

1 scientific research program on developing
2 these kinds of tools that will bridge from the
3 NIH-type study that we're used to doing in the
4 Academy to those that serve the regulatory
5 purpose, and combining it with those studies
6 that are already designed for advancing the
7 regulatory purpose.

8 DR. VANDENBERG: In the context of
9 this report, part of what we're talking about
10 there is that if we had better information on
11 absorption, distribution, metabolism, and
12 excretion, that's the basis for
13 physiologically-based pharmacokinetic models.

14 The advantage of such models is it
15 allows us to put the data that are available
16 on a common scale, which may be internal blood
17 dose, typically. At least, that's the starting
18 point, and so, when you've got disparate
19 findings, or a variety of findings from,
20 particularly from, subcutaneous, oral, and in
21 other cases, we may have inhalation exposures,
22 it allows us to do a comparison when the

1 concern is not at the portal of entry, not at
2 the nose or the mouth or the stomach. It's
3 actually distant to that.

4 So, it allows us that sort of --
5 the ability to consider more information in a
6 coherent way, and that's part of what I think
7 is being pointed to there is, is the
8 tremendous value of such modeling approaches.

9 But they do depend upon data that can be
10 collected, not through GLP studies, but
11 through the academic and government research
12 that is underway.

13 DR. MCNEIL: Garret, are you still
14 on the line?

15 DR. FITZGERALD: Yes, I am.

16 DR. MCNEIL: Would you like to make
17 any comments with regard to this last question
18 or any of the other comments so far?

19 DR. FITZGERALD: No, I'm in
20 agreement with all the things that -- I think
21 it's quite reasonable to include the
22 consideration of the studies that were not

1 designed for regulatory purpose with the
2 recognition that they are likely to raise
3 questions rather than answer them.

4 So, they're really hypothesis-
5 generating types of studies, whereas, I think
6 the distinction with the design of the
7 regulatory studies that were first the prime
8 focus of the FDA's consideration has been
9 nicely made.

10 DR. MCNEIL: Garret, we had a
11 little bit of trouble hearing you. Is it our
12 line or --

13 DR. FITZGERALD: Oh, I can hear you
14 perfectly well. I'm speaking into the phone.
15 Can you hear me now?

16 DR. MCNEIL: We can hear you now.
17 Yes. You must have changed your phone service.

18 DR. FITZGERALD: I'm sorry.

19 DR. MCNEIL: Do you want to
20 summarize, just a couple sentences of what you
21 just said so we're sure we have it?

22 DR. FITZGERALD: Well, I'm in

1 agreement with the distinction between the
2 nature of the studies performed for regulatory
3 purposes and the more hypothesis-generating
4 studies in smaller groups of individuals or
5 animals, as the case might be, that has been
6 made quite nicely.

7 DR. MCNEIL: David and then Jack, I
8 believe.

9 DR. PARKINSON: This is a question
10 from somebody who is not in the area. But to
11 follow up -- even with additional studies,
12 which I absolutely agree are necessary
13 listening to all of this -- is it possible to
14 give an isolated, fairly absolute answer
15 related just to the food safety exposure?

16 Isn't the tolerance really
17 dependent on other sources of exposure and
18 what the epidemiology is of exposure to these
19 agents from all sources?

20 So, in other words, the food
21 safety is just on top of other exposures, and
22 so, in the recommendations, doesn't one need

1 to consider some sort of broader
2 epidemiological study to understand what the
3 relative contributions of different sources of
4 exposure beyond those of food safety need to
5 be?

6 This is a common-sense thing, but
7 maybe it's outside of my, obviously, it's
8 outside of my realm of experience.

9 DR. MCNEIL: That was certainly
10 raised in one of the commentators. So Martin
11 or Antonio?

12 DR. CALAFAT: Well, I'm not an
13 epidemiologist either, but data,
14 epidemiological data, on BPA particularly are
15 not very abundant.

16 DR. PARKINSON: I figured out
17 because I couldn't find very much.

18 DR. CALAFAT: Yes. And then,
19 regarding your question about the cumulative
20 exposure, that's basically what we were saying
21 -- that maybe by using bio-monitoring data,
22 which is something that can provide an idea of

1 exposure from all different routes and
2 sources. And it's something that wasn't
3 addressed in the assessment report.

4 DR. PARKINSON: I understand that,
5 and I agree with that. The issue is, we're
6 going to have an independent activity in the
7 future on this kind of exercise for other
8 sources of exposure. How can one look at the
9 two separately? That's what I'm having trouble
10 with.

11 DR. PHILBERT: I don't think
12 there's any problem with the current approach
13 of isolating, evaluating, but it must be
14 closed by bringing everything together at the
15 end, and having some sort of capstone activity
16 that looks at the totality of exposure, body
17 burden, and disease processes that ensue.

18 DR. MCNEIL: Jack, you had a
19 comment?

20 DR. LINEHAN: I was just going to
21 ask a question. I read somewhere in the
22 copious materials that we were looking at that

1 the half-life, so to speak, in the body is
2 short.

3 So, how do you normalize in a
4 pharmacodynamic setting, exposure versus --
5 what, if you have a time-line like that.

6 DR. VANDENBERG: I think you're
7 pointing to one of the things that struck the
8 sub-committee in our discussions. And it was
9 really highlighted in the presentation by Dr.
10 Bucher where he illustrated through a very
11 effective figure, that in fact the metabolism
12 in young animals, neonates, doesn't seem to be
13 the same as the metabolism in the adults.
14 Much of the data we're working with here is
15 from the adult animal, and yet, with less
16 metabolism in the neonates, you're likely to
17 have increased exposure to those neonates
18 compared to the adults.

19 And so we're -- I think that was a
20 significant point of that data set that we
21 were presented with by Dr. Bucher and FDA.
22 So, you're talking about the pharmacodynamics,

1 which is the response. That actually affects
2 the exposure to free BPA in the infants or the
3 neonates as compared to the adults. So that's
4 really, kind of the level that we're looking
5 at it at this stage, but that -- given a
6 certain exposure in an adult versus the
7 neonate, how they respond to that is yet the
8 pharmacodynamic aspect and again, a lot of
9 uncertainty about that.

10 DR. PHILBERT: Sorry. Just to add
11 to that, Dr. Benet at the open meeting on the
12 16th also pointed to the fact that there's
13 likely to be pharmacogenetic or toxicogenetic
14 variation. And that there are already known,
15 some variations in the specific enzymes that
16 govern these reactions, and we don't know
17 anything about that in children. We're just
18 beginning to learn about this in adults.

19 DR. SASICH: Just to kind of follow
20 on what Jack was saying would a bio-monitoring
21 program or bio-monitoring study, would that be
22 difficult? Would this be urine, blood --

1 either/or? Is it expensive and is it something
2 that can be done in the field, say, in the
3 average clinical laboratory?

4 DR. CALAFAT: Bio-monitoring is not
5 cheap. It normally, for compounds such as BPA,
6 which are fast-metabolizing, so they're non-
7 persistent in the body. Normally, in
8 epidemiological studies, we're looking at
9 urinary markers. So, it is a measurement that
10 is being done in urine.

11 In animal studies, normally the
12 measurement is in blood. The concentrations of
13 -- the technology exists for measuring BPA in
14 blood products as well. The limitation is that
15 the concentrations in blood tend to be much
16 lower than the concentrations in urine. This
17 is in humans. In animals, you know, those are
18 the animals, then you can have very high
19 concentrations.

20 So, it probably would be a good
21 idea to have -- a bio-monitoring program
22 exists, and CDC is conducting such a bio-

1 monitoring program. NHANES, the so-called
2 NHANES, and this one is based in urinary
3 measures only, and is also a program that has
4 one limitation in the way that the younger
5 population, that is, the youngest population
6 that is being evaluated, is six years of age.

7 So, we do not have, from NHANES,
8 from a national program, we do not have bio-
9 monitoring data from children that are younger
10 than six years of age.

11 This doesn't mean that this data
12 cannot be available from smaller
13 epidemiological studies that may be designed
14 to address some particular questions.

15 DR. MCNEIL: Could I just ask for
16 clarification? The study that you're talking
17 about is the one that the JAMA article was
18 based on, correct?

19 DR. CALAFAT: Yes.

20 DR. MCNEIL: And the concern there
21 was, it wasn't clear when the exposure
22 occurred relative to any of the subsequent --

1 DR. CALAFAT: Yes, and then because

2 --

3 DR. MCNEIL: Is that going to be
4 remedied in some fashion by what approach
5 you're mentioning or is it just more of the
6 same?

7 DR. CALAFAT: No, it's basically --
8 One of the limitations -- NHANES is a cross-
9 section of data, so we're talking about one
10 sample from one person collected at one time.

11 And it reflects recent exposure to
12 BPA. It's not something -- maybe for some
13 studies, it would be better to collect
14 multiple samples, but the half-life of the
15 compound is really not going to change.

16 DR. MCNEIL: But, just to pursue
17 this another minute, could we agree then, that
18 that study is going to provide this sub-
19 committee or Board very little additional
20 information? If it's cross-sectional, one
21 point unrelated to knowledge about when the
22 disease state started?

1 DR. PHILBERT: I think there's
2 general agreement on the sub-committee that
3 was -- Oh, Garret, did you want to --

4 DR. FITZGERALD: No, no, no. I was
5 just about to echo in that I think we felt
6 that it has raised some questions that
7 obviously need to be pursued, but was by no
8 means conclusive in itself of any relationship
9 between BPA exposure in adults, and neither
10 cardiovascular disease or diabetes.

11 DR. MCNEIL: So, did you just agree
12 with what I said, Garret? That the NHANES
13 study is not going to provide an answer here?

14 DR. FITZGERALD: I would concur,
15 yes.

16 DR. MCNEIL: Okay. Just checking.

17 DR. TORTI: I had a question, but
18 maybe before I ask that question, I just
19 wanted to -- maybe this is the time to chime
20 in and also thank the sub-committee. This is
21 an enormous amount of work and we really do
22 appreciate it.

1 And I just want to remind folks
2 that the FDA provided a draft assessment
3 because it recognized this was an
4 extraordinarily complex scientific issue and
5 sought external advice. I just want to mention
6 that, so that's to say that.

7 I just had a question. As people
8 have suggested these future studies to more
9 completely understand -- more definitively
10 understand the issues, understanding that they
11 in themselves may not be perfect, do you
12 recommend or how do you think about the
13 presence of natural estrogens, phytoestrogens,
14 and whether those should be included in such
15 proposed studies?

16 Have you discussed or thought
17 about that because obviously, they bind the
18 estrogen receptor at a higher affinity than
19 BPA?

20 DR. PHILBERT: We didn't discuss it
21 as a sub-committee, but clearly it's something
22 that ought to be factored in.

1 DR. HEWLETT: I'm thinking about
2 some of the statements that were made about
3 not knowing when exposure was and magnitude of
4 exposure. I'm struck by the fact that this is
5 a problem of technology, that this is a recent
6 development and that probably there are other
7 parts of the world in which their -- or this
8 should be a question, not a statement.

9 Are there parts of the world in
10 which these sorts of products are not being
11 used now that might be appropriate for
12 comparisons to be made, especially in
13 children?

14 DR. MCNEIL: Do we know? You're
15 looking for a control group, that's right.
16 Does anybody have any idea? It would probably
17 be hard to get.

18 DR. PHILBERT: It's plausible. As a
19 non-epidemiologist, I think you would need to
20 find people who can design those studies. I
21 suspect that it's going to be a matter of
22 time. This is not something that we're going

1 to answer overnight.

2 DR. CALAFAT: Just speaking off
3 recollection, I know there was a study that
4 was conducted and published a few years ago in
5 Japan on a handful of Japanese university
6 students, and they were -- It was a bio-
7 monitoring study. They had been drinking, I
8 believe it was coffee now, I cannot really
9 recall, from some cans, and then they
10 collected some samples, measured the
11 concentrations of BPA in the urine. And then
12 years later, they had been out of formulation
13 of the canned packaging in the country or
14 something alike, and they collected some
15 additional samples from different students. I
16 don't think they were the same students. And
17 they show some differences in the
18 concentrations of the bio-marker in the urine.

19 So, your point is well taken, and
20 I think there may be some research -- maybe
21 unpublished. There has been quite a bit done
22 in southern Asia.

1 DR. MCNEIL: Are there any comments
2 from the FDA staff? Are there any other
3 questions or comments from the Science Board?

4 Well, let's do the following,
5 then. Why don't we put up our options, at
6 least in draft form, and this may lead to more
7 questions and more discussion, so we can at
8 least have something to discuss?

9 So, I put these up not to be
10 inclusive, but just to have something written
11 down that we could start from rather than just
12 have an up or down kind of vote.

13 Basically, the first two options
14 here -- and I believe the audience has copies
15 of this. Garret, I don't know if you do, but
16 we could probably e-mail them to you right
17 away.

18 DR. FITZGERALD: Okay.

19 DR. MCNEIL: Carlos will try and do
20 that now.

21 DR. FITZGERALD: Okay.

22 DR. MCNEIL: Do you have your

1 BlackBerry on?

2 DR. FITZGERALD: Yes. I have a
3 computer on.

4 DR. MCNEIL: Okay, good. You'll get
5 them in a couple of minutes.

6 Basically, the first two options
7 say accept the report essentially as is --
8 either totally as is or with some minor
9 editorial changes. For example, we already
10 discussed two of them with regard to the last
11 bullet, and I showed you those and you have
12 those. And if we take either one of those,
13 then we probably are able to transmit the
14 report to the FDA. You give it to me and I
15 give it to them is basically the way it would
16 work.

17 The second two say we can't quite
18 do that now. We really need more information.
19 And if we need more information, than we have
20 to get that information and re-present
21 whatever it is that we want at our February
22 meeting.

1 And the information can come from
2 one of two sources. The Science Board right
3 now, on the basis of the comments that we've
4 had, can, in general ways, list the kinds of
5 information that we would like the FDA to go
6 back and think about getting as a way of
7 resolving the uncertainties in the data and
8 hence, to help us make a better conclusion.

9 On the other hand, we could say
10 the FDA staff is in a much better position,
11 having written the original report, having
12 seen the report of the sub-committee, and have
13 heard this discussion, to go back and dig
14 deeply and find out what kinds of studies
15 would be possible to do that would answer
16 ambiguities and hence, arrive at a conclusion.

17 Those are four options I could
18 think of. I think the fifth option, which I
19 didn't sense a lot of enthusiasm for, was just
20 reject the whole report and say forget it. We
21 can put that on the table, but it doesn't
22 sound like that's a good one.

1 Can anybody -- yes?

2 DR. LINEHAN: I was going to
3 comment on what you just said, but maybe
4 you're not finished.

5 DR. MCNEIL: No, I'm finished. You
6 go ahead.

7 DR. LINEHAN: Well, as a non-expert
8 in this area, and I'm looking at the traces,
9 I'm sort of thinking that one of the first two
10 choices is something I would sort of naturally
11 want to do because I don't think I can,
12 sitting here, write out a list of instructions
13 for the FDA to identify areas in which
14 additional research would clarify ambiguities.

15 We had a conversation here. A lot
16 of it was anecdotal conversation about, well,
17 what about this and what about that? And so we
18 all learned a lot, but I'm not sure we've
19 learned enough to be able to give directions
20 to the FDA in a manner that would be, in some
21 sense, supercede what this excellent sub-
22 committee has done, with a panel of experts

1 who have spent a lot of time thinking about
2 it.

3 So if we as a Board -- the fifth
4 choice would be, I guess, to accept and
5 transmit this to the FDA and anyone on the
6 Science Board who feels like they would like
7 to submit a little bit of a white paper or an
8 addendum to this, that they write it up in a
9 context where they can think about it enough
10 so that it's really an intelligent document.

11 DR. MCNEIL: Okay. So, you're
12 basically saying, take the second option, but
13 with the sub-option that individual members
14 can write to the FDA and say, what about
15 whatever.

16 Yes, David?

17 DR. PARKINSON: I would second
18 that, and I see no reason in waiting until
19 February to do something further. This gives
20 the FDA a chance, the FDA reviewers and staff,
21 a chance to respond to the sub-committee
22 report and the discussion here.

1 And then maybe allows us a chance
2 in February, to look at a plan or some sort of
3 FDA reaction to the sub-committee. But why
4 delay things? I don't have a lot more to
5 contribute to Jack's point. I think the sub-
6 committee has done a really thoughtful job and
7 let's get on with it.

8 DR. MCNEIL: Larry, you have a
9 comment?

10 DR. SASICH: Yes, I -- during the
11 public comments I think I sensed the public's
12 frustration with not knowing what's going on,
13 what's happening, who can be believed and who
14 can't be believed.

15 Everyone is an expert. Everything
16 is evidence-based. That term has become so
17 worn as to become almost meaningless. And I
18 think they would like to see some kind of a
19 decision or recommendation, and I'll use the
20 term recommendation because this is an
21 advisory committee.

22 So I think we would be free, as a

1 Science Board, to make any recommendations
2 that we wanted to the commissioner, and the
3 commissioner and the FDA can decide whether to
4 accept or not accept those.

5 I can see -- listening to, again,
6 to some of the public speakers, we have
7 competing studies. Who do we believe anymore?
8 And I think the system -- both the scientific
9 system and the FDA is running the risk of
10 losing any credibility or losing credibility
11 with the public unless we start to take some
12 more definitive actions that the public can
13 really kind of understand.

14 And so, I suppose I would follow
15 Jack and David with the first option with some
16 editorial changes. And I wouldn't mind seeing
17 some kind of statement that would immediately
18 limit infants= exposure to BPA that's coming
19 from the committee, and that's a
20 recommendation that's being made to the FDA
21 commissioner, and then a statement where we
22 would recommend to the commissioner that the

1 agency do a much better job in informing the
2 public exactly about what's going on and what
3 we know. Let the public kind of be part of
4 the process.

5 DR. MCNEIL: So, can I repeat what
6 you said just to make sure I have it. I think
7 what you said, Larry, was to accept the report
8 with the thought that individual members of
9 the Science Board could write to the FDA with
10 their own comments about possible additional
11 studies or areas and you had two additional
12 comments that are important. But that was the
13 first level. Accept it with additional
14 comments that get sent to Carlos and somehow
15 or other they get incorporated.

16 But then you also added two other
17 things that would be very different, and
18 they're not on the list. Accept, but make a
19 statement requesting the FDA to limit infants=
20 exposure -- now?

21 DR. SASICH: To immediately examine
22 the possibility of limiting infants= exposure.

1 DR. MCNEIL: Oh, to examine the
2 possibility.

3 DR. SASICH: Yes.

4 DR. MCNEIL: Okay. We're going to
5 need to write this down. To examine the
6 possibility.

7 DR. PHILBERT: So, as stated in the
8 first instance, I would just like to remind
9 the Science Board that we were charged to
10 review the science, not to make policy
11 decisions, which we view in the last bullet,
12 as consistent with the remit of the
13 commissioner.

14 So we're reviewing the science.
15 We've submitted the report, and I think the
16 Science Board should feel free to make
17 whatever additional recommendations they are.
18 But as part of the sub-committee report, we
19 think that goes beyond the job.

20 DR. SASICH: No, you did an
21 excellent job in this. There becomes a point
22 in time when the science has to become policy

1 and somebody has to make a suggestion --

2 DR. MCNEIL: But that's not our
3 job. That is not our job.

4 DR. SASICH: Well, you can't
5 separate it, and that's why we're losing --
6 why the system is losing credibility, I think,
7 with the public.

8 We do a lot of hard work. We
9 develop a lot of really good science, and here
10 it is, and we don't do anything with it. We
11 don't give the public any kind of direction or
12 guidance.

13 We can make a recommendation to
14 the commissioner. The commissioner then makes
15 that kind of decision. I mean, that's what
16 the point of this whole process is -- do we
17 have a chemical out there that is potentially
18 harmful to infants and small children?

19 And so, we can't -- it would be
20 nice to be able to sit here in isolation and
21 look at the data. It's a very interesting kind
22 of thing to do, but they expect us to come up

1 with some solutions to this problem -- either
2 to say that there's no problem at all, that
3 this stuff is perfectly safe. There's no
4 question about it at all.

5 But if there is some uncertainty,
6 to take some kind of steps to limit exposure
7 to this particular product until we get better
8 data, where we can answer in confidence,
9 safety or lack of safety.

10 DR. MCNEIL: This is an important
11 discussion, Larry, and I'm trying to pull out
12 -- we have to function within our charge.
13 That's clear, and to go beyond the charge will
14 not be appropriate.

15 And I think that's why Martin and
16 his group very carefully edited the last
17 bullet in the manner that you see there, and
18 tried to separate in the first sentence the
19 science, and in the second sentence, the
20 policy recommendations that would be derived
21 from the science as well as from other
22 considerations.

1 So, what I'm pulling up now is our
2 charge, the charge to the Science Board, and
3 it basically says, the Board will provide
4 advice to the agency on keeping pace with
5 technical and scientific evolutions in the
6 field of regulatory science on formulating an
7 appropriate research agenda and upgrading
8 science facilities, provide the means for
9 critical review of agency-sponsored intramural
10 and extramural programs.

11 So, I think it narrows our job a
12 little. That's not to say that what you've
13 said is not incorporated into our minutes and
14 discussion. I think your comment about asking
15 the FDA to inform the public better is
16 something that we talked about this morning.
17 And I think we recognized that as an area for
18 potential addition to the members of this
19 Board.

20 But unless I'm wrong, don't both
21 of those go beyond our charge or not? Randy,
22 do both of those issues go beyond our charge?

1 I don't want to get ahead of ourselves here.
2 The issue of asking you to limit exposures to
3 infants and asking you to inform the public
4 better -- this Board is asking you.

5 DR. LUTTER: I think I heard two
6 comments earlier. One was that we immediately
7 consider. And the one I think I heard -- I
8 wasn't sure -- that we immediately take
9 action, and surely the former is within your
10 charge.

11 DR. MCNEIL: Say that again.

12 DR. LUTTER: I think the question
13 was -- I think I heard you say that you were
14 contemplating a recommendation that we should
15 immediately consider taking action.

16 DR. MCNEIL: Yes. That's what he
17 said.

18 DR. LUTTER: Okay, and that's a
19 recommendation on what we should consider, and
20 I think that's permissible and consistent with
21 the charter.

22 I think that the recommendation

1 that we should immediately take action is a
2 different step.

3 DR. MCNEIL: Okay. Martin?

4 DR. PHILBERT: In the interest of
5 keeping the process clean, might I request
6 that any such consideration be kept separate
7 from whether or not the Science Board adopt
8 the sub-committee report?

9 DR. MCNEIL: Yes, you should.

10 DR. PHILBERT: And that that just
11 be isolated because I think I speak on behalf
12 of my colleagues. We've expended a great deal
13 of time in coming up with a scientific
14 analysis, and that should be kept clean and
15 separate from any policy decision.

16 DR. MCNEIL: Good point. We'll do
17 that, so we'll just move those two comments
18 off to the side for the moment, and bring them
19 back. But for the moment, we will just --

20 So, let me repeat where I think we
21 are. I think we're on accept with the proviso
22 that individual members of the Science Board,

1 as individuals, are encouraged to write to the
2 FDA about those areas that they think would be
3 useful in helping to reduce the uncertainty
4 about the conclusions of the sub-committee
5 report.

6 DR. LINEHAN: And I agree exactly
7 what you said, and I would move that just to
8 get the conversation going. As a discussion
9 point -- I guess -- do we have to have a --

10 DR. MCNEIL: Well, we do, but --

11 DR. LINEHAN: So I would make that
12 as a motion, and then when we get to
13 discussion, I'll make a point.

14 DR. MCNEIL: Martin, do you want to
15 say a word?

16 DR. PHILBERT: May I offer a
17 friendly amendment. Not uncertainties about
18 the Science Board report, but uncertainties
19 identified within the sub-committee report.

20 DR. MCNEIL: I'm sorry. Could we do
21 a couple of things here? We have to get --
22 this is important, so we have to get the

1 language exactly right.

2 So, Jack, do you want to repeat
3 what you just said?

4 DR. LINEHAN: Well, I would say --
5 I make a motion that we accept and transmit
6 the sub-committee's report to the FDA.

7 DR. MCNEIL: Number 1.

8 DR. LINEHAN: Number 1. And the
9 second point in the motion would be that we
10 encourage our colleagues on the Science Board
11 to communicate with the FDA their analysis of
12 the issues underlying BPA issues in a very
13 timely manner to the commissioner of the FDA.

14 DR. MCNEIL: Could you define
15 timely, just as a friendly suggestion.

16 DR. LINEHAN: Within a week.

17 DR. MCNEIL: A week. Fine. And
18 Martin, you had something to add to that?

19 DR. PHILBERT: I think it was
20 encapsulated -- it was just word-smithing that
21 it's uncertainties identified within the
22 report, and not uncertainties about the

1 report.

2 DR. MCNEIL: Oh. Uncertainties
3 within the report.

4 DR. PHILBERT: I'm very certain
5 about the report.

6 DR. MCNEIL: Okay. The report was
7 clear. All 16 versions of it that the sub-
8 committee wrote. David?

9 DR. PARKINSON: Just to add to the
10 discussion around this should be incorporated.
11 I don't want to have send in what I've already
12 said.

13 DR. MCNEIL: Should we have --
14 that's a motion, right? We have to second it.
15 We need a second.

16 DR. PARKINSON: Oh, yes. Seconded.

17 DR. MCNEIL: Seconded by Larry and
18 David, for the record. Okay.

19 DR. PARKINSON: But if the
20 discussion we've just had could be reflected
21 so I don't have to write in exactly what I've
22 already said. That's all. Within a week.

1 DR. MCNEIL: And your discussion
2 was specifically related to the sensitive
3 patients.

4 DR. PARKINSON: Well, I think we've
5 had very robust discussion about other
6 potential populations at risk, et cetera, and
7 that discussion should be accurately
8 reflected. But it basically, what we're
9 calling for here is a request for approval of
10 the second option, so --

11 DR. MCNEIL: Is there further
12 discussion on this motion that has now been
13 moved and seconded, that basically says
14 accept, transmit with the elaboration that
15 Jack just proposed that involves sending to
16 the FDA, within a week, any additional
17 considerations for further studies that you
18 would recommend?

19 Garret, I can hear you moving.

20 DR. FITZGERALD: Yes. I'm
21 concurring.

22 DR. MCNEIL: You're concurring.

1 Okay, I could tell. This is important. I want
2 to make sure we have not left any stone
3 unturned here.

4 So, the voting members for this
5 purpose are David, Erik, Lonnie, Larry, Jack,
6 and myself if there's a tie. Is that correct,
7 Carlos? All right. So, can I have a show of
8 hands as to who approves the motion as -- And
9 Garret, I'm sorry. Garret, would you raise
10 your hand?

11 DR. FITZGERALD: I will.

12 DR. MCNEIL: And Garret --

13 DR. FITZGERALD: I approve.

14 DR. MCNEIL: He's also on the
15 Board, though, so he can vote. We're trying
16 to decide whether you can vote, Garret.

17 DR. FITZGERALD: Okay.

18 DR. MCNEIL: It doesn't matter. Let
19 me just check -- I think it's irrelevant
20 whether you can vote or not because I saw
21 yeses from everybody. All -- Larry, did I see
22 a yes from you? Okay, so I have five yeses. I

1 don't count. Garret, if you count, it doesn't
2 matter because you're not going to change --

3 DR. FITZGERALD: Okay.

4 DR. MCNEIL: But we love you
5 anyhow. But vote on November 4th, right.

6 DR. FITZGERALD: I will. Don't
7 worry.

8 DR. MCNEIL: All right. So, the
9 report has been accepted now. Let's move on to
10 -- we've now done that and we can move on to
11 Larry's specific concerns about recommending
12 the feasibility -- this is outside the report
13 -- recommending the feasibility of the FDA's
14 examining the possibility -- I think there
15 were too many words here -- of limiting
16 infants= exposure to BPA. I think I've got too
17 many feasibilities and possibilities there.

18 But this is a statement asking the
19 FDA to study the possibility of limiting
20 infants= exposure to BPA. Is that right? And
21 we can just say --

22 And the second one was, asking the

1 FDA to consider ways to increase their
2 information to the public about BPA. Is that
3 right? Do I have those right, Larry?

4 DR. SASICH: Yes, I think so. I
5 think the point that I was getting across was
6 as an encouragement to try to move forward in
7 the policy and the regulatory process.

8 I think, again, from what I sensed
9 from the comments that I've read and the
10 public statement is, it's always appropriate
11 to call for more scientific study. I don't
12 think anybody would disagree with that, but
13 there can become a point when you call for it
14 so many times that it's simply the status quo,
15 and the public views this is as, oh, this is
16 part of the game.

17 It's time to say, would you please
18 consider -- I don't know what the right adverb
19 is here. I think it's more than feasibility. I
20 mean, certainly the FDA commissioner and the
21 FDA, they have the authority to propose new
22 regulations, but I would like to see them be -

1 - again, I don't have the adverb for it. I
2 would like to see them be a little bit more
3 affirmative, a little bit more aggressive in
4 trying to come to some kind of conclusion.

