IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

Plaintiff,

v. Washington, D.C.
Monday, November 24, 2025
EDWARDS LIFESCIENCES CORPORATION 9:30 a.m.
and JENAVALVE TECHNOLOGY, INC.,

Defendants.
- x

TRANSCRIPT OF EVIDENTIARY HEARING - DAY 5
*** MORNING SESSION ***
HELD BEFORE THE HONORABLE RUDOLPH CONTRERAS
UNITED STATES DISTRICT JUDGE

APPEARANCES:

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

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

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

APPEARANCES CONTINUED:

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

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

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

C O N T E N T S

WITNESS: **PAGE:**

NATHAN WILSON:
Direct Examination by Mr. Lippard.....8
Cross-Examination by Ms. France.....55
Redirect Examination by Mr. Lippard.....105

JAN KELTJENS:
Direct Examination by Mr. McGinnis.....112

P R O C E E D I N G S

MR. SHORES: Good morning, Your Honor.

THE COURT: Good morning.

MR. SHORES: We have a couple of housekeeping matters, if I could go over to begin with.

THE COURT: Sure.

MR. SHORES: First of all, we have one transcription issue that we were going to email the court reporter about. I just wanted to flag it. The purchase price in the transcript for J-Valve is recorded as 150 as opposed to 115. And some of the testimony -- I think it was just a misunderstanding. So I wanted to flag that we're going to do that. I understand the Government has no opposition to that, but I didn't want to just do it out of the blue, if that's okay.

THE COURT: Okay.

MR. SHORES: Okay. The second housekeeping matter is that, for demonstratives, we're going to have two additional demonstratives to our opening demonstratives over the next couple of days. I understand that those have not -- the opening demonstratives have not been submitted to the Court electronically. So we're going to be doing that today, and I just wanted to flag that, as well.

THE COURT: Okay.

MR. SHORES: The third thing is the Government is

going to rest its case today after calling Dr. Wilson. And we've made a schedule of what our case would be over the next two days in order to get done by the end of the day tomorrow so we can all enjoy Thanksgiving. Permission to approach. I'd like to give that schedule to you and just walk through what we'll be doing over the next couple of days, because I do believe it's been adjusted just a little bit.

THE COURT: Okay. So this is outdated; the one I have is outdated?

MR. SHORES: I believe it is, Your Honor.

THE COURT: Okay.

MR. SHORES: May I approach?

THE COURT: You may.

MR. SHORES: And this is a result of us going over the weekend and trying to figure out, again, how to ensure we can get things done. So we have some live witnesses today and two videos. We do think it's very important for the Court to hear Dr. Thourani's testimony, which will be present by video subject to, I know, an issue counsel wants to raise related to that. I did want to flag that we've put at the end of the day some video designations from Boston Scientific. If we run out of time today, we would, you know, respectfully request that's something, maybe, Your Honor could review separately just to save time.

THE COURT: Sure.

MR. SHORES: And then tomorrow, we've structured it so that we have one examination by Zoom, a doctor who couldn't be here, but we'll have a videoconference on that. And then we have two experts. And with this timing, we're confident that we can get through -- done by the end of the day tomorrow. I think counsel's going to raise the possibility of a rebuttal case. I've been very transparent that I'm not committing to leaving time for that, neither do I think that is necessary in this circumstance. That said, if we finish early and counsel would like to put on their expert for 30 minutes of rebuttal, so long as we have, you know, some time to cross-examine, I'm not opposed to that. But we've worked really hard to squeeze our own time -- and we'll be below our time limit -- to get this done over the next two days. So I just wanted to walk through that with the Court.

THE COURT: Okay.

MS. HALL: Good morning, Your Honor.

As Mr. Shores has mentioned, we had flagged that we would like to call Dr. Wilson for 30 minutes in rebuttal following Dr. Bailey. We also -- because Dr. Thourani is now being called by deposition, we'd like to renew our motion to exclude his testimony. I don't know if you'd like me to address that now or when they call for that video to

be played.

THE COURT: I mean, if all you're doing is renewing your motion, I'll take it under advisement and I'll hear the testimony.

MS. HALL: Okay. We would just like to note, Your Honor, that you had directed that we cross-examine Dr. Thourani, and we are unable to do so. We would like to submit some of the exhibits from our motion to exclude him in the nature of impeachment, if we could do that.

THE COURT: Sure.

MS. HALL: Thank you. Those will be the declaration of Varnitha Siva and the following exhibits to the declaration of Laura Hall: C, G, I, J, K, L, M, N, O, P, Q, R, V, W, X, Y and AA, with O being the confidential white paper that counsel for Edwards provided to his counsel.

THE COURT: Okay.

MR. SHORES: We have no objection to that, Your Honor.

THE COURT: All right. They're admitted.

Anything else in the matter -- in preliminary matters?

MR. SHORES: Nothing from us, Your Honor.

THE COURT: All right.

MS. HALL: And just to confirm, Your Honor, that

you do intend to listen to the Thourani video in open court. Just -- we want to be prepared, if you move up the live witnesses, to have the right people here.

THE COURT: Okay. I do.

MR. LIPPARD: Good morning, Your Honor.

THE COURT: Good morning.

MR. LIPPARD: Wade Lippard on behalf of plaintiff, Federal Trade Commission. The FTC would like to call Dr. Nathan Wilson to the stand.

NATHAN WILSON, WITNESS FOR THE PLAINTIFF, SWORN

MR. LIPPARD: May I proceed, Your Honor?

THE COURT: You may.

DIRECT EXAMINATION

BY MR. LIPPARD:

Q. Dr. Wilson, please state your name for the record and spell it for the record.

A. It's Nathan Wilson, N-A-T-H-A-N, W-I-L-S-O-N.

Q. Thank you, Dr. Wilson.

We'd like to pass out binders containing your demonstrative slides and expert reports --

MR. LIPPARD: Or have they already been passed out?

THE COURT: I have one.

MR. LIPPARD: Oh, great. They beat me to it.

BY MR. LIPPARD:

Q. Dr. Wilson, we passed out binders that contain demonstrative slides relating to your testimony today, as well as your expert reports. Were the demonstrative slides prepared at your direction?

A. Yes, they were.

MR. LIPPARD: And for the record, the demonstrative slides are labeled P-D-X-0009. Dr. Wilson's initial expert report is labeled P-X-8001. And his reply report is P-X-8005.

BY MR. LIPPARD:

Q. Dr. Wilson, did you prepare your reports?

A. Yes, I did.

Q. What was your process for preparing your reports?

A. Based on my experience and the overarching economic literature on the evaluation of horizontal mergers, I developed an outline. Then my team at Econic Partners and I worked to fill in that outline based on our review of the totality of the evidence.

Q. Dr. Wilson has the FTC retained you to reach an expert opinion in this case?

A. The FTC retained me to evaluate whether or not the proposed acquisition would harm American consumers.

Q. What is your expert opinion about the impact of Edwards's acquisition of JenaValve on American consumers?

A. My overarching conclusion was that this transaction has

a high likelihood of harming competition and, thereby, harming American consumers.

Q. I'd like to talk about your opinion in more detail in a moment. But first, I want to discuss your qualifications, Dr. Wilson. Where do you work?

A. I'm a founding partner at Econic Partners. That's an economic consultancy.

Q. Would you please give the Court a brief overview of your educational background.

A. Of course. I received a bachelor's in history from Brown University. Subsequently, I received a master's from the London School of Economics. And then I received a Ph.D. from the University of Michigan where I focused on the study of industrial organization.

Q. What is industrial organization?

A. Industrial organization is a subfield of microeconomics that is specifically focused on the relationship between market structure and market outcomes, particularly in imperfectly competitive situations.

Q. How does the study of industrial organization relate to the analysis of mergers?

A. Microeconomics in general is all about the understanding of how the incentives of individual decision-makers impact the choices they make. And industrial organization in particular is focused on the strategic decision-making of

firms, focused on their overarching profits over the long run. And when we're evaluating the potential consequences of a merger, we're focused on how that change in market structure of going from two independent firms to one may impact the combined firms' incentives.

Q. Dr. Wilson, after receiving your Ph.D., where do you go on to work?

A. After receiving my Ph.D. from the University of Michigan, I went to work for the Bureau of Economics at the Federal Trade Commission.

Q. How long did you work in the Federal Trade Commission?

A. I worked in various capacities at the FTC for 11 years.

Q. As an economist at the Federal Trade Commission, what did you do?

A. Overall, my work involved the consideration of different transactions or types of conduct to ascertain whether or not it was likely to redound to the detriment of American consumers. The vast majority of the matters on which I worked focused on horizontal mergers.

Q. What roles did you hold at the Federal Trade Commission?

A. I was a staff economist, commissioner advisor, and deputy assistant director in the Bureau of Economics.

Q. After you left the Federal Trade Commission, where did you work?

A. Upon leaving the Federal Trade Commission, I joined

Compass Lexecon, an economic consultancy, as an executive vice president.

Q. In total, between your government service and private consulting, approximately how many merger matters have you worked on?

A. I would estimate that in some capacity, I've worked on at least 100 different mergers.

Q. Could you describe for the Court the kinds of merge -- matters you've worked on?

A. Of course. It has been my experience to work on a wide variety of different types of transactions. These have included those in industrial chemicals, the potential provision of recycled plastic for use in carpet, tech, and then quite a few in the broader health care and life sciences arena.

Q. Have you published on any antitrust or competition topics?

A. Yes, I have some two dozen articles on industrial organization and antitrust topics.

Q. Have you testified as an economic expert in an antitrust merger case before?

A. Yes, I was the FTC's testifying expert in its successful challenge of the Hershey Medical and PinnacleHealth transaction.

Q. Does your CV, which is attached to your report,

accurately reflect your education, qualifications, and work experience?

A. Yes, it does.

MR. LIPPARD: Your Honor, at this time, I'd like to offer Dr. Wilson as an expert in the field of industrial organization economics as applied to mergers.

MS. FRANCE: No objection.

THE COURT: We'll hear his testimony.

BY MR. LIPPARD:

Q. Dr. Wilson, earlier, you testified that the FTC retained you to evaluate the potential competitive effects of the Edwards-JenaValve transaction on American consumers; is that right?

A. That is correct.

Q. At a high level, what is your opinion based on?

A. As indicated, my overarching conclusion is that this transaction is likely to substantially lessen competition and harm American consumers.

Q. And what findings is that opinion based on?

A. That finding builds atop a number of subsidiary conclusions. I'll step through those now. First, I determined that the relevant market in which to evaluate the potential consequences of this transaction is the supply of TAVR-AR devices to American consumers.

Second, I determined that the proposed transaction

would dramatically increase market concentration in that relevant market.

Third, consistent with what the economic literature says about the consequences of increased concentration, I found evidence that this would reduce beneficial competition that has already benefited American consumers and would likely continue to do so going forward.

And, fourth, I determined that there were neither merger-specific efficiencies nor other effects that would be likely to offset the anticompetitive effects of the transaction.

Q. How did you reach those conclusions?

A. I followed the standard approach that I have taken in the many different matters I have worked on in the past. I began by thinking about what economics indicates are indicia of transactions that are likely to harm competition and consumers. Then I turned to the available evidence to consider whether or not those indicia were present in the transaction of interest. And so specifically, that involved considering quantitative evidence. In this case, that included things like the number of units implanted, the prices that have been charged and are projected to be charged, and other projections, including those of market shares in a post-FDA approval market going forward.

In addition to those quantitative evidence --

pieces of evidence, I also drew on the qualitative record, specifically ordinary course business documents and the testimony of various stakeholders.

Q. Do you rely on any single piece of evidence to form your opinions?

A. No. My conclusions reflect my review of the record in toto and not any particular piece of evidence.

Q. Have you attended or listened to any of this hearing prior to today?

A. Yes, I have attended this court on several days, and when I've been unable to attend, I've endeavored to review transcripts.

Q. Dr. Wilson, do all mergers harm consumers?

A. No, they do not.

Q. Do all mergers benefit consumers?

A. Similarly, no, there is no uniformity.

Q. So how do you determine how a specific merger will affect consumers?

A. To determine whether a given merger is likely to harm competition and consumers requires a deep investigation of the specific facts at issue in that transaction. It is necessarily forward-looking.

Q. So Dr. Wilson, what was your first step in applying the economic framework to this merger?

A. My first step was to determine the relevant market in

which to consider the impacts of the transaction.
Q. What is a market?
A. So as, I think, I indicated on the next slide, a market can be thought of as a collection of the products and geographic locations that are important to understand when making inferences about how the transaction could increase market power and possibly cause anticompetitive effects. It's been referred to as the metaphorical arena in which competition takes place.
Q. And what is a relevant market?
A. A relevant market is a term of art in antitrust by which we mean a collection of the, kind of, core competitive constraints on the products or firms at issue in the transaction.
Q. What is a competitive constraint?
A. A competitive constraint is, essentially, an alternative available to consumers to which they may turn if the focal firm that they're interested in offers them terms of trade that are not to their liking; in other words, charging a price they find to be too high for the value being delivered.
Q. You used the term "focal firm." What is a focal firm?
A. A focal firm would be a term of art to refer to perhaps a firm that we are thinking about being the focus of our interest. In this case, when evaluating a merger, the focal

firm would be one of the merging parties. We're thinking about what would happen if that party's product increased in price and where would consumers go to the extent that they have alternatives available to them?

Q. So how do you know if a company acts as a competitive constraint?

A. In general, we would focus -- we, as economists, would focus on evidence of, kind of, direct interaction with other firms in the market. If a firm is a competitive constraint, typically we would see other firms in that market reacting to its presence and choices.

Q. Does a relevant market contain different dimensions?

A. Yes. Typically, we divide the relevant market into two different buckets. One is the product market which delineates the particular characteristics of the products or services at issue. And then the other, kind of, chief, kind of, delineated set of characteristics would have to do with what we call the geographic market, whether or not there are particularities related to geography in some sense that mean that certain types of consumers have only a limited potential set of alternatives available to them for some reason.

Q. Is there a framework for defining these two components of the relevant market?

A. Yes. Economists typically rely on what's known as the

hypothetical monopolist test, which is defined in the merger guidelines.

Q. At a high level, what is the hypothetical monopolist test?

A. At a high level, the hypothetical monopolist test is essentially an algorithm by which an analyst can work through what the relevant competitive constraints are on the focal firm in order to make sure that they are contained in the relevant product market.

Q. How does the hypothetical monopolist test work?

A. The hypothetical monopolist test works by proposing a candidate market that contains a number of products that may be relevant, and then the analyst poses the question, what would happen if a hypothetical monopolist owned all of those products and elected to raise the price of one by a small but significant and nontrivial amount, often colloquially called a SSNIP. Then the question is, there will be some consumers that had been buying that focal product that has now experienced a price increase. They are likely to -- if it -- the firm had been price-setting appropriately, some of those firms will no -- excuse me, those consumers will no longer find it worthwhile to buy that product. And as a result, they will shift or divert to some other option available to them. If they shift to other products in the candidate market, then the hypothetical monopolist is

retaining those sales; it's not losing those sales. And because it is capturing a higher margin on those consumers that are continuing to buy the focal product even at a higher price, the hypothetical monopolist's overarching profits would go up. In other words, charging a SSNIP would be profitable. In that circumstance, we would say that the hypothetical candidate market has passed the hypothetical monopolist test.

Conversely, let's imagine a scenario where our candidate market does not contain all of the relevant substitutes, in which case, after our hypothetical monopolist imposes a SSNIP on one product, a nontrivial and perhaps quite meaningful number of consumers would divert to products outside of the candidate market. And the hypothetical monopolist would lose those sales entirely, making the SSNIP unprofitable. In that situation, we would say that the candidate market has failed the hypothetical monopolist test and the candidate market should be expanded to include additional substitute products.

Q. Could you walk us through an example of the application of the hypothetical monopolist test.

A. Yes, I have one framed around a market near and dear to my heart. So Your Honor, my wife and I are big fans of pizza, particularly going out for pizza and dining in. We are D.C. residents, and so I framed my example around a

possible situation that confronts us and fellow D.C. residents.

So let's think about D.C. pizzerias. Two ones in particular include Andy's Pizza and Little Grand. Let's imagine that those two pizzerias decide to merge. Okay? The question becomes, if that's our candidate market, what happens if our hypothetical monopolist controlling both of those products imposes a SSNIP on one of the two pizzerias. Let's, for the sake of convenience, say it imposes that SSNIP on Andy's. Well, the question becomes, what would consumers who would have been going to Andy's do? Okay. If we observe that a large fraction of D.C. residents who would have been going to Andy's Pizza instead go to 2Amys, another District-based pizzeria, then that SSNIP would likely be unprofitable. The hypothetical monopolist is losing too many sales to a product outside of the relevant market for the hypothetical monopolist test to be passed. As a result, the exercise now changes. We add 2Amys to the relevant market and repeat the exercise. So we again impose -- we assume our hypothetical monopolist imposes a SSNIP on Andy's and evaluate what consumers would do in this regard. Well, a number of possibilities are open to consumers. They could switch to an entirely different product; right? They could divert to, say, getting coffee at La Colombe. Alternatively, they could continue to consume pizza but via

some other modality, perhaps delivery via Domino's. Or finally, they could travel further. They could leave the District and still dine in at a pizzeria in a neighboring area, perhaps Bugsy's in Alexandria. And so the analysis would require the investigation of what the diversion patterns of D.C. residents would be in response to this SSNIP.

Now, in practice, I think in most circumstances, one would agree that we do not need to specifically investigate diversion to a radically different product, like coffee or hammers or the greater use of hardware stores, for example. Intuition and common sense would indicate that's clearly not likely to be where consumers are going. However, greater questions could be raised about the potential constraining influence of delivery or the ability to travel further in order to access the product.

Q. Dr. Wilson, as an economist, what types of evidence do you rely on in determining the relevant market?

A. As an economist, I rely on whatever information I can find that is reliable and pertinent in order to understand the question. In some circumstances, that very much includes data on the historical preferences of consumers. That can be probative in order to understand potentially thorny questions that do not have an obvious and unanimously agreed-upon answer.

In other circumstances, the qualitative record speaks very directly to whether or not certain options are likely or reasonable alternatives to our consumer group. So for example here, a textbook on the application of quantitative techniques for antitrust analysis emphasizes the important role that qualitative assessment can play in the course of market definition.

Q. And, Dr. Wilson, do you have a view on whether qualitative information can be more or less useful than quantitative information for determining consumer preferences?

A. So I think it's fair to say that I like doing numerical work more than the average person, but quantitative work is a tool, and the point is to answer questions. And sometimes there is not usable or credible data that can be applied to answer a question. And sometimes the question is directly answerable using, you know, testimonial or ordinary course business documents that specifically address whether or not consumers would be likely to see a given type of alternative product as a good substitute in response to a SSNIP on a focal product in the candidate market.

Q. All right. Dr. Wilson, let's turn to the specifics of this case. What is the relevant antitrust market in which to analyze the Edwards-JenaValve merger?

A. My review of the evidence led me to the conclusion that

the relevant product market includes only TAVR-AR products that can be supplied to American consumers.

Q. How did you arrive at that relevant market?

A. I followed the thought exercise of the hypothetical monopolist test. In other words, I posited the existence of a hypothetical monopolist that controlled all of the available TAVR-AR devices available for implantation and use by American consumers, and I imagined what would happen if the price of one of those products increased by a small but significant and nontrivial amount. Would that lead those patients on that focal TAVR-AR device to switch to other TAVR-AR devices, in which case, the market would pass the hypothetical monopolist test? Or would some material fraction of them divert to another form of treatment for their -- of their aortic regurgitation, in which case, it might be conceivably appropriate to expand the candidate market.

Q. What other forms of treatment for aortic regurgitation did you consider in defining the relevant market?

A. Well, I considered the three types laid out in this ordinary course business document from JenaValve, and specifically considered the testimonial and record evidence relating to whether or not consumers would be likely to switch to them in response to a SSNIP on a single TAVR-AR device. And I have individual slides covering those topics.

Q. Let's start with medical management. Why isn't medical management in the relevant product market?
A. As we have heard over the past week, medical management is not a means of treating the disease. It only treats the symptoms. And as we have repeatedly been informed, this is a terribly dangerous disease with a high mortality rate and, as a result, it is not reasonable to expect American consumers to switch away from TAVR-AR to medical management.
Q. Another product that was listed on this slide was surgical valve replacement. Why isn't surgical valve replacement in the relevant product market?
A. Well, as discussed on this excerpt from a JenaValve ordinary course document, surgical valve replacement is highly invasive and, quite frankly, some patients are at too high of a risk to even undergo the procedure. But even for some of those patients who are not at high surgical risk, the invasiveness and burdensomeness of the process of having their chest cracked open for the treatment makes that option unappealing to them. We heard Dr. Vahl talk about that in this court earlier.
Q. And, finally, off-label use of TAVR-AS products is listed. Why aren't -- why isn't off-label use of TAVR-AS products in the relevant product market?
A. Well, as discussed on this next slide, off-label use of a TAVR-AS device is associated with the potential for quite

terrible health consequences, a very high possibility of embolization and, as a result, we see testimony from doctors such as Dr. Kereiakes indicating that should prices of TAVR-AR valves go up, that they would not switch to using a TAVR-AS device instead, specifically answering the question posited by the hypothetical monopolist test.

Q. And, Dr. Wilson, I know you've defined the relevant product market as the supply of TAVR-AR devices, but I want to push back on that for a moment. Defendants have suggested that the market should actually be defined as a worldwide innovation market. Do you agree with that?

A. I do not.

Q. Why not?

A. So to an economist, competition and markets are about delivering products ultimately to consumers. That is where the value is created, is when a consumer finds a product that adds value to their life. And so endeavoring to fully distinguish the process of a consumer making a choice that they will consume from the process of developing those products in general does not make a great deal of economic sense. So certainly, there may be markets in which competition, in order to serve specific customers, is influenced by dynamic elements like investment in innovation, but ultimately the point is on providing products to specific consumers, and here the focus is on who

can provide TAVR-AR devices to American consumers.

Q. So you've defined the relevant product market. What was your next step in determining the relevant market?

A. The next question I turned to was the appropriate geographic market.

Q. And what is the relevant geographic market?

A. As we've covered, the relevant geographic market is United States consumers, the ability to supply United States consumers.

Q. How did you reach that conclusion?

A. The hypothetical monopolist test can be used in order to evaluate the options available to any particular candidate set of consumers. In some cases, all different types of consumers may have the same types of options available to them. In other circumstances, there may be factors that cause some consumers to have only a subset of the entire world of different products available to them as options. And as we've heard from Mr. Wood and others this week, one has to go through the FDA approval process in order to be able to deliver medical devices to American consumers. Thus, the relevant question is, which firms out there in the world, whatever their own location, are in the process or in the actuality of being able to provide products to American consumers?

Q. What information did you rely on in reaching your

conclusion that the United States is the relevant geographic market?

A. So I relied on the opinions of Dr. Aaron Kesselheim, which broadly echoed those of other stakeholders whose materials I reviewed and heard in this court.

Q. All right. Dr. Wilson, you defined the market in general as the supply of TAVR-AR devices to American consumers. What was your next step in determining the effects of the Edwards-JenaValve merger?

A. My next step turned to identifying the active market participants in my relevant market so that I could calculate market concentration and market shares.

Q. What is market concentration?

A. Market concentration is, essentially, a shorthand used by economists to summarize the market structure. Markets that are more concentrated have fewer firms, all else equal, or the firms in that market are more asymmetric. The market may be dominated by particularly large firms.

Q. Why did you seek to determine the market concentration?

A. The economic literature has recognized that market concentration is informative about the effects on consumers, and in particular that changes in market concentration can tell us about how a given transaction is likely to affect consumers.

Q. And, I believe, you mentioned a moment ago that you

identified the market participants. Who are the market participants in the supply of TAVR-AR devices to American consumers?

A. Insofar as only they have begun the process of getting FDA approval to provide products on a commercial basis, only JenaValve and Edwards are. Those are the only two sources of products today for implantation, and they are poised to be the only source of products for years to come.

Q. How did you make that determination?

A. Again, I relied on the overarching evidence, and in particular saw evidence consistent with it in the parties' communications and testimony. For example, here, we see Mr. Kilcoyne, on the first day of this hearing, noting that he is not aware of any other TAVR-AR device currently in clinical trials; meaning, currently able to implant devices in Americans.

Similarly, we see a third party noting -- echoing Mr. Kilcoyne that he is unaware of other parties involved in the FDA approval process for this particular type of medical device.

And then finally, Mr. Bierman's deposition testimony is in keeping with this theme.

Q. Why aren't TAVR-AR devices available outside the United States' market participants?

A. TAVR-AR devices developed outside of the U.S. could

possibly become market participants in my relevant market; however, the fact that they have not received approval from the FDA to engage in clinical trials means that they cannot -- their devices cannot be implanted in Americans. Moreover, the fact that they have not commenced the clinical trial process means the point at which they could provide those valves for widespread post-commercialization use is many years down the road and, as a result, they are unable to provide a competitive constraint equivalent to the one the parties place on each other today, and that is very much consistent with what I see elsewhere in the record.

So for example, Mr. McWilliams, a defendant's -- one of defendants' experts specifically notes that there is only one source of competitive pressure on JenaValve today, and that would be the J-Valve associated with Edwards and JC Medical. And similarly, in his investigational hearing testimony, Mr. Kilcoyne notes that other companies are irrelevant because they're not in our universe.

Q. Dr. Wilson, after you identified the market participants, what did you do next?

A. Once I identified the specific market participants active in my relevant market, I turned to the calculation of market shares and concentration.

Q. How did you calculate market concentration?

A. I utilized -- or I calculated a form of market

concentration known as the Herfindahl-Hirschman Index, or HHI. The HHI is a specific metric with a lengthy pedigree in antitrust economics for evaluating concentration. It is calculated as the square of firms in the relevant market's shares. So for example, a monopolist would have a 100 percent share. As a result, the HHI in a monopolized market would be 10,000. Now, if you had a very large number of very tiny firms, the HHI would be approaching zero because each of those tiny firms would effectively have a zero percent share.

Q. And are there different standards in the economic literature for how HHI changes might inform your view of competitive effects?

A. Yes. So in general, economic theory shows that changes in concentration are associated with worse outcomes for consumers because it transfers or adds to the market power of the combining firms, and it does not take a terribly large change in the HHI index in order for there to be potentially significant consequences on consumer welfare. A recent publication in the American Economic Review, you know, notes the possibility of significant -- that significant offsetting efficiencies would be required in order to address HHI changes of even a, you know -- a few hundred points.

Q. How does Edwards's acquisition of JenaValve affect

market concentration in the supply of TAVR-AR devices to American consumers?

A. So I calculated market shares using two different metrics. One of those was the number of clinical sites in which each party was active, and the other was the number of units implanted in Americans. In both cases, I reached qualitatively similar conclusions. I'll focus in particular on my calculations as relates to clinical sites. So I calculated shares based on the number of different clinical sites associated with each party and then calculated a concentration metric for this in a pre merger world. That pre-merger HHI, I found to be 5,356. That is well in excess of the threshold identified in the merger guidelines as indicating a highly-concentrated market.

Now, as discussed, economic theory places particular emphasis on the impact of the change in concentration. And so, in this case, the change or delta HHI would be the difference between that pre-merger level and the post-merger, monopolized, kind of, maximum HHI level of 10,000. For sites, I found that to be 4,644. That is orders of magnitude beyond the threshold flagged in the merger guidelines as indicating a presumptively anticompetitive transaction and well beyond what's flagged in the economic literature that I discussed.

Q. Dr. Wilson, did you assess whether any other evidence

would verify your market concentration analysis?
A. Yes. Obviously, mergers-to-monopoly are dramatic, and I thought it would be important to ascertain whether or not other evidence echoed that identification of the parties as the only market participants, and I found repeated evidence consistent with that view. So for example, on the slide here is my reproduction of an ordinary course-projected market share for the post-FDA approval TAVR-AR market in the United States. And as you'll see, it delineates market shares for just two products over time. The market is indicated to be split between JenaValve, which becomes active earlier, and the J-Valve which enters subsequently. And we see that according to this ordinary course projection, the parties will be the only providers of these devices to American consumers on a commercialized basis through at least 2035.
Q. Dr. Wilson, is there any other information that you assessed to verify your conclusion?
A. Yes. In addition to the fact that I saw a similar projection from JenaValve, I saw evidence, including evidence from third parties, that corroborates this broad view. So for example, on the redacted slide is an ordinary course document from a third party that, again, highlights this split, effectively, of the market between just JenaValve and the JC Medical device.

Q. Dr. Wilson, aside from the quantitative evidence that you examined, did you look at qualitative evidence to inform your market concentration analysis?

A. I did. And on the next slide are a number of ordinary course materials specifically from JenaValve, again, echoing this view that the parties are unique in their participation in this market. So for example, we see Mr. Baerenwald noting that if it was indeed true that Edwards had acquired JC Medical in addition to JenaValve, that they had just, quote, "bought the AR market." And then, similarly, an email from a JenaValve employee notes that "Who are the competitors? The only real competition is J-Valve."

Q. Dr. Wilson, you mentioned a moment ago this merger would combine the only two market participants. What does economic theory say about that situation?

A. As discussed, economics has found that large changes in concentration are associated with harmful effects on consumers. And perhaps nowhere is that likely to be more true than in the case of monopolies. So for example, on the left-hand side is an excerpt from perhaps the most widely used textbook on industrial organization, at least at the moment, noting the baleful consequences of monopoly, specifically that a firm exercising monopoly power can raise its price above marginal costs because its customers are -- lack alternative options. And in addition to transferring

surplus -- or welfare, effectively -- from consumers to the combined firm, a merger-to-monopoly is also likely to lead to what's known to economists as deadweight loss; meaning, that there is loss to the overall economy that is not captured by any entity, and that is because the elevation of prices above their competitive level causes some consumers to be effectively priced out and they no longer, you know, purchase a product of any -- that addresses their particular need.

Q. Does the creation of a monopoly affect innovation incentives?

A. Yes. As highlighted in the guidelines, monopolies are also associated with harmful consequences in terms of innovation. In general, economics emphasizes that when you experience a loss in head-to-head competition, such as is likely to be associated with a merger-to-monopoly, you can expect to observe both price and innovation effects. So in terms of innovation, this effect is perhaps most widely associated with Nobel laureate Ken Arrow. And his theory is highlighted and discussed here by also Nobelist Jean Tirole, again, who notes that a monopolist may have less incentive to innovate than competitive firms because the monopolist knows that if it innovates a new product active in the same general space, that new product is just going to be taking sales that it would already have been making. It is

effectively cannibalizing itself. And as a result, the monopolist has less of an incentive to develop a new product than a potential competitor to that monopolist would. That potential competitor, when thinking about its own incentives, recognizes that any sale it makes is purely beneficial to it, and that gives it, kind of, an extra nudge relative to the monopolist to go after new product ideas. Broadly speaking -- sorry. Didn't mean to interrupt you.

Q. No, please go ahead.

A. Broadly speaking, the intuition for pricing effects is similar. When there are -- when there is head-to-head competition between firms in a market, each of them is thinking about the desirability of taking sales from the other, and that gives them an incentive to sharpen their pencil and -- when it comes to setting prices. And thus when you, kind of, take away that head-to-head competition, it can serve as an increase on -- or an upward pressure on the prices they would set.

Q. So you mentioned the elimination of head-to-head competition. Have you formed an opinion about whether this merger would eliminate head-to-head competition?

A. Yes. My review of the evidence suggests that this transaction is likely to reduce head-to-head competition with associated unfortunate consequences for consumers.

Q. And how does the elimination of head-to-head competition

affect consumers?

A. The elimination of head-to-head competition to -- harms consumers because it takes away the leverage they have of being able to appeal to an alternative that delivers a similar product that satisfies their needs. I think I have an example here to walk through that. Yep.

All right. So in this example, I'm positing that there are firms -- there are two firms, Firm 1 and Firm 2, that are each providing a product to a set of consumers. So as independent firms, these firms provide products to consumers in exchange for money. Standard competition. Now, what happens, say, if Firm 1 decides that it was leaving money on the table and, therefore, charges a higher price? That higher price is obviously an undesirable new circumstance for consumers who may be inclined to evaluate whether or not they're continuing to get a sufficient value from Firm 1's good. Some of them may switch to Firm 2 instead. The -- take advantage of the existence of the head-to-head competition that exists. That obviously is undesirable for Firm 1 who is losing those sales and, in that sense, the ability to divert to another option imposes competitive discipline on a given firm.

Now, let's think about what happens if the two firms merge. If there become a single combined firm, well, now when Firm 1's product increases in price and causes some

consumers who had previously been purchasing it to switch to Firm 2's good, the combined firm is still capturing the revenue associated with those sales. And as a result, the combined firm internalizes the fact that it is able to recapture the lost sales on the good that experienced a price increase, and this serves, essentially, as the upward pricing pressure that I discussed earlier.

Q. How did you apply that economic framework to this merger?

A. So I specifically looked for evidence consistent with the existence of direct head-to-head competition. In particular, I evaluated whether or not the parties' products would be close substitutes, particularly without reasonable alternatives. Then I considered a variety of different types of direct evidence of competition.

Q. So you mentioned that you determined whether there -- the parties are close substitutes. Are they close substitutes?

A. The evidence that I have reviewed indicates that indeed the parties' products are close substitutes. So for example, Mr. Larkin notes that the two products are similar and that they're both designed to treat the same patient, effectively. Separately, elsewhere in his deposition, Mr. Larkin notes that there would not be -- there is not a competitive constraint out there for a near term use to

the -- relative to the parties. Dr. McCabe of Beth Israel, again, broadly echoes this perspective. And we heard testimony consistent with it from a variety of witnesses, I think, particularly of Dr. Vahl who discussed the transfer of some patients to JenaValve when the J-Valve trial was paused.

Q. So if products are close substitutes, how would that be borne out in the ordinary course materials?

A. If products are close substitutes for consumers, typically we would expect them to be in head-to-head competition, and so I looked for evidence consistent with that, and in particular looking for evidence of them reacting to each other, as highlighted earlier, one of the ways in which we might identify the presence of close competition. And, as described on the slide here, a variety of ordinary course materials indicates that the parties recognize and react that they are substitutes to each other and in competition for the same consumers.

Q. Are Edwards and JenaValve competing today?

A. Yes, they are. And in particular, I think there is clear evidence in the parties' documents that they have focused on competition for clinical trial sites. So for example, here, we see a reference in a JenaValve document from March of 2023 that they observed JC Medical targeting their clinical sites. Similarly, JenaValve sought to limit

the JC Medical access to those sites in response. And then, again, the reference we have seen and heard about the fact that, at a given interventional cardiology conference, J-Valve was quite literally chasing the JenaValve PIs around.

Q. Would the elimination of this competition affect prices?

A. Yes. As discussed, kind of, core IO theory associates the elimination of close competition with upward pricing pressure. And I see evidence in the parties' documents and -- that -- and testimony that is consistent with the fact that they anticipate their competition would, but for this merger, lead to downward pressure on prices. So for example, Ms. Darby, in her deposition, notes that, based on her past experience, she would anticipate J-Valve's FDA approval would result in a lower price for J-Valve. Similarly, Edwards noted that when they are first to market, it's only going to be them and they're not going to have to deal with the fact that there could be alternatives available to consumers.

And then finally, we see an email from Mr. Sun noting that they anticipate getting creative -- or he proposes that they get creative in order to induce clinical trial sites to prioritize Trilogy implants over their competitor.

Q. So we have discussed how the merger affects pricing.

But what about patient access?

A. Yes. The record also contains a variety of materials speaking to the probability that the transaction would reduce patient access to TAVR-AR devices, and this reduction could take a variety of different forms. So a particularly dramatic form would be if the combined firm simply decided, as postulated here by Mr. Baerenwald, that they will just kill one of the technologies so that they are not competing with themselves and can save the costs of developing that product. That is consistent with the possibility con- -- mooted [sic] by Edwards that they would not proceed with the J-Valve clinical trial in the second document excerpted here. But one could also imagine other ways in which patient access would be diminished as a result of the transaction. And for example, it could simply be a more prolonged period of time before a particular type of innovation took place. So for example, the ARTIST trial is aimed at expanding the indications for which TAVR-AR devices can be used on label. If less emphasis is placed on completing that trial, that delays those lower and more moderate surgical risk patients' ability to access the device. And then finally, simply by leading to higher pricing pressure, there is an associated expected knock-on effect on device access. So for example, Dr. Kereiakes here talks about, well, if devices cost too much, then hospitals

simply will not stock them, making it harder for patients to be able to access these devices.

Q. Have you considered any other markets to test your conclusions about how the elimination of head-to-head competition would affect pricing?

