UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION,

Plaintiff(s),

v.

EDWARDS LIFESCIENCES CORPORATION, et al.,

Defendant(s).

Civil Case
No. 25-02569 RC

Washington, D.C.

November 21, 2025
**Afternoon Session**

---

EVIDENTIARY HEARING
BEFORE THE HONORABLE RUDOLPH CONTRERAS
UNITED STATES DISTRICT JUDGE

APPEARANCES:

FOR THE PLAINTIFF(S):
Laura Hall, Esquire
Lisa DeMarchi Sleigh, Esquire
Barrett J. Anderson, Esquire
Jacob Danziger, Esquire
Will Segal, Esquire
Evan Johnson, Esquire
Habin Chung, Esquire
Michelle J. Seo, Esquire
Jay Tymkovich, Esquire
Federal Trade Commission
600 Pennsylvania Avenue Northwest
Washington, D.C. 20580

James R. Weiss, Esquire
Jordan Andrew, Esquire
Federal Trade Commission
400 Seventh Street Southwest
Washington, D.C. 20580

FOR THE DEFENDANT(S):
Joshua Lipton, Esquire
Jamie E. France, Esquire
Stephanie Pearl, Esquire
Gibson, Dunn & Crutcher, LLP
1700 M Street Northwest
Washington, D.C. 20036

APPEARANCES (Cont.):

FOR DEFENDANT(S):

Ryan A. Shores, Esquire
Cleary, Gottlieb, Steen
& Hamilton, LLP
2112 Pennsylvania Avenue Northwest
Room 1138
Washington, D.C. 20037

Samer M. Musallam, Esquire
Elizabeth T. McInerney, Esquire
Matthew L. McGinnis, Esquire
Ropes & Gray, LLP
2099 Pennsylvania Avenue Northwest
Washington, DC 20006

REPORTED BY:

Tammy Nestor, RMR, CRR
Official Court Reporter
333 Constitution Avenue Northwest
Washington, D.C. 20001
tammy_nestor@dcd.uscourts.gov

I-N-D-E-X


| WITNESS | DIRECT | CROSS | REDIRECT | RECROSS |
|---|---|---|---|---|
| MARK TURCO | | | | |
| BY MR. TYMKOVICH | | | 4 | |
| AARON KESSELHEIM | | | | |
| BY MS. SEO | 7 | | 86 | |
| BY MR. LIPTON | | 40 | | |

The following proceedings began at 2:02 p.m.:

(The following was heard in closed session.)

(The following was heard in open session.)

CROSS EXAMINATION

BY MR. LIPTON:

Q Good afternoon, Dr. Kesselheim.

A Good afternoon.
Q You and I spoke last week when I took your deposition, is that correct?
A Yes.
Q And that's the only time we have ever spoken before today, correct?
A Yes.
Q It's good to see you again.
A You too.
Q I would like to start with some questions about your background and what you did or didn't study in this case, and then we will talk through some substantive issues. Is that okay?
A Yes.
Q You are a practicing physician, is that correct?
A Yes.
Q But you are not a cardiologist, is that correct?
A I am not.
Q Have you ever performed a TAVR procedure?
A I have not.
Q Have you ever been present for a TAVR procedure being performed?
A I have not.
Q Have you ever worked for a medical device company?
A I have never worked for a medical device company.

Q You have you ever brought a medical device through the FDA process?
A I have never brought a medical device through the FDA approval process.
Q Have you ever worked on a clinical trial for a medical device?
A I have never worked on a clinical trial for a medical device.
Q And you have only ever testified in a case involving a medical device one time, which was over ten years ago, is that correct?
A I believe that's correct, yes.
Q And you told me that was a case involving the ethical review processes for orthopedic surgeons and their use of medical devices. Does that sound right?
A Yes.
Q And you have never testified in a case in which a medical device manufacturer was one of the parties to the case, is that correct?
A I believe that's correct.
Q And you have never testified in a litigation about a merger, correct?
A No, I have not.
Q And in this case, you are not offering any opinion that this proposed transaction harms competition, is that

correct?

A That was not part of my report.

Q Are you offering any opinion about that here?

A No.

Q Okay. And, in fact, you told me that your opinions don't address competition in the medical device space at all, is that correct?

A My opinions relate to the FDA approval process for high-risk devices and the other topics that we just covered.

Q So is that yes to my question?

A Yes.

Q Okay. So let's talk close to where you ended in your testimony about the FDA approval process and, in particular, the IDE application stage of the process.

Is it correct that before a medical device manufacturer can do a feasibility study in the United States, they would need an IDE authorizing clinical use in human patients, correct?

A I think, generally speaking, that is true. For significant risk devices like the TAVR-AR devices at issue in this case, there again, we talked a little bit earlier about the early feasibility study pathway as a variant of that, but I think that, generally speaking, you're right, that the IDE is required to authorize clinical use in human patients.

Q Okay. And an IDE can be based on nonclinical data alone, correct? You don't need clinical data to apply for an IDE, is that correct?
A An IDE can be based on nonclinical data alone, correct.
Q Or an IDE can be based on nonclinical data or clinical data from outside the United States, correct?
A So correct. As we discussed just a few minutes ago, data submitted as part of an IDE can come from outside the United States with the caveat about the FDA's general concern about some of that data and its generalizability to the U.S.
Q And, in fact, if you are applying for an IDE using clinical data, in almost all cases that has to come from outside the U.S., right, because you can't do clinical studies in human patients in the United States unless you have an IDE, right?
A If there is any clinical data involved in an IDE application for a new device like a TAVR-AR device, I guess it would have to come from outside the United States.
Q And you didn't do any analysis in connection with your work in this case about the ability of a device manufacturer to use clinical data from outside the United States for purposes of an IDE application, correct?
A So I -- my analysis in this case relates to describing how the FDA approval process proceeds and the role of the

IDE and the review of data submitted as part of that IDE. I did not review specifically the IDE applications that were filed in this case.

Q And you didn't do any analysis at all of the extent to which ex-U.S. data can be used in an IDE application, correct?

A So as I describe in my report, the IDE application can involve -- involves the collection of data and the review of it by the FDA to determine whether or not it is reasonable for a program of human clinical testing to go forward. I did not analyze the specific contents of any IDE application as part of my review process.

Q And, Doctor, I will make a request. My time is short. We are all trying to get this hearing done before Thanksgiving. I will ask you, if I ask you a yes or no question, please answer yes or no. If I ask you whether you didn't study something for purposes of this case, please answer that directly. Don't tell me first about something else that you did study before you say that you didn't study the thing I asked about. Okay? Is that all right?

A I'll do my best.

Q Okay. Thank you.

Did you study the extent to which any developer of TAVR-AR technology -- did you study the extent to which their clinical data from outside the U.S. would be suitable

for use in an IDE?
A That was not part of my analysis.
Q And you are not offering an opinion that Jenscare's data, for example, can't be used to get a IDE, correct?
A I did not specifically review Jenscare's data.
Q And you told me in your deposition that device developers doing clinical trials outside the United States would have data available to them to prepare an IDE application, correct?
A Yes.
Q Okay. You haven't done any analysis to estimate how long it takes to get an IDE that would authorize a medical device company to perform clinical testing in the United States, correct?
A As I said, the FDA approval process takes -- the IDE process is supposed to be done in 30 days, but it can take much longer than that.
Q You have done no analysis of the amount of time it takes to prepare an IDE application, correct?
A Correct, I did not analyze that.
Q And you have said that the FDA is supposed to respond within a 30-day time period, but you haven't done any analysis of the average time it takes to get an IDE, for example, correct?
A I did not analyze that; although, that information is in

the JAMA Network Open study that we reviewed a few minutes ago where those authors estimated that the preclinical process that includes the IDE application can take about five years.

Q Did they -- did that article estimate the time it takes to get an IDE to conduct clinical trials in the United States?

A They didn't break out that part of that specifically.

Q And you didn't do that analysis either, did you, Doctor?

A I did not.

MR. LIPTON: Okay. And let's pull up, if we could, Dr. Kesselheim's expert report, please, paragraph 47. Let's see. Thank you, Mr. McCloud.

BY MR. LIPTON:

Q In your report, paragraph 47, you wrote, in 2013, the FDA introduced the early feasibility study program to facilitate clinical evaluations in the United States of devices that are early in development, correct?

A Yes. That's the first sentence there.

Q And that program was intended to make it easier to initiate early-stage clinical trials being conducted in the United States, correct?

A Well, it was intended to make the process for IDE application and initiation of feasibility studies more efficient and -- but I think that, you know, I think that's

a better way of characterizing it.
Q Okay. But you don't -- you told me a moment ago you don't have an estimate of the average time it takes to get an IDE, correct?
A Correct.
MR. LIPTON: So let's pull up, if we could, Mr. McCloud --
BY MR. LIPTON:
Q And, Doctor, you have this in front of you in your binder at tab A. This is an article titled navigating the regulatory pathway for medical devices, a conversation with the FDA clinicians, researchers, and industry experts.
It's tab A toward the back of your binder, Doctor.
Are you familiar with this article, Doctor?
A No.
Q Let's turn, if we could, please, to page No. 932. It's about the fifth or sixth page in. And on the left-hand column --
MR. LIPTON: I believe it's the next page, Mr. McCloud. Thank you.
BY MR. LIPTON:
Q Left-hand column, the first full paragraph in that article, and it states the EFS process. Tell me when you're there, Doctor.
A I think I see where you are reading from.

Q The EFS process has become increasingly popular with a doubling of IDEs for EFS over the last seven years.

And this is an article written in 2022.

There are now more than 200 EFS IDEs approved with more than 2500 patients enrolled. As FDA has gained more experience, approximately 80 percent of EFS IDEs are now approved in the first review cycle.

Do you see that, Doctor?

A I do.

Q The first review cycle means the first 30 days, correct?

A Well, no. A review cycle can be delayed longer than 30 days if there are questions or other issues that come up. A first review cycle traditionally in the ways that the FDA tends to use that word is from the submission process to the first final decision. So it's not clear exactly how long that is.

Q Okay. Do you have any reason to disagree with the statement in this article?

A Well, I don't know how the authors came to that. There doesn't appear to be a -- there doesn't appear to be a method section of this article that I could read to try to determine where these numbers come from. And there's no citations, as you can see, in that paragraph. So I don't know.

Q And you've never done your own analysis of this issue,

correct?
A Correct.
MR. LIPTON: Okay. We can take that down, please.
BY MR. LIPTON:
Q You talked in your initial testimony about probabilities of achieving FDA approval from various stages in the FDA process, correct?
A Yes.
Q Okay. And those probabilities were based on average probabilities from an article that you've read, correct?
A Yes, from the JAMA Network Open article that we discussed earlier.
Q You didn't do your own analysis of those probabilities, correct?
A I did not.
Q Okay. And the probabilities that you cited are average estimates taken across the sample of devices that were part of the study in that article, correct?
A Yes.
Q For any particular device under development, it might be more likely or less likely to get the FDA than the average estimate for that given stage of development, correct?
A Yes. I mean, I believe that's -- that number is a good guidepost for other high-risk devices, but it's an average number.

Q For example, if you have a device near the end of a pivotal trial and the trial has gone well, that device might have a higher likelihood of getting to FDA approval than the 61 percent average figure that you quoted, correct?
A Well, that's certainly one hypothetical scenario that could affect it. Also, there are other ones such as special designations or pathways that the device is qualifying for. But I believe that in general, it's an average number that is derived from a large cohort of high-risk devices.
Q On the other hand, if you have a device near the beginning of its pivotal trial that is encountering problems and has to pause the pivotal trial, that device might have a lower likelihood of getting to FDA approval than the 61 percent average for the pivotal trial stage, correct?
A Again, that's one factor, but this is -- this number, the likelihood of progressing to the next stage is a number that was derived from about a couple decades' worth of review of high-risk devices.

Many of those experienced those kinds of steps in their process as well. So, you know, I think that it's important to consider -- you know, to understand, as you point out, that is it an average number but that there are a lot of factors that might affect the ultimate application of it to a specific device.

Q Have you read the testimony from this hearing about how

the J-Valve pivotal trial is paused at an early stage because Edwards has encountered problems in that trial?

A I am aware that there's a pause in that trial, yes.

Q And these issues suggest that Edwards' likelihood of getting to FDA approval with the J-Valve device is lower than the 61 percent average for this stage of development, correct?

A That wasn't something that I analyzed as part of my report and I think would be a much more -- you know, would be a complicated conclusion to reach that I did not -- that analysis is not something that I performed.

Q You can't tell us the likelihood of J-Valve getting through to FDA approval, can you?

A That wasn't part of my analysis. I can say that for devices at that stage, according to that JAMA Network Open article, what the average likelihood of approval is. And, of course, there are factors in the J-Valve case such as its breakthrough designation or other factors that might make it more likely, but as you said, there's also the pause in the trial as well.

Q You testified earlier, your words were that the probabilities in that article, quote, are applicable to Trilogy and J-Valve.

Do you recall testifying that way?

A Yes. As I said, those are probabilities derived from a

large number of high-risk devices, and so because TAVR-AR is a high-risk device, it is reasonable to use that as a guidepost.

Q And when you were asked that question by FTC's counsel and you gave that answer, you provided no analysis and gave no reason for that conclusion that those figures are applicable to Trilogy and J-Valve, correct?

A I think that I'm trying to provide that now. But I think that that's -- I think that it is reasonable to apply those numbers in this case because this was taken from high-risk devices approved over the last few decades, and TAVR-AR devices are high-risk devices, and so it is a reasonable estimate.

Q You have done no analysis in this case as to whether the J-Valve device is higher or lower or close to the average that was cited in that article, correct?

A I did not do that analysis.

Q And you can't even tell us whether it's greater than a 50-50 chance that J-Valve will make it through to FDA approval, correct?

A Again, you can use those estimates, probabilities, provided in that article to try to make those -- to try to make those estimates, but I did not do that analysis.

MR. LIPTON: Let's pull up, if we could, please, Mr. McCloud, pages 196 and 197 of Dr. Kesselheim's

deposition, in particular 196 at 16 to 197 at 2.

Thank you, Mr. McCloud.

BY MR. LIPTON:

Q Sir, I asked you:

And you can't tell us whether the likelihood of J-Valve getting through to FDA approval is above 50 percent, correct?

And you answered, I feel like, again, as I said, based on the stage where it's at, the likelihood of approval is over 60 percent, but I didn't look at the specific circumstances of the J-Valve trial in order to make a determination about what the specific number is.

Did I read that correctly, Dr. Kesselheim?

A Yes. Again, in that first sentence, I am quoting from the JAMA Network Open article. And I said just now, I did not do a specific analysis as part of my report to come up with a specific number for J-Valve.

Q Okay. Thank you, Doctor.

And I would like to, if you could, please, look in front of you at tab 283 in your binder. I would like to not show it on the screen because we are in a public session.

Could you please open tab 283 in your binder, Doctor.

A Yes.

Q Okay. This is the deficiency letter that the FDA sent to JenaValve in late September 2025, correct?

A Yes.

MR. LIPTON: Okay. Mr. McCloud, if we could pull up from Dr. Kesselheim's report paragraph 55 on page 21, please.

And looking in the third line --

THE COURTROOM DEPUTY: Counsel, this should be on the public screen, correct?

MR. LIPTON: Yes. Thank you very much.

BY MR. LIPTON:

Q In the third line, you say, deficiency letters generally include at least one major issue and place the PMA application on hold pending the FDA's receipt of the requested information.

Is that what you wrote?

A Yes.

Q Okay. If you look back at the FDA's deficiency letter to JenaValve, I don't want you to tell me the content of it, but just tell us, please, which paragraph number or numbers qualify as major issues identified by the FDA to JenaValve.

A I didn't analyze the specific issues in this deficiency letter to determine whether they were major issues or other issues.

Q Okay. The FDA does use the phrase significant deficiencies in the letter, correct?

A That's in the second paragraph there.

Q Okay. Thank you.

MR. LIPTON: We can take that down. Thank you, Mr. McCloud.

BY MR. LIPTON:

Q You don't know what JenaValve has to do to remedy the issues identified by the FDA because you didn't study that, is that correct?

A That was not part of my report.

Q You also don't know the likelihood that JenaValve will be able to remedy the issues identified by the FDA because you didn't study that either, correct?

A I didn't study that specific question, but again, deficiency letters are a normal part --

Q That's fine, Doctor. You have answered my question. Just answer my question. If FTC's counsel has additional questions, they can ask them of you. I have limited time here. Thank you.

You can't even tell us whether it's greater than a 50 percent likelihood that JenaValve will ever be able to resolve the deficiencies identified by the FDA and get commercial approval in the United States, is that correct?

A Again, I did not review the specific issues and whether -- and the details of them, but deficiency letters are a normal part of the process. And you know, if over 80 percent of PMA devices are approved, then deficiency

letters are often handled by the manufacturer that receives them.

Q And when I took your deposition last week, you told me, I didn't look at the specific likelihood or the percentage likelihood of responding in this case.

That related to a question about JenaValve. Do you recall that testimony, Doctor?

A Yes.

Q Okay. And does that testimony remain true?

A I did not look at the specifics of this deficiency letter and the response.

Q Did you look at the specifics of the likelihood of JenaValve achieving FDA approval for Trilogy?

A Again, I didn't look at the specifics of that and would, again, refer you back to the JAMA Open article.

Q Thank you.

MR. LIPTON: For the record, the portion of the deposition I just quoted was page 185, lines 15 to 24.

BY MR. LIPTON:

Q Doctor, I would like to talk, if we could, about the timing of the various stages in the FDA process if we could. That was something you testified about a few moments ago.

You did some analysis of the time it typically takes to make it through the feasibility -- strike that.

You did your own analysis of the time it takes to get

through the pivotal trial stage and the PMA approval process stage of that FDA time line that you talked about, correct?

A Yes, I did.

Q And those were the only stages where you did your own analysis, correct?

A Yes.

Q Okay. For the feasibility study stage, you didn't do your own analysis of the amount of time it takes, correct?

A I did not do my own analysis, correct.

Q And the article that you used for those sites, the article that you used for those sites reports that a feasibility study on average takes about two years. Is that correct?

A Yes.

Q But you didn't do an analysis of what proportion or what the range of outcomes might be at the feasibility study stage, correct, in terms of timing?

A In terms of timing outcomes, I did not look at that specifically.

Q You understand that the article you cited, that two-year figure is a median figure and, therefore, a given trial might take more time or less time at the feasibility study stage, correct?

