IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

Plaintiff,

v. **Washington, D.C.**
Tuesday, November 25, 2025
EDWARDS LIFESCIENCES CORPORATION **9:30 a.m.**
and JENAVALVE TECHNOLOGY, INC.,

Defendants.
- x

TRANSCRIPT OF EVIDENTIARY HEARING - DAY 6
***** MORNING SESSION *****
HELD BEFORE THE HONORABLE RUDOLPH CONTRERAS
UNITED STATES DISTRICT JUDGE

APPEARANCES:

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

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

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

APPEARANCES CONTINUED:

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

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

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

C O N T E N T S

WITNESS: **PAGE:**

STANLEY CHETCUTI:
Direct Examination by Mr. Perry.....6
Cross-Examination by Mr. Anderson.....26

DENNIS MCWILLIAMS:
Direct Examination by Mr. Perry.....67
Cross-Examination by Mr. Hoogendoorn.....104
Redirect Examination by Mr. Perry.....133

ELIZABETH BAILEY:
Direct Examination by Ms. West Matthews.....136

P R O C E E D I N G S

MR. SHORES: A few preliminaries, Your Honor.

THE COURT: Sure.

MR. SHORES: We have a couple of demonstratives that were shown in open court and we're going to be just submitting those. I wanted to flag that. I've raised that with the Government's counsel with no objection.

The binder for the Boston Scientific testimony that you will view separately, it's been handed up, and also, given to your law clerk, as well. So that is now available. And I wanted to ask if there's anything else you needed with regard to Dr. Thourani's testimony.

THE COURT: I don't think so.

MR. SHORES: Okay. Thank you.

Let's see. The last thing you want to raise -- rebuttal?

MS. HALL: Yes, Your Honor. As we calculate today's exams, we should finish defendants' case by 4:30 and have an hour for the rebuttal case, which would be Dr. Wilson returning. We'll do our best, on our side at least, to try to meet that. And then at the conclusion of our rebuttal case, we'll submit our deposition designations in a binder with the exhibits that go with them.

THE COURT: Okay.

MR. SHORES: May I address the rebuttal issue,

Your Honor?

THE COURT: Sure.

MR. SHORES: I mean, from our perspective, a rebuttal is not necessary. Dr. Wilson was here yesterday. He submitted a reply report to our expert. There's been a lot of paper submitted here. So from our perspective, it's not necessary. If the Court allows it, I would respectfully request that we get equitable time to cross-examine after that's done.

THE COURT: Of course. I will allow it and you'll get your time.

MR. SHORES: Okay.

MS. HALL: I think the other -- the only other issue was we had proposed to defendants an additional 10 pages of briefing because we're not doing closings. Apparently, they don't want to do an additional 10 pages of briefing. So whatever Your Honor would prefer.

THE COURT: Let's make it 20 pages of additional briefing.

MS. HALL: All right.

THE COURT: I'm joking.

MR. SHORES: I mean, our perspective, Your Honor, is there's nothing new under the sun here, but we're happy to do whatever the Court would like.

THE COURT: I'll leave it to your discretion

whether you want to submit -- an extra 10 pages is fine by me, but you don't -- by all means, you don't have to.

MR. SHORES: Okay. Thank you, Your Honor.

THE COURT: All right.

MR. SHORES: Could I ask -- just to get our realtime connected. It's not up and running again. I'm sorry.

MR. PERRY: Good morning, Your Honor. Michael Perry for Edwards Lifesciences. Defendants call Dr. Stanley Chetcuti.

STANLEY CHETCUTI, WITNESS FOR THE DEFENDANTS, SWORN

DIRECT EXAMINATION

BY MR. PERRY:

Q. Good morning, Dr. Chetcuti. Thank you for taking the time to be with us today. Could you state your full name for the record, please.

A. Stanley Joseph Chetcuti -- or Chetcuti, depending upon how you want to pronounce it.

Q. Where do you currently work?

A. I work at University of Michigan Health Systems, or Michigan Medicine sometimes called.

Q. And what is your position at the University of Michigan Medical School and the University of Michigan Health System?

A. I'm a clinical professor. I'm an endowed professor of cardiovascular medicine. I'm the director of the cardiac

catheterization lab and the interventional services. And the medical director of the structural heart service.

Q. Thank you, Dr. Chetcuti. And we're having a little audio trouble. So if you could just speak a little more slowly, it will help the court reporter and all of us here in the courtroom understand.

A. If I bring my microphone closer, is it better?

Q. Yes. Thank you very much.

A. Perfect.

Q. And I believe you may have mentioned that in response to my last question, but what is your area of medical specialty?

A. It's interventional cardiology. So endovascular treatment of coronary artery disease. But over the last 15 years I have especially -- specifically specialized in structural heart interventions, valvular heart disease and -- involved in the aortic, mitral and other positions.

Q. Does your clinical practice involve transcatheter aortic valve replacement for aortic stenosis?

A. Yes, sir.

Q. And can we refer to that as TAVR-AS?

A. Yeah, TAVR-AS is perfect. Yes.

Q. And approximately how many TAVR-AS procedures do you perform annually?

A. As a team -- and we have a team approach -- we're

between 300, 400 cases. This year, we're going to be over 400 cases.

Q. And have you and your team at the University of Michigan participated in clinical trials for TAVR-AS devices?

A. Yes, sir. We've been -- at least a colleague of mine had 12 of them, all in Medtronic studies from the early -- extreme risk, high risk, intermediate risk, low risk. All the subsidies [sic] of those, five more. I could go through a whole list of them, but yes, multiple studies. Also, for Edwards and -- I'm actively involved in studies with Medtronic for TAV-in-SAV, with Edwards, with -- excuse me, with Abbott for ENVISION which is when they migrate to one valve versus the other.

Q. Thank you. We may ask some follow-up questions about some of that experience.

But have you also performed TAVR procedures for aortic regurgitation, or TAVR-AR?

A. Yes, sir. Do you want me to elaborate?

Q. Well, let me ask you this question. Have you participated in any of the clinical trials for JenaValve's Trilogy device in development for TAVR-AR?

A. Yes, sir.

Q. And were you involved in the ALIGN-AR trial?

A. Yes, I was.

Q. And was University of Michigan one of the top enrolling

sites for the ALIGN-AR trial?
A. We were definitely top 10. And last -- on last account, which I got from -- at last -- our meeting at TCT, which is the biggest interventional meeting with continued access, we're the top three in the country right now.
Q. And what has your role been in the ALIGN-AR trial?
A. I am the site PI -- site principal investigator. It was something I felt a lot of passion because I wanted -- I knew this device before it was even in a study format. So I have chased the company, because I saw the potential of it. And my role is to enroll patients and to make sure that the study is performed with the highest level of integrity, appropriateness, the criteria we use for appropriate study -- clinical research is maintained at the University of Michigan. It is also my responsibility that the data is kept in a safe fashion and that we keep it for 10 years after the end of the study.
Q. In your role as site principal investigator for the ALIGN-AR trial, have you attended investigative meetings on a regular basis?
A. Yes, sir.
Q. And have you participated in any scientific advisory boards in the structural heart space?
A. For Jena or for anybody in general?
Q. For any of the companies active in the structural heart

space?
A. Yes, sir. I have -- in my capacity, I -- in -- over the years, have been advisory board for Boston Scientific, active still for Medtronic and Abbott, and -- yeah, those three for now. And I did a non- -- I'm also an advisory board for Pi-Cardia with non-remuneration.
Q. And could you explain at a very high level, what is an advisory board? What role do you play?
A. So you give your expert opinion about where the state of the -- of the science is in the domain. You also give your opinion where you think research should be pushed forward, what development should happen, to help us deliver better care to our patients, especially patients with unmet clinical needs at the moment. So you're always -- I see my role in these advisory boards -- it's a two-part role. One is to help the company make proper decisions, but when I'm in this role, I am more of a patient -- I find myself more of a patient advocate to tell the company what my patients need.
Q. Have you been an author on publications in medical journals regarding TAVR procedures or other structural heart therapies?
A. Yes, sir. There is a list of PubMed -- you've seen my name in about -- over 60, 70 papers in this domain, at least.

Q. Okay. You mentioned just now unmet patient need and your perspective of what your patients need. Do you consider to be -- there to be unmet patient need for patients with severe aortic regurgitation today?

A. Absolutely. You look at the data, then we know that surgery is a very good option for patients in -- both here and in Europe. In spite of there being an indication for surgery, less than 30 percent of patients are offered this procedure for a variety of reasons. And the implication of not having surgery when you have severe symptoms, a 3 or 4, could be a mortality rate as high as 30 percent.

Q. And approximately how many hospitals around the country are currently participating in JenaValve's clinical trials for the Trilogy device?

A. I don't want to -- I don't want to speak out of turn. I would say 20 -- about 20. I'm not sure, though, exactly.

Q. And that's a very small fraction of the total number of hospitals that currently perform TAVR procedures for aortic stenosis; is that right?

A. At my last count, for aortic stenosis, the number of sites in the U.S. is around 850.

Q. Based on your experience, including serving as site principal investigator for JenaValve's clinical trials, do you expect that JenaValve, as a stand-alone company, has the resources and capabilities needed to support a national

commercial launch of the Trilogy device?
A. I do not believe so.
Q. And why not?
A. Well, the company has done a great job at getting us here, but if you look at these scalability of what is needed to do what you're asking, the sales force, the clinical field team would have to be significantly altered. Even right now with the study, as well as Jena has done the study, we do have to, sort of, navigate timing of our procedures because the field team has to be shared around all the sites that need implants, or sometimes you have to, sort of, wait a week or two because that's when the Jena field team's available.
Q. Based on the limited field team that you just described, have you had any difficulty scheduling cases or have you had to reschedule or delay procedures?
A. We've worked together. We've, sort of -- we found a compromise. We've had to delay, but, you know, it's -- we're also realistic. We know the size of the company, so we're not going to demand that you come tomorrow, because it's impossible. So I don't -- I try not to make unnecessary demands or unrealistic demands. But we've had to put pressure on the company sometimes; we need it done sooner. And they try to help. But the navigating probably 20 different -- 20 similar requests from all around the

country -- we all think our patients are the most important at the time we're doing it.

Q. And for a procedure like this, like these TAVR procedures, could you explain briefly the importance of a clinical field team?

A. Yes. I mean, even though we're trained to do these procedures, they're not something we do on a regular basis. So the clinical field team helps you determine the appropriateness of the procedure and gives you guidance because they have the experience of not just your site -- I have my experience. The clinical field team comes with the experience of all the sites that are proctored and trained. So they multiply their experience, and it adds to the knowledge base when you're doing a procedure. There could be tips and tricks that they give you that you may not be aware of that, for example, a doctor, whoever she or he may be at a different site, did that they can share with you.

Q. And you have experience performing TAVR-AR procedures and, over the course of the hearing, we've heard from other principal investigators that also have experience with this TAVR-AR procedure. For a doctor who does not yet have that experience, is the clinical support team important?

A. Critical. Could not be done without it.

Q. And based on your experience, including your work on the JenaValve clinical trials, do you believe that JenaValve has

the clinical field team that would be necessary to disseminate the Trilogy device to the 850 or so hospitals around the country that you described earlier?

A. In the current, (inaudible) -- I would say no.

Q. And in your experience, does JenaValve have the manufacturing capacity to support that kind of national commercial launch for the Trilogy device?

A. I do not believe so, but I am not a supply chain expert. But I do not believe so. I have seen in the past, even during studies, where we've had to delay implanting because of manufacturing issues or supply chain issues. Issue for the valve -- (inaudible.)

Q. Let's turn now to Edwards Lifesciences. Based on your experience, including the clinical trial experience that you described earlier, do you expect that if Edwards is allowed to acquire JenaValve, that Edwards will have the resources and capabilities needed to support a national commercial launch of the Trilogy valve?

A. Absolutely. At the risk of sounding like I'm some sycophant of Edwards, and I am not, Edwards has been a pioneer in this domain, TAVR-AS and all kind of valvular disease in general. Edwards is a valve company. When you look at the Edwards infrastructure, it's not about the valve per se, but it's every element of the valve: The tissue of the valve, the preparation of the tissue of the valve, the

surrounding structures, the mechanism of the valve, the delivery catheters, the sheaths that come with the catheters. They're a complete company, from A to Z.

Q. And based on that experience, has Edwards shown that it can support a nationwide launch for other structural heart therapies?

A. I mean, you look at their dominance in market share in TAVR-AS, that answers your question. It's not conjecture. You see it. They are the ones who open more sites. They've done a fantastic job also now in the tricuspid domain with their EVOQUE valve and the way they've been able to launch EVOQUE in the community and have tricuspid valve -- so replacing the tricuspid position in multiple sites, the way they launched PASCAL which is an edge-to-edge detection -- edge-to-edge repairing a mitral position for functional -- (inaudible.)

THE COURT REPORTER: (Indicating.)

THE COURT: Okay.

THE WITNESS: All these things, Edwards has done. They are --

THE COURT: Doctor --

THE WITNESS: -- the standard bearer of --

THE COURT: Doctor, can you slow down a little.

THE WITNESS: I will, sir.

THE COURT: Okay.

THE WITNESS: They have been standard bearer for launched products.

BY MR. PERRY:

Q. And based on the experience that you've described, if Edwards is allowed to acquire JenaValve, what impact do you expect that will have on the patients around the country that are suffering from severe aortic regurgitation?

A. It will be a multi-fold impact, in my opinion. Number one, we would see more -- a bigger field team that could allow more sites to be launched at a faster pace. Number two, we would have a scale of manufacturing to have more devices available. And, number three, which comes part and parcel with being a big company like Edwards in the, (inaudible) -- of -- that Edwards has in this domain, I would also anticipate further iterative changes in the device itself to make it more deliverable and more favorable for use in the public.

Q. You mentioned earlier that you've been very impressed with what JenaValve has been able to do to date with the Trilogy device. Are there aspects of the JenaValve Trilogy device that you, as a physician, would like to see improved?

A. We physicians are always greedy, where we like the device delivery to be smaller. A smaller device has less complications. We would like further iterative changes in sizes. Maybe a bigger size to help us deliver this therapy

in patients who have large annuli. We've learned a lot during the study to make the procedure simpler. But anytime we can make it much more prescriptive, that everyone in general can use it, and I would -- Edwards has a track record of doing this in the TAVR-AS; I would feel would be able to do it at a quicker pace.

Q. In your experience, has JenaValve, as a startup company, had the resources to make those types of improvements to the Trilogy device that you just described?

A. I want to, again, give my praise to Jena to get us to where we are today, but Jena had -- they had to finish ALIGN-AR. They had to have enough money to be able to finish the study, which is expensive. And if you look at when they got investment from Bain, it wasn't to develop newer technology. It was to finish a study and to be able to get us where we are today, which hopefully the FDA will approve it. So they've not really pushed technological advances at this point with the investment they've had. They would need much bigger investment than what they've had so far.

Q. And have you seen Edwards make improvements to their TAVR-AS devices over different versions of the SAPIEN valve system?

A. I mean, yes. The answer is an absolute yes. If you look at the first SAPIEN we used in 2009 compared to what we

use today, the size, the tissue, the metal, the delivery catheter. And that's just in the TAVR-AS. If you look at even EVOQUE, which is just newly released last year, there's EVOQUE second generation and third generation already being developed. So this is the nature of how Edwards behaves. It's always improving.

Q. If Edwards is allowed to acquire JenaValve, do you expect that Edwards will continue to invest in developing improved therapies for aortic regurgitation?

A. I believe, yes.

Q. And what --

A. I'm, (inaudible) -- Edwards's board or leadership, but going by what I know about Edwards to what -- the areas I've known -- I've worked with Edwards -- the answer is absolute yes.

Q. And in some of the other structural heart therapies that you mentioned, including TAVR-AS, have you seen Edwards invest in expanding the eligible patient population, for example, into lower surgical risk patients?

A. If you look at the nature of the studies that Edwards has pioneered for all of us, they went with prohibitive risk, high risk, intermediate risk, low risk. Once Edwards -- once -- had really given -- taught the world how to do this -- and I have to commend Edwards, too. And I'm not a -- I wasn't in any of these studies. They even

insisted on long-term follow-up. So just in September, we had -- just recently, we had our seven-year follow-up for low-risk which this is proof of concept how well this technology has developed, but then they went even beyond that. They went to valve-in-valve. They went for TAV-in-SAV, which is TAVR in a surgical aortic valve. They went for asymptomatic patients. They even went for moderate-risk patients. And it's always expanding.

Q. Based on that experience, if Edwards is allowed to acquire JenaValve, do you expect that Edwards will continue to invest in expanding the patient population that can be treated with TAVR-AR devices?

A. Absolutely.

Q. Are you familiar with Dr. Torsten Vahl of Columbia University?

A. I know him personally and I know him -- he was the leader of the study.

Q. And when you first started performing TAVR procedures with JenaValve's Trilogy device, was Dr. Vahl involved in that in any way?

A. Yes. First of all, he was part of our training, because there's a training process that you have to before you can implant, and then if I remember correctly we invited Torsten to be a proctor. So -- (inaudible.) Torsten came to our site, Dr. Vahl, and was proctoring me in the first case I

implanted.
Q. Would you consider Dr. Vahl to be a well-regarded interventional cardiologist in the TAVR space?
A. Absolutely. A world expert.
Q. Are you familiar with Dr. Vinod Thourani at the Piedmont Heart Institute?
A. Yes, sir. Both on a personal level and a professional level.
Q. Do you consider Dr. Thourani to be a well-regarded cardiac surgeon in the TAVR space?
A. Absolutely. He's also been head of the STS, the Society of Thoracic Surgeons. He's one of the leaders in this domain. Yes, sir.
Q. Are you familiar with companies that are developing or have developed TAVR-AR devices outside the U.S.?
A. There's one company in particular, and I have no personal knowledge; it's just academic knowledge and then I -- I'm -- it's part of my, you know -- Google alerts me if something new comes out in this domain. There's a Hanchor valve from China that I've been trying to see if there's any interest in the U.S. I think it has interesting aspects to it that will also help expand how we could deliver therapy in AR, aortic regurgitation. H-A-N-C-H-O-R, Hanchor. There's a 128-patient study from China. I have not seen them have any interest yet in the U.S., but I wouldn't be

surprised if a company -- a big company would jump onto it.
Q. Have you personally implanted patients with the Hanchor valve?
A. No, sir.
Q. And you mentioned earlier this morning a conference known as TCT; is that right?
A. Yes.
Q. And did you attend this year's TCT conference?
A. I did.
Q. Were you able to attend the panel at TCT this year on TAVR-AR?
A. I did not because I had a simultaneous panel that I was on myself. So -- sometimes it's very difficult for some of us to be in two places at once.
Q. Understood.
A. There's usually five or six sessions going on simultaneously, and some of us are on different panels.
Q. But I believe you mentioned you became aware of the Hanchor valve through academic presentations; is that right?
A. Yes. Yes, sir. So I have, like, one of these Google alerts, and when something -- TAVR-AS or TAVR-AR comes out, it alerts me. I look it up, and then I do my background research to get into the paper -- and I found the paper.
Q. And as an interventional cardiologist, why do you monitor what TAVR-AR or other devices are being developed

outside the U.S.?
A. Number one, it's because I have an interest for my patients. I'm primarily a patient advocate. So if there's a technique or a technology that can help me expand what I do for my patients in a safer and less invasive way, I'm interested in it. I want to also see the feasibility of it. And if I'm advising somebody about it, I need to know the background of what I'm advising about. And then, also, I have a selfish interest. If somebody's coming to the U.S. and I can bring it to my institution, it expands the delivery of care of what I can get to my patients through my institution. There's also the academic reward of having a new device, whether it's first-in-man or in a pivotal study, that increases your academic performance by being able to be in a study.
Q. In your experience, does important innovation in the structural heart space occur outside the United States?
A. It can happen anywhere. I think, over the last four years, we've done significant improvements in the U.S. In the past, some of it was -- because of the way the rules were, with CE mark and other things, the Europeans, they have an advantage over us. But many of the development is here in the U.S. We have the know-how. I can say we now -- I'm an American citizen for the last seven months, so I can proudly say "we." We have all the technical know-how here.

We have the smarts, the engineering, the infrastructure. And we've also been very lucky that the FDA has partnered with us to be able to get these devices to us in a much quicker pace than we had in the past.

Q. And you mentioned earlier that you've served on advisory boards for companies like Medtronic. Have you discussed technologies like the Hanchor valve in those advisory boards?

A. Yes, sir. In fact, I have advised companies like Medtronic to purchase Jena at some point in the past, too.

Q. In your experience, for a company like the developer of the Hanchor valve that has conducted clinical trials in patients outside the U.S., would that help speed up the timeline for FDA approval if a company took that device into the U.S.?

A. The FDA has been very favorable -- and, again, I'm not the world's expert on the FDA's workings -- but when I'm dealing with the FDA is they're beginning to look at outside data, some of it. We still would expect and demand that there would be a U.S. study to collaborate [sic] what the outside data suggests.

Q. And would the availability of at least some feasibility data from patients outside the U.S. help speed up the timeline for eventual --

A. Absolutely.

Q. -- FDA --
A. Absolutely. Absolutely. Absolutely.
Q. You mentioned earlier that you've been in -- you were involved in some of the earliest clinical trials for the Medtronic's Evolut device; is that right?
A. Yes, sir.
Q. If a company like Medtronic were to acquire rights to the Hanchor valve or another TAVR-AR device currently only available outside the U.S., how quickly, in your experience, could Medtronic pursue FDA approval in the U.S.?
A. It depends on interest from the clinic, but it could catch up very quickly in the sense -- if you look at the TAVR-AS domain, Edwards has a big head start with regards to TAVR-AS. And when Medtronic bought CoreValve, within three years they were really getting neck and neck. So you could look at -- like, when Edwards finished their low-risk study, Edwards -- Medtronic was only a year behind them even though they are, sort of, what, three or four years behind them at the time.
Q. And prior to Medtronic's acquisition of CoreValve, had CoreValve even started any clinical trials in the U.S.?
A. There was an attempt to start a clinical trial. They were doing site selections, but we did not -- nothing was started yet.
Q. And in your experience as one of the investigators in

those early Medtronic clinical trials, how rapidly was Medtronic able to scale up in the U.S. after acquiring CoreValve?

A. It was impressive because we were still -- when it was CoreValve, before, they were still, kind of, debating how many sites, 20, 25. When Medtronic bought it -- I remember we met in December or October of '08. And they had to whittle down 80 sites to 40; then we got 40 sites; and then quickly, by -- excuse me -- by 2011 -- 2010, we were enrolling; and by 2011, we were just really, (inaudible) -- in the study.

Q. And you mentioned that in the TAVR-AS space, Edwards was the first company to launch -- commercially launch a TAVR-AS device in the United States, and then Medtronic quickly followed. Is that a phenomenon you've seen in other structural heart therapies?

A. Yes, sir. Edwards usually tends to lead, but there are other places where a company like Abbott has led, for example, in the TEER space, which is repair of the mitral valve, MitraClip. And Edwards is catching up very quickly with their PASCAL device.

Q. Dr. Chetcuti, earlier, we mentioned the unmet need for patients suffering from aortic regurgitation for whom surgery may not be a good option. Based on your experience as a physician who treats those types of patients, do you

expect that Edwards's proposed acquisition of JenaValve, if it is allowed to go forward, will help address that unmet patient need?

A. Absolutely.

MR. PERRY: Thank you. I pass the witness.

MR. ANDERSON: May I proceed, Your Honor?

THE COURT: You may.

CROSS-EXAMINATION

BY MR. ANDERSON:

Q. Good morning, Dr. Chetcuti. My name is Barrett Anderson. I'm an attorney with --

A. Good morning.

Q. Good morning. I'm an attorney with the Federal Trade Commission. I know that we've never met before. So I'd just like to introduce myself. And I'm going to ask you a few questions this morning. Okay?

A. I'll answer as quickly as I can, sir.

Q. I appreciate that very much.

Dr. Chetcuti, on direct examination, you testified about JenaValve's and Edwards's comparative abilities -- your opinion about their comparative abilities to commercialize Trilogy. Do you recall that testimony?

A. Yes, sir.

Q. It's fair to say that you don't have a background in medical device manufacturing?

A. No, sir. I said that in my testimony.
Q. Dr. Chetcuti, could you bring the mic up towards your mouth?
A. Yes, sir. I said also in my testimony.
Q. Yes. Thank you. It's fair to say that you don't have a background in medical device commercialization or launch?
A. I do not have experience in commercialization or launch, but I have been on the receiving end of commercialization and launching of various companies. So I can speak from a client -- from a recipient of those companies.
Q. Dr. Chetcuti, you don't have experience with medical device marketing; correct?
A. I have helped create marketing campaigns for some company [sic], but I am not a marketing person myself.
Q. And you've never done fundraising for medical device startups; correct?
A. I have been an expert witness for some investment companies that asked me. When Jena was executing investments from Bain, I was one of the people they had -- they put forward to have companies like Bain use me as an expert witness to see if it was worth their money to invest in a company like Jena. So experience -- that's the kind of experience I have.
Q. Dr. Chetcuti, you yourself have never been involved in the actual fundraising aspect; correct?

A. No. No, sir.
Q. Dr. Chetcuti, you haven't spoken to anyone at JenaValve about JenaValve's plans for the Trilogy device if the proposed acquisition does not occur; correct?
A. Not in the last six months because it's -- once this lawsuit was there, I refused to talk to Edwards or Jena about anything related to the valve.
Q. So you don't know JenaValve's plans with respect to hiring a field team if the proposed transaction does not --
A. I do not.
Q. And you don't know any plans at JenaValve to improve manufacturing or supply chain, correct?
A. I do not.
Q. And I believe you said this as well, but just to clarify, you haven't spoken to anyone at Edwards about Edwards's plans for the Trilogy device; correct?
A. I did speak to an engineer two years ago. It was in Vancouver in 2024 when the -- when this was being proposed. I offered my services if they wanted to come and see implants. So this would be for full disclosure. And I'd be happy to give my opinion. Knowing Edwards and knowing how they've done -- how aggressive they've been in every domain, I would be surprised if it was any different, but I have not specifically -- have details of what you're asking. No.
Q. All right. So Dr. Chetcuti, just to be clear, you

haven't spoken to anyone at Edwards about plans to increase a field team for -- with respect to the Trilogy device?

A. No, sir.

Q. You haven't spoken --

A. I have intentionally not spoken to Edwards about anything Jena-related since I've been deposed or testified in my deposition, intentionally. Because I don't want to be biased.

Q. We appreciate that, Dr. Chetcuti. You're -- just to clarify, you're not aware of any specific plans that Edwards might have with respect to --

A. No, sir.

Q. -- manufacturing; correct?

A. No, sir.

Q. Or developing a next generation of Trilogy?

A. No, sir.

Q. Okay. On direct examination, I believe counsel asked you your opinion about whether or not Edwards's acquisition of JenaValve would ensure that Edwards would improve therapies or continue to invest in improved therapies for treating aortic regurgitation. Do you recall that testimony?

A. Yes, sir.

Q. Counsel asked you, if allowed to acquire JenaValve, would Edwards continue to invest in those improved

therapies? Dr. Chetcuti, you're aware that Edwards purchased J-Valve; correct?

A. Yes, sir.

Q. And J-Valve is also a TAVR-AR device?

A. Yes, sir.

Q. So Dr. --

A. Some different -- (inaudible.)

Q. Dr. Chetcuti, would you expect that even if the proposed transaction does not occur, that Edwards would continue to invest in improved TAVR-AR therapies?

A. Again, it would be conjecture on my part because I'm not in these discussion. I would presume yes, but I don't know the answer.

Q. You were also asked if Edwards would continue to expand the AR patient population. Do you remember that question?

A. Yes, sir.

Q. It's fair to say, Dr. Chetcuti, that given Edwards owns J-Valve, you would expect them to continue to invest in expanding the AR patient population even without acquiring JenaValve?

A. You are implying that Jena and J are the same valve and the same patient population. They're different valves that have different platforms. For example, I've been -- I was part of the Jena study. I've had to refer patients to Cincinnati to -- three patients with AR who were not

candidates for the JenaValve.
Q. Doctor --
A. Based on the size of their veins.
Q. Doctor --
A. So I would think that company -- again, I'm not advising Edwards, but I would think the company would expand both platforms, or integrate both platforms into something bigger.
Q. Dr. Chetcuti, you haven't talked to anyone at Edwards about their plans to integrate the platforms; correct?
A. No, sir. No, sir.
Q. And you're aware that the J-Valve does treat patients that have aortic regurgitation; correct?
A. Yes, sir.
Q. So would you expect that even without acquiring JenaValve, that Edwards would continue to invest in expanding the AR patient population?
A. As you said, without me talking to them, it's my impression, but I would think so.
Q. Thank you, Doctor.
I'd like to ask you some questions about the Trilogy valve. On direct examination, you testified that you're a principal investigator for the Trilogy valve in several clinical trials; correct?
A. Local principal investigator. The national was

Dr. Vahl.

Q. Fair to say that you've implanted a fair number of Trilogy valves in your own practice?

A. Yes, sir.

Q. In fact, in the ALIGN-AR trial, fair to say you implanted between 10 and 15 Trilogy valves?

A. At least. Yes, sir.

Q. And after the ALIGN-AR trial, you'd agree that you've continued to implant Trilogy valves at a steady clip; correct?

A. Yes, sir.

Q. Just in the last --

A. (Inaudible.)

Q. Oh, excuse me.

A. (Inaudible.) If I can elaborate, I mean, when you think that we're doing, maybe, 8 to 10 TAVR-AS cases per week, when it comes to AR, population's a bit less. It could be sometimes one or two a month, or even less.

Q. Dr. Chetcuti, fair to say when you were deposed on October 14th, as of that date, you'd implanted three or four Trilogy valves in the prior month; correct?

A. That's correct, sir.

Q. Okay.

A. That's what I testified.

Q. Dr. Chetcuti, you're the co-author on the recent Lancet

article that published the ALIGN-AR study results; correct?
A. Yes, sir.
MR. ANDERSON: Okay. I'd like to pull up that document. That's D-X-0297.
BY MR. ANDERSON:
Q. Dr. Chetcuti, we're going to display a document on the screen -- if we give it just a moment here.
Dr. Chetcuti, do you recognize this as the Lancet article that was recently published?
A. Yes, sir. Yes, sir.
Q. And this lists --
A. I go by "Stan" or "Stanley." So it's easier to go with "Stan" sometimes -- (inaudible.)
Q. Thank you, Dr. Chetcuti.
That is your name on the first line, the second from the right?
A. Yes, sir.
Q. Is it fair to say that the co-authors on this article represent the physicians who implant Trilogy valves in the United States?
A. The highest volume people. Yes, sir.
Q. And you'd say that's a fairly tight-knit community; correct?
A. Yes, sir.
Q. Okay. I'd like to look at the second page of this

article. There's a pink box in the middle, and in the lower right corner there's a section titled, "Implications of all the available evidence."

Do you see that, Dr. Chetcuti?

A. Very well, sir.

Q. Okay. The first sentence says, "The totality of prospective data now indicates that the anatomical barriers limiting off-label TAVI in native aortic regurgitation can be overcome with a dedicated leaflet-engaging device."

I'm going to stop there, Dr. Chetcuti. The dedicated leaflet-engaging device, that's referring to the Trilogy valve; correct?

A. In this article, yes. That's what we wrote. That was our intent when we wrote this conclusion.

Q. And it continues, "Yielding excellent safety and effectiveness, valve function, favorable myocardial remodeling, and sustained improvement in health status in a population with limited options for treatment."

I'd like to look at the excellent safety and effectiveness there, Dr. Chetcuti. Fair to say that the ALIGN-AR study had very few complications reported; correct?

A. Absolutely. Yes. And we improved throughout the years of the study. If you look at the time points, our patient rates in our first year compared to the second year compared to the continued access continued to improve as we refined

techniques. We went from a very aggressive general anesthesia protocol with transesophageal echo, where you put a tube down into the stomach to look at the implant, to now doing it mostly with fluoroscopy and surface echos. So yes, we improved it, because this is what we do in this domain.

Q. That's great to hear, Dr. Chetcuti.

The second sentence here says, "Amid updated European guidelines and ongoing U.S. guideline update and regulatory review, this expanded ALIGN-AR analysis delivers important evidence needed to inform clinical use and future guidelines."

Dr. Chetcuti, it's fair to say that the ALIGN-AR results were so robust that, in your opinion, regulatory authorities should use them to inform clinical use?

A. I would hope and I would -- I am praying that the FDA looks at this and makes the decision that they think is appropriate. And I have to let the FDA make their own decisions on what, (inaudible) -- the FDA. But I think this is very robust data. I'm -- we're waiting -- I'm -- I hear through the grapevine this is not -- that there's some -- FDA's checking some things with manufacturing at Jena, but, again, I'm not -- I don't know this for a fact. It's just the grumblings. Because we -- I was honestly expecting to have an FDA indication by -- the rumor was at TCT we're going to have an indication from the FDA. So I'm surprised

they don't have it yet.
Q. It's fair to say, Dr. Chetcuti, that if there were any concerns about Trilogy's safety, you would not be implanting it in patients?
A. No. In fact, this is why I'm here. I want to make sure that Trilogy is available to my patients and there's no more delay, because it's such an important tool to -- I'm here in -- (inaudible.) I'm here -- I will appear to be here today. I'm not really paid by anyone. I just want to be here to be an advocate for patients. I want this valve to be available to us in the market.
Q. Dr. Chetcuti, in your opinion, the ALIGN-AR study is a very ground-breaking paper; correct?
A. It's the first of its kind. Again, as I said before, I wanted to commend Jena who brought us here, the leadership of Mr. Kilcoyne and Duane Pinto, the medical director --
Q. Dr. Chetcuti, apologies for interrupting --
A. I'll bring the microphone back.
Q. Thank you very much. Thank you.
A. Mr. Kilcoyne -- I wanted to commend Mr. Kilcoyne. I wanted to commend Duane Pinto, clinical director; and Torsten Vahl, the PI, for getting us here. People like Raj Makkar, who enrolled a lot of patients. A lot of good people in the study. It was a symbiotic experience and we got here. So yes, I -- my reason here is not, in any way,

to diminish what Jena did. I want this to be given to our patients in the next stage.

Q. It's fair to say these excellent clinical outcomes, Dr. Chetcuti, were run by a study -- were from a study run by JenaValve as a stand-alone company?

A. Yes, sir.

Q. Okay. Dr. Chetcuti, let's shift gears just for a moment. You believe Trilogy valves are so safe and effective that, as you testified, you'd like to continue to have access to them for your AR patients; correct?

A. Yes, sir. If I am allowed to elaborate, I would --

Q. Oh.

A. -- like also to expand who had high-risk, (inaudible) -- going to intermediate and low-risk, but I also believe this particular technology has potential for TAVR-AS. And I don't want to get too technical. Maybe this is not the forum for it, but because of --

Q. Dr. Chetcuti, not to interrupt. We do have limited time this morning. So --

A. Okay. Sorry. Sorry.

Q. -- we'll proceed with the questions.

A. But it has potential for TAVR-AS; has potential for valve-in-valve, too.

Q. Thank you, Dr. Chetcuti. Your excitement for the Trilogy valve is quite obvious, and we appreciate that.

Dr. Chetcuti, Edwards is not the only medical device company in the world that could provide support for Trilogy access; correct?

A. Yes, sir.

Q. You're familiar with Medtronic, I believe you testified.

A. If you'll look at the, (inaudible) -- I am very close to Medtronic. I'm also paid for advisory reasons from Medtronic. In fact, people would think it's strange that I'm here testifying for Edwards when I'm seen in the domain as a Medtronic person.

Q. You're familiar with Abbott Laboratories?

A. Yes, sir. In the last six months, I've also become an advisor for Abbott.

Q. And Boston Scientific?

A. Yes, although Boston is in limbo and I'm -- they don't have much going on.

Q. Fair to say, Dr. Chetcuti, that each of these large companies sells medical devices across the United States?

A. Yes, sir.

Q. Each of these large companies has clinical field teams?

A. Yes, sir.

Q. In fact, I believe you testified, Dr. Chetcuti, you had advised Medtronic to buy JenaValve; correct?

A. Before Edwards did, yes.

Q. If that were still possible, Dr. Chetcuti, fair to say

that you'd be in favor of Medtronic buying JenaValve?
A. I mean, I would ask you, can -- what -- why they didn't do it before. So I -- again, I'm -- you make very many -- (inaudible.) I'm not a finance expert. I don't know the thinking of Medtronic. Medtronic is a different structure from Edwards, as you know. They respond to a board and dividends have to be shared by the board. And so the way money flows at Medtronic and Edwards is very different. The way profits are rediverted into research and internally is very different in Edwards and Medtronic. I am not an expert. So I -- please don't grill me on this.
Q. I promise not to grill you, Dr. Chetcuti. I just want to make sure that we're clear, though. You weren't involved in any of JenaValve's discussions with any of these other companies; correct?
A. No. No, sir. No, sir.
Q. So you --
A. It's above my pay.
Q. You don't know if any of them made an offer for JenaValve; correct?
A. I do not know.
Q. And you don't know if any of them would make an offer for JenaValve today if given the chance?
A. Absolutely not.
Q. Okay. Dr. Chetcuti, let's move on to another topic.

The only two TAVR-AR devices that you know of in U.S. clinical trials are the Trilogy and the J-Valve; correct?

A. Actually, the only one I know is Trilogy right now. The J-Valve is -- and I checked this morning before I -- when I woke up. I went to ClinicalTrials.gov, and the J-Valve is on hold, if I read the -- if I interpreted the website correctly.

Q. Fair to say that the J-Valve study is on hold, but it is pending; correct?

A. It's pending. Yes, sir, unless there's something drastic that I don't know of.

Q. Right. So it's fair to say you're not aware of why that study is paused?

A. Absolutely not, sir.

Q. So the only two TAVR-AR devices with pending U.S. clinical trials are the Trilogy and the J-Valve?

A. Yes. I mean, the -- I would think that the Trilogy hopefully would be approved clinically for high risk, and then they'll continue with the Trilogy, if allowed to, in low and intermediate risk and in the LVAD population, the ventricular assist device population.

Q. Dr. Chetcuti, as a physician, you would not implant a valve that is only in clinical trials in another country but not in clinical trials in the United States; correct?

A. That would be a big no.

Q. Okay. You mentioned a device in China named the Hanchor valve. Do you remember that?
A. Yes, sir.
Q. You aren't aware of a forthcoming U.S. clinical trial for the Hanchor valve; correct?
A. No, sir. No, sir.
Q. In fact, I believe you testified that you're not aware of any interest yet in the Hanchor valve in the United States; correct?
A. No, sir. Just for full disclosure, I have an advisory board meeting with Medtronic in about two weeks. That's one of the things that I'll bring up on the 10th, 11th, 12th of December in New York.
Q. Dr. Chetcuti, you don't know if JenaValve or Edwards have patents this would block the Hanchor valve from coming to the United States?
A. I do not know that, sir.
Q. Based --
A. They have an implant that is slightly different than the J and Hanchor. But, again, I am not a patent law expert. So I would defer to your team of people who understand that more than I do.
Q. Based on your experience, it would take at least 7 to 10 years to bring the Hanchor valve from China to the United States commercially; correct?

A. I would say probably seven years, yes.
Q. It's fair to say 7 to 10 on the outside; correct?
A. Probably, yes.
Q. Okay.
A. It depends on how much money a company like X company would invest, how many sites are enrolled, how quick the enrollment would be. Because it's all about enrollment, and if you can enroll something in a year instead of three, four years, and your follow-up is three more years, then the time frame would change --
Q. Dr. Chetcuti --
A. -- how much money you invest in it.
Q. Thank you, Dr. Chetcuti.