5 I think what I'm trying to say is
6 let's limit exposure till we do get an answer
7 -- not to ban the product, but to limit
8 exposure to babies and young children.

9 DR. MCNEIL: I think we've heard
10 that, and I think they have heard that. I
11 think that's as far as we can go in terms of
12 this particular Board.

13 DR. SASICH: Okay.

14 DR. MCNEIL: I really want to be
15 very careful that we don't go beyond what
16 we're charged to do. That would get us all in
17 trouble.

18 DR. PENA: Barbara, can we just get
19 some clarification on the first point that was
20 recommended. It seems that the recommendation
21 was recommending feasibility of FDA examining
22 the possibility of limiting infants' exposure.

1 Is that accurate?

2 DR. MCNEIL: Yes. I think what was
3 intended there was -- Martin made the clear
4 and correct statement that we should vote on
5 the report, and we did.

6 Then Larry wanted to make a couple
7 of comments that went beyond our charge, that
8 moved into the policy realm, that we can't
9 really do as part of our charge. But he did
10 want to make it clear to you that he felt
11 strongly about the FDA's looking into that --
12 without making it a recommendation, which we
13 can't do.

14 DR. SASICH: I think we can
15 recommend --

16 DR. PARKINSON: Larry can
17 incorporate those comments in his remarks to
18 the FDA, in his personal remarks. I think
19 that's most appropriate.

20 DR. SASICH: But I think it would
21 certainly would carry more weight, but I think
22 we can make recommendations to the

1 commissioner. That's the purpose of advisory
2 committees.

3 DR. MCNEIL: I don't know if we
4 vote on them as a committee. I don't think we
5 vote on them as a committee. I think maybe
6 David hit it on -- it's outside our charge.

7 Let's do the following. Let's
8 erase those two for the moment, and let's --
9 everybody heard them. If they would like to
10 incorporate them into their discussions or
11 their notes -- to you, Carlos, is that where
12 we're sending them or to the commissioner or
13 to Dr. Torti or to Dr. Lutter? Who gets these
14 epistles?

15 DR. PENA: Have them addressed to
16 me and I'll make sure that the agency receives
17 them on behalf of the Science Board.

18 COMMENTS FROM THE SCIENCE BOARD CHAIR:

19 DR. MCNEIL: Okay, because the
20 agency has to receive them. And you need to do
21 that by next Friday, as over our previous
22 agreement.

1 So, I think what we've done is
2 we've accepted what we accepted. By doing
3 that, I now, according to the official rules,
4 say that I have transmitted the report to the
5 FDA on Friday, October 31, so that there's no
6 ambiguity about whether it's sitting in this
7 room when we walk out. It's now across the
8 street.

9 Are we all squared away on this?
10 Well, I have to say, I think this was -- first
11 of all, a couple of comments.

12 I think this absolutely
13 illustrates the process by which a Science
14 Board like ours can contribute to the work of
15 the agency, and I think Martin and his group
16 did an admirable job, and they all deserve our
17 thanks. Tremendous thanks.

18 I also am very grateful for the
19 members of the Science Board who took such
20 enormous pains to read the hundreds of pages
21 that flooded our desk, and to learn about
22 these micrograms per kilogram of body weight

1 per day, and you know, whatever, that may not
2 necessarily be part of all our vocabulary.

3 Everybody was very responsive and
4 responsible, and I think everybody did that
5 because they knew that this is a very
6 important area for the public. People are
7 concerned about it, and I think the members of
8 the committee really showed that they care a
9 lot about being responsive to the public
10 concerns, as well as being responsive to the
11 extremely hard work that the FDA did.
12 Everybody wanted to work hard to do the best
13 job possible.

14 So, in that regard then, I thank
15 everybody in the FDA who worked so hard to put
16 the draft policy together. Martin and his
17 committee who then worked very hard in
18 responding to it, and the Board members who
19 worked so hard in reading everything, learning
20 about BPA, and having such a thoughtful
21 discussion.

22 I also want to thank everybody in

1 the audience who are here, who's here, who
2 made their public comments, and in absentia,
3 to those who wrote in.

4 And Carlos wants to make two
5 comments, and then I have a couple more words
6 before we end.

7 DR. PENA: I just have two quick
8 comments. There was a comment this morning
9 about risk assessor, risk communicator --
10 there is a risk communication advisory
11 committee that is under jurisdiction at FDA.

12 If those topics were to come up
13 next year at a future Science Board meeting,
14 it would be helpful to invite members of the
15 committee, a joint committee meeting, to the
16 Science Board meeting.

17 DR. MCNEIL: Oh, that's a great
18 idea.

19 DR. PENA: The other comment is the
20 meeting frequency of the Science Board is
21 going to increase dramatically from two to
22 four times a year, and it's an incredible

1 burden on each of the Science Board members.

2 So we encourage the Science Board,
3 as well as the public, if they have any
4 additional -- any nominees -- that would like
5 to submit to the agency for consideration for
6 membership to the Science Board, that they
7 send it to fda.gov. There's a website on
8 advisory committees. And please submit your
9 nominations.

10 DR. MCNEIL: By when?

11 DR. PENA: It's on a rolling basis,
12 so there's no timeline. You can submit
13 anytime. Self-nomination or nomination of a
14 colleague.

15 And we are looking for a few good
16 Science Board members.

17 DR. MCNEIL: Thank you very much.
18 Yes, this is a real advance in our view
19 because if you recall at the last meeting, the
20 commissioner indicated that because of the
21 complexity of our work, it would be useful to
22 meet more often and have more members. So this

1 will accomplish that.

2 So, I think we could close with
3 just a couple of things. I just want to make
4 sure that we are all on the same page with
5 regard to our next steps.

6 And the next steps basically mean
7 two things. One is the one that we just did -
8 - encouraging the FDA to deal with our report
9 and reporting back, I think, at whatever time
10 is within your appropriate period for
11 deliberations, but certainly no later than
12 February.

13 And then, in addition, I wanted to
14 summarize what we said this morning about
15 future topics that in February we're going to
16 follow up on the terrific presentations we had
17 this morning on rapid detection of
18 contaminants, as well as rapid detection of
19 both food and bacterial products.

20 Think also about one additional
21 review of a center within the FDA, and I think
22 we will ask the FDA staff to think about what

1 center would make the most sense because I did
2 hear from the group, from ORA and NCTR, that
3 they benefitted a lot from the evaluations in
4 the past couple of years. And maybe that's
5 something we can deal with off-line.

6 And then finally, I guess, would
7 be to think a little bit about BPA II, and how
8 and who and when -- because that probably will
9 be complicated as well, although a lot of work
10 has been done to bring this Board up to snuff,
11 intellectually at least, on some of the
12 components.

13 And there will be four meetings,
14 as Carlos mentioned. Are there other issues
15 that we'd like to bring before this group now?
16 Are there any parting words from the FDA?

17 DR. TORTI: I just want to thank
18 everyone for being here as well, and Larry, we
19 heard what you said. And we respect it, so we
20 understand all of the issues here and the
21 sense of urgency. So, thank you all.

22 DR. MCNEIL: So, with that, the

1 meeting is adjourned, and safe travels.

2 DR. FITZGERALD: Thank you.

3 (Whereupon, the above-entitled

4 matter was concluded at 3:13 p.m.)

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A			
AACR 85:2	36:12 75:12	177:20,21 178:1,6	add 138:11 195:13
Aaron 2:19 258:12	159:21 263:14	178:20 179:3,7,10	207:11 208:11
261:4	academic 79:22	180:12,16,21	216:21 217:3
ability 25:8 36:16	88:21 93:11	181:8,19 182:1	308:10 331:18
37:9 45:16 69:1,20	300:13 302:11	197:19 198:5,11	332:9
78:20 122:1	Academy 301:4	198:13	added 89:21 187:1
194:10 239:16	acceleration 65:12	acknowledge	187:4 188:2
299:20 302:5	accept 16:2 63:13	220:20 281:2	323:16
able 4:7 28:9 30:12	69:21 240:5	acknowledged	addendum 320:8
32:11,16 34:11	282:13,13,19	276:8	adding 140:9,10
35:15 64:19 73:17	317:7 320:4 322:4	acquire 21:4	183:19,20 195:8
74:8 81:1 83:3,6	322:4 323:7,13,18	acquired 175:19	addition 11:16
89:19 92:21	329:21 331:5	across-disease	12:12 21:13 37:3
107:20 109:4,7	333:14	79:22	172:21 178:20
114:22 116:13,15	acceptable 170:16	act 188:22 189:16	222:2 235:10
116:21 117:19	284:19 287:13,13	193:13 210:19	236:1 237:13
129:3 139:10	287:17 288:4	232:1 257:14	292:22 299:3
146:4,18 152:17	accepted 228:15	259:21	327:18 344:13
153:2 154:8 155:6	282:22 335:9	acting 14:21	additional 11:10
165:3 175:20	340:2,2	action 181:18	35:17 89:8,20
181:16 182:22	access 50:19 239:17	188:21 191:17	102:18 160:17
183:11 222:13	249:19	216:11 221:1	175:16 231:1,15
260:19 300:9	accommodate	226:3 227:5	231:19 269:7
317:13 319:19	222:13	233:14 234:4,9	271:16 275:11,14
325:20	accomplish 344:1	245:19 255:20	276:10,16 282:16
ably 281:13	accord 266:4	328:9,15 329:1	292:7 304:11
above-entitled	account 257:2	actions 95:7 146:2	311:19 315:15
220:9 346:3	272:15	186:18 233:18	319:14 323:10,11
abroad 187:18	accounting 268:6	322:12	323:13 324:17
200:10	297:20	active 57:13 100:16	333:16 343:4
absentia 342:2	accounts 194:10	102:20 279:17	344:20
absolute 44:10 45:4	195:10 196:20	actively 13:1 83:16	Additionally 248:6
304:14	199:17	191:19	250:7 251:7,19
absolutely 37:7 46:4	accurate 80:6 83:17	activities 11:22 24:7	additive 216:8
50:18 59:1 62:6	101:10 277:16	31:4 89:12 90:17	259:5,15,22 260:6
63:13 67:1 75:20	338:1	93:15 99:1	260:9 297:14
75:20 101:21	accurately 333:7	activity 155:15	298:5
111:1 162:11	Acheson 2:2 7:3,3	232:22 267:1	additives 298:7
190:10 304:12	91:10 105:12,16	291:19 306:6,15	address 10:8 14:8
340:12	145:15 148:15	actual 31:8 32:7	14:20 32:13,19
absorption 301:11	151:17,20 154:2	57:5 63:5 95:17	36:20 53:8,13
abstracted 189:9	155:10 156:18	110:12	71:13 72:13 97:13
266:8	achieve 21:4 59:17	acute 164:15,18	103:4 116:19
abundant 131:8	75:21 80:10	176:13 179:17	123:2 144:21
305:15	239:16	180:17 181:8	185:11 191:12
academia 13:17	achieved 277:7	adapt 37:9 140:11	203:8 223:19
	acid 161:21 176:4,7	141:12 143:4	225:10 231:19
	176:18 177:1,2,10	adapting 38:19	232:20 258:21
			259:8,11 261:19
			277:14 279:3,9
			298:2 310:14
			addressed 14:22
			26:4 42:6 44:6
			45:5 56:5 74:15
			98:1 202:11
			263:17 299:17
			306:3 339:15
			addresses 8:9
			addressing 186:8
			adequate 222:14
			225:15 230:3,10
			230:19 231:6
			248:1 260:10
			268:21 269:20
			270:7,12,13
			284:16 285:19
			286:11,20 287:7
			287:10,12
			adequately 108:3
			272:15 294:4
			296:6
			adiponectin 278:16
			Adjourn 3:19
			adjourned 346:1
			adjust 219:7
			adjusted 176:2
			Administration 1:1
			13:10 21:8 27:13
			191:10 222:19
			249:4
			Administration's
			12:22
			administrator
			300:14
			admirable 340:16
			adopt 152:21
			153:16 258:19
			329:7
			Adopting 225:8
			adult 216:14 243:16
			269:8 307:15
			308:6
			adulterant 167:22
			adulterants 183:15
			adulterate 183:17
			adulterated 100:14

174:8 187:11 211:17 215:20 adulteration 3:12 53:16 54:15 161:3 184:17 185:13 186:9,14,18 189:1 189:4,14 192:17 193:10,14 195:6 197:4 200:14 201:3 202:6,8 218:20 adults 224:19 228:3 266:15 276:2 307:13,18 308:3 308:18 312:9 advance 239:15 343:18 advanced 141:22 154:15 advancement 18:17 123:15 advances 14:11 66:15 advancing 106:5 301:6 advantage 301:14 advantages 116:4 adverb 336:18 337:1 adverse 20:21 45:13 68:13 151:11 173:12 187:14 198:13 274:16 advice 54:19 240:8 313:5 327:4 advise 24:12 223:7 223:16 advisor 52:9 advisors 1:18 29:13 advisory 1:5,9 22:22 23:12 223:1 321:21 339:1 342:10 343:8 advocacy 224:6 239:14 advocate 74:16 101:15 Affairs 7:6 94:22	affect 48:20 70:3 182:11 189:6 275:8 affinity 313:18 affirmative 260:4 337:3 affirmatively 260:14 afternoon 1:14 9:22 220:15 224:4 227:15 232:16,20 239:7 248:21 254:1 258:11 299:13 age 239:16 278:22 310:6,10 agencies 69:6,13 91:14 93:10 152:22 156:12 187:18 191:5 210:16 211:8 228:11 238:11 244:22 245:2 246:2,6,12 263:14 agency 11:22 12:4 13:15 14:4,16,22 15:2,2,8,13 17:6 17:20 18:5 21:10 23:13 25:17 26:17 26:20 27:19 29:13 29:18 30:4 32:22 33:2 35:20 36:8,19 37:6,8,16 38:12,19 41:18,19 42:11 43:20 52:3 56:4 59:19 66:8 70:18 72:11 74:22 76:14 76:15 77:3 78:14 78:17 79:8 80:15 82:18 90:2,7 99:14 99:16,20 100:2 101:4,16 105:2 142:1 149:11 150:1 185:22 204:10 234:8 240:2 261:15,20 290:3,4 323:1 327:4 339:16,20	340:15 343:5 agency's 25:17 agency-sponsored 327:9 agenda 4:6 8:4,18 8:22 10:10 24:2 27:6 29:19,20 30:13 54:6 104:5 220:3 299:10 327:7 agents 203:22 304:19 aggressive 337:3 agile 186:1 ago 13:13 25:15 34:20 79:17 99:21 132:8 155:18 161:7 166:6 188:21 190:7 192:4 193:3 202:11 215:15 315:4 agree 98:17 214:1 231:14 235:19 236:14,15 268:17 292:18 304:12 306:5 311:17 312:11 330:6 agreed 283:8 agreement 206:8 302:20 304:1 312:2 339:22 agreements 205:18 agrees 159:18 266:15 Agriculture 147:6 169:15 Ah 198:4 ahead 65:19 66:4 86:10 89:1 97:1,7 104:20 153:15 170:19 219:15 319:6 328:1 aims 73:21 air 143:16 akin 280:18 al 270:17 271:10 alarmingly 225:18	alcoholic 188:13 alert 117:19 151:9 alerted 165:5 algorithms 58:14,16 align 25:20 29:19 alignment 26:9 alike 228:4 252:13 299:5 315:14 allegedly 188:14 Alliance 2:18 248:19 249:1 allocation 71:11 allow 98:6 120:16 121:10 133:8 137:14 199:4 251:20 271:15 272:20 allowed 132:3 170:18 268:14 allowing 260:15 allows 115:21 116:20 249:17 301:15,22 302:4 321:1 alluded 57:20 146:22 218:4 272:1 alluding 78:7 79:3 Alright 28:16 alter 226:18 alterations 210:14 altered 232:10 alternative 247:8,17 248:4 275:6 280:16 295:3 alternatives 247:5 257:9,11 amazing 80:11 amber-colored 176:17 ambiguities 318:16 319:14 ambiguity 340:6 amenable 290:16 amendment 330:17 America 86:18 87:5 243:18 American 2:18	13:15 14:6 17:4 18:22 24:3 26:11 28:4 204:21 221:3 227:19 228:3 234:3 238:16 248:19 249:1 256:12,17 Americans 18:19 24:6 237:12 ammelide 178:21 ammeline 178:21 amount 132:20 137:4 209:20 213:2 267:6 268:7 312:21 amounts 246:13 256:22 amplification 289:18 amplify 62:10 analogs 181:20 analogy 89:3 analyses 290:17 analysis 23:1 28:2 32:5 110:9 127:20 138:14 140:18,19 140:22 144:7 218:17 228:6 230:3,14 238:1,2 250:11 254:10,22 255:3,6 258:21 272:20 273:9,15 276:19 280:12,14 290:12 294:9,12 294:18 295:3,20 296:19 329:14 331:11 analytical 31:22 32:1 201:20 203:19 228:21 analyze 255:14 289:11 analyzed 128:8 analyzing 168:5 anatomy 106:8 108:11 110:2 Anderson 13:18 28:18
---	--	--	--	---

ANDREW 2:1	194:19 202:5	259:6 260:16	333:9	arrows 178:15,17
Andy 40:9 42:5	anticipatory 208:9	263:1,11 266:13	approve 23:14	article 81:1 189:7,8
47:9,12 49:11	209:5	272:3,7	170:19 259:22	288:21,22 310:17
53:22 56:4 57:20	antigens 139:6	applied 2:6,8 7:17	334:13	articles 21:20
63:14 70:18 74:15	anti-aging 204:19	31:1 67:8 143:12	approved 11:7	215:16
86:9,10	anti-cytokine 48:19	196:17 197:2	49:20 149:11	articulate 268:11
and/or 242:9	anti-microbial	268:12 280:13	216:8 247:14	artificially 166:20
anecdotal 319:16	84:19	applies 298:4	259:14 260:2,6,9	174:16
animal 107:18	Antonia 1:19	300:12	approves 334:8	Asia 50:8 52:16
115:18 131:18	221:17	apply 96:20 106:10	approximate	173:4 315:22
152:19 169:3	Antonio 281:9	298:12	256:22	Asian 171:15 172:5
175:13 185:19	305:11	applying 78:3	approximately	173:5
210:5,6,8 241:2	anybody 100:19	appreciate 12:17	10:13 221:21	asked 9:14 15:17
255:15 269:8	161:6 190:12	61:17 94:13	233:12	24:13 25:15 29:15
276:2 307:15	195:18 261:7	229:12 245:9	April 50:1	31:11 44:4 46:8
309:11	314:16 319:1	249:2 254:9	Aqua-cultured 49:3	51:2 52:12 53:6,7
animals 49:1 169:8	336:12	292:21 312:22	area 5:6 6:9 60:15	54:1 72:5 75:9
169:21 170:20	anymore 182:13	appreciated 95:9	61:11 62:5 63:2,11	151:7 171:22
179:17 197:20	190:3 322:7	appreciates 249:8	84:17 102:20	183:8 193:4 206:9
198:15 210:9	anytime 343:13	approach 69:18	107:1 219:4 236:6	206:19 222:1
257:1 288:15,18	apologies 106:21	70:4 74:5 85:22	250:14,16 276:14	251:11,12 254:19
304:5 307:12	apologize 56:7	93:8 138:14 142:5	304:10 319:8	259:16
309:17,18	85:14 105:21	142:20 145:1	327:17 341:6	asking 25:12 30:7
announced 52:4	263:19	148:5 159:6,16	areas 4:20 5:17	226:9 253:10
162:10 171:8	apparent 177:16	202:18 208:5	20:14 30:9 46:20	327:14 328:2,3,4
172:10 226:2	187:2,7 268:13	244:21 255:12	62:22 63:9 73:6	335:18,22
announcement 8:8	apparently 173:21	273:19 295:7	84:18 87:13 93:12	aspect 42:2 105:4
11:7	187:1,4 188:2	306:12 311:4	141:18 157:15	144:13 308:8
annual 51:15	195:14 216:18	approaches 73:8,11	207:18 217:12	aspects 60:22 62:17
196:13	230:3	123:17 140:16,16	283:9 319:13	191:19 207:21
annually 94:16	appear 230:13	144:9 157:21	323:11 330:2	271:2
annum 190:12	appendix 265:11	271:14 290:14	argument 185:21	aspires 18:15
answer 9:15 65:10	applaud 34:8 85:20	302:8	288:10	assay 134:11 139:18
72:2 75:16 83:10	241:4 242:10	appropriate 22:12	argumentation	204:7 208:3 215:3
98:5 119:16	254:12 256:9	91:17 95:16	291:6	assembling 111:7
156:20 209:10	Applebaum 1:13	200:21 229:20	arithmetic 190:13	assertions 261:16
218:1 253:8	9:19 85:13 103:19	231:4 239:18	arm 206:11	assess 25:20 46:22
271:15 283:4	155:1 218:3	244:9 249:19	armamentarium	159:15 272:5
300:15 303:3	applicability 196:16	268:11 269:4	81:6	assessed 247:6
304:14 312:13	applicants 48:2	275:13 279:14	aromatase 291:11	assessing 245:4,20
315:1 318:15	application 96:2	286:3 314:11	291:12 292:16	255:13 256:16
326:8 337:6	143:22 144:1	326:14 327:7	293:13	assessment 8:13
answers 28:21 39:4	193:2 230:7	336:10 338:19	arose 266:6	21:16 23:8 49:6
254:19 288:6	270:13 284:13	344:10	array 144:8 296:14	93:4 103:17
anticipate 186:19	290:13	appropriately	arrays 140:18	111:16 169:13,14
192:22 200:12	applications 8:15	24:22 67:7 96:20	arrive 270:5 318:16	170:8,11 175:10
anticipated 12:20	228:20 229:12	280:16 284:20	arrived 13:13 14:3	175:17,21 181:2
anticipating 30:9	239:10 257:16	approval 280:20	arriving 108:17	213:16 224:12

225:15 229:2,17 229:22 230:18,22 231:3 232:2 239:9 242:11 244:20 245:8,13 249:11 250:13 252:3,6 254:8 255:5 256:4 262:22 263:3,4,9 264:11 265:6 266:16 267:12,21 268:10,14,19 269:1,6,10,11,18 269:20 270:5,6,19 270:21 272:2,10 272:11,14 273:5 273:18,22 274:8 275:12,12,14 276:8 280:5 285:2 287:2 290:6 292:10 293:21 306:3 313:2	Atlanta 5:16 attempt 21:22 71:5 attempted 251:13 attend 4:8 258:15 attended 151:3 attendees 10:20 attention 59:21 202:17 227:7 271:3,13 attorney 258:12 261:5 attractive 174:13,14 attributed 172:19 audience 4:9 258:5 261:8 282:11 285:17 316:14 342:1 augmented 263:13 285:6 August 188:16 auspices 233:17 authorities 183:4 225:22 authority 158:18 210:13,15 229:5 250:7 252:8 253:9 253:12 297:5 336:21 authors 251:2,9 253:10 automated 136:6 availability 121:16 290:2 available 156:9 196:19 225:10 228:9 230:5 231:22 244:15 257:11 263:20 270:9 275:17 284:11 301:15 310:12 average 309:3 avoided 198:9,11 awakening 15:9 aware 10:2 113:19 118:18 141:10 149:13 156:1 173:12 252:10	A's 228:7 231:16 a.m 1:9 <hr/> B <hr/> babies 244:8 246:11 247:18,22 248:3 337:8 baby 32:9,10 225:3 233:4 234:10 238:13 bacillus 131:9 back 28:17 36:11 51:3 52:12,15 54:17 55:11 57:2 58:4 85:17 95:17 110:1 114:17 115:16 118:13,13 118:19 119:10,13 120:5,6,15 122:15 132:2 135:4 145:17 147:10 160:18 166:8 195:22 213:14,15 218:5,15,15 293:19 318:6,13 329:19 344:9 background 6:6 52:1 76:8 102:2 106:3 184:4,13 backgrounds 101:20 105:20 144:5 back-room 204:20 205:5 back-up 72:19 bacteria 63:6 142:6 142:7 bacterial 6:2 344:19 bad 163:4 169:1 188:7,9 bag 132:10,11 bags 114:22 Bailey 264:15 balance 148:9 ban 234:10 238:12 257:14,22 337:7 bands 135:21 bank 197:7 198:8	banks 193:5 banned 238:11 297:16 bar 135:15 137:17 289:7 Barbara 1:10,12 6:14 12:8 15:22 39:14 40:6 52:7,17 64:11 337:18 Barbara's 12:12 barrel 42:1 barrier 18:16 barriers 148:11 bar-coded 129:9,10 bar-codes 135:15 137:20 base 76:14 77:4 249:10 300:5 based 8:22 15:2,5 17:8,11 23:1,7 41:16 62:21 66:12 68:20 70:5 76:6 82:9 149:5 174:15 175:18,18 187:18 194:9 201:5 209:6 210:8 228:20 230:13 231:6 235:9 240:22 243:17 245:8,15 250:2,17 275:7 285:2 294:12,21 310:2,18 basic 29:21 193:2 193:12 194:13 basically 135:10,15 137:16 138:13 139:13 141:19 142:4 161:11 170:13 282:13 305:20 311:7 316:13 317:6,15 320:12 327:3 333:8,13 344:6 basis 77:15 93:1 167:2 192:10 194:6 217:1,6 230:8 237:21 244:19 255:9	270:11 284:15 286:8 301:12 318:3 343:11 batches 164:8 BCR-ABL 77:18 beads 139:3 bear 160:1 208:6 becoming 57:3 82:5 bedside 81:7 beef 150:18,20 began 61:8 beginning 76:12 88:22 89:2 106:16 118:9 223:6,16,20 262:4 308:18 begins 78:9 114:3 163:10 begs 237:18 behalf 221:10 234:2 234:15 243:18 248:9 329:11 339:17 behave 200:1,11 behavior 196:4 behavioral 271:22 Beijing 86:13 believe 36:16 37:1 52:9 72:8 105:3 185:21 222:19 250:22 257:13 304:8 315:8 316:14 322:7 believed 321:13,14 believes 223:1 249:14 253:3 256:6 benchmark 270:22 290:13 295:7 beneficial 182:21 benefit 157:1 271:3 285:1 benefited 186:1 benefiting 69:16 benefits 122:7,10 151:10 248:7 benefitted 345:3 Benet 308:11 Bernadette 2:3 7:13
---	--	---	---	---