A As with the other numbers from that article, it's an average from a number of years of experience with high-risk

devices, yes.
Q And you are aware that JC Medical took less time than that two-year figure for its feasibility study for J-Valve, correct?
A I don't know that off the top of my head.
Q You were here for Dr. Turco's testimony earlier today, weren't you?
A A portion of it.
MR. LIPTON: Let's turn to page 80 of Dr. Kesselheim's report, please.
BY MR. LIPTON:
Q In this paragraph of your report, you listed out the dates, the various dates, for the J-Valve process through the feasibility study, correct?
A Yes.
Q Okay. And you say that J-Valve received its IDE on August 31, 2023, correct?
A Yes.
Q Okay. And then you say that J-Valve enrolled its first patient in the feasibility study on October 16, 2023, correct?
A Yes.
Q And completed enrollment in February 2024?
A Yes.
Q And received FDA approval to start the pivotal trial in

May of 2024, correct?

A Yes. Although, again, the subsequent increase in EFS enrollment was completed in July 2024 finishes that sentence, and then the next sentence is what you just quoted.

Q Based on the figures in your report, JC Medical went from initial IDE approval to completion of the feasibility study in about six months, and then it received FDA approval to start the pivotal trial about nine months after the initial IDE, correct?

A Based on these dates, yes, that's correct.

MR. LIPTON: Thank you, Mr. McCloud. We can take that down.

BY MR. LIPTON:

Q Now I would like to talk about the timing for the pivotal trial stage, which is something you did do an analysis of.

For your study, you analyzed high-risk devices approved by the FDA within the last year, correct?

A Yes.

MR. LIPTON: Okay. So, Mr. McCloud, can we please have paragraph 62 of Dr. Kesselheim's report on page 23.

BY MR. LIPTON:

Q Based on your study, you show a median time period of 4.1 years, correct?

A The median time between the pivotal trial treatment start date and the data collection completion date for the device -- the high-risk devices approved by the FDA in the last year was 4.1 years median.

Q And you reported an interquartile rage of 3.2 to 5 years, correct?

A Yes.

Q So that's from the 25th percentile to the 75 percentile, you have a variance of about two years, correct?

A Yes.

Q And there could be outliers -- by definition, there are outliers beyond either end of that interquartile range, correct?

A By definition, that's true.

Q And you also looked at the amount of time it took manufacturers of TAVR-AS devices to go from pivotal trials to FDA approval, correct?

A Yes, that was part of my analysis.

Q When you looked at TAVR-ASs, you observed a wide variation in the timing that it took them to get through the pivotal trial and PMA process, correct?

A Yes. It was from about three to seven years for the TAVR-AS devices.

Q And Medtronic was about three years to get through the entirety of the pivotal trial and PMA approval process,

correct?
A Yes. The Medtronic device used U.S. data for that whole process, but yes.
Q And Abbott took nearly seven and a half years to go from the start of their pivotal trial to PMA approval, correct?
A Yes. That was on the chart that we looked at earlier.
Q And so even for two devices designed to treat the same disease, you can see a variation of years in the timing for pivotal trials and the PMA approval process between those two devices, correct?
A In looking at the length of time for the pivotal trials and the PMA approval process, yes.
Q We will come back to be those time lines in just a moment. I would like to ask you about -- you described them as ex-U.S. developers of TAVR-AR devices. Do you recall testifying about that?
A Yes.
Q As part of your work in this case, you looked at whether there are companies other than JenaValve and Edwards that are working on TAVR-AR treatments, correct?
A Yes. That's listed in my report, yes.
Q Okay. And, in fact, you identified at least seven companies around the world other than JenaValve and Edwards that are developing TAVR-AR devices, correct?
A According to the discovery documents in this case, yes.

Q I would like to, if we could, please, pull up a demonstrative that we created, and this is based on information from your report, Dr. Kesselheim. And if you, please -- do you have a copy of your report in front of you?
A I believe it's in this binder.
Q Please turn to page 35 of your report, in particular footnote 212. It's also paragraph 94.
The reason I'm asking you that is we prepared this demonstrative that summarizes the information in your report about the companies developing TAVR-AR devices around the world. I would like you to, if you don't mind, take a moment, look at this demonstrative, and let me know if it looks like an accurate summary of the information you included in your report.
A Okay.
Q Okay. All of these companies that you list are either in clinical studies for TAVR-AR devices or they have already obtained commercial approval outside the United States, correct?
A The first row received approval in China in 2025, and the rest of them are in testing in various places around the world.
Q And all testing involving testing in human patients, correct?
A Yes.

Q Okay. Any of these companies could have an IDE approval within a matter of a few months to conduct clinical trials in the U.S., is that correct?
A Well, no, I don't think that that's necessarily -- I didn't look at that. And I think that a lot depends on things like the data and the quality of it that the FDA would review as part of that process.
Q Have you done any examination of the quality of the data possessed by these companies that are undergoing clinical trials outside the U.S.?
A That wasn't part of my report.
Q Okay. Can you provide any assessment of how long it would take any of these companies to get IDE approval to conduct clinical trials in the U.S.?
A All of these companies are before the FDA approval process, and I did not look at that -- I did not do that analysis as part of my report.
Q And you don't know either way how long it will take these companies to get an IDE approval to start conducting clinical trials in the U.S., is that fair to say?
A I did not look at the specific time it might require for one of these companies, but again, in my report, I laid out the principles for what it requires to get an IDE approval. That was what that part of my report was about.
MR. LIPTON: Can we pull up, please, Mr. McCloud,

page 236 of Dr. Kesselheim's testimony; 236, lines 18 to 23, please.

BY MR. LIPTON:

Q I asked you in your deposition last week, I asked you:

But you don't know either way how long it will take these companies to get an IDE approval to start conducting clinical trials in the U.S., is that fair to say?

And you answered, I did not assess that as part of this report.

Did I read that correctly?

A Yes.

Q Before the middle of 2023, JC Medical had done clinical trials outside the United States, but it had not started a U.S. clinical trial, correct?

A I'm sorry. Hold on one second. Can you repeat that question.

Q Sure. Before the middle of 2023, JC Medical had done clinical trials outside the United States, but it had not started a U.S. clinical trial, correct?

A I don't know that specifically, but I'm happy to review the details of it if you would like.

Q We talked about that a moment ago in your report, did we not?

A Was that on the time line that we looked at in the closed session?

Q It was the time line we looked at a few moments ago in my exam.
A Where was that?
MR. LIPTON: That's paragraph 80, please, of Dr. Kesselheim's report.
MS. SEO: Your Honor, I apologize for interrupting. It seems like Dr. Kesselheim is having trouble hearing.
Can you hear what Mr. Lipton is saying?
THE WITNESS: The last couple questions came quickly on the top of the last one, so I was having trouble hearing the beginning of it. It's not so much the volume as it is the speed.
MR. LIPTON: I will try to be clearer and slower.
BY MR. LIPTON:
Q Let me ask it this way. Before the middle of 2023, JC Medical had not started a U.S. clinical trial, is that correct?
A That's correct.
Q Okay. So in terms of the pathway through the FDA approval process, as of mid 2023, the only step that JC Medical had done that the other seven developers of TAVR-AR devices that we saw on your report -- the only step they had not done -- strike that.
The only step that JC Medical had done that the other seven companies had not done as of mid 2023 was that

JC Medical had an IDE application on file, is that correct?
A I mean, that's a pretty big step, but yes.
Q Okay. And JC Medical got its initial IDE approval in August of 2023 and, we talked earlier, got its approval to start a U.S. pivotal trial in May 2024, about nine months later, correct?
A Yes.
Q Okay. Are you aware of any reason why the other companies developing TAVR-AR devices around the world couldn't get through the feasibility stage on the same time line that JC Medical did?
A I didn't assess that as part of my report.
Q Okay. If Medtronic were to acquire one of the other TAVR-AR devices around the world that we saw in your report, get through the feasibility study on the same time line that JC Medical did, about nine months, and then get through the pivotal trial and the PMA process on the same time line that Medtronic did with its TAVR-AS device, you would be talking a total of about four years, is that right?
A I mean, that's a lot of hypotheticals. Again, the possibility of that happening or what would happen with a Medtronic acquisition like you describe is not something that I reviewed. So I think that's a complicated question that I would have to review which was not part of my report.
Q Okay. One year for a feasibility study just like

JC Medical, right?
A I don't know -- I'm not sure what you mean.
Q Is that possible?
A So JC Medical had a -- it passed through its feasibility study phase in about a year.
Q And Medtronic did the pivotal trial stage and PMA approval stage in about three years in the case of TAVR-AS, correct?
A Right, but that doesn't mean the pivotal trial phase in that stage was comparable to the type of data that it would have gotten in the TAVR-AR phase.
Putting those things together, I don't think, is necessarily reasonable because the timing of the pivotal trial phase can be dependent on the kind of information that one collects during the feasibility study phase. So, you know, I think that's a hard comparison to make.
Q You showed us in your analysis that the timing of the pivotal trial stage and the PMA approval stage, you can have a very wide variation, correct?
A Yeah. I mean, looking at the record from high-risk devices approved over the last few decades, there is some variation, yes.
Q Variants of four years from two devices in the TAVR-AS example that you looked at, correct?
A Yes.

Q Okay. And you found two years' variation in the interquartile range of your study of all high-risk medical devices in the last year, correct?
A For the pivotal trial and PMA approval faces, yes.
Q Would you agree it's very difficult to predict the timing of FDA approval of a medical device that's, let's say, early in the pivotal stage process?
A Again, from my review, based on my analysis and the other data, the FDA PMA approval process takes about five to ten years on average.
Q You saw in the case of Medtronic, it took three years, correct?
A Again, that's an average. Medtronic, the three years was only the PMA approval and the pivotal trial phase. There were phases before that as well. So that's -- so again -- but again, it's just an average range, and that's, I think, what my analysis showed.
Q We are now in late 2025. If Medtronic were to buy one of these companies, go through a feasibility study in the time that JC Medical did, go through the pivotal trial and the PMA process on the pace that Medtronic itself did and TAVR-AS, that's four years, you are talking late 2029 or 2030 to have FDA approval for a TAVR-AR device in the U.S., correct?
A Again, the analysis was not part of what I did, so I

don't know -- I think that's a complicated question that I would have to -- that would involve -- that might involve some analysis that I didn't do.

Q Very difficult to predict the timing or likelihood of FDA approval of devices four years or more out, is that correct?

A Again, I think that the analysis that I did do provides some guidance as to the length of time it takes for high-risk devices to go through the various guideposts of the FDA approval process, but I did not apply that to the particular circumstances of the hypotheticals that you are talking about.

Q Can you provide any likelihood that the J-Valve device will achieve FDA approval before another device brought by another manufacturer in the future?

A That wasn't something I analyzed.

Q Okay. Let's talk about your opinions about the use of ex-U.S. data for the FDA approval process in the U.S.

MR. LIPTON: And let's pull up, please, Mr. McCloud, paragraph 15 of Dr. Kesselheim's report, please.

BY MR. LIPTON:

Q Okay. In 15, in the boldface sentence, you write, it is rare for high-risk medical devices to rely solely on clinical data obtained outside the United States in proceeding through the FDA approval process.

Did I read that correctly?
A Yes.
Q And the word solely in that sentence is doing a lot of work, is it not?
A Well, that's the conclusion I reached based on my analysis.
Q Based on the information you have studied, it's normal for high-risk medical devices to rely on a mixture of ex-U.S. and U.S. data for the FDA approval process, is that correct?
A Yes, with U.S. data as the primary data that the FDA relies on for approval.
Q And you studied the use of U.S. and ex-U.S. data and the approval process for TAVR-AS devices, correct?
A Yes.
MR. LIPTON: Let's pull up, if we could, please, Mr. McCloud, paragraph 113 of Dr. Kesselheim's report on page 45.
And in the third line, you wrote, six of the seven original TAVR-AS PMA approvals included both and ex-U.S. data in their submissions to the FDA, is that correct?
A Yes.
Q And in the first line of that paragraph, you wrote, all six TAVR-AS devices that received FDA PMA approval were first commercialized in European countries, is that correct?

A Yes.
Q And you tell us in your report and in your testimony earlier that you expect the TAVR-AR business to develop in a manner similar to the TAVR-AS business, is that correct?
A That's what the parties in this case suggested.
Q You offered that as your opinion, did you not?
A Well, based on the estimates from the parties in this case, yes.
Q So it would be consistent with what you observed in TAVR-AS for developers of TAVR-AR devices to start with clinical trials and approvals outside the U.S. and then move into the U.S. approval process, correct?
A I'm sorry. Can you ask that question again.
Q It would be consistent with what you observed in TAVR-AS for the developers of TAVR-AR devices to start with clinical trials and approvals outside the U.S. and then move into the U.S. approval process, correct?
A That would be consistent, yes.
Q Okay. So if someone wanted to understand the devices that are under development for TAVR-AR, if they looked only at the companies that have already started clinical trials in the U.S., they would miss at least seven companies that are already in the clinical trial process outside the U.S., correct?
A But the important point for getting those devices

approved in the U.S. by the FDA is the extent to which they have entered the FDA approval process, which in your hypothetical scenario they didn't do. So they have not -- the companies that you are describing in your question have not yet started the FDA approval process.

Q And any or all of the seven companies could be in the FDA approval process in a matter of months, correct?

A In order to do that, they would have to file and get approved an IDE application, which I am not aware that any of them have done, but you know, I don't have an estimate for how long that could take.

Q It could take a matter of months, correct?

A I don't have an estimate for that.

Q Okay. Let's look at paragraph 18B of your report, please.

MR. LIPTON: If we can pull that up, please, Mr. McCloud.

BY MR. LIPTON:

Q You wrote, Doctor, in paragraph B, based on my experience, expertise, and the analysis done for this report and the materials available to me, the post-PMA approval experience of TAVR-AS provides a reasonable guide for what we may expect from TAVR-AR in the future.

Is that one of your opinions in this case, Doctor?

A Yes.

Q You observed that post-PMA approvals in TAVR-AS led to TAVR-AS devices being available to more patients through expanded indications, correct?
A The supplemental PMA approvals, is that what you mean? Yes.
Q Yes, Doctor.
And you are aware that Edwards used innovations and expanded indications in TAVR-AS to reach more patients with its TAVR-AS devices, correct?
A Well, there was -- you know, there were a lot of changes to the TAVR-AS devices after approval as registered through the supplemental PMA applications, and some of those involved expanded indications of the TAVR-AS devices.
MR. LIPTON: Okay. Let's turn, please, to slide 18 of Dr. Kesselheim's demonstratives.
BY MR. LIPTON:
Q So in this chart, Dr. Kesselheim -- you talked about this charter earlier, correct?
A Yes.
Q In this chart, you are showing the number of PMA supplements in each year for each of these devices, correct?
A Yes.
Q And you told us that PMA supplements are a measure of changes in these devices which can be a measure of innovation, correct?

A Yes.
Q For the years 2012 and 2013, you observed about 20 PMA supplements each year for Edwards with its Sapien device, correct?
A That's the yellow line, yes.
Q And during the 2012 to 2013 time period, you were also aware that Edwards was working on next generation Sapien devices, the Sapien XT and Sapien 3 devices, correct?
A Yes. And Medtronic was working on its product during those years as well.
Q Okay. And how many TAVR-AS competitors had commercial approval in the U.S. during that 2012 and 2013 time period?
A Well, just the Edwards Sapien had FDA approval, but the Medtronic TAVR-AS device was in its pivotal trials.
Q Okay. No one other than Edwards had approval in that 2012-2013 time period, correct?
A Correct.
Q And you testified earlier about -- you talked about innovation and the presence of multiple manufacturers, correct?
A Yes.
Q So when you mean multiple manufactures present, you don't mean multiple manufacturers that have FDA approval, correct?
A Well, this chart, again, just to be clear, this chart is

about post-approval changes and does not register the innovation or evaluate the innovation that's going on for these approved devices before they were approved for which we know that the Medtronic device was in FDA development as a result of conducting its pivotal trial during those years.

Q Okay. And you are aware that Edwards was working on its next generation devices, Sapien XT and Sapien 3, for years before Medtronic received FDA approval for its CoreValve device, correct?

A Yes.

Q You are also aware that Edwards was working on its next generation Sapien XT device before Medtronic even began U.S. clinical trials, correct?

A I don't remember that specifically.

Q Okay. So let's look at tab B in your binder, please, Doctor. And this is an article titled Edwards Lifesciences announces first human implants of next generation transcatheter heart valve. It's dated March 5, 2008.

Do you see that, Doctor?

A Yes.

Q Now, let's look at tab C in your binder.

MR. LIPTON: Can you match that up, Mr. McCloud?

BY MR. LIPTON:

Q Tab C in your binder is an article from February of 2009, so it's almost a year later, that says CoreValve, Inc.

to be acquired by Medtronic, Inc. for 700-plus million.

Do you see that?

A Yes.

Q And the CoreValve product became Medtronic's first TAVR-AS product, is that correct?

A Yes.

Q And if we look on the second page of that article, they talk about CoreValve. It says, the CoreValve revalving system -- tell me when you are there. I'm at the last substantive paragraph on page 2.

The CoreValve revalving system is not currently available in the USA for clinical trials or for commercialization.

So at the time Edwards was doing first in human implantations for its next generation device, Medtronic or its predecessor company had not even begun clinical trials in the U.S., correct?

A Again, I don't know that I have seen these documents before. Is the one in tab B -- again, I'm not sure exactly where it says it relates to the XT or 3. Is that -- is that somewhere in the second page?

Q I don't know. It says it in that article, Doctor. If you aware of that -- are you aware of when the Sapien XT was first implanted in human subjects?

A I am not aware of that.

Q If it was in 2008, would that tell you Edwards was developing its next generation Sapien device before any other competitor had even begun U.S. clinical trials?
A If that's the case, then yes.
MR. LIPTON: Okay. We can pull that down, please. Thank you, Mr. McCloud.
BY MR. LIPTON:
Q I would like to switch subjects, Doctor, to an article that you wrote in 2014. I believe it's in your binder at tab 298.
MR. LIPTON: Mr. McCloud, that's DX298.
BY MR. LIPTON:
Q Doctor, is this an article that you coauthored?
A Yes.
Q This is an article about the development of coronary artery stents, which was based on interviews you and your colleagues conducted with people involved in the development of those products, is that correct?
A With the early physician inventors, yes.
Q Okay. And the article reports your findings from those interviews, correct?
A Yes.
Q And one of things that you studied was the role of large medical device companies in connection with developing innovative medical devices, correct?