It's fair to say that if there is already a commercial rival to that valve in the United States, in your experience, it would take an extra three to four years to bring that device to the United States?
A. Again, that's not necessary. Depends on the labeling of the device, of its ease of use. It depends on how many sites you have. It depends on the clinical incentive -- on the financial incentive you might get as a site to enroll in a study. Patients -- the -- now, the widget test, different characteristics. If the widget test, (inaudible) -- that makes it more favorable or has potential benefit that you can prove once you do a study, you present these data --

these points to your patients. It's one versus the other usually at this point. And you can catch up very quickly. So I would -- I mean, me saying three years, four years, two years, is complete conjecture.

Q. Doctor --

A. It would depend on the robustness of the design of the study and how the study is designed.

Q. Dr. Chetcuti, it's fair to say that at your deposition you testified that it usually takes an extra three, four years if there's a commercial rival to what you're doing?

Do you remember that testimony?

A. I do now, and at the risk of impeaching myself, I don't want to, like, say something different.

Q. Okay. But it's fair to say that you remember --

A. I'll keep the same response.

Q. Okay. Thank you, Dr. Chetcuti.

A. I could elaborate a little bit more today than I did at the deposition because, again, what I tried to show -- it's not that I'm trying to change my answer. It all depends on the framework of the study. If you have 40 sites, I can enroll X per month. If I have 80 sites, I can enroll X times two. If I have -- you know, do the math. And it depends how much money you invest. To do a study, anytime you invest more sites, for every 100 patients you enroll in the study or how big a study is, you're talking about a

hundred million dollars or something like that. An increased investment.

Q. But it's fair to say one of the factors that would cause an increase in the amount of time to bring a valve to the United States from a foreign country is whether or not there is a pre-existing commercial rival. That's something you would consider; correct?

A. I would, but it didn't stop Medtronic from doing it with TAVR-AS. And then they quickly forgot.

Q. Okay. Dr. Chetcuti, I'd like to move to another topic. You're familiar with the requirement that researchers disclose any potential conflicts when they present their work; correct?

A. Absolutely.

Q. And disclosures should include any financial interest, like research funding?

A. Yes. So if I can elaborate, when -- as a local PI, the company that -- for whom I'm doing the study in the name of the University of Michigan Health System, so it's not in my name, but the name -- the money goes to the regents of the University of Michigan. And it defrays some of the costs of my academic study. So let's say -- if I'm making 100,000 and I get 2 percent protected time to do the study, then 2 percent of the 100,000 gets given to the university, not to me personally --

Q. Thank you.
A. -- which is very different from when an advisory board -- than when it comes to me directly.
Q. Thank you, Dr. Chetcuti.
It's fair to say, though, that disclosures of financial interest are important?
A. Absolutely, because there is inherent conscious and unconscious bias, and the most important thing is unconscious bias. And when you read a paper, you have to read knowing that there could be unconscious bias in our conclusions and things -- (inaudible.)
Q. I'd like to just pause on that for a second. The most important thing that could be disclosed are any interests that might cause an unconscious bias; is that fair?
A. Both. Both conscious and unconscious bias.
Q. And that is because disclosing those potential conflicts allows independent observers to evaluate for themselves if your presentation might be biased. That's right?
A. That's correct.
Q. And, Dr. Chetcuti, fair to say --
A. That's correct.
Q. Fair to say that when you're in charge of your own disclosures, you're very scrupulous in including anything possible that could lead to an unconscious bias; correct?
A. I try to do that with my best intentions.

Q. Thank you.
A. Not only that -- just to make things very clear -- in my clinical practice, I do not enroll these patients in the study because I'm conflicted, and every year I have a slide that shows all my conflicts from all the team when we have our heart team meetings. And we also disclose -- we have a website called M-Inform where my disclosures are visible for the public. It -- they're all there.
Q. Dr. Chetcuti, in the interest of full transparency, it's fair to say that you have been paid money by Edwards Lifesciences in the past; correct?
A. If I'm not mistaken, once -- and I think I said this in my deposition. I gave a talk in January. And this is going to sound really silly. Physicians are not good with money matters. I never put in my proper invoice for it. I don't believe I got paid. So you can check in the, (inaudible) -- what I got paid. I don't think I got paid.
Q. Okay. Thank you, Dr. Chetcuti.
A. And that's me being a stupid physician that's not good with money.
Q. I'm married to a physician. I understand completely, Dr. Chetcuti.
I'd like to ask you about some communications made by your lawyer to the Federal Trade Commission on your behalf in this case. Now, I see that your lawyer has joined

us on this particular hearing. And his name is Brian Robison; correct?

A. Yes, sir.

Q. Dr. Chetcuti, you're not paying Mr. Robison for his time today, are you?

A. No, sir.

Q. Edwards is paying for Mr. Robison?

A. That is my impression. Yes, sir.

Q. Okay. I'd like to talk about how you came to retain Mr. Robison in this case. Let's go back to the evening of September 8th, 2025, just a few weeks ago. Do you recall joining someone named Kristin Skelton for dinner that night, Dr. Chetcuti?

A. Yes, sir.

Q. Ms. Skelton is the senior vice president of sales for thoracic heart valve devices at Edwards?

A. Mm-hmm. Yes, sir. Yes, sir. I'm trying to think. September 8th. Was this in Vancouver or in Ann Arbor?

Q. Dr. Chetcuti, we'll look at a document just a bit later, and that might refresh your recollection.

A. I don't remember when I met her, to be honest.

Q. Do you recall that it was about in the early September 2025 time frame?

A. Yeah. I would think so. Yes.

Q. Okay. Dr. Chetcuti, did you pay for your own dinner

that night?
A. If it was in Vancouver, no -- no, I did not.
Q. Okay?
A. If it was in Vancouver, it was paid by the study. If it was in Ann Arbor, it was paid by Edwards.
Q. Would that have been the first time that Edwards had treated you to dinner, Dr. Chetcuti?
A. No -- (inaudible.) I mean, it's not just me -- (inaudible.) It's the whole team, (inaudible) -- sometimes, (inaudible) -- as far as new technology. So yes, it may have been -- (inaudible.) So if you look at my, (inaudible) -- there should be something --
Q. Oh, sorry, Dr. Chetcuti. Could I ask you to speak just a little bit slower.
A. I will.
Q. Thank you.
A. If you look at my, (inaudible) -- you might see some dinners or things like that that may come up. So even when we go to these meetings, there could be an investigator meeting where there's food and you sign in and they pay you for the food even though you might not eat the food.
Q. Right. Dr. Chetcuti, it's fair to say that I've never bought you dinner?
A. No.
Q. No.

A. No. I don't know you.
Q. No.
(Laughter.)
Fair to say no one at the FTC has bought you dinner before; correct?
A. Not that I know of. I don't who the FTC -- (inaudible.) No, no, of course not.
Q. Thank you.
Now, Dr. Chetcuti, after this dinner that Edwards may have paid for -- or, excuse me, at that dinner, you recall that Ms. Skelton talked to you about this case; correct?
A. Not specifics of it. I remember there was a dinner. There was a -- we were in Vancouver. This is my biggest recollection of this whole interaction. He didn't really mention the thing at this dinner, but in Vancouver -- maybe, it's the same date -- I went up to Kristin myself. There was Aamir Abbas [ph], some other people on the table. Just, sort of, was a communal meeting: Edwards, Medtronic, Abbott, Boston, all there. And I went up to Kristin and I said, "Look, I don't know what's going on with this lawsuit, but if you need an independent witness, someone who's not seen as an Edwards guy, I volunteer myself." That was the most of it. Then she told me -- she gave me some details. I said, "Look, I want to go as an independent person. I'm

not" -- "I don't want to be trained by your lawyers or do anything. I'm just here to talk from a patient perspective."

Q. Okay. Do you recall that Ms. Skelton did connect you with an Edwards in-house attorney following that dinner?

A. Yes, sir.

Q. Okay.

MR. ANDERSON: I'd like to introduce --

THE WITNESS: Attorney --

MR. ANDERSON: Introduce P-X-3093097.

BY MR. ANDERSON:

Q. Dr. Chetcuti, we'll look at this set of emails. This might help refresh your recollection. P-X-3097.

MR. ANDERSON: If we could start at the bottom email on Page 4 and look at the email in the middle of the page.

BY MR. ANDERSON:

Q. Dr. Chetcuti, this is an email on September 9th, 2025, from Kristin Skelton, who we just discussed. And she writes, "Stan, by way of this email, I am introducing you to Heather Haworth, who is our associate general counsel. She is working on the Jena/FTC actions. I offered that you said you would speak to her, and she asked me to connect the two of you. Thanks for joining us for dinner last night. I will leave it all -- leave it with you all.

Fair to say Ms. Haworth was the individual -- the senior VP and associate general counsel at Edwards that was mentioned in this email?

A. Yes. I do not recall meeting Ms. Haworth, though. I thought I met the gentleman who was interrogating me today.

Q. Okay.

A. That's the word I am supposed to use.

Q. That you're supposed to use. That's -- you're referring to Mr. Robison?

A. No, no. The other gentleman who was asking me questions for Edwards.

Q. Okay. We'll -- let's go to Page 3. There's a response from you here, Dr. Chetcuti. This is on the same day, September 9th. And you replied to Ms. Skelton and Ms. Haworth -- you write "Hi, I would be very happy to help in any way I can or you would need."

And you also provided your cell phone number in the redacted box.

Fair to say, Dr. Chetcuti, this was your offer of help to Edwards to assist in testifying in this hearing?

A. Yes, sir.

Q. Okay. If we can flip up --

A. I gave -- you have my cell phone, because I am horrible at emails.

Q. Understood. And we've redacted it so you don't get a

lot of annoying text messages. We're the FTC, after all.

(Laughter.)

Could we look at the bottom of Page 2. You see a response from Ms. Haworth Thursday, September 11th, and you see CC'd on this email chain Connor Leydecker and Michael Perry. Dr. Chetcuti, fair to say Mr. Perry was just up here asking you questions; right?

A. Yes. So I met Connor and Michael. And basically, they described the process. They did not in any way, shape, or form go into the merits of the case. I then asked, because it's the FTC and it's a federal agency, do I need to get legal counsel? I went to the university -- we have our own counsel. And being the university is pedantic and slow -- it would take weeks to get me the right support, and I did not have the time or the infrastructure at the time. When you asked me for old emails over a 10-year period, I panicked because I didn't know how to do it; I had to get IT support. And this is when Michael or Connor said, "We have a lawyer that can help you with this." And so I felt it was a better option for me. So Brian Robison -- I retained Brian Robison, but as you just heard, it was paid by Edwards for me.

Q. Okay. Dr. Chetcuti, you spoke to Mr. Perry and Mr. Leydecker on a call; correct? That's where you spoke to them about the case?

A. A Zoom meeting, just like this.
Q. A Zoom meeting. Thank you.
Were you aware that four days before that Zoom meeting that you had with Edwards's lawyers, Edwards had already told us at the FTC that you would be one of its witnesses at this hearing?
A. I was not aware.
Q. Okay. So no one told you that you would be listed as one of the Edwards witnesses; correct?
A. I was not -- it was interesting because the FTC had already -- even after the decision was made, someone from the FTC, before this lawsuit, had asked me. I had a meeting with the FTC for about two hours with some of your team. I don't remember -- there was, like, four or five people in the room. You should have records of this. And it was done before I was even volunteering myself for Edwards. That's when I got deposed the first time -- again, this is my naivete -- I didn't know who deposed me, if it was you or Edwards. I genuinely did not have any idea.
Q. Dr. Chetcuti, fair to say, after you had this call -- excuse me -- after you were listed as a fact witness in this case, you got an email from the FTC with the subpoenas that you mentioned?
A. Yes, sir.
Q. Dr. Chetcuti, fair to say that, unlike the email that

you sent to Ms. Skelton, you did not tell the FTC that you would be very happy to help in any way you can or that the FTC would need?

A. That is because it's implied, when the Federal Government asks for something, you stop what you're doing and do it. I didn't think I had to say I would be happy to help. I had no choice but to be happy to help. I'm not trying to be funny --

(Laughter.)

THE WITNESS: I mean, I do not want to mess with the Government.

BY MR. ANDERSON:

Q. Doctor --

A. (Inaudible.) It's not like they -- (inaudible.) Just do it.

(Laughter.)

Q. That's fair, Dr. Chetcuti.

But it is fair, also, that you never replied to that email?

A. As I told you from my -- I am not really good with email. In fact, Mr. Robison said, "Look, you have an email to subpoena; don't fool around." So -- and then at that point, I answered.

Q. Okay. You --

A. I have -- oh, I can share, I have probably 3,400

unopened emails at this point in time on my inbox. So this is -- it's the bane of my existence.

Q. Dr. Chetcuti, fair to say that you never personally responded to the FTC, correct?

A. If you say so, I agree.

Q. Do you recall sending an email to the FTC yourself, Dr. Chetcuti?

A. I recall sending a bunch of emails to Mr. Robison with all the emails. I -- it wasn't instantaneous, because I panicked. I did not know how to get all the emails you were asking me for. So I had to get my IT team. And this is a university, just as pedantic sometimes as a federal agency. So I had to get the right people to teach me how to find all these questions you had, and I -- and then I responded. It wasn't for lack of -- it wasn't for disrespect. I was working on what they were asking me for. Plus -- and I don't want to, sort of, be, you know, playing a violin here. I have a very, very busy clinical practice. So when you tell me I have to stop for three or four hours to find emails, I don't have the time in the day to do it. So I was, kind of, panicking, see how I can get help. That's where Mr. Robison came in very, (inaudible) -- because without him I would not have been able to deliver what you wanted in the time you wanted.

Q. So Dr. Chetcuti, when you received those subpoenas, you

had not yet retained Mr. Robison; correct?
A. It was very similar. It was --
Q. Around that time?
A. Around the same time. Because I did not respond until I retained him. I was still looking if the university would give me their own legal counsel, and they didn't have the bandwidth at the time. So I had to get someone else. Again --
Q. Dr. Chetcuti, it's fair --
A. -- this sounds naive. I have --
Q. Apologies.
A. We are scared -- and when the Federal Government subpoenas you, I hear all these, like -- I see too many shows where you have to get a lawyer. And so I was panicked before I responded. I wanted to make sure I responded in the appropriate way.
Q. Fair to say that Edwards's lawyers connected you to Mr. Robison?
A. Absolutely. Yes, sir.
Q. And you trusted Mr. Robison to respond to the Federal Government on your behalf; correct?
A. I did talk to Mr. Robison first. I know this sounds naive, but when you talk to someone and you have an interaction, you feel -- a trust was built right away, and I felt, yes, this is going to work.

Q. Did you know --
A. I interviewed him and he interviewed me kind of thing.
Q. He interviewed you; is that right, Dr. Chetcuti?
A. In the sense that we got to know each other; right? We talked to each other.
Q. Okay. Were you aware at that time, when you first talked to Mr. Robison, that he'd already spoken to Edwards's in-house counsel and told them it will be great to work with you on this case? Did you know that?
A. I did not know that.
Q. Okay. So you decided to use Mr. Robison as your lawyer. When you retained him, did you think that you were getting an independent lawyer to represent you personally?
A. I knew he was retained by Edwards, but to be completely honest -- which is why I'm here; I'm being completely honest -- I was using -- I was partnering with Mr. Robison -- the word, maybe, is not appropriate -- I was working with Mr. Robison to facilitate the requests of the FTC and to make sure I do not walk into a legal quagmire or quicksand. He was just there to give me advice. Not once at any point in this procedure -- and I know this is also attorney-client privilege, but I can share that not once --
Q. I caution you, Dr. Chetcuti, please do not reveal any attorney-client privileged information.
A. Okay.

Q. We're not interested in that.
A. Okay.
Q. Thank you.
A. Okay.
Q. Fair to say that after you retained Mr. Robison -- you know that he reached out to the FTC in an email around September 25th. Does that time frame sound correct?
A. Yes.
Q. I'd like to look at that email.
A. (Inaudible.)
Q. Thank you, Dr. Chetcuti. I'd like to look at that email. It's P-X-0069.

P-X-0069. It's just a single email dated September 25th, 2025. This was an email from Mr. Robison, Dr. Chetcuti, sent on your behalf. Did you see this email before Mr. Robison sent it to the FTC?
A. We discussed that he would send it. I did not see the email.
Q. Okay. Do you see in the "to" line it's to someone named Varnitha Siva at FTC.gov?
A. I see that.
Q. Okay. And you see in the "to" line, also, Mr. Perry, Mr. Leydecker, and Joshua Lipton, who's also an attorney at Gibson Dunn; do you see that?
A. I see it now.

Q. Okay. Dun that Mr. Robison had previously worked at Gibson Dunn for about a decade?
A. No, sir.
Q. Okay. Mr. Robison writes, "Nita and defense counsel: Dr. Chetcuti from Michigan retained me today to represent him in connection with the subpoenas that the FTC served on him."
Dr. Chetcuti, fair to say that nowhere in this email does Mr. Robison disclose that he was selected by Edwards's lawyers for you?
A. Can we just -- that is correct.
Q. Okay. Nowhere does he disclose in this email that he's being paid by lawyers -- or by Edwards's lawyers?
A. I do not see it.
Q. Okay. We can put that to the side.
Mr. -- or excuse me, Dr. Chetcuti, a few weeks later, you recall that Mr. Robison produced documents on your behalf to the FTC. Do you recall that?
A. (Inaudible.)
Q. Okay. I'd like to look at the --
A. (Inaudible.)
Q. Oh, please hold that up to your mouth, if you could. Go ahead.
A. They were mostly emails the FTC had requested, presentations and anything I mentioned with Trilogy valve or

anything in the domain.

Q. Okay.

MR. ANDERSON: If we can put that document up. It's P-X-0067.

BY MR. ANDERSON:

Q. Dr. Chetcuti, this is the email -- or excuse me, the cover letter that Mr. Robison sent with the documents that he produced dated October 9th, 2025, sent to the Federal Trade Commission. Did you review this letter before Mr. Robison sent it?

A. Not the letter itself, but we reviewed the contents of the -- we discussed the contents of what is in the subpoena.

Q. Can you please hold the mic up, Dr. Chetcuti? Apologies.

A. He discussed the contents of the letter. I did not see the letter.

Q. Okay. Looking down at the second paragraph, right at the top there, the first sentence says, "As we did with Dr. Thourani from Atlanta."

Do you know Dr. Thourani?

A. Yes. As I stated in my -- in an earlier part of my deposition [sic] today, I know Dr. Thourani professionally and also from a personal standpoint.

Q. Did you know that Mr. Robison is also representing Mr. -- Dr. Thourani in this case?

A. I did not know that.
Q. Okay. Looking down at the sentence beginning in the middle of the paragraph, Mr. Robison writes, "As an individual non-party, Dr. Chetcuti cannot be expected to conduct a massive search for every document that could conceivably be responsive to the document subpoena, nor does Federal Rule 45 require him to do so."
Dr. Chetcuti, I'd like to look at the phrase "an individual non-party." Are you testifying as an individual non-party or as an Edwards witness today?
A. Today, I understand I'm here as an Edwards --
Q. Okay.
A. -- I'm here at the request of the Edwards lawyers. When I put myself forward, I wanted to do this as an independent. I did not have the money or the point -- or the time to do it on my own.
Q. All right. Dr. Chetcuti, nowhere in this letter does Mr. Robison disclose that he was selected by Edwards's lawyers to represent you, does he?
A. I don't see it. So no.
Q. Nowhere does he disclose that he's being paid by Edwards?
A. No, sir.
Q. Okay. If we look at the second page of this letter, the first sentence of that paragraph reads, "With this document

production, Dr. Chetcuti has fully satisfied his obligations under the document subpoena."

Dr. Chetcuti, were you aware that the document subpoena asked you to provide documents related to your interactions with this case?

A. Can you clarify? I don't understand the question.

Q. Were you aware that the FTC had asked you to provide any communications that you'd had with anybody about this particular case today?

A. Yes. In fact, that's what I did. Every email that mentioned the word "Edwards." The only thing I did not give you are when there were patient-related HIPAA issues that had Edwards or Jena in them, I did not -- (inaudible.)

Q. All right. Dr. Chetcuti, were you aware that Mr. Robison did not send us the emails showing that Edwards had connected you to Mr. Robison?

A. I was not aware of that.

Q. Okay. The document subpoena also asked you to provide documents disclosing anything of value that Edwards had given to you. Were you aware of that?

A. Yes, sir.

Q. Were you aware that Mr. Robison did not send us any of the communications or documents showing that Edwards was paying his legal fees?

A. I was not aware of that.

Q. All right. A few days after this October 9th letter, you recall being deposed on October 14th?
A. Yeah. I do remember.
Q. Dr. Chetcuti, did you know that a few weeks before that deposition, Edwards's lawyers sent to Mr. Robison a highly confidential 34-page white paper that Edwards had submitted to the FTC making arguments for why we should not file this very lawsuit?
A. I was not aware of that. As I told you before, Mr. Robison and I did not discuss anything about the case or the merits of the case.
Q. All right. Did you know that the white paper was authored by Gibson Dunn lawyers representing Edwards in this case?
A. As I said, I know nothing about that document. So everything is going to be a "no" you're asking me.
Q. Okay. So it's fair to say that Edwards -- you did not know that Edwards's lawyers specifically instructed your lawyer to keep that document secret from you, his client?
A. I do not. I don't know what Edwards told him to do. I can tell you I did not see the document and I would not have wanted to see the document because my job -- I felt my job was not to represent Edwards, but to represent my impressions and my patients, the benefit of my patients and the medical community at large.

Q. Okay.
A. I was not here to work for Edwards. That's what my feeling was. I didn't care what Edwards was saying in the case.
Q. Would it surprise you to learn that your deposition was the first time the FTC learned that Mr. Robison was being paid by Edwards?
A. I wouldn't be surprised. I'm not surprised. I don't know how these things work. So -- everything you tell me today, I'm learning. This is my second time testifying in a court in my life. So this is all news to me. I don't know how these things work.
Q. We appreciate your time, Dr. Chetcuti. Do you recall in your deposition that you told us to ask Mr. Robison about the fee arrangement? Do you remember that?
A. Yes. Yes. Because I had no idea.
Q. Right. And we did ask Mr. Robison. Did you know that he immediately forwarded our request to Edwards's lawyers and asked them, We should probably discuss this?
Did you know that?
A. News to me, as I said.
Q. Did you know that he did have a call with Edwards's lawyers to discuss the fact that you had revealed that he was being paid by Edwards?
A. As I said, I'm here to tell the truth. I'm not hiding

anything. So I'm happy he did.

Q. Dr. Chetcuti, since Mr. Robison became your lawyer, fair to say you've not communicated directly with the FTC?

A. No, sir. Apart from the deposition, I have not talked to you or any of your lawyers.

Q. Every communication you've had with --

A. There was one -- as I said before, I -- and I want to be honest. I thought it was -- it was after you made the decision. And, in fact, if you look at the wording of that document, my first question to you: Why are you talking to me now when you've made the decision already?

Q. All right. Fair to say that --

A. That was very -- (inaudible.) The FTC talked to me after a decision was made.

Q. Thank you, Dr. Chetcuti.

I just want to be clear. Since Mr. Robison became your lawyer, after that --

A. No, sir. No, sir.

Q. Correct?

A. No, sir.

Q. So every communication that you've had with the FTC has been through Mr. Robison?

A. Yes, sir.

Q. And you've trusted Mr. Robison to look out for your interests; correct?

A. Yes, that's absolutely right, sir.
Q. Mr. Robison was selected for you by Edwards?
A. We've -- we've declared that already.
Q. Yeah. And he's being paid for by Edwards?
A. We've said that already.
Q. And so has it been your impression this whole time that Mr. Robison is representing you and not Edwards?
A. That's my feeling.
MR. ANDERSON: Nothing further.
THE COURT: Okay.
MR. PERRY: Nothing further, Your Honor. Thank you.
THE COURT: Thank you, Doctor. And in your expert opinion, what do you think Michigan's chances are against Ohio State?
(Laughter.)
THE WITNESS: To be honest, last year, I thought we'd lose by 40. So -- (inaudible.) If we stay true to form, we'll lose by 20, 25 points. We're a basketball school now.
(Laughter.)
THE COURT: All right. Thank you for your time.
THE WITNESS: Thank you, sir. Thank you, Your Honor. I may leave, sir?
THE COURT: You may. You're excused.

MR. PERRY: Your Honor, defendants call Dennis McWilliams.

DENNIS MCWILLIAMS, WITNESS FOR THE DEFENDANTS, SWORN

DIRECT EXAMINATION

BY MR. PERRY:

Q. Good morning, Mr. McWilliams. Could you state your full name for the record, please.

A. Dennis Lee McWilliams.

Q. Did you prepare an expert report in this case?

A. I did.

MR. PERRY: Your Honor, Mr. McWilliams's expert report has been previously admitted as D-X-288.

BY MR. PERRY:

Q. Have you prepared a set of demonstrative exhibits for your testimony today?

A. I have.

MR. PERRY: Your Honor, permission to approach with unredacted copies of these demonstrative exhibits.

If we could start with Slide 2.

BY MR. PERRY:

Q. Could you briefly describe your professional background.

A. Yes. I've spent the last 30 years of my career working in the life science innovation ecosystem, first as an entrepreneur in the biotech space, then as an entrepreneur in the medical device space. And then I recently moved into

venture capital.
Q. Over the course of that career, do you have any experience developing medical devices?
A. I do. I have worked on regulatory approvals for Class III PMA devices, 510(k) de novo and Class II 510(k) devices.
Q. And it -- I understand that you spent a number of years at a company called Apollo Endosurgery; is that right?
A. I did. Apollo Endosurgery were developing a new class of surgical devices that allowed surgeons to perform what's called natural orifice surgery. It was a first-in-class procedure, first-in-class devices, and I was CEO of that company for over a decade and, you know, responsible, you know, for all aspects of the development of that technology.
Q. And were you a founder of Apollo Endosurgery?
A. Yes, I was the founder and first employee.
Q. And could you describe at a high level the course of Apollo Endosurgery from being the founder and first employee to when you left Apollo Endosurgery?
A. Yes, it was a long journey. You know, we raised, you know -- raised probably over $100 million of capital over the years of that company, initially, starting working to develop our devices and prototypes, getting those devices approved by the FDA, and then, you know, we needed to commercialize those devices, and then so, kind of,

restructured the company to build a sales organization and manufacturing and regulatory reimbursement in order to get that company -- and drive our revenue. We were ultimately listed as a public company. And then, after I left, the company was ultimately acquired by Boston Scientific.

Q. And where do you currently work?

A. I now work at Sante Ventures.

Q. Could you describe your work at Sante Ventures at a high level?

A. Sante Ventures is an early-stage venture capital firm. We invest only in health care, but we invest in medical devices, health technology, biopharmaceutical products, and make investment decisions -- we manage just over $1 billion in capital over five different venture funds.

Q. And do you have any experience evaluating or making investments in companies developing medical devices in the cardiovascular space?

A. We do. Sante has been very active in investing in the cardiovascular space.

Q. What about the structural heart space, specifically? Have you screened potential investments in the structural heart space?

A. We have. We've screened and actually made investments. We -- we listed a few of these down below. Laminar with structural heart in the left atrial appendage. VeriPulse.

We have cardiac EP, slightly different. Millipede was structural heart in the mitral valve space. And we've had others, as well.

Q. Have you been selected to serve as a director on the board of any of the companies in which Sante Ventures has invested?

A. I do. I've been a board member in over a dozen companies.

Q. And at a high level, what are your responsibilities as a board member for those companies?

A. As a board member for an earlier-stage life science company, you know, we spend a lot of time -- I would say CEO therapy. We advise the CEOs on, you know, obviously, some of the day-to-day operations, but a lot of time we're really helping them think through strategic issues. You know, they have to access capital. Since we're the first investors, we're typically helping these companies raise additional capital down the road. So we're, you know, giving them access to our network. We're making introductions. We're helping them with strategy. And then, ultimately, our goal is to generate a return on these investments. And so we're ultimately helping them, you know, think through M&A or other exit scenarios, if those make sense.

Q. Beyond the work you've described at Apollo and at Sante, have you taught any courses or otherwise been involved in

what you've described as the medical innovation ecosystem?
A. I like to think I've given back a lot to the med-tech ecosystem. I do a lot of mentoring and teaching at Stanford Biodesign and Johns Hopkins school -- Center For Biodesign. I also teach a class for the last 14 years internationally on medical innovation. We teach medical students and engineering students the basics of how to get a medical device onto the market and how to commercialize that. We've taught over 500 students over the past 14 years across multiple countries.
Q. Could you describe the methodology you applied in reaching the opinions you are offering in this case?
A. So in generating the expert report, you know, I, you know, leveraged each of those experience areas. First, as a venture capital, you know, we do significant due diligence on companies on a regular basis. And so -- you know, analyzing things such as regulatory pathway, regulatory timelines, you know, clinical trial design. And then, you know, a big part of what we do is analyzing the M&A market. You know, who do we think are the likely acquirers for a particular technology is a big piece of our diligence process. So that was one methodology relative to this case.
The second one was my experience as CEO of Apollo Endosurgery so, you know, I've sat in the shoes of the JenaValve CEO, you know, having to make the tradeoffs of

building a commercial organization, not having enough capital and having to, kind of, eke out an existence and raise capital to try to grow and develop your business.

And then the third area is -- the work we do is board advisers and board members to our companies. You know, in that case, it's thinking through your strategic options, trying to predict, you know, if certain scenarios happen, how you're going to respond to those. And so those were, kind of, the three primary elements that I used to generate my expert report.

MR. PERRY: Your Honor, defendants offer Dennis McWilliams as an expert on medical device development, commercialization, and financing.

MR. HOOGENDOORN: No objection, Your Honor.

THE COURT: We'll hear his testimony.

MR. PERRY: If we turn to Slide 3.

BY MR. PERRY:

Q. Could you describe at a high level the typical path to FDA approval for a Class III medical device.

A. Yes. I mean, first, you have to come up with the device. And so you know, on the far left here, we talk about, you know, building your prototypes, doing a lot of bench testing. There's often a lot of animal testing involved. And you get that point -- that product to a point where you feel that it's safe enough to evaluate in human

use. And so there are pathways to be able to do that. You know, in the United States, you submit what's called an investigational device exemption, or an IDE. That allows you to start evaluating that trial. And you then conduct a series of feasibility studies. In Class III, we usually break it down and do what we would call, you know, early feasibility or pilot studies. And then, based on the success of that, you know, progress to larger feasibility studies. And then, you know, when you feel ready and you feel you have a device that's ready for it, you initiate your pivotal studies in the United States. After that, you compile all this information into a huge document, which includes lots of other information the FDA requires, and you submit what's called a premarket authorization application, or PMA. FDA reviews that. There's a lot of back and forth. And then, you know, ultimately, hopefully, you receive approval of that PMA application by the FDA.

Q. And we've heard about -- from some of the average timelines for FDA approval for a Class III medical device. In your experience, does every company face the same approval timeline?

A. No, there's wide variety in those timelines driven by a number of different factors.

Q. And we've heard testimony about how long it has taken for JenaValve to make its way through the FDA approval

process to where they are today. In your experience, does the FDA approval timeline often take longer for the first-in-class device?

A. That's been my experience throughout my years doing this. You know, you're pioneering a brand-new procedure. There's technical aspects of a device. You're having to design, you know -- you're having to design a pivotal study, and you heard the testimony earlier -- you know, those pivotal studies are important. There are a lot of nuances to that. You have to figure that out on your own. And then, moreover, you know, oftentimes it's the FDA's first time to learn about your device in that particular area. And so the FDA has lots of questions. And so you spend a lot of time educating on that. And then you learn things. You, you know, you make mistakes and you stub your toe and so -- you know, it's not always the case, but it's been my experience that the pioneer usually has to bear a lot of the bruises of developing first.

Q. In the real world, in your experience, does the FDA approval pathway for medical devices necessarily follow this linear path shown in this flowchart?

A. No, it doesn't, and that's actually been changing more and more more recently.

MR. PERRY: If we turn to Slide 4.

BY MR. PERRY:

Q. Have you reviewed Dr. Kesselheim's reports and testimony in this case?
A. I have read his report.
Q. Last week, the FTC presented a summary of the timeline for FDA approval of TAVR-AR devices. Have you seen this slide?
A. I have seen this slide.
Q. As a starting point, do you agree with the FTC that Edwards and JenaValve are currently the only two companies in U.S. clinical trials for TAVR-AR devices?
A. I would agree with that.
Q. The red arrow in the FTC's slide labeled, "All other conditions" seems to suggest that any other company seeking FDA approval for a TAVR device would have to start at the very beginning of this process. Do you agree with that assumption?
A. No, I do not.
Q. And why not?
A. It's become more common these days for companies to do a lot of their, you know -- what's listed here as feasibility studies, to do those internationally. There are a number of reasons why you would do that. You know, one is cost. But also, if you're an international company, it's actually easier and more convenient to work with maybe your local physicians and doctors to do that. The FDA has become more

accepting of that over the years. They actually recently published a guidance document in 2018 or 2019 detailing how data can be -- international patient data can be used. And so, like, a number of our companies that I sit on the board of doing Class III medical devices, we've done all of our feasibility studies outside the United States. We then compile that information and we submit an IDE to the FDA to go straight to a pivotal study. FDA even has guidance on using international patients for your pivotal study. You know, I would say that including international patients is becoming more common, but I would agree with the testimony earlier that the FDA and most physicians want to see some U.S. patients in that pivotal study, though, but, you know -- you know, a lot of the companies could be able to enter right at pivotal stage here on this chart.

Q. What about devices that are developed in China or data from China? Under the FDA guidance that you described, is it possible to use data from China to support an IDE?

A. Yes, the FDA does not delineate, you know, countries that it does and does not accept data from.

Q. And have you seen an increase in the activity of Chinese medical device companies and them increasingly moving into the United States?

A. We've seen a big increase in the activity, not just in the medical devices, but it's probably the hottest theme in

biotech right now, as well. There was a big article this morning about Chinese companies, you know, you know -- really, you know, reaching the peak of development. And so, you know, you're seeing, you know, Chinese companies who are developing initially in their domestic market, because the Chinese market is a big market. And as they're -- as the standards in China have increased, they have their -- CFDA is what -- China FDA. The standards have increased there. It's been easier for them to bridge, then, those products into the United States.

Q. So companies like Hanchor Valve that we heard about earlier today that have tested TAVR-AR devices in patients outside the U.S., would they have the ability, potentially, to proceed directly to a U.S. pivotal trial without having first to go through the early feasibility studies shown in this slide?

A. Yes, if their data meets the standards set up by the FDA CFR, and that they also have the other elements of the IDE application included.

Q. So if the developer of the Hanchor valve or another company that would have rights to a device like that were to proceed straight to a pivotal trial, in your estimation, how far behind where the J-Valve is today would they be?

MR. HOOGENDOORN: Objection. Scope. May I briefly be heard, Your Honor? Mr. McWilliams testified in

his deposition --

THE DEPUTY CLERK: Can you please use the microphone for the court reporter.

MR. HOOGENDOORN: My apologies. Mr. McWilliams testified in his deposition that he did not include this particular opinion in his expert report. And he further testified in his deposition that he did not intend to offer any opinions not in his expert report at trial today. So I would object to scope as to the particular question being elicited here.

MR. PERRY: And, Your Honor, in Paragraphs 128 to 130 of Mr. McWilliams's expert report, he discloses opinions very similar to what he just described; in particular, that many of the competitors currently developing TAVR-AR devices outside the U.S. are similarly positioned to JC Medical prior to Edwards's acquisitions. And specifically in Paragraph 130 he offers the opinion that, even assuming J-Valve could get approval and be commercialized on its earliest timeline, at this point, perhaps 2029 in a best-case scenario. Others will likely be close behind, particularly if Edwards is able to establish commercial success with Trilogy, and thereby spur investment in other startups.

THE COURT: All right.

MR. HOOGENDOORN: Your Honor, missing from that

was any particular estimation as to when a foreign competitor may be able to go through and complete that process, and that's the very narrow scope objection I'm making.

THE COURT: All right. You can ask the question and he can answer it.

THE WITNESS: Can you ask the question again.

BY MR. PERRY:

Q. I figured you may want me to do that. I'll try to ask it again.

If the developer of the Hanchor valve or another company, with data from patients outside the U.S., were to proceed straight to a pivotal trial, in your estimation, how far behind where the J-Valve is today would they be?

A. Sure. And I'll caveat this with a lot of the different variables that drive this. But, you know, assuming that they have a lot of the other elements and -- I believe, actually, Hanchor Valve is commercial in China, so you would assume they would have all the commercial, you know, manufacturing of those pieces, and the animal testing -- you know, they need to submit the IDE to start their pivotal study, but they would, you know, most likely just mimic what both J-Valve and JenaValve have done in their pivotal study in terms of design to the extent that those are applicable.

If you look at, kind of, the enrollment period of

that clinical trial, you know -- and we heard some testimony around that earlier -- you know, you could assume anywhere from a two to four-year enrollment period. The studies up to date have only required 12 month follow-up. And so, you know, those pivotal studies you would think would be in the three to four range period once they've started. So you know, if somebody had the resources to do it and started today, you know, I would think 2030 could be the earliest that somebody could go, maybe, late 2029, if I think of where we are in the calendar year right now. But, you know -- you know, again, you know -- and based on where, you know, J-Valve is, you know, J-Valve has started their U.S. pivotal study, but it's my understanding that that study's now on clinical hold due to some complications they had with the device. So it's uncertain, really, how much of a head start they actually have against subsequent international competitors who chose to come into the market.

Q. Do you have the details about any specific company's plans to begin U.S. clinical trials?

A. I don't have any details. The only company that's actually listed on the chart here that has, I know, an expressed interest is Laguna Tech. It's a small startup based in Irvine, ironically, down the street from Edwards. They actually submitted their business plan to Sante, but they've also stated their intent and desire to start

feasibility studies in the United States. They have not, I believe, done any testing yet that I'm aware of. But they're not able to do that because they don't have the funding, and they're trying to get the funding to do that.

Q. Turning back to the path for medical device development, is FDA approval the only hurdle to bringing a new medical device like this to patients?

A. No. It's really only the start of the journey.

MR. PERRY: If we could turn to Slide 5.

BY MR. PERRY:

Q. Could you describe at a high level the commercial infrastructure needed to successfully commercialize a novel Class III medical device like JenaValve's Trilogy?

A. Sure. You heard the testimony today. You know, these physicians require a significant amount of clinical support from the team. So every case you're going to do as the manufacturer, you're going need, at least for the first couple years, your people in those cases physically. And so in order to make sure you can ramp and grow sufficiently and hit, you know, robust revenue numbers, you have to be able to do that in parallel. So you have to hire a lot of this organization, you know, from scratch. You have to find the people, you have to train the people, and then you have to, kind of, get them out there in the feed. You've got to do significant investment in training and education resources,

you know, invest in the facilities to be able to do that. You know, manufacturing and supply chain has been discussed, I'm sure. That's a huge investment required to get these products and do them sufficiently.

FDA also requires post-market surveillance studies for all phase -- all pivotal Class III medical devices, which is another burden. And also, you typically want to run other clinical studies post-market approval, as well. So you need an expanded department for that. And then you need, you know, reimbursement and coverage people to help hospitals get paid for -- for these devices. So it's just this massive expansion that you have to, kind of, build from scratch, which is really why, you know, when we're investing in these companies, you know, our desire is to fund them through, showing the really great clinical evidence that JenaValve showed, and then to get the company acquired so that the large companies who have that infrastructure, then, can take over that commercialization.