62:9 64:13 84:14	biosensor 141:18	4:5 6:15,22 8:6,12	273:14 274:15	297:21 305:14
best 18:13 35:20	biostatistically-ba...	8:15,17,18 9:13,15	295:5 306:16	308:2 309:5,13
47:14 75:15 150:9	58:15	9:17 11:3,9,12	307:1 309:7	311:12 312:9
170:14 248:2	biostatistics 60:22	13:5,9 15:18,20	340:22	313:19 315:11
341:12	biotech 6:8	23:12 25:16 26:7	bond 179:8	322:18 331:12
better 11:21 18:4	bioterrorism 53:18	26:18 29:13,13	bonds 179:8	335:16,20 336:2
24:2 61:20 103:22	55:15	41:3,7,9,11,16	Bongori 126:4,15	341:20 345:7
116:3 121:21	bio-engineered	42:16 47:5,18 52:9	book 145:9	BPA's 240:17
133:19 144:14,19	204:11,20	52:10,11,19 53:8	books 155:3	255:10
181:16,20 182:10	Bio-Ethics 235:12	54:2,9 59:16 65:7	boost 166:20	BPA-linked 278:15
182:22 192:1	bio-fuels 219:2	70:22 75:6 88:13	border 58:2 63:16	brain 5:2 226:18
253:5 257:19	bio-marker 315:18	89:21 90:18 92:10	191:1	branch 234:7
272:10 280:8	bio-monitoring	95:11,13 97:2 99:2	borders 70:11 87:9	brand 68:7 113:11
300:11 301:10	276:10 305:21	100:5,17 101:14	born 226:22 227:2	113:18 114:4
311:13 318:8,10	308:20,21 309:4	102:14 103:15	borne 84:13 106:10	brands 162:13
323:1 326:7	309:21	157:5 190:6 220:6	bottles 225:3 233:5	break 88:8,16 220:2
327:15 328:4	Bio-Plex 139:1,17	220:18,21 221:6	234:11 238:13	220:8 294:9
beverages 219:6	140:20,20	222:8,11,16	240:18 257:10	breaking 178:8
237:10,11	Bisphenol 1:18 3:15	225:13 227:3,21	275:20	breast 77:11,16
beyond 87:9 265:1	8:14 227:16,22	234:20 237:17	bottom 41:22	221:1 247:18
305:4 324:19	228:7,19 231:9,16	239:8,22 240:16	100:12 126:4	248:3,5
326:13 327:21,22	234:10 261:22	242:2,10 243:20	130:8	bribery 199:4
337:15 338:7	262:22 263:10	245:21 249:3,9	bottom-up 72:19	bricks 219:5,5
bicycle 298:10	265:4 266:12,14	252:3 258:19	78:18	bridge 18:16,21
big 105:18 109:15	268:8 269:1	261:10,21 262:12	bought 72:20	19:5,10,14,18,22
195:18 236:17	278:13 291:18	262:17,18 263:8	box 57:7	20:4 22:6 24:5
biggest 212:9	300:18	263:13 264:6	BPA 3:16 8:15 9:17	27:9 36:17 301:2
Bill 7:8 30:2 92:18	bit 42:12 60:10 72:2	280:22 281:8	53:22 96:1,5,18	bridged 14:14
156:21	88:19 89:2 102:10	282:4,6,15,21	100:15,15 220:17	bridges 36:18
billion 196:9,12	107:1 118:8 134:4	283:8,12 292:8	221:3 224:8,13,17	brief 88:8 258:7,8
Bill's 159:11	146:14 147:20	311:19 316:3	224:18 225:1,17	258:17 275:22
bind 313:17	160:9 186:12	318:2 320:3,6	226:3,11,12,18	briefing 155:3
bio 45:11 139:16	190:13 205:1	322:1 323:9 324:9	227:5 236:12,19	briefly 122:17 220:7
309:22 310:8	216:18 217:15	324:16 327:2,3,19	238:9,12,12,16	232:21
315:6	282:10 283:5	328:4 329:7,22	239:10 240:12,16	Brigham 6:18
Bioequivalence	294:5 303:11	330:18 331:10	240:21 241:12,18	bright 34:12
48:21	315:21 320:7	334:15 337:12	241:21 244:9,16	brightest 35:21
biofilms 131:14	337:2,3 345:7	339:17,18 340:14	245:2,5,11,13,19	brilliant 36:21
bioinformatic 141:8	bite 299:10	340:19 341:18	246:8,13,15,21	38:15
bioinformatics	BlackBerry 317:1	342:13,16,20	247:2 248:8 249:9	bring 15:17 40:10
49:22 52:21	BlackBerrys 10:21	343:1,2,6,16	250:15 254:5,8,18	42:12 50:9 51:17
biological 278:9	block 96:19	345:10	255:6,13,20 256:4	61:13 67:4 85:3
279:1	blood 96:6 181:22	Boards 299:11	256:16,20 257:3	91:12 94:11 110:1
biologists 35:10	182:2 278:18	Board's 95:5 185:11	257:15 259:4	138:14 159:22
biomarker 78:15	301:16 308:22	259:20	260:15 261:22	168:16 247:12
biomarkers 80:4	309:12,14,15	bodies 229:4 252:7	269:8 273:7	329:18 345:10,15
85:4	blue 56:13	body 32:21 238:19	278:18 279:5	bringing 29:10
biomedical 5:5	board 1:3 3:7,15,18	241:13 270:3	280:19 292:12	120:14 205:5

207:19 244:16 306:14 brings 31:22 35:20 67:3 77:12 broad 13:3 34:3,3 35:6 61:11 236:13 broader 153:21 186:6 187:8 203:9 305:1 broadly 154:4 191:21 broadly-based 59:5 broken 217:16,18 broth 133:10 brought 40:12 53:22 91:14 94:9 153:17 208:6 brush 18:22 Brussels 86:17 bubble 72:11 Bucher 264:19 307:10,21 Bucher's 269:2 buck 219:19 budget 59:14 71:10 74:14,17,21 budgetary 75:3 build 30:13 63:15 63:16 77:4 93:12 122:20 154:10 156:10 building 157:10 274:11 built 19:15 33:16 277:8 bullet 41:8 149:20 232:9 284:5,8 285:5,11 317:11 324:11 326:17 bullets 41:4 283:20 284:6 bunch 116:21 297:15 burden 260:8,13 276:18 306:17 343:1 Bush 191:13 Bushnell 281:8	business 80:17 businesses 199:12 busy 85:1 219:8 220:3 butter 113:9 114:4 buy 150:22 257:21 buying 217:6 buy-in 72:22	cancer 13:16,18 28:19 77:11,16,21 221:1 234:13 candies 173:7,7 candor 254:10 candy 173:2 canned 225:2,2 226:4 240:19 257:9 315:13 cans 294:14 315:9 cantaloupes 133:4 133:18 canthaxanthin 216:7 capabilities 280:8 capability 153:8 capacity 50:17 69:17 153:17 154:6 276:1 capital 36:10 capstone 306:15 capture 34:3 57:15 189:3 captures 40:17 cardiac 49:1 cardiovascular 312:10 care 158:2,4,11 213:11 341:8 cared 197:5 career 36:7 37:5,15 52:2 careful 66:21 71:19 254:11 337:15 carefully 23:21 64:6 189:2 241:5 245:22 247:6 266:11 326:16 Carlos 2:6 6:20 8:4 281:12 316:19 323:14 334:7 339:11 342:4 345:14 carried 76:22 carries 38:7 carry 78:21 338:21 cascade 77:20	case 95:12 97:15 110:14 111:10,11 112:3,14 113:10 114:16,20 119:5 124:11 127:8 135:14 139:11 166:17 182:21 185:5 186:17,20 191:5 192:16 194:1,7,21 202:5 203:1 223:7 233:12 298:13 300:12 304:5 cases 82:9 108:15 111:18 112:1 115:13 117:13,22 173:12 233:13,14 301:21 Cassell's 99:14 catalyze 25:10 29:17 36:16 cats 164:6,8,12 178:4 179:9 180:11,17 181:8 198:2 caught 197:6 199:2 cause 164:15,22 165:14 177:16 181:22 182:14 188:9 213:20 231:10,17 257:1 caused 181:8 185:18 causes 186:14 causing 165:8 233:10 caution 255:22 cavalier 255:22 caveats 272:13 CDC 5:16 106:22 113:6 117:18 136:5 137:3 139:5 147:1 152:7,21 211:6 281:9 309:22 CDC's 107:1 134:19 151:15 CDRH 31:7	cell 10:21 cells 291:15 cellular 255:15 ensorship 242:9 center 2:3,5,7,8,10 2:15 5:4,14 7:9,13 7:16,19,22 13:19 43:21 44:3,10 45:5 46:2,8 47:1 48:8,9 51:4 58:5 71:1 72:6,17,20 74:18 92:7,15 95:16 100:14 114:8,10 116:1 119:13,17 119:19 161:7 177:18 235:1,5,7 235:12 250:8 344:21 345:1 centers 31:2 45:1 46:12,13 51:8 71:6 72:14 75:11,14 77:1 78:9 87:19,20 92:3,3,22 94:6 95:11 106:17 111:4 118:22 119:4,11 147:6 156:11 162:18 163:3 207:16 218:17 central 87:4 111:3 279:4 centrality 160:10 cents 195:9,12,16 195:16 196:6,7 century 55:5 189:18 202:15 CEO 6:8 CERHR 230:19 231:14 268:21 269:6 270:7 CERHR's 231:5 certain 67:19 72:8 114:4 116:17 149:12 157:14 170:5 174:14 219:16 230:2 231:10 308:6 332:4
---	---	---	---	--

certainly 12:19 60:16 93:15 94:3,7 94:13 96:21 98:8 118:2,7 121:1 151:21 153:13 157:2 287:18 305:9 336:20 338:21 344:11	changeable 71:18 changed 55:7 172:14 200:8 303:17 changes 26:12 29:18 31:15 37:10 55:12 71:18 133:1 205:1 212:3,15 213:6 282:22 317:9 322:16 changing 17:2 212:13 213:18 chaos 68:22 70:7 Chapel 265:4 character 102:16 characteristics 201:5 298:5 characterization 255:19 269:20 273:17 288:21 characterize 203:2 characterized 294:5 charge 65:8 259:2 263:1 326:12,13 327:2,2,21,22 328:10 338:7,9 339:6 charged 37:12 262:20 324:9 337:16 chart 124:1 charter 328:21 cheap 309:5 cheaper 212:6 216:17 check 214:14 334:19 checking 149:4 312:16 cheese 143:13 chemical 166:18 226:7 241:14 247:9 257:18 325:17 chemicals 256:19 279:17 chemist 198:7 Chemistry 221:3	227:19 chemists 165:3 168:3 175:1 176:20 chemo 292:12 chemotherapy 241:22 292:13 chicken 210:7 chickens 169:9,18 170:1 chief 2:11 6:11 29:16 37:13 42:1 43:18 199:14 child 226:22 241:16 children 188:15 226:16 227:1 228:4 233:10 234:13 237:7,13 242:15 244:2 266:14,17 273:13 276:17 308:17 310:9 314:13 325:18 337:8 chime 62:9 66:10 312:19 China 38:2 86:13 161:19 171:3,13 172:1,5 173:20,22 192:6 195:15 196:9 198:14 199:19 205:6,19 206:3 211:15 Chinese 171:8 172:10,13 173:8 174:1,5 183:4 199:12 205:19 206:11,20 207:8 Chinese-made 171:17 choice 274:5 320:4 choices 74:4 319:10 choke 128:20 134:10 chondroitin 187:12 choose 223:18 chooses 274:7 chops 135:11 chosen 52:22	263:16 chromatography 168:4 174:19 175:3 chromosomes 64:3 chronic 274:22 275:1 277:6 circuitry 31:15 circumstances 53:9 circumstantial 194:17 cities 171:16 citizens 69:22 City 233:16 civil 233:3 claim 255:10 claims 224:22 261:16 clarification 283:5 285:11 297:5 310:16 337:19 clarifies 285:10 clarify 294:3 299:2 319:14 clarifying 244:8 class 34:21 36:6 233:13 classic 54:21 59:7 clean 329:5,14 cleaner 130:11 cleaning 158:14 clear 24:18 59:2 75:20,20 121:3,19 123:8 151:16,18 151:21 152:9 254:20 256:6 264:16 270:14,16 276:10 287:22 310:21 326:13 332:7 338:3,10 clearance 182:16 clearer 152:9 clearly 55:17 73:6 116:5 189:2,13 199:20 264:21 266:12 267:5 272:11 277:19 313:21	clever 198:3,7 clients 234:3,5 clinical 26:1 29:21 45:15 81:2 82:2,4 82:6,12,16,17 108:17 110:8,13 112:21 118:6 127:22 137:21 140:5 309:3 clinical-trials 82:9 close 224:19 277:21 344:2 closed 306:14 closely 156:5 219:13 closer 20:14,17 closest 71:2 close-up 130:6 clue 111:22 164:14 coalition 151:6 coated 189:10 code 124:4 135:16 158:13 coding 137:18 coffee 315:8 cognizant 127:20 192:7 coherence 196:17 coherent 273:19 274:10 302:6 Colangelo 2:19 258:11,12 260:20 261:3,4 collaboration 46:22 collaborative 33:3 73:8 collateral 291:14 colleague 106:3,21 110:20 111:20 185:17 274:2 281:8 343:14 colleagues 93:19 101:19 153:5 329:12 331:10 collect 128:4 311:13 collected 61:13 302:10 311:10 315:10,14 collecting 133:22
---	--	---	---	--

collection 191:11	258:6,7 291:4	committee 1:5,9	80:1,14 93:11,12	159:6
collective 203:5	292:5 293:6,6	8:16 9:2,3 10:1	207:19,19 241:9	complicated 58:15
collectively 154:1	306:19 319:3	65:21 94:9 99:18	279:8,11	117:16 123:4
colony 142:15	321:9 327:14	143:7 221:11,12	compacted 123:7	125:17 145:12
color 216:7	342:8,19	223:1,8,17 230:2	companies 201:16	207:17 237:4,9
colored 176:15	commentators	231:14 259:17	240:6 243:22	345:9
189:10	305:10	262:13 283:14	246:16 249:4	complicates 126:18
color-coded 139:3	commenting 297:7	286:2 287:19	company 6:8	complied 265:15
combination 19:8	comments 3:18 65:2	288:8 299:19	113:12 164:6,13	component 32:1
176:10 180:13	70:15 71:6 84:7	311:19 319:22	173:2,11 199:13	102:4 155:13
181:18	145:18 153:19	321:6,21 322:19	211:14	components 32:9
combine 178:2	220:20 221:6	332:8 339:4,5	comparable 50:16	33:4 87:15 100:2
combining 301:5	222:1 224:11	341:8,17 342:11	compare 137:22	168:6 345:12
come 23:21,22	225:12 227:16	342:15,15	compared 194:4	composed 263:12
45:22 52:12,15	228:18 240:15	committees 339:2	307:18 308:3	compound 165:4
54:17 60:10,13,17	258:4,17 261:17	343:8	comparison 153:11	181:12 267:3
71:1 95:16 98:5	261:20 265:14	committee's 96:4	301:22	311:15
101:19,20 120:6	283:13 285:15	99:14 229:13	comparisons	compounding
122:15 136:9	302:17,18 316:1,3	235:19 245:10	314:12	204:18
157:7 160:18	318:3 321:11	246:4 249:22	compelling 196:19	compounds 4:22
180:8 190:19	323:10,12,14	252:17 295:15	compensation	181:11 183:12
191:9 210:17	328:6 329:17	commodities 150:4	201:5	309:5
265:7 272:13	336:9 338:7,17	184:19	competing 322:7	comprised 147:1
283:10 296:20	339:18 340:11	common 112:6,9,10	competitive 131:5	computational 35:9
318:1 325:22	342:2,5,8	129:5 130:2	competitors 223:10	35:10
337:4 342:12	commerce 65:14,16	168:21 228:1	complaint 162:18	computer 141:8
comes 68:11,13	67:6	255:16 301:16	162:20 163:3	317:3
97:19 114:18	commercial 140:19	commonly 139:9,20	complement 96:9	concealed 189:12
291:9 298:19,21	commissioner 2:1,2	267:15	156:16	concentrate 138:19
300:2	2:4,11 6:11 7:2,4	common-sense	complemented	165:18,19 166:1
comfortable 300:10	11:17 12:3,5,13	305:6	30:22	182:22
coming 57:13 69:6	13:7 14:21 28:9,13	communicate	complements	concentrated 182:6
69:21 85:15 88:20	34:7 39:11 40:3	102:15 103:11	142:22	concentration
92:7 99:6 104:19	88:5 89:14 101:12	108:10 242:6	complete 47:1,2	181:21 273:12
154:4 175:21	284:21 287:14,20	331:11	50:19 141:14	concentrations
204:13 205:13	322:2,3,21,22	communicating	232:2	224:20 309:12,15
214:10 227:13	324:13 325:14,14	114:2 160:14	completed 229:7	309:16,19 315:11
234:7 322:18	331:13 336:20	communication	231:21	315:18
329:13	339:1,12 343:20	49:6 99:11 102:6	completely 75:1	concept 40:2 80:12
commend 233:22	COMMISSIONER...	102:17,18 103:1	313:9	88:1 181:9
235:18 236:18	12:6	116:13 121:16	completion 269:9	concern 142:9
comment 10:11,12	commissioner's 3:3	342:10	complex 15:12	182:12 250:15,16
96:15 101:7 159:9	47:16 85:15	communications	101:18 163:22	250:18 279:19
159:11 205:8,10	145:18	87:18	185:4 214:5 313:4	302:1 310:20
207:10 208:21	commit 23:18	communicator	complexities 146:13	concerned 120:4
213:15 214:8	commitment 23:12	103:20,21 342:9	complexity 23:10	162:12 163:8
232:8 243:19	25:13 27:15 28:5	community 21:14	79:2 96:17 343:21	167:22 209:1
253:13 254:15	228:1 232:4	25:6 26:19 54:1	compliance 69:20	211:9 216:19

217:8,9 240:20 253:2 255:18 341:7 concerning 240:16 concerns 76:10 149:16 182:19 225:11 238:13 252:10,19 258:22 278:2 279:10 335:11 341:10 concert 111:12 255:14 concerted 300:22 concise 264:17 conclude 230:8 270:11 284:15 286:8 concluded 230:17 231:7 240:21 241:7 246:13 286:22 346:4 concludes 145:5 225:13 conclusion 55:4 143:6 202:7 226:2 230:11 268:17 271:5 287:5 318:8 318:16 337:4 conclusions 229:1,3 229:9 230:2 231:13 241:12 246:2 250:12 330:4 conclusive 312:8 concrete 81:15 concur 275:3 312:14 concurring 333:21 333:22 concur 95:13 conditions 178:14 260:2 297:11 conducted 175:16 195:14 228:14 254:22 315:4 conducting 231:2 309:22 conducts 21:4	conference 211:4,4 264:3,4 conferences 163:6 confidence 247:5 249:16 257:20 326:8 confident 245:21 297:9 confirm 110:16,18 confirmation 120:2 123:22 134:12 confirmed 172:20 173:19 278:7 conflict 8:9 9:5 16:15 conflicts 16:14 235:6 242:9 254:4 258:10,13 confused 234:6 confusing 287:11 congratulate 208:9 Congress 188:21 202:12 235:16 252:13 conjunction 92:22 94:5 223:13 connected 81:9 Connecticut 173:16 connections 185:2 consensus 93:12 238:9,15 246:6 254:17 265:22 276:6 consequences 38:8 70:6 197:3,12 199:9 226:19 conservative 285:8 consider 27:6 30:6 143:7 230:18 240:10 245:22 252:5 302:5 305:1 328:7,15,19 336:1 336:18 considerably 124:15 consideration 230:21 251:22 254:11 282:7	302:22 303:8 329:6 343:5 considerations 285:4 326:22 333:17 considered 231:3 269:10 279:3 295:17 298:6 considering 240:11 267:13 considers 242:2 consistency 40:21 46:19 consistent 136:18 229:3 269:4 324:12 328:20 consolidate 233:18 conspiracy 204:9 constant 22:8,11 33:1 36:9 79:7,10 constantly 17:18 33:8 111:5 131:22 constituencies 72:18 constituent 189:8 constituted 263:7 constrained 196:2 constraints 148:10 275:15 construct 286:16 constructed 19:12 24:5 construction 286:9 287:9 288:2 constructively 200:19 consulting 151:5 consume 15:20 consumed 110:5 115:13 170:10 237:10,12 consumer 2:19 5:9 9:8,10 116:12 122:8 151:1 215:10 233:13 247:5 253:20 254:3 257:20 consumers 108:10	121:16 149:17,18 150:17 151:9 163:8 215:14 228:3 249:15,18 256:10,21 257:16 Consumer's 254:2 255:11,18 consuming 122:7 consumption 23:17 267:4 contact 8:14 19:1 96:2 184:5,6 228:19 229:11 239:10 257:15 259:6 260:16 261:18 263:1,11 266:13 272:2,6 273:7 275:17 298:20,21 contacted 171:21 contacts 298:18 contain 173:18 183:6 container 247:9 273:2 containers 96:7 236:20 237:1 240:18 247:12 275:20 298:15 contaminant 63:6,7 176:21 193:21 198:19 215:5 contaminants 3:9 8:20 58:19 64:8 90:4,4,22 105:14 161:1 344:18 contaminate 215:4 contaminated 32:20 110:5 114:7 145:4 169:6,17 170:15 174:8 197:18 210:2 212:7 contamination 24:9 32:11 45:19 62:12 116:14,17 117:7 130:3,21 184:17 187:20 226:11 contemplate 209:9	contemplated 97:6 contemplating 328:14 contemporary 290:10 content 102:16 166:20 167:2,9 174:10,15 180:22 183:21 187:3,7 192:7,10 204:8 contentious 266:3 CONTENTS 3:1 context 16:9 26:11 29:20 32:8 67:18 79:9,16 105:17 106:10,19 107:12 108:11 109:5,19 117:10 149:9 157:13 186:12 223:2 271:7 301:8 320:9 continually 246:17 continue 21:2,6,15 26:3 32:22 36:21 52:17 54:18 79:4,5 85:8 162:1 173:14 184:13 185:11 228:12 244:13 257:17 continued 29:1,17 37:8 246:22 continues 26:5 119:3 continuing 29:5 93:14 119:21 238:14 continuous 128:10 continuously 34:5 207:22 continuum 23:19 124:20 127:20 143:19,21 contribute 12:1 57:18 62:22 321:5 340:14 contribution 105:4 160:3 contributions 305:3
---	---	--	---	---

control 67:20 106:17 111:5 112:15 113:10 119:4,5 147:6 164:10 168:18 170:22 203:7 314:15	cost 44:22,22 82:3 193:15 194:3,4 195:7,16 197:12 205:3,4 Costa 87:2 costs 141:4 194:21 195:2 197:3 199:9	128:21 132:15 237:11 278:1 282:16 293:14 courses 48:15 court 199:15 cows 188:13 co-held 72:10 co-mingled 198:12 co-mingling 210:9 create 24:10 25:8 37:14 70:9 79:7 291:13 created 43:18 87:16 202:12 creates 23:2,5,15 27:3 35:13,16 creating 66:1 creativity 165:2 credibility 322:10 322:10 325:6 credible 98:6 213:20 cried 253:1 criminal 199:18 211:12,13 criteria 22:13 33:19 245:9 268:12 279:7,8 critical 16:18 17:19 20:22 21:6,11,15 23:1,7,11 24:7 44:5 69:12 78:10 79:18 83:13 108:5 130:1 132:5 150:15,16 152:21 153:15 240:17 290:6 296:8 327:9	311:20 crucial 13:8 23:1 crucible 17:13 21:18 crystallization 181:22 182:14 crystallizes 76:9 crystals 176:14,17 177:13 178:3 179:9,15,18,20 180:1 182:4 183:1 183:5 cues 256:9 culminating 264:5 culture 34:10 135:20 cultures 135:20 192:3 cumulative 240:12 267:13 276:19 305:19 cups 233:5 234:11 275:19 cure 28:18 curiosity 25:4 currency 53:12 current 3:9 8:19 10:8 37:14 105:13 160:22 161:18 171:2 172:12 185:6 202:1 212:12 224:17 225:1 235:10 246:8 256:1 306:12 currently 6:15 31:9 221:20 244:21 256:21 curriculum-driven 35:1,5 curtailed 256:20 curve 66:4 219:15 curves 56:17 customs 57:6 cut 86:20 cutting 93:3 cutting-edge 16:16 51:18	CVs 11:15 cyanuric 161:21 176:4,7,18 177:1,2 177:10,20,21 178:1,6,20 179:3,7 179:10 180:12,16 180:21 181:7,19 182:1 197:19 198:5,11,12 cycle 23:17 57:22 cytokine 48:20 cytometer 139:2 C-O-L-A-N-G-E-... 261:4
controlling 239:20 controls 117:8 149:4,21 157:11 controversial 29:6 controversy 16:19 28:1 conundrum 15:15 15:19 16:22 18:4 23:4 76:3 convened 1:9 convening 239:8 conventional 198:20 conversation 216:3 297:22 319:15,16 330:8 conversations 206:20 converse 287:8 convert 15:1 27:7 converted 21:17 conviction 13:8 convinced 58:13 cool 128:22 copies 285:16 316:14 copious 306:22 core 18:7 21:6 25:18 26:17 30:3,3 30:21 43:6 160:10 244:5 corn 219:3 cornerstone 17:21 correct 90:6 96:14 103:22 256:4 296:21 297:19 298:4 310:18 334:6 338:4 corresponding 137:13 Cosmetic 259:21	council 2:17,20 221:2 227:20 242:20 243:2,12 243:21 248:9 257:8 Council's 221:3 count 194:22 335:1 335:1 counterfeit 163:13 counterfeited 204:12 205:14 206:6 counterfeiting 218:10 counterpart 187:17 counterparts 171:12 countries 87:3 168:12 175:8 192:3,9 205:22 country 14:5 60:14 164:2 171:12 190:19 201:16 204:6,14 205:13 206:4 207:3 233:4 236:8 315:13 couple 46:13 52:13 62:4 71:13 135:18 155:17 171:12 178:8 215:15 303:20 317:5 330:21 338:6 340:11 342:5 344:3 345:4 Coupling 230:5 284:11 courage 25:4 course 11:13 41:22 43:17 45:8 47:22 53:21 58:22 72:17 87:14 96:2 118:16	created 43:18 87:16 202:12 creates 23:2,5,15 27:3 35:13,16 creating 66:1 creativity 165:2 credibility 322:10 322:10 325:6 credible 98:6 213:20 cried 253:1 criminal 199:18 211:12,13 criteria 22:13 33:19 245:9 268:12 279:7,8 critical 16:18 17:19 20:22 21:6,11,15 23:1,7,11 24:7 44:5 69:12 78:10 79:18 83:13 108:5 130:1 132:5 150:15,16 152:21 153:15 240:17 290:6 296:8 327:9 critically 25:19 249:15 criticisms 258:21 criticized 241:7 critics 252:18 cross 73:13 311:8 crossed 56:20 cross-center 71:7 72:7 cross-cutting 82:1 cross-sectional	CVs 11:15 cyanuric 161:21 176:4,7,18 177:1,2 177:10,20,21 178:1,6,20 179:3,7 179:10 180:12,16 180:21 181:7,19 182:1 197:19 198:5,11,12 cycle 23:17 57:22 cytokine 48:20 cytometer 139:2 C-O-L-A-N-G-E-... 261:4	
			D	
			daily 170:16 211:4 dairy 187:2 damage 169:1 189:11 Dan 7:18 31:7 80:18 97:3 dangerous 207:6 dangerously 226:6 dark 56:13 DARPA 141:22 147:3 data 17:13 21:16 25:1 56:8 61:13 80:7 82:12 137:9 144:12 152:17 190:5 194:9 196:19 226:1 228:22 238:17 249:13 251:5,12 251:13 252:5 253:15 260:10 261:16 267:17 268:13 272:9 273:8,9 275:16 276:13 280:19 289:11 290:2,8,15 301:15 302:9 305:13,14,21 307:14,20 310:9 310:11 311:9 318:7 325:21 326:8	

database 111:3 137:5,7,9,13 142:21,21 212:9	deaths 172:18 188:15	270:12 284:16 286:9,11,20 287:10	275:7 287:1,3 295:4,11,13,16	detection 3:9,10 5:1 8:20 20:21 45:10 45:13 53:9,14 54:14 90:3,22 105:13,15 106:7,9 106:13,19 107:5,7 107:11 108:6 109:10 110:12 112:20 114:18 116:5 118:3 120:22 121:7 122:11 138:12 145:3,22 146:12 146:15 149:8 160:22 197:9,14 198:9,18,18 344:17,18
date 42:12 115:14 162:4 169:3 171:6 171:7 194:15	debacle 234:12	definitely 120:2 149:6 291:20	depend 302:9	detects 142:8
dates 263:21	debate 19:16 24:22 25:6,11	definition 286:20 297:8	dependant 278:20 289:13	determination 116:9 167:6 224:16 250:3
daughters 36:11	debated 244:4	definitions 288:2	depended 240:1	determine 20:9 108:20 109:7 117:1 170:8 171:16 211:21 251:21 259:19 273:10
Dave 28:14 91:10 91:19 104:19 105:12	decades 13:20 22:6 249:7	definitive 230:11 231:13 322:12	dependent 304:17	determined 9:3 109:2 167:21 201:6 277:7
David 1:16 2:2 6:5 7:3 37:18 76:1 122:19,20 145:14 147:18 155:1 156:6 221:4 304:7 320:16 322:15 332:8,18 334:5 339:6	decade-old 225:19	definitively 112:16 194:16 313:9	depends 212:21 300:15	determining 32:9 32:10
Davis 180:10	December 86:15,20	degradation 178:9 178:16	deprivation 292:15	develop 32:12 43:12 43:19 46:6,8 47:7 47:11 52:2 72:18 80:2,22 83:4,16,19 84:16 145:21 147:1 151:8 152:20 156:22 183:10 299:20 325:9
day 14:2,21 18:22 53:16 72:19 81:16 85:1,7 99:9,21 128:13,17 134:19 160:2 162:9 180:18,19 270:4 273:14 274:15 295:5 341:1	decide 90:15 322:3 334:16	degree 124:17 131:19	deputy 2:4,9,10 6:11 7:1,21	developed 44:14 47:9 49:20 103:3 110:6 126:15 139:5 140:21 168:3 174:18 180:17 183:10 232:22
days 34:20 52:13 86:12 88:3 121:14 133:22 134:13,20 135:18 141:4 171:12 244:3	decision 22:14 23:3 23:14 33:18 54:3 77:14 93:1 95:17 96:13 105:6 222:21 245:15 283:1 287:16,16 300:5 321:19 325:15 329:15	delay 262:4 321:4	derived 188:13 326:20	
DC 1:9 60:15 236:6	decisions 17:2,7,10 17:16,17 18:9 20:11 22:4,7,10 27:5 30:11 32:7 40:20 45:20 48:21 52:14 59:20 77:4 78:5 81:15,15,20 98:7 245:16 284:22 324:11	deliberately 198:10	DES 234:12	
dead 98:22	decision-making 19:18 33:17,20 42:18 282:20	deliberation 25:12	describe 18:14 31:1 43:22 92:21 93:2	
deal 65:22 205:16 329:12 344:8 345:5	decisive 234:4,9	deliberations 286:21 344:11	described 70:7	
dealing 106:15 111:22 113:20 117:14 118:1 125:19 152:5 161:8 175:11 300:8	deemed 225:15 252:22	delighted 51:20	descriptive 280:11	
deals 57:6	deep 13:7 27:11 45:19 266:5 281:2	deliver 41:11 160:6	deserve 340:16	
dealt 52:10 165:15 191:17	deeply 318:14	deliverables 44:20 73:22	deserves 103:11	
dean 6:1	defense 2:19 141:22 184:1 221:2 242:20	delivered 14:17 195:5	desiccated 204:5 205:11 208:3,17 214:9	
	defensible 229:21	delivery 14:12 18:19	design 82:2 269:16 280:1 303:6 314:20	
	defensive 256:16	deluged 162:11	designated 6:21	
	deficient 271:19	demand 69:19 168:10 253:4	designed 61:3 245:19 271:20 276:4 279:5 301:6 303:1 310:13	
	define 50:3 102:8 331:14	demanding 82:6	designs 45:15 279:15	
	defined 36:8 61:7 230:9 245:9	demographic 273:10	desire 150:2	
		demographics 60:13 61:11	desired 253:1	
		demonstrate 260:5 225:4	desk 340:21	
		Denver 146:10,21	detail 41:8 44:9 45:6 53:5 55:17 72:2 282:10	
		department 5:10 6:16 111:13 142:22 147:2,5 169:15 211:7	detailed 103:20	
		departments 106:17	detect 108:2 126:9 126:12 132:4 138:20 142:3,6 158:14 183:11	
		departure 270:2	detectability 197:21	
			detectable 197:14	