A. Yes. I specifically focused on what the TAVR-AS market might be able to tell us about the relationship between competition and prices. And as indicated on these slides here, that market echoes what economics would predict about the relationship between competition and prices. Specifically, the document cited in the upper left speaks to the fact that after Edwards experienced an increase in competition with the entry of an alternative CoreValve device into the post-commercialized market, that was associated with an increase in price flexibility in a fairly dramatic way. And similarly, an email sent in the ordinary course of business, again, notes that, in response to anticipated pressure from CoreValve in 2014, Edwards preemptively started offering rebates. And, in general, the availability of alternative options is associated with downward pricing pressure.

Q. Dr. Wilson, I'd like to turn now to innovation, which we've heard a lot about in this past week. Have you formed an opinion on whether the combination of Edwards and JenaValve would affect their incentives to innovate?

A. Yes, I have.
Q. And what is your opinion?
A. My view is that this transaction is likely to reduce innovation relative to what would be expected with -- in its absence.
Q. And what is that opinion based on?
A. So I think it is fair to acknowledge that the economic literature acknowledges a variety of factors that may increase the probability that mergers, even ones that may have some anticompetitive effect, could nevertheless increase innovation; however, that literature does not indicate that this is a high -- that there is a high probability of this. Moreover, the economic literature identifies a number of factors that one can consider in reaching a conclusion about whether we are in one of these circumstances where an elimination of some competition could nevertheless increase innovation. And so I specifically reviewed whether or not those different indicia were present in this circumstance.
Q. What indicia did you review?
A. So the economic literature on the relationship between competition and innovation is large, as you would expect, for such an important topic. But there are three rough buckets that have been identified as speaking to this question. The first of these is what's been referred to as

contestability. Essentially, are the products that the firms are developing -- are they ultimately close substitutes for final consumers? And in -- when those products are close substitutes, and they will be vying intently to make sales to the same consumers, then we would have a greater concern about that replacement effect identified by Ken Arrow being the dominant influence. And as we've been discussing, there is abundant evidence that the parties are anticipating and already are active in their competition with each other.

Q. Have you seen any indication that Edwards and JenaValve are innovating in response to each other?

A. Yes. So if we flip to the next screen here, I think perhaps the clearest example of how the parties' competition is specifically driving forward certain types of innovative activity, maybe, in connection with JenaValve's large valve or XL valve. So as we've heard, J-Valve at present has the ability to treat more patients who have AR than does the current version of the Trilogy valve. The current version of the Trilogy valve is not able to treat as many patients if their aortic annuli are larger. Recognizing the fact that they were vulnerable to competition on this front, JenaValve has specifically pushed, and pushed in a way that they might not have done otherwise in terms of its rapidity, to pursue the development of this XL valve in response. So

for example, here, on the right-hand side, we see an ordinary course document from mid-March speaking to the fact that they need to develop the large valve now, noting that their competitor already has that valve size in their portfolio, and this will prevent the loss of customers who may only want to stock one AR valve going forward.

Q. You so you mentioned that this factor would suggest less innovation. What about the factors that would suggest more innovation from this merger?

A. Right. So I identified that there were three, kind of, large buckets into which economic theory has, kind of, tried to, sort of, sort the relationship between innovation and competition. Contestability was one. A second is what's been referred to as appropriability. And that is a -- essentially, a multi-syllabic way of describing the ability to capture the returns of coming up with a better product. So imagine a world in which I build a better mousetrap. Now, that's going to take, you know, investment in terms of time, resources. Those investments will only be worth undertaking if I am confident that I will be able to be on the market with my better mousetrap, taking sales away from incumbents who have inferior products long enough to at least recapture and cover my investment costs. But let's postulate a world where my neighbor has -- can easily pay attention to what's been going on in my garage, and once

I've identified a successful new mousetrap innovation, can immediately and largely costlessly follow me in developing that product and go to market at exactly the same time as me. In that circumstance, it's going to be very difficult for me to generate the returns necessary to offset those upfront costs and expenditures I've made in developing a better mousetrap.

Now, in this world, it -- neither my neighbor nor I is likely to undertake these research efforts on our own, recognizing that we won't be able to capture or appropriate the returns of our innovation, and in that circumstance, it's possible that if my neighbor and I merged our efforts and, you know, took pains to prevent other neighbors from paying attention, that could lead to higher innovation.

Now, in practice, economists are most worried about appropriability concerns restraining efficient innovation in circumstances where there are not robust intellectual property protections. And from my review of the evidence, including the excerpt here from Mr. Bierman, there's no indication that patents are not a good means of protecting innovative ideas.

Q. What was the third factor you considered?

A. The third factor I considered is, kind of, loosely associated with the term complementarity, the idea that, essentially, the two firms are better together than they are

as stand-alone entities. And that could arise for a variety of reasons. Perhaps the most intuitive would be if they are associated with products that are consumed at the same time. So let's think about an innovative marketplace where there are, kind of, potentially quite differentiated products that are simultaneously used by final consumers, say, hardware and software utilized in the -- a corporate enterprise. Well, in the pre-merger world, the software developer does not think about the fact that when it makes its software better, it's likely to also lead to some increase in demand for hardware and, as a result, it perhaps invests a little bit less, or perhaps a lot less, in innovating than in -- than would be efficient in, kind of, a global overall sense. And same goes for the hardware manufacturer. Post-merger, however, the combined firm that spans these two broadly complementary products will internalize the fact that when it makes one of its constituent elements better, it's going to increase demand for both, and that will naturally give rise to greater innovation efforts than observed in the pre-merger world.

Now, that particular example of complements at the point of consumption fairly clearly does not apply to this merger. One does not need both a J-Valve and a Trilogy valve in order to address aortic regurgitation. Alternatively, one might posit that the firms are

complementary in terms of their ability to produce something or -- on the supply side. So if there was evidence consistent with, you know, bringing the two firms together, you know, being likely to, you know, either increase innovation by combining different types of specialists in materials -- but there is nothing in the record here to indicate that that is likely. Instead, there's evidence along the lines of this text exchange between Mr. Baerenwald and Mr. Sun indicating that in the event that this transaction proceeds, that it's likely to lead to one of the products being killed.

Q. Okay, Dr. Wilson. You've walked us through the three economic indicia you've considered with respect to innovation. But have you seen any evidence directly discussing how the transaction might affect innovation incentives?

A. Yes. One of the most striking things that I've seen in the review of the evidence is -- are materials essentially speaking directly to the relevant question of, what does innovation look like in a merger world relative to the counterfactual world of JenaValve and Edwards continuing as separate entities, trying -- each trying to develop TAVR-AR devices to serve American consumers? And we see, as on the slide here, you know, from JenaValve, specific indications that should this transaction not proceed, they will put

their firm -- foot a bit more firmly down on the gas when it comes to pursuing specific types of innovation that are likely associated with benefits to American consumers. So specifically, the development of a large valve product that would compete directly for -- with the J-Valve for treatment -- the treatment of patients with larger aortic annuli, and also the pursuit of this full ARTIST launch relative to a softer one, enabling the on-label treatment of patients with lower surgical risk.

And similarly, if we turn to the next slide, there is, again, an indication that Edwards, too, anticipates that in a -- the non-merger counterfactual world, they would endeavor to accelerate the delivery of the J-Valve to American consumers on a commercial basis relative to what they would do should the transaction actually occur.

Q. Earlier, you mentioned that you examined TAVR-AS to verify your conclusions about potential price effects in the supply of TAVR-AR devices to American consumes. Have you conducted the same analysis with respect to innovation effects?

A. Yes. I, again, reviewed the record to consider what evidence there was in this at least somewhat analogous market when it came to the relationship between competition and innovation. And, again, we see fairly direct evidence consistent with what economics predicts. So for example, in

the upper left, there is an ordinary course Edwards document emphasizing that should they not continue innovating, it will cost them market share and that that loss of market share is worth, you know, nine figures easily.

Moreover, if we move to the right, we see, again, ordinary course evidence, this from back in 2011, that competition, you know, drives them to focus on innovation and that this conclusion is echoed by the deposition testimony of Mr. Woods [sic] who affirmed that to maintain its leadership, Edwards has had to continuously pursue innovation.

Q. Have you seen any other indication of that with respect to TAVR-AS?

A. Yes. One of the more striking things that I've seen in court this past week was the testimony of a third party in the redacted space here who utilized the language that they cannot rest on their laurels because it will cost them market share; it will specifically cause it to erode and, as a result, they don't rest on their laurels. And what was so striking to me was how precisely the language maps to what appears in the IO textbook that I've referenced several times where the language is, again, a monopolist tends to rest on his laurels because they're not being challenged by competitors trying to take share away. And here, we heard this third party specifically affirm exactly that

relationship.

Q. Dr. Wilson, earlier in our conversation, you testified that some mergers can benefit consumers. When can a merger benefit consumers?

A. A merger can benefit consumers if it gives rise to effects that would not be reasonable to anticipate or expect unless that merger took place.

Q. And have you evaluated whether this merger would generate any benefits?

A. Yes, I have considered whether or not the proposed transaction would likely be associated with these procompetitive efficiencies or this type of procompetitive efficiency.

Q. What is your assessment of the claimed efficiencies from this merger?

A. My overarching review of the possibility of efficiencies broadly follows the approach laid out in the merger guidelines of looking for evidence that the benefits are merger-specific. In other words, they are specifically associated with the proposed merger and would not be reasonable to expect in some -- in a but-for world that the transaction did not take place. Moreover, I looked for clear and compelling evidence that these transactions -- or excuse me, that these effects -- these procompetitive effects would be likely to take place. And as highlighted

on this slide here, I do not feel that those criteria are met. In particular, there's no evidence to suggest there are efficiency plans that can be reviewed and evaluated as to whether or not they are likely.

Q. And, Dr. Wilson, recognizing we're in an open session, have you considered JenaValve's prospects for alternative sources of funding in reaching this conclusion?

A. Yes, I have.

Q. And what is your assessment of that?

A. Based on my review as synopsized in my reports, I do not think it is reasonable to conclude that but for this merger, the JenaValve products would not progress towards FDA approval and widespread availability to American consumers.

Q. Let's turn now to entry, Dr. Wilson, which we've also heard a lot about. Defendants have suggested that entrants would likely enter the TAVR-AR market quickly. Have you considered whether future entry would affect your analysis?

A. Yes, I have.

Q. And in evaluating this transaction, did you look for indications of future entry?

A. Yes, I did.

Q. And how did you evaluate entry?

A. I evaluated entry using the standard tools and approach taken throughout my career of looking for evidence to indicate that the entry would be specifically in response to

some deterioration in competitive conditions and not -- in other words, it would -- it's not just entry that would already be taking place; that the entry would be sufficient to offset any anticompetitive effects from the transaction; and that the entry would be timely; meaning, happening soon.

Q. What is your assessment of whether entry would offset the effects of this merger?

A. My view is that the record does not support a conclusion that entry would meet those criteria. And in particular, the important role played by FDA approval, or the need to receive FDA approval means that the transaction would meaningfully increase the combined firms' market power for a meaningful period of time to the detriment of consumers.

THE COURT: How do you define "meaningful period of time"?

THE WITNESS: Typically, it's several years.

THE COURT: How do you define "several"?

THE WITNESS: So timely entry, I think -- I associate with being within the next two. A meaningful period of time of a market in which the market would be harmed, I would think, would be two to five or more. And since we have seen ordinary course projections indicating that the parties do not anticipate seeing rivals come into the supply of TAVR-AR devices until after 2035, which is consistent with what -- Dr. Kesselheim and Dr. Bailey's

predictions about the length of, from a standing start at the start of clinical trials to receiving their PMA, that seems broadly right. And so if we're thinking that J-Valve would arrive on the market in '28, '29, that leaves the parties as the only suppliers of a commercialized product for five, six years.

THE COURT: So let's say -- if it got down to five, would you still find that that would be problematic?

THE WITNESS: Five years of a monopoly seems bad to me. The price effects that we've seen highlighted, perhaps in the reference to TAVR-AS, are fairly meaningful. Those are -- those would be nontrivial transfers of surplus from consumers to the combined firm. I also worry a great deal about the effect on innovation which, in this space in particular, when we're thinking about coming up with new products to address a population that is, per Mr. Bierman, starving for these products, that seems, again, quite harmful.

BY MR. LIPPARD:

Q. Dr. Wilson, suppose a company obtained an IDE tomorrow. What would that mean for the potential effects of this transaction?

A. So let me be clear. I think that would be great if one of these foreign products commenced the FDA approval process and received an IDE tomorrow, but I don't think that that

should cause us to not be concerned about this transaction and its effect on competition. So certainly, let's say that it is appropriate to consider the firm that has received the IDE as a relevant market participant. That would fit with the fact that JenaValve began to take JC Medical much more seriously as a competitor once it had received its IDE and breakthrough designation. But that doesn't mean that this new firm that had just received its own IDE would be an equivalent competitive constraint to the one the parties impose on each other at present. If it had just received its IDE, it would be able to commence EFS studies. It would then need to proceed through the pivotal trial phase, and then the application for a PMA. All of that takes time. And the two parties' products are meaningfully further along in that process. As a result, they are closer competitive constraints to each other than this new third firm would be.

Q. So after considering alleged efficiencies and potential future entry, what is your conclusion about the effects of the Edwards-JenaValve merger?

A. As indicated at the start of our conversation, my overarching conclusion is that this transaction is likely to lessen competition and result in harm to American consumers.

Q. Thank you, Dr. Wilson.

MR. LIPPARD: Your Honor, I have no further questions at this time.

THE COURT: All right. Thank you.

Let's take a 10-minute break.

(Brief recess taken.)

THE COURT: Are we ready?

MS. FRANCE: Yes.

CROSS-EXAMINATION

BY MS. FRANCE:

Q. Good morning, Dr. Wilson.

A. Good morning, Counsel.

Q. Nice to see you again.

A. Nice to see you, as well.

Q. Doctor, when you're evaluating a merger, it's standard in economic models to think about the expected outcomes of a merger; right?

A. Yes, the point of the analysis is to think about the expected effect of the transaction.

Q. And those expectations in economic modeling reflect the relative likelihood of different potential merger effects; is that right?

A. Yes, it would be important to think through the different possible effects the transaction could have.

Q. And it's also important to think through what the magnitudes of those effects might be?

A. Yes, it would be important to think about the potential magnitudes of different types of merger effect.

Q. You agree that most merger analysis requires an assessment of what will likely happen if the merger proceeds as compared to what will likely happen if it does not; right?
A. As, I think, we covered, it is an important consideration of the analysis to evaluate what the merger would be likely to lead to relative to what the counterfactual non-merger world is.
Q. But you did not quantify the number of TAVR-AR devices that are likely to be implanted in patients with the transaction versus without; right?
A. Correct. My reports did not contain a quantitative analysis about the number of transplants to be expected.
Q. And you did not quantify the delta between the amount of R&D spend that could be expected with the transaction versus without?
A. Correct, I did not come up with a numerical estimate of the difference in R&D spend.
Q. And you did not quantify the likelihood that any particular TAVR-AR device receives premarket approval from the FDA with the transaction versus without?
A. No, I did not. That was not part of my specific assignment.
Q. So just to be clear, you did not quantify the likelihood that Trilogy receives premarket approval from the FDA with

the transaction versus without?
A. My reports reviewed the likely competitive effects of this transaction based on a review of what the ordinary course materials and testimony indicated was likely, and particularly in terms of how those likelihoods affected the incentives of the individual firms and would affect the combined firm. But I did not perform a specific calculation.
Q. And also, to clarify, you did not perform a specific calculation to quantify the likelihood that J-Valve receives premarket approval from the FDA with the transaction versus without?
A. I would echo my previous answer.
Q. So the answer is correct, you did not quantify that?
A. The answer is I did not develop my own specific quantitative estimate of the likelihood that J-Valve would receive PMA from the FDA.
Q. And you did not do any quantitative analysis to compare the likely effectiveness of Edwards's commercialization of Trilogy with the merger to the likely effectiveness of JenaValve's commercialization of Trilogy without the merger?
A. There, I'm not sure I would agree.
Q. And why not?
A. So as discussed in my reports, I did evaluate whether or not there was a basis to believe that but for the

transaction, JenaValve would not be able to proceed with the development of Trilogy and found there was no basis for such a belief.

Q. Let me ask you my question again. You did not do any quantitative analysis to compare the likely effectiveness of Edwards's commercialization of Trilogy with the merger to the likely effectiveness of JenaValve's commercialization of Trilogy without the merger?

A. So I think my previous answer applies, that I found there was no basis to conclude that there would be a benefit from Edwards's acquisition, but I will concede that there's no algebra in my report speaking to this effect.

Q. And you did not do any quantitative analysis of JenaValve's output rates with or without the merger?

A. I think my answer is going to be similar to those just given; that I reviewed the record to see what evidence there was that Edwards would be expected to achieve better performance than JenaValve alone, and found there was no basis for such a perspective.

Q. But you did not do any quantitative analysis of JenaValve's output rates with or without the merger?

A. There is no Excel or other form of numerical exercise in my backup speaking to this point.

Q. And you did not calculate or quantify the number of patient lives that would be saved with the transaction

versus without, did you?
A. Once more, I would indicate that I saw no basis in the record to anticipate procompetitive benefits from the transaction, but there is nothing in terms of a spreadsheet or mathematical model that endeavors to put specific numbers on this point.
Q. Again -- and, Doctor, I understand the context. You can address that with the FTC's counsel as you'd like. But let me ask you again: You did not calculate or quantify the number of patient lives that would be saved with the transaction versus without; correct?
A. Apologies, Counselor, if we're talking past each other, but my analysis found no basis to suggest there would be a difference. So I'm not sure what your question is asking me to calculate.
Q. Doctor, you recall when I deposed you a little over a week ago?
A. I do.
Q. And you testified under oath at your deposition?
A. I do. I did.
MS. FRANCE: Let's put up Dr. Wilson's deposition at Page 181, Lines 14 through 21.
BY MS. FRANCE:
Q. "QUESTION: Did you quantify the number of AR patient lives that are likely to be saved with the transaction

versus without?"

There's an objection.

"ANSWER: I did not engage in any specific effort to calculate or quantify the number of patient lives that would be saved or affected by avoiding the transaction."

Did I read that correctly?

A. You did.

Q. To the extent a change in the world with the transaction versus without is connected to an increase in consumer welfare, standard economic frameworks would suggest that change was good for consumers; right?

A. Could you repeat that for me, Counselor?

Q. Sure. To the extent a change in the world with the transaction versus without is connected to an increase in consumer welfare, standard economic frameworks would suggest that change was good for consumers; correct?

A. Yes, I think if the world improves and consumers are better off, then the world has improved and consumers are better off.

Q. So if the Court finds that more patients will receive TAVR-AR treatment with the transaction than without and that leaves consumers with greater welfare, as a matter of economics, that would be considered a benefit to consumers; right?

A. I don't mean to presume on what the Court will conclude,

but if consumers benefit, I think consumers benefit.

Q. And so as a matter of economics, it would be considered a consumer benefit, as well?

A. I think economics would track other disciplines in identifying benefits as benefits.

Q. And then if -- post transaction, if there is a greater emphasis on innovation and development of TAVR-AR products and consumers appreciate those incremental changes, as a matter of economics, that would seem to also be a benefit to consumers, wouldn't it?

A. In an event, such as a merger, specifically causes some benefit in terms of more innovation taking place and consumers appreciating those innovations, as well as their ability to consume products bearing them on reasonable and equitable terms, then I agree that economics would consider that beneficial to consumers.

Q. And if the Court finds that more lives will be saved with the transaction versus without and that change is connected to an increase in consumer welfare, as a matter of economics, that would also be a benefit to consumers; right?

A. I think my answer's going to be similar. If it is -- if there is a causal relationship between an event and effects that redound to the benefit of consumers, that seems beneficial.

Q. Dr. Wilson, I want to clarify a few things about the

work that you did in this case. Your analysis focused on interpreting the evidence in the record in light of what's predicted in the economic literature?

A. Yes, I viewed the record through the lens of economic theory and the economic literature.

Q. And the evidence in the record primarily consists of ordinary course documents and testimony?

A. There -- I think I will happily grant you that there is a lot of ordinary course documents and testimony in the record.

Q. And you think that the documents and testimony in the record in this case provide a basis for inferring the likelihood of both price and non-price harms; is that fair to say?

A. Yes, my review of the totality of the evidence leads me to the conclusion that the transaction will harm competition and consumers.

Q. And your interpretation of the evidence suggests that the transaction could harm consumers by raising prices?

A. Yes, I identified the likelihood of price effects as one of the reasons I'm concerned about the consequences of the transaction.

Q. But you did not quantify the amount of price harm that might result from the transaction, did you?

A. I did not perform a specific calculation about the

magnitude of price harm to be expected.
Q. So in other words, you did not calculate an estimated price effect from the transaction?
A. As I think I just said, I did not perform a specific calculation but noted in the record a variety of evidence consistent with price effects.
Q. And you did not perform an upward pricing pressure analysis, for example?
A. I did not conduct a UPP analysis that combined a specific numerical estimate of diversion and a specific numerical estimate of the unit margin in order to come up with a specific numerical estimate of the UPP that could be expected.
Q. And so we just talked about the price harm conclusions that you drew. It's also your opinion that the transaction could harm consumers by potentially reducing innovation; is that fair to say?
A. Yes, I identified the likelihood of innovation effects as another reason to be concerned about this potential transaction.
Q. But you also did not quantify the amount of innovation that would be anticipated with the merger versus without?
A. Could you repeat that for me, Counselor? I'm sorry.
Q. Sure. You did not quantify the amount of innovation that would be anticipated with the merger versus without?

A. I think similar to a number of my previous answers, I did not perform a specific numerical calculation speaking to the amount of innovation at risk.

Q. And you mentioned earlier in your direct, to support your opinion that the transaction could potentially harm innovation, that the parties have competed to develop relationships with clinical test sites; is that correct?

A. Yes, that is.

Q. But you did not quantify how much greater innovation is by Edwards because of that supposed competition for test sites, did you?

A. I did not quantify how much greater innovation by Edwards? I'm sorry. Could you repeat that question for me?

Q. Yes. You did not quantify how much greater the innovation has been by Edwards because of that supposed competition for test sites.

A. Innovation in the TAVR-AR market?

Q. Let me ask you again. You did not quantify how much greater innovation is by Edwards because of that supposed competition between the parties for test sites; right?

A. I did not perform a specific numerical exercise calculating a point estimate of the impact on innovation from the competition for trial sites.

Q. And that goes for both Edwards and JenaValve; right?

A. Correct.

Q. I want to take a look at Slide 32 from your demonstrative. That's P-D-X-0009. The quote on the right from Mr. Kilcoyne is dated March 5th, 2023. It will be on the screen for you, as well.

A. All right. Thank you.

Q. Do you see that?

A. Yes, I do.

Q. And this email from March 2023, are you aware that that's before JC Medical had an IDE to conduct trials in the United States?

A. My recollection is that JC Medical received its IDE and breakthrough designation in that same period. Let me consult the timeline in my report.

Q. I believe your report cites documents showing that JC Medical received its IDE on August 31st, 2023. Fair to say that's after March?

A. I think you have identified an area of agreement between us, Counselor. Yes, I see that JC Medical received its breakthrough designation and IDE in the middle of 2023, after this point in time.

Q. Thanks.

MS. FRANCE: We can take that down.

BY MS. FRANCE:

Q. You think innovation, in and of itself, is difficult to connect to consumer welfare, don't you?

A. Yes, as discussed in my direct testimony, economists think about consumer welfare as being associated with consumers' ability to access and consume a product. Clearly, innovation is important in developing the products that they consume, but the entire chain is the relevant way of thinking through the relationships.

Q. And it's your opinion that the transaction will result in potential price and non-price harms because the parties' products are close substitutes for consumers; is that a fair characterization of your testimony?

A. Yes, owing to the economic theory highlighting the potentially baleful consequences of allowing a merger of close substitutes, I am anticipating a likelihood of both price and non-price effects.

Q. But you did not calculate a measure of the substitutability of the parties' products, did you?

A. As discussed in my direct testimony, I reviewed the broader record indicating that they are substitutes, but I did not calculate a specific metric of my own.

Q. So you did not calculate a quantitative estimate of diversion, for example, between the parties' products?

A. As I just indicated, I did not specifically calculate a numerical measure.

Q. Doctor, in circumstances where transactions may give rise to both procompetitive effects and anticompetitive

effects, economists may gauge -- engage in a balancing exercise that attempts to address the likely net effect of the overarching transaction; correct?

A. That sounds right.

Q. But based on your interpretation of the evidence, you think there is no reason to anticipate benefits from the transaction that could offset what you have characterized as clear evidence of likely harms; right?

A. That is correct.

Q. And based on your interpretation of the evidence, you find that there is no basis to expect benefits from the transaction?

A. Based on my review of the evidence, there is no reason to anticipate benefits from allowing JenaValve to be merged with its closest competitor relative to a world where it continued as a stand-alone firm or ultimately is partnered with another strategic medical device manufacturer.

Q. And because of that, you didn't think it was necessary to do some sort of quantitative weighing of potential harms versus potential benefits from the merger; right?

A. Insofar as I identified no basis for anticipating procompetitive effects relative to the but-for world, I don't see how I could have done some sort of weighing.

Q. So just to be clear for the Court, you did not perform any quantitative balancing of potential merger harms versus

benefits in this particular case?
A. Correct, insofar as I identified no potentially offsetting benefits, I did not weight them against the harms that I anticipated.
Q. But if the Court disagrees with you and the Court concludes that the transaction is likely to give rise to benefits, you have not engaged in any sort of quantitative analysis that would assist the Court with balancing those benefits against any competitive harms, have you?
A. I -- insofar as my report indicates no basis for there being benefits, it contains no quantitative comparison of their relative magnitudes to the significant harms I anticipate.
Q. But focusing, again, just on the competitive harm piece of that, you have done nothing to quantify the magnitude of any competitive harm to assist the Court with any balancing against potential benefits?
A. I advanced no numerical estimate of different types of harm, but I think my report contains a variety of evidence speaking to the types of procompetitive effects of competition that would be lost if this transaction proceeds.
Q. Doctor, in your direct examination, you talked about performing the hypothetical monopolist test to define your market. Do you recall that?
A. I do.

Q. You did not perform a quantitative hypothetical monopolist test in this case; correct?
A. Correct. In this case, I did not rely on quantitative tools to perform the hypothetical monopolist test.
Q. And as, I believe, you said earlier, you did not rely on any historical data in defining your product market, did you?
A. Correct. I did not rely on historical data for these products.
Q. And you did not rely on any data to calculate a quantitative measure of consumer demand for TAVR-AR devices, did you?
A. I did not estimate or calculate a quantitative measure of demand for TAVR-AR devices.
Q. Your initial report defined the product market as the supply of TAVR-AR devices to American consumers; right?
A. That is correct.
Q. And that's also the market definition you told the Court about earlier today?
A. Also correct.
Q. But your reply report defined the product market as, quote, "the development and provision of TAVR-AR devices to American consumers"; correct?
A. Yes.
Q. And at your deposition, you told me there's no

difference in your mind between those two product market definitions?

A. I see them as synonymous.

Q. You were present in the courtroom for the FTC's opening statement; correct?

A. Yes, I was.

Q. Do you agree with counsel for the FTC that only devices that have some form of FDA approval to treat U.S. patients can comprise the market?

A. I think that would be consistent with my conclusions reached in my report.

Q. So it's fair to say, then, that the only market participants in your market are firms with TAVR-AR devices that have some form of FDA approval to treat U.S. patients?

A. Yes, as discussed in my direct, I believe -- or I endeavored to be clear that part of how I identified active market participants was by looking for firms able to supply TAVR-AR devices to American patients.

Q. So does that mean FDA approval to conduct a U.S. clinical trial?

A. Yes.

Q. And for TAVR-AR devices, FDA approval to conduct a U.S. clinical trial means receiving an investigational device exemption, or an IDE?

A. Based on my review of the testimony and the expert

report work of Dr. Kesselheim, I believe that to be correct.

Q. Dr. Wilson, you relied on the 2023 FTC and DOJ merger guidelines in your analysis in this case?

A. The '23 guidelines were one of the materials I relied on.

Q. And the '23 guidelines section on market participants has some language that I want to ask you about. It says, "All firms that currently supply products in a relevant market are considered participants in that market."

I think -- you would agree with that statement?

A. It sounds somewhat tautological, which makes it easy to agree with.

Q. And then the same section of the merger guidelines from 2023 also says, "Firms not currently supplying products in the relevant market but that have committed to entering the market in the near future are also considered market participants."

Do you agree with that, as well?

A. Could you repeat that language for me, please?

Q. Sure. "Firms not currently supplying products in the relevant market but that have committed to entering the market in the near future are also considered market participants."

Do you agree with that?

A. I think firms that are clearly embarked on the ability

to provide products to the relevant population of consumers and who will clearly be able to do so in many circumstances should be accounted active market participants.

Q. The same section, again, of the 2023 merger guidelines has another sentence that says, "Firms that are not currently active in a relevant market but that very likely would rapidly enter with direct competitive impact in the event of a small but significant change in competitive conditions without incurring significant sunk costs are also considered market participants. These firms are termed rapid entrants."

Do you agree with that statement, as well?

A. I'm sorry. Are you asking me if I -- what exactly are you asking me to agree with?

Q. Let me read this to you again. I'm asking if you agree with all of this. "Firms that are not currently active in a relevant market but that very likely would rapidly enter with direct competitive impact in the event of a small but significant change in competitive conditions without incurring significant sunk costs are also considered market participants."

Do you agree?

A. I agree the guidelines say that, and I agree that it makes sense to think about the actions of potential entrants when evaluating the likely competitive consequences of a

transaction.

Q. I have just one more quote for you. If you'd bear with me. Again, from the '23 merger guidelines, it says, "Firms that are active in the relevant product market but not in the relevant geographic market may be rapid entrants."

Is it fair to say you agree with that statement, as well?

A. I think it's reasonable in some circumstances to think that firms that are not currently in the geographic market but which could be, should they elect to so reposition, should be a consideration in the evaluation of competitive effects.

Q. So just in a general sense, if you define a market that includes market participants who are rapid entrants, when you're calculating shares in that market, you have to consider the shares of those rapid entrants; isn't that right?

A. I think, in general, it's reasonable to try and think through the potential discipline that could be imposed by potential entrants if it's indeed likely that they would enter as a result of the transaction.

Q. And when you're thinking about those entrants, the typical time frame for analyzing entry in the context of a merger is approximately two to three years; is that right?

A. In my general experience, that is a time frame that is

often utilized.
Q. So let's turn back now to your market in this case. You agree that the possible commencement of U.S. clinical trials by a firm with a TAVR-AR device other than the parties would be competitively salient; right?
A. I would agree that it would be something to think about in terms of evaluating competitive consequences.
Q. You agree it would be competitively salient?
A. I think that's consistent with what I said.
Q. So in other words, the possible commencement of U.S. clinical trials by a firm with a TAVR-AR device other than the parties would be relevant to determining whether that firm is a participant in your market; right?
A. Yes, as, I think, I discussed with Mr. Lippard, if I learned that a -- one of the firms active in other parts of the world had received an IDE, it would likely be appropriate to think of them as an active participant and factor in their presence in terms of shares, concentration, potentially, but given the difference in their position on the FDA approval pipeline, I don't think that it would be appropriate to conclude they would present the same sort of competitive constraint as the merging parties currently do on each other.
Q. The possible commencement of U.S. clinical trials by a firm other than the parties with a TAVR-AR device would be

relevant to determining whether that firm should be considered a rapid entrant in your market; right?

A. I'm sorry. Could you repeat that for me, Counselor?

Q. Yeah. The possible commencement of U.S. clinical trials by a firm with a TAVR-AR device other than the parties would be relevant to determining whether that firm should be considered a rapid entrant.

A. Yes, I think I agree, and that's -- was part of my evaluation as contained in my reports.

Q. And it's your view that the degree to which JC Medical was a competitive constraint on JenaValve changed after JC Medical began U.S. clinical trials; right?

A. Yes, I think that's consistent with the broader record.

Q. And we actually looked at a document earlier that's quoted in your slides from today that showed JenaValve thinking about what JC Medical was doing before it began U.S. clinical trials; right?

A. Yes.

Q. And you think that type of evidence would be relevant for determining whether another device developer other than the parties is a market participant in your market; right?

A. Yes, if I saw evidence consistent with a third party eliciting the same sort of reaction from JenaValve that JC Medical did, that would certainly be very relevant to my assessment.

Q. Your demonstrative on Page 19 had some language that says, "There is no evidence that other potential AR treatments put equivalent competitive pressure on the merging parties."

But that standard, equivalent competitive pressure, that's not the standard outlined in the merger guidelines for how to determine whether a firm is a market participant; right?

A. I'm sorry. You'd have to refresh my memory of what's in the guidelines.

Q. I'm asking you, is the language here that you have about other companies not putting equivalent competitive pressure on the parties -- that's not a standard outlined in the FTC or DOJ merger guidelines for how to determine whether a firm is a market participant; is it?

A. I would have to review the guidelines.

Q. Sitting here today, you don't recall whether or not that's part of the standard?

A. In general, economics emphasizes the importance of evaluating direct responses to the presence and actions of competitors. That's why my slides emphasize what I see as far as the parties reacting to each other.

Q. We can go ahead and take the slide down.

Just more generally, whether another firm puts equivalent competitive pressure on the merging parties is

not the standard economic framework for how to determine whether a firm is a market participant; is it?

A. I -- so the standard approach to determining what's in the relevant market, at least as far as economics is concerned, is the hypothetical monopolist test. And evidence or indicia of close competition reacting to each other is something that is commonly used to inform an understanding that can be applied to the hypothetical monopolist test.

Q. But that's not about measuring whether another firm puts equivalent competitive pressure on the merging parties, is it?

A. I think, in general, markets may contain firms that impose a variety of different degrees of competitive pressure on each other. For example, one might define a market of cola that could potentially include -- I think it still exists -- RC Cola as well as Coke and Pepsi. I think everyone would agree that Coke and Pepsi impose more competitive pressure on each other than does RC Cola on either.

Q. I'm asking you this in the context of determining who's a market participant in your market. Ultimately, what matters to you as an economist are the actions you observe and whether or not they point to different firms imposing a competitive constraint on the merging parties; is that fair

to say?
A. Could you repeat that language for me?
Q. To determine if another firm is a participant in your market, what matters to you as an economist are the actions you observe and whether or not they point to different firms imposing a competitive constraint on the merging parties?
A. I think I broadly agree with that. I suspect those are my words and might have been able to have been put a little bit more pithily.
Q. And you think firms that are not engaged in clinical trials in the U.S. today do not impose a sufficient competitive constraint on the merging parties to be considered market participants?
A. That is correct. My review of the record and the testimony indicates that firms that have not yet embarked on FDA approval are not imposing a sufficiently meaningful constraint on the merging parties to restrain anticompetitive effects.
Q. So if the Court concludes that there is evidence that a TAVR-AR supplier that had not yet received an IDE imposed a competitive constraint on the merging parties, almost definitionally, you would need to account for that device to understand whether a merger of just the parties would harm competition and consumers; correct?
A. If there was clear evidence that another entity,

irrespective of its, you know, participation in the FDA regulatory pipeline, was influencing the parties' competitive choices, then that party is certainly something that I would want to take into account when thinking through the competitive effects of this transaction.

Q. And that other supplier would need to be factored into your analysis when you're defining the relevant market; right?

A. I'm not exactly sure what you mean, but if a firm appears to be a sufficiently close competitor that it deserves to be in the relevant market, then it should be included in the relevant market for purposes of the calculation of shares and concentration metrics.

Q. If the Court concludes that there is evidence suggesting that firms that had not yet received an IDE would seek and obtain an IDE rapidly, that would be something you would also need to consider in defining your market; right?

A. If there was clear evidence that there were firms who were likely to receive IDEs and that, as I observed in the case of JC Medical, such receipt is associated with increased ability to act as a competitive constraint, then that would be something to figure into the overarching assessment.

Q. So for example, if the Court were to see evidence that Laguna Tech is planning to file for an IDE in the near term,

that's something that would have to be considered in defining the market; correct?

A. So as observed from the parties' own experience, simply filing for an IDE is no guarantee of receiving one, and certainly not in a timely fashion. I don't mean to dismiss that point -- that piece of evidence as potentially relevant, but it does not signal necessarily that Laguna Tech would be able to act as a supplier of TAVR-AR devices in the near future.

Q. But it's something that would need to be considered; correct?

A. I -- in general, I think an antitrust analyst's assessment should endeavor to factor in as much of the record as possible.

