

1 treatment in adjuvant patients. Is it at 120? Is it
2 at 100? What?

3 CHAIRPERSON DUTCHER: One hundred.

4 DR. TEMPLE: Well, if you don't like that,
5 you could suggest something else.

6 (Laughter.)

7 CHAIRPERSON DUTCHER: Dr. Miller?

8 DR. MILLER: Both treatment schedules and
9 starting doses are incorporated into the proposed
10 package insert, appropriate dose modifications, and so
11 on.

12 CHAIRPERSON DUTCHER: So you're talking
13 about a day one/day eight and a day one?

14 DR. MILLER: Yeah, in essence the specific
15 instructions are provided as to how to administer the
16 drug either with a day one or a day one/eight schedule
17 and with the two doses, and of course, the clinical
18 results from the two trials are thoroughly outlined
19 within the package insert.

20 CHAIRPERSON DUTCHER: Dr. Nerenstone?

21 DR. NERENSTONE: Just a point of
22 clarification. The FEC 100 has never been compared to

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1 CMF. The only one that was compared to a standard
2 adjuvant is the CEF 120, the day one/day eight.

3 So if there is a difference between of
4 scheduling, we don't know that that could be lost in
5 the 100, day one, every three week drug dosage. Just
6 like CMF, we found out at least in metastatic disease
7 it's probably given day one/day eight, and because of
8 that, many people give the adjuvant the same way.

9 It's not clear to me that the company has
10 shown that these two schedules are interchangeable,
11 and I raise that as a question. We're talking about
12 adjuvant patients where a cure or overall survival
13 advantage is what we're looking for, and so, again,
14 I'm confused as to do we want to approve both of them
15 or one of them or neither of them, but if we decide
16 we're going to approve one, do we need to approve both
17 of them at the same time because that's what the
18 application is asking us?

19 CHAIRPERSON DUTCHER: No. We can make our
20 own decision as to what we think is the most effect --
21 correct? We're making it. We're giving advice based
22 on what we've seen.

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1 DR. TEMPLE: Yeah, one of the things we're
2 always interested in is whether a finding is
3 replicable or confirmable. You could conclude that
4 the comparison with standard therapy is the most
5 persuasive and that the other one sort of gives you
6 proof of principle. There's a lot of ways to reason
7 about this, or you could conclude they don't have
8 enough data.

9 DR. SANTANA: It's not a minor issue
10 because it regards the development of second leukemia.
11 The schedule may be very important, and you kind of
12 get a suggestion here that there were more cases of
13 second leukemia in the one in eight than when they
14 looked at the data in which the epirubicin was only
15 given on day one. Am I correct, Langdon?

16 DR. MILLER: That's true, but of course,
17 we're talking about four cases --

18 DR. SANTANA: Right.

19 DR. MILLER: -- versus one. So --

20 DR. SANTANA: We're talking limited data.
21 I agree.

22 DR. MILLER: -- you know, it's a little

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1 difficult to draw a whole lot of conclusion from that,
2 I think.

3 The other thing that I would point out is
4 that the results, given that there are some
5 differences in the patient populations, are extremely
6 reproducible between study one and study two.

7 And the other thing is that in study two,
8 the effect was seen even though approximately half of
9 the patients were postmenopausal patients, and all of
10 the meta analyses looking at chemotherapy versus no
11 chemotherapy clearly show that the effect in
12 postmenopausal women of chemotherapy, while there and
13 highly significant, is not as dramatic as it is in
14 premenopausal women.

15 So I think there are some reason to
16 believe that the effect is fairly reproducible and
17 universal.

18 CHAIRPERSON DUTCHER: Dr. Margolin.

19 DR. MARGOLIN: Well, just a couple of
20 minor comments about Dr. Nerenstone's attempt to be
21 careful and precise, which is laudable, but
22 unfortunately when these drugs get out, you really

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1 don't have much control over what people do, and
2 people tend to cut corners, and there are safety
3 issues as well.

4 And I really think also that even though
5 we don't see it, it wasn't tested per se here, what we
6 know in the adriamycin-doxorubicin situation would
7 suggest that it's maybe not so much of a dose
8 intensity effect, and that the difference between
9 starting at 100 versus starting at 120 with the
10 appropriate safety adjustments may not be as important
11 as exceeding a threshold below which 50 milligram per
12 meter squared dose is certain found, but you know,
13 maybe the threshold is 80 and we're good at all doses
14 above that.

15 CHAIRPERSON DUTCHER: Dr. Ozols.

16 DR. OZOLS: Yeah, I think as these studies
17 were done and when they were developed, I think they
18 really have met the objective that they were looking
19 at, and I think that they do show that they're
20 effective, and I think it's up to the physician to
21 look at this data with the patient and to evaluate it
22 and to see if it's worth it, as was pointed out

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1 earlier.

2 I think that these differences in survival
3 and adjuvant situation are as good as we've seen with
4 any individual trial, and better actually. I think
5 that both indications are correct.

6 CHAIRPERSON DUTCHER: Yes?

7 DR. KROOK: I would just second that.

8 CHAIRPERSON DUTCHER: So we're going to
9 vote on question one. Do these randomized trials
10 demonstrate that epirubicin at the planned doses of
11 100 and 120 milligrams per meter squared in
12 combination with 5 FU and cyclophosphamide is
13 effective for the proposed indication? And this is
14 for adjuvant therapy of node positive breast cancer.

15 All those who would say yes?

16 (Show of hands.)

17 CHAIRPERSON DUTCHER: Ten yes. No no.
18 That's it.

19 We lost two -- three. So it is nine.
20 You're right.

21 All right. The next table is looking at
22 the toxicity with the adjuvant trials, and the comment

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1 is made that serotonin specific antiemetic therapy and
2 colony stimulating factors were not used in these
3 studies. The applicant provided calculations of the
4 incidence of congestive heart failure in acute
5 leukemia based on all toxicity information in their
6 database, and an estimate of the number of treated
7 patients based on sales -- sales? Based on sales.
8 Okay.

9 These calculations suggest a four percent
10 incidence of congestive heart failure at epirubicin
11 doses of 900 milligrams per meter squared or higher.
12 The incidence of asymptomatic decreases in left
13 ventricular ejection fraction is probably higher.

14 The calculations also suggest 0.24 risk of
15 AML at three years and a 0.77 percent risk at five
16 years.

17 Do these trials demonstrate acceptable
18 safety for epirubicin in combination with
19 cyclophosphamide and 5 FU at planned doses of 100 and
20 120 milligram per meter squared for the proposed
21 indication?

22 Dr. Krook?

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1 DR. KROOK: Just, well, to comment, that
2 in neither the 100 nor the 120 do we reach the 900.
3 We're actually at two-thirds, and my answer to this
4 would be that, yes, it is acceptable for the toxicity,
5 provided it's discussed with the person.

6 CHAIRPERSON DUTCHER: Other comments?

7 (No response.)

8 CHAIRPERSON DUTCHER: All those who would
9 vote yes?

10 (Show of hands.)

11 CHAIRPERSON DUTCHER: Eight yes.

12 No?

13 (Show of hands.)

14 CHAIRPERSON DUTCHER: One no. Do you want
15 to make any comment? No.

16 MS. ZOOK-FISCHLER: No.

17 CHAIRPERSON DUTCHER: Just a vote. Okay.

18 Number three --

19 DR. TEMPLE: Can I ask a question? Was
20 there some implication that the labeling ought to
21 remind people that when this is used in the adjuvant
22 setting it may limit your ability to take some more

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1 drugs later or does everybody already know that?

2 DR. KROOK: I think most people who are
3 informed know that.

4 DR. TEMPLE: Well, that's true.

5 DR. KROOK: There are the uninformed out
6 there, Bob, but I think most people who deal with it
7 know it.

8 DR. TEMPLE: So you don't think it's
9 necessary to state the obvious, say, in the label?

10 DR. WILLIAMS: I'm sure there will be
11 something in the labeling about what the dose of
12 anthracycline, the total dose of anthracyclines you
13 should take just like there would be in doxorubicin.

14 DR. TEMPLE: With its implications for use
15 of subsequent anthracyclines? I don't remember that
16 from other labels.

17 DR. WILLIAMS: We'll put it there, yeah.

18 DR. MARGOLIN: No, I think --

19 DR. TEMPLE: That's why I asked.

20 DR. MARGOLIN: I think if anything, that
21 could have the detrimental effect of convincing some
22 doctors that one should save the anthracyclines for

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1 later, which is certainly not what you want to convey.

2 CHAIRPERSON DUTCHER: I mean, we've been
3 pretty aggressive of moving anthracyclines up.

4 DR. MARGOLIN: Yeah.

5 CHAIRPERSON DUTCHER: Yeah.

6 DR. TEMPLE: So you're saying that would
7 really be in some ways the wrong implication.

8 CHAIRPERSON DUTCHER: Well, I guess the
9 answer is if you've got two effective anthracyclines
10 at this stage of the disease and they may have some
11 impact on long term survival, you don't want to
12 necessarily limit their use, effective use. I mean,
13 you don't want to see dose reductions in doses that
14 would be less than effective.

15 Is that the sense of the group?

16 DR. JUSTICE: But I don't think that's
17 what Dr. Williams meant. I think what he says is
18 something about the rise in the cytotoxicity with the
19 cumulative dose of such-and-such and --

20 CHAIRPERSON DUTCHER: Absolutely. No,
21 absolutely.

22 Dr. Margolin.

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1 DR. MARGOLIN: And is it safe to assume
2 also there will be some mention, although I haven't
3 heard anything quantitative here, about the potential
4 additive risks of left chest radiation in these
5 patients as well?

6 DR. HONIG: That's already, I think, in
7 your proposed labeling.

8 DR. MILLER: No, the proposed labeling
9 provides the curve that I showed you to show the risk
10 of specific doses based on those 9,000 patients, and
11 then goes into the potential risk factors of age, of
12 prior chest wall radiation, and the fact that one has
13 to be careful about patients who have received prior
14 doxorubicin or epirubicin and then doxorubicin or
15 mytozantrone.

16 So all of that is discussed in the
17 labeling.

18 DR. MARGOLIN: We probably don't have any
19 elegant animal data, for example that show the
20 leftward shift of the curve based on a particular
21 radiation port and dose and --

22 DR. MILLER: Well, what's cited is a paper

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1 that was published in the JCO not too long ago with
2 469 patients that actually looked at various risk
3 factors, and chest wall radiation was among the risk
4 factors that was significantly predictive of greater
5 cardiotoxicity.

6 In terms of specific risk, of course, it's
7 hard to say for a given patient, but we felt at least
8 it should be mentioned in the package insert.

9 CHAIRPERSON DUTCHER: Dr. Krook.

10 DR. KROOK: Part of the problem, and
11 perhaps I'm putting my hand up as a community
12 physician, is as we go from one anthracycline to
13 another, who knows what happens? I mean, we could go
14 through three and at least personally as I calculate
15 doses for cardiac toxicity going from adriamycin to
16 mitoxantrone to God knows what, here comes a third
17 one, and I don't think that anybody has any idea as we
18 add anthracyclines back to back what happens.

19 I mean we presume that the mechanism is
20 the same in each of them, but how do we know?

21 I mean, perhaps somebody has done --
22 perhaps our friends in Canada have gone from epi. to

1 adria. at some time, and you know, there may be some
2 experience. I don't know.

3 CHAIRPERSON DUTCHER: Other comments?

4 DR. LEVINE: We're a little reluctant
5 after a patient has received 720 milligrams per meter
6 squared as adjuvant therapy, if unfortunately the
7 cancer comes back. We would generally use a -- and
8 chemotherapy was indicated -- we would generally move
9 forward with a taxane or even CMF if it hasn't been
10 used. We'd be a little reluctant to restate an
11 anthracycline.

12 CHAIRPERSON DUTCHER: Dr. Margolin?

13 DR. MARGOLIN: I'm sorry, but the paper
14 that Dr. Miller just quoted, I believe, actually has
15 a graph that suggests that the two groups are
16 completely superimposable in terms of the -- although
17 there's mislabeling throughout this about the solid
18 curves and the dotted curves. They look
19 superimposable here, the irradiated patients and the
20 nonirradiated patients and the incidence of CHF versus
21 the cumulative dose of epi. Is that also?

22 DR. MILLER: We'll have to pull that out.

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1 DR. MARGOLIN: Okay, because I have it
2 here. That would be good, I guess.

3 That's true. That was all I was
4 wondering.

5 DR. MILLER: Well, you know, I'd have to
6 take a look at it.

7 DR. MARGOLIN: It's extraneous to the
8 discussion.

9 CHAIRPERSON DUTCHER: All right. Can we
10 go on? We can proceed to question three?

11 Is epirubicin at planned doses of 100 and
12 120 milligrams per meter squared in combination with
13 cyclophosphamide and 5 FU approvable for adjuvant
14 patients with node positive breast cancer?

15 (No response.)

16 CHAIRPERSON DUTCHER: All those who would
17 vote yes?

18 (Show of hands.)

19 CHAIRPERSON DUTCHER: Nine yes. No noes.

20 Okay. On to the discussion of metastatic
21 disease. Two randomized controlled trials were
22 submitted for the indication. Epirubicin is indicated

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1 for therapy of patients with locally advanced or
2 metastatic breast cancer. Study HEPI-013 randomized
3 women with metastatic breast cancer and no chemo. to
4 receive FE -- no prior chemotherapy -- to receive FEC
5 100 or CMF.

6 Study HEPI-010 randomized a similar
7 patient population to receive FEC 100 or FEC 50.
8 Patients with the initial presentation of locally
9 advanced breast cancer without metastases were not
10 included in these trials and cannot be considered in
11 this indication.

12 The table that demonstrates the efficacy
13 looking at survival, time to regression, response
14 rate, and time to treatment failure.

15 Neither trial demonstrated a survival
16 advantage for FEC 100 over the comparator. Forty-four
17 percent of patients on the CMF arm subsequently
18 received an anthracycline based regimen. Significant
19 differences we limited to a TTP advantage over CMF and
20 an improved response rate with FEC 100 compared to FEC
21 50.

22 So you see now we have a real case

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1 scenario after all morning yacking about it.

2 (Laughter.)

3 CHAIRPERSON DUTCHER: What a coincidence,
4 yeah.

5 All right. In general, is an effect on
6 time to progression alone sufficient for demonstrating
7 clinical benefit in first line treatment of metastatic
8 breast cancer? In your answer please consider both
9 the activity of the control and the influence of the
10 crossover.

11 Dr. Simon.

12 DR. SIMON: Well, I would say no. First
13 of all, I say we don't have a reproducible effect on
14 time to progression demonstrated. We only have it on
15 one study. It's a very, very small effect. As I said
16 this morning, I don't think there's actually an issue
17 of the crossover because I think the medically
18 important question to the woman is: does this
19 treatment provide a survival benefit?

20 And in the real world, where other
21 anthracyclines are available, the observed lack of
22 effect on survival is the correct -- the medically

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1 relevant effect on survival. So I don't think that
2 there's any confounding here due to crossover.

3 And I think basically we have no
4 reproducible effect on time to progress or time to
5 treatment failure. In the one study where there is an
6 effect, it's such a small effect, I would not expect
7 it to have any influence on survival.

8 CHAIRPERSON DUTCHER: Dr. Nerenstone.

9 DR. NERENSTONE: Just a question for the
10 study authors. In the metastatic disease when there
11 was subsequent treatment with anthracyclines, was it
12 with adriamycin or was it with epirubicin or do we
13 know?

14 DR. MILLER: There was a mixture of
15 patients in terms of the drug received. Some received
16 epirubicin, some doxorubicin, and some mitoxantrone,
17 and all of those were included. I can give you the
18 breakdown.

19 But more patients in the CMF arm received
20 an anthracycline than did patients who had already
21 received an anthracycline.

22 CHAIRPERSON DUTCHER: Dr. Temple.

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1 DR. TEMPLE: I just want to make a comment
2 about approval standards. I'm sure what Rick says is
3 correct, that from the point of view of the patient,
4 the fact that it all turned out the same when you
5 crossed over is true.

6 But our immediate interest is in whether
7 the therapy is effective, that is, whether it has the
8 desired effect. It doesn't really have to be better
9 than what's available. It just has to be as good. In
10 many disciplines it doesn't even have to be as good,
11 but I think in oncology most of the time you'd say it
12 ought to be at least as good.

13 So if crossover to another therapy
14 undermined what was a real benefit, that would obscure
15 a real benefit. Now, I'm not saying there's a real
16 benefit here. That's a different question.

17 But on the question of whether if it all
18 come out in the end because a crossover obliterates
19 it, whether that could obscure a real effect, I'm a
20 little troubled by that because drugs are supposed to
21 be effective. They don't have to be superior.

22 I mean we've all heard why everyone wants

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1 them to be superior, because they're not good enough
2 yet, but from the Food, Drug, and Cosmetic Act's point
3 of view, it's just supposed to be effective, and maybe
4 in oncology you'd say, well, it ought to be at least
5 as effective as what's available, but it doesn't have
6 to be better.

7 CHAIRPERSON DUTCHER: Dr. Nerenstone.

8 DR. NERENSTONE: But then from a
9 regulatory point of view, shouldn't this have been
10 designed as an equivalence study? And if so, given
11 this patient numbers, isn't there a possibility that
12 it could be worse and that this study is not powered
13 enough to show that?

14 DR. TEMPLE: Well, that's a good question.
15 Whether a study attempting to show superiority that
16 fails to do so can be interpreted as an equivalence
17 study is one of those grand debated, but you know,
18 you'd have to say this shows some evidence that it's
19 not worse than the control, but the goal is to be
20 better than the control, and it clearly only in the
21 most borderline way achieved that.

22 But, see, I have other troubles with

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1 equivalence. I mean, you first have to know what the
2 survival or time to progression effect of the control
3 is, and in particular of the part that's been
4 substituted with the control, and you can't say what
5 that is. We just don't know.

6 So I think equivalent studies need some
7 more attention by the committee. We'll bring that to
8 you one of these days.

9 CHAIRPERSON DUTCHER: Dr. Krook.

10 DR. KROOK: I personally believe that this
11 is an effective drug, and in saying that, I would turn
12 and say that in terms of this question, I don't
13 believe my answer would be, no, it does not show that
14 pursuant to this morning's question or discussion, I
15 should say, because I think we saw this morning the
16 effects on metastatic disease is two months to six
17 months at the best, but I think that epirubicin is as
18 effective drug as those we're using now, be it that
19 it's an equivalent.

20 Now, that gets back to what you said, the
21 question.

22 CHAIRPERSON DUTCHER: Dr. Simon.

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1 DR. SIMON: Well, given that we have one
2 study with a time to regression benefit of two months
3 median and the other one that has no time to
4 progression benefit, it really makes one question
5 whether adriamycin is effective with regard to
6 survival.

7 I mean, I don't see how one could conclude
8 that this would have -- I mean, we can't even conclude
9 that we have reproducible benefit with regard to time
10 to progression, and even if we could conclude that,
11 how could we translate that into believing in the
12 absence of a crossover with a two month median time to
13 progression improvement, that that's going to
14 translate into a survival benefit? It's beyond me.

15 CHAIRPERSON DUTCHER: Dr. Margolin.

16 DR. MARGOLIN: This is not to argue that
17 I disagree with you, but just to clarify. These
18 aren't two things that are comparable because one is
19 a dose response or a threshold response effect, and so
20 I'm not sure you can say one shows a TTP benefit and
21 one doesn't. They're really different questions in
22 these two studies for that.

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1 DR. SIMON: That's true, although in the
2 adjuvant situation, we used when it came out the other
3 way --

4 DR. MARGOLIN: Right, yes.

5 DR. SIMON: -- we used it as a basis.

6 DR. MARGOLIN: Yeah, just clarifying.

7 (Laughter.)

8 CHAIRPERSON DUTCHER: Dr. Temple.

9 DR. TEMPLE: Well, we encourage people to
10 look for differences because it's too hard to know
11 what the control did. I mean, you have to know what
12 the survival effect of methotrexate is to know how
13 much better this therapy is, and since we're probably
14 not equipped to know that, you're stuck with what Rich
15 points out is this teeny-weeny difference, which
16 doesn't look like very much.

17 But it's hard to know what to do. You
18 can't leave people untreated. So you can't get an
19 estimate of the full effect of the drug. The only way
20 to do it is to compare to the available therapies.

21 CHAIRPERSON DUTCHER: Any suggestions? Do
22 you want to vote?

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1 (No response.)

2 CHAIRPERSON DUTCHER: Okay. In general,
3 is an effect on time to progression alone sufficient
4 for demonstrating clinical benefit in first line
5 treatment of metastatic breast cancer?

6 And basically we're looking at one study.

7 DR. KROOK: This is a general question.

8 DR. MARGOLIN: We answered the general
9 question this morning really.

10 DR. KROOK: Do you want to answer it
11 again? We can do it again.

12 CHAIRPERSON DUTCHER: Okay.

13 DR. KROOK: We said no.

14 CHAIRPERSON DUTCHER: Okay. We said no.

15 DR. KROOK: We said no this morning.

16 CHAIRPERSON DUTCHER: So then we'll go on
17 to number five. We don't want to talk about this
18 anymore.

19 If not, does the evidence of epirubicin
20 activity and survival benefit in the adjuvant setting
21 permit greater reliance on time to progression in this
22 setting?

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1 Dr. Margolin?

2 DR. MARGOLIN: No.

3 CHAIRPERSON DUTCHER: Other comments?

4 Dr. Krook.

5 DR. KROOK: I'll say yes.

6 (Laughter.)

7 DR. KROOK: Make it simple, Kim.

8 DR. OZOLS: Well, I'll agree it's yes,
9 too. I mean, I think I'm influenced by the adjuvant
10 data. This is an active drug. The meta analyses,
11 again, are not perfect, but they show equivalency. I
12 think it would make it difficult for patients and for
13 doctors in some sense if we just narrowly allow this
14 to approve this drug for adjuvant situation and no
15 other complications with reimbursement and so forth,
16 and not have it be available for metastatic disease.

17 CHAIRPERSON DUTCHER: Dr. Temple?

18 DR. TEMPLE: Let me inquire a little bit.
19 What I heard this morning was that evidence of
20 activity alone, which can be shown by a response rate
21 or by an effect on time to progression -- you all
22 advised us that that is not sufficient except perhaps

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1 in the narrow setting where it looks like there may be
2 an important advantage, in which case it's worth
3 taking the risk.

4 Now, how does this fit into all of that?
5 This isn't an accelerated approval case. Nobody is
6 saying this is better than what's available for
7 metastatic disease. I mean it hasn't been compared
8 with anything.

9 So why do some people say yes and some
10 people say no here? Help us fit it into this
11 morning's discussion.

12 DR. MARGOLIN: Well, I guess I'm trying to
13 be a little bit more skeptical about not the quality
14 per se, but just the convincingness of the data we
15 heard. I mean, I think we know in general in this
16 field that it's harder to influence clinical benefit
17 and survival endpoints, the gold standard endpoints
18 when treating advanced disease than it is to influence
19 similar endpoints in the adjuvant disease setting.

20 So I mean, obviously if the drug is
21 approved for its adjuvant use, it will be used in
22 advanced disease. I don't think we're saying that

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1 it's too dangerous or shouldn't be used, but simply --
2 at least I'm just interpreting the data that the
3 studies that were done for advanced disease are not
4 convincing based on the endpoints that were selected
5 and the results.

6 CHAIRPERSON DUTCHER: Dr. Krook.

7 DR. KROOK: I guess I'm looking at it as
8 a -- and I cautiously say the word. It's a little bit
9 of a "me, too," another anthracycline, and we're
10 comparing it to an active control. This is not best
11 supportive care.

12 I mean we would all like to see FEC versus
13 best supportive care and would we see a survival
14 difference. I don't know. You know, I don't think
15 we'll ever see that.

16 There may be somewhere -- I don't remember
17 -- where there's a CMF in first line breast cancer
18 versus best supportive care. I don't remember one
19 anyway. So that's my feeling, is that it's there to
20 be used if we approve it in the adjuvant, and it gets
21 into other socioeconomic problems.

22 DR. OZOLS: But would you really like to

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1 see an 800-plus equivalency trial? I mean, do you
2 think that's a good use of resources, and then to go
3 forward with an epirubicin versus doxorubicin study?

4 I mean I don't think that's a good use of
5 patient resources. Again, I agree that we should be
6 trying to look for better things than that.

7 CHAIRPERSON DUTCHER: But I think Kim's
8 point is actually valid, that the problem is the
9 disease state at the time that person is being
10 treated, no matter what combination therapy. I mean,
11 these results are no different from the results of
12 other regimens.

13 And the question is: is that an
14 approvable indication or is it -- you know, everything
15 we've heard today is saying we need new, different
16 types of drugs that are better than the older classes
17 of drugs. We don't need another similar type of drug
18 because we can't impact on this stage of the disease.
19 We can impact on other stages.

20 Now, maybe in a different combination
21 epirubicin will be a better drug. I don't know. You
22 know, I don't want it to not be available so that

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1 those trials can proceed, and they are proceeding
2 elsewhere, just not in the U.S., you know,
3 combinations with taxan, herceptin, blah, blah, blah,
4 blah, blah, some of the newer agents.

5 So is it a better anthracycline? I think
6 we don't know the answer to that so far, and so it has
7 to be studied in other combinations because in this
8 setting it's the same as everything else we have.

9 So, you know, it's tough to make -- we
10 know what we want to do, but based on the data we
11 have, it's tough to work with it.

12 So do you want to answer the time to
13 progression question or do you want to answer -- can
14 we answer the time to progression?

15 Pardon me?

16 DR. HONIG: I think the sponsor has
17 something on his mind.

18 DR. MILLER: I don't know --

19 CHAIRPERSON DUTCHER: I hope so.

20 (Laughter.)

21 DR. MILLER: I mean, i think that perhaps
22 it would be reasonable to look at the issue of how

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1 well doxorubicin has fared in the adjuvant setting or
2 anthracyclines in general have fared in the adjuvant
3 setting.

4 If I get this adjusted here, but these are
5 the data from the recently published meta analysis
6 comparing anthracycline based regimens versus CMF in
7 about 7,000 patients, and what you can see is that
8 there is a significant improvement in replace free
9 survival and in overall survival. The P value here is
10 0.02.

11 One of the things you have to know about
12 this, there were 11 studies involved in this. Of
13 those 11 studies, five were with epirubicin, six with
14 doxorubicin. The MA-5 study was among those and
15 contributed substantially to the fact that these
16 results are positive, as did several other epirubicin
17 studies.

18 So doxorubicin has proved to have some
19 benefit in the adjuvant setting, some benefit.
20 Epirubicin has also proved to have this benefit, and
21 in fact, substantial benefit as reviewed in this
22 particular meta analysis.

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1 So by inference one might assume that it
2 is, in fact, an active agent. We already have
3 established that in the adjuvant setting, and in the
4 metastatic setting, the same could be held true.

5 The other thing is that the drug does
6 provide some potential benefits over doxorubicin if
7 used in equal molar doses. It's not something we're
8 advocating. Okay?

9 We're advocating 100 milligrams per meter
10 squared, but a meta analysis was done, as Dr. Honig
11 alluded to, and in that meta analysis we looked at
12 survival in six trials as requested by the FDA, and
13 let me just find the results. Suddenly they
14 disappeared, naturally.

15 I'm sorry. It's here somewhere. Here we
16 go.

17 And what you can see, as Dr. Honig
18 mentioned, is that there's near unity in terms of
19 survival across these six trials, fairly large in
20 size, with use of the drug in the metastatic setting.

21 Now, the other thing that has been done is
22 that Dr. Levine was involved in a meta analysis that

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1 was done for the Ontario Ministry of Health to
2 evaluate epi. versus doxorubicin and try to provide
3 some guidelines to clinicians who might be considering
4 either use of epirubicin or doxorubicin, and all of
5 these trials use equimolar doses of epirubicin or
6 doxorubicin in first or second line settings, and the
7 overall results of those trials are shown here.

8 They looked at response rate, complete
9 response rate, and one year survival, and again, you
10 can see that the risk ratios are basically at unity,
11 and then there's some potential toxicity benefits to
12 the use of epirubicin as compared to doxorubicin in
13 this type of analysis.

14 So I think that it's clear that the drug
15 is active. There are data to support the notion that
16 it provides survival advantages that are similar to
17 those of doxorubicin in this setting, and there may be
18 some toxicity advantages for patients as well.

19 It's unique in the fact that it can be
20 dose escalated to provide better outcomes for
21 patients.

22 DR. WILLIAMS: Jana, I don't really think

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1 we can take the data on a bunch of literature studies
2 very seriously in our deliberations. It's
3 interesting, but it doesn't compare with the data that
4 we have.

5 I think the central question was can you
6 or can you not make the inferences that Langdon
7 mentioned, that the adjuvant data suggests that there
8 is a potential benefit here as demonstrated going from
9 disease free survival to survival in an adjuvant
10 setting.

11 Take that inference and then move it to
12 this setting and give more weight than you would
13 usually to the time to progression endpoint.

14 CHAIRPERSON DUTCHER: That's right.

15 So you say yes; you say no. You say yes.
16 Dr. Simon?

17 DR. SIMON: Well, I think obviously the
18 treatment of metastatic breast cancer is a totally
19 different therapeutic situation than the treatment of
20 adjuvant breast cancer. One is almost uniformly
21 noncurable. The other is curable in a large
22 percentage of the case.

1 So I don't think we can translate one to
2 the other. I think we have two trials here of almost
3 1,000 patients in metastatic disease, and we have to
4 make our judgment based on those two trials.

5 CHAIRPERSON DUTCHER: Okay. Other
6 comments?

7 So does the evidence of epirubicin
8 activity and survival benefit in the adjuvant setting
9 permit greater reliance on the time to progression
10 endpoint in the metastatic setting?

11 All those who would vote yes?

12 (Show of hands.)

13 CHAIRPERSON DUTCHER: One, two, yes.

14 All those who would vote no?

15 (Show of hands.)

16 CHAIRPERSON DUTCHER: One, two, three,
17 four, five, six, seven.

18 Okay. Does the 2.5 month different in
19 time to progression for FEC 100 compared to a dose
20 intense CMF regimen represent a clinically meaningful
21 effect of epirubicin in first line treatment of
22 metastatic breast cancer?

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1 Anyone?

2 DR. KROOK: I take for granted this is
3 referring to the --

4 CHAIRPERSON DUTCHER: To the MA-5 study.
5 I'm sorry. The 013 study.

6 DR. KROOK: Wait. Okay.

7 CHAIRPERSON DUTCHER: The time to
8 progression table previously.

9 DR. KROOK: Okay.

10 DR. WILLIAMS: You've already answered the
11 other question and said the time to progression wasn't
12 adequate.

13 CHAIRPERSON DUTCHER: Okay. So you want
14 us to pass that one?

15 DR. WILLIAMS: Right.

16 CHAIRPERSON DUTCHER: Okay. All right.
17 So then question number seven. Can the relapse free
18 survival results observed on the adjuvant -- let's
19 see.

20 Approval requires independent
21 substantiation of the results from the 013 study. Can
22 the reported response rate advantage for FEC 100 in

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1 study 010 have provide sufficient support? Can the
2 relapse free and survival results observed in the
3 adjuvant studies provide sufficient support?

4 I guess we've already answered that, too.

5 DR. MARGOLIN: I'll stick my neck out
6 again and say based on our discussions of the previous
7 questions, the answer would have to be no for both of
8 those.