A That was one of the topics that came up in the interviews, yes.
Q One of your findings was that large medical device companies typically came into the device development process after the initial innovation work was done by smaller innovators, correct?
A In the case of this article, which was, again, about individual physician inventors and their attempt to push forward this new stent technology, they often -- in this article, one of our findings was that these initial inventors often took the stents, you know, took the stents fairly far along in their development before they connected with larger medical device companies.
Q These weren't individual people, like, working out of their garages, were they?
A Actually, some of them actually were working out of their garages, yeah.
Q Let's look on page 3 of the article, on the top left, and there's a paragraph that starts in boldface, the Wallstent and Multi-link stent. Do you see that, Doctor?
A The top left of page 3?
Q Yes.
A Yes, I see that.
Q If you go about six lines down, it says, initial -- see the sentence starting initial prototypes?

A Initial prototypes, yes.
Q Initial prototypes in animal studies were supported by the university. And that's the University of Lausanne in Switzerland. Do you see that?
A Yes.
Q They were supported by the University's experimental surgery department and a grant from the Swiss National Fund. Do you see that?
A Yes. The Swiss National Fund is like the equivalent of the National Institute of Health for the U.S.
Q So this developer of a stent wasn't working out of his garage, correct?
A No, this one wasn't. It was Palmaz, I believe, who was doing a lot of work in his garage.
Q In your paper, the large medical device manufacturers that you observed acquiring the small innovators in the coronary stent space included Medtronic, Boston Scientific, and Johnson & Johnson, correct?
A Where is that? Where are you looking on that specifically? I'm sorry. Can you reask that question.
Q Sure. In your paper, the large medical device manufacturers that you observed acquiring small innovators included Medtronic, Boston Scientific, and Johnson & Johnson?
A I believe that that's right, yes.

Q And when the large medical device companies became involved, they provided financial resources and engineering support to the innovators, correct?
A Yes. A lot of these innovators tended to be based in academic medical centers and weren't situated to manufacture devices at scale.
Q And the large device manufacturers provided necessary support in organizing clinical trials and negotiating the FDA process, correct?
A I believe that was one of our conclusions in this case.
Q The large medical device companies provided their existing sales channels to deploy the technology, correct?
A Again, these individual physician inventors didn't have their own sales forces.
Q And the large medical device companies provided support for the manufacturability of the products to enable to be produced at scale, correct?
A Again, I believe that's one of the conclusions from this paper, yes.
Q Have you read the testimony in this case about how JenaValve and Edwards expect Edwards to provide needed support to JenaValve in all of those areas?
A That wasn't something that I analyzed in this case.
Q Based on your research into the coronary stent business, the resources and knowhow that large medical device

companies provided were important in helping to bring early-stage innovations forward, get them through the FDA process, and make them commercially available and on a large scale, is that correct?

A Those were things that these individual physician inventors couldn't do.

Q Is the answer to my question yes?

A So yes.

Q You would agree that it is a normal step in the development of medical devices for an innovator to be acquired by a large medical device manufacturer, correct?

A Well, I mean, that is what we found in this coronary artery stent case, yes.

Q In the interviews for your study in the coronary stent business, you heard from the innovators that they initially had difficulties getting these large medical device companies to be interested in the devices they were developing, correct?

A Yes. That was a common theme we heard, yes.

Q And eventually, the large device companies became involved, right?

A In each of the cases, yes, eventually that did happen.

Q So if we look at page 5 of your paper, in the right-hand column in the second full paragraph -- I apologize for the small font. It's bigger on the screen.

A Okay. I'm there.
Q I apologize. Here we go.
MR. LIPTON: Thank you, Mr. McCloud.
BY MR. LIPTON:
Q In that paragraph, you wrote, established companies and venture capitalists were and remain generally risk averse regarding the highest risk and most innovative medical technology, correct?
A Yes, that's from the first sentence there.
Q So now let's flip back to page 3 of your paper, on the right-hand side under the heading role of industry. In the first paragraph about five lines up from the bottom, there's a sentence that starts with the word finally. Do you see that?
Now it's highlighted on the screen.
A Yes.
Q You wrote, finally, according to interviewees, many companies perceived substantial business risks. According to one inventor, consultants from McKinsey & Company provided a strong recommendation to Johnson & Johnson against investing in the Palmaz-Schatz stent believing the market size to be too small.
Do you see that?
A Yes. That's strike one million against McKinsey.
Q In fact, the coronary stent business ended up being a

multibillion-dollar business, correct?
A Yes.
Q Did you read the testimony -- strike that. That was confidential. I won't ask that.
In the coronary stent case that you studied in this article, once the market opportunity was established, all of the device manufacturers that you listed in your report eventually made large investments in the space, correct?
A I don't know that we analyzed that as part of the report, like the size of the investment. We just analyzed the movement of these devices from individual inventor ultimately to their commercialization with large companies.
Q Okay. But once the market opportunity was established, all of those device manufacturers made investments in the space and moved into it, correct?
A I believe so.
Q Okay. And that market grew into a multibillion-dollar business with multiple competitors developing innovative devices, correct?
A Again, that wasn't part of what we studied in this report.
Q But you observed -- in the TAVR-AS business that you did study in this case, you observed, after Edwards established the market opportunity there, you observed entry into that business from Medtronic, Abbott, and Boston Scientific,

correct?
A Well, I mean, in the TAVR-AS space, Medtronic, Abbott, and Boston Scientific all had their devices approved by the FDA after -- you know, in terms of number of years after Edwards' device was approved, but -- and we -- as part of my analysis, I also looked at the time when those companies acquired their device in relation to when the device was approved. But I don't think I looked at specifically the question that you are asking.
Q After Edwards was moving forward in the clinical trial process for its Sapien device, you saw entry into the TAVR-AS business from Medtronic, Abbott, and Boston Scientific, correct?
A I think that you saw FDA approval of devices from those companies, yes.
Q And you saw them make acquisitions and move into the TAVR-AS business after Edwards started with the clinical trial process, correct?
A Well, I think that that's right as my recollection is to the specific dates of the acquisition with respect to the clinical trials, so I think that that's right.
MR. LIPTON: Let's pull up page 81, line 7 to 13 of Dr. Kesselheim's deposition from last week.

BY MR. LIPTON:

Q I asked you:

So after Edwards was moving forward in the clinical trial process for its Sapien device, you saw entry into TAVR-AS from Medtronic, Abbott, and Boston Scientific, correct.

And you said, yes, yes.

Did I read that correctly?

A You read that correctly, but again, I think that in this case, I think what we are talking about is FDA approval when you mean entry into. I guess that's what I am trying to think more about right now.

Q One of your opinions in this case is that the TAVR-AS experience provides a reasonable guide for TAVR-AR, is that correct?

A Yes.

MR. LIPTON: Thank you, Dr. Kesselheim. I have no further questions.

THE COURT: Madam court reporter, do you need a break?

Go ahead.

MS. SEO: Thank you, Your Honor. We have a couple of additional questions for Dr. Kesselheim.

REDIRECT EXAMINATION

BY MS. SEO:

Q Dr. Kesselheim, early in that line of questions from Mr. Lipton, he had suggested that it was human clinical data that was necessary in support of an IDE application. Can the clinical data in support of the IDE application come from preclinical data?

A I'm sorry. Can you ask your question one more time.

Q Sure. Can the data in support of an IDE application, can that be from preclinical data?

A Yes.

Q And preclinical data is not necessarily in human clinical data, correct?

A Correct. Preclinical data can be data from laboratory studies or animal studies.

Q And earlier Mr. Lipton had asked you about the likelihood that JenaValve would be able to receive FDA approval in light of its deficiency letter.

Do you have any additional thoughts on the likelihood of JenaValve's approval in light of its deficiency letter?

A Again, as I was trying to explain to Mr. Lipton, deficiency letters are very common in the FDA approval process. Based on FDA's data, you know, anywhere from 70 to 90 percent of them get them in a year for a new PMA application. And based on FDA's data, you know, 70-, 80-plus percent of applications for high-risk medical

devices are approved.

So all I was trying to explain was that, you know, again, this is a very normal part of the process that occurs for a lot of devices that are approved by the FDA, and I think that was what I was trying to explain.

MS. SEO: Could we please pull up paragraph 113 or could you please turn to paragraph 113 of your expert report, your initial expert report, Dr. Kesselheim. It's on page 45.

Mr. Lipton had read part of a sentence of paragraph 113 beginning with six of the seven. Do you mind reading us the full sentence there. I believe it is the third sentence of paragraph 113.

A Six of the seven original TAVR-AS PMA approvals included both U.S. and ex-U.S. data in the primary and supplemental clinical data sections of their SSEDs while one from Medtronic relied solely on U.S. data.

Q Thank you, Dr. Kesselheim.

MS. SEO: Now, could we pull up slide 23, please, from the slide deck for the demonstrative for Dr. Kesselheim.

BY MS. SEO:

Q Dr. Kesselheim, are you familiar with Medtronic's TAVR-AS device?

A I'm sorry. I thought something was going to come up.

There it is.

Sorry. Can you ask your question again.

Q Yes, of course.

Are you familiar with Medtronic's TAVR-AS device?

A Yes, it's on the third line here.

Q Is that the CoreValve system?

A Yes.

Q Currently known as Evolut?

A Yes.

Q And does this chart show that Medtronic's CoreValve device was approved solely based on U.S. clinical data?

A Yes, U.S. pivotal trial data. That was -- Medtronic used only U.S. pivotal trial data to get its approval of its TAVR-AS device.

MS. SEO: Could we please turn to slide 21 of this demonstrative, please.

BY MS. SEO:

Q This shows that Medtronic acquired CoreValve in 2009, is that correct?

A Yes.

Q Are you aware whether Medtronic's TAVR-AS device, CoreValve, prior to its acquisition, if it was approved outside of the U.S. in any jurisdiction?

A I believe it was.

Q And where was it approved?

A In Europe.

MS. SEO: And turning back to slide 23, please.

BY MS. SEO:

Q And even though Medtronic's CoreValve device was approved in Europe, did they use that data in support of their PMA application?

A No. In seeking FDA approval of their high-risk device, they began the FDA approval process and obtained pivotal trial data from an exclusively U.S. trial that then they used to support approval of their device.

THE COURT: So none of these AS devices used data from China?

THE WITNESS: Correct. None of them used pivotal trial data or supplemental data to support their pivotal trials from China, yes.

MS. SEO: We can take down the demonstrative slide. Thank you.

BY MS. SEO:

Q Now, earlier today we had discussed the FDA requirements, the regulatory requirements, for the use of ex-U.S. data in clinical data approvals. Are those FDA standards under the regulatory requirements, are they the same for clinical data submitted for an IDE and for a PMA and for all FDA regulatory approval purposes?

A Well, I think the principles are the same in terms of

what the FDA is looking for. Obviously the specifics are going to be different because, you know, an IDE is -- you know, can be based on purely laboratory and animal data, whereas a PMA approval can be -- is based on trial data. So the particulars are going to be, you know, relevant to data collected in each of those settings. But the principles about the, you know, the validity of the data, the reliability of it, the generalizability of it to the U.S., the quality of it, and the quality of the collection of it, all of those things are the principles that the FDA evaluates when it evaluates ex-U.S. data at any of those stages.

Q Earlier Mr. Lipton showed you articles at tab A, tab B, and tab C of your binder. Had you seen any of these articles before today?

A No, I don't think so.

Q Did Mr. Lipton give you the opportunity to read any of them before he asked you questions?

A There wasn't a lot of time, no.

Q Turning to DX0298, which was your coronary artery stent article, Mr. Lipton asked you several questions about this article.

You have mentioned individual physician inventors a couple of times. What are individual physician inventors?

A They are literally that. They are individual physicians

who get an idea about something that they want to address in the care of patients and then undertake the process to try to invent a, in this case, a device that would try to help their patients.

In this case, these were generally cardiologists attempting to address the issue of how to deal with heart attacks in needing to, you know, keep the coronary artery blood flow through the coronary arteries.

Q What was your overall thesis of that paper?

A Well, I mean, I think some of the key theses you can see there if you highlight the conclusion section, that these were, you know, individual inventors developing ideas for dividend models of coronary stents and that these individuals saw the need for their stents in their clinical practice and developed their own prototypes, some of them with support of their academic medical center in which they worked. And then ultimately, you know, at later stages in the development, partnering with companies that, you know, offered manufacturing and sales support that these doctors didn't have themselves.

MS. SEO: We can take that down. Thank you.

BY MS. SEO:

Q Dr. Kesselheim, are you aware of any ex-U.S. TAVR-AR device that has plans to pursue FDA clinical trials?

A I haven't seen any evidence of that in the documents

discovered in this case.

MS. SEO: Thank you. No additional questions.

THE COURT: Thank you, Doctor.

THE WITNESS: Thank you.

All right. We will take a ten-minute break.

(A recess was taken at 4:20 p.m.)

THE COURT: Do we have enough people to start the videos?

MS. HALL: We will need to seal the courtroom.

MR. SHORES: Yes.

(The following was heard in closed session.)

(The hearing adjourned at 5:37 p.m.)

- - -

C E R T I F I C A T E

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

11/21/25

s/ Tammy Nestor
Tammy Nestor, RMR, CRR
Official Court Reporter
333 Constitution Avenue NW
Washington, D.C. 20001
tammy_nestor@dcd.uscourts.gov

MR. LIPTON: [28] 10/23 37/6 40/19 47/11 48/6 48/19 50/3 53/24 55/2 55/8 56/2 57/17 59/9 60/12 60/21 64/25 66/4 66/13 70/19 71/16 73/16 74/14 76/22 78/5 78/11 83/3 85/22 86/17
MR. SHORES: [10] 37/9 93/10 93/14 93/21 94/1 94/4 94/9 94/20 95/5 95/7
MR. TYMKOVICH: [1] 7/10
MS. HALL: [8] 93/9 93/17 93/25 94/10 94/14 94/18 94/22 94/25
MS. SEO: [18] 7/12 7/21 10/2 10/18 18/3 30/25 31/5 31/17 36/25 66/6 86/22 88/6 88/19 89/15 90/2 90/16 92/21 93/2
THE COURT: [36] 7/11 7/22 10/22 10/24 12/10 12/19 30/4 30/6 31/2 31/7 34/18 34/20 35/6 35/18 36/2 37/5 37/7 37/10 40/18 40/21 86/19 90/11 93/3 93/7 93/12 93/15 94/2 94/5 94/7 94/12 94/15 94/21 94/24 95/3 95/6 95/8
THE COURTROOM DEPUTY: [3] 7/15 7/20 55/6
THE WITNESS: [10] 12/11 12/21 30/5 34/19 34/22 35/9 35/22 66/9 90/13 93/4

0

02569 [1] 1/3

1

11/21/25 [1] 95/18
113 [5] 71/17 88/6 88/7 88/11 88/13
1138 [1] 2/4
13 [1] 85/22
15 [3] 57/18 70/20 70/22
16 [2] 54/1 59/20
1700 [1] 1/23
18 [2] 65/1 74/14
185 [1] 57/18
18B [1] 73/14
196 [2] 53/25 54/1
197 [2] 53/25 54/1

2

20 [1] 75/2
200 [1] 49/4
20001 [2] 2/12 95/20
20006 [1] 2/8
20036 [1] 1/24
20037 [1] 2/4
2008 [2] 76/18 78/1
2009 [2] 76/25 89/18
2012 [3] 75/2 75/6 75/12
2012-2013 [1] 75/16
2013 [5] 47/15 75/2 75/6 75/12 75/16
2014 [1] 78/9
2022 [1] 49/3
2023 [8] 59/17 59/20 65/12 65/17 66/15 66/20 66/25 67/4
2024 [4] 59/23 60/1 60/3 67/5
2025 [4] 1/6 54/25 63/20 69/18
2029 [1] 69/22
2030 [1] 69/23
20580 [2] 1/16 1/20
2099 [1] 2/8
21 [3] 1/6 55/3 89/15
2112 [1] 2/3
212 [1] 63/7
23 [4] 60/22 65/1 88/19 90/2
236 [2] 65/1 65/1
24 [1] 57/18
25 [1] 95/18
25-02569 [1] 1/3
2500 [1] 49/5
25th [1] 61/8
283 [2] 54/20 54/22
298 [1] 78/10
2:02 [1] 4/1

3

3.2 [1] 61/5
30 [3] 46/16 49/10 49/11
30-day [1] 46/22
31 [1] 59/17
333 [2] 2/11 95/19
35 [1] 63/6

4

4.1 [2] 60/25 61/4
400 [1] 1/19
45 [2] 71/18 88/9
47 [2] 47/12 47/15
4:20 [1] 93/6

5

50 [1] 53/19
50 percent [2] 54/6 56/19
50-50 [1] 53/19
55 [1] 55/3
5:37 [1] 95/9

6

60 percent [1] 54/10
600 [1] 1/16
61 percent [3] 51/4 51/14 52/6
62 [1] 60/22
7
70 [2] 87/22 87/24
700-plus [1] 77/1
75 [1] 61/8