I liken it to -- I give a talk on this in my courses, and we -- I show a slide of Sisyphus, who's the guy who had to push the rock up the hill, and every time he pushes the rock up the hill, it rolls back down because you have another burden to hit. And that's, kind of, what FDA approval's like.

Q. And based on the analysis you've done in this case and

your experience, does JenaValve have the resources and capabilities necessary to successfully commercialize the Trilogy device at scale?

A. No.

Q. And why not?

A. Well, they don't, you know -- they've been designed as a clinical -- R&D and clinical organization to date. They have a small clinical field support group to support their existing clinical sites, which you heard today that the doctors are currently having to schedule their cases around the availability as that team rotates around the country. And so to do it at scale, they're going to have to go invest in massive parallel to bring that infrastructure on board. That's one of many things that they're going to have to do.

Q. And does Edwards have the resources and capabilities necessary to commercialize Trilogy at scale?

A. Yes.

Q. I'd like to turn to JenaValve's options and plans if this deal were enjoined. Have you evaluated JenaValve's contingency plans if this transaction with Edwards is blocked?

A. Yes, I have.

Q. And do you understand that JenaValve's management team has mapped out a plan to try to commercialize Trilogy on their own if the transaction is blocked?

A. Yes. They call it their financing contingency plan.
Q. As a starting point, do you consider JenaValve to be a well-run company?
A. I do.
Q. And, in your experience, does JenaValve have well-resourced investors today?
A. I do -- I know a number of their investors and they have a good solid investment syndicate.
Q. All right. If we turn to Slide 6, and I'll just note that the public version is redacted --
A. Redacted.
Q. Yeah. But the Court and counsel have an unredacted copy. I would just ask, for these and other slides, not to reveal the specific numbers, but we should be able to speak generally to them, and others we'll be able to see the specifics.

Have you analyzed JenaValve's current cash position and burn rate?
A. Yes, I have.
Q. And based on your analysis, if this transaction is blocked, do you believe that JenaValve will have the financial resources needed to continue even its current operations?
A. No, they do not.
Q. And could you explain how you reached that conclusion?

A. So if you look at the chart on here, you see right now they have a small existing cash balance, small double-digit million. And their current burn rate, which is several millions of dollars, is currently being offset by monthly payments from Edwards. And so were this to be blocked, those would stop. They do receive a termination payment as part of the deal, but, as you can see from the number of lawyers here, they're going to have a large accounts payable to do. So if you -- if I estimate it, best-case scenario, if they don't receive any new additional financing, they may have two months of runway, you know, maybe even just, you know, six to eight weeks of runway, before they would need to access capital, which their current plan is they would do that from their existing investors. And I believe their existing investors would give them, you know, the emergency financing. You'll see -- we can -- I don't know if you want to go to the next side.

Q. Sure. Let's go to Slide 7. That makes sense.

A. If we go to Slide 7, you can see some of the numbers that they have disclosed in there. The, you know -- a mid-sized double-digit characteristic infusion from their existing investors. It's my understanding that that has not been committed by their existing investors, but I would imagine the investors would give them that. But based on that existing burn rate that you saw on the previous slide,

that's less than, you know, around six months of runway for them. So that runway is meant to give them time to figure out what they're going to do. And so during that time, they have to figure out their plan B.

Whether they get FDA approval or not during that time frame, they'll be in no position to increase their burn rate to be able to do that. And if I were on their board, you know, I -- and there's already some evidence of this -- I'd be asking them to reduce their expenses, to extend that runway as long as I can so that I have time to figure out my plan B.

Q. And based on -- following up on what you just mentioned, based on the information you have analyzed in this case and your experience with other similar startup companies, do you expect that JenaValve will have to make tradeoffs between priorities, such as building out a commercial infrastructure, versus funding additional R&D?

A. Yes, I do.

Q. And I believe you mentioned earlier that you expect JenaValve will be able to raise at least some emergency funding from its current investors; is that right?

A. I would think that their existing investors would be incentivized to give them additional financing.

Q. So let's assume that they're able to do that. Do you have a sense of approximately how much runway that may give

them?
A. Sure. On their existing burn rate, you know, that would be, you know, around six months -- six to seven months of cash with no increase in burn rate.
Q. Okay. And let's assume they're able to do that, raise enough money from existing investors to extend out that time horizon to, maybe, six months. What options would JenaValve have at that point?
A. So if I'm on the board, you have two options. One is to try to find another strategic buyer to pick up the cause and pick up the burn rate. And then the other would be to raise a, you know -- try to attempt to raise additional financing from the private markets to give you the capital to do some form of commercial launch.
Q. I'd like to talk through those two potential points. And we've heard testimony about JenaValve not yet receiving FDA approval and the uncertainty around that. Let's assume for the moment that JenaValve is successful in obtaining FDA approval in the near term. Is that okay?
A. Sure.
Q. Okay. The first option you mentioned, I believe, was trying to find another company to buy or invest in it -- in JenaValve. Based on your experience and the analysis you've done in this case, do you expect that to be a realistic alternative?

A. No, I do not.
Q. Let's turn to Slide 8.
Why is that?
A. Well, you know, the company ran a banker-run sales process in 2024 that led to the Edwards acquisition. And while -- and I know the bankers very well in the situation. They talked to all the potential acquirers, none of which, even though they're in the structural heart space, chose to even make a bid on the asset. You know, the -- one of the parties, I think, several years before had expressed some interest in, maybe, doing that, but when the time came to actually put in an offer and acquire the business, they didn't. So it doesn't, you know, appear, based on that process, that any of the other structural heart companies have an interest in, today, going after the TAVR-AR market.
Q. And over the course of the hearing, we've heard from one of those companies that if this deal were blocked, they may consider acquiring JenaValve. Have you reviewed that testimony?
A. I have reviewed that testimony from that company.
Q. Does that testimony change your opinion about JenaValve's realistic chances to find an alternative buyer that would invest in creating the TAVR-AR market?
A. I mean, no, it doesn't. I mean, I -- when I was at a -- CEO of Apollo, Boston Scientific had real interest in us in

2009, and it was 14 years later, in 2023, before they finally bought the company. And a lot of -- there's just a lot of -- look, it's very expensive. As you see from the numbers and the costs to go do this, it's very expensive to develop and build out these new markets. And so a lot of these big companies have other priorities. And so, you know, it's clear that particular company that you're referring to, that we're not disclosing their name, they have three stated priorities of what the company is forward-investing in, and structural heart is not one of those at this point. And so I just don't see why they would, you know, magically change their mind after they had had a chance just, you know, a few months ago to be able to do that.

Q. Have you analyzed the evidence from these potential strategic buyers as to why they don't seem interested in making this investment, at least at this stage?

A. I have, and most of it surrounds the concern around the size of the TAVR-AR market relative to the TAVR-AS market. You heard testimony earlier today that, you know, the clinical site in Michigan, Dr. Chetcuti's site, was doing, you know, 10 TAVR-AS procedures a week and, maybe, doing two to three TAVR-AR procedures per month. And so I think there's this perception that, while it's an important clinical market, it's just not a very large market. And so

the return for a company to go do all the heavy lifting of deploying this product and launching it would not generate an interesting enough return for them.

Q. Let's turn to the other option that JenaValve would have that you mentioned. I think you described it as raising additional money from the private markets. Beyond the initial emergency funding that you testified to earlier, do you expect that JenaValve will realistically be able to raise additional funding to extend the cash runway beyond the six months or so you mentioned earlier?

A. I think it will be difficult for them. I mean, look, you know, they will have just come off a failed M&A process and, you know, as an investor, as I mentioned before, we always want to know who the acquirer is, and in this particular case, you know that the only company who's expressed an interest in wanting to develop the TAVR-AR market today is Edwards. They'd be off the table. And so, as an investor, I would know that they couldn't be a potential acquirer. So I know, then, I have to do the long haul of commercializing this myself as an investor. And a lot of these investors who do these later-stage growth rounds, they want to see that early evidence of commercial traction. So you get in this really -- I was in this at Apollo. You get in this really tough Catch-22 of you need capital to go prove out your revenue opportunity in your

market, you know, but you can't get that capital because people want to see evidence of it. And so it just creates this long cycle of trying to eke out and build that revenue until you can get to the point where you can access capital from those.

Now, look, I'm not saying it's not impossible. I'm sure there will be a number of companies that will look at it, but it's just, you know -- time horizons now, you know, we tell our companies it's a minimum of six months to raise new capital from new investors. You know, I'm seeing that going 12 to 18 months in some of my companies. This could be different. But I think those are some of the dynamics working against JenaValve as they attempt to go raise the capital to commercialize on their own.

Q. What about the possibility of an IPO? Have you analyzed whether JenaValve would realistically be able to launch a successful IPO?

A. Yes, and I don't feel like there's any way they can do an IPO today.

Q. What do you base that conclusion on?

A. You know, in the decades plus that I've been doing this, the bar for a medical device company -- different from biotech. In biotech, you know, non-revenue companies go all the time. But in medical devices, the bar has consistently been, you need to be generating revenue of $50 million or

more annually, high growth rate, with good gross margins. And, you know, the company right now, I believe, in Europe is doing, you know, small single-digit millions in revenue. And so to go public, they're going to have to get to that 50 million bar somehow, and that's going to take a significant amount of capital to do so. If they start getting traction towards that number, yes, they could, but I see that being many, many years out before they could do that.

Q. And if JenaValve were able to raise capital through an IPO, does that necessarily ensure that they have the resources that they need to build out the commercial infrastructure, pursue further R&D, and everything else that they would hope to do?

A. No. I mean, raising -- going IPO is not a blank check of cash. It's like raising money from private investors. It's just a different pool of investors. And so, you know, look, it's hard to predict exact amounts of what you can raise in an IPO, but, you know, 150 to $200 million of new cash is not a -- like, is a reasonable estimate of what you see. I mean, you know, from the estimates that I've seen, JenaValve, you know, feels it needs over $300 million to, kind of, go and fully commercialize the device. And so, you know, one, they have to raise the capital just to get to the point where they can try to do the revenue build in order to

go public, and then you've got to be able to successfully do the IPO, and you can't always control when the IPO window is open or closed. And so, you know, there's just a lot of uncertainty as it relates to that.

Q. So we've been discussing JenaValve's options under the assumption that JenaValve receives FDA approval early next year. If JenaValve has further delays in obtaining FDA approval, what impact would that have on its ability to secure additional funding?

A. Well, I can't imagine any new investor would come into this without knowing you had FDA approval. Also, every month you delay, you know, think of this cash balance that they have is diminishing on the burn rate. It just gives you more time for that burn -- for that cash position to fall before you have this milestone that will hopefully enable you to raise more capital.

Q. So let's assume that JenaValve is able to raise the emergency funding. I think you've assumed that that's the case. They are able to raise additional funding from new investors. They are able to get FDA approval before that funding were to run out. In that scenario, do you expect that JenaValve will be able to commercialize Trilogy successfully?

A. Not in the near term.

Q. And why is that?

A. Well, again, they have to build all this by scratch. You know, they have to go out and hire and build an entire sales and commercial organization, you know, all those boxes I showed before. Those aren't single people. Those are departments. And so they have to go out and build that from scratch. And there's just a big lag time to be able to effectively do that and, you know, while you're doing that, yes, you're trying to build your revenue and scale, but it just takes a long time to do that.

Q. And if we turn to Slide 9, have you analyzed JenaValve's plan for how it would attempt to build a commercial infrastructure to support a launch of the Trilogy device?

A. Yes, and I see this has all been blacked out as well, but you can read the -- this is an organizational chart -- now, mind you, this is just for the commercial organization. So each one of those boxes I showed you before will have a similar chart of this which shows, in dark blue, this is existing head count within the company. You know, light blues are hires they were planning to make in the near term in anticipation of approval, but have since been delayed, most likely due to some of the cash things that I talked about. And then the yellow boxes are projected hirings in the future. And it's really hard to see on the chart, but each one of those boxes isn't just a single person. These are teams of people. So like, you know, several of the

commercial groups, they're blocks of 10, blocks of 8, and so, you know, on this chart alone, it's a head count of 50 people that they need to try to hire in order to try to build out the infrastructure required to meet the projections that they've communicated to potential investors.

Q. If we turn to Slide 10, assuming JenaValve were able to at least start building out that commercial infrastructure to support a launch of the Trilogy device, would you expect JenaValve would be able to bring this device to as many patients or as quickly as Edwards would?

A. No.

Q. And why is that?

A. Well, again, you know, this -- maybe flip on the other side. Edwards already has all this infrastructure. So, you know, you heard testimony before. There are 850 sites in the United States that implant TAVRs today for aortic stenosis. But, you know, they already have field staff that can support those 850 sites. And so for Edwards, yes, they still have to train that organization of -- how the nuances and the specifics of implanting the TAVR-AR devices. There will be some differences to that. But they already have it. So they don't have to hire it. They don't have to build that. And so in each of those areas, you know, they'll have the ability to start turning on those sites without having

the resource constraints that a startup company like JenaValve would have.

Q. And have you attempted to try to quantify how quickly JenaValve might be able to roll out this device versus what Edwards might be able to do?

A. Yes. I, you know -- I reviewed the JenaValve projections in the past. I've had to develop projections similar to this. And you really do it by estimating the number of sites, and that's what I've attempted to reflect here, a comparison. And I compare it, actually, not -- so Edwards had projections as well, too, and we'll talk about those on the next demonstrative, but what I used as a reference point was really looking at what Edwards did for TAVR-AS previously. Now, there, they didn't have the infrastructure in place; they were building a lot of that infrastructure. But I think it gives a good metric of a company, you know, unconstrained by resources, what they're able to accomplish in a launch. And so that's what's reflected here, is their actual results for TAVR-AS, and this is compared to the JenaValve projections, and those JenaValve projections assume all the hiring that I showed you on the previous slide.

Q. And if we turn to Slide 11, during their opening statement, the FTC showed a demonstrative exhibit comparing JenaValve's sales projections with the assumptions in an

Edwards deal model. Have you seen that exhibit and the underlying projections?

A. I have.

Q. All right. So if, you know -- the FTC pointed out with these red arrows that the numbers in those two look very similar. If that's the case, why do you expect that Edwards will be able to reach more patients more quickly than JenaValve would be?

A. There are different reasons why you do projections in different audiences that you have. As I mentioned, JenaValve is developing projections to try to convince investors why they should invest in the company. So they tend to be overly optimistic. They're also, you know, developing these projections in a way that is trying to justify to Edwards the price that they're paying to acquire the company. So that's their motivation and justification. I just think it's, again, overly aggressive and just a very rosy set of assumptions that, even if they were able to raise the capital needed to hire the people, I don't think they can come close to those projections, whereas Edwards, their projections, you see the actual numbers are very, very similar. You know, for this deal model -- I mean, you know, my read of it is that Edwards was just, you know, building a deal model that took those JenaValve projections to justify the price. Their audience, if you're Edwards, is your Board

of Directors, who you're trying to convince to approve the deal for the price, and your analysts down the road who are going to, you know, give you a number that you have told them you're going to hit in terms of revenue. So your objective there is to do that as low as possible so that you have the ability to overachieve on that, and that's, kind of, again, the nuance behind, you know, the different lens you do when you're developing projections.

Q. And do you know exactly how fast the ramp-up would be with either company?

A. No, I don't.

Q. And -- but what is your basis at a high level for concluding that it's likely to be faster with Edwards's resources?

A. Well, again, because -- you know, to me, the biggest thing is they're already in 850 sites around the United States with a very similar technology and they have full infrastructure over the past, you know, decade that they've built doing this. So for them, yes, there is work and training that has to go, but it's a much lower bar for them to repurpose and retrain those resources than it is for a company -- which, again, is why, you know, in the -- in our world, you know, when you're developing these complex devices -- and JenaValve spent almost 400, $500 million in private capital just to get to here -- that you really hope

somebody acquires it at this time so that you don't have to make the other several hundred million dollars of investment to, then, go commercialize and prove out the market.

Q. And if we turn to Slide 12, have you analyzed any other evidence in the record that corroborates your view that Edwards is likely to be able to do this at greater scale and more quickly than JenaValve would on its own?

A. Yes, I pulled out a couple of quotes that I found interesting. You know, Dr. Pinto is obviously at JenaValve, as CMA, lamenting the small size of their sales force and the impact that's had on revenue. You know, you heard -- well, you heard testimony today about Dr. Chetcuti, you know, having challenges getting devices due to inventory challenges, also having challenges related to having staff to be able to support those cases. And so I think the field and the community out there of physicians, you know, has a lot of concerns about their ability to be able to do it to the level that an Edwards could.

THE COURT: Hold on one second.

Tim, do you need a break?

THE COURT REPORTER: Yeah.

THE COURT: Let's take a 10-minute break.

(Brief recess taken.)

MR. PERRY: We can take those slides down. Thank you.

BY MR. PERRY:

Q. So Mr. McWilliams, before the break, we were talking about JenaValve's commercial capabilities. Given your conclusion that JenaValve is unlikely to be able to support a successful commercial launch on its own, if you're JenaValve today, who do you consider to be the most significant competitor in the U.S. TAVR-AR space?

A. Well, today, there are no competitors in the TAVR-AR space because -- in the U.S., because no products have been approved by the FDA. So if I project and start to think forward as -- in terms of, you know, how I think about competition, the first bar is getting the FDA approval. You know, JenaValve has had some challenges getting FDA approval to date, despite a successful clinical study, but I expect that they will, I mean, just based on what we've seen from the clinical data and the patient need.

And then if you look at, you know, some of the other technologies that are out there, you know, we've mentioned J-Valve has started their U.S. pivotal study, and there are a number of international companies out there. But if you think about the other element, you know, consistent with my testimony and opinion of what would be required to be a competitor in the space -- and that's resources. And, you know, while there are a number of large medical device companies in the structural heart space that

have significant resources and infrastructure, you know, you also have to have intent. And the only one that has shown the intent to want to develop the TAVR-AR market is Edwards. So by that definition, I would say it would be Edwards.

Q. And if you're Edwards and this deal with JenaValve goes forward, what will put pressure on Edwards to innovate and compete?

A. Well, your first goal is to maximize the number -- types of patients that you can treat. So you're highly incentivized to do that because that drives your revenue. So you know, all the elements around getting to as many sites as safely and reasonably possible, you know, drives your revenue model and your deal model. And then, you know, you're incentivized to expand the indication as much as you can. Edwards has shown -- you heard today Edwards has consistently done that in the TAVR-AS space.

But you also know that, like -- you know, what you worry about is these fast followers that are going to come, and you don't really worry about these small companies that are there. You worry about, you know, when does a, you know -- a Medtronic, an Abbott, or one of these other companies, you know, who has real resources decides to acquire one of these technologies and make the investment to be a fast follower?

Q. That fast follower approach that you just mentioned, is

that something you've seen with other structural heart therapies?

A. Yes. I mean, we've done it at Sante as an investor. One of our successful investments was a company called Laminar and, you know, Laminar was developing a device for left atrial appendage. That's a market that was pioneered and built by Boston Scientific. But, actually, they acquired -- it's a similar story. They acquired a small venture-backed company called Atritech, who was struggling to, kind of, get approval. Boston got the product approved and made significant investments in all the areas that I've talked about to prove that this product that -- you implanted it in the left atrial appendage -- would reduce stroke. That market became a billion-dollar market and was growing fast with Boston Scientific, and a lot of us started investing in other technologies. We invested in Laminar, and it was acquired by Johnson & Johnson and is currently in its pivotal study.

Q. And have you observed a similar phenomenon in the TAVR-AS space?

A. Well, it's exactly what happened in TAVR-AS. You know, Edwards pioneered that space, as well. Acquired -- again, you see a theme. They acquired a smaller venture-backed company, invested in that, and -- you know, SAPIEN was the name of that product. And, look, when you know that you're

building a billion-dollar category, you know eventually you're going to have competition. So you're trying to optimize your product as best you can. You're trying to build the best clinical evidence that you can. Yes, that helps you on your own revenue as you go, but you know you've got to build that up because you will have competitors at some point enter the market.

Q. Conversely, if this deal is blocked and JenaValve has to try to launch this device on its own, what impact do you expect that would have on investment by these other strategic players in the TAVR-AR space?

A. I think there's a lot of potential challenges there. Like, you know, look, without having the resources, you know, like, do they have mistakes? Do they have complications because they don't have the clinical support staff to successfully support it? You know, do they have manufacture -- you know, all these issues that -- you know, these risks. One, you know, they're likely only to reinforce this existing view by those other large corporates that this is a small, niche market. And so, you know, until they prove that otherwise, you know, there's going to be no incentive for these other companies to want to jump into the space.

MR. PERRY: Thank you. I pass the witness.

MR. HOOGENDOORN: Taylor Hoogendoorn on behalf of

the Federal Trade Commission. May I proceed?

THE COURT: You may.

CROSS-EXAMINATION

BY MR. HOOGENDOORN:

Q. Good morning, Mr. McWilliams. I know we met a couple of weeks ago in your office. I'm going to ask you some questions today, if that's okay.

Start with the softball. Edwards's J-Valve and JenaValve's Trilogy are the two TAVR-AR devices furthest along in the FDA's approval process; right?

A. Yes.

Q. They're the only two devices with any FDA submissions that you're aware of for TAVR-AR?

A. Yes.

Q. There are hundreds of different types of Class III medical devices approved in the United States; right?

A. Yes.

Q. In offering your opinions in this case, you did not consider a single example ever where a company purchased the two Class III medical devices furthest along in the FDA approval pipeline; correct?

A. I did not specifically analyze that scenario.

Q. And when I asked you at your deposition two weeks ago, you weren't aware of a single example ever of that happening for a Class III medical device; correct?

A. Correct.
Q. What about if we broaden it -- not just Class III medical devices, but all medical devices, all classes? In forming your opinions, you didn't consider a single example ever for any type of medical device where a single company bought the two medical devices furthest along in the FDA approval process; correct?
A. Correct.
Q. And when I asked you at your deposition a couple weeks ago, once again, you could not think of a single example in U.S. history where a company had bought the two medical devices furthest along in the FDA approval pipeline; right?
A. That's correct.
Q. I think you said earlier Trilogy is the TAVR-AR device most likely to receive FDA approval in the United States; right?
A. That's correct.
Q. I think you also said you expect it to receive approval?
A. Yes. I mean, again, you know, it's hard to predict, but I would expect that they would receive approval.
Q. I'd like to talk a little bit about competition. Medical device competition is generally a good thing?
A. Yes. Sure.
Q. Medical device competition is a factor that can drive innovation?

A. Yes, it is a factor.
Q. Medical devices compete to be the most clinically effective?
A. Yes.
Q. And medical device competition for clinical effectiveness occurs during the FDA approval process; right?
A. Make sure I understand your question -- do you mind asking it again.
Q. Medical device manufacturers are competing on the basis of clinical effectiveness through the FDA approval process; correct?
A. Yes. I mean, the nuance I would add is that they're proving the effectiveness of their device. It's not really improving at that point, because they've already established it, but yes, they're using the FDA process to prove out the effectiveness of their devices.
Q. They're using the FDA approval process -- or through that process they're competing on clinical effectiveness?
A. They're trying to get approval for their own product which is going to generate data. Your data is what your data is at the end of the day.
Q. Medical devices compete on safety?
A. Yes.
Q. They compete on pricing?
A. Yes.

Q. Edwards's J-Valve and JenaValve's Trilogy are competing to be the first to receive premarket approval in the United States?

A. Yes.

Q. J-Valve and Trilogy are competing to go against -- after one of the same patient populations; right?

A. Generally, yes.

Q. You would agree, also, that for Edwards's J-Valve, JenaValve's Trilogy device is the closest competitor for U.S. TAVR-AR; correct?

A. Yes, based on its approval standing, yes.

Q. And on JenaValve today, you would agree that the only competitive pressure for JenaValve would be Edwards and JC Medical; correct?

A. I don't know that I would say it's the only competitive pressure, but yeah, it would be a big piece of your competitive pressure.

Q. Your testimony is that you would not say Edwards and JC Medical are the only competitive pressure on JenaValve today?

A. I wouldn't say that today.

MR. HOOGENDOORN: Mr. Nguyen, if we could please pull up Mr. McWilliams's November 12 depo, Page 241, Lines 6 through 13.

BY MR. HOOGENDOORN:

Q. Mr. McWilliams, you remember testifying at your deposition a couple of weeks ago, I take it?
A. I do remember.
Q. You testified truthfully at that time?
A. I did.
Q. You can follow along as I read aloud.
"QUESTION: Which company is the most significant competitive threat or, if you prefer, puts the most competitive pressure on JenaValve today?
"ANSWER: On JenaValve today?
"MR. PERRY: Objection. Vague.
"FURTHER ANSWER: Well, on JenaValve today, the only competitive pressure for JenaValve would be Edwards and JC Medical."
I read that correctly?
A. Yes.
Q. I'd like to pivot now and talk a little bit about patents. You're familiar with patents?
A. Yes.
Q. You're the named inventor on several of them?
A. Yes.
Q. Patents provide the ability to exclude things that read on a claim from the United States; right?
A. Correct.
Q. You would always want to understand the state of

intellectual property protections, including patents, before making an investment in a medical device company?

A. Absolutely.

Q. Intellectual property protections can be a substantial barrier to entry for a Class III medical device; right?

A. Yes, they can.

MR. HOOGENDOORN: Could we please pull up what has been previously entered as P-X-1390, Mr. Nguyen.

BY MR. HOOGENDOORN:

Q. You reviewed this document, Mr. McWilliams, at your deposition a couple of weeks ago?

A. Yeah. Can I just refamiliarize myself? Yes. Thank you.

Q. And there's an unredacted copy in your binder, but I don't think you'll need it.

A. This -- yeah, I can read it. Just give me just a second just to refresh.

(Brief pause.)

Yes, these are the U.S. field -- field organization FAQs.

Q. This is an email exchange between Jeremy Bierman and Pooja Sharma; right?

A. Correct.

Q. They both work for Edwards?

A. Yes.

Q. And, as you said, there were documents attached to this?
A. It was a multiple-page -- yes, it was a multi-page document -- email document. Yes.
Q. And, I think, Mr. Nguyen's making it a little easier for you. You see it has attachments to the document?
A. Yes, I did. These are FAQs for their field organization.
MR. HOOGENDOORN: Mr. Nguyen, could we please turn to Page 6.
BY MR. HOOGENDOORN:
Q. Do you see that third question and answer from the bottom in the FAQ, Mr. McWilliams? I'll read it aloud and you can keep me honest if I've read it incorrectly.
"QUESTION: Why are we buying AR innovation instead of building it?
"ANSWER: After careful evaluation of both technologies and the intellectual property behind them, our team concluded that it would be very difficult to build a best-in-class AR technology without violating their patents. The acquisition of both companies, including their IP, clears the way for us to build off of what they've developed to date, leveraging our deep engineering experience in the TAVR space."
I read that correctly?
A. Yes.

Q. Edwards concluded it would be very difficult to build a best-in-class aortic regurgitation TAVR technology device, at least in this document, without violating the JC Medical or JenaValve patents in the United States; right?
A. So for my expert report, I was not asked to evaluate intellectual property on it. So I can't give you an opinion as to the relative merits of the comment.
Q. You reviewed this document?
A. Yes, I reviewed the document. Yes.
Q. And what this document is saying is that Edwards concluded it would be very difficult to build a best-in-class aortic regurgitation TAVR device without violating the JC Medical or JenaValve patents in the U.S.; right?
A. I agree. That's the statement in the FAQ.
Q. If this transaction closes, Edwards would have the power to use the JC Medical and JenaValve patents to attempt to exclude possible foreign entrants from the U.S. TAVR-AR market; right?
A. Yes.
MR. HOOGENDOORN: I'm going to use the Elmo projector, if that's okay, Ms. Johnson.
BY MR. HOOGENDOORN:
Q. And I know this will probably seem a little antiquated to you -- I've been to your office. But we still use these

in courtrooms sometimes.

THE COURT: Not often, though.

THE WITNESS: Is this -- you said the Elmo? What did you call it?

MR. HOOGENDOORN: Elmo, yes. Sesame Street.

THE WITNESS: I hear that correctly.

BY MR. HOOGENDOORN:

Q. Now, I've put on the slide -- and we have paper copies if needed, but I think the Elmo should suffice for present purposes.

I've put on the screen D-D-X-1-19. Do you see that, Mr. McWilliams.

A. Yes, I do.

Q. You may or may not have seen this. I'll represent this is one of the slides from the opening statement provided by Edwards. Have you seen it before?

A. Not the -- I don't believe I've seen this specific rendering, but I've seen generally this information.

Q. Mr. McWilliams, you don't know whether, if this transaction closes, the JC Medical and JenaValve patents would give Edwards the power to exclude Laguna Tech's Zeta valve device from the U.S. market; correct?

A. I just want to clarify what I heard. You're asking if I knew or evaluated whether the combined patents of both JenaValve and J-Valve would block this particular company

from -- correct, I don't know that.
Q. You don't know whether Edwards could use those patents to exclude Laguna Tech from the United States?
A. Correct. I do not know that.
Q. You don't know whether Edwards could use those patents to exclude Cuspa's Cusper device from the United States; right?
A. Correct. I do not know that.
Q. You don't know whether Edwards could use those patents to exclude the next two in that row, MicroPort's VitaFlow Liberty or KOKA Lifesciences's Pioneer; correct?
A. Correct. I do not.
Q. You don't know whether the patents being acquired in this transaction would give Edwards the power to exclude Jenscare's Ken-Valve device from the U.S. market; correct?
A. Correct.
Q. We heard today about Hanchor valve. You don't know if the patents being acquired in this transaction would give Edwards the power to exclude Hanchor valve from the U.S. market; right?
A. Correct.
Q. And I take it you'd give the same answer for the remaining three -- SAT, Vycor [ph], and Venus Medtech -- you don't know if the Edwards patents that they're acquiring would give them the power to exclude those three companies

from the U.S. market; right?
A. I'd love to give you a different answer, but no, I cannot.
Q. Do you see at the bottom of this slide there are three -- well, there's a line called, "Capable fast followers"?
A. Yes.
Q. There are three companies listed there, right, Mr. McWilliams?
A. Yes.
Q. That's Medtronic, Abbott, and Boston Scientific?
A. Correct.
Q. Start with Medtronic. The same intellectual property protections from the JC Medical and JenaValve patents, those claims, they would apply to Medtronic just as much as they'd apply to Edwards; right?
A. To Edwards or to the startup companies? To --
Q. The same claims of the JC Medical and JenaValve patents, they would apply to Medtronic just as they would have applied to Edwards had it not purchased them; correct?
A. I just want to make sure I understand. You mean if Medtronic owned those claims in those patents would they? Or you're saying if Edwards, similar to what you asked me on the startup companies, would that same IP be -- could it potentially block Medtronic from entering the market?

Q. Correct. That same IP would apply to Medtronic; right?
A. Yes, it would apply to, yes, to any company trying to enter the U.S. market.
Q. It would apply to Medtronic, to Abbott, and to Boston Scientific?
A. Yes.
Q. Let's turn now -- I think this is one of your slides. And there are no redactions on this slide. But this is the third slide of your presentation. Here, you were describing medical device development for premarket authorization of Class III devices. Do you recall that from your testimony this morning?
A. Yes, I do.
Q. Here, the document lists a -- kind of, T-equals, and then a number of months. Do you see that?
A. Yes, I do.
Q. That's presenting an average number of months for a given stage in, kind of, development for a medical device?
A. Yes. I mean, the methodology here was an attempt to aggregate a bunch of Class III medical devices and estimate the timeline for each development category.
Q. And using that methodology, they calculated an average of 57 months for a pivotal study; right?
A. Yes.
Q. 17 months for a PMA application to be processed; right?

A. Yes.
Q. And you can correct me if I have my math wrong. 57 months plus 17 months, that's 74 months, right, Mr. McWilliams.
A. Yes.
Q. A little over six years?
A. Yes.
Q. I'd like to touch back on something you said this morning in your direct. You testified, I believe, to something about, kind of, foreign entry potentially as soon as 2030. Do you recall that testimony?
A. Yes.
Q. You probably recall the objections around it, too, but I just want to make clear. You did not offer that projected timeline for potential foreign entry in your expert report in this case; correct?
A. I did not make a specific date to do it. I gave a general estimate.
Q. That testimony relies on a series of assumptions, doesn't it?
A. Yes, it does.
Q. One assumption would be that there's willingness to enter the U.S. market; right?
A. Correct.
Q. Another assumption would be that there is sufficient

funding to pursue the U.S. market; right?
A. Yes.
Q. There -- another assumption is that there would be a sufficient quality of manufacturing systems for U.S. market; right?
A. Yes, to build sufficient inventory. Yes.
Q. Your projection also assumes that there would be a sufficient pool of U.S. -- of out-of-U.S. data, excuse me, to support a U.S. pivotal study, right?
A. Correct.
Q. We have limited time here today. But in forming your opinions in this case, you don't know whether any company outside of the United States has a sufficient pool of out-of-U.S. data to support a U.S. pivotal study; correct?
A. Correct.
Q. I'd like to now talk a little bit about some of the potential acquirers you discussed on direct. I take it you're aware there's no antitrust exception for deals where no one will pay more than your closest competitor for your business; right?
A. Yes.
MR. HOOGENDOORN: Mr. Nguyen, could you please pull up Page 1 -- or excuse me, Paragraph 103. I believe it's on Page 54 of D-X-288.
BY MR. HOOGENDOORN:

Q. You'll recognize, Mr. McWilliams, this is from your expert report.
A. Okay.
Q. Now, I'd like to just be very precise in the analysis and conclusion that you offer with respect to these potential acquirers. And so you can let me know if I've read it incorrectly.
MR. HOOGENDOORN: Mr. Nguyen, were we able to pull up that document?
THE WITNESS: And what paragraph?
BY MR. HOOGENDOORN:
Q. This is Paragraph 103?
A. Just a second.
(Brief pause.)
MR. HOOGENDOORN: Thank you, Mr. Nguyen.
Your Honor, would you like a moment to turn there or should I proceed?
THE COURT: I'm sorry?
MR. HOOGENDOORN: Have you been able to turn there. I know you like the paper copies, Your Honor.
THE COURT: Go ahead.
BY MR. HOOGENDOORN:
Q. Mr. McWilliams, I'm going to read in the back half of this paragraph the conclusion from this paragraph: "It is unlikely that JenaValve will be able to find another

structural heart buyer aside from Edwards at an offer level that would be more attractive to it than continuing independently."

Did I read that correctly?

A. Yes, you did.

Q. That was the opinion you offered in your report; right?

A. Correct.

Q. And that, of course, means that for some offers JenaValve could receive from other firms in the marketplace, JenaValve might think its independent prospects were more attractive than making a sale; correct?

A. Yes, that would be the board conversation.

Q. And the board could choose that their prospects independently were more attractive or could choose, obviously, to take any given offer; right?

A. Those would be the two choices they have, yes.

Q. And you did think about what sort of offer would be necessary for Edwards to prefer a sale rather than its own independent prospects; right?

A. Can you ask that one more time?

Q. In your view, it would be more attractive to JenaValve to continue independently, as you discussed this morning, than to accept an offer that is not the same or higher than the $950 million after from Edwards; correct?

A. Yeah, I didn't make a specific assessment as to what I

thought that offer would be, but made the assumption based on the lack of the apparent interest of any of the other suitors to come make a purchase that, if they were, they would, you know -- you know, the only incentive you could see is that they would acquire -- yeah, I made the assumption that, you know, given that none of the other acquirers made an offer on the first attempt when they tried to sell the company, that for them to be incentivized to do it again, maybe, they would do it at a smaller price and, you know, made the assumption that, if you're the board, knowing the value that you just received, you would likely make the choice to go independent in order to try to achieve -- reachieve that return value if you were one of the investors.

Q. My question is pretty specific. You wrote "an offer level that would be more attractive to it than continuing independently."

A. Correct.

Q. And by that you meant that it would be more attractive for JenaValve to continue independently than to accept an offer that was not the same or higher than the $950 million offer from Edwards; correct?

A. Correct.

Q. You have financial interests in venture capital investments --

A. I do.
Q. -- for which Edwards is a -- well, so you have interests --
A. Yes.
Q. No problem. No problem. Some of those interests, Edwards is a potential acquirer of your financial interests; right?
A. Yes.
Q. You have a financial interest in a firm called CardiacBooster?
A. Correct.
Q. Edwards is a potential acquirer for CardiacBooster; right?
A. Correct.
Q. And I want to be very respectful in this public session about investments that might be in stealth mode. But it's fair to say that you have personal financial interests in other firms for which Edwards may also be an acquirer that are in stealth mode; right?
A. Yes.
Q. For similar reasons, I don't want to ask you in public about your firm's future investment plans. But it's fair to say your firm has been active in the structural heart space; right?
A. Correct.

Q. And you certainly are not foreclosing future investments in structural heart?
A. Correct.
Q. Edwards is a potential strategic acquirer for your firm's potential future investments in structural heart; right?
A. Yes, they are.
Q. JenaValve has been well funded?
A. Yes.
Q. JenaValve has an experienced team?
A. Yes.
Q. You believe that JenaValve's management team is comprised of smart and diligent medical device innovators?
A. Yes, I do.
Q. JenaValve's losses to date are consistent with what you'd expect from a Class III medical device innovator?
A. Yes, I'd say they're consistent.
Q. JenaValve is backed by good and experienced venture capitalists?
A. Yes.
Q. And you did not do a specific estimate of what any current JenaValve investor may be able to invest in the company going forward; correct?
A. Correct. I did not go by -- firm by firm.
Q. And here, again, I want to be careful about confidential

information of JenaValve. So I'd ask if you could just answer with a yes or no in this public setting. But you believe that JenaValve has a sufficient set of existing investors to fund the planned Series C extension; right?

A. Yes, the emergency contingency financing detailed in that one board slide. Yes.

Q. You did not create your own estimate of how many Trilogy devices would be sold if Edwards acquires JenaValve or it not acquire JenaValve; correct?