9 PARTICIPANT: If you take the vote, it'll
10 be the same.

11 CHAIRPERSON DUTCHER: Take the vote and it
12 would be the same?

13 DR. MARGOLIN: Let's do it.

14 CHAIRPERSON DUTCHER: Okay. All those who
15 would say that they provide sufficient support.

16 PARTICIPANT: Adequate support.

17 CHAIRPERSON DUTCHER: Well, it says
18 "sufficient."

19 DR. TEMPLE: The trouble is in six you
20 said that the primary study wasn't support.

21 CHAIRPERSON DUTCHER: Right.

22 DR. TEMPLE: So there's nothing to

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1 confirm.

2 CHAIRPERSON DUTCHER: All right.

3 DR. TEMPLE: Feel free to reconsider any
4 and all of those, but the logic says that if six is
5 no, seven had got to be irrelevant.

6 CHAIRPERSON DUTCHER: All right. We can
7 accept that summary of our vote.

8 DR. MARGOLIN: Okay.

9 CHAIRPERSON DUTCHER: Do we need to keep
10 going?

11 DR. TEMPLE: Why don't you vote on nine?

12 CHAIRPERSON DUTCHER: Okay. Is epirubicin
13 as administered in FEC 100 regimen approvable for
14 first line treatment of metastatic breast cancer?

15 All those who would vote yes.

16 (Show of hands.)

17 CHAIRPERSON DUTCHER: One, two, three.

18 All those who would vote no?

19 (Show of hands.)

20 CHAIRPERSON DUTCHER: One, two, three,
21 four, five, six.

22 All right. Thank you all very much. We

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appreciate all of the careful comments.

Tomorrow we start at eight o'clock.

(Whereupon, at 5:21 p.m., the meeting was adjourned, to reconvene at 8:00 a.m., Tuesday, June 8, 1999.)

CERTIFICATE

This is to certify that the foregoing transcript in the
matter of: 62ND MEETING

Before: ONCOLOGIC DRUGS ADVISORY COMMITTEE

Date: JUNE 7, 1999

Place: SILVER SPRING, MARYLAND

represents the full and complete proceedings of the
aforementioned matter, as reported and reduced to
typewriting.

Irene Gray

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WORD RANGES @ BOTTOM
 OF PAGE

- 0 -

000-something [1] 106:8

- 1 -

100-plus [1] 105:18
 10:48 [1] 73:18
 11:10 [1] 73:19
 12A30 [2] 8:2; 187:6
 15-17 [1] 244:15
 1970s [1] 29:16
 1990s [1] 29:16
 1:08 [1] 182:15

- 2 -

2-doxorubicin [1] 179:2
 2/3 [1] 300:8
 28th [1] 15:1
 2:00 [1] 182:16
 2:04 [1] 183:2

- 3 -

3/4 [12] 210:13, 18; 211:1, 4;
 218:4, 13; 221:19, 20; 229:22;
 230:5, 8
 30s [1] 67:19
 31st [1] 193:12
 3:34 [1] 259:15
 3:54 [1] 259:16

- 5 -

5:21 [1] 337:3

- 6 -

62nd [1] 5:5

- 7 -

70s [1] 261:10

- 8 -

80-something [1] 140:2
 800-plus [1] 327:1
 80s [2] 192:4; 234:7

8:00 [1] 337:4

- 9 -

90s [1] 192:4
 9:29 [1] 5:2
 9th [1] 193:3

- A -

a.m. [4] 5:2; 73:18, 19; 337:4
 AACR [1] 69:9
 ABC [1] 226:6
 ABC-1 [4] 223:20; 224:15;
 226:15; 229:15
 ABC-2 [4] 224:2, 8; 228:4;
 229:16
 ABC-3 [2] 224:8; 227:9
 ABC-4 [2] 224:10; 228:10
 ability [5] 70:15; 109:6;
 112:12; 294:20; 308:22
 able [21] 37:22; 68:5; 70:21;
 76:17; 90:12; 92:2; 93:18;
 101:18, 20; 103:7, 9; 112:20;
 117:18; 129:15; 136:20; 160:3,
 5; 260:8; 273:7; 278:18;
 282:15
 abnormalities [3] 207:1;
 244:9, 15
 absence [3] 51:22; 275:16;
 321:12
 absolute [3] 103:10; 107:20;
 206:5
 Absolutely [2] 140:4; 310:20
 absolutely [5] 50:17; 132:11;
 143:4; 170:12; 310:21
 abstract [1] 290:21
 AC [3] 258:11, 13; 292:9
 accelerated [33] 24:17, 19;
 28:10, 16; 63:4, 12, 22; 64:3;
 65:18; 66:3; 77:10, 19, 22;
 85:16; 137:22; 152:12, 19, 21;
 153:12; 154:5; 155:14; 157:4,
 9, 11; 158:10; 162:6, 12, 16;
 163:3; 283:7, 8; 325:5
 accelerating [1] 66:14
 accept [6] 29:6; 79:5; 84:7;
 155:14; 163:20; 336:7
 acceptable [6] 52:13; 57:13;
 90:22; 268:6; 307:17; 308:4
 acceptably [2] 218:20; 222:4
 accepted [1] 289:21
 accepting [1] 144:2
 access [9] 61:17; 62:9, 11,
 20; 63:11, 13; 66:12; 189:8;
 194:12
 accommodate [1] 224:19
 accompany [1] 117:8
 accompanying [1] 198:6
 accomplished [1] 273:8
 accordance [2] 7:18; 186:22
 account [5] 60:10; 70:22;
 115:16; 209:12; 213:20
 accounted [2] 268:12; 269:1
 accounting [1] 210:5
 accumulation [2] 66:15;
 170:22
 accurate [5] 22:1, 4, 5; 50:15
 accurately [1] 65:3
 ache [1] 93:10
 achieve [3] 70:19; 143:14;
 145:8

achieved [5] 48:15; 57:7;
 109:5; 217:5; 319:21
 achieves [1] 75:2
 Ackland [1] 225:1
 acknowledge [2] 184:4;
 260:3
 acknowledges [2] 9:20;
 55:15
 Act [1] 319:2
 Acting [2] 6:16, 21
 acting [2] 71:3; 128:5
 Action [6] 9:11, 16; 10:3;
 11:4; 12:21; 15:19
 action [1] 198:10
 active [12] 32:5, 6; 34:14;
 50:7; 124:17; 149:22; 179:22;
 293:16; 324:10; 326:10; 330:2;
 331:15
 actively [1] 172:4
 activity [11] 31:2; 70:16;
 129:18; 192:11; 193:1; 197:13;
 198:16; 316:9; 323:20; 324:20;
 333:8
 actual [3] 234:19; 243:13;
 300:11
 acute [7] 212:14, 15; 215:16;
 242:13; 274:2; 282:21; 307:4
 acutely [1] 235:18
 add [11] 71:21; 114:8; 115:21;
 162:19; 171:3; 173:18; 175:1;
 186:3; 222:18; 238:11; 312:18
 added [10] 40:1; 82:18;
 107:13; 109:21; 162:8; 176:6,
 8; 178:18; 200:12
 adding [2] 193:19; 238:9
 addition [9] 8:4; 17:6; 154:6;
 187:8; 199:2; 201:9; 222:14;
 264:8, 18
 additional [13] 23:6; 53:1;
 109:15; 117:2; 127:9; 195:1;
 205:7; 222:19; 224:6; 253:16;
 274:22; 275:20; 297:11
 Additionally [2] 58:8; 191:20
 additive [1] 311:4
 address [12] 8:21; 9:13, 20;
 27:4; 58:20; 73:2; 128:10;
 188:3; 196:9; 237:1, 3; 250:5
 addressed [5] 14:15; 15:20;
 119:18; 245:9; 270:17
 addresses [5] 7:7; 63:12, 14;
 186:11; 188:11
 addressing [2] 167:16;
 290:16
 adds [1] 247:8
 adduced [1] 192:14
 adequacy [1] 138:4
 Adequate [2] 206:18; 335:16
 adequate [5] 10:21; 18:9;
 65:6; 243:8; 334:12
 adequately [1] 165:3
 adjourned [1] 337:4
 adjust [2] 242:14; 246:3
 adjusted [4] 20:5, 16; 68:16;
 329:4
 adjustments [1] 305:10
 administer [1] 301:15
 administered [7] 56:19; 59:3;
 192:7; 202:13; 208:12; 217:8;
 336:13
 Administration [2] 184:1;
 185:19

administration [8] 193:16;
 208:4; 216:17, 22; 218:11;
 242:20; 280:20; 281:2
 adria [5] 177:12; 291:11, 15;
 313:1
 adriamycin [8] 35:9; 240:8;
 247:15; 293:12, 13; 312:15;
 317:12; 321:5
 adriamycin-cyclophosphami
 [1] 36:13
 adriamycin-doxorubicin [1]
 305:6
 Adrienne [1] 67:18
 advanced [32] 20:7; 80:8;
 96:18; 196:7; 197:3; 199:18;
 200:5, 14, 18; 201:22; 223:11,
 18; 227:11, 14, 20; 229:17;
 231:13, 19; 241:16; 243:15;
 257:5; 260:15; 275:2, 4; 282:3;
 287:20; 288:2; 315:1, 9;
 325:18, 22; 326:3
 Advances [1] 299:1
 advantage [38] 21:10; 53:21;
 57:1; 71:19; 76:7; 77:12, 17,
 20; 81:10, 11, 13, 19; 109:17;
 118:19, 21; 128:22; 129:17;
 130:15; 131:19; 133:15; 134:9;
 162:13; 166:15, 21; 168:4;
 178:20; 179:8; 225:20; 241:20;
 287:19; 290:18; 293:15;
 302:13;
 315:16, 19; 325:2; 334:22
 advantages [3] 12:18;
 331:16, 18
 adverse [9] 12:2; 30:20;
 206:22; 210:13; 211:11;
 215:16; 218:19; 222:3; 229:15
 advertisements [1] 65:8
 advertising [2] 65:3, 14
 advice [4] 78:1; 120:6;
 183:20; 302:21
 advise [1] 65:10
 advised [1] 324:22
 Advisory [4] 5:5; 14:14;
 183:17; 185:20
 advisory [1] 191:5
 advocacy [3] 10:4; 73:10, 11
 Advocate [4] 190:18, 21;
 191:1; 194:4
 advocate [6] 62:8, 20, 22;
 72:15, 18; 288:10
 advocated [1] 238:17
 advocates [7] 15:11, 14;
 72:16; 169:1; 171:12; 174:3;
 185:16
 advocating [2] 330:8, 9
 affect [3] 32:2; 70:12; 114:12
 affected [3] 10:8; 78:21;
 159:17
 affects [2] 114:3, 5
 affiliation [1] 64:20
 affirmed [1] 192:5
 afternoon [4] 178:1; 182:14;
 195:8; 292:3
 afterwards [2] 272:6; 294:15
 age [4] 67:3; 207:13; 246:8;
 311:11
 agency [6] 7:12; 8:9, 12;
 186:16; 187:13, 16
 agenda [4] 7:11; 8:15;
 186:15; 187:19

- agendas** [1] 16:8
agent [25] 11:12; 13:13; 15:22; 21:18; 32:7; 41:12; 43:14; 51:20, 22; 76:3, 5; 129:1; 154:9; 170:16; 171:5; 195:1; 196:19; 224:12; 228:10, 15; 242:21; 252:17; 255:15; 261:16; 330:2
agents [24] 12:12; 21:16; 32:5, 6; 69:21; 70:11; 78:11; 98:4; 99:9; 114:19; 115:1; 117:1; 148:18; 192:8; 194:20; 205:2; 212:9, 19; 225:9; 226:22; 227:22; 233:2; 328:4
aggressive [4] 62:8, 20; 63:13; 310:3
agony [2] 67:16; 87:7
agree [25] 81:3; 98:8; 106:21; 114:14; 118:4; 121:12; 138:7; 143:5; 145:3, 4; 148:22; 151:5, 16; 156:20; 165:15; 172:10; 176:2; 179:10; 180:22; 270:11; 303:21; 324:8; 327:5
agreed [2] 155:19; 201:1
agreeing [1] 88:1
agrees [2] 87:5; 112:11
AIDS [1] 157:15
aim [2] 51:18; 299:17
aimed [1] 199:21
alive [1] 213:17
alkylating [2] 212:9; 242:21
allow [4] 15:2; 90:20; 224:20; 324:13
allowed [9] 14:6; 34:17; 129:19; 169:8; 181:16; 201:5; 205:9; 256:5; 292:16
allowing [3] 188:18; 265:8; 298:10
allows [3] 70:17; 199:3, 8
alluded [2] 283:5; 330:11
alone [10] 34:8; 189:3; 192:7; 203:10; 220:4, 16; 221:12; 316:6; 323:3; 324:20
alopecia [4] 211:2; 218:14; 221:21; 230:6
alternative [9] 55:1; 56:22; 113:20; 138:2; 166:4, 10; 167:11, 12; 245:10
Alternatively [1] 203:9
Altogether [2] 207:3; 234:20
altogether [1] 232:20
ambiguity [1] 182:5
amenable [2] 15:18; 206:13
America [1] 194:17
American [6] 89:4; 117:13; 194:11; 205:13; 258:9, 20
AML [10] 212:17; 213:1, 3, 20; 222:11; 242:1; 243:12, 14, 17; 307:15
amongst [1] 250:14
amount [7] 104:2; 236:16; 248:5; 260:6; 262:20; 276:2; 297:6
amounts [2] 44:20; 93:21
analogue [1] 192:10
analogies [1] 92:11
analogue [1] 49:10
analyses [12] 20:13; 40:14; 112:12; 168:11; 199:19; 207:10; 214:17; 267:16; 278:12; 289:8; 304:10; 324:10
analysis [50] 20:5, 6, 15, 16, 19; 39:22; 40:13; 41:3, 15; 42:3; 45:1; 58:2; 88:17; 107:3; 117:22; 119:4; 126:9; 127:11, 15; 168:3; 176:16; 181:5; 182:2; 206:8; 209:6; 210:3, 8; 213:2, 4; 238:9; 246:21; 259:20; 267:12, 14; 271:5; 272:11; 273:17; 276:17; 281:10; 284:2, 5; 285:2, 3; 294:10; 329:5, 22; 330:10, 11, 22; 331:13
analyze [5] 237:5; 262:21; 269:5; 278:10; 295:15
analyzed [3] 19:19; 134:7; 214:15
Anderson [2] 89:16; 194:1
Andy [1] 106:4
anecdotal [2] 57:8; 84:17
Anemia [1] 279:17
anemia [1] 210:18
Angeles [1] 6:11
angiogenesis [2] 69:22; 71:1
animal [2] 249:16; 311:19
Ann [3] 53:6; 298:15
Anna [1] 263:1
Annie [1] 298:16
announcement [3] 7:7; 14:13; 186:11
announcements [1] 183:4
annoying [1] 95:6
answer [46] 32:19; 37:16; 85:13; 99:4; 103:20; 104:13; 119:9; 129:4; 131:5; 132:9, 12, 14; 134:12, 19; 147:10; 149:7; 154:16; 155:1, 7, 20; 157:1; 160:2, 12; 162:3; 166:7; 170:21; 177:16; 181:11; 232:2; 248:15, 16; 257:13; 286:7; 287:3; 290:12; 308:3; 310:9; 316:8; 320:13; 323:10; 328:6, 12, 13, 14; 335:7
answered [6] 153:18, 20; 323:8; 334:10; 335:4
answers [2] 204:7; 216:12
answers [6] 15:19; 92:22; 164:15, 17; 180:19; 288:9
anthracenedione [2] 211:17; 226:1
anthracenediones [1] 242:17
anthracycline [37] 42:2, 3; 130:2, 5, 6, 10; 132:20, 22; 133:10, 13, 14; 162:2; 189:14, 19; 198:6, 19; 211:16; 226:1; 236:4; 243:18; 245:18; 246:6; 248:19; 249:18; 276:1; 278:5; 285:10; 309:12; 312:12; 313:11; 315:18; 317:20, 21; 326:9; 328:5; 329:6
anthracyclines [13] 130:12; 193:20; 198:11; 242:17; 309:12, 15, 22; 310:3, 9; 312:18; 316:21; 317:11; 329:2
anti-tumor [4] 30:8, 22; 171:4; 245:11
antibiotic [3] 189:14; 204:15; 264:1
antibiotics [1] 210:16
anticipated [2] 256:7; 272:19
antiemetic [3] 269:21; 279:14; 307:1
Anybody [2] 135:1; 287:7
anybody [7] 133:10; 145:16, 17; 171:6; 184:9; 312:17
anymore [2] 257:15; 323:18
Anyway [1] 185:11
anyway [5] 58:9; 121:9; 127:14; 155:7; 326:19
anywhere [2] 31:17; 283:16
apart [1] 33:17
apoptosis [1] 56:6
apparent [3] 94:5; 133:15; 215:4
appear [2] 268:12; 274:8
appearance [6] 7:10; 8:8; 186:13; 187:12; 213:7; 233:21
appeared [2] 235:7; 269:17
appears [4] 21:12; 198:11, 16; 268:18
appetite [1] 49:14
Appause [2] 185:2; 186:7
Appleseed [2] 53:7; 298:16
applicable [2] 159:7; 203:16
applicant [11] 267:1, 3, 16; 270:12; 271:7; 272:11; 275:4; 281:14; 284:1, 22; 307:3
application [6] 17:4; 165:21; 197:12; 260:16; 283:8; 302:18
applications [1] 17:5
applied [1] 240:2
applies [1] 122:11
apply [3] 25:21; 92:18; 179:18
appreciate [4] 52:20; 87:14; 184:15; 337:1
appreciation [1] 183:15
approach [3] 238:13; 250:14; 294:17
approached [1] 235:15
appropriate [14] 10:13; 11:8, 10; 59:4; 86:17; 96:1; 121:10, 19; 133:5; 146:11; 159:20; 233:5; 301:10; 305:10
Appropriately [1] 63:3
appropriately [2] 112:12; 121:6
approvable [4] 260:17; 314:13; 327:14; 336:13
Approval [1] 334:20
Approvals [1] 196:18
approvals [2] 157:9, 11
approve [10] 113:9; 163:17; 173:12, 20; 190:13; 302:14, 16; 324:14; 326:20
approved [23] 27:9, 16, 19; 28:1, 3, 9, 15, 19; 29:3; 44:16; 45:7, 10; 58:19; 65:5; 72:3; 84:11; 162:22; 190:6; 197:4; 199:12; 244:20; 255:14; 325:21
approving [6] 15:14; 54:2; 97:9; 140:10; 173:18; 215:8
approximate [1] 41:16
Approximately [5] 207:20; 225:5; 226:17; 227:19; 228:21
approximately [11] 43:11; 193:14; 205:16; 208:10; 212:21; 217:11; 225:9; 226:22; 262:16; 264:16; 304:8
area [7] 33:20; 90:19; 110:3; 111:14; 168:6; 170:13
areas [1] 120:1
Aren't [1] 119:1
aren't [6] 40:14; 90:1; 146:13, 17; 253:19; 321:18
argue [3] 110:1; 120:12; 321:16
arguing [2] 106:17; 115:12
argument [8] 76:19; 79:4; 80:20; 93:7; 108:20; 133:22; 165:4; 285:7
arguments [2] 78:21; 145:5
arimdex [1] 67:4
armamentarium [2] 148:13; 173:19
arms [37] 33:16; 34:18; 35:21; 36:3; 38:18; 48:9; 122:11; 173:4; 202:21, 22; 207:17; 210:15; 216:22; 218:5, 20; 219:8; 220:22; 225:8; 226:20; 227:21; 229:3; 230:14, 19, 20; 231:2; 263:4; 264:8, 13, 14, 17; 265:4, 5; 266:7; 273:9; 274:9; 277:5; 285:14
article [2] 51:2; 58:22
articulate [1] 51:2
Asails [1] 67:18
Ascend [1] 216:10
ascertainment [6] 33:15; 119:16; 125:10, 11, 13; 126:11
ASCO [3] 36:18; 37:18; 253:11
asking [9] 54:22; 79:11; 80:18; 131:5; 132:1, 2; 136:3; 240:9; 302:18
aspect [5] 38:21; 48:3; 82:11; 97:21; 99:17
aspects [2] 62:6; 192:17
assertion [1] 132:6
assess [6] 20:4; 25:21; 95:1; 134:7; 252:7; 294:20
assessed [6] 21:22; 22:3; 119:13; 205:22; 206:22; 230:22
assessing [5] 115:2; 120:3; 171:9; 208:4; 209:8
assessment [11] 23:3, 8, 9; 49:10; 118:12; 214:4; 224:20; 232:8; 270:12; 296:21
assessments [5] 23:10; 24:3, 4; 92:17; 118:14
assign [1] 268:20
assigned [6] 121:4; 204:12; 207:4, 5; 216:15; 220:15
assignment [1] 17:10
assist [3] 196:12; 204:7; 216:12
assistance [1] 188:15
association [15] 17:22; 48:22; 135:19; 150:22; 199:17; 206:5; 209:13; 210:9; 245:2, 14; 266:17; 268:17; 269:14; 270:20; 274:2
association [1] 152:6
assume [6] 120:7; 128:13; 153:17, 20; 311:1; 330:1
assumes [1] 143:9
assuming [1] 155:19
assumption [3] 119:9, 11; 190:6
assurance [2] 18:20; 19:7

assure [2] 15:8; 143:3
asthenia [1] 233:13
astonishingly [2] 87:18, 20
asymptomatic [21] 39:2;
 48:16; 89:19; 98:21; 100:11;
 18:6; 140:3, 13, 22; 144:11,
 12, 13; 146:18; 172:2; 211:22;
 219:4; 272:1; 296:3; 297:4, 15;
 307:12
attack [1] 109:14
attempt [1] 304:20
attempting [1] 319:15
attempts [2] 75:13; 92:19
attended [1] 184:9
attention [8] 64:22; 84:13, 17;
 94:12; 148:20; 169:22; 231:21;
 320:7
attitude [2] 122:19; 185:22
attractiveness [2] 233:22;
 234:12
attributable [1] 143:10
attribute [2] 265:9; 274:20
attributed [1] 205:5
audience [4] 43:21; 51:7;
 53:2; 74:3
auditors [1] 121:10
audits [1] 121:11
August [1] 193:3
Australia [1] 225:2
Australian [1] 47:7
author [2] 40:18; 51:1
authority [2] 14:11; 63:19
authors [2] 49:18; 317:10
automatically [1] 117:17
AV [1] 35:13
availability [3] 24:9; 194:11,
 17
available [47] 16:7; 20:8, 11;
 42:20; 45:22; 53:9; 77:12, 17;
 82:10; 83:15, 21; 97:7; 124:21;
 125:4, 7, 17; 129:9; 130:12;
 131:1, 6; 133:6; 135:9; 157:14;
 162:14, 19, 21; 190:4; 197:5;
 201:10, 11; 244:6; 251:11;
 252:18; 253:19; 269:22;
 279:15;
 290:8; 316:21; 318:9; 319:5;
 322:20; 324:16; 325:6; 327:22
average [5] 108:9, 11; 109:1;
 288:16
award [3] 185:4, 11; 186:1
aware [4] 8:17; 132:3; 187:21;
 240:7
awareness [1] 189:1
awfully [1] 54:12
axillary [14] 191:9; 201:17;
 202:7; 203:21; 204:12; 206:14;
 215:10; 216:5, 13; 219:13;
 220:5, 12; 231:5; 300:1

- B -

background [1] 195:20
balance [2] 181:2; 267:11
balanced [14] 34:17; 207:14;
 208:1; 216:21; 220:22; 221:8;
 225:7; 226:19; 227:21; 229:3;
 264:8, 14, 15, 21
Barbara [3] 9:10; 16:4; 27:2
Based [7] 7:11; 186:15;
 197:17; 199:19; 201:13;

218:22; 307:7
baseline [15] 23:9, 17; 41:5;
 94:14; 95:4; 111:17, 18; 119:4;
 158:8; 206:18; 209:8, 10;
 263:6; 296:9; 297:4
bases [2] 18:9; 150:10
basic [2] 190:10; 288:1
basically [9] 103:8; 118:11;
 140:5; 163:16; 246:15; 296:3;
 317:3; 323:6; 331:10
basis [23] 11:18; 41:21; 46:3;
 64:5; 77:14, 16, 18; 78:2;
 79:16; 80:6; 96:7; 99:2;
 104:19; 128:2; 150:15; 153:15;
 157:16; 158:20; 200:4, 21;
 204:10; 251:20; 322:5
BCQ [2] 214:4; 215:4
BEAMAN [6] 6:12; 86:14;
 167:10; 232:7, 11; 233:9
Beaman [3] 6:12; 86:13;
 184:14
beauty [1] 241:1
becomes [4] 22:13; 95:9;
 97:7; 102:1
becoming [1] 168:5
beg [1] 299:17
begs [1] 102:7
behalf [1] 190:22
behavior [2] 148:16; 159:22
beings [1] 256:4
BEITZ [5] 6:16; 130:20; 171:8,
 21; 172:10
Beitz [3] 6:16; 130:19; 170:10
Belgium [1] 227:17
belief [2] 125:18; 190:11
believable [1] 24:2
believe [20] 10:21; 22:14;
 62:13; 64:10; 65:17; 68:17;
 75:9; 152:17; 154:2; 163:4;
 173:6, 11; 175:9; 189:11;
 238:4; 268:18; 304:16; 313:14;
 320:10, 13
believer [1] 173:6
believes [4] 11:4; 125:22;
 134:3; 189:7
believing [1] 321:11
belonging [1] 190:5
beneficial [5] 79:2, 10;
 116:11; 205:4, 10
benefits [21] 14:12; 45:3;
 78:22; 82:15; 138:3; 149:2;
 203:18; 215:12; 219:21;
 222:19; 231:18; 269:3; 274:3;
 286:16, 21; 288:7; 289:6, 18;
 295:16; 330:6; 331:11
benefitted [1] 209:19
benefitting [1] 269:10
Bethesda [1] 5:14
bi-monthly [1] 59:1
bias [12] 33:15; 117:18;
 119:16; 120:13, 15; 123:17,
 22; 124:19; 125:10, 11, 13;
 284:16
biased [1] 172:9
biases [7] 74:21; 93:3, 7, 18;
 94:4; 125:20; 126:11
bigger [5] 105:22; 109:8, 12;
 110:5; 124:6
biggest [1] 245:17
billed [1] 94:15
biologic [6] 11:22; 12:1, 11;

31:2; 37:10; 115:1
biological [1] 99:9
Biologics [1] 29:5
biologics [2] 28:22; 70:6
biology [1] 132:12
biostatistician [1] 114:8
biotech [2] 61:22; 62:15
biotechnology [1] 65:22
bisantrene [1] 43:18
bit [12] 29:9; 81:15; 123:10;
 152:8; 155:12; 245:20; 247:10;
 281:13; 299:7; 324:18; 325:13;
 326:8
Blackstein [1] 228:19
blah [5] 328:3, 4
blind [2] 121:16; 122:13
blinded [1] 75:13
blinding [5] 75:4, 10; 119:19;
 120:1; 121:13
blood [3] 189:20; 279:21;
 280:5
blue [1] 247:3
blur [1] 64:14
board [4] 159:7; 191:1, 6;
 194:15
Bob [8] 5:16; 6:21; 103:7;
 108:15; 132:17; 142:2; 145:22;
 309:6
body [3] 135:13, 16; 150:15
Bonadonna [4] 257:6; 273:6;
 282:6, 9
bone [7] 31:19; 33:9; 92:9;
 93:11; 124:13; 159:18; 191:22
Bonnetterre [3] 216:9, 11;
 232:1
borderline [2] 48:2; 319:21
BORWHAT [1] 190:20
Borwhat [1] 190:21
bound [1] 284:11
boundaries [1] 64:15
boxes [1] 297:13
break [2] 73:14; 259:12
breakdown [1] 317:18
breakthrough [1] 63:14
Breast [11] 9:11, 16; 10:3;
 11:4; 12:21; 15:19; 31:14;
 61:20; 188:20; 194:3; 208:12
Brenner [3] 9:10; 16:4; 27:2
bride [1] 68:6
brief [1] 91:4
briefly [3] 110:8; 235:10;
 298:8
bringing [1] 30:16
brings [1] 290:4
broad [3] 27:20; 175:10;
 197:13
broadens [1] 70:15
broader [2] 62:6; 63:15
broken [1] 54:5
Bruffman [1] 226:12
build [3] 166:20, 22; 259:4
Building [2] 8:3; 187:7
built [2] 15:9; 74:14
bulk [3] 89:13, 19; 157:13
Bull [1] 291:5
bunch [1] 332:1
burner [1] 169:6
Burroughs-Wellcome [1]
 69:10
business [5] 58:15; 87:10;
 169:12; 170:13; 197:7

busy [1] 64:22

- C -

CA [1] 128:1
CAF [7] 290:19; 291:5, 11, 19;
 293:21, 22
calculate [1] 312:14
calculated [2] 30:1; 33:7
calculates [1] 30:18
calculating [1] 213:21
calculation [1] 101:12
calculations [3] 307:3, 9, 14
California [2] 6:11; 61:20
call [10] 26:16; 28:4; 40:13;
 46:16; 60:17; 84:12; 88:2;
 113:15, 20; 148:11
calling [1] 10:11
campaigns [1] 65:4
Canada [6] 204:1; 228:19;
 289:16; 290:8; 291:22; 312:22
Canadian [1] 293:2
Cancer [20] 5:16, 18, 22; 6:5;
 9:11, 16; 10:3; 11:4; 12:21;
 15:19; 56:11; 61:11, 14, 20;
 112:1; 188:20; 194:3; 204:1, 3;
 220:8
cancers [3] 58:12; 63:6; 239:5
capacity [1] 248:19
Capcitabine [1] 28:15
Cardiac [1] 279:9
cardiac [17] 193:22; 194:7;
 206:18; 207:1; 211:17; 219:3;
 247:17; 248:6; 270:14; 271:17;
 272:3, 4; 274:4; 281:4; 283:1;
 288:5; 312:15
cardioprotectors [1] 193:19
cardiotoxicity [11] 190:1;
 245:2, 11, 14; 246:10; 247:2,
 19; 248:11; 249:10, 17; 312:5
cardiotoxics [1] 193:20
cardiovascular [1] 110:3
care [3] 57:17; 59:6; 95:10;
 117:2; 298:22; 326:11, 13, 18
careers [1] 166:21
careful [8] 22:19; 62:22;
 64:10; 86:1; 121:6; 304:21;
 311:13; 337:1
carefully [5] 33:6, 7; 61:2;
 73:11; 289:17
Carole [1] 67:2
Carolyn [2] 6:12; 184:14
carried [1] 239:19
carries [1] 173:15
carry [1] 10:7
case [42] 12:10; 42:22; 44:14;
 78:17; 79:13, 21; 81:5, 9; 85:1;
 91:16; 95:8; 121:7; 129:22;
 131:20; 132:17; 133:5, 18, 21;
 141:8; 143:11; 159:3; 177:6, 8,
 21; 181:15; 212:15; 213:14;
 258:3; 268:5; 285:14; 288:14;
 294:27; 296:11; 297:4, 9,
 11; 315:22; 325:2, 5; 332:22
cases [24] 12:9, 22; 36:1;
 81:22; 84:22; 99:19; 121:13;
 130:7; 179:13; 190:5; 212:13,
 14; 243:3, 11, 13, 14, 16;
 244:13; 261:17; 266:16; 271:5;
 281:16; 303:12, 17
categories [1] 17:21