8

80 [2] 59/9 66/4
80 percent [2] 49/6 56/25
80-plus [1] 87/25
81 [1] 85/22

9

90 percent [1] 87/23
932 [1] 48/16
94 [1] 63/7

A

AARON [1] 3/6
Abbott [5] 62/4 84/25 85/2 85/12 86/5
ability [1] 44/21
able [3] 56/10 56/19 87/16
about [58] 41/10 42/21 43/3 43/13 43/22 44/9 44/10 44/21 45/18 45/20 47/3 48/17 50/5 51/17 51/25 54/12 57/6 57/20 57/22 58/2 58/12 60/8 60/9 60/15 61/9 61/22 61/24 62/14 62/16 63/10 64/24 65/22 67/5 67/16 67/19 68/5 68/7 69/9 70/12 70/17 70/17 74/17 75/2 75/18 75/18 76/1 77/8 78/15 79/7 79/24 81/20 83/12 86/10 86/12 87/15 91/7 91/21 92/1
above [2] 54/6 95/14
above-entitled [1] 95/14
academic [2] 81/5 92/16
according [4] 52/15 62/25 83/17 83/18
accurate [2] 63/13 95/13
achieve [1] 70/14
achieving [2] 50/6 57/13
acquire [1] 67/13
acquired [4] 77/1 82/11 85/7 89/18
acquiring [2] 80/16 80/22
acquisition [3] 67/22 85/20 89/22
acquisitions [1] 85/16
across [1] 50/17
actually [2] 79/16 79/16
additional [4] 56/15 86/23 87/18 93/2
address [3] 43/6 92/1 92/6
admitted [1] 95/9
affect [2] 51/6 51/23
after [9] 60/9 74/11 79/5 84/23 85/4 85/4 85/10 85/17 86/3
afternoon [3] 1/6 40/25 41/1
again [31] 41/8 43/21 51/15 53/21 54/8 54/14 56/12 56/22 57/14 57/15 60/2 64/22 67/20 69/8 69/13 69/16 69/16 69/25 70/7 72/13 75/25 77/18 77/19 79/7 81/13 81/18 84/20 86/9 87/20 88/3 89/2
against [2] 83/21 83/24
ago [7] 42/10 44/7 47/2 48/2 57/22 65/22 66/1
agree [2] 69/5 82/9
ahead [1] 86/21
al [1] 1/5
all [19] 43/7 44/13 45/4 45/14 45/20 63/16 63/23 64/15 69/2 71/23 73/6 81/22 84/6 84/14 85/3 88/2 90/24 91/10 93/5
almost [2] 44/13 76/25
alone [2] 44/2 44/4
along [1] 79/12
already [3] 63/17 72/21 72/23
also [8] 51/6 52/19 56/9 61/15 63/7 75/6 76/11 85/6
although [2] 46/25 60/2
am [6] 41/18 52/3 54/14 73/9 77/25 86/11
amount [3] 46/18 58/8 61/15
analysis [35] 44/20 44/24 45/4 46/2 46/11 46/18 46/23 47/9 49/25 50/13 52/11 52/14 53/5 53/14 53/17 53/23 54/16 57/23 57/25 58/5 58/8 58/9 58/15 60/17 61/18 64/17 68/17 69/8 69/17 69/25 70/3 70/7 71/6 73/20 85/6
analyze [4] 45/11 46/20 46/25 55/20
analyzed [6] 52/8 60/18 70/16 81/23 84/9 84/10
Anderson [1] 1/12
Andrew [1] 1/18
animal [3] 80/2 87/14 91/3
announces [1] 76/17
another [2] 70/14 70/15
answer [5] 45/16 45/18 63/15 82/7
answered [3] 54/8 56/14 65/8
any [27] 42/24 43/3 44/17 44/20 45/4 45/11 45/23 46/11 46/22 49/17 50/20 64/1 64/8 64/12 64/13 67/8 70/13 73/6 73/9 78/2 87/18 89/23 91/11 91/14 91/17 92/23 92/25
anywhere [1] 87/22
apologize [3] 66/6 82/24 83/2
appear [2] 49/20 49/20
APPEARANCES [2] 1/10 2/1
applicable [2] 52/22 53/7
application [19] 43/14 44/18 44/23 45/5 45/7 45/11 46/9 46/19 47/3 47/24 51/23 55/12 67/1 73/9 87/4 87/5 87/8 87/24 90/6
applications [3] 45/2 74/12 87/25
apply [3] 44/2 53/9 70/10
applying [1] 44/12
approval [76] 42/4 43/8 43/13 44/25 46/15 50/6 51/3 51/13 52/5 52/13 52/16 53/20 54/6 54/9 56/21 57/13 58/1 59/25 60/7 60/8 61/17 61/25 62/5 62/9 62/12 63/18 63/20 64/1 64/13 64/15 64/19 64/23 65/6 66/20 67/3 67/4 68/7 68/18 69/4 69/6 69/9 69/14 69/23 70/5 70/10 70/14 70/18 70/25 71/9 71/12 71/14 71/24 72/12 72/17 73/2 73/5 73/7 73/21 74/11 75/12 75/13 75/15 75/23 76/1 76/8 85/14 86/10 87/17 87/19 87/21 89/13 90/7 90/8 90/10 90/24 91/4
approvals [7] 71/20 72/11 72/16 74/1 74/4 88/14 90/21
approved [20] 49/4 49/7 53/11 56/25 60/18 61/3 68/21 73/1 73/9 76/3 76/3 85/3 85/5 85/8 88/1 88/4 89/11 89/22 89/25 90/5
approximately [1] 49/6
AR [22] 43/20 44/18 45/24 53/1 53/12 62/15 62/20 62/24 63/10 63/17 66/22

A
AR... [11] 67/9 67/14 68/11 69/23 72/3 72/10 72/15 72/20 73/23 86/14 92/23
are [68] 41/15 41/17 42/24 43/3 44/12 45/14 46/3 47/18 48/14 48/25 49/4 49/6 49/12 50/16 51/6 51/22 52/17 52/22 52/25 53/6 53/12 54/21 56/13 56/24 56/25 57/1 59/2 61/11 62/19 62/20 62/24 63/16 63/21 64/9 64/15 67/8 69/18 69/22 70/11 72/20 72/23 73/4 74/7 74/20 74/23 76/6 76/11 77/9 77/23 80/19 85/9 86/10 87/21 88/1 88/4 88/23 89/4 89/21 90/21 90/22 90/25 91/1 91/5 91/10 91/24 91/25 91/25 92/23
areas [1] 81/22
around [5] 62/23 63/10 63/21 67/9 67/14
arteries [1] 92/8
artery [4] 78/16 82/13 91/20 92/7
article [34] 47/5 48/10 48/14 48/23 49/3 49/18 49/21 50/10 50/11 50/18 52/16 52/22 53/16 53/22 54/15 57/15 58/10 58/11 58/20 58/24 76/16 76/24 77/7 77/22 78/8 78/13 78/15 78/20 79/7 79/10 79/18 84/6 91/21 91/22
articles [2] 91/13 91/15
as [78] 43/22 44/7 44/8 45/1 45/7 45/12 46/15 49/5 49/23 51/6 51/20 51/21 52/8 52/17 52/19 52/20 52/25 53/2 53/14 54/8 54/16 55/19 58/24 61/16 61/23 62/15 62/18 64/7 64/17 65/8 66/11 66/20 66/25 67/12 67/18 68/7 68/23 69/15 69/22 70/8 71/11 71/14 71/20 71/24 72/4 72/6 72/10 72/14 73/22 74/1 74/2 74/8 74/9 74/11 74/11 74/13 75/10 75/11 75/14 76/4 77/5 84/9 84/22 85/2 85/5 85/12 85/17 85/19 86/5 86/13 87/20 88/14 88/24 89/4 89/8 89/14 89/21 90/11
ask [10] 45/15 45/15 45/16 62/14 66/15 72/13 84/4 87/7 89/2
asked [9] 45/20 53/4 54/4 65/4 65/4 86/2 87/15 91/18 91/21
asking [2] 63/8 85/9
ASs [1] 61/19
assess [2] 65/8 67/12
assessment [1] 64/12
attacks [1] 92/7
attempt [1] 79/8
attempting [1] 92/6
August [2] 59/17 67/4
August 31 [1] 59/17
authorize [2] 43/24 46/12
authorizing [1] 43/17
authors [2] 47/2 49/19
available [5] 46/8 73/21 74/2 77/12 82/3
Avenue [5] 1/16 2/3 2/8 2/11 95/19
average [18] 46/23 48/3 50/9 50/16 50/21 50/24 51/4 51/8 51/14 51/22 52/6 52/16 53/15 58/12 58/25 69/10 69/13 69/16
averse [1] 83/6
aware [13] 52/3 59/2 67/8 73/9 74/7 75/7 76/6 76/11 77/23 77/23 77/25 89/21 92/23

B
back [6] 48/13 55/16 57/15 62/13 83/10 90/2
background [1] 41/11
Barrett [1] 1/12
based [22] 44/1 44/4 44/5 50/9 54/8 60/6 60/11 60/24 63/2 69/8 71/5 71/7 72/7 73/19 78/16 81/4 81/24 87/22 87/24 89/11 91/3 91/4
be [41] 44/1 44/4 44/5 45/5 45/25 46/4 46/16 49/11 49/20 49/20 50/20 52/9 52/10 55/6 56/10 56/19 58/16 61/11 62/13 66/13 67/18 68/14 72/9 72/14 72/18 73/6 74/24 75/25 77/1 81/4 81/16 82/10 82/17 83/22 87/9 87/13 87/16 91/2 91/3 91/4 91/5
became [3] 77/4 81/1 82/20
because [9] 44/14 52/2 53/1 53/10 54/21 56/6 56/10 68/13 91/2
become [1] 49/1
been [1] 41/21
before [19] 1/8 41/5 44/5 45/14 45/18 64/15 65/12 65/17 66/15 69/15 70/14 76/3 76/8 76/12 77/19 78/2 79/12 91/15 91/18
began [3] 4/1 76/12 90/8
beginning [3] 51/11 66/11 88/11
begun [2] 77/16 78/3
being [4] 41/21 47/21 74/2 83/25
believe [14] 42/12 42/20 48/19 50/23 51/8 63/5 78/9 80/13 80/25 81/10 81/18 84/16 88/12 89/24
believing [1] 83/21
best [1] 45/21
better [1] 48/1
between [2] 61/1 62/9
beyond [1] 61/12
big [1] 67/2
bigger [1] 82/25
binder [10] 48/10 48/13 54/20 54/22 63/5 76/15 76/21 76/24 78/9 91/14
bit [1] 43/21
blood [1] 92/8
boldface [2] 70/22 79/19
Boston [6] 80/17 80/23 84/25 85/3 85/12 86/5
both [2] 71/20 88/15
bottom [1] 83/12
break [3] 47/8 86/20 93/5
breakthrough [1] 52/18
bring [1] 82/1
brought [3] 42/1 42/3 70/14
business [12] 72/3 72/4 81/24 82/15 83/18 83/25 84/1 84/18 84/22 84/25 85/12 85/17
buy [1] 69/18

C
came [4] 49/19 66/9 79/1 79/4
can [44] 43/16 44/1 44/4 44/5 44/8 45/5 45/7 46/16 47/3 49/11 49/23 50/3 52/13 52/14 53/21 56/2 56/16 60/12 60/21 62/8 64/12 64/25 65/15 66/8 68/14 68/18 70/13 72/13 73/16 74/24 76/22 78/5 80/20 87/4 87/7 87/8 87/9 87/13 89/2 90/16 91/3 91/4 92/10 92/21
can't [6] 44/14 46/4 52/12 53/18 54/5 56/18
capitalists [1] 84/6
cardiologist [1] 41/17
cardiologists [1] 92/5
care [1] 92/2
case [36] 1/3 41/11 42/9 42/13 42/17 42/19 42/24 43/21 44/21 44/24 45/3 45/17 52/17 53/10 53/14 57/5 62/18 62/25 68/7 69/11 72/5 72/8 73/24 78/4 79/7 81/10 81/20 81/23 82/13 84/5 84/23 86/10 86/13 92/3 92/5 93/1
cases [2] 44/13 82/22
caveat [1] 44/9
center [1] 92/16
centers [1] 81/5
certainly [1] 51/5
certify [1] 95/13
chance [1] 53/19
changes [3] 74/10 74/24 76/1
channels [1] 81/12
characterizing [1] 48/1
chart [6] 62/6 74/17 74/20 75/25 75/25 89/10
charter [1] 74/18
China [3] 63/20 90/12 90/15
Chung [1] 1/14
circumstances [2] 54/11 70/11
citations [1] 49/23
cited [3] 50/16 53/16 58/20
Civil [1] 1/3
clear [2] 49/15 75/25
clearer [1] 66/13
Cleary [1] 2/2
clinical [51] 42/5 42/7 43/17 43/24 44/2 44/5 44/13 44/14 44/17 44/22 45/10 45/25 46/7 46/13 47/6 47/17 47/21 63/17 64/2 64/9 64/14 64/20 65/7 65/12 65/14 65/18 65/19 66/16 70/24 72/11 72/15 72/21 72/23 76/13 77/12 77/16 78/3 81/8 85/10 85/17 85/21 86/3 87/3 87/5 87/12 88/16 89/11 90/21 90/23 92/14 92/24
clinicians [1] 48/12
close [2] 43/12 53/15
closed [3] 4/2 65/25 93/11
coauthored [1] 78/13
cohort [1] 51/9
colleagues [1] 78/17
collected [1] 91/6
collection [3] 45/8 61/2 91/9
colleots [1] 68/15
COLUMBIA [1] 1/1
column [3] 48/18 48/22 82/24
come [9] 44/8 44/13 44/19 49/12 49/22 54/16 62/13 87/5 88/25
commercial [3] 56/21 63/18 75/11
commercialization [2] 77/13 84/12
commercialized [1] 71/25
commercially [1] 82/3
COMMISSION [3] 1/2 1/15 1/19
common [2] 82/19 87/21
companies [33] 62/19 62/23 63/10 63/16 64/1 64/9 64/13 64/15 64/19 64/22 65/6 66/25 67/9 69/19 72/21 72/22 73/4 73/6 78/24 79/4 79/13 81/1 81/11 81/15 82/1 82/17 82/20 83/5 83/18 84/12 85/6 85/15 92/18
company [5] 41/24 41/25 46/13 77/16 83/19
comparable [1] 68/10
comparison [1] 68/16
competition [2] 42/25 43/6
competitor [1] 78/3
competitors [2] 75/11 84/18
completed [2] 59/23 60/3
completion [2] 60/7 61/2
complicated [3] 52/10 67/23 70/1
concern [1] 44/10
conclusion [4] 52/10 53/6 71/5 92/11
conclusions [2] 81/10 81/18
conduct [3] 47/6 64/2 64/14
conducted [2] 47/21 78/17
conducting [3] 64/19 65/6 76/5
confidential [1] 84/4
connected [1] 79/12
connection [2] 44/20 78/24
consider [1] 51/21
consistent [3] 72/9 72/14 72/18
Constitution [2] 2/11 95/19
consultants [1] 83/19
Cont [1] 2/1
content [1] 55/17

C

contents [1] 45/11
CONTRERAS [1] 1/8
conversation [1] 48/11
copy [1] 63/4
CoreValve [11] 76/8 76/25 77/4 77/8 77/8 77/11 89/6 89/10 89/18 89/22 90/4
coronary [11] 78/15 80/17 81/24 82/12 82/14 83/25 84/5 91/20 92/7 92/8 92/13
CORPORATION [1] 1/5
correct [145] 41/3 41/6 41/15 41/17 42/11 42/12 42/19 42/20 42/22 43/1 43/7 43/15 43/18 44/2 44/3 44/4 44/6 44/7 44/23 45/6 46/4 46/9 46/14 46/19 46/20 46/24 47/18 47/22 48/4 48/5 49/10 50/1 50/2 50/7 50/10 50/14 50/18 50/22 51/4 51/14 52/7 53/7 53/16 53/20 54/7 54/25 55/7 55/24 56/7 56/11 56/21 58/2 58/5 58/8 58/9 58/13 58/17 58/23 59/4 59/14 59/17 59/21 60/1 60/10 60/11 60/19 60/25 61/6 61/9 61/13 61/17 61/21 62/1 62/5 62/10 62/20 62/24 63/19 63/24 64/3 65/14 65/19 66/17 66/18 67/1 67/6 68/8 68/19 68/24 69/3 69/12 69/24 70/6 71/10 71/14 71/21 71/25 72/4 72/12 72/17 72/24 73/7 73/12 74/3 74/9 74/18 74/21 74/25 75/4 75/8 75/16 75/17 75/20 75/24 76/9 76/13 77/5 77/17 78/18 78/21 78/25 79/6 80/12 80/18 81/3 81/9 81/12 81/17 82/4 82/11 82/18 83/8 84/1 84/8 84/15 84/19 85/1 85/13 85/18 86/6 86/15 87/12 87/13 89/19 90/13
correctly [5] 54/13 65/10 71/1 86/8 86/9
could [22] 47/11 48/6 48/16 49/21 51/6 53/24 54/19 54/22 55/2 57/20 57/21 61/11 63/1 64/1 71/16 73/6 73/11 73/12 88/6 88/7 88/19 89/15
couldn't [2] 67/10 82/6
counsel [3] 53/4 55/6
countries [1] 71/25
couple [4] 51/17 66/9 86/22 91/24
course [2] 52/17 89/3
court [4] 1/1 2/11 86/19 95/19
courtroom [1] 93/9
covered [1] 43/9
created [1] 63/2
CROSS [2] 3/2 40/23
CRR [2] 2/10 95/18
Crutcher [1] 1/23
currently [2] 77/11 89/8
cycle [4] 49/7 49/10 49/11 49/13