A. Correct.

Q. On direct, you testified to a number of potential efficiencies between Edwards and JenaValve; correct?

A. Yes.

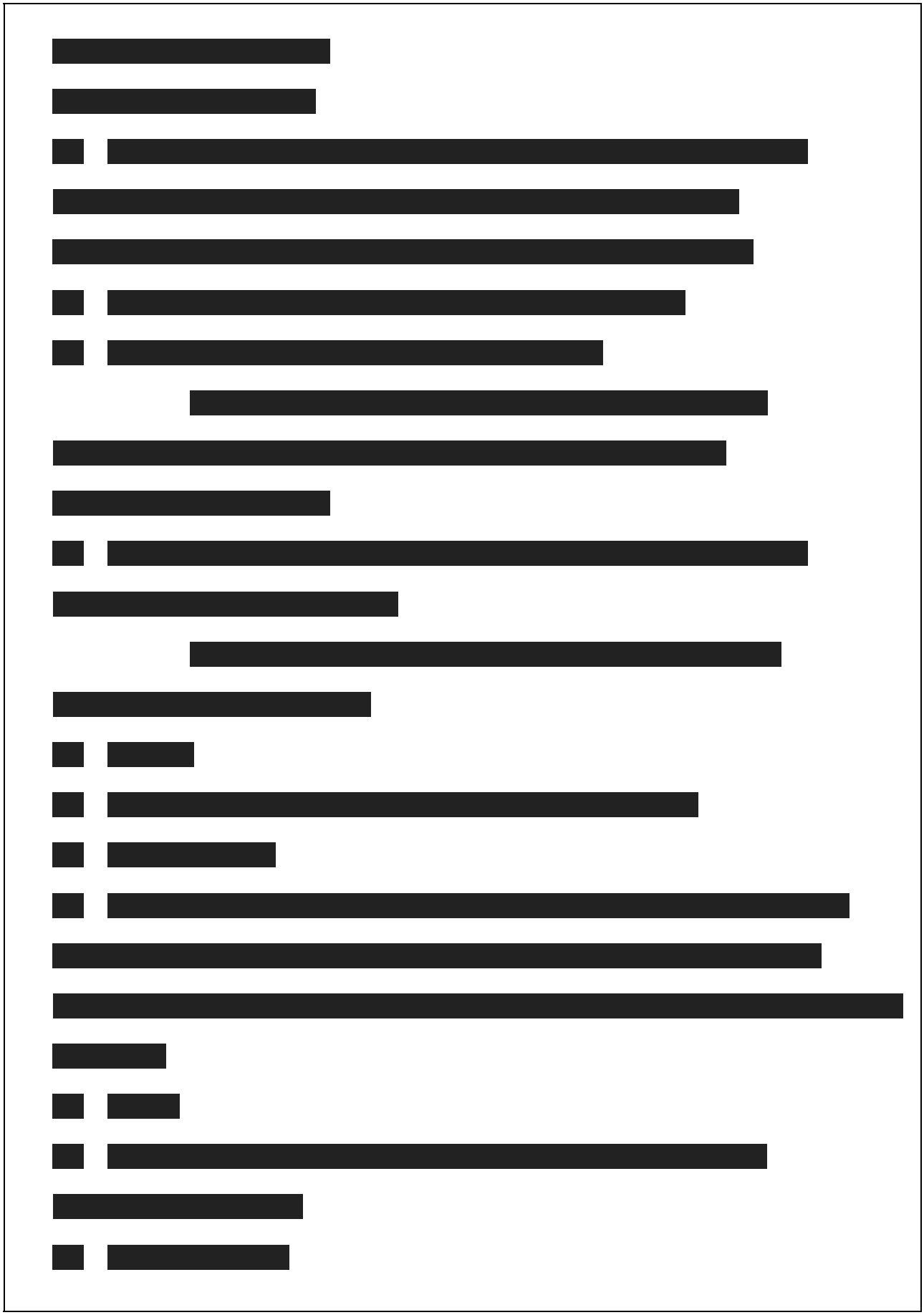
Q. I'd like to pull up from the day 1 transcript, a.m., a portion of opening. Lines -- Page 72, Line 25 to 73:4. This is from Mr. Shores' opening. It says: "In reality, in trying to frame this as an efficiencies defense, the FTC is saying it can speculate all it wants about the harms of the merger, but the defendants, in showing the benefits, have to validate, with a spreadsheet, I guess, the benefits from the merger."

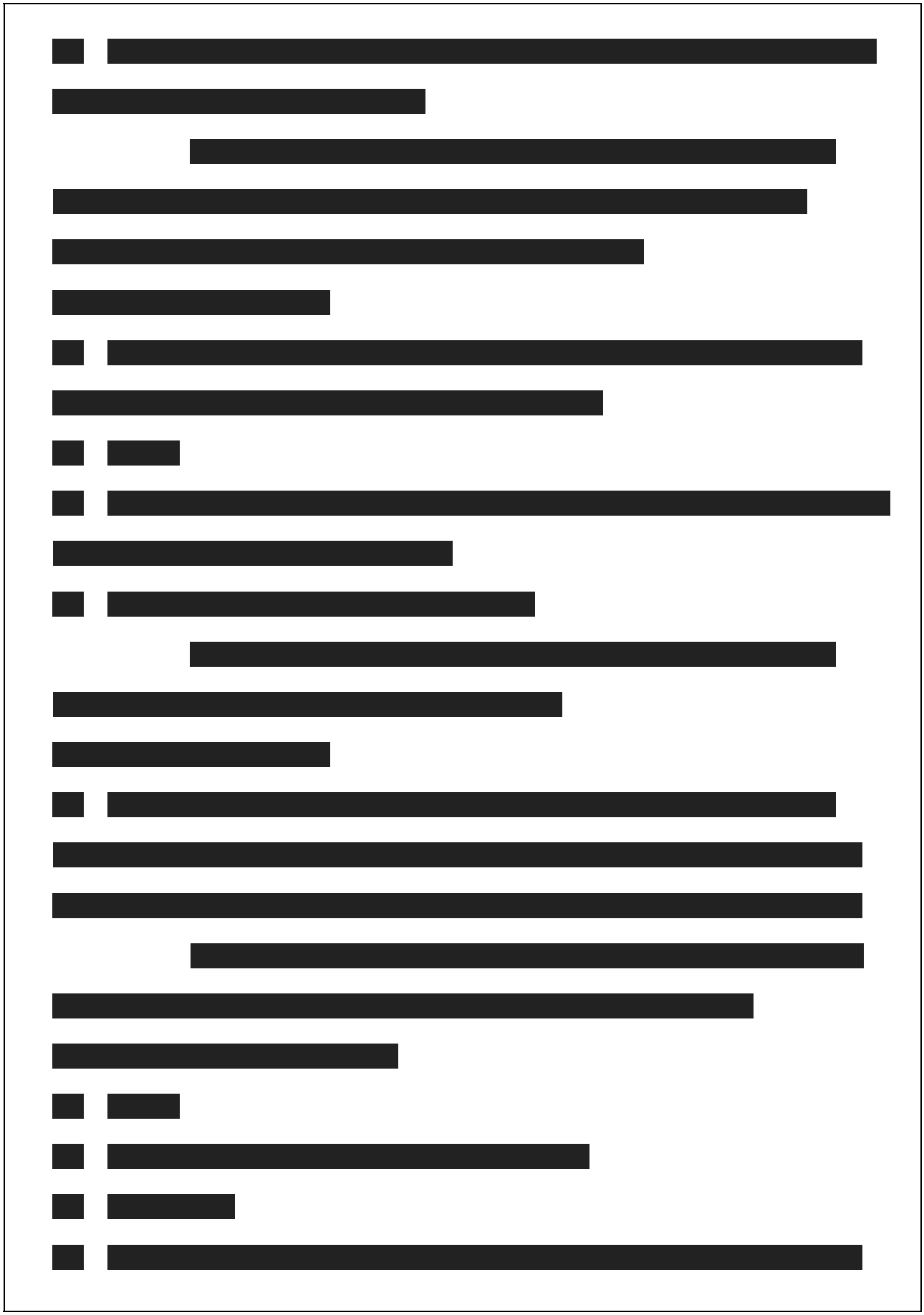
I read that correctly?

A. Yes.

Q. You have seen spreadsheets projecting sales from JenaValve and Edwards; right?

A. Yes, I have.
Q. Indeed, you've seen the deal model from Edwards. I think you talked about that a little bit in your testimony this morning.
A. Yes, I did.
Q. Deal models are prepared to advise the Board of Directors about whether to proceed with a transaction; correct?
A. Correct.
Q. Here, that was, at least in JenaValve's case, almost a billion-dollar transaction?
A. Yes.
Q. You've also reviewed JenaValve's most recent estimates for independent commercial launch of Trilogy; right?
A. Yes, I have.
MR. HOOGENDOORN: Your Honor, I'd like to talk a little bit about those estimates. So I believe going into a confidential session would probably be best.
THE COURT: Okay. Let's close the courtroom.
MR. SHORES: Everybody not associated with the parties, please exit.
(Following proceedings under seal:)
[redacted]







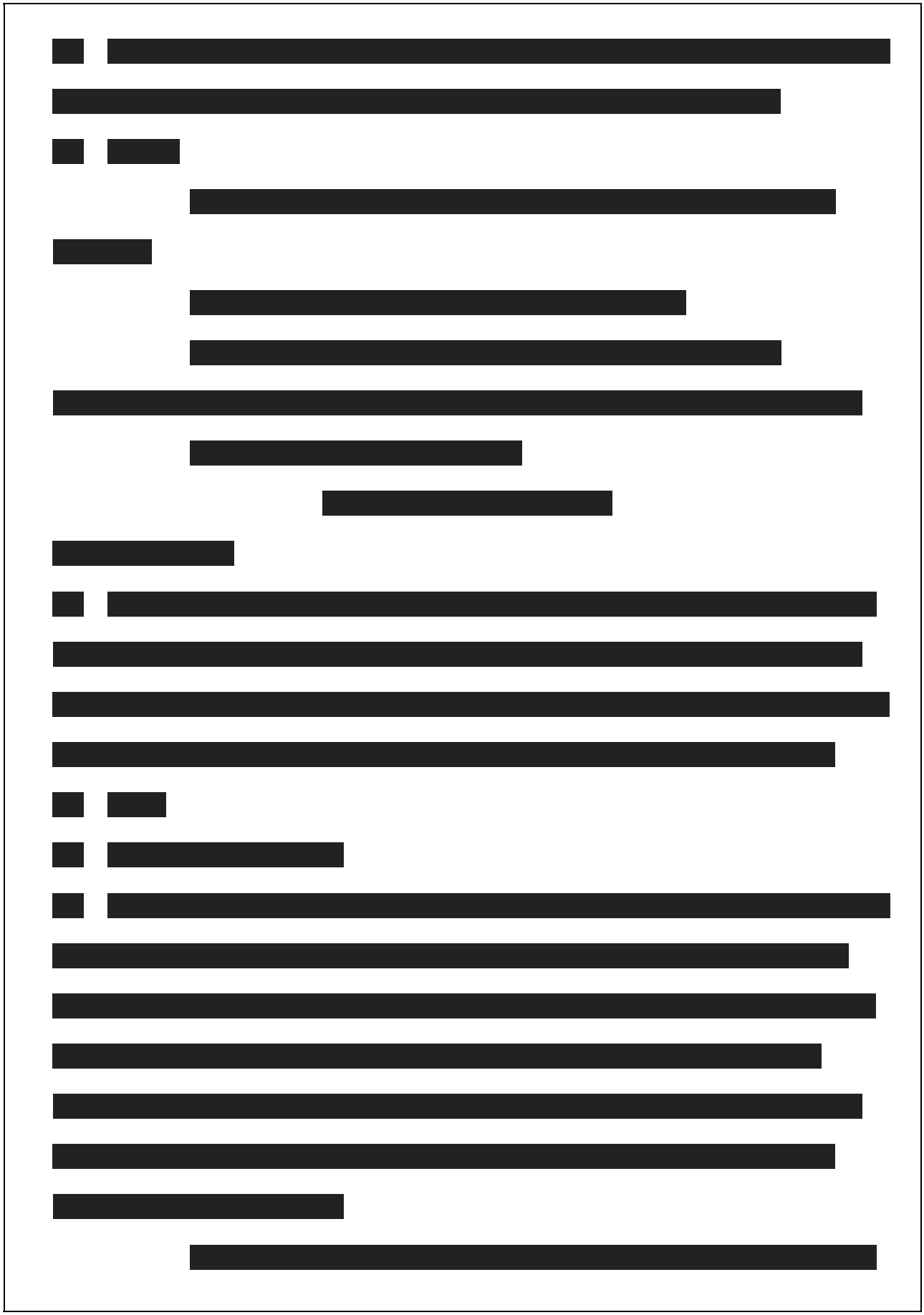














[redacted]

(Following proceedings in open court:)

MS. WEST MATTHEWS: And for the modus operandi of the afternoon, Your Honor, I think we can start in open

court, but then we're going to be going through some company-specific data, so we'll need to close things, and I'll try to open it back up at the end.

THE COURT: Okay.

MS. WEST MATTHEWS: And defendants call Dr. Elizabeth Bailey to the stand.

ELIZABETH BAILEY, WITNESS FOR THE DEFENDANTS, SWORN

MS. WEST MATTHEWS: May I proceed, Your Honor?

THE COURT: You may.

DIRECT EXAMINATION

BY MS. WEST MATTHEWS:

Q. Good afternoon, Dr. Bailey. Could you briefly introduce yourself for the Court.

A. Good afternoon. I'm Liz Bailey. I'm a vice president at Charles River Associates in the competition practice. I have a Ph.D. in economics from the Massachusetts Institute of Technology. I did my undergraduate degree at Colgate University. Before Charles River, I was an instructor at the Wharton School, teaching finance to executives at the University of Pennsylvania. Before that, I taught finance at the Haas School of Business at the University of California, Berkeley. And before that, I was a clinical associate professor at Arizona State in the economics department.

Q. And how many mergers would you say you've analyzed over

the course of your career, Dr. Bailey?
A. Gosh. Hundreds.
Q. And have you been published?
A. Yes.
Q. Have you also been qualified as an expert in other cases?
A. I have.
MS. WEST MATTHEWS: Your Honor, I tender Dr. Bailey as an expert in the field of industrial organization.
MR. ANDREW: No objection.
THE COURT: We'll hear her testimony.
MS. WEST MATTHEWS: Great.
BY MS. WEST MATTHEWS:
Q. And Dr. Bailey, did you provide an expert report in this matter?
A. I did.
MS. WEST MATTHEWS: And for the Court, that's D-X-0289.
BY MS. WEST MATTHEWS:
Q. And, Dr. Bailey, have you also prepared a demonstrative for your testimony today?
A. I did.
MS. WEST MATTHEWS: And that's marked D-X-002 for the Court.

BY MS. WEST MATTHEWS:

Q. And that's the slide deck we're currently looking at?

A. Yes.

Q. Can you describe your assignment in this matter?

A. In this matter, my assignment was to evaluate the opinions from Dr. Wilson, to evaluate his opinions specifically with respect to the competitive effects of the proposed transaction.

Q. And turning to the next slide, what types of data did you rely on in forming your opinion in this matter?

A. So I relied on a wide variety of data. I relied on data from the U.S. Government called ClinicalTrials.gov. I relied on data from JenaValve related to their reimbursement rate, data for Trilogy. I relied on data from JC Medical from their Sojourn site data, data from JenaValve's Trilogy European sales data. As well I created a database based on the medical academic literature as well as medical conferences.

Q. And did Dr. Wilson rely on any data in providing his opinion?

A. He primarily relied on economic theory, as well as his reading of documents and testimony in this matter.

Q. And turning to the next slide, when you use economic analysis to consider the effects of a merger, what framework do you use?

A. Sure. So this is the framework that I use in all potential transactions that I look at. It really boils down to three pieces. I look at the potential procompetitive effects of the transaction, the potential anticompetitive effects of the transaction, and then, of course, I look at the market -- the area of competition where you want to evaluate those possible effects.

Q. So that's our general framework. To set out our agenda for the day, I'd like to take a look at the next slide and talk through the conclusions that you reach. First, let's cover your conclusions on procompetitive effects of the transaction.

A. Sure. So my first conclusion is that there will be procompetitive effects from the transaction and, in particular, Edwards's resources and its know-how complement the capabilities that JenaValve has today as a startup. And then, second, data, as well as the historical real-world evidence that's available, demonstrates Edwards's incentive to innovate.

Q. And looking here at the bottom, what conclusions do you reach about the economic support for anticompetitive effects here?

A. Sure. So I find there's no data-driven economic evidence that supports the anticompetitive effects in any of the markets that Dr. Wilson has talked about.

Q. And it looks like you've broken out, kind of, three separate ways that one could think about a market at the bottom here. Why did you do that?

A. Well, it's really important to be precise about the anticompetitive harms that you're thinking about, and they need to be tied to the particular market, the particular area of competition where those anticompetitive harms might happen. So for my purposes, in thinking about what Dr. Wilson had been describing in his report and his -- in his second report, they fell into three categories: thinking about the future commercial, thinking about possible harm to innovation, and then -- I have it in quotes -- the premarket market. What I mean by that is the clinical trial phases.

Q. And thinking about the future commercial market specifically, what is, kind of, the most important framework that you use when thinking about what Dr. Wilson has done there?

A. Well, for the -- maybe, the place to start is there is no U.S. commercial TAVR-AR product. So just by its nature, it's in the future, and it's speculative what might happen. And, as I understand, the earliest that J-Valve could possibly be commercialized is 2029. So when we're thinking about this future commercial market, we're thinking about something that's at least three years from now. So that was just an important component for me for when I'm thinking

about those types of harms.

Q. Got it.

MS. WEST MATTHEWS: Your Honor, at this point, we'd like to go ahead and close the court as we're going to be diving into some data.

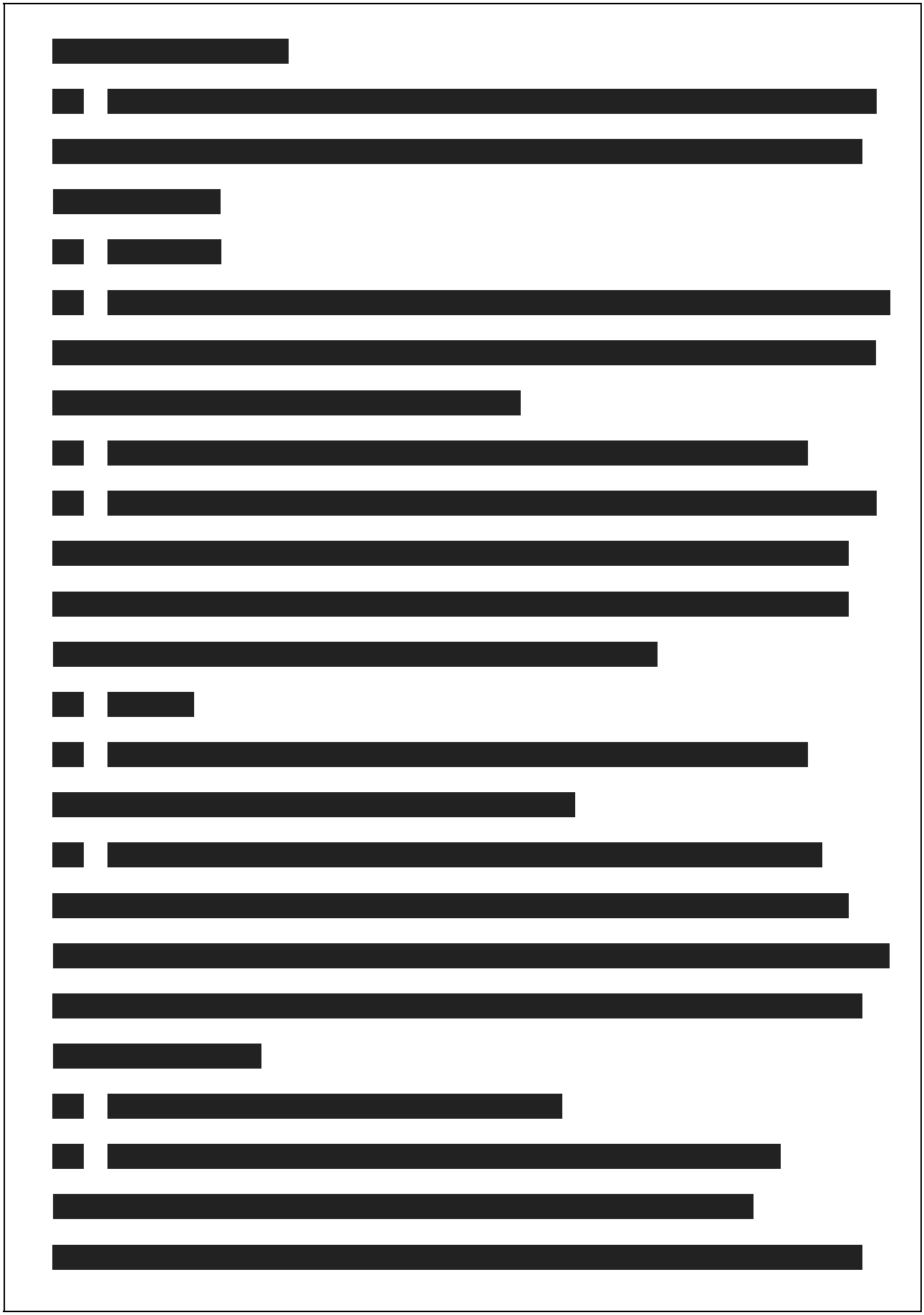
THE COURT: All right. Let's close the court again.

(Following proceedings under seal:)

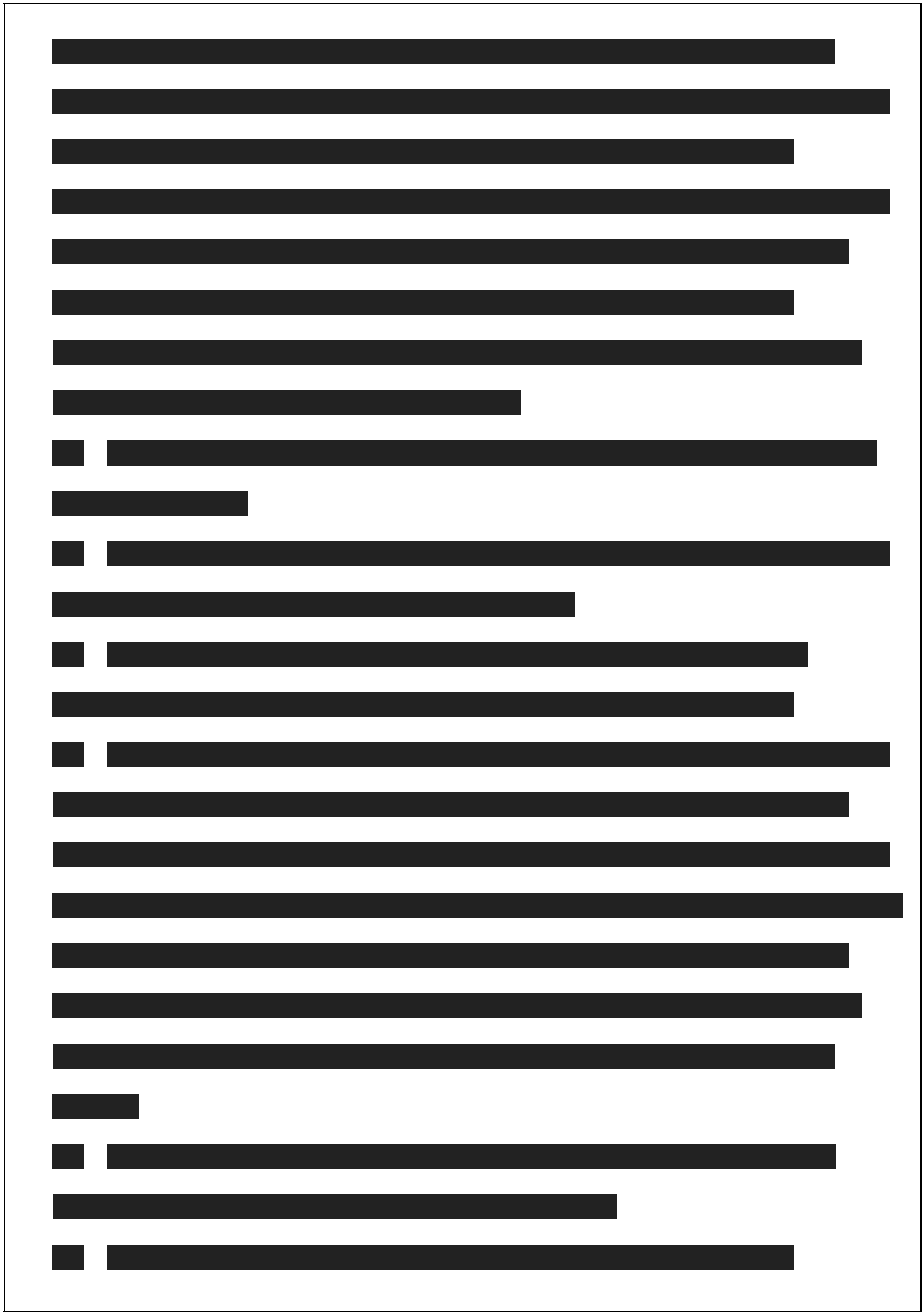
[redacted]







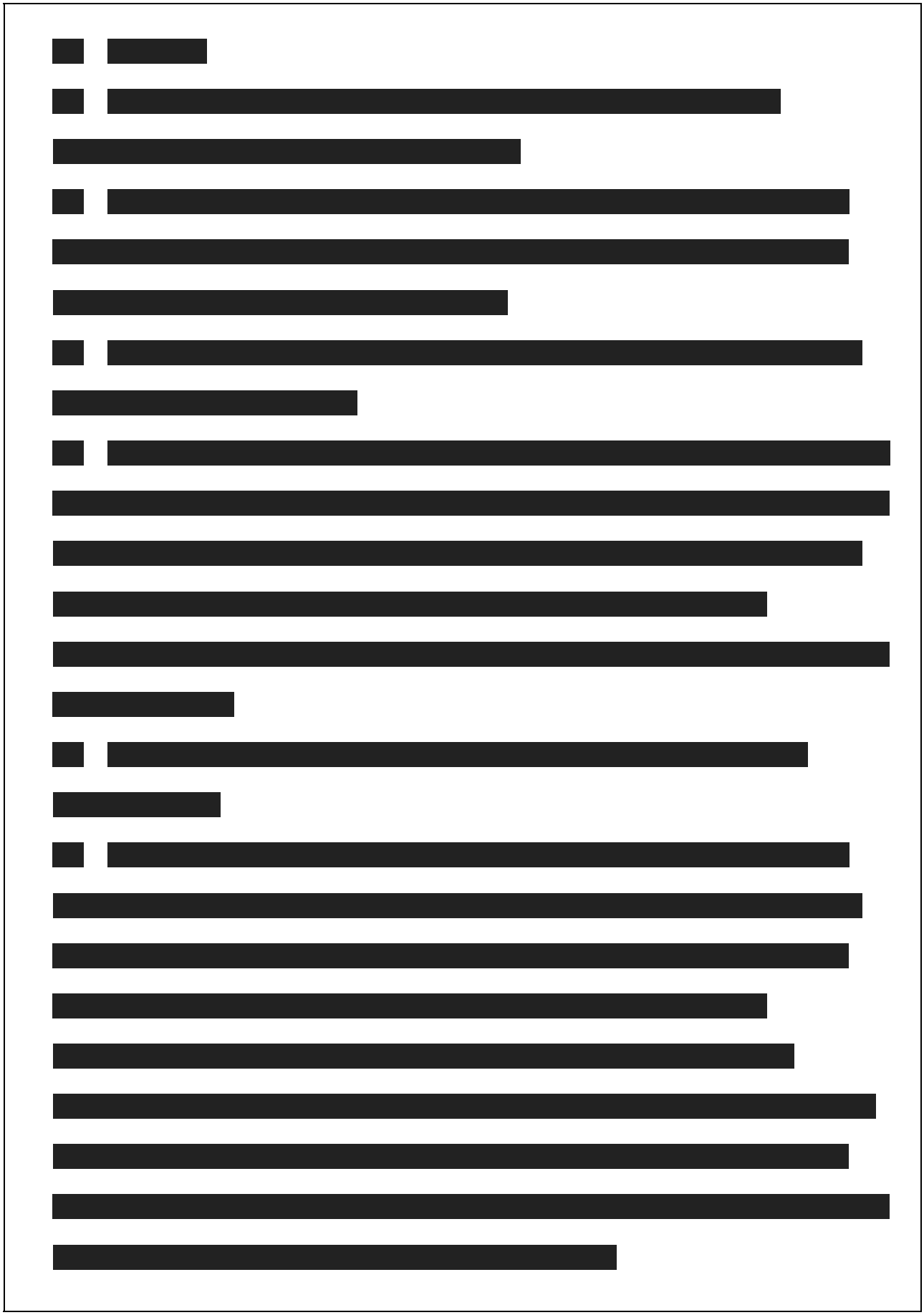




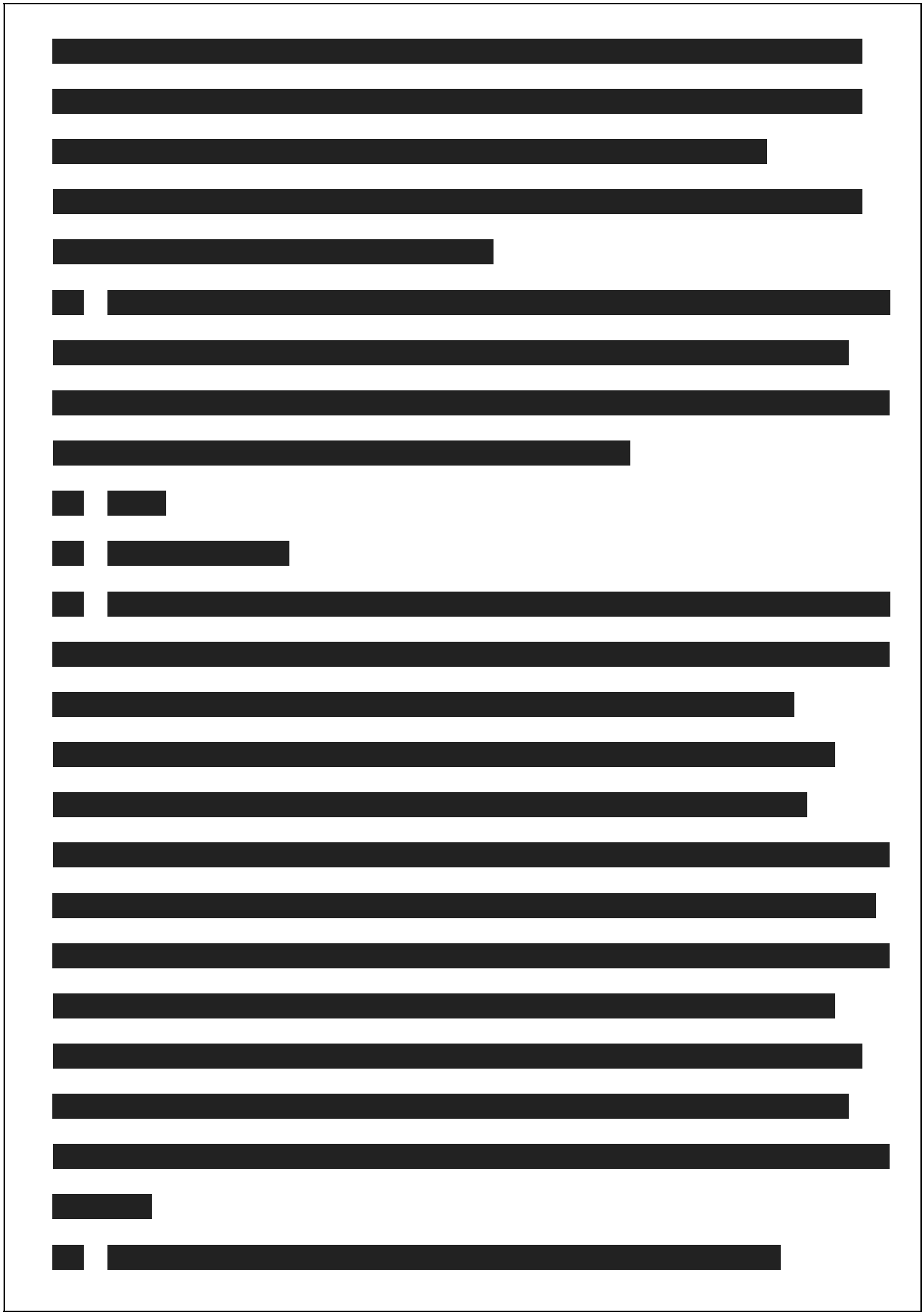










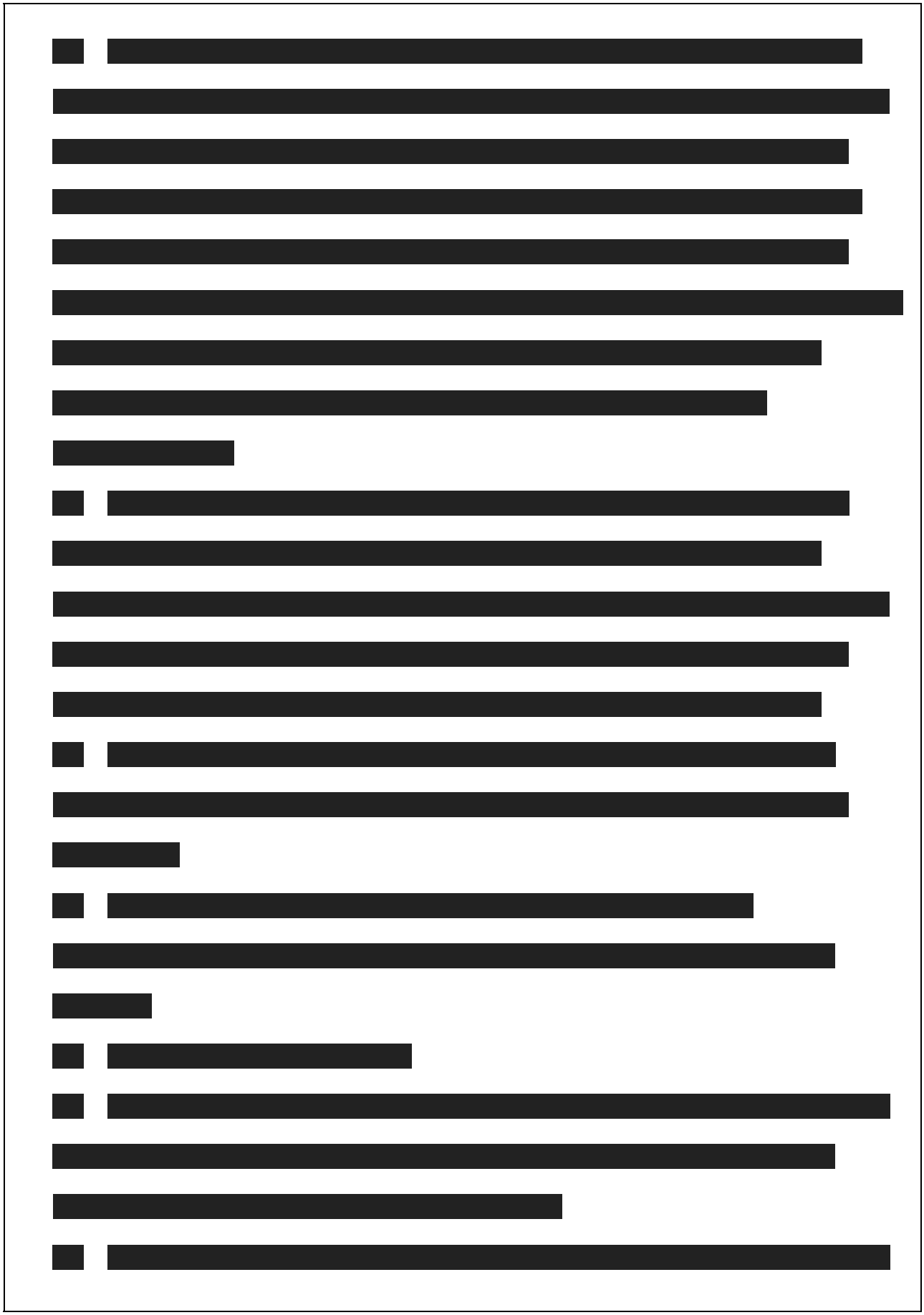




















* * * * * * * * * * * * * *

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 25th 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

$

$100 [1] - 68:21
$200 [1] - 92:19
$300 [1] - 92:22
$50 [1] - 91:25
$500 [1] - 98:24
$950 [2] - 119:24, 120:21

'

'08 [1] - 25:7

/

/s/Timothy [1] - 162:8

1

1 [3] - 69:13, 117:23, 123:14
10 [12] - 5:14, 5:16, 6:1, 9:2, 9:16, 32:6, 32:16, 41:23, 42:2, 89:22, 95:1, 95:7
10-minute [1] - 99:22
10-year [1] - 52:16
100 [1] - 43:24
100,000 [2] - 44:22, 44:24
103 [2] - 117:23, 118:12
1050 [1] - 1:22
10th [1] - 41:12
11 [1] - 96:23
11th [2] - 41:12, 52:4
12 [5] - 8:6, 80:4, 91:11, 99:4, 107:23
128 [1] - 78:11
128-patient [1] - 20:24
12th [1] - 41:12
13 [1] - 107:24
130 [2] - 78:12, 78:17
14 [3] - 71:5, 71:9, 89:1
14th [2] - 32:20, 63:2
15 [2] - 7:14, 32:6
150 [1] - 92:19
17 [2] - 115:25, 116:3
18 [1] - 91:11
1:25-cv-02569-RC [1] - 1:2

2

2 [4] - 44:23, 52:3, 67:19
20 [7] - 5:18, 11:16, 12:25, 25:6, 66:19
20001 [2] - 2:8, 162:10
20006 [1] - 2:5
20036 [1] - 1:23
20037 [1] - 1:19
2009 [2] - 17:25, 89:1
2010 [1] - 25:9
2011 [2] - 25:9, 25:10
2018 [1] - 76:2
2019 [1] - 76:2
202 [5] - 1:16, 1:20, 1:23, 2:5, 2:9
2023 [1] - 89:1
2024 [2] - 28:18, 88:5
2025 [7] - 1:5, 47:11, 47:23, 50:18, 58:14, 60:8, 162:7
2029 [3] - 78:19, 80:9, 140:22
2030 [2] - 80:8, 116:11
20580 [1] - 1:16
2099 [1] - 2:4
2112 [1] - 1:19
241 [1] - 107:23
25 [4] - 1:5, 25:6, 66:19, 123:15
25th [3] - 58:7, 58:14, 162:7

3

3 [3] - 11:10, 51:12, 72:16
3,400 [1] - 54:25
30 [3] - 11:8, 11:11, 67:22
300 [1] - 8:1
326-3282 [1] - 1:16
333 [2] - 2:8, 162:10
34-page [1] - 63:6
354-3111 [1] - 2:9

4

4 [3] - 11:10, 50:15, 74:24
40 [4] - 25:8, 43:20, 66:18
400 [3] - 8:1, 8:2, 98:24
45 [1] - 61:7
4:30 [1] - 4:18

5

5 [1] - 81:9
50 [2] - 92:5, 95:2
500 [1] - 71:9
508-4850 [1] - 2:5
510(k [2] - 68:5
54 [1] - 117:24
57 [2] - 115:23, 116:2

6

6 [4] - 1:8, 84:9, 107:23, 110:9
60 [1] - 10:24
600 [1] - 1:15
6722 [2] - 2:7, 162:9

7

7 [4] - 41:23, 42:2, 85:18, 85:19
70 [1] - 10:24
72 [1] - 123:15
73:4 [1] - 123:15
74 [1] - 116:3

8

8 [3] - 32:16, 88:2, 95:1
80 [2] - 25:8, 43:21
850 [5] - 11:21, 14:2, 95:16, 95:19, 98:16
8th [2] - 47:11, 47:18

9

9 [1] - 94:10
955-8226 [1] - 1:23
974-1876 [1] - 1:20
9:30 [1] - 1:5
9th [4] - 50:18, 51:14, 60:8, 63:1