developers 80:8,9	79:16,16 81:8 82:7	58:5 72:6,21 74:19	291:21 306:17	282:4 320:10
developing 33:10	97:11,22 101:20	disagree 336:12	311:22 312:10	documenting
80:16 81:12,12	105:10 113:17	discipline 19:13	diseases 5:16 49:4	241:21
183:1 226:18	123:12,22 134:15	disciplines 35:6,7,8	80:3	documents 96:3
241:15 301:1	135:21 157:21,21	35:9 36:1 263:16	disparate 280:9	266:10
development 4:22	159:5,12 160:9	disclaimer 286:3	301:18	dog 176:16
6:7 14:11 20:6	166:4,16 211:11	disclose 242:8	disprove 25:2	dogs 173:21,22
27:3 30:18 33:6	226:2 238:20	disclosure 233:7	disproved 24:20	174:2
36:3 37:5,15 52:2	286:22 293:7,8	discovered 14:1	dispute 22:1	doing 59:2 69:15
82:22 133:14	298:8 299:22	187:19 193:15	disrespect 233:21	78:17 81:11 82:22
152:13,14 153:1	300:20,20 305:3	discovery 14:11	disseminate 32:17	87:16 90:16 92:21
266:20,21 267:8	306:1 315:15	16:16 25:22 30:17	dissenters 82:2	96:13 101:12
271:22 276:21	323:17 329:2	36:3	dissimilar 250:12	109:21 111:6
277:18 279:17	differential 267:14	discrimination	dissolve 179:20	118:14 123:13,14
280:7 314:6	276:20 294:21	124:2	distant 302:3	124:5 127:4,7
developmental 30:6	differentiate 126:13	discuss 8:13,17	distill 41:2	136:15 148:3,11
30:20 274:20	127:2	282:10 313:20	distinct 125:7	148:13 152:10
279:4,13	differently 175:17	316:8	distinction 303:6	155:9,20 179:16
develops 94:5	differs 125:17	discussed 9:13 29:8	304:1	196:11 197:3
deviation 274:13	difficult 16:4 74:14	113:13 244:4	distinguished 50:22	200:3,15 220:19
device 31:17 49:2	125:20 126:19	265:16 286:6	distributed 164:1,2	301:3 340:2
57:22 80:8 82:20	132:1 144:12	294:16 313:16	173:4,5	dollar 194:6
82:22 139:1 240:6	153:11 196:1	317:10	distributor 118:13	dollars 196:12
devices 5:7 7:19	198:19 199:19	discussing 24:16	distribution 114:8	domestic 56:11,15
31:9 55:14 57:9	272:5 308:22	207:8 220:16	114:10 116:1	56:22 62:13
61:21 72:9 82:7	difficulty 125:4	283:3	118:22 119:11,13	107:21 191:5
97:10 276:17	dig 318:13	discussion 3:4,6,8	119:17,19,21	dose 181:9 224:21
devoted 220:16	dilute 177:8,9	3:17 10:3 19:16	120:1 212:4,12	268:22 270:22
282:2	dilution 195:14	26:21 28:7 39:16	272:12 273:8,9	276:13 278:20
diabetes 242:1	209:16,18,21	40:13 49:22 59:22	301:11	290:13 295:7
312:10	210:1	74:10 84:15 92:13	distributor 114:15	301:17
diagnosed 164:15	direct 5:4 27:2 96:1	103:12 104:13	115:7	dosed 180:11
dialogue 29:12,17	175:11 222:8	145:19 147:17	dis-positive 260:14	doses 231:9
50:10	direction 18:8 38:11	203:11 222:15	diverge 265:5	dose-response
Diana 2:15 234:22	76:1 77:10 95:6	266:4 274:3	diverse 227:22	295:8
235:4	98:10,18 178:16	281:18 316:7	diversity 105:20	dosing 269:15
died 174:2 179:17	238:20 325:11	318:13 320:22	124:21	Doug 7:21 79:17
dietary 266:13,17	directions 276:9	326:11 327:14	divide 14:14,14	207:12 208:19
267:16,20	319:19	330:8,13 332:10	divvied 50:7	212:17,18
diethylene 187:22	directly 51:4 67:20	332:20 333:1,5,7	DNA 135:11,21	DOUGLAS 2:9
196:18,22 200:7	67:22 70:1 103:2	333:12 341:21	153:7	downstream 68:5
diets 177:20	155:14 172:19	discussions 33:12	doctor 110:7,7	70:6
difference 28:1	175:14 259:10	84:6 87:7 157:8	doctrine 16:20	Dr 4:3,18 5:3,8,13
125:1 132:22	director 2:3,5,7,8,9	307:8 339:10	document 70:20	5:20 6:4,10,14,20
133:2,16 158:17	5:14 7:9,13,16,18	disease 5:19 80:5,12	71:17,17 74:7,11	7:1,3,5,8,12,15,18
196:7 285:19	7:21 161:7 239:12	84:14 106:17	81:4 221:13,15	7:20 8:2,5 9:7,18
differences 315:17	directors 43:21 44:4	111:5 119:4 147:6	254:17 263:18	9:21 11:1,2 12:7
different 55:20 64:3	45:5 46:3,8 51:5	242:1 276:18	264:7,18 267:22	28:8,11,12,14,16

28:17,20,22 29:9
 34:7,16 37:18,19
 38:21,22 39:2,5,7
 39:9,13,15 40:6
 54:4 60:1,3,5,12
 61:18 62:6 64:13
 64:14 65:5,6 66:9
 67:10 70:14 71:12
 75:22 79:14 80:20
 83:8 84:1,10 85:10
 85:13,16 86:9,11
 88:4,14 90:11,13
 90:19,20 91:9,20
 91:21,22 92:14,17
 92:19 93:16,17
 94:2,7,17,20 95:10
 96:16 97:5 98:20
 100:4 101:6
 102:12 103:13,19
 103:21 104:18,20
 104:22 105:16
 122:19 145:7,15
 147:15,18 148:15
 150:10,11 151:14
 151:17,19,20
 152:8 154:2 155:1
 155:10,13,16
 156:6,18 157:19
 159:8,10 160:15
 161:4 185:16,17
 187:3 188:5
 189:20 197:16
 202:21 203:12,16
 205:7,9 207:9,11
 208:8 209:7,12,14
 209:15,16 210:4
 210:10,11,12
 211:1 212:1,16,18
 212:20 213:8,13
 214:7,13,18,20
 215:7,9 216:2
 217:21 218:3
 219:20 220:13
 221:4,11 222:14
 224:1,4 227:8,11
 227:14,17 232:7
 232:11,12,13
 234:17,22,22

235:3,4 239:1,3
 242:17,19,20
 243:5,5,7 247:10
 248:11,17,18,19
 248:21,22 253:6
 253:18,19,20,22
 258:3,4,13 260:18
 261:1,6,14 262:1,5
 262:7,12,16,17
 264:19 265:2
 274:2 281:6,7,8,19
 283:14,17,21
 285:18,22 288:7,9
 288:14 289:3,8,17
 289:20,21 290:1
 290:19,21 291:3
 292:4,6,11,14,20
 292:22 293:5,7,10
 293:16,22 294:2,7
 294:16 295:22
 296:2,9,18 297:1,2
 297:3 298:1,3,14
 298:17,19,21
 299:1,2,12,18
 300:13 301:8
 302:13,15,16,19
 303:10,13,16,18
 303:19,22 304:7,9
 305:9,12,16,18
 306:4,11,18,20
 307:6,9,21 308:10
 308:11,19 309:4
 310:15,19,20
 311:1,3,7,16 312:1
 312:4,11,14,16,17
 313:20 314:1,14
 314:18 315:2
 316:1,18,19,21,22
 317:2,4 319:2,5,7
 320:11,17 321:8
 321:10 323:5,21
 324:1,3,4,7,20
 325:2,4 326:10
 328:5,11,12,16,18
 329:3,4,9,10,16
 330:6,10,11,14,16
 330:20 331:4,7,8
 331:14,16,17,19

332:2,4,6,9,13,16
 332:17,19 333:1,4
 333:11,20,22
 334:11,12,13,14
 334:17,18 335:3,4
 335:6,8 336:4
 337:9,13,14,18
 338:2,14,16,20
 339:3,13,13,15,19
 342:7,17,19
 343:10,11,17
 345:17,22 346:2
draft 8:13 24:15
 224:12 227:17
 228:18 236:5
 237:19 239:9
 240:20 245:12
 250:12 254:8
 259:7 262:21
 263:2,9 265:6,16
 266:16 268:10,14
 269:10,19 270:5
 273:5 274:14
 275:2 285:1
 286:10,18 287:1
 288:3,11 294:7
 313:2 316:6
 341:16
dramatic 201:13,16
dramatically 56:18
 126:17 342:21
drastically 55:8
draw 241:11
drill 53:1 143:2
drilling 75:18
drinking 298:15
 315:7
drive 42:17 49:13
 52:6 54:16 146:11
 147:4 154:17
driven 38:6,14
 50:21 63:11
 189:21
drives 43:8
driving 46:3
Drs 264:15
drug 1:1 2:10 7:22
 12:21 13:10 21:8

27:12 48:22 57:22
 80:8 187:20
 212:10 214:11,15
 222:18 240:6
 249:3 259:21
 289:12
drugs 2:1 48:22
 55:14 188:2,22
 204:11 212:11,21
 212:22 213:5,9
 214:21
due 4:21 118:2
 267:10 276:18
 278:1,15
dump 158:7
Dunham 2:3 7:12
 7:13 64:14
dye 215:21
dying 131:22 164:5
 198:3
D.C 224:7
D.V.M 1:15 2:3,8

E

earlier 77:22 86:2
 98:16 108:8 116:4
 145:19 157:7
 190:5,6 197:16
 253:2 264:13
 268:1 272:1 274:3
 275:5 277:3 299:4
 328:6
early 5:1 51:11
 108:14 179:14
 188:11 212:3
 226:17
ease 215:11
easier 171:6
easily 179:4
East 38:3 87:8
easy 109:9 113:15
 134:16 177:5
 206:18 208:13
 215:4 262:19
eat 111:14,15
 170:15 209:20
eating 122:5
EC 86:17

echo 312:5
eclipsed 25:18
ecological 152:18
ecology 58:9
economic 53:18
 148:2,10 167:12
 183:15,17 185:12
 192:1 193:14
 196:15 197:1
 204:22 216:14
 217:9,10 218:22
economically 3:12
 53:15 54:14 161:2
 186:8,13 194:14
economically-mot...
 186:17 189:3,14
 192:16 200:13
 201:3 202:6,8
 210:20
economics 209:6
economies 73:12
economists 207:14
 207:20
economy 73:11
 219:17
ecosystems 62:15
 63:8
edge 93:3
edited 284:6 326:16
editorial 317:9
 322:16
educational 102:1
 106:1
effect 11:7 274:16
 278:16 291:20
 292:12
effective 209:5
 239:18 307:11
effectively 209:10
effectiveness 199:18
effects 173:13
 197:20 198:13
 224:20 228:8
 231:10,17 240:12
 258:2 269:8,22
 274:21 277:15
 278:10,21 279:1
 279:16

efficacy 45:12	emerges 16:15 23:22	endpoints 257:4 271:17,20,21 279:11,15	126:20	Erik 1:14 5:21 147:16 209:14 297:2 299:3 334:5
efficient 83:17 276:2	emerging 16:13 18:18 35:8 36:1,17	ends 21:4	enthusiasm 318:19	eroded 253:4
efficiently 73:10 75:16 80:9,17 98:3	emotional 148:5,10	endure 17:11 22:4 22:10 33:22	enthusiastic 96:22	erroneous 255:8
effort 13:1 18:20 23:13 25:19 27:14 30:4 50:3 79:7 147:21	emphasis 149:22 258:8	enduring 77:14	entire 21:3 23:16,19 30:4 31:19 41:3 48:12 57:21 78:3 78:14 96:17 189:12	Eschenbach 2:1 11:2 12:3,7 28:11 28:14,17 29:9 34:16 38:21 39:2,7 39:13 67:10 75:22 86:11
efforts 155:21 168:15 184:22 191:5,12 234:1 241:5 244:13 249:10 256:10 281:2,3	emphasize 51:6 106:14 241:13	end-quote 284:19	entirely 166:4	especially 13:6 34:11 195:19 226:4 235:20 240:11 241:15 242:14 255:15 256:21 275:18 276:15 297:13 314:12
eggs 174:5	emphasized 83:18	energetic 191:12	entirety 295:18	essence 57:15 108:22 157:6 169:22 202:22
either 99:8 104:11 120:14 178:8 196:2 198:20 206:3 233:6 253:11 272:21 280:21 282:14 305:13 317:8,12 326:1	emphasizing 27:10	enforceable 17:8	entitled 234:9	essential 12:21 20:13 21:11 22:3 23:11 37:7 42:6 50:18 58:10 59:1 64:10
either/or 309:1	employed 264:10,22 270:22 279:16	enforcement 198:22 217:17	entrusting 256:18	essentially 70:3 81:11 106:15 112:1 113:9 132:2 147:3 189:21 291:13 317:7
elaboration 287:20 333:14	Emporia 162:7 163:15	engage 27:19,22 47:7 52:18 54:9 75:13 82:17 83:21 83:22 84:15 97:2 159:21 275:14	entry 302:1	establish 245:7 260:1,15
electrophoresis 110:21 124:14 134:2,8,18 135:11 153:9	enable 32:13 277:15 280:8	engaged 31:3 74:9 155:14 245:3	entwined 186:22	established 35:16 77:3 279:7
electrophysiology 49:1	enables 77:13	engaging 24:11 49:10	environment 83:22 115:16 123:19 131:19 133:9	establishes 260:4
elegant 32:4	encapsulated 266:9 331:20	engineer 5:6 206:18	environmental 2:13 107:16 115:17 116:1,16,22 121:8 131:10 136:20 137:22 145:4 220:22 224:2,5 228:8 231:17 290:2,4	establishing 51:12 68:16,19 154:12 200:16
element 21:6 149:7 201:19	encephalopathies 4:21	engineering 66:15	enzymes 136:1,1 308:15	establishment 117:1 273:20 285:7
elevate 278:18	encompassed 264:8	engineers 35:11 60:20 61:16	EPA 211:8 281:9 286:3,5,9	estimate 295:6
eliminate 100:19 121:12 226:10	encompasses 35:6	enhance 43:6 45:15 59:3 276:14	Epel 221:4	estimated 227:1 273:12
emanating 30:17	encounter 126:3	enhanced 58:18 59:3 276:14	epidemiological 268:9 305:2,14 309:8 310:13	estimates 170:14 224:18 269:21
embrace 20:12 22:21	encountered 179:14	enhances 78:20	epidemiologist 305:13	
embraced 22:17,17	encourage 88:9 101:16 219:12 232:1 234:14 242:3 261:18 266:10 331:10 343:2	enormous 46:16 60:18 137:9 312:21 340:20	epidemiology 5:18 152:15 153:12 235:13 304:18	
embracing 35:8	encouraged 330:1	enormously 101:17 281:4	episodes 187:8 200:20	
emerge 112:7	encouragement 336:6	enrich 131:5 138:15	epistles 339:14	
emerged 32:2	encourages 223:5 223:15 250:20	enriching 143:18	epoxy 229:10	
emergency 154:13 154:17	encouraging 344:8	enrichment 37:14 66:14 130:22 131:12 132:15,18 138:12 144:22 145:3	equals 165:22	
	endeavor 33:11	ensue 306:17	equation 205:1	
	endeavors 36:13	ensure 222:21 246:19 247:22 256:18	equipment 175:5	
	ended 117:12 169:10 211:13	enteric 5:15	equity 68:8	
	endocrine 277:18 279:10,16	enterica 126:1,14	erase 339:8	
	endocrine-mediat... 279:12		Erie 5:11	

272:16	187:14	208:17 214:9	197:12,13 198:17	255:6 266:14
estimating 273:7	eventually 40:22	218:18 223:11	199:3 238:21	267:18,21 269:15
estrogen 241:3	85:5 165:1	230:4 243:15	expended 329:12	269:22 270:15
292:14 313:18	everybody 105:19	245:1 251:11	expenditure 124:15	272:10,10,14,17
estrogenic 291:19	126:10 160:4	294:17 299:6	expense 278:1	274:22 276:20
estrogens 291:17	168:8,13 175:5	317:9	expenses 223:13	277:1,6 286:14
292:12 313:13	219:8 284:2	examples 21:2	expensive 82:5	287:6,17 294:9,10
estrogen-deprived	334:21 339:9	40:11 48:14 62:4	198:21 214:12	294:11,21 297:21
293:12	341:3,4,12,15,22	64:12 76:2 105:2	309:1	304:15,17,18
estrogen-free	evidence 19:17	201:10 295:21	expensively 196:21	305:4,20 306:1,8
291:13	194:15,17 231:5,9	exceeds 193:14	experience 14:3	306:16 307:4,17
et 35:11 50:8 58:9	231:12 238:19	Excellence 75:12	49:14 69:16 305:8	308:2,6 310:21
62:18 210:17	240:2,10 241:13	excellent 156:7	experiment 288:18	311:11 312:9
264:9 270:17	242:13 245:22	237:22 319:21	experimental	314:3,4 322:18
271:10 333:6	250:17 256:2	324:21	177:17 279:14,21	323:20,22 326:6
etcetera 84:19 85:5	270:1 285:7	exceptional 186:2	280:1	335:16,20 337:6,8
91:16 152:19	295:17,18	excessive 256:8	experimentation	337:22
etched 162:4	evidence-based	excited 35:12 65:7	97:16	exposures 156:15
ethical 49:6 278:2	245:7 321:16	127:10	experiments 251:8	225:1,17 226:3
ethylene 164:20	evolution 22:1 77:6	exciting 29:11 43:21	expert 63:9 265:4	237:14 240:14
EU 50:8 86:5,17	evolutions 327:5	64:16,22 67:14	289:1 321:15	257:3 266:17,18
155:7	evolve 34:5 69:14	exclude 10:2	expertise 5:17 13:2	267:14,19 271:9
Europe 86:16 245:1	79:5 80:12	excluded 245:13	24:14 43:7 157:4	272:4,6,16 275:1
246:7	evolved 53:10	268:18	175:6 263:16	275:18 276:4,12
European 155:19	EWG 225:11 226:4	exclusion 10:5	experts 24:11	276:16 277:5
229:5,6 250:7	exact 136:22	268:16 274:11	265:10 319:22	284:18 299:6,12
252:7	exactly 100:8	exclusively 107:22	expired 169:2	301:21 304:21
evaded 201:22	112:17 136:14	excretion 301:12	explanations 123:8	328:2
evading 199:5	178:18 181:21	Excuse 247:10	explicit 68:2 71:14	express 93:7 262:11
evaluate 25:16	187:19 285:13	executive 2:6 6:20	84:3	expressed 194:5
57:21 229:18	292:20 323:2	191:13 199:14	exploiting 193:8	252:11
241:5 246:17	330:6 331:1	230:4 243:10	exploration 17:22	expressly 259:7,16
279:16	332:21	exercise 95:4 271:2	22:8,11,15	extend 264:14,19
evaluated 175:10	examination 250:1	306:7	exploratory 77:18	265:12
294:14 310:6	266:5	exist 192:2 215:14	explore 23:18 194:1	extended 190:14
evaluates 246:3	examine 323:21	279:15	208:4	extensive 228:6
evaluating 150:13	324:1,5	existed 66:18	explored 17:18,19	extensively 265:17
264:22 306:13	examining 335:14	202:10	explosion 14:9	extent 43:3 84:5
evaluation 2:10	337:21	existence 200:9	explosive 25:22	99:2 103:6 191:2
7:22 16:18,19 22:7	example 30:2,11	exists 127:21 279:20	expose 267:5	194:14,18 200:6
231:6 244:18	31:7 32:16 33:8	309:13,22	exposed 48:12	external 54:1 83:11
245:10 250:9	49:19 62:3,11 67:4	expand 294:3	51:19 226:6	83:22 313:5
268:15 269:5	67:5 72:9 84:12	expect 60:15 69:19	273:11,13	extramural 327:10
279:9 280:9	108:11,13 113:7	70:17 325:22	exposes 48:7	extraordinarily
294:15	114:21 124:3	expectation 21:21	exposure 96:9 97:20	63:4 313:4
evaluations 345:3	137:19 154:14	35:18 36:4 79:9	111:11 225:1	extraordinary 56:2
event 45:13	158:2,11 188:1	expected 193:13,15	226:17 236:21	extrapolation
events 20:21 57:11	192:3 201:4,6,9	193:19 197:3,9,10	237:2 245:5 246:8	277:10,16

extrapolations 274:22	fail 25:10	144:19	249:10,17,19,22	335:13 338:11
extremely 35:12	failed 251:14	fast-metabolizing 309:6	250:2,19,20 251:2	FDA-registered 56:10,21
98:18 144:3 163:8	fails 259:22	fat 192:10	251:3,20 252:5	FDA-Regulated 3:9
170:3 291:16	failure 25:13 164:16	favorite 57:4	253:9,14 254:8,13	8:20 105:14
341:11	164:19 179:17	FBI 137:5	254:17,19,21	111:21 161:1
eyes 80:13 149:17	180:17 181:8	FDA 1:3,22 3:5 6:12	255:3,8,11,19	186:9 190:9,18
e-mail 99:11 261:18	fair 213:2	7:2,4,6 8:7 12:13	256:4,6,13,14	191:18 192:17
265:17 316:16	fairly 110:3 124:21	13:14 14:4,14,15	257:13,18,22	FDA-wide 49:20
E.coli 108:2 109:3	168:20 174:7	14:22 17:1,18	258:20 259:21	fda.gov 343:7
110:17 115:1	175:7 180:13	18:15,21 20:2,14	260:5,14 263:10	feasibilities 335:17
125:2,5,6,15,18	202:13 213:7	21:3,4 22:17,20	264:10 265:6	feasibility 335:12
158:5	304:14	24:4 25:10 27:6	266:7,16 268:20	335:13 336:19
E.colis 125:8,13	fairness 10:7	29:3 34:10,19,21	269:5 270:12	337:21
	false 163:13	35:13 36:11,15	272:1 275:12	feature 112:9
	familiar 77:7	38:4 39:20 40:2,5	276:8 278:8 279:7	features 112:7
	155:10 190:12	40:18 41:4 42:22	280:6 281:14	February 11:11
	292:15	43:6,9 47:15 48:6	282:14 284:16	89:18,19 90:10
face 26:8 27:19	Families 2:16 235:2	48:12,20 49:3,15	286:11,20 287:4	91:7 99:1,6 100:10
57:18 175:9 185:9	235:6	50:22 51:17 52:12	287:10,14,19	199:11 282:21
facilitate 67:8	family 19:2	52:18 55:2,7,7,16	288:3 289:9	317:21 320:19
249:18	fancy 139:2	57:6 59:6 61:6,10	290:18 292:9	321:2 344:12,15
facilities 118:12	far 74:2 124:13	66:19 67:7,14	293:19 295:4	fecal 115:18
170:4 327:8	155:20 191:1	74:15 76:16 78:21	296:1 297:16	fed 169:6 177:19
facility 116:18	202:2 248:7 276:1	84:21 86:4 87:9	300:22 307:21	180:16 188:13
170:7	293:11 302:18	92:16 93:13 96:4	313:2 316:2	215:21 216:6
fact 14:18 17:3	337:11	106:12,17 113:1	317:14 318:5,10	247:18
25:13 30:15 32:15	farm 58:9 62:15	121:2 123:9	319:13,20 320:5	federal 6:21 11:8
33:16 36:18 43:9	109:14 114:17	126:11 136:20	320:14,20,20	124:4 188:22
44:21 63:14 76:21	115:20 116:11	146:11 147:1	321:3 322:3,9,20	259:21
89:13 126:20	118:13 120:9	151:4,7 154:5	323:9,19 327:15	feed 169:4,17 174:7
129:9 162:22	149:21	155:12 156:11,11	330:2 331:6,11,13	185:19 216:8
176:19 192:9	farms 118:21,22	156:17 162:18,21	333:16 335:19	feedback 95:5,9
207:17 216:3,6	119:1 120:6,8	177:18 185:7	336:1,20,21	98:16 102:18
218:4 230:10	farm-raised 215:17	187:15 190:1	337:21 338:18	185:11 200:16
236:1 238:17	far-reaching 34:1	199:19,22 200:12	340:5 341:11,15	feeds 178:7
270:13 284:17	241:18	200:17 202:12	342:11 344:8,21	feel 150:8 151:13
286:22 287:7	fascinating 203:14	205:20 211:11	344:22 345:16	269:17 277:11,12
296:10 307:11	fashion 78:19	219:12 223:1,4,15	FDAAA 101:9	277:21 324:16
308:12 314:4	141:14 296:11	224:16,18 225:18	FDA's 16:9,22	feels 320:6
factor 133:11	311:4	227:4 228:11	25:20 67:18 69:11	feet 219:10
198:16 209:16,19	fast 108:2 123:7	229:16 230:9,18	69:16,16 151:16	fellow 61:8 235:11
214:1,6 275:2,9	128:22 145:6	230:22 231:14,18	224:12,22 228:18	fellows 34:21 35:19
factored 313:22	281:17	232:1 234:4 238:6	229:2,18 230:21	40:2 47:16 48:8
factors 118:4	faster 56:3 107:10	238:13 240:8,20	236:5 237:19	60:7
197:11 201:2	108:4,18 110:11	241:7 242:3,6,12	239:8 240:3,16	fellowship 34:22
230:7 270:14	111:1 115:4 118:6	243:20 244:21	241:5,9 245:10,12	35:17 37:2 49:12
274:6,12,17	118:6 120:21	246:5 247:14	247:19 250:12	felt 173:18 312:5
284:14 286:15	121:11,12,22		255:9 260:6 303:8	
287:7				