D

D.C [7] 1/4 1/16 1/20 1/24 2/4 2/12 95/20
Danziger [1] 1/12
data [60] 44/1 44/2 44/4 44/5 44/6 44/8 44/10 44/13 44/17 44/22 45/1 45/5 45/8 45/25 46/4 46/5 46/8 61/2 62/2 64/6 64/8 68/10 69/9 70/18 70/24 71/9 71/11 71/11 71/13 71/21 87/3 87/5 87/6 87/8 87/9 87/11 87/12 87/13 87/13 87/22 87/24 88/15 88/16 88/17 89/11 89/12 89/13 90/5 90/9 90/11 90/14 90/14 90/21 90/21 90/23 91/3 91/4 91/5 91/7 91/11
date [2] 61/2 61/2
dated [1] 76/18
dates [4] 59/13 59/13 60/11 85/20
day [1] 46/22
days [3] 46/16 49/10 49/12
DC [1] 2/8
dcd.uscourts.gov [2] 2/12 95/20
deal [1] 92/6
decades [2] 53/11 68/21
decades' [1] 51/17
decision [1] 49/15
deck [1] 88/20
Defendant [3] 1/6 1/21 2/2
deficiencies [2] 55/24 56/20
deficiency [11] 54/24 55/10 55/16 55/20 56/13 56/23 56/25 57/10 87/17 87/19 87/21
definition [2] 61/11 61/14
delayed [1] 49/11
DeMarchi [1] 1/11
demonstrative [6] 63/2 63/9 63/12 88/20 88/23 89/16
demonstratives [1] 74/15
department [1] 80/7
dependent [1] 68/14
depends [1] 64/5
deploy [1] 81/12
deposition [7] 41/2 46/6 54/1 57/3 57/18 65/4 85/23
derived [3] 51/9 51/17 52/25
describe [2] 45/7 67/22
described [1] 62/14
describing [2] 44/24 73/4
designation [1] 52/18
designations [1] 51/7
designed [1] 62/7
details [2] 56/23 65/21
determination [1] 54/12
determine [3] 45/9 49/22 55/21
develop [1] 72/3
developed [1] 92/15
developer [2] 45/23 80/11
developers [5] 46/7 62/15 66/21 72/10 72/15
developing [8] 62/24 63/10 67/9 78/2 78/24 82/18 84/18 92/12
development [12] 47/18 50/20 50/22 52/6 72/20 76/4 78/15 78/17 79/4 79/12 82/10 92/18
device [70] 41/24 41/25 42/1 42/3 42/6 42/8 42/10 42/18 43/6 43/15 44/18 44/18 44/21 46/6 46/13 50/20 51/1 51/2 51/7 51/10 51/12 51/24 52/5 53/2 53/15 61/3 62/2 67/18 69/6 69/23 70/13 70/14 75/3 75/14 76/4 76/9 76/12 77/15 78/2 78/24 79/3 79/4 79/13 80/15 80/21 81/1 81/7 81/11 81/15 81/25 82/11 82/16 82/20 84/7 84/14 85/5 85/7 85/7 85/11 86/4 88/24 89/4 89/11 89/14 89/21 90/4 90/7 90/10 92/3 92/24
devices [64] 42/15 43/9 43/20 43/20 47/18 48/11 50/17 50/24 51/9 51/18 52/15 53/1 53/11 53/12 53/12 56/25 59/1 60/18 61/3 61/16 61/23 62/7 62/10 62/15 62/24 63/10 63/17 66/22 67/9 67/21 68/23 69/3 70/5 70/9 70/23 71/8 71/14 71/24 72/10 72/15 72/19 72/25 74/2 74/9 74/11 74/13 74/21 74/24 75/8 75/8 76/3 76/7 78/25 81/6 82/10 82/17 84/11 84/19 85/3 85/14 88/1 88/4 90/11
did [52] 41/11 45/2 45/11 45/19 45/23 45/24 46/5 46/20 46/25 47/5 47/5 47/9 47/10 50/15 52/10 53/17 53/23 54/13 54/15 56/22 57/10 57/12 57/23 57/25 58/3 58/4 58/9 58/18 60/16 64/16 64/16 64/21 65/8 65/10 65/22 67/11 67/16 67/18 68/6 69/20 69/21 69/25 70/7 70/10 71/1 72/6 82/22 84/3 84/22 86/8 90/5 91/17
didn't [23] 41/11 44/20 45/4 45/17 45/19 47/8 47/9 50/13 54/10 55/20 56/6 56/11 56/12 57/4 57/14 58/7 58/15 64/5 67/12 70/3 73/3 81/13 92/20
different [1] 91/2
difficult [2] 69/5 70/4
difficulties [1] 82/16
DIRECT [1] 3/2
directly [1] 45/18
disagree [1] 49/17
discovered [1] 93/1
discovery [1] 62/25
discussed [3] 44/7 50/12 90/19
disease [1] 62/8
DISTRICT [3] 1/1 1/1 1/9
dividend [1] 92/13
do [39] 43/16 44/14 44/20 45/4 45/21 47/9 49/8 49/9 49/17 50/13 52/24 53/17 53/23 54/16 56/5 57/6 58/7 58/9 58/15 60/16 62/15 63/4 64/16 70/3 70/7 73/3 73/8 76/19 77/2 79/20 80/4 80/8 82/6 83/13 83/23 86/19 87/18 88/11 93/7
Doctor [22] 45/13 47/9 48/9 48/13 48/14 48/24 49/8 54/18 54/22 56/14 57/7 57/20 73/19 73/24 74/6 76/16 76/19 77/22 78/8 78/13 79/20 93/3
doctors [1] 92/19
documents [3] 62/25 77/18 92/25
does [5] 42/15 55/23 57/9 76/1 89/10
doesn't [3] 49/20 49/20 68/9
doing [4] 46/7 71/3 77/14 80/14
dollar [2] 84/1 84/17
don't [28] 43/6 44/2 45/18 48/2 48/3 49/19 49/23 55/17 56/5 56/9 59/5 63/11 64/4 64/18 65/5 65/20 68/2 68/12 70/1 73/10 73/13 75/23 76/14 77/18 77/22 84/9 85/8 91/16
done [17] 45/14 46/11 46/16 46/18 46/22 49/25 53/14 64/8 65/12 65/17 66/21 66/23 66/24 66/25 73/10 73/20 79/5
doubling [1] 49/2
down [7] 50/3 56/2 60/13 78/5 79/24 90/16 92/21
Dr [24] 40/25 47/12 53/25 54/13 55/3 59/6 59/9 60/22 63/3 65/1 66/4 66/7 70/20 71/17 74/15 74/17 85/23 86/17 86/23 87/2 88/8 88/20 88/23 92/23
Dr. [1] 88/18
Dr. Kesselheim [1] 88/18
Dunn [1] 1/23
during [5] 68/15 75/6 75/9 75/12 76/5
DX0298 [1] 91/20
DX298 [1] 78/11

E

each [5] 74/21 74/21 75/3 82/22 91/6
earlier [12] 43/21 50/12 52/21 59/6 62/6 67/4 72/3 74/18 75/18 87/15 90/19 91/13
early [9] 43/22 47/16 47/18 47/21 52/1 69/7 78/19 82/2 87/2
early-stage [2] 47/21 82/2
easier [1] 47/20
EDWARDS [20] 1/5 52/2 62/19 62/23 74/7 75/3 75/7 75/13 75/15 76/6 76/11 76/16 77/14 78/1 81/21 81/21 84/23 85/10 85/17 86/3
Edwards' [2] 52/4 85/5
efficient [1] 47/25
EFS [6] 48/23 49/1 49/2 49/4 49/6 60/2
either [6] 47/9 56/11 61/12 63/16 64/18

E

either... [1] 65/5
Elizabeth [1] 2/6
else [1] 45/19
enable [1] 81/16
encountered [1] 52/2
encountering [1] 51/11
end [2] 51/1 61/12
ended [2] 43/12 83/25
engineering [1] 81/2
enough [1] 93/7
enrolled [2] 49/5 59/19
enrollment [2] 59/23 60/3
entered [1] 73/2
entirety [1] 61/25
entitled [1] 95/14
entry [4] 84/24 85/11 86/4 86/11
equivalent [1] 80/9
Esquire [18] 1/11 1/11 1/12 1/12 1/13 1/13 1/14 1/14 1/15 1/18 1/18 1/21 1/22 1/22 2/2 2/6 2/6 2/7
established [4] 83/5 84/6 84/13 84/23
estimate [7] 46/11 47/5 48/3 50/22 53/13 73/10 73/13
estimated [1] 47/2
estimates [4] 50/17 53/21 53/23 72/7
et [1] 1/5
ethical [1] 42/13
Europe [2] 90/1 90/5
European [1] 71/25
evaluate [1] 76/2
evaluates [2] 91/11 91/11
evaluations [1] 47/17
Evan [1] 1/13
even [7] 53/18 56/18 62/7 76/12 77/16 78/3 90/4
eventually [3] 82/20 82/22 84/8
ever [8] 41/5 41/19 41/21 41/24 42/1 42/5 42/9 56/19
evidence [1] 92/25
EVIDENTIARY [1] 1/8
Evolut [1] 89/8
ex [10] 45/5 62/15 70/18 71/9 71/13 71/20 88/15 90/21 91/11 92/23
ex-U.S [10] 45/5 62/15 70/18 71/9 71/13 71/20 88/15 90/21 91/11 92/23
exactly [2] 49/15 77/19
exam [1] 66/2
examination [3] 40/23 64/8 86/24
example [4] 46/4 46/24 51/1 68/24
exclusively [1] 90/9
existing [1] 81/12
expanded [3] 74/3 74/8 74/13
expect [3] 72/3 73/23 81/21
experience [5] 49/6 58/25 73/20 73/22 86/14
experienced [1] 51/19
experimental [1] 80/6
expert [3] 47/12 88/7 88/8
expertise [1] 73/20
experts [1] 48/12
explain [3] 87/20 88/2 88/5
extent [4] 45/4 45/23 45/24 73/1

F

faces [1] 69/4
facilitate [1] 47/17
fact [4] 43/5 44/12 62/22 83/25
factor [1] 51/15
factors [3] 51/23 52/17 52/18
fair [2] 64/20 65/7
fairly [1] 79/12
familiar [3] 48/14 88/23 89/4
far [1] 79/12
FDA [74] 42/2 42/3 43/8 43/13 44/25 45/9 46/15 46/21 47/16 48/12 49/5 49/13 50/6 50/6 50/21 51/3 51/13 52/5 52/13 53/19 54/6 54/24 55/19 55/23 56/6 56/10 56/20 57/13 57/21 58/2 59/25 60/8 60/19 61/3 61/17 64/6 64/15 66/19 69/6 69/9 69/23 70/5 70/10 70/14 70/18 70/25 71/9 71/11 71/21 71/24 73/1 73/2 73/5 73/7 75/13 75/23 76/4 76/8 81/9 82/2 85/4 85/14 86/10 87/16 87/21 88/4 90/7 90/8 90/19 90/21 90/24 91/1 91/10 92/24
FDA's [5] 44/9 55/12 55/16 87/22 87/24
feasibility [19] 43/16 43/22 47/16 47/24 57/24 58/7 58/12 58/16 58/22 59/3 59/14 59/20 60/7 67/10 67/15 67/25 68/4 68/15 69/19
February [2] 59/23 76/24
February 2024 [1] 59/23
FEDERAL [3] 1/2 1/15 1/19
feel [1] 54/8
few [7] 44/7 47/1 53/11 64/3 66/21 68/21 73/21
fifth [1] 48/17
figure [4] 51/4 58/21 58/21 59/3
figures [2] 53/6 60/6
file [2] 67/1 73/8
filed [1] 45/3
final [1] 49/15
finally [2] 83/13 83/17
financial [1] 81/2
findings [3] 78/20 79/3 79/10
fine [1] 56/14
finishes [1] 60/3
first [19] 45/18 47/19 48/22 49/7 49/10 49/10 49/13 49/15 54/14 59/19 63/20 71/23 71/25 76/17 77/4 77/14 77/24 83/9 83/12
five [3] 47/4 69/9 83/12
flip [1] 83/10
flow [1] 92/8
following [4] 4/1 4/2 40/22 93/11
font [1] 82/25
footnote [1] 63/7
forces [1] 81/14
foregoing [1] 95/13
forward [5] 45/10 79/9 82/2 85/10 86/3
found [2] 69/1 82/12
four [4] 67/19 68/23 69/22 70/5
France [1] 1/22
front [3] 48/9 54/19 63/4
FTC's [2] 53/4 56/15
full [3] 48/22 82/24 88/12
Fund [2] 80/7 80/9
further [1] 86/18
future [2] 70/15 73/23

G

gained [1] 49/5
garage [2] 80/12 80/14
garages [2] 79/15 79/17
gave [2] 53/5 53/5
general [2] 44/9 51/8
generalizability [2] 44/10 91/8
generally [5] 43/19 43/23 55/10 83/6 92/5
generation [6] 75/7 76/7 76/12 76/17 77/15 78/2
get [23] 45/14 46/4 46/12 46/23 47/6 48/3 50/21 56/20 57/25 61/20 61/24 64/13 64/19 64/23 65/6 67/10 67/15 67/16 73/8 82/2 87/23 89/13 92/1
getting [7] 51/3 51/13 52/5 52/12 54/6 72/25 82/16
Gilbert [1] 1/23
give [1] 91/17
given [2] 50/22 58/21
go [9] 45/10 61/16 62/4 69/19 69/20 70/9 79/24 83/2 86/21
going [4] 76/2 88/25 91/2 91/5
gone [1] 51/2
good [4] 40/25 41/1 41/8 50/23
got [2] 67/3 67/4
gotten [1] 68/11
Gottlieb [1] 2/2
grant [1] 80/7
Gray [1] 2/7
greater [2] 53/18 56/18
grew [1] 84/17
guess [2] 44/18 86/11
guidance [1] 70/8
guide [2] 73/22 86/14
guidepost [2] 50/24 53/3
guideposts [1] 70/9

H

Habin [1] 1/14
had [23] 65/12 65/13 65/17 65/18 66/16 66/21 66/23 66/24 66/25 67/1 68/4 75/11 75/13 75/15 77/16 78/3 82/16 85/3 87/3 87/15 88/10 90/19 91/14
half [1] 62/4
Hall [1] 1/11
Hamilton [1] 2/3
hand [5] 48/17 48/22 51/10 82/23 83/11
handled [1] 57/1
happen [2] 67/21 82/22
happening [1] 67/21
happy [1] 65/20
hard [1] 68/16
harms [1] 42/25
has [9] 44/13 49/1 49/5 51/2 51/12 52/2 56/5 56/15 92/24
have [61] 41/5 41/19 41/20 41/21 41/23 41/24 41/25 42/1 42/3 42/5 42/7 42/9 42/17 42/21 42/23 44/16 44/19 46/8 46/18 46/21 48/3 48/9 49/17 51/1 51/3 51/10 51/12 51/25 53/14 56/14 56/16 60/22 61/9 63/4 63/17 64/1 64/8 67/24 68/11 68/18 69/23 70/2 71/7 72/21 73/2 73/3 73/4 73/8 73/10 73/10 73/13 75/23 77/18 81/13 81/20 86/17 86/22 87/18 91/23 92/20 93/7
haven't [3] 46/11 46/22 92/25
having [2] 66/7 66/10
he [2] 87/3 91/18
head [1] 59/5
heading [1] 83/11
Health [1] 80/10
hear [1] 66/8
heard [5] 4/2 40/22 82/15 82/19 93/11
hearing [6] 1/8 45/14 51/25 66/7 66/10 95/9
heart [2] 76/18 92/6
help [1] 92/3
helping [1] 82/1
here [5] 43/3 56/17 59/6 83/2 89/5
hereby [1] 95/13
high [18] 43/9 50/24 51/9 51/18 53/1 53/2 53/11 53/12 58/25 60/18 61/3 68/20 69/2 70/9 70/23 71/8 87/25 90/7
high-risk [18] 43/9 50/24 51/9 51/18 53/1 53/2 53/11 53/12 58/25 60/18 61/3 68/20 69/2 70/9 70/23 71/8 87/25 90/7
higher [2] 51/3 53/15
highest [1] 83/7
highlight [1] 92/11
highlighted [1] 83/15
his [2] 80/11 80/14
hold [2] 55/12 65/15
Honor [2] 66/6 86/22
HONORABLE [1] 1/8
how [12] 44/25 46/11 49/15 49/19 51/25 64/12 64/18 65/5 73/11 75/11 81/20 92/6
human [10] 43/17 43/24 44/15 45/10 63/23 76/17 77/14 77/24 87/3 87/11
hypothetical [2] 51/5 73/3
hypotheticals [2] 67/20 70/11

I

I'll [1] 45/21
I'm [12] 53/8 63/8 65/15 65/20 68/2 72/13 77/9 77/19 80/20 83/1 87/7 88/25
I-N-D-E-X [1] 2/14
IDE [45] 43/14 43/17 43/24 44/1 44/3 44/4 44/5 44/8 44/12 44/16 44/17 44/23 45/1 45/1 45/2 45/5 45/7 45/11 46/1 46/4 46/8 46/12 46/15 46/19 46/23 47/3 47/6 47/23 48/4 59/16 60/7 60/10 64/1 64/13 64/19 64/23 65/6 67/1 67/3 73/9 87/4 87/5 87/8 90/23 91/2