Q. Doctor, you're not specifically opining on how long it will be before other TAVR-AR devices, besides the parties', commence U.S. clinical trials; correct?

A. No, that is not part of my assessment, but, as indicated, I have relied on the opinions of others like Dr. Kesselheim that speak to the expected length of the FDA regulatory timeline.

Q. At your deposition, you told me you think there's no basis for anticipating that other potential competing TAVR-AR devices will commence U.S. clinical trials, quote, "anytime terribly soon." How long is "anytime terribly

soon"?

A. So my perspective that I do not anticipate an incipient commencement of new clinical trials is based on the comments I observed from the parties, including the categorization of Laguna Tech as a corpse and Mr. Kilcoyne's broad dismissal of other players as not in their universe, as well as the fact that third parties, including -- I'm not sure if -- one who testified here indicated materially greater uncertainty about entities still in the preclinical phase, perhaps -- especially those overseas. So I am not anticipating the likelihood of additional clinical trials anytime soon.

Q. Doctor, it's going to be a long day if you don't respond directly to my questions. My question was, how long is "anytime terribly soon"?

A. Years, plural.

Q. How many years?

A. I am not sure I have the expertise to put a precise number on the number of years, but, I think, if we think through the implications of the timeline involved in reach -- in getting through the FDA, we're talking -- if it's years before trials commence, then it could be 10, if not more, or in the neighborhood of 10, before another device could expect to receive its PMA.

Q. Yeah. I'm focused on the clinical trials component, though. Let me ask you this. You did not do a quantitative

analysis to determine how long it will be before other TAVR-AR devices besides the merging parties begin U.S. clinical trials; right?

A. I did not conduct a quantitative analysis estimating the start time of incremental clinical trials.

Q. And, again, for TAVR-AR devices, FDA approval to conduct a U.S. clinical trial means receiving an IDE?

A. My understanding is that beginning a clinical trial involves receiving an IDE.

Q. You conducted no quantitative analysis related to the barriers to receiving an IDE; correct?

A. I conducted no quantitative analysis speaking to the barriers to receiving an IDE.

Q. So you did no quantitative analysis of the potential costs associated with another TAVR-AR device developer receiving an IDE?

A. I believe Dr. Kesselheim's report may speak to the dollar figures associated with different parts of the FDA timeline.

Q. But you did not conduct a quantitative analysis of the potential costs associated with another TAVR-AR device developer receiving an IDE?

A. I did not specifically estimate the costliness of receiving an IDE.

Q. And you did no quantitative analysis of the potential

time associated with another TAVR-AR device developer receiving an IDE; right?

A. As I note in my reports, the parties' own experiences indicate that this can be prolonged, but I did no separate effort at quantifying what is typical.

Q. And you did no quantitative analysis to assess the likelihood of another TAVR-AR device developer receiving an IDE; correct?

A. Correct. I did no separate quantitative analysis about the likelihood of another device developer receiving an IDE.

Q. Page 48 of your demonstrative today has language that said "Potential rivals have not sought or obtained regulatory clearance to pursue clinical trials needed for FDA approval."

So that means those potential rivals have not sought or obtained an IDE?

A. It is my understanding that other potential rivals have not sought or obtained regulatory clearance to pursue a trial. So yes, an IDE.

MS. FRANCE: We can take that down.

BY MS. FRANCE:

Q. So you conducted no quantitative analysis, though, related to the barriers to those potential rivals seeking or obtaining an IDE; correct?

A. As, I think, we discussed, that was not part of my

assignment. I believe Dr. Kesselheim may have some numerical estimates.

Q. Dr. Wilson, you're not an expert in the FDA regulatory approval process, are you?

A. No, I am not.

Q. And you're not presenting opinions based on your own analysis of expected FDA approval timelines?

A. That is correct.

Q. And, I think, you've mentioned this, but you relied on Dr. Kesselheim for his analysis of the FDA approval process?

A. Correct.

Q. You were present in the courtroom when Dr. Kesselheim testified; right?

A. I was.

Q. And you heard him testify that he did not analyze the barriers to a company receiving an IDE. Do you recall that?

A. I do.

Q. And you did not do any separate quantitative analyses of the potential costs or challenges associated with FDA approval; right?

A. Yes, as indicated, I did not do a separate analysis.

Q. And you did no separate quantification of the time and costs that may be involved in the FDA regulatory process as a whole; correct?

A. Correct.

Q. So you've conducted no analyses of the amount of time it takes to receive a PMA from the FDA; correct?
A. My overarching conclusions depend on Dr. Kesselheim's analysis of that, which is consistent with the estimates reported by Dr. Bailey in her expert report.
Q. And you've conducted no quantitative analyses of the amount of time it takes to receive an IDE from the FDA; correct?
A. I've done no analysis beyond referencing the time it has taken the merging parties to receive their IDEs.
Q. And you did no quantitative analysis of the competitive pressure an IDE recipient would exert on JenaValve or Trilogy; right?
A. As discussed in my reports, I observed that receipt of an IDE and the movement along that pipeline is associated with being at closer constraints, but I didn't do some sort of numerical exercise to try and specifically extend what was observed for the merging parties to a hypothetical third party.
Q. I think I know the answer to this question, but just so we're on the same page, you do not have any experience receiving or seeking an IDE from the FDA to begin U.S. clinical trials; right?
A. Correct.
Q. You're not a medical doctor; right?

A. Correct.
Q. Despite the confusion at your deposition --
A. Indeed.
Q. -- on not either of our parts. You don't have experience manufacturing Class 3 medical devices?
A. I do not.
Q. You don't have experience manufacturing heart valves?
A. No.
Q. You do not have a background in medical device manufacturing?
A. Correct.
Q. And you do not have experience conducting any sort of clinical trial; correct?
A. Correct.
Q. I want to look back at Page 21 of your demonstrative. And we can put that up on the screen for you. This is a recreation of Table 1 in your report; right?
A. Yes, that's correct.
Q. And Table 1 in your report replicates part of a document marked P-X-1066?
A. Yes, that's correct.
Q. And P-X-1066 is a valuation model that was prepared by JC Medical before it was acquired by Edwards; right?
A. Correct.
Q. You did not investigate what assumptions JC Medical may

have employed when it created this valuation model, did you?
A. So the deck that was attached to this projection, as well as other broadly contemporaneous materials, contained discussion about what JC Medical thought the total addressable market might be for TAVR-AR devices. But in terms of the specific time series of different variables here, I did not see or find an explication of the assumptions involved.
Q. I want to ask you a few questions about the slide here. Just be careful not to say anything about the redacted portions. They're marked with a red box in your binder. Is it fair to say that the projections made in this deck in February 2024 have not borne out with respect to the timing of JenaValve's FDA approval?
A. Insofar as this deck contemplates JenaValve's having received its PMA so as to be able to provide devices beginning in 2025, that has turned out not to be correct.
Q. And the projections in this deck also have not turned out to be correct with respect to the number of cases that Trilogy would treat in 2025; right?
A. Insofar as JenaValve has yet to receive its PMA and, therefore, has yet to do any commercialized cases, I would agree it seems unlikely that it can hit the number on this slide.
Q. You did not do a specific analysis of whether JenaValve

had the ability to produce the number of Trilogy valves that the valuation model projected for 2025, did you?
A. I did not do a specific analysis relating to whether or not JenaValve had the ability to produce this number of cases.
Q. And in your reports, you did not cite any testimony about this JC Medical valuation model?
A. I do not specifically recall any testimony on this projection.
Q. Were you in the courtroom last week when Dr. Turco testified about a version of this same valuation model?
A. No, but I reviewed that transcript.
Q. And just for clarity, Dr. Turco is the former CEO of JC Medical?
A. Yes.
Q. Do you recall that Dr. Turco testified that the valuation model was based on a number of assumptions?
A. Yes.
Q. And Dr. Turco testified that the model would not have been accurate in predicting true market share; right?
A. I recall testimony to that effect.
Q. Do you also recall his testimony that when he made these projections, he was not making an affirmative prediction that there would only be two TAVR-AR competitors?
A. I recall his testimony to that effect.

Q. And do you also recall his testimony that JC Medical was aware that there were many other players, including large strategics, that were working on aortic regurgitation technology?
A. I -- yes.
Q. I'm going to be careful, again, here, just because of the confidentiality. The valuation model, as we talked about, includes certain assumptions surrounding price changes. And in your report, you said that those price changes are attributable to competition between Trilogy and J-Valve. But you did not determine whether the modeled price changes are attributable to any factor other than competition, did you?
A. I don't think that's a completely accurate characterization of the language I used.
Q. You say this is evidence that indicates that there could be a price effect?
A. I believe I indicated that the price decline observed in these projections that occurs following the anticipated receipt of a PMA by JC Medical is consistent with what economics would predict.
Q. But did not determine whether the modeled price changes are attributable to any factor other than competition; right?
A. As, I think, we covered earlier, I did not find or

observe explanations specifically linking any of the changes over time to specific assumptions.

Q. You're unable to opine at all as to the specific drivers of the different magnitudes of price changes in the valuation model; right?

A. Owing to my inability to confirm what assumptions underlie the different changes, I cannot say specifically what is associated with the different patterns observed with respect to price. That is why my language endeavored to be conservative about simply noting its consistency with what economics would predict.

Q. And, in fact, you have not conducted any specific numerical or quantitative analysis that considers the effect of different factors impacting supply and demand and how that could impact TAVR-AR prices post commercialization; right?

A. I think, as we have largely already covered, I have not done a specific quantitative analysis allowing me to draw concrete inferences about the precise numerical magnitudes of the price effects I anticipate.

Q. And you also haven't been able to rule out the possibility that the price changes in the valuation model are due to any factors that are entirely unrelated to competition; right?

A. With respect to this particular set of projections, I

did not find or rely on materials providing a breakdown or decomposition of the factors that may be explaining the observed price changes; however, as discussed in my reply report, for JenaValve's similar projections that also show price declines, there is corroborating ordinary course information and testimony cited in my direct that part of the reason for those price declines reflects competitive entry.

Q. Well, your report even cites an Edwards document that shows price changes like those in the JC Medical valuation model, but that's in the context of Edwards owning both Trilogy and J-Valve; right?

A. Yes, I think, as we covered in my deposition, I cite an Edwards presentation that includes a forecast where -- in which Edwards says that they will be charging a premium price, but that there will also be price erosion of some sort.

Q. But the price changes like the ones you attributed to competition were modeled by Edwards even in a scenario where Edwards owned both Trilogy and J-Valve; right?

A. So I would agree that there is a pattern of price erosion in the Edwards document that is similar or -- well, that there is also price erosion in other projections. Now, the Edwards document does not go out as far in time, so the extent of price erosion there cannot be compared to what is

predicted by both the JC Medical and JenaValve documents. Moreover, the different starting spots of prices may lead to different price changes being optimal.

Q. Doctor, it's just a simple "yes" or "no" question. Just to be clear, that Edwards document models price changes like the ones that you attributed to competition even in a scenario where Edwards owned both Trilogy and J-Valve; correct?

A. So I'm endeavoring to be clear. It models price changes, that those start at an earlier point in time than those observed in the other projections, and then the trajectory is different in its length, inhibiting our ability to say whether or not the long-run declines are different.

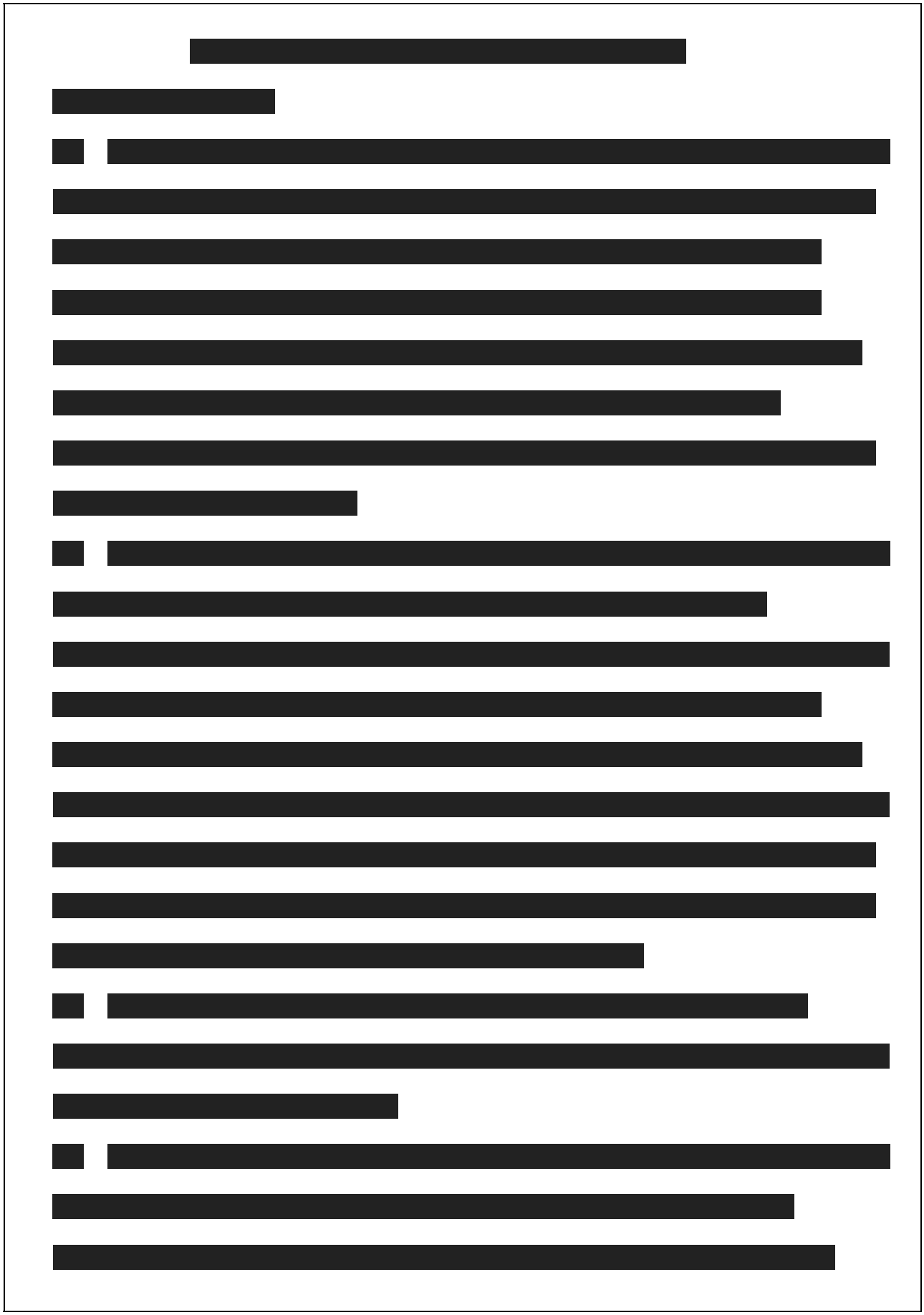
MS. FRANCE: Your Honor, at this time, I have a few questions that I would need to move into a closed session for.

THE COURT: Okay. We'll close the courtroom.

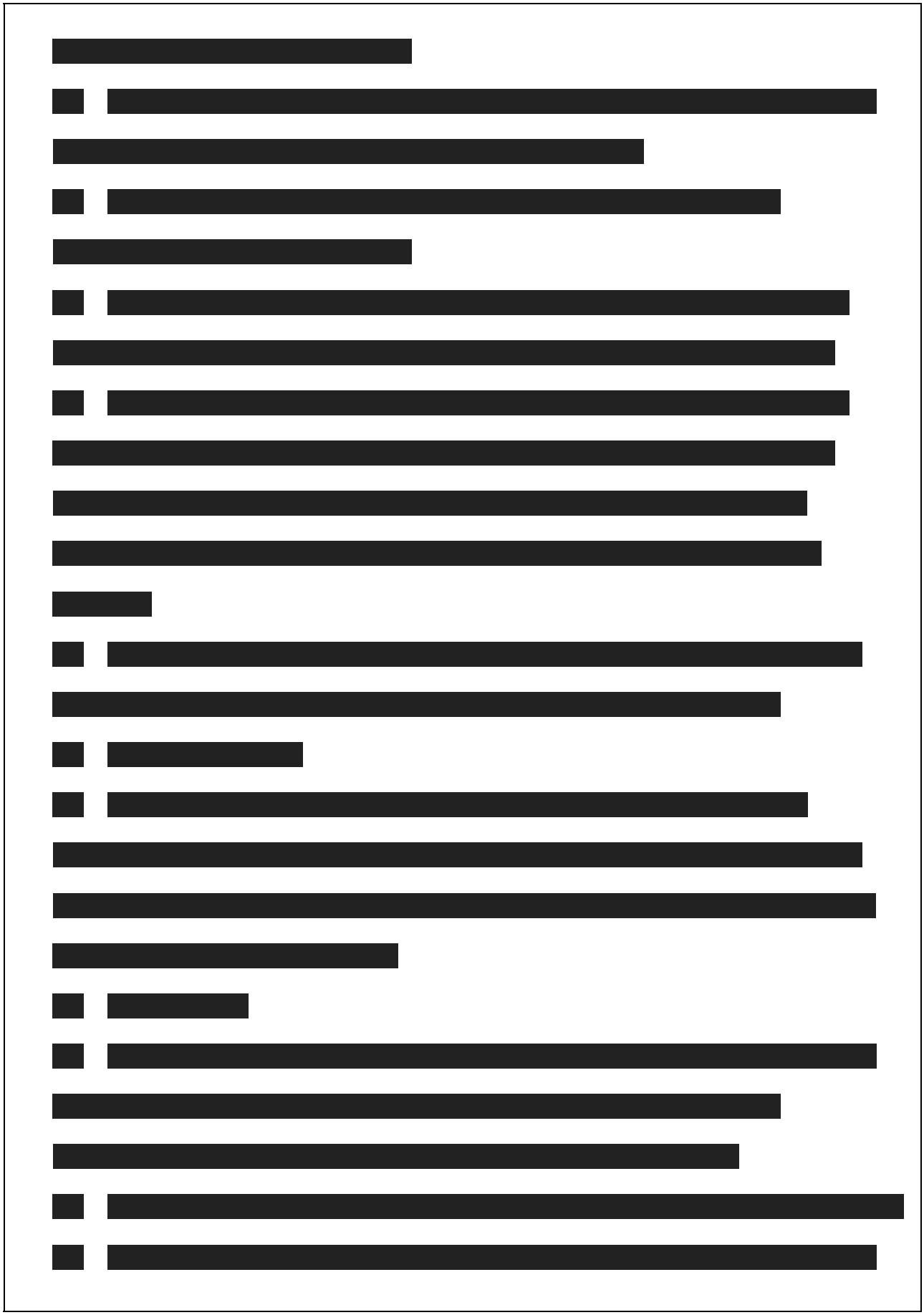
MR. SHORES: Everybody except counsel for the parties, please depart.

(Following proceedings under seal:)

[redacted]









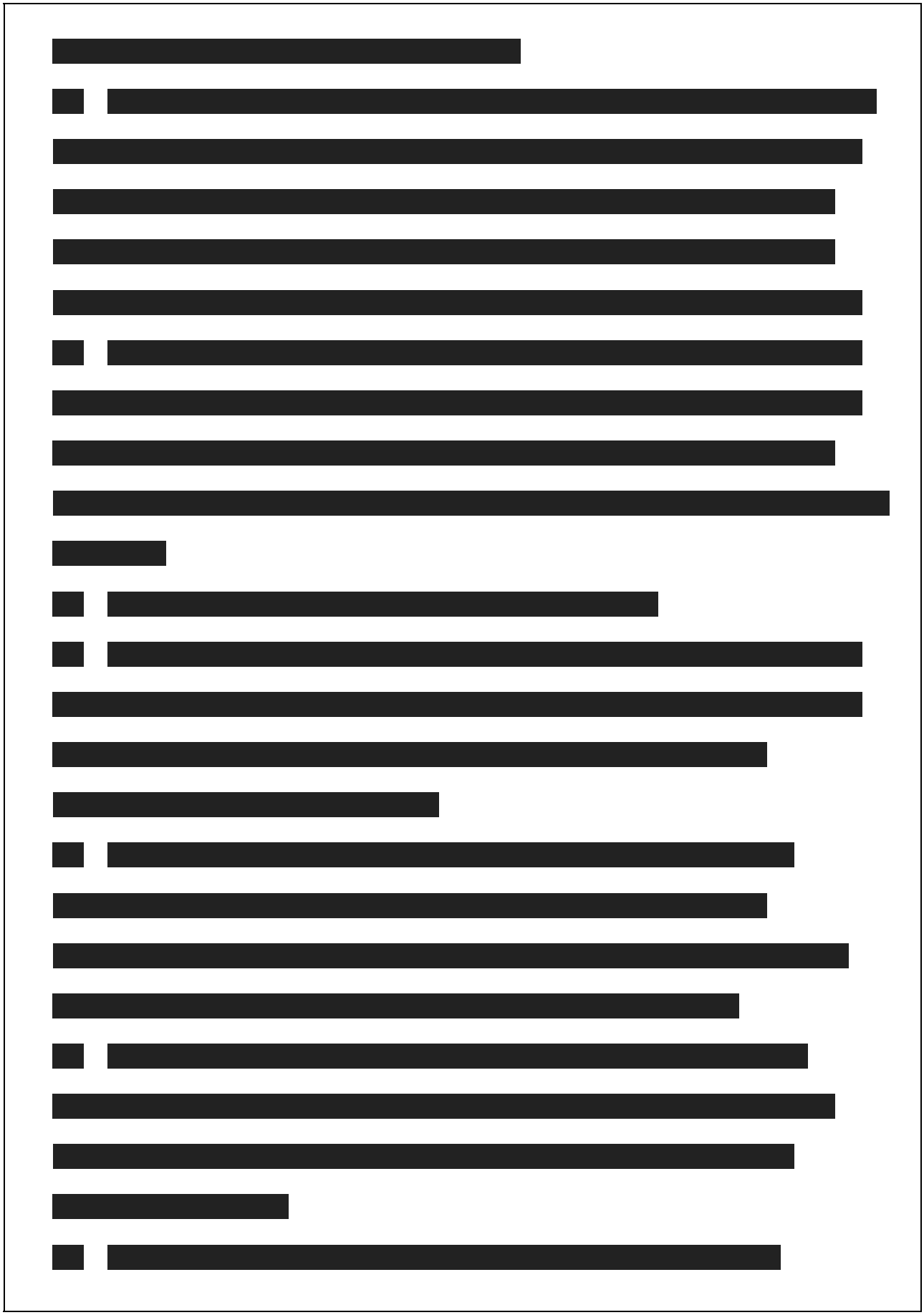






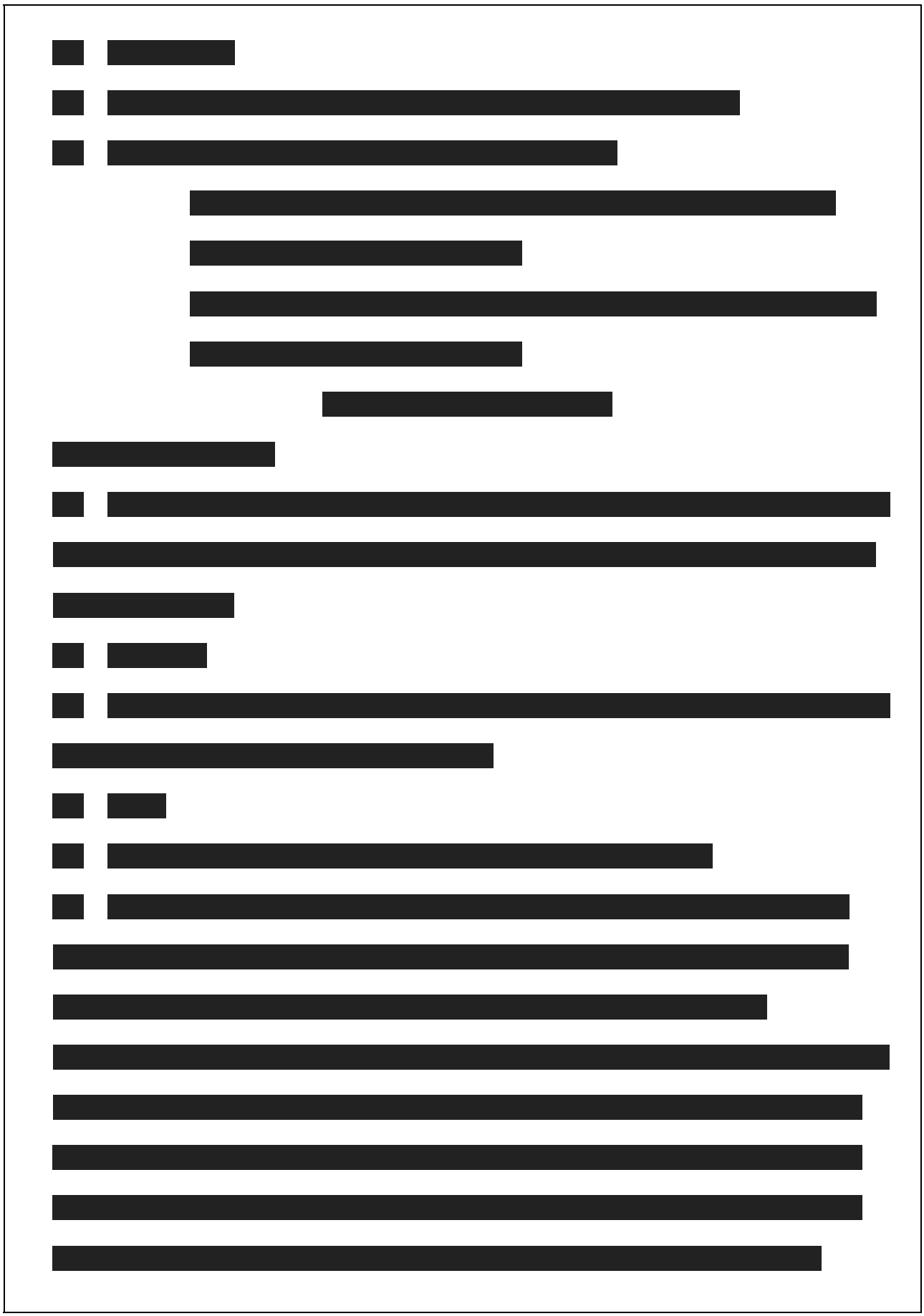


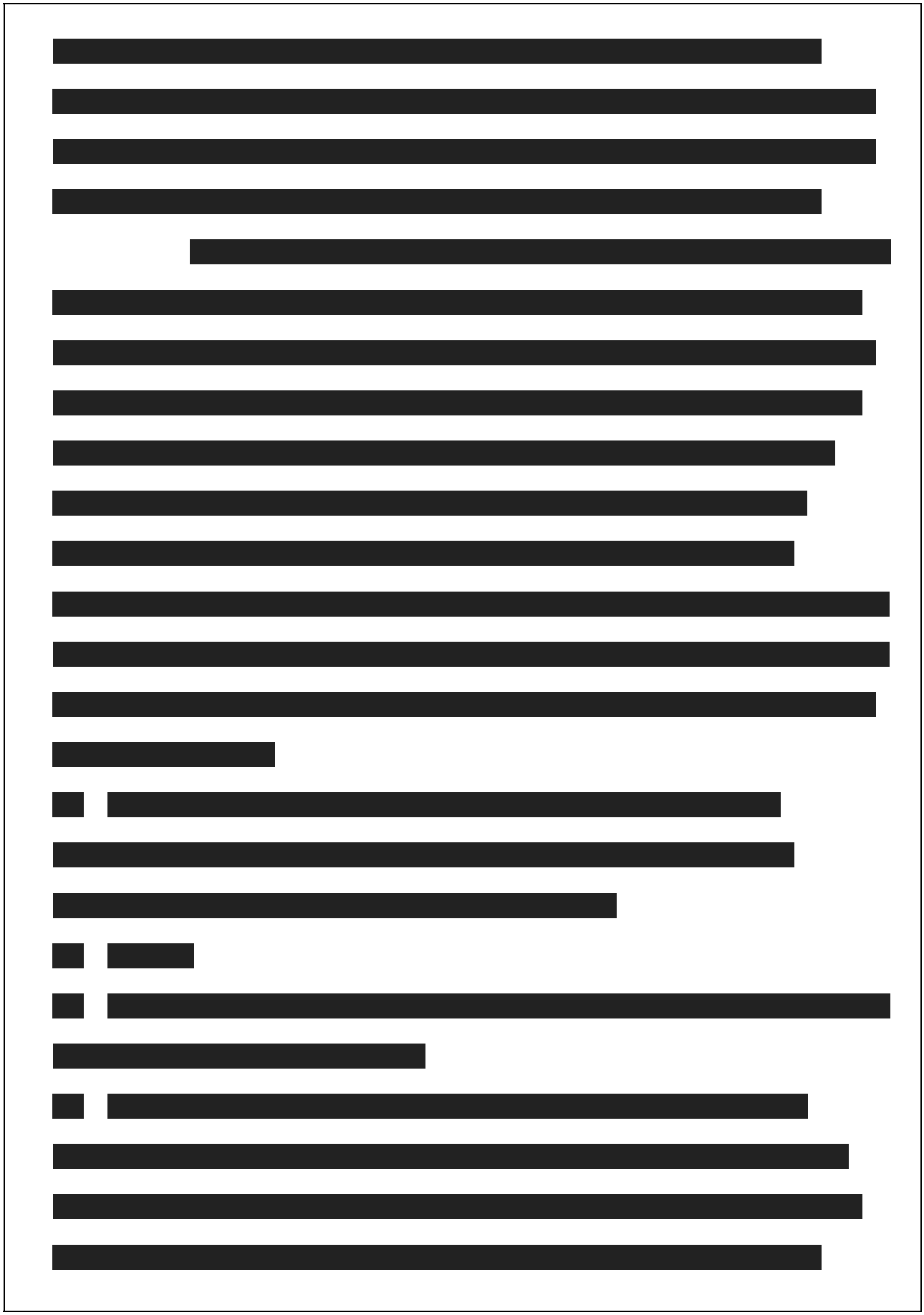




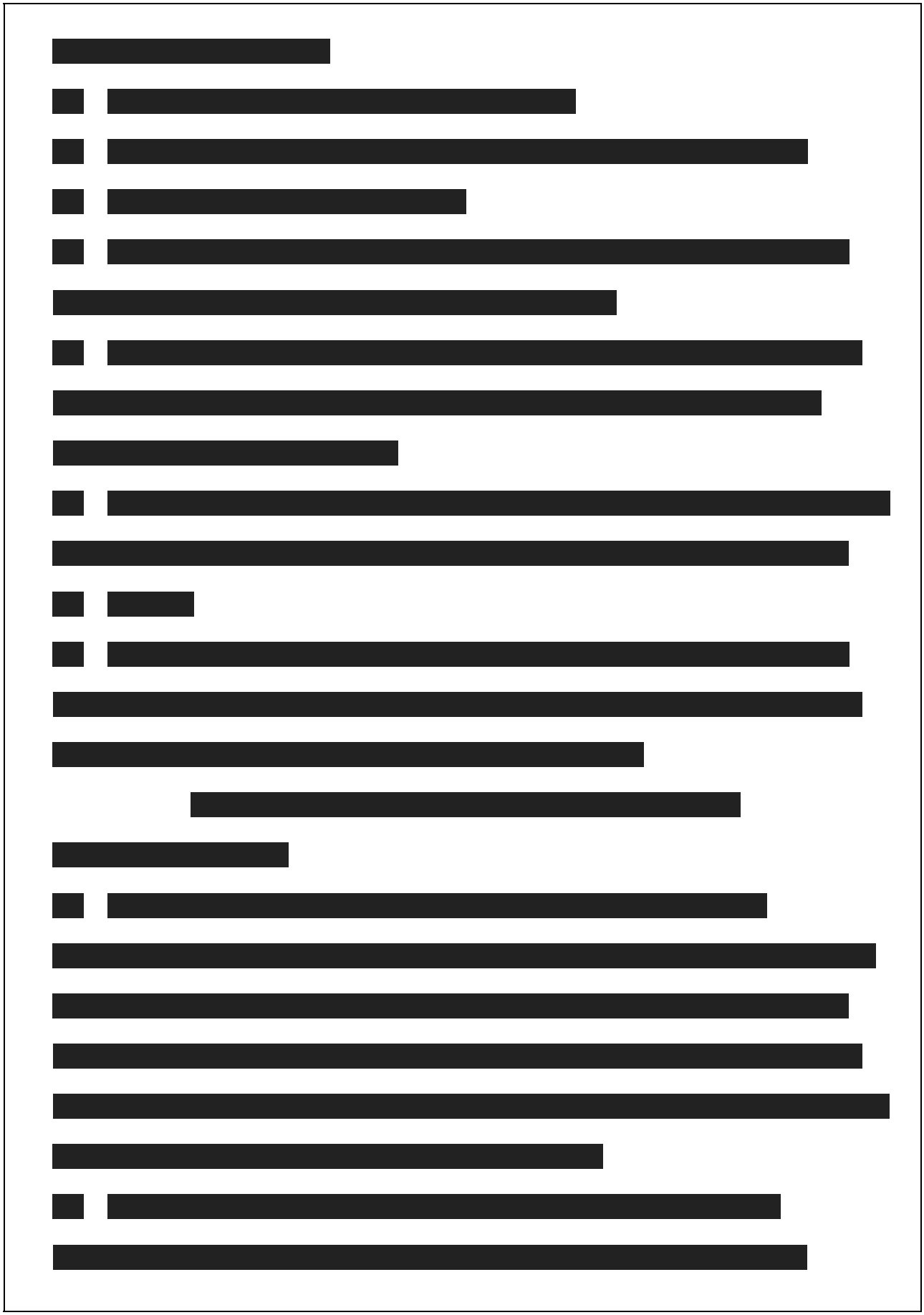
















[redacted]

(Following proceedings in open court:)

MS. HALL: Your Honor, on behalf of the FTC and subject to our request for time for rebuttal, we rest our case.

THE COURT: Okay.

MR. SHORES: Your Honor, cognizant it's 12:40, would you like us to start -- to open our case or would you like to take a break?

THE COURT: Let's go forward.

MR. SHORES: Okay.

THE COURT: Let's go forward.

MR. SHORES: Yeah, that's what --

THE DEPUTY CLERK: Counsel, can I have someone to take these, please.

MR. MCGINNIS: Your Honor, Matt McGinnis of Ropes & Gray on behalf of JenaValve. Defendants call Jan Keltjens to the stand.

JAN KELTJENS, WITNESS FOR THE DEFENDANTS, SWORN

MR. MCGINNIS: Your Honor, just so you're aware, I'm going to start in open session today. There is a portion of this that, I think, we will need to do in closed session. And I'll let you know when we're there.

THE COURT: Okay.

DIRECT EXAMINATION

BY MR. MCGINNIS:

Q. Good afternoon, Mr. Keltjens.

A. Good afternoon, Mr. McGinnis.

Q. You're chairman of the board of JenaValve?

A. I am. Yes.

Q. And where do you live?

A. I live in the Netherlands.

Q. Could you briefly describe for the Court your educational background, please.

A. Yeah. So I graduated in the equivalent of a master degree in physics at the Technical University in Eindhoven in the Netherlands.

Q. And could you also please briefly walk through your employment history.

A. Yeah. So early on, I worked in research in food and detergents for a large company called Unilever. Then I spent a couple of years overlooking a number of high-tech companies within the greenhouse industry, agricultural industry. And then '95 I became fully committed to medical devices.

Q. And could you walk, then -- I think you said in '95, you became focused on medical tech companies?

A. Yes.

Q. Okay. And what med-tech companies have you worked for since 1995?

A. So I initially joined an American listed company called Cordis Corporation. I was responsible for all their OUS technology, so manufacturing, R&D, clinical research, regulatory affairs. Large-scale facility, happened to be in the Netherlands, but within a year after that, we got acquired by Johnson & Johnson.

Q. Okay. And what happened after that?

A. So still the same division, but now under ownership of Johnson & Johnson, I ran operations for a few years. I then moved to Brussels and I became head of European marketing for all cardiovascular devices. And then in '99, I got transferred to the U.S. where I had two subsequent roles,

one as the head of global marketing for interventional cardiology, and I ended up being in charge of their global neurovascular division for six years.

Q. And what was your role after that?

A. I left the safety of the large corporation and I went into the startup world. So I started off joining a company called CryoCath in Montreal. The company was listed at the Toronto Stock Exchange. And their claim to fame is an innovative device to treat atrial fibrillation. The company got acquired by Medtronic two years later, and I'd love to add that they've become one of the leading devices in the world. So very successful device.