338:10	127:11,13 130:19	258:17 262:18	focus 24:1 26:7,22	136:20 142:18
fertility 239:20	130:21 172:4	265:11 283:18	30:8 33:6,13 76:21	143:12,22 145:1
fertilization 73:14	173:9 181:3	284:7 303:7	107:6 145:17	146:15 148:1,21
Fertilizer 167:14	198:13 271:20	316:13 317:6	148:16 193:19	150:17 154:13,17
fetus 241:15	292:2 305:17	319:9 322:15	217:12 219:1	157:3,4,10 158:13
field 7:6 31:20,21	314:20 318:14	323:13 324:8	237:7,8 243:21	161:8 162:6,9,12
58:9,17 86:4 87:19	finding 81:2 110:14	326:18 337:19	263:2 266:16	162:13 163:14,17
109:13 110:20	121:13 129:21	340:10	303:8	164:8,9 166:2
112:5 124:14	173:6,19 183:5,6	fish 49:4 169:11	focused 31:4 263:10	167:5 168:21
128:4 130:6 134:1	294:3 296:7	216:17	270:15 272:2	169:6,11 172:22
134:7,18 135:10	findings 21:21 22:1	Fisheries 216:4,19	277:13 300:22	174:2,3 175:14,15
153:8 156:8,13	81:12 90:9 91:6	fit 39:15 107:2	focuses 239:21	175:20 176:5
158:4 171:15	112:4 225:4	143:20 215:22	focusing 150:1	178:22 179:14
186:3 271:13	235:20 236:15	fits 71:9	297:13	180:8 183:17,22
309:2 327:6	242:7 265:3,5	Fitzgerald 1:13	fold 195:5,17	184:5,5,6,8,9,11
fields 33:11 36:1	267:11 301:19,19	9:21 221:19 262:3	folks 49:9 150:5	185:3,6,19 187:6
60:11,18	finds 229:20	262:7 281:6	313:1	188:3,22 193:10
fifth 318:18 320:3	fine 243:7 331:17	283:15 302:15,19	follow 15:21 84:2	194:21 199:21
fighting 219:9	finer 124:17	303:13,18,22	150:11 214:7	201:21 209:17
figure 40:15 82:10	fines 199:6	312:4,14 316:18	244:3 256:13	218:19 219:6
82:18 99:3 100:8	finger 67:12	316:21 317:2	304:11 308:19	222:18 224:13
100:17,22 114:5	fingerprint 111:2	333:20 334:11,13	322:14 344:16	225:17 226:4,10
116:16 307:11	120:19 135:13	334:17 335:3,6	followed 161:10	227:5 228:19
figured 202:3	fingerprinting	346:2	264:3 265:10	229:5,11 236:20
305:16	110:19 137:6,17	five 35:14 82:14	following 8:8 84:6	236:22 239:10
figuring 131:3	153:7	89:4 94:15 112:8	138:12 155:12	240:12,18 246:8
filed 233:3,12,14,18	fingerprints 112:12	134:13 171:21	156:4 316:4 339:7	246:13,17 247:16
fill 42:21 64:18	137:7	222:9 263:13	follows 70:14	249:3,6 250:7
260:19	finished 43:14	274:14 334:22	230:15 263:6	252:7 257:15
filled 16:18 129:16	319:4,5	fix 217:17	266:8	259:4,6,15,21,22
189:16	fires 219:9	fixing 179:21	follow-on 89:11	260:5,9,16 262:22
filling 258:16	firm 10:9 151:5	flavor 45:7 49:8	96:8	263:11 266:13
filtering 207:22	166:4 196:2 222:9	flawed 241:10 250:4	follow-up 152:11	267:4 272:2,6,22
final 159:8 237:15	first 4:11 14:21	256:6	276:5	273:7 275:17
249:10 269:11	15:17 20:15 25:5,9	flaws 238:2	food 1:1 2:1,5,8	296:11 297:14
finalized 265:19	34:21 40:12,16	flexibility 23:7	7:16 8:14 12:21	298:5,6,16,17
finally 31:18 87:6	42:22 43:16 51:15	154:8	13:10 21:7 24:9,10	304:15,20 305:4
117:9 144:21	55:13 56:16 62:7	flip 178:17	27:12 32:9 57:22	344:19
170:21 259:18	72:5,13 78:8 81:10	flooded 340:21	62:7,13 63:11 64:4	foods 2:2 7:4 53:17
345:6	86:15 90:1 117:22	Florida 118:20	66:12,17 67:4	55:14 57:10,19
finances 74:13	135:18 146:9	119:2	72:11 84:13 85:18	100:14 107:22
financial 9:1,4 10:8	148:22 159:15	flour 165:21,22	90:3,4,22 96:1	112:9 127:21
223:8,11,18,19	160:21 161:17	187:6	105:22 106:10	140:12 143:12
224:8	162:15 175:18	flourish 34:15	107:15 108:20,21	150:13 162:6
financially 73:12	186:12 197:12	flow 70:10 139:2	110:5 112:6,18,22	163:11 168:5,6,9
find 92:16 108:7,8	204:1,3 211:2,3	flowing 163:7	113:2 115:5	183:13 203:21
110:9 115:1,19	214:14 222:16	flows 31:17	117:15 121:7,8	218:12 225:2
119:11 120:8	233:3,19 244:8	flux 16:17	127:22 129:2	237:9,11 240:19

243:16 245:3 246:16 force 90:2,2 122:22 127:19 159:13,14 191:15 forecasting 202:7 forefront 59:12,20 foreign 56:11,13,18 56:21 57:19 62:14 foresee 154:21 forever 171:1 forgot 318:20 forgot 145:14 formal 8:3 formalin 179:20 formation 182:5 formative 121:1 formed 233:16 285:3 former 328:9 formica 166:14 184:9 formula 2:17 32:10 161:19 171:5,9,18 171:19 172:21 187:1 225:2,20 226:5,9,11 227:6 235:22 236:5 243:1,11 244:10 244:13 247:15 248:4,7 257:9,12 268:2 273:3 296:15 formulas 172:5 243:16 formulated 243:14 formulating 327:6 formulation 242:14 257:8 315:12 forth 60:11 216:1 fortunate 188:19 Fortunately 189:17 forum 27:20 51:14 forward 12:10 20:2 20:11 29:10 41:14 44:15 47:3 52:6 65:1 92:6 93:21 100:3 122:17	146:6 147:10 154:11 157:14 193:18 203:19 217:20 231:21 244:17 336:6 for-profit 240:6 foul 253:1 found 110:13 112:13 120:9,17 163:2 164:13 168:19 171:5 174:5 176:7 177:4 178:22 179:9,19 180:14 241:17 268:3 269:19 294:8 foundation 18:7 19:6,14 20:4 23:2 23:5 27:4,9 30:14 33:17 35:15 77:2 four 11:19 52:22 89:4 95:22 98:22 99:4 100:13 112:8 121:14 172:18 227:1 318:17 342:22 345:13 fourteen 225:20 233:11 fourth 96:11 fragile 58:7,8 63:19 63:20 64:1,2 frame 48:1 105:1,7 framework 186:16 192:12 200:18 216:1 264:21 268:14 274:10 frame-work 19:10 228:21 Francisco 6:9 Frank 2:10 6:10 29:15 37:12 39:19 40:3 60:2,6 61:18 64:15 65:6 70:15 84:1 88:5 89:7,12 90:6 94:7 95:14 96:14 99:13,18 101:12 146:22 159:9 207:9	292:18 frankly 98:12 121:17 272:19 300:17 Frank's 78:13 81:21 83:9 fraud 216:14,14 217:9,10 Frederick 265:2 free 44:21 308:2 321:22 324:16 freedom 239:17 freeze 217:3 frequency 342:20 frequently 213:7,19 214:21 275:21 fresh 44:7 109:21 114:16 122:3,5 149:10,21 Friday 1:7 162:10 339:21 340:5 friendly 330:17 331:15 front 80:13 98:14 274:10 frontier 300:17 fruits 149:10,12 frustration 321:12 FSIS 106:18 fuel 219:4 fulfills 79:8 full 41:12 237:17 239:17 249:11 251:4 257:3,3 258:20 267:19 290:15 fullest 43:3 fully 35:16 224:15 230:20 249:21 258:1 fun 45:3 function 36:15 182:20 279:18 326:12 fund 50:20 fundamental 18:2 26:8,17 191:22 238:2	funded 241:1 funding 240:5 further 39:9 64:20 78:11 80:5 90:17 126:19 201:19 229:16 246:12 253:4 271:13 276:15 282:14,19 285:5 320:19 333:11,17 furthermore 238:4 future 18:8 20:8 24:6 26:15 27:4 93:22 101:4 141:16,17 147:11 156:16 276:9 283:9 292:1 299:11 306:7 313:8 342:13 344:15 FYI 99:13 F.A.S.H.P 1:17 F.R.C.P 2:2	gauge 218:18 gearing 146:18 gears 123:12 gee-whiz 54:12 gel 110:20 112:5 134:1,7,18 135:10 135:13 136:3,4 153:8 gels 134:22 gender 278:21 gene 144:8 general 10:1 99:15 186:10 238:8 246:10 247:20 312:2 318:4 generalize 213:14 generally 55:2 162:16 167:1 170:1 290:9 generate 25:4 generated 128:9 280:19 generating 303:5 generation 30:10 35:21 128:16 291:12 generations 234:12 generic 48:22 genetic 66:15 109:6 110:18 112:12 118:7 120:19 124:16,18 125:7 135:15 genome 140:22 141:5 genuine 194:5 geographic 118:19 geography 272:12 geology 62:18 George 7:5 Germany 252:8 getting 61:16 65:22 69:18 75:7 95:4 108:16 110:4 128:20 133:17 134:1 168:18 175:13 180:3 209:17 216:16,17
G				
G 2:13 Gail 99:13 gained 122:10 272:22 gains 121:20 167:12 194:11 197:5 Gaithersburg 1:10 Galson 247:21 Gamble 176:20 game 183:16 336:16 gap 84:8 118:1 277:22 gaps 64:18 Garret 1:13 9:21 221:19 262:3 281:4 283:15 302:13 303:10 312:3,12 316:15 333:19 334:9,9,12 334:16 335:1 gas 168:4 174:19 gather 27:6 gathering 222:20				

217:4,5 234:13	200:7	85:17,21 91:7	232:16 239:7	greatly 29:8
271:15 290:11,22	go 4:11 28:17 36:11	95:22 101:18	248:21 253:22	green 56:14 144:6
318:6 336:5	45:6 46:11 48:18	104:22 105:5	254:22 258:11	150:4 179:4
give 11:21 27:14	53:4 54:7 72:1	106:2,22 107:2,13	283:22 290:11,20	greeting 12:18
32:18 45:7 56:6	78:16 80:9,17 81:5	107:15,22 110:2	292:7 300:7	grocery 129:10,13
60:19 62:3 66:11	81:17 86:10,22	111:9,13 113:7	309:20 317:4	129:16 168:19
84:11 86:6 102:17	92:6 94:4 98:10,15	114:12,14 115:7	318:22 325:9	ground 17:13 219:9
117:19 122:13	104:20 106:5,7	116:12 118:12	329:16 343:15	228:1
136:1 294:19	110:2 114:7,11	119:11,17 120:1	gossip 209:2	groundwork 87:11
295:9,20 300:14	115:4 118:20	120:12 122:12,13	gotten 50:5 60:8	group 2:13,14 41:21
304:14 317:14,15	121:10 124:12	122:15,20 123:7	74:2	100:10 125:7
319:19 325:11	127:15 128:1,4	130:19 131:8,12	govern 308:16	147:1 206:9,14,16
given 48:14 61:5	129:10,12 130:18	131:22 135:9	governing 17:8 69:9	207:14,14,15,16
71:21 104:12	133:22 135:4	138:18 144:9,11	259:18	207:21 220:22
105:20 231:4	137:13 145:6,20	152:20 155:5,7	government 69:12	221:1,4 224:2,6
267:7 308:5	146:6 148:18	160:6 161:5,17	69:13 93:10	227:12,19 314:15
givens 100:18,21	153:15 154:8,20	162:8 166:4 174:6	172:13 229:4	326:16 340:15
gives 32:6 136:22	159:19 170:19	174:12 175:12	234:8 256:7	345:2,15
167:17 180:22	175:2 216:15	184:1 193:22	263:14 302:11	grouper 216:16
216:7 320:19	217:20 218:5	197:6 205:20	governments 201:2	groups 102:21
giving 46:14 102:14	219:18 222:10	208:5,14 212:16	graciously 283:7	152:3 207:20
103:4	293:19 299:12	214:2 218:18	grade 196:20	220:21 252:13
glad 103:12 260:19	318:5,13 319:6	219:14,17 220:16	graduating 36:6	304:4
glands 215:1	326:13 327:21,22	222:5 234:4	grams 165:13	grow 37:8,9 131:12
glazing 217:2	337:11,15	237:10 238:19	grand 199:11	132:3 133:9
glean 155:7	goal 24:11 35:14,18	296:16 306:6,20	grateful 15:22	135:19 170:3
global 2:13 65:16	80:15 108:5	311:3,15,18	221:16 224:10	growing 131:16,16
67:15 69:2,5 70:10	109:10 147:9	312:13 314:21,22	340:18	238:19 241:13
70:12 85:21 86:1,4	156:20 246:19	319:2 321:12	gratified 266:1	grown 35:22
185:2 221:4	goals 37:21	323:2 324:4 330:8	gratifying 34:18	growth 190:7,10,15
227:12,19	goes 115:2 213:15	335:2 342:21	61:2	204:17 206:15
globalization 66:7	284:7 324:19	344:15	gratitude 27:11	Guangzhou 86:14
190:1,21 200:9	going 12:9 30:5	gold 14:16	262:12	guarantee 246:18
202:16	31:7 34:13 39:18	good 4:3 5:13,20 6:4	grayness 152:1	guard 20:1
globally 153:3	39:19 41:7,13 42:3	7:12,15,20 8:5	great 38:18 53:11	guess 92:1,8 96:14
GLP 271:18 280:9	42:8,12,20 43:2,10	12:8 38:19 46:21	60:5 66:9 71:8,12	155:18 166:1
288:11,20 289:1,7	43:13 44:22 45:6	83:6 88:7,11 94:3	91:22 92:20	179:6 213:1
289:10 290:14	45:10,22 46:16,22	95:12 98:20 100:8	102:12 124:20	215:10,19 237:15
302:10	47:6 48:13 50:1,9	103:7 125:12	128:12 139:21	320:4 330:9 345:6
GLP-type 271:14	50:20 51:10 52:8	130:20 137:15	142:7 185:9	guests 4:8 220:1
glucuronidases	52:14,17 53:3,13	139:8 142:21	205:16 237:7	guidance 81:3 85:6
266:22	53:15 54:3,10,11	143:15,16 148:15	261:6 266:4	94:6 244:10
gluten 163:13	54:15,17 55:10,16	152:10,12 158:6	329:12 342:17	325:12
165:22 166:22	58:19 59:11,12,16	172:9 182:20	greater 69:18	guide 24:7 240:3
187:5,8 211:15	64:14,19 65:3	185:21 188:7,7	101:16 122:1	
glycerin 188:3	68:21 69:12 73:6	203:3,18 206:5	191:2 266:18	<hr/>
glycol 164:20	73:20 75:7 76:18	209:8 211:1 215:8	267:5 271:3 276:7	H
187:22 196:18,22	82:11,13 83:5	224:4 227:14	greatest 34:17	H 1:15 2:15
				half 104:14 139:14

166:6 181:7,7 halfway 104:14,16 half-life 307:1 311:14 hand 85:12 95:19 125:9 289:22 318:9 334:10 handful 73:2 315:5 handle 116:3 257:19 300:9 handouts 263:21 hands 334:8 happen 127:12 154:19 155:5 192:18 197:7 happened 119:22 179:2 happening 38:14 56:17 65:13 66:8 80:13 213:7 321:13 happens 31:12 102:7 130:5 131:10 142:16 216:18 happy 98:8 147:13 258:18 265:21 hard 74:3 99:7 202:8 221:11 262:13 314:17 325:8 341:11,12 341:15,17,19 harm 17:4 188:10 213:21 233:10 256:11 257:1,19 298:12 harmful 241:14 297:10 325:18 harmonization 69:1 69:10 harmonize 69:7 Harvard 6:17 221:20 235:14 HASSOP 86:1 hat 74:19 hats 193:7 haystack 111:8 hazard 166:12	268:22 271:16 head 80:18 heading 95:7 heads 69:5 129:17 147:3 165:10 health 2:16 6:17 7:19 14:19 17:7,10 18:20 22:22 25:14 28:4 32:14 58:10 61:1 64:21 65:21 66:16,22 70:8 79:1 106:16 108:9 109:18 111:13 116:5,19 118:5 121:3,4,20 122:3,7 132:2 136:19 140:1,2 144:4,10 150:9 151:11 152:19,22 153:5 157:1 161:22 163:9 173:12 197:14 198:13 210:20,22 215:6 217:11,13 224:20 225:22 226:16 228:2,8 229:6 231:10,17 232:4 233:1 235:16 239:5,13,19,22 241:9,18,19,20 242:15 244:1 246:10,14,20 248:6 271:9 healthcare 13:22 healthier 215:18,18 healthy 19:15 24:5 24:22 hear 8:12,19 45:11 53:3 54:4,8 58:20 95:22 105:5 108:3 110:19 115:3 156:18 203:4 215:12 303:13,15 303:16 333:19 345:2 heard 39:20 64:15 146:13 161:15 185:4,16 186:22	202:21 209:2 318:13 328:5,7,13 337:9,10 339:9 345:19 hearing 2:12 3:14 99:7 100:9 217:14 220:12 222:22 223:5 260:21 303:11 hearings 265:9 heart 242:1 heavily 97:3 102:22 heavy 164:19 heed 240:8 held 163:6 233:19 264:2,12 267:15 helmet 298:10 help 13:2 17:4 20:5 24:7 29:16 45:20 53:2 54:2 59:11 61:15 62:18 67:8 70:13 75:16 79:12 82:13 89:22 91:11 91:15 93:20 95:7 99:3,3 101:4 116:12 131:2 153:13 156:16 192:22 206:11 218:18 229:15 231:15 240:3 273:15 281:16 294:2 318:8 helped 47:19 95:6 168:14 176:21 helpful 34:6 92:16 98:19 131:8 137:8 137:12 180:4 269:3 292:10 342:14 helping 47:21 128:15 330:3 helps 116:19 121:9 Hentges 2:13 227:11,14,18 232:12 289:3 heparin 32:11,20 187:10,11 200:6 204:2,3	HER2/neu 77:9 heterogeneity 300:8 Hewlett 1:14 5:20 5:21 28:22 147:18 209:15 210:10 297:3 298:14,19 299:1 314:1 HHS 211:5 hidden 59:18 high 32:3 124:13,21 137:4 146:9,17,19 167:1 178:12 180:14 190:13,15 190:17 194:7,8 197:17 205:3 213:10 226:6 230:20 231:7 271:17 280:10 309:18 higher 130:10 131:13 133:10 136:1 144:19 174:10,17 238:21 288:20 289:7 294:15 313:18 highest 232:5 247:6 highest-possible 244:14 highlight 122:21 highlighted 307:9 highlighting 141:17 highlights 264:1 274:9 276:19 296:10 300:21 highly 48:5 136:18 142:21 206:5,17 247:15 high-profile 191:11 high-quality 198:10 271:7 high-risk 62:22 242:1 Hill 265:4 Hilton 1:9 hints 219:14 histopathology 179:16 historically 202:14	histories 112:6 history 186:13 192:19 198:22 218:19 291:20 hit 41:8 339:6 hold 89:15 holistic 93:8 Homeland 142:22 147:2 210:17 211:7,19 homeostasis 278:16 homes 115:1 homologous 125:10 hope 35:15 40:15 54:8 88:15 98:21 123:7 145:6 192:18 219:14 237:16 242:5 285:10 288:6 hopefully 41:10 89:19 106:1 151:12 281:5 hoping 11:9 222:12 262:2 Hopkins 221:5 horizon 27:2 horizontal 33:5 hormone 48:22 204:8,17 206:15 Hospital 6:19 hospitalizations 172:18 hotel 264:2 hour 104:3,17 hours 132:15,17,18 Howard 281:10,11 Hu 281:11 huge 147:21 209:20 human 66:16,22,22 80:12 107:14 108:16 112:20 126:2 139:20 152:19 204:16 209:12,17 240:13 246:14 250:9 255:15 278:11 humanly 281:17 humans 269:8
--	---	---	---	---

277:9,16 309:17 hundreds 154:20 225:4 255:4 340:20 hydrogen 179:8 hypersensitivity 291:15 hypotheses 24:21 25:8 178:8 hypothesis 24:19 25:5 73:21 176:6 303:4 hypothesis-gener... 304:3 hypothetically 196:9	183:14 192:14 206:9,22 247:1 258:9 278:12 319:13 identifying 58:1 61:9 78:10 123:13 212:6 283:9 identity 21:7 IFC 243:13,18 246:16 ignore 242:13 ignored 237:22 299:7 II 345:7 ill 172:16 illicit 207:4 illness 106:11 illuminate 26:15 76:3 illuminated 30:15 77:5 illuminates 18:8 illuminating 22:18 illumination 19:22 22:9 23:20 illustrated 307:10 illustrates 201:8 340:13 image 136:4,4 images 20:16 immediate 90:17 226:2 227:4 246:10 immediately 32:18 171:14,21 177:12 251:2 322:17 323:21 328:6,8,15 329:1 immerse 262:18 immersed 13:21 16:3 33:9 imminent 246:9 immutable 19:20 impact 34:1 55:18 105:8 121:15 127:5 280:15 impacts 109:22 241:18 242:15	implement 47:12 100:22 202:4 229:19 implementation 44:2 implemented 37:4 87:10 implementing 90:3 100:3 191:19 202:2 implicated 111:17 113:13 116:6 118:10 119:6,8 121:7 122:2 127:14 129:22 implications 34:1 78:16 109:17 implied 84:3 implies 190:16 import 57:5,11 109:16 149:5 191:16 importance 21:11 93:8,13 106:12,19 114:19 important 4:5 24:15 25:11,19 30:16 31:10,16 40:22 49:4,17 56:1 63:4 64:19,21 72:4 77:20 84:17 85:19 105:2,4 109:22 112:2 117:6 121:3 137:2 143:21 159:4 160:13 189:22 223:2 229:13 233:1 245:10 247:21 249:15 262:5 265:8 267:22 296:4 323:12 326:10 330:22 334:1 341:6 importantly 68:7 121:11 229:2 295:11 imported 129:19 190:8 212:11	213:10 importer 165:17 importing 165:17 211:15,17 imports 107:21 imposes 196:3 impress 227:4 imprisoned 199:7 improve 20:10 34:5 40:20 45:16 66:16 70:7 138:9 139:14 140:10 145:3 174:9 205:21 229:16 231:15 improvement 49:13 135:7 improves 138:21 improving 141:9 inadequacy 235:21 inadequate 198:22 230:10 237:20 238:3 256:5 259:12 268:4 284:17 285:20 287:8 inappropriate 71:21 98:11 incentives 192:2 include 213:22 223:12 250:1 251:5 271:21 273:6 274:7 302:21 included 211:5 225:14 250:10 251:9 273:18 313:14 includes 270:6 including 10:20 35:9 66:15 72:15 225:1 230:6 241:20 246:11 252:7 255:4 269:14 270:13 284:13 289:3 295:17 inclusion 268:15 269:6,11 274:11	280:15 292:9 inclusive 160:12 316:10 incomplete 178:10 inconclusive 231:8 231:12 inconsistent 234:6 incorporate 338:17 339:10 incorporated 85:5 323:15 327:13 332:10 incorporates 35:2 83:13 increase 11:4 174:17 183:19,21 187:2,6 194:22 195:11 196:6 336:1 342:21 increased 50:13 57:19 307:17 increasing 11:16,18 56:2,18 66:4 incredible 16:3 37:9 57:15 342:22 incredibly 15:22 48:4 269:3 incubating 132:14 indelibly 162:4 indemnify 169:16 independence 252:12,20 independent 22:2 55:3 240:9 242:8 280:21 306:6 India 86:4,14 indicate 188:6 indicated 81:3,14 162:8 190:9 195:2 226:5 265:19 285:8 343:20 indicates 22:15 133:13 241:14 indictment 199:10 individual 126:21 127:1 133:2 210:8 222:6 265:14 320:13 323:8
--	--	---	--	--

329:22	328:3 335:16,20	infrastructures	324:8	62:12 63:3 64:2
individually 152:2	337:22	26:3	instantiate 44:12	71:8 140:7 159:22
individuals 29:4	infection 126:6	infusion 36:6	Institute 13:17	228:17
36:7 37:5 221:22	128:3	ingenuity 165:3	216:4,19	interesting 39:21
273:1 304:4 330:1	infectious 5:19	ingest 210:7	institution 26:16	60:9 62:8 77:19
individual's 223:3	inferiority 189:11	ingesting 256:22	instructions 319:12	81:2,12 126:8
266:6	influence 67:22	257:17	instrument 129:1	132:21 161:12
industrial 93:11	182:11	ingredient 194:5	137:11	176:6 180:7 208:2
167:14	influenced 278:21	ingredients 172:1	insufficient 250:17	278:7 325:21
industries 83:2	inform 13:2 232:21	inhalation 301:21	insulin 278:13,14	interests 9:1,4,10
217:14 247:9	265:8 269:17	inhibition 292:17	intake 170:16	10:4 84:20
industry 36:12	327:15 328:3	inhibitors 291:11	224:18 267:16,20	interface 33:14
38:14 79:22 83:15	informatics 52:21	291:12 293:13	integrate 71:5 73:10	interference 242:5
85:19 109:18	58:22,22 144:11	initial 132:17	integrated 11:22	interferes 241:21
121:18 143:9	information 11:14	197:22	30:22 33:3,9 78:19	interim 90:12,13
149:14 156:12	17:14,14 21:17	initially 106:6	81:9 139:1	91:4,16
157:3,4,11,14,20	50:16 79:11 97:18	initiate 118:11	integrating 277:1	interjected 64:9
158:2,20,22 159:5	100:1 101:10	initiated 113:14	integration 33:5	intermediates
159:21 167:5	102:6 111:11	118:21 173:11	46:17,22 69:18	178:21
169:4 201:1,21	112:14 113:20	174:16	87:20 112:4	internal 29:18
204:19 216:13	124:18 128:21	initiating 191:14	integrity 68:3 242:6	31:14 276:13
218:20 241:1	141:13 155:6	201:20	252:11,20	301:16
244:11 251:16	156:4 162:1 163:7	initiatives 30:8	intel 209:12	internally 146:19
257:12 280:18	168:16 175:19	79:18	intellectual 36:10	201:1
industry's 158:17	180:3,4 181:14	injured 131:15	37:16	international 2:17
ineffective 133:6	183:3 184:3 191:6	injuriously 189:5	intellectually 73:13	50:3 209:3 229:7
inert 165:11	200:18,22 201:13	innovation 5:5	345:11	238:9 243:1,11
inexpensive 207:2	208:1 213:2,4	18:17 24:8	intelligent 320:10	252:6
infant 161:19 171:5	218:16 222:20	innovator 48:22	intended 28:3 187:6	internationally
171:9,18,19 172:4	223:11 230:6	input 58:16 94:13	189:13 297:10	187:17
172:21 187:1	234:7 237:21	98:9 254:12	338:3	interpret 144:12
225:2,20 226:5,9	244:15,17 245:18	282:14	intent 159:13 189:3	interpretation
235:22 236:4	249:20 251:4,6,8	insensitive 215:3	207:12	16:14 277:21
241:15 243:15	251:15,19 261:14	inside 15:8 36:19	intentional 3:12	interpreted 16:11
244:10,13 247:15	270:10 273:10	82:18 131:20	90:4 161:2 185:12	17:1
248:3,7 257:8,11	282:20 284:12	insight 26:22 80:5	210:13,15 233:6	interrupt 289:17
267:1 268:2	301:10 302:5	insights 13:22	inter 277:14	interruption 70:10
infants 171:10	311:20 317:18,19	294:20 295:10	interaction 87:20	interspecies 274:19
172:16 182:19	317:20 318:1,5	insofar 125:3	interactions 83:11	intervened 185:18
183:6 198:14	336:2	inspect 58:12 64:10	87:18	interwoven 274:6
224:19 226:3,5,19	informative 145:9	inspecting 116:10	interest 5:6,17 7:10	inter-governmental
233:10 244:1	informed 226:14	inspection 58:14	8:9 9:5 10:7 56:9	159:14
246:11,20 266:14	informing 101:17	62:21 63:21	61:12 102:20	intramural 327:9
267:5 270:16	323:1	inspections 107:20	150:9 211:10	intraspecies 274:18
275:19 276:16	infrastructure	109:16 115:6	235:6 242:5,9	intriguing 63:13
285:9 297:13	25:18 33:7,21 42:9	118:21	247:4 252:13	intrinsic 209:21
308:2 322:18	52:11 87:17 99:16	instance 187:15	254:4,5 329:4	intrinsically 191:3
323:19,22 325:18	118:5 154:15	272:18 298:11	interested 29:3	introduce 4:12 11:2

