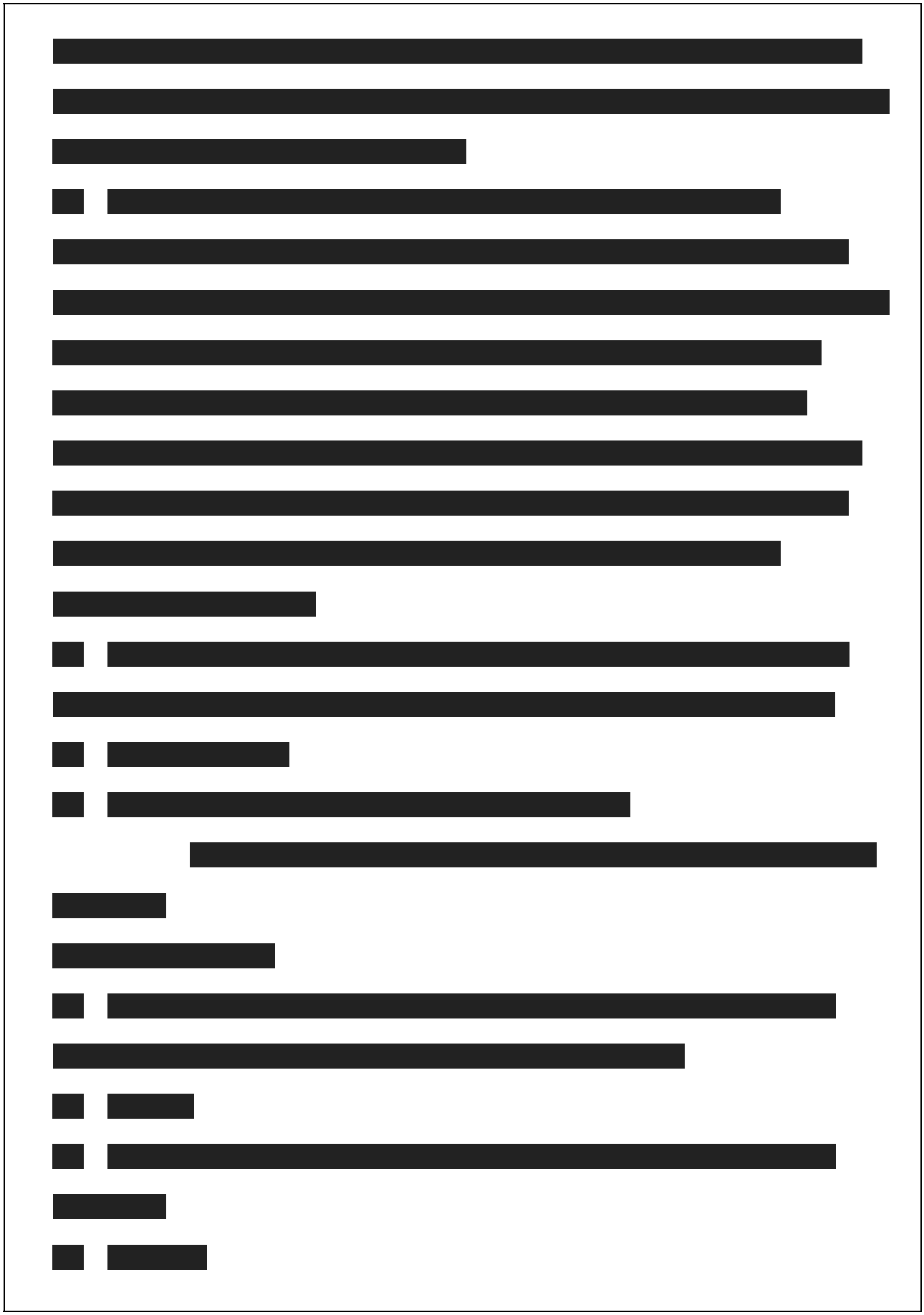



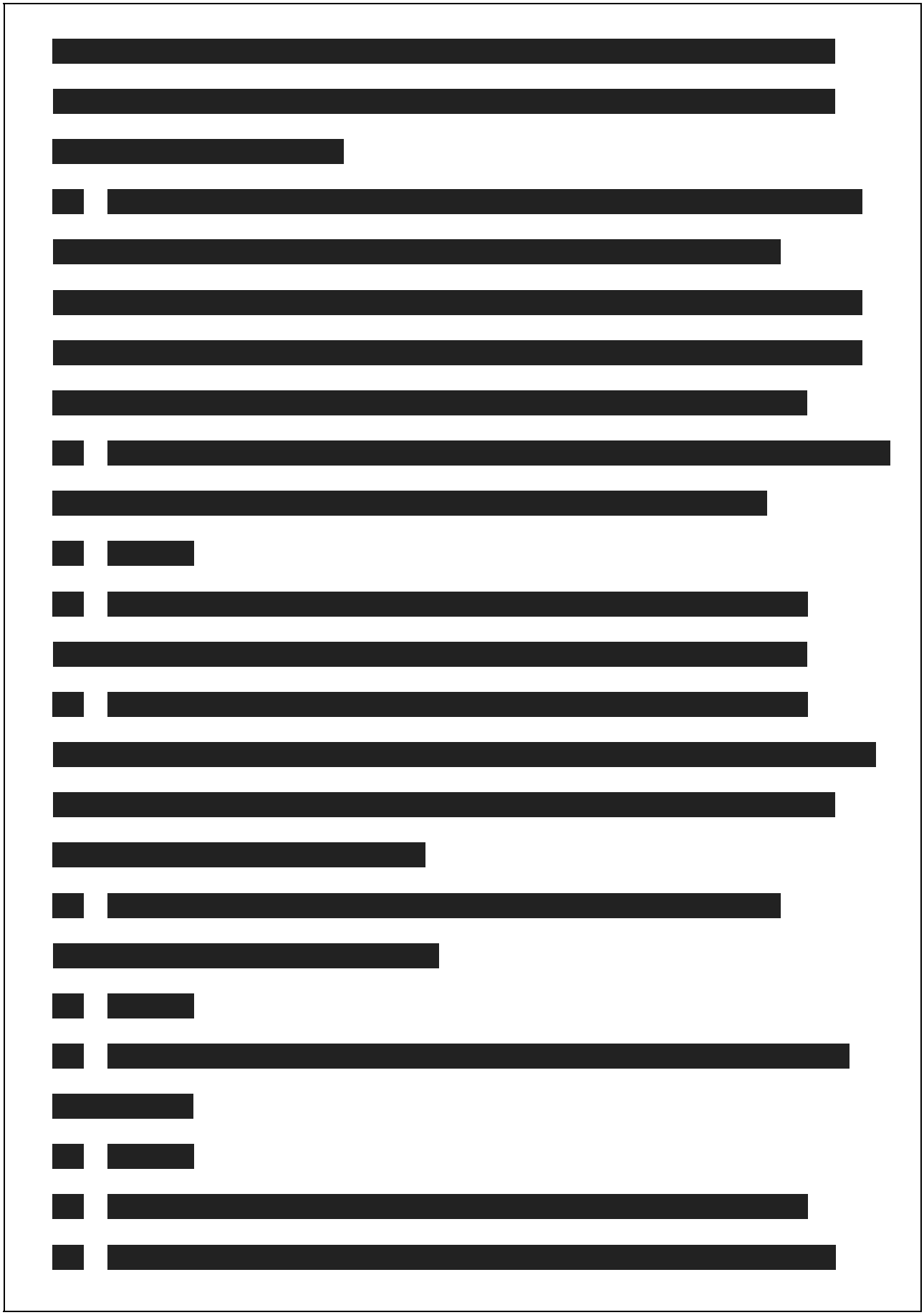









[redacted]

(Following proceedings in open court:)

BY MR. SHAW:

Q. Mr. Wood, you mentioned earlier in your testimony with Mr. Shores, sort of, the revolutionary nature of TAVR in the early 2000s. Do you remember that?

A. I do.

Q. It's fair to say, though, that TAVR's not a new

technology anymore; isn't it?
A. Well, it's not new in terms of a timeline, but people still struggle to enter the space.
Q. But interventional cardiologists are aware of TAVR; right?
A. Yes.
Q. In fact, I think you mentioned that they're asking for it for aortic regurgitation, isn't that right?
A. They are.
Q. Thank you.
Let's look at D-X-114 which Mr. Shores showed you. And I just want to establish a timeline here. So discussions between Edwards and JC Medical, I think you testified, started in February of 2024; is that right?
A. Whatever the date of that email was, yeah, I believe that was February.
Q. And is it fair to say that they were fairly advanced by April of 2024?
A. I actually wouldn't know. Once I turned it over to Don, Don would have handled the negotiations and I wouldn't have known how close we were getting in April.
Q. So Mr. Bobo would be the most knowledgeable person about the state of those negotiations?
A. He'd be the most knowledgeable person about those discussions, yes.

Q. All right. And I think you testified that you -- Edwards had been discussing with JenaValve even going back to 2023; is that right?
A. We -- I think we got -- I got interested in JenaValve in 2023 when I saw the data at TCT and I spoke to clinicians at TCT.
Q. And JenaValve and Edwards had a signed letter of intent by May 21st of 2024; isn't that right?
A. I don't know when they signed everything. Again, once we turn it over to Don, Don runs those things in a silo and keeps the rest of us pretty much out of it.
Q. But that letter of intent would have been signed before you sent this email on May 24th, 2024; isn't that right?
A. Again, I don't know when the letter of intent was signed. So if that's when the letter of intent was signed, this would have been the date that I was sent this message.
Q. And by the time a letter of intent has been signed, Edwards's lawyers would have been involved; isn't that right?
A. Again, I'm not involved in that part of the process.
Q. I finally would like to look at D-X-160. And Mr. Shore showed you -- I think it was Slide 28. Do you remember looking at that?