Q. And did you have another role at a different company after that?

A. Yeah. Then I became CEO of a U.S. company in upstate New York. I jokingly told the recruiter I was the only candidate that had to move south for the job. So I was CEO of AngioDynamics, which is a more involving company, had three divisions, had meaningful revenue -- certainly 200-plus million in revenue, was profitable. And I was leading that company for two years. And then we came to a fork in the road and, for a number of reasons, we decided to move back. My wife is Dutch, as well. So we wanted to move back to Europe, to the Netherlands.

Q. And how long have you been back in the Netherlands?

A. I think one -- we moved back at the end of 2011. So it comes up to 14 years already. Fifteen, I guess, yeah. Fourteen.

Q. And what have you been doing since then?

A. Keeping busy. So I've been CEO of a number of companies. In chronological order, Surpass Medical, an Israeli-American early-stage startup developing a device treating brain aneurysms. The company was sold -- or acquired by Stryker. Also -- yeah, '12 or '13. I was CEO and chairman, actually, combined, of a company called Endosense, a Swiss, Geneva-based company, again, back in the space of treating atrial fibrillation. And that company was acquired by St. Jude, currently part of Abbott. And, again, also, you know, very successful device, as is the Surplus Medical device.

It was Endosense. Then Sapiens Steering Brain Stimulation, spin-out from Philips Corporation focused on novel technology for treating Parkinson's through implantable DBS probes. And, again, Medtronic was knocking on the door and they acquired the company at some point.

Q. And in addition to being on the board of JenaValve today, are you on any other boards?

A. I am. I'm also chairman of the board of a commercial-stage insulin patch pump company headquartered in the Netherlands. And I'm, you know, associated in different

roles, either as an adviser or part of an investment committee or chairing the board of investment funds, not all of them related to medical devices.

Q. And just to identify a couple of things in your testimony, sir, have you been CEO of both publicly traded as well as privately held companies?

A. That is correct.

Q. And approximately how long have you worked in the medical device industry overall?

A. Well, it adds up to -- so dedicated medical device firms, over 30 years.

Q. And I believe you had identified a number of the companies there that were actually acquired during your tenure as CEO; is that fair?

A. Actually, all of them.

Q. All? And rough -- in rough numbers, how many acquisitions have you been involved with?

A. 5.0.

Q. And --

A. Complete corporations. I've also been involved in transactions of selling a division, again, also in this case to where -- to a group of companies that was acquired by Medtronic. Those were more business -- you know, smaller business transactions, not company acquisitions.

Q. And speaking of Medtronic, how many companies have you

sold to Medtronic?
A. Full transactions, two.
Q. I'd now like to turn to your tenure as chairman -- or on the board of JenaValve. First off, how long have you served on the board of JenaValve?
A. So I joined the board early 2014 and became chairman in 2015.
Q. And do you have an understanding as to why you were selected as chairman of the board in 2015?
A. You know, it's always a combination of elements. I was on the board. The chairman at that time got very busy and founded a company in Orange County, Irvine. Got too busy to continue to be chairman of the company. And we had also decided to move the company. The company was founded -- JenaValve was founded in Germany, was headquartered in Munich. So it was, kind of, a home game for me, but it was decided to move the company to Orange County, which was the right thing to do. That is the center of the universe when it comes to structural heart, engineering and the whole skill set. And, you know, the board felt that I, of course, substantial U.S. background, lived in the U.S., worked in the U.S. for 12, 13 years. The accent reached a plateau, if I can add that; I apologize for that. Yeah. And, you know, I -- experience with transactions. I mean, typically, venture capitalists, they are all targeting a liquidity

event where they can get their funds back and invest in new companies. So I had developed an experience. It was -- it is a very technical role, certainly, at that time, early on. Now it becomes more commercial. So the board asked me to volunteer for becoming chairman, which I did.

Q. And you had mentioned, obviously, the -- your experience with leading the sales of companies to Medtronic, Philips, and others. To the best of your knowledge, did that play -- was that a factor in why you were selected as chairman of the board?

A. I'd like to believe so.

Q. And as chairman today, Mr. Keltjens, what are your responsibilities?

A. Yeah. So I, you know -- the way I look at my chairman role is, first and foremost, be a sounding board to the CEO, very much in strategic and operational, difficult questions. Intermediary with the board. And in a privately held company, of course, the board is equal to the investors, the owners of the company. So it's not like in a public company where those are two different entities. I'd say that probably is the center of my work. It all revolves around that.

Q. And you referred to the investors or the owners of the company there. Just as a very general matter, and bearing in mind that we are in open session right now, who are the

owners of JenaValve?
A. So I don't have the actual count. There's four investment firms that are represented on the board. Between the four of them, they have a majority stake in the company. And then there's at least two or three significant shareholders that don't have a direct representation on the board. They may have an observer seat in some cases.
Q. Now, as chairman, have you also played a role in the company's efforts to explore potential strategic alternatives, including a potential sale of the company?
A. Yes, I have.
Q. And were you involved, sir, in negotiating JenaValve's acquisition by Edwards?
A. I was very much involved, yes.
Q. Now I'd like to turn to the current state of JenaValve's operations, and there's a couple of questions here I'll just note that we're going to be in open session. So please, obviously, keep your answers at the appropriate level of generality.
There's been a lot of testimony in this case about the status of PMA -- the PMA process for JenaValve's Trilogy product. Can you summarize for the Court just where it stands today.
A. So we applied for PMA approval and thus far that has not been granted, and the most recent development is that we

have received a few weeks back what's called a deficiency letter, which is a normal step in the process. The contents is, of course, what matters.

Q. Okay. And, again, without getting into the details of the deficiency letter, does JenaValve plan to provide information to the FDA in response to that deficiency letter?

A. Yeah, we are currently preparing a reply to that deficiency letter which we are internally targeting to send to the agency first week of December.

Q. And do you know how the FDA will respond to the additional information that JenaValve provides in response to that letter?

A. No, I do not. I only know by when they will respond, not what the response will be.

Q. And in light of that, do you know when or if JenaValve will receive FDA approval in connection with its Trilogy PMA application?

A. I do not.

Q. Do you have an outside date on when you think approval is possible, or even likely?

A. No, there's no outside date.

Q. All right?

A. There's no mandate whatsoever for the FDA to approve a device.

Q. Okay. Did -- now, in the course of your time, has JenaValve had various projections over when it would accept -- or, excuse me -- when it would receive PMA approval from the FDA?
A. Part of running a company, and also, talking with investors and soliciting new investments in the company, you want to project the future and that includes, of course, getting approval. So yes, we do.
Q. And has that projection changed over time?
A. I can be snarly [sic] and say we can recycle the same slides and change the year on that a little bit, but it has been moving quite a bit. Quite a bit.
Q. And at a high level, what is your understanding or interpretation of the reasons why PMA approval has been delayed repeatedly?
A. Well, in the more recent three years, it has been revolving around the very specific test called AWT test, accelerated wear test. And we -- I guess -- there's a lot of complexity there, but we failed that test, I'd say, Christmas Eve of '23, and that threw us back at least, I'd say, 18 months.
Q. And how have these AWT challenges over the last two to three years impacted the company's focus on its, you know, strategic direction?
A. Well, so in any -- when you consider a strategic

acquisition, there needs to be clear line of sight to PMA approval. I mean, the prices, of course -- U.S. market excess, with all respect -- and we are commercial in Europe -- that will not win the day for us; cannot sustain the company from a revenue basis, let alone from a profitability point of view. So in any strategic discussion, we need to be able to articulate what our plan is and provide reasons to believe when we would get PMA approval and why it's realistic that we -- to assume we would get approval. So that hampers that quite a bit. Sorry for the long-winded answer.

Q. Speaking of AWT, we're here today, as you know, for the transaction with Edwards. Do you have a view on how -- whether Edwards could assist with JenaValve and the AWT issues that it has encountered over the last few years?

A. Yes, and I'll start at the very end. I do believe, if this transaction would have closed as we originally hoped for a year ago, I think we would have PMA approval by today. Now, let me add some details to that. I recited earlier, to an earlier question, we moved the company to Irvine for a reason. We're surrounded by at least two of the three major companies in this space that have -- well, Edwards's, of course, headquarters is there. Other companies have major operating locations there. So the talent to deal with these very, very specific test environments sits there. So we

moved the company for that. And we may have -- on AWT testing, we may have one person in the R&D team that has done it once. A company like Edwards has a department, oodles of people, their own machines, that do this for a living. And -- yeah, so that's certainly part of the reason of, you know -- this merger being attractive to us.

Q. Thank you.

There's also been some testimony in this case about what is sometimes referred to as JenaValve's large valve project, or Trilogy XL. Are you familiar with that term?

A. Yes.

Q. What is the current status of JenaValve's work on the large valve project?

A. Yeah. So large valve project for us -- there's really two elements. There's the valve itself and the delivery system that has to be upsized, as well. The latter work is progressing. It's not the most complex, but it takes time and money, and money has always been a scarce resource for us. There's also early development work on that larger valve. It could also be -- end up being two valves. The latest thinking I heard last week, it's going to be one valve. And that's progressing. But as a minimum, I would say two to three years away from any clinical or commercial activity.

Q. Since you mentioned money, how does money factor into JenaValve's ability to execute on the large valve project?
A. I'd say two ways. So money is always scarce in these kind of companies. So that's nothing new, and you have to work within your means and you have to very much focus. So that certainly prevents us from doing certain things. But it gets compounded when an AWT test fails. The whole company has to scramble, as an engineering department, as an R&D department, but, frankly, also a regulatory department dealing with the agency. So it absorbs all resources in the company, so that also creates what we sometimes call opportunity costs. So you cannot work on what you really wanted to work on because you have to resolve this issue. So that's very, very disruptive.
Q. And turning to another topic, Mr. Keltjens, are you generally familiar with the company's plans for commercializing Trilogy if it receives PMA approval?
A. Yes.
Q. And what is the current status of those commercialization plans?
A. And, Mr. McGinnis, maybe, a clarifying question: In the stand-alone scenario or in the scenario with Edwards?
Q. Good question. My question right now is focused on the stand-alone scenario.
A. Well, first order will be raise some funding. The

company today does not have the financial resources to do a meaningful launch independently. We currently serve, in the U.S., around 25, maybe, 30 accounts that have been involved also with the clinical study -- which, by the way, was just this morning press released; Lancet accepted a landmark article on that. So we will serve those, and the most recent plans I've seen is that we would try in the first year expand that to, maybe, up to 60 accounts in the U.S. of A.

Q. Okay. And what is the status of your ability to hire to support any potential commercial launch?

A. Well, today, it's a bit of an uphill battle because people -- under the merger agreement, they assume that if they join us, you know, they're going to merge into Edwards and then it would be uncertain. Certainly, good candidates that come out of good jobs would be hesitant to do that. Once we would be, you know -- if the merger does not close and we would need to move forward as an independent company, again, I keep coming back, fundraising will be step number one. These resources are very expensive, and we can only do that -- I would almost say -- in a hand-to-mouth fashion.

Q. All right. And we're going to come back to fundraising in a few minutes in a closed session, Mr. Keltjens.

With respect to manufacturing, can -- as a stand-alone company today, can JenaValve meet the demand for

its valves in either Europe or the United States?
A. Yeah. No. The answer is no. I believe we have CE mark in Europe for -- European certificate is the regional approval for these kind of devices.
Q. And speaking of Europe versus the United States, what proportion of the demand for Trilogy valves is in the United States versus in Europe?
A. So we --
Q. Approximately.
A. Yeah. We prioritize the U.S., so we make Europe separate. So the scarcity lands in Europe. And the reason is, in the U.S., we're dealing with developing clinical indications, and we think that's strategically more important. I think in the last 12 months, I would round it to probably 50-50.

So the three big needs for valves is, of course, in clinical work in the U.S., there's commercial use in Europe, and there's, frankly, also in R&D. So an AWT test itself eats up 36 valves. And they have to be real time-aged. So we have a number of sets in storage where they can just, you know, gather -- aging. So it is -- yeah.
Q. As you sit here today, Mr. Keltjens, does JenaValve make a profit on any Trilogy valves?
A. No.
Q. Why not?

A. Because, you know, the manufacturing of -- just the manufacturing of the valve is very complex. So we harvest tissue from slaughterhouses, pericardial tissue from pigs. The yield -- so we harvest, let's say, 100 of those tissues; 3 percent make it into the production floor; then there's about, I'd say, 7, 800 sutures on each of the valves. The yield of that is probably 50, 60, 70 percent. So we lose a lot of production. It's medical devices. There's a lot of overhead. Our volume is low. The regulations are -- you need very sophisticated organizations in your quality departments, storage, just about everything. It's impossible to make a profit at this footprint.

Q. Now, in the United States, Trilogy is just available as part of clinical sales -- clinical trial sales -- or delivery; is that right?

A. Yeah, "available" is a big word. We are granted every six months -- I think we can do 80 procedures every six months, and the FDA has to sign off on each and every one of those. It is not commercially available.

Q. Thank you for that clarification.

Is it possible even to make a profit on clinical use of a device in the United States?

A. By law, it's prohibited to make a profit on non-commercial sales in the U.S.

Q. Turning to funding today --

A. And that's an easy problem to solve. It is far more expensive to support these cases than supply valves.

MR. MCGINNIS: And, Your Honor, just on timing, I expect I have about 10 more minutes of open session --

THE COURT: Go ahead.

MR. MCGINNIS: -- if that would be acceptable.

THE COURT: Yeah.

BY MR. MCGINNIS:

Q. With respect to funding, where -- what is the current source of funding? Where is JenaValve -- excuse me, JenaValve, getting funding today?

A. Yeah. For the last almost 18 months, our only source of funding is what's called the interim funding note provided to us by Edwards.

Q. And are you familiar with the term "cash runway"?

A. Yes.

Q. Is it something you hear a lot these days?

A. I'm living that one. Yeah.

Q. Okay. And what is -- first of all, could you describe for the Court, what is -- when I say cash runway, what does that refer to?

A. Well, in the world of these kind of startup companies, it's always you have cash left on the bank account and for how many months or weeks or years can that sustain the operation of the company. So it's very simple. Cash

runway, if it's four weeks, it means four weeks from now, you don't know how to pay your salaries, or the products, pay for lunch, anything like that.

Q. And for JenaValve, what is your current understanding of JenaValve's cash runway?

A. It's between one and two months, and that is excluding unpaid bills. So if we add those in, it's negative.

Q. And you said one to two months; is that right?

A. Yes.

Q. Now, I'd like to -- just last topic of open session is -- I'd like to start by talking about the company's options or plans if that transaction with Edwards is blocked. First off, Mr. Keltjens, if the transaction is blocked, what impact would that have in your view on JenaValve's efforts to implant Trilogy at additional sites in the United States?

A. Those would come to a grinding halt. Frankly, we will be scrambling to maintain or sustain what we do right now. It will be crisis day one.

Q. And why is that?

A. Because we don't have the cash and, without PMA approval, it will be very, very hard to raise cash.

Q. If the transaction is blocked, will JenaValve be able to meet the demand for its valves even at its existing sites where it supports implants?

A. I mean, we haven't discussed in great detail what we would do, but we would struggle to maintain that.
Q. And --
A. We would try to maintain it, because it's a commitment also to patients that are severely ill. A lot of the use in the U.S. is -- it's -- how do you call that? -- for exceptional cases, patients that are about to -- last resort therapy. We will try to support that as long as we can.
Q. But your testimony, sir -- and this is all in reference to sites supporting U.S. patients; is that correct?
A. Yes.
Q. Okay. If the transaction is blocked, what is the risk to the company with respect to its personnel and its key employees?
A. Well, we employ a significant number of highly skilled, highly trained professionals; you know, engineers, technical professionals, quality, people that know the way about regulatory, reimbursement, clinical support. And this is a very attractive market, and most companies are growing, hiring people. And if we tell them, "You cannot do with us, for the next 6 to 12 months, what you were trained to do," they will be tempted to leave us and seek their employment elsewhere.
Q. So do you believe that the -- if the transaction is blocked, there's an attrition risk for employees?

A. Oh, yes.
Q. Do you believe there's a risk that you won't be able to hire the people that you need?
A. There may be a risk that we have to lay off people.
Q. Speaking of employees, do you know if employees are monitoring the litigation that we are in right now?
A. The U.S. employees, more than I ever thought they would, yes. Very much.
Q. And what is your understanding of their reaction to what has been shared publicly?
A. Yeah. So, listen, there's -- there's two sides to that. So they follow it because it involves them and their company and their possible future. I would say they cannot quite assess what's in the public domain; that's only part of the story, of course. It creates angst, gossip, distraction, uncertainty. It's not helpful. Not helpful at all. It's one of the things -- we want to focus on AWT, getting this device approved, develop next generation devices. This does not help. And it has been a little while, of course.
Q. You had mentioned earlier the -- JenaValve's commercialization plans. If the transaction is blocked, what impact do you expect that would have on JenaValve's plans for preparing for commercialization in the event of FDA approval?
A. Making a plan doesn't cost much more than the paper it's

written on. And so there will be plenty of plans.

The question is, what do we need to do to have a fighting chance to start executing, and it's back to fundraising and getting PMA approval. And I think, in the immediate future, there will be no steps, and hopefully we can avoid scaling back.

Q. All right. Last couple of questions for the open section.

MR. MCGINNIS: If Mr. McCloud can actually put up P-X-2323, please, and in particular Slide 12 of that document.

BY MR. MCGINNIS:

Q. Sir, I'm just going to ask you a couple of questions about a slide that appears in some -- JenaValve's slide deck. Do you see that in front of you?

A. I do.

Q. As far as you know -- and you've been chairman of the board since 2015; is that right?

A. Yes.

Q. Has the board ever discussed or reviewed this slide?

A. Not since 2015.

Q. Okay. Does it accurately reflect the board's thinking on what it thinks would happen if the deal with Edwards were to be terminated?

A. Was this slide in one of the board decks? I mean, I

hope it wasn't presented, because it makes no sense whatsoever.

Q. Okay. And why is that?

A. I mean -- and I'm digesting in real time here. It says deal closes, deal terminates, and then I look at clinical, for instance; under Edwards, it would be a soft ARTIST launch and, as an independent company, a full ARTIST launch.

I mean, that just is not only counterintuitive, it's just flat-out wrong. If we are independent -- deal terminates; build a new OUS manufacturing site.

So you know, again, it's -- I would have known if this were represented to the board because it would have inflamed the board, yeah.

Q. Directing your attention, sir, to the box in the middle of the bottom for R&D where it says "If the deal terminates, significant" ever -- "effort on large valve."

Do you see that?

A. I do.

Q. If the deal terminates, does the company -- does JenaValve have money to exert a significant effort on large valve?

A. So we're going to be working hard to maintain our current effort, which is subpar. So we'll certainly not be able to accelerate.

Q. Mr. Keltjens, last question. There's been a suggestion

that this slide, the slide you're looking at, shows that in the event the transaction is blocked, that JenaValve will put its foot a bit more firmly on the gas pedal and pursue everything in that bottom row there. What's your reaction to that?

A. You can put a foot on the gas pedal, but if there's no gas in the tank, nothing will happen. I mean, first of all, it's a -- and I, you know -- I choose my words here -- it's a very confusing slide, and that's the kindest word I can find, and it's just not reality. We will be running on fumes if this transaction does not close. We have to fight hard, look at our syndicate, see whether they're willing to sustain the operation as is until we may have chances in developing future leases on life.

MR. MCGINNIS: Your Honor, the rest of my questions would be for closed session.

THE COURT: All right. Which -- we will start back up in closed section at 2:00.

MR. MCGINNIS: All right. Thank you.

THE COURT: Thank you.

(Witness steps down.)

(Luncheon recess taken at 1:11 p.m.)

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

CERTIFICATE OF OFFICIAL COURT REPORTER

I, TIMOTHY R. MILLER, RPR, CRR, NJ-CCR, do hereby certify

that the above and foregoing constitutes a true and accurate transcript of my stenographic notes and is a full, true and complete transcript of the proceedings to the best of my ability, dated this 24th day of November 2025.

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

'

'12 [1] - 115:9
'13 [1] - 115:9
'23 [4] - 71:4, 71:6, 73:3, 121:20
'28 [1] - 53:4
'29 [1] - 53:4
'95 [2] - 113:7, 113:9
'99 [1] - 113:24

/

/s/Timothy [1] - 135:5

1

1 [5] - 36:8, 36:12, 36:20, 86:17, 86:19
1's [2] - 36:17, 36:25
10 [3] - 81:21, 81:22, 128:4
10,000 [2] - 30:7, 31:20
10-minute [1] - 55:2
100 [3] - 12:7, 30:5, 127:4
1050 [1] - 1:22
11 [1] - 11:12
115 [1] - 4:11
12 [4] - 117:22, 126:14, 130:21, 132:10
12:40 [1] - 111:20
13 [1] - 117:22
14 [2] - 59:22, 115:2
150 [1] - 4:10
18 [2] - 121:21, 128:12
181 [1] - 59:22
19 [1] - 76:1
1995 [1] - 113:13
1:11 [1] - 134:22
1:25-cv-02569-RC [1] - 1:2

2

2 [2] - 36:8, 36:17
2's [1] - 37:2
200-plus [1] - 114:20
20001 [2] - 2:8, 135:7
20006 [1] - 2:5
20036 [1] - 1:23
20037 [1] - 1:19
2011 [2] - 49:6, 115:1
2014 [2] - 41:18, 117:6
2015 [4] - 117:7, 117:9, 132:18, 132:21
202 [5] - 1:16, 1:20, 1:23, 2:5, 2:9
2023 [8] - 38:24, 65:3, 65:8, 65:15, 65:19, 71:2, 71:14, 72:4
2024 [1] - 87:13
2025 [5] - 1:5, 87:17, 87:20, 88:2, 135:4
2035 [2] - 32:16, 52:24
20580 [1] - 1:16
2099 [1] - 2:4
21 [2] - 59:22, 86:15
2112 [1] - 1:19
24 [1] - 1:5
24th [1] - 135:4
25 [1] - 125:3
2:00 [1] - 134:18
2Amys [2] - 20:13, 20:18

3

3 [2] - 86:5, 127:5
30 [4] - 6:12, 6:21, 116:11, 125:3
31st [1] - 65:15
32 [1] - 65:1
326-3282 [1] - 1:16
333 [2] - 2:8, 135:7
354-3111 [1] - 2:9
36 [1] - 126:19

4

4,644 [1] - 31:20
48 [1] - 83:11

5

5 [1] - 1:8
5,356 [1] - 31:12
5.0 [1] - 116:18
50 [1] - 127:7
50-50 [1] - 126:15
508-4850 [1] - 2:5
5th [1] - 65:3

6

6 [1] - 130:21
60 [2] - 125:8, 127:7
600 [1] - 1:15
6722 [2] - 2:7, 135:6

7

7 [1] - 127:6
70 [1] - 127:7

8

80 [1] - 127:17
800 [1] - 127:6

9

955-8226 [1] - 1:23
974-1876 [1] - 1:20
9:30 [1] - 1:5

A

a.m [1] - 1:5
AA [1] - 7:14
Aaron [1] - 27:3
Abbott [1] - 115:13
ability [17] - 21:15, 26:8, 36:21, 40:21, 43:18, 44:15, 47:1, 61:14, 66:3, 71:25, 79:21, 88:1, 88:4, 92:13, 124:2, 125:10, 135:4
able [22] - 26:20, 26:23, 28:15, 36:4, 37:4, 41:2, 41:7, 43:20, 44:20, 45:10, 54:11, 58:1, 70:17, 72:2, 78:8, 80:8, 87:16, 90:21, 122:7, 129:23, 131:2, 133:24
absence [1] - 42:5
absorbs [1] - 124:10
abundant [1] - 43:8
accelerate [2] - 48:13, 133:24
accelerated [1] - 121:18
accent [1] - 117:22
accept [1] - 121:3
acceptable [1] - 128:6
accepted [1] - 125:5
access [9] - 21:16, 39:1, 40:1, 40:4, 40:14, 40:21, 40:24, 41:2, 66:3
according [1] - 32:13
account [3] - 78:22, 79:4, 128:23
accounted [1] - 72:3
accounts [2] - 125:3, 125:8
accurate [3] - 88:20, 89:14, 135:1
accurately [2] - 13:1, 132:22
achieve [1] - 58:17
acknowledge [1] - 42:7
acknowledges [1] - 42:8
acquired [9] - 33:8, 86:23, 113:19, 114:10, 115:9, 115:13, 115:20, 116:13, 116:22
acquisition [6] - 9:22, 9:24, 30:25, 58:11, 119:13, 122:1
acquisitions [2] - 116:17, 116:24
act [2] - 79:21, 80:8
actions [4] - 72:24, 76:20, 77:23, 78:4
active [13] - 27:10, 29:22, 31:5, 32:12, 34:23, 43:9, 70:16, 72:3, 72:6, 72:16, 73:4, 74:15, 74:17
activity [2] - 43:16, 123:25
acts [1] - 17:5
actual [1] - 119:2
actuality [1] - 26:23
add [5] - 20:18, 114:11, 117:23, 122:19, 129:7
addition [5] - 14:25, 32:19, 33:9, 33:25, 115:21
additional [5] - 4:19, 19:19, 81:11, 120:12, 129:15
address [7] - 6:25, 22:18, 30:23, 46:24, 53:16, 59:8, 67:2
addressable [1] - 87:5
addresses [1] - 34:8
adds [3] - 25:17, 30:16, 116:10
adjusted [1] - 5:7
admitted [1] - 7:20
advanced [1] - 68:18
advantage [1] - 36:18
advisement [1] - 7:3
adviser [1] - 116:1
advisor [1] - 11:21
affairs [1] - 113:17
affect [11] - 15:18, 27:23, 30:25, 34:10, 36:1, 39:6, 41:5, 41:25, 47:15, 51:17, 57:6
affected [2] - 57:5, 60:5
affects [1] - 39:25
affirm [1] - 49:25
affirmed [1] - 49:9
afternoon [2] - 112:15, 112:16
aged [1] - 126:20
agency [2] - 120:10, 124:10
aging [1] - 126:21
ago [4] - 27:25, 33:13, 59:17, 122:18
agree [25] - 21:9, 25:11, 56:1, 57:22, 61:15, 70:7, 71:10, 71:12, 71:18, 71:24, 72:12, 72:14, 72:15, 72:22, 72:23, 73:6, 74:3, 74:6, 74:8, 75:8, 77:18, 78:7, 87:23, 91:21
agreed [1] - 21:25
agreed-upon [1] - 21:25
agreement [2] - 65:17, 125:13
agricultural [1] - 113:6
ahead [3] - 35:9, 76:23, 128:5
aided [1] - 2:11
aimed [1] - 40:18
Alexandria [1] - 21:4
algebra [1] - 58:12
algorithm [1] - 18:6
alleged [1] - 54:17
allowing [3] - 66:12, 67:14, 90:18
almost [3] - 78:21, 125:21, 128:12
alone [7] - 46:1, 58:18, 67:16, 122:5, 124:22, 124:24, 125:25
alternative [7] - 16:16, 22:19, 33:25, 36:4, 41:13, 41:20, 51:6
alternatively [2] - 20:25, 46:25
alternatives [6] - 17:4, 17:21, 22:3, 37:14, 39:18, 119:10
American [30] - 9:22, 9:24, 10:2, 11:17, 13:12, 13:18, 13:24, 14:6, 23:2, 23:8, 24:7, 26:1, 26:20, 26:23, 27:7, 28:2, 30:20, 31:2, 32:15, 47:23, 48:3, 48:14, 48:18, 51:13, 54:22, 69:16, 69:23, 70:18, 113:14, 115:7
Americans [3] - 28:16,

29:4, 31:6
amount [9] - 18:16, 23:10, 56:14, 62:23, 63:21, 63:24, 64:3, 85:1, 85:7
analogous [1] - 48:22
analyses [3] - 84:18, 85:1, 85:6
analysis [42] - 10:21, 21:4, 22:5, 32:1, 33:3, 48:19, 51:17, 55:15, 56:1, 56:6, 56:13, 57:18, 58:5, 58:13, 58:20, 59:13, 62:1, 63:8, 63:9, 68:8, 71:3, 79:7, 82:1, 82:4, 82:10, 82:12, 82:14, 82:20, 82:25, 83:6, 83:9, 83:22, 84:7, 84:10, 84:21, 85:4, 85:9, 85:11, 87:25, 88:3, 90:13, 90:18
analyst [2] - 18:6, 18:13
analyst's [1] - 80:12
analyze [2] - 22:24, 84:15
analyzing [1] - 73:23
Anderson [1] - 1:12
Andrew [1] - 1:14
Andy's [5] - 20:4, 20:10, 20:11, 20:13, 20:20
aneurysms [1] - 115:8
AngioDynamics [1] - 114:18
angst [1] - 131:15
annuli [2] - 43:21, 48:7
answer [11] - 21:25, 22:14, 22:16, 57:13, 57:14, 57:15, 58:9, 58:15, 85:20, 122:11, 126:2
ANSWER [1] - 60:3
answer's [1] - 61:21
answerable [1] - 22:17
answering [1] - 25:5
answers [2] - 64:1, 119:18
anticipate [11] - 39:11, 39:14, 39:21, 50:6, 52:23, 59:3, 67:6, 67:14, 68:13, 81:2, 90:20
anticipated [5] - 41:18, 63:22, 63:25, 68:4, 89:19
anticipates [1] - 48:11
anticipating [5] - 43:9, 66:13, 67:21, 80:23, 81:10
anticompetitive [7] - 14:10, 16:7, 31:23, 42:10, 52:4, 66:25, 78:18
antitrust [8] - 12:16, 12:19, 12:20, 16:11, 22:5, 22:23, 30:3, 80:12
anytime [4] - 80:25, 81:11, 81:14
aortic [6] - 23:15, 23:18, 43:21, 46:24, 48:6, 89:3
apologies [1] - 59:12
apologize [1] - 117:23
appeal [1] - 36:4
APPEARANCES [2] - 1:11, 2:1
application [4] - 19:20, 22:4, 54:13, 120:18
applied [4] - 13:6, 22:15, 77:8, 119:24
applies [1] - 58:9
apply [2] - 37:8, 46:22
applying [1] - 15:23
appreciate [1] - 61:8
appreciating [1] - 61:13
approach [6] - 5:5, 5:13, 14:13, 50:17, 51:23, 77:3
approaching [1] - 30:8
appropriability [2] - 44:14, 45:16
appropriate [7] - 23:16, 26:4, 45:10, 54:3, 74:17, 74:21, 119:18
appropriately [1] - 18:20
approval [42] - 14:24, 26:19, 28:5, 28:19, 29:2, 32:8, 39:15, 51:13, 52:10, 52:11, 53:24, 56:20, 56:25, 57:11, 70:8, 70:14, 70:19, 70:22, 74:20, 78:16, 82:6, 83:14, 84:4, 84:7, 84:10, 84:20, 87:14, 119:24, 120:17, 120:20, 121:4, 121:8, 121:14, 122:2, 122:9, 122:10, 122:18, 124:17, 126:4, 129:22, 131:24, 132:4
approve [1] - 120:24
approved [1] - 131:18
AR [57] - 13:24, 23:1, 23:7, 23:11, 23:12, 23:24, 24:8, 25:4, 25:8, 26:1, 27:7, 28:2, 28:14, 28:23, 28:25, 31:1, 32:8, 33:10, 40:4, 40:18, 43:18, 44:6, 47:22, 48:18, 51:16, 52:24, 56:9, 56:20, 59:24, 60:21, 61:7, 64:17, 69:11, 69:14, 69:16, 69:22, 70:13, 70:18, 70:22, 74:4, 74:11, 74:25, 75:5, 76:2, 78:20, 80:8, 80:16, 80:24, 82:2, 82:6, 82:15, 82:21, 83:1, 83:7, 87:5, 88:24, 90:15
area [2] - 21:4, 65:17
arena [2] - 12:15, 16:8
arise [1] - 46:1
arrive [2] - 23:3, 53:4
Arrow [2] - 34:19, 43:7
art [2] - 16:11, 16:23
article [1] - 125:6
articles [1] - 12:18
articulate [1] - 122:7
ARTIST [4] - 40:17, 48:7, 133:6, 133:7
AS [8] - 24:21, 24:22, 24:25, 25:5, 41:6, 48:16, 49:13, 53:11
ascertain [2] - 11:16, 32:3
aside [1] - 33:1
assess [3] - 31:25, 83:6, 131:14
assessed [1] - 32:18
assessment [9] - 22:6, 50:14, 51:9, 52:6, 56:2, 75:25, 79:23, 80:13, 80:18
assignment [2] - 56:23, 84:1
assist [3] - 68:8, 68:16, 122:14
assistant [1] - 11:22
associate [1] - 52:19
associated [28] - 24:25, 29:15, 30:15, 31:10, 33:17, 34:13, 34:16, 34:19, 35:24, 37:3, 40:23, 41:15, 41:20, 45:24, 46:3, 48:3, 50:11, 50:20, 66:2, 79:20, 82:15, 82:18, 82:21, 83:1, 84:19, 85:15, 90:8, 115:25
associates [1] - 39:7
assume [3] - 20:20, 122:9, 125:13
assumptions [6] - 86:25, 87:8, 88:17, 89:8, 90:2, 90:6
asymmetric [1] - 27:17
atop [1] - 13:20
atrial [2] - 114:9, 115:12
attached [2] - 12:25, 87:2
attempts [1] - 67:2
attend [1] - 15:11
attended [2] - 15:8, 15:10
attention [3] - 44:25, 45:14, 133:14
attractive [2] - 123:6, 130:19
attributable [3] - 89:10, 89:12, 89:23
attributed [2] - 91:18, 92:6
attrition [1] - 130:25
August [1] - 65:15
availability [2] - 41:20, 51:13
available [15] - 14:17, 16:17, 17:4, 17:21, 18:24, 23:7, 26:12, 26:14, 26:17, 28:23, 39:19, 127:13, 127:16, 127:19
Avenue [6] - 1:15, 1:19, 1:22, 2:4, 2:8, 135:7
average [1] - 22:13
avoid [1] - 132:6
avoiding [1] - 60:5
aware [4] - 28:14, 65:8, 89:2, 112:8
AWT [8] - 121:17, 121:22, 122:12, 122:14, 123:1, 124:7, 126:18, 131:17

B

bachelor's [1] - 10:10
background [4] - 10:9, 86:9, 112:22, 117:21
backup [1] - 58:23
bad [1] - 53:9
Baerenwald [3] - 33:7, 40:7, 47:8
Bailey [2] - 6:22, 85:5
Bailey's [1] - 52:25
balancing [4] - 67:1, 67:25, 68:8, 68:16
baleful [2] - 33:22, 66:12
bank [1] - 128:23
Barrett [1] - 1:12
barriers [4] - 82:11, 82:13, 83:23, 84:16
based [18] - 9:14, 9:17, 13:15, 13:19, 20:14, 31:9, 39:13, 42:6, 51:10, 57:3, 67:5, 67:10, 67:13, 70:25, 81:3, 84:6, 88:17, 115:11
basis [15] - 28:5, 32:15, 48:14, 57:25, 58:2, 58:10, 58:19, 59:2, 59:13, 62:12, 67:11, 67:21, 68:10, 80:23, 122:5
battle [1] - 125:12
bear [1] - 73:2
bearing [2] - 61:14, 118:24
beat [1] - 8:24
became [5] - 113:7, 113:10, 113:23, 114:15, 117:6
become [3] - 29:1, 36:24, 114:11
becomes [4] - 20:6, 20:10, 32:11, 118:4
becoming [1] - 118:5
BEFORE [1] - 1:9
began [4] - 14:15, 54:5, 75:12, 75:16
begin [3] - 4:5, 82:2, 85:22
beginning [2] - 82:8, 87:17
begun [1] - 28:4
behalf [3] - 8:7, 111:16, 112:5
belief [1] - 58:3
below [1] - 6:15
beneficial [4] - 14:6, 35:6, 61:16, 61:24
benefit [13] - 15:15, 50:3, 50:4, 50:5, 58:10, 60:23, 61:1, 61:3, 61:9, 61:12,