12:3	irreducible 271:5	345:14,20	journals 50:14,15	34:2 52:5 54:12
introduced 40:2	irrelevant 334:19	item 29:8 114:17	228:10	76:9 77:6 79:8
introducing 12:9,11	irreversible 274:20	299:10	judge 199:20	91:16 102:10
introduction 12:12	irrigation 120:10	itemized 258:22	233:17	105:18 117:4,12
Introductions 3:2	130:13	items 54:7 240:22	judged 230:19	128:8,10 137:10
4:2	ISAC 219:11	it's 137:7	268:21	140:4 151:11
intuitive 62:8	ISACs 218:16	it=s 17:3 63:12	judgment 237:20	152:11 153:20,20
inventory 97:8,11	isolate 109:7 110:15	IV 96:6	juice 219:5	153:22 161:14,21
invest 195:22	119:18	i.e 268:13 273:12	July 146:8 191:14	167:16 175:5
invested 137:3	isolated 304:14	275:7,19 279:6	June 118:9	181:10 205:1
investigate 181:17	329:11	280:9	jurisdiction 342:11	206:19,21 211:22
investigated 226:13	isolating 306:13		jury 199:11	224:9 306:7 308:4
investigation 127:7	isolation 325:20	J	justice 96:18 199:18	308:19 316:12
211:12,13	issue 8:9 29:6 42:5,9	J 1:12	justify 22:13	321:18 322:13,17
investigations	49:4 53:9,21 54:14	Jack 5:3 60:4 61:15		323:3 325:11,15
109:14 115:15	55:15 57:2,3 66:19	283:7 304:7	K	325:21 326:6
investigators 21:10	69:7 96:5 97:13	306:18 308:20	K 2:2	337:4
29:2 35:22 109:13	103:10 119:15	322:15 331:2	Kansas 162:7	kindly 265:2
120:12,17 171:14	144:22 150:15	333:15 334:5	163:15 233:16	kinds 30:16 48:15
290:8,22	161:9 172:22	Jack's 321:5	keep 146:5 157:20	48:17 70:9 73:16
investing 159:16	174:3 188:12	jalapeno 119:7,12	163:7 217:20	82:7,16 93:22 94:9
investment 41:17	223:19 233:1	JAMA 278:4	keeping 327:4 329:5	94:10 97:12
investments 52:15	234:15 236:17	310:17	Ken 15:16	105:10 156:14
52:20	237:5 244:5,7	Janssen 242:19,20	kept 329:6,14	184:20 204:19
invite 224:1 342:14	262:19 306:5	243:5 258:13	key 45:8 72:12,14	206:1 207:7
invited 155:18	313:4 328:2	Japan 245:1 246:7	116:8 117:3 121:2	212:21 301:2
265:10	issued 9:12 191:16	252:8 315:5	135:3 136:10	318:4,14
involve 50:2 84:6	254:16	Japanese 315:5	148:19,20 149:19	King 1:15 5:13,14
involved 6:6 47:20	issues 15:11 23:22	Javiana 158:12	149:22 152:16	34:7 65:6 91:20
48:16 71:3 91:10	25:11 31:6 33:13	Jennifer 2:16 239:4	157:9 231:19	106:22 152:8
97:3 102:22 151:7	40:10 41:6,15	239:11	keys 136:15	210:12 294:2
162:14 169:9,10	42:16 44:7 46:17	Jersey 163:18	kicking 119:9	296:2
211:13,18,20	49:3,5,6 50:4,6	job 55:1 92:2	kid 12:15	Kingdom 252:9
involvement 10:3,9	52:11 53:11,11,13	100:22 152:10	kidney 28:19	Kjeldahl 167:6
involves 74:4	72:14 74:13 76:10	321:6 323:1	171:10 179:21	knew 18:11 39:5
333:15	78:10 84:20 85:4	324:19,21 325:3,3	182:5	96:18 113:10,11
involving 104:3	93:5 94:9,11 96:21	327:11 340:16	kidneys 198:4	164:5,16 165:7
112:20	101:18,22 102:22	341:13	kilo 196:6,7	171:19 211:16
in-depth 36:13	105:2 109:22	John 1:15,19 2:18	kilogram 165:13	341:5
264:8 272:20	116:19 122:22	221:18 248:18,22	180:20,21 181:1,5	knock 73:19
iodine 204:8	151:11 159:22	264:19 269:2	195:8,9,11,12	know 4:13 6:16
irradiate 150:7	169:2 185:12	281:10 285:22	270:3 273:14	12:8 13:16 17:17
irradiated 150:17	207:17 217:8	289:18,21	274:15 295:5	18:10 24:13 34:9
150:18,20	235:16 244:11	join 262:3,8	340:22	34:12 42:15 48:13
irradiating 148:1	245:5 257:5	joining 221:21	kilos 196:9,12	48:19 59:15 60:8,9
irradiation 149:19	263:17 266:6	281:5	Kim 52:7 99:18	62:14 63:2 65:18
150:3,12,14	300:19 313:10	joint 265:18 342:15	100:4	66:13 67:7 68:9
151:10	327:22 331:12,12	journal 51:12	kind 19:5 29:16	71:17 73:1 75:10

77:8,17 81:13,16 81:17 82:3,4 84:18 93:20 107:6 111:19 112:15 113:5 114:3 116:18 120:6 121:6 125:14 128:2,17 129:20 130:13 138:1,3 142:11 143:2,16 144:6 148:8,16 150:20 151:20 152:5 155:11,12 157:5 158:22 159:10 161:6 163:16 164:4 166:5 167:15 169:20 171:2 172:15 174:4 182:18 183:2,8 184:4,12,15 194:20 198:4 199:15,16 204:22 205:10 206:18 208:15,16 210:18 212:2 214:3,10,15 214:22 215:5,13 218:5 219:4 225:21 226:17,20 234:13 236:3,7,11 238:18 241:6 253:8,8 296:22 300:1 308:16 309:17 314:14 315:3 316:15 323:3 336:18 339:3 341:1 knowing 58:7 119:18 314:3 321:12 knowledge 17:15 21:18 79:11 160:1 297:1 311:21 known 96:10 111:3 192:5 210:2 223:10 235:8,9 308:14 knows 190:13	L	336:3 338:6,16 345:18 Larry's 214:8 335:11 Las 163:11 lasting 19:19 lastly 130:22 242:12 late 85:14,16 86:3 89:2 117:18 265:15 Latin 86:18 law 2:14 19:8 35:3 217:16 232:14 233:3 Laws 19:9 lay 44:8 54:10 271:12 282:1 laying 269:3 lays 106:9 185:21 leachates 296:14 lead 25:1 26:15 40:22 114:12 115:16 201:2 316:6 leadership 15:21 41:17 42:2,18 67:18 68:19 69:11 72:22 187:16 leading 12:4 65:7 197:11 198:17 214:3 leads 112:3,17 271:4 277:20 287:4 296:13 leaf 129:7 leafs 129:17 leafy 150:4 learn 20:5 117:6 208:22 308:18 340:21 learned 107:8 117:4 161:16,17,20 162:3 171:11 176:4 185:2 319:18,19 learning 25:9 37:17 341:19 leave 48:14 232:18	leaving 86:12 Leavitt 191:15 LECOM 5:11 led 16:12 255:8 leech 184:11 left 104:10 115:8,12 130:6 334:2 leftover 114:20,22 legal 196:3 199:3 232:22 259:18 legally 206:3 legislation 43:17 legitimate 252:22 lengthens 126:17 lenses 19:1 lesions 177:22 178:1 lesser 200:6 lesson 107:8 lessons 117:4 185:1 lethal 197:20 letter 297:7 lettuce 129:7,9,11 129:17,18 132:9 let's 39:18 44:7,7,8 44:9,11,17,18 104:13 109:15 177:3 237:13 293:22 316:4 321:7 335:9 337:6 339:7,7,8 level 31:18 33:19 50:16 73:16,19 75:3 77:12 78:13 80:22 121:5 126:14 143:3 144:14 146:3 149:2 166:21 180:15,16 181:3,3 182:12 191:15 250:16,18 254:9 274:16 291:19 308:4 323:13 levels 123:22 174:21 180:13,14,20 184:4,11,13 201:7 226:6,12 227:5 236:12,19 238:16 241:16 246:8	256:22 291:16 leverage 43:3 65:19 leveraging 93:9 liability 68:6 life 14:4 23:16 37:16 57:21 132:1 142:5 226:17 life-altering 17:15 life-cycle 61:21 85:17 life-span 170:2 light 20:4,15,18 21:12,14 22:9 23:22 27:7,7 144:7 276:11 293:21 light-red 144:7 liked 83:9 164:8 likelihood 197:9,13 197:14,19 198:17 Likewise 223:15 limit 322:18 323:19 326:6 328:2 337:6 337:7 limitation 296:7 309:14 310:4 limitations 245:14 255:3,6 267:22 269:12 311:8 limited 217:12 230:20 231:7,8,11 236:9 237:21 272:11 275:16 277:13 278:1 280:14 294:13,21 limiting 323:22 335:15,19 337:22 line 56:20 57:6 100:12 117:2 151:15,17,21,22 262:10 283:15 302:14 303:12 lined 255:16 Linehan 1:15 5:3,3 60:5 215:9 283:7 306:20 319:2,7 330:6,11 331:4,8 331:16 lines 57:5 117:12
---	----------	--	--	---

190:8	129:19	96:17 99:21	325:9 341:9 345:3	making 74:4 93:2
line-item 74:17,20	locals 147:7 154:9	164:19,19,20	345:9	219:18 222:21
linings 240:19	located 163:16	176:11 179:9	lots 76:4 84:11	231:21 245:16
link 89:10	locations 118:20	208:10 235:21	101:3 140:13,13	274:4 338:12
linked 126:5	lodging 223:13	looking 12:10 31:8	140:13 144:15	mammalian 182:15
links 278:12	logarithmically	37:13 57:9,10 71:3	164:7 221:14	mammary 271:21
liquid 175:2 225:2	56:3	85:22 91:3 102:5,5	297:17	management 85:18
226:4	logically 296:13	103:8 110:22	love 156:18 335:4	263:5
list 73:20 81:21	logistical 148:2	111:6 115:17	low 133:7 180:13,19	manner 278:20
100:20 101:3	London 86:16	118:15 120:7	182:13 184:11	295:1 297:18
208:10 216:9	long 6:6 77:19	127:8,13,17 138:8	194:4 197:11,13	319:20 326:17
251:14 318:4	109:15 132:16	140:15 141:12	197:14,20,21	331:13
319:12 323:18	174:7	142:19 144:8	198:17 199:2,5,6,6	manufacture 58:8
listened 79:17	longer 88:1 119:20	149:3 157:5,22	201:18 207:6	163:14
listening 220:1	124:19 132:20	159:11 164:17	224:21 231:9	manufactured
304:13 322:5	Lonnie 1:15 4:14	181:11 183:22	241:16 291:16	173:9 206:2,12,13
literally 14:2	5:13 34:6,17 63:9	199:22 201:12	lower 189:5 250:18	manufacturer
literature 50:20	65:5 66:10 67:10	204:11 206:1	270:3 271:9	162:7 178:11
165:12 225:6	91:10,18 106:22	208:1 218:10,11	295:15 309:16	manufacturers
294:11 300:2,3,7	152:1,6 154:2	237:13 291:5	lowest 180:15,16	166:2 171:20
litigation 233:15	210:11 294:1	295:11 299:21	181:2	233:4 240:7
little 42:12 49:16	296:1 334:5	300:11 306:22	low-dose 245:13	243:14
60:9 72:2 88:19	look 20:17 23:21	308:4 309:8	277:6	manufacturing
89:1 91:7 106:1	41:14 53:15 57:1,8	314:15 319:8	low-levels 131:4	45:21 56:11,21,22
107:1 118:8 124:1	57:12 65:1 68:16	338:11 343:15	lucid 45:19	58:6 64:11 254:5
130:11,17 133:13	80:7 81:21 82:3	looks 18:15 112:7	luck 290:20	map 212:14
134:4 141:2	83:20 90:14 97:15	176:12 306:16	lumps 176:17	March 162:4,5
146:14 147:20	124:1,7,8,8,9	losing 322:10,10	lunch 220:8	163:10 233:2
160:9 170:17	125:21 130:4	325:5,6	Lutter 2:4 7:1,1	MARDI 2:17
186:12 190:13	133:4 141:20	lost 164:11	174:12 185:16	margin 225:6 238:3
205:1 213:12	143:8,21 147:4	lot 11:20 40:10 42:3	209:7 328:5,12,18	255:8 259:12
217:15 219:17	149:5 152:17	45:3,9 47:13 48:13	339:13	285:8 286:14,17
267:17 272:5	156:21 157:13	54:20 59:4,9,10		287:6
282:10 283:5	158:1 165:12	76:10,10,11 80:2	M	margins 230:9
285:18 294:5	173:20 174:1	81:22 88:17 97:22	M 1:19 2:10 248:15	240:11 270:11
303:11 311:19	176:14 177:3,13	103:16 115:8	macrosize 31:13	284:15 286:8
320:7 327:12	182:16 189:1	128:15 130:8,20	magic 79:6	Marine 221:5
337:2,3 345:7	212:3 215:8,22	138:14 143:8	magnitude 314:3	marked 276:12
live 80:19 131:18	218:22 219:12	144:3,6 149:15	main 163:15	markedly 226:1
200:8	226:15 231:20	164:21 167:14	maintain 34:14	markers 45:12
liver 266:20 267:1	236:13,19 237:1	168:10 169:18	maintains 63:7	271:12 309:9
lives 14:13	237:13 263:8	175:1 183:9,12	major 33:6 113:2	market 82:15 170:5
live-stock 169:4,6	264:8 272:3 276:4	187:10 188:9	121:20 148:4	173:5 195:21
living 36:18 131:17	280:6 293:19	211:10,11,18	171:16 186:17	247:12 260:16
131:19,20 133:9	294:18,19 299:11	218:19 238:18	267:16 273:21	marketed 45:14
load 89:22 158:8	306:8 321:2	277:20 308:8	majority 172:17	204:6
local 106:16 110:15	325:21	318:19 319:15,18	291:1	marketers 243:14
111:12 121:4	looked 91:14 94:12	320:1 321:4 325:8	makers 226:11	marketplace 41:1

45:17 67:16 69:2 69:22 70:12 255:10 256:19 markets 171:16 172:6 Marti 243:10 Martin 1:16 4:15,16 4:18 96:3 221:11 281:20 283:13 289:9 292:4 296:18 299:18 305:10 326:15 329:3 330:14 331:18 338:3 340:15 341:16 Martin's 96:10 Maryland 1:10 mash 188:13 mass 141:19 168:4 174:19 175:3 match 137:10,14,19 137:20 139:10 matched 119:18 136:5 137:20 matches 124:14 158:3 matching 134:2 137:8 268:9 material 115:18 132:12 164:1 183:7 267:6 materially 250:3 materials 174:7 213:6,18 221:7,14 263:22 281:15 306:22 matter 68:10 88:3 89:13 148:2 189:11 198:8 213:17 220:10 234:19 265:8 266:2 314:21 334:18 335:2 346:4 matters 9:17 197:8 199:1,20 mature 69:14,17 maturing 70:12	McNeil 1:10,12 4:3 6:14,14 8:2 11:1 15:22 28:8,12,16 37:18 38:22 39:5,9 39:15 60:1 61:18 64:13 65:5 84:1 85:10 88:4,14 90:13,20 91:22 92:17 93:16 94:17 95:10 98:20 103:13,21 104:20 145:7 147:15 150:10 151:14,19 159:8 160:15 203:12 205:7 207:9 209:14 210:11 212:1,18 213:8 214:7,18 217:21 219:20 220:13 227:8 232:7,13 234:17 234:22 239:1 242:17 243:5,7 247:10 248:11,17 253:6,19 258:3 260:18 261:1,6 262:1,17 281:19 283:21 288:7 289:21 290:19 292:4,11 293:5,10 293:22 295:22 296:18 297:2 298:1 302:13,16 303:10,16,19 304:7 305:9 306:18 310:15,20 311:3,16 312:11 312:16 314:14 316:1,19,22 317:4 319:5 320:11 321:8 323:5 324:1 324:4 325:2 326:10 328:11,16 329:3,9,16 330:10 330:14,20 331:7 331:14,17 332:2,6 332:13,17 333:1 333:11,22 334:12	334:14,18 335:4,8 337:9,14 338:2 339:3,19 342:17 343:10,17 345:22 MDs 60:19 meal 19:2 mean 22:5 46:18 62:17 63:13 64:16 80:20,22 82:11 85:7 97:6 103:10 103:17 109:15 126:15 148:20 156:20 165:7 193:18 200:2 207:12 213:22 233:21 236:14 268:5 284:17 290:20 294:12,18 298:14 310:11 325:15 336:20 344:6 meaning 92:10 meaningful 244:10 meaningless 321:17 meanings 16:10 means 18:5 36:6 80:8 194:1,3 200:10 277:5 287:10 312:8 327:8 meant 286:12 295:19 measure 167:7 168:9 181:10 measured 167:4 315:10 measurement 309:9 309:12 measures 37:4 200:21 201:21 202:4 310:3 measuring 167:10 168:1 296:17 309:13 meat 170:15 209:20 210:2,3,4,9 mechanism 245:18 mechanisms 154:13	267:10 mechanism-based 279:10 mechanistic 161:21 271:8 280:10 mechanistically-f... 269:14 277:4 media 132:15 163:6 medical 5:6 6:1,5,17 19:3 24:8 35:7 57:20 183:4 235:7 235:13 276:17 300:2,3,6 medication 19:5 medicine 2:3 5:18 5:18,21 7:14 49:2 161:8 177:19 medium 132:3 MedWatch 49:5 meet 24:11 33:18 220:6 251:21 279:6 286:19 298:7,8 343:22 meeting 1:5 4:4,5 8:7,10 9:1,6 10:19 11:6,11 12:20 13:4 15:17 39:17 47:15 69:5 79:16 84:12 84:22 89:11 151:3 155:17 209:11 221:8 223:1,14 233:19 239:9 240:16 252:16 262:18 264:2,12 278:5 292:16 308:11 317:22 342:13,15,16,20 343:19 346:1 meetings 11:19 12:21 101:3,21 345:13 meets 22:12 melamine 90:5 104:4,7,9 160:16 161:3,5,10,18,19 161:20,20 165:4,7 165:8,11,21,22 166:7,13,15	167:14,17,21 168:5,9 169:5 171:4,9 172:19 173:6,9,14,18 174:9 175:12 176:4,8,9,9,16,18 176:21,22 177:9 177:20,21,22 178:6,8,11,12,13 179:4,5,10 180:11 180:15,22,22 181:7,12,19 182:2 183:11,21 184:4,5 184:7 185:5,19 186:7,21 192:14 192:15 194:2,8,11 194:13,21 195:7,8 195:13 197:17 198:2,10,12 200:4 201:7 203:1,7,9 209:17 210:6 211:2,3,3,20 mela-who 166:8 member 27:12 103:15 243:22 246:16 249:4 262:7 297:4 members 8:5,6 11:5 11:10 75:5 99:17 207:15 221:17 233:22 243:17 252:12 254:6 258:5 263:13,15 283:12,14 285:16 320:13 323:8 327:18 329:22 334:4 340:19 341:7,18 342:14 343:1,16,22 membership 11:5 11:12,17 343:6 memory 162:5 men 242:15 menopausal 291:11 mention 86:3 237:6 313:5 mentioned 11:5,17 42:19 61:20 86:5,5
---	---	---	--	--

89:12 90:21 99:13 99:18 188:5,18 189:20 197:22 203:21 209:18 212:3 237:3 257:6 264:13 267:7 268:1 275:5 277:3 283:18 293:2,4,15 345:14 mentioning 311:5 mentor 48:10 mentored 35:4 Menu 162:6 163:11 men's 241:19 merited 295:16 merits 201:19 message 33:1 172:9 207:13 messaging 151:1 met 15:16 44:3 152:2 158:10 159:2 262:14 metabolic 266:19 276:1 metabolism 267:6 301:11 307:11,13 307:16 Metal 2:18 248:19 249:1 metals 164:19 metaphor 18:12,13 18:14 meta-analysis 300:5 meta-analytical 280:7 299:21 method 3:9 136:19 139:4 167:6 168:4 168:11,13,14 174:18 175:3,6,7 269:4 methodologies 32:4 32:12 122:14 123:16 228:15 methodology 21:1 32:17 184:14 methods 8:19 105:13 124:21 143:8 160:22	175:1 177:2 183:11 187:16,19 198:20 264:9 270:21 296:12 Mexico 87:5 109:14 118:20 119:2,14 120:6,7,9,12,13,20 153:5 Michigan 4:19 281:11 microbial 6:3 45:19 130:3 178:9 microbiology 146:10 microflora 131:5 micrograms 273:14 340:22 microlab 110:8 118:6 microphones 10:15 microscope 177:13 microwaved 273:2 microwaving 296:5 middle 38:3 51:9 87:8 midst 95:3 mid-April 117:22 mike 218:2 milk 184:19 188:12 189:16 192:7 195:4,8,12 248:3,5 milk-based 172:1 millennium 55:6 milligram 295:5 milligrams 180:20 180:21 181:1,4 270:3 274:15 million 57:10,11 81:19 162:9 169:9 196:11 227:1 millions 14:13,13 129:16,17 169:17 mind 102:11 146:6 157:20 204:4 217:20 271:12 280:17 291:9 293:18 322:16 mindful 158:15	minds 34:12 36:22 38:15 59:13 297:9 mine 89:15 miniaturize 31:14 minimal 144:5 250:15 minimum 251:22 Minnesota 136:12 minor 266:9 317:8 minority 265:22 minute 43:22 247:10 311:17 minutes 52:8 53:4 54:5 88:8,17 139:17,18 220:7 222:6,7,9 317:5 327:13 misconception 130:2 misconceptions 129:5 mislead 238:7 misrepresentations 233:6 missed 296:1 missing 80:2 85:14 97:17 259:2 mission 40:18 42:11 46:1 59:6 75:2 78:21 121:21 239:15 mistaken 204:7 mistakes 274:5 mitochondrial 4:21 mixed 135:20 142:8 189:9 mixture 179:12 mode 10:21 123:11 model 194:18 196:15 modeling 82:20,20 270:22 271:2 277:8 290:13 295:8 302:8 models 82:13 218:8 241:2 276:2,22 277:8,14 279:11 279:21 280:3	301:13,14 modern 32:1 53:2 modulate 64:20 moisture 169:1 molecular 127:2 moment 18:22 193:7 194:2 293:18 329:18,19 339:8 moments 34:18 47:14 money 137:4 169:19 193:5,10 195:20 monitoring 310:1,9 315:7 monolithic 296:11 month 65:17 69:4 98:22 99:5,21 265:20 months 170:21 233:11 morality 196:3 morning 1:13 4:3 5:13,20 6:4 7:12 7:15,20 8:5 9:20 12:8,18 88:18 299:14 300:19 327:16 342:8 344:14,17 morning's 219:21 mother's 248:3 motion 330:12 331:5,9 332:14 333:12 334:8 motivated 3:12 53:15 54:14 161:2 186:9,13 194:15 mound 129:11,12 Mountford 2:17 243:3,6,9,10 247:11 248:15,15 mouse 277:20 mouth 302:2 move 33:16 47:3 73:18 78:14 83:19 90:15 97:1 100:3 104:2 122:16 123:7 131:3 135:9	147:10 154:11 159:9 160:15 161:9 203:19 223:22 227:10,10 232:14 242:18,22 248:18 256:7 282:20 329:17 330:7 335:9,10 336:6 moved 77:22 99:19 100:6 132:13 333:13 338:8 moves 120:20 moving 32:3 44:15 66:1 68:15 93:21 97:7 98:17 157:14 193:18 333:19 MRSA 140:5 mud 130:12 multilocus 140:17 multiple 87:2 112:3 112:13 117:14,15 121:9 122:10 124:14 135:22 146:14 168:14 311:14 multiplication 112:6 multiply 167:7 multitude 240:13 multi-district 233:15 multi-layered 87:14 multi-step 245:6 Murakami 2:14 232:16,17 234:21 Musser 2:5 106:4 110:20 122:19 157:19 mutable 71:18 mutual 73:7 84:20 M.D 1:10,12,13,14 1:16 2:1,2,9,10 13:18 28:18 M.P.A 1:15 M.P.H 1:17 2:10 M.S 2:6
--	--	--	--	---

N				
Naidenko 2:13 224:1,4	102:19 191:2 304:12	needs 25:16 59:2 61:10 94:12 99:16	200:11 201:15,15 201:16 202:17	288:13 290:5 291:1 295:18
naive 148:4	necessity 285:21	146:3 147:4,5	204:1 215:12	non-green 179:5
name 5:20 64:3 103:3 232:17	need 10:2 20:18 21:13 22:8 26:5,7	151:1 154:7	244:15 245:17	non-human 277:9 277:12,19 278:3
239:11 243:9	26:10,22 27:21	157:21 158:9,18	247:5,12 269:13	non-oral 277:1
248:14,21 254:1	44:6,13 49:16 52:5	158:19 159:2,5	291:12 297:4	non-prescription 213:5,9
258:12 260:22,22	59:11 63:17 64:18	160:11 176:1	336:21	non-profit 224:6 235:15 239:14
261:2,3 285:22	69:14 72:12 73:17	181:14 202:16	newer 20:12 156:8 267:7	254:3
named 206:16	76:13,16 77:1	256:12 275:3	newest 35:21	non-responsive 241:3
names 11:15	78:11 80:22 85:8,9	276:5 277:8	Newport 124:8 126:22 142:12	non-selective 131:11
NAMPA 249:4,8,10	98:1 107:10,13,14	negative 121:15 241:18 289:5	158:12	non-specific 201:6
249:14 250:20	108:1,4 109:6	negatives 121:12	news 187:10 188:1 188:7,7,8,9	normalize 307:3
252:2,10 253:3	110:16 114:14	negligent 233:7	NHANES 310:1,2,7 311:8 312:12	normally 162:20 164:18 309:5,7,11
nanotechnologies 5:1	124:12,21 127:17	negligible 250:15	NIAID 84:13,16	North 2:18 243:17 248:19,22
nanotechnology 30:11 50:2,4,7	130:1,22 131:2,4	neither 312:9	nice 60:2 70:15 88:16 120:15	Northwestern 5:4
narrowed 296:16	132:6 133:13,18	neonatal 276:1	131:19 137:11	North/Gaithersb... 1:10
narrows 327:11	133:19 135:6	neonate 308:7	142:7 147:18	nose 302:2
nation 136:13	141:10 144:18	neonates 267:14 276:5,7,20 291:7	153:3 325:20	notable 274:13
national 2:7,15 5:14 7:9 13:16 216:4,19	146:15 147:19	293:11 307:12,16	nicely 303:9 304:6	note 9:7,18 136:10 229:14 230:1
221:2 235:1,5	148:12 149:7	307:17 308:3	night 12:15	231:11 245:12
239:14,22 242:19	152:9 153:15,16	nephropathy 176:13,13	NIH 50:17 76:17 79:21 84:4,6,21	253:7 269:12
250:8 264:20	153:22 154:3	nervous 226:20 267:9 279:18	147:1	noted 10:5 246:5 250:5
310:8	158:20 160:7	net 196:10	NIH's 81:11	notes 339:11
nationals 87:12 199:12	168:1 170:8	network 84:14 154:14,18	NIH-style 288:16	noteworthy 276:3
natural 2:19 209:21 215:2 291:20	181:16 182:9,14	neural 271:22	NIH-type 301:3	notice 212:15
313:13	183:2,3,8,10,14,21	never 22:5 28:15 212:14	nine 221:22	notified 118:10
naturally 184:15 319:10	184:3,12,15,18	new 13:22 14:1,8,20 15:20 16:13,16	nitroaromatic 4:22	notion 193:12 194:13
nature 15:9 16:17 20:22 21:7 33:20	191:22 209:19	20:12,13 22:12,13	nitrogen 166:19,19 167:7 195:3 201:9	novel 21:20
36:14 46:18 191:6 304:2	212:3 217:15,19	22:21,21,21,22	NOAEL 181:6	November 49:21 51:15 191:16
NCI 79:21	218:16 219:5	35:9 36:1 38:4,15	nodding 80:18	233:19 335:5
NCTR 30:2,5,21 92:4,17,22 94:5	226:14,14 227:4	41:1 45:16 47:15	noise 21:1	no-effect 181:3
345:2	236:10 237:8	55:19 67:19 79:11	nomination 343:13	NRDC 258:13,14 258:18 261:5
nearing 219:21	257:2,22 274:9	79:11 84:16	nominees 343:9	297:7
necessarily 70:8 286:4 341:2	276:19,21 277:11	101:22,22 110:22	non 309:6	NTP 225:16 250:14
necessary 19:11	278:12,14 279:20	123:16,17,17	non-epidemiologist 314:19	
	279:22 282:15	128:11,22 136:16	non-existent 225:7	
	297:3,4 300:21	140:15,16 143:7	non-expert 319:7	
	304:22 305:4	143:10 159:17	non-GLP 268:18 275:7 280:10	
	312:7 314:19	163:18 175:19,21		
	317:18,19 324:5	185:10 188:5,12		
	332:15 339:20	188:16 189:20,21		
	needed 22:16 165:15 168:11,13			
	169:12,13,20			
	174:21 276:11			
	281:16			
	needles 111:7			