- category** [1] 274:6
caution [1] 86:7
cautiously [1] 326:8
caveat [1] 157:2
caveats [1] 40:12
cell [3] 56:5; 68:1; 189:21
cells [1] 198:22
ensor [1] 147:13
censored [4] 30:9; 38:12; 127:10; 294:19
censoring [3] 295:4, 6, 9
Center [7] 5:17, 22; 6:5; 7:14; 186:18; 204:3; 274:13
center [6] 220:14; 227:13; 264:21; 292:19, 20
centering [1] 34:2
centers [10] 64:21; 204:1; 216:8; 220:8; 225:1; 226:12; 227:17; 228:19; 292:20, 22
central [5] 121:3; 122:2, 14, 21; 332:5
Centre [1] 216:10
cerebral [1] 281:3
certificate [1] 184:2
certificates [1] 184:5
cetera [9] 34:3; 67:15; 100:1; 121:7; 127:5; 152:15; 278:13; 280:4
CF [1] 253:17
Chair [3] 26:1; 290:12; 292:17
chair [2] 184:18; 186:4
chairing [1] 5:6
Chairman [2] 19:2; 61:19
challenge [2] 59:19; 69:5
challenges [1] 120:20
challenging [2] 26:10; 120:19
chance [2] 40:10; 56:19
change [17] 50:1; 59:18; 94:22; 98:17; 99:3; 102:9; 104:2; 141:3; 146:3; 148:15; 166:8, 9; 167:5; 214:12; 271:7; 298:19, 20
changed [5] 57:15; 157:16; 197:9; 252:6; 296:16
changes [5] 10:9; 116:14, 15; 141:13; 253:6
changing [2] 13:8; 59:15
characteristics [11] 94:15; 207:12, 22; 209:11; 216:21; 220:21; 225:7; 226:19; 227:21; 229:2; 271:2
characterize [1] 260:21
characterized [2] 13:21; 197:22
chart [1] 121:10
Chase [1] 5:16
check [1] 297:13
chemo [7] 68:2; 69:12; 70:3, 6, 11; 143:1; 315:3
chemo'ed [1] 67:17
chemotherapeutic [2] 12:12; 13:22
chest [6] 23:16; 264:3, 5; 311:4, 12; 312:3
CHF [8] 212:4, 6; 219:6; 246:12, 13; 248:6; 272:15; 313:20
Chicago [1] 6:3
child [1] 93:12
Children [1] 6:15
choice [7] 68:9; 98:2, 3; 143:14, 15; 292:6; 297:19
choices [5] 141:5; 164:18; 189:10, 12; 190:12
choose [8] 85:10; 237:18; 289:18; 292:8, 11, 12; 293:4, 20
choosing [1] 55:14
chose [3] 35:2; 237:9; 256:15
chosen [3] 258:13; 273:5; 282:7
chromosomal [1] 271:5
chromosome [1] 244:8
cigarette [1] 61:21
circulating [1] 112:2
circumstance [1] 126:4
circumstances [4] 11:7; 47:2; 121:19; 131:20
cited [2] 131:20; 311:22
citing [1] 194:17
City [2] 6:10; 298:16
claim [1] 152:4
claiming [1] 152:7
clarification [3] 119:8; 294:4; 301:22
clarify [3] 251:7, 15; 321:17
clarifying [2] 178:13; 322:6
clarity [1] 203:14
class [2] 190:6, 8
classes [1] 327:16
classic [6] 35:3, 6; 257:6, 8; 273:6; 282:6
classically [1] 242:17
classification [1] 242:2
clear [15] 18:14; 51:15; 66:8; 81:12; 142:18; 149:22; 177:21; 182:3; 219:10; 231:17; 247:16; 249:9; 280:2; 302:9; 331:14
clearance [1] 199:5
clearer [1] 180:17
clinic [2] 116:9; 234:14
Clinical [3] 50:21; 189:13; 234:8
Clinically [1] 161:7
clinically [9] 161:5; 165:6; 210:12; 214:13; 215:3; 218:3; 229:14; 268:19; 333:20
clinician [2] 149:13; 150:21
clinicians [2] 247:5; 331:3
closed [1] 175:4
closer [1] 73:3
closest [1] 47:15
closing [2] 25:13; 72:14
CMF-like [2] 35:10; 46:8
CMF-prednisone [1] 35:14
CMFP [1] 35:13
Coates [3] 50:11; 90:7; 151:8
codified [1] 203:12
cohort [2] 234:9; 239:21
coincidence [1] 316:3
Collaborative [1] 220:8
collate [1] 244:1
colleagues [4] 26:6; 113:12; 147:8; 231:22
collect [3] 71:12; 100:5, 10
collected [2] 238:16; 296:8
collection [2] 218:12; 276:16
colony [1] 307:2
colorectal [2] 20:7, 10
column [1] 282:12
columns [1] 229:18
combination [25] 19:4; 38:5, 7, 16; 46:4; 70:6; 92:5; 177:7; 189:14; 192:8; 193:17; 194:21; 196:22; 208:20; 249:13, 14; 255:15; 261:11, 18; 300:17; 306:12; 307:18; 314:12; 327:10, 20
combinations [3] 245:3; 328:3, 7
combined [3] 68:16; 170:16; 223:2
combines [1] 65:18
combining [1] 176:16
comfort [2] 155:11; 235:20
comfortable [8] 58:17; 78:14; 79:21; 137:13; 144:6; 155:11, 12; 163:11
coming [7] 115:1; 154:5; 188:15; 255:16; 258:16, 17; 296:14
comment [31] 9:1; 43:15; 62:6; 80:19; 83:5; 94:20; 120:17; 124:3; 125:9; 151:5; 167:10; 168:18; 174:22; 188:5; 205:7; 234:1; 235:10; 236:3, 9, 10; 238:12; 254:17; 256:19; 287:8, 9; 289:2; 298:7; 306:22; 308:1, 15; 318:1
commentary [1] 80:14
commenting [1] 138:4
Comments [1] 180:20
comments [24] 74:2, 7, 11; 77:10; 80:10; 92:22; 113:7; 114:17; 137:13; 141:3; 176:8; 186:9; 194:16; 257:13; 259:6; 288:20; 289:4; 294:2; 304:20; 308:6; 313:3; 324:3; 333:6; 337:1
commercially [1] 125:17
Committee [5] 5:5; 9:12; 14:14; 183:17; 185:20
committees [1] 121:4
common [13] 19:10; 23:7; 59:12; 120:4; 189:18; 206:1; 210:14; 211:5, 8; 262:7; 267:18; 275:8; 291:22
commonly [2] 233:1; 289:20
community [7] 62:8; 169:18; 175:10; 183:21; 250:4; 254:4; 312:11
companies [14] 23:5; 24:12; 30:15; 55:20; 63:20; 65:4; 66:3; 69:5, 18; 94:7; 121:4; 146:1; 172:4; 299:6
company [10] 25:1; 53:12; 58:16; 61:22; 66:9; 166:15; 177:15; 201:20; 286:15; 302:9
comparability [1] 284:12
comparable [10] 42:13, 18; 136:1; 208:15; 217:9; 274:10; 284:14; 286:21; 291:11; 321:18
comparative [2] 119:4; 255:5
comparator [5] 172:18; 256:22; 273:5; 315:16
compare [8] 102:22; 111:17; 112:7; 247:17; 258:17; 265:4; 322:20; 332:3
Compared [1] 225:12
compared [41] 19:6; 40:2; 44:4, 10; 54:3; 119:2, 4; 133:9; 181:22; 193:1; 214:1; 218:9; 221:11; 253:6; 256:11, 21; 267:8; 270:3; 273:3, 11, 18; 276:21; 277:9, 20; 278:1; 279:1, 18; 280:10, 17; 282:11; 283:3; 290:19; 291:9; 293:22; 301:22; 302:1; 315:20; 325:7; 331:12; 333:19
compares [2] 246:21; 257:7
comparing [14] 28:6; 38:4; 45:7; 75:21; 90:9; 179:1; 209:2, 21; 217:18; 224:9; 231:1; 284:3; 326:10; 329:6
Comparison [1] 202:16
comparison [14] 21:20; 179:6; 205:9; 210:1; 223:22; 227:5; 237:10; 240:14, 16; 256:20; 267:6; 274:4; 284:15; 303:4
comparisons [4] 41:11; 42:1, 6; 75:20
compassionate [1] 66:12
compel [1] 10:8
compensation [1] 191:2
competition [2] 241:18; 288:22
complaints [1] 124:1
complementary [1] 55:1
Complete [1] 230:18
complete [12] 23:3; 46:5; 70:20; 78:19; 96:22; 97:3; 192:15; 193:9; 231:16; 238:14; 281:20; 331:8
completed [15] 191:14; 201:4; 208:5; 215:19; 217:2; 234:17, 21; 236:12; 237:8, 11, 21, 22; 240:12; 251:10, 22
completely [11] 57:12; 58:7; 76:8; 111:10; 143:5; 172:10; 181:20; 182:2; 235:11; 237:7; 313:16
completes [1] 26:1
completing [2] 235:13; 238:5
completion [9] 204:20; 208:13; 212:20; 219:16; 221:7; 236:20; 250:13; 262:12; 272:4
complex [3] 27:3; 52:11; 112:16
complexity [2] 9:21; 113:2
compliance [3] 235:1; 237:13; 281:19
compliant [1] 281:7
complicated [9] 9:16; 15:5, 18; 66:13; 84:2; 95:6; 133:8; 179:21; 257:20
complications [5] 32:22; 46:22; 180:10; 280:14; 324:15
component [7] 119:20; 191:8; 195:16; 196:22; 201:15; 222:18; 231:4
components [1] 91:10
compound [1] 193:2
compounded [1] 23:21
comprehensive [2] 214:17; 269:12
compromising [1] 245:11
computed [1] 214:10
conceivable [1] 110:11
conceivably [2] 77:18, 22
concept [2] 128:4; 142:19
concern [15] 8:12; 63:12, 15;

81:4; 82:8, 9; 83:11; 111:15;
124:2; 149:14; 187:15; 211:18;
233:13; 246:11; 288:4
concerned [9] 19:20; 39:14;
85:20; 86:4; 112:22; 179:4;
47:7; 268:21; 290:6
concerns [6] 53:19; 73:2;
110:18; 156:3; 175:11; 288:8
concertedly [1] 242:10
conclude [9] 50:6, 19;
150:16; 151:2; 303:3, 7; 321:7,
8, 10
conclusion [9] 15:16; 87:21;
90:21; 96:5; 215:6; 219:9;
260:22; 263:3; 304:1
conclusions [4] 179:11, 18;
181:21; 196:9
concomitant [1] 263:22
concrete [2] 126:16; 288:9
concurrence [1] 137:17
concurrent [1] 242:20
condition [2] 51:21; 192:21
conditional [2] 63:4; 71:11
conditions [1] 51:14
conduct [3] 110:20; 146:2;
205:8
conducted [10] 157:5;
196:11; 200:7; 201:1, 3, 14;
203:19; 242:22; 249:7; 251:21
confer [3] 43:8; 44:2; 52:13
confidence [2] 284:10, 11
confident [1] 255:1
confined [1] 213:13
confirm [3] 174:22; 222:17;
336:1
confirmable [1] 303:3
confirmation [2] 153:12;
158:11
confirmed [1] 228:4
conflict [9] 7:2, 6, 8, 15; 8:9;
186:9, 11, 19; 187:12
confound [3] 13:10; 82:4, 19
confounded [3] 80:22;
148:18; 285:9
confounder [1] 112:13
confounding [2] 82:8; 317:2
confronted [1] 122:18
confuse [1] 82:19
confused [2] 300:21; 302:14
Congestive [1] 230:11
congestive [11] 192:1;
193:13; 212:1; 222:10; 245:16;
271:21; 272:10; 281:11, 22;
307:4, 10
congratulate [1] 73:8
conjunction [3] 86:2; 175:5;
249:8
cons [1] 27:11
consequence [1] 197:15
consequences [2] 12:3;
280:3
conservation [2] 192:20;
257:22
conservative [1] 93:13
consider [14] 15:22; 41:15;
62:19; 90:11; 91:1; 95:18;
100:4; 130:20; 249:13; 283:1,
6; 294:17; 300:22; 316:8
considerable [1] 236:21
considerably [2] 102:17;
152:22

consideration [6] 13:8; 52:15;
95:15; 112:11; 140:20; 259:22
considerations [2] 14:10;
16:19
considered [18] 10:14; 17:3;
18:8; 75:16; 76:21; 86:19;
133:20; 169:4; 177:3; 179:6;
211:14; 214:13; 233:5; 245:1,
6; 283:14; 295:3; 315:10
considering [1] 331:3
considers [1] 65:1
Consistent [1] 206:7
consistent [4] 185:16; 242:3;
248:7; 271:6
consistently [6] 223:3;
230:15, 19; 267:21; 268:9, 13
consists [1] 214:7
consolation [1] 68:5
constant [3] 171:1; 265:15;
279:22
constitute [3] 8:7; 187:10;
295:2
constitutes [2] 111:22;
121:21
consumer [4] 6:13; 65:20;
183:19; 184:15
consumers [3] 64:9, 19;
185:7
containing [6] 35:9; 46:6;
221:2, 10; 289:14; 290:19
contending [1] 293:17
context [14] 10:12; 13:7;
83:14; 86:17; 129:8; 130:11;
139:16; 147:4; 152:18; 162:7;
175:7; 209:8; 240:1; 283:7
continue [16] 34:13, 17;
46:14, 18; 47:1; 61:6; 63:19;
71:10, 12; 98:22; 99:15; 106:2;
146:17; 147:5; 156:7; 181:16
continued [3] 46:12; 48:19;
49:7
continues [2] 9:21; 84:21
continuous [4] 47:6, 9, 20;
213:19
contrast [1] 280:7
contribute [1] 136:20
contributed [3] 92:3; 280:4;
329:15
contribution [1] 251:13
control [31] 16:21; 17:18;
20:20; 21:5; 47:15; 76:3;
108:4; 119:2; 128:5, 17, 21;
130:2; 179:4; 180:1; 200:18;
203:3; 205:8; 230:20, 22;
287:17, 20, 21; 305:1; 316:9;
319:19, 20; 320:2, 4; 322:11;
326:10
controlled [22] 17:16; 18:13;
21:8, 11, 14; 25:9, 17; 128:13,
16; 134:7; 176:16; 197:22;
200:2; 201:4; 202:5; 215:7;
223:16; 231:8, 14; 251:22;
299:22; 314:21
convenient [1] 258:14
convention [1] 69:9
conventional [1] 70:4
convert [2] 24:19; 102:8
converted [2] 102:12, 13
convey [1] 310:1
conveyed [1] 258:20
conveys [2] 283:12, 15

conviction [1] 183:18
convinced [3] 86:10; 87:16;
136:9
convincing [2] 309:21; 326:4
convincingness [1] 325:14
Cooper [2] 40:1, 2
cooperative [9] 89:4; 94:8;
105:13, 17; 106:15; 122:1;
123:11; 159:16; 250:14
Copenhagen [1] 193:15
Copies [2] 7:22; 187:4
copies [4] 16:6; 53:8; 74:4;
188:11
core [1] 15:22
corners [1] 305:2
correlate [8] 42:21; 50:10;
55:4; 96:5; 149:3, 4; 167:7;
298:3
correlated [4] 53:22; 137:5;
150:12
correlates [1] 81:8
correlation [1] 127:3
corresponding [2] 203:14;
205:2
corresponds [1] 137:2
corroborate [3] 217:14;
219:20; 254:3
corroborating [1] 254:6
Cosmetic [1] 319:2
cost [2] 145:1; 174:5
cotrimoxisol [1] 204:16
Council [1] 61:20
counted [4] 22:12; 30:10;
104:9
counting [2] 104:11; 294:8
countries [6] 130:22; 191:18;
196:15, 17; 225:1; 226:12
country [1] 255:18
counts [1] 189:21
couple [9] 45:17; 74:10;
92:21; 113:7; 157:21; 161:21;
238:22; 266:10; 304:19
coupled [1] 139:4
course [29] 12:9; 22:12;
56:21; 58:13; 75:12; 78:1;
79:2; 87:2; 90:15; 91:15;
109:15; 111:19; 120:13;
139:13; 145:13; 155:12; 165:9;
176:3; 212:20; 213:13; 243:1;
244:1; 245:17; 246:7; 253:18;
270:11; 301:17; 303:16; 312:6
cover-up [1] 22:18
Cowan [1] 43:17
CPT [2] 20:10, 16
CR [3] 46:5, 14; 48:15
Craig [1] 19:1
crawling [1] 54:4
crazy [1] 133:16
create [3] 8:8; 187:12; 188:22
credible [3] 76:20; 132:6;
147:19
criteria [7] 112:2, 4, 5; 206:1;
238:1; 254:11; 263:15
critical [6] 64:6; 75:10;
145:11; 208:20; 215:11;
230:13
critically [2] 167:18; 252:1
criticism [1] 19:10
cross [2] 13:1; 130:3
cross-resistance [1] 192:19
crossed [5] 21:11; 37:15;

38:11; 83:1; 318:5
crosses [1] 147:11
crossing [1] 20:19
Crossover [1] 21:5
crossover [22] 13:4, 10; 21:3;
37:9; 38:18, 19; 66:11; 71:19;
78:22; 79:1; 83:6, 9; 84:4;
128:15, 21; 285:9; 316:10, 17;
317:2; 318:13, 18; 321:12
crucial [1] 102:7
crux [1] 154:19
cumulative [10] 193:18;
245:1, 18; 246:6, 17; 248:1;
270:20; 272:15; 310:19;
313:21
curable [1] 332:21
cure [3] 45:2; 141:12; 302:12
curious [1] 241:19
current [7] 8:22; 55:2; 60:12;
63:3; 65:17; 188:4; 261:2
currently [7] 10:20; 64:4;
172:6; 196:14; 197:19; 205:17;
221:16
curve [6] 141:17; 248:7;
277:13, 18; 311:9, 20
curves [20] 13:21; 41:17;
209:3, 22; 213:6, 8, 16, 18, 22;
217:18, 22; 221:14, 16; 238:7;
263:2; 266:11; 267:20; 272:13;
313:18
cut [1] 305:2
Cutaneous [1] 211:6
cutaneous [2] 218:17; 230:9
cycle [6] 202:14; 222:6;
265:18, 19; 277:8; 300:13
cycles [17] 33:17; 46:6; 47:11,
13, 14; 48:9; 49:12; 204:20;
208:5; 217:3; 220:18; 221:7;
258:15; 262:9; 275:18, 20
cyclophosphamide [13]
27:18; 202:11, 17; 204:22;
208:7, 17; 215:14; 224:17;
240:1; 300:17; 306:12; 307:19;
314:13
cytogenetic [2] 244:4, 5
cytonan [6] 239:3, 8; 265:7,
14; 274:18; 276:22
cytonan/5 [1] 274:22
cytotoxic [12] 16:21; 18:2, 7;
19:1; 27:10, 16; 80:7; 114:19;
128:11; 154:7, 9; 198:12
cytotoxicity [1] 310:18
cytoxan [1] 277:11

- D -

daily [2] 220:18; 264:10
damned [1] 59:9
dangerous [2] 94:1; 326:1
dangers [1] 62:17
Data [3] 202:4; 223:15; 229:17
database [10] 87:19, 21; 97:6,
7; 243:7; 251:10; 270:22;
271:15; 272:12; 307:6
date [8] 23:22; 24:1; 30:1, 18;
33:11, 18; 42:11; 176:4
dates [1] 33:13
daughter [4] 67:20, 21; 68:4,
6
Davenport-Ennis [2] 190:17,
22

- Davey** [1] 263:1
David [2] 7:21; 187:2
davosamine [1] 198:9
day [30] 14:20; 21:22; 22:2; 57:11; 113:4; 182:17; 265:22; 266:1, 2; 277:9, 10; 291:6, 8, 15; 301:13, 16; 302:2, 5, 7; 303:15
days [5] 110:5; 266:2; 277:9, 10; 320:8
De [1] 87:13
deal [5] 119:15; 125:14; 170:6; 172:13; 309:6
dealing [2] 95:20; 128:13
deals [1] 185:6
dealt [1] 126:12
Dear [1] 9:12
death [18] 18:15; 22:12, 15, 18; 23:22; 24:2; 30:3, 20; 38:10; 55:7; 67:17; 101:19; 210:11; 213:18; 230:12; 294:22; 295:1
deaths [16] 18:17; 101:13, 19; 109:16; 161:20; 211:12; 215:20; 218:21; 219:18; 230:13; 270:10; 278:22; 279:4, 5; 280:12, 16
debatable [1] 107:15
debate [2] 62:6; 171:1
debated [1] 319:17
decades [1] 64:8
decant [4] 54:21; 60:11; 88:6, 8
decide [5] 17:8; 100:8; 172:21; 290:10; 302:15
decided [1] 60:3
decimal [1] 128:2
decision [6] 36:8; 102:19; 137:6; 160:22; 197:7; 302:20
decisions [4] 68:7, 14; 99:2; 174:8
decline [2] 211:22; 292:13
declines [1] 219:4
declining [1] 13:20
decrease [5] 32:13; 39:7; 122:5; 188:22; 214:22
decreased [4] 36:3; 43:1; 48:20; 297:22
decreases [2] 122:8; 307:12
decrement [2] 118:9, 15
decrements [1] 215:21
dedicated [1] 62:7
dedication [1] 183:10
deepest [1] 183:15
default [1] 267:13
defend [1] 249:1
define [10] 29:9, 20, 22; 42:9; 156:9; 159:10; 160:5, 20; 161:6, 8
defined [7] 30:13; 33:22; 41:20; 169:14; 255:21; 276:5; 294:13
defines [1] 38:9
defining [1] 162:20
definite [1] 198:20
definitely [3] 123:22; 148:15; 182:1
definition [7] 29:12, 17; 38:13; 40:8; 55:6; 152:20; 159:21
definitions [2] 111:21; 121:20
definitively [2] 30:13; 205:5
degree [1] 155:18
delay [10] 32:21; 46:21; 76:12; 103:13; 109:4; 113:22; 126:1; 144:9, 10
delayed [4] 54:1; 142:12; 173:17; 262:11
delaying [3] 32:20; 142:7; 274:11
delete [1] 62:4
deliberations [3] 45:16; 185:19; 332:2
deliver [1] 253:8
delivered [4] 274:18; 277:8; 282:9; 300:11
delivers [1] 191:21
delivery [2] 97:22; 109:3
demands [1] 59:15
demonstrable [1] 144:4
demonstrate [19] 60:6; 86:3; 91:8; 111:3, 5; 118:8, 9, 20; 135:12; 200:8; 215:7; 219:10; 222:13; 231:8; 283:20; 290:18; 300:15; 306:10; 307:17
demonstrated [10] 14:12; 17:16; 81:9; 96:3; 110:12; 135:9; 289:6; 315:15; 316:14; 332:8
demonstrates [2] 200:11; 315:12
demonstrating [2] 316:6; 323:4
Demonstration [1] 206:14
demonstration [3] 51:19; 118:15; 232:9
denominator [4] 76:10; 103:17; 106:19; 109:21
dent [1] 97:18
depend [3] 121:20; 163:22; 179:22
dependent [1] 33:13
depending [8] 31:17; 74:17; 77:22; 91:12; 122:19; 268:3; 273:16; 283:17
depends [5] 103:8; 104:8; 141:9; 155:1; 183:19
depicts [1] 213:2
depression [1] 233:15
Deputy [1] 6:16
derivative [1] 198:5
describe [6] 136:14; 157:6; 195:14, 22; 202:2; 223:8
described [4] 40:8; 74:20; 119:15; 234:13
describes [2] 17:22; 229:14
describing [1] 14:15
design [20] 21:19; 57:18; 72:20; 94:18; 100:5; 120:22; 133:7; 165:20; 200:15; 204:21; 205:3; 206:8; 208:6; 224:8; 240:22; 252:2; 253:4, 11; 275:9, 18
designated [2] 202:10; 203:8
designed [17] 11:15; 34:16; 66:11; 105:2; 121:6; 132:18; 166:20; 214:5; 233:3; 258:8; 263:13, 15; 265:13; 273:7; 282:5; 297:12; 319:10
designing [1] 76:11
designs [7] 201:5; 240:18; 252:9, 12, 21; 253:22; 287:22
desire [1] 62:21
desired [1] 318:8
desk [3] 16:7; 74:4; 108:5
desperate [1] 64:18
desperation [1] 87:11
Despite [2] 208:17; 214:20
despite [5] 71:17; 75:1; 87:16; 215:13; 239:9
detail [5] 30:5; 260:9; 265:1; 268:4; 279:7
details [1] 279:3
detect [10] 21:17; 70:15; 76:10; 101:18, 20; 103:9; 105:14; 106:16; 109:6; 165:6
detectable [1] 163:8
detecting [2] 101:10; 105:3
deterioration [1] 150:22
determinant [2] 92:1; 109:8
determine [6] 11:10; 19:21; 70:17, 21; 239:22; 242:12
determined [5] 7:13; 8:9; 102:20; 186:17; 187:13
determining [2] 12:22; 93:3
detriment [4] 133:3; 173:14; 174:11, 16
detrimental [1] 309:21
devastating [2] 241:7, 9
develop [3] 9:22; 168:14; 297:7
developed [8] 189:6; 212:16; 222:10; 234:7; 241:11; 242:1; 271:21; 305:17
developing [1] 62:1
development [5] 15:9, 12; 195:10; 199:20; 303:10
developmental [1] 200:3
dexrazoxane [3] 249:6, 8, 9
dextrosoxane [1] 245:9
diagnosed [2] 59:8; 189:8
diagnostic [1] 136:15
diagram [1] 198:7
Diarrhea [1] 270:2
diarrhea [3] 211:4; 218:17; 230:9
die [6] 57:12; 68:15; 116:7; 143:1; 242:6; 295:6
died [6] 67:1, 2, 13; 100:7; 211:13; 222:5
dies [1] 23:20
differed [1] 277:3
differences [33] 71:18; 97:11; 101:5, 7; 105:8; 106:16; 120:9, 11, 14; 138:13; 164:10; 174:9; 190:9; 206:9; 209:2, 22; 215:3; 217:18; 218:10, 12; 263:7, 21; 265:3; 267:2; 273:13; 275:22; 276:20; 277:10; 304:5; 306:2; 315:19; 322:10
differently [4] 156:12; 175:15, 18; 190:7
differing [1] 277:8
difficult [26] 21:17; 29:19; 33:8, 12; 40:16; 45:21; 52:12; 76:10; 89:7; 98:6, 16; 99:3; 100:7; 110:19; 112:7; 113:4; 127:22; 131:13; 161:7; 252:7; 262:21; 271:11; 272:2; 284:19; 304:1; 324:12
difficulties [2] 157:7; 171:9
dilemma [1] 12:22
dilute [1] 178:11
diluted [2] 109:18; 178:18
diminution [1] 236:1
Direct [1] 95:21
direct [1] 62:16
directed [1] 92:6
direction [3] 69:18; 178:9; 227:18
Director [3] 6:22; 9:10; 16:5
disadvantage [1] 131:19
disagree [3] 123:9; 163:13; 321:17
disagreed [1] 96:5
disagreement [1] 174:15
disappear [1] 157:18
disappeared [1] 330:14
discipline [1] 167:17
disciplines [1] 318:10
disclose [2] 8:5; 187:8
Discontinuation [2] 218:19; 222:3
discontinued [2] 211:11; 294:22
discovering [1] 58:17
discovery [1] 97:22
discuss [12] 27:8, 11; 46:1; 57:16; 75:19; 168:11; 178:1; 261:21; 262:4; 275:5; 281:15; 294:15
discussed [8] 24:16; 32:2; 147:3; 261:6; 268:4; 285:7; 308:5; 311:16
discussing [6] 80:5; 261:19; 276:17; 282:13; 285:22; 287:2
discussion [35] 5:9; 26:11, 12; 46:3; 52:18, 22; 73:16, 22; 74:6; 77:9; 78:8, 14; 80:12; 92:6, 11; 114:18; 115:8; 128:7; 142:18; 156:4; 170:19; 203:12; 239:2; 262:10; 272:14; 273:4; 278:6; 283:10; 286:3, 6; 296:1; 314:8, 20; 320:14; 325:11
Discussions [1] 56:10
discussions [5] 8:14; 187:18; 239:1; 283:6; 335:6
dismiss [1] 167:19
dismissing [1] 167:3
disregarding [1] 57:12
distance [2] 14:21; 102:10
distant [1] 206:16
distinction [2] 141:20; 294:6
distinguished [1] 183:22
distress [1] 234:14
distribution [2] 16:9; 264:12
divided [1] 213:6
Division [2] 6:21; 29:5
divisiveness [1] 155:18
divorce [1] 139:13
DNA [1] 198:13
Docetaxel [1] 28:9
docetaxel [1] 44:10
doctor [1] 56:18
Doctors [1] 189:10
doctors [5] 123:5, 6; 190:11; 309:22; 324:13
document [3] 200:16; 231:14; 288:1
documentation [4] 121:6; 197:5; 222:19; 243:22
documented [7] 23:20; 227:3; 229:7; 242:14; 243:3, 12; 287:14

documenting [1] 219:20
 doesn't [21] 31:1; 69:12;
 82:20; 88:8; 93:14; 101:6;
 102:16; 106:22; 107:15;
 120:12; 141:16; 154:6; 171:17;
 87:3; 290:7; 318:8, 10; 319:5;
 321:21; 322:16; 332:3
 dollars [3] 54:9; 87:11; 299:12
 domains [1] 234:11
 dominated [1] 179:14
 Dongsheng [1] 204:6
 Donna [1] 88:17
 donorubicin [1] 198:5
 dosage [1] 302:5
 dosages [2] 59:2, 4
 Dosing [1] 194:2
 dotted [1] 313:18
 double [1] 291:10
 doubling [2] 105:10; 217:4
 dox [2] 290:7; 291:3
 Doxorubicin [1] 194:2
 doxorubicin [48] 19:4; 27:19;
 38:4; 39:19; 40:1, 4, 6, 10;
 43:18; 44:2, 7; 46:6; 178:20;
 190:4; 192:10; 193:19; 194:18;
 198:7; 199:1, 6; 245:15, 18;
 246:10; 247:3; 249:10; 256:1,
 12; 257:18; 283:13; 284:2, 8;
 286:22; 290:7; 291:15; 309:13;
 311:14; 317:16; 327:3; 329:1,
 14, 18; 330:6; 331:2, 4, 6, 12,
 17
 dozens [1] 239:20
 dramatic [1] 304:13
 dramatically [2] 77:14; 94:22
 draw [1] 304:1
 Drawbacks [1] 284:21
 drawn [1] 261:1
 dredging [1] 134:18
 drive [1] 13:8
 drop [1] 235:16
 dropout [1] 297:18
 drops [1] 271:22
 Drs [4] 62:4; 73:9; 187:1, 9
 Drug [9] 5:5; 7:14; 14:2, 14;
 184:1; 185:19, 20; 186:18;
 319:2
 Drugs [1] 183:16
 dubious [1] 76:1
 due [19] 14:21; 30:20; 76:3;
 148:1, 2; 174:11, 12, 17;
 197:4; 198:17; 210:16; 211:11;
 218:19; 222:3; 225:21; 280:15,
 16; 294:22; 317:2
 Duluth [1] 6:1
 dumps [1] 233:16
 durability [1] 70:15
 duration [10] 21:2; 90:10, 11;
 104:15; 193:7; 200:17; 204:16;
 215:22; 225:14; 228:6
 Dutcher [6] 5:6; 6:4; 26:6;
 184:18; 185:11; 188:16
 dying [2] 40:10; 66:14

- E -

early [31] 62:8; 161:19;
 189:16; 192:4, 9; 195:16;
 196:4; 200:6; 202:4; 203:5, 12;
 212:20; 213:13; 214:6, 21;
 219:14; 222:20; 223:4; 235:5,