I
idea [1] 92/1
ideas [1] 92/12
identified [5] 55/19 56/6 56/10 56/20 62/22
IDEs [3] 49/2 49/4 49/6
implantations [1] 77/15
implanted [1] 77/24
implants [1] 76/17
important [3] 51/20 72/25 82/1
Inc [2] 76/25 77/1
include [1] 55/11
included [5] 63/14 71/20 80/17 80/23 88/14
includes [1] 47/3
increase [1] 60/2
increasingly [1] 49/1
indications [3] 74/3 74/8 74/13
individual [9] 79/8 79/14 81/13 82/5 84/11 91/23 91/24 91/25 92/12
individuals [1] 92/14
industry [2] 48/12 83/11
information [7] 46/25 55/13 63/3 63/9 63/13 68/14 71/7
initial [11] 50/5 60/7 60/10 67/3 79/5 79/10 79/24 79/25 80/1 80/2 88/8
initially [1] 82/15
initiate [1] 47/21
initiation [1] 47/24
innovation [5] 74/25 75/19 76/2 76/2 79/5
innovations [2] 74/7 82/2
innovative [3] 78/25 83/7 84/18
innovator [1] 82/10
innovators [6] 79/6 80/16 80/22 81/3 81/4 82/15
Institute [1] 80/10
intended [2] 47/20 47/23
interested [1] 82/17
interquartile [3] 61/5 61/12 69/2
interrupting [1] 66/6
interviewees [1] 83/17
interviews [4] 78/16 78/21 79/2 82/14
introduced [1] 47/16
invent [1] 92/3
inventor [2] 83/19 84/11
inventors [8] 78/19 79/8 79/11 81/13 82/6 91/23 91/24 92/12
investing [1] 83/21
investment [1] 84/10
investments [2] 84/8
involve [3] 45/8 70/2 70/2
involved [5] 44/17 74/13 78/17 81/2 82/21
involves [1] 45/8
involving [3] 42/9 42/13 63/23
is [108] 41/3 41/12 41/15 41/17 42/10 42/19 42/25 43/7 43/10 43/15 43/19 43/24 44/3 44/17 45/9 45/13 45/20 46/16 46/21 46/25 48/10 49/3 49/14 49/16 50/23 51/7 51/9 51/11 51/15 51/16 51/22 52/1 52/5 52/11 52/16 53/1 53/2 53/9 53/12 53/15 54/6 54/9 54/12 54/24 55/14 56/7 56/21 58/12 58/21 60/4 60/16 63/2 63/8 64/3 64/20 65/7 66/7 66/8 66/11 66/16 67/1 67/19 67/22 68/3 68/12 68/21 70/5 70/22 71/3 71/4 71/9 71/21 71/25 72/4 73/1 73/24 74/4 75/25 76/16 76/24 77/5 77/11 77/19 77/20 77/20 78/13 78/15 78/18 80/9 80/19 82/4 82/7 82/9 82/12 85/19 86/10 86/13 86/14 87/11 88/3 88/12 89/1 89/6 89/18 91/1 91/2 91/4 95/13
issue [4] 43/20 49/25 55/11 92/6
issues [10] 41/12 49/12 52/4 55/19 55/20 55/21 55/22 56/6 56/10 56/22
it [79] 43/15 44/19 45/9 45/9 46/12 46/16 46/18 46/23 47/5 47/20 47/23 48/1 48/3 48/23 50/20 51/6 51/22 51/23 52/18 53/2 53/9 53/12 53/19 54/21 55/17 57/23 57/24 57/25 58/8 59/8 60/8 61/15 61/20 61/22 63/12 64/6 64/12 64/18 64/21 64/23 65/5 65/13 65/18 65/21 66/1 66/7 66/11 66/11 66/15 68/4 68/10 69/11 70/8 70/22 71/4 72/9 72/14 73/12 77/8 77/20 77/20 77/22 77/22 78/1 79/24 80/13 82/9 84/15 87/3 88/12 89/1 89/22 89/24 89/25
it's [25] 41/8 48/13 48/16 48/19 49/15 50/24 51/8 51/20 53/18 54/9 56/18 58/24 63/5 63/7 66/11 69/5 69/16 71/7 76/18 76/25 78/9 82/25 83/15 88/8 89/5
its [28] 44/10 51/11 52/17 59/3 59/16 59/19 67/3 67/4 67/18 68/4 74/9 75/3 75/9 75/14 76/5 76/6 76/8 76/11 77/15 77/16 78/2 85/11 86/4 87/17 87/19 89/13 89/13 89/22
itself [1] 69/21
J
J-Valve [16] 52/1 52/5 52/12 52/17 52/23 53/7 53/15 53/19 54/5 54/11 54/17 59/3 59/13 59/16 59/19 70/13
Jacob [1] 1/12
JAMA [5] 47/1 50/11 52/15 54/15 57/15
James [1] 1/18
Jamie [1] 1/22
Jay [1] 1/15
JC [14] 59/2 60/6 65/12 65/17 66/16 66/21 66/24 67/1 67/3 67/11 67/16 68/1 68/4 69/20
JC Medical [4] 66/16 66/21 67/1 68/1
JenaValve [13] 54/25 55/17 55/19 56/5 56/9 56/19 57/6 57/13 62/19 62/23 81/21 81/22 87/16
JenaValve's [1] 87/19
Jenscare's [2] 46/3 46/5
Johnson [7] 1/13 80/18 80/18 80/23 80/24 83/20 83/20
Jordan [1] 1/18
Joshua [1] 1/21
JUDGE [1] 1/9
July [1] 60/3
July 2024 [1] 60/3
jurisdiction [1] 89/23
just [13] 43/9 44/7 54/15 55/18 56/15 57/18 60/4 62/13 67/25 69/16 75/13 75/25 84/10
K
keep [1] 92/7
KESSELHEIM [14] 3/6 40/25 54/13 63/3 66/7 74/17 86/17 86/23 87/2 88/8 88/18 88/21 88/22 92/23
Kesselheim's [11] 47/12 53/25 55/3 59/10 60/22 65/1 66/5 70/20 71/17 74/15 85/23
key [1] 92/10
kind [1] 68/14
kinds [1] 51/19
know [36] 47/25 49/19 49/24 51/20 51/21 52/9 56/5 56/9 56/24 59/5 63/12 64/18 65/5 65/20 68/2 68/16 70/1 73/10 74/10 76/4 77/18 77/22 79/11 84/9 85/4 87/22 87/24 88/2 91/2 91/3 91/5 91/7 92/7 92/12 92/17 92/18
knowhow [1] 81/25
known [1] 89/8
L
laboratory [2] 87/13 91/3
laid [1] 64/22
large [17] 51/9 53/1 78/23 79/3 80/15 80/21 81/1 81/7 81/11 81/15 81/25 82/3 82/11 82/16 82/20 84/8 84/12
larger [1] 79/13
last [13] 41/2 49/2 53/11 57/3 60/19 61/4 65/4 66/9 66/10 68/21 69/3 77/9 85/23
late [3] 54/25 69/18 69/22
later [3] 67/6 76/25 92/17
Laura [1] 1/11
Lausanne [1] 80/3
least [3] 55/11 62/22 72/22
led [1] 74/1
left [4] 48/17 48/22 79/18 79/21
left-hand [2] 48/17 48/22
length [2] 62/11 70/8
less [3] 50/21 58/22 59/2
let [2] 63/12 66/15
let's [18] 43/12 47/11 47/12 48/6 48/16 53/24 59/9 69/6 70/17 70/19 71/16 73/14 74/14 76/15 76/21 79/18 83/10 85/22
letter [7] 54/24 55/16 55/21 55/24 57/11 87/17 87/19
letters [5] 55/10 56/13 56/23 57/1 87/21
LIFESCIENCES [2] 1/5 76/16
light [2] 87/17 87/19
like [21] 41/10 43/20 44/13 54/8 54/19 54/20 57/20 60/15 62/14 63/1 63/11 63/13 64/6 65/21 66/7 67/22 67/25 78/8 79/14 80/9 84/10
likelihood [17] 51/3 51/13 51/16 52/4 52/12 52/16 54/5 54/9 56/9 56/19 57/4 57/5 57/12 70/4 70/13 87/16 87/18
likely [3] 50/21 50/21 52/19
limited [1] 56/16
line [14] 55/5 55/10 58/2 65/24 66/1 67/11 67/15 67/17 71/19 71/23 75/5 85/22 87/2 89/5
lines [5] 57/18 62/13 65/1 79/24 83/12
link [1] 79/20
Lipton [10] 1/21 3/8 66/8 87/3 87/15 87/20 88/10 91/13 91/17 91/21
Lisa [1] 1/11
list [1] 63/16
listed [3] 59/12 62/21 84/7
literally [1] 91/25
litigation [1] 42/21
little [1] 43/21
LLP [3] 1/23 2/3 2/7
long [6] 46/12 49/15 64/12 64/18 65/5 73/11
longer [2] 46/17 49/11
look [18] 54/10 54/19 55/16 57/4 57/10 57/12 57/14 58/18 63/12 64/5 64/16 64/21 73/14 76/15 76/21 77/7 79/18 82/23
looked [10] 61/15 61/19 62/6 62/18 65/24 66/1 68/24 72/20 85/6 85/8
looking [5] 55/5 62/11 68/20 80/19 91/1
looks [1] 63/13
lot [9] 51/22 64/5 67/20 71/3 74/10 80/14 81/4 88/4 91/19
lower [3] 51/13 52/5 53/15
M
Madam [1] 86/19
made [2] 84/8 84/14
major [3] 55/11 55/19 55/21
make [12] 45/13 47/20 47/23 52/18 53/19 53/22 53/23 54/11 57/24 68/16 82/3 85/16
manner [1] 72/4

M

manufacturability [1] 81/16
manufacture [1] 81/5
manufacturer [6] 42/18 43/15 44/21 57/1 70/15 82/11
manufacturers [8] 61/16 75/19 75/23 80/15 80/22 81/7 84/7 84/14
manufactures [1] 75/22
manufacturing [1] 92/19
many [3] 51/19 75/11 83/17
March [1] 76/18
MARK [1] 3/4
market [5] 83/22 84/6 84/13 84/17 84/24
match [1] 76/22
materials [1] 73/21
matter [4] 64/2 73/7 73/12 95/15
Matthew [1] 2/7
may [3] 60/1 67/5 73/23
May 2024 [1] 67/5
McCloud [17] 47/13 48/7 48/20 53/25 54/2 55/2 56/3 60/12 60/21 64/25 70/19 71/17 73/17 76/22 78/6 78/11 83/3
McGinnis [1] 2/7
McInerney [1] 2/6
McKinsey [2] 83/19 83/24
me [12] 42/13 43/5 45/18 46/6 48/2 48/23 55/17 57/3 63/12 66/15 73/21 77/9
mean [13] 50/23 67/2 67/20 68/2 68/9 68/20 74/4 75/22 75/23 82/12 85/2 86/11 92/10
means [1] 49/10
measure [2] 74/23 74/24
median [4] 58/21 60/24 61/1 61/4
medical [48] 41/24 41/25 42/1 42/3 42/5 42/7 42/10 42/15 42/18 43/6 43/15 46/12 48/11 59/2 60/6 65/12 65/17 66/16 66/21 66/24 67/1 67/3 67/11 67/16 68/1 68/4 69/2 69/6 69/20 70/23 71/8 78/24 78/25 79/3 79/13 80/15 80/21 81/1 81/5 81/11 81/15 81/25 82/10 82/11 82/16 83/7 87/25 92/16
Medtronic [26] 61/24 62/2 67/13 67/18 69/13 69/18 69/21 75/9 75/14 76/4 76/8 76/12 77/1 77/15 80/17 80/23 84/25 85/2 85/12 86/5 88/17 89/12 89/18
Medtronic's [6] 77/4 88/23 89/4 89/10 89/21 90/4
mentioned [1] 91/23
merger [1] 42/22
method [1] 49/21
Michelle [1] 1/14
mid [2] 66/20 66/25
middle [3] 65/12 65/17 66/15
might [9] 50/20 51/2 51/12 51/23 52/18 58/16 58/22 64/21 70/2
million [2] 77/1 83/24
mind [2] 63/11 88/11
minute [1] 93/5
minutes [2] 44/7 47/1
miss [1] 72/22
mixture [1] 71/8
models [1] 92/13
moment [4] 48/2 62/14 63/12 65/22
moments [2] 57/22 66/1
months [7] 60/8 60/9 64/2 67/5 67/16 73/7 73/12
more [13] 47/24 49/4 49/4 49/5 50/21 52/9 52/19 58/22 70/5 74/2 74/8 86/12 87/7
most [1] 83/7
move [3] 72/11 72/16 85/16
moved [1] 84/15
movement [1] 84/11
moving [2] 85/10 86/3
MR [4] 3/5 3/8 66/8 83/3
Mr. [23] 47/13 48/7 48/20 53/25 54/2 55/2 56/3 60/12 60/21 64/25 70/19 71/17 73/17 76/22 78/6 78/11 87/3 87/15 87/20 88/10 91/13 91/17 91/21
Mr. Lipton [7] 87/3 87/15 87/20 88/10 91/13 91/17 91/21
Mr. McCloud [16] 47/13 48/7 48/20 53/25 54/2 55/2 56/3 60/12 60/21 64/25 70/19 71/17 73/17 76/22 78/6 78/11
MS [1] 3/7
much [4] 46/17 52/9 55/8 66/11
Multi [1] 79/20
Multi-link [1] 79/20
multibillion [2] 84/1 84/17
multibillion-dollar [2] 84/1 84/17
multiple [4] 75/19 75/22 75/23 84/18
Musallam [1] 2/6
my [34] 43/2 43/8 43/10 44/24 45/7 45/12 45/13 45/21 46/2 52/8 52/14 54/16 56/8 56/14 56/15 58/9 59/5 61/18 62/21 64/11 64/17 64/22 64/24 66/2 67/12 67/24 69/8 69/8 69/17 71/5 73/19 82/7 85/5 85/19

N

National [3] 80/7 80/9 80/10
navigating [1] 48/10
near [2] 51/1 51/10
nearly [1] 62/4
necessarily [3] 64/4 68/13 87/11
necessary [2] 81/7 87/4
need [5] 43/17 44/2 86/19 92/14 93/9
needed [1] 81/21
needing [1] 92/7
negotiating [1] 81/8
nestor [5] 2/10 2/12 95/18 95/18 95/20
Network [4] 47/1 50/11 52/15 54/15
never [6] 41/25 42/3 42/7 42/17 42/21 49/25
new [3] 44/18 79/9 87/23
next [9] 48/19 51/16 60/4 75/7 76/7 76/11 76/17 77/15 78/2
nine [3] 60/9 67/5 67/16
no [20] 1/3 42/23 43/4 45/15 45/16 46/18 48/15 49/11 49/22 53/5 53/6 53/14 64/4 75/15 80/13 86/17 90/7 91/16 91/19 93/2
No. [1] 48/16
No. 932 [1] 48/16
nonclinical [3] 44/1 44/4 44/5
none [2] 90/11 90/13
normal [5] 56/13 56/24 71/7 82/9 88/3
Northwest [5] 1/16 1/23 2/3 2/8 2/11
not [56] 41/17 41/18 41/20 41/23 42/23 42/24 43/2 45/2 45/9 45/11 46/2 46/3 46/5 46/20 46/25 47/10 49/15 50/15 52/10 52/11 53/17 53/23 54/3 54/4 54/20 56/6 56/22 57/10 58/9 58/18 64/16 64/16 64/21 65/8 65/13 65/18 65/23 66/11 66/16 66/23 66/25 67/22 67/24 68/2 69/25 70/10 71/4 72/6 73/3 73/5 73/9 76/1 77/11 77/16 77/19 77/25 87/11
November [1] 1/6
now [12] 49/4 49/6 53/8 54/15 60/15 69/18 76/21 83/10 83/15 86/12 88/19 90/19
number [13] 50/23 50/25 51/8 51/15 51/16 51/22 53/1 54/12 54/17 55/18 58/25 74/20 85/4
numbers [4] 49/22 53/10 55/18 58/24
NW [1] 95/19

O

observed [10] 61/19 72/9 72/14 74/1 75/2 80/16 80/22 84/22 84/23 84/24
obtained [3] 63/18 70/24 90/8
Obviously [1] 91/1
occurs [1] 88/3
October [1] 59/20
October 16 [1] 59/20
off [1] 59/5
offered [2] 72/6 92/19
offering [3] 42/24 43/3 46/3
Official [2] 2/11 95/19
often [3] 57/1 79/9 79/11
okay [49] 41/13 43/5 43/12 44/1 45/20 45/22 46/11 47/11 48/2 49/17 50/3 50/9 50/16 54/18 54/24 55/2 55/16 55/23 56/1 57/9 58/7 59/16 59/19 60/21 62/22 63/15 63/16 64/1 64/12 66/19 67/3 67/8 67/13 67/25 69/1 70/17 70/22 72/19 73/14 74/14 75/11 75/15 76/6 76/15 78/5 78/20 83/1 84/13 84/17
once [2] 84/6 84/13
one [27] 42/10 42/18 51/5 51/15 55/11 64/22 65/15 66/10 67/13 67/25 68/15 69/18 73/24 75/15 77/19 78/23 79/1 79/3 79/10 80/13 81/10 81/18 83/19 83/24 86/13 87/7 88/16
ones [1] 51/6
only [9] 41/5 42/9 58/4 66/20 66/22 66/24 69/14 72/20 89/13
open [7] 40/22 47/1 50/11 52/15 54/15 54/22 57/15
opinion [4] 42/24 43/3 46/3 72/6
opinions [5] 43/5 43/8 70/17 73/24 86/13
opportunity [4] 84/6 84/13 84/24 91/17
order [2] 54/11 73/8
organizing [1] 81/8
original [2] 71/20 88/14
orthopedic [1] 42/14
other [17] 43/9 49/12 50/24 51/6 51/10 52/18 55/21 58/24 62/19 62/23 66/21 66/24 67/8 67/13 69/9 75/15 78/3
our [2] 79/10 81/10
out [8] 47/8 51/21 59/12 64/22 70/5 79/14 79/16 80/11
outcomes [2] 58/16 58/18
outliers [2] 61/11 61/12
outside [16] 44/6 44/8 44/14 44/19 44/22 45/25 46/7 63/18 64/10 65/13 65/18 70/24 72/11 72/16 72/23 89/23
over [6] 42/10 49/2 53/11 54/10 56/24 68/21
overall [1] 92/9
own [8] 49/25 50/13 57/25 58/4 58/8 58/9 81/14 92/15

P

p.m [3] 4/1 93/6 95/9
pace [1] 69/21
page [19] 48/16 48/17 48/19 55/3 57/18 59/9 60/22 63/6 65/1 71/18 77/7 77/10 77/21 79/18 79/21 82/23 83/10 85/22 88/9
pages [1] 53/25
Palmaz [2] 80/13 83/21
Palmaz-Schatz [1] 83/21
paper [6] 80/15 80/21 81/19 82/23 83/10 92/9
paragraph [25] 47/12 47/15 48/22 49/23 55/3 55/18 55/25 59/12 60/22 63/7 66/4 70/20 71/17 71/23 73/14 73/19 77/10 79/19 82/24 83/5 83/12 88/6 88/7 88/10 88/13
part [28] 43/2 44/8