A. I do.
Q. And Slide 28 --

THE DEPUTY CLERK: Counsel, this is to be shown to the --

MR. SHAW: Yes, this is not, to my knowledge --

Mr. Shores, Slide 28 is not marked --

MR. SHORES: No, no, it's not. Thank you.

BY MR. SHAW:

Q. And so there's -- this is the aortic regurgitation portfolio strategy; right?

A. That's correct.

Q. And so one is speed to market; right?

A. Yes.

Q. Two is expand portfolio options for patients; right?

A. That's correct.

Q. And then the third is design for durable leadership; right?

A. That's correct.

Q. And durable leadership means leading the market; right?

A. Yeah, you want to lead for a long time.

Q. And leading the market means having the highest market share; right?

A. It means having the best product which gives you the highest market share.

Q. And Edwards does plan to be the market leader; right?

A. We strive to have the best product and, therefore, be the market leader.

Q. And in TAVR-AS, Edwards has durable leadership, isn't that right?

A. We've had the best product which has led to the highest market share.

MR. SHAW: All right. No further questions.

THE COURT: Thank you.

(Witness steps down.)

MR. SHORES: Thank you, Mr. Wood.

MS. HALL: Your Honor, the FTC's next witness will be Mr. Larkin. So we've just gone to collect him.

(Brief pause.)

MR. DANZIGER: Your Honor, Jacob Danziger on behalf of the plaintiff Federal Trade Commission. The Federal Trade Commission would like to call Gregory Larkin to the stand. Mr. Larkin is represented by Jennifer Milici, his outside counsel from Wilmer Hale, as well as Peter Levitas, in-house counsel for Medtronic.

GREGORY LARKIN, WITNESS FOR THE PLAINTIFF, SWORN

DIRECT EXAMINATION

BY MR. DANZIGER:

Q. Good afternoon, Mr. Larkin.

A. Good afternoon.

Q. Can you please tell the Court where you work?

A. I work at Medtronic.

Q. Before I ask any further questions, I want to note that

we are currently in public session of your testimony. There will be a separate in camera session that will not be open to the public. For this session, I've tried to prepare questions that do not require you to reveal sensitive or confidential information. That said, if you feel like you cannot answer a question because it will reveal confidential information, please let me know and I will try to revisit it in sealed session or ask the question differently. Is that all right?