16; 239:1, 4; 242:5; 243:13;
 260:1; 261:9; 287:18; 288:2;
 290:16; 291:4
 ease [1] 203:11
 easier [3] 60:9; 73:2; 168:15
 easiest [1] 31:8
 easily [2] 31:7; 118:8
 easy [7] 26:17; 98:11; 107:12;
 121:3; 122:20; 148:1; 161:6
 EBC-1 [13] 202:11; 203:13,
 17; 205:13, 20; 214:4; 217:1,
 15; 218:9, 21; 219:20; 224:17;
 233:18
 EBC-2 [6] 202:19; 203:13;
 216:1; 217:13; 218:4; 254:6
 EBC-3 [4] 203:4, 13; 220:1;
 243:19
 EC [1] 259:3
 ECF [1] 202:14
 echoed [1] 278:5
 ECO [1] 38:2
 ECOG [8] 29:17; 35:7, 12;
 38:8; 39:2; 46:3; 88:18;
 117:14
 economic [1] 288:21
 educated [1] 57:14
 education [1] 10:4
 educational [1] 191:3
 eentsy-teensy [1] 299:7
 effective [27] 10:11; 17:18;
 19:4; 56:19; 57:16; 62:14;
 64:15; 69:15; 73:4; 157:18, 19;
 179:22; 189:15; 249:11;
 300:18; 305:20; 306:13; 310:9,
 12, 14; 318:7, 21; 319:3, 5;
 320:11, 18; 321:5
 effectiveness [1] 111:12
 effects [39] 18:5; 41:14;
 60:13, 15, 17, 18, 21; 67:6;
 85:7; 87:4, 9; 100:8; 105:15;
 108:17; 137:7; 161:6, 7;
 171:15; 189:18, 22; 191:21;
 192:21; 193:1, 11; 194:7, 14,
 19; 198:12; 201:6; 205:4, 10;
 209:8; 265:9; 279:7; 288:13,
 15; 297:17;
 320:16
 efficacy [31] 13:12; 16:20;
 17:11, 14; 18:21; 20:15; 21:21;
 22:10, 11; 23:1; 24:8; 25:6;
 27:5; 29:3, 7; 31:3; 36:6;
 45:14; 50:18; 56:3; 62:22;
 63:21; 191:16; 195:12; 197:21;
 207:10; 215:13; 223:12;
 260:20; 266:5; 315:12
 efficient [1] 62:13
 effort [2] 50:22; 260:8
 efforts [3] 183:15; 193:21;
 245:9
 Eight [1] 308:11
 eight [18] 60:20; 108:12;
 109:1; 173:15; 193:6; 265:22;
 277:9; 279:11; 291:6, 8, 16;
 301:13, 16; 302:2, 7; 303:13;
 337:2
 ejection [5] 211:22; 219:5;
 271:18; 297:22; 307:13
 electronic [1] 201:10
 elegant [1] 311:19
 element [1] 55:19
 elements [1] 169:14

Eleven [1] 158:16
 eligibility [1] 238:1
 eligible [2] 263:17; 275:12
 elimination [2] 62:10; 199:5
 Ellence [1] 189:5
 eloquently [1] 292:2
 elsewhere [3] 240:14; 255:14;
 328:2
 emboli [1] 280:18
 emerge [1] 120:11
 emotional [3] 214:8; 234:14;
 237:16
 emphasize [3] 109:10;
 287:12; 295:14
 emphasized [1] 215:12
 emphasizes [1] 239:13
 emphasizing [1] 208:19
 empirical [1] 57:4
 employed [1] 206:10
 empowerment [1] 189:2
 enclosed [1] 184:2
 encounter [1] 127:8
 encourage [4] 56:6; 65:21;
 172:4; 322:9
 encourages [1] 59:2
 end [12] 10:9; 11:21; 58:5;
 60:20; 95:8, 13; 113:3; 167:12;
 168:3; 193:2, 22; 318:18
 endanetron [1] 269:21
 endpoints [24] 21:21; 25:4, 6;
 28:2; 41:19; 50:16; 63:7; 64:5;
 68:13, 15, 19; 74:8; 100:6, 9;
 166:14; 205:21; 227:6; 262:14;
 276:5; 286:4; 325:17, 19;
 326:4
 energy [2] 233:14; 286:19
 Engelsman [2] 35:3; 106:4
 enhanced [4] 65:15; 194:19;
 214:1; 256:5
 enlighten [1] 39:10
 enroll [2] 61:16; 73:2
 enrolled [14] 111:6; 204:2;
 216:14, 20; 220:13, 20;
 224:22; 226:11; 227:12, 17;
 228:18; 262:7; 263:9; 275:9
 enrolls [1] 93:8
 entails [1] 242:12
 enter [3] 61:2; 89:7, 9
 entering [1] 89:5
 epi [9] 229:5, 6; 240:7; 273:9;
 291:3, 9; 312:22; 313:21;
 331:2
 epidemic [1] 10:9
 Epirubicin [11] 192:10, 22;
 197:10; 198:4, 18, 21; 199:8;
 220:17; 229:8; 314:22; 329:20
 episodes [1] 212:6
 equal [7] 40:21; 42:12; 43:2;
 201:7; 223:1; 264:17; 330:7
 equally [2] 11:1; 122:11
 equation [1] 113:13
 equatorial [1] 199:2
 equimolar [2] 256:10; 331:5
 equipped [1] 322:14
 equivalence [9] 17:18; 77:16;
 120:12; 179:3, 5, 20; 319:10,
 16; 320:1
 equivalency [2] 324:11; 327:1
 equivalent [9] 75:17; 78:3;
 132:18; 133:2; 149:9; 258:11,
 12; 320:6, 19

ER [2] 67:5; 300:7
 era [1] 61:2
 ere [1] 215:4
 erroneously [1] 207:8
 ERWIN [1] 61:12
 Erwin [2] 61:10, 13
 escalated [5] 199:13; 200:16;
 224:19; 259:3; 331:20
 escalation [1] 199:9
 essence [7] 88:18; 90:19;
 252:13; 258:15; 287:17, 22;
 301:14
 essential [4] 10:21; 50:15, 17;
 166:20
 essentially [7] 10:18; 12:4;
 129:5; 238:8; 251:1, 11;
 260:17
 established [6] 63:6; 191:17;
 243:6; 246:8; 258:11; 330:3
 estimate [5] 21:3; 91:10;
 293:2; 307:6; 322:19
 estimated [2] 19:4; 272:13
 estimates [5] 197:18; 205:16;
 266:20; 268:1; 271:14
 estimating [1] 271:9
 estimation [1] 262:19
 Estrogen [1] 208:2
 estrogen [2] 220:21; 263:18
 et [9] 34:2; 67:14; 99:22;
 121:7; 127:5; 152:14, 15;
 278:12; 280:4
 etoposide [1] 242:16
 European [4] 191:13, 18;
 194:10, 13
 evaluable [2] 33:10; 275:12
 evaluate [5] 11:15, 22; 209:7;
 305:21; 331:2
 evaluated [13] 28:2; 202:11,
 20; 203:18; 216:2; 220:2;
 223:21; 224:3; 226:6; 227:10;
 228:10; 234:20; 246:12
 evaluating [2] 74:8; 111:16
 Evaluation [2] 7:14; 186:18
 evaluation [13] 33:14, 15;
 83:7; 119:21; 126:1, 2, 4, 6, 7;
 176:4, 9; 180:13; 201:6
 evaluations [5] 113:3; 206:20;
 272:4; 281:5, 17
 event [14] 8:14; 22:1, 2, 5, 6;
 30:10, 11, 20; 32:12; 187:18;
 212:8; 241:6, 12; 245:15
 events [24] 101:12, 13, 16;
 103:3; 107:2, 5; 116:15;
 121:18; 179:14; 206:22;
 210:13; 211:1, 11; 215:17;
 218:4, 13, 20; 222:4; 229:15;
 230:5; 272:6; 294:8
 everybody [5] 112:10;
 131:17; 164:15; 296:9; 309:1
 evidence [16] 65:6; 79:5;
 81:5; 84:17; 131:12; 191:9;
 201:16; 206:16; 219:3; 231:5;
 254:6; 300:1; 319:18; 323:19;
 324:19; 333:7
 evidenced [1] 219:16
 evident [2] 34:13; 231:1
 exact [3] 101:22; 103:15;
 267:6
 exactly [10] 29:20; 90:6;
 99:16; 109:19; 133:7; 173:1;
 239:12; 248:7; 254:1; 291:6

examined [3] 207:18; 242:9; 249:16
examining [1] 55:13
example [21] 12:10; 23:15; 57:21; 72:9; 84:3; 91:13; 92:1; 102:7; 105:13; 125:10; 126:17; 130:1; 161:15; 182:8; 232:21; 237:15; 247:22; 257:3; 259:3; 278:9; 311:19
examples [6] 65:9; 115:22; 116:1; 169:16; 232:14, 18
exceeding [1] 305:11
exceedingly [1] 112:16
excellent [5] 62:3; 96:4; 217:1; 229:5; 235:1
except [4] 40:21; 81:14; 83:2; 324:22
exception [1] 145:19
exceptionally [3] 110:19; 112:19; 157:4
exceptions [2] 7:17; 186:21
excessive [2] 247:6; 297:18
excited [1] 288:17
exciting [1] 288:18
exclude [2] 8:17; 187:21
excluded [4] 92:8; 159:18; 222:8; 262:8
exclusion [2] 8:18; 187:22
exclusively [1] 198:17
Excuse [1] 245:19
excuse [1] 28:12
Executive [3] 6:7; 9:10; 16:5
executive [1] 191:1
exert [1] 63:19
exhibits [1] 192:22
exist [1] 57:1
exists [1] 132:14
expect [13] 19:14; 47:12; 55:11; 102:10, 11, 12; 170:5; 235:2; 248:8; 271:22; 272:5; 285:2; 317:6
expected [8] 91:17; 210:13; 212:18; 222:2; 233:1; 234:21; 242:2; 244:8
expecting [1] 143:18
expense [2] 14:22; 95:12
expensive [4] 54:12; 95:6; 112:17; 113:1
experience [8] 62:16; 84:19; 89:14; 214:16; 217:14; 248:13; 292:15; 313:2
experienced [2] 224:11; 271:22
experiences [2] 112:8; 235:3
experimental [7] 61:17; 62:9, 21; 84:4; 121:14; 124:21; 203:2
expiration [1] 256:6
explain [5] 17:12; 83:1; 289:17; 291:21
explanation [1] 235:8
explicitly [1] 65:14
exploring [1] 56:22
exposure [1] 194:7
expounding [1] 288:8
express [2] 183:14; 191:6
expresses [1] 86:15
extend [2] 70:11; 91:5
extended [3] 12:6, 19; 17:7
extension [3] 66:2; 68:22; 87:1

extensive [5] 205:3; 206:20; 207:18; 239:19; 243:21
extensively [2] 197:11; 260:5
extent [2] 123:1; 125:19
extraneous [1] 314:7
extreme [2] 64:13; 87:9
extremely [9] 14:14; 40:16; 54:13; 58:6; 65:2; 95:5; 121:2; 169:12; 304:5
eyes [1] 16:1

- F -

FAB [2] 242:1, 18
FAC [1] 290:19
face [5] 21:18; 58:14; 59:15; 60:19; 147:7
faces [1] 189:2
facility [1] 181:20
facing [1] 120:21
fact [31] 31:22; 40:15; 58:15; 78:12; 81:14; 87:16; 89:6, 7; 91:8; 111:21; 123:15; 174:17; 175:14; 191:14; 205:14; 213:12; 225:21; 235:17; 254:15; 255:21; 256:9; 261:8; 264:7; 269:5; 297:5; 311:12; 318:4; 329:15, 21; 330:2; 331:19
factor [7] 53:19; 120:10; 245:17; 246:7, 8, 9; 291:13
factored [1] 85:2
factors [13] 11:9; 31:18; 181:3; 182:9; 210:6; 242:20; 267:11, 17; 273:22; 307:2; 311:11; 312:3, 4
factory [1] 247:8
failed [2] 123:15; 295:4
fails [3] 13:4; 70:19; 319:16
failure [42] 29:15, 21; 30:16; 38:8, 9; 39:12; 40:7, 17, 22; 42:7, 15; 56:7; 139:22; 192:1; 193:14; 212:1; 222:11; 224:11; 225:16; 228:7; 230:11; 231:1; 245:17; 271:21; 272:10; 281:3, 11, 22; 292:5; 294:7, 8, 12, 14, 21; 295:3, 9, 19; 298:1; 307:4, 10; 315:14; 317:5
fair [4] 76:12; 245:4; 248:5; 297:6
fairer [1] 260:21
fairly [9] 81:7; 120:21; 150:4; 157:14; 269:19; 279:22; 294:17; 304:16; 330:19
fairness [2] 8:21; 188:3
Falksen [1] 136:5
fall [3] 12:9; 17:21; 69:12
falling [1] 161:20
falls [1] 160:7
false [2] 56:17, 20
familiar [1] 29:2
family [3] 59:12; 116:15; 189:19
fantasy [1] 126:16
fared [2] 329:1, 2
fashion [4] 90:17; 239:17; 258:18; 262:22
fast [2] 71:10; 77:10
faster [3] 22:21; 60:7; 199:5
fastest [1] 62:13
fatal [2] 120:13; 212:6

fatigue [1] 234:12
favor [6] 22:20; 40:4; 80:20; 239:11; 273:13; 295:8
favorable [5] 17:15, 17, 21; 128:18; 129:12
favoring [1] 229:12
FE [1] 315:4
features [3] 65:19; 262:6; 275:9
Febrile [1] 279:10
febrile [2] 269:15; 280:17
February [1] 193:8
FEC [47] 265:11; 266:14, 15, 16; 268:17; 269:17, 18; 270:6, 7; 272:9; 276:21; 277:1, 14, 20; 278:1, 17; 279:1, 10, 18; 280:6, 10, 17, 18; 281:11; 282:1, 2, 11; 283:3; 300:5, 9; 301:22; 315:4, 7, 16, 20; 326:12; 333:19; 334:22; 336:13
fee [1] 66:2
Feel [1] 336:3
feel [11] 31:4; 49:20; 58:17; 79:21; 84:15; 137:12; 140:8; 164:11; 165:22; 243:21; 299:16
feeling [4] 69:14; 90:18; 296:13; 326:19
feelings [2] 233:21; 234:14
felt [8] 49:2; 136:7; 233:14, 15; 254:3, 11; 268:5; 312:7
females [1] 236:6
FESG [1] 216:7
fever [4] 210:15; 218:6; 221:20; 230:2
Fewer [1] 211:9
fewer [1] 191:21
field [5] 13:5; 54:5, 7; 168:5; 325:16
fifth [1] 222:5
fifty-six [1] 207:4
figure [2] 76:2; 169:20
figured [1] 116:16
fill [3] 48:7; 237:18
filled [2] 50:3; 236:14
fills [1] 23:18
final [3] 126:9; 231:3; 238:11
financial [8] 8:7, 16, 22; 53:5; 187:10, 20; 188:4, 14
find [12] 40:16; 47:17; 56:8; 58:2; 77:7; 101:12; 116:3; 132:6; 135:18; 235:20; 248:20; 330:13
finding [5] 69:18; 136:16; 142:12; 147:18; 303:2
findings [3] 217:14; 273:2; 278:13
fine [2] 122:10; 160:17
firm [2] 9:1; 188:5
firms [4] 7:13; 8:15; 186:17; 187:19
First [5] 16:14; 18:2; 263:8; 278:22; 316:12
firstly [1] 237:6
FISCHLER [1] 286:13
fit [2] 325:4, 10
fits [1] 248:6
Five [3] 217:16, 20; 271:20
five [39] 35:6; 39:22; 40:19; 47:14; 58:5, 8; 81:20; 82:22;

102:8, 9, 11; 103:16; 106:6; 107:13; 110:4; 154:16, 18, 20; 155:5, 7; 164:8; 168:17; 206:6; 209:19; 212:2, 3, 10, 13; 217:12; 262:16; 266:21; 278:22; 295:20; 307:15; 323:17; 329:13; 333:17; 336:21
five-month [1] 21:9
five-year [2] 208:21; 267:22
fix [1] 122:20
fledged [1] 155:22
flexible [1] 138:20
flower [1] 68:4
fluoroquinolone [1] 204:16
fluorouracil [7] 202:12, 18; 204:22; 208:7, 18; 215:14; 224:17
Focan [1] 227:18
focus [5] 84:16; 118:14; 197:11; 214:8; 234:11
focused [3] 171:16; 232:20; 252:8
focuses [1] 233:12
focusing [2] 223:12; 252:15
folks [2] 155:10; 299:10
follow [3] 14:8; 74:5; 141:2
follow-up [20] 23:11; 30:21; 32:18; 89:17; 103:3; 158:8; 208:21; 212:3, 5, 20; 213:10, 13, 18; 215:3; 217:11; 221:9; 243:8; 262:15; 272:6; 295:1
followed [13] 23:12, 13, 16, 18; 43:12; 44:13; 127:1; 229:19; 259:3; 275:19; 276:7, 8
Following [2] 204:9; 296:1
following [12] 7:7, 16; 128:10; 186:10, 20; 191:10; 192:6; 201:17; 212:8; 222:5; 231:6; 300:2
FONFA [4] 53:10, 16; 298:9, 15
Fonfa [2] 298:8, 15
fonfa [1] 53:6
Food [3] 184:1; 185:19; 319:2
foregoing [2] 73:17; 259:14
forget [1] 157:15
forgetting [1] 119:1
form [5] 35:4; 50:4; 152:4; 167:13; 290:21
formal [1] 152:20
formation [1] 198:15
formed [2] 57:10; 200:4
former [1] 19:2
formidable [1] 169:12
forms [6] 48:7; 94:16; 121:7; 297:5, 9, 12
formulate [1] 112:20
forth [3] 116:9; 131:8; 324:15
fortunate [2] 148:8, 9
Forty-four [1] 315:16
Forty-nine [1] 278:16
Forty-two [1] 193:5
forward [5] 52:18; 160:16; 286:5; 313:9; 327:3
Fossati [1] 41:3
found [20] 26:9; 33:19; 35:5, 8, 13; 40:3, 15; 41:8; 48:8; 50:1; 58:10; 72:6; 96:20; 104:18; 135:15, 17; 256:4;

260:20; 302:6; 305:12
Foundation [6] 61:11, 14; 190:18, 21; 191:1; 194:5
founded [1] 10:5
founding [1] 10:10
four [1] 222:9
four [39] 31:19; 36:13; 44:21; 47:14; 67:19; 76:9; 81:20; 107:14; 108:8; 153:21; 154:16; 155:2; 164:8; 166:6; 183:8; 184:7; 198:9; 200:14; 207:21; 212:14; 218:6; 220:17, 19; 223:15; 231:14; 246:15; 252:5; 258:15; 263:16; 272:8, 14; 275:6; 281:15; 292:15; 300:7; 303:17; 307:9; 333:17; 336:21
Fox [1] 5:16
fraction [6] 52:3; 212:1; 219:5; 271:18; 297:22; 307:13
France [1] 196:16
Francisco [1] 10:3
frankly [2] 9:18; 172:12
free [45] 11:2; 24:1; 52:5; 62:12; 65:19; 72:4, 7, 12; 198:14; 200:9, 12; 205:21; 206:6, 9; 208:18, 22; 209:9, 14; 213:9, 11; 215:9; 217:12, 16; 219:12; 221:10, 13; 222:15; 223:3; 231:9; 253:4, 14; 262:14; 266:6, 18, 20; 267:7; 273:13; 274:15; 275:13; 300:19; 329:8; 332:9; 334:17; 335:2; 336:3
Freedom [2] 8:2; 187:6
French [2] 192:3; 216:8
frequencies [2] 215:16; 218:8
frequency [4] 111:20; 212:8; 230:4; 245:15
frequent [4] 23:3, 10; 35:18; 112:13
frequently [7] 29:19; 33:16; 210:19; 211:3; 218:15; 221:22; 230:6
friendly [1] 73:1
friends [2] 66:22; 312:22
front [6] 53:18; 82:5; 118:5; 119:3; 172:1; 300:22
FU [13] 27:19; 239:8; 240:1; 265:7, 14; 274:18, 22; 276:22; 277:11; 300:17; 306:12; 307:19; 314:13
full [13] 7:18; 12:13; 28:6, 11; 64:4; 65:11; 155:22; 186:22; 201:9; 205:19; 208:5; 217:2; 322:19
fully [7] 12:7; 57:17; 87:3; 175:22; 198:11; 292:7, 11
function [4] 11:11; 63:10; 206:18; 207:2
fundamental [2] 192:5; 240:19
fundamentally [2] 37:11; 83:2
funded [2] 62:22; 63:2
funding [1] 65:22
funds [1] 61:20
future [6] 17:4; 78:13; 112:7; 142:2, 8; 259:4

- G -

gain [1] 61:17
gained [1] 196:15
gains [1] 19:8
gave [6] 38:13; 91:13; 125:11; 154:11; 266:1; 277:6
Gee [1] 145:6
gemzar [2] 67:14; 113:10
generalizations [1] 143:16
generalize [1] 142:21
George [7] 6:8; 37:19; 48:12; 140:2; 141:3, 21; 226:12
German [2] 192:3; 193:5
gets [10] 12:6; 118:11; 119:20; 128:5; 142:20; 147:11; 173:9; 259:12; 320:20; 326:20
GFEA-04 [1] 263:10
GFEA-05 [14] 261:22; 263:13; 264:2, 20; 265:11; 266:1, 4, 14; 268:22; 270:4; 272:2, 20; 273:6; 300:5
gift [1] 184:21
girl [1] 68:4
Give [1] 256:16
give [20] 31:1; 39:6; 46:2; 47:12; 56:13; 60:13; 142:20; 160:8; 163:21; 164:18; 184:5, 21; 247:5, 19; 271:16; 275:20; 291:12; 302:8; 317:17; 332:12
given [40] 11:17; 14:2; 20:12; 21:13; 28:7; 31:11; 32:1, 14; 53:12; 59:5; 109:7; 128:21; 133:1; 155:17; 168:2; 185:4; 196:21; 197:16; 200:22; 203:7; 220:17, 18; 223:9; 224:12; 228:15; 233:2; 239:17; 247:2; 248:5; 256:9; 258:18; 274:16; 275:19; 285:2; 302:7; 303:15; 304:4; 312:7; 319:10; 321:1
gives [4] 14:10; 134:19; 258:21; 303:5
giving [12] 32:18; 57:11; 64:13; 98:10; 123:20; 140:12, 14, 21; 216:2; 220:2; 247:20; 302:21
glass [1] 54:5
glean [1] 51:10
global [4] 116:2; 130:21; 296:20; 298:13
glucuronidation [3] 199:3; 255:22; 256:5
goal [4] 11:5; 73:3; 175:20; 319:19
God [1] 312:16
goes [3] 171:2; 287:2; 311:11
gold [4] 69:4; 136:18; 149:4; 325:17
gotten [1] 67:10
government [2] 8:11; 187:14
Grade [17] 174:18; 210:13, 18; 211:1, 4, 9; 218:4, 13; 221:19, 20; 222:6; 229:22; 230:5, 8; 279:13; 300:8
grade [2] 263:20; 296:9
grain [1] 115:19
grand [1] 319:17
granesitron [1] 269:22
Grant [1] 6:17
grant [2] 64:4; 191:4
granted [4] 7:19; 187:1; 296:2; 334:2

graph [5] 199:7; 213:8, 16; 246:14; 313:15
graphical [1] 213:7
grateful [2] 184:10, 20
gratifying [1] 209:18
grave [1] 116:22
Great [1] 259:11
great [7] 75:13; 138:18; 163:20; 170:6, 9; 172:13; 243:22
greater [20] 37:14; 56:3; 163:11; 201:7; 210:14; 215:13, 17; 217:7; 223:1, 10; 236:20; 239:8; 255:1; 269:16; 270:5; 275:13; 300:6; 312:4; 323:21; 333:9
greatest [1] 246:7
greatly [2] 87:14; 183:19
greed [1] 62:17
green [4] 266:7, 15; 277:13, 18
ground [1] 283:2
Group [1] 220:8
groups [29] 19:16; 73:10; 94:8; 105:13, 17; 106:15; 129:15, 19; 159:10; 176:16; 181:4; 207:15; 208:1, 3, 16; 214:20; 215:5; 216:18; 217:7, 22; 221:8; 225:10, 19; 227:8; 250:14; 262:13; 263:11; 269:9; 313:15
grow [2] 148:14
growing [2] 146:15; 168:5
growth [3] 56:6; 144:4; 291:13
guarantee [1] 109:15
guess [37] 80:17; 82:7; 83:6, 10; 88:1; 89:1; 90:17; 108:14; 110:7; 113:8, 15; 115:21; 118:11; 124:3; 133:17; 144:1, 12; 148:5; 150:6, 8; 152:16; 157:21; 173:9; 174:15; 175:9; 177:19; 178:1; 181:22; 239:3; 286:14; 288:4, 7; 310:8; 314:2; 325:12; 326:7; 335:4
guidance [1] 183:15
guidelines [2] 28:20; 331:3

- H -

habit [1] 167:2
hadn't [1] 37:15
Haentzel [1] 267:9
hair [6] 69:12, 16; 189:21; 232:21; 236:5; 237:17
half [9] 44:21; 48:6; 50:3; 172:16; 248:10; 250:8, 9; 299:14; 304:8
Hamilton [1] 204:3
hand [7] 48:21; 75:5; 89:11; 125:6; 253:10; 299:21; 312:11
hand-foot [1] 256:10
handle [1] 31:2
handled [1] 294:10
handout [1] 43:20
Hands [1] 80:10
hands [12] 54:5; 80:9; 158:15; 159:1; 306:16; 308:10, 13; 314:18; 333:12, 15; 336:16, 19
happens [2] 312:13, 18
happy [1] 286:7
harbor [1] 125:20
hard [17] 56:9; 69:11; 77:15; 91:9; 92:10; 102:9; 103:11; 116:3, 6; 131:18; 151:19; 169:15; 170:10, 13; 312:7; 322:10, 17
harder [4] 106:10, 19; 150:1; 325:15
hardest [1] 12:9
hardly [1] 85:14
Hartford [1] 5:21
hasn't [4] 53:21; 244:6; 313:9; 325:7
haven't [10] 28:18; 55:16; 91:7; 114:21; 116:16; 138:12; 140:7; 142:12, 14; 311:2
hazard [18] 40:3; 41:14, 17; 75:22; 101:10, 15, 19, 21; 102:14; 103:9, 18; 104:1, 11, 17, 20; 107:9, 11; 109:18
head [1] 264:1
Health [2] 185:5; 331:1
health [4] 12:2; 57:17; 59:6; 183:21
healthy [1] 72:1
hear [7] 98:3; 115:8; 133:17; 232:15; 257:13; 265:6; 286:17
heard [29] 32:2; 87:15; 88:15; 90:4; 97:15; 113:16, 17, 18; 114:6, 11; 139:17; 144:19; 155:15; 171:8; 176:8; 259:21; 260:5, 12, 16; 262:1; 267:3; 269:16; 278:3; 283:16; 311:3; 318:22; 324:19; 325:15; 327:15
hearing [7] 9:5, 7; 14:19; 116:19; 188:8; 288:21; 298:8
hearings [1] 72:17
heart [14] 109:14; 192:1; 193:13; 212:1; 222:10; 230:11; 245:17; 271:21; 272:10; 281:22; 292:5; 298:1; 307:4, 10
heavily [3] 64:17; 121:20; 185:7
held [1] 330:4
Helen [1] 66:19
helicase [1] 198:14
hell [1] 145:7
Hello [1] 183:3
Help [1] 325:10
help [14] 26:11; 59:4; 60:8; 61:16; 64:18; 97:21; 137:15; 161:18; 171:17; 172:12; 184:16; 189:11; 213:1; 292:6
helped [1] 254:10
helpful [4] 73:13; 115:8, 17; 155:6
helping [1] 185:8
hematologic [2] 218:8; 230:3
hemorrhage [1] 211:14
Henderson [2] 19:2; 39:17
Henney [1] 183:12
Hepatic [1] 211:8
hepatoma [1] 123:11
HEPI-010 [3] 275:3; 281:17; 315:6
HEPI-013 [5] 275:3; 276:6; 277:13; 281:4; 315:2
herceptin [18] 21:8, 12, 14;