61:20, 61:23
benefited [1] - 14:6
benefits [16] - 48:3, 50:9, 50:18, 59:3, 61:5, 67:6, 67:11, 67:14, 67:20, 68:1, 68:3, 68:7, 68:9, 68:11, 68:17
best [2] - 118:8, 135:3
Beth [1] - 38:1
better [10] - 44:16, 44:17, 44:21, 45:7, 45:25, 46:10, 46:17, 58:17, 60:18, 60:19
between [21] - 10:17, 12:3, 31:18, 32:11, 32:24, 35:12, 41:7, 41:10, 42:21, 44:12, 47:8, 48:23, 56:14, 61:22, 64:20, 65:17, 66:21, 70:1, 89:10, 119:3, 129:6
beyond [3] - 31:21, 31:23, 85:9
Bierman [2] - 45:19, 53:16
Bierman's [1] - 28:21
big [3] - 19:23, 126:16, 127:16
bills [1] - 129:7
binder [1] - 87:11
binders [2] - 8:19, 9:1
bit [10] - 5:8, 46:12, 48:1, 78:9, 121:11, 121:12, 122:10, 125:12, 134:3
blocked [7] - 129:13, 129:14, 129:23, 130:12, 130:25, 131:21, 134:2
blue [1] - 4:15
board [22] - 112:17, 115:21, 115:23, 116:2, 117:4, 117:5, 117:6, 117:9, 117:11, 117:20, 118:4, 118:10, 118:15, 118:17, 118:18, 119:3, 119:7, 132:18, 132:20, 132:25, 133:12, 133:13
board's [1] - 132:22
boards [1] - 115:22
borne [2] - 38:8, 87:13
Boston [1] - 5:22
bottom [2] - 133:15, 134:4
bought [1] - 33:10
box [2] - 87:11, 133:14
brain [1] - 115:8
Brain [1] - 115:16
break [2] - 55:2, 111:22
breakdown [1] - 91:1
breakthrough [3] - 54:7, 65:12, 65:19
brief [1] - 10:8
Brief [1] - 55:3
briefly [2] - 112:21, 113:1
bringing [1] - 47:3
broad [2] - 32:21, 81:5
broader [3] - 12:14, 66:18, 75:13
broadly [9] - 27:4, 35:8, 35:10, 38:2, 46:15, 50:17, 53:3, 78:7, 87:3
Brown [1] - 10:11
Brussels [1] - 113:23
buckets [3] - 17:14, 42:24, 44:11
Bugsy's [1] - 21:4
build [2] - 44:17, 133:10
builds [1] - 13:20
burdensomeness [1] - 24:17
Bureau [2] - 11:9, 11:22
business [6] - 15:2, 22:18, 23:21, 41:17, 116:23, 116:24
busy [3] - 115:5, 117:11, 117:12
but-for [2] - 50:21, 67:22
buy [2] - 18:22, 19:3
buying [1] - 18:18
BY [12] - 8:14, 8:25, 9:10, 13:9, 53:19, 55:7, 59:23, 65:23, 83:21, 112:14, 128:8, 132:12

C

calculate [13] - 27:11, 29:24, 58:24, 59:9, 59:15, 60:4, 63:2, 66:15, 66:19, 66:20, 66:22, 69:10, 69:13
calculated [5] - 29:25, 30:4, 31:3, 31:9, 31:10
calculating [2] - 64:22, 73:15
calculation [7] - 29:22, 57:8, 57:10, 62:25, 63:5, 64:2, 79:13
calculations [1] - 31:8
candidate [12] - 18:12, 18:25, 19:7, 19:10, 19:14, 19:17, 19:18, 20:6, 22:21, 23:16, 26:12, 114:17
candidates [1] - 125:15
cannibalizing [1] - 35:1
cannot [9] - 29:4, 49:17, 90:7, 91:25, 122:4, 124:12, 130:20, 131:13
capacities [1] - 11:12
capacity [1] - 12:6
capitalists [1] - 117:25
capture [2] - 44:16, 45:10
captured [1] - 34:5
capturing [2] - 19:2, 37:2
cardiology [2] - 39:3, 114:2
cardiovascular [1] - 113:24
care [1] - 12:14
career [1] - 51:24
careful [2] - 87:10, 89:6
carpet [1] - 12:13
case [26] - 5:1, 5:2, 6:8, 9:20, 12:21, 14:20, 16:25, 19:11, 22:23, 23:12, 23:15, 31:17, 33:19, 62:1, 62:12, 68:1, 69:2, 69:3, 71:3, 74:2, 79:20, 111:18, 111:21, 116:21, 119:20, 123:8
cases [8] - 26:13, 31:6, 87:19, 87:22, 88:5, 119:7, 128:2, 130:7
cash [7] - 128:15, 128:20, 128:23, 128:25, 129:5, 129:21, 129:22
categorization [1] - 81:4
causal [1] - 61:22
causes [3] - 34:6, 36:25, 61:11
CCR [3] - 2:6, 134:25, 135:5
CE [1] - 126:2
center [2] - 117:18, 118:21
CEO [8] - 88:13, 114:15, 114:17, 115:5, 115:9, 116:5, 116:14, 118:15
certain [5] - 17:20, 22:2, 43:15, 89:8, 124:6
certainly [11] - 25:21, 54:2, 75:24, 79:3, 80:5, 114:19, 118:3, 123:5, 124:6, 125:15, 133:23
CERTIFICATE [1] - 134:24
certificate [1] - 126:3
certify [1] - 134:25
chain [1] - 66:5
chairing [1] - 116:2
chairman [14] - 112:17, 115:10, 115:23, 117:3, 117:6, 117:9, 117:11, 117:13, 118:5, 118:9, 118:12, 118:14, 119:8, 132:17
challenge [1] - 12:23
challenged [1] - 49:23
challenges [2] - 84:19, 121:22
chance [1] - 132:3
chances [1] - 134:13
change [12] - 11:3, 30:18, 31:16, 31:17, 60:8, 60:11, 60:13, 60:16, 61:18, 72:8, 72:19, 121:11
changed [2] - 75:11, 121:9
changes [21] - 20:18, 27:22, 30:12, 30:14, 30:23, 33:16, 61:8, 89:9, 89:10, 89:12, 89:22, 90:1, 90:4, 90:7, 90:22, 91:3, 91:10, 91:18, 92:3, 92:5, 92:10
characteristics [2] - 17:15, 17:17
characterization [2] - 66:10, 89:15
characterized [1] - 67:7
charge [1] - 114:2
charged [2] - 14:22, 14:23
charges [1] - 36:13
charging [3] - 16:19, 19:5, 91:15
chasing [1] - 39:4
chemicals [1] - 12:12
chest [1] - 24:18
chief [1] - 17:16
choice [1] - 25:18
choices [3] - 10:24, 17:11, 79:3
choose [1] - 134:8
Christmas [1] - 121:20
chronological [1] - 115:6
circumstance [6] - 6:10, 19:6, 36:15, 42:19, 45:4, 45:11
circumstances [9] - 21:8, 21:21, 22:1, 26:15, 42:16, 45:17, 66:24, 72:2, 73:8
cite [2] - 88:6, 91:13
cited [2] - 41:11, 91:6
cites [2] - 65:14, 91:9
claim [1] - 114:8
claimed [1] - 50:14
clarification [1] - 127:20
clarify [2] - 57:9, 61:25
clarifying [1] - 124:21
clarity [1] - 88:13
Class [1] - 86:5
clear [12] - 38:21, 50:23, 53:23, 56:24, 67:8, 67:24, 70:16, 78:25, 79:18, 92:5, 92:9, 122:1
clearance [2] - 83:13, 83:18
clearest [1] - 43:14
clearly [5] - 21:13, 46:22, 66:4, 71:25, 72:2
CLEARY [1] - 1:18
CLERK [1] - 112:2
clinical [43] - 28:15, 29:3, 29:5, 31:4, 31:8, 31:9, 38:22, 38:25, 39:22, 40:12, 53:2, 64:7, 70:20, 70:23, 74:3, 74:11, 74:24, 75:4, 75:12, 75:17, 78:10, 80:17, 80:24, 81:3, 81:11, 81:24, 82:3, 82:5, 82:7, 82:8, 83:13, 85:23, 86:13, 113:16, 123:24, 125:4, 126:12, 126:17, 127:14, 127:21, 130:18, 133:5

close [17] - 37:13, 37:17, 37:20, 38:7, 38:9, 38:14, 39:8, 43:2, 43:4, 66:9, 66:13, 77:6, 79:10, 92:18, 125:17, 134:11
closed [6] - 92:16, 112:10, 122:17, 125:23, 134:16, 134:18
closer [2] - 54:15, 85:16
closes [1] - 133:5
closest [1] - 67:15
Coate [1] - 1:18
coffee [2] - 20:24, 21:11
cognizant [1] - 111:20
Coke [2] - 77:17, 77:18
cola [1] - 77:16
Cola [2] - 77:17, 77:19
collection [2] - 16:4, 16:12
colloquially [1] - 18:16
Colombe [1] - 20:24
COLUMBIA [1] - 1:1
combination [2] - 41:24, 117:10
combine [1] - 33:14
combined [12] - 11:5, 34:2, 36:24, 37:2, 37:4, 40:6, 46:15, 52:12, 53:13, 57:7, 63:9, 115:10
combining [2] - 30:17, 47:5
coming [3] - 44:16, 53:15, 125:19
commence [4] - 54:11, 80:17, 80:24, 81:21
commenced [2] - 29:5, 53:24
commencement [5] - 74:3, 74:10, 74:24, 75:4, 81:3
comments [1] - 81:3
commercial [9] - 28:5, 48:14, 115:24, 118:4, 122:3, 123:24, 125:11, 126:17, 127:24
commercial-stage [1] - 115:24
commercialization [9] - 29:7, 57:19, 57:21, 58:6, 58:7, 90:15, 124:20, 131:21, 131:23
commercialized [4] - 32:15, 41:14, 53:5, 87:22
commercializing [1] - 124:17
commercially [1] - 127:19
COMMISSION [2] - 1:2, 1:15
Commission [7] - 8:8, 11:10, 11:11, 11:13, 11:20, 11:23, 11:25
commissioner [1] - 11:21
commitment [1] - 130:4
committed [3] - 71:15, 71:21, 113:7
committee [1] - 116:2
committing [1] - 6:9
common [1] - 21:12
commonly [1] - 77:7
communications [1] - 28:12
companies [17] - 29:17, 76:12, 113:6, 113:10, 113:12, 115:6, 116:6, 116:13, 116:22, 116:25, 118:2, 118:7, 122:22, 122:23, 124:4, 128:22, 130:19
company [46] - 17:5, 53:20, 84:16, 113:4, 113:14, 114:6, 114:7, 114:9, 114:13, 114:15, 114:18, 114:21, 115:8, 115:10, 115:11, 115:12, 115:20, 115:24, 116:24, 117:12, 117:13, 117:14, 117:17, 118:18, 118:19, 118:24, 119:4, 119:10, 121:5, 121:6, 122:5, 122:20, 123:1, 123:3, 124:8, 124:11, 125:1, 125:18, 125:25, 128:25, 130:13, 131:12, 133:7, 133:19
company's [4] - 119:9, 121:23, 124:16, 129:11
compare [2] - 57:18, 58:5
compared [2] - 56:3, 91:25
comparison [1] - 68:11
Compass [1] - 12:1
compelling [1] - 50:23
compete [1] - 48:5
competed [1] - 64:6
competing [3] - 38:19, 40:8, 80:23
competition [57] - 10:1, 12:16, 13:17, 14:6, 14:16, 15:20, 16:9, 25:14, 25:22, 33:12, 34:15, 35:12, 35:16, 35:20, 35:21, 35:23, 35:25, 36:2, 36:11, 36:19, 37:11, 37:15, 38:11, 38:15, 38:18, 38:22, 39:6, 39:8, 39:11, 41:5, 41:8, 41:10, 41:13, 42:16, 42:22, 43:10, 43:14, 43:22, 44:13, 48:23, 49:7, 54:2, 54:22, 62:16, 64:10, 64:16, 64:20, 64:23, 68:21, 77:6, 78:24, 89:10, 89:13, 89:23, 90:24, 91:19, 92:6
competitive [47] - 10:19, 13:11, 16:12, 16:15, 16:16, 17:5, 17:9, 18:7, 29:9, 29:14, 30:13, 34:6, 34:22, 36:22, 37:25, 52:1, 54:9, 54:15, 57:2, 68:9, 68:14, 68:16, 72:7, 72:8, 72:18, 72:19, 72:25, 73:11, 74:7, 74:22, 75:11, 76:3, 76:5, 76:12, 76:25, 77:11, 77:14, 77:19, 77:25, 78:6, 78:12, 78:21, 79:3, 79:5, 79:21, 85:11, 91:7
competitively [2] - 74:5, 74:8
competitor [7] - 35:3, 35:4, 39:24, 44:4, 54:6, 67:15, 79:10
competitors [4] - 33:12, 49:24, 76:21, 88:24
complementarity [1] - 45:24
complementary [2] - 46:16, 47:1
complements [1] - 46:21
complete [2] - 116:20, 135:3
completely [1] - 89:14
completing [1] - 40:20
complex [2] - 123:18, 127:2
complexity [1] - 121:19
component [1] - 81:24
components [1] - 17:23
compounded [1] - 124:7
comprise [1] - 70:9
computer [1] - 2:11
computer-aided [1] - 2:11
con [1] - 40:10
concede [1] - 58:11
conceivably [1] - 23:16
concentrated [2] - 27:16, 31:14
concentration [21] - 14:1, 14:5, 27:12, 27:13, 27:14, 27:19, 27:21, 27:22, 29:23, 29:24, 30:1, 30:3, 30:15, 31:1, 31:11, 31:17, 32:1, 33:3, 33:17, 74:18, 79:13
concern [1] - 43:6
concerned [4] - 54:1, 62:21, 63:19, 77:5
concerns [1] - 45:16
conclude [4] - 51:11, 58:10, 60:25, 74:21
concludes [3] - 68:6, 78:19, 79:14
conclusion [13] - 9:25, 13:16, 22:25, 26:10, 27:1, 32:18, 42:15, 49:8, 51:7, 52:8, 54:18, 54:21, 62:16
conclusions [9] - 13:21, 14:12, 15:6, 31:7, 41:4, 48:17, 63:14, 70:10, 85:3
concrete [1] - 90:19
conditions [3] - 52:1, 72:9, 72:19
conduct [8] - 11:16, 63:9, 65:9, 70:19, 70:22, 82:4, 82:6, 82:20
conducted [7] - 48:19, 82:10, 82:12, 83:22, 85:1, 85:6, 90:12
conducting [1] - 86:12
conference [1] - 39:3
confident [2] - 6:6, 44:20
confidential [1] - 7:14
confidentiality [1] - 89:7
confirm [2] - 7:25, 90:6
confronts [1] - 20:1
confusing [1] - 134:9
confusion [1] - 86:2
connect [1] - 65:25
connected [3] - 60:9, 60:14, 61:19
Connecticut [1] - 1:22
connection [2] - 43:16, 120:17
consequences [12] - 11:2, 13:23, 14:4, 25:1, 30:19, 33:22, 34:13, 35:24, 62:21, 66:12, 72:25, 74:7
conservative [1] - 90:10
consider [10] - 14:18, 16:1, 23:19, 42:14, 48:21, 54:3, 61:15, 73:16, 79:17, 121:25
consideration [3] - 11:15, 56:6, 73:11
considered [22] - 23:20, 23:22, 37:14, 41:3, 45:22, 45:23, 47:13, 50:10, 51:6, 51:17, 60:23, 61:2, 71:9, 71:16, 71:22, 72:10, 72:20, 75:2, 75:7, 78:13, 80:1, 80:10
considering [2] - 14:20, 54:17
considers [1] - 90:13
consistency [1] - 90:10
consistent [19] - 14:3, 28:11, 29:11, 32:6, 37:10, 38:3, 38:11, 39:10, 40:10, 47:3, 48:25, 52:25, 63:6, 70:10, 74:9, 75:13, 75:22, 85:4, 89:20
consists [1] - 62:6
constituent [1] - 46:17
constitutes [1] - 135:1
Constitution [2] - 2:8, 135:7
constraining [1] -

21:15
constraint [15] - 16:15, 16:16, 17:6, 17:9, 29:9, 37:25, 54:9, 74:22, 75:11, 77:25, 78:6, 78:12, 78:17, 78:21, 79:21
constraints [4] - 16:13, 18:7, 54:16, 85:16
consult [1] - 65:13
consultancy [2] - 10:7, 12:1
consulting [1] - 12:4
consume [5] - 20:25, 25:19, 61:14, 66:3, 66:5
consumed [1] - 46:3
consumer [12] - 22:3, 22:10, 25:16, 25:18, 30:19, 60:9, 60:15, 61:3, 61:19, 65:25, 66:2, 69:11
consumers [95] - 9:22, 9:24, 10:2, 11:18, 13:12, 13:18, 13:24, 14:7, 14:17, 15:13, 15:15, 15:18, 15:20, 16:17, 17:3, 17:20, 18:18, 18:21, 19:2, 19:13, 20:11, 20:21, 20:22, 21:13, 21:22, 22:19, 23:2, 23:8, 23:23, 24:8, 25:15, 25:25, 26:1, 26:8, 26:9, 26:13, 26:14, 26:16, 26:20, 26:24, 27:8, 27:21, 27:24, 28:3, 30:16, 31:2, 32:15, 33:18, 34:1, 34:6, 35:24, 36:1, 36:3, 36:9, 36:11, 36:15, 37:1, 38:9, 38:18, 39:19, 43:3, 43:5, 46:6, 47:23, 48:3, 48:14, 50:3, 50:4, 50:5, 51:13, 52:13, 53:13, 54:22, 60:11, 60:16, 60:17, 60:18, 60:22, 60:23, 61:1, 61:8, 61:10, 61:13, 61:16, 61:20, 61:23, 62:17, 62:19, 63:16, 66:9, 69:16, 69:23, 72:1, 78:24
consumers' [1] - 66:3
consumes [1] - 48:18
consumption [1] - 46:22
contain [5] - 9:1, 17:12, 19:10, 56:12, 77:13
contained [3] - 18:8, 75:9, 87:3
containing [1] - 8:19
contains [4] - 18:12, 40:2, 68:11, 68:19
contemplates [1] - 87:15
contemporaneous [1] - 87:3
contents [1] - 120:2
contestability [2] - 43:1, 44:13
context [4] - 59:7, 73:23, 77:21, 91:11
continue [4] - 14:7, 20:25, 49:2, 117:13
CONTINUED [1] - 2:1
continued [1] - 67:16
continuing [3] - 19:3, 36:16, 47:21
continuously [1] - 49:10
CONTRERAS [1] - 1:9
controlled [1] - 23:6
controlling [1] - 20:7
convenience [1] - 20:9
conversation [2] - 50:2, 54:20
conversely [1] - 19:9
Cordis [1] - 113:15
core [2] - 16:12, 39:7
CoreValve [2] - 41:13, 41:18
corporate [1] - 46:7
Corporation [2] - 113:15, 115:17
CORPORATION [1] - 1:5
corporation [1] - 114:5
corporations [1] - 116:20
corpse [1] - 81:5
correct [47] - 13:14, 56:12, 56:17, 57:14, 59:11, 60:16, 64:7, 64:25, 67:3, 67:9, 68:2, 69:2, 69:3, 69:8, 69:17, 69:20, 69:23, 70:5, 71:1, 78:14, 78:24, 80:2, 80:11, 80:17, 82:11, 83:8, 83:9, 83:24, 84:8, 84:11, 84:24, 84:25, 85:2, 85:8, 85:24, 86:1, 86:11, 86:13, 86:14, 86:18, 86:21, 86:24, 87:17, 87:19, 92:8, 116:7, 130:10
correctly [1] - 60:6
corroborates [1] - 32:21
corroborating [1] - 91:5
cost [4] - 40:25, 49:3, 49:17, 131:25
costlessly [1] - 45:2
costliness [1] - 82:23
costs [11] - 33:24, 40:9, 44:23, 45:6, 72:9, 72:20, 82:15, 82:21, 84:19, 84:23, 124:12
Counsel [1] - 55:9
counsel [8] - 5:20, 6:11, 7:15, 7:16, 59:8, 70:7, 92:19, 112:2
counsel's [1] - 6:7
Counselor [5] - 59:12, 60:12, 63:23, 65:18, 75:3
count [1] - 119:2
counterfactual [3] - 47:21, 48:12, 56:8
counterintuitive [1] - 133:8
County [2] - 117:12, 117:17
couple [8] - 4:4, 4:20, 5:6, 113:5, 116:4, 119:16, 132:7, 132:13
course [32] - 10:10, 12:10, 15:2, 22:7, 22:17, 23:21, 24:13, 32:7, 32:13, 32:23, 33:5, 38:8, 38:16, 41:17, 44:2, 49:1, 49:6, 52:22, 57:4, 62:7, 62:9, 91:5, 117:20, 118:18, 120:3, 121:1, 121:7, 122:2, 122:23, 126:16, 131:15, 131:19
course-projected [1] - 32:7
COURT [35] - 1:1, 4:3, 4:6, 4:16, 4:24, 5:9, 5:12, 5:14, 6:1, 6:18, 7:2, 7:10, 7:17, 7:20, 7:24, 8:4, 8:6, 8:12, 8:23, 13:8, 52:14, 52:17, 53:7, 55:1, 55:4, 92:18, 111:19, 111:23, 111:25, 112:12, 128:5, 128:7, 134:17, 134:20, 134:24
Court [3] - 2:6, 2:7, 135:5
court [27] - 4:8, 4:22, 5:19, 6:17, 8:1, 10:8, 12:8, 15:10, 24:20, 27:5, 49:15, 60:20, 60:25, 61:17, 67:24, 68:5, 68:8, 68:16, 69:18, 78:19, 79:14, 79:24, 111:15, 112:21, 119:22, 128:20
Courthouse [2] - 2:7, 135:6
courtroom [4] - 70:4, 84:12, 88:10, 92:18
cover [1] - 44:23
covered [5] - 26:7, 56:5, 89:25, 90:17, 91:13
covering [1] - 23:25
cracked [1] - 24:18
created [2] - 25:16, 87:1
creates [2] - 124:11, 131:15
creation [1] - 34:10
creative [2] - 39:21, 39:22
credible [1] - 22:15
crisis [1] - 129:19
criteria [2] - 51:1, 52:9
cross [2] - 6:13, 7:6
Cross [1] - 3:4
CROSS [1] - 55:6
Cross-Examination [1] - 3:4
CROSS-EXAMINATION [1] - 55:6
cross-examine [2] - 6:13, 7:6
CRR [3] - 2:6, 134:25, 135:5
CRUTCHER [1] - 1:22
CryoCath [1] - 114:7
current [8] - 43:19, 119:15, 123:13, 124:19, 128:9, 129:4, 133:23
customers [3] - 25:22, 33:24, 44:5
CV [2] - 1:2, 12:25

D

D.C [6] - 1:4, 19:25, 20:1, 20:3, 20:12, 21:6
dangerous [1] - 24:6
Darby [1] - 39:13
data [5] - 21:22, 22:15, 69:6, 69:8, 69:10
date [2] - 120:20, 120:22
dated [2] - 65:3, 135:4
DAY [1] - 1:8
days [6] - 4:20, 5:3, 5:7, 6:16, 15:10, 128:17
DBS [1] - 115:19
DC [6] - 1:16, 1:19, 1:23, 2:5, 2:8, 135:7
deadweight [1] - 34:3
deal [10] - 25:20, 39:18, 53:14, 122:24, 132:23, 133:5, 133:9, 133:15, 133:19
dealing [2] - 124:10, 126:12
dear [1] - 19:22
December [1] - 120:10
decide [1] - 20:5
decided [4] - 40:6, 114:22, 117:14, 117:17
decides [1] - 36:12
decision [2] - 10:23, 10:25
decision-makers [1] - 10:23
decision-making [1] - 10:25
deck [5] - 87:2, 87:12, 87:15, 87:18, 132:15
decks [1] - 132:25
declaration [2] - 7:12, 7:13
decline [1] - 89:18
declines [3] - 91:5, 91:7, 92:13
decomposition [1] - 91:2
dedicated [1] - 116:10
deep [1] - 15:20
defendant's [1] - 29:12
defendants [3] - 25:9, 51:15, 112:5
Defendants [3] - 1:7, 1:17, 2:2
DEFENDANTS [1] - 112:7

defendants' [1] - 29:13
deficiency [4] - 120:1, 120:5, 120:6, 120:9
define [5] - 52:14, 52:17, 68:23, 73:13, 77:15
defined [7] - 18:1, 25:7, 25:10, 26:2, 27:6, 69:15, 69:21
defining [6] - 17:23, 23:19, 69:6, 79:7, 79:17, 80:2
definition [2] - 22:7, 69:18
definitionally [1] - 78:22
definitions [1] - 70:2
degree [2] - 75:10, 112:24
degrees [1] - 77:14
delayed [1] - 121:15
delays [1] - 40:20
delineated [1] - 17:17
delineates [2] - 17:15, 32:9
deliver [1] - 26:20
delivered [1] - 16:21
delivering [1] - 25:15
delivers [1] - 36:4
delivery [5] - 21:1, 21:15, 48:13, 123:16, 127:15
delta [2] - 31:17, 56:14
demand [8] - 46:10, 46:18, 69:11, 69:14, 90:14, 125:25, 126:6, 129:24
DeMarchi [1] - 1:14
demonstrative [8] - 8:20, 9:2, 9:3, 9:7, 65:2, 76:1, 83:11, 86:15
demonstratives [4] - 4:18, 4:19, 4:21
depart [1] - 92:20
department [4] - 123:3, 124:8, 124:9
departments [1] - 127:11
deposed [1] - 59:16
deposition [11] - 6:23, 28:21, 37:23, 39:13, 49:8, 59:19, 59:21, 69:25, 80:22, 86:2, 91:13
deputy [1] - 11:22
DEPUTY [1] - 112:2
describe [3] - 12:8, 112:21, 128:19
described [1] - 38:15
describing [1] - 44:15
deserves [1] - 79:11
designation [3] - 54:7, 65:12, 65:19
designations [1] - 5:22
designed [1] - 37:22
desirability [1] - 35:13
despite [1] - 86:2
detail [2] - 10:3, 130:1
details [2] - 120:4, 122:19
detergents [1] - 113:4
deterioration [1] - 52:1
determination [1] - 28:9
determine [11] - 15:17, 15:19, 15:25, 27:19, 76:7, 76:14, 77:1, 78:3, 82:1, 89:11, 89:22
determined [4] - 13:22, 13:25, 14:8, 37:16
determining [10] - 21:18, 22:10, 26:3, 27:8, 74:12, 75:1, 75:6, 75:20, 77:3, 77:21
detriment [2] - 11:17, 52:13
develop [6] - 35:2, 44:3, 47:22, 57:15, 64:6, 131:18
developed [3] - 9:16, 28:25, 118:2
developer [7] - 46:8, 75:20, 82:15, 82:22, 83:1, 83:7, 83:10
developing [9] - 25:19, 40:9, 43:2, 45:2, 45:6, 66:4, 115:7, 126:12, 134:14
development [7] - 43:25, 48:4, 58:2, 61:7, 69:22, 119:25, 123:20
device [36] - 23:11, 23:25, 24:25, 25:5, 28:14, 28:20, 32:25, 40:22, 40:24, 41:14, 56:20, 67:17, 70:23, 74:4, 74:11, 74:25, 75:5, 75:20, 78:22, 81:23, 82:15, 82:21, 83:1, 83:7, 83:10, 86:9, 114:9, 114:12, 115:7, 115:14, 115:15, 116:9, 116:10, 120:25, 127:22, 131:18
devices [45] - 13:24, 23:7, 23:12, 25:8, 26:1, 26:20, 27:7, 28:2, 28:15, 28:23, 28:25, 29:4, 31:1, 32:15, 40:4, 40:18, 40:25, 41:2, 47:23, 48:18, 52:24, 56:9, 69:11, 69:14, 69:16, 69:22, 70:7, 70:13, 70:18, 70:22, 80:8, 80:16, 80:24, 82:2, 82:6, 86:5, 87:5, 87:16, 113:8, 113:24, 114:11, 116:3, 126:4, 127:8, 131:18
difference [5] - 31:18, 56:18, 59:14, 70:1, 74:19
different [37] - 11:15, 12:7, 12:11, 14:14, 17:12, 17:14, 20:23, 21:10, 26:13, 26:17, 30:11, 31:3, 31:9, 37:14, 40:5, 42:18, 47:5, 55:18, 55:21, 55:25, 68:18, 77:14, 77:24, 78:5, 82:18, 87:6, 90:4, 90:7, 90:8, 90:14, 92:2, 92:3, 92:12, 92:14, 114:13, 115:25, 118:20
differentiated [1] - 46:5
difficult [3] - 45:4, 65:24, 118:16
digesting [1] - 133:4
dimensions [1] - 17:12
diminished [1] - 40:14
dine [1] - 21:3
dining [1] - 19:24
direct [14] - 17:8, 37:11, 37:15, 48:24, 64:4, 66:1, 66:17, 68:22, 70:15, 72:7, 72:18, 76:20, 91:6, 119:6
Direct [2] - 3:3, 3:6
DIRECT [2] - 8:13, 112:13
directed [1] - 7:6
directing [1] - 133:14
direction [2] - 9:4, 121:24
directly [6] - 22:2, 22:16, 47:14, 47:19, 48:5, 81:13
director [1] - 11:22
disagrees [1] - 68:5
discipline [2] - 36:22, 73:19
disciplines [1] - 61:4
discuss [1] - 10:4
discussed [20] - 24:12, 24:24, 31:15, 31:24, 33:16, 34:20, 37:7, 38:4, 39:7, 39:25, 57:24, 66:1, 66:17, 70:15, 74:14, 83:25, 85:14, 91:3, 130:1, 132:20
discussing [2] - 43:8, 47:15
discussion [2] - 87:4, 122:7
disease [2] - 24:4, 24:6
dismiss [1] - 80:5
dismissal [1] - 81:5
disruptive [1] - 124:14
distinguish [1] - 25:18
distraction [1] - 131:15
district [2] - 20:14, 21:3
DISTRICT [3] - 1:1, 1:1, 1:10
district-based [1] - 20:14
diversion [4] - 21:5, 21:10, 63:10, 66:21
divert [5] - 18:23, 19:13, 20:24, 23:14, 36:21
divide [1] - 17:13
division [3] - 113:21, 114:3, 116:21
divisions [1] - 114:19
doctor [8] - 6:3, 59:16, 66:24, 68:22, 80:15, 81:12, 85:25, 92:4
Doctor [2] - 55:12, 59:7
doctors [1] - 25:2
document [15] - 23:21, 24:13, 32:23, 38:23, 40:12, 41:11, 44:2, 49:1, 75:14, 86:19, 91:9, 91:22, 91:24, 92:5, 132:11
documents [9] - 15:2, 22:18, 38:21, 39:9, 62:7, 62:9, 62:11, 65:14, 92:1
DOJ [2] - 71:2, 76:14
dollar [1] - 82:18
domain [1] - 131:14
dominant [1] - 43:7
dominated [1] - 27:18
Domino's [1] - 21:1
done [10] - 5:3, 5:17, 6:6, 6:15, 43:24, 67:23, 68:15, 85:9, 90:18, 123:3
door [1] - 115:20
down [7] - 29:8, 48:1, 53:7, 65:22, 76:23, 83:20, 134:21
downward [2] - 39:12, 41:21
dozen [1] - 12:18
Dr [61] - 5:1, 5:19, 6:21, 6:22, 7:7, 8:9, 8:15, 8:18, 9:1, 9:7, 9:11, 9:19, 10:5, 11:6, 13:5, 13:10, 15:13, 15:23, 21:17, 22:8, 22:22, 24:19, 25:3, 25:7, 27:3, 27:6, 29:19, 31:25, 32:17, 33:1, 33:13, 38:1, 38:4, 40:24, 41:22, 47:12, 50:2, 51:5, 51:14, 52:25, 53:20, 54:23, 55:8, 59:21, 61:25, 71:1, 71:2, 80:20, 82:17, 84:1, 84:3, 84:10, 84:12, 85:3, 85:5, 88:10, 88:13, 88:16, 88:19
dramatic [3] - 32:2, 40:6, 41:16
dramatically [1] - 14:1
draw [1] - 90:18
drew [2] - 15:1, 63:15
drivers [1] - 90:3
drives [1] - 49:7
driving [1] - 43:15
due [1] - 90:23
DUNN [1] - 1:22
during [1] - 116:13
Dutch [1] - 114:23
dynamic [1] - 25:23

E

early [6] - 6:11, 113:3, 115:7, 117:6, 118:3, 123:20
early-stage [1] - 115:7
easily [2] - 44:24, 49:4
easy [2] - 71:11, 128:1

eats [1] - 126:19
echo [1] - 57:13
echoed [3] - 27:4, 32:4, 49:8
echoes [2] - 38:2, 41:9
echoing [2] - 28:17, 33:5
Econic [2] - 9:16, 10:6
Economic [1] - 30:20
economic [28] - 9:14, 10:7, 12:1, 12:20, 14:3, 15:24, 25:20, 27:20, 30:11, 30:14, 31:15, 31:24, 33:15, 37:8, 42:7, 42:13, 42:21, 44:11, 47:13, 55:13, 55:17, 60:10, 60:15, 62:3, 62:4, 62:5, 66:11, 77:1
economics [17] - 13:6, 14:15, 30:3, 33:16, 34:14, 41:9, 48:25, 60:23, 61:2, 61:4, 61:9, 61:15, 61:20, 76:19, 77:4, 89:21, 90:11
Economics [3] - 10:12, 11:9, 11:22
economist [7] - 11:13, 11:21, 21:17, 21:19, 25:14, 77:23, 78:4
economists [7] - 17:7, 17:25, 27:15, 34:3, 45:15, 66:1, 67:1
economy [1] - 34:4
education [1] - 13:1
educational [2] - 10:9, 112:22
Edwards [46] - 7:15, 13:12, 22:24, 27:9, 28:6, 29:15, 33:8, 38:19, 39:16, 40:11, 41:12, 41:18, 41:24, 43:11, 47:21, 48:11, 49:1, 49:10, 54:19, 58:17, 64:10, 64:13, 64:15, 64:19, 64:24, 86:23, 91:9, 91:11, 91:14, 91:15, 91:19, 91:20, 91:22, 91:24, 92:5, 92:7, 119:13, 122:13, 122:14, 123:3, 124:22, 125:14, 128:14, 129:12, 132:23, 133:6
EDWARDS [1] - 1:5
Edwards's [6] - 9:24, 30:25, 57:19, 58:6, 58:11, 122:22
Edwards-JenaValve [4] - 13:12, 22:24, 27:9, 54:19
effect [15] - 34:18, 40:24, 42:10, 43:6, 53:14, 54:2, 55:16, 55:25, 58:12, 63:3, 67:2, 88:21, 88:25, 89:17, 90:13
effectively [6] - 30:9, 32:24, 34:1, 34:7, 35:1, 37:23
effectiveness [4] - 57:19, 57:20, 58:5, 58:7
effects [37] - 13:11, 14:9, 14:10, 16:7, 27:9, 27:21, 30:13, 33:17, 34:17, 35:10, 48:17, 48:20, 50:6, 50:24, 50:25, 52:4, 52:7, 53:10, 53:21, 54:18, 55:18, 55:21, 55:23, 57:2, 61:22, 62:20, 63:6, 63:18, 66:14, 66:25, 67:1, 67:22, 68:20, 73:12, 78:18, 79:5, 90:20
efficiencies [6] - 14:9, 30:22, 50:12, 50:14, 50:16, 54:17
efficiency [2] - 50:13, 51:3
efficient [2] - 45:16, 46:13
effort [5] - 60:3, 83:5, 133:16, 133:20, 133:23
efforts [5] - 45:9, 45:12, 46:19, 119:9, 129:15
EFS [1] - 54:11
Eindhoven [1] - 112:24
either [5] - 47:4, 77:20, 86:4, 116:1, 126:1
elect [1] - 73:10
elected [1] - 18:15
electronically [1] - 4:22
elements [4] - 25:23, 46:17, 117:10, 123:16
elevation [1] - 34:5
eliciting [1] - 75:23
eliminate [1] - 35:21
elimination [7] - 35:19, 35:25, 36:2, 39:6, 39:8, 41:4, 42:16
Elizabeth [1] - 2:3
elsewhere [3] - 29:11, 37:23, 130:23
email [5] - 4:8, 33:11, 39:20, 41:16, 65:8
embarked [2] - 71:25, 78:15
embolization [1] - 25:2
emphasis [3] - 31:16, 40:19, 61:7
emphasize [1] - 76:21
emphasizes [3] - 22:5, 34:14, 76:19
emphasizing [1] - 49:2
employ [1] - 130:15
employed [1] - 87:1
employee [1] - 33:11
employees [5] - 130:14, 130:25, 131:5, 131:7
employment [2] - 113:2, 130:22
enabling [1] - 48:8
encountered [1] - 122:15
end [6] - 5:3, 5:22, 6:6, 115:1, 122:16, 123:21
endeavor [2] - 48:13, 80:13
endeavored [3] - 15:11, 70:16, 90:9
endeavoring [2] - 25:17, 92:9
endeavors [1] - 59:5
ended [1] - 114:2
Endosense [2] - 115:11, 115:16
engage [3] - 29:3, 60:3, 67:1
engaged [2] - 68:7, 78:10
engineering [2] - 117:19, 124:8
engineers [1] - 130:16
enjoy [1] - 5:4
ensure [1] - 5:16
enter [4] - 51:16, 72:7, 72:17, 73:21
entering [2] - 71:15, 71:21
enterprise [1] - 46:7
enters [1] - 32:12
entire [2] - 26:16, 66:5
entirely [3] - 19:15, 20:23, 90:23
entities [4] - 46:1, 47:22, 81:9, 118:20
entity [2] - 34:5, 78:25
entrant [2] - 75:2, 75:7
entrants [8] - 51:15, 72:11, 72:24, 73:5, 73:14, 73:16, 73:20, 73:22
entry [16] - 41:13, 51:14, 51:17, 51:20, 51:22, 51:23, 51:25, 52:2, 52:3, 52:5, 52:6, 52:9, 52:18, 54:18, 73:23, 91:8
environments [1] - 122:25
equal [2] - 27:16, 118:18
equitable [1] - 61:15
equivalent [8] - 29:9, 54:9, 76:3, 76:5, 76:12, 76:25, 77:11, 112:23
erode [1] - 49:18
erosion [4] - 91:16, 91:22, 91:23, 91:25
especially [1] - 81:10
Esq [14] - 1:12, 1:12, 1:13, 1:13, 1:14, 1:14, 1:17, 1:18, 1:21, 1:21, 2:2, 2:2, 2:3, 2:3
essentially [8] - 16:16, 18:6, 27:14, 37:6, 43:1, 44:15, 45:25, 47:18
estimate [11] - 12:6, 56:17, 57:16, 63:10, 63:11, 63:12, 64:22, 66:20, 68:18, 69:13, 82:23
estimated [1] - 63:2
estimates [2] - 84:2, 85:4
estimating [1] - 82:4
Europe [9] - 114:24, 122:4, 126:1, 126:3, 126:5, 126:7, 126:10, 126:11, 126:18
European [2] - 113:23, 126:3
evaluate [9] - 9:21, 13:11, 13:22, 20:21, 26:12, 36:15, 51:22, 56:6, 57:24
evaluated [4] - 37:12, 50:8, 51:3, 51:23
evaluating [8] - 11:2, 16:25, 30:3, 51:19, 55:12, 72:25, 74:7, 76:20
evaluation [3] - 9:15, 73:11, 75:9
Eve [1] - 121:20
event [8] - 47:9, 61:11, 61:22, 72:8, 72:18, 118:1, 131:23, 134:2
evidence [64] - 9:18, 14:5, 14:17, 14:20, 14:25, 15:1, 15:4, 15:7, 17:8, 21:17, 22:25, 23:22, 28:10, 28:11, 31:25, 32:4, 32:5, 32:20, 32:21, 33:1, 33:2, 35:22, 37:10, 37:15, 37:19, 38:11, 38:12, 38:21, 39:9, 43:8, 45:19, 47:2, 47:7, 47:14, 47:18, 48:22, 48:24, 49:6, 50:18, 50:23, 51:2, 51:24, 58:16, 62:2, 62:6, 62:15, 62:18, 63:5, 67:5, 67:8, 67:10, 67:13, 68:19, 75:19, 75:22, 76:2, 77:6, 78:19, 78:25, 79:14, 79:18, 79:24, 80:6, 89:16
EVIDENTIARY [1] - 1:8
exactly [4] - 45:3, 49:25, 72:13, 79:9
examination [2] - 6:3, 68:22
Examination [4] - 3:3, 3:4, 3:4, 3:6
EXAMINATION [3] - 8:13, 55:6, 112:13
examine [2] - 6:13, 7:6
examined [2] - 33:2, 48:16
example [27] - 19:20, 19:25, 21:12, 22:4, 28:12, 29:12, 30:5, 32:6, 32:22, 33:7, 33:19, 36:6, 36:7, 37:21, 38:23, 39:13, 40:15, 40:17, 40:24, 43:14, 44:1, 46:21, 48:25, 63:8, 66:21, 77:15, 79:24
Excel [1] - 58:22
except [1] - 92:19
exceptional [1] - 130:7
excerpt [3] - 24:12, 33:20, 45:19
excerpted [1] - 40:12
excess [2] - 31:12,