A. Okay.

Q. Great. What is your current title?

A. My current title is vice president of business development and strategy for the cardiovascular portfolio.

Q. And how long have you been in that role?

A. About a year-and-a-half.

Q. And at a high level, can you describe your responsibilities in your current role.

A. Sure. Me and my team are charged with evaluating the inorganic landscape and strategy for Medtronics. That includes acquisitions and investments in places that we would be interested in acquiring companies.

Q. And is that in a particular division within Medtronic?

A. Yeah, strictly within our cardiovascular group.

Q. Okay. And can you briefly describe Medtronic for the Court?

A. Sure. Medtronic is a medical device manufacturer. We have a long history in developing and creating markets. Started with the introduction of a battery-powered pacemaker through our founder back in the '50s. And we've continued to grow the company over time and serve medical technology needs across multiple therapies.

Q. Does Medtronic have a structural heart division?

A. We do.

Q. And does Medtronic have expertise in developing and commercializing medical devices for the United States?

A. Yes, we do.

Q. Does Medtronic have expertise in achieving FDA approval for medical devices in the United States?

A. We do.

Q. Are you familiar with accelerated wear testing, also referred to as AWT?

A. Yes, I am.

Q. Does Medtronic have expertise in the FDA's AWT requirements for medical devices?

A. We do.

Q. Mr. Larkin, I'd like to talk about transcatheter aortic replacements for aortic stenosis. It's commonly referred to as TAVR-AS; is that right?

A. Okay.

Q. Are you familiar with companies that develop,

manufacture, or sell TAVR-AS valves?
A. I am.
Q. Is Medtronic active in the TAVR-AS space?
A. Yes, we are.
Q. Does Medtronic sell a TAVR-AS valve called Evolut?
A. We do.
Q. Could you describe the Evolut valve?
A. The Evolut valve is a transcatheter aortic valve designed to treat patients with aortic stenosis. The valve is made out of a material called nitinol with porcine pericardial tissue. It's introduced into the femoral artery, navigated to the heart, and then deployed to the takeover function of the patient's native aortic valve, the diseased aortic valve. Yeah.
Q. And did Medtronic's Evolut valve originate from an acquisition?
A. It did.
Q. Which acquisition was that?
A. So we acquired a company called CoreValve, and that was the basis for the Evolut technology.
Q. Do you know what year Medtronic acquired CoreValve?
A. We acquired CoreValve in 2009.
Q. And when Medtronic acquired CoreValve, was there already an FDA approved TAVR-AS device?
A. No, there was not.

Q. And when did the Evolut valve ultimately receive FDA approval?
A. So we received FDA approval for our first indication in 2014.
Q. And was Medtronic the first to commercialize a TAVR-AS valve in the United States?
A. No.
Q. Who was first to commercialize?
A. Edwards Lifesciences.
Q. When Medtronic acquired CoreValve, did it acquire a company called Ventor Technologies?
A. Yes, we did.
Q. And what is Ventor Technologies?
A. Ventor Technologies is another developer of a transcatheter aortic valve, based in -- previously based in Israel.
Q. Why did Medtronic acquire Ventor Technologies?
A. So we acquired both Ventor and CoreValve at the same time. At the time, Ventor's product was designed to address the cardiac surgeon. So it was a device that was introduced not through the femoral artery but through the apex of the heart, and that was, you know, more designed for a cardiac surgeon. And then the Evolut -- the CoreValve was for interventional cardiology.
Q. So would these be for two different types of physicians?

A. Correct.
Q. Mr. Larkin, I'd like to discuss the term "fast follower." Are you familiar with the term "fast follower"?
A. Yes.
Q. What is your definition of a fast follower?
A. A fast follower is someone who's not first to a -- to market, but closely -- comes to market closely thereafter.
Q. Were you aware that defendants cited your deposition testimony in their opposition brief?
A. I'm not sure if I follow.
Q. It might help if -- Mr. Larkin, I'm going to quote what is in defendants' -- what defendants have defined as a fast follower. And just for readability, I'm going to put the relevant portion of defendants' public redacted opposition brief on the board so you can see it.
A. Okay.
MR. DANZIGER: Mr. Nguyen, could you put on Page 15 of the public redacted opposition brief.
BY MR. DANZIGER:
Q. So I'm going to direct your attention to the middle of the first full paragraph on that page. Do you see where it says, "These developers are fast followers, waiting for a pioneer such as Edwards to establish the viability of a medical device market before either launching a competing device"?

Did I read that properly?

A. Yes.

Q. Does this align with your definition of a fast follower?

A. It does not.

Q. And I'd note in the cite here, it cites to your deposition in cite -- what looks like 69. Was Medtronic waiting for Edwards to establish the viability of a TAVR-AS -- of TAVR-AS in the United States before commercially launching Evolut in the United States?

A. We weren't waiting for Edwards to establish the viability of the space. We were actively pursuing the space independently, as well. We happened to become -- we happened to be second to market in the United States in a fast follower fashion, but that wasn't a deliberate strategy to say, Edwards, be the pioneer, establish the viability, and then we start any activity.

Q. And when you use the term "fast follower," you're using it in your sense of fast follower, someone who's just second to market?

A. Correct.

Q. Thank you.

MR. DANZIGER: Mr. Nguyen, you can take the document down.

Your Honor, at this point, any further questions I have will cover topics and material that Medtronic has

identified as confidential; therefore, we request that we move to closed session.

THE COURT: Any objection?

MR. SHORES: No objection, Your Honor.

THE COURT: All right. Let's close the courtroom, then. If all the parties can check, make sure that excluded parties are excluded.