P

part... [26] 45/1 45/12 46/2 47/8 50/17 52/8 52/14 54/16 56/8 56/13 56/24 61/18 62/18 64/7 64/11 64/17 64/24 65/8 67/12 67/24 69/25 84/9 84/20 85/5 88/3 88/10
particular [5] 43/13 50/20 54/1 63/6 70/11
particulars [1] 91/5
parties [3] 42/18 72/5 72/7
partnering [1] 92/18
passed [1] 68/4
pathway [3] 43/22 48/11 66/19
pathways [1] 51/7
patient [1] 59/20
patients [9] 43/17 43/25 44/15 49/5 63/23 74/2 74/8 92/2 92/4
pause [3] 51/12 52/3 52/19
paused [1] 52/1
Pearl [1] 1/22
pending [1] 55/12
Pennsylvania [3] 1/16 2/3 2/8
people [3] 78/17 79/14 93/7
perceived [1] 83/18
percent [10] 49/6 51/4 51/14 52/6 54/6 54/10 56/19 56/25 87/23 87/25
percentage [1] 57/4
percentile [2] 61/8 61/8
perform [1] 46/13
performed [3] 41/19 41/22 52/11
period [5] 46/22 60/24 75/6 75/12 75/16
phase [6] 68/5 68/9 68/11 68/14 68/15 69/14
phases [1] 69/15
phrase [1] 55/23
physician [7] 41/15 78/19 79/8 81/13 82/5 91/23 91/24
physicians [1] 91/25
pivotal [33] 51/2 51/11 51/12 51/14 52/1 58/1 59/25 60/9 60/16 61/1 61/16 61/21 61/25 62/5 62/9 62/11 67/5 67/17 68/6 68/9 68/13 68/18 69/4 69/7 69/14 69/20 75/14 76/5 89/12 89/13 90/8 90/13 90/14
place [1] 55/11
places [1] 63/21
Plaintiff [2] 1/3 1/11
plans [1] 92/24
please [32] 45/16 45/17 47/12 48/16 50/3 53/24 54/19 54/22 55/4 55/18 59/10 60/21 63/1 63/4 63/6 64/25 65/2 66/4 70/19 70/20 71/16 73/15 73/16 74/14 76/15 78/5 88/6 88/7 88/19 89/15 89/16 90/2
plus [2] 77/1 87/25
PMA [29] 55/11 56/25 58/1 61/21 61/25 62/5 62/9 62/12 67/17 68/6 68/18 69/4 69/9 69/14 69/21 71/20 71/24 73/21 74/1 74/4 74/12 74/20 74/23 75/2 87/23 88/14 90/6 90/23 91/4
point [2] 51/21 72/25
popular [1] 49/1
portion [2] 57/17 59/8
possessed [1] 64/9
possibility [1] 67/21
possible [1] 68/3
post [3] 73/21 74/1 76/1
post-approval [1] 76/1
post-PMA [2] 73/21 74/1
practice [1] 92/15
practicing [1] 41/15
preclinical [5] 47/2 87/6 87/9 87/11 87/13
predecessor [1] 77/16
predict [2] 69/5 70/4
prepare [2] 46/8 46/19
prepared [1] 63/8
presence [1] 75/19
present [2] 41/21 75/22
pretty [1] 67/2
primary [2] 71/11 88/15
principles [4] 64/23 90/25 91/6 91/10
prior [1] 89/22
probabilities [8] 50/5 50/9 50/10 50/13 50/16 52/22 52/25 53/21
problems [2] 51/11 52/2
procedure [2] 41/19 41/21
proceeding [1] 70/25
proceedings [2] 4/1 95/14
proceeds [1] 44/25
process [53] 42/2 42/4 43/8 43/13 43/14 44/25 45/12 46/15 46/16 47/3 47/23 48/23 49/1 49/14 50/7 51/20 56/24 57/21 58/1 59/13 61/21 61/25 62/3 62/9 62/12 64/7 64/16 66/20 67/17 69/7 69/9 69/21 70/10 70/18 70/25 71/9 71/14 72/12 72/17 72/23 73/2 73/5 73/7 79/4 81/9 82/3 85/11 85/18 86/4 87/22 88/3 90/8 92/2
processes [1] 42/14
produced [1] 81/17
product [3] 75/9 77/4 77/5
products [2] 78/18 81/16
program [3] 45/10 47/16 47/20
progressing [1] 51/16
proportion [1] 58/15
proposed [1] 42/25
prototypes [4] 79/25 80/1 80/2 92/15
provide [4] 53/8 64/12 70/13 81/21
provided [8] 53/5 53/22 81/2 81/7 81/11 81/15 82/1 83/20
provides [3] 70/7 73/22 86/14
public [2] 54/21 55/7
pull [13] 47/11 48/6 53/24 55/2 63/1 64/25 70/19 71/16 73/16 78/5 85/22 88/6 88/19
purely [1] 91/3
purposes [3] 44/23 45/17 90/24
pursue [1] 92/24
push [1] 79/8
Putting [1] 68/12

Q

qualify [1] 55/19
qualifying [1] 51/7
quality [4] 64/6 64/8 91/9 91/9
question [17] 43/10 45/16 53/4 56/12 56/14 56/15 57/6 65/16 67/23 70/1 72/13 73/4 80/20 82/7 85/9 87/7 89/2
questions [10] 41/10 49/12 56/16 66/9 86/18 86/23 87/2 91/18 91/21 93/2
quickly [1] 66/9
quote [1] 52/22
quoted [3] 51/4 57/18 60/5
quoting [1] 54/14

R

rage [1] 61/5
range [4] 58/16 61/12 69/2 69/16
rare [1] 70/23
RC [1] 1/3
reach [2] 52/10 74/8
reached [1] 71/5
read [12] 49/21 50/10 71/1 81/20 84/3 86/8 86/9 88/10 91/17
reading [2] 48/25 88/11
reask [1] 80/20
reason [4] 49/17 53/6 63/8 67/8
reasonable [7] 45/9 53/2 53/9 53/13 68/13 73/22 86/14
recall [3] 52/24 57/7 62/15
receipt [1] 55/12
receive [1] 87/16
received [6] 59/16 59/25 60/8 63/20 71/24 76/8
receives [1] 57/1
recess [1] 93/6
recollection [1] 85/19
recommendation [1] 83/20
record [2] 57/17 68/20
RECROSS [1] 3/2
REDIRECT [2] 3/2 86/24
refer [1] 57/15
regarding [1] 83/7
register [1] 76/1
registered [1] 74/11
regulatory [4] 48/11 90/20 90/22 90/24
relate [1] 43/8
related [1] 57/6
relates [2] 44/24 77/20
relation [1] 85/7
relevant [1] 91/5
reliability [1] 91/8
relied [1] 88/17
relies [1] 71/12
rely [2] 70/23 71/8
remain [2] 57/9 83/6
remedy [2] 56/5 56/10
remember [1] 76/14
repeat [1] 65/15
report [39] 43/2 45/7 47/12 47/15 52/9 54/16 55/3 56/8 59/10 59/12 60/6 60/22 62/21 63/3 63/4 63/6 63/9 63/14 64/11 64/17 64/22 64/24 65/9 65/22 66/5 66/22 67/12 67/14 67/24 70/20 71/17 72/2 73/14 73/20 84/7 84/10 84/21 88/8 88/8
reported [2] 2/10 61/5
reporter [3] 2/11 86/19 95/19
reports [2] 58/11 78/20
request [1] 45/13
requested [1] 55/13
require [1] 64/21
required [1] 43/24
requirements [3] 90/20 90/20 90/22
requires [1] 64/23
research [1] 81/24
researchers [1] 48/12
resolve [1] 56/20
resources [2] 81/2 81/25
respect [1] 85/20
respond [1] 46/21
responding [1] 57/5
response [1] 57/11
rest [1] 63/21
result [1] 76/5
revalving [2] 77/8 77/11
review [16] 42/14 45/1 45/2 45/8 45/12 46/5 49/7 49/10 49/11 49/13 51/18 56/22 64/7 65/20 67/24 69/8
reviewed [2] 47/1 67/23
right [16] 42/15 43/23 44/14 44/16 45/20 67/19 68/1 68/9 80/25 82/21 82/23 83/11 85/19 85/21 86/12 93/5
right-hand [2] 82/23 83/11
risk [21] 43/9 43/20 50/24 51/9 51/18 53/1 53/2 53/11 53/12 58/25 60/18 61/3 68/20 69/2 70/9 70/23 71/8 83/6 83/7 87/25 90/7
risks [1] 83/18
RMR [2] 2/10 95/18
role [3] 44/25 78/23 83/11
Room [1] 2/4
Ropes [1] 2/7
row [1] 63/20
RUDOLPH [1] 1/8
Ryan [1] 2/2

S

said [7] 46/15 46/21 52/19 52/25 54/8 54/15 86/7
sales [3] 81/12 81/14 92/19
same [6] 62/7 67/10 67/15 67/17 90/23 90/25
Samer [1] 2/6
sample [1] 50/17
Sapien [12] 75/3 75/7 75/8 75/8 75/13 76/7 76/7 76/12 77/23 78/2 85/11 86/4
saw [8] 66/22 67/14 69/11 85/11 85/14 85/16 86/4 92/14
say [8] 45/19 52/14 55/10 59/16 59/19 64/20 65/7 69/7
saying [1] 66/8
says [5] 76/25 77/8 77/20 77/22 79/24
scale [3] 81/6 81/17

S

scale... [1] 82/4
scenario [2] 51/5 73/3
Schatz [1] 83/21
Scientific [6] 80/17 80/23 84/25 85/3 85/13 86/5
screen [4] 54/21 55/7 82/25 83/15
seal [1] 93/9
second [5] 55/25 65/15 77/7 77/21 82/24
section [2] 49/21 92/11
sections [1] 88/16
see [16] 41/8 47/13 48/25 49/8 49/23 62/8 76/19 77/2 79/20 79/23 79/24 80/4 80/8 83/13 83/23 92/10
seeking [1] 90/7
seems [1] 66/7
seen [3] 77/18 91/14 92/25
Segal [1] 1/13
sent [1] 54/24
sentence [12] 47/19 54/14 60/4 60/4 70/22 71/3 79/25 83/9 83/13 88/10 88/12 88/12
Seo [2] 1/14 3/7
September [1] 54/25
September 2025 [1] 54/25
session [6] 1/6 4/2 40/22 54/21 65/25 93/11
settings [1] 91/6
seven [11] 49/2 61/22 62/4 62/22 66/21 66/25 71/19 72/22 73/6 88/11 88/14
Seventh [1] 1/19
several [1] 91/21
Shores [1] 2/2
short [1] 45/13
should [1] 55/6
show [3] 54/20 60/24 89/10
showed [3] 68/17 69/17 91/13
showing [1] 74/20
shows [1] 89/18
side [1] 83/11
significant [2] 43/20 55/23
similar [1] 72/4
Sir [1] 54/4
sites [2] 58/10 58/11
situated [1] 81/5
six [6] 60/8 71/19 71/24 79/24 88/11 88/14
sixth [1] 48/17
size [2] 83/22 84/10
Sleigh [1] 1/11
slide [6] 74/14 88/19 88/20 89/15 90/2 90/16
slower [1] 66/13
small [4] 80/16 80/22 82/25 83/22
smaller [1] 79/5
so [42] 43/10 43/12 44/7 44/24 45/7 48/6 49/15 49/23 51/20 53/1 53/12 60/21 61/8 62/7 66/10 66/11 66/19 67/23 68/4 68/15 69/15 69/15 69/25 72/9 72/19 73/3 74/17 75/22 76/15 76/25 77/14 80/11 82/8 82/23 83/10 84/16 85/21 86/3 88/2 90/11 91/4 91/16
solely [4] 70/23 71/3 88/17 89/11
some [11] 41/10 41/12 44/10 57/23 68/21 70/3 70/8 74/12 79/16 92/10 92/15
someone [1] 72/19
something [11] 45/17 45/18 52/8 52/11 57/22 60/16 67/22 70/16 81/23 88/25 92/1
somewhere [1] 77/21
sorry [6] 65/15 72/13 80/20 87/7 88/25 89/2
sound [1] 42/15
Southwest [1] 1/19
space [5] 43/6 80/17 84/8 84/15 85/2
speaking [2] 43/19 43/23
special [1] 51/6
specific [12] 45/11 51/24 54/10 54/12 54/16 54/17 55/20 56/12 56/22 57/4 64/21 85/20
specifically [8] 45/2 46/5 47/8 58/19 65/20 76/14 80/20 85/8
specifics [4] 57/10 57/12 57/14 91/1
speed [1] 66/12
spoke [1] 41/2
spoken [1] 41/5
SSEDs [1] 88/16
stage [23] 43/14 47/21 50/22 51/14 51/16 52/1 52/6 52/15 54/9 58/1 58/2 58/7 58/17 58/23 60/16 67/10 68/6 68/7 68/10 68/18 68/18 69/7 82/2
stages [5] 50/6 57/21 58/4 91/12 92/17
standards [1] 90/22
start [11] 41/10 59/25 60/9 61/2 62/5 64/19 65/6 67/5 72/10 72/15 93/7
started [6] 65/13 65/19 66/16 72/21 73/5 85/17
starting [1] 79/25
starts [2] 79/19 83/13
statement [1] 49/18
states [19] 1/1 1/9 43/16 44/6 44/9 44/15 44/19 44/22 46/7 46/14 47/7 47/17 47/22 48/23 56/21 63/18 65/13 65/18 70/24
Steen [1] 2/2
stent [11] 79/9 79/20 80/11 80/17 81/24 82/13 82/14 83/21 83/25 84/5 91/20
stents [5] 78/16 79/11 79/11 92/13 92/14
step [5] 66/20 66/22 66/24 67/2 82/9
Stephanie [1] 1/22
steps [1] 51/19
Street [2] 1/19 1/23
strike [4] 57/24 66/23 83/24 84/3
strong [1] 83/20
studied [5] 71/7 71/13 78/23 84/5 84/20
studies [6] 44/15 47/24 63/17 80/2 87/14 87/14
study [32] 41/11 43/16 43/22 45/17 45/19 45/19 45/23 45/24 47/1 47/16 50/18 56/6 56/11 56/12 58/7 58/12 58/16 58/22 59/3 59/14 59/20 60/8 60/18 60/24 67/15 67/25 68/5 68/15 69/2 69/19 82/14 84/23
subjects [2] 77/24 78/8
submission [1] 49/14
submissions [1] 71/21
submitted [3] 44/8 45/1 90/23
subsequent [1] 60/2
substantial [1] 83/18
substantive [2] 41/12 77/10
such [2] 51/6 52/17
suggest [1] 52/4
suggested [2] 72/5 87/3
suitable [1] 45/25
summarizes [1] 63/9
summary [1] 63/13
supplemental [4] 74/4 74/12 88/15 90/14
supplements [3] 74/21 74/23 75/3
support [12] 81/3 81/8 81/15 81/22 87/4 87/5 87/8 90/5 90/10 90/14 92/16 92/19
supported [2] 80/2 80/6
supposed [2] 46/16 46/21
sure [5] 65/17 68/2 72/3 80/21 82/6
surgeons [1] 42/14
surgery [1] 80/7
Swiss [2] 80/7 80/9
switch [1] 78/8
Switzerland [1] 80/4
system [3] 77/9 77/11 89/6

T

tab [12] 48/10 48/13 54/20 54/22 76/15 76/21 76/24 77/19 78/10 91/13 91/13 91/14
take [15] 46/16 47/3 50/3 56/2 58/22 60/12 63/11 64/13 64/18 65/5 73/11 73/12 90/16 92/21 93/5
taken [3] 50/17 53/10 93/6
takes [12] 46/12 46/15 46/18 46/23 47/5 48/3 57/23 57/25 58/8 58/12 69/9 70/8
talk [6] 41/12 43/12 57/20 60/15 70/17 77/8
talked [7] 43/21 50/5 58/2 65/22 67/4 74/17 75/18
talking [4] 67/18 69/22 70/12 86/10
tammy [5] 2/10 2/12 95/18 95/18 95/20
TAVR [58] 41/19 41/21 43/20 44/18 45/24 53/1 53/12 61/16 61/19 61/23 62/15 62/20 62/24 63/10 63/17 66/22 67/9 67/14 67/18 68/7 68/11 68/23 69/22 69/23 71/14 71/20 71/24 72/3 72/4 72/10 72/10 72/14 72/15 72/20 73/22 73/23 74/1 74/2 74/8 74/9 74/11 74/13 75/11 75/14 77/5 84/22 85/2 85/12 85/17 86/5 86/13 86/14 88/14 88/24 89/4 89/14 89/21 92/23
TAVR-AR [22] 43/20 44/18 45/24 53/1 53/12 62/15 62/20 62/24 63/10 63/17 66/22 67/9 67/14 68/11 69/23 72/3 72/10 72/15 72/20 73/23 86/14 92/23
TAVR-AS [33] 61/16 61/23 67/18 68/7 68/23 69/22 71/14 71/20 71/24 72/4 72/10 72/14 73/22 74/1 74/2 74/8 74/9 74/11 74/13 75/11 75/14 77/5 84/22 85/2 85/12 85/17 86/5 86/13 88/14 88/24 89/4 89/14 89/21
TAVR-ASs [1] 61/19
technology [4] 45/24 79/9 81/12 83/8
tell [11] 45/18 48/23 52/12 53/18 54/5 55/17 55/18 56/18 72/2 77/9 78/1
ten [3] 42/10 69/10 93/5
ten-minute [1] 93/5
tended [1] 81/4
tends [1] 49/14
terms [5] 58/17 58/18 66/19 85/4 90/25
testified [6] 42/9 42/17 42/21 52/21 57/22 75/18
testifying [2] 52/24 62/16
testimony [10] 43/13 50/5 51/25 57/7 57/9 59/6 65/1 72/2 81/20 84/3
testing [5] 45/10 46/13 63/21 63/23 63/23
than [14] 46/17 49/4 49/5 49/11 50/21 51/3 51/13 52/6 53/18 56/18 59/2 62/19 62/23 75/15
Thank [21] 45/22 47/13 48/20 54/2 54/18 55/8 56/1 56/2 56/17 57/16 60/12 78/6 83/3 86/17 86/22 88/18 90/17 92/21 93/2 93/3 93/4
Thanksgiving [1] 45/15
that [354] 41/3 41/13 41/15 41/17 42/11 42/13 42/15 42/19 42/24 42/25 43/2 43/3 43/5 43/7 43/9 43/10 43/15 43/19 43/23 43/23 43/24 44/3 44/10 44/13 45/1 45/2 45/18 45/19 45/19 45/20 46/2 46/3 46/6 46/12 46/17 46/20 46/21 46/25 46/25 47/1 47/2 47/3 47/5 47/8 47/8 47/9 47/18 47/20 47/25 48/22 49/8 49/12 49/13 49/14 49/16 49/19 49/21 49/23 50/3 50/10 50/11 50/16 50/17 50/18 50/22 50/23 51/2 51/4 51/5 51/7 51/8 51/8 51/11 51/12 51/17 51/20 51/22 51/22 51/23 52/2 52/3 52/3 52/4 52/8 52/8 52/10 52/10 52/11 52/14 52/14