A

a.m [2] - 1:5, 123:14
Aamir [1] - 49:18
Abbas [1] - 49:18
Abbott [9] - 8:12, 10:4, 25:18, 38:11, 38:13, 49:20, 101:21, 114:11, 115:4
abilities [2] - 26:20, 26:21
ability [7] - 77:13, 93:8, 95:25, 98:6, 99:17, 108:22, 162:7
able [48] - 15:11, 16:19, 17:6, 17:12, 17:15, 21:10, 22:14, 23:3, 25:2, 55:23, 73:1, 76:14, 78:21, 79:2, 81:3, 81:20, 82:1, 84:14, 84:15, 86:7, 86:20, 86:24, 87:5, 89:13, 90:8, 91:16, 92:10, 93:1, 93:17, 93:19, 93:20, 93:22, 94:6, 95:7, 95:10, 96:4, 96:5, 96:18, 97:7, 97:18, 99:6, 99:15, 99:17, 100:4, 118:8, 118:19, 118:25, 122:22
absolute [2] - 17:24, 18:14
absolutely [18] - 11:5, 14:19, 19:13, 20:4, 20:11, 23:25, 24:2, 26:4, 34:22, 39:24, 40:14, 44:14, 45:7, 56:19, 66:1, 109:3
academic [6] - 20:17, 21:19, 22:12, 22:14, 44:22, 138:17
accept [3] - 76:20, 119:23, 120:20
accepting [1] - 76:1
access [8] - 9:4, 34:25, 37:10, 38:3, 70:16, 70:19, 85:13, 91:4
accomplish [1] - 96:18
account [1] - 9:2
accounts [1] - 85:8
accurate [1] - 162:4
achieve [1] - 120:13
acquire [11] - 14:16, 16:5, 18:7, 19:10, 24:7, 29:24, 88:12, 97:15, 101:23, 120:5, 123:9
acquired [9] - 69:5, 82:16, 102:8, 102:17, 102:22, 102:23, 113:13, 113:18
acquirer [6] - 90:14, 90:19, 121:6, 121:12, 121:18, 122:4
acquirers [5] - 71:20, 88:7, 117:17, 118:6, 120:7
acquires [2] - 99:1, 123:8
acquiring [5] - 25:2, 30:19, 31:15, 88:18, 113:24
acquisition [6] - 24:20, 26:1, 28:4, 29:18, 88:5, 110:20
acquisitions [1] - 78:16
actions [1] - 50:22
active [4] - 9:25, 10:4, 69:18, 121:23
actively [1] - 8:10
activity [2] - 76:21, 76:24
actual [3] - 27:25, 96:19, 97:21
add [1] - 106:12
additional [12] - 5:14, 5:16, 5:18, 70:17, 85:10, 86:17, 86:23, 87:12, 90:6, 90:9, 93:9, 93:19
address [2] - 4:25, 26:2
adds [1] - 13:13
admitted [1] - 67:12
advances [1] - 17:18
advantage [1] - 22:22
advice [1] - 57:20
advise [2] - 70:13, 124:6
advised [2] - 23:9, 38:23
advisers [1] - 72:5
advising [3] - 22:7, 22:8, 31:5
advisor [1] - 38:13
advisory [10] - 9:22, 10:3, 10:5, 10:8, 10:15, 23:5, 23:7, 38:7, 41:10, 45:2
advocate [3] - 10:18, 22:3, 36:10
afternoon [3] - 135:25, 136:12, 136:14
agency [2] - 52:11, 55:12
agenda [1] - 139:8
aggregate [1] - 115:20
aggressive [3] - 28:22, 35:1, 97:17
ago [8] - 28:17, 47:11, 89:13, 104:6, 104:23, 105:10, 108:2, 109:11
agree [9] - 32:8, 55:5, 75:8, 75:11, 75:15, 76:11, 107:8, 107:12, 111:15
ahead [3] - 59:23, 118:21, 141:4
aided [1] - 2:11
alerts [3] - 20:18, 21:21, 21:22
ALIGN [12] - 8:23, 9:1, 9:6, 9:19, 17:12,

32:5, 32:8, 33:1, 34:21, 35:9, 35:12, 36:12
ALIGN-AR [12] - 8:23, 9:1, 9:6, 9:19, 17:12, 32:5, 32:8, 33:1, 34:21, 35:9, 35:12, 36:12
allow [2] - 5:10, 16:10
allowed [9] - 14:15, 16:5, 18:7, 19:9, 26:2, 29:24, 37:11, 40:19, 68:10
allows [3] - 5:7, 45:17, 73:3
almost [2] - 98:24, 124:10
alone [3] - 11:24, 37:5, 95:2
aloud [2] - 108:6, 110:12
altered [1] - 12:7
alternative [2] - 87:25, 88:22
American [1] - 22:24
Amid [1] - 35:7
amount [3] - 44:4, 81:15, 92:6
amounts [1] - 92:18
analysis [6] - 35:9, 82:25, 84:20, 87:23, 118:4, 138:24
analysts [1] - 98:2
analyze [1] - 104:22
analyzed [7] - 84:17, 86:13, 89:15, 91:15, 94:10, 99:4, 136:25
analyzing [2] - 71:17, 71:19
anatomical [1] - 34:7
Anderson [2] - 1:12, 26:11
ANDERSON [13] - 26:6, 26:9, 33:3, 33:5, 50:8, 50:10, 50:11, 50:14, 50:17, 54:12, 60:3, 60:5, 66:9
Anderson..... 26 [1] - 3:4
ANDREW [1] - 137:11
Andrew [1] - 1:14
anesthesia [1] - 35:2
animal [2] - 72:23, 79:20
Ann [2] - 47:18, 48:5
annoying [1] - 52:1
annually [2] - 7:24, 92:1
annuli [1] - 17:1
ANSWER [3] - 108:10, 108:12, 110:16
answer [10] - 17:24, 18:14, 26:17, 30:13, 43:19, 79:6, 110:11, 113:22, 114:2, 123:2
answered [1] - 54:23
answers [1] - 15:8
anticipate [1] - 16:15
anticipation [1] - 94:20
anticompetitive [5] - 139:4, 139:21, 139:24, 140:5, 140:7
antiquated [1] - 111:24
antitrust [1] - 117:18
anytime [2] - 17:2, 43:23
aortic [18] - 7:17, 7:18, 7:19, 8:17, 11:4, 11:18, 11:20, 16:7, 18:9, 19:6, 20:23, 25:23, 29:21, 31:13, 34:8, 95:17, 111:2, 111:12
apart [1] - 65:4
Apollo [9] - 68:8, 68:9, 68:15, 68:18, 68:19, 70:24, 71:23, 88:25, 90:24
apologies [4] - 36:17, 56:11, 60:14, 78:4
apparent [1] - 120:2
appear [2] - 36:8, 88:13
APPEARANCES [2] - 1:11, 2:1
appendage [3] - 69:25, 102:6, 102:13
applicable [1] - 79:24
application [4] - 73:14, 73:17, 77:19, 115:25
applied [2] - 71:11, 114:20
apply [6] - 114:15, 114:16, 114:19, 115:1, 115:2, 115:4
appreciate [4] - 26:18, 29:9, 37:25, 64:13
approach [3] - 7:25, 67:17, 101:25
appropriate [4] - 9:13, 35:17, 56:16, 57:17
appropriateness [2] - 9:13, 13:9
approval [38] - 23:14, 24:10, 72:19, 73:17, 73:19, 73:21, 73:25, 74:2, 74:20, 75:5, 75:14, 78:18, 81:6, 82:8, 86:5, 87:17, 87:19, 93:6, 93:8, 93:11, 93:20, 94:20, 100:12, 100:13, 102:10, 104:10, 104:21, 105:7, 105:12, 105:15, 105:18, 105:20, 106:6, 106:10, 106:17, 106:19, 107:2, 107:11
approval's [1] - 82:24
approvals [1] - 68:4
approve [2] - 17:17, 98:1
approved [5] - 40:18, 68:24, 100:10, 102:10, 104:16
AR [55] - 8:17, 8:21, 8:23, 9:1, 9:6, 9:19, 13:18, 13:21, 17:12, 19:12, 20:15, 20:23, 21:11, 21:21, 21:25, 24:8, 30:4, 30:10, 30:15, 30:19, 30:25, 31:17, 32:5, 32:8, 32:17, 33:1, 34:21, 35:9, 35:12, 36:12, 37:10, 40:1, 40:15, 75:5, 75:10, 77:12, 78:14, 88:15, 88:23, 89:19, 89:23, 90:16, 95:21, 100:7, 100:8, 101:3, 103:11, 104:9, 104:13, 105:14, 107:10, 110:14, 110:19, 111:18, 140:19
Arbor [2] - 47:18, 48:5
area [5] - 7:11, 72:4, 74:12, 139:6, 140:7
areas [4] - 18:13, 71:14, 95:24, 102:11
arguments [1] - 63:7
Arizona [1] - 136:23
arrangement [1] - 64:15
arrow [1] - 75:12
arrows [1] - 97:5
artery [1] - 7:14
article [6] - 33:1, 33:9, 33:18, 34:1, 34:13, 77:1
AS [26] - 7:21, 7:22, 7:23, 8:4, 14:21, 15:8, 17:5, 17:22, 18:2, 18:17, 21:21, 24:13, 24:14, 25:12, 25:13, 32:16, 37:15, 37:22, 44:9, 89:19, 89:22, 96:14, 96:19, 101:16, 102:20, 102:21
aside [1] - 119:1
aspect [1] - 27:25
aspects [4] - 16:20, 20:21, 68:14, 74:6
assessment [1] - 119:25
asset [1] - 88:9
assignment [2] - 138:4, 138:5
assist [2] - 40:21, 51:20
associate [3] - 50:21, 51:2, 136:23
associated [1] - 124:20
Associates [1] - 136:15
assume [7] - 79:19, 80:2, 86:24, 87:5, 87:17, 93:17, 96:21
assumed [1] - 93:18
assumes [1] - 117:7
assuming [3] - 78:17, 79:16, 95:7
assumption [8] - 75:16, 93:6, 116:22, 116:25, 117:3, 120:1, 120:6, 120:10
assumptions [3] - 96:25, 97:18, 116:19
asymptomatic [1] - 19:7
Atlanta [1] - 60:19
atrial [3] - 69:25, 102:6, 102:13
Atritech [1] - 102:9
attached [1] - 110:1
attachments [1] - 110:5
attempt [7] - 24:22, 87:12, 91:13, 94:11, 111:17, 115:19, 120:7
attempted [2] - 96:3, 96:9
attend [2] - 21:8, 21:10
attended [1] - 9:19
attorney [7] - 26:11, 26:13, 50:5, 50:9, 57:22, 57:24, 58:23
attorney-client [2] - 57:22, 57:24
attractive [6] - 119:2, 119:11, 119:14, 119:21, 120:16, 120:19
audience [1] - 97:25
audiences [1] - 97:10
audio [1] - 7:4
author [2] - 10:20, 32:25
authored [1] - 63:13
authorities [1] - 35:14
authorization [2] - 73:14, 115:10
authors [1] - 33:18
availability [2] - 23:22, 83:11
available [8] - 4:11, 12:13, 16:12, 24:9, 34:3, 36:6, 36:11, 139:18
Avenue [6] - 1:15, 1:19, 1:22, 2:4, 2:8, 162:10
average [3] - 73:18, 115:17, 115:22
aware [23] - 13:16, 21:18, 29:10, 30:1, 31:12, 40:12, 41:4, 41:7, 53:3, 53:7, 57:6, 62:3, 62:7, 62:14, 62:17, 62:20, 62:22, 62:25, 63:9, 81:2, 104:13, 104:24, 117:18

B

backed [3] - 102:9, 102:23, 122:18
background [5] - 21:22, 22:8, 26:24, 27:6, 67:21
Bailey [7] - 136:6, 136:12, 136:14, 137:1, 137:9, 137:15, 137:21
BAILEY [2] - 3:7, 136:7
Bain [3] - 17:14, 27:19, 27:20
balance [2] - 85:2, 93:12
bandwidth [1] - 56:7
bane [1] - 55:2
banker [1] - 88:4
banker-run [1] - 88:4
bankers [1] - 88:6
bar [5] - 91:22, 91:24, 92:5, 98:20, 100:12
Barrett [2] - 1:12, 26:10
barrier [1] - 109:5

barriers [1] - 34:7
base [2] - 13:14, 91:20
based [25] - 11:22, 12:14, 13:24, 14:13, 15:4, 16:4, 19:9, 25:24, 31:3, 41:18, 41:23, 73:7, 80:11, 80:23, 82:25, 84:20, 85:24, 86:12, 86:13, 87:23, 88:13, 100:15, 107:11, 120:1, 138:16
basics [1] - 71:7
basis [5] - 9:20, 13:7, 71:16, 98:12, 106:9
basketball [1] - 66:19
bear [1] - 74:17
bearer [2] - 15:22, 16:1
became [4] - 21:18, 65:2, 65:16, 102:14
become [3] - 38:12, 75:19, 75:25
becoming [1] - 76:11
BEFORE [1] - 1:9
begin [1] - 80:19
beginning [3] - 23:18, 61:2, 75:15
behalf [5] - 46:25, 56:21, 58:15, 59:18, 103:25
behaves [1] - 18:5
behind [7] - 24:17, 24:18, 77:23, 78:20, 79:14, 98:7, 110:17
below [1] - 69:24
bench [1] - 72:23
benefit [2] - 42:24, 63:24
benefits [2] - 123:19, 123:20
Berkeley [1] - 136:22
best [11] - 4:20, 45:25, 78:20, 85:9, 103:3, 103:4, 110:19, 111:2, 111:12, 124:18, 162:6
best-case [2] - 78:20, 85:9
best-in-class [3] - 110:19, 111:2, 111:12
better [3] - 7:7, 10:12, 52:20
between [5] - 8:1, 32:6, 86:15, 109:21, 123:12
beyond [4] - 19:4, 70:24, 90:6, 90:9
bias [6] - 45:8, 45:9, 45:10, 45:14, 45:15, 45:24
biased [2] - 29:8, 45:18
bid [1] - 88:9
Bierman [1] - 109:21
big [13] - 16:13, 21:1, 24:13, 40:25, 43:25, 71:19, 71:21, 76:24, 77:1, 77:6, 89:6, 94:6, 107:16
bigger [4] - 16:9, 16:25, 17:19, 31:8
biggest [3] - 9:4, 49:14, 98:15
billion [4] - 69:13, 102:14, 103:1, 124:11
billion-dollar [3] - 102:14, 103:1, 124:11
binder [3] - 4:8, 4:23, 109:14
Biodesign [2] - 71:4
biopharmaceutical [1] - 69:12
biotech [4] - 67:24, 77:1, 91:23
bit [9] - 32:17, 43:17, 47:19, 48:14, 105:21, 108:17, 117:16, 124:3, 124:17
blacked [1] - 94:13
blank [1] - 92:15
block [3] - 41:15, 112:25, 114:25
blocked [6] - 83:21, 83:25, 84:21, 85:5, 88:17, 103:8
blocks [2] - 95:1
blue [1] - 94:17
blues [1] - 94:19
Board [2] - 97:25, 124:6
board [22] - 10:3, 10:6, 10:8, 18:12, 39:7, 41:11, 45:3, 70:5, 70:7, 70:10, 70:11, 72:5, 76:4, 83:13, 86:7, 87:9, 119:12, 119:13, 120:10, 123:6
boards [4] - 9:23, 10:15, 23:6, 23:8
boils [1] - 139:2
Boston [12] - 4:8, 10:3, 38:14, 38:15, 49:20, 69:5, 88:25, 102:7, 102:10, 102:15, 114:11, 115:4
bottom [6] - 50:14, 52:3, 110:12, 114:4, 139:20, 140:3
bought [7] - 24:14, 25:6, 48:23, 49:4, 89:2, 105:6, 105:11
box [2] - 34:1, 51:18
boxes [4] - 94:3, 94:16, 94:22, 94:24
brand [1] - 74:5
brand-new [1] - 74:5
break [4] - 73:6, 99:20, 99:22, 100:2
breaking [1] - 36:13
Brian [3] - 47:1, 52:20, 52:21
bridge [1] - 77:9
Brief [3] - 99:23, 109:18, 118:14
briefing [3] - 5:15, 5:17, 5:19
briefly [4] - 13:4, 67:21, 77:25, 136:12
bring [10] - 7:7, 22:10, 27:2, 36:18, 41:12, 41:24, 42:17, 44:4, 83:13, 95:10
bringing [1] - 81:6
broaden [1] - 105:2
broken [1] - 140:1
brought [1] - 36:15
bruises [1] - 74:18
build [20] - 69:1, 82:12, 89:5, 91:3, 92:12, 92:25, 94:1, 94:2, 94:5, 94:8, 94:11, 95:4, 95:23, 103:4, 103:6, 110:18, 110:21, 111:1, 111:11, 117:6
building [8] - 72:1, 72:22, 86:16, 95:8, 96:15, 97:23, 103:1, 110:15
built [3] - 56:24, 98:19, 102:7
bunch [2] - 55:8, 115:20
burden [2] - 82:7, 82:23
burn [9] - 84:18, 85:3, 85:25, 86:6, 87:2, 87:4, 87:11, 93:13, 93:14
business [4] - 72:3, 80:24, 88:12, 117:20
Business [1] - 136:21
busy [1] - 55:18
buy [2] - 38:23, 87:22
buyer [3] - 87:10, 88:22, 119:1
buyers [1] - 89:16
buying [2] - 39:1, 110:14
BY [29] - 6:13, 16:3, 26:9, 33:5, 50:11, 50:17, 54:12, 60:5, 67:5, 67:13, 67:20, 72:17, 74:25, 79:8, 81:10, 100:1, 104:4, 107:25, 109:9, 110:10, 111:23, 112:7, 117:25, 118:11, 118:22, 136:11, 137:14, 137:20, 138:1

C

calculate [1] - 4:17
calculated [1] - 115:22
calendar [1] - 80:10
California [1] - 136:22
campaigns [1] - 27:13
candidates [1] - 31:1
cannot [2] - 61:4, 114:3
capabilities [6] - 11:25, 14:17, 83:2, 83:15, 100:3, 139:16
Capable [1] - 114:5
capacity [2] - 10:2, 14:6
capital [23] - 68:1, 68:21, 69:10, 69:14, 70:16, 70:18, 71:15, 72:2, 72:3, 85:13, 87:13, 90:25, 91:1, 91:4, 91:10, 91:14, 92:6, 92:10, 92:24, 93:16, 97:19, 98:25, 120:24
capitalists [1] - 122:19
Cardia [1] - 10:6
cardiac [3] - 6:25, 20:10, 70:1
CardiacBooster [2] - 121:10, 121:12
cardiologist [2] - 20:3, 21:24
cardiology [1] - 7:13
cardiovascular [3] - 6:25, 69:17, 69:19
care [4] - 10:13, 22:11, 64:3, 69:11
career [3] - 67:22, 68:2, 137:1
careful [2] - 110:16, 122:25
case [37] - 4:18, 4:19, 4:22, 19:25, 46:25, 47:10, 49:11, 52:10, 52:25, 53:22, 57:9, 60:25, 62:5, 62:9, 63:10, 63:11, 63:14, 64:4, 67:9, 71:12, 71:22, 72:6, 74:16, 75:2, 78:20, 81:16, 82:25, 85:9, 86:13, 87:24, 90:15, 93:19, 97:6, 104:18, 116:16, 117:12, 124:10
cases [8] - 8:1, 8:2, 12:15, 32:16, 81:18, 83:10, 99:15, 137:6
cash [9] - 84:17, 85:2, 87:4, 90:9, 92:16, 92:20, 93:12, 93:14, 94:21
catch [2] - 24:12, 43:2
Catch-22 [1] - 90:24
catching [1] - 25:20
categories [1] - 140:10
category [2] - 103:1, 115:21
catheter [1] - 18:2
catheterization [1] - 7:1
catheters [2] - 15:2, 15:3
caution [1] - 57:23
caveat [1] - 79:15
CC'd [1] - 52:5
CCR [3] - 2:6, 162:3, 162:8
CE [1] - 22:21
cell [2] - 51:17, 51:23
Center [1] - 71:4
CEO [5] - 68:12, 70:12, 71:23, 71:25, 88:25
CEOs [1] - 70:13
certain [1] - 72:7
certainly [1] - 122:1
CERTIFICATE [1] - 162:2
certify [1] - 162:3
CFDA [1] - 77:7
CFR [1] - 77:18
chain [5] - 14:8, 14:11, 28:12, 52:5, 82:2
challenges [5] - 99:13, 99:14, 100:13, 103:12

chance [2] - 39:23, 89:13
chances [2] - 66:14, 88:22
change [4] - 42:10, 43:19, 88:21, 89:12
changes [2] - 16:15, 16:24
changing [1] - 74:22
characteristic [1] - 85:21
characteristics [1] - 42:23
charge [1] - 45:22
Charles [2] - 136:15, 136:18
chart [7] - 76:15, 80:21, 85:1, 94:14, 94:17, 94:23, 95:2
chased [1] - 9:10
check [2] - 46:16, 92:15
checked [1] - 40:4
checking [1] - 35:21
CHETCUTI [2] - 3:3, 6:11
Chetcuti [94] - 6:10, 6:14, 6:17, 7:3, 25:22, 26:10, 26:19, 27:2, 27:11, 27:24, 28:2, 28:25, 29:9, 30:1, 30:8, 30:17, 31:9, 32:19, 32:25, 33:6, 33:8, 33:14, 34:4, 34:10, 34:20, 35:6, 35:12, 36:2, 36:12, 36:17, 37:4, 37:7, 37:18, 37:24, 38:1, 38:17, 38:22, 38:25, 39:12, 39:25, 40:22, 41:14, 42:11, 42:13, 43:8, 43:16, 44:10, 45:4, 45:20, 46:9, 46:18, 46:22, 47:4, 47:13, 47:19, 47:25, 48:7, 48:13, 48:22, 49:9, 50:12, 50:18, 51:13, 51:19, 52:6, 52:23, 53:20, 53:25, 54:17, 55:3, 55:7, 55:25, 56:9, 57:3, 57:23, 58:11, 58:15, 59:5, 59:8, 59:16, 60:6, 60:13, 61:4, 61:8, 61:17, 62:1, 62:3, 62:14, 63:4, 64:13, 65:2, 65:15, 99:12
Chetcuti's [1] - 89:21
China [10] - 20:20, 20:24, 41:1, 41:24, 76:16, 76:17, 76:18, 77:7, 77:8, 79:18
Chinese [4] - 76:21, 77:2, 77:4, 77:6
choice [2] - 54:7, 120:12
choices [1] - 119:16
choose [2] - 119:13, 119:14
chose [2] - 80:17, 88:8
Cincinnati [1] - 30:25
citizen [1] - 22:24
claim [1] - 108:23
claims [3] - 114:15, 114:18, 114:22
clarify [4] - 28:15, 29:10, 62:6, 112:23
class [8] - 68:9, 68:11, 68:12, 71:5, 74:3, 110:19, 111:2, 111:12
Class [16] - 68:5, 72:19, 73:5, 73:19, 76:5, 81:13, 82:6, 104:15, 104:20, 104:25, 105:2, 109:5, 115:11, 115:20, 122:16
classes [1] - 105:3
clear [6] - 28:25, 39:13, 46:2, 65:16, 89:7, 116:14
clears [1] - 110:21
CLEARY [1] - 1:18
CLERK [1] - 78:2
clerk [1] - 4:10
client [4] - 27:10, 57:22, 57:24, 63:19
clinic [1] - 24:11
clinical [58] - 6:24, 7:18, 8:4, 8:20, 9:14, 10:14, 11:13, 11:23, 12:6, 13:5, 13:8, 13:11, 13:22, 13:25, 14:1, 14:14, 23:12, 24:4, 24:21, 24:22, 25:1, 31:24, 35:10, 35:14, 36:21, 37:3, 38:20, 40:2, 40:16, 40:23, 40:24, 41:4, 42:20, 46:3, 55:18, 71:18, 75:10, 80:1, 80:14, 80:19, 81:15, 82:8, 82:15, 83:7, 83:8, 83:9, 89:21, 89:25, 100:14, 100:16, 103:4, 103:15, 106:5, 106:10, 106:18, 136:22, 140:13
clinically [2] - 40:18, 106:2
ClinicalTrials.gov [2] - 40:5, 138:12
clip [1] - 32:9
close [7] - 38:6, 78:20, 97:20, 124:19, 136:2, 141:4, 141:6
closed [1] - 93:3
closer [1] - 7:7
closes [2] - 111:16, 112:20
closest [2] - 107:9, 117:19
closings [1] - 5:15
CMA [1] - 99:10
co [2] - 32:25, 33:18
co-author [1] - 32:25
co-authors [1] - 33:18
Coate [1] - 1:18
Colgate [1] - 136:17
collaborate [1] - 23:20
colleague [1] - 8:5
COLUMBIA [1] - 1:1
Columbia [1] - 19:14
combined [1] - 112:24
coming [2] - 22:9, 41:15
commend [4] - 18:24, 36:15, 36:20, 36:21
comment [1] - 111:7
commercial [27] - 12:1, 14:7, 14:17, 42:15, 43:10, 44:6, 72:1, 78:21, 79:18, 79:19, 81:11, 86:16, 87:14, 90:22, 92:12, 94:3, 94:11, 94:15, 95:1, 95:8, 100:3, 100:5, 124:14, 140:11, 140:14, 140:19, 140:23
commercialization [5] - 27:6, 27:7, 27:8, 72:13, 82:18
commercialize [11] - 26:22, 68:25, 71:8, 81:12, 83:2, 83:16, 83:24, 91:14, 92:23, 93:22, 99:3
commercialized [2] - 78:18, 140:22
commercializing [1] - 90:20
commercially [2] - 25:13, 41:25
COMMISSION [2] - 1:2, 1:15
Commission [4] - 26:14, 46:24, 60:9, 104:1
committed [1] - 85:23
common [2] - 75:19, 76:11
communal [1] - 49:19
communicated [2] - 65:3, 95:5
communication [2] - 65:6, 65:21
communications [3] - 46:23, 62:8, 62:23
community [4] - 15:12, 33:22, 63:25, 99:16
companies [46] - 9:25, 20:14, 23:6, 23:9, 27:9, 27:10, 27:18, 27:20, 38:18, 38:20, 39:15, 69:16, 70:5, 70:8, 70:10, 70:17, 71:16, 72:5, 75:9, 75:19, 76:4, 76:14, 76:22, 77:2, 77:4, 77:11, 82:14, 82:17, 86:14, 88:14, 88:17, 89:6, 91:7, 91:9, 91:11, 91:23, 100:20, 100:25, 101:19, 101:22, 103:22, 110:20, 113:25, 114:8, 114:17, 114:24
company [75] - 9:10, 10:16, 10:18, 11:24, 12:4, 12:19, 12:23, 14:22, 15:3, 16:13, 17:7, 20:16, 21:1, 23:11, 23:14, 24:7, 25:13, 25:18, 27:14, 27:22, 31:5, 31:6, 37:5, 38:2, 42:5, 44:18, 68:8, 68:13, 68:22, 69:1, 69:3, 69:4, 69:5, 70:12, 73:20, 75:13, 75:23, 77:21, 79:12, 80:20, 82:16, 84:3, 87:22, 88:4, 88:20, 89:2, 89:7, 89:9, 90:1, 90:15, 91:22, 92:2, 94:18, 96:1, 96:17, 97:12, 97:16, 98:10, 98:22, 102:4, 102:9, 102:24, 104:19, 105:5, 105:11, 108:7, 109:2, 112:25, 115:2, 117:12, 120:8, 122:23, 136:2
company's [1] - 80:18
company-specific [1] - 136:2
comparative [2] - 26:20, 26:21
compare [1] - 96:10
compared [4] - 17:25, 34:24, 96:20
comparing [1] - 96:24
comparison [1] - 96:10
compete [4] - 101:7, 106:2, 106:22, 106:24
competing [4] - 106:9, 106:18, 107:1, 107:5
competition [9] - 100:12, 103:2, 105:21, 105:22, 105:24, 106:5, 136:15, 139:6, 140:7
competitive [8] - 107:13, 107:15, 107:17, 107:19, 108:8, 108:9, 108:13, 138:7
competitor [5] - 79:2, 100:7, 100:23, 107:9, 117:19
competitors [4] - 78:14, 80:17, 100:8, 103:6
compile [2] - 73:12, 76:7
complement [1] - 139:15
complete [4] - 15:3, 43:4, 79:2, 162:6
completely [3] - 46:21, 57:14, 57:15
complex [1] - 98:23
complications [4] - 16:24, 34:21, 80:14, 103:15
component [1] - 140:25
comprised [1] - 122:13
compromise [1] - 12:18
computer [1] - 2:11
computer-aided [1] - 2:11
conceivably [1] - 61:6
concept [1] - 19:3
concern [1] - 89:18
concerns [2] - 36:3, 99:17
concluded [3] - 110:18, 111:1,

111:11
concluding [1] - 98:13
conclusion [8] - 4:21, 34:14, 84:25, 91:20, 100:4, 118:5, 118:24, 139:13
conclusions [4] - 45:11, 139:10, 139:11, 139:20
conditions [1] - 75:13
conduct [2] - 61:5, 73:4
conducted [1] - 23:12
conference [2] - 21:5, 21:8
conferences [1] - 138:18
confidential [3] - 63:6, 122:25, 124:18
conflicted [1] - 46:4
conflicts [3] - 44:12, 45:16, 46:5
conjecture [3] - 15:8, 30:11, 43:4
connect [2] - 50:4, 50:23
connected [3] - 6:6, 56:17, 62:16
Connecticut [1] - 1:22
connection [1] - 59:6
Connor [3] - 52:5, 52:8, 52:18
conscious [2] - 45:7, 45:15
consider [10] - 11:3, 20:2, 20:9, 44:7, 84:2, 88:18, 100:6, 104:19, 105:4, 138:24
consistent [3] - 100:22, 122:15, 122:17
consistently [2] - 91:24, 101:16
constitutes [1] - 162:4
Constitution [2] - 2:8, 162:10
constraints [1] - 96:1
contents [3] - 60:11, 60:12, 60:15
contingency [3] - 83:20, 84:1, 123:5
continue [13] - 18:8, 19:10, 29:20, 29:25, 30:9, 30:14, 30:18, 31:16, 37:9, 40:19, 84:22, 119:22, 120:20
continued [4] - 9:4, 32:9, 34:25
CONTINUED [1] - 2:1
continues [1] - 34:15
continuing [2] - 119:2, 120:16
CONTRERAS [1] - 1:9
control [1] - 93:2
convenient [1] - 75:24
conversation [1] - 119:12
conversely [1] - 103:8
convince [2] - 97:11, 98:1
copies [3] - 67:18, 112:8, 118:20
copy [2] - 84:13, 109:14
CoreValve [5] - 24:14, 24:20, 24:21, 25:3, 25:5
corner [1] - 34:2
coronary [1] - 7:14
corporates [1] - 103:19
CORPORATION [1] - 1:5
correct [96] - 27:12, 27:16, 27:25, 28:4, 28:12, 28:16, 29:13, 30:2, 31:10, 31:13, 31:24, 32:10, 32:21, 32:22, 33:1, 33:23, 34:12, 34:21, 36:13, 37:10, 38:3, 38:23, 39:15, 39:20, 40:2, 40:9, 40:24, 41:5, 41:9, 41:25, 42:2, 44:7, 44:13, 45:19, 45:21, 45:24, 46:11, 47:2, 49:5, 49:12, 52:24, 53:9, 55:4, 56:1, 56:21, 58:7, 59:11, 65:19, 65:25, 104:21, 104:25, 105:1, 105:7, 105:8, 105:13, 105:17, 106:11, 107:10, 107:14, 108:24, 109:23, 112:22, 113:1, 113:4, 113:8, 113:11, 113:12, 113:15, 113:16, 113:21, 114:12, 114:20, 115:1, 116:2, 116:16, 116:24, 117:10, 117:14, 117:15, 119:7, 119:11, 119:24, 120:18, 120:22, 120:23, 121:11, 121:14, 121:25, 122:3, 122:23, 122:24, 123:9, 123:10, 123:12, 124:8, 124:9
correctly [7] - 19:23, 40:7, 108:15, 110:24, 112:6, 119:4, 123:22
corroborates [1] - 99:5
cost [1] - 75:22
costs [2] - 44:21, 89:4
counsel [11] - 4:7, 29:17, 29:24, 50:21, 51:2, 52:12, 52:13, 56:6, 57:8, 59:4, 84:12
count [3] - 11:20, 94:18, 95:2
countries [2] - 71:10, 76:19
country [8] - 9:5, 11:12, 13:1, 14:3, 16:6, 40:23, 44:5, 83:11
couple [7] - 4:4, 81:18, 99:8, 104:5, 105:9, 108:2, 109:11
course [9] - 5:10, 13:19, 49:7, 68:2, 68:17, 88:16, 119:8, 137:1, 139:5
courses [2] - 70:25, 82:20
COURT [36] - 1:1, 4:3, 4:13, 4:24, 5:2, 5:10, 5:18, 5:21, 5:25, 6:4, 15:17, 15:18, 15:21, 15:23, 15:25, 26:7, 66:10, 66:13, 66:22, 66:25, 72:15, 78:24, 79:5, 99:19, 99:21, 99:22, 104:2, 112:2, 118:18, 118:21, 124:19, 136:4, 136:9, 137:12, 141:6, 162:2
Court [5] - 2:6, 2:7, 5:24, 137:18, 162:8
court [12] - 4:5, 5:7, 7:5, 64:11, 78:3, 84:12, 135:23, 136:1, 136:13, 137:25, 141:4, 141:6
Courthouse [2] - 2:7, 162:9
courtroom [2] - 7:6, 124:19
courtrooms [1] - 112:1
cover [2] - 60:7, 139:11
coverage [1] - 82:10
create [2] - 27:13, 123:7
created [1] - 138:16
creates [1] - 91:2
creating [1] - 88:23
criteria [1] - 9:13
critical [1] - 13:23
cross [1] - 5:8
Cross [2] - 3:4, 3:6
CROSS [2] - 26:8, 104:3
Cross-Examination [2] - 3:4, 3:6
CROSS-EXAMINATION [2] - 26:8, 104:3
cross-examine [1] - 5:8
CRR [3] - 2:6, 162:3, 162:8
CRUTCHER [1] - 1:22
current [7] - 14:4, 84:17, 84:22, 85:3, 85:13, 86:21, 122:22
Cuspa's [1] - 113:6
Cusper [1] - 113:6
CV [1] - 1:2
cycle [1] - 91:3

D

D-D-X-1-19 [1] - 112:11
D-X-002 [1] - 137:24
D-X-0289 [1] - 137:19
D-X-0297 [1] - 33:4
D-X-288 [2] - 67:12, 117:24
D.C [1] - 1:4
dark [1] - 94:17
data [35] - 9:15, 11:5, 23:19, 23:21, 23:23, 34:7, 35:19, 42:25, 76:3, 76:16, 76:18, 76:20, 77:17, 79:12, 100:16, 106:20, 106:21, 117:8, 117:14, 136:2, 138:9, 138:11, 138:13, 138:14, 138:15, 138:16, 138:19, 139:17, 139:23, 141:5
data-driven [1] - 139:23
database [1] - 138:16
date [9] - 16:19, 32:20, 49:17, 80:4, 83:7, 100:14, 110:22, 116:17, 122:15
dated [3] - 58:13, 60:8, 162:7
DAY [1] - 1:8
day-to-day [1] - 70:14
days [3] - 53:3, 63:1, 75:19
DC [6] - 1:16, 1:19, 1:23, 2:5, 2:8, 162:10
de [1] - 68:5
deal [12] - 83:19, 85:7, 88:17, 97:1, 97:22, 97:24, 98:2, 101:5, 101:13, 103:8, 124:2, 124:6
dealing [1] - 23:18
deals [1] - 117:18
debating [1] - 25:5
decade [3] - 59:2, 68:13, 98:18
decades [1] - 91:21
December [2] - 25:7, 41:13
decided [1] - 57:11
decides [1] - 101:22
decision [5] - 35:16, 53:11, 65:9, 65:11, 65:14
decisions [3] - 10:16, 35:18, 69:13
deck [1] - 138:2
declared [1] - 66:3
dedicated [2] - 34:9, 34:11
deep [1] - 110:22
DEFENDANTS [3] - 6:11, 67:3, 136:7
defendants [6] - 5:14, 6:9, 67:1, 72:11, 123:19, 136:5
Defendants [3] - 1:7, 1:17, 2:2
defendants' [1] - 4:18
defense [2] - 59:4, 123:17
defer [1] - 41:21
definitely [1] - 9:2
definition [1] - 101:4
defrays [1] - 44:21
degree [1] - 136:17
delay [5] - 12:16, 12:18, 14:10, 36:7, 93:12
delayed [1] - 94:20
delays [1] - 93:7
delineate [1] - 76:19
deliver [4] - 10:12,