29:2; 36:4, 9, 11, 21; 67:9, 11; 71:14, 19; 82:20; 84:3; 125:1; 249:15, 19; 328:3	I'd [17] 5:11; 7:4; 62:5; 80:17; 86:14; 90:3; 94:19; 106:21; 141:19; 151:4; 174:22; 188:18; 232:7; 256:19; 257:13; 260:3; 314:5	225:16; 253:13; 274:14; 277:16; 289:15, 21; 296:20; 321:13; 329:8	indicating [1] 247:17
heterogeneous [1] 31:14	I've [12] 29:11; 30:14; 33:19; 50:9; 52:14; 54:15, 21; 81:6; 84:22; 90:3; 113:8; 267:3	improvements [3] 230:16, 21; 266:17	indication [11] 124:22; 177:4; 229:17; 231:20; 286:1; 300:18; 306:13; 307:21; 314:22; 315:11; 327:14
hey [1] 141:11	ICCG [1] 220:7	improves [5] 11:20; 51:20; 200:17; 231:9, 15	indications [4] 157:16; 259:22; 261:4; 306:5
Hi [1] 53:10	idea [6] 17:9; 21:15; 131:9; 134:1; 160:2; 312:17	improving [2] 16:2; 219:12	indicator [1] 156:10
hidden [1] 87:8	identical [1] 277:6	inadequate [1] 167:4	individual [7] 7:5; 37:5; 57:20; 62:17; 241:9; 268:8; 306:4
high [11] 121:8; 168:5; 192:22; 213:11; 219:16, 17; 241:8; 273:11; 277:5; 299:6; 300:6	identified [1] 79:14	inaudible [1] 244:11	indolent [1] 92:9
higher [34] 59:7; 123:21; 199:4, 12, 16, 17; 225:13; 227:4, 7; 228:5, 9; 229:9; 230:19; 241:21; 245:20; 252:22; 261:17; 263:14; 265:7, 17; 266:3; 269:17; 270:2, 21; 271:22; 273:14; 274:1, 19; 276:22; 280:7; 299:11, 17; 307:11, 13	identify [5] 53:4; 58:11; 101:14; 188:13; 234:2	incentive [1] 14:3	induced [4] 225:12; 227:3; 228:5; 246:10
highest [2] 54:8; 253:1	ignore [2] 99:5; 156:11	incentives [2] 63:1; 65:19	industries [2] 62:15; 65:22
highlight [1] 269:15	ignoring [1] 75:3	incidence [21] 193:13; 230:8; 241:8; 243:14; 245:3; 246:15; 248:6; 270:4, 7; 271:13; 272:15; 274:2; 279:13, 21; 281:22; 282:21, 22; 307:4, 10, 12; 313:20	industry [2] 9:22; 33:5
highlights [1] 15:7	II [9] 191:11; 198:13; 205:17; 212:9, 18; 213:14; 242:3, 15; 300:3	inclined [1] 162:21	ineffective [2] 61:1; 63:17
highly [3] 64:16; 230:16; 304:13	III [9] 191:11; 200:2; 201:4; 203:17; 216:2; 220:2; 223:15; 252:1; 300:3	include [7] 15:13; 176:13; 192:17; 193:4; 194:13; 237:10; 242:20	inevitable [1] 110:1
histologic [1] 263:19	Ills [1] 159:16	included [13] 94:7; 179:4; 203:15; 205:22; 206:11; 207:10; 212:14; 219:3; 233:4; 263:10; 284:20; 315:10; 317:17	inevitably [2] 103:19, 22
histologically [1] 206:13	illness [1] 77:13	includes [1] 261:2	infarction [1] 281:3
histology [1] 244:14	imagine [5] 103:12; 129:22; 131:20; 132:1; 133:8	Inclusion [2] 25:2; 231:19	infection [1] 218:6
historical [1] 112:8	imbalance [1] 20:3	Incomplete [1] 23:8	inference [2] 330:1; 332:11
historically [2] 239:6; 246:22	immediate [1] 318:6	incomplete [4] 23:10; 260:17, 22; 276:16	inferences [1] 332:6
history [4] 27:10; 54:2; 111:1; 195:21	immediately [4] 55:21; 93:11; 123:3; 128:4	inconvenience [2] 233:6; 234:13	infinite [1] 134:16
Hochberg [1] 67:2	imminently [2] 101:8; 172:3	incorporate [1] 185:17	influence [6] 83:7; 264:6; 316:9; 317:7; 325:16, 18
Hoff [1] 246:22	impact [9] 71:17; 103:18; 118:12; 188:22; 210:5; 226:6; 310:11; 327:18, 19	incorporated [2] 275:18; 301:9	influenced [2] 264:11; 324:9
hold [2] 59:6; 299:5	impacted [1] 55:11	increase [38] 35:5, 6, 8, 11; 36:11; 38:6, 8, 15, 17, 20; 40:7; 43:12, 13; 44:3, 12, 13, 20; 45:9, 11; 46:11; 47:19, 20; 48:1; 50:9, 12; 68:20; 71:8; 105:9; 124:6, 11; 136:2; 161:1; 163:15, 20; 164:3; 189:1; 280:11	inform [1] 174:7
holding [1] 54:7	impacts [2] 11:19; 139:11	increased [28] 36:1, 3; 37:7; 39:11; 40:5; 42:15, 16, 17; 43:2; 47:3; 48:8, 18; 50:12; 53:22; 54:20; 65:22; 76:9; 117:6; 124:14; 145:11; 149:15, 18; 151:13; 253:4; 280:5; 282:21	Information [2] 8:2; 187:6
home [3] 138:16; 163:18; 268:16	impaired [2] 170:5, 6	increases [4] 72:11; 103:18; 122:7; 231:15	information [25] 7:12; 38:1; 51:11; 57:19; 58:11; 68:12; 87:2; 98:10; 126:18; 138:21; 156:17, 22; 167:6; 168:9; 174:6; 186:16; 189:2; 195:12, 20; 214:10; 236:16, 18; 238:17; 297:11; 307:5
hone [1] 156:8	imperatives [1] 54:20	increasing [3] 149:1; 199:21; 293:16	informed [6] 15:2, 10; 62:9; 292:7, 11; 309:3
honestly [1] 262:18	implemented [1] 22:17	increasingly [2] 59:12; 125:14	infrequent [1] 215:21
HONIG [9] 236:10; 259:19; 294:11; 296:6, 15; 297:1; 298:4; 311:6; 328:16	implication [3] 109:6; 308:20; 310:7	incremental [2] 138:13; 205:4	infrequently [6] 24:4; 210:15; 211:6; 218:6; 244:13; 251:3
Honig [5] 236:8; 259:18; 286:11; 330:10, 17	implications [4] 25:17; 107:10; 198:21; 309:14	incurable [1] 192:13	infrequently [1] 182:7
honorable [1] 191:5	implies [1] 152:5	independent [6] 64:11; 121:17; 122:3, 9; 181:21; 334:20	inherent [2] 123:17; 194:14
Hope [2] 6:10; 62:20	implying [1] 65:15	index [1] 49:15	inhibiting [1] 212:19
hope [7] 26:10; 56:17; 57:3; 61:6; 234:15; 244:7; 328:19	importance [9] 13:7; 22:7, 8; 87:9; 91:10, 20; 112:10; 175:9; 254:5	Indiana [1] 6:8	inhibition [2] 198:14
hopefully [2] 39:10; 286:5	importantly [2] 149:5; 223:5	indicate [3] 205:16; 206:21; 219:11	inhibitor [1] 242:3
hoping [1] 67:9	impossible [4] 13:16; 120:2; 121:11; 254:14	indicated [9] 19:13; 56:4; 93:15; 201:15, 21; 231:4, 12; 313:8; 314:22	inhibitors [5] 69:22; 71:1; 212:9; 213:15; 242:15
hormonal [2] 67:4; 70:2	impress [1] 9:21	indicates [2] 209:15; 210:10	initial [19] 16:22; 21:8; 25:10, 15; 70:16; 79:15; 80:7; 122:3; 128:12; 159:13; 176:13, 17, 20; 177:1; 235:16, 19; 252:17; 255:20; 315:8
horrendous [1] 145:1	impressed [1] 80:14		initially [3] 133:13; 169:14; 256:6
horrible [2] 171:1; 174:18	impression [1] 150:6		initiated [1] 194:5
Hospital [3] 5:21; 6:15; 220:10	impressions [1] 150:20		initiatives [1] 185:17
hospitals [1] 64:21	improve [7] 10:1; 11:6; 14:3; 55:5; 92:16; 174:4; 223:6		injection [2] 189:6; 191:8
huge [2] 39:20; 170:7	improved [32] 39:4; 44:17; 49:3, 11; 51:22; 52:4, 5, 9; 60:5; 76:2; 88:19; 89:12; 93:20; 94:3, 11; 103:12, 14; 115:12, 22; 116:2; 117:5; 136:17, 18; 162:10; 209:13; 210:9; 222:15; 223:3; 225:14; 227:6; 263:4; 315:20		innovative [1] 62:14
human [1] 256:4	improvement [31] 76:18, 20, 21; 86:3; 96:12, 13; 102:10; 117:12; 139:1, 21, 22; 144:22; 150:9, 13, 18; 162:17; 163:5, 7; 169:21; 170:4; 206:6;		input [4] 15:2; 24:6; 168:22; 286:6
hundred [3] 207:4; 291:14; 301:3			inquire [1] 324:18
hundreds [2] 197:18; 299:15			insert [5] 36:16; 244:2; 301:10, 19; 312:8
hydrochloride [4] 189:5; 190:4; 191:7; 198:4			insist [3] 54:18; 77:6; 165:17
hydroxyl [2] 198:8; 199:3			inspire [1] 10:8
hypothesis [1] 206:4			instance [5] 133:19; 178:19; 179:1; 233:3; 249:15
hypothesized [1] 49:5			instances [3] 211:21; 222:11; 286:22
hypothetical [1] 131:4			Institute [3] 5:19; 112:1;

204:1
institutional [1] 62:17
instructions [1] 301:15
instrument [5] 98:9; 214:5;
 233:2; 236:17, 22
insure [4] 59:4; 189:1; 194:6,
 12
insured [1] 205:3
insuring [1] 194:19
integrity [2] 8:12; 187:16
intelligent [1] 133:12
intended [3] 11:16; 77:17;
 269:11
intense [3] 273:5; 282:5;
 333:20
intensities [8] 208:8, 10;
 217:6; 219:17; 225:9; 226:21;
 227:22; 229:4
intensity [10] 221:3; 239:7;
 241:21; 242:21; 253:8; 273:7;
 274:18; 282:9; 300:11; 305:8
intensive [5] 35:4; 94:13;
 235:19; 257:20; 259:2
intent [3] 207:11; 267:14;
 273:20
interaction [1] 274:22
intercalation [1] 198:13
interchangeable [1] 302:10
interest [16] 7:3, 6, 8, 16;
 8:16, 21; 76:2; 170:9; 186:9,
 12, 20; 187:11, 20; 188:3;
 239:7; 318:6
interested [3] 168:10; 239:3;
 303:2
Interesting [1] 114:16
interesting [9] 38:21; 48:3,
 10; 80:13; 131:12; 249:13;
 286:5; 290:5; 332:3
interests [9] 7:13; 8:6, 7, 10;
 186:17; 187:10, 14
Interim [1] 181:9
intermittent [2] 47:10
internal [1] 170:9
International [1] 220:8
interpret [1] 156:12
interpretable [1] 167:1
interpretation [3] 82:5, 8;
 273:17
interpreted [1] 319:16
interpreting [3] 179:21;
 180:10; 326:2
interrelated [1] 31:13
interruption [1] 238:2
interval [3] 200:12; 275:13;
 284:11
intervals [4] 124:6; 213:6;
 271:19; 284:10
interventions [1] 55:18
intracerebral [1] 211:14
intravenously [1] 266:1
introduce [1] 5:12
introduced [1] 19:9
introducing [1] 117:17
intuitively [1] 151:12
invaluable [1] 15:11
invested [1] 286:19
investigate [1] 63:20
investigational [2] 172:18;
 193:21
investigator [12] 75:15;
 93:18; 122:3; 204:4; 211:15;

216:11; 220:11; 225:3; 226:14;
 228:20; 234:5; 297:10
investigators [7] 20:12;
 29:20; 33:6; 43:6; 49:4;
 178:10; 196:11
investment [1] 112:18
involve [4] 8:14; 75:20;
 175:20; 187:18
involved [8] 59:5; 72:19, 22;
 254:9; 263:13, 22; 329:12;
 330:22
involvement [13] 8:18, 22;
 72:15, 18; 187:22; 188:4;
 191:10; 201:17; 206:15; 225:4;
 226:16; 231:6; 300:2
involves [1] 17:3
involving [2] 198:2; 223:16
Ireland [1] 68:3
irradiated [1] 313:19
irradiation [7] 208:12; 246:7;
 250:12; 251:2, 3; 264:3, 6
irrelevant [5] 10:16; 85:8;
 86:21; 121:16; 336:5
isolate [1] 240:20
isolated [3] 55:19; 251:12, 14
isolation [1] 205:9
Israel [1] 226:13
Issue [1] 185:6
Issues [1] 233:6
issues [23] 12:15; 14:15;
 29:14; 30:4; 34:2; 43:4; 49:9;
 84:16; 95:20; 111:19; 116:5;
 128:10; 149:18; 167:7; 176:7;
 232:20; 233:7, 15; 251:15;
 278:11; 285:4; 299:20; 305:3
it'll [5] 26:17; 107:12; 109:20;
 179:21; 335:9
Italian [2] 192:2; 193:7
IV [13] 35:4; 153:13; 157:9,
 11, 13; 158:12; 253:3, 5;
 257:4; 277:9; 282:6, 7, 8

- J -

Jacques [2] 216:9; 220:9
Jan [2] 134:2; 178:12
Jana [1] 331:22
Janice [3] 5:6; 6:4; 184:18
JCO [2] 41:4; 312:1
Jim [2] 5:22; 184:8
job [6] 33:3; 168:15; 184:14,
 20; 271:8
John [3] 6:19; 16:14; 177:17
JOHNSON [14] 6:19; 16:16;
 106:21; 107:22; 145:22; 146:5,
 9, 12, 19; 147:1, 3; 177:10, 13,
 18
Johnson [17] 6:19; 7:21;
 16:15; 27:11; 29:14; 31:7;
 33:3; 37:9; 39:16; 43:14,
 50:15; 62:4; 73:9; 106:20;
 119:12; 134:3; 187:3
Joint [1] 274:13
joint [1] 50:22
Jones [2] 43:10; 93:9
Journal [2] 50:21; 234:8
Jude [1] 6:14
judgment [3] 46:16; 110:15;
 333:4
judgments [3] 64:11; 112:20;
 296:12

Julie [2] 6:16; 170:10
July [1] 260:14
June [1] 337:4
JUSTICE [7] 6:21; 79:13;
 153:2; 174:21; 183:7; 184:13;
 310:16
Justice [3] 6:21; 174:20;
 183:4
justified [1] 11:19

- K -

Kaplan [3] 213:5; 266:20;
 268:1
Karen [1] 6:6
Karin [2] 188:12, 16
Kathleen [2] 204:5; 256:13
Kathy [4] 256:17; 259:1;
 289:16; 292:20
keep [3] 16:1; 127:15; 336:9
keeping [1] 138:5
Kim [7] 6:10; 7:21; 148:19;
 167:16; 187:1; 324:7; 327:7
kinds [9] 14:6; 17:7; 25:18,
 22; 105:12; 108:15; 138:14;
 167:22; 180:9
knees [1] 54:5
knowing [1] 179:17
knowledge [2] 64:19; 173:1
KROOK [46] 5:22; 8:4; 113:7;
 114:11, 20; 141:2; 177:17;
 184:12; 234:16; 235:4; 236:3;
 238:22; 239:11, 15; 240:6;
 247:10, 15; 249:20; 250:20;
 251:5; 255:13, 18; 256:2;
 292:14; 293:4; 295:22; 296:11,
 16; 297:20; 298:5; 306:7;
 308:1; 309:2, 5;
 312:10; 320:10; 323:7, 10, 13,
 15; 324:5, 7; 326:7; 334:2, 6, 9
Krook [12] 5:22; 113:6; 141:1;
 143:5; 184:8; 238:21; 250:18;
 307:22; 312:9; 320:9; 324:4;
 326:6

- L -

L'Ambrais [1] 216:10
label [1] 309:9
labeling [8] 25:2; 231:20;
 255:11; 308:20; 309:11; 311:7,
 8, 17
labels [1] 309:16
laboratory [1] 207:1
lack [8] 21:16; 22:19; 118:15;
 119:19; 219:18; 225:20;
 260:20; 316:21
Lady [1] 6:5
lady [1] 141:8
Langdon [6] 195:8; 234:13;
 238:15; 241:5; 303:15; 332:6
language [1] 144:15
large [30] 37:18; 38:2; 44:11;
 52:3; 89:13; 92:6, 8; 97:2, 7;
 101:7; 105:14; 106:15; 109:16;
 123:8; 129:14; 136:5; 159:16,
 19; 164:6; 198:2; 200:22;
 213:19; 231:7; 242:22; 243:7;
 248:13; 292:20, 22; 330:19;
 332:21
largely [2] 11:10; 235:2
larger [11] 76:14; 104:15;
 105:2; 106:9, 18; 107:4, 18;
 109:21; 221:1; 228:6; 251:10
largest [1] 223:14
last [13] 28:22; 44:16; 52:7;
 53:13; 97:17; 98:9; 106:3;
 108:3; 151:4; 169:17; 184:17,
 19; 243:2
lasted [1] 67:7
Late [1] 215:20
late [3] 192:4; 245:14; 261:10
latency [1] 271:3
laudable [1] 304:21
Laughter [23] 26:20; 51:4;
 53:15; 88:4; 114:10; 129:6;
 134:5; 148:6; 153:7; 154:1;
 169:10; 175:2; 184:22; 185:14;
 246:4; 249:2; 287:10; 290:3;
 301:6; 316:2; 322:7; 324:6;
 328:20
launched [1] 65:4
Laurentius [1] 220:10
Leader [2] 6:18, 19
leads [1] 31:22
lean [1] 113:14
leap [1] 54:6
learn [1] 156:14
leave [4] 65:8; 185:12;
 282:12; 322:18
leaves [2] 139:10; 141:8
lectern [1] 16:18
leftward [1] 311:20
leg [2] 160:7; 161:20
legitimate [1] 116:5
length [2] 139:18
lengths [1] 244:1
lesion [1] 146:16
lessened [1] 151:14
lesser [1] 218:8
lesson [1] 72:12
lethargy [1] 280:4
Letter [1] 56:11
letter [6] 9:4, 9; 16:6; 27:1;
 183:12; 260:18
letters [1] 16:7
Leukemia [1] 270:14
leukemia [26] 182:7; 190:1;
 212:13, 15; 213:9, 11, 12;
 219:7; 241:6, 12, 15, 19;
 242:4, 8, 13, 18; 243:3, 11;
 244:16; 272:12; 274:5; 292:5;
 303:10, 13; 307:5
Leukemias [1] 212:10
leukemias [4] 212:7, 19;
 270:19; 271:3
leukopenia [2] 221:19; 222:6
leukopenic [1] 221:20
level [5] 155:11; 247:18;
 256:10; 263:5; 273:22
levels [4] 45:8; 125:18;
 149:15; 155:5
leverage [1] 64:2
LEVINE [14] 234:4; 237:3;
 238:11; 250:7; 289:3; 290:9,
 12, 15; 292:16, 19; 293:6, 18,
 21; 313:4
Levine [9] 204:3, 5; 232:1;
 234:4; 237:4; 238:12; 289:1;
 290:1; 330:22
lifestyle [2] 116:8, 14
lifted [1] 93:12
lightly [1] 64:14

likelihood [7] 21:3; 213:9, 11, 17, 22; 247:2; 248:11
 likened [1] 46:20
 likewise [1] 145:1
 Lille [1] 216:10
 limit [2] 308:22; 310:12
 limitation [1] 193:16
 limitations [2] 285:3; 296:12
 limited [6] 11:7; 148:12; 197:5; 294:13; 303:20; 315:19
 limiting [1] 193:18
 linear [2] 49:10
 lines [1] 263:15
 lipophilic [1] 198:22
 list [1] 206:20
 listed [4] 24:10; 167:11, 12; 272:18
 listen [1] 113:12
 listing [1] 269:12
 literally [1] 197:17
 Literature [1] 199:15
 literature [24] 26:14, 17, 19; 27:4, 12; 29:11, 19; 31:17; 32:3; 33:20; 34:13; 35:17; 41:5, 16, 22; 45:21; 46:13; 152:7; 243:4; 264:5; 283:17; 284:7; 290:18; 332:1
 live [10] 12:6; 14:4; 31:15, 20; 60:8; 88:2; 89:15; 143:19; 145:7; 213:22
 liver [3] 23:17, 18
 lives [6] 10:22; 11:2; 32:12; 54:10; 116:3
 living [3] 10:5; 15:9; 175:17
 locally [8] 200:18; 201:21; 227:11, 14, 20; 231:12; 315:1, 8
 located [2] 8:2; 187:6
 log [7] 104:19; 206:10; 209:3; 210:1; 217:19; 221:15; 268:6
 logic [1] 336:4
 logical [1] 64:13
 longest [1] 70:12
 looks [6] 21:1; 70:5; 265:2, 16; 266:6; 325:1
 Los [1] 6:11
 lose [2] 127:11; 178:15
 losing [3] 69:16; 183:8; 283:21
 loss [7] 189:21; 232:21; 233:22; 234:11; 236:5; 237:17; 295:1
 lost [4] 19:8; 30:21; 302:4; 306:19
 lot [32] 30:4; 32:5, 8; 33:10; 34:21; 37:15, 22; 42:20; 45:21, 22; 62:4; 75:20; 82:22; 96:11; 107:2; 115:4; 116:15; 128:3; 136:7; 161:19; 167:6; 238:18; 258:4; 260:7, 8; 270:16; 284:4; 297:4, 11; 299:2; 303:6; 304:1
 lots [1] 113:1
 love [2] 145:18; 288:10
 loved [1] 59:13
 low [12] 189:20; 212:7; 218:20; 222:4; 230:3, 13; 233:14; 243:13; 245:15, 22; 270:3; 282:1
 lower [16] 193:1; 198:21; 205:1; 208:8, 17; 215:13; 224:18; 240:16; 241:17;

254:18; 256:21; 257:1; 263:2; 270:21; 273:11; 284:11
 lowering [1] 245:10
 lumpectomy [5] 72:6; 250:9, 11, 17; 262:11
 lunch [1] 182:16
 lung [2] 23:15, 19
 LVEF [2] 271:18; 272:1
 lymph [4] 204:12; 258:2; 263:13; 300:4
 lymphocytic [1] 212:15

- M -

M-1 [1] 244:14
 M-2 [1] 244:14
 M-base [1] 41:8
 M.D. [2] 89:16; 194:1
 M4 [2] 242:18; 271:4
 M5 [2] 242:18; 271:4
 MA-5 [29] 233:17, 18; 239:1; 247:21; 249:22; 254:5; 261:21; 262:18; 263:9, 12; 264:1, 19; 265:6, 17, 22; 266:3, 6; 267:5; 268:22; 269:2; 270:2, 8; 271:17; 272:20; 273:3; 274:19; 300:3; 329:14; 334:4
 Madame [3] 26:1; 290:12; 292:17
 magazine [2] 58:22; 59:1
 magic [2] 103:22; 141:12
 magnitude [8] 159:3; 160:5; 161:12; 163:19; 269:9; 289:9, 15, 19
 main [5] 21:15; 53:18; 80:2; 94:10; 229:16
 mainly [1] 33:4
 maintain [5] 34:10; 64:20; 117:3; 236:19; 282:15
 maintaining [1] 65:17
 maintenance [2] 63:1; 273:8
 major [12] 64:21; 71:17; 77:20; 79:6, 7; 95:12; 120:5; 167:21; 174:14; 200:2; 260:19; 287:15
 majority [7] 84:22; 143:21; 207:19; 225:3; 226:15; 230:1; 234:17
 malignancies [1] 148:12
 malignancy [1] 280:19
 manage [1] 145:16
 manageable [1] 219:15
 managed [1] 145:18
 manager [1] 94:14
 mandate [1] 126:21
 mandated [3] 271:19; 281:5, 18
 mandating [1] 172:11
 manifested [1] 211:21
 manifests [2] 242:18; 245:16
 manipulations [1] 70:2
 Mantel [1] 267:8
 manufacturers [3] 14:2, 8; 16:1
 manuscript [1] 237:9
 Margaret [1] 190:20
 marginal [1] 106:10
 MARGOLIN [41] 6:10; 91:3; 119:6; 120:18; 126:15; 132:8; 142:17; 148:20; 155:17; 159:9, 15; 164:14; 166:19; 168:1;

172:14; 177:19; 180:22; 244:19; 249:3; 257:11; 290:1, 4, 10; 304:19; 309:18, 20; 310:4; 311:1, 18; 313:13; 314:1, 7; 321:16; 322:4, 6; 323:8; 324:2; 325:12; 335:5, 13; 336:8
 Margolin [23] 6:10; 7:21; 91:2; 119:5; 120:17; 126:14; 127:17; 132:7; 142:16; 155:16; 159:8; 164:13; 166:18; 179:11; 180:21; 187:1; 257:10; 289:22; 304:18; 310:22; 313:12; 321:15; 324:1
 Mark [8] 204:2; 234:1, 4; 237:1, 3; 238:12; 250:5; 259:1
 marker [6] 91:20; 125:22; 127:8, 21; 149:22; 156:15
 markers [5] 125:16; 126:19, 21; 147:4
 market [6] 58:21; 62:13; 65:19; 71:7; 127:18; 147:7
 marketed [6] 20:22; 21:1; 43:14; 131:1; 260:6, 13
 marketing [13] 17:11, 15; 18:9; 63:5, 11, 15; 64:1; 66:1, 7; 80:6; 128:11; 176:17, 21
 markets [2] 191:18; 194:10
 marrow [1] 191:22
 Marti [2] 61:11, 13
 Maryland [1] 5:15
 mastectomy [11] 72:7; 204:19; 208:14; 221:6; 250:1, 10, 22; 251:2; 258:2; 264:3, 5
 matter [12] 59:20; 73:17; 78:11; 110:4; 130:21; 172:1; 238:8; 259:14; 267:22; 278:10; 295:4; 327:10
 matters [2] 17:2; 299:12
 mature [1] 107:1
 maximum [3] 66:5; 199:10; 272:18
 MCF [1] 253:6
 meaning [4] 8:7; 138:9; 144:3; 187:11
 meaningful [10] 60:5; 97:13; 105:1, 15; 127:17; 163:5; 262:21; 268:19; 271:10; 333:20
 meaningless [3] 10:18; 12:20; 86:22
 means [12] 24:1; 31:20; 115:12; 119:13; 142:1, 10, 12; 150:4; 162:21, 22; 175:12; 197:20
 meant [3] 42:10; 132:1; 310:17
 measurable [2] 159:19; 275:11
 measure [11] 10:20; 33:9; 34:1; 74:14; 92:10; 98:7; 116:17; 140:19; 147:12; 166:15; 214:5
 measured [13] 31:8; 75:14; 76:16; 77:1; 92:2; 104:19; 109:7; 141:21; 142:14; 206:2; 230:17; 285:6; 286:4
 measurement [2] 31:9; 299:8
 measurements [5] 77:2; 93:13; 117:5; 119:14; 271:19
 measures [5] 10:20; 95:21;

117:2; 121:3; 138:13
 Measuring [1] 98:15
 measuring [8] 33:4; 88:11; 92:13; 94:21; 104:9; 141:22; 166:13; 180:5
 mechanism [5] 28:17; 65:18; 97:22; 198:10; 312:19
 Median [2] 227:22; 277:22
 median [31] 21:10; 31:19; 47:13; 48:1; 50:9; 103:16; 108:5, 6, 7, 9, 10; 109:5; 159:4; 173:16; 193:6; 208:9, 21; 217:6, 11; 221:3, 9; 225:8; 226:21; 228:8; 229:4; 241:16; 248:2; 277:19; 295:19; 321:3, 12
 medians [2] 31:16; 42:12
 medical [7] 5:20; 62:14; 64:11, 21; 83:21; 105:4; 137:6
 medically [10] 102:4, 21; 104:22; 105:15; 106:16; 130:16; 136:22; 165:12; 316:17, 22
 medication [2] 85:7; 289:19
 medications [1] 60:21
 medicine [3] 61:18; 98:17; 132:11
 Medline [1] 41:8
 meeting [23] 5:5, 8; 7:9, 10, 16; 14:13, 20; 15:2; 19:3; 167:2; 168:10; 175:1, 5, 11, 19; 182:15; 186:12, 14, 20; 188:15; 254:9; 337:3
 meetings [5] 169:9; 170:12; 183:11; 185:8, 10
 Meier [3] 213:5; 266:20; 268:1
 melphalan [2] 43:11; 44:11
 member [4] 59:12; 62:7; 67:18; 183:16
 Members [1] 9:12
 members [16] 5:12; 10:6; 15:3; 26:6; 43:19; 53:1; 73:9; 168:2; 183:9; 184:4; 189:19; 190:22; 191:5; 194:16; 232:5; 260:4
 Memphis [1] 6:15
 men [2] 16:2; 189:7
 menopausal [5] 207:13; 222:20; 227:13; 264:9; 269:6
 mention [9] 28:22; 37:17; 38:22; 96:14; 239:19; 254:9; 264:4; 296:7; 311:2
 mentioned [12] 37:8; 39:16; 45:6; 51:10; 99:22; 139:18; 252:3; 262:10; 273:4; 312:8; 330:18; 332:7
 Mercy [1] 6:5
 message [3] 247:4; 258:19; 268:16
 meta [15] 39:22; 40:13, 14; 41:3, 15; 44:22; 284:2; 289:8; 304:10; 324:10; 329:5, 22; 330:10, 11, 22
 metabolites [1] 198:18
 metastases [6] 23:16, 19; 206:16; 228:13, 22; 315:9
 metastasized [1] 67:3
 Metastatic [1] 194:2
 meter [47] 196:19, 21; 199:14; 201:8, 19; 202:1, 14; 203:1, 3, 7; 220:4; 223:2, 10; 224:13,