122:3
exchange [2] - 36:11, 47:8
Exchange [1] - 114:8
exclude [2] - 6:24, 7:8
excluding [1] - 129:6
excuse [4] - 18:21, 50:24, 121:3, 128:10
execute [1] - 124:2
executing [1] - 132:3
executive [1] - 12:1
exemption [1] - 70:24
exercise [7] - 20:18, 20:19, 23:4, 58:22, 64:21, 67:2, 85:17
exercising [1] - 33:23
exert [2] - 85:12, 133:20
exhibits [2] - 7:8, 7:12
existence [3] - 23:5, 36:18, 37:11
existing [1] - 129:24
exists [2] - 36:19, 77:17
expand [2] - 23:16, 125:8
expanded [1] - 19:18
expanding [1] - 40:18
expect [10] - 24:7, 34:17, 38:10, 42:22, 50:6, 50:21, 67:11, 81:23, 128:4, 131:22
expectations [1] - 55:17
expected [11] - 40:23, 42:4, 55:13, 55:16, 56:13, 56:15, 58:17, 63:1, 63:13, 80:20, 84:7
expenditures [1] - 45:6
expensive [2] - 125:20, 128:2
experience [14] - 9:14, 12:10, 13:2, 34:15, 39:14, 73:25, 80:3, 85:21, 86:5, 86:7, 86:12, 117:24, 118:2, 118:6
experienced [3] - 18:19, 37:5, 41:12
experiences [1] - 83:3
expert [12] - 6:12, 8:20, 9:3, 9:8, 9:19, 9:23, 12:20, 12:22, 13:5, 70:25, 84:3, 85:5
expertise [1] - 81:17
experts [2] - 6:5, 29:13
explaining [1] - 91:2
explanations [1] - 90:1
explication [1] - 87:7
explore [1] - 119:9
extend [1] - 85:17
extent [4] - 17:3, 60:8, 60:13, 91:25
extra [1] - 35:6

F

facility [1] - 113:17
fact [15] - 29:2, 29:5, 32:19, 37:4, 39:2, 39:11, 39:18, 41:12, 43:21, 44:2, 46:9, 46:16, 54:5, 81:7, 90:12
factor [9] - 44:7, 45:22, 45:23, 74:18, 80:13, 89:12, 89:23, 118:9, 124:1
factored [1] - 79:6
factors [7] - 26:15, 42:8, 42:14, 44:8, 90:14, 90:23, 91:2
facts [1] - 15:21
failed [2] - 19:17, 121:19
fails [1] - 124:7
fair [11] - 22:12, 42:7, 62:13, 63:17, 65:15, 66:9, 70:12, 73:6, 77:25, 87:12, 116:14
fairly [4] - 41:15, 46:22, 48:24, 53:11
fame [1] - 114:8
familiar [3] - 123:10, 124:16, 128:15
fans [1] - 19:23
far [6] - 76:22, 77:4, 91:24, 119:24, 128:1, 132:17
fashion [2] - 80:5, 125:21
FDA [43] - 14:24, 26:19, 28:5, 28:19, 29:3, 32:8, 39:14, 51:12, 52:10, 52:11, 53:24, 56:21, 56:25, 57:11, 57:17, 70:8, 70:14, 70:19, 70:22, 74:20, 78:16, 79:1, 80:20, 81:20, 82:6, 82:18, 83:14, 84:3, 84:7, 84:10, 84:19, 84:23, 85:2, 85:7, 85:22, 87:14, 120:6, 120:11, 120:17, 120:24, 121:4, 127:18, 131:24
February [1] - 87:13
Federal [7] - 8:8, 11:10, 11:11, 11:13, 11:20, 11:23, 11:25
FEDERAL [2] - 1:2, 1:15
fellow [1] - 20:1
felt [1] - 117:20
few [9] - 12:14, 30:23, 61:25, 87:9, 92:16, 113:22, 120:1, 122:15, 125:23
fewer [1] - 27:16
fibrillation [2] - 114:9, 115:12
field [1] - 13:5
fifteen [1] - 115:2
fight [1] - 134:11
fighting [1] - 132:3
figure [2] - 5:16, 79:22
figures [2] - 49:4, 82:18
file [1] - 79:25
filing [1] - 80:4
fill [1] - 9:17
final [2] - 43:3, 46:6
finally [5] - 21:2, 24:21, 28:21, 39:20, 40:22
financial [1] - 125:1
findings [1] - 13:19
finish [1] - 6:11
firm [45] - 16:18, 16:22, 16:23, 16:24, 17:1, 17:9, 18:8, 18:20, 33:23, 34:2, 36:8, 36:12, 36:17, 36:20, 36:22, 36:24, 36:25, 37:2, 37:4, 40:6, 46:15, 48:1, 53:13, 54:3, 54:8, 54:16, 57:7, 67:16, 74:4, 74:11, 74:13, 74:25, 75:1, 75:5, 75:6, 76:7, 76:14, 76:24, 77:2, 77:10, 78:3, 79:9
Firm [1] - 37:2
firmly [2] - 48:1, 134:3
firms [44] - 11:1, 11:4, 16:13, 17:9, 17:10, 18:21, 26:21, 27:16, 27:17, 27:18, 30:4, 30:8, 30:9, 30:17, 34:22, 35:12, 36:8, 36:10, 36:24, 43:2, 45:25, 46:25, 47:3, 57:6, 70:13, 70:17, 71:8, 71:20, 71:25, 72:10, 72:16, 73:9, 74:15, 77:13, 77:24, 78:5, 78:10, 78:15, 79:15, 79:18, 116:11, 119:3
Firms [3] - 71:14, 72:5, 73:3
firms' [2] - 11:5, 52:12
first [16] - 4:7, 10:4, 13:21, 15:23, 15:25, 28:13, 39:16, 42:25, 117:4, 118:15, 120:10, 124:25, 125:7, 128:19, 129:13, 134:7
fit [1] - 54:4
five [4] - 52:21, 53:6, 53:8, 53:9
flag [4] - 4:9, 4:12, 4:23, 5:21
flagged [3] - 6:20, 31:21, 31:23
flat [1] - 133:9
flat-out [1] - 133:9
flexibility [1] - 41:15
flip [1] - 43:13
floor [1] - 127:5
focal [10] - 16:17, 16:22, 16:23, 16:25, 18:8, 18:18, 19:3, 22:21, 23:11
focus [9] - 16:24, 17:7, 17:8, 25:25, 31:7, 49:7, 121:23, 124:5, 131:17
focused [13] - 10:13, 10:17, 10:25, 11:1, 11:3, 11:19, 38:22, 41:6, 62:1, 81:24, 113:10, 115:17, 124:23
focusing [1] - 68:14
follow [2] - 45:2, 131:12
followed [2] - 14:13, 23:4
Following [2] - 92:21, 111:15
following [3] - 6:22, 7:12, 89:19
follows [1] - 50:17
food [1] - 113:3
foot [3] - 48:1, 134:3, 134:6
footprint [1] - 127:12
FOR [3] - 1:1, 8:10, 112:7
forecast [1] - 91:14
foregoing [1] - 135:1
foreign [1] - 53:24
foremost [1] - 118:15
fork [1] - 114:22
form [7] - 15:4, 23:14, 29:25, 40:6, 58:22, 70:8, 70:14
formed [2] - 35:20, 41:23
former [1] - 88:13
forms [2] - 23:18, 40:5
forward [8] - 14:7, 14:24, 15:22, 43:15, 44:6, 111:23, 111:25, 125:18
forward-looking [1] - 15:22
founded [3] - 117:12, 117:14, 117:15
founding [1] - 10:6
four [4] - 119:2, 119:4, 129:1
fourteen [1] - 115:3
fourth [1] - 14:8
fraction [2] - 20:12, 23:14
frame [2] - 73:23, 73:25
framed [2] - 19:22, 19:25
framework [4] - 15:24, 17:23, 37:8, 77:1
frameworks [2] - 60:10, 60:15
FRANCE [10] - 13:7, 55:5, 55:7, 59:21, 59:23, 65:22, 65:23, 83:20, 83:21, 92:15
France [1] - 1:21
France.....55 [1] - 3:4
frankly [4] - 24:14, 124:9, 126:18, 129:17
front [2] - 43:22, 132:15
FTC [9] - 8:8, 9:19, 9:21, 11:12, 13:10, 70:7, 71:2, 76:13, 111:16
FTC's [3] - 12:22, 59:8, 70:4
full [4] - 48:7, 117:2, 133:7, 135:2
fully [2] - 25:17, 113:7
fumes [1] - 134:11
funding [8] - 51:7, 124:25, 127:25, 128:9, 128:10, 128:11, 128:13
fundraising [3] -

125:19, 125:22, 132:4
funds [2] - 116:2, 118:1
future [10] - 51:17, 51:20, 54:18, 71:16, 71:22, 80:9, 121:7, 131:13, 132:5, 134:14

G

game [1] - 117:16
garage [1] - 44:25
gas [4] - 48:1, 134:3, 134:6, 134:7
gather [1] - 126:21
gauge [1] - 67:1
general [15] - 10:22, 17:7, 25:20, 27:7, 30:14, 34:14, 34:24, 41:19, 73:13, 73:18, 73:25, 76:19, 77:13, 80:12, 118:24
generality [1] - 119:19
generally [2] - 76:24, 124:16
generate [2] - 45:5, 50:9
generation [1] - 131:18
Geneva [1] - 115:11
Geneva-based [1] - 115:11
geographic [8] - 16:5, 17:18, 26:5, 26:6, 26:7, 27:1, 73:5, 73:9
geography [1] - 17:19
Germany [1] - 117:15
GIBSON [1] - 1:22
given [7] - 15:19, 22:19, 27:23, 36:22, 39:3, 58:16, 74:19
global [3] - 46:13, 114:1, 114:2
gossip [1] - 131:15
GOTTLIEB [1] - 1:18
government [3] - 4:13, 4:25, 12:3
graduated [1] - 112:23
Grand [1] - 20:4
grant [1] - 62:8
granted [2] - 119:25, 127:16
GRAY [1] - 2:4
Gray [1] - 112:5
great [5] - 8:24, 25:20, 53:13, 53:23, 130:1
greater [11] - 21:11, 21:14, 43:6, 46:19, 60:22, 61:6, 64:9, 64:12, 64:14, 64:19, 81:8
greenhouse [1] - 113:6
grinding [1] - 129:17
group [2] - 22:3, 116:22
growing [1] - 130:19
guarantee [1] - 80:4
guess [2] - 115:2, 121:18
guidelines [16] - 18:2, 31:13, 31:22, 34:12, 50:18, 71:3, 71:4, 71:6, 71:13, 72:4, 72:23, 73:3, 76:7, 76:10, 76:14, 76:16

H

Hall [2] - 1:12, 7:13
HALL [5] - 6:19, 7:5, 7:11, 7:25, 111:16
halt [1] - 129:17
HAMILTON [1] - 1:18
hammers [1] - 21:11
hampers [1] - 122:10
hand [3] - 33:20, 44:1, 125:21
hand-to-mouth [1] - 125:21
happily [1] - 62:8
hard [4] - 6:14, 129:22, 133:22, 134:12
harder [1] - 41:1
hardware [4] - 21:11, 46:6, 46:11, 46:14
harm [17] - 9:22, 13:18, 14:16, 15:13, 15:19, 54:22, 62:16, 62:19, 62:23, 63:1, 63:14, 63:16, 64:5, 68:14, 68:16, 68:19, 78:23
harmed [1] - 52:21
harmful [3] - 33:17, 34:13, 53:18
harming [2] - 10:1, 10:2
harms [9] - 36:2, 62:13, 66:8, 67:8, 67:19, 67:25, 68:3, 68:9, 68:12
harvest [2] - 127:2, 127:4
head [26] - 34:15, 35:11, 35:16, 35:19, 35:21, 35:23, 35:25, 36:2, 36:19, 37:11, 38:10, 41:4, 113:23, 114:1
head-to-head [12] - 34:15, 35:11, 35:16, 35:19, 35:21, 35:23, 35:25, 36:2, 36:19, 37:11, 38:10, 41:4
headquartered [2] - 115:24, 117:15
headquarters [1] - 122:23
health [2] - 12:14, 25:1
hear [4] - 5:19, 7:4, 13:8, 128:17
heard [12] - 24:3, 24:19, 26:18, 27:5, 38:2, 39:2, 41:23, 43:17, 49:24, 51:15, 84:15, 123:22
hearing [3] - 15:8, 28:13, 29:16
HEARING [1] - 1:8
heart [3] - 19:23, 86:7, 117:19
held [2] - 116:6, 118:17
HELD [1] - 1:9
help [1] - 131:19
helpful [2] - 131:16
hereby [1] - 134:25
Herfindahl [1] - 30:1
Herfindahl-Hirschman [1] - 30:1
Hershey [1] - 12:23
hesitant [1] - 125:16
HHI [10] - 30:2, 30:6, 30:8, 30:12, 30:18, 30:23, 31:12, 31:18, 31:19
high [13] - 10:1, 13:15, 16:20, 18:3, 18:5, 24:6, 24:15, 24:16, 25:1, 42:12, 113:5, 121:13
high-tech [1] - 113:5
higher [6] - 19:2, 19:4, 36:13, 36:14, 40:22, 45:14
highlighted [5] - 34:12, 34:20, 38:13, 50:25, 53:10
highlighting [1] - 66:11
highlights [1] - 32:23
highly [4] - 24:14, 31:14, 130:15, 130:16
highly-concentrated [1] - 31:14
hire [2] - 125:10, 131:3
hiring [1] - 130:20
Hirschman [1] - 30:1
historical [3] - 21:22, 69:6, 69:8
history [2] - 10:10, 113:2
hit [1] - 87:23
hold [1] - 11:20
home [1] - 117:16
Honor [20] - 4:2, 5:11, 5:25, 6:19, 7:6, 7:19, 7:23, 7:25, 8:5, 8:11, 13:4, 19:23, 54:24, 92:15, 111:16, 111:20, 112:4, 112:8, 128:3, 134:15
HONORABLE [1] - 1:9
hope [1] - 133:1
hoped [1] - 122:17
hopefully [1] - 132:5
horizontal [2] - 9:15, 11:19
hospitals [1] - 40:25
housekeeping [2] - 4:4, 4:17
hundred [1] - 30:24
hypothetical [29] - 18:1, 18:3, 18:5, 18:10, 18:11, 18:14, 18:25, 19:4, 19:7, 19:11, 19:15, 19:17, 19:21, 20:7, 20:15, 20:17, 20:20, 23:4, 23:6, 23:13, 25:6, 26:11, 68:23, 69:1, 69:4, 77:5, 77:8, 85:18

I

IDE [35] - 53:20, 53:25, 54:4, 54:6, 54:8, 54:11, 65:9, 65:11, 65:15, 65:19, 70:24, 74:16, 78:20, 79:15, 79:16, 79:25, 80:4, 82:7, 82:9, 82:11, 82:13, 82:16, 82:22, 82:24, 83:2, 83:8, 83:10, 83:16, 83:19, 83:24, 84:16, 85:7, 85:12, 85:15, 85:22
idea [1] - 45:24
ideas [2] - 35:7, 45:21
identification [1] - 32:4
identified [15] - 28:1, 29:19, 29:21, 31:13, 42:24, 43:7, 44:10, 45:1, 62:20, 63:18, 65:17, 67:21, 68:2, 70:16, 116:12
identifies [1] - 42:14
identify [2] - 38:14, 116:4
identifying [2] - 27:10, 61:5
IDEs [2] - 79:19, 85:10
ill [1] - 130:5
imagine [4] - 19:9, 20:5, 40:13, 44:17
imagined [1] - 23:8
immediate [1] - 132:5
immediately [1] - 45:2
impact [10] - 9:23, 10:23, 11:5, 31:16, 64:22, 72:7, 72:18, 90:15, 129:14, 131:22
impacted [1] - 121:23
impacting [1] - 90:14
impacts [1] - 16:1
impeachment [1] - 7:9
imperfectly [1] - 10:19
implant [2] - 28:15, 129:15
implantable [1] - 115:19
implantation [2] - 23:7, 28:7
implanted [4] - 14:21, 29:4, 31:6, 56:10
implants [2] - 39:23, 129:25
implications [1] - 81:19
importance [1] - 76:19
important [12] - 5:18, 16:5, 22:6, 32:3, 42:23, 52:10, 55:20, 55:22, 55:24, 56:5, 66:4, 126:14
impose [5] - 20:19, 54:10, 77:14, 77:18, 78:11
imposed [2] - 73:19, 78:20
imposes [5] - 19:12, 20:8, 20:9, 20:20, 36:21
imposing [3] - 77:24, 78:6, 78:16
impossible [1] - 127:12
improved [1] - 60:18
improves [1] - 60:17

IN [1] - 1:1
inability [1] - 90:6
INC [1] - 1:6
incentive [3] - 34:21, 35:2, 35:14
incentives [7] - 10:23, 11:5, 34:11, 35:5, 41:25, 47:16, 57:6
incipient [1] - 81:2
inclined [1] - 36:15
include [3] - 19:19, 20:4, 77:16
included [3] - 12:12, 14:21, 79:12
includes [6] - 21:22, 23:1, 73:14, 89:8, 91:14, 121:7
including [7] - 14:23, 32:20, 45:19, 81:4, 81:7, 89:2, 119:10
increase [17] - 14:1, 16:6, 18:19, 35:17, 37:6, 41:12, 41:15, 42:9, 42:11, 42:17, 46:10, 46:18, 47:4, 52:12, 60:9, 60:14, 61:19
increased [4] - 14:4, 17:2, 23:9, 79:21
increases [1] - 36:25
incremental [2] - 61:8, 82:5
incumbents [1] - 44:22
incurring [2] - 72:9, 72:20
indeed [4] - 33:8, 37:19, 73:20, 86:3
independent [5] - 11:4, 36:10, 125:18, 133:7, 133:9
independently [1] - 125:2
index [1] - 30:18
Index [1] - 30:1
indicate [6] - 21:12, 42:12, 47:7, 51:25, 59:2, 83:4
indicated [11] - 13:16, 16:3, 32:11, 41:8, 54:20, 57:4, 66:22, 80:19, 81:8, 84:21, 89:18
indicates [6] - 14:15, 37:19, 38:16, 68:10, 78:15, 89:16
indicating [6] - 25:3, 31:14, 31:22, 47:9, 52:22, 66:18
indication [4] - 43:11, 45:20, 48:11, 49:12
indications [4] - 40:18, 47:24, 51:20, 126:13
indicia [6] - 14:15, 14:18, 42:18, 42:20, 47:13, 77:6
individual [3] - 10:23, 23:25, 57:6
induce [1] - 39:22
industrial [9] - 10:14, 10:15, 10:16, 10:20, 10:24, 12:12, 12:18, 13:5, 33:21
industry [3] - 113:6, 113:7, 116:9
inferences [2] - 16:6, 90:19
inferior [1] - 44:22
inferring [1] - 62:12
inflamed [1] - 133:13
influence [2] - 21:15, 43:7
influenced [1] - 25:23
influencing [1] - 79:2
inform [3] - 30:12, 33:2, 77:7
information [8] - 21:19, 22:9, 22:10, 26:25, 32:17, 91:6, 120:6, 120:12
informative [1] - 27:21
informed [1] - 24:5
inhibiting [1] - 92:12
initial [2] - 9:8, 69:15
innovate [2] - 34:22, 41:25
innovates [1] - 34:23
innovating [3] - 43:12, 46:12, 49:2
innovation [46] - 25:11, 25:24, 34:10, 34:14, 34:17, 34:18, 40:17, 41:22, 42:4, 42:11, 42:17, 42:22, 44:8, 44:9, 44:12, 45:1, 45:11, 45:14, 45:17, 46:19, 47:5, 47:14, 47:15, 47:20, 48:2, 48:19, 48:24, 49:7, 49:11, 53:14, 61:7, 61:12, 63:16, 63:18, 63:21, 63:24, 64:3, 64:6, 64:9, 64:12, 64:15, 64:17, 64:19, 64:22, 65:24, 66:4
innovations [1] - 61:13
innovative [4] - 43:15, 45:21, 46:4, 114:9
insofar [6] - 28:4, 67:21, 68:2, 68:10, 87:15, 87:21
instance [1] - 133:6
instead [4] - 20:13, 25:5, 36:18, 47:7
insulin [1] - 115:24
intellectual [1] - 45:18
intend [1] - 8:1
intently [1] - 43:5
interaction [1] - 17:8
interest [2] - 14:19, 16:25
interested [1] - 16:18
interim [1] - 128:13
intermediary [1] - 118:17
internalize [1] - 46:16
internalizes [1] - 37:4
internally [1] - 120:9
interpretation [4] - 62:18, 67:5, 67:10, 121:14
interpreting [1] - 62:2
interrupt [1] - 35:8
interventional [2] - 39:3, 114:1
intuition [2] - 21:12, 35:10
intuitive [1] - 46:2
invasive [1] - 24:14
invasiveness [1] - 24:17
invest [1] - 118:1
investigate [2] - 21:10, 86:25
investigation [2] - 15:20, 21:5
investigational [2] - 29:16, 70:23
investment [6] - 25:23, 44:18, 44:23, 116:1, 116:2, 119:3
investments [2] - 44:19, 121:6
investors [3] - 118:18, 118:23, 121:6
invests [1] - 46:11
involved [11] - 11:15, 14:19, 28:18, 81:19, 84:23, 87:8, 116:17, 116:20, 119:12, 119:14, 125:3
involves [2] - 82:9, 131:12
involving [1] - 114:18
IO [2] - 39:7, 49:21
irrelevant [1] - 29:18
irrespective [1] - 79:1
Irvine [2] - 117:12, 122:20
Israel [1] - 38:1
Israeli [1] - 115:7
Israeli-American [1] - 115:7
issue [6] - 4:8, 5:20, 15:21, 16:13, 17:16, 124:13
issues [1] - 122:15
itself [4] - 35:1, 65:24, 123:16, 126:19

J

J-Valve [19] - 4:10, 29:15, 32:12, 33:12, 38:5, 39:4, 39:15, 40:12, 43:17, 46:23, 48:5, 48:13, 53:3, 57:10, 57:16, 89:11, 91:12, 91:20, 92:7
J-Valve's [1] - 39:14
Jacob [1] - 1:18
James [1] - 1:13
Jamie [1] - 1:21
JAN [2] - 3:5, 112:7
Jan [1] - 112:5
Jay [1] - 1:13
JC [24] - 29:16, 32:25, 33:9, 38:24, 39:1, 54:5, 65:9, 65:11, 65:15, 65:18, 75:10, 75:12, 75:16, 75:24, 79:20, 86:23, 86:25, 87:4, 88:7, 88:14, 89:1, 89:20, 91:10, 92:1
Jean [1] - 34:20
JenaValve [60] - 9:24, 13:12, 22:24, 23:21, 24:12, 27:9, 28:6, 29:14, 30:25, 32:11, 32:20, 32:25, 33:5, 33:9, 33:11, 38:5, 38:19, 38:23, 38:25, 39:4, 41:25, 43:11, 43:23, 47:21, 47:24, 51:12, 54:5, 54:19, 58:1, 58:18, 64:24, 67:14, 75:11, 75:15, 75:23, 85:12, 87:21, 87:25, 88:4, 92:1, 112:5, 112:17, 115:21, 117:4, 117:5, 117:15, 119:1, 120:5, 120:12, 120:16, 121:2, 122:14, 125:25, 126:22, 128:10, 128:11, 129:4, 129:23, 133:20, 134:2
JENAVALVE [1] - 1:6
JenaValve's [20] - 43:16, 51:6, 57:21, 58:7, 58:14, 58:21, 87:14, 87:15, 91:4, 119:12, 119:15, 119:21, 123:9, 123:13, 124:2, 129:5, 129:15, 131:20, 131:22, 132:14
job [1] - 114:17
jobs [1] - 125:16
Johnson [4] - 113:19, 113:22
join [1] - 125:14
joined [3] - 11:25, 113:14, 117:6
joining [1] - 114:6
jokingly [1] - 114:16
Jordan [1] - 1:14
Joshua [1] - 1:21
Jude [1] - 115:13
JUDGE [1] - 1:10

K

keep [2] - 119:18, 125:19
keeping [2] - 28:22, 115:5
KELTJENS [2] - 3:5, 112:7
Keltjens [8] - 112:6, 112:15, 118:12, 124:15, 125:23, 126:22, 129:13, 133:25
Ken [2] - 34:19, 43:7
Kereiakes [2] - 25:3, 40:24
Kesselheim [7] - 27:3, 52:25, 71:1, 80:20, 84:1, 84:10, 84:12
Kesselheim's [2] - 82:17, 85:3
key [1] - 130:13
Kilcoyne [4] - 28:13, 28:18, 29:17, 65:3
Kilcoyne's [1] - 81:5
kill [1] - 40:8
killed [1] - 47:11
kind [17] - 16:12, 17:8, 17:16, 31:19, 35:6, 35:16, 39:7, 44:10, 44:11, 45:23, 46:5, 46:13, 117:16,

124:4, 126:4, 128:22
kindest [1] - 134:9
kinds [1] - 12:8
knock [1] - 40:23
knock-on [1] - 40:23
knocking [1] - 115:19
knowledge [1] - 118:8
known [4] - 17:25, 30:1, 34:3, 133:11
knows [1] - 34:23

L

label [5] - 24:21, 24:22, 24:24, 40:19, 48:8
labeled [2] - 9:7, 9:8
lack [1] - 33:25
Laguna [3] - 79:25, 80:7, 81:5
laid [2] - 23:20, 50:17
Lancet [1] - 125:5
landmark [1] - 125:5
lands [1] - 126:11
language [11] - 49:16, 49:20, 49:22, 71:7, 71:19, 76:1, 76:11, 78:2, 83:11, 89:15, 90:9
large [20] - 20:12, 27:18, 30:7, 30:18, 33:16, 42:22, 43:16, 44:3, 44:11, 48:4, 89:2, 113:4, 113:17, 114:5, 123:9, 123:14, 123:15, 124:2, 133:16, 133:20
large-scale [1] - 113:17
largely [2] - 45:2, 90:17
larger [3] - 43:21, 48:6, 123:20
Larkin [2] - 37:21, 37:24
last [10] - 88:10, 121:22, 122:15, 123:22, 126:14, 128:12, 129:10, 130:7, 132:7, 133:25
latest [1] - 123:22
latter [1] - 123:17
launch [5] - 48:7, 125:2, 125:11, 133:7
Laura [2] - 1:12, 7:13
laureate [1] - 34:19
laurels [3] - 49:17, 49:19, 49:23
law [1] - 127:23
lay [1] - 131:4
lead [8] - 23:10, 34:2, 39:12, 45:14, 46:10, 47:10, 56:7, 92:2
leadership [1] - 49:10
leading [4] - 40:22, 114:11, 114:21, 118:7
leads [1] - 62:15
learned [1] - 74:15
leases [1] - 134:14
least [9] - 12:7, 32:16, 33:21, 44:23, 48:22, 77:4, 119:5, 121:20, 122:21
leave [2] - 21:2, 130:22
leaves [2] - 53:4, 60:22
leaving [3] - 6:9, 11:25, 36:13
led [1] - 22:25
left [6] - 11:23, 33:20, 41:11, 49:1, 114:5, 128:23
left-hand [1] - 33:20
length [3] - 53:1, 80:20, 92:12
lengthy [1] - 30:2
lens [1] - 62:4
less [7] - 22:9, 34:21, 35:2, 40:19, 44:7, 46:12
lessen [2] - 13:17, 54:22
letter [5] - 120:2, 120:5, 120:7, 120:9, 120:13
level [8] - 13:15, 18:3, 18:5, 31:18, 31:19, 34:6, 119:18, 121:13
leverage [1] - 36:3
Lexecon [1] - 12:1
life [3] - 12:14, 25:17, 134:14
LIFESCIENCES [1] - 1:5
light [2] - 62:2, 120:16
likelihood [13] - 10:1, 55:18, 56:19, 56:24, 57:10, 57:16, 62:13, 62:20, 63:18, 66:13, 81:11, 83:7, 83:10
likelihoods [1] - 57:5
likely [50] - 11:17, 13:17, 14:7, 14:10, 14:16, 15:19, 18:19, 20:14, 21:13, 22:3, 22:19, 23:23, 27:23, 33:18, 34:2, 34:16, 35:23, 42:3, 45:9, 46:10, 47:4, 47:7, 47:10, 48:3, 50:11, 50:25, 51:4, 51:16, 54:21, 56:2, 56:3, 56:7, 56:10, 57:2, 57:4, 57:19, 57:20, 58:5, 58:7, 59:25, 67:2, 67:8, 68:6, 72:6, 72:17, 72:25, 73:20, 74:16, 79:19, 120:21
limit [2] - 6:15, 38:25
limited [1] - 17:20
line [1] - 122:1
lines [2] - 47:8, 59:22
linking [1] - 90:1
LIPPARD [13] - 8:5, 8:7, 8:11, 8:14, 8:21, 8:24, 8:25, 9:6, 9:10, 13:4, 13:9, 53:19, 54:24
Lippard [2] - 8:7, 74:14
Lippard.....8 [1] - 3:3
Lippard.....105 [1] - 3:4
Lipton [1] - 1:21
liquidity [1] - 117:25
Lisa [1] - 1:14
listed [4] - 24:9, 24:22, 113:14, 114:7
listen [2] - 8:1, 131:11
listened [1] - 15:8
literally [1] - 39:4
literature [11] - 9:15, 14:4, 27:20, 30:12, 31:24, 42:8, 42:11, 42:13, 42:21, 62:3, 62:5
litigation [1] - 131:6
live [4] - 5:17, 8:2, 112:19, 112:20
lived [1] - 117:21
lives [5] - 58:25, 59:10, 59:25, 60:4, 61:17
living [2] - 123:5, 128:18
LLP [3] - 1:18, 1:22, 2:4
location [1] - 26:22
locations [2] - 16:5, 122:24
London [1] - 10:12
long-run [1] - 92:13
long-winded [1] - 122:11
look [8] - 33:2, 47:20, 51:19, 65:1, 86:15, 118:14, 133:5, 134:12
looked [4] - 37:10, 38:11, 50:22, 75:14
looking [6] - 15:22, 38:12, 50:18, 51:24, 70:17, 134:1
loosely [1] - 45:23
lose [2] - 19:15, 127:7
losing [3] - 19:1, 20:15, 36:20
loss [5] - 34:3, 34:4, 34:15, 44:5, 49:3
lost [2] - 37:5, 68:21
love [1] - 114:10
low [1] - 127:9
lower [3] - 39:15, 40:20, 48:9
lunch [1] - 129:3
luncheon [1] - 134:22