T

that... [264] 52/15 52/15 52/18 52/21 52/22 52/24 53/2 53/4 53/5 53/6 53/6 53/8 53/8 53/9 53/9 53/16 53/16 53/17 53/19 53/22 53/23 54/13 54/14 54/24 55/14 56/2 56/6 56/7 56/8 56/9 56/11 56/12 56/19 56/21 57/1 57/6 57/7 57/9 57/14 57/22 57/24 58/2 58/2 58/10 58/11 58/11 58/12 58/18 58/20 58/20 58/24 59/2 59/3 59/5 59/16 59/19 60/3 60/13 61/12 61/18 61/20 62/2 62/6 62/6 62/16 62/19 62/24 63/2 63/8 63/9 63/16 64/3 64/4 64/5 64/5 64/6 64/7 64/9 64/11 64/16 64/16 64/20 64/24 64/24 65/7 65/8 65/10 65/15 65/20 65/22 65/24 65/24 66/3 66/16 66/20 66/21 66/22 66/23 66/24 66/24 66/25 67/1 67/11 67/12 67/14 67/15 67/17 67/19 67/21 67/23 67/24 68/3 68/9 68/10 68/10 68/14 68/17 68/24 69/15 69/20 69/21 70/1 70/2 70/2 70/3 70/5 70/7 70/7 70/10 70/11 70/13 70/16 71/1 71/3 71/9 71/11 71/21 71/23 71/24 71/25 72/3 72/4 72/6 72/13 72/18 72/20 72/21 72/22 73/4 73/8 73/9 73/11 73/13 73/16 73/24 74/1 74/4 74/7 74/23 75/7 75/12 75/15 75/23 76/4 76/6 76/11 76/14 76/19 76/22 76/25 77/2 77/5 77/7 77/18 77/20 77/20 77/22 77/23 77/25 78/1 78/5 78/9 78/13 78/18 78/23 79/1 79/1 79/3 79/10 79/19 79/20 79/23 80/4 80/8 80/16 80/19 80/19 80/20 80/22 80/25 81/10 81/23 81/23 81/25 82/4 82/5 82/9 82/12 82/15 82/19 82/22 83/5 83/13 83/14 83/23 84/3 84/3 84/4 84/5 84/7 84/9 84/9 84/17 84/20 84/22 84/24 85/9 85/14 85/19 85/21 86/14 87/2 87/3 87/4 87/9 87/16 88/2 88/3 88/4 88/5 89/6 89/10 89/12 89/18 89/19 90/5 90/9 91/10 91/25 92/1 92/3 92/9 92/11 92/13 92/18 92/19 92/21 92/24 92/25 95/13

that's [42] 41/5 42/12 42/20 47/19 47/25 50/23 51/5 51/15 53/9 55/25 56/14 60/11 61/8 61/14 62/21 64/4 66/4 66/18 67/2 67/20 67/23 68/16 69/6 69/13 69/15 69/16 69/22 70/1 71/5 72/5 75/5 76/2 78/4 78/11 80/3 80/25 81/18 83/9 83/24 85/19 85/21 86/11

their [24] 42/14 45/25 51/19 62/5 71/21 79/8 79/12 79/15 79/17 81/11 81/14 84/12 85/3 85/7 88/16 90/6 90/7 90/10 90/14 92/4 92/14 92/14 92/15 92/16

them [17] 46/8 56/16 56/23 57/2 61/20 62/14 63/21 73/10 79/16 82/2 82/3 85/16 87/23 87/23 90/13 91/18 92/15

theme [1] 82/19

themselves [1] 92/20

then [12] 41/12 56/25 59/19 60/4 60/8 67/16 72/11 72/16 78/4 90/9 92/2 92/17

there [27] 43/21 44/17 47/19 48/24 49/4 49/12 49/19 49/20 51/6 51/22 52/17 55/25 61/11 61/11 62/19 68/21 69/15 74/10 74/10 77/9 83/1 83/9 84/24 88/12 89/1 91/19 92/11

there's [5] 49/22 52/3 52/19 79/19 83/12

therefore [1] 58/21

these [29] 49/22 52/4 60/11 63/16 64/1 64/9 64/13 64/15 64/19 64/22 65/6 69/19 74/21 74/24 76/3 77/18 79/10 79/14 81/4 81/13 82/5 82/16 84/11 90/11 91/14 92/5 92/11 92/13 92/19

theses [1] 92/10

thesis [1] 92/9

they [30] 43/16 47/5 47/8 55/21 56/16 72/22 73/1 73/3 73/3 73/8 76/3 77/7 79/9 79/12 79/15 80/6 81/2 82/15 82/17 90/5 90/8 90/9 90/22 91/25 91/25 92/1 92/16

thing [1] 45/20

things [5] 64/6 68/12 78/23 82/5 91/10

think [29] 43/19 43/23 47/25 47/25 48/25 51/20 52/9 53/8 53/9 53/9 64/4 64/5 67/23 68/12 68/16 69/17 70/1 70/7 85/8 85/14 85/19 85/21 86/9 86/10 86/12 88/5 90/25 91/16 92/10

third [5] 55/5 55/10 71/19 88/12 89/5

this [72] 41/11 42/24 42/25 43/21 44/21 44/24 45/3 45/14 45/17 48/9 48/10 48/14 49/3 49/18 49/21 49/25 51/15 51/15 51/25 52/6 53/10 53/10 53/14 54/24 55/6 55/20 57/5 57/10 59/12 62/18 62/25 63/2 63/5 63/8 63/12 65/8 66/15 72/5 72/7 73/20 73/24 74/17 74/18 74/20 75/25 75/25 76/16 78/13 78/15 79/7 79/9 79/9 80/11 80/13 81/10 81/18 81/20 81/23 82/12 84/5 84/20 84/23 86/9 86/13 88/3 89/10 89/15 89/18 91/21 92/3 92/5 93/1

those [32] 47/2 50/9 50/13 51/19 51/19 52/25 53/6 53/10 53/21 53/22 53/23 58/4 58/10 58/11 62/9 62/13 68/12 72/25 74/12 75/10 76/5 78/18 78/20 81/22 82/5 84/14 85/6 85/14 90/21 91/6 91/10 91/11

though [1] 90/4

thought [1] 88/25

thoughts [1] 87/18

three [5] 61/22 61/24 68/7 69/11 69/13

through [24] 41/12 42/1 42/3 52/13 53/19 54/6 57/24 58/1 59/13 61/20 61/24 66/19 67/10 67/15 67/16 68/4 69/19 69/20 70/9 70/25 74/2 74/11 82/2 92/8

time [36] 41/5 42/10 46/23 47/5 48/3 56/16 57/23 57/25 58/2 58/8 58/22 58/22 59/2 60/24 61/1 61/15 62/11 62/13 64/21 65/24 66/1 67/10 67/15 67/17 69/20 70/8 75/6 75/12 75/16 77/14 85/6 87/7 91/19

times [1] 91/24

timing [10] 57/21 58/17 58/18 60/15 61/20 62/8 68/13 68/17 69/6 70/4

titled [2] 48/10 76/16

today [4] 41/6 59/6 90/19 91/15

together [1] 68/12

told [6] 42/13 43/5 46/6 48/2 57/3 74/23

too [2] 41/9 83/22

took [9] 41/2 57/3 59/2 61/15 61/20 62/4 69/11 79/11 79/11

top [4] 59/5 66/10 79/18 79/21

topics [2] 43/9 79/1

total [1] 67/19

toward [1] 48/13

TRADE [3] 1/2 1/15 1/19

traditionally [1] 49/13

transaction [1] 42/25

transcatheter [1] 76/18

transcription [1] 95/14

treat [1] 62/7

treatment [1] 61/1

treatments [1] 62/20

trial [44] 42/5 42/7 51/2 51/2 51/11 51/12 51/14 52/1 52/2 52/3 52/20 54/11 58/1 58/21 59/25 60/9 60/16 61/1 61/21 61/25 62/5 65/14 65/19 66/16 67/5 67/17 68/6 68/9 68/14 68/18 69/4 69/14 69/20 72/23 76/5 85/10 85/18 86/4 89/12 89/13 90/9 90/9 90/14 91/4

trials [25] 46/7 47/6 47/21 61/16 62/9 62/11 64/2 64/10 64/14 64/20 65/7 65/13 65/18 72/11 72/16 72/21 75/14 76/13 77/12 77/16 78/3 81/8 85/21 90/15 92/24

Trilogy [3] 52/23 53/7 57/13

trouble [2] 66/7 66/10

true [3] 43/19 57/9 61/14

try [6] 49/21 53/22 53/22 66/13 92/2 92/3

trying [8] 45/14 53/8 86/11 87/20 88/2 88/5

TURCO [1] 3/4

Turco's [1] 59/6

turn [6] 48/16 59/9 63/6 74/14 88/7 89/15

turning [2] 90/2 91/20

two [8] 58/12 58/20 59/3 61/9 62/7 62/10 68/23 69/1

two-year [2] 58/20 59/3

Tymkovich [2] 1/15 3/5

type [1] 68/10

typically [2] 57/23 79/4

U

U.S [48] 44/11 44/14 45/5 45/25 62/2 62/15 64/3 64/10 64/14 64/20 65/7 65/14 65/19 66/16 67/5 69/23 70/18 70/18 71/9 71/9 71/11 71/13 71/13 71/20 72/11 72/12 72/16 72/17 72/22 72/23 73/1 75/12 76/12 77/17 78/3 80/10 88/15 88/15 88/17 89/11 89/12 89/13 89/23 90/9 90/21 91/8 91/11 92/23

ultimate [1] 51/23

ultimately [2] 84/12 92/17

under [4] 50/20 72/20 83/11 90/22

undergoing [1] 64/9

understand [3] 51/21 58/20 72/19

undertake [1] 92/2

UNITED [18] 1/1 1/9 43/16 44/6 44/9 44/15 44/19 44/22 46/7 46/13 47/6 47/17 47/22 56/21 63/18 65/13 65/18 70/24

university [2] 80/3 80/3

University's [1] 80/6

unless [1] 44/15

up [19] 47/11 48/6 49/12 53/24 54/16 55/2 63/1 64/25 70/19 71/16 73/16 76/22 79/1 83/12 83/25 85/22 88/6 88/19 88/25

us [9] 52/12 53/18 54/5 55/18 56/18 68/17 72/2 74/23 88/11

USA [1] 77/12

use [13] 42/14 43/17 43/24 44/22 46/1 49/14 53/2 53/21 55/23 70/17 71/13 90/5 90/20

used [10] 45/5 46/4 58/10 58/11 62/2 74/7 89/13 90/10 90/11 90/13

U

using [1] 44/12

V

validity [1] 91/7
valve [17] 52/1 52/5 52/12 52/17 52/23 53/7 53/15 53/19 54/5 54/11 54/17 59/3 59/13 59/16 59/19 70/13 76/18
variance [1] 61/9
variant [1] 43/22
Variants [1] 68/23
variation [5] 61/20 62/8 68/19 68/22 69/1
various [5] 50/6 57/21 59/13 63/21 70/9
venture [1] 83/6
very [6] 55/8 68/19 69/5 70/4 87/21 88/3
videos [1] 93/8
volume [1] 66/11

W

Wallstent [1] 79/20
want [2] 55/17 92/1
wanted [1] 72/19
was [79] 4/2 40/22 42/10 42/13 42/18 43/2 46/2 47/20 47/23 51/17 53/10 53/16 56/8 57/18 57/22 60/3 61/4 61/18 61/22 61/24 62/6 64/24 64/24 65/24 66/1 66/3 66/10 66/25 67/24 68/10 69/14 69/25 74/10 75/7 75/9 75/14 76/4 76/6 76/11 77/14 77/23 78/1 78/1 78/16 78/23 79/1 79/3 79/5 79/7 79/10 80/13 80/13 81/10 82/19 84/3 84/6 84/13 85/5 85/7 85/10 86/3 87/3 87/4 87/20 88/2 88/2 88/5 88/5 88/25 89/11 89/12 89/22 89/24 89/25 90/4 91/20 92/9 93/6 93/11
Washington [8] 1/4 1/16 1/20 1/24 2/4 2/8 2/12 95/20
wasn't [9] 52/8 52/14 64/11 70/16 80/11 80/13 81/23 84/20 91/19
way [5] 48/1 52/24 64/18 65/5 66/15
ways [1] 49/13
we [59] 41/5 41/12 43/9 43/21 44/7 45/14 47/1 47/11 48/6 48/16 50/3 50/11 53/24 54/21 55/2 56/2 57/20 57/21 60/12 60/21 62/6 62/13 63/1 63/2 63/8 64/25 65/22 66/1 66/22 67/4 67/14 69/18 71/16 73/16 73/23 76/4 77/7 78/5 82/12 82/19 82/23 83/2 84/9 84/10 84/20 85/5 86/10 86/22 88/6 88/19 89/15 90/16 90/19 92/21 93/5 93/7 93/9
week [4] 41/2 57/3 65/4 85/23
Weiss [1] 1/18
well [20] 47/23 49/11 49/19 51/2 51/5 51/20 52/20 64/4 69/15 71/5 72/7 74/10 75/10 75/13 75/25 82/12 85/2 85/19 90/25 92/10
went [1] 60/6
were [25] 45/2 50/9 50/17 52/21 53/4 55/21 58/4 59/6 67/13 69/15 69/18 71/24 74/10 75/6 76/3 79/15 79/16 80/2 80/6 82/1 82/5 82/17 83/6 92/5 92/12
weren't [3] 59/7 79/14 81/5
what [28] 41/11 52/16 54/12 55/14 56/5 58/15 58/15 60/4 64/23 64/24 66/8 67/21 68/2 69/17 69/25 72/5 72/9 72/14 73/22 74/4 82/12 84/20 86/10 86/11 88/5 91/1 91/24 92/9
when [13] 41/2 48/23 53/4 57/3 61/19 75/22 77/9 77/23 81/1 85/6 85/7 86/10 91/11
where [11] 43/12 47/2 48/25 49/22 54/9 58/4 66/3 77/20 80/19 80/19 89/25
whereas [1] 91/4
whether [10] 45/9 45/16 53/14 53/18 54/5 55/21 56/18 56/23 62/18 89/21
which [17] 42/10 42/17 45/5 45/23 45/24 55/18 60/16 67/24 73/1 73/2 73/9 74/24 76/3 78/16 79/7 91/20 92/16
while [1] 88/16
who [2] 80/13 92/1
whole [1] 62/2
why [1] 67/8
wide [2] 61/19 68/19
will [14] 1/13 41/12 45/13 45/15 53/19 56/9 56/19 62/13 64/18 65/5 66/13 70/14 93/5 93/9
within [3] 46/22 64/9 64/2
WITNESS [1] 3/2
won't [1] 84/4
word [3] 49/14 71/3 83/13
words [1] 52/21
work [5] 44/21 62/18 71/4 79/5 80/14
worked [5] 41/24 41/25 42/5 42/7 92/17
working [8] 62/20 75/7 75/9 76/6 76/11 79/14 79/16 80/11
world [5] 62/23 63/11 63/22 67/9 67/14
worth [1] 51/17
would [36] 41/10 43/16 44/19 45/25 46/8 46/12 52/9 52/9 54/19 54/20 57/14 57/20 60/15 62/14 63/1 63/11 64/7 64/13 65/21 67/18 67/21 67/24 68/10 69/5 70/2 70/2 72/9 72/14 72/18 72/22 73/8 78/1 78/8 82/9 87/16 92/3
write [1] 70/22
written [1] 49/3
wrote [8] 47/15 55/14 71/19 71/23 73/19 78/9 83/5 83/17

X

XT [5] 75/8 76/7 76/12 77/20 77/23

Y

yeah [2] 68/20 79/17
year [11] 58/20 59/3 60/19 61/4 67/25 68/5 69/3 74/21 75/3 76/25 87/23
years [26] 42/10 47/4 49/2 58/12 58/25 60/25 61/4 61/6 61/9 61/22 61/24 62/4 62/8 67/19 68/7 68/23 69/10 69/11 69/13 69/22 70/5 75/2 75/10 76/5 76/7 85/4
years' [1] 69/1
yellow [1] 75/5
yes [110] 41/4 41/7 41/14 41/16 42/12 42/16 43/10 43/11 45/15 45/16 46/10 47/19 50/8 50/11 50/19 50/23 52/3 52/25 54/14 54/23 55/1 55/8 55/15 57/8 58/3 58/6 58/14 59/1 59/15 59/18 59/22 59/24 60/2 60/11 60/20 61/7 61/10 61/18 61/22 62/2 62/3 62/6 62/12 62/17 62/21 62/21 62/25 63/25 65/11 67/2 67/7 68/2 68/25 69/12 70/13 70/22 71/7 71/11 71/15 71/22 72/1 72/8 72/18 73/25 74/5 74/6 74/19 74/22 75/1 75/5 75/9 75/21 76/10 76/20 77/3 77/6 78/4 78/14 78/19 78/22 79/2 79/22 79/23 80/1 80/5 80/9 80/25 81/4 81/19 82/7 82/8 82/13 82/19 82/19 82/22 83/9 83/16 83/24 84/2 85/15 86/7 86/7 86/16 87/10 89/3 89/5 89/7 89/9 89/12 89/20 90/15 93/10
yet [1] 73/5
you [288] 41/2 41/8 41/9 41/11 41/15 41/17 41/19 41/21 41/24 42/1 42/1 42/5 42/9 42/13 42/17 42/21 42/24 43/3 43/5 43/12 44/2 44/12 44/14 44/15 44/20 45/4 45/15 45/15 45/16 45/16 45/19 45/19 45/19 45/22 45/23 45/24 46/3 46/6 46/11 46/18 46/21 46/22 47/9 47/9 47/13 47/15 47/25 48/2 48/2 48/2 48/9 48/9 48/14 48/20 48/25 49/8 49/17 49/23 50/5 50/13 50/16 51/1 51/4 51/10 51/20 51/21 51/21 51/25 52/9 52/12 52/13 52/19 52/21 52/24 53/4 53/5 53/5 53/14 53/18 53/21 54/2 54/4 54/5 54/8 54/18 54/19 54/20 54/22 55/8 55/10 55/14 55/16 55/17 56/1 56/2 56/5 56/6 56/9 56/11 56/14 56/16 56/17 56/18 56/24 57/3 57/6 57/12 57/15 57/16 57/22 57/23 57/25 58/2 58/4 58/7 58/10 58/11 58/15 58/20 58/20 59/2 59/6 59/7 59/12 59/16 59/19 60/4 60/12 60/16 60/18 60/24 61/5 61/9 61/15 61/19 61/19 62/8 62/14 62/14 62/15 62/18 62/22 63/3 63/4 63/4 63/8 63/11 63/11 63/13 63/16 64/8 64/12 64/18 65/4 65/4 65/5 65/8 65/15 65/21 66/8 67/8 67/18 67/22 68/2 68/15 68/17 68/18 68/24 69/1 69/5 69/11 69/22 70/11
you're [2] 43/23 48/23
you've [2] 49/25 50/10
your [67] 41/2 41/10 43/5 43/12 44/20 46/6 47/15 48/9 48/13 49/25 50/5 50/13 52/21 54/20 54/22 57/3 57/25 58/4 58/8 59/12 60/6 60/18 60/24 62/18 63/3 63/4 63/6 63/9 63/14 65/4 65/22 66/6 66/22 67/14 68/17 69/2 70/17 72/2 72/2 72/6 73/2 73/4 73/14 73/24 76/15 76/21 76/24 78/9 78/16 78/20 79/3 80/15 80/21 81/24 82/14 82/23 83/10 84/7 86/13 86/22 87/7 88/7 88/8 89/2 91/14 91/20 92/9