- 14; 228:16, 17; 246:17;
247:22; 248:3, 9; 252:15;
253:3; 255:2; 256:8; 261:11,
16; 265:18, 19; 270:21;
272:16; 274:17; 276:3; 277:7;
281:9, 21; 291:8,
14; 300:12, 16; 305:12;
306:11; 307:11, 20; 313:5;
314:12; 330:9
method [1] 58:10
methodology [1] 21:16
methods [3] 55:14; 57:8;
218:12
methotrexate [3] 27:18;
202:18; 322:12
microphone [1] 232:17
mid [1] 234:7
middle [1] 213:16
Milan [1] 193:15
Miller [9] 195:6, 9; 261:6;
270:17, 22; 287:9; 294:15;
301:7; 313:14
milligram [3] 291:7; 305:11;
307:20
milligrams [48] 196:19, 20;
199:14; 201:8, 19; 202:1, 13;
203:1, 2, 7; 220:3; 223:1, 10;
224:13, 14; 228:16, 17;
246:16; 247:22; 248:3, 9;
252:15; 253:3; 255:2; 256:8,
14; 261:11, 16; 264:10;
265:18, 19; 270:20; 272:16;
274:17; 276:3; 277:7;
281:9, 21; 291:8, 9, 14;
300:12, 16; 306:11; 307:11;
313:5; 314:12; 330:9
millions [4] 54:9; 72:1;
197:17; 299:11
mind [10] 69:16; 82:2; 87:2;
88:5; 89:12; 138:6; 142:7;
164:22; 290:20; 328:17
minds [1] 128:6
mine [1] 66:22
mini [1] 284:2
minimal [3] 81:20; 82:1; 105:7
minimally [3] 54:2; 57:16;
118:6
minimization [1] 192:21
minimize [1] 193:22
Ministry [1] 331:1
minor [2] 303:9; 304:20
minority [2] 18:3; 279:15
minute [4] 108:3; 164:22;
266:13; 279:8
minutes [3] 73:15; 140:9;
259:12
miracle [1] 67:10
misguided [1] 129:5
misinformation [1] 128:3
misinterpreted [1] 81:12
mislabeled [1] 313:17
misleading [3] 247:11; 250:8;
279:5
miss [2] 33:18; 178:21
missed [1] 24:3
missing [6] 107:8; 112:13;
13:2; 236:16, 18; 262:20
mission [1] 188:21
mistake [1] 43:20
mistaken [1] 92:4
mistakes [1] 43:21
mitomycin [1] 44:11
mitoxantrone [6] 43:18; 44:4;
92:4; 245:16; 312:16; 317:16
mix [1] 114:22
mixture [1] 317:14
modality [1] 264:7
model [1] 249:16
models [1] 255:22
modes [1] 264:19
modest [7] 18:6; 50:8; 218:5;
221:19; 222:16; 230:2; 289:11
modifications [1] 301:10
modulated [1] 235:20
modulators [1] 70:1
molar [1] 330:7
moment [4] 75:4; 95:10, 14;
232:13
money [3] 53:12; 61:21;
286:18
monitor [1] 124:9
monitoring [2] 124:7; 181:9
monoclonals [1] 70:1
monotoxicity [1] 34:10
month [45] 35:6, 8, 10; 36:10;
38:15; 39:18, 21; 43:12, 13;
44:12, 13; 45:9; 46:11; 47:20;
48:2; 82:17; 87:6; 93:14; 95:4;
102:9, 12, 13; 109:1, 14;
113:11; 119:21; 124:11, 13,
14; 138:9; 139:8; 141:11;
144:21; 160:9, 11; 162:10;
163:7, 15;
173:17; 263:6; 283:15; 287:1;
291:15; 321:12; 333:18
mood [1] 49:14
morning [28] 5:3, 9; 7:5;
16:16, 19; 17:10; 86:16; 87:15;
90:4; 175:5; 278:6, 9; 283:6,
10, 16; 285:8; 286:3; 287:3;
296:1; 316:1, 16; 320:14, 15;
323:9, 15; 324:19; 325:11
Morrison [1] 257:3
mortality [1] 41:14
mostly [1] 64:16
mother [1] 67:19
move [5] 132:12; 134:4;
273:16; 313:8; 332:11
moved [1] 80:3
moves [1] 273:22
moving [3] 257:19; 258:22;
310:3
Mrs [1] 93:9
MS [18] 6:12; 53:10, 16;
66:21; 84:12; 86:14; 167:10;
168:20; 188:16; 190:20; 232:7,
11; 233:9; 286:13; 288:4;
298:9, 15; 308:16
Ms [6] 86:13; 168:19; 184:13;
187:3; 286:12; 298:8
Mucositis [1] 280:6
mucositis [3] 174:18; 291:16;
297:6
multi-center [2] 202:5; 223:15
multi-focal [1] 297:2
multi-national [1] 223:20
multiple [6] 182:8; 192:18;
209:6; 210:7; 225:1; 226:17
murine [1] 255:22
mutually [1] 73:4
myelogenous [1] 212:14
myelomonocytic [1] 242:18
myelosuppression [1] 291:17
mytozantrone [1] 311:15
- N -
- Nabholtz** [1] 45:6
Name [1] 298:14
name [4] 5:6; 195:8; 234:4;
256:16
Nancy [2] 190:17, 22
narrow [2] 164:19; 325:1
narrowly [1] 324:13
National [4] 5:18; 112:1;
188:20; 204:1
national [2] 10:4; 292:1
natural [3] 55:13; 56:2; 111:1
naturally [1] 330:14
nature [2] 15:5; 267:6
Nausea [1] 269:19
nausea [9] 49:2; 189:20;
191:22; 218:14; 221:21; 230:6;
233:20; 279:13; 297:6
navelbine [1] 67:14
NCI [1] 50:22
NCIC [10] 203:22; 204:6;
206:1, 7; 217:15; 239:19;
256:18; 257:6; 259:1; 267:18
nd [1] 97:19
NDA [9] 24:12; 197:1, 4, 8, 10;
260:14; 261:2, 5; 296:8
neck [1] 335:5
needs [12] 25:19; 30:13;
58:20; 62:18; 75:19; 94:11;
167:5; 171:16; 176:8; 258:20;
285:16; 287:3
negative [7] 142:11; 170:14;
263:19; 284:18; 290:22; 294:1;
300:7
negatives [2] 31:12; 33:1
Nelson [2] 61:11, 13
neoplasms [1] 199:22
NERENSTONE [12] 5:20;
92:21; 123:9; 129:14; 132:16;
149:12; 165:15; 173:13;
300:21; 301:21; 317:9; 319:8
Nerenstone [15] 5:20; 7:20;
92:20; 119:15, 17; 122:17;
129:13; 149:11; 165:14; 187:2;
300:20; 301:20; 304:20; 317:8;
319:7
net [1] 18:17
Netherlands [1] 220:10
Network [1] 6:13
neurotoxicity [1] 233:1
neutral [3] 273:2; 274:6;
283:2
neutropenia [8] 210:13;
218:5; 229:22; 256:10; 269:15;
279:10; 280:17
neutropenic [2] 210:15; 230:2
Newburg [1] 88:17
Newcastle [1] 225:2
newer [4] 58:17; 70:22; 99:9;
328:4
news [1] 59:1
nice [3] 33:3; 271:8; 296:7
niece [1] 287:8
nil [1] 67:6
Nine [1] 314:19
nine [14] 27:15; 42:5, 10;
60:20; 106:12; 108:10; 109:16;
135:22; 164:4; 227:17; 243:2;
279:18; 306:19; 336:11
Nobody [1] 325:5
nobody [2] 119:18; 155:21
Nodal [1] 207:17
nodal [5] 206:15; 209:11;
210:7; 262:13; 263:11
node [23] 189:16; 191:9;
200:6; 201:17; 202:7; 203:21;
215:10; 216:5, 14; 219:13;
220:6, 12; 231:5; 234:9; 262:7;
263:13; 293:1, 7; 300:1, 4, 6;
306:14; 314:14
nodes [8] 204:12; 207:18, 20,
21; 258:3; 263:16, 17; 300:7
noes [1] 314:19
Noise [1] 120:14
noise [2] 120:8, 11
nominated [1] 184:15
non-governmental [1] 183:20
non-hematologic [3] 211:1;
221:20; 230:5
non-significant [1] 268:3
noncredible [2] 75:3, 8
noncurable [1] 332:21
noncytotoxic [1] 198:18
Nonetheless [1] 272:8
nonetheless [2] 237:14;
289:5
nonhematologic [1] 218:13
nonirradiated [1] 313:20
nonprofit [3] 61:15; 62:7;
188:21
nonstatistician [1] 105:6
nonstratified [2] 267:14;
278:12
nonsymptomatic [1] 95:21
nontoxic [3] 34:9; 55:13; 57:7
North [2] 205:13; 258:8
NOSS [1] 188:16
Noss [2] 188:12, 17
note [8] 48:10; 203:11;
204:21; 205:12; 207:6; 210:3;
214:12; 229:12
noted [7] 8:19; 13:10; 188:1;
212:5; 228:8; 229:15; 284:21
notes [1] 296:19
notice [1] 60:16
noticed [3] 30:14; 151:17;
284:22
notices [1] 185:21
notion [4] 80:21; 144:2, 7;
331:15
notoriously [1] 123:12
notwithstanding [2] 8:10;
187:13
novel [2] 69:21; 70:11
NSAPB [1] 258:10
nuances [3] 64:22; 65:2;
160:17
null [1] 74:21
Number [2] 35:20; 308:18
number [42] 35:18; 40:17;
65:7; 74:11; 85:11; 93:6;
100:20; 101:16, 19, 22; 103:3,
15; 107:5, 9, 20; 109:16;
115:7; 123:10; 143:14, 15;
163:22; 164:22; 200:22;
204:11; 219:5; 225:22; 235:12;
240:12; 244:7; 245:4; 262:6;
264:18; 271:22; 275:8,

15; 280:14, 22; 292:14; 296:8;
307:6; 323:17; 334:17
numbers [13] 36:7; 40:4;
47:13; 105:8; 198:2; 203:15;
234:19; 241:7; 246:14; 248:13;
266:21; 281:14; 319:11
numerically [1] 106:9
numerous [2] 183:11
nutrients [1] 56:4
nutritional [2] 55:18; 64:17
ny [1] 286:8

- O -

o'clock [2] 182:13; 337:2
Objective [1] 79:17
objective [8] 18:22; 121:3, 5;
149:5; 199:17; 225:13; 230:17;
305:18
obliterated [2] 38:19; 78:22
obliterates [1] 318:18
obscure [12] 19:12, 16; 21:6;
74:22; 81:1; 84:5; 120:9;
130:8; 133:15; 278:7; 318:14,
19
obscured [4] 22:22; 84:1;
131:10; 134:9
obscuring [3] 128:18; 129:11;
131:7
observation [5] 46:9; 74:13;
109:11; 117:7; 275:19
observations [1] 74:10
observe [2] 74:16; 103:2
observed [16] 193:14; 212:2,
8; 218:18; 221:20; 229:22;
269:13; 274:5; 278:16, 22;
279:17; 280:1; 281:12; 316:21;
334:18; 335:2
observing [1] 83:19
obstacles [1] 62:10
obtain [2] 97:3; 176:17
obtained [4] 8:1; 24:13;
187:5; 209:4
obtaining [2] 195:15; 215:12
obvious [4] 57:1; 132:14;
155:20; 309:9
Obviously [2] 114:4; 241:5
obviously [14] 24:2; 39:7;
47:17; 79:3; 97:18; 99:16;
106:19; 113:19; 156:12; 168:3;
239:2; 251:20; 325:20; 332:17
occasional [1] 23:9
occasionally [2] 169:8;
244:13
occasions [3] 183:11; 234:22;
235:15
occur [2] 20:7; 211:18
occurred [14] 108:3; 210:19,
21; 211:2; 212:3, 19; 218:14;
221:22; 230:6, 11; 240:17;
244:9; 270:10, 21
occurrence [2] 241:6, 7
occurrences [1] 213:12
occurs [3] 33:18; 125:10;
246:16
October [1] 193:12
ODAC [6] 19:2; 26:6; 56:10;
72:16, 17; 167:2
odds [2] 104:19; 284:8
offer [11] 55:22; 56:12; 57:2;
60:14; 61:5; 85:12; 134:16;
162:13; 288:10, 11; 292:9
offered [1] 131:13
Office [4] 8:2; 88:18; 185:5;
187:6
office [2] 122:2; 185:6
offset [1] 60:15
offsets [1] 288:6
Ofentimes [1] 240:15
oftentimes [1] 111:7
Oh [4] 130:13; 140:7, 11;
179:10
oh [1] 188:8
Okay [44] 80:10; 104:3; 128:9;
132:13; 134:6, 20; 154:12;
158:9; 176:1, 19; 186:8;
188:10; 232:18; 233:10, 11;
235:15; 246:2; 248:17; 250:20;
251:5; 254:13; 256:2; 259:8,
10, 17; 298:5; 299:21; 307:8;
308:17; 314:1, 20; 323:2, 12,
14; 330:8;
333:5, 18; 334:6, 9, 13, 16;
335:14; 336:8, 12
okay [4] 141:10; 162:1;
245:22; 292:9
old [3] 67:19; 112:4; 246:22
older [2] 43:17; 327:16
ominous [1] 281:1
omitting [1] 106:22
Oncologic [5] 5:5; 14:14;
183:16; 185:20; 193:3
oncologic [2] 54:7; 125:19
oncologist [1] 5:21
Oncologists [1] 57:10
oncologists [2] 56:12; 71:15
Oncology [2] 50:21; 234:8
oncology [9] 56:8; 59:1, 16;
75:13; 88:2; 157:20; 195:9;
318:11; 319:4
one-third [1] 227:19
ones [5] 54:3; 179:7; 279:6;
286:17; 291:1
ongoing [2] 253:16; 254:17
onset [2] 144:10; 242:5
Ontario [2] 204:3; 331:1
open [10] 9:5, 7; 56:7; 74:6;
94:3; 116:19; 188:8; 190:12;
288:20; 298:8
opens [1] 258:4
operations [2] 8:13; 187:16
opinion [2] 31:1; 72:21
opportunity [4] 9:13; 156:8;
191:6; 258:21
opposite [3] 11:21; 173:14;
178:8
opt [1] 293:7
Optimal [1] 194:1
optimal [3] 246:18, 20; 261:15
opting [1] 293:3
option [1] 195:17
optional [2] 94:17; 272:4
options [3] 57:17; 133:6;
189:9
oral [3] 253:6, 7; 282:6
order [9] 60:22; 81:20; 111:2;
112:15; 143:8; 157:1; 205:8;
206:21; 224:19
orders [1] 125:22
ordinary [1] 153:1
organ [3] 206:18; 225:5;
275:16

Organization [1] 188:20
organization [6] 10:4; 53:4;
61:15; 188:14, 21; 190:19
orientation [1] 199:2
original [5] 157:22; 203:14;
261:5, 8; 267:5
originally [2] 26:7; 199:12
OSHI [1] 185:6
ought [4] 92:17; 308:20;
318:12; 319:4
ourselves [3] 111:12; 167:17;
294:13
outcome [5] 32:3; 82:19;
170:18; 264:12; 285:15
outcomes [4] 115:2; 120:3;
143:8; 331:20
outlined [1] 301:18
outlook [1] 232:22
outside [3] 53:9; 152:18;
199:12
outstanding [2] 184:14, 20
outweigh [2] 51:16; 52:16
outweighs [3] 8:11; 187:15;
214:2
ovarian [5] 96:15, 18; 104:18;
126:20; 164:7
Overall [1] 216:22
overdue [1] 55:9
overlap [2] 241:18; 298:4
overlooked [1] 254:12
overly [1] 126:16
overriding [2] 10:12; 86:17
oversight [3] 63:10; 64:9;
66:1
overstating [1] 154:8
overview [4] 39:15; 223:13;
289:7, 12
OZOLS [19] 5:16; 97:15;
124:19; 127:20; 130:9, 16;
139:4; 140:11; 144:19; 146:10,
14, 20; 156:6; 161:11; 162:5;
164:6; 305:16; 324:8; 326:22
Ozols [12] 5:16; 7:21; 8:6;
97:14; 124:18; 127:19; 156:5;
164:5; 184:6; 187:2, 9; 305:15

- P -

p.m. [6] 182:15, 16; 183:2;
259:15, 16; 337:3
package [5] 36:16; 244:2;
301:10, 19; 312:8
Paclitaxel [1] 194:2
paclitaxel [8] 27:22; 28:3, 6;
36:12; 38:4; 45:6, 8; 79:14
paid [1] 53:11
pain [3] 116:1; 122:18; 166:7
palliation [1] 95:22
palliative [1] 83:13
pancreas [1] 113:9
pancreatic [2] 154:10, 13
panel [1] 84:13
panels [1] 72:16
paper [8] 26:19; 41:18; 49:22;
50:20; 74:1; 258:13; 311:22;
313:13
papers [2] 41:18; 42:9
parallel [3] 167:20; 200:15;
236:2
paramount [1] 12:15
Pardon [1] 328:15
parent [1] 193:2
parentheses [1] 203:16
Parklawn [2] 8:3; 187:7
Part [3] 170:2; 255:21; 312:10
part [19] 7:9; 9:4; 48:4, 16;
77:2; 94:18; 103:20; 131:11;
136:10, 11; 138:19; 165:21;
170:10; 181:15; 186:13;
207:10; 210:16; 256:9; 320:3
partial [8] 18:5; 70:19;
193:10; 204:18; 208:14; 221:5;
250:1, 22
PARTICIPANT [3] 233:17;
335:9, 16
participant [3] 8:16; 62:12;
187:20
PARTICIPANTS [1] 176:5
participants [8] 7:12; 8:17,
20; 185:9; 186:16; 187:21;
188:2
participated [3] 41:9; 202:9;
238:6
participation [3] 8:11; 183:20;
187:15
pass [1] 334:14
pathophysiologic [1] 152:14
Patient [9] 190:18, 21; 191:1;
194:4; 216:21; 220:21; 225:7;
226:18; 227:20
Patients [23] 49:19; 55:14;
59:5, 15; 128:1; 202:20;
204:12, 14, 18; 206:16;
207:19; 220:14; 221:5; 224:4;
227:12, 15; 228:12, 14; 229:2;
275:11, 15; 281:19; 315:8
pattern [1] 238:19
patterns [1] 255:22
patting [1] 111:12
pay [5] 58:13; 64:22; 84:17;
94:12; 169:22
paying [1] 148:20
pediatric [2] 242:16; 246:9
peer [1] 189:2
penalize [1] 69:21
penetrate [1] 198:22
People [1] 137:12
perceive [1] 51:17
percentage [1] 332:22
percentages [1] 271:10
perception [2] 296:17, 20
perfect [3] 237:13; 284:15;
324:11
perfectly [1] 237:19
performance [8] 39:2; 48:14;
117:14, 15, 16; 166:8; 207:13;
296:4
performed [8] 207:16; 209:7;
261:14; 267:15; 271:6; 272:11;
273:20; 284:1
perimenopausal [3] 203:20;
206:12; 300:4
period [4] 85:9; 144:14;
213:13; 272:14
periods [2] 111:9; 198:3
permissible [1] 263:22
permit [2] 323:21; 333:9
permitted [2] 206:17; 264:3
permitting [1] 260:22
person [13] 53:6; 91:9; 114:1,
5; 115:11; 119:20; 120:3;
122:20; 127:14; 141:12;

- 142:13; 308:5; 327:9
Personally [1] 173:7
personally [8] 57:6; 85:6; 90:11; 120:9; 160:1; 299:14; 312:14; 320:10
personnel [1] 196:10
perspective [5] 15:8; 54:10; 213:2; 272:17; 298:17
persuaded [2] 82:7; 144:11
persuasive [4] 80:1, 20; 81:7; 303:5
pertinent [2] 171:11; 250:3
PETO [1] 289:7
pharmaceutical [10] 9:22; 23:5; 24:11; 25:1; 33:5; 53:12; 62:15; 65:21; 69:5; 177:15
pharmaceuticals [1] 64:15
Pharmacia [10] 189:6; 191:4; 195:10; 196:10; 198:1; 199:20; 201:14; 231:22; 243:1; 249:6
pharmacologic [2] 198:20; 199:8
pharmacology [1] 195:22
pharmacovigilance [1] 242:8
Phase [21] 28:4, 5, 12; 66:12; 153:13; 157:9, 11, 13; 158:12; 159:16; 182:7; 200:2; 201:4; 203:17; 216:2; 220:1; 223:15; 239:20; 252:1; 261:9, 13
Philadelphia [1] 5:17
phonetic [2] 226:13; 299:7
physical [5] 49:13; 169:14; 170:3; 214:8; 234:12
physically [1] 170:5
physician [14] 46:16; 49:15; 103:8; 113:18, 22; 114:4, 13; 21:2; 126:5; 127:21; 152:1; 296:17; 305:20; 312:12
physicians [10] 64:9, 20; 98:19; 121:9; 123:18; 125:18, 20; 134:16; 173:22; 289:9
pick [5] 74:4; 123:22; 174:19; 254:15; 286:2
picked [1] 16:8
picking [1] 174:13
pill [3] 60:13, 15, 16
pilot [2] 205:3; 239:20
piloted [1] 240:4
pipeline [1] 69:22
pivotal [5] 202:10; 203:17; 223:20; 229:16; 250:3
PKA [1] 198:21
place [3] 5:4; 64:7; 80:21
placebo [2] 47:15; 49:19
placebos [2] 54:13; 56:13
plan [4] 107:19; 160:21; 196:5; 284:6
planned [16] 62:5; 126:19; 208:10, 11; 216:17; 217:6; 221:4; 248:1; 262:18; 274:16; 276:7; 282:17; 300:16; 306:10; 307:19; 314:11
plaque [1] 185:15
play [2] 123:22; 124:20
Please [5] 53:4; 203:11; 234:2; 290:14; 299:17
lease [8] 43:19; 53:3; 73:20; 143:17; 188:13; 204:21; 299:17; 316:8
pleased [4] 184:2; 186:2; 196:9; 232:2
plot [1] 213:7
plotted [1] 128:1
plotting [1] 246:19
plus [8] 36:9; 67:9; 133:9; 177:12; 203:8; 218:6; 222:10; 262:5
PO-cyclo-Bonadonna [1] 257:8
podium [1] 53:3
point [41] 15:11; 34:12; 49:18; 64:2; 80:13; 81:16; 90:12; 94:10, 11, 22; 103:7; 106:13; 107:8; 108:1; 112:14; 117:9; 121:1; 126:10; 130:20; 141:17; 145:10; 152:7; 156:7; 168:8; 170:8, 19; 193:6; 214:9; 238:3, 18; 260:11; 269:20; 274:7; 290:22; 291:3; 301:21; 304:3; 318:3; 319:2, 9; 327:8
pointed [7] 29:14; 31:7; 95:18; 111:2; 170:3; 238:15; 305:22
pointing [2] 75:17; 76:22
pointless [1] 130:5
points [8] 91:1; 100:2; 113:2; 128:2; 261:7; 269:15; 270:18; 322:15
policy [1] 62:6
poll [1] 164:16
polychemotherapy [2] 41:12; 42:2
poor [5] 10:17; 37:12; 86:22; 276:15; 281:18
popular [1] 59:11
population [4] 207:11; 263:9; 268:7; 315:7
populations [1] 304:5
port [1] 311:21
portion [1] 236:14
posed [2] 14:19; 133:21
posing [1] 288:7
position [7] 148:13; 191:16, 20; 194:4; 198:9; 267:13; 283:18
positions [1] 192:5
Positive [1] 284:17
positive [35] 67:5; 147:18; 148:11; 166:16; 178:11; 185:22; 189:16; 191:15; 200:6; 202:7; 203:21; 204:12; 207:20, 21; 215:10; 216:5, 14; 219:13; 220:6, 13; 234:9; 258:2; 262:7; 263:16, 17; 268:17; 291:2; 293:1, 7; 300:4, 6, 7; 306:14; 314:14; 329:16
positively [1] 55:11
positivity [1] 208:3
possibilities [2] 56:22; 57:3
possibility [3] 131:14; 156:13; 319:11
post [7] 63:10; 66:1; 222:20; 250:12; 264:2, 5, 9
Postmenopausal [1] 220:12
postmenopausal [11] 200:13; 203:4; 216:5, 13; 220:5; 263:10; 264:12, 15; 269:4; 304:9, 12
potential [22] 7:15; 20:18; 38:20; 66:5; 82:4; 108:19; 111:16; 138:5; 150:10; 186:19; 193:15; 194:6; 211:18; 222:7; 242:19; 278:7; 284:22; 311:3, 11; 330:6; 331:11; 332:8
potentially [8] 63:13; 83:7; 84:5; 150:7; 230:13; 254:14; 280:13; 285:8
potentiate [1] 56:5
power [5] 64:1; 101:10; 103:8; 104:4; 165:6
powered [8] 37:2, 4; 165:3; 176:3; 180:11; 268:10; 269:6; 319:12
powerful [2] 13:13; 72:2
practical [3] 101:8; 134:13, 17
practice [9] 55:15; 57:10; 98:17; 125:19; 146:11, 22; 206:7; 208:6; 267:18
practices [1] 142:18
Pre [1] 216:13
pre [4] 203:20; 206:12; 216:4; 300:3
pre-NDA [1] 254:9
precautions [1] 194:5
precedent [1] 45:15
precious [1] 54:11
precise [2] 198:10; 304:21
preclude [2] 7:9; 186:13
precluded [1] 276:16
predetermined [1] 121:20
predict [1] 152:14
predictive [3] 50:2; 96:12; 312:4
prednisone [1] 92:4
predominant [1] 270:6
predominantly [2] 236:6; 264:4
predominated [1] 207:20
preferable [1] 166:9
preference [1] 143:8
premature [1] 119:8
premenopausal [8] 215:10; 253:12; 263:9; 269:1, 2; 293:1, 6; 304:14
premise [1] 291:19
prepared [1] 53:16
prescribed [1] 235:14
prescription [1] 66:2
presence [3] 83:20; 275:16; 296:18
present [13] 7:15; 17:11, 14; 23:17; 26:11; 53:2; 184:2; 186:19; 190:1; 259:13, 20; 271:10; 292:4
presentation [11] 19:2; 26:2; 27:12; 54:15; 80:16; 96:4; 151:17; 195:6, 19; 259:18; 315:8
presentations [9] 9:6, 8; 16:14; 53:8; 62:3; 73:12; 80:15; 85:19; 87:15
presented [20] 36:18; 37:18; 45:13; 73:12; 81:6, 7; 85:21; 86:5, 9; 138:21; 159:17; 195:14; 235:4; 241:11, 14; 246:5; 267:4, 16; 292:2
presenters [1] 113:18
presenting [4] 33:3; 36:7; 37:19; 151:6
presently [2] 22:17; 23:4
presents [1] 300:10
preservation [1] 144:13
preserved [2] 76:8; 283:21
press [1] 59:11
pressure [1] 63:20
prestratify [1] 181:1
Presumably [1] 115:10
presumably [5] 12:6; 166:16; 174:11; 265:8; 280:18
presume [4] 118:3; 122:14; 159:5; 312:19
pretend [1] 161:9
pretty [7] 81:19, 22; 142:17; 147:19; 155:20; 177:21; 310:3
prevent [1] 47:2
preventing [1] 99:11
previous [3] 8:22; 188:4; 335:6
previously [6] 59:7; 213:5; 229:10; 260:11; 261:3; 334:8
price [1] 190:9
primarily [2] 233:13; 245:16
prime [1] 198:9
principal [7] 204:4; 216:10; 220:11; 225:2; 226:13; 228:20; 234:5
principle [1] 303:6
principles [2] 15:21; 288:2
prior [12] 206:17; 225:6; 226:16; 228:12, 13; 229:1; 246:7; 275:10; 276:1; 311:12, 13; 315:4
priori [2] 117:17; 172:9
PRITCHARD [2] 256:14, 17
Pritchard [3] 204:6; 232:1; 256:17
private [1] 61:22
prize [1] 16:1
probability [1] 66:7
problem [27] 21:15; 23:9; 34:4; 74:16; 75:18; 76:11; 117:10; 132:15; 133:17, 20; 148:17; 160:15, 16; 169:12; 170:2, 11; 172:22; 178:9, 11; 179:17; 181:10; 240:15; 256:11; 284:16; 312:10; 327:8
probematic [1] 179:13
problems [15] 23:8, 10; 24:3; 29:13; 75:7; 88:13; 93:3; 168:13; 170:7; 240:19; 270:15; 280:22; 284:22; 292:5; 326:21
procedure [1] 204:11
procedures [1] 63:3
proceed [5] 9:5; 16:13; 195:5; 314:10; 328:1
proceeding [1] 328:1
process [6] 15:14; 63:12; 64:3; 72:19, 22; 162:20
produce [1] 14:3
produces [1] 200:8
producing [1] 99:10
product [3] 66:9; 194:10, 11
products [10] 8:15; 9:1; 63:16, 21; 64:11; 65:5; 131:1; 183:19; 187:19; 188:5
professionals [1] 59:1
Professor [3] 216:9, 11; 232:1
profile [2] 121:15; 199:8
profit [1] 58:15
profitable [1] 64:16
progesterone [2] 208:2; 263:19

- prognosis** [2] 37:12; 295:10
prognostic [3] 31:17; 182:9; 210:6
program [3] 199:21; 200:4; 243:1
programs [3] 8:12; 187:16; 198:2
progress [17] 12:8; 19:15; 25:11; 35:20; 36:11; 46:11, 15; 60:7; 84:20; 98:6; 100:3; 136:2; 142:3, 8; 147:16; 165:2; 317:4
progressed [6] 23:22; 67:8; 93:4; 114:3; 125:5; 140:8
progresses [4] 127:8, 14; 131:17; 133:10
progressing [7] 99:12; 111:4, 6; 123:4; 140:17, 22; 171:11
progressions [2] 101:17; 164:2
progressive [6] 30:2, 19; 95:14; 111:22; 280:15; 297:7
progrorsors [1] 101:22
prohibit [1] 20:22
prohibited [1] 65:16
prohibitively [1] 112:17
Project [2] 53:7; 298:16
prolong [7] 19:1, 5; 20:11; 67:20; 68:21; 83:13; 128:17
prolongation [4] 25:5; 51:19; 68:8; 192:18
prolonged [5] 34:15; 44:2; 46:15; 111:9; 194:7
prolongs [1] 200:12
promise [2] 13:18; 24:22
promising [1] 63:13
promoted [1] 64:17
prompt [1] 126:1
promyelocytic [1] 244:15
proof [2] 62:21; 303:6
properly [1] 66:11
prophylactic [2] 204:15; 210:16
prophylaxis [1] 264:1
proportion [4] 19:21; 92:8; 100:21; 208:14
proportions [1] 217:9
proposal [1] 176:12
propose [5] 82:15; 231:3, 11; 255:11; 288:16
proposed [9] 20:15; 175:3; 201:7; 300:18; 301:9; 306:13; 307:20; 311:7, 8
proposes [2] 201:15, 20
pros [2] 27:11; 32:16
prospective [1] 284:6
prospectively [7] 33:22; 126:18; 202:20; 219:10; 224:3; 276:5; 294:12
prosper [1] 88:3
prostate [3] 92:5, 12; 116:2
protect [1] 249:9
protection [2] 65:20; 249:17
protocol [12] 11:12; 20:14, 22; 72:20; 74:15; 126:4, 8; 203:15; 251:4; 267:5; 272:19; 276:11
protocols [7] 15:10, 14; 20:13; 23:11, 13; 182:4; 194:13
prototypic [1] 198:5
protracted [1] 198:3
prove [2] 63:16; 154:3
proved [2] 329:18, 20
proven [1] 206:13
provide [24] 23:6; 63:4; 66:5, 13; 83:13, 17; 112:19; 129:10; 131:11; 189:12; 195:20; 196:2; 230:16; 236:21; 284:6; 286:19; 288:21; 316:19; 330:6; 331:2, 20; 335:1, 3, 15
provided [9] 7:12; 13:19; 183:11; 186:16; 206:21; 263:18; 301:15; 307:3; 308:5
providers [2] 57:17; 59:7
provides [5] 63:9; 83:20; 287:17; 311:9; 331:16
providing [1] 196:8
provisions [2] 66:11; 275:20
psychiatric [1] 169:15
psychologically [1] 116:11
Psychotherapy [1] 140:11
psychotherapy [3] 140:6, 10; 152:4
public [10] 9:5, 7; 15:3; 16:7; 77:9; 116:19; 188:8; 288:21; 298:8
publication [2] 284:16, 20
publications [2] 197:16; 274:12
publicized [1] 173:21
published [20] 39:16; 41:4, 7; 43:10; 47:8; 49:22; 50:21; 58:22; 108:4; 112:2; 191:13; 192:3; 234:7; 237:9; 258:10; 260:7; 284:17; 290:21; 312:1; 329:5
pull [2] 232:13; 313:22
Pulmonary [1] 280:18
purporting [1] 150:5
purpose [2] 18:19; 134:18
purposes [2] 181:2; 182:2
pursuant [1] 320:14
pursue [1] 197:8
push [2] 69:17; 245:20
putative [2] 115:19; 152:11
putting [1] 312:11
puzzled [1] 9:18
-
- Q -
- qualification** [1] 169:4
qualify [2] 142:19; 158:12
qualitatively [2] 22:15; 166:13
Quality [3] 115:7; 214:15; 262:17
quantitate [1] 116:6
quantitative [1] 311:3
queries [1] 196:13
Question [4] 155:20; 176:2, 10; 300:14
questionable [2] 295:7, 13
questioned [2] 8:13; 187:17
questionnaire [14] 206:3; 234:7, 17, 22; 235:1, 13; 236:15; 237:6, 7, 8, 11, 17, 18, 21
questionnaires [2] 48:5; 236:12
Questions [6] 153:3, 18; 155:18; 157:1; 232:5; 233:20
questions [43] 13:11; 14:19; 15:4; 58:20; 74:3; 79:7; 100:17; 113:14; 115:3; 119:10; 128:10; 130:15; 137:16; 153:20; 154:19; 167:22; 196:10; 204:8; 214:7; 216:12; 232:2, 10, 14, 19, 20, 21, 22; 233:21; 237:22; 241:3; 250:4; 258:4; 259:5; 268:15; 270:18; 285:22; 286:7, 10; 290:5; 299:21; 321:21; 335:7
quick [1] 259:11
quicker [1] 32:19
quickly [1] 148:14
Quote [2] 192:12; 193:18
quote [6] 41:3; 52:7; 116:11; 152:13; 193:2, 22
quoted [5] 47:8; 48:4; 246:16; 289:8; 313:14
quotes [2] 50:20; 51:7
-
- R -
- Radiation** [1] 221:7
radiation [10] 208:15; 221:6; 258:1; 262:11; 274:11; 311:4, 12, 21; 312:3
radical [1] 198:14
radiographic [1] 146:3
radiographically [1] 144:3
radiologic [1] 77:1
Radiotherapy [1] 217:8
radiotherapy [3] 204:19; 249:22; 250:2
raise [4] 13:11; 145:10; 180:9; 302:11
raised [3] 9:19; 111:15; 119:18
raises [4] 24:5; 71:4; 82:2; 182:5
raising [2] 80:17; 278:5
ramifications [1] 95:11
randomization [11] 30:2, 18; 204:14; 212:22; 238:1; 264:21; 267:12, 17; 268:8, 11; 273:21
randomize [1] 300:8
range [7] 31:17; 108:6; 161:17; 215:2; 254:21; 255:1
ranged [1] 108:8
ranging [1] 45:3
rank [6] 206:10; 209:3; 210:1; 217:19; 221:15; 268:6
rapid [1] 63:11
rare [2] 221:19; 242:15
rarer [1] 189:22
rate [41] 18:8; 21:1; 28:10, 17; 38:7; 39:12; 40:3, 5; 45:14; 79:17; 96:10, 12, 17, 21, 22; 97:3; 99:8; 104:20; 105:3; 123:14; 137:21; 154:6; 193:9; 200:17; 225:13; 227:4; 228:5; 276:8, 12; 283:3, 7; 285:9, 10, 12; 287:2; 315:14, 20; 324:20; 331:8, 9; 334:22
Rates [1] 230:12
rates [19] 41:13; 79:20; 137:18; 193:4; 194:20; 199:15, 17; 219:16; 229:9; 230:2, 17, 18; 231:16; 236:19; 241:8; 274:7, 10; 278:16, 20
ratio [18] 40:3; 41:14; 101:15; 103:9, 18; 104:1, 11, 17, 20; 107:9, 11; 109:18; 209:15; 210:10; 273:8; 282:16; 283:1; 284:8
ration [1] 101:11
rational [1] 65:19
rationale [1] 17:13
ratios [4] 41:17; 75:22; 102:15; 331:10
reach [1] 308:2
reacting [1] 144:15
read [6] 9:4; 29:10; 59:11; 183:13; 186:9; 296:11
readers [1] 59:2
readily [3] 157:14; 198:22; 219:15
reading [5] 7:2; 29:18; 255:16; 286:2; 296:13
reaffirm [1] 175:9
real [19] 25:3; 33:18; 34:3; 57:3; 82:9; 84:10; 115:22; 116:22; 124:15; 129:7; 138:8; 149:16; 163:6; 315:22; 316:20; 318:14, 15, 19
realistic [1] 165:6
realize [8] 29:12; 71:5; 134:15; 170:11; 239:5; 296:12, 17, 22
reason [11] 13:9; 17:9; 18:11, 21; 43:6; 152:16; 166:16; 258:13; 295:15; 303:6; 304:15
reasonable [9] 63:6; 77:21; 78:17; 79:4; 134:19; 137:18; 172:4; 237:19; 328:22
reasonably [5] 117:22; 152:13, 21; 153:9; 174:13
reasons [9] 17:20, 22; 25:20; 109:17; 152:15, 17; 169:19; 197:7; 261:14
reassured [1] 77:8
reassuring [1] 117:8
recall [2] 145:17; 147:4
receive [25] 30:8; 44:7; 66:3; 171:15; 191:2; 197:19; 202:21; 203:6, 10; 204:15, 19; 211:20; 221:6; 224:5, 12; 262:3; 264:9; 278:4; 281:8; 293:3; 300:5, 8; 315:4, 7
received [29] 28:11; 36:21; 40:6, 10; 176:12; 191:3; 206:17; 207:7, 8; 208:15; 225:6; 226:1, 4; 228:11; 229:18, 20; 230:1; 235:19; 250:2; 262:2; 281:20; 311:13; 313:5; 315:18; 317:15, 19, 21
receiving [12] 13:3; 194:20; 202:17; 205:18, 19; 211:19; 214:6; 222:4, 12; 234:10; 243:17; 296:18
recent [5] 20:14; 21:7; 36:17; 78:11; 264:4
Recently [2] 20:6; 176:12
recently [6] 28:20; 30:14, 15; 58:22; 78:10; 329:5
receptivity [1] 185:22
receptor [7] 204:11; 208:2; 210:6; 220:21; 263:19; 264:14, 20
recessed [1] 182:16
recipe [1] 300:22
recognition [3] 14:9; 183:22; 185:16