M

machine [1] - 2:10
machines [1] - 123:4
magnitude [3] - 31:21, 63:1, 68:15
magnitudes [5] - 55:23, 55:25, 68:12, 90:4, 90:19
maintain [5] - 49:9, 129:18, 130:2, 130:4, 133:22
major [2] - 122:21, 122:23
majority [2] - 11:18, 119:4
makers [1] - 10:23
management [4] - 24:1, 24:2, 24:3, 24:8
mandate [1] - 120:24
manufacturer [2] - 46:14, 67:17
manufacturing [8] - 86:5, 86:7, 86:10, 113:16, 125:24, 127:1, 127:2, 133:10
maps [1] - 49:20
March [5] - 38:24, 44:2, 65:3, 65:8, 65:16
margin [2] - 19:2, 63:11
marginal [1] - 33:24
mark [1] - 126:2
marked [2] - 86:20, 87:11
market [165] - 10:18, 11:3, 13:22, 14:1, 14:2, 14:23, 14:24, 15:25, 16:2, 16:3, 16:7, 16:10, 16:11, 17:9, 17:10, 17:12, 17:13, 17:14, 17:18, 17:24, 18:9, 18:12, 18:25, 19:7, 19:10, 19:14, 19:17, 19:18, 19:22, 20:6, 20:16, 20:19, 21:18, 22:7, 22:21, 22:23, 23:1, 23:3, 23:12, 23:17, 23:19, 24:2, 24:11, 24:23, 25:8, 25:10, 25:11, 26:2, 26:3, 26:5, 26:6, 26:7, 27:2, 27:6, 27:10, 27:11, 27:12, 27:13, 27:14, 27:15, 27:17, 27:19, 27:20, 27:22, 28:1, 28:24, 29:1, 29:19, 29:21, 29:22, 29:23, 29:24, 29:25, 30:6, 30:16, 31:1, 31:3, 31:14, 32:1, 32:5, 32:8, 32:9, 32:10, 32:24, 33:3, 33:7, 33:10, 33:14, 35:12, 39:16, 41:6, 41:9, 41:14, 44:21, 45:3, 48:23, 49:3, 49:18, 51:16, 52:12, 52:20, 53:4, 54:4, 64:17, 68:24, 69:6, 69:15, 69:18, 69:21, 70:1, 70:9, 70:12, 70:13, 70:17, 71:6, 71:9, 71:15, 71:16, 71:21, 71:22, 72:3, 72:6, 72:10, 72:17, 72:20, 73:4, 73:5, 73:9, 73:13, 73:14, 73:15, 74:2, 74:13, 75:2, 75:21, 76:7, 76:15, 77:2, 77:4, 77:16, 77:22, 78:4, 78:13, 79:7, 79:11, 79:12, 79:17, 80:2, 87:5, 88:20, 122:2, 130:19
market's [1] - 30:4
marketing [2] - 113:23, 114:1
marketplace [1] - 46:4
markets [5] - 25:14, 25:21, 27:15, 41:3, 77:13
Masselink [1] - 2:3
master [1] - 112:23

master's [1] - 10:11
material [1] - 23:13
materially [1] - 81:8
materials [11] - 27:5, 33:5, 38:8, 38:16, 40:2, 47:6, 47:18, 57:4, 71:4, 87:3, 91:1
mathematical [1] - 59:5
Matt [1] - 112:4
matter [7] - 4:17, 7:21, 60:22, 61:2, 61:9, 61:19, 118:24
matters [9] - 4:5, 7:22, 11:18, 12:4, 12:9, 14:14, 77:23, 78:4, 120:3
Matthew [1] - 2:2
maximum [1] - 31:19
McCabe [1] - 38:1
McCloud [1] - 132:9
MCGINNIS [10] - 112:4, 112:8, 112:14, 128:3, 128:6, 128:8, 132:9, 132:12, 134:15, 134:19
McGinnis [4] - 2:2, 112:4, 112:16, 124:21
McGinnis..... 112 [1] - 3:6
McInerney [1] - 2:3
McWilliams [1] - 29:12
mean [17] - 7:2, 16:12, 17:19, 35:8, 53:21, 54:7, 60:25, 70:19, 79:9, 80:5, 117:24, 122:2, 130:1, 132:25, 133:4, 133:8, 134:7
meaning [3] - 28:15, 34:3, 52:5
meaningful [8] - 19:13, 52:13, 52:14, 52:19, 53:11, 78:16, 114:19, 125:2
meaningfully [2] - 52:12, 54:14
means [10] - 24:4, 29:3, 29:6, 45:20, 52:11, 70:23, 82:7, 83:15, 124:5, 129:1
measure [4] - 66:15, 66:23, 69:11, 69:13
measuring [1] - 77:10
med [1] - 113:12
med-tech [1] - 113:12
Medical [27] - 12:23, 29:16, 32:25, 33:9, 38:24, 39:1, 54:5, 65:9, 65:11, 65:15, 65:18, 75:10, 75:12, 75:16, 75:24, 79:20, 86:23, 86:25, 87:4, 88:7, 88:14, 89:1, 89:20, 91:10, 92:1, 115:6, 115:15
medical [16] - 24:1, 24:3, 24:8, 26:20, 28:19, 67:17, 85:25, 86:5, 86:9, 113:7, 113:10, 116:3, 116:9, 116:10, 127:8
Medtronic [6] - 114:10, 115:19, 116:23, 116:25, 117:1, 118:7
meet [3] - 52:9, 125:25, 129:24
memory [1] - 76:9
mentioned [12] - 6:20, 27:25, 33:13, 35:19, 37:16, 44:7, 48:16, 64:4, 84:9, 118:6, 124:1, 131:20
merge [4] - 12:8, 20:5, 36:24, 125:14
merged [2] - 45:12, 67:14
merger [73] - 11:3, 12:4, 12:21, 14:9, 15:17, 15:19, 15:24, 16:25, 18:1, 22:24, 27:9, 31:11, 31:12, 31:13, 31:18, 31:19, 31:22, 33:13, 34:2, 34:16, 35:21, 37:9, 39:12, 39:25, 44:9, 46:8, 46:14, 46:20, 46:23, 47:20, 48:12, 50:3, 50:5, 50:7, 50:8, 50:15, 50:17, 50:19, 50:20, 51:11, 52:7, 54:19, 55:12, 55:14, 55:18, 55:25, 56:1, 56:2, 56:6, 56:8, 57:20, 57:21, 58:6, 58:8, 58:14, 58:21, 61:11, 63:22, 63:25, 66:12, 67:20, 67:25, 71:2, 71:13, 72:4, 73:3, 73:24, 76:6, 76:14, 78:23, 123:6, 125:13, 125:17
merger-specific [2] - 14:9, 50:19
merger-to-monopoly [2] - 34:2, 34:16
mergers [10] - 9:15, 10:21, 11:19, 12:7, 13:6, 15:13, 15:15, 32:2, 42:9, 50:3
mergers-to-monopoly [1] - 32:2
merging [13] - 17:1, 74:22, 76:4, 76:25, 77:11, 77:25, 78:6, 78:12, 78:17, 78:21, 82:2, 85:10, 85:18
met [1] - 51:2
metaphorical [1] - 16:8
metric [3] - 30:2, 31:11, 66:19
metrics [2] - 31:4, 79:13
Michigan [2] - 10:13, 11:9
microeconomics [2] - 10:16, 10:22
mid [1] - 44:2
mid-March [1] - 44:2
middle [2] - 65:19, 133:14
might [12] - 23:16, 30:12, 38:14, 41:7, 43:24, 46:25, 47:15, 55:23, 62:24, 77:15, 78:8, 87:5
MILLER [1] - 134:25
Miller [2] - 2:6, 135:5
million [1] - 114:20
mind [2] - 70:1, 118:25
minimum [1] - 123:23
minutes [4] - 6:12, 6:21, 125:23, 128:4
misunderstanding [1] - 4:12
modality [1] - 21:1
model [12] - 59:5, 86:22, 87:1, 88:2, 88:7, 88:11, 88:17, 88:19, 89:7, 90:5, 90:22, 91:11
modeled [3] - 89:11, 89:22, 91:19
modeling [1] - 55:17
models [3] - 55:13, 92:5, 92:9
moderate [1] - 40:21
moment [5] - 10:4, 25:9, 27:25, 33:13, 33:22
Monday [1] - 1:5
money [8] - 36:11, 36:13, 123:19, 124:1, 124:3, 133:20
monitoring [1] - 131:6
monopolies [2] - 33:19, 34:12
monopolist [33] - 18:1, 18:3, 18:5, 18:10, 18:11, 18:14, 18:25, 19:8, 19:12, 19:15, 19:18, 19:21, 20:7, 20:15, 20:17, 20:20, 23:5, 23:6, 23:13, 25:6, 26:11, 30:5, 34:21, 34:22, 35:2, 35:3, 35:7, 49:22, 68:23, 69:2, 69:4, 77:5, 77:9
monopolist's [1] - 19:4
monopolized [2] - 30:6, 31:19
monopoly [7] - 32:2, 33:22, 33:23, 34:2, 34:10, 34:16, 53:9
months [9] - 121:21, 126:14, 127:17, 127:18, 128:12, 128:24, 129:6, 129:8, 130:21
Montreal [1] - 114:7
mooted [1] - 40:11
moreover [5] - 29:5, 42:13, 49:5, 50:22, 92:2
MORNING [1] - 1:9
morning [8] - 4:2, 4:3, 6:19, 8:5, 8:6, 55:8, 55:9, 125:5
mortality [1] - 24:6
most [11] - 21:8, 33:20, 34:18, 45:15, 46:2, 47:17, 56:1, 119:25, 123:18, 125:6, 130:19
motion [3] - 6:24, 7:3, 7:8
mousetrap [4] - 44:17, 44:21, 45:1, 45:7
mouth [1] - 125:21
move [9] - 8:2, 49:5, 92:16, 114:17, 114:23, 117:14, 117:17, 125:18
moved [4] - 113:23, 115:1, 122:20, 123:1
movement [1] - 85:15
moving [1] - 121:12
MR [38] - 4:2, 4:4, 4:7, 4:17, 4:25, 5:11, 5:13, 5:15, 6:2, 7:18, 7:23, 8:5, 8:7, 8:11, 8:14, 8:21, 8:24, 8:25, 9:6, 9:10, 13:4, 13:9, 53:19, 54:24, 92:19, 111:20, 111:24, 112:1, 112:4, 112:8, 112:14, 128:3, 128:6, 128:8, 132:9, 132:12, 134:15, 134:19
MS [15] - 6:19, 7:5, 7:11, 7:25, 13:7, 55:5, 55:7, 59:21, 59:23, 65:22, 65:23, 83:20, 83:21, 92:15, 111:16
multi [1] - 44:15
multi-syllabic [1] - 44:15
Munich [1] - 117:16
Musallam [1] - 2:2

N

name [1] - 8:15
NATHAN [3] - 3:3, 8:10, 8:17
Nathan [2] - 8:9, 8:17
naturally [1] - 46:18
nature [1] - 7:9
near [6] - 19:22, 37:25, 71:16, 71:22, 79:25, 80:9
necessarily [2] - 15:22, 80:7
necessary [3] - 6:10, 45:5, 67:18
need [17] - 21:9, 34:9, 44:3, 46:23, 52:10, 54:12, 78:22, 79:6, 79:17, 80:10, 92:16, 112:10, 122:7, 125:18, 127:10, 131:3, 132:2
needed [1] - 83:13
needs [3] - 36:5, 122:1, 126:16
negative [1] - 129:7
negotiating [1] - 119:12
neighbor [3] - 44:24, 45:8, 45:12
neighborhood [1] - 81:22
neighboring [1] - 21:3
neighbors [1] - 45:13
net [1] - 67:2
Netherlands [6] - 112:20, 112:25,

113:18, 114:24, 114:25, 115:25
neurovascular [1] - 114:3
nevertheless [2] - 42:10, 42:17
new [14] - 34:23, 34:24, 35:2, 35:7, 36:14, 45:1, 53:15, 54:8, 54:16, 81:3, 118:1, 121:6, 124:4, 133:10
New [1] - 114:16
next [17] - 4:20, 5:3, 5:6, 6:16, 16:3, 24:24, 26:3, 26:4, 27:8, 27:10, 29:20, 33:4, 43:13, 48:10, 52:19, 130:21, 131:18
nice [2] - 55:10, 55:11
nine [1] - 49:4
NJ [3] - 2:6, 134:25, 135:5
NJ-CCR [3] - 2:6, 134:25, 135:5
Nobel [1] - 34:19
Nobelist [1] - 34:20
non [6] - 48:12, 56:8, 62:13, 66:8, 66:14, 127:24
non-commercial [1] - 127:24
non-merger [2] - 48:12, 56:8
non-price [3] - 62:13, 66:8, 66:14
nontrivial [4] - 18:16, 19:12, 23:10, 53:12
normal [1] - 120:2
note [4] - 7:5, 83:3, 119:17, 128:13
noted [2] - 39:16, 63:5
notes [10] - 29:13, 29:17, 30:21, 33:11, 34:21, 37:21, 37:24, 39:13, 41:17, 135:2
nothing [6] - 7:23, 47:6, 59:4, 68:15, 124:4, 134:7
noting [7] - 28:13, 28:17, 33:8, 33:22, 39:21, 44:3, 90:10
novel [1] - 115:18
November [2] - 1:5, 135:4
nowhere [1] - 33:18
nudge [1] - 35:6
number [32] - 13:20, 14:21, 18:12, 19:13, 20:22, 30:7, 31:4, 31:5, 31:9, 33:4, 42:14, 56:9, 56:13, 58:24, 59:10, 59:24, 60:4, 64:1, 81:18, 87:19, 87:23, 88:1, 88:4, 88:17, 113:5, 114:22, 115:5, 116:12, 125:19, 126:20, 130:15
numbers [2] - 59:5, 116:16
numerical [14] - 22:12, 56:17, 58:22, 63:10, 63:11, 63:12, 64:2, 64:21, 66:23, 68:18, 84:2, 85:17, 90:13, 90:19
NW [6] - 1:15, 1:19, 1:22, 2:4, 2:8, 135:7

O

oath [1] - 59:19
objection [3] - 7:18, 13:7, 60:2
observe [5] - 20:12, 34:17, 77:23, 78:5, 90:1
observed [11] - 38:24, 46:19, 79:19, 80:3, 81:4, 85:14, 85:18, 89:18, 90:8, 91:3, 92:11
observer [1] - 119:7
obtain [1] - 79:16
obtained [4] - 53:20, 83:12, 83:16, 83:18
obtaining [1] - 83:24
obvious [1] - 21:24
obviously [5] - 32:2, 36:14, 36:19, 118:6, 119:18
occur [1] - 48:15
occurs [1] - 89:19
OF [3] - 1:1, 1:8, 134:24
off-label [3] - 24:21, 24:22, 24:24
offer [1] - 13:5
offering [1] - 41:19
offers [1] - 16:18
OFFICIAL [1] - 134:24
Official [2] - 2:7, 135:5
offset [5] - 14:10, 45:5, 52:4, 52:6, 67:7
offsetting [2] - 30:22, 68:3
often [2] - 18:16, 74:1
on-label [1] - 48:8
once [6] - 29:21, 44:25, 54:6, 59:2, 123:3, 125:17
one [54] - 4:7, 5:9, 6:3, 8:23, 11:4, 17:1, 17:14, 18:15, 19:12, 19:22, 20:8, 21:9, 23:9, 26:18, 29:9, 29:13, 29:14, 31:4, 38:13, 40:8, 40:13, 42:14, 42:15, 44:6, 44:13, 46:17, 46:23, 46:25, 47:10, 47:17, 48:8, 49:14, 53:23, 54:9, 62:20, 71:4, 73:2, 74:15, 77:15, 80:4, 81:7, 114:1, 114:11, 115:1, 123:2, 123:22, 125:20, 127:18, 128:18, 129:6, 129:8, 129:19, 131:17, 132:25
ones [4] - 20:3, 42:9, 91:18, 92:6
oodles [1] - 123:4
open [12] - 8:1, 20:22, 24:18, 51:5, 111:15, 111:21, 112:9, 118:25, 119:17, 128:4, 129:10, 132:7
opening [3] - 4:19, 4:21, 70:4
operating [1] - 122:24
operation [2] - 128:25, 134:13
operational [1] - 118:16
operations [2] - 113:22, 119:16
opine [1] - 90:3
opining [1] - 80:15
opinion [12] - 9:20, 9:23, 10:3, 13:15, 13:19, 35:20, 41:24, 42:2, 42:6, 63:15, 64:5, 66:7
opinions [4] - 15:5, 27:3, 80:19, 84:6
opportunity [1] - 124:12
opposed [2] - 4:11, 6:13
opposition [1] - 4:14
optimal [1] - 92:3
option [3] - 18:23, 24:18, 36:21
options [7] - 22:2, 26:12, 26:14, 26:17, 33:25, 41:20, 129:12
Orange [2] - 117:12, 117:17
order [15] - 5:3, 18:8, 21:16, 21:20, 21:23, 25:22, 26:11, 26:19, 30:18, 30:23, 39:22, 46:24, 63:11, 115:6, 124:25
orders [1] - 31:21
ordinary [19] - 15:2, 22:17, 23:21, 24:13, 32:7, 32:13, 32:22, 33:4, 38:8, 38:16, 41:16, 44:2, 49:1, 49:6, 52:22, 57:3, 62:7, 62:9, 91:5
organization [8] - 10:14, 10:15, 10:16, 10:20, 10:24, 12:19, 13:6, 33:21
organizations [1] - 127:10
originally [1] - 122:17
otherwise [1] - 43:24
OUS [2] - 113:15, 133:10
outcomes [3] - 10:18, 30:15, 55:13
outdated [2] - 5:9, 5:10
outline [2] - 9:16, 9:17
outlined [2] - 76:6, 76:13
output [2] - 58:14, 58:21
outside [6] - 19:14, 20:16, 28:23, 28:25, 120:20, 120:22
overall [4] - 11:15, 34:4, 46:13, 116:9
overarching [11] - 9:14, 9:25, 11:1, 13:16, 19:4, 28:10, 50:16, 54:21, 67:3, 79:22, 85:3
overhead [1] - 127:9
overlooking [1] - 113:5
overseas [1] - 81:10
overview [1] - 10:8
owing [2] - 66:11, 90:6
own [11] - 6:14, 26:22, 35:4, 45:9, 54:8, 57:15, 66:19, 80:3, 83:3, 84:6, 123:4
owned [3] - 18:14, 91:20, 92:7
owners [3] - 118:19, 118:23, 119:1
ownership [1] - 113:21
owning [1] - 91:11

P

P-D-X-0009 [2] - 9:7, 65:2
P-X-1066 [2] - 86:20, 86:22
P-X-2323 [1] - 132:10
P-X-8001 [1] - 9:8
P-X-8005 [1] - 9:9
p.m [1] - 134:22
PAGE [1] - 3:2
page [2] - 83:11, 85:21
Page [3] - 59:22, 76:1, 86:15
pains [1] - 45:13
paper [2] - 7:15, 131:25
Parkinson's [1] - 115:18
part [14] - 56:22, 70:16, 75:8, 76:18, 80:18, 83:25, 86:19, 91:6, 115:13, 116:1, 121:5, 123:5, 127:14, 131:14
participant [9] - 54:4, 74:13, 74:17, 75:21, 76:8, 76:15, 77:2, 77:22, 78:3
participants [20] - 27:11, 28:1, 28:2, 28:24, 29:1, 29:20, 29:21, 32:5, 33:14, 70:13, 70:17, 71:6, 71:9, 71:17, 71:23, 72:3, 72:10, 72:21, 73:14, 78:13
participation [2] - 33:6, 79:1
particular [23] - 10:25, 15:7, 17:15, 20:4, 26:12, 27:22, 28:11, 28:19, 31:7, 31:16, 34:8, 37:12, 38:12, 38:20, 40:16, 46:21, 51:2, 52:9, 53:15, 56:20, 68:1, 90:25, 132:10
particularities [1] - 17:19
particularly [7] - 10:18, 19:24, 27:18, 37:13, 38:4, 40:5, 57:5
parties [39] - 17:1, 28:18, 29:10, 32:4,

32:14, 32:21, 33:6, 37:17, 38:1, 38:16, 43:9, 52:23, 53:5, 54:9, 64:6, 64:20, 74:4, 74:12, 74:22, 74:25, 75:5, 75:21, 76:4, 76:13, 76:22, 76:25, 77:11, 77:25, 78:6, 78:12, 78:17, 78:21, 78:23, 81:4, 81:7, 82:2, 85:10, 85:18, 92:20
parties' [14] - 28:11, 37:12, 37:20, 38:21, 39:9, 43:14, 54:14, 66:8, 66:16, 66:21, 79:2, 80:3, 80:16, 83:3
partner [1] - 10:6
partnered [1] - 67:16
Partners [2] - 9:16, 10:6
parts [3] - 74:15, 82:18, 86:4
party [9] - 28:17, 31:5, 31:10, 32:23, 49:15, 49:25, 75:22, 79:3, 85:19
party's [1] - 17:2
pass [2] - 8:19, 23:12
passed [4] - 8:21, 9:1, 19:7, 20:17
past [6] - 14:14, 24:3, 39:14, 41:23, 49:15, 59:12
patch [1] - 115:24
patents [1] - 45:20
patient [8] - 37:22, 40:1, 40:4, 40:14, 58:25, 59:10, 59:24, 60:4
patients [17] - 23:11, 24:14, 24:16, 38:5, 41:1, 43:18, 43:20, 48:6, 48:9, 56:10, 60:20, 70:8, 70:14, 70:18, 130:5, 130:7, 130:10
patients' [1] - 40:21
pattern [1] - 91:21
patterns [2] - 21:6, 90:8
paused [1] - 38:6
pay [3] - 44:24, 129:2, 129:3
paying [1] - 45:14
pedal [2] - 134:3, 134:6
pedigree [1] - 30:2
pencil [1] - 35:15
Pennsylvania [3] - 1:15, 1:19, 2:4
people [7] - 8:3, 123:4, 125:13, 130:17, 130:20, 131:3, 131:4
Pepsi [2] - 77:17, 77:18
per [1] - 53:16
percent [4] - 30:6, 30:10, 127:5, 127:7
perform [10] - 57:7, 57:9, 62:25, 63:4, 63:7, 64:2, 64:21, 67:24, 69:1, 69:4
performance [1] - 58:18
performing [1] - 68:23
perhaps [13] - 16:23, 19:13, 21:1, 21:4, 33:18, 33:20, 34:18, 43:14, 46:2, 46:11, 46:12, 53:11, 81:9
pericardial [1] - 127:3
period [5] - 40:16, 52:13, 52:14, 52:20, 65:12
permission [1] - 5:4
person [2] - 22:13, 123:2
personnel [1] - 130:13
perspective [3] - 38:2, 58:19, 81:2
pertinent [1] - 21:20
Ph.D [3] - 10:12, 11:6, 11:8
phase [2] - 54:12, 81:9
Philips [2] - 115:17, 118:7
physics [1] - 112:24
piece [4] - 15:4, 15:7, 68:14, 80:6
pieces [1] - 15:1
pigs [1] - 127:3
PinnacleHealth [1] - 12:23
pipeline [3] - 74:20, 79:2, 85:15
Pls [1] - 39:4
pithily [1] - 78:9
pivotal [1] - 54:12
Pizza [2] - 20:4, 20:13
pizza [3] - 19:24, 20:25
pizzeria [2] - 20:14, 21:3
pizzerias [3] - 20:3, 20:5, 20:8
place [8] - 16:9, 29:10, 40:17, 50:7, 50:22, 50:25, 52:3, 61:12
placed [1] - 40:19
places [1] - 31:15
plaintiff [1] - 8:7
Plaintiff [2] - 1:3, 1:12
PLAINTIFF [1] - 8:10
plan [3] - 120:5, 122:7, 131:25
planning [1] - 79:25
plans [8] - 51:3, 124:16, 124:20, 125:7, 129:12, 131:21, 131:23, 132:1
plastic [1] - 12:13
plateau [1] - 117:22
play [2] - 22:6, 118:8
played [3] - 7:1, 52:10, 119:8
players [2] - 81:6, 89:2
plenty [1] - 132:1
plural [1] - 81:15
PMA [20] - 53:2, 54:13, 57:17, 81:23, 85:2, 87:16, 87:21, 89:20, 119:21, 119:24, 120:17, 121:3, 121:14, 122:1, 122:8, 122:18, 124:17, 129:21, 132:4
point [15] - 22:14, 25:24, 29:6, 46:22, 55:15, 58:23, 59:6, 64:22, 65:20, 77:24, 78:5, 80:6, 92:10, 115:20, 122:6
points [1] - 30:24
poised [1] - 28:7
population [2] - 53:16, 72:1
portfolio [1] - 44:5
portion [1] - 112:10
portions [1] - 87:11
poses [1] - 18:13
posit [1] - 46:25
posited [2] - 23:5, 25:6
positing [1] - 36:7
position [1] - 74:19
possibilities [1] - 20:22
possibility [6] - 6:8, 25:1, 30:21, 40:10, 50:16, 90:22
possible [11] - 20:1, 45:12, 55:21, 74:3, 74:10, 74:24, 75:4, 80:14, 120:21, 127:21, 131:13
possibly [2] - 16:7, 29:1
post [8] - 14:24, 29:7, 31:19, 32:8, 41:14, 46:14, 61:6, 90:15
post-commercialization [1] - 29:7
post-commercialized [1] - 41:14
post-FDA [2] - 14:24, 32:8
post-merger [2] - 31:19, 46:14
postulate [1] - 44:24
postulated [1] - 40:7
Potential [1] - 83:12
potential [35] - 11:2, 12:12, 13:11, 13:23, 17:21, 21:15, 24:25, 35:3, 35:4, 48:17, 53:21, 54:17, 55:18, 55:24, 63:19, 66:8, 67:19, 67:20, 67:25, 68:17, 72:24, 73:19, 73:20, 76:2, 80:23, 82:14, 82:21, 82:25, 83:15, 83:17, 83:23, 84:19, 119:9, 119:10, 125:11
potentially [10] - 21:23, 30:19, 46:5, 63:16, 64:5, 66:12, 68:2, 74:19, 77:16, 80:6
power [4] - 16:7, 30:16, 33:23, 52:12
practice [2] - 21:8, 45:15
pre [5] - 31:11, 31:12, 31:18, 46:8, 46:20
pre-merger [4] - 31:12, 31:18, 46:8, 46:20
precise [2] - 81:17, 90:19
precisely [1] - 49:20
preclinical [1] - 81:9
predict [3] - 41:9, 89:21, 90:11
predicted [2] - 62:3, 92:1
predicting [1] - 88:20
prediction [1] - 88:23
predictions [1] - 53:1
predicts [1] - 48:25
preemptively [1] - 41:19
preferences [2] - 21:22, 22:11
preliminary [1] - 7:21
premarket [3] - 56:20, 56:25, 57:11
premium [1] - 91:15
prepare [1] - 9:11
prepared [3] - 8:2, 9:4, 86:22
preparing [3] - 9:13, 120:8, 131:23
presence [4] - 17:11, 38:14, 74:18, 76:20
present [8] - 5:20, 14:18, 42:18, 43:17, 54:10, 70:4, 74:21, 84:12
presentation [1] - 91:14
presented [1] - 133:1
presenting [1] - 84:6
president [1] - 12:2
press [1] - 125:5
pressure [17] - 29:14, 35:17, 37:7, 39:9, 39:12, 40:23, 41:18, 41:21, 63:7, 76:3, 76:6, 76:12, 76:25, 77:11, 77:15, 77:19, 85:12
presume [1] - 60:25
presumptively [1] - 31:22
prevent [2] - 44:5, 45:13
prevents [1] - 124:6
previous [3] - 57:13, 58:9, 64:1
previously [1] - 37:1
price [53] - 4:10, 16:20, 17:3, 18:15, 18:19, 18:20, 19:4, 23:9, 33:24, 34:17, 36:14, 36:25, 37:6, 39:15, 41:15, 48:17, 53:10, 62:13, 62:20, 62:23, 63:1, 63:3, 63:6, 63:14, 66:8, 66:14, 89:8, 89:9, 89:12, 89:17, 89:18, 89:22, 90:4, 90:9, 90:20, 90:22, 91:3, 91:5, 91:7, 91:10, 91:16, 91:18, 91:21, 91:23, 91:25, 92:3, 92:5, 92:9
price-setting [1] - 18:20
priced [1] - 34:7
prices [13] - 14:22, 25:3, 34:6, 35:15,

35:18, 39:6, 39:12, 41:8, 41:10, 62:19, 90:15, 92:2, 122:2
pricing [8] - 35:10, 37:7, 39:8, 39:25, 40:23, 41:5, 41:21, 63:7
primarily [1] - 62:6
prioritize [2] - 39:23, 126:10
private [1] - 12:3
privately [2] - 116:6, 118:17
probability [3] - 40:3, 42:9, 42:13
probative [1] - 21:23
probes [1] - 115:19
problem [1] - 128:1
problematic [1] - 53:8
procedure [1] - 24:15
procedures [1] - 127:17
proceed [5] - 8:11, 40:11, 47:25, 54:12, 58:1
Proceedings [1] - 2:10
proceedings [3] - 92:21, 111:15, 135:3
proceeds [3] - 47:10, 56:2, 68:21
process [16] - 9:13, 24:17, 25:18, 25:19, 26:19, 26:22, 28:4, 28:19, 29:6, 53:24, 54:15, 84:4, 84:10, 84:23, 119:21, 120:2
procompetitive [7] - 50:12, 50:24, 59:3, 66:25, 67:22, 68:20
produce [3] - 47:1, 88:1, 88:4
produced [1] - 2:11
product [41] - 17:2, 17:14, 18:9, 18:18, 18:22, 19:3, 19:12, 20:16, 20:23, 21:10, 21:16, 22:20, 22:21, 23:1, 24:2, 24:9, 24:11, 24:23, 25:8, 25:16, 26:2, 34:8, 34:23, 34:24, 35:2, 35:7, 36:5, 36:9, 36:25, 40:10, 44:16, 45:3, 48:4, 53:5, 66:3, 69:6, 69:15, 69:21, 70:1, 73:4, 119:22
production [2] - 127:5, 127:8
products [52] - 16:4, 16:13, 17:15, 18:12, 18:15, 18:24, 19:14, 19:19, 20:8, 23:1, 23:9, 24:21, 24:23, 25:15, 25:20, 25:25, 26:17, 26:23, 28:5, 28:7, 28:8, 32:10, 36:10, 37:12, 37:20, 37:21, 38:7, 38:9, 43:1, 43:4, 44:22, 46:3, 46:5, 46:16, 47:11, 51:12, 53:16, 53:17, 53:24, 54:14, 61:7, 61:14, 66:4, 66:9, 66:16, 66:21, 69:9, 71:8, 71:14, 71:20, 72:1, 129:2
professionals [2] - 130:16, 130:17
profit [4] - 126:23, 127:12, 127:21, 127:23
profitability [1] - 122:6
profitable [2] - 19:6, 114:20
profits [2] - 11:1, 19:5
progress [1] - 51:12
progressing [2] - 123:18, 123:23
prohibited [1] - 127:23
project [5] - 121:7, 123:10, 123:14, 123:15, 124:2
projected [3] - 14:22, 32:7, 88:2
projection [5] - 32:14, 32:20, 87:2, 88:9, 121:9
projections [11] - 14:23, 52:22, 87:12, 87:18, 88:23, 89:19, 90:25, 91:4, 91:23, 92:11, 121:2
prolonged [2] - 40:16, 83:4
property [1] - 45:18
proportion [1] - 126:6
proposed [4] - 9:22, 13:25, 50:10, 50:20
proposes [1] - 39:22
proposing [1] - 18:11
prospects [1] - 51:6
protecting [1] - 45:21
protections [1] - 45:18
provide [11] - 26:1, 26:23, 28:5, 29:6, 29:9, 36:10, 62:12, 72:1, 87:16, 120:5, 122:8
provided [2] - 7:15, 128:13
providers [1] - 32:14
provides [1] - 120:12
providing [3] - 25:24, 36:9, 91:1
provision [2] - 12:13, 69:22
public [2] - 118:19, 131:14
publication [1] - 30:20
publicly [2] - 116:5, 131:10
published [1] - 12:16
pump [1] - 115:24
purchase [2] - 4:9, 34:8
purchasing [1] - 37:1
purely [1] - 35:5
purposes [1] - 79:12
pursue [5] - 43:25, 49:10, 83:13, 83:18, 134:3
pursuing [1] - 48:2
pursuit [1] - 48:7
push [1] - 25:9
pushed [2] - 43:23
put [12] - 5:21, 6:11, 47:25, 59:5, 59:21, 76:3, 78:8, 81:17, 86:16, 132:9, 134:3, 134:6
puts [2] - 76:24, 77:10
putting [1] - 76:12

Q

qualifications [2] - 10:4, 13:1
qualitative [5] - 15:1, 22:1, 22:6, 22:9, 33:2
qualitatively [1] - 31:7
quality [2] - 127:10, 130:17
quantification [1] - 84:22
quantify [18] - 56:9, 56:14, 56:19, 56:24, 57:10, 57:14, 58:24, 59:9, 59:24, 60:4, 62:23, 63:21, 63:24, 64:9, 64:12, 64:14, 64:18, 68:15
quantifying [1] - 83:5
quantitative [36] - 14:20, 14:25, 22:5, 22:10, 22:13, 33:1, 56:12, 57:16, 57:18, 58:5, 58:13, 58:20, 66:20, 67:19, 67:25, 68:7, 68:11, 69:1, 69:3, 69:11, 69:13, 81:25, 82:4, 82:10, 82:12, 82:14, 82:20, 82:25, 83:6, 83:9, 83:22, 84:18, 85:6, 85:11, 90:13, 90:18
QUESTION [1] - 59:24
questions [12] - 21:14, 21:24, 22:14, 54:25, 81:13, 87:9, 92:16, 118:16, 119:16, 132:7, 132:13, 134:16
quickly [1] - 51:16
quite [11] - 12:14, 19:13, 24:14, 24:25, 39:4, 46:5, 53:17, 121:12, 122:10, 131:13
quote [5] - 33:10, 65:2, 69:22, 73:2, 80:24
quoted [1] - 75:15

R

R&D [7] - 56:15, 56:18, 113:16, 123:2, 124:9, 126:18, 133:15
radically [1] - 21:10
raise [6] - 5:21, 6:7, 18:15, 33:23, 124:25, 129:22
raised [1] - 21:14
raising [1] - 62:19
ran [1] - 113:22
rapid [6] - 72:11, 73:5, 73:14, 73:16, 75:2, 75:7
rapidity [1] - 43:24
rapidly [3] - 72:7, 72:17, 79:16
rate [1] - 24:6
rates [2] - 58:14, 58:21
RC [2] - 77:17, 77:19
reach [4] - 9:19, 14:12, 26:10, 81:20
reached [3] - 31:6, 70:11, 117:22
reaching [3] - 26:25, 42:15, 51:7
react [1] - 38:17
reacting [4] - 17:10, 38:13, 76:22, 77:6
reaction [3] - 75:23, 131:9, 134:4
read [2] - 60:6, 72:15
ready [1] - 55:4
real [3] - 33:12, 126:19, 133:4
realistic [1] - 122:9
reality [1] - 134:10
really [3] - 6:14, 123:15, 124:12
reason [8] - 17:22, 63:19, 67:6, 67:13, 91:7, 122:21, 123:5, 126:11
reasonable [9] - 22:3, 24:7, 37:13, 50:6, 50:21, 51:11, 61:14, 73:8, 73:18
reasons [5] - 46:2, 62:21, 114:22, 121:14, 122:8
rebates [1] - 41:19
rebuttal [4] - 6:8, 6:12, 6:21, 111:17
recapture [2] - 37:5, 44:23
receipt [3] - 79:20, 85:14, 89:20
receive [11] - 52:11, 57:17, 60:20, 79:19, 81:23, 85:2, 85:7, 85:10, 87:21, 120:17, 121:3
received [17] - 10:10, 10:11, 10:12, 29:2, 53:25, 54:3, 54:6, 54:8, 54:10, 65:11, 65:15, 65:18, 74:16, 78:20, 79:15, 87:16, 120:1
receives [4] - 56:20, 56:25, 57:10, 124:17
receiving [17] - 11:6, 11:8, 53:2, 70:23, 80:4, 82:7, 82:9, 82:11, 82:13, 82:16, 82:22, 82:24, 83:2, 83:7, 83:10, 84:16, 85:22
recent [4] - 30:20, 119:25, 121:16, 125:7
recess [2] - 55:3, 134:22
recipient [1] - 85:12
recited [1] - 122:19
recognize [1] - 38:17
recognized [1] - 27:20
recognizes [1] - 35:5
recognizing [3] -