(Following proceedings under seal:)

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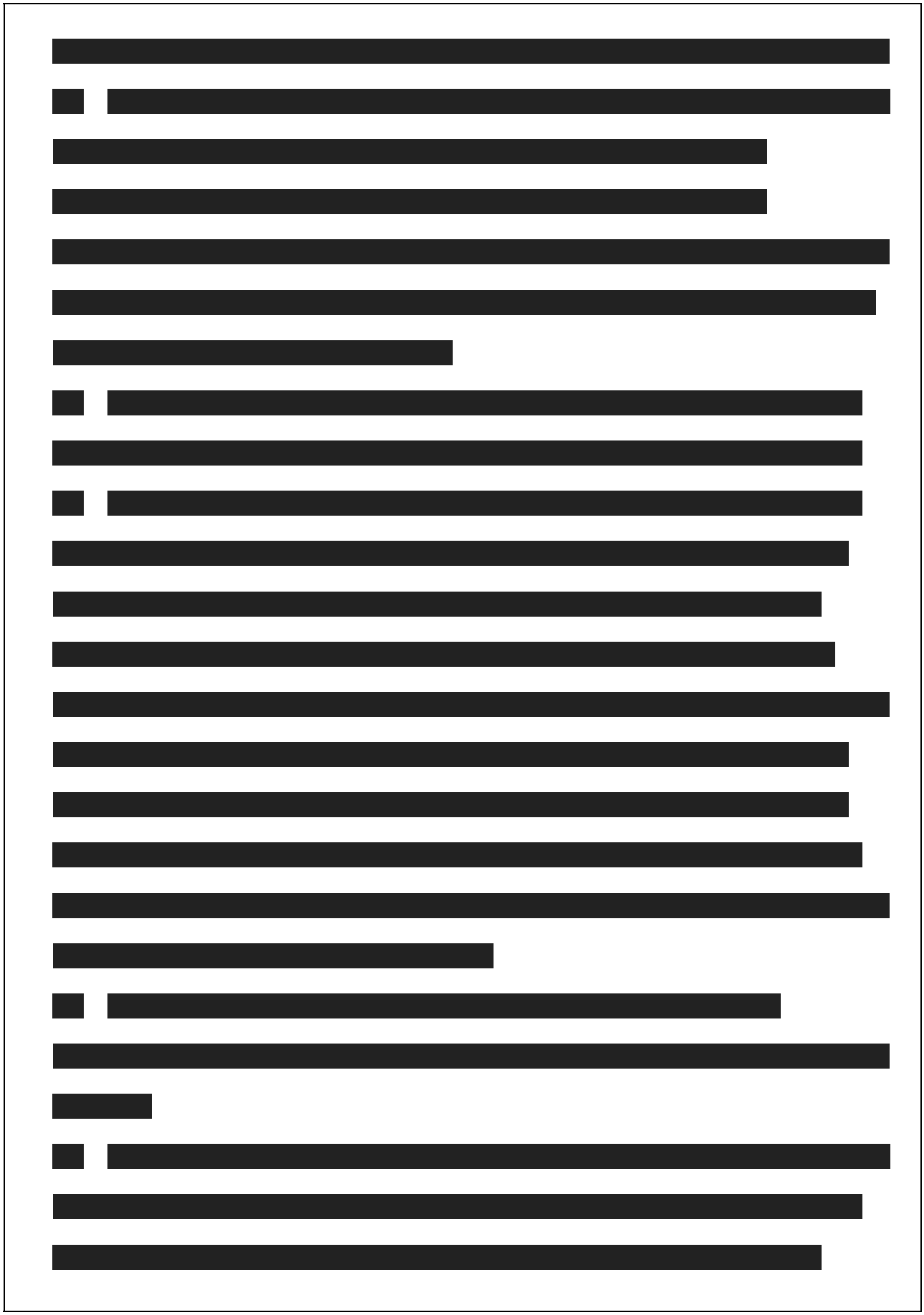