250:18 268:21 275:22 nuance 16:7 nucleotide 140:21 number 11:19 43:4 43:5,7 46:9,12 48:3 85:4 87:15 95:21,22 102:21 140:17 164:12 167:8,8 173:17 187:13 190:8 216:14 217:7 261:19 268:2 273:11 278:6 288:15 331:7,8 numbers 57:8 172:14 278:2 288:17 numerous 123:9 125:13 241:17 244:22 nursed 132:2 nursery 111:21 nutrition 2:6,9 7:17 45:18 243:15 248:1,2 nutritional 243:16 248:7 nutritious 24:10 247:17 nutshell 34:2	184:10 207:4 218:8 237:7 305:7 312:7 313:17 occur 31:15 32:22 117:7 137:10 206:2 occurred 32:16 55:10 113:3 116:14 117:22 172:7 184:16 187:21 310:22 occurring 29:20 30:18,21 31:2 33:11,15 37:10 68:22 77:6 87:21 111:12 139:9,20 178:5,7 occurs 24:9 137:17 137:18 177:6 182:5 209:21 ochratoxins 164:20 October 1:7 225:13 246:5 247:20 264:4,4 340:5 odd 141:2 offensive 256:17 offer 196:10 202:20 256:14 330:16 office 2:5 7:5 43:18 86:16 87:1 94:21 211:6,12 299:13 officer 199:14 offices 2:14 38:4 86:4,7,12,14 87:3 87:8,19 171:15 186:3 209:4 232:15 official 6:21 340:3 offline 253:16 off-line 345:5 oh 127:13 130:18 137:15 145:14 150:10 243:7 283:21 289:20 294:1 296:1 303:13 312:3 324:1 332:2,16 336:15 342:17	okay 90:20 91:22 95:10 111:8 120:5 145:15 150:6 166:5 167:13 197:6 219:20 220:13 227:9 232:13 234:22 239:4 242:18,22 243:7 248:18 253:13,18,20 261:6 293:22 297:2 299:1 312:16 316:18,21 317:4 320:11 324:4 328:18 329:3 332:6,18 334:1,17,22 335:3 337:13 339:19 old 14:6 82:13 167:5 172:17 188:19 189:16 236:2,9 273:13 oldest 183:16 218:21 Olga 2:13 224:1 omission 255:4 273:21 once 65:2 68:11 75:18 78:14 109:1 110:12 113:1 120:10 121:6 134:5 162:10 167:21 176:22 180:4 217:18 247:13 284:9 oncologist 6:5,12 289:16 291:10 oncology 6:7 52:1 76:9 ones 94:18 125:14 130:7,10 138:19 178:3 200:6 229:19 282:17 293:14,17 one's 24:19 one-dimensional 255:12 ongoing 54:9 79:7	79:10 113:21 155:12 184:18 276:18 ONH 139:6 on-going 13:1 open 2:12 3:14 10:12 21:19 27:20 86:12,15,19 220:12 222:22 223:5 265:9 308:11 opened 38:4 146:8 146:20 operate 199:12 operations 12:22 93:21 opinion 28:1 254:10 opportunities 20:20 29:12 36:2 65:1 66:17 67:3 71:7 73:7,13 82:1 83:20 193:9 199:22 247:1 opportunity 12:11 12:18 13:14 21:14 21:15 23:20 32:6 32:19 35:16 38:1 40:8 46:16 51:21 61:5 64:16 66:22 67:14,17,21 92:20 93:2 160:5 195:22 210:22 224:11 227:15 232:20 243:19 249:2 254:14 255:14 opposed 111:9 148:11 219:9 optical 140:18 optimally 25:20 optimize 280:4 option 248:5 318:18 320:12 322:15 333:10 options 226:15 282:6,8,17 283:3 316:5,13 317:6 318:17 ORA 71:2 72:15	92:4,17 94:17 95:3 140:9 345:2 oral 223:7,7 264:5 277:6 301:20 orange 179:6 orchestrated 111:4 order 42:14 43:12 44:14,15 47:1 50:11 72:11 165:13 174:9 191:13 270:5 282:1 288:16 organ 182:4 organism 131:9,13 135:12,16,19 139:19 organisms 130:14 130:15 133:7 organization 16:6,8 16:12 37:17 224:7 239:15 244:6 organizations 235:15 241:8 organs 279:19 orient 116:12 origin 63:17 212:4 original 100:5 181:2 318:11 originally 140:20 250:2 Ortrie 233:17 ought 98:15 313:22 outbreak 106:8,11 107:9,12 108:7,12 109:8 110:2 111:9 113:21 117:5,10 117:13 118:17 119:2 121:2 122:2 124:12 127:5,7,9 127:15 128:21 130:1 134:3 138:2 138:5,11 163:21 174:22,22 175:20 176:5 179:14 180:9 185:7 outbreaks 123:12 151:19 outcome 12:14
--	---	---	---	--

O

Oak 33:7
objectives 29:4
obligation 260:4
observation 77:12
observations
255:16
observed 278:10
obtain 213:4
obtained 78:6 115:5
214:17
obviously 97:17
101:3 115:11
121:20 122:6
135:21 150:1
156:21 182:1

68:13 72:4 77:21 199:15 259:19,20 outcomes 210:21 outdated 225:19 outgrow 170:7 outgrown 170:4 outlets 119:1 outline 98:14 outlined 36:8 outside 13:1 15:8 36:19 41:19 82:18 131:19 149:6 205:13 241:8 261:19 305:7,8 335:12 339:6 outweigh 248:8 overabundance 255:21 overall 50:14 75:4 167:9 241:20 overnight 133:8 154:19 315:1 overseas 55:13 190:20 191:9 overview 3:9 8:19 102:14 105:13 160:22 264:17 265:3 overwhelmed 101:22 over-subscribed 51:20 over-sulfated 187:12 over-the-counter 19:4 owners 162:12 O-U-N-T-F-O-R-D 248:16	246:17 247:2 248:19 249:1 298:16 315:13 packed 104:3 Padzur 52:3 page 105:20 344:4 pages 340:20 paid 192:6 pains 340:20 paint 105:18 palatability 164:12 panel 233:22 240:9 241:6,11 242:10 265:4,10 319:22 panels 266:2 panel's 241:5 paper 17:2 282:9 289:13 320:7 papers 180:8 paradigm 161:3 197:2 Paratyphi 126:22 parent 267:3 parentheses 284:13 parents 226:13 244:7 247:22 Parkinson 1:16 6:4 6:5 28:15,20 37:19 70:14 79:14 83:8 91:21 208:8 209:12 289:8,20 291:3 292:14 304:9 305:16 306:4 320:17 332:9,16,19 333:4 338:16 parsed 238:6 part 5:16 8:10 13:7 30:16 34:9 36:2 37:6 38:9 39:22 49:15 64:10 73:4 75:13,14 77:14,20 81:6 86:15 94:14 99:1,13 100:15 102:1,3 106:18 107:11 109:8,10 110:12 112:2,19 112:21 113:1	116:8 117:3 121:3 123:14 130:17 139:21 146:10 148:20 149:1 153:1,14 157:6,9 159:20 160:13 164:9 183:22 184:21 189:7,9 197:1 202:12 205:18 206:8 221:6,13 228:5 238:11 301:9 302:6 323:3 324:18 336:16 338:9 341:2 participants 1:22 9:2,3 10:1,6 participate 64:17 100:7 participating 9:8,20 9:21 13:12 219:22 particular 13:5 61:21 125:15 126:7 129:22 131:21 132:12 134:10 135:16 138:11 141:13 142:20 144:1 166:12 203:1 205:17 206:10 213:5 230:14 282:4 286:6 287:17 310:14 326:7 337:12 particularly 101:7 125:12 127:6,19 140:7 194:7 221:16 293:12 301:20 305:14 parties 253:4 parting 345:16 partner 43:1,2 partnership 157:8 partnerships 41:18 41:19 157:10 191:4 parts 191:17 314:7 314:9	party 228:17 path 20:11 22:19 24:7 26:15 79:18 83:13 pathogen 110:9 112:20 pathogenesis 6:3 pathogenic 77:20 125:10 pathogens 125:18 126:2 131:4,15 139:20 143:1 pathologist 176:11 pathologists 180:5 paths 36:7 pathway 20:2 24:2 63:6 178:16,18,19 pathways 14:1 patient 111:13 patients 81:7,18,19 114:20 115:1 293:12 333:3 pattern 134:2,3 158:3 patterns 111:7 136:9 137:14 267:4 paucity 276:12 payment 223:12 PBPK 277:8,14 PCR 138:11 141:20 158:6 peanut 113:9 114:4 pediatric 49:7 pediatricians 226:13 peer 17:21 135:20 175:22 225:5 228:10 237:22 262:21 263:9 289:13 peer-reviewed 170:13 pelts 173:22 Pena 6:20,20 8:5 261:14 281:12 337:18 339:15 342:7,19 343:11	penalized 193:16 penalties 196:4 199:5,5 penalty 197:10 199:3 Pennsauken 163:18 Pennsylvania 5:12 235:12 penultimate 98:2 people 4:10 13:15 14:18 24:3 26:11 38:3 47:18,20 48:4 49:14 57:18 60:21 75:4,5,15 82:5 87:11,15 98:10 108:16 112:10 122:4 130:14 144:5 151:13 157:2 163:1,3 166:5 168:15 171:14 176:8,14 179:15 192:4 199:1 208:13 209:1 211:11,18 261:15 273:11 296:10 313:7 314:20 341:6 peoples 59:13 pepper 109:3,14 120:8 127:11 peppers 91:2 112:16 119:7,10 119:12,22 120:10 perceive 23:9 percent 36:5 126:1 142:1 167:3 179:10,10 190:11 190:17 196:13 273:12 percentage 194:22 212:10 percentile 272:18 294:19 percentiles 294:16 perennial 216:5 perfect 300:14 313:11 perfectly 303:14
P				
pace 327:4 package 65:2 packaged 245:3 246:15 packaging 2:18 224:13 225:17 226:12 246:9,14				

326:3	PEÑA 2:6	phone 162:11	planning 93:22 94:4	163:20 182:7
performance	PFGE 136:9 139:12	221:21 262:8,15	97:1 122:16	188:5 209:19
144:14	142:15 144:17,18	303:14,17	plans 87:7	210:16,18 214:4
performed 300:20	PH 182:10	phones 10:21	plant 116:11 163:16	219:4 221:10
304:2	pharmaceutical	physicians 81:6	163:18	235:22 237:15
period 10:13 48:7	196:20 203:22	103:2	plants 156:14	270:2 272:16
98:4,22 99:5	280:18	physicists 35:11	plasma 182:6	275:6 282:12
162:21 163:5	pharmaceuticals	physiologically-b...	plastic 167:15 184:7	286:7,22 287:3
190:14 222:7	167:19 204:21	301:13	229:10 240:18,19	289:10,19 292:7
283:4 344:10	218:11	phytoestrogens	257:10	295:10,12,15
periodically 92:4	pharmacists 204:18	313:13	plastics 167:18	297:4 299:14
permanency 71:21	pharmacodynamic	Ph.D 1:10,12,13,15	257:21	300:16 301:18
permanently 55:8	307:4 308:8	1:16,19,19 2:3,4,5	plate 185:8 257:22	307:20 311:21
permissible 328:20	pharmacodynami...	2:6,7,8	platform 140:8	315:19 321:5
permission 11:4	307:22	pick 10:16 44:9	141:21	324:21 325:16
permitted 259:5	pharmacogenetic	67:11 76:6 80:1	plating 132:19	329:16 330:9,13
persistent 309:7	308:13	128:5 142:15	plausibility 278:9,9	331:9 336:5,13
person 4:17 14:5	pharmacokinetic	177:2	plausible 314:18	337:19
151:4 170:14	276:22 301:13	picking 180:5	play 13:9 67:15	pointed 65:20
311:10	pharmacokinetics	picture 105:19	68:18 106:18	127:16 206:4
personal 338:18	182:15	pictures 130:5	117:11	236:11 289:4,14
personalized 45:17	pharmacology 5:22	piece 118:3 131:21	played 187:15	302:7 308:12
45:18	7:11	143:13 213:21	plays 108:12	pointing 178:15
perspective 18:14	Pharmacy 5:10,11	pieces 96:20 135:12	please 27:6 218:2	307:7
34:4 68:18 79:21	PharmDs 60:20	pig 210:7	234:14 258:9,9	points 43:11 58:7,8
106:12 147:20	Pharm.D 1:17	pigs 169:10,18	283:16 297:2	89:8 133:19
149:18 153:21	PhDs 60:20	170:4,6	336:17 343:8	134:10 138:8
154:5 156:17,19	phenomenon	pilot 156:2	pleased 4:7 224:13	143:7 266:9 295:3
218:22 219:11	189:22 291:14	pilots 155:8	235:20 237:3,16	poisoned 176:16
295:15	Phil 281:8	pink 216:7	Plex 139:17	policies 240:1,4
perspectives 122:4	Philbert 1:16 4:18	pinker 215:22	PLLC 2:15	286:5
pertinent 146:7	4:18 9:11 54:4	pipette 177:11	plot 211:22	policy 2:4 6:17 7:2
251:7 275:18	221:12 232:11	pitched 272:7	plus 161:20 165:22	35:3 60:21 200:17
285:3	262:6,13,16 281:7	Pittsburgh 281:12	176:18 177:21	235:16 239:12
perturbations	288:14 289:17	place 11:10 25:5,9	podium 166:15	242:14 284:20,22
278:15	292:6 293:16	76:18 87:8 148:22	point 46:10,15 57:2	287:16 324:10,22
pet 126:5 161:8	294:16 296:9	188:3 205:17	59:5 62:2 68:6,7	326:20 329:15
162:6,9,12,12,13	297:1 300:13	214:2 276:7	77:9,18 78:1,15,19	336:7 338:8
162:14 163:14,17	306:11 308:10	placement 267:18	80:1 90:14,16 94:3	341:16
164:8 166:2 168:5	312:1 313:20	places 38:3,7,9	98:21 103:7	polite 39:6
168:6,9,21 169:6	314:18 324:7	112:13 114:9	108:19 112:21,22	political 242:4
172:22 174:2,3	329:4,10 330:16	127:17 282:9	113:4 116:15	polycarbonate
175:20 176:5	331:19 332:4	plan 34:10 47:2,7,8	117:21 123:21	221:3 225:3
178:22 179:14	Philbert's 222:14	52:2 70:21 71:4	124:22 126:8	229:10 273:2
180:8 185:6 187:6	Philly 12:16	89:1,18 94:5,8,14	128:19,20 129:4	275:19
194:21	philosophical 44:18	94:15 96:16,19	132:21 134:9	Polycarbonate/B...
pets 19:3 163:9	66:6 80:21	104:4 148:21	136:10 137:2	2:13 227:12,18
164:5	philosophy 83:13	191:17 321:2	145:19 148:19	polymer 167:17

polymerizes 179:3	341:13	259:15	president 191:12	43:4,5,7 87:1
polymorphism 140:21	possibly 181:19	pregnant 237:8,10	199:13 235:4	193:3
poor 178:13	post 291:10	293:1,13	243:11	principles 42:17
popped 102:11	post-market 20:20	premiums 192:6	presidents 85:2	prior 278:5
population 246:11	potential 9:5 84:8	prenatal 237:14	presiding 1:10	priorities 41:20
257:5 291:9,10	89:11 103:14	preparation 132:7,7	press 114:1 163:6	44:5,10,15,19 45:4
293:3,3,9,11 310:5	149:16 207:5	133:1,20 296:13	194:9 195:10	46:5,7,11 47:1,4
populations 97:21	214:4 219:6 228:7	preparatory 221:7	196:19 199:17	51:4,7 58:4 72:22
142:9 276:14	231:16 244:8	prepare 186:19	204:16 247:19	75:18 99:22 100:4
291:5 293:20	245:4 248:8 255:7	296:11	pressure 278:18	prioritization 71:4
333:6	256:11 257:19	prepared 128:7	pressures 27:18	71:11
porcine 204:3,6	267:18 272:16	180:1 184:9	presumable 197:5	prioritize 95:7
portal 302:1	284:18 291:8	220:17 273:1,3	Presumably 86:20	priority 41:20 46:20
portend 271:8	293:20 294:20	292:1	presume 196:8	73:18,19 232:6
portfolio 13:3 21:3	297:21 327:18	preponderance	presumptive 134:6	private 55:3 68:1
25:21 26:10 31:20	333:6	19:17 60:14	pretty 58:13 74:2	70:2 242:5 253:11
76:14 97:8	potentially 81:13	prescribed 214:21	152:10 165:11	probably 65:10,16
pose 204:21 226:19	100:16 164:21	prescription 19:4	prevent 24:9 116:20	90:9 95:14 96:12
246:9	212:6 233:9 284:9	213:1 214:11,15	117:3 148:21	104:12 126:7,21
posed 194:13	291:5 325:17	presence 313:13	156:14 192:22	161:6 209:4
200:13	pound 170:14	present 1:11,18 9:4	214:2	212:21 309:20
poses 188:4 190:22	pounds 170:15	9:14 54:15 89:5	preventable 148:1	314:6,16 316:16
203:8	powdered 189:10	108:21 127:21	preventative 117:8	317:13 345:8
position 22:14,20	power 219:15	128:1 129:8 142:6	149:1,3,20 157:11	probes 126:9,10,12
22:20 25:2 235:11	powerfully 291:7	142:13,13,17	prevention 148:20	problem 54:16 58:1
252:4,5 254:17	practical 49:16	148:7 186:15	preventive 5:18	61:10 68:14 70:4
259:14 318:10	80:22	213:19 246:6	previous 10:8 15:16	73:18 91:15 108:8
positions 27:16	practicality 144:13	266:12	22:19 24:19 92:14	113:3 116:4
positive 119:12	practice 5:10 35:4	presentation 39:21	92:15 339:21	121:11 138:3
120:8 134:6	134:20 168:21	47:9 60:2,6 76:3	previously 13:17	142:14 148:4
138:20 158:7	174:6 265:1	85:15 104:6,6	293:2	160:2 164:14
164:22 289:5	practiced 198:21	147:19 148:17	pre-emptive 43:10	165:5,15 171:8,13
positives 121:13	preceptor 61:8,9	160:18 185:20	pre-enrichment	172:11 175:11
possibilities 335:17	preceptor-based	190:6 222:15	132:17	186:6,7 188:4,8,19
possibility 11:6	61:4	223:3 232:11	price 174:10 195:11	189:17 197:2
90:21 156:9	precious 267:17	262:6 264:5 269:3	196:6 201:17	202:9 203:9 214:4
296:14 323:22	precipitates 182:7	281:21 307:9	priced 196:21	216:5 270:20
324:2,6 335:14,19	precipitating 182:3	presentations	primarily 37:1	306:12 314:5
337:22	precisely 271:19	145:10 152:12	125:22	326:1,2
possible 25:9 98:4	precision 19:13	156:7 203:14,17	primary 19:10	problematic 272:8
129:6 202:5 212:8	preclude 223:21	344:16	78:21 243:21	problems 44:16
212:13 234:16	predicated 210:1	presented 55:19	primate 277:19	53:1 61:6,7 62:1
247:7,13 251:1	predict 45:12 62:19	261:11 282:6	primates 277:9,12	62:19 70:9 74:5
257:3,4 281:17	predictably 70:8	289:14 307:21	278:3	75:16 101:22
283:1 304:13	predominantly	presenter 222:16	prime 303:7	115:19,22 129:1
318:15 323:10	190:4 243:17	presenting 90:9	primitive 82:21	138:6 148:3,6,22
	preempt 155:4	91:6 103:16	Principal 2:10	149:6 157:22
	preferred 131:17	presents 217:10	principle 6:11 18:2	159:1 161:22

167:20 171:10 179:13 288:12 procedure 19:4 proceed 27:5 process 22:2 23:13 33:22 36:4 44:1,2 46:3 48:9 51:6 52:6 53:3 61:4 63:19,22 64:7,9 67:9 71:15 72:3,4 72:16 74:6,12 75:3 75:4 78:9 93:13 94:4 98:16 110:10 114:15 117:16 128:10,13,20 131:1 132:1 134:11 136:6 138:8 139:13 143:4 158:14 160:12 182:9 191:7 222:20 244:18 245:4,7,11 245:16 246:1 249:6 252:20,21 263:6 269:18 323:4 325:16 329:5 336:7 340:13 processes 27:1 64:20 69:8 76:22 87:21 132:16 264:8,17 279:13 306:17 processing 116:17 132:11 134:1 156:14 209:22 Proctor 176:20 produce 109:21 114:16 122:3,5 130:3 131:16,21 135:13 141:5 145:4 149:21 150:13 158:1 207:2 229:20 244:13 produced 135:22 173:4 178:13 206:6 263:10	producers 169:16 224:9 226:9 producing 137:4 143:9 264:18 product 10:10 23:15,16 31:12 45:14 64:4 66:1 68:11 71:15 74:7 77:15 81:16,17 83:7 97:19,19 109:19,20 110:5 111:17 113:5,11 113:12 114:2,7,20 115:12 116:2,18 118:11 121:17 130:19,21 132:14 135:5 140:19 141:19,21,22 143:20 165:17 168:18 195:1 198:19 201:14 205:3,5 206:6,16 206:19 209:22 215:2 216:22,22 217:4 246:18 280:20 297:14 326:7 337:7 production 23:17 55:14 57:19 63:17 63:19 191:7 194:8 196:13 205:4 264:10 products 3:9 8:21 14:12,17 20:5,7 24:8 30:16 31:5 32:7 41:1 45:13,16 57:20 63:12 68:4 68:17 69:9,21 70:11 78:5 82:7,15 83:5 85:18 97:9,12 97:14,22 105:14 122:1 123:10 133:3 141:20 142:2 160:7,9 161:1 162:18 163:22 166:14,16 166:21 170:9 173:1,10,16,17	174:14 182:17 183:12,14 186:10 187:2 190:2,9,18 191:9,18 192:17 193:22 200:1 201:4 205:12,22 206:2,9,14,17 207:2,4 211:17 212:4,6 213:1,3 223:10 233:8 240:13 243:15 244:14 249:17 298:6 309:14 314:10 344:19 profession 218:21 professional 103:1 professor 4:19 5:21 9:11 profit 150:21 profitable 206:5,17 profiting 69:15 profound 15:11 67:1,13 72:8 242:16 program 34:22 35:2 35:4,20 48:5 49:12 52:2 103:3 142:3 144:11 184:1 250:8 264:20 301:1 308:21 309:21 310:1,3,8 programs 159:7 239:12 240:3 327:10 progress 14:12 25:22 26:4,6 37:10 43:15 45:2 87:22 100:11 project 2:17 48:11 96:9 145:2 239:5 239:13 projects 30:8 44:13 44:19 46:9,11,14 46:18 47:3 48:18 49:9 73:16 proliferate 217:18 prominent 288:15 promise 18:19	promising 159:17 promote 14:18 18:20 28:3 78:22 promoting 25:14 promptly 220:4 232:1 proof 260:8,13 properly 107:3 134:21 proportion 297:20 propose 336:21 proposed 65:3 75:10 250:19 260:1 313:15 333:15 proposing 146:22 proscribing 189:1 prosecution 211:14 prospectively 53:19 prostate 271:21 protect 14:18 18:20 28:3 64:21 78:22 108:9 226:15 228:2 256:10 protected 249:6 protecting 25:14 57:18 58:10 121:4 157:9 protection 121:21 148:21 191:1 290:3,4 protein 165:18,19 166:1,21 167:1,2,3 167:4,9,11 174:9 174:15 183:21 184:19 187:3,7 192:7 194:22 195:1 201:7 proteins 184:20,20 184:21 protocol 134:19 protocols 136:11 prove 194:16 provide 19:9 21:12 98:14 144:14 224:11 227:16 245:17 263:3 292:8 305:22	311:18 312:13 327:3,8 provided 150:3 225:12 228:17 240:2,15 263:22 264:16 265:11 313:2 provides 121:21 122:1 229:14 230:7 270:1,10 284:14 providing 19:11 66:17 101:9 244:9 254:14 281:15 proviso 329:21 proximate 31:5 pro-active 208:9 209:5 256:17 pro-bono 100:7 public 2:12 3:14 8:6 8:11 10:12,20 17:5 17:7,9 25:11,14 32:13,19 58:10 60:22 64:21 70:8 78:22 81:5 101:10 101:17 103:1 108:9 109:18 114:2 116:5,19 118:4 121:3,4,19 136:19 140:1,2 144:4,10 150:9 152:22 153:5 155:17 157:1 170:18 172:10 204:21 210:22 215:6 217:11,13 220:4,12 222:1,19 222:22 223:5 232:4 233:1 234:3 234:5,15 238:7,16 239:22 242:7,14 252:13,18 253:3 254:11,15 256:12 256:18 264:2,12 265:9 321:11 322:6,11,12 323:2 323:3 325:7,11 327:15 328:3
---	---	--	---	--

336:2,10,15 341:6 341:9 342:2 343:3 publicly 225:9 228:9 public's 321:11 publish 242:7 published 17:3 21:21 170:12 175:4,22 225:5 228:9 245:17 251:10 269:9 288:19 315:4 publisher 254:3 pull 65:3 74:19 145:16 293:17 326:11 pulling 327:1 pulsed 110:20 112:5 124:14 134:1,7,18 135:10 153:8 PulseNet 111:3 112:5 136:8 purchase 114:12 purchased 167:1 174:15 pure 208:19 purely 156:21 157:1 purpose 24:20 151:8 189:12 301:5,7 303:1 334:5 339:1 purposes 168:2 183:18 245:20 252:1 279:6 282:11 304:3 pursue 311:16 pursued 312:7 purview 31:10 push 108:18 put 19:1 25:5 54:22 67:12 68:11 117:7 117:9 127:18 147:19 151:5 168:7 170:12 173:10 193:6 204:13 218:14 238:12 244:7 283:22 301:15	316:5,9 318:21 341:15 putative 91:1 puts 74:17 131:21 putting 101:2 156:2 168:13 207:12 Pyrosequencing 140:22 P-R-O-C-E-E-D-... 4:1 p.m 10:13 220:10 220:11 346:4 <hr/> Q <hr/> qualify 194:12 qualitative 230:5 270:10 284:12 quality 20:10 40:19 63:15,16 137:5 164:10 169:2 178:12 189:6 197:17 201:21 205:21 224:14 229:16 231:2 244:14 246:19 247:7 251:21 271:18 280:10 quantification 273:16,20 quantitative 230:6 270:9,18 284:12 290:12,17 quantities 137:9 207:6 quantity 193:22 213:10 quarterly 49:20 50:21 quarters 104:3,17 quartiles 268:8 quest 27:22,22 28:2 question 26:18 28:15 38:20 44:4 60:7 61:19 66:10 70:14 71:12 72:3 75:10 76:1,7,16,20 81:10 85:11 92:5 96:8 97:12 98:3	101:1 120:11 148:16 150:12 151:14 155:2 156:7 157:8 165:8 169:7 193:4 201:10 204:15 209:15 210:12 211:2 212:2 215:10 217:22 225:16 237:19 251:3 257:21 259:4,8,11 278:14 279:4 283:4,22 288:10 289:15 291:4 296:2,19 302:17 304:9 305:19 306:21 312:17,18 313:7 314:8 326:4 328:12 questionable 257:18 questioned 24:20 questions 9:16 24:15 26:8 28:6,10 28:12,19 30:7 31:5 31:11,16 38:22 39:3,10 40:13 60:3 65:9 72:9 75:13 81:10 98:1 104:9 104:10,11 122:18 145:13 147:13,15 159:1 203:13,18 215:19 222:8,11 227:9 231:20 232:8 234:18 239:3 242:18 246:21 248:13 254:19 258:4 259:3 261:9 278:7 282:3 283:13,18 285:15 288:6 295:22 303:3 310:14 312:6 316:3,7 question-driven 277:22 quick 113:15	145:16 202:20 217:22,22 218:1,1 247:2 288:9 296:2 342:7 quicker 115:2 116:7 quickly 109:5,21 110:3 115:22 163:22 164:3 168:14 169:14 247:13 250:22 quiet 252:19 quietly 95:20 quintiles 268:8 quite 59:2 63:3 197:20 216:18 285:20 287:14 302:21 304:6 315:21 317:17 quo 336:14 quote 188:16 284:18 quoted 193:4 quote-unquote 286:11 <hr/> R <hr/> R 1:16 Rachel 220:22 racoon 174:1 racoons 173:21 174:1 radar 166:9 radiation 148:12 149:9 radical 14:10 26:12 Radiological 7:19 radiologist 6:18 rails 20:1 rain 130:12 raise 95:19 150:16 173:22 204:15 291:22 303:2 334:9 raised 18:1 24:15 41:7 225:11 246:22 250:16 285:12 305:10 312:6	raises 103:13 278:6 ramp 35:18 RANDALL 2:4 Randy 7:1 174:12 184:1 203:12 219:1 327:21 Randy's 207:15 214:4 Rangan 2:19 253:20 253:22 254:1 258:4 range 49:9 236:12 236:12 239:22 255:7 257:3,4 258:2 267:19 272:6 273:6 Rankin 243:1 rapid 3:10 14:10 26:11 45:9 50:19 53:9,14 54:13 58:18 65:11 71:22 90:3,22 96:12 105:15 106:13,19 107:10 108:6 109:10 114:18 116:5 118:2 120:22 121:7 122:11 126:10 146:11,15 149:8 183:10 186:1 203:2 344:17,18 rapidly 66:5 116:15 120:17 170:3 212:13 rascals 219:18 rat 277:19 rate 56:1 190:10,15 rated 250:14 rates 182:16 ratio 179:8 195:17 raw 251:5 253:14 289:11 290:7 Rawlins 221:1 reach 75:15,19 113:1 reached 205:19 209:19 reaches 108:19
---	---	--	--	---