43:21, 45:10, 51:5
recollection [1] - 65:11
record [24] - 8:15, 8:16, 9:6, 15:1, 15:6, 22:1, 23:22, 29:11, 40:2, 47:6, 48:21, 52:8, 58:16, 59:3, 62:2, 62:4, 62:6, 62:10, 62:12, 63:5, 66:18, 75:13, 78:14, 80:14
recorded [2] - 2:10, 4:10
recreation [1] - 86:17
recruiter [1] - 114:16
recycle [1] - 121:10
recycled [1] - 12:13
red [1] - 87:11
redacted [3] - 32:22, 49:16, 87:10
Redirect [1] - 3:4
redound [2] - 11:17, 61:23
reduce [4] - 14:5, 35:23, 40:4, 42:3
reducing [1] - 63:16
reduction [1] - 40:4
refer [2] - 16:23, 128:21
reference [4] - 38:23, 39:2, 53:11, 130:9
referenced [1] - 49:21
referencing [1] - 85:9
referred [5] - 16:8, 42:25, 44:14, 118:23, 123:9
reflect [4] - 13:1, 15:6, 55:17, 132:22
reflects [1] - 91:7
refresh [1] - 76:9
regard [1] - 20:21
regional [1] - 126:3
regulations [1] - 127:9
regulatory [9] - 79:2, 80:21, 83:13, 83:18, 84:3, 84:23, 113:17, 124:9, 130:18
regurgitation [4] - 23:15, 23:18, 46:24, 89:3
reimbursement [1] - 130:18
relate [1] - 10:20
related [5] - 5:21, 17:19, 82:10, 83:23, 116:3
relates [1] - 31:8
relating [3] - 9:2, 23:23, 88:3
relationship [8] - 10:17, 41:7, 41:10, 42:21, 44:12, 48:23, 50:1, 61:22
relationships [2] - 64:7, 66:6
relative [11] - 35:7, 38:1, 42:4, 47:20, 48:8, 48:14, 55:18, 56:7, 67:15, 67:22, 68:12
released [1] - 125:5
relevant [54] - 13:22, 14:2, 15:25, 16:10, 16:11, 17:12, 17:13, 17:24, 18:7, 18:9, 18:13, 19:10, 20:16, 20:18, 21:18, 22:23, 23:1, 23:3, 23:19, 24:2, 24:11, 24:23, 25:7, 26:2, 26:3, 26:6, 26:7, 26:21, 27:1, 27:11, 29:1, 29:22, 30:4, 47:19, 54:4, 66:5, 71:8, 71:15, 71:21, 72:1, 72:6, 72:17, 73:4, 73:5, 74:12, 75:1, 75:6, 75:19, 75:24, 77:4, 79:7, 79:11, 79:12, 80:7
reliable [1] - 21:20
relied [6] - 27:3, 28:10, 71:2, 71:4, 80:19, 84:9
rely [10] - 15:4, 17:25, 21:18, 21:19, 26:25, 69:3, 69:5, 69:8, 69:10, 91:1
renew [1] - 6:23
renewing [1] - 7:3
repeat [7] - 20:19, 60:12, 63:23, 64:13, 71:19, 75:3, 78:2
repeated [1] - 32:5
repeatedly [2] - 24:5, 121:15
replacement [4] - 24:10, 24:11, 24:13, 43:6
replicates [1] - 86:19
reply [4] - 9:8, 69:21, 91:3, 120:8
report [19] - 9:8, 9:9, 12:25, 58:12, 65:13, 65:14, 68:10, 68:19, 69:15, 69:21, 70:11, 71:1, 82:17, 85:5, 86:17, 86:19, 89:9, 91:4, 91:9
reported [1] - 85:5
REPORTER [1] - 134:24
Reporter [3] - 2:6, 2:7, 135:5
reporter [1] - 4:9
reports [12] - 8:20, 9:3, 9:11, 9:13, 51:10, 56:12, 57:2, 57:24, 75:9, 83:3, 85:14, 88:6
reposition [1] - 73:10
representation [1] - 119:6
represented [2] - 119:3, 133:12
reproduction [1] - 32:7
request [2] - 5:24, 111:17
require [1] - 21:5
required [1] - 30:22
requires [2] - 15:20, 56:1
research [3] - 45:9, 113:3, 113:16
residents [4] - 19:25, 20:2, 20:12, 21:6
resolve [1] - 124:13
resort [1] - 130:7
resource [1] - 123:19
resources [4] - 44:19, 124:10, 125:1, 125:20
respect [11] - 47:13, 48:19, 49:12, 87:13, 87:19, 90:9, 90:25, 122:3, 125:24, 128:9, 130:13
respectfully [1] - 5:24
respond [3] - 81:12, 120:11, 120:14
response [11] - 21:6, 22:20, 23:24, 39:1, 41:17, 43:12, 43:25, 51:25, 120:6, 120:12, 120:15
responses [1] - 76:20
responsibilities [1] - 118:13
responsible [1] - 113:15
rest [6] - 5:1, 49:17, 49:19, 49:23, 111:17, 134:15
restrain [1] - 78:17
restraining [1] - 45:16
result [18] - 5:15, 18:23, 20:17, 24:7, 25:2, 29:8, 30:6, 35:1, 37:3, 39:15, 40:14, 46:11, 49:19, 54:15, 54:22, 62:24, 66:7, 73:21
retained [3] - 9:19, 9:21, 13:10
retaining [1] - 19:1
returns [3] - 44:16, 45:5, 45:11
revenue [4] - 37:3, 114:19, 114:20, 122:5
Review [1] - 30:20
review [17] - 5:25, 9:17, 15:6, 15:11, 22:25, 35:22, 42:20, 45:18, 47:18, 50:16, 51:10, 57:3, 62:15, 67:13, 70:25, 76:16, 78:14
reviewed [10] - 27:5, 37:19, 42:18, 48:21, 51:3, 57:2, 58:16, 66:17, 88:12, 132:20
revolves [1] - 118:21
revolving [1] - 121:17
right-hand [1] - 44:1
rise [4] - 46:19, 50:5, 66:25, 68:6
risk [9] - 24:15, 24:16, 40:21, 48:9, 64:3, 130:12, 130:25, 131:2, 131:4
rivals [5] - 52:23, 83:12, 83:15, 83:17, 83:23
road [2] - 29:8, 114:22
robust [1] - 45:17
role [7] - 22:6, 52:10, 114:4, 114:13, 118:3, 118:15, 119:8
roles [3] - 11:20, 113:25, 116:1
Room [2] - 2:7, 135:6
Ropes [1] - 112:5
ROPES [1] - 2:4
rough [3] - 42:23, 116:16
round [1] - 126:14
row [1] - 134:4
RPR [3] - 2:6, 134:25, 135:5
RUDOLPH [1] - 1:9
rule [1] - 90:21
run [3] - 5:23, 11:2, 92:13
running [2] - 121:5, 134:10
runway [4] - 128:15, 128:20, 129:1, 129:5
Ryan [1] - 1:17

S

safety [1] - 114:5
sake [1] - 20:9
salaries [1] - 129:2
sale [2] - 35:5, 119:10
sales [15] - 19:1, 19:15, 20:16, 34:25, 35:13, 36:20, 37:3, 37:5, 43:5, 44:21, 118:7, 127:14, 127:24
salient [2] - 74:5, 74:8
Samer [1] - 2:2
Sandra [1] - 2:3
Sapiens [1] - 115:16
satisfies [1] - 36:5
save [2] - 5:25, 40:9
saved [5] - 58:25, 59:10, 59:25, 60:5, 61:17
saw [5] - 28:11, 32:19, 32:20, 59:2, 75:22
scale [1] - 113:17
scaling [1] - 132:6
scarce [2] - 123:19, 124:3
scarcity [1] - 126:11
scenario [6] - 19:9, 91:19, 92:7, 124:22, 124:24
schedule [2] - 5:2, 5:5
School [1] - 10:12
sciences [1] - 12:15
Scientific [1] - 5:23
scramble [1] - 124:8
scrambling [1] - 129:18
screen [3] - 43:13, 65:4, 86:16
seal [1] - 92:21
seat [1] - 119:7
second [4] - 4:17, 13:25, 40:12, 44:13
section [5] - 71:6, 71:13, 72:4, 132:8, 134:18
see [29] - 17:10, 22:19, 25:2, 28:12, 28:17, 29:11, 32:9, 32:13, 33:7, 38:23, 39:9, 39:20, 44:1, 47:23, 48:24, 49:5, 55:10, 55:11, 58:16, 65:6, 65:18, 67:23, 70:3, 76:21, 79:24, 87:7, 132:15, 133:17, 134:12

seeing [1] - 52:23
seek [3] - 27:19, 79:15, 130:22
seeking [2] - 83:23, 85:22
seem [1] - 61:9
selected [2] - 117:9, 118:9
selling [1] - 116:21
send [1] - 120:9
sense [8] - 17:19, 21:12, 25:21, 36:21, 46:13, 72:24, 73:13, 133:1
sent [1] - 41:16
sentence [1] - 72:5
separate [7] - 47:22, 83:4, 83:9, 84:18, 84:21, 84:22, 126:11
separately [2] - 5:25, 37:23
series [1] - 87:6
seriously [1] - 54:6
serve [5] - 25:22, 35:17, 47:23, 125:2, 125:6
served [1] - 117:4
serves [1] - 37:6
service [1] - 12:3
services [1] - 17:16
SESSION [1] - 1:9
session [10] - 51:5, 92:17, 112:9, 112:11, 118:25, 119:17, 125:23, 128:4, 129:10, 134:16
set [7] - 17:17, 17:21, 26:13, 35:18, 36:9, 90:25, 117:20
sets [1] - 126:20
setting [2] - 18:20, 35:15
several [4] - 15:10, 49:21, 52:16, 52:17
severely [1] - 130:5
share [8] - 30:6, 30:10, 32:8, 49:3, 49:4, 49:18, 49:24, 88:20
shared [1] - 131:10
shareholders [1] - 119:6
shares [11] - 14:24, 27:12, 29:23, 30:5, 31:3, 31:9, 32:10, 73:15, 73:16, 74:18, 79:13
sharpen [1] - 35:14
shift [2] - 18:23, 18:24
SHORES [15] - 4:2, 4:4, 4:7, 4:17, 4:25, 5:11, 5:13, 5:15, 6:2, 7:18, 7:23, 92:19, 111:20, 111:24, 112:1
shores [1] - 6:20
Shores [1] - 1:17
shorthand [2] - 2:10, 27:14
show [1] - 91:4
showed [1] - 75:15
showing [1] - 65:14
shows [3] - 30:14, 91:10, 134:1
sic [3] - 40:11, 49:9, 121:10
side [3] - 33:20, 44:1, 47:2
sides [1] - 131:11
sight [1] - 122:1
sign [1] - 127:18
signal [1] - 80:7
significant [14] - 18:16, 23:10, 30:19, 30:21, 30:22, 68:12, 72:8, 72:9, 72:19, 72:20, 119:5, 130:15, 133:16, 133:20
similar [10] - 31:7, 32:19, 35:11, 36:5, 37:21, 58:15, 61:21, 64:1, 91:4, 91:22
similarly [8] - 15:16, 28:17, 29:16, 33:10, 38:25, 39:16, 41:16, 48:10
simple [2] - 92:4, 128:25
simply [6] - 40:6, 40:15, 40:22, 41:1, 80:3, 90:10
simultaneously [1] - 46:6
single [3] - 15:4, 23:24, 36:24
sit [1] - 126:22
site [1] - 133:10
sites [16] - 31:4, 31:8, 31:10, 31:20, 38:22, 38:25, 39:1, 39:23, 64:7, 64:11, 64:16, 64:20, 64:23, 129:15, 129:24, 130:10
sits [1] - 122:25
sitting [1] - 76:17
situation [3] - 19:16, 20:1, 33:15
situations [1] - 10:19
Siva [1] - 7:12
six [4] - 53:6, 114:3, 127:17
size [1] - 44:4
skill [1] - 117:20
skilled [1] - 130:15
slaughterhouses [1] - 127:3
Sleigh [1] - 1:14
slide [21] - 16:3, 24:9, 24:24, 32:6, 32:22, 33:4, 38:15, 47:24, 48:10, 51:1, 65:1, 76:23, 87:9, 87:24, 132:14, 132:20, 132:25, 134:1, 134:9
Slide [1] - 132:10
slides [9] - 8:20, 9:2, 9:3, 9:7, 23:25, 41:8, 75:15, 76:21, 121:11
small [4] - 18:15, 23:9, 72:8, 72:18
smaller [1] - 116:23
snarly [1] - 121:10
soft [1] - 133:6
softer [1] - 48:8
software [3] - 46:7, 46:8, 46:9
sold [2] - 115:8, 117:1
soliciting [1] - 121:6
solve [1] - 128:1
someone [1] - 112:2
sometimes [4] - 22:14, 22:16, 123:9, 124:11
somewhat [2] - 48:22, 71:11
soon [5] - 52:5, 80:25, 81:1, 81:11, 81:14
sophisticated [1] - 127:10
sorry [7] - 35:8, 63:23, 64:13, 72:13, 75:3, 76:9, 122:11
sort [10] - 44:12, 67:19, 67:23, 68:7, 74:21, 75:23, 85:16, 86:12, 91:17
sought [4] - 38:25, 83:12, 83:16, 83:18
sounding [1] - 118:15
sounds [2] - 67:4, 71:11
source [4] - 28:8, 29:14, 128:10, 128:12
sources [2] - 28:6, 51:7
south [1] - 114:17
space [5] - 34:24, 49:16, 53:14, 115:12, 122:22
spans [1] - 46:15
speaking [15] - 35:8, 35:10, 40:3, 42:24, 44:2, 47:19, 58:12, 58:23, 64:2, 68:20, 82:12, 116:25, 122:12, 126:5, 131:5
speaks [2] - 22:2, 41:11
specialists [1] - 47:5
specific [33] - 14:9, 15:17, 15:21, 25:22, 25:25, 29:21, 30:2, 47:24, 48:2, 50:19, 56:22, 57:7, 57:9, 57:15, 59:5, 60:3, 62:25, 63:4, 63:10, 63:12, 64:2, 64:21, 66:19, 87:6, 87:25, 88:3, 90:2, 90:3, 90:12, 90:18, 121:17, 122:25
specifically [29] - 10:17, 14:19, 15:2, 21:9, 22:18, 23:22, 25:5, 29:13, 33:5, 33:23, 37:10, 41:6, 41:11, 42:17, 43:15, 43:23, 48:4, 49:18, 49:25, 50:19, 51:25, 61:11, 66:22, 80:15, 82:23, 85:17, 88:8, 90:1, 90:7
specifics [1] - 22:22
spell [1] - 8:16
spend [2] - 56:15, 56:18
spent [1] - 113:5
spin [1] - 115:17
spin-out [1] - 115:17
split [2] - 32:11, 32:24
spots [1] - 92:2
spreadsheet [1] - 59:4
square [1] - 30:4
squeeze [1] - 6:14
SSNIP [11] - 18:17, 19:5, 19:12, 19:16, 20:8, 20:10, 20:14, 20:20, 21:7, 22:20, 23:24
St [1] - 115:13
staff [1] - 11:21
stage [2] - 115:7, 115:24
stake [1] - 119:4
stakeholders [2] - 15:3, 27:4
stand [7] - 8:9, 46:1, 67:16, 112:6, 124:22, 124:24, 125:25
stand-alone [5] - 46:1, 67:16, 124:22, 124:24, 125:25
standard [12] - 14:13, 36:11, 51:23, 55:12, 60:10, 60:15, 76:5, 76:6, 76:13, 76:18, 77:1, 77:3
standards [1] - 30:11
standing [1] - 53:1
stands [1] - 119:23
start [12] - 24:1, 53:1, 53:2, 54:20, 82:5, 92:10, 111:21, 112:9, 122:16, 129:11, 132:3, 134:17
started [2] - 41:19, 114:6
starting [1] - 92:2
startup [3] - 114:6, 115:7, 128:22
starving [1] - 53:17
state [2] - 8:15, 119:15
statement [4] - 70:5, 71:10, 72:12, 73:6
STATES [2] - 1:1, 1:10
States [12] - 26:8, 27:1, 32:9, 65:10, 126:1, 126:5, 126:7, 127:13, 127:22, 129:16, 135:6
States' [1] - 28:24
status [4] - 119:21, 123:13, 124:19, 125:10
STEEN [1] - 1:18
Steering [1] - 115:16
stenographic [1] - 135:2
step [8] - 13:21, 15:23, 15:25, 26:3, 27:8, 27:10, 120:2, 125:19
steps [2] - 132:5, 134:21
still [6] - 21:3, 37:2, 53:8, 77:17, 81:9, 113:21
Stimulation [1] - 115:17
stock [2] - 41:1, 44:6
Stock [1] - 114:8
storage [2] - 126:20, 127:11
stores [1] - 21:11
story [1] - 131:15

strategic [7] - 10:25, 67:17, 118:16, 119:9, 121:24, 121:25, 122:6
strategically [1] - 126:13
strategics [1] - 89:3
striking [3] - 47:17, 49:14, 49:20
structural [1] - 117:19
structure [3] - 10:18, 11:4, 27:15
structured [1] - 6:2
struggle [1] - 130:2
Stryker [1] - 115:9
studies [1] - 54:11
study [3] - 10:13, 10:20, 125:4
subfield [1] - 10:16
subject [2] - 5:20, 111:17
submit [1] - 7:8
submitted [1] - 4:21
subpar [1] - 133:23
subsequent [1] - 113:25
subsequently [2] - 10:11, 32:12
subset [1] - 26:16
subsidiary [1] - 13:20
substantial [1] - 117:21
substantially [1] - 13:17
substitutability [1] - 66:16
substitute [2] - 19:19, 22:20
substitutes [13] - 19:11, 37:13, 37:17, 37:18, 37:20, 38:7, 38:9, 38:17, 43:3, 43:4, 66:9, 66:13, 66:18
successful [4] - 12:22, 45:1, 114:12, 115:14
sufficient [3] - 36:16, 52:3, 78:11
sufficiently [2] - 78:16, 79:10
suggest [6] - 44:7, 44:8, 51:2, 59:13, 60:10, 60:15
suggested [2] - 25:10, 51:15
suggesting [1] - 79:14
suggestion [1] - 133:25
suggests [2] - 35:22, 62:18
summarize [2] - 27:15, 119:22
sun [2] - 39:20, 47:9
sunk [2] - 72:9, 72:20
supplied [1] - 23:2
supplier [3] - 78:20, 79:6, 80:8
suppliers [1] - 53:5
supply [14] - 13:23, 25:8, 26:8, 27:7, 28:2, 31:1, 47:2, 48:18, 52:24, 69:16, 70:17, 71:8, 90:14, 128:2
supplying [2] - 71:14, 71:20
support [6] - 52:8, 64:4, 125:11, 128:2, 130:8, 130:18
supporting [1] - 130:10
supports [1] - 129:25
suppose [1] - 53:20
supposed [3] - 64:10, 64:15, 64:19
surgical [6] - 24:10, 24:13, 24:16, 40:21, 48:9
Surpass [1] - 115:6
surplus [2] - 34:1, 53:12
Surplus [1] - 115:14
surrounded [1] - 122:21
surrounding [1] - 89:8
suspect [1] - 78:7
sustain [4] - 122:4, 128:24, 129:18, 134:13
sutures [1] - 127:6
Swiss [1] - 115:11
switch [7] - 20:23, 23:11, 23:24, 24:8, 25:4, 36:17, 37:1
SWORN [2] - 8:10, 112:7
syllabic [1] - 44:15
symptoms [1] - 24:5
syndicate [1] - 134:12
synonymous [1] - 70:3
synopsized [1] - 51:10
system [1] - 123:17

T

table [1] - 36:13
Table [2] - 86:17, 86:19
talent [1] - 122:24
talks [1] - 40:25
tank [1] - 134:7
targeting [3] - 38:24, 117:25, 120:9
tautological [1] - 71:11
TAVR [60] - 13:24, 23:1, 23:7, 23:11, 23:12, 23:24, 24:8, 24:21, 24:22, 24:25, 25:4, 25:5, 25:8, 26:1, 27:7, 28:2, 28:14, 28:23, 28:25, 31:1, 32:8, 40:4, 40:18, 41:6, 47:22, 48:16, 48:18, 49:13, 51:16, 52:24, 53:11, 56:9, 56:20, 60:21, 61:7, 64:17, 69:11, 69:14, 69:16, 69:22, 70:13, 70:18, 70:22, 74:4, 74:11, 74:25, 75:5, 78:20, 80:8, 80:16, 80:24, 82:2, 82:6, 82:15, 82:21, 83:1, 83:7, 87:5, 88:24, 90:15
TAVR-AR [52] - 13:24, 23:1, 23:7, 23:11, 23:12, 23:24, 24:8, 25:4, 25:8, 26:1, 27:7, 28:2, 28:14, 28:23, 28:25, 31:1, 32:8, 40:4, 40:18, 47:22, 48:18, 51:16, 52:24, 56:9, 56:20, 60:21, 61:7, 64:17, 69:11, 69:14, 69:16, 69:22, 70:13, 70:18, 70:22, 74:4, 74:11, 74:25, 75:5, 78:20, 80:8, 80:16, 80:24, 82:2, 82:6, 82:15, 82:21, 83:1, 83:7, 87:5, 88:24, 90:15
TAVR-AS [8] - 24:21, 24:22, 24:25, 25:5, 41:6, 48:16, 49:13, 53:11
team [2] - 9:16, 123:2
Tech [3] - 79:25, 80:8, 81:5
tech [4] - 12:13, 113:5, 113:10, 113:12
technical [2] - 118:3, 130:16
Technical [1] - 112:24
techniques [1] - 22:5
technologies [1] - 40:8
technology [3] - 89:4, 113:16, 115:18
TECHNOLOGY [1] - 1:6
tempted [1] - 130:22
tends [1] - 49:22
tenure [2] - 116:14, 117:3
term [8] - 16:11, 16:22, 16:23, 37:25, 45:24, 79:25, 123:11, 128:15
termed [1] - 72:10
terminated [1] - 132:24
terminates [4] - 133:5, 133:10, 133:15, 133:19
terms [13] - 16:18, 34:13, 34:18, 43:24, 44:18, 47:1, 57:5, 59:4, 61:12, 61:15, 74:7, 74:18, 87:6
terrible [1] - 25:1
terribly [5] - 24:6, 30:17, 80:25, 81:14
test [30] - 18:1, 18:4, 18:5, 18:10, 18:11, 19:8, 19:18, 19:21, 20:17, 23:5, 23:13, 25:6, 26:11, 41:3, 64:7, 64:10, 64:16, 64:20, 68:23, 69:2, 69:4, 77:5, 77:9, 121:17, 121:18, 121:19, 122:25, 124:7, 126:18
testified [9] - 12:20, 13:10, 50:2, 59:19, 81:8, 84:13, 88:11, 88:16, 88:19
testify [1] - 84:15
testifying [1] - 12:22
testimonial [2] - 22:17, 23:22
testimony [35] - 4:11, 5:19, 6:24, 7:4, 9:2, 13:8, 15:3, 25:2, 28:12, 28:22, 29:17, 38:3, 39:10, 49:9, 49:15, 57:4, 62:7, 62:9, 62:11, 66:1, 66:10, 66:17, 70:25, 78:15, 88:6, 88:8, 88:21, 88:22, 88:25, 89:1, 91:6, 116:5, 119:20, 123:8, 130:9
testing [1] - 123:2
text [1] - 47:8
textbook [3] - 22:4, 33:21, 49:21
Thanksgiving [1] - 5:4
THE [42] - 1:1, 1:1, 1:9, 4:3, 4:6, 4:16, 4:24, 5:9, 5:12, 5:14, 6:1, 6:18, 7:2, 7:10, 7:17, 7:20, 7:24, 8:4, 8:6, 8:10, 8:12, 8:23, 13:8, 52:14, 52:16, 52:17, 52:18, 53:7, 53:9, 55:1, 55:4, 92:18, 111:19, 111:23, 111:25, 112:2, 112:7, 112:12, 128:5, 128:7, 134:17, 134:20
theme [1] - 28:22
themselves [1] - 40:9
theory [8] - 30:14, 31:15, 33:15, 34:19, 39:7, 44:11, 62:5, 66:11
therapy [1] - 130:8
thereby [1] - 10:1
therefore [2] - 36:13, 87:22
they've [1] - 114:11
thinking [13] - 14:15, 16:24, 17:1, 35:4, 35:13, 53:3, 53:15, 66:6, 73:22, 75:16, 79:4, 123:22, 132:22
thinks [1] - 132:23
third [13] - 4:25, 14:3, 28:17, 32:21, 32:23, 45:22, 45:23, 49:15, 49:25, 54:16, 75:22, 81:7, 85:18
thorny [1] - 21:24
Thourani [3] - 6:22, 7:7, 8:1
Thourani's [1] - 5:19
three [12] - 23:20, 42:23, 44:10, 47:12, 73:24, 114:19, 119:5, 121:16, 121:23, 122:21, 123:24, 126:16
threshold [2] - 31:13, 31:21
threw [1] - 121:20
throughout [1] - 51:24
time-aged [1] - 126:20
timeline [4] - 65:13, 80:21, 81:19, 82:19
timelines [1] - 84:7
timely [3] - 52:5, 52:18, 80:5

timing [3] - 6:5, 87:13, 128:3
TIMOTHY [1] - 134:25
Timothy [1] - 2:6
tiny [2] - 30:8, 30:9
Tirole [1] - 34:20
tissue [2] - 127:3
tissues [1] - 127:4
today [27] - 4:23, 5:1, 5:18, 5:23, 9:2, 15:9, 28:7, 29:10, 29:14, 38:19, 69:19, 75:15, 76:17, 78:11, 83:11, 112:9, 115:22, 118:12, 119:23, 122:12, 122:18, 125:1, 125:12, 125:25, 126:22, 127:25, 128:11
together [2] - 45:25, 47:3
tomorrow [5] - 5:4, 6:2, 6:7, 53:20, 53:25
took [3] - 40:17, 45:13, 50:7
tool [1] - 22:14
tools [2] - 51:23, 69:4
topic [3] - 42:23, 124:15, 129:10
topics [3] - 12:17, 12:19, 23:25
Toronto [1] - 114:8
total [2] - 12:3, 87:4
totality [2] - 9:18, 62:15
toto [1] - 15:7
towards [1] - 51:12
track [1] - 61:4
Trade [7] - 8:8, 11:10, 11:11, 11:13, 11:20, 11:23, 11:25
trade [1] - 16:18
TRADE [2] - 1:2, 1:15
traded [1] - 116:5
trained [2] - 130:16, 130:21
trajectory [1] - 92:12
transaction [76] - 9:25, 12:24, 13:12, 13:17, 13:23, 13:25, 14:11, 14:19, 15:21, 16:1, 16:6, 16:14, 27:23, 31:23, 35:23, 40:3, 40:15, 42:3, 47:10, 47:15, 47:25, 48:15, 50:11, 50:22, 51:19, 52:4, 52:11, 53:22, 54:1, 54:21, 55:16, 55:21, 56:11, 56:15, 56:21, 57:1, 57:3, 57:11, 58:1, 58:25, 59:4, 59:11, 59:25, 60:5, 60:8, 60:14, 60:21, 61:6, 61:18, 62:16, 62:19, 62:22, 62:24, 63:3, 63:15, 63:20, 64:5, 66:7, 67:3, 67:7, 67:12, 68:6, 68:21, 73:1, 73:21, 79:5, 122:13, 122:17, 129:12, 129:13, 129:23, 130:12, 130:24, 131:21, 134:2, 134:11
transactions [9] - 11:16, 12:11, 14:16, 50:23, 66:24, 116:21, 116:24, 117:2, 117:24
transcript [5] - 2:10, 4:10, 88:12, 135:2, 135:3
TRANSCRIPT [1] - 1:8
transcription [2] - 2:11, 4:8
transcripts [1] - 15:12
transfer [1] - 38:4
transferred [1] - 113:25
transferring [1] - 33:25
transfers [2] - 30:16, 53:12
transparent [1] - 6:8
transplants [1] - 56:13
travel [2] - 21:2, 21:16
treat [7] - 37:22, 43:18, 43:20, 70:8, 70:14, 87:20, 114:9
treating [4] - 24:4, 115:8, 115:12, 115:18
treatment [7] - 23:14, 23:18, 24:18, 48:6, 48:8, 60:21
treatments [1] - 76:3
treats [1] - 24:4
trial [16] - 29:6, 38:5, 38:22, 39:23, 40:12, 40:17, 40:20, 54:12, 64:23, 70:20, 70:23, 82:7, 82:8, 83:19, 86:13, 127:14
trials [21] - 28:15, 29:3, 53:2, 65:9, 74:3, 74:11, 74:24, 75:4, 75:12, 75:17, 78:11, 80:17, 80:24, 81:3, 81:11, 81:21, 81:24, 82:3, 82:5, 83:13, 85:23
tried [1] - 44:11
Trilogy [25] - 39:23, 43:19, 43:20, 46:23, 56:25, 57:20, 57:21, 58:2, 58:6, 58:8, 85:13, 87:20, 88:1, 89:10, 91:12, 91:20, 92:7, 119:21, 120:17, 123:10, 124:17, 126:6, 126:23, 127:13, 129:15
true [5] - 33:8, 33:19, 88:20, 135:1, 135:2
try [5] - 73:18, 85:17, 125:7, 130:4, 130:8
trying [4] - 5:16, 47:22, 49:24
Turco [4] - 88:10, 88:13, 88:16, 88:19
turn [8] - 16:17, 22:22, 41:22, 48:10, 51:14, 74:2, 117:3, 119:15
turned [6] - 14:17, 26:4, 27:10, 29:22, 87:17, 87:18
turning [2] - 124:15, 127:25
two [43] - 4:18, 5:3, 5:18, 6:5, 6:16, 11:4, 12:18, 17:13, 17:23, 20:3, 20:5, 20:8, 28:6, 31:3, 32:10, 33:14, 36:8, 36:23, 37:21, 45:25, 46:15, 47:3, 52:19, 52:21, 54:14, 70:1, 73:24, 88:24, 113:25, 114:10, 114:21, 117:2, 118:20, 119:5, 121:22, 122:21, 123:16, 123:21, 123:24, 124:3, 129:6, 129:8, 131:11
Tymkovich [1] - 1:13
type [5] - 22:19, 28:19, 40:16, 50:12, 75:19
types [14] - 11:16, 12:11, 17:20, 21:17, 23:20, 26:13, 26:14, 37:15, 43:15, 47:5, 48:2, 55:25, 68:18, 68:20
typical [2] - 73:23, 83:5
typically [6] - 17:10, 17:13, 17:25, 38:10, 52:16, 117:24

U

U.S [33] - 2:7, 28:25, 70:8, 70:14, 70:19, 70:22, 74:3, 74:10, 74:24, 75:4, 75:12, 75:17, 78:11, 80:17, 80:24, 82:2, 82:7, 85:22, 113:25, 114:15, 117:21, 117:22, 122:2, 125:3, 125:8, 126:10, 126:12, 126:17, 127:24, 130:6, 130:10, 131:7
ultimately [5] - 25:15, 25:24, 43:2, 67:16, 77:22
unable [4] - 7:7, 15:11, 29:8, 90:3
unanimously [1] - 21:24
unappealing [1] - 24:19
unaware [1] - 28:18
uncertain [1] - 125:15
uncertainty [2] - 81:8, 131:16
under [6] - 7:3, 59:19, 92:21, 113:21, 125:13, 133:6
undergo [1] - 24:15
underlie [1] - 90:7
undertake [1] - 45:9
undertaking [1] - 44:20
undesirable [2] - 36:14, 36:20
unfortunate [1] - 35:24
uniformity [1] - 15:16
Unilever [1] - 113:4
unique [1] - 33:6
unit [1] - 63:11
UNITED [2] - 1:1, 1:10
United [13] - 26:8, 27:1, 28:23, 32:9, 65:10, 126:1, 126:5, 126:6, 127:13, 127:22, 129:16, 135:6
units [2] - 14:21, 31:6
universe [3] - 29:18, 81:6, 117:18
University [4] - 10:11, 10:13, 11:8, 112:24
unless [1] - 50:7
unlikely [1] - 87:23
unpaid [1] - 129:7
unprofitable [2] - 19:16, 20:15
unrelated [1] - 90:23
up [17] - 8:2, 19:5, 25:4, 44:16, 53:15, 56:17, 59:21, 63:11, 86:16, 114:2, 115:2, 116:10, 123:21, 125:8, 126:19, 132:9, 134:18
upfront [1] - 45:6
uphill [1] - 125:12
UPP [2] - 63:9, 63:12
upper [2] - 41:11, 49:1
upsized [1] - 123:17
upstate [1] - 114:15
upward [4] - 35:17, 37:6, 39:8, 63:7
usable [1] - 22:15
useful [1] - 22:9
utilized [4] - 29:25, 46:7, 49:16, 74:1

V

Vahl [2] - 24:19, 38:4
valuation [10] - 86:22, 87:1, 88:2, 88:7, 88:11, 88:17, 89:7, 90:5, 90:22, 91:10
value [4] - 16:20, 25:16, 25:17, 36:16
valve [23] - 24:10, 24:13, 43:16, 43:17, 43:19, 43:20, 43:25, 44:3, 44:4, 44:6, 46:24, 48:4, 123:10, 123:14, 123:15, 123:16, 123:21, 123:23, 124:2, 127:2, 133:16, 133:21
Valve [19] - 4:10, 29:15, 32:12, 33:12, 38:5, 39:4, 39:15, 40:12, 43:17, 46:23, 48:5, 48:13, 53:3, 57:10, 57:16, 89:11, 91:12, 91:20, 92:7
Valve's [1] - 39:14
valves [13] - 25:4, 29:7, 86:7, 88:1, 123:21, 126:1, 126:6, 126:16, 126:19, 126:23, 127:6, 128:2, 129:24
variables [1] - 87:6
variety [11] - 12:11,

37:14, 38:3, 38:15, 40:2, 40:5, 42:8, 46:1, 63:5, 68:19, 77:14
various [3] - 11:12, 15:3, 121:2
Varnitha [1] - 7:12
vast [1] - 11:18
venture [1] - 117:25
verify [3] - 32:1, 32:18, 48:17
version [3] - 43:19, 88:11
versus [17] - 56:11, 56:15, 56:21, 57:1, 57:11, 59:1, 59:11, 60:1, 60:9, 60:14, 61:18, 63:22, 63:25, 67:20, 67:25, 126:5, 126:7
via [2] - 20:25, 21:1
vice [1] - 12:2
video [4] - 5:20, 5:22, 6:25, 8:1
videoconference [1] - 6:4
videos [1] - 5:18
view [11] - 22:8, 30:12, 32:6, 32:22, 33:6, 42:3, 52:8, 75:10, 122:6, 122:13, 129:14
viewed [1] - 62:4
volume [1] - 127:9
volunteer [1] - 118:5
vulnerable [1] - 43:22
vying [1] - 43:4

W

W-I-L-S-O-N [1] - 8:17
wade [1] - 8:7
walk [6] - 5:6, 6:16, 19:20, 36:6, 113:1, 113:9
walked [1] - 47:12
wants [1] - 5:20
Washington [7] - 1:4, 1:16, 1:19, 1:23, 2:5, 2:8, 135:7
ways [3] - 38:14, 40:13, 124:3
wear [1] - 121:18
week [8] - 24:3, 26:18, 41:23, 49:15, 59:17, 88:10, 120:10, 123:22
weekend [1] - 5:16
weeks [4] - 120:1, 128:24, 129:1
weighing [2] - 67:19, 67:23
weight [1] - 68:3
Weiss [1] - 1:13
welfare [8] - 30:19, 34:1, 60:10, 60:15, 60:22, 61:19, 65:25, 66:2
whatsoever [2] - 120:24, 133:2
white [1] - 7:15
whole [3] - 84:24, 117:19, 124:7
wide [1] - 12:10
widely [2] - 33:20, 34:18
widespread [2] - 29:7, 51:13
wife [2] - 19:23, 114:23
willing [1] - 134:12
WILSON [2] - 3:3, 8:10
Wilson [36] - 5:1, 6:21, 8:9, 8:15, 8:17, 8:18, 9:1, 9:11, 9:19, 10:5, 11:6, 13:5, 13:10, 15:13, 15:23, 21:17, 22:8, 22:22, 25:7, 27:6, 29:19, 31:25, 32:17, 33:1, 33:13, 41:22, 47:12, 50:2, 51:5, 51:14, 53:20, 54:23, 55:8, 61:25, 71:2, 84:3
Wilson's [2] - 9:7, 59:21
win [1] - 122:4
winded [1] - 122:11
Witness [1] - 134:21
WITNESS [6] - 3:2, 8:10, 52:16, 52:18, 53:9, 112:7
witnesses [3] - 5:17, 8:3, 38:3
wood [1] - 26:18
woods [1] - 49:9
word [2] - 127:16, 134:9
words [9] - 16:19, 19:5, 23:5, 50:19, 52:2, 63:2, 74:10, 78:8, 134:8
works [1] - 18:11
world [23] - 26:17, 26:22, 31:11, 44:17, 44:24, 45:8, 46:8, 46:20, 47:20, 47:21, 48:12, 50:21, 56:8, 60:8, 60:13, 60:17, 60:18, 67:15, 67:22, 74:16, 114:6, 114:12, 128:22
worldwide [1] - 25:11
worried [1] - 45:15
worry [1] - 53:13
worse [1] - 30:15
worth [2] - 44:19, 49:4
worthwhile [1] - 18:22
written [1] - 132:1

X

XL [3] - 43:17, 43:25, 123:10

Y

year [4] - 113:18, 121:11, 122:18, 125:8
years [24] - 11:12, 28:8, 29:8, 52:16, 53:6, 53:9, 73:24, 81:15, 81:16, 81:18, 81:21, 113:5, 113:22, 114:3, 114:10, 114:21, 115:2, 116:11, 117:22, 121:16, 121:23, 122:15, 123:24, 128:24
yield [2] - 127:4, 127:7
York [1] - 114:16

Z

zero [2] - 30:8, 30:9
zoom [1] - 6:3