16:25, 20:22, 55:23
deliverable [1] - 16:16
delivers [1] - 35:9
delivery [4] - 15:2, 16:23, 18:1, 22:11
demand [2] - 12:20, 23:19
demands [2] - 12:22
DeMarchi [1] - 1:14
demonstrates [1] - 139:18
demonstrative [5] - 67:14, 67:18, 96:12, 96:24, 137:21
demonstratives [1] - 4:4
Dennis [3] - 67:1, 67:8, 72:11
DENNIS [2] - 3:5, 67:3
department [2] - 82:9, 136:24
departments [1] - 94:5
deploying [1] - 90:2
depo [1] - 107:23
deposed [5] - 29:6, 32:19, 53:17, 53:18, 63:2
deposition [17] - 4:22, 29:7, 43:8, 43:18, 46:13, 60:22, 63:5, 64:5, 64:14, 65:4, 78:1, 78:5, 78:7, 104:23, 105:9, 108:2, 109:11
DEPUTY [1] - 78:2
describe [7] - 67:21, 68:17, 69:8, 71:11, 72:18, 81:11, 138:4
described [11] - 12:14, 14:3, 14:15, 16:4, 17:9, 52:9, 70:24, 71:1, 76:17, 78:13, 90:5
describing [2] - 115:9, 140:9
design [5] - 43:6, 71:18, 74:7, 79:24
designations [1] - 4:22
designed [2] - 43:7, 83:6
desire [2] - 80:25, 82:14
despite [1] - 100:14
detailed [1] - 123:5
detailing [1] - 76:2
details [4] - 28:24, 49:24, 80:18, 80:20
detection [1] - 15:14
determine [1] - 13:8
develop [7] - 17:14, 68:23, 72:3, 89:5, 90:16, 96:7, 101:3
developed [6] - 18:5, 19:4, 20:15, 21:25, 76:16, 110:21
developer [3] - 23:11, 77:20, 79:11
developing [14] - 18:8, 20:14, 29:15, 68:3, 68:9, 69:16, 74:18, 77:5, 78:14, 97:11, 97:14, 98:8, 98:23, 102:5
development [10] - 8:21, 10:12, 22:22, 68:14, 72:12, 77:3, 81:5, 115:10, 115:18, 115:21
device [82] - 8:21, 9:9, 11:14, 12:1, 14:2, 14:7, 16:16, 16:20, 16:21, 16:23, 17:9, 19:19, 22:13, 23:14, 24:5, 24:8, 25:14, 25:21, 26:25, 27:6, 27:12, 27:15, 28:3, 28:16, 29:2, 30:4, 34:9, 34:11, 38:2, 40:21, 41:1, 42:17, 42:19, 67:25, 71:8, 72:12, 72:19, 72:21, 73:3, 73:10, 73:19, 74:3, 74:6, 74:12, 75:14, 76:22, 77:21, 80:15, 81:5, 81:7, 81:13, 83:3, 91:22, 92:23, 94:12, 95:9, 95:10, 96:4, 100:25, 102:5, 103:9, 104:25, 105:5, 105:14, 105:22, 105:24, 106:5, 106:9, 106:13, 107:9, 109:2, 109:5, 111:2, 111:12, 112:22, 113:6, 113:15, 115:10, 115:18, 122:13, 122:16
devices [49] - 8:4, 16:12, 17:22, 19:12, 20:15, 21:25, 23:3, 38:18, 40:1, 40:15, 47:16, 68:3, 68:5, 68:6, 68:10, 68:12, 68:23, 68:25, 69:12, 69:16, 74:20, 75:5, 75:10, 76:5, 76:16, 76:25, 77:12, 78:14, 82:6, 82:11, 91:24, 95:21, 98:24, 99:13, 104:9, 104:12, 104:16, 104:20, 105:3, 105:6, 105:12, 106:2, 106:16, 106:22, 115:11, 115:20, 123:8
differences [1] - 95:22
different [27] - 12:25, 13:17, 17:22, 21:17, 28:23, 30:7, 30:22, 30:23, 39:5, 39:9, 39:10, 41:19, 42:22, 43:13, 45:2, 69:14, 70:1, 73:23, 79:15, 91:12, 91:22, 92:17, 97:9, 97:10, 98:7, 104:15, 114:2
difficult [5] - 21:13, 90:11, 110:18, 111:1, 111:11
difficulty [1] - 12:15
digit [3] - 85:2, 85:21, 92:3
diligence [2] - 71:15, 71:21
diligent [1] - 122:13
diminish [1] - 37:1
diminishing [1] - 93:13
dinner [11] - 47:12, 47:25, 48:7, 48:23, 49:5, 49:9, 49:10, 49:13, 49:16, 50:5, 50:24
dinners [1] - 48:18
DIRECT [3] - 6:12, 67:4, 136:10
Direct [3] - 3:3, 3:5, 3:8
direct [6] - 26:19, 29:17, 31:22, 116:9, 117:17, 123:11
directly [3] - 45:3, 65:3, 77:14
director [5] - 6:25, 7:2, 36:16, 36:21, 70:4
Directors [2] - 98:1, 124:7
disclose [6] - 44:12, 46:6, 59:9, 59:12, 61:18, 61:21
disclosed [2] - 45:13, 85:20
discloses [1] - 78:12
disclosing [3] - 45:16, 62:19, 89:8
disclosure [2] - 28:20, 41:10
disclosures [4] - 44:15, 45:5, 45:23, 46:7
discretion [1] - 5:25
discuss [3] - 63:10, 64:19, 64:23
discussed [8] - 23:6, 50:19, 58:17, 60:12, 60:15, 82:2, 117:17, 119:22
discussing [1] - 93:5
discussion [1] - 30:12
discussions [1] - 39:14
disease [3] - 7:14, 7:16, 14:22
display [1] - 33:6
disrespect [1] - 55:15
disseminate [1] - 14:2
DISTRICT [3] - 1:1, 1:1, 1:10
dividends [1] - 39:7
diving [1] - 141:5
doctor [6] - 13:16, 13:21, 15:21, 15:23, 31:4, 43:5
Doctor [4] - 31:2, 31:20, 54:13, 66:13
doctors [2] - 75:25, 83:10
document [27] - 33:4, 33:6, 47:19, 60:3, 61:5, 61:6, 61:25, 62:2, 62:3, 62:18, 63:15, 63:19, 63:21, 63:22, 65:10, 73:12, 76:2, 109:10, 110:3, 110:5, 111:3, 111:8, 111:9, 111:10, 115:14, 118:9
documents [7] - 59:17, 60:7, 62:4, 62:19, 62:23, 110:1, 138:22
dollar [3] - 102:14, 103:1, 124:11
dollars [3] - 44:1, 85:4, 99:2
domain [12] - 10:10, 10:24, 14:21, 15:10, 16:14, 20:13, 20:19, 24:13, 28:22, 35:5, 38:9, 60:1
domestic [1] - 77:5
dominance [1] - 15:7
done [19] - 5:9, 12:4, 12:8, 12:23, 13:23, 15:10, 15:19, 22:19, 27:15, 28:22, 53:15, 76:5, 79:23, 81:2, 82:25, 87:24, 101:16, 102:3, 140:16
double [2] - 85:2, 85:21
double-digit [2] - 85:2, 85:21
down [13] - 15:23, 25:8, 35:3, 60:17, 61:2, 69:24, 70:18, 73:6, 80:23, 82:22, 98:2, 99:24, 139:2
dozen [1] - 70:7
dr [1] - 60:6
Dr [120] - 4:12, 4:20, 5:4, 6:9, 6:14, 7:3, 19:14, 19:19, 19:25, 20:2, 20:5, 20:9, 25:22, 26:10, 26:19, 27:2, 27:11, 27:24, 28:2, 28:25, 29:9, 30:1, 30:6, 30:8, 30:17, 31:9, 32:1, 32:19, 32:25, 33:6, 33:8, 33:14, 34:4, 34:10, 34:20, 35:6, 35:12, 36:2, 36:12, 36:17, 37:4, 37:7, 37:18, 37:24, 38:1, 38:17, 38:22, 38:25, 39:12, 39:25, 40:22, 41:14, 42:11, 42:13, 43:8, 43:16, 44:10, 45:4, 45:20, 46:9, 46:18, 46:22, 47:4, 47:13, 47:19, 47:25, 48:7, 48:13, 48:22, 49:9, 50:12, 50:18, 51:13, 51:19, 52:6, 52:23, 53:20, 53:25, 54:17, 55:3, 55:7, 55:25, 56:9, 57:3, 57:23, 58:11, 58:15, 59:5, 59:8, 59:16, 60:13, 60:19, 60:20, 60:22, 60:25, 61:4, 61:8, 61:17, 62:1, 62:3, 62:14, 63:4, 64:13, 65:2, 65:15, 75:1, 89:21, 99:9, 99:12, 136:6, 136:12, 137:1, 137:9, 137:15, 137:21, 138:6, 138:19, 139:25, 140:9, 140:16
drastic [1] - 40:11
drive [3] - 69:3, 79:16, 105:24

driven [2] - 73:22, 139:23
drives [2] - 101:10, 101:12
Duane [2] - 36:16, 36:21
due [4] - 71:15, 80:14, 94:21, 99:13
dun [1] - 59:1
DUNN [1] - 1:22
Dunn [3] - 58:24, 59:2, 63:13
during [6] - 14:10, 17:2, 86:3, 86:5, 96:23, 106:6
dynamics [1] - 91:13

E

earlier-stage [1] - 70:11
earliest [4] - 24:4, 78:19, 80:8, 140:21
early [8] - 8:6, 25:1, 47:22, 69:10, 73:6, 77:15, 90:22, 93:6
early-stage [1] - 69:10
ease [1] - 42:19
easier [4] - 33:12, 75:24, 77:9, 110:4
eat [1] - 48:21
echo [1] - 35:2
echos [1] - 35:4
economic [4] - 138:21, 138:23, 139:21, 139:23
economics [2] - 136:16, 136:23
ecosystem [3] - 67:23, 71:1, 71:3
edge [4] - 15:14, 15:15
edge-to-edge [2] - 15:14, 15:15
educating [1] - 74:14
education [1] - 81:25
EDWARDS [1] - 1:5
Edwards [156] - 6:9, 8:10, 8:11, 14:13, 14:15, 14:16, 14:20, 14:22, 14:23, 15:4, 15:19, 16:5, 16:13, 16:14, 17:4, 17:21, 18:5, 18:7, 18:8, 18:13, 18:14, 18:17, 18:20, 18:23, 18:24, 19:9, 19:10, 24:13, 24:16, 24:17, 25:12, 25:17, 25:20, 28:6, 28:15, 28:21, 29:1, 29:5, 29:10, 29:19, 29:25, 30:1, 30:9, 30:14, 30:17, 31:6, 31:9, 31:16, 38:1, 38:9, 38:24, 39:6, 39:8, 39:10, 41:14, 46:10, 47:7, 47:16, 48:5, 48:6, 49:9, 49:19, 49:23, 50:5, 51:2, 51:11, 51:20, 52:21, 53:4, 53:9, 53:16, 53:19, 57:14, 61:10, 61:11, 61:13, 61:22, 62:11, 62:13, 62:15, 62:19, 62:23, 63:6, 63:13, 63:17, 63:20, 63:23, 64:2, 64:3, 64:7, 64:24, 66:2, 66:4, 66:7, 75:9, 78:21, 80:23, 83:15, 83:20, 85:5, 88:5, 90:17, 95:11, 95:15, 95:19, 96:5, 96:11, 96:13, 97:1, 97:6, 97:15, 97:20, 97:23, 97:25, 99:6, 99:18, 101:3, 101:4, 101:5, 101:6, 101:15, 102:22, 107:13, 107:18, 108:13, 109:24, 111:1, 111:10, 111:16, 112:16, 112:21, 113:2, 113:5, 113:9, 113:14, 113:19, 113:24, 114:16, 114:17, 114:20, 114:23, 119:1, 119:18, 119:24, 120:22, 121:2, 121:6, 121:12, 121:18, 122:4, 123:8, 123:12, 123:25, 124:2
Edwards's [22] - 18:12, 26:1, 26:20, 28:16, 29:18, 53:4, 56:17, 57:7, 59:10, 59:13, 61:18, 63:5, 63:18, 64:18, 64:22, 78:16, 98:13, 104:8, 107:1, 107:8, 139:15, 139:18
effective [2] - 37:9, 106:3
effectively [1] - 94:7
effectiveness [7] - 34:16, 34:20, 106:6, 106:10, 106:13, 106:16, 106:18
effects [9] - 138:7, 138:24, 139:4, 139:5, 139:7, 139:11, 139:14, 139:21, 139:24
efficiencies [2] - 123:12, 123:17
eight [1] - 85:12
either [1] - 98:10
eke [2] - 72:2, 91:3
elaborate [5] - 8:18, 32:15, 37:11, 43:17, 44:17
element [2] - 14:24, 100:21
elements [4] - 72:9, 77:18, 79:17, 101:11
elicited [1] - 78:10
eligible [1] - 18:18
Elizabeth [2] - 2:3, 136:6
ELIZABETH [2] - 3:7, 136:7
Elmo [4] - 111:21, 112:3, 112:5, 112:9
email [25] - 50:15, 50:18, 50:20, 51:3, 52:5, 53:22, 53:25, 54:19, 54:21, 55:6, 58:6, 58:9, 58:12, 58:13, 58:14, 58:15, 58:18, 59:9, 59:12, 60:6, 62:10, 109:21, 110:3
emails [10] - 50:12, 51:24, 52:16, 55:1, 55:8, 55:9, 55:10, 55:20, 59:24, 62:15
emergency [5] - 85:15, 86:20, 90:7, 93:18, 123:5
employee [2] - 68:16, 68:18
enable [1] - 93:16
end [4] - 9:17, 27:8, 106:21, 136:3
Endosurgery [6] - 68:8, 68:9, 68:15, 68:18, 68:19, 71:24
endovascular [1] - 7:13
endowed [1] - 6:24
engaging [2] - 34:9, 34:11
engineer [1] - 28:17
engineering [3] - 23:1, 71:7, 110:22
enjoined [1] - 83:19
enroll [7] - 9:11, 42:8, 42:21, 43:21, 43:24, 46:3
enrolled [2] - 36:23, 42:6
enrolling [2] - 8:25, 25:10
enrollment [4] - 42:7, 79:25, 80:3
ensure [2] - 29:19, 92:11
enter [4] - 76:15, 103:7, 115:3, 116:23
entered [1] - 109:8
entering [1] - 114:25
entire [1] - 94:2
entrants [1] - 111:18
entrepreneur [2] - 67:24
entry [3] - 109:5, 116:10, 116:15
ENVISION [1] - 8:12
EP [1] - 70:1
equals [1] - 115:14
equitable [1] - 5:8
especially [2] - 7:15, 10:13
Esq [14] - 1:12, 1:12, 1:13, 1:13, 1:14, 1:14, 1:17, 1:18, 1:21, 1:21, 2:2, 2:2, 2:3, 2:3
establish [1] - 78:21
established [1] - 106:14
estimate [6] - 85:9, 92:20, 115:20, 116:18, 122:21, 123:7
estimates [3] - 92:21, 124:13, 124:17
estimating [1] - 96:8
estimation [3] - 77:22, 79:1, 79:13
Europe [2] - 11:7, 92:2
European [2] - 35:8, 138:16
Europeans [1] - 22:21
evaluate [6] - 45:17, 72:25, 111:5, 138:5, 138:6, 139:7
evaluated [2] - 83:19, 112:24
evaluating [2] - 69:15, 73:4
evaluation [1] - 110:16
evening [1] - 47:10
eventual [1] - 23:24
eventually [1] - 103:1
evidence [11] - 34:3, 35:10, 82:15, 86:8, 89:15, 90:22, 91:2, 99:5, 103:4, 139:18, 139:24
EVIDENTIARY [1] - 1:8
Evolut [1] - 24:5
EVOQUE [4] - 15:11, 15:12, 18:3, 18:4
exact [1] - 92:18
exactly [3] - 11:16, 98:9, 102:21
Examination [6] - 3:3, 3:4, 3:5, 3:6, 3:6, 3:8
EXAMINATION [5] - 6:12, 26:8, 67:4, 104:3, 136:10
examination [3] - 26:19, 29:17, 31:22
examine [1] - 5:8
example [8] - 13:16, 18:19, 25:19, 30:23, 104:19, 104:24, 105:4, 105:10
exams [1] - 4:18
excellent [3] - 34:15, 34:19, 37:3
exception [1] - 117:18
exchange [1] - 109:21
excitement [1] - 37:24
exclude [9] - 108:22, 111:18, 112:21, 113:3, 113:6, 113:10, 113:14, 113:19, 113:25
excuse [9] - 8:11, 25:9, 32:14, 49:10, 53:21, 59:16, 60:6, 117:8, 117:23
excused [1] - 66:25
executing [1] - 27:18
executives [1] - 136:19
exemption [1] - 73:3
exhibit [2] - 96:24, 97:1
exhibits [3] - 4:23, 67:14, 67:18
existence [2] - 55:2, 72:2
existing [14] - 44:6, 83:9, 85:2, 85:14, 85:15, 85:22, 85:23, 85:25, 86:22, 87:2, 87:6, 94:18, 103:19, 123:3
exit [2] - 70:23, 124:21
expand [6] - 20:22, 22:4, 30:14, 31:6, 37:13, 101:14
expanded [2] - 35:9,

82:9
expanding [5] - 18:18, 19:8, 19:11, 30:19, 31:17
expands [1] - 22:10
expansion [1] - 82:12
expect [22] - 11:24, 14:15, 16:6, 18:8, 19:10, 23:19, 26:1, 30:8, 30:18, 31:15, 86:15, 86:19, 87:24, 90:8, 93:21, 95:9, 97:6, 100:14, 103:10, 105:18, 105:20, 122:16
expected [1] - 61:4
expecting [1] - 35:23
expenses [1] - 86:9
expensive [3] - 17:13, 89:3, 89:4
experience [43] - 8:15, 11:22, 13:10, 13:11, 13:12, 13:13, 13:18, 13:20, 13:22, 13:24, 14:5, 14:14, 15:4, 16:4, 17:7, 19:9, 22:16, 23:11, 24:9, 24:25, 25:24, 27:7, 27:11, 27:22, 27:23, 36:24, 41:23, 42:16, 68:3, 69:15, 71:14, 71:23, 73:20, 74:1, 74:4, 74:17, 74:19, 83:1, 84:5, 86:14, 87:23, 110:22
experienced [2] - 122:10, 122:18
expert [25] - 5:5, 10:9, 14:8, 20:4, 23:17, 27:17, 27:21, 39:4, 39:11, 41:20, 66:13, 67:9, 67:11, 71:13, 72:10, 72:12, 78:6, 78:8, 78:12, 111:5, 116:15, 118:2, 137:5, 137:9, 137:15
explain [3] - 10:7, 13:4, 84:25
expressed [3] - 80:22, 88:10, 90:16
extend [3] - 86:9, 87:6, 90:9
extension [1] - 123:4
extent [1] - 79:24
extra [3] - 6:1, 42:16, 43:9
extreme [1] - 8:7

F

face [1] - 73:20
facilitate [1] - 57:18
facilities [1] - 82:1
fact [12] - 23:9, 32:5, 35:22, 36:5, 38:8, 38:22, 41:7, 53:21, 54:21, 62:10, 64:23, 65:9
factor [2] - 105:24, 106:1
factors [2] - 44:3, 73:23
failed [1] - 90:12
fair [45] - 26:24, 27:5, 30:17, 32:2, 32:5, 32:19, 33:18, 34:20, 35:12, 36:2, 37:3, 38:17, 38:25, 40:8, 40:12, 42:2, 42:14, 43:8, 43:14, 44:3, 45:5, 45:14, 45:20, 45:22, 46:10, 48:22, 49:4, 51:1, 51:19, 52:6, 53:20, 53:25, 54:17, 54:18, 55:3, 56:9, 56:17, 58:5, 59:8, 63:17, 65:2, 65:12, 121:17, 121:22
fairly [1] - 33:22
fall [1] - 93:15
familiar [7] - 19:14, 20:5, 20:14, 38:5, 38:11, 44:11, 108:18
fantastic [1] - 15:10
FAQ [2] - 110:12, 111:15
FAQs [2] - 109:20, 110:6
far [5] - 17:20, 48:10, 72:21, 77:23, 79:14
fashion [1] - 9:16
fast [6] - 98:9, 101:18, 101:24, 101:25, 102:15, 114:5
faster [2] - 16:10, 98:13
favor [1] - 39:1
favorable [4] - 16:16, 23:16, 34:16, 42:24
FDA [54] - 17:16, 23:2, 23:14, 23:16, 23:18, 24:1, 24:10, 35:15, 35:17, 35:18, 35:24, 35:25, 68:24, 72:19, 73:13, 73:15, 73:17, 73:19, 73:25, 74:2, 74:13, 74:19, 75:5, 75:14, 75:25, 76:7, 76:8, 76:12, 76:17, 76:19, 77:8, 77:17, 81:6, 82:5, 82:23, 86:5, 87:17, 87:18, 93:6, 93:7, 93:11, 93:20, 100:10, 100:12, 100:13, 104:12, 104:20, 105:6, 105:12, 105:15, 106:6, 106:10, 106:15, 106:17
FDA's [4] - 23:17, 35:21, 74:11, 104:10
feasibility [9] - 22:6, 23:22, 73:5, 73:7, 73:8, 75:20, 76:6, 77:15, 81:1
federal [2] - 52:11, 55:12
Federal [8] - 26:13, 46:24, 54:4, 56:12, 56:20, 60:8, 61:7, 104:1
FEDERAL [2] - 1:2, 1:15
fee [1] - 64:15
feed [1] - 81:24
fees [1] - 62:24
fell [1] - 140:10
felt [4] - 9:8, 52:19, 56:25, 63:22
few [9] - 4:2, 26:16, 34:21, 47:11, 59:16, 63:1, 63:4, 69:24, 89:13
field [19] - 12:7, 12:10, 12:13, 12:14, 13:5, 13:8, 13:11, 14:1, 16:9, 28:9, 29:2, 38:20, 83:8, 95:18, 99:15, 109:19, 110:6, 137:9
figure [4] - 74:10, 86:2, 86:4, 86:10
figured [1] - 79:9
file [1] - 63:7
finally [1] - 89:2
finance [3] - 39:4, 136:19, 136:20
financial [8] - 42:21, 44:15, 45:6, 84:22, 120:24, 121:6, 121:9, 121:17
financing [7] - 72:13, 84:1, 85:10, 85:16, 86:23, 87:12, 123:5
fine [1] - 6:1
finish [4] - 4:18, 17:11, 17:13, 17:15
finished [1] - 24:16
firm [5] - 69:10, 121:9, 121:23, 122:24
firm's [2] - 121:22, 122:5
firms [2] - 119:9, 121:18
first [38] - 17:25, 19:18, 19:21, 19:25, 22:13, 25:13, 33:15, 34:6, 34:24, 36:14, 48:6, 53:17, 56:22, 57:6, 60:18, 61:25, 64:6, 65:10, 67:23, 68:11, 68:12, 68:16, 68:18, 70:16, 71:14, 72:20, 74:3, 74:11, 74:18, 77:15, 81:17, 87:21, 100:12, 101:8, 107:2, 120:7, 139:10, 139:13
first-in-class [3] - 68:11, 68:12, 74:3
first-in-man [1] - 22:13
five [4] - 8:8, 21:16, 53:14, 69:14
flag [1] - 4:6
flip [2] - 51:22, 95:14
flowchart [1] - 74:21
flows [1] - 39:8
fluoroscopy [1] - 35:4
fold [1] - 16:8
follow [7] - 8:14, 19:1, 19:2, 42:9, 74:20, 80:4, 108:6
follow-up [5] - 8:14, 19:1, 19:2, 42:9, 80:4
followed [1] - 25:15
follower [2] - 101:24, 101:25
followers [2] - 101:18, 114:6
Following [3] - 124:22, 135:23, 141:8
following [2] - 50:5, 86:12
food [3] - 48:20, 48:21
fool [1] - 54:22
FOR [4] - 1:1, 6:11, 67:3, 136:7
force [2] - 12:6, 99:10
foreclosing [1] - 122:1
foregoing [1] - 162:4
foreign [5] - 44:5, 79:1, 111:18, 116:10, 116:15
forgot [1] - 44:9
form [3] - 52:10, 66:19, 87:14
format [1] - 9:9
forming [3] - 105:4, 117:11, 138:10
forth [1] - 73:15
forthcoming [1] - 41:4
forum [1] - 37:17
forward [8] - 10:11, 26:2, 27:20, 61:14, 89:10, 100:11, 101:6, 122:23
forward-investing [1] - 89:10
forwarded [1] - 64:18
founder [3] - 68:15, 68:16, 68:18
four [12] - 22:18, 24:18, 32:20, 42:8, 42:16, 43:3, 43:9, 53:3, 53:14, 55:19, 80:3, 80:6
four-year [1] - 80:3
fraction [1] - 11:17
frame [5] - 42:10, 47:23, 58:7, 86:6, 123:17
framework [5] - 43:20, 138:24, 139:1, 139:8, 140:15
France [1] - 1:21
FTC [30] - 49:4, 49:6, 52:1, 52:11, 53:5, 53:10, 53:12, 53:13, 53:22, 54:1, 54:3, 55:4, 55:6, 57:19, 58:6, 58:16, 59:6, 59:18, 59:24, 62:7, 63:7, 64:6, 65:3, 65:13, 65:21, 75:4, 75:8, 96:24, 97:4, 123:17
FTC's [1] - 75:12
FTC.gov [1] - 58:20
full [7] - 6:15, 28:20, 41:10, 46:9, 67:6, 98:17, 162:5
fully [2] - 62:1, 92:23
function [1] - 34:16
functional [1] - 15:15
fund [2] - 82:14, 123:4
funded [1] - 122:8
funding [12] - 44:16, 81:4, 86:17, 86:21, 90:7, 90:9, 93:9, 93:18, 93:19, 93:21, 117:1
fundraising [2] - 27:15, 27:25

funds [1] - 69:14
funny [1] - 54:8
FURTHER [1] - 108:12
furthest [4] - 104:9, 104:20, 105:6, 105:12
future [9] - 35:10, 94:23, 121:22, 122:1, 122:5, 140:11, 140:14, 140:20, 140:23

G

gears [1] - 37:7
general [8] - 9:24, 14:22, 17:4, 35:1, 50:21, 51:2, 116:18, 139:8
generally [4] - 84:15, 105:22, 107:7, 112:18
generate [4] - 70:21, 72:10, 90:2, 106:20
generating [2] - 71:13, 91:25
generation [3] - 18:4, 29:15
gentleman [2] - 51:5, 51:10
genuinely [1] - 53:19
GIBSON [1] - 1:22
Gibson [3] - 58:24, 59:2, 63:13
given [12] - 4:10, 18:23, 30:17, 37:1, 39:23, 44:24, 62:20, 71:2, 100:3, 115:18, 119:15, 120:6
goal [2] - 70:20, 101:8
Google [2] - 20:18, 21:20
gosh [1] - 137:2
GOTTLIEB [1] - 1:18
Government [5] - 54:5, 54:11, 56:12, 56:21, 138:12
government's [1] - 4:7
grapevine [1] - 35:20
GRAY [1] - 2:4
great [5] - 12:4, 35:6, 57:8, 82:15, 137:13
greater [1] - 99:6
greedy [1] - 16:22
grill [2] - 39:11, 39:12
gross [1] - 92:1
ground [1] - 36:13
ground-breaking [1] - 36:13
group [1] - 83:8
groups [1] - 95:1
grow [2] - 72:3, 81:19
growing [1] - 102:15
growth [2] - 90:21, 92:1
grumblings [1] - 35:23
guess [1] - 123:20
guidance [4] - 13:9, 76:2, 76:8, 76:17
guideline [1] - 35:8
guidelines [2] - 35:8, 35:11
guy [2] - 49:23, 82:20

H

Haas [1] - 136:21
half [1] - 118:23
HALL [3] - 4:17, 5:13, 5:20
Hall [1] - 1:12
HAMILTON [1] - 1:18
Hanchor [19] - 20:19, 20:23, 21:2, 21:19, 23:7, 23:12, 24:8, 41:1, 41:5, 41:8, 41:15, 41:20, 41:24, 77:11, 77:20, 79:11, 79:18, 113:17, 113:19
HANCHOR [1] - 20:23
handed [1] - 4:9
happy [7] - 5:23, 28:21, 51:15, 54:2, 54:6, 54:7, 65:1
hard [3] - 92:18, 94:23, 105:19
harm [1] - 140:11
harms [4] - 123:18, 140:5, 140:7, 141:1
haul [1] - 90:20
Haworth [5] - 50:21, 51:1, 51:4, 51:15, 52:4
head [5] - 20:11, 24:13, 80:15, 94:18, 95:2
health [3] - 34:17, 69:11, 69:12
Health [3] - 6:20, 6:23, 44:19
hear [6] - 35:6, 35:19, 56:13, 72:15, 112:6, 137:12
heard [19] - 13:19, 52:21, 73:18, 73:24, 74:8, 77:11, 77:25, 80:1, 81:14, 83:9, 87:16, 88:16, 89:20, 95:16, 99:11, 99:12, 101:15, 112:23, 113:17
HEARING [1] - 1:8
hearing [5] - 13:19, 47:1, 51:20, 53:6, 88:16
Heart [1] - 20:6
heart [25] - 7:2, 7:16, 9:23, 9:25, 10:21, 15:5, 18:16, 22:17, 25:16, 46:6, 47:16, 69:20, 69:22, 69:25, 70:2, 88:8, 88:14, 89:10, 100:25, 102:1, 119:1, 121:23, 122:2, 122:5
Heather [1] - 50:21
heavy [1] - 90:1
HELD [1] - 1:9
help [19] - 7:5, 10:12, 10:16, 12:24, 16:25, 20:22, 22:4, 23:13, 23:23, 26:2, 50:13, 51:15, 51:20, 52:19, 54:2, 54:7, 55:21, 82:10
helped [1] - 27:13
helping [4] - 70:15, 70:17, 70:20, 70:22
helps [2] - 13:8, 103:5
hereby [1] - 162:3
Hi [1] - 51:15
hiding [1] - 64:25
high [13] - 8:7, 10:7, 11:11, 18:22, 37:13, 40:18, 68:17, 69:8, 70:9, 72:18, 81:11, 92:1, 98:12
high-risk [1] - 37:13
higher [2] - 119:23, 120:21
highest [2] - 9:12, 33:21
highly [2] - 63:5, 101:9
hill [2] - 82:21, 82:22
HIPAA [1] - 62:12
hire [5] - 81:21, 94:2, 95:3, 95:23, 97:19
hires [1] - 94:19
hiring [2] - 28:9, 96:21
hirings [1] - 94:22
historical [1] - 139:17
history [1] - 105:11
hit [3] - 81:20, 82:23, 98:4
hmm [1] - 47:17
hold [6] - 40:6, 40:8, 59:22, 60:13, 80:14, 99:19
honest [6] - 47:21, 57:15, 57:16, 65:8, 66:17, 110:13
honestly [1] - 35:23
Honor [25] - 4:2, 4:17, 5:1, 5:17, 5:22, 6:3, 6:8, 26:6, 66:11, 66:24, 67:1, 67:11, 67:17, 72:11, 72:14, 77:25, 78:11, 78:25, 118:16, 118:20, 124:16, 135:25, 136:8, 137:8, 141:3
HONORABLE [1] - 1:9
HOOGENDOORN [24] - 72:14, 77:24, 78:4, 78:25, 103:25, 104:4, 107:22, 107:25, 109:7, 109:9, 110:8, 110:10, 111:21, 111:23, 112:5, 112:7, 117:22, 117:25, 118:8, 118:11, 118:15, 118:19, 118:22, 124:16
Hoogendoorn [1] - 103:25
Hoogendoorn..... ..104 [1] - 3:6
hope [3] - 35:15, 92:14, 98:25
hopefully [4] - 17:16, 40:18, 73:16, 93:15
Hopkins [1] - 71:4
horizon [1] - 87:7
horizons [1] - 91:8
horrible [1] - 51:23
hospitals [4] - 11:12, 11:18, 14:2, 82:11
hottest [1] - 76:25
hour [1] - 4:19
hours [2] - 53:13, 55:19
house [2] - 50:5, 57:8
huge [2] - 73:12, 82:3
human [1] - 72:25
hundred [2] - 44:1, 99:2
hundreds [2] - 104:15, 137:2
hurdle [1] - 81:6

I

IDE [5] - 73:3, 76:7, 76:18, 77:18, 79:21
idea [2] - 53:19, 64:16
II [1] - 68:5
III [15] - 68:5, 72:19, 73:5, 73:19, 76:5, 81:13, 82:6, 104:15, 104:20, 104:25, 105:2, 109:5, 115:11, 115:20, 122:16
imagine [2] - 85:24, 93:10
immediately [1] - 64:18
impact [5] - 16:5, 16:8, 93:8, 99:11, 103:9
impeaching [1] - 43:12
implant [7] - 19:23, 32:9, 33:19, 35:3, 40:22, 41:19, 95:17
implanted [6] - 20:1, 21:2, 32:2, 32:6, 32:20, 102:13
implanting [3] - 14:10, 36:3, 95:21
implants [2] - 12:11, 28:20
implication [1] - 11:9
Implications [1] - 34:2
implied [1] - 54:4
implying [1] - 30:21
importance [1] - 13:4
important [13] - 13:1, 13:22, 22:16, 35:10, 36:7, 45:6, 45:8, 45:13, 74:9, 89:24, 140:4, 140:15, 140:25
impossible [2] - 12:21, 91:6
impressed [1] - 16:18
impression [3] - 31:19, 47:8, 66:6
impressions [1] - 63:24
impressive [1] - 25:4
improve [3] - 28:11, 29:19, 34:25
improved [7] - 16:21, 18:9, 29:20, 29:25, 30:10, 34:22, 35:5
improvement [1] - 34:17
improvements [3] - 17:8, 17:21, 22:19
improving [2] - 18:6, 106:14
IN [1] - 1:1
in-house [2] - 50:5, 57:8

inaudible [36] - 14:4, 14:12, 15:16, 16:14, 18:12, 19:24, 25:10, 30:7, 32:13, 32:15, 33:13, 35:18, 36:8, 37:13, 38:6, 39:4, 42:23, 45:11, 46:16, 48:8, 48:9, 48:10, 48:11, 48:12, 48:17, 49:6, 54:14, 55:22, 58:10, 59:19, 59:21, 62:13, 65:13, 66:18
inbox [1] - 55:1
INC [1] - 1:6
incentive [5] - 42:20, 42:21, 103:22, 120:4, 139:18
incentivized [4] - 86:23, 101:10, 101:14, 120:8
include [2] - 44:15, 78:5
included [1] - 77:19
includes [1] - 73:13
including [8] - 11:22, 13:24, 14:14, 18:17, 45:23, 76:10, 109:1, 110:20
incorrectly [2] - 110:13, 118:7
increase [6] - 29:1, 44:4, 76:21, 76:24, 86:6, 87:4
increased [3] - 44:2, 77:7, 77:8
increases [1] - 22:14
increasingly [1] - 76:22
indeed [1] - 124:2
independent [9] - 45:17, 49:22, 49:25, 57:13, 61:14, 119:10, 119:19, 120:12, 124:14
independently [5] - 119:3, 119:14, 119:22, 120:17, 120:20
indicates [1] - 34:7
indicating [1] - 15:17
indication [4] - 11:7, 35:24, 35:25, 101:14
individual [4] - 51:1, 61:4, 61:9
industrial [1] - 137:9
inform [2] - 35:10, 35:14
Inform [1] - 46:7
information [7] - 57:24, 73:12, 73:13, 76:7, 86:13, 112:18, 123:1
infrastructure [16] - 14:23, 23:1, 52:15, 81:12, 82:17, 83:13, 86:17, 92:13, 94:12, 95:4, 95:8, 95:15, 96:15, 96:16, 98:18, 101:1
infusion [1] - 85:21
inherent [1] - 45:7
initial [1] - 90:7
initiate [1] - 73:10
innovate [2] - 101:6, 139:19
innovation [7] - 22:16, 67:23, 71:1, 71:6, 105:25, 110:14, 140:12
innovator [1] - 122:16
innovators [1] - 122:13
insisted [1] - 19:1
instantaneous [1] - 55:9
instead [2] - 42:8, 110:15
Institute [2] - 20:6, 136:16
institution [2] - 22:10, 22:12
instructed [1] - 63:18
instructor [1] - 136:18
integrate [2] - 31:7, 31:10
integrity [1] - 9:12
intellectual [5] - 109:1, 109:4, 110:17, 111:6, 114:13
intend [1] - 78:7
intent [4] - 34:14, 80:25, 101:2, 101:3
intentionally [2] - 29:5, 29:7
intentions [1] - 45:25
interaction [2] - 49:15, 56:24
interactions [1] - 62:5
interest [16] - 20:21, 20:25, 22:2, 22:9, 24:11, 41:8, 44:15, 45:6, 46:9, 80:22, 88:11, 88:15, 88:25, 90:16, 120:2, 121:9
interested [3] - 22:6, 58:1, 89:16
interesting [4] - 20:21, 53:10, 90:3, 99:9
interests [7] - 45:13, 65:25, 120:24, 121:3, 121:5, 121:6, 121:17
intermediate [4] - 8:7, 18:22, 37:14, 40:20
internally [1] - 39:10
international [6] - 75:23, 76:3, 76:9, 76:10, 80:16, 100:20
internationally [2] - 71:5, 75:21
interpreted [1] - 40:6
interrogating [1] - 51:5
interrupt [1] - 37:18
interrupting [1] - 36:17
interventional [5] - 7:1, 7:13, 9:4, 20:3, 21:24
interventions [1] - 7:16
interviewed [3] - 57:2, 57:3
introduce [4] - 26:15, 50:8, 50:10, 136:12
introducing [1] - 50:20
introductions [1] - 70:19
invasive [1] - 22:5
inventor [1] - 108:20
inventory [2] - 99:13, 117:6
invest [21] - 18:8, 18:18, 19:11, 27:21, 29:20, 29:25, 30:10, 30:18, 31:16, 42:6, 42:12, 43:23, 43:24, 69:11, 82:1, 83:12, 87:22, 88:23, 97:12, 122:22
invested [3] - 70:6, 102:16, 102:24
investigational [1] - 73:3
investigative [1] - 9:19
investigator [6] - 9:7, 9:18, 11:23, 31:23, 31:25, 48:19
investigators [2] - 13:20, 24:25
investing [4] - 69:18, 82:13, 89:10, 102:16
investment [16] - 17:14, 17:18, 17:19, 27:17, 44:2, 69:13, 78:22, 81:25, 82:3, 84:8, 89:17, 99:2, 101:23, 103:10, 109:2, 121:22
investments [11] - 27:19, 69:16, 69:21, 69:23, 70:21, 102:4, 102:11, 120:25, 121:16, 122:1, 122:5
investor [6] - 90:13, 90:18, 90:20, 93:10, 102:3, 122:22
investors [20] - 70:16, 84:6, 84:7, 85:14, 85:15, 85:22, 85:23, 85:24, 86:21, 86:22, 87:6, 90:21, 91:10, 92:16, 92:17, 93:20, 95:6, 97:12, 120:14, 123:4
invited [1] - 19:23
invoice [1] - 46:15
involve [1] - 7:18
involved [9] - 7:17, 8:10, 8:23, 19:19, 24:4, 27:24, 39:13, 70:25, 72:24
IP [3] - 110:20, 114:24, 115:1
IPO [8] - 91:15, 91:17, 91:19, 92:11, 92:15, 92:19, 93:2
ironically [1] - 80:23
Irvine [1] - 80:23
issue [3] - 4:25, 5:14, 14:11
issues [5] - 14:11, 62:12, 70:15, 103:17
IT [2] - 52:17, 55:11
iterative [2] - 16:15, 16:24
itself [2] - 16:16, 60:11

J

J-Valve [22] - 30:2, 30:4, 30:18, 31:12, 40:2, 40:4, 40:5, 40:8, 40:16, 77:23, 78:18, 79:14, 79:23, 80:12, 100:19, 104:8, 107:1, 107:5, 107:8, 112:25, 140:21
Jacob [1] - 1:18
James [1] - 1:13
Jamie [1] - 1:21
January [1] - 46:13
Jay [1] - 1:13
JC [11] - 78:15, 107:14, 107:19, 108:14, 111:3, 111:13, 111:17, 112:20, 114:14, 114:18, 138:14
Jena [16] - 9:24, 12:8, 12:12, 17:10, 17:11, 23:10, 27:18, 27:22, 28:6, 29:6, 30:21, 30:24, 35:21, 36:15, 37:1, 62:13
Jena-related [1] - 29:6
Jena/FTC [1] - 50:22
JenaValve [100] - 11:24, 13:25, 14:5, 14:16, 16:5, 16:19, 16:20, 17:7, 18:7, 19:10, 26:1, 28:2, 28:11, 29:19, 29:24, 30:20, 31:1, 31:16, 37:5, 38:23, 39:1, 39:20, 39:23, 41:14, 71:25, 73:25, 75:9, 79:23, 82:16, 83:1, 84:2, 84:5, 84:21, 86:15, 86:20, 87:7, 87:16, 87:18, 87:23, 88:18, 90:4, 90:8, 91:13, 91:16, 92:10, 92:22, 93:6, 93:7, 93:17, 93:22, 95:7, 95:10, 96:2, 96:4, 96:6, 96:20, 96:21, 97:8, 97:11, 97:24, 98:24, 99:7, 99:9, 100:4, 100:6, 100:13, 101:5, 103:8, 107:12, 107:13, 107:19, 108:9, 108:10, 108:12, 108:13, 111:4, 111:13, 111:17, 112:20, 112:25, 114:14, 114:18, 118:25, 119:9, 119:10, 119:21, 120:20, 122:8, 122:10, 122:18, 122:22, 123:1, 123:3, 123:8, 123:9, 123:12, 123:25, 138:13, 139:16
JENAVALVE [1] - 1:6
JenaValve's [26] - 8:20, 11:13, 11:23, 19:19, 26:20, 28:3, 28:8, 39:14, 81:13, 83:18, 83:19, 83:23, 84:17, 88:22, 93:5, 94:10, 96:25, 100:3, 104:9, 107:1, 107:9,

122:12, 122:15, 124:10, 124:13, 138:15
Jenscare's [1] - 113:15
Jeremy [1] - 109:21
job [4] - 12:4, 15:10, 63:22
Johns [1] - 71:4
Johnson [3] - 102:17, 111:22
joined [1] - 46:25
joining [2] - 47:12, 50:24
joking [1] - 5:21
Jordan [1] - 1:14
Joseph [1] - 6:17
Joshua [2] - 1:21, 58:23
journals [1] - 10:21
journey [2] - 68:20, 81:8
JUDGE [1] - 1:10
jump [2] - 21:1, 103:22
justification [1] - 97:16
justify [2] - 97:15, 97:24