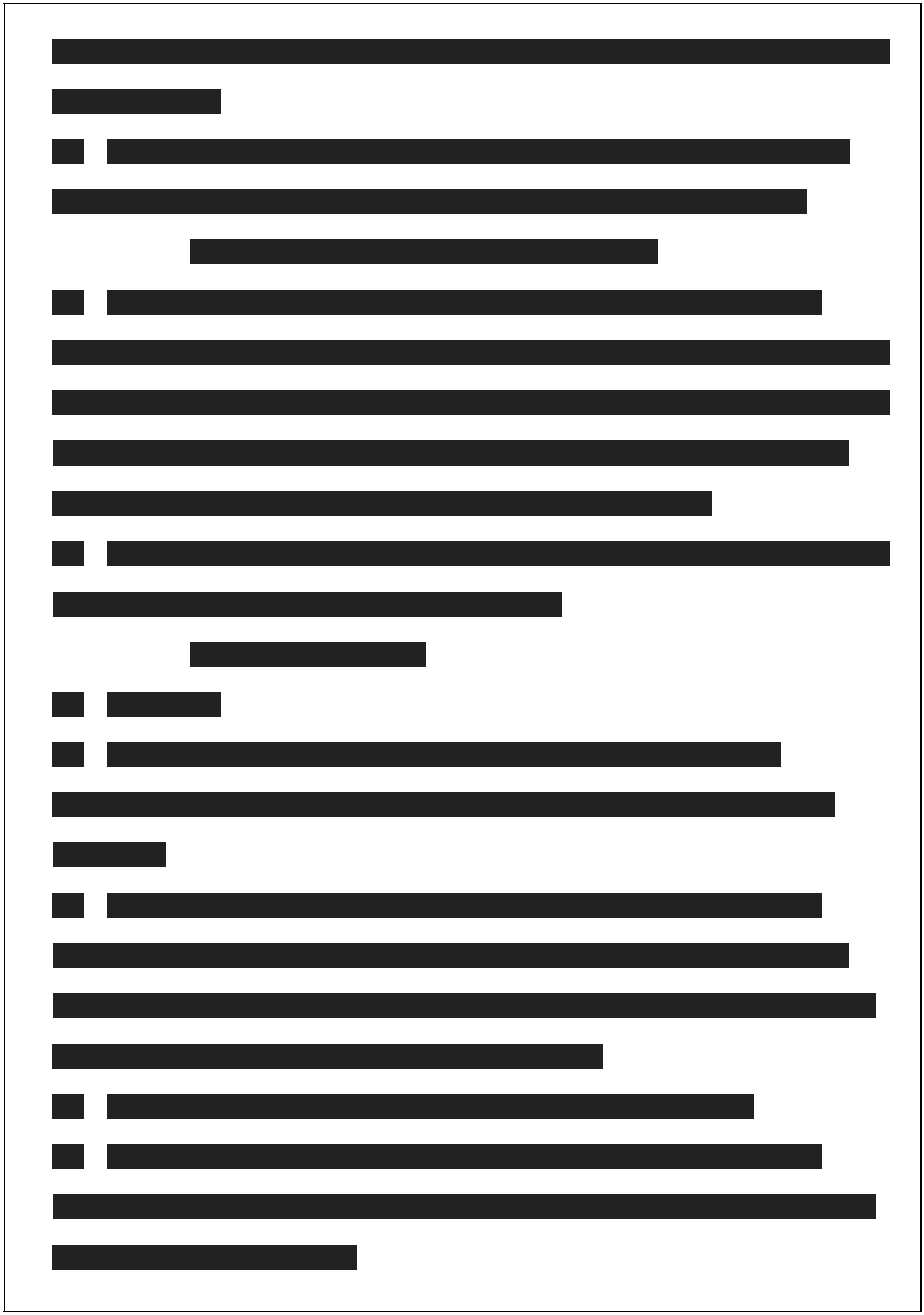

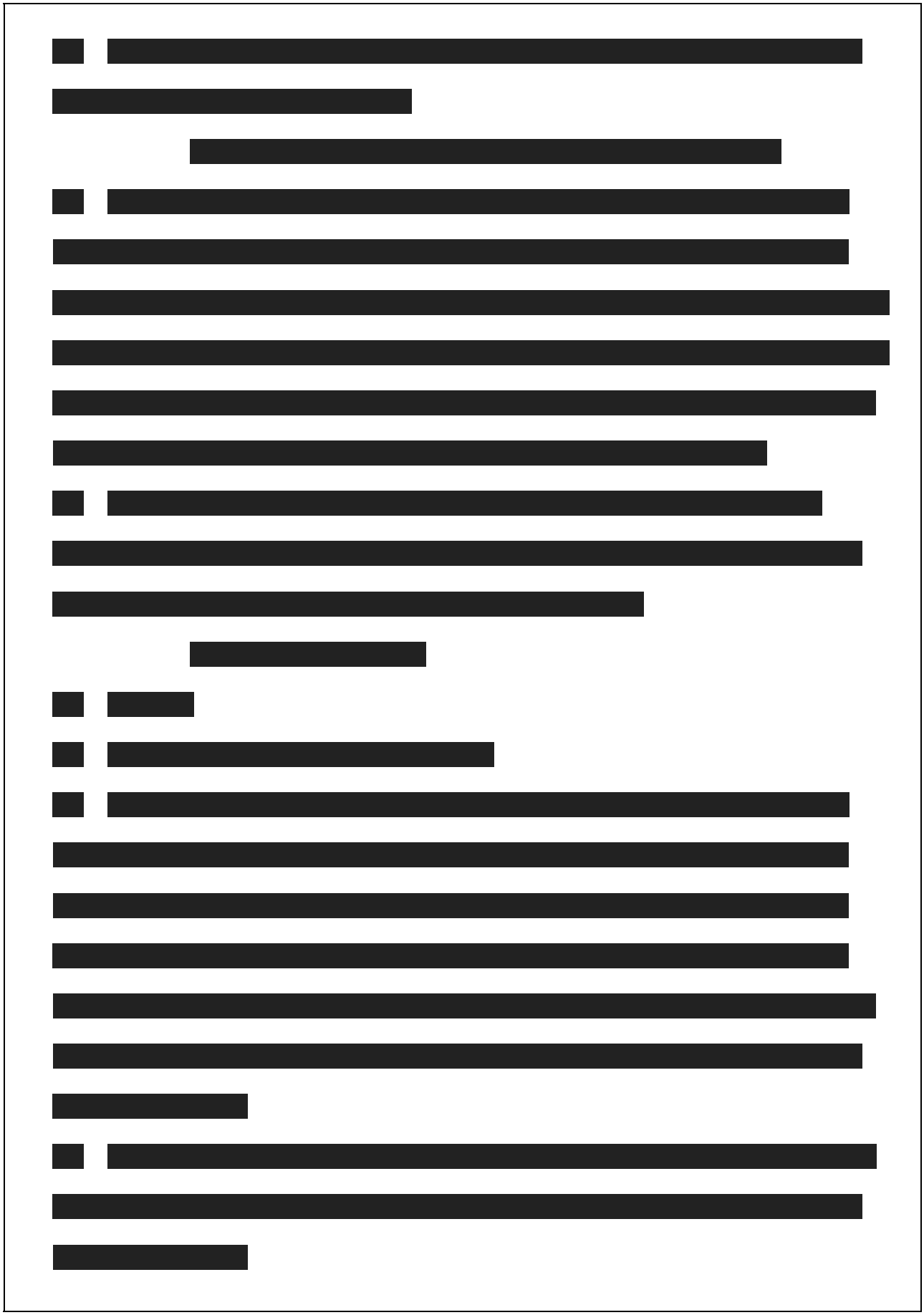





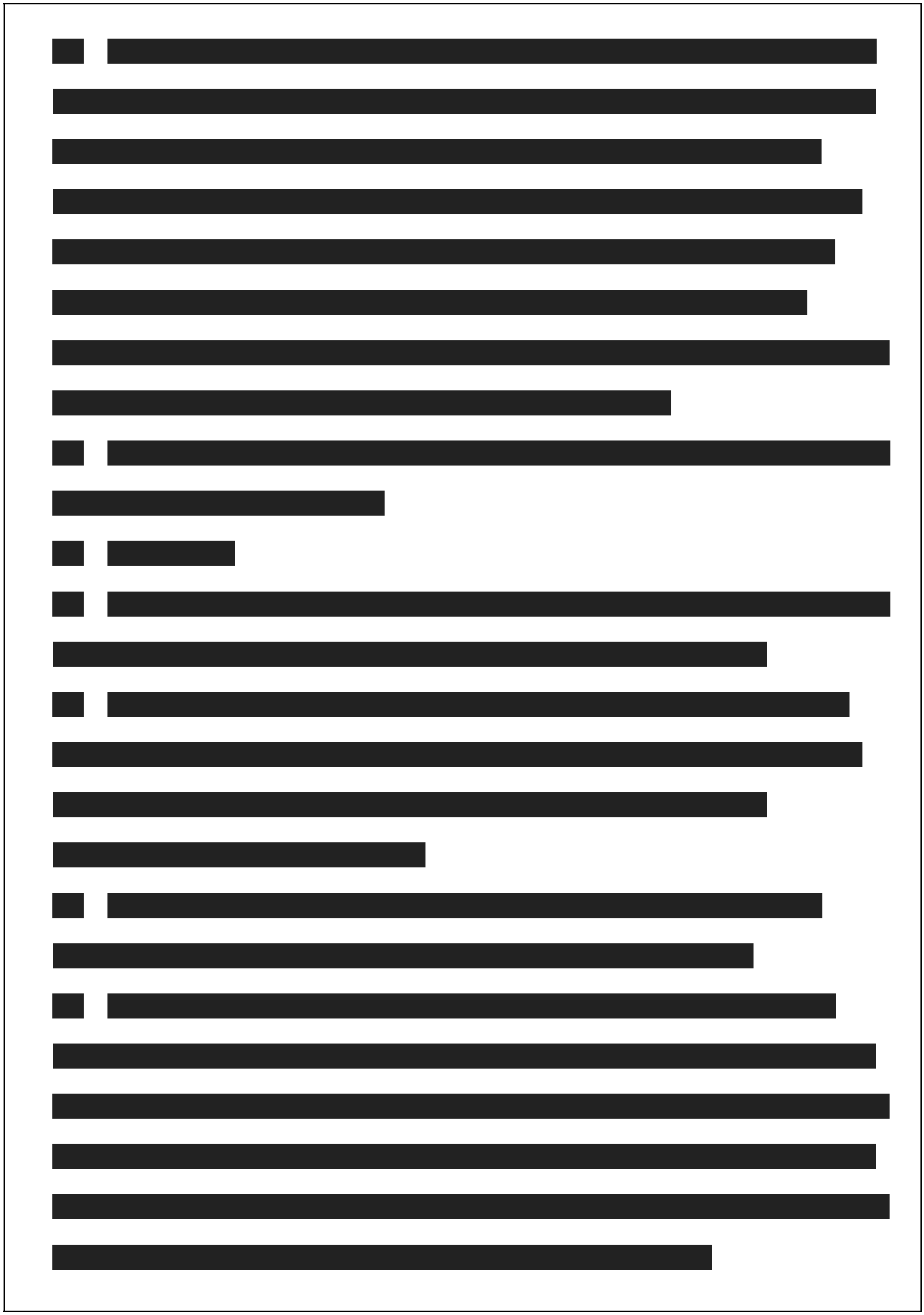



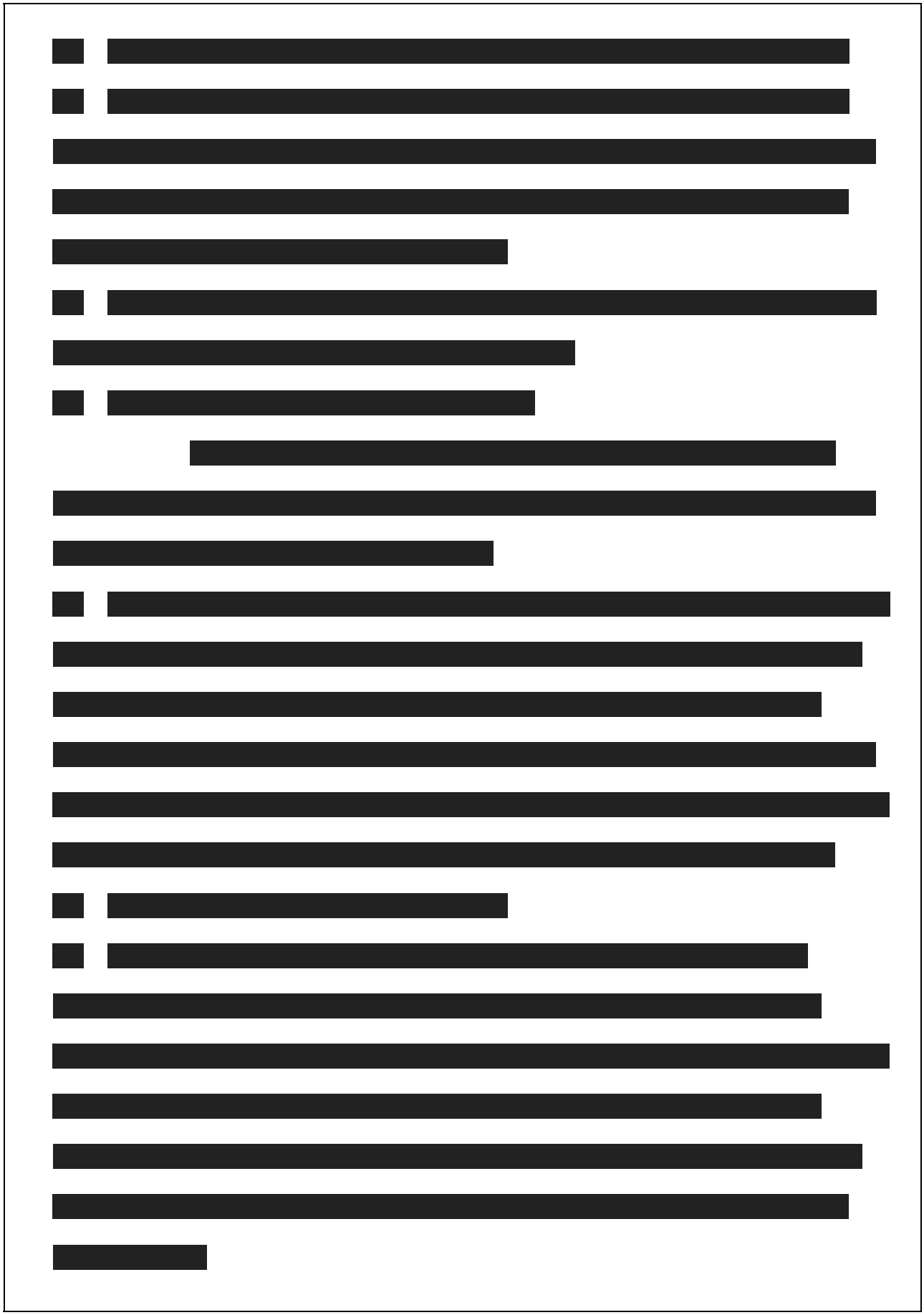