- recognize** [4] 10:19; 11:6; 55:20; 183:10
recommend [1] 15:20
recommendation [3] 17:6; 25:14; 262:1
recommendations [2] 25:20; 168:14
recommended [2] 261:8, 12
recommending [1] 247:12
reconsider [1] 336:3
reconvene [2] 182:16; 337:4
record [11] 7:9; 8:5, 19; 73:18, 19; 127:11; 186:13; 187:9; 188:1; 259:15, 16
recorded [1] 222:11
recording [1] 234:3
recovery [1] 235:22
recur [1] 58:3
recurrence [4] 11:16; 72:10; 192:16; 274:8
recurrences [1] 52:4
recurrent [3] 213:19; 225:4; 226:16
recurring [1] 58:9
red [3] 266:8, 14; 277:14
redefine [1] 199:10
redefined [1] 261:14
reduce [4] 11:16; 58:21; 60:13; 91:18
reduced [3] 58:4; 194:17, 19
reduces [1] 72:10
reducing [3] 58:1; 66:6; 194:14
reduction [5] 72:1; 101:18, 21; 209:16; 210:10
reductions [1] 310:13
reemphasize [1] 86:14
refer [3] 107:8, 9; 294:11
referred [5] 53:17; 88:16; 119:20; 177:22; 270:22
referring [1] 334:3
reflect [2] 51:13; 297:5
reflected [2] 65:3; 244:2
reflective [1] 248:13
refractory [2] 137:19; 171:10
refusal [1] 30:21
regard [6] 7:8; 186:12; 249:11; 286:1; 321:5, 9
Regarding [1] 168:20
regarding [8] 14:16; 25:14; 114:19; 128:11; 195:12, 21; 233:20, 21
regardless [2] 91:21; 268:19
regards [1] 303:10
regimen [39] 17:19; 35:9, 10; 40:2; 46:6, 8; 83:8; 84:4; 200:10; 202:17; 203:19; 205:1, 2, 5, 11; 215:17, 18; 216:3; 217:13; 224:1, 18; 226:2; 228:9; 257:7; 273:6; 275:1; 282:5; 289:14, 19; 291:6, 16; 293:13, 14, 16; 315:18; 333:20; 336:13
regimens [15] 19:1, 5; 55:13; 177:9, 10, 14; 230:4, 10; 233:4; 265:1; 276:19; 289:14; 290:19; 327:12; 329:6
regiment [1] 224:19
regimes [1] 192:19
registered [2] 196:14, 17
regression [5] 51:20; 209:6; 210:8; 315:13; 321:2
regret [1] 183:8
regular [8] 24:20, 21; 68:2; 153:14, 15; 158:13, 21; 271:19
regularly [1] 206:22
regulated [2] 7:14; 186:18
regulation [2] 64:8; 183:19
regulations [2] 63:22; 152:11
regulatory [4] 149:20; 195:21; 285:4; 319:9
reimbursement [1] 324:15
reinforces [1] 183:18
reintegrate [1] 169:18
reiterate [2] 50:14; 298:22
reiterating [1] 261:8
reiteration [1] 91:5
relapse [28] 46:22; 79:1; 200:9; 205:21; 206:6, 9; 208:18, 21; 209:9, 13, 16; 215:9; 217:12, 16; 219:12; 221:10, 13; 222:15; 223:3; 231:9; 241:19; 245:7; 253:4, 14; 266:20; 300:19; 334:17; 335:2
relapsed [1] 229:1
relate [2] 32:17; 137:8
related [34] 18:11, 21; 32:11; 74:7; 96:10; 115:11, 16; 144:9, 10; 171:4; 176:7; 211:12, 15; 215:19; 218:10, 21; 230:13; 232:22; 233:6, 7, 15; 235:17; 241:13; 244:16; 255:21; 256:9; 270:13; 271:3, 7; 279:6; 280:13, 19; 281:2; 297:17
relates [3] 52:7; 90:16; 194:6
relating [1] 103:10
relationship [11] 51:13; 96:16, 21; 97:1, 5; 137:3, 4, 11; 222:7; 247:6; 285:17
Relative [2] 208:9; 217:6
relative [10] 47:21; 102:21; 120:20; 137:7; 180:5; 219:17; 225:8; 226:21; 227:22; 229:4
relatively [17] 12:20; 26:9; 54:16; 61:1; 75:15; 89:6; 105:7; 172:2; 198:18; 212:19; 230:3; 242:5; 244:12; 247:1; 270:3; 276:2; 281:18
release [1] 14:18
relegated [2] 94:10; 169:6
relevance [1] 105:4
relevant [8] 106:16; 125:19; 165:12; 210:12; 215:3; 218:4; 229:15; 317:1
reliable [7] 110:10, 21; 122:12; 153:11, 15; 158:10, 20
reliably [2] 92:2; 119:13
reliance [2] 323:21; 333:9
relief [3] 32:21; 46:17; 118:8
reluctant [2] 313:4, 10
rely [1] 79:20
relying [1] 79:21
remain [3] 69:2; 71:22; 143:9
remained [2] 111:10; 215:1
remaining [3] 213:9, 11, 17
remains [2] 23:19; 205:14
Remember [3] 250:8; 269:2; 281:7
remember [8] 92:15; 113:10; 114:18; 166:12; 258:9; 309:15; 326:16, 18
remembering [1] 77:11
remind [5] 25:13; 66:10; 80:5; 188:13; 308:21
reminds [1] 153:6
Remission [1] 193:4
remission [3] 193:6; 194:19; 281:20
Remissions [1] 192:13
remissions [2] 192:15, 19
remotely [1] 151:8
reorientation [1] 198:8
rep [1] 6:13
repeat [1] 260:10
repeated [2] 95:4; 266:2
repeatedly [2] 52:14; 194:16
replace [2] 144:20; 329:8
replicable [1] 303:3
report [8] 14:9; 121:7; 125:12; 236:11; 262:2; 297:5, 9, 11
reported [22] 7:13; 55:8; 56:10; 77:4; 136:11; 186:17; 191:13; 193:7, 11; 194:1; 212:10; 219:7; 243:17; 253:11; 266:22; 272:9; 274:7, 10, 11; 280:2; 281:14; 334:22
reporting [2] 50:16; 271:8
reports [4] 201:9; 243:4; 275:6; 296:11
represent [7] 88:8; 108:18; 109:2; 193:21; 253:21; 299:15; 333:20
representation [1] 175:10
representative [3] 149:9; 184:15; 295:12
Representing [1] 10:6
representing [2] 195:9; 298:15
represents [7] 12:8; 88:6; 90:22; 144:4; 150:4; 214:16; 251:19
reproduce [1] 268:18
reproducible [5] 304:6, 16; 316:13; 317:4; 321:9
reproducibly [1] 160:8
request [6] 8:1; 167:17; 177:14; 187:5; 201:12; 284:1
requested [3] 168:9, 17; 330:12
requesting [1] 197:2
require [4] 23:2; 117:2, 13; 154:14
required [11] 14:22; 24:19; 100:21; 101:3; 111:20; 158:12; 165:5; 206:12, 19; 263:12; 275:12
requirement [5] 17:14; 19:11; 166:1, 11; 167:21
requirements [4] 17:11, 13; 155:6; 157:5
requires [4] 14:8; 101:11; 162:17; 334:20
requiring [3] 17:20; 18:12, 22
requisite [1] 206:15
Research [6] 6:15; 7:15; 61:11, 14, 20; 186:19
research [8] 10:11; 61:21; 62:1; 63:1, 2; 92:16; 168:5; 245:8
researchers [1] 58:16
resection [5] 191:10; 201:17; 206:14; 231:6; 300:2
resources [3] 23:6; 327:2, 5
respect [6] 8:20; 136:17; 145:5; 157:6; 172:15; 188:2
Respectfully [1] 16:4
respiratory [1] 281:2
respond [3] 15:4; 89:2; 190:7
responded [1] 88:20
responders [1] 281:8
responding [3] 98:12; 196:12; 275:20
Response [1] 276:12
responses [3] 18:4; 149:6; 193:10
responsible [3] 183:18; 185:8; 199:4
rest [1] 181:16
restate [1] 313:10
restrict [1] 118:1
result [14] 12:7; 38:16; 58:5; 72:13; 118:10, 15; 126:1, 8; 170:4; 253:9; 259:4; 287:18, 19, 21
resulted [4] 200:3; 222:14; 229:8; 230:12
resulting [2] 199:11; 260:17
results [47] 30:12; 36:19; 41:19; 82:5; 122:12; 136:12; 157:17; 178:8; 180:16; 191:15; 193:2; 196:2; 201:13; 202:3; 213:7; 215:6; 219:9, 19; 222:13, 17; 223:9, 12; 231:7, 13; 238:10; 239:9; 246:21; 251:11; 253:19; 254:2; 264:20; 266:5; 267:20; 268:9; 277:12; 300:10; 301:18; 304:4; 326:5; 327:11; 329:16; 330:13; 331:7; 334:18, 21; 335:2
retiring [1] 184:4
return [2] 115:19; 190:10
revealing [1] 87:8
reversed [2] 157:10, 11
review [28] 15:4; 17:9, 10; 26:13; 27:12; 35:17; 41:5, 16, 22; 52:20; 78:9; 121:3, 17; 122:2, 9, 13, 15, 21; 151:6; 167:18; 168:13; 191:12; 218:22; 238:4; 252:18; 260:4, 20; 285:1
reviewed [7] 36:15, 19; 40:15; 42:1; 44:14; 163:14; 329:21
reviewing [4] 33:19; 34:19; 45:21; 192:2
reviews [3] 199:15; 243:5; 249:21
revisiting [1] 51:8
revoke [2] 14:11; 64:1
revolving [1] 116:8
rhetorical [1] 257:12
Rich [8] 76:6; 102:6; 124:3; 138:8; 144:20; 152:16; 180:11; 322:14
Richard [5] 5:18; 6:2; 7:20; 8:5; 187:9
Rick [2] 113:16; 318:2
ridiculous [1] 119:22
Right [18] 114:20; 131:15; 146:7, 14; 147:2; 153:4; 236:3, 7; 239:10, 12, 15; 247:14; 255:17; 297:1; 303:18; 322:4; 334:15; 335:21

right [43] 5:4; 16:13; 32:6;
53:17; 55:14; 59:16; 60:19;
68:11; 79:11; 80:4; 92:19;
98:1; 104:12, 13; 105:16;
106:14; 107:11; 112:18; 128:9;
153:4; 155:9; 160:7; 167:1;
168:6; 171:20; 178:1; 182:6,
12; 188:7; 229:20; 233:17;
254:18; 255:16;
292:6; 306:20, 21; 314:9;
316:5; 332:14; 334:16; 336:2,
6, 22
rigorous [1] 28:20
ring [1] 198:9
rise [2] 245:2; 310:18
rising [1] 147:7
risk [39] 11:16; 47:21; 51:13,
16; 71:22; 72:10; 138:3;
209:15, 16; 210:10, 11; 213:1,
3, 18, 20; 214:2; 242:12, 19;
245:11, 17; 246:7, 8, 9, 12;
247:17; 263:14; 271:15; 274:5;
288:6; 300:6; 307:14, 15;
311:9, 11; 312:2, 3, 6; 325:3;
331:10
risk-benefit [1] 283:1
risks [2] 289:18; 311:4
Robert [7] 7:20; 8:6; 61:10,
13; 184:6; 187:2, 9
robustness [1] 85:22
Roermond [1] 220:10
role [4] 112:21; 208:20;
215:11; 239:13
Room [2] 8:2; 187:6
room [7] 45:19; 91:8; 114:6;
140:7; 141:4; 245:21; 297:10
roughly [1] 248:9
route [1] 62:14
routes [1] 218:11
routinely [1] 79:5
rule [6] 77:19, 22; 100:19;
122:4; 132:11; 137:22
rules [2] 33:21; 124:8
run [2] 63:16; 163:18
runs [1] 138:16
Ruth [1] 262:22

- S -

sacrifice [1] 68:22
safe [3] 66:8; 149:10; 311:1
safeguards [1] 64:6
safely [1] 199:13
safety [14] 18:13; 22:10, 13;
63:6; 191:16; 194:6; 195:12;
197:21; 205:22; 223:13; 247:8;
305:2, 10; 307:18
sales [3] 307:7
salvage [3] 130:4; 134:17;
147:12
salvaged [1] 241:12
sample [2] 102:16; 197:4
sampling [2] 207:17; 232:8
San [1] 10:3
Sandra [6] 5:14; 7:19; 8:5;
26:4; 88:16; 187:3
Sandy [3] 80:18; 81:6; 91:13
SANTANA [9] 6:14; 85:18;
167:15; 168:18; 241:5; 243:16;
303:9, 18, 20
Santana [6] 6:14; 7:20; 85:17;

98:8; 187:2; 241:4
Sat [1] 220:9
sat [1] 85:18
satisfactory [1] 68:18
save [1] 309:22
saying [29] 51:3; 53:10;
92:14; 108:15; 109:10; 115:15,
18; 116:20; 127:17; 137:4;
140:5, 7; 142:2; 146:10, 12,
14; 164:4; 165:9; 174:3;
247:18; 286:17; 287:16;
293:20; 310:6; 318:15; 320:11;
325:6, 22; 327:15
scale [5] 141:22; 142:9, 12;
214:9; 215:2
scales [3] 214:11; 238:14;
296:22
scan [3] 93:11; 124:13; 143:2
scatter [1] 120:8
scenario [7] 24:11, 14, 15, 17,
21; 132:2; 316:1
scenarios [1] 24:10
schedule [11] 253:7; 265:3;
266:1; 277:8; 281:19; 282:7, 8;
285:15; 291:6; 301:16; 303:11
scheduled [1] 175:6
schedules [6] 218:11; 245:10;
252:6; 265:21; 301:8; 302:10
scheduling [1] 302:4
SCHIFF [1] 66:21
Schiff [1] 66:19
SCHILSKY [16] 6:2; 80:12;
110:7; 118:3; 121:12; 122:6,
10, 16; 125:9; 131:3, 15, 22;
144:1; 145:3; 156:20; 175:8
Schilsky [9] 6:2; 7:20; 8:6;
80:11; 110:6; 126:17; 143:22;
156:19; 187:9
scientific [1] 194:15
scientifically [1] 124:16
score [4] 166:8; 214:10, 13,
22
scored [2] 24:1; 296:9
scores [6] 49:11, 13; 50:1;
214:20; 215:1, 4
scoring [1] 23:21
se [3] 247:17; 305:5; 325:14
seats [1] 73:21
second [46] 18:11; 21:13;
24:17; 27:13; 28:12; 43:3, 4, 9;
44:3, 5, 8, 19; 60:16; 71:20;
79:16; 81:16, 19; 82:3; 128:20;
168:18; 176:14, 20; 177:1, 15;
178:6, 16, 19, 22; 179:5, 15;
180:1, 7, 15; 241:6, 11, 13, 15,
19; 245:7; 276:12; 278:6;
291:3; 303:10, 13; 306:7;
331:6
secondarily [1] 20:12
Secondary [2] 205:21; 212:7
secondary [23] 19:11, 18;
20:9, 16; 22:22; 32:1, 2; 64:5;
70:14; 71:16; 79:9; 80:22;
82:16; 83:16, 18, 20; 100:9;
128:15; 129:8, 10, 18; 131:9;
134:8
secondly [1] 192:20
Secretary [1] 6:7
secrets [1] 56:8
SEF [1] 291:1
SEG [1] 290:20

selected [11] 23:11; 96:7;
99:19; 135:14; 199:22; 200:21;
201:2; 243:8; 251:9; 296:10;
326:4
selection [7] 136:10, 11;
205:7; 251:8, 20; 254:11;
263:11
self-assessment [1] 49:10
self-assessments [1] 121:8
selling [2] 63:21; 66:9
senior [1] 51:1
sense [15] 78:19; 98:11;
100:20; 105:11; 115:14; 123:7;
127:13; 134:3; 247:1; 253:7;
265:5; 271:12; 272:3; 310:15;
324:13
sensitive [1] 285:15
sensitivity [1] 136:16
separate [9] 42:4; 180:18;
181:4, 7, 8, 21; 182:2; 259:22;
298:2
sequence [2] 123:19; 249:14
sequencing [1] 250:2
sequential [1] 177:7
serial [1] 281:5
series [2] 14:18; 123:13
Serious [1] 218:17
serious [6] 20:21; 77:12;
116:22; 162:14, 18; 189:22
seriously [2] 100:4; 332:2
serotonin [3] 269:20; 279:14;
307:1
serve [2] 14:6; 72:16
served [1] 226:13
serves [1] 22:18
service [3] 183:10; 184:1, 7
session [2] 7:6; 175:4
sets [1] 123:13
settings [1] 331:6
settle [1] 143:15
Seven [1] 200:2
seven [14] 42:11; 135:22;
165:1; 193:9; 200:21; 201:13;
213:10, 17; 214:9; 234:11;
279:19; 333:17; 334:17; 336:5
Severe [1] 230:8
severity [1] 211:9
shape [2] 89:6; 238:8
SHARE [2] 67:1, 18
share [3] 58:21; 73:4; 195:11
SHARE-New [1] 66:19
shared [4] 86:16; 87:3, 4;
275:8
shift [1] 311:20
shortest [1] 89:15
Show [10] 158:15; 159:1;
306:16; 308:10, 13; 314:18;
333:12, 15; 336:16, 19
showing [10] 35:1, 15; 36:19;
43:10, 11; 44:16; 45:14; 179:8;
293:12, 14
shows [14] 21:20; 23:7;
26:21; 36:20; 42:20; 56:11;
94:2; 173:10; 213:4; 214:19;
270:10; 277:12; 319:18;
321:20
shrink [2] 99:12; 109:22
shrinkage [3] 97:2; 230:17;
287:18
shut [1] 65:7
sick [2] 12:15; 95:9

sides [1] 266:10
signal [1] 70:1
significance [2] 106:7; 124:16
Significant [1] 315:18
significantly [19] 49:1; 164:9;
200:9; 208:19; 209:13; 210:9;
222:15; 223:6; 225:13, 15, 18;
227:4, 8; 228:5; 229:9; 278:2;
285:13; 288:12; 312:4
similarity [1] 74:19
SIMON [42] 5:18; 83:5; 95:17;
101:9; 103:11; 104:8; 105:12;
106:13; 107:19; 108:14; 129:3,
7; 135:3, 8, 13; 136:4, 21;
150:3; 154:15, 20; 163:3;
165:9; 168:8; 175:3; 179:10;
180:17; 181:9; 182:3; 251:7,
17; 252:11, 20; 253:20;
254:13; 294:4;
295:5, 18; 316:12; 321:1;
322:1, 5; 332:17
Simon [20] 5:18; 26:16; 83:4;
95:16; 106:22; 129:2; 150:2;
163:2; 165:8; 168:7; 174:21;
176:2; 179:9; 251:6; 254:8;
268:14; 294:3; 316:11; 320:22;
332:16
simple [4] 15:19; 98:14;
172:5; 324:7
simplicity [1] 255:11
single [14] 17:4; 41:12; 55:19;
90:12; 95:3; 152:6; 177:3;
194:20; 196:18; 224:12;
228:10, 15; 255:14; 261:16
sir [1] 293:18
sis [1] 97:18
Sisters [1] 6:12
sit [1] 290:1
site [1] 228:12
sites [8] 23:12, 13, 14; 95:5;
111:16; 225:5; 226:17; 275:16
sitting [4] 5:13; 37:19; 51:1, 3
situation [24] 11:13; 36:2;
37:6; 44:6; 46:20, 21; 47:5;
55:21; 61:1; 103:4, 5; 130:9;
135:8; 140:15; 158:3; 197:9;
237:16; 251:18; 284:14; 305:6;
306:3; 322:2; 324:14; 332:19
situations [2] 45:18; 137:4
six [35] 19:5; 22:4; 27:17;
35:10; 39:17; 45:3; 46:6; 50:8;
76:9; 138:10; 163:11, 15;
164:3; 204:20; 208:5; 217:2;
220:18; 221:7; 229:1; 239:21;
248:2; 258:15; 262:9; 275:18;
283:15, 17; 299:14; 320:16;
329:13; 330:12, 19; 333:17;
335:19;
336:4, 21
sixth [1] 175:1
Sixty-one [1] 193:8
size [17] 102:2, 16, 19;
105:10; 106:14; 109:7; 137:1,
2, 6, 8, 10; 180:5, 19; 209:11;
210:6; 221:2; 330:20
sizes [2] 108:16; 197:4
skeptical [2] 163:7; 325:13
SLEDGE [27] 6:8; 87:14; 88:5;
100:16; 105:5; 108:20; 117:10;
121:22; 122:7; 123:1; 134:12,
22; 139:20; 140:4; 147:20;

- 151:21; 153:17; 160:1; 161:3; 166:12; 171:19, 22; 172:11, 22; 174:9; 177:5, 11
- Sledge** [11] 6:8; 39:10; 48:13; 87:13; 95:17; 100:14; 103:21; 104:14; 108:2; 134:11; 170:2
- slide** [27] 17:22; 19:14; 21:20; 23:7; 24:5, 10; 43:20; 45:5; 199:7; 202:15; 203:8, 14, 15; 209:10; 210:12; 211:7; 214:19; 218:3; 229:14; 234:18; 235:5; 253:20; 260:12; 266:19; 269:11; 273:16; 285:21
- slides** [2] 135:22; 266:10
- slightly** [3] 265:21; 266:3; 280:8
- sloppiness** [1] 75:2
- slow** [2] 56:5; 71:3
- slowly** [1] 148:14
- slows** [1] 70:21
- smaller** [6] 102:14; 103:19; 104:1, 6, 12, 20
- smart** [1] 26:15
- SMDC** [1] 5:22
- SMF** [1] 291:2
- so-called** [1] 64:16
- social** [1] 169:15
- socioeconomic** [1] 326:21
- sole** [1] 79:16
- solely** [2] 160:4, 5
- solid** [2] 27:21; 313:17
- somebody** [11] 93:4; 95:8; 98:20; 114:2; 124:22; 130:4; 140:12, 21; 296:13, 18; 312:21
- somehow** [3] 37:10; 82:18; 285:15
- someone** [22] 39:5, 6; 57:5; 75:1; 76:17; 77:20; 100:11; 111:3; 112:17; 115:10; 116:1; 122:2, 18; 125:22; 133:18; 144:9; 145:11; 146:20; 147:11; 190:18; 248:20; 293:19
- Somers** [1] 6:6
- somewhat** [12] 27:11; 29:5; 38:12; 74:17; 79:22; 177:20; 225:17; 239:4; 254:18; 263:2; 270:2; 277:22
- somewhere** [3] 261:15; 326:16; 330:15
- sooner** [3] 81:15; 126:6; 247:20
- Sorry** [4] 158:18; 183:7; 238:2, 12
- sorry** [8] 107:7; 147:11; 207:8; 242:13; 295:1; 313:13; 330:15; 334:5
- sort** [31] 78:12; 91:5; 93:7; 95:10; 96:8; 97:5, 9; 103:10; 117:22; 119:22; 122:21; 125:7, 11; 134:18; 138:2; 143:20; 144:5; 147:16; 152:1, 17; 157:2; 161:16; 162:1, 2; 171:4; 246:21; 252:5; 295:11; 297:16; 298:12; 303:5
- sorts** [3] 121:19; 157:7; 295:2
- sounds** [1] 53:20
- Spanish** [1] 192:2
- speak** [5] 16:17; 54:4; 66:19; 188:11; 298:10
- speaker** [4] 26:4; 61:10; 190:17; 292:3
- speakers** [3] 9:6; 73:9; 288:20
- speaking** [3] 116:19; 171:12; 190:21
- speaks** [1] 278:8
- Special** [1] 185:5
- special** [2] 178:14; 185:3
- specific** [23] 25:20; 27:7; 28:2; 51:14; 58:10; 132:17; 133:5; 163:21; 166:7; 171:18; 201:6; 224:20; 252:7; 267:10; 269:21; 270:13; 279:14; 280:21; 286:14; 301:14; 307:1; 311:10; 312:6
- specifically** [10] 35:2; 36:5; 37:17; 49:8; 51:10; 78:7; 159:5; 214:5; 285:22; 298:12
- specificity** [1] 136:16
- specified** [4] 101:10; 272:19; 276:12
- specifies** [1] 126:4
- specify** [1] 169:22
- spectrum** [5] 11:21; 143:18; 155:13, 15; 197:13
- speed** [2] 71:6; 97:22
- speeding** [1] 109:3
- spend** [4] 262:18; 270:16; 284:4; 286:2
- spending** [1] 299:11
- spent** [2] 54:9, 22
- spoke** [1] 53:13
- sponsor** [5] 20:14; 168:15; 195:5; 232:6; 328:16
- sponsored** [3] 203:22; 216:7; 220:7
- sponsors** [3] 61:22; 168:4, 14
- sponsorship** [1] 53:5
- spontaneous** [1] 243:4
- springboard** [1] 26:12
- square** [1] 281:21
- squared** [47] 196:20, 21; 199:14; 201:8, 19; 202:1, 14; 203:1, 3, 8; 220:4; 223:2, 11; 224:14; 228:16, 17; 246:17; 247:13, 22; 248:3, 10; 252:15; 253:3; 255:2; 256:8; 261:11, 16; 265:18, 19; 270:21; 272:16; 274:17; 276:3; 277:7; 281:9; 291:8, 14; 300:12, 17; 305:12; 306:11; 307:11, 20; 313:6; 314:12; 330:10
- St** [1] 6:14
- stab** [1] 177:20
- stability** [1] 70:18
- stabilization** [1] 57:7
- stable** [4] 23:19; 84:20; 111:10; 143:9
- Stacy** [8] 5:20; 7:20; 113:17, 22; 124:20; 125:11; 131:16; 187:2
- Stage** [3] 191:11; 205:17; 300:3
- stage** [9] 11:11; 15:22; 27:21; 189:16; 207:14; 260:1; 290:17; 310:10; 327:18
- stages** [1] 327:19
- stairstepped** [1] 213:7
- stamp** [2] 64:12, 14
- stance** [1] 92:15
- standard** [40] 17:18; 55:9; 59:7, 19, 21; 69:4; 95:10; 122:4; 136:18; 146:22; 149:4; 152:11, 21; 162:8, 17; 170:16, 17; 174:5; 177:13; 200:10; 202:17; 205:10, 13, 15; 206:1; 223:22; 238:13; 250:13; 254:4; 256:22; 257:7, 14; 258:9; 283:14; 284:12; 291:22; 294:17; 302:1; 303:4; 325:17
- standards** [7] 54:8; 57:15; 61:5; 70:19; 94:21; 299:6; 318:2
- standing** [1] 16:18
- standpoint** [5] 52:11; 87:11; 88:13; 89:20; 134:13
- start** [19] 5:8; 28:21; 53:10; 66:21; 71:2; 82:6; 87:22; 89:18; 142:21; 143:7; 147:6; 164:1; 168:6; 182:13; 183:4; 244:20; 258:22; 259:4; 337:2
- started** [8] 5:11; 20:6, 12; 78:6; 88:20, 21; 89:1; 255:13
- starters** [1] 169:13
- Starting** [1] 199:13
- starting** [27] 73:21; 196:19, 20; 197:3; 199:9, 11, 16, 22; 201:7, 18, 22; 202:13, 22; 203:7; 216:18; 220:3; 223:9; 224:13; 228:15; 242:21; 247:11; 252:14, 16, 21; 301:9; 305:9
- starts** [2] 132:10; 154:20
- State** [1] 61:19
- state** [2] 309:9; 327:9
- stated** [3] 27:1; 262:17; 285:1
- statement** [8] 78:12; 114:4; 150:4; 151:16, 18; 168:21; 188:19; 262:22
- statements** [4] 7:3, 6, 22; 187:4
- States** [5] 10:7; 131:2; 191:15; 199:13; 205:18
- statistical** [8] 93:7; 104:4; 106:6; 152:6; 267:6; 273:17; 284:5, 6
- statistically** [25] 85:4; 88:10; 93:20; 94:3; 97:10; 139:21; 144:22; 161:4, 5; 165:18; 210:2; 214:21; 218:1; 221:14, 17; 227:7; 266:11, 17; 268:10; 269:7; 273:19; 277:15; 278:2; 282:10; 288:18
- statistician** [3] 104:10; 263:1; 268:5
- statisticians** [3] 30:6; 100:18; 284:21
- statistics** [1] 13:11
- Stats** [1] 88:18
- status** [18] 39:2; 48:14; 117:14, 15, 16; 166:8; 168:16; 204:11; 207:13; 209:12; 210:7; 220:22; 227:13; 264:14; 269:6; 296:4
- stay** [1] 12:13
- stays** [1] 109:19
- steep** [1] 245:2
- steeply** [1] 13:20
- stem** [1] 68:1
- step** [2] 20:3; 78:18
- Steve** [1] 225:1
- stick** [1] 335:5
- stimulating** [1] 307:2
- stomatitis** [6] 191:22; 211:2; 218:14; 221:22; 230:8; 270:5
- stop** [2] 24:12; 71:1
- stopped** [7] 48:20; 49:17; 58:12; 67:12; 111:3; 181:11, 15
- stopping** [1] 34:14
- story** [2] 57:9; 69:8
- straightforward** [2] 26:9; 120:22
- strata** [6] 37:5; 181:12, 19; 268:8, 9, 11
- stratify** [1] 192:16
- stratification** [5] 181:2; 216:15; 226:8; 262:13; 267:11
- stratified** [17] 180:14; 181:7; 204:10; 206:7, 10; 209:3, 22; 220:14; 224:15; 227:12; 228:12; 264:19; 267:17; 268:6; 273:21; 275:15; 278:12
- stratifying** [1] 264:18
- strength** [1] 282:12
- strengths** [1] 273:1
- strict** [1] 158:8
- strikes** [1] 120:5
- striking** [2] 90:4, 20
- strong** [4] 63:10; 150:4; 151:16; 173:6
- stronger** [1] 152:22
- strongly** [5] 62:8; 181:1; 194:22; 217:13; 219:19
- structural** [1] 198:7
- structure** [1] 198:20
- stuck** [1] 322:14
- studied** [7] 47:16; 90:19; 116:1; 193:5; 197:11; 280:7; 328:7
- Study** [6] 224:8; 226:6; 228:10; 300:3; 315:2, 6
- subgroups** [1] 182:8
- subject** [2] 113:1; 197:16
- subjective** [3] 119:20; 121:1; 124:1
- submission** [2] 261:5; 296:7
- submit** [4] 14:22; 24:12; 25:1; 188:19
- submitted** [10] 7:11; 16:4; 186:15; 197:1; 224:7; 260:14; 261:3, 22; 272:22; 314:22
- submitting** [2] 8:1; 187:5
- suboptimal** [1] 21:18
- subsequent** [9] 71:16, 18; 176:9; 235:22; 236:15; 285:10; 295:10; 309:15; 317:11
- subsequently** [4] 223:13; 225:22; 226:4; 315:17
- subset** [3] 39:9; 264:15; 268:12
- substances** [2] 56:1, 3
- substantial** [7] 97:1; 98:4; 225:21; 236:16; 288:11, 12; 329:21
- substantially** [5] 104:15; 197:9; 263:5; 264:11; 329:15
- substantiation** [1] 334:21
- substitute** [2] 68:18; 72:4
- substituted** [3] 11:14; 291:20; 320:4
- substitution** [1] 193:19
- substrata** [2] 37:1; 180:14