K

keep [4] - 9:16, 43:15, 63:19, 110:13
Ken [1] - 113:15
Ken-Valve [1] - 113:15
kept [1] - 9:16
Kesselheim's [1] - 75:1
Kilcoyne [3] - 36:16, 36:20
kind [22] - 14:6, 14:21, 25:5, 27:22, 36:14, 55:21, 57:2, 68:25, 72:2, 72:9, 79:25, 81:24, 82:12, 82:23, 92:23, 98:6, 102:10, 115:14, 115:18, 116:10, 140:1, 140:15
knit [1] - 33:22
know-how [3] - 22:23, 22:25, 139:15
knowing [5] - 28:21, 45:10, 93:11, 120:11
knowledge [3] - 13:14, 20:17
known [2] - 18:14, 21:6
KOKA [1] - 113:11
Kristin [4] - 47:12, 49:17, 49:20, 50:19

L

lab [1] - 7:1
label [1] - 34:8
labeled [1] - 75:12
labeling [1] - 42:18
Laboratories [1] - 38:11
lack [2] - 55:15, 120:2
lag [1] - 94:6
Laguna [3] - 80:22, 112:21, 113:3
lamenting [1] - 99:10
Laminar [4] - 69:24, 102:5, 102:16
Lancet [2] - 32:25, 33:8
large [9] - 17:1, 38:17, 38:20, 63:25, 82:17, 85:8, 89:25, 100:24, 103:19
larger [1] - 73:8
last [18] - 4:15, 7:11, 7:14, 9:2, 9:3, 11:20, 18:3, 22:18, 22:24, 28:5, 32:12, 38:12, 50:24, 66:17, 67:22, 71:5, 75:4
late [1] - 80:9
later-stage [1] - 90:21
laughter [6] - 49:3, 52:2, 54:9, 54:16, 66:16, 66:21
launch [17] - 12:1, 14:7, 14:18, 15:5, 15:11, 25:13, 27:6, 27:7, 87:14, 91:16, 94:12, 95:9, 96:18, 100:5, 103:9, 124:14
launched [3] - 15:14, 16:2, 16:10
launching [2] - 27:9, 90:2
Laura [1] - 1:12
law [2] - 4:10, 41:20
lawsuit [4] - 28:6, 49:21, 53:12, 63:8
lawyer [9] - 46:24, 46:25, 52:19, 56:14, 57:11, 57:13, 63:19, 65:2, 65:17
lawyers [15] - 50:1, 53:4, 56:17, 59:10, 59:13, 61:13, 61:19, 63:5, 63:13, 63:18, 64:18, 64:23, 65:5, 85:8
lead [2] - 25:17, 45:24
leader [1] - 19:17
leaders [1] - 20:12
leadership [2] - 18:12, 36:15
leaflet [2] - 34:9, 34:11
leaflet-engaging [2] - 34:9, 34:11
learn [3] - 64:5, 74:12, 74:14
learned [2] - 17:1, 64:6
learning [1] - 64:10
least [13] - 4:21, 8:5, 10:25, 23:22, 32:7, 41:23, 81:17, 86:20, 89:17, 95:8, 111:3, 124:10, 140:24
leave [4] - 5:25, 50:25, 66:24
led [2] - 25:18, 88:5
Lee [1] - 67:8
left [6] - 68:19, 69:4, 69:25, 72:21, 102:6, 102:13
legal [4] - 52:12, 56:6, 57:19, 62:24
lens [1] - 98:7
less [6] - 11:8, 16:23, 22:5, 32:17, 32:18, 86:1
letter [8] - 60:7, 60:9, 60:11, 60:15, 60:16, 61:17, 61:24, 63:1
level [13] - 9:12, 10:7, 20:7, 20:8, 68:17, 69:9, 70:9, 72:18, 81:11, 98:12, 99:18, 119:1, 120:16
leveraged [1] - 71:14
leveraging [1] - 110:22
Leydecker [3] - 52:5, 52:24, 58:23
Liberty [1] - 113:11
life [3] - 64:11, 67:23, 70:11
LIFESCIENCES [1] - 1:5
Lifesciences [3] - 6:9, 14:13, 46:11
Lifesciences's [1] - 113:11
lifting [1] - 90:1
light [1] - 94:18
likely [9] - 71:20, 78:20, 79:22, 94:21, 98:13, 99:6, 103:18, 105:15, 120:11
liken [1] - 82:19
limbo [1] - 38:15
limited [4] - 12:14, 34:18, 37:18, 117:11
limiting [1] - 34:8
Line [1] - 123:15
line [4] - 33:15, 58:19, 58:22, 114:5
linear [1] - 74:21
lines [1] - 123:15
Lines [1] - 107:23
Lipton [2] - 1:21, 58:23
Lisa [1] - 1:14
list [2] - 8:9, 10:23
listed [7] - 53:8, 53:21, 69:4, 69:24, 75:20, 80:21, 114:8
lists [2] - 33:11, 115:14
literature [1] - 138:17
Liz [1] - 136:14
LLP [3] - 1:18, 1:22, 2:4
local [3] - 31:25, 44:17, 75:24
long-term [1] - 19:1
Look [3] - 49:21, 49:25, 54:21
look [45] - 11:5, 12:5, 14:23, 15:7, 17:13, 17:25, 18:2, 18:20, 21:22, 23:18, 24:12, 24:16, 33:25, 34:19, 34:23, 35:3, 38:6, 47:19, 48:11, 48:17, 50:12, 50:15, 52:3, 58:9, 58:11, 59:20, 61:8, 61:24, 65:9, 65:24, 79:25, 85:1, 89:3, 90:11, 91:6, 91:7, 92:18, 97:5, 100:17, 102:25, 103:13, 139:2, 139:3, 139:5, 139:9
looking [6] - 56:5, 60:17, 61:2, 96:13, 138:2, 139:20
looks [2] - 35:16, 140:1
lose [2] - 66:18, 66:19
losses [1] - 122:15
love [1] - 114:2
low [7] - 8:7, 18:22, 19:3, 24:16, 37:14, 40:20, 98:5
low-risk [3] - 19:3, 24:16, 37:14
lower [3] - 18:19, 34:1, 98:20
lucky [1] - 23:2
LVAD [1] - 40:20

M

M&A [3] - 70:22, 71:19, 90:12
M-Inform [1] - 46:7
machine [1] - 2:10
magically [1] - 89:12
maintained [1] - 9:14
Makkar [1] - 36:23
man [1] - 22:13
manage [1] - 69:13
management [2] - 83:23, 122:12
manufacture [1] - 103:17
manufacturer [1] - 81:17
manufacturers [1] - 106:9
manufacturing [11] - 14:6, 14:11, 16:11, 26:25, 28:12, 29:13, 35:21, 69:2, 79:20, 82:2, 117:4
mapped [1] - 83:24
margins [1] - 92:1
mark [1] - 22:21
marked [1] - 137:24
market [41] - 15:7, 36:11, 71:8, 71:19, 77:5, 77:6, 80:17, 82:5, 82:8, 88:15, 88:23, 89:19, 89:25, 90:17, 91:1, 99:3, 101:3, 102:6, 102:14, 103:7, 103:20, 111:19, 112:22, 113:15, 113:20, 114:1, 114:25, 115:3, 116:23, 117:1, 117:4, 139:6, 140:2, 140:6, 140:13, 140:14, 140:23
marketing [3] - 27:12, 27:13, 27:14
marketplace [1] - 119:9
markets [4] - 87:13, 89:5, 90:6, 139:25
married [1] - 46:21
Massachusetts [1] - 136:16
Masselink [1] - 2:3
massive [3] - 61:5, 82:12, 83:13
math [2] - 43:22, 116:2

matter [5] - 137:16, 138:4, 138:5, 138:10, 138:22
matters [1] - 46:15
Matthew [1] - 2:2
MATTHEWS [12] - 135:24, 136:5, 136:8, 136:11, 137:8, 137:13, 137:14, 137:18, 137:20, 137:24, 138:1, 141:3
Matthews.....136 [1] - 3:8
maximize [1] - 101:8
McGinnis [1] - 2:2
McInerney [1] - 2:3
McWilliams [17] - 67:2, 67:6, 67:8, 72:12, 77:25, 78:4, 100:2, 104:5, 108:1, 109:10, 110:12, 112:12, 112:19, 114:9, 116:4, 118:1, 118:23
MCWILLIAMS [2] - 3:5, 67:3
McWilliams's [3] - 67:11, 78:12, 107:23
mean [25] - 5:3, 5:22, 13:6, 15:7, 17:24, 32:15, 39:2, 40:17, 43:3, 48:8, 54:10, 72:20, 88:24, 90:11, 92:15, 92:21, 97:22, 100:15, 102:3, 105:19, 106:12, 114:21, 115:19, 140:13
means [2] - 6:2, 119:8
meant [2] - 86:2, 120:19
mechanism [1] - 15:1
med [1] - 71:2
med-tech [1] - 71:2
Medical [12] - 6:23, 78:15, 107:14, 107:19, 108:14, 111:3, 111:13, 111:17, 112:20, 114:14, 114:18, 138:14
medical [56] - 7:2, 7:11, 10:20, 26:25, 27:6, 27:11, 27:15, 36:16, 38:1, 38:18, 63:25, 67:25, 68:3, 69:11, 69:16, 71:1, 71:6, 71:7, 72:12, 72:19, 73:19, 74:20, 76:5, 76:22, 76:25, 81:5, 81:6, 81:13, 82:6, 91:22, 91:24, 100:25, 104:16, 104:20, 104:25, 105:3, 105:5, 105:6, 105:11, 105:22, 105:24, 106:2, 106:5, 106:9, 106:22, 109:2, 109:5, 115:10, 115:18, 115:20, 122:13, 122:16, 138:17
Medicine [1] - 6:21
medicine [1] - 6:25
Medtech [1] - 113:23
Medtronic [35] - 8:6, 8:11, 10:4, 23:6, 23:10, 24:7, 24:10, 24:14, 24:17, 25:1, 25:2, 25:6, 25:14, 38:5, 38:7, 38:8, 38:10, 38:23, 39:1, 39:5, 39:8, 39:10, 41:11, 44:8, 49:19, 101:21, 114:11, 114:13, 114:15, 114:19, 114:22, 114:25, 115:1, 115:4
Medtronic's [2] - 24:5, 24:20
meet [2] - 4:21, 95:4
meeting [10] - 9:3, 9:4, 41:11, 48:20, 49:19, 51:4, 53:1, 53:2, 53:4, 53:12
meetings [3] - 9:19, 46:6, 48:19
meets [1] - 77:17
member [3] - 70:7, 70:10, 70:11
members [1] - 72:5
mention [1] - 49:16
mentioned [24] - 7:10, 11:1, 16:18, 18:17, 21:5, 21:18, 23:5, 24:3, 25:12, 25:22, 41:1, 51:3, 53:23, 59:25, 62:11, 86:12, 86:19, 87:21, 90:5, 90:10, 90:13, 97:10, 100:19, 101:25
mentoring [1] - 71:3
merger [3] - 123:19, 123:21, 138:24
mergers [1] - 136:25
merits [3] - 52:10, 63:11, 111:7
mess [1] - 54:10
messages [1] - 52:1
met [6] - 25:7, 26:14, 47:21, 51:5, 52:8, 104:5
metal [1] - 18:1
methodology [4] - 71:11, 71:22, 115:19, 115:22
metric [1] - 96:16
mic [2] - 27:2, 60:13
Michael [4] - 6:8, 52:5, 52:8, 52:18
Michigan [11] - 6:20, 6:21, 6:22, 6:23, 8:3, 8:25, 9:15, 44:19, 44:21, 59:5, 89:21
Michigan's [1] - 66:14
microphone [3] - 7:7, 36:18, 78:3
MicroPort's [1] - 113:10
mid [1] - 85:21
mid-sized [1] - 85:21
middle [3] - 34:1, 50:15, 61:3
might [14] - 29:11, 42:21, 45:14, 45:18, 47:20, 48:17, 48:21, 50:13, 96:4, 96:5, 119:10, 121:16, 140:7, 140:20
migrate [1] - 8:12
milestone [1] - 93:15
MILLER [1] - 162:3
Miller [2] - 2:6, 162:8
million [11] - 44:1, 68:21, 85:3, 91:25, 92:5, 92:19, 92:22, 98:24, 99:2, 119:24, 120:21
millions [2] - 85:4, 92:3
Millipede [1] - 70:1
mimic [1] - 79:22
mind [3] - 89:12, 94:15, 106:7
mine [1] - 8:5
minimum [1] - 91:9
missing [1] - 78:25
mistaken [1] - 46:12
mistakes [2] - 74:15, 103:14
MitraClip [1] - 25:20
mitral [4] - 7:17, 15:15, 25:19, 70:2
mode [2] - 121:16, 121:19
model [6] - 97:1, 97:22, 97:24, 101:13, 124:2
models [1] - 124:6
moderate [1] - 19:8
moderate-risk [1] - 19:8
modus [1] - 135:24
moment [5] - 10:14, 33:7, 37:8, 87:18, 118:16
money [14] - 17:12, 27:21, 39:8, 42:5, 42:12, 43:23, 44:20, 46:10, 46:14, 46:20, 61:15, 87:6, 90:6, 92:16
monitor [1] - 21:25
month [6] - 32:18, 32:21, 43:21, 80:4, 89:23, 93:12
monthly [1] - 85:4
months [19] - 22:24, 28:5, 38:12, 85:11, 86:1, 87:3, 87:7, 89:13, 90:10, 91:9, 91:11, 115:15, 115:17, 115:23, 115:25, 116:3
moreover [1] - 74:11
MORNING [1] - 1:9
morning [16] - 6:8, 6:14, 21:5, 26:10, 26:12, 26:13, 26:16, 37:19, 40:4, 67:6, 77:2, 104:5, 115:12, 116:9, 119:22, 124:4
mortality [1] - 11:11
most [15] - 13:1, 45:8, 45:12, 49:24, 76:12, 79:22, 89:18, 94:21, 100:6, 105:15, 106:2, 108:7, 108:8, 124:13, 140:15
mostly [2] - 35:4, 59:24
motivation [1] - 97:16
mouth [2] - 27:3, 59:22
move [2] - 39:25, 44:10
moved [1] - 67:25
moving [1] - 76:22
MR [72] - 4:2, 4:4, 4:14, 4:25, 5:3, 5:12, 5:22, 6:3, 6:5, 6:8, 6:13, 16:3, 26:5, 26:6, 26:9, 33:3, 33:5, 50:8, 50:10, 50:11, 50:14, 50:17, 54:12, 60:3, 60:5, 66:9, 66:11, 67:1, 67:5, 67:11, 67:13, 67:17, 67:20, 72:11, 72:14, 72:16, 72:17, 74:24, 74:25, 77:24, 78:4, 78:11, 78:25, 79:8, 81:9, 81:10, 99:24, 100:1, 103:24, 103:25, 104:4, 107:22, 107:25, 108:11, 109:7, 109:9, 110:8, 110:10, 111:21, 111:23, 112:5, 112:7, 117:22, 117:25, 118:8, 118:11, 118:15, 118:19, 118:22, 124:16, 124:20, 137:11
MS [15] - 4:17, 5:13, 5:20, 135:24, 136:5, 136:8, 136:11, 137:8, 137:13, 137:14, 137:18, 137:20, 137:24, 138:1, 141:3
multi [2] - 16:8, 110:2
multi-fold [1] - 16:8
multi-page [1] - 110:2
multiple [4] - 8:9, 15:13, 71:10, 110:2
multiple-page [1] - 110:2
multiply [1] - 13:13
Musallam [1] - 2:2
myocardial [1] - 34:16

N

naive [2] - 56:10, 56:23
naivete [1] - 53:18
name [11] - 6:15, 10:24, 26:10, 33:15, 44:18, 44:20, 47:1, 67:7, 89:8, 102:25
named [4] - 41:1, 47:12, 58:19, 108:20
narrow [1] - 79:3
national [4] - 11:25, 14:6, 14:17, 31:25
nationwide [1] - 15:5
native [1] - 34:8
natural [1] - 68:11
nature [3] - 18:5, 18:20, 140:19
navigate [1] - 12:9
navigating [1] - 12:24
near [3] - 87:19, 93:24, 94:19
necessarily [2] -

74:20, 92:11
necessary [7] - 5:4, 5:7, 14:1, 42:18, 83:2, 83:16, 119:18
neck [2] - 24:15
need [28] - 10:19, 11:1, 11:2, 11:3, 12:11, 12:23, 17:19, 22:7, 25:22, 26:3, 49:22, 51:16, 52:11, 54:3, 79:21, 81:17, 82:9, 82:10, 85:12, 90:24, 91:25, 92:12, 95:3, 99:20, 100:16, 109:15, 136:2, 140:6
needed [10] - 4:12, 11:25, 12:5, 14:17, 35:10, 68:24, 81:12, 84:22, 97:19, 112:9
needs [2] - 10:14, 92:22
network [1] - 70:19
never [7] - 26:14, 27:15, 27:24, 46:15, 48:22, 54:18, 55:3
new [14] - 5:23, 20:19, 22:13, 48:10, 68:9, 74:5, 81:6, 85:10, 89:5, 91:10, 92:19, 93:10, 93:19
New [1] - 41:13
newer [1] - 17:15
newly [1] - 18:3
news [2] - 64:11, 64:21
next [9] - 29:15, 37:2, 85:17, 93:6, 96:12, 113:10, 138:9, 138:23, 139:9
Nguyen [6] - 107:22, 109:8, 110:8, 117:22, 118:8, 118:15
Nguyen's [1] - 110:4
niche [1] - 103:20
night [3] - 47:12, 48:1, 50:24
Nita [1] - 59:4
NJ [3] - 2:6, 162:3, 162:8
NJ-CCR [3] - 2:6, 162:3, 162:8
non [6] - 10:5, 10:6, 61:4, 61:9, 61:10, 91:23
non-party [3] - 61:4, 61:9, 61:10
non-remuneration [1] - 10:6
non-revenue [1] - 91:23
none [2] - 88:7, 120:6
note [1] - 84:9
notes [1] - 162:5
nothing [5] - 5:23, 24:23, 63:15, 66:9, 66:11
novel [1] - 81:12
November [3] - 1:5, 107:23, 162:7
novo [1] - 68:5
nowhere [4] - 59:8, 59:12, 61:17, 61:21
nuance [2] - 98:7, 106:12
nuances [2] - 74:9, 95:20
number [24] - 11:17, 11:20, 16:8, 16:10, 16:12, 22:2, 32:2, 51:17, 68:7, 73:23, 75:21, 76:4, 84:7, 85:7, 91:7, 92:7, 96:9, 98:3, 100:20, 100:24, 101:8, 115:15, 115:17, 123:11
numbers [6] - 81:20, 84:14, 85:19, 89:4, 97:5, 97:21
NW [6] - 1:15, 1:19, 1:22, 2:4, 2:8, 162:10

O

object [1] - 78:9
objection [6] - 4:7, 72:14, 77:24, 79:3, 108:11, 137:11
objections [1] - 116:13
objective [1] - 98:5
obligations [1] - 62:1
observed [1] - 102:19
observers [1] - 45:17
obtaining [2] - 87:18, 93:7
obvious [1] - 37:25
obviously [3] - 70:13, 99:9, 119:15
occur [3] - 22:17, 28:4, 30:9
occurs [1] - 106:6
October [5] - 25:7, 32:20, 60:8, 63:1, 63:2
OF [3] - 1:1, 1:8, 162:2
off-label [1] - 34:8
offer [17] - 39:19, 39:22, 51:19, 72:11, 78:7, 88:12, 116:14, 118:5, 119:1, 119:15, 119:17, 119:23, 120:1, 120:7, 120:15, 120:21, 120:22
offered [4] - 11:8, 28:19, 50:22, 119:6
offering [2] - 71:12, 104:18
offers [2] - 78:17, 119:8
office [2] - 104:6, 111:25
Official [2] - 2:7, 162:8
OFFICIAL [1] - 162:2
offset [1] - 85:4
often [3] - 72:23, 74:2, 112:2
oftentimes [1] - 74:11
Ohio [1] - 66:15
old [1] - 52:16
once [10] - 18:22, 18:23, 21:14, 28:5, 42:25, 46:12, 57:20, 57:22, 80:6, 105:10
one [46] - 8:12, 8:25, 10:15, 16:9, 20:12, 20:16, 21:20, 22:2, 24:25, 27:19, 32:18, 40:3, 41:11, 43:1, 44:3, 49:4, 53:5, 53:8, 53:9, 65:7, 71:22, 71:23, 75:22, 83:14, 87:9, 88:9, 88:16, 89:10, 92:24, 94:16, 94:24, 99:19, 101:2, 101:21, 101:23, 102:4, 103:18, 107:6, 112:15, 115:7, 116:22, 117:19, 119:20, 120:13, 123:6, 140:2
ones [1] - 15:9
ongoing [1] - 35:8
open [6] - 4:5, 15:9, 93:3, 135:23, 135:25, 136:3
opening [4] - 96:23, 112:15, 123:15, 123:16
operandi [1] - 135:24
operations [2] - 70:14, 84:23
opinion [17] - 10:9, 10:11, 16:8, 26:21, 28:21, 29:18, 35:13, 36:12, 66:14, 78:6, 78:17, 88:21, 100:22, 111:6, 119:6, 138:10, 138:20
opinions [8] - 71:12, 78:8, 78:12, 104:18, 105:4, 117:12, 138:6
opportunity [1] - 90:25
optimistic [1] - 97:13
optimize [1] - 103:3
option [5] - 11:6, 25:24, 52:20, 87:21, 90:4
options [6] - 34:18, 72:7, 83:18, 87:7, 87:9, 93:5
order [5] - 69:2, 81:19, 92:25, 95:3, 120:12
organization [10] - 69:1, 72:1, 81:22, 83:7, 94:3, 94:15, 95:20, 109:20, 110:7, 137:10
organizational [1] - 94:14
orifice [1] - 68:11
otherwise [2] - 70:25, 103:21
out-of-U.S [2] - 117:8, 117:14
outcomes [1] - 37:3
outside [14] - 20:15, 22:1, 22:17, 23:13, 23:18, 23:21, 23:23, 24:9, 42:2, 76:6, 77:13, 78:15, 79:12, 117:13
overachieve [1] - 98:6
overcome [1] - 34:9
overly [2] - 97:13, 97:17
own [17] - 32:3, 35:17, 45:22, 47:25, 52:12, 56:6, 61:16, 74:10, 83:25, 91:14, 99:7, 100:5, 103:5, 103:9, 106:19, 119:18, 123:7
owned [1] - 114:22
owns [1] - 30:17

P

P-X-0067 [1] - 60:4
P-X-0069 [2] - 58:12, 58:13
P-X-1390 [1] - 109:8
P-X-3093097 [1] - 50:10
P-X-3097 [1] - 50:13
pace [3] - 16:10, 17:6, 23:4
PAGE [1] - 3:2
page [5] - 33:25, 50:16, 61:24, 110:2
Page [8] - 50:15, 51:12, 52:3, 107:23, 110:9, 117:23, 117:24, 123:15
pages [4] - 5:15, 5:16, 5:18, 6:1
paid [16] - 36:9, 38:7, 46:10, 46:16, 46:17, 48:4, 48:5, 49:10, 52:21, 59:13, 61:21, 64:7, 64:24, 66:4, 82:11
panel [2] - 21:10, 21:12
panels [1] - 21:17
panicked [3] - 52:17, 55:10, 56:14
panicking [1] - 55:21
paper [9] - 5:6, 21:23, 36:13, 45:9, 63:6, 63:12, 112:8, 118:20
papers [1] - 10:24
Paragraph [2] - 117:23, 118:12
paragraph [7] - 60:17, 61:3, 61:25, 78:17, 118:10, 118:24
paragraphs [1] - 78:11
parallel [2] - 81:21, 83:13
parcel [1] - 16:13
part [9] - 10:15, 16:12, 19:21, 20:18, 30:11, 30:24, 60:21, 71:19, 85:7
participated [3] - 8:4, 8:20, 9:22
participating [1] - 11:13
particular [16] - 20:16, 37:15, 47:1, 62:9, 71:21, 74:12, 78:6, 78:9, 78:13, 79:1, 89:7, 90:15, 112:25, 139:15, 140:6
particularly [1] - 78:21
parties [2] - 88:10, 124:21
partnered [1] - 23:2
partnering [1] - 57:16
party [3] - 61:4, 61:9, 61:10
PASCAL [2] - 15:14, 25:21

pass [2] - 26:5, 103:24
passion [1] - 9:8
past [8] - 14:9, 22:20, 23:4, 23:10, 46:11, 71:9, 96:7, 98:18
patent [1] - 41:20
patents [20] - 41:15, 108:18, 108:22, 109:1, 110:19, 111:4, 111:13, 111:17, 112:20, 112:24, 113:2, 113:5, 113:9, 113:13, 113:18, 113:24, 114:14, 114:18, 114:22
path [3] - 72:18, 74:21, 81:5
pathway [2] - 71:17, 74:20
pathways [1] - 73:1
patient [18] - 10:17, 10:18, 11:1, 11:3, 18:18, 19:11, 22:3, 26:3, 30:15, 30:19, 30:22, 31:17, 34:23, 50:2, 62:12, 76:3, 100:16, 107:6
patient-related [1] - 62:12
patients [46] - 9:11, 10:13, 10:18, 11:2, 11:4, 11:6, 11:8, 13:1, 16:6, 17:1, 18:19, 19:7, 19:8, 21:2, 22:3, 22:5, 22:11, 23:13, 23:23, 25:23, 25:25, 30:24, 30:25, 31:12, 36:4, 36:6, 36:10, 36:23, 37:2, 37:10, 42:22, 43:1, 43:24, 46:3, 63:24, 76:9, 76:10, 76:13, 77:12, 79:12, 81:7, 95:11, 97:7, 101:9
pause [3] - 45:12, 109:18, 118:14
paused [1] - 40:13
pay [4] - 39:18, 47:25, 48:20, 117:19
payable [1] - 85:8
paying [4] - 47:4, 47:7, 62:24, 97:15
payment [1] - 85:6
payments [1] - 85:5
peak [1] - 77:3
pedantic [2] - 52:13, 55:12
pending [3] - 40:9, 40:10, 40:15
Pennsylvania [4] - 1:15, 1:19, 2:4, 136:20
people [18] - 27:19, 33:21, 36:22, 36:24, 38:8, 41:21, 49:18, 53:14, 55:13, 81:18, 81:23, 82:10, 91:2, 94:4, 94:25, 95:3, 97:19
per [4] - 14:24, 32:16, 43:21, 89:23
percent [4] - 11:8, 11:11, 44:23, 44:24
perception [1] - 89:24
perfect [2] - 7:9, 7:22
perform [3] - 7:24, 11:18, 68:10
performance [1] - 22:14
performed [2] - 8:16, 9:12
performing [2] - 13:18, 19:18
perhaps [1] - 78:19
period [4] - 52:16, 79:25, 80:3, 80:6
permission [1] - 67:17
PERRY [24] - 6:8, 6:13, 16:3, 26:5, 66:11, 67:1, 67:5, 67:11, 67:13, 67:17, 67:20, 72:11, 72:16, 72:17, 74:24, 74:25, 78:11, 79:8, 81:9, 81:10, 99:24, 100:1, 103:24, 108:11
perry [3] - 52:6, 52:23, 58:22
Perry [2] - 6:9, 52:6
Perry.....6 [1] - 3:3
Perry.....67 [1] - 3:5
Perry.....133 [1] - 3:6
person [4] - 27:14, 38:10, 49:25, 94:24
personal [4] - 20:7, 20:17, 60:23, 121:17
personally [5] - 19:16, 21:2, 44:25, 55:3, 57:13
perspective [5] - 5:3, 5:6, 5:22, 11:2, 50:3
ph [2] - 49:18, 113:23
Ph.D [1] - 136:16
phase [1] - 82:6
phases [1] - 140:13
phenomenon [2] - 25:15, 102:19
phone [2] - 51:17, 51:23
phrase [1] - 61:8
physically [1] - 81:18
physician [5] - 16:21, 25:25, 40:22, 46:19, 46:21
physicians [7] - 16:22, 33:19, 46:14, 75:25, 76:12, 81:15, 99:16
PI [3] - 9:7, 36:22, 44:17
Pi [1] - 10:6
Pi-Cardia [1] - 10:6
pick [2] - 87:10, 87:11
piece [2] - 71:21, 107:16
pieces [2] - 79:20, 139:3
Piedmont [1] - 20:5
pilot [1] - 73:7
pink [1] - 34:1
Pinto [3] - 36:16, 36:21, 99:9
pioneer [2] - 14:21, 74:17
Pioneer [1] - 113:11
pioneered [3] - 18:21, 102:6, 102:22
pioneering [1] - 74:5
pipeline [2] - 104:21, 105:12
pivot [1] - 108:17
pivotal [21] - 22:13, 73:11, 74:7, 74:9, 76:8, 76:9, 76:13, 76:15, 77:14, 77:22, 79:13, 79:21, 79:23, 80:5, 80:13, 82:6, 100:19, 102:18, 115:23, 117:9, 117:14
place [2] - 96:15, 140:18
places [2] - 21:14, 25:18
Plaintiff [2] - 1:3, 1:12
plan [7] - 80:24, 83:24, 84:1, 85:13, 86:4, 86:11, 94:11
planned [1] - 123:4
planning [1] - 94:19
plans [11] - 28:3, 28:8, 28:11, 28:16, 29:1, 29:10, 31:10, 80:19, 83:18, 83:20, 121:22
platforms [4] - 30:23, 31:7, 31:10
play [1] - 10:8
players [1] - 103:11
playing [1] - 55:17
plus [3] - 55:16, 91:21, 116:3
PMA [4] - 68:5, 73:15, 73:17, 115:25
point [20] - 17:18, 23:10, 43:2, 54:23, 55:1, 57:21, 61:15, 72:24, 75:8, 78:19, 84:2, 87:8, 89:11, 91:4, 92:25, 96:13, 103:7, 106:14, 141:3
pointed [1] - 97:4
points [4] - 34:23, 43:1, 66:19, 87:15
Pooja [1] - 109:22
pool [3] - 92:17, 117:8, 117:13
population [9] - 18:18, 19:11, 30:15, 30:19, 30:22, 31:17, 34:18, 40:20, 40:21
population's [1] - 32:17
populations [1] - 107:6
portion [1] - 123:15
position [6] - 6:22, 15:13, 15:15, 84:18, 86:6, 93:14
positioned [1] - 78:15
positions [1] - 7:17
possibility [1] - 91:15
possible [8] - 38:25, 45:24, 76:18, 98:5, 101:12, 111:18, 139:7, 140:11
possibly [1] - 140:22
post [2] - 82:5, 82:8
post-market [2] - 82:5, 82:8
potential [25] - 9:10, 37:15, 37:22, 42:24, 44:12, 45:16, 69:21, 87:15, 88:7, 89:15, 90:19, 95:5, 103:12, 116:15, 117:17, 118:6, 121:6, 121:12, 122:4, 122:5, 123:11, 139:2, 139:3, 139:4
potentially [3] - 77:13, 114:25, 116:10
power [5] - 111:16, 112:21, 113:14, 113:19, 113:25
practice [5] - 7:18, 32:3, 46:3, 55:18, 136:15
praise [1] - 17:10
praying [1] - 35:15
pre [1] - 44:6
pre-existing [1] - 44:6
precise [2] - 118:4, 140:4
predict [3] - 72:7, 92:18, 105:19
prefer [3] - 5:17, 108:8, 119:18
preliminaries [1] - 4:2
premarket [4] - 73:14, 107:2, 115:10, 140:12
preparation [1] - 14:25
prepare [1] - 67:9
prepared [3] - 67:14, 124:6, 137:21
prescriptive [1] - 17:3
present [3] - 42:25, 44:12, 112:9
presentation [2] - 45:18, 115:9
presentations [2] - 21:19, 59:25
presented [1] - 75:4
presenting [1] - 115:17
president [2] - 47:15, 136:14
pressure [8] - 12:23, 101:6, 107:13, 107:16, 107:17, 107:19, 108:9, 108:13
presume [1] - 30:12
pretty [1] - 120:15
previous [2] - 85:25, 96:22
previously [4] - 59:1, 67:12, 96:14, 109:8
price [4] - 97:15, 97:25, 98:2, 120:9
pricing [1] - 106:24
primarily [2] - 22:3, 138:21
primary [1] - 72:9
principal [6] - 9:7, 9:18, 11:23, 13:20, 31:23, 31:25
priorities [3] - 86:16, 89:6, 89:9
private [4] - 87:13, 90:6, 92:16, 98:25
privilege [1] - 57:22
privileged [1] - 57:24
problem [2] - 121:5
procedure [9] - 11:9,

13:3, 13:9, 13:14, 13:21, 17:2, 57:21, 68:12, 74:5
procedures [12] - 7:23, 8:16, 10:21, 11:18, 12:10, 12:16, 13:4, 13:7, 13:18, 19:18, 89:22, 89:23
proceed [9] - 26:6, 37:21, 77:14, 77:22, 79:13, 104:1, 118:17, 124:7, 136:8
proceedings [4] - 124:22, 135:23, 141:8, 162:6
Proceedings [1] - 2:10
process [16] - 19:22, 52:9, 71:22, 74:1, 75:15, 79:3, 88:5, 88:14, 90:12, 104:10, 105:7, 106:6, 106:10, 106:15, 106:17, 106:18
processed [1] - 115:25
procompetitive [3] - 139:3, 139:11, 139:14
proctor [1] - 19:24
proctored [1] - 13:12
proctoring [1] - 19:25
produced [3] - 2:11, 59:17, 60:8
product [8] - 72:24, 90:2, 102:10, 102:12, 102:25, 103:3, 106:19, 140:19
production [1] - 62:1
products [5] - 16:2, 69:12, 77:9, 82:4, 100:9
professional [2] - 20:7, 67:21
professionally [1] - 60:22
professor [3] - 6:24, 136:23
profits [1] - 39:9
progress [1] - 73:8
prohibitive [1] - 18:21
project [1] - 100:10
projected [2] - 94:22, 116:14
projecting [1] - 123:24
projection [1] - 117:7
projections [15] - 95:5, 96:7, 96:11, 96:20, 96:21, 96:25, 97:2, 97:9, 97:11, 97:14, 97:20, 97:21, 97:24, 98:8
projector [1] - 111:22
promise [1] - 39:12
pronounce [1] - 6:18
proof [1] - 19:3
proper [2] - 10:16, 46:15
property [5] - 109:1, 109:4, 110:17, 111:6, 114:13
proposed [7] - 5:14, 26:1, 28:4, 28:9, 28:18, 30:8, 138:8
prospective [1] - 34:7
prospects [3] - 119:10, 119:13, 119:19
protected [1] - 44:23
protections [3] - 109:1, 109:4, 114:14
protocol [1] - 35:2
prototypes [2] - 68:23, 72:22
proudly [1] - 22:25
prove [6] - 42:25, 90:25, 99:3, 102:12, 103:21, 106:15
provide [6] - 38:2, 62:4, 62:7, 62:18, 108:22, 137:15
provided [2] - 51:17, 112:15
providing [1] - 138:19
proving [1] - 106:13
public [9] - 16:17, 46:8, 69:4, 84:10, 92:4, 93:1, 121:15, 121:21, 123:2
publications [1] - 10:20
published [4] - 33:1, 33:9, 76:2, 137:3
PubMed [1] - 10:23
pull [6] - 33:3, 107:23, 109:7, 117:23, 118:8, 123:14
pulled [1] - 99:8
purchase [2] - 23:10, 120:3
purchased [3] - 30:2, 104:19, 114:20
purposes [2] - 112:10, 140:8
pursue [3] - 24:10, 92:13, 117:1
push [1] - 82:21
pushed [2] - 10:11, 17:17
pushes [1] - 82:22
put [11] - 12:23, 27:20, 35:2, 46:15, 59:15, 60:3, 61:14, 88:12, 101:6, 112:8, 112:11
puts [1] - 108:8

Q

quagmire [1] - 57:19
qualified [1] - 137:5
quality [1] - 117:4
quantify [1] - 96:3
QUESTION [2] - 108:7, 110:14
questions [9] - 8:14, 26:16, 31:21, 37:21, 51:10, 52:7, 55:14, 74:13, 104:7
quick [1] - 42:6
quicker [2] - 17:6, 23:4
quickly [12] - 24:9, 24:12, 25:9, 25:14, 25:20, 26:17, 43:2, 44:9, 95:11, 96:3, 97:7, 99:7
quicksand [1] - 57:20
quite [1] - 37:25
quotes [2] - 99:8, 140:12