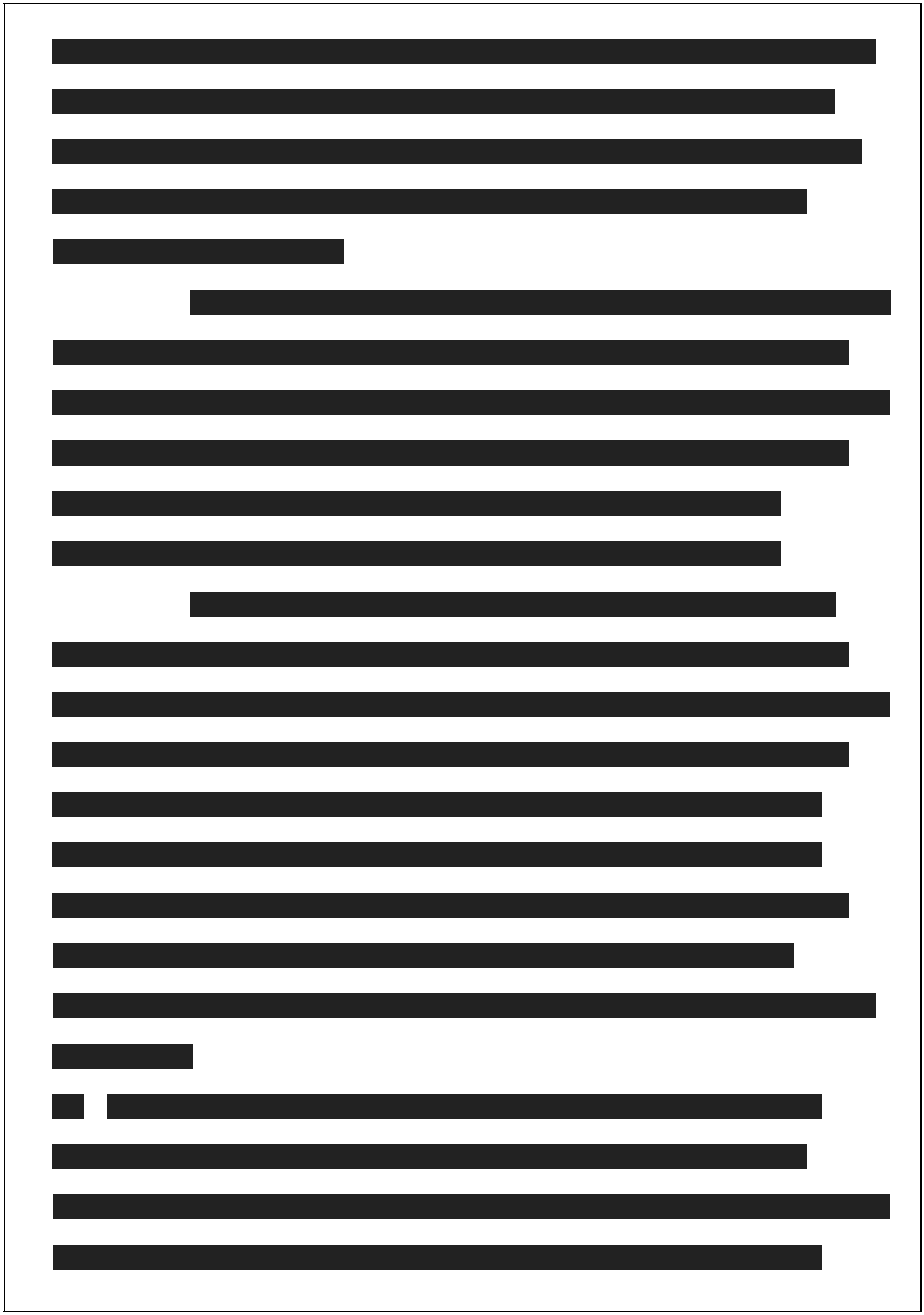







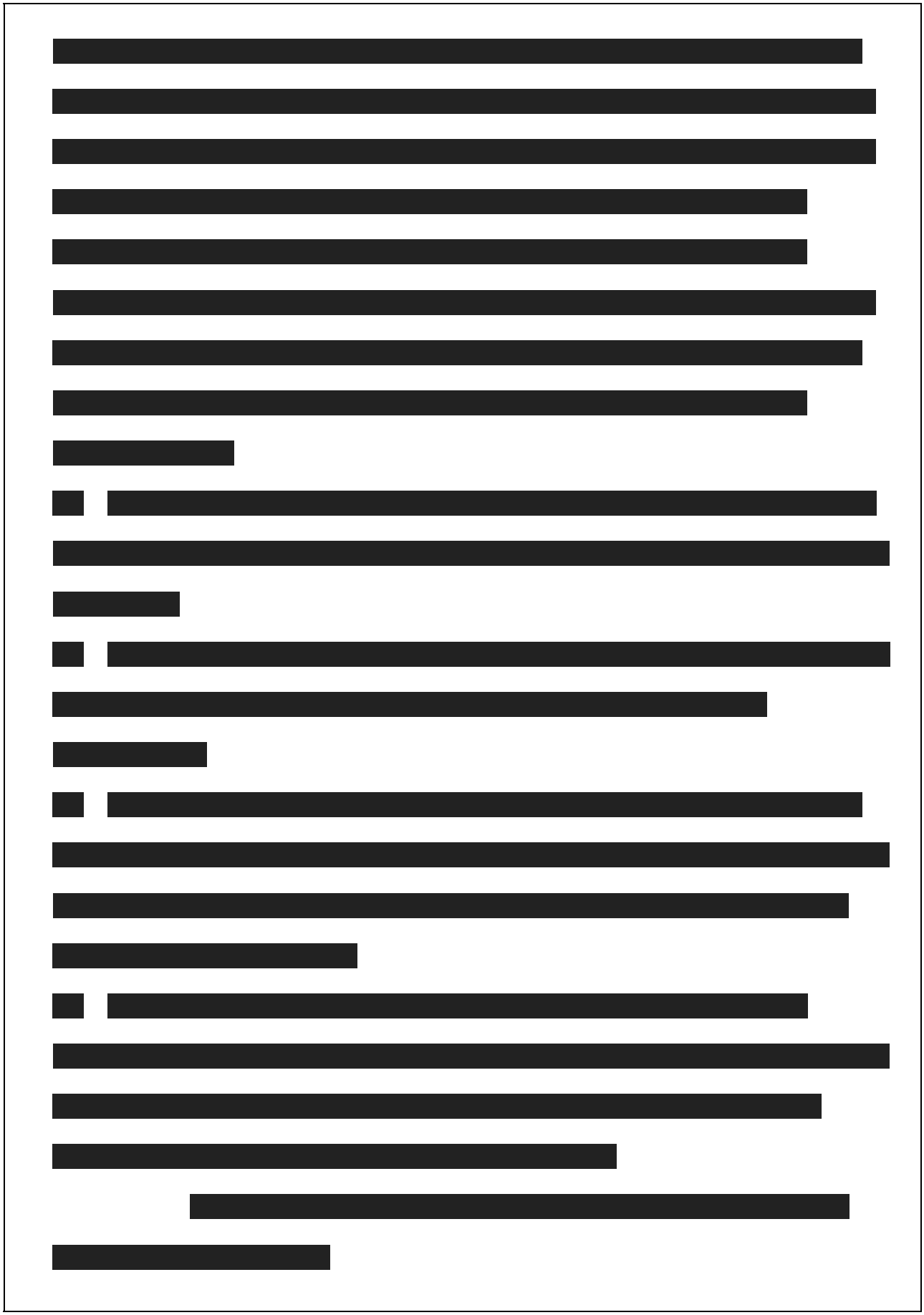



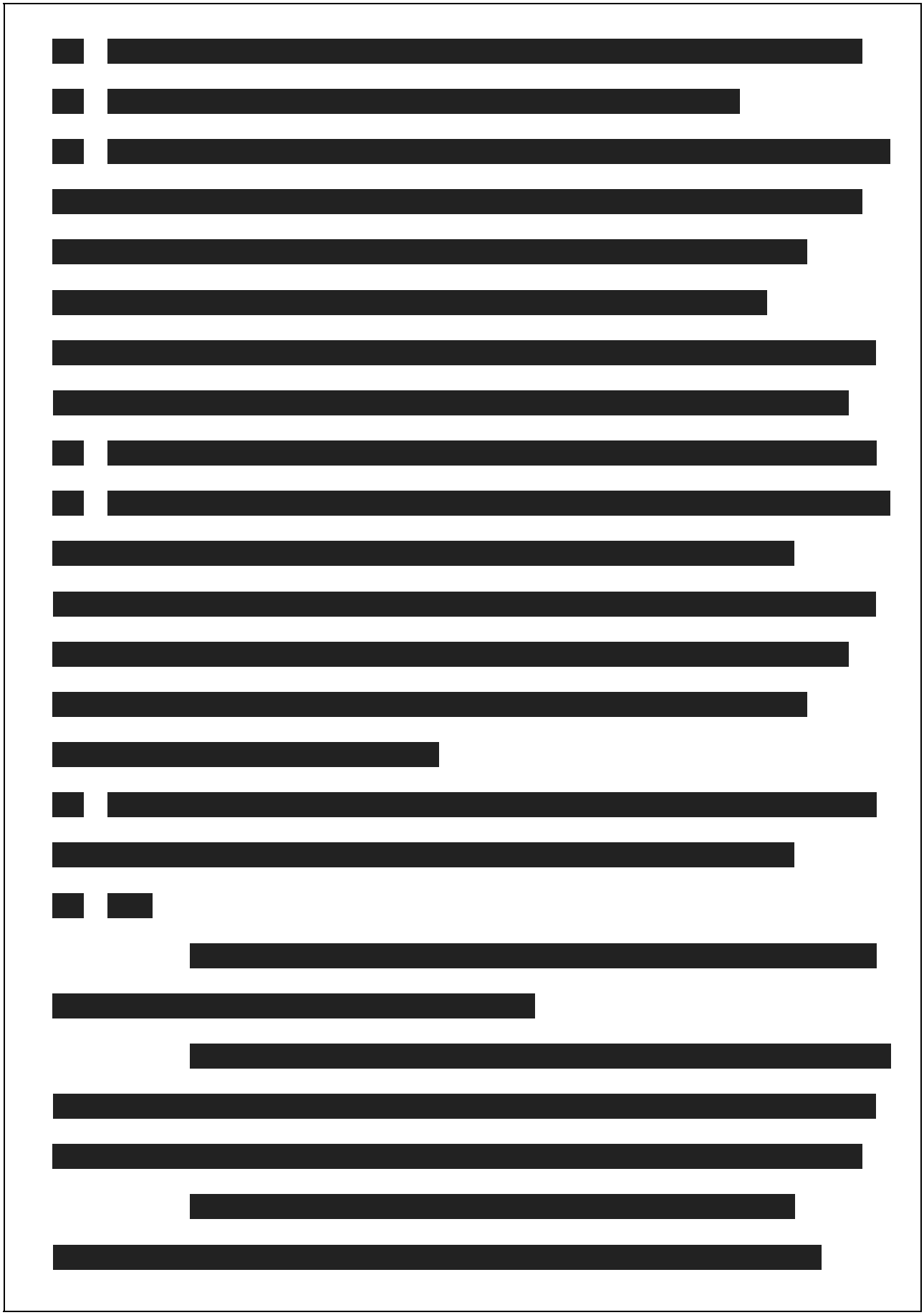

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CERTIFICATE OF OFFICIAL COURT REPORTER

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 19th day of November 2025.

/s/Timothy R. Miller, RPR, CRR, NJ-CCR
Official Court Reporter
United States Courthouse
Room 6722
333 Constitution Avenue, NW
Washington, DC 20001

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