- subtypes** [1] 271:4
success [3] 171:5, 6; 183:17
successful [3] 168:16; 194:9, 12
such-and-such [1] 310:19
suffering [1] 85:6
sufficient [10] 110:15; 159:4; 165:6; 316:6; 323:3; 324:22; 335:1, 3, 15, 18
sufficiently [6] 153:11, 14; 158:10, 19; 177:2; 181:6
suggest [12] 55:12; 56:21; 72:17; 131:6; 132:3; 138:22; 193:15; 284:13; 301:5; 305:7; 307:9, 14
suggested [4] 91:14; 122:17; 193:22; 199:16
suggesting [5] 65:15; 103:11; 264:5; 274:20; 280:11
suggestion [4] 38:18; 126:17; 166:3; 303:12
suggestions [1] 322:21
suggests [8] 32:3; 110:14; 128:20; 138:12; 194:10; 269:9; 313:15; 332:7
summarize [2] 44:18; 196:5
summarizes [4] 210:12; 218:3; 266:19; 285:21
summary [11] 25:3; 214:9, 13, 19, 22; 215:4; 222:22; 230:15; 231:3; 274:14; 336:7
superimposable [2] 313:16, 19
superior [4] 91:14; 292:1; 318:21; 319:1
superiority [4] 17:17; 215:7; 219:11; 319:15
supplements [2] 55:18; 64:17
support [29] 49:21; 52:2; 65:22; 79:6; 82:21; 134:1; 151:8; 157:22; 185:16; 189:2, 4; 190:2; 191:7, 12; 195:15; 202:5, 19; 203:4; 223:17; 224:10; 231:19; 234:15; 261:22; 331:15; 335:1, 3, 15, 16, 20
supported [1] 79:18
supporting [1] 229:16
supportive [7] 79:18; 117:2; 224:2, 6; 326:11, 13, 18
supports [3] 21:15; 46:12; 51:21
suppose [3] 118:13; 145:20; 161:15
supposed [4] 154:16; 162:13; 318:20; 319:3
supposing [1] 144:21
surgery [4] 204:9; 207:16; 257:22; 264:20
surgical [3] 120:2; 204:11; 206:14
surprised [1] 49:4
surprising [2] 89:1, 3
surprisingly [1] 34:20
surrogate [47] 25:11; 34:6; 52:5, 9; 77:21; 88:7, 9; 90:3, 5, 7, 13, 22; 95:19; 96:3; 108:22; 110:13; 112:21; 134:21; 135:10; 137:18; 138:5; 139:2; 144:5, 17; 148:21; 149:2, 8, 10; 150:3, 5, 8, 16; 151:2, 18; 152:5, 12, 13, 18; 153:9, 11; 154:21; 155:6; 158:10, 20; 160:18, 19
surrogates [3] 25:6; 115:13; 167:9
surveillance [2] 198:1; 242:22
survey [2] 170:22; 173:10
surveying [1] 194:15
Survival [4] 18:17; 21:22; 22:9; 69:2
survivals [2] 108:5; 277:22
survive [2] 85:5; 116:21
survivors [2] 89:18; 171:13
susceptible [1] 246:10
suspect [4] 97:4; 174:19; 175:14, 16
SWAIN [16] 5:14; 26:5, 21; 51:5; 82:11; 135:11, 21; 140:2; 151:4; 154:2; 158:3; 160:20; 163:13; 166:3; 178:5; 180:11
Swain [12] 5:13, 14; 7:19; 8:5; 26:4; 62:4; 73:9; 80:18; 100:17; 111:1; 166:2; 178:4
symmetrical [11] 201:5; 240:18, 21; 252:2, 9, 12, 21; 253:4, 11, 21; 287:22
sympathetic [1] 289:4
symptom [2] 148:1, 2
Symptomatic [1] 212:1
symptomatic [24] 39:11; 46:2; 48:12, 18; 52:4; 76:18; 88:20; 89:13; 95:20; 98:15; 117:12; 118:1, 7; 142:13; 144:7; 145:12; 146:6; 147:16, 22; 150:9, 12, 17, 22; 246:13
symptoms [26] 32:21; 39:7; 46:18; 76:16; 88:21; 89:2; 91:21; 99:3, 22; 115:16; 118:8; 142:4; 144:9, 10; 150:13; 151:14; 160:10; 171:1, 4; 172:16; 214:8; 233:7; 234:12; 296:8, 10
syndrome [1] 256:11
synonymous [1] 12:4
synthetic [1] 198:4
system [1] 71:11
systemic [1] 206:17
-
- T -
- T-4** [1] 262:8
table [17] 5:12, 13; 16:18; 51:1; 53:9; 134:14; 164:15; 169:5; 213:2, 3; 246:21; 254:10; 267:8; 300:10; 306:21; 315:12; 334:8
tailed [1] 206:10
takes [1] 169:17
talk [14] 76:6; 86:7; 113:16, 17, 18; 127:12; 143:6; 182:14; 185:8; 273:1; 275:3; 279:9; 287:1; 323:17
talked [4] 71:15; 115:4; 166:4; 283:9
talking [38] 28:21; 29:9; 54:15; 69:9; 76:22; 83:9, 12; 89:5; 93:5, 17, 21; 102:14; 105:7, 9, 16, 21; 107:12; 108:22; 124:19; 134:2; 138:15; 158:4, 7; 159:5, 12, 13; 165:4; 171:19; 172:14; 177:6, 8, 11; 299:22; 301:12; 302:11; 303:17, 20
Tamoxifen [19] 57:21; 58:6; 72:9; 203:6, 10; 220:4, 15, 16, 18; 221:12; 222:1, 10, 14; 223:2; 243:17; 262:5; 264:10
tamoxifen [1] 200:13
target [6] 101:14; 102:2, 3, 20; 124:4, 5
targeted [3] 37:12; 70:2; 83:3
targeting [1] 104:22
targets [1] 61:4
task [2] 26:8; 121:11
Tastefully [1] 246:5
tax [2] 61:21; 259:3
taxan [1] 328:3
taxane [1] 313:9
taxitere [1] 259:3
taxol [4] 67:9; 125:1; 177:12
taxotere [1] 67:14
teaching [1] 64:21
Team [2] 6:17, 19
team [1] 260:4
tearful [1] 233:16
tease [1] 138:22
technical [2] 64:22; 65:1
techniques [1] 10:19
teeny-weeny [1] 322:15
telecons [1] 184:9
telling [4] 66:22; 114:1, 2; 124:16
Temple [21] 51:1; 74:7; 102:5; 106:22; 119:12; 127:6; 129:21; 136:13; 137:14; 145:9; 152:9; 161:13; 169:7; 181:13; 183:5; 184:21; 278:9; 293:9; 317:22; 322:8; 324:17
TEMPLETON-SOMERS [5] 6:6; 7:4; 9:9; 183:3; 186:10
temporary [1] 189:21
Ten [1] 306:17
ten [21] 31:18; 42:5; 51:8; 52:1; 58:3; 73:15; 102:8, 12; 105:8; 108:7; 109:20, 21; 140:8; 192:15; 193:9; 206:5; 207:18; 210:21; 279:10; 280:10; 281:10
tend [8] 74:21; 89:14, 18; 122:5; 127:10; 135:19; 279:5; 305:2
tended [2] 135:14; 157:22
tends [3] 120:9; 123:7, 8
Tennessee [1] 6:15
term [22] 29:15; 53:18; 61:6; 66:7; 85:12; 89:15, 17, 18; 141:20; 142:5; 171:10, 14; 175:13, 17; 183:16; 191:17; 193:16; 197:20; 270:9; 286:20; 298:22; 310:11
terminal [1] 199:5
terms [37] 12:13; 13:17, 19; 76:8; 87:19; 89:10; 92:13; 94:22; 95:12; 105:6; 108:18; 109:2; 115:2; 134:16; 135:19; 138:20; 150:17; 169:2; 180:10; 209:19; 233:14; 235:16; 240:19; 241:8; 258:22; 266:19; 271:17; 281:4; 283:12; 291:2; 297:15; 312:6; 313:16; 317:15; 320:12; 330:18
terrible [1] 68:9
terrific [2] 131:10; 186:3
terror [1] 116:13
tertiary [1] 292:22
test [24] 19:13, 17; 20:20, 21; 21:1, 6, 7, 12, 16, 17; 128:18, 19; 130:1, 10; 136:15; 206:10; 209:5; 210:1; 217:19; 218:2; 221:15; 240:20; 267:9; 268:6
tested [3] 31:3; 256:4; 305:5
testify [3] 57:6; 60:3; 72:16
testimony [2] 14:22; 66:22
testing [4] 22:19; 95:13; 121:5; 130:10
text [1] 53:16
Thank [41] 7:1; 9:2, 3, 13; 16:11, 12; 26:3, 5; 52:19; 61:8, 9, 12; 66:17, 18; 73:6, 7; 86:12; 87:12; 182:12; 184:12; 185:1; 186:5, 6; 188:6; 190:15, 16; 195:3, 4, 7; 231:21; 232:4; 259:8, 19; 286:9; 294:3; 298:6, 9; 299:18; 336:22
thank [5] 52:17; 184:7, 10; 188:18; 191:6
Thanks [3] 62:3; 74:9; 246:1
theme [1] 230:21
theoretical [4] 81:3; 82:8; 83:17; 131:14
theoretically [1] 263:14
theory [1] 56:14
therapeutic [2] 41:11; 332:19
therapeutics [1] 62:21
therapies [17] 13:3; 15:12; 20:9; 32:9, 14; 63:14; 73:5; 79:10; 80:3, 22; 91:17; 134:17; 178:13; 194:21; 226:5; 269:21; 322:20
There'll [1] 125:16
Thereafter [1] 196:2
They're [5] 16:9; 33:4; 60:19; 146:5; 321:21
they're [30] 54:3; 58:9; 63:21; 65:2; 71:3; 74:3; 82:18; 98:18, 19, 21; 116:11; 123:3; 126:22; 129:11; 140:22; 143:1, 13; 146:15, 16, 18; 182:1, 4, 5; 251:10; 292:22; 297:12; 305:19; 319:1
they've [2] 114:2; 145:12
thinking [3] 115:9, 20; 162:22
thiotepa [1] 27:18
third [6] 24:21; 79:19; 94:10; 129:18; 262:2; 312:16
thorough [1] 52:20
thoroughly [4] 63:20; 197:22; 206:22; 301:18
thoughtful [1] 185:16
thousands [4] 197:18; 242:11; 299:15, 16
threatening [3] 77:13; 162:14, 19
Three [2] 24:9; 207:4
three-arm [1] 42:6
three-quarters [3] 37:9; 228:22; 244:22
threshold [5] 254:15; 285:16; 305:11, 13; 321:19
thrombocytopenia [1] 210:18
throw [1] 151:15
thrown [1] 114:22

thumb [2] 100:19; 122:4
 tie [1] 88:10
 tied [1] 65:14
 tighten [2] 124:7, 9
 till [1] 143:1
 times [12] 33:14, 15; 65:7;
 74:13; 98:10, 13, 16; 115:8;
 127:22; 149:21; 164:9; 294:18
 token [1] 15:5
 tolerate [1] 60:22
 tolerated [1] 199:10
 Tomorrow [1] 337:2
 tool [1] 86:4
 tools [1] 92:18
 topic [3] 16:19; 27:7; 110:7
 topoisomerase [6] 198:13;
 212:9, 18; 213:14; 242:3, 15
 Tormey [1] 291:5
 total [18] 27:15; 41:8; 75:21;
 76:3; 87:7; 202:9; 214:15;
 216:20; 220:20; 224:22;
 226:11; 227:16; 228:18; 243:3,
 11; 251:2; 291:7; 309:12
 totally [5] 57:4; 87:8; 107:17;
 253:4; 332:18
 touch [1] 79:8
 tough [3] 121:13; 328:9, 11
 towards [3] 113:14; 162:21;
 257:19
 toxic [21] 10:11; 34:6; 38:10;
 39:5; 54:13; 55:2; 57:2, 16;
 58:6; 60:22; 70:4; 71:9; 73:4;
 77:15; 91:17; 219:18; 235:18;
 279:6; 288:13, 15; 291:18
 Toxicities [1] 219:15
 toxicities [17] 98:4; 102:21;
 210:21; 211:6; 215:20; 218:9,
 17; 221:18, 21; 222:16; 230:3,
 9; 235:22; 269:12, 14; 270:9;
 278:21
 Toxicity [1] 269:11
 track [2] 71:10; 77:10
 tradeoff [1] 68:8
 traditionally [1] 159:15
 transduction [1] 70:1
 transfusions [2] 279:22;
 280:5
 transient [2] 189:20; 214:21
 translate [11] 59:21; 97:8, 12;
 104:6; 163:5, 8; 165:11;
 178:16; 321:11, 14; 333:1
 translated [1] 104:20
 translates [2] 103:14; 137:9
 transplants [2] 68:1, 2
 trastuzumab [1] 29:2
 TRC [1] 45:14
 treat [4] 60:21; 207:11;
 267:14; 273:21
 treated [21] 11:11; 12:11;
 207:9; 210:19, 20; 211:3, 4;
 214:22; 215:14; 218:15, 16;
 222:1, 2; 226:4; 229:10; 230:7;
 248:21; 271:9; 307:6; 327:10
 Treating [1] 72:1
 treating [4] 151:22; 152:1;
 181:20; 325:18
 Treatment [1] 56:7
 treatments [27] 10:1; 11:22;
 13:22; 14:3; 32:1; 55:1; 56:5;
 57:15; 62:2; 71:7; 74:18, 19;
 82:13, 16; 83:9, 15, 16, 18, 20;

128:15; 129:8, 10; 134:8, 10;
 169:16; 171:15; 284:13
 tremendous [2] 75:7; 260:6
 tremendously [1] 90:18
 trend [4] 221:1; 225:14;
 229:12; 273:18
 trivial [3] 101:5; 105:7; 120:19
 trouble [2] 94:8; 335:19
 troubled [1] 318:20
 troubles [1] 319:22
 troublesome [1] 181:22
 troubling [1] 251:9
 true [20] 39:19; 40:14; 55:7;
 60:6; 79:3; 131:12, 21; 132:2,
 4; 140:4; 154:13; 271:12;
 272:3; 303:16; 309:4; 314:3;
 318:5; 322:1; 330:4
 Truly [1] 177:10
 truly [5] 15:2; 60:8, 22; 177:8;
 239:16
 truth [3] 171:22; 172:6;
 174:12
 TTF [1] 295:15
 TTP [8] 70:20; 119:13; 139:2;
 153:5, 10; 154:21; 315:19;
 321:20
 Tu [2] 204:6; 232:1
 Tuesday [1] 337:4
 Tumori [2] 193:8, 11
 tumors [5] 27:21; 111:10;
 262:8; 263:18; 300:8
 Turning [1] 220:1
 turning [1] 56:21
 turns [1] 185:12
 Twelve [3] 158:18; 159:2
 twenty [1] 291:14
 Twenty-two [1] 243:11
 twice [1] 164:16
 two-day [1] 5:8
 two-thirds [2] 244:22; 308:3
 type [14] 20:6; 40:1, 2; 83:2;
 170:15; 179:20; 204:10;
 207:16; 240:11, 14; 242:3;
 264:19; 327:17; 331:13
 types [7] 118:14; 126:11;
 197:14; 199:19; 232:19; 233:8;
 327:16
 typical [2] 271:2; 291:5
 typically [3] 147:14; 162:1;
 213:14

- U -

U.S. [3] 197:1, 10; 328:2
 ultimate [3] 11:5; 31:10;
 142:13
 ultimately [5] 13:19; 14:12;
 113:5; 249:15; 297:7
 unacceptable [1] 24:15
 unavoidable [1] 192:16
 unblinded [1] 125:14
 uncertainty [1] 74:12
 unclear [2] 131:4; 267:5
 uncomfortable [1] 144:1
 uncommon [2] 230:9, 12
 underestimate [1] 139:5
 undergo [1] 59:22
 undergone [4] 204:18;
 208:14; 221:5; 226:18
 undermined [1] 318:14
 understand [15] 12:21; 14:18;

55:7; 83:8, 11; 93:2; 94:17;
 98:11; 103:6; 105:6; 174:3;
 175:22; 255:20; 267:18;
 293:10
 understood [1] 161:21
 undertaken [1] 126:6
 underwent [1] 250:12
 unfortunate [2] 148:8
 Unfortunately [2] 48:6;
 276:14
 unfortunately [6] 32:3; 50:6;
 68:10; 242:6; 304:22; 313:6
 unhappy [2] 168:12; 299:15
 uniformly [2] 244:7; 332:20
 uninformed [1] 309:5
 uninvolved [1] 121:10
 unique [4] 15:11; 198:19;
 258:5; 331:19
 unit [1] 214:12
 United [5] 10:6; 131:1;
 191:15; 199:13; 205:18
 unity [2] 330:18; 331:10
 universal [1] 304:17
 universally [1] 235:13
 University [2] 6:3, 9
 unlikely [4] 53:13; 71:16;
 247:5; 264:11
 unlink [1] 161:11
 unnecessary [2] 58:7; 95:13
 unpublished [1] 260:7
 unqualified [2] 153:15;
 158:20
 unquestionable [1] 167:20
 unquestioned [1] 22:8
 unquote [2] 41:3; 116:12
 unresponsive [1] 123:12
 unselected [3] 96:8, 19;
 135:16
 unspecified [2] 125:15; 126:7
 unstratified [6] 209:5; 210:3;
 217:19; 218:2; 221:15; 273:20
 untreated [1] 322:18
 unusual [2] 75:15; 147:17
 unwanted [4] 60:13, 15, 17,
 21
 Upjohn [10] 189:7; 191:4;
 195:10; 196:11; 198:1; 199:20;
 201:14; 231:22; 243:1; 249:6
 upper [1] 215:2
 urge [5] 9:19; 65:10; 72:14;
 190:13; 194:22
 urged [2] 171:3; 194:16
 urges [1] 15:19
 USC [4] 7:18; 8:8; 186:22;
 187:11
 useful [4] 57:20; 61:7; 156:10,
 18
 usefulness [1] 51:12
 useless [1] 56:15
 user [2] 66:2; 72:22
 uses [2] 29:12; 127:21
 usual [4] 161:17, 21; 238:19;
 239:21
 utilize [6] 164:21; 165:2;
 175:13, 14, 17, 18
 utilized [1] 86:5
 utilizing [1] 55:22

- V -

vaccines [1] 69:22

vague [1] 14:14
 valid [6] 52:5, 9; 135:10;
 140:9; 179:6; 327:8
 validated [1] 234:8
 validity [3] 124:12; 236:21;
 238:9
 valuable [1] 112:19
 valuations [1] 111:20
 value [22] 107:4, 6; 178:14,
 17; 209:3, 4, 16; 210:2, 4, 11;
 217:19; 218:1; 221:15; 227:5;
 266:9, 13; 268:2, 19; 273:20;
 277:21; 278:18; 329:9
 valueless [1] 64:16
 values [1] 109:22
 variability [3] 113:17; 143:20;
 160:15
 variable [4] 74:13; 111:1;
 113:15; 114:9
 variables [3] 113:15; 114:8;
 209:9
 variance [1] 113:19
 variety [3] 134:16; 152:17;
 261:14
 VCQ [1] 232:8
 ventricular [5] 211:22; 219:4;
 271:18; 297:22; 307:13
 verify [1] 278:19
 Victor [3] 6:14; 7:19; 187:1
 view [14] 15:12; 18:7; 60:12;
 84:7, 13; 121:1; 150:21;
 163:10; 175:12; 180:18;
 281:16; 318:3; 319:3, 9
 viewed [1] 18:13
 viewing [1] 16:10
 viewpoint [1] 57:4
 views [4] 9:16; 53:2; 86:15;
 185:17
 vinblastine [1] 27:18
 vincristine [1] 233:3
 vinorelbine [1] 43:11
 Virtually [1] 217:2
 virtually [8] 81:9, 18; 122:7, 8;
 134:13; 208:5; 250:11
 virtue [1] 91:15
 visceral [4] 225:4; 226:16;
 228:22; 275:17
 visit [4] 235:14; 236:13, 20
 visits [2] 23:11; 236:15
 vitamin [1] 55:17
 voices [1] 10:7
 volume [1] 89:19
 vomiting [10] 189:20; 191:22;
 211:2; 218:14; 221:22; 230:6;
 233:20; 269:19; 279:14; 297:6
 Von [1] 246:22
 vote [21] 119:10; 143:20;
 158:1, 14, 22; 164:17; 176:3;
 178:2; 306:9; 308:9, 17;
 314:17; 322:22; 333:11, 14;
 335:9, 11; 336:7, 11, 15, 18
 Vulcan [1] 88:2

- W -

Wait [1] 334:6
 wait [6] 93:14; 95:7; 108:12;
 127:14; 146:5; 164:21
 waited [1] 55:16
 waiting [1] 234:13
 waiver [2] 7:22; 187:4

waivers [2] 7:19; 187:1
walk [1] 184:5
walking [1] 140:7
wall [4] 264:3, 5; 311:12; 312:3
wanted [24] 28:22; 29:8; 37:17; 39:15; 43:3; 45:17; 46:1; 49:19; 50:19; 51:6; 67:21; 84:12; 100:16; 101:9; 17; 104:21; 107:22; 108:1; 110:8, 17; 119:7; 125:4; 181:17; 294:4
wanting [1] 98:3
wants [4] 19:7; 45:19; 177:15; 318:22
war [1] 195:2
warns [1] 62:16
warranted [1] 249:12
wash [5] 32:7; 123:2, 8; 125:8
wastebasket [1] 30:17
wasting [1] 54:11
watch [1] 93:13
watched [2] 111:8; 236:4
watching [1] 148:14
ways [6] 95:2; 123:20; 167:16; 252:7; 303:6; 310:7
We'd [2] 183:3; 313:10
we'd [3] 77:7; 120:5; 183:9
We'll [7] 7:2; 73:15; 182:14; 299:20; 309:17; 313:22; 320:7
we'll [10] 37:16, 22; 73:16; 78:13; 93:13; 156:21; 266:12; 279:9; 323:16; 326:15
We're [25] 16:13; 54:11; 69:11; 73:21; 83:12; 87:10; 105:21; 159:13; 162:20, 21; 165:9; 182:13; 247:19; 257:21; 258:16; 259:17; 298:7; 302:11, 21; 303:20; 308:3; 313:4; 330:9
We've [4] 75:19; 78:21; 242:22; 283:15
we've [41] 28:20; 32:1; 37:21; 44:18; 57:14; 59:11; 78:18; 79:11; 87:15, 17; 88:15; 92:19; 97:12, 16, 17; 98:9; 112:14; 114:6, 11; 115:4, 21; 138:14, 15; 139:16; 145:22; 155:15, 19; 157:20; 162:22; 163:15; 166:4; 171:3, 8; 283:5, 9; 302:22; 306:3; 310:2; 318:22; 327:15; 335:4
weak [1] 152:6
weakly [1] 79:18
weaknesses [2] 273:1, 15
wealth [1] 148:18
wedding [1] 68:3
week [2] 15:1; 302:5
weekly [2] 67:9; 128:2
weeks [5] 26:8; 29:11; 81:20; 126:6; 220:18
weigh [1] 145:13
weighed [1] 274:4
weighing [1] 138:2
weight [2] 166:8; 332:12
welcome [3] 7:4; 55:10; 59:10
welcoming [1] 59:14
well-being [1] 49:14
whatsoever [1] 173:5
whenever [1] 270:15

Whereas [1] 101:7
whereas [3] 75:12; 130:5; 211:4
Whereupon [4] 73:17; 182:15; 259:14; 337:3
whichever [1] 84:13
white [2] 50:20; 189:20
widely [4] 47:8; 48:4; 260:13; 271:14
widespread [2] 194:9; 205:15
WILLIAMS [14] 6:17; 99:21; 106:3; 119:1; 134:2; 141:19; 155:5; 178:12; 254:8; 309:10, 17; 331:22; 334:10, 15
Williams [5] 6:17; 99:20; 118:22; 141:18; 310:17
willing [13] 23:5; 58:16; 112:18; 121:5; 146:2, 5, 13; 147:5, 6, 8; 155:22; 175:1; 255:11
Wils [1] 220:9
wise [1] 46:18
wish [2] 9:1; 188:5
withdrawal [2] 30:20; 294:9
woman [5] 69:9; 85:5, 6; 213:22; 316:18
Women [2] 262:8; 263:16
wonder [7] 13:6; 58:13; 78:18; 147:10; 200:20; 251:15; 286:18
wonderful [4] 67:7; 138:11, 17; 168:21
wondering [3] 81:2, 4; 314:4
word [6] 130:4; 147:11; 148:21; 152:10; 298:18; 326:8
words [3] 147:15; 248:8; 298:2
work [9] 57:5; 61:22; 66:8, 9; 71:2; 78:2; 183:18; 205:3; 328:11
worked [3] 57:3, 5; 71:14
working [4] 33:20; 69:11; 143:4; 170:9
works [3] 61:16; 163:1; 245:3
world [4] 56:22; 191:19; 242:10; 316:20
worldwide [4] 195:21; 196:15; 197:17; 260:6
worried [4] 77:7; 120:10; 122:21; 178:17
worrisome [1] 74:21
worry [4] 57:17; 60:12; 120:13; 270:15
worse [31] 18:20; 49:1, 6, 13, 16; 88:22; 89:3; 93:14; 98:22; 99:13; 115:15, 19; 139:7, 9, 10; 140:13, 19; 141:7, 13, 14; 143:2, 11; 161:17; 170:17; 172:19, 20; 178:7; 319:12, 19
worsening [1] 144:9
worth [12] 67:16; 75:17; 76:22; 77:11; 138:5; 145:8; 171:7; 172:19; 174:6; 261:7; 305:22; 325:2
worthwhile [4] 47:1; 69:1; 149:14; 173:18
wouldn't [17] 69:15; 78:2; 95:18; 98:22; 102:11; 115:12; 129:4; 144:18; 145:1; 146:21; 147:8; 161:22; 163:21; 166:10; 178:15; 181:14

Write [1] 26:19
write [1] 297:10
writing [1] 15:1
written [2] 8:1; 187:5
Wrong [1] 147:11
wrong [2] 130:4; 310:7

- X -

X-ray [1] 23:16
xeloda [1] 67:14

- Y -

Y-Me [4] 188:12, 17, 20; 189:7
yacking [1] 316:1
Yeah [25] 106:17; 107:22; 130:20; 146:4; 156:6; 171:8; 235:9; 241:5; 244:18; 251:19; 253:1; 254:19; 255:7, 10, 19; 256:13; 286:13; 287:11; 295:21; 301:14; 303:1; 305:16; 310:4, 5; 322:6
yeah [6] 74:4; 139:5; 154:14; 244:9; 309:17; 316:4
year [20] 29:1; 44:16; 67:7; 19; 71:20; 85:19; 86:8; 97:17; 110:4; 138:18; 175:1; 197:19; 206:6; 209:20; 213:6; 217:16, 20; 253:11; 292:21; 331:9
years [37] 20:8; 28:1; 31:20; 47:8; 49:5; 51:9; 52:1; 54:22; 55:12; 62:15; 67:3; 87:18; 91:22; 96:14; 98:10; 123:10; 166:6; 184:7, 19; 212:3; 213:10, 17; 217:12; 220:19; 221:9; 242:19; 243:2; 258:3; 262:16; 264:10; 266:21; 271:15, 16; 299:13, 14; 307:15, 16
yellow [1] 247:3
yesterday [1] 108:3
yield [1] 58:10
York [3] 6:5; 66:20; 298:16
You'd [1] 102:12
you'd [14] 100:5, 8; 108:12; 118:3; 134:1; 135:13; 147:15; 158:5; 163:22; 169:21; 233:8; 318:11; 319:4, 18
you'll [4] 103:7; 127:2; 179:17; 285:22
You've [4] 248:18; 262:1; 265:1; 334:10
you've [10] 118:4; 157:21; 186:3; 259:21; 260:4; 264:1; 266:21; 269:16; 276:19; 310:9
young [1] 67:19
yours [1] 245:20
yourself [4] 53:4; 188:14; 234:3; 249:1

- Z -

Zealand [1] 192:3
zero [9] 39:2; 48:14; 117:14, 16; 154:14; 237:15; 281:15; 296:4, 10
ZOOK [1] 286:13
ZOOK-FISCHLER [4] 84:12; 168:20; 288:4; 308:16
Zook-Fischler [4] 7:21; 168:19; 187:3; 286:12