R

R&D [3] - 83:7, 86:17, 92:13
raise [17] - 4:15, 70:17, 72:3, 86:20, 87:5, 87:11, 87:12, 90:9, 91:10, 91:14, 92:10, 92:19, 92:24, 93:16, 93:17, 93:19, 97:19
raised [3] - 4:6, 68:20, 68:21
raising [3] - 90:5, 92:15, 92:16
Raj [1] - 36:22
ramp [2] - 81:19, 98:9
ramp-up [1] - 98:9
ran [1] - 88:4
range [1] - 80:6
rapidly [1] - 25:1
rate [11] - 11:11, 84:18, 85:3, 85:25, 86:7, 87:2, 87:4, 87:11, 92:1, 93:13, 138:14
rates [1] - 34:24
rather [1] - 119:18
reach [3] - 97:7, 139:10, 139:21
reached [2] - 58:6, 84:25
reachieve [1] - 120:13
reaching [2] - 71:12, 77:3
read [17] - 40:6, 45:9, 45:10, 75:3, 94:14, 97:23, 108:6, 108:15, 108:22, 109:16, 110:12, 110:13, 110:24, 118:7, 118:23, 119:4, 123:22
reading [1] - 138:22
reads [1] - 61:25
ready [2] - 73:9, 73:10
real [4] - 74:19, 88:25, 101:22, 139:17
real-world [1] - 139:17
realistic [3] - 12:19, 87:24, 88:22
realistically [2] - 90:8, 91:16
reality [1] - 123:16
really [24] - 17:17, 18:23, 24:15, 25:10, 36:9, 46:14, 49:15, 54:20, 70:14, 77:3, 80:15, 81:8, 82:13, 82:15, 90:23, 90:24, 94:23, 96:8, 96:13, 98:25, 101:19, 106:13, 139:2, 140:4
realtime [1] - 6:6
reason [1] - 36:25
reasonable [1] - 92:20
reasonably [1] - 101:12
reasons [5] - 11:9, 38:7, 75:22, 97:9, 121:21
rebuttal [5] - 4:16, 4:19, 4:22, 4:25, 5:4
receive [8] - 73:16, 85:6, 85:10, 105:15, 105:18, 105:20, 107:2, 119:9
received [2] - 55:25, 120:11
receives [1] - 93:6
receiving [2] - 27:8, 87:16
recent [2] - 32:25, 124:13
recently [5] - 19:2, 33:9, 67:25, 74:23, 76:1
recess [1] - 99:23
recipient [1] - 27:10
recognize [2] - 33:8, 118:1
recollection [3] - 47:20, 49:15, 50:13
record [4] - 6:16, 17:5, 67:7, 99:5
recorded [1] - 2:10
records [1] - 53:15
red [2] - 75:12, 97:5
redacted [4] - 51:18, 51:25, 84:10, 84:11
redactions [1] - 115:8
Redirect [1] - 3:6
rediverted [1] - 39:9
reduce [2] - 86:9, 102:13
refamiliarize [1] - 109:12
refer [2] - 7:21, 30:24
reference [1] - 96:13
referring [3] - 34:11, 51:8, 89:8
refined [1] - 34:25
reflect [1] - 96:9
reflected [1] - 96:19
refresh [3] - 47:20, 50:13, 109:17
refused [1] - 28:6
regard [1] - 4:12
regarded [2] - 20:2, 20:9
regarding [1] - 10:21
regards [1] - 24:13
regents [1] - 44:20
regular [3] - 9:20, 13:7, 71:16
regulatory [6] - 35:9, 35:13, 68:4, 69:2, 71:17
regurgitation [11] - 8:17, 11:4, 16:7, 18:9, 20:23, 25:23, 29:21, 31:13, 34:8, 111:2, 111:12
reimbursement [3] - 69:2, 82:10, 138:13
reinforce [1] - 103:19
related [6] - 28:7, 29:6, 62:4, 62:12, 99:14, 138:13
relates [1] - 93:4
relative [3] - 71:22, 89:19, 111:7
released [1] - 18:3
relied [5] - 138:11, 138:13, 138:14, 138:21
relies [1] - 116:19

rely [2] - 138:10, 138:19
remaining [1] - 113:23
remember [13] - 19:23, 25:6, 30:15, 41:2, 43:11, 43:14, 47:21, 49:13, 53:14, 63:3, 64:15, 108:1, 108:3
remodeling [1] - 34:17
remuneration [1] - 10:6
rendering [1] - 112:18
repair [1] - 25:19
repairing [1] - 15:15
replacement [1] - 7:19
replacing [1] - 15:13
replied [2] - 51:14, 54:18
reply [1] - 5:5
report [16] - 5:5, 67:9, 67:12, 71:13, 72:10, 75:3, 78:6, 78:8, 78:12, 111:5, 116:15, 118:2, 119:6, 137:15, 140:9, 140:10
reported [1] - 34:21
reporter [2] - 7:5, 78:3
Reporter [3] - 2:6, 2:7, 162:8
REPORTER [3] - 15:17, 99:21, 162:2
reports [1] - 75:1
represent [7] - 33:19, 57:13, 59:5, 61:19, 63:23, 112:14
representing [3] - 60:24, 63:13, 66:7
repurpose [1] - 98:21
request [3] - 5:8, 61:13, 64:18
requested [1] - 59:24
requests [2] - 12:25, 57:18
require [2] - 61:7, 81:15
required [4] - 80:4, 82:3, 95:4, 100:23
requirement [1] - 44:11
requires [2] - 73:13, 82:5
reschedule [1] - 12:16
research [5] - 9:14, 10:11, 21:23, 39:9, 44:16
researchers [1] - 44:11
resource [1] - 96:1
resourced [1] - 84:6
resources [17] - 11:25, 14:16, 17:8, 80:7, 81:25, 83:1, 83:15, 84:22, 92:12, 96:17, 98:14, 98:21, 100:24, 101:1, 101:22, 103:13, 139:15
respect [5] - 28:8, 29:2, 29:11, 118:5, 138:7
respectful [1] - 121:15
respectfully [1] - 5:7
respond [4] - 39:6, 56:4, 56:20, 72:8
responded [4] - 55:4, 55:14, 56:15
response [4] - 7:10, 43:15, 51:12, 52:4
responsibilities [1] - 70:9
responsibility [1] - 9:15
responsible [1] - 68:13
responsive [1] - 61:6
restructured [1] - 69:1
results [3] - 33:1, 35:13, 96:19
retain [1] - 47:9
retained [7] - 52:20, 56:1, 56:5, 57:12, 57:14, 58:5, 59:5
retrain [1] - 98:21
return [4] - 70:21, 90:1, 90:3, 120:13
returning [1] - 4:20
reveal [2] - 57:23, 84:14
revealed [1] - 64:23
revenue [14] - 69:3, 81:20, 90:25, 91:3, 91:23, 91:25, 92:3, 92:25, 94:8, 98:4, 99:11, 101:10, 101:13, 103:5
review [2] - 35:9, 60:9
reviewed [9] - 60:11, 75:1, 88:18, 88:20, 96:6, 109:10, 111:8, 111:9, 124:13
reviews [1] - 73:15
reward [1] - 22:12
rights [2] - 24:7, 77:21
risk [18] - 8:7, 14:19, 18:19, 18:22, 19:3, 19:8, 24:16, 37:13, 37:14, 40:18, 40:20, 43:12
risks [1] - 103:18
rival [3] - 42:15, 43:10, 44:6
River [2] - 136:15, 136:18
road [2] - 70:18, 98:2
Robison [44] - 47:2, 47:4, 47:7, 47:10, 51:9, 52:20, 52:21, 54:21, 55:8, 55:22, 56:1, 56:18, 56:20, 56:22, 57:7, 57:11, 57:17, 57:18, 58:5, 58:14, 58:16, 59:1, 59:4, 59:9, 59:17, 60:7, 60:10, 60:24, 61:3, 61:18, 62:15, 62:16, 62:22, 63:5, 63:10, 64:6, 64:14, 64:17, 65:2, 65:16, 65:22, 65:24, 66:2, 66:7
robust [3] - 35:13, 35:19, 81:20
robustness [1] - 43:6
rock [2] - 82:21, 82:22
role [7] - 9:6, 9:11, 9:18, 10:8, 10:15, 10:17
roll [1] - 96:4
rolls [1] - 82:22
Room [2] - 2:7, 162:9
room [1] - 53:15
ROPES [1] - 2:4
rosy [1] - 97:18
rotates [1] - 83:11
rounds [1] - 90:22
row [1] - 113:10
RPR [3] - 2:6, 162:3, 162:8
RUDOLPH [1] - 1:9
Rule [1] - 61:7
rules [1] - 22:20
rumor [1] - 35:24
run [6] - 37:4, 82:8, 84:3, 88:4, 93:21
running [1] - 6:6
runway [7] - 85:11, 85:12, 86:1, 86:2, 86:10, 86:25, 90:9
Ryan [1] - 1:17

S

safe [3] - 9:16, 37:8, 72:25
safely [1] - 101:12
safer [1] - 22:5
safety [4] - 34:15, 34:19, 36:3, 106:22
sale [2] - 119:11, 119:18
sales [9] - 12:6, 47:15, 69:1, 88:4, 94:3, 96:25, 99:10, 123:24, 138:16
Samer [1] - 2:2
Sandra [1] - 2:3
Sante [8] - 69:7, 69:8, 69:10, 69:18, 70:5, 70:24, 80:24, 102:3
SAPIEN [3] - 17:22, 17:25, 102:24
sat [1] - 71:24
SAT [1] - 113:23
satisfied [1] - 62:1
SAV [2] - 8:11, 19:6
saw [2] - 9:10, 85:25
scalability [1] - 12:5
scale [7] - 16:11, 25:2, 83:3, 83:12, 83:16, 94:8, 99:6
scared [1] - 56:12
scenario [4] - 78:20, 85:9, 93:21, 104:22
scenarios [2] - 70:23, 72:7
schedule [1] - 83:10
scheduling [1] - 12:15
School [3] - 6:23, 136:19, 136:21
school [2] - 66:20, 71:4
science [3] - 10:10, 67:23, 70:11
scientific [1] - 9:22
Scientific [9] - 4:8, 10:3, 38:14, 69:5, 88:25, 102:7, 102:15, 114:11, 115:5
scope [3] - 77:24, 78:9, 79:3
scratch [4] - 81:22, 82:13, 94:1, 94:6
screen [2] - 33:7, 112:11
screened [2] - 69:21, 69:23
scrupulous [1] - 45:23
se [1] - 14:24
seal [2] - 124:22, 141:8
search [1] - 61:5
second [15] - 18:4, 33:15, 33:25, 34:24, 35:7, 45:12, 60:17, 61:24, 64:10, 71:23, 99:19, 109:16, 118:13, 139:17, 140:10
secret [1] - 63:19
section [1] - 34:2
secure [1] - 93:9
see [50] - 4:15, 10:14, 15:9, 16:9, 16:21, 20:20, 22:6, 27:21, 28:19, 34:4, 46:25, 48:17, 52:3, 52:5, 55:21, 56:13, 58:15, 58:17, 58:19, 58:21, 58:22, 58:24, 58:25, 59:14, 60:15, 61:20, 63:21, 63:22, 76:12, 84:15, 85:1, 85:7, 85:16, 85:19, 89:3, 89:11, 90:22, 91:2, 92:8, 92:21, 94:13, 94:23, 97:21, 102:23, 110:5, 110:11, 112:11, 114:4, 115:15, 120:5
seeing [2] - 77:4, 91:10
seeking [1] - 75:13
seem [2] - 89:16, 111:24
selected [4] - 59:9, 61:18, 66:2, 70:4
selections [1] - 24:23
selfish [1] - 22:9
sell [1] - 120:8
sells [1] - 38:18
send [3] - 58:17, 62:15, 62:22
sending [2] - 55:6, 55:8
senior [2] - 47:15, 51:2
sense [5] - 24:12, 57:4, 70:23, 85:18, 86:25
sent [7] - 54:1, 58:15, 58:16, 60:7, 60:8, 60:10, 63:5
sentence [5] - 34:6, 35:7, 60:18, 61:2, 61:25
separate [1] - 140:2
separately [1] - 4:9
September [9] - 19:1, 47:11, 47:18, 47:22, 50:18, 51:14, 52:4, 58:7, 58:14
Series [1] - 123:4
series [2] - 73:5, 116:19
serve [1] - 70:4
served [2] - 23:5, 59:6
service [1] - 7:2

services [2] - 7:1, 28:19
serving [1] - 11:22
Sesame [1] - 112:5
session [2] - 121:15, 124:18
SESSION [1] - 1:9
sessions [1] - 21:16
set [6] - 50:12, 67:14, 77:17, 97:18, 123:3, 139:8
setting [1] - 123:2
seven [4] - 19:2, 22:24, 42:1, 87:3
seven-year [1] - 19:2
several [6] - 31:24, 85:3, 88:10, 94:25, 99:2, 108:20
severe [3] - 11:4, 11:10, 16:7
shape [1] - 52:9
share [4] - 13:17, 15:7, 54:25, 57:22
shared [2] - 12:10, 39:7
Sharma [1] - 109:22
sheaths [1] - 15:2
shift [1] - 37:7
shoes [1] - 71:24
Shores [1] - 1:17
SHORES [10] - 4:2, 4:4, 4:14, 4:25, 5:3, 5:12, 5:22, 6:3, 6:5, 124:20
Shores' [1] - 123:16
shorthand [1] - 2:10
show [2] - 43:18, 82:20
showed [5] - 82:16, 94:4, 94:16, 96:21, 96:24
showing [4] - 62:15, 62:23, 82:15, 123:19
shown [6] - 4:5, 15:4, 74:21, 77:15, 101:2, 101:15
shows [3] - 46:5, 56:14, 94:17
sic [4] - 8:8, 23:20, 27:14, 60:22
side [4] - 4:20, 59:15, 85:17, 95:15
sign [1] - 48:20
significant [9] - 22:19, 71:15, 81:15, 81:25, 92:6, 100:7, 101:1, 102:11, 108:7
significantly [1] - 12:7
silly [1] - 46:14
similar [13] - 12:25, 56:2, 78:13, 86:14, 94:17, 96:8, 97:6, 97:22, 98:17, 102:8, 102:19, 114:23, 121:21
similarly [1] - 78:15
simpler [1] - 17:2
simultaneous [1] - 21:12
simultaneously [1] - 21:17
single [9] - 58:13, 92:3, 94:4, 94:24, 104:19, 104:24, 105:4, 105:5, 105:10
single-digit [1] - 92:3
Sisyphus [1] - 82:20
sit [1] - 76:4
site [12] - 9:7, 9:18, 11:22, 13:10, 13:17, 19:25, 24:23, 42:21, 89:21, 138:15
sites [22] - 9:1, 11:21, 12:11, 13:12, 15:9, 15:13, 16:10, 25:6, 25:8, 42:6, 42:20, 43:20, 43:21, 43:24, 83:9, 95:16, 95:19, 95:25, 96:9, 98:16, 101:12
situation [1] - 88:6
Siva [1] - 58:20
six [11] - 21:16, 28:5, 38:12, 85:12, 86:1, 87:3, 87:7, 90:10, 91:9, 116:6
size [6] - 12:19, 16:25, 18:1, 31:3, 89:19, 99:10
sized [1] - 85:21
sizes [1] - 16:25
Skelton [7] - 47:12, 47:15, 49:11, 50:4, 50:19, 51:14, 54:1
Sleigh [1] - 1:14
Slide [4] - 72:16, 81:9, 85:18, 85:19
slide [25] - 46:4, 67:19, 74:24, 75:6, 75:7, 75:12, 77:16, 82:20, 84:9, 85:25, 88:2, 94:10, 95:7, 96:22, 96:23, 99:4, 112:8, 114:4, 115:8, 115:9, 123:6, 138:2, 138:9, 138:23, 139:9
slides [4] - 84:13, 99:24, 112:15, 115:7
slightly [2] - 41:19, 70:1
slow [2] - 15:23, 52:13
slower [1] - 48:14
slowly [1] - 7:5
small [10] - 11:17, 80:22, 83:8, 85:2, 92:3, 99:10, 101:19, 102:8, 103:20
smaller [4] - 16:23, 102:23, 120:9
smart [1] - 122:13
smarts [1] - 23:1
Society [1] - 20:11
softball [1] - 104:8
Sojourn [1] - 138:15
sold [1] - 123:8
solid [1] - 84:8
someone [6] - 47:12, 49:22, 53:11, 56:7, 56:23, 58:19
sometimes [9] - 6:21, 12:11, 12:23, 21:13, 32:18, 33:13, 48:9, 55:12, 112:1
soon [1] - 116:10
sooner [1] - 12:24
sorry [5] - 6:7, 37:20, 48:13, 118:18
sort [7] - 12:9, 12:12, 12:17, 24:18, 49:19, 55:17, 119:17
sound [2] - 46:14, 58:7
sounding [1] - 14:19
sounds [2] - 56:10, 56:22
space [26] - 9:23, 10:1, 20:3, 20:10, 22:17, 25:12, 25:19, 67:24, 67:25, 69:17, 69:19, 69:20, 69:22, 70:2, 88:8, 100:7, 100:9, 100:23, 100:25, 101:16, 102:20, 102:22, 103:11, 103:23, 110:23, 121:23
specialized [1] - 7:15
specialty [1] - 7:12
specific [9] - 29:10, 80:18, 84:14, 112:17, 116:17, 119:25, 120:15, 122:21, 136:2
specifically [8] - 7:15, 28:24, 63:18, 69:20, 78:16, 104:22, 138:7, 140:15
specifics [3] - 49:13, 84:16, 95:21
speculate [1] - 123:18
speculative [1] - 140:20
speed [2] - 23:13, 23:23
spend [2] - 70:12, 74:13
spent [3] - 67:22, 68:7, 98:24
spite [1] - 11:7
spoken [6] - 28:2, 28:15, 29:1, 29:4, 29:5, 57:7
spreadsheet [1] - 123:20
spreadsheets [1] - 123:24
spur [1] - 78:22
staff [3] - 95:18, 99:14, 103:16
stage [7] - 37:2, 69:10, 70:11, 76:15, 89:17, 90:21, 115:18
Stan [3] - 33:12, 33:13, 50:20
stand [3] - 11:24, 37:5, 136:6
stand-alone [2] - 11:24, 37:5
standard [2] - 15:22, 16:1
standards [3] - 77:7, 77:8, 77:17
standing [1] - 107:11
standpoint [1] - 60:23
Stanford [1] - 71:3
Stanley [3] - 6:9, 6:17, 33:12
STANLEY [2] - 3:3, 6:11
start [18] - 24:13, 24:22, 50:14, 67:19, 73:4, 75:14, 79:21, 80:16, 80:25, 81:8, 92:6, 95:8, 95:25, 100:10, 104:8, 114:13, 135:25, 140:18
started [8] - 19:18, 24:21, 24:24, 80:6, 80:7, 80:12, 100:19, 102:15
starting [3] - 68:22, 75:8, 84:2
startup [7] - 17:7, 80:22, 86:14, 96:1, 114:17, 114:24, 139:16
startups [2] - 27:16, 78:23
State [2] - 66:15, 136:23
state [4] - 6:15, 10:9, 67:6, 108:25
statement [3] - 96:24, 111:15, 112:15
STATES [2] - 1:1, 1:10
States [28] - 22:17, 25:14, 33:20, 38:18, 40:24, 41:9, 41:16, 41:25, 42:15, 42:17, 44:5, 73:2, 73:11, 76:6, 76:23, 77:10, 81:1, 95:17, 98:17, 104:16, 105:15, 107:3, 108:23, 111:4, 113:3, 113:6, 117:13, 162:9
status [1] - 34:17
stay [1] - 66:18
steady [1] - 32:9
stealth [2] - 121:16, 121:19
STEEN [1] - 1:18
stenographic [1] - 162:5
stenosis [4] - 7:19, 11:19, 11:20, 95:18
still [8] - 10:4, 23:19, 25:4, 25:5, 38:25, 56:5, 95:20, 111:25
stomach [1] - 35:3
stop [5] - 34:10, 44:8, 54:5, 55:19, 85:6
story [1] - 102:8
straight [3] - 76:8, 77:22, 79:13
strange [1] - 38:8
strategic [6] - 70:15, 72:6, 87:10, 89:16, 103:11, 122:4
strategy [1] - 70:20
street [1] - 80:23
Street [1] - 112:5
stroke [1] - 102:14
structural [22] - 7:2, 7:16, 9:23, 9:25, 10:21, 15:5, 18:16, 22:17, 25:16, 69:20, 69:21, 69:25, 70:2, 88:8, 88:14, 89:10, 100:25, 102:1, 119:1, 121:23, 122:2, 122:5
structure [1] - 39:6
structures [1] - 15:1
struggling [1] - 102:9
STS [1] - 20:11
stub [1] - 74:15
students [3] - 71:6, 71:7, 71:9

studies [19] - 8:6, 8:9, 8:10, 14:10, 18:20, 18:25, 73:5, 73:7, 73:9, 73:11, 74:9, 75:21, 76:6, 77:15, 80:3, 80:5, 81:1, 82:5, 82:8
study [52] - 9:9, 9:12, 9:14, 9:17, 12:8, 12:9, 17:2, 17:13, 17:15, 19:17, 20:24, 22:13, 22:15, 23:20, 24:16, 25:11, 30:24, 33:1, 34:21, 34:23, 36:12, 36:24, 37:4, 40:8, 40:13, 42:22, 42:25, 43:7, 43:20, 43:23, 43:25, 44:18, 44:22, 44:23, 46:4, 48:4, 74:7, 76:8, 76:9, 76:13, 79:22, 79:23, 80:13, 100:14, 100:19, 102:18, 115:23, 117:9, 117:14
study's [1] - 80:13
stupid [1] - 46:19
submissions [1] - 104:12
submit [6] - 4:22, 6:1, 73:2, 73:14, 76:7, 79:21
submitted [4] - 5:5, 5:6, 63:6, 80:24
submitting [1] - 4:6
subpoena [6] - 54:22, 60:12, 61:6, 62:2, 62:4, 62:18
subpoenas [4] - 53:22, 55:25, 56:13, 59:6
subsequent [1] - 80:16
subsidies [1] - 8:8
substantial [1] - 109:4
success [2] - 73:8, 78:22
successful [5] - 87:18, 91:17, 100:5, 100:14, 102:4
successfully [5] - 81:12, 83:2, 93:1, 93:23, 103:16
suffering [2] - 16:7, 25:23
suffice [1] - 112:9
sufficient [6] - 116:25, 117:4, 117:6, 117:8, 117:13, 123:3
sufficiently [2] - 81:19, 82:4
suggest [1] - 75:13
suggests [1] - 23:21
suitors [1] - 120:3
summary [1] - 75:4
sun [1] - 5:23
supply [4] - 14:8, 14:11, 28:12, 82:2
support [22] - 11:25, 13:22, 14:6, 14:17, 15:5, 38:2, 52:14, 52:18, 76:18, 81:15, 83:8, 94:12, 95:9, 95:19, 99:15, 100:4, 103:15, 103:16, 117:9, 117:14, 139:21
supports [1] - 139:24
supposed [2] - 51:7, 51:8
surface [1] - 35:4
surgeon [1] - 20:10
surgeons [1] - 68:10
Surgeons [1] - 20:12
surgery [5] - 11:6, 11:8, 11:10, 25:24, 68:11
surgical [3] - 18:19, 19:6, 68:10
surprise [1] - 64:5
surprised [5] - 21:1, 28:23, 35:25, 64:8
surrounding [1] - 15:1
surrounds [1] - 89:18
surveillance [1] - 82:5
sustained [1] - 34:17
SWORN [3] - 6:11, 67:3, 136:7
sycophant [1] - 14:20
symbiotic [1] - 36:24
symptoms [1] - 11:10
syndicate [1] - 84:8
system [1] - 17:23
System [2] - 6:23, 44:19
systems [1] - 117:4
Systems [1] - 6:20

T

T-equals [1] - 115:14
table [2] - 49:18, 90:17
taught [4] - 18:23, 70:25, 71:9, 136:20
TAV [2] - 8:11, 19:6
TAV-in-SAV [2] - 8:11, 19:6
TAVI [1] - 34:8
TAVR [72] - 7:21, 7:22, 7:23, 8:4, 8:16, 8:17, 8:21, 10:21, 11:18, 13:3, 13:18, 13:21, 14:21, 15:8, 17:5, 17:22, 18:2, 18:17, 19:6, 19:12, 19:18, 20:3, 20:10, 20:15, 21:11, 21:21, 21:25, 24:8, 24:13, 24:14, 25:12, 25:13, 30:4, 30:10, 32:16, 37:15, 37:22, 40:1, 40:15, 44:9, 75:5, 75:10, 75:14, 77:12, 78:14, 88:15, 88:23, 89:19, 89:22, 89:23, 90:16, 95:21, 96:14, 96:19, 100:7, 100:8, 101:3, 101:16, 102:20, 102:21, 103:11, 104:9, 104:13, 105:14, 107:10, 110:23, 111:2, 111:12, 111:18, 140:19
TAVR-AR [34] - 8:17, 8:21, 13:18, 13:21, 19:12, 20:15, 21:11, 21:21, 21:25, 24:8, 30:4, 30:10, 40:1, 40:15, 75:5, 75:10, 77:12, 78:14, 88:15, 88:23, 89:19, 89:23, 90:16, 95:21, 100:7, 100:8, 101:3, 103:11, 104:9, 104:13, 105:14, 107:10, 111:18, 140:19
TAVR-AS [26] - 7:21, 7:22, 7:23, 8:4, 14:21, 15:8, 17:5, 17:22, 18:2, 18:17, 21:21, 24:13, 24:14, 25:12, 25:13, 32:16, 37:15, 37:22, 44:9, 89:19, 89:22, 96:14, 96:19, 101:16, 102:20, 102:21
TAVRs [1] - 95:17
Taylor [1] - 103:25
TCT [5] - 9:3, 21:6, 21:8, 21:10, 35:24
teach [3] - 55:13, 71:5, 71:6
teaching [2] - 71:3, 136:19
team [26] - 7:25, 8:3, 12:7, 12:10, 12:14, 13:5, 13:8, 13:11, 13:22, 14:1, 16:9, 28:9, 29:2, 41:21, 46:5, 46:6, 48:9, 53:13, 55:11, 81:16, 83:11, 83:23, 110:18, 122:10, 122:12
team's [1] - 12:13
teams [2] - 38:20, 94:25
Tech [2] - 80:22, 113:3
tech [1] - 71:2
Tech's [1] - 112:21
technical [3] - 22:25, 37:16, 74:6
technique [1] - 22:4
techniques [1] - 35:1
technological [1] - 17:17
technologies [5] - 23:7, 100:18, 101:23, 102:16, 110:17
TECHNOLOGY [1] - 1:6
technology [11] - 17:15, 19:4, 22:4, 37:15, 48:10, 68:14, 69:12, 71:21, 98:17, 110:19, 111:2
Technology [1] - 136:17
TEER [1] - 25:19
tend [1] - 97:13
tender [1] - 137:8
tends [1] - 25:17
term [4] - 19:1, 87:19, 93:24, 94:19
termination [1] - 85:6
terms [3] - 79:24, 98:4, 100:11
test [2] - 42:22, 42:23
tested [1] - 77:12
testified [16] - 26:19, 29:6, 31:22, 32:24, 37:9, 38:5, 38:22, 41:7, 43:9, 77:25, 78:5, 78:7, 90:7, 108:4, 116:9, 123:11
testifying [5] - 38:9, 51:20, 61:9, 64:10, 108:1
testimony [31] - 4:8, 4:12, 26:22, 27:1, 27:4, 29:22, 43:11, 67:15, 72:15, 73:24, 74:8, 75:1, 76:11, 80:1, 81:14, 87:16, 88:19, 88:20, 88:21, 89:20, 95:16, 99:12, 100:22, 107:18, 115:11, 116:11, 116:19, 124:3, 137:12, 137:22, 138:22
testing [4] - 72:23, 79:20, 81:2
text [1] - 52:1
THE [53] - 1:1, 1:1, 1:9, 4:3, 4:13, 4:24, 5:2, 5:10, 5:18, 5:21, 5:25, 6:4, 6:11, 15:17, 15:18, 15:19, 15:21, 15:22, 15:23, 15:24, 15:25, 16:1, 26:7, 50:9, 54:10, 66:10, 66:13, 66:17, 66:22, 66:23, 66:25, 67:3, 72:15, 78:2, 78:24, 79:5, 79:7, 99:19, 99:21, 99:22, 104:2, 112:2, 112:3, 112:6, 118:10, 118:18, 118:21, 124:19, 136:4, 136:7, 136:9, 137:12, 141:6
theme [2] - 76:25, 102:23
themselves [1] - 45:17
theory [1] - 138:21
therapies [10] - 10:22, 15:6, 18:9, 18:16, 25:16, 29:20, 30:1, 30:10, 102:2
therapy [3] - 16:25, 20:22, 70:13
thereby [1] - 78:22
they've [14] - 15:9, 15:11, 17:17, 17:18, 17:19, 28:22, 80:6, 80:25, 83:6, 95:5, 98:18, 106:14, 110:21
thinking [11] - 39:5, 72:6, 140:5, 140:8, 140:10, 140:11, 140:14, 140:16, 140:22, 140:23, 140:25
third [4] - 18:4, 72:4, 110:11, 115:9
thoracic [1] - 47:16
Thoracic [1] - 20:12
Thourani [6] - 20:5, 20:9, 60:19, 60:20, 60:22, 60:25
Thourani's [1] - 4:12
threat [1] - 108:8
three [25] - 9:5, 10:5, 16:12, 24:14, 24:18,

30:25, 32:20, 42:8, 42:9, 42:16, 43:3, 43:9, 55:19, 72:9, 80:6, 89:9, 89:23, 113:23, 113:25, 114:5, 114:8, 139:3, 140:1, 140:10, 140:24
throughout [2] - 34:22, 74:4
Thursday [1] - 52:4
tied [1] - 140:6
tight [1] - 33:22
tight-knit [1] - 33:22
Tim [1] - 99:20
timeline [8] - 23:14, 23:24, 73:21, 74:2, 75:4, 78:19, 115:21, 116:15
timelines [3] - 71:18, 73:19, 73:22
timing [1] - 12:9
TIMOTHY [1] - 162:3
Timothy [1] - 2:6
tips [1] - 13:15
tissue [3] - 14:24, 14:25, 18:1
titled [1] - 34:2
today [46] - 6:15, 11:4, 17:11, 17:16, 18:1, 36:9, 39:23, 43:17, 47:5, 51:5, 59:5, 60:22, 61:10, 61:11, 62:9, 64:10, 67:15, 74:1, 77:12, 77:23, 78:8, 79:14, 80:8, 81:14, 83:9, 84:6, 88:15, 89:20, 90:17, 91:19, 95:17, 99:12, 100:6, 100:8, 101:15, 104:7, 107:12, 107:20, 107:21, 108:9, 108:10, 108:12, 113:17, 117:11, 137:22, 139:16
today's [1] - 4:18
toe [1] - 74:15
together [1] - 12:17
tomorrow [1] - 12:20
took [2] - 23:14, 97:24
tool [1] - 36:7
top [4] - 8:25, 9:2, 9:5, 60:18
topic [2] - 39:25, 44:10
Torsten [4] - 19:14, 19:23, 19:24, 36:22
total [1] - 11:17
totality [1] - 34:6
touch [1] - 116:8
tough [1] - 90:24
towards [2] - 27:2, 92:7
track [1] - 17:4
traction [2] - 90:23, 92:7
TRADE [2] - 1:2, 1:15
Trade [4] - 26:13, 46:24, 60:9, 104:1
tradeoffs [2] - 71:25, 86:15
train [2] - 81:23, 95:20
trained [3] - 13:6, 13:12, 50:1
training [4] - 19:21, 19:22, 81:25, 98:20
transaction [16] - 28:9, 30:9, 83:20, 83:25, 84:20, 111:16, 112:20, 113:14, 113:18, 124:7, 124:11, 138:8, 139:4, 139:5, 139:12, 139:14
transactions [1] - 139:2
transcatheter [1] - 7:18
TRANSCRIPT [1] - 1:8
transcript [4] - 2:10, 123:14, 162:5, 162:6
transcription [1] - 2:11
transesophageal [1] - 35:2
transparency [1] - 46:9
treat [2] - 31:12, 101:9
treated [2] - 19:12, 48:7
treating [1] - 29:21
treatment [2] - 7:14, 34:18
treats [1] - 25:25
trial [17] - 8:23, 9:1, 9:6, 9:19, 14:14, 24:22, 32:5, 32:8, 41:4, 71:18, 73:4, 77:14, 77:22, 78:8, 79:13, 80:1, 140:13
trials [16] - 8:4, 8:20, 11:13, 11:23, 13:25, 23:12, 24:4, 24:21, 25:1, 31:24, 40:2, 40:16, 40:23, 40:24, 75:10, 80:19
tricks [1] - 13:15
tricuspid [3] - 15:10, 15:12, 15:13
tried [2] - 43:18, 120:7
Trilogy [50] - 8:21, 11:14, 12:1, 14:2, 14:7, 14:18, 16:20, 17:9, 19:19, 26:22, 28:3, 28:16, 29:2, 29:15, 31:22, 31:23, 32:3, 32:6, 32:9, 32:21, 33:19, 34:12, 36:6, 37:8, 37:25, 38:3, 40:2, 40:3, 40:16, 40:17, 40:19, 59:25, 78:22, 81:13, 83:3, 83:16, 83:24, 93:22, 94:12, 95:9, 104:9, 105:14, 107:1, 107:5, 107:9, 123:7, 124:14, 138:14, 138:15
Trilogy's [1] - 36:3
trouble [1] - 7:4
true [3] - 66:18, 162:4, 162:5
trust [1] - 56:24
trusted [2] - 56:20, 65:24
truth [1] - 64:25
truthfully [1] - 108:4
try [17] - 4:21, 12:21, 12:24, 45:25, 72:3, 79:9, 83:24, 87:10, 87:12, 92:25, 95:3, 96:3, 97:11, 103:9, 120:12, 136:3
trying [16] - 20:20, 43:19, 47:17, 54:8, 72:7, 81:4, 87:22, 91:3, 94:8, 97:14, 98:1, 103:2, 103:3, 106:19, 115:2, 123:17
tube [1] - 35:3
Tuesday [1] - 1:5
turn [17] - 11:15, 14:13, 72:16, 74:24, 81:9, 83:18, 84:9, 88:2, 90:4, 94:10, 95:7, 96:23, 99:4, 110:8, 115:7, 118:16, 118:19
turning [4] - 81:5, 95:25, 138:9, 138:23
two [28] - 10:15, 12:12, 16:11, 21:14, 28:17, 32:18, 40:1, 40:15, 41:11, 43:3, 43:22, 50:23, 53:13, 75:9, 80:3, 85:11, 87:9, 87:15, 89:22, 97:5, 104:9, 104:12, 104:20, 104:23, 105:6, 105:11, 113:10, 119:16
two-part [1] - 10:15
Tymkovich [1] - 1:13
type [1] - 105:5
types [6] - 17:8, 25:25, 101:8, 104:15, 138:9, 141:1
typical [1] - 72:18
typically [2] - 70:17, 82:7

U

U.S [52] - 2:7, 11:21, 20:15, 20:21, 20:25, 22:1, 22:9, 22:19, 22:23, 23:13, 23:15, 23:20, 23:23, 24:9, 24:10, 24:21, 25:2, 35:8, 40:1, 40:15, 41:4, 75:10, 76:13, 77:13, 77:14, 78:15, 79:12, 80:12, 80:19, 100:7, 100:9, 100:19, 105:11, 107:10, 109:19, 111:13, 111:18, 112:22, 113:15, 113:19, 114:1, 115:3, 116:23, 117:1, 117:4, 117:8, 117:9, 117:14, 138:12, 140:19
ultimately [5] - 69:3, 69:5, 70:20, 70:22, 73:16
uncertain [1] - 80:15
uncertainty [2] - 87:17, 93:4
unconscious [6] - 45:8, 45:9, 45:10, 45:14, 45:15, 45:24
unconstrained [1] - 96:17
under [6] - 5:23, 62:2, 76:17, 93:5, 124:22, 141:8
undergraduate [1] - 136:17
underlying [1] - 97:2
understood [2] - 21:15, 51:25
United [28] - 22:17, 25:14, 33:20, 38:18, 40:24, 41:8, 41:16, 41:24, 42:15, 42:17, 44:5, 73:2, 73:11, 76:6, 76:23, 77:10, 81:1, 95:17, 98:16, 104:16, 105:15, 107:2, 108:23, 111:4, 113:3, 113:6, 117:13, 162:9
UNITED [2] - 1:1, 1:10
university [5] - 44:24, 52:12, 52:13, 55:12, 56:5
University [12] - 6:20, 6:22, 6:23, 8:3, 8:25, 9:14, 19:15, 44:19, 44:21, 136:18, 136:20, 136:21
unless [1] - 40:10
unlike [1] - 53:25
unlikely [2] - 100:4, 118:25
unmet [5] - 10:13, 11:1, 11:3, 25:22, 26:2
unnecessary [1] - 12:22
unopened [1] - 55:1
unrealistic [1] - 12:22
unredacted [3] - 67:18, 84:12, 109:14
up [42] - 4:9, 6:6, 8:14, 19:1, 19:2, 21:22, 23:13, 23:23, 24:12, 25:2, 25:20, 27:2, 33:3, 40:5, 41:12, 42:9, 43:2, 48:18, 49:17, 49:20, 51:22, 52:6, 59:22, 60:3, 60:13, 72:20, 77:17, 80:3, 80:4, 82:21, 82:22, 86:12, 87:10, 87:11, 98:9, 103:6, 107:23, 109:7, 117:23, 118:9, 123:14, 136:3
update [1] - 35:8
updated [1] - 35:7

V

vague [1] - 108:11
Vahl [6] - 19:14, 19:19, 19:25, 20:2, 32:1, 36:22
validate [1] - 123:20
value [3] - 62:19, 120:11, 120:13
valve [49] - 7:19, 8:13, 14:12, 14:18, 14:22, 14:23, 14:24, 14:25, 15:1, 15:11, 15:12, 17:22, 19:5, 19:6, 20:20, 21:3, 21:19,

23:7, 23:12, 24:8, 25:20, 28:7, 30:21, 31:22, 31:23, 34:12, 34:16, 36:10, 37:23, 37:25, 40:23, 41:2, 41:5, 41:8, 41:15, 41:24, 42:15, 44:4, 47:16, 59:25, 70:2, 77:20, 79:11, 112:22, 113:17, 113:19
Valve [25] - 30:2, 30:4, 30:18, 31:12, 40:2, 40:4, 40:5, 40:8, 40:16, 77:11, 77:23, 78:18, 79:14, 79:18, 79:23, 80:12, 100:19, 104:8, 107:1, 107:5, 107:8, 112:25, 113:15, 140:21
valve-in-valve [2] - 19:5, 37:23
valves [7] - 30:22, 32:3, 32:6, 32:9, 32:21, 33:19, 37:8
valvular [2] - 7:16, 14:21
Vancouver [6] - 28:18, 47:18, 48:2, 48:4, 49:14, 49:16
variables [1] - 79:16
variety [3] - 11:9, 73:22, 138:11
various [1] - 27:9
Varnitha [1] - 58:20
veins [1] - 31:3
ventricular [1] - 40:21
venture [8] - 68:1, 69:10, 69:14, 71:15, 102:9, 102:23, 120:24, 122:18
venture-backed [2] - 102:9, 102:23
Ventures [4] - 69:7, 69:8, 69:10, 70:5
Venus [1] - 113:23
VeriPulse [1] - 69:25
version [1] - 84:10
versions [1] - 17:22
versus [4] - 8:13, 43:1, 86:17, 96:4
vice [2] - 47:15, 136:14
view [4] - 4:9, 99:5, 103:19, 119:21
Vinod [1] - 20:5
violating [3] - 110:19, 111:3, 111:13
violin [1] - 55:17
visible [1] - 46:7
VitaFlow [1] - 113:10
volume [1] - 33:21
volunteer [1] - 49:23
volunteering [1] - 53:16
VP [1] - 51:2
Vycor [1] - 113:23

W

wait [1] - 12:12
waiting [1] - 35:19
walk [1] - 57:19
wants [1] - 123:18
Washington [7] - 1:4, 1:16, 1:19, 1:23, 2:5, 2:8, 162:10
ways [1] - 140:2
website [2] - 40:6, 46:7
week [4] - 12:12, 32:16, 75:4, 89:22
weeks [11] - 41:11, 47:11, 52:14, 59:16, 63:4, 85:12, 104:6, 104:23, 105:9, 108:2, 109:11
Weiss [1] - 1:13
well-regarded [2] - 20:2, 20:9
well-resourced [1] - 84:6
well-run [1] - 84:3
WEST [12] - 135:24, 136:5, 136:8, 136:11, 137:8, 137:13, 137:14, 137:18, 137:20, 137:24, 138:1, 141:3
West [1] - 3:8
Wharton [1] - 136:19
whereas [1] - 97:20
white [2] - 63:6, 63:12
whittle [1] - 25:8
whole [4] - 8:9, 48:9, 49:15, 66:6
wide [2] - 73:22, 138:11
widget [2] - 42:22, 42:23
willingness [1] - 116:22
Wilson [7] - 4:20, 5:4, 138:6, 138:19, 139:25, 140:9, 140:16
window [1] - 93:2
WITNESS [16] - 3:2, 6:11, 15:19, 15:22, 15:24, 16:1, 50:9, 54:10, 66:17, 66:23, 67:3, 79:7, 112:3, 112:6, 118:10, 136:7
witness [7] - 26:5, 27:17, 27:21, 49:22, 53:21, 61:10, 103:24
witnesses [2] - 53:6, 53:9
woke [1] - 40:5
word [3] - 51:7, 57:17, 62:11
wording [1] - 65:9
workings [1] - 23:17
world [6] - 18:23, 20:4, 38:2, 74:19, 98:23, 139:17
world's [1] - 23:17
worry [3] - 101:18, 101:19, 101:20
worth [1] - 27:21
write [1] - 51:15
writes [3] - 50:20, 59:4, 61:3
wrote [3] - 34:13, 34:14, 120:15

Y

year [13] - 8:1, 18:3, 19:2, 21:10, 24:17, 34:24, 42:8, 46:4, 66:17, 80:3, 80:10, 93:7
year's [1] - 21:8
years [30] - 7:15, 9:16, 10:3, 22:19, 24:15, 24:18, 28:17, 34:22, 41:24, 42:1, 42:9, 42:16, 43:3, 43:4, 43:10, 67:22, 68:7, 68:22, 71:5, 71:9, 74:4, 76:1, 81:18, 88:10, 89:1, 92:8, 116:6, 140:24
yellow [1] - 94:22
yesterday [1] - 5:4
Yielding [1] - 34:15
York [1] - 41:13
yourself [3] - 27:24, 55:6, 136:13

Z

Zeta [1] - 112:21
zoom [3] - 53:1, 53:2, 53:3