230:2	103:9 123:1 124:7	receive 162:20	205:4 226:3,12	67:7 78:22
reaction 122:8	125:16,20 127:21	248:1 339:20	227:5 277:17	regulations 17:9
148:5,10 177:12	128:15,22 131:2,7	received 11:4 162:5	330:3	19:9 57:7 124:4
198:1 321:3	135:3,6 137:11,15	162:22 165:6	reexamine 250:20	244:19 260:7,8,13
reactions 308:16	143:15,16,20	222:3	refer 135:14 290:14	336:22
reactive 43:10	148:15 152:12	receives 339:16	referred 232:9	regulators 29:2
149:7	153:9,11 156:3	receiving 227:21	274:3	49:15 79:20 80:7
read 8:4 42:15 91:2	158:2 168:14	232:2	refined 61:7 142:21	regulatory 2:5 7:6,7
96:3 136:4 222:18	171:20 174:21	receptor 313:18	reflect 34:19 41:6	14:16 15:2,13 16:6
266:11 284:3,4,6,9	180:7 185:7,21	recognition 303:2	51:3 160:5	17:6,16 18:5 19:17
288:3 289:8	186:2,7,22 194:1,4	recognize 78:14	reflected 38:13	20:10 22:14 23:6
306:21 336:9	196:1,1 197:17	128:19 299:16	332:20 333:8	25:21 26:9,17 27:4
340:20	201:17 203:2,8	recognized 14:3	reflecting 20:19	27:9 29:19 30:7,10
readily 180:6	207:13 208:6,12	202:10 313:3	reflection 37:20	31:1 33:17,22 35:2
257:11	216:17 217:9,13	327:17	38:20	35:3,3,4 36:14,15
reading 300:3	217:19 236:3,7,10	recollection 315:3	reflects 311:11	40:18,19,20,21
341:19	236:15 272:9	recommend 258:20	refrain 9:16	44:6,16 45:20 48:9
reads 254:18	292:6,21 294:13	280:6 313:12	refuted 16:21	48:20 50:3,6 51:12
ready 58:18 81:17	294:14 303:4	322:22 333:18	regard 37:15 41:13	51:13 53:2 57:17
81:19 134:14	304:16 307:9	338:15	42:19 63:4 68:22	59:13,15 64:20
175:2 247:12	308:4 311:15	recommendation	70:9 77:10 151:22	69:5,8,13 74:16
read-outs 80:6	312:21 315:8	70:20 249:22	234:2 275:17	76:22 77:4,14 78:4
Reagan-Udall	317:18 320:10	321:19,20 322:20	296:19 302:17	93:1 94:21 145:21
35:15	321:6 322:13	325:13 328:14,19	317:10 341:14	146:1,1 152:13
real 32:15 59:14	325:9 337:14	328:22 337:20	344:5	153:22 154:6
61:6 88:2 103:12	338:9 341:8	338:12	regarding 26:8	157:16 158:18
123:19 127:10	realm 305:8 338:8	recommendations	224:12 236:22	159:6 168:2
132:5 142:14	real-time 123:19	70:22 85:3 123:2	245:11 290:1	187:18 191:4
145:2 150:22	134:10 138:11	225:9 229:15,19	294:20 305:19	200:10 216:11
158:6 195:1	reason 161:22	230:16 232:3	regardless 48:10,11	228:11 238:10
208:11 296:6	166:16 168:22	252:17 304:22	regards 205:12	240:17 244:17,22
343:18	169:13 204:15	322:1 324:17	regenerative 49:2	245:16 246:1,2,6
realities 36:17	223:4 226:8	326:20 338:22	regimes 200:10	252:1,7 279:6
reality 14:8,20	288:15 320:18	recommended	269:15	301:4,7 303:1,7
67:19 70:12	reasonable 91:19	248:4 337:20	region 201:15	304:2 327:6 336:7
208:21	98:4 268:11 279:7	recommending	regional 60:15	reinforce 27:8
realization 286:17	295:12 297:8	335:11,13 337:21	regions 50:5	93:15
realize 29:5 148:1	298:11 302:21	record 8:11 10:5	Register 11:8	reinforced 94:10
realized 208:17	reasons 13:5 62:12	220:10 248:14	regular 184:21	reiterate 64:15
realizing 66:5	76:5 293:8 300:21	332:18	regulate 20:6 23:15	260:7
really 12:10,17	reassure 238:15	recovers 133:7,10	66:20 183:13	reject 318:20
29:11,16 30:5 34:7	recall 58:4 92:1	recovery 133:11,18	regulated 184:6	rejected 250:2,6
35:5 48:5 64:17	113:15 119:21	recruit 34:12 47:19	200:1 204:12	269:5
65:6 67:17 70:2,5	166:3 315:9	89:20	247:16 297:18	relate 49:3 52:8
72:11 76:9,20 83:9	343:19	recruitment 42:7	regulates 162:19,22	70:21 76:8 293:5
83:12 84:20 85:20	recalling 162:8	recurrence 116:21	regulation 19:8	related 9:17 74:13
88:10,17 89:18	recalls 114:13	117:3	20:7 22:21 32:8	85:4 103:5 118:5
99:12 102:10	173:11	reduce 148:12	33:21 38:8 49:2	138:1 183:12

251:5 263:17 304:15 333:2 relates 40:18 46:1 55:11 58:3 62:14 69:20 70:16,19 97:14 105:5 155:8 218:9 219:2 relation 251:16 relationship 42:10 223:8 224:8 286:14 295:8 312:8 relationships 223:18,19 relative 267:1 305:3 310:22 relatively 96:13 180:19 200:9 206:18 207:2 290:10 relax 150:7 release 114:1 164:7 164:7 247:19,20 released 238:6 278:4 280:21 relevant 10:9 228:22 230:21 249:12 291:18 reliably 168:1 relies 268:5 270:16 rely 191:1 229:9 remain 232:5 244:1 260:15 remains 247:16 248:4 remarkable 46:19 84:22 remarks 39:12 84:3 88:6 99:19 239:2 338:17,18 remedied 189:18 311:4 remedy 202:13 remember 53:7 111:17 159:4 171:6 206:15 285:13 296:5 remind 10:14 11:3	313:1 324:8 remiss 148:18 192:19 202:3 remit 324:12 removed 168:19 renal 164:16,18 179:17 180:17 181:8 182:20 repackage 226:10 repair 22:7 repeat 140:17 260:7 289:4 323:5 329:20 331:2 repeated 135:1 repeating 299:4 replenish 36:21 replenishment 36:10 replicate 251:13 report 3:3,15 9:12 9:15 12:6 41:3,9 41:16 42:16 52:12 52:17 96:4,5,11 99:14 128:9,16,17 147:10 208:13,19 220:17 224:15 227:17 228:18 229:14 230:2,12 231:14 235:19 236:6,16 237:19 238:5 240:21 241:6,6 242:4 243:19 246:4 252:16 254:7,12 254:15 255:2 256:3 257:6 258:19 259:1,7,9 259:10 261:21 265:12,16,21,21 265:22 266:7 268:3 269:12 274:14,14 275:2 281:21 282:13,22 284:8 285:2 286:10 288:2,12 289:6,9 293:4 294:8 296:3,20,21 299:19 301:9	306:3 317:7,14 318:11,12,20 320:22 323:7 324:15,18 329:8 330:5,18,19 331:6 331:22 332:1,3,5,6 335:9,12 338:5 340:4 344:8 reported 9:2 179:11 251:16 REPORTER 260:21 reporting 215:11 216:1 289:2 344:9 reports 2:19 204:16 215:13 240:2 241:20 251:10,15 253:21 254:3 represent 125:7 126:1 217:13 227:18 238:14 representative 5:9 9:9 155:19 236:3,7 representatives 85:2 represented 127:6 representing 7:6 157:3 286:1,4,4 represents 124:20 265:21 273:19 reproducible 136:18 144:3 Reproduction 250:10 reproductive 2:16 226:20 239:5,13 239:17 241:19 274:20 reptiles 126:5 repudiates 22:19 request 10:19 290:7 329:5 333:9 requested 251:10 253:10 requesting 323:19 requests 143:8 require 20:14,17,17 58:16 123:21	271:13 283:5 required 251:4,15 281:16 requirement 15:12 requirements 101:8 158:17 251:22 288:20 289:3 requires 16:17 19:22 27:22 79:3 124:16 rescue 168:3 research 2:7,10,15 4:20 6:2,2 7:10 8:1 16:7 17:12,12 20:13 21:5 25:20 26:16 27:8 29:1,5 29:19,22 30:5,8,8 30:13 31:3,6,11,16 32:21 33:2 34:13 81:3,14 92:21 141:22 145:2 228:6,9,13 230:22 231:15,19,22 235:1,5,8,9 246:18 250:19 251:3,17 276:15 295:2 301:1 302:11 315:20 319:14 327:7 residues 49:1 resins 167:15 229:11 resistance 84:19 149:18 278:13,15 resolution 124:16 136:2 144:19 resolve 18:3 26:20 234:15 resolving 318:7 resource 26:2 30:3 30:21 71:10 resources 2:19 25:18 93:9 217:11 221:2 242:20 respect 8:10 10:6 191:21 195:4 197:13 202:22 266:21 267:11	294:11 345:19 respected 228:14 respond 308:7 320:21 responded 185:18 responding 341:18 response 41:12 70:21 84:9 117:5 148:17 149:7 154:13,17 166:7 185:22 203:2 238:5 257:7 268:22 278:19 308:1 responsibilities 190:1 responsibility 79:20 83:12 151:15,16 responsible 188:14 256:12 341:4 responsibly 257:14 responsive 281:4 341:3,9,10 responsiveness 281:14 rest 32:17 43:8 234:3 282:2 287:18 restaurant 112:11 restrict 255:20 restricted 245:2 246:15 rests 284:20 287:13 287:19 result 136:14,22 151:12 173:13 232:22 289:6 resulting 277:14 results 9:14 17:14 231:21 253:1 266:13 300:8 resumed 220:11 retail 114:11 118:13 119:1 retailer 115:7 retain 34:11 36:5 retention 42:7 retreat 99:21
---	--	--	--	---

retrospectively 196:17	85:11 103:18 155:11 157:5 218:1	213:15,19 215:6 217:11,14 224:12 225:14 245:8 246:10,14 250:9 254:8 263:4,4 267:14 270:18 274:4 276:7,18,20 277:2 280:4,11,19 322:9 333:6 342:9 342:9,10	253:18 round 73:9 75:17 route 267:16 269:15 routes 267:18 272:4 277:2 306:1 routine 107:19 123:15 124:6 routinely 158:21 166:10 213:4 290:5 rugged 144:3 156:8 rules 340:3 rumors 209:2 run 111:4 128:12,18 135:12 136:3 137:1 169:1 running 87:10 134:7 153:10 204:2 322:9 runs 151:5 rushed 237:20	260:5,15 268:19 268:22 270:12 280:11,19 284:16 285:8 286:8 304:15,21 305:4 326:9,9 safe-guarding 185:3 Saintpaul 107:9 108:13 117:14,20 120:18 124:9 127:1,8 142:12 153:4,6 Salem 7:5,5 sales 194:7 salmon 215:16,20 216:6 salmonella 3:10 91:1 100:14 104:4 104:7,9,13 105:15 105:18 107:7,9 108:2,13,21 109:2 109:5 110:13,17 113:8 115:3 117:13,20 118:15 120:3,18 123:5 124:3,5,7,10 125:3 125:9,16,21 126:4 126:6,10,13 127:10,11,14 133:15 134:6,15 138:5,15,17,20 139:7 140:8 142:10,12,12 143:3 153:4,6 158:10,13,14 160:18 163:21 salmonellosis 111:19 sample 107:20 108:21 109:4 110:8 116:22 119:12 127:20 130:20 131:10 132:6,7,9,11,22 133:19,22 137:21 137:22 142:14,17 142:18 145:3
return 195:5,10,15 195:22 returns 196:10 reversible 274:18 274:19 review 8:13 17:21 47:8 52:13 63:22 74:10 92:6 95:1,5 95:16 97:1 100:5 100:15 176:1 201:19 228:10,21 239:9 242:4,8 244:18 245:15 249:6,11,22 251:4 252:3 259:20 262:21 263:3,9 264:1,7 280:21 288:8 289:13 324:10 327:9 344:21 reviewed 92:4 225:5 237:22 275:12 reviewers 289:9 320:20 reviewing 92:3 221:12,14 324:14 reviews 29:7 92:15 92:15 94:11 249:17 250:6,10 revised 287:2 revisions 285:1 revisited 275:4 revitalization 95:4 revitalizing 100:1 revolution 13:21 reward 193:13,19 re-do 258:20 re-invent 279:22 re-position 31:19 re-present 317:20 re-sample 135:5 re-sold 204:18 Re-state 261:1 re-wrote 262:15 RFP 84:16 Rhona 1:13 9:18	RHTP 239:13,21 240:5,15,20 ribbons 86:20 ribotyping 140:16 Rica 87:2 rice 165:18,19 166:1 Rick 52:3 right 6:8 8:2 38:11 39:10 50:12 55:4,5 67:2 74:17 80:19 85:19 88:14 90:11 90:18,19 98:17 101:18 104:2,21 108:3 110:19 120:19 124:13 126:9 133:21 140:15 141:3,16 142:16,16 146:7 149:15 154:3 209:13 212:18 226:21 228:2 232:8 256:11 261:12 262:3 288:7 292:21 314:15 316:16 318:2 331:1 332:14 334:7 335:5,8,20 336:3,3 336:18 rightly 287:14 rigor 19:12 33:19 78:11 rigorous 289:2 rinse 133:5 rinsed 132:12 rinsing 133:17 rises 75:2 risk 49:5 103:11,14 103:17,20,21 122:9 149:5 169:12,14 170:8 170:11,18 175:10 175:16,21 181:2 183:1 206:5,21	risks 68:5 96:9 103:16 204:20 205:12 206:1,2 207:7 238:20 244:8 248:8 271:9 290:3 risk-based 58:14 rob 193:5 198:8 robbed 197:7 Robert 2:15 232:17 233:2 243:1 robust 19:17 249:11 276:22 277:10 278:16 280:2 333:5 robustness 146:4 rock 23:4 Rockette 281:12 rodent 181:4 278:10 279:2 rodents 165:14 Rogers 2:16 239:4,7 239:11 role 13:8 23:11 30:3 100:16 101:1,15 101:16 105:17 106:11 113:2 121:2 187:16 229:18 240:17 245:10 288:5 rolling 343:11 Roma 130:5,7 Ronald 232:14 room 12:9 15:10 192:5 340:7 rooted 255:22 Rost 2:18 97:5 248:18,20,21,22	Sa Saal 265:2 safe 121:17 229:11 238:9,16 240:21 247:8,17 254:18 256:19 259:4 260:2,11 297:8 326:3 346:1 safely 169:22 170:10 safer 226:12 safest 239:18 safety 2:6,8 7:17 24:15 45:12 93:4 105:22 190:2 191:17 224:17,22 225:6,16,21 228:3 228:19 229:5 230:9 231:2 236:22 238:3 240:11 241:12 244:11 245:11,20 246:19 247:4 249:11 250:7 252:8 255:9,10,13 256:5,16 259:12	
S				

236:10 272:19,21 294:13,22 311:10 samples 107:14,15 107:16,18 108:17 115:5,17 116:11 118:16 120:9,13 121:8 123:20 127:22,22 128:6,7 128:13 138:15,20 139:14 140:5 145:1,4 146:14 149:5 225:20 235:21 236:2,5,8 268:2,7 273:6 311:14 315:10,15 sampling 117:16 118:14 127:15 130:20 144:22 San 6:9 Sangtae 52:7 99:18 Sarah 242:19 Sasich 1:17 5:8,8 9:8 92:14 93:17 101:6 203:16 214:20 283:17 285:18 288:9 299:18 308:19 321:10 323:21 324:3,20 325:4 336:4 337:13 338:14,20 sat 205:22 satellite 87:2 saved 274:4 savings 193:20 saw 65:15 178:3 179:18 190:5 295:14 334:20 saying 44:12 57:14 111:14 115:8 117:5 150:20 165:10 200:4 236:18 305:20 308:20 320:12 says 68:10 81:2,4 124:4 127:9 158:13 165:12 212:9 286:7 327:3	333:13 scale 192:16 301:16 scenarios 97:16 schedule 86:21 88:11 222:5,13 scheduled 10:13 school 5:11 6:1,17 88:22 89:2 190:13 235:14 Schultz 7:18,18 31:8 80:20 299:12 science 1:3 2:5 3:5,7 3:15,18 4:5 6:15 6:22 8:6,12,15,17 8:18 9:13 11:3,9 13:4,9,21 14:8,9 15:1,4 16:6,13,16 16:18 18:6,7,18 19:8,11 20:3,9,12 20:13 22:11,12,18 23:5,8,18,22 24:21 25:21 26:1,9,12,14 26:18 30:7,14,20 31:2,22 32:2 33:9 34:12,14 35:2 36:14 38:15 39:20 40:1,5,17,19 41:3 41:7,8,11,16,20 42:10,15 44:5 45:21 47:5,18 48:8 48:12 49:21 50:8 51:12,16,17,18 52:9,10,11,19,19 53:2,8,14,19 54:2 54:9,22 55:11 56:1 57:17 58:6,11,20 59:2,4,8,12,14,15 59:16,18 62:22 63:10,22 64:4,11 65:12,18 66:5,14 67:3,6 68:20 70:5 70:22 71:7,18,22 72:7,7,12 73:8 74:16,17 75:6 76:13,14,16,17,18 77:2,6,11 79:7 81:1 88:13 90:17 92:9 95:5,11,13	96:17,21 97:2 99:2 100:5,17 101:13 101:14 102:3,4,14 103:15 105:3,7,10 123:15 144:5 157:4 160:6 185:10 190:6 200:17 207:19 208:6 220:6,18 222:8,11,15 225:12 227:3,21 234:20 237:17 239:8 240:16 241:10 242:2,10 243:20 244:4 245:21 249:3,5,9 252:3 261:10,21 262:12,17,18 263:8,12 280:22 281:8 282:4,15,21 283:8,12,14 288:8 292:8 299:11 300:17 316:3 318:2 320:6 322:1 323:9 324:9,10,14 324:16,22 325:9 326:19,21 327:2,6 327:8 329:7,22 330:18 331:10 339:17,18 340:13 340:19 342:13,16 342:20 343:1,2,6 343:16 science-based 15:13 16:8,15 17:10 18:6 23:3 34:8 62:21 68:21 76:4 244:12 science-led 15:3,5 15:14 16:9,12 17:1 18:6 19:21 20:2 34:9 76:4 scientific 16:5,7 17:19,21 18:1 20:22 21:13,20 22:2,9 23:2,11 25:11,16 31:19 32:5,12 33:7 35:7 41:17,17 42:7,11	43:6,9,19 46:5 47:4,8 55:20 58:16 62:16 66:14 70:16 70:19 72:9 75:2,13 78:11 105:6 149:17 158:19 160:3 186:2 203:3 225:5 228:15 229:1,4 230:8,14 230:21 231:4,19 235:8 240:2,9 241:4 242:8,13 244:18 245:7,18 246:18 249:5 254:7,11,16,20 255:4 256:2 260:10 262:21 263:3,9,16 264:9 268:12 270:1,11 279:8,11 284:15 301:1 313:4 322:8 327:5 329:13 336:11 scientifically 63:18 98:6 101:9 229:21 scientist 2:11 6:12 29:16 37:13 42:1 43:18 50:18 224:5 254:2 scientists 21:9,22 29:2 35:10,22 49:14 50:11,22 51:13 207:14 228:14 251:11 263:13 297:9 scope 172:3 266:7 scrape 41:22 scratch 284:7 scratched 83:3 scratching 165:10 screens 166:9 scribe 283:8 scrutinizes 235:7 scrutiny 20:14 21:12,16 228:16 se 103:17 203:7 263:4 seafood 216:5,13	seamless 87:17 152:4 search 79:10 seated 220:14 second 55:15 84:2 90:20 119:5 165:16 184:2 204:10 211:3 218:21 259:2 317:17 320:12,17 326:19 331:9 332:14,15 333:10 335:22 secondary 114:13 seconded 332:16,17 333:13 secretary 2:6 6:21 86:22 191:15 Secretary's 299:13 Secretary=s 211:6 section 99:15 160:16 286:7 311:9 sector 68:1 70:2 218:7 security 143:1 147:2 191:8 210:17 211:7,19 see 20:1,7,11 21:19 24:1 27:21 36:22 38:19 39:18 40:14 56:15,16 57:2 65:2 71:9 80:18 84:10 94:7 98:13 104:5 104:14 105:9 108:10 110:6 115:19 126:16 129:3 130:16 133:12 135:17 147:8 156:15 157:17 160:11 166:17 176:1 177:5,22 178:1,19 179:18 182:3 212:17 214:14 219:2,3,3,10,16 232:10 235:8 283:2 284:2,10
---	---	---	--	---

285:18 289:21 293:22 295:8 320:18 321:18 322:5 326:17 334:21 336:22 337:2 seeing 38:16 73:5 153:6 178:6 179:15 322:16 seek 54:18 162:2 201:4 278:8 seeking 25:2 seemingly 234:6 seen 150:18 190:22 221:6 318:12 SEER 268:22 select 268:13 selected 87:12,13 274:14 294:12 295:4 selection 61:4 275:6 275:8 286:15 selective 48:5 132:3 132:18,19 280:16 selfish 156:22 self-critical 28:2 self-feeding 51:6 Self-nomination 343:13 sell 150:19 170:6 selling 143:10 sell-by 169:2 send 332:11 343:7 sending 110:15 333:15 339:12 senior 85:1 224:5 254:2 sense 44:18 45:20 53:17,18 55:21 59:8 67:1 79:12 93:6 188:6 193:14 196:2,16 197:8 200:4 202:17 213:9 215:21 318:19 319:21 345:1,21 sensed 321:11 336:8 senses 212:20	sensitive 174:20 184:15 291:16 333:2 sensitivity 124:2 273:8 280:14 295:20 sent 52:16 110:8 169:21 171:14 253:7 323:14 sentence 287:15 326:18,19 sentences 4:16 199:6 303:20 separate 21:1 222:2 293:6 325:5 326:18 329:6,15 separately 228:17 306:9 September 55:18 171:5 264:1,11 265:16 278:5 sequence 141:6 sequencing 141:1 series 12:14 43:13 55:1 215:16 282:5 serious 226:19 245:14 258:21 seriously 224:21 244:12 Serological 134:12 serology 139:19 140:4 serotype 109:4 120:3 139:11 serotyping 134:9 serovar 139:3,7 141:6 143:3 serovars 126:21 134:16 142:13 158:12 serrano 119:7 120:9 serve 13:14 24:2 26:10 301:4 serves 18:6 194:11 254:16 service 303:17 session 9:20,22 54:12 219:21	220:4,15 262:5 set 24:2 179:22 201:15 226:1 279:8 290:16 294:13,22 307:20 sets 152:17 setting 40:9 88:22 109:12 112:14 291:18 307:4 settings 41:20 152:18 seven 170:2 severe 255:3 292:14 sexual 267:8 shadows 20:16 shaking 132:10 shame 24:18 25:3 Shanghai 86:13 shape 20:6 56:16 share 155:5 186:18 192:12 202:18 228:1 232:5 shared 79:19 83:12 228:10 shares 190:18 sharing 187:16 218:16 sharp 26:22 shed 21:14 276:11 shelf 114:11 shelf-life 109:20 shelves 68:12 168:19 shifted 113:20 shifts 201:13,15 shiga-producing 125:6 158:5 Shine 15:16 shining 20:15 ship 57:8 shipment 163:17 shipping 120:14 short 47:22 109:20 156:20 307:2 shortcomings 255:5 shorten 121:9 shortened 118:7 shortly 9:19 52:4	282:12 short-hand 192:15 shot 109:15 show 42:4,8 43:13 43:15 45:22 49:18 54:18 55:11 56:7 74:8 135:9 137:16 167:16 224:20 315:17 334:7 showed 40:16 317:11 341:8 showing 20:13 shown 241:2 260:10 282:12 shows 141:9 263:21 shut 108:7 121:22 shutting 116:3 sick 108:16 110:4 111:15 112:11 114:9 125:11,13 130:14 side 36:22 38:16 39:1 83:15 92:10 130:8,10 146:17 146:17 148:12 152:7 157:16 161:12 329:18 Sidebar 262:1 sign 258:6 signal 21:1 118:2 signals 20:16,21 48:20 signed 191:13 258:14 significance 13:6 significant 125:1 133:16 137:3 158:16 164:11 187:13 271:8 307:20 significantly 182:7 205:4 silent 10:21 silver 149:20 similar 137:5 230:12 233:13 Similarly 189:15 196:18 241:7	simple 15:4 79:6 300:4,11 simplest 63:8 simply 107:1 132:13 186:6 191:8 192:15 199:5 225:6 336:14 Singapore 69:4 single 14:2,5,6 19:3 27:12 28:4 81:15 97:13 140:21 142:15 181:9,12 250:16 271:11 single-point 295:6 sippy 233:5 234:11 275:19 sit 325:20 site 112:10 120:20 146:15 221:20 sites 56:11,13,15,18 56:22 57:1,13 63:19,20 64:1,2 sitting 36:22 114:10 128:14 165:10 319:12 340:6 situ 273:3 situation 107:13 113:17 123:5 161:18 170:22 171:2 172:12 211:21 238:14 situations 107:19 115:12 122:8 152:5 six 137:6 170:1 195:19,20 310:6 310:10 size 272:11,19 skills 160:1 slaughter 169:21 170:20 sleuthing 186:2 203:3 slide 41:3 57:4 127:18 129:4 185:15 slides 56:6 180:1 slight 60:14
---	---	---	---	---

slightly 76:1 131:20	solved 40:7 61:10 188:8,20 202:9	318:22	31:3,5,9 37:4 65:10 73:21 99:4 112:11 157:16 203:20 206:16,19 257:4 277:18 308:15 335:11	spray 217:2
Slikker 2:7 7:8,8 30:2 92:19 94:2 156:6	somebody 65:20 103:15 110:4 114:8 128:3 304:10 325:1	sounded 15:4	sounds 74:20 84:7 95:11	spring 50:10 51:11 86:3
slots 48:3 89:20	somebody's 114:12	sound-bite 15:6	source 36:9 58:1 62:1 113:7 116:9 117:17 204:3,7 214:22 236:21 248:2	squared 340:9
slow 131:1	somewhat 39:19 66:6	sources 62:19 123:13 212:12 213:6,18 237:2 253:15 297:17 304:17,19 305:3 306:2,8 318:2	specifically 51:22 54:2 58:3 155:3 194:2 263:17 265:5 266:20 292:11 299:8 333:2	stable 19:19
slurp 141:7	sons 36:11	sourcing 171:22	specificity 124:2,13	staff 8:7 37:14 92:9 92:10,16 95:15 186:3 316:2 318:10 320:20 344:22
small 48:3 236:10 263:19 268:1 272:19 282:22 288:17 297:20 325:18	soon 91:8 96:13 234:16 247:7 262:9	South 12:16 87:4	specifics 122:13 155:11	staffed 144:4 281:13
smaller 271:7 277:4 304:4 310:12	sooner 108:8,9,9	southern 315:22	spectrometry 141:20 168:4 174:20	staff's 221:13
smaller-scale 269:13	sophisticated 109:12 144:8	soy 184:20	spectrum 13:3 33:1 35:6 48:12 78:17	stage 40:9 111:18 308:5
smart 144:10	sorry 4:15 104:19 145:14,14 150:10 222:17 259:9 284:1 289:17,20 296:1 303:18 308:10 330:20 334:9	so-called 310:1	speaking 176:8	stages 108:15 121:1
smarter 43:2 82:10 82:16	sort 40:9 41:16,21 42:17,20 45:8 49:16 54:21 55:3,3 55:4 60:8 61:3,4 62:15 63:8 64:1 66:12 71:3 72:10 74:16,19 80:15,21 98:2 102:13,15 106:9 112:14 117:11 122:15 134:5 145:16 157:20 159:14 207:18,22 208:4 213:14,15 214:5 215:9 299:5,9 302:4 305:1 306:15 319:9,10 321:2	space 33:15 67:15 68:2,18	speech 18:11	stained 189:10
smearing 134:22	sorts 314:10	spans 124:20	speed 45:15 108:5 108:14,22 134:4 138:9 153:17 234:10	stakeholder 253:2
Smith 233:17	sought 313:5	spatter 130:8,9,12	speeding 41:1	stake-holders 151:6
smuggled 204:17 205:14	sound 91:18 228:20 229:21 230:13 244:17 245:8 246:1 249:5 270:18 271:2	speak 10:15 76:19 87:10 93:18 152:6 155:20 197:18 244:7 249:2 258:14 307:1 329:11	speaking 176:8	stand 247:11
snip 140:19		speaker 223:6 227:9	speaking 10:18 223:21 288:4 289:15 303:14 315:2	standard 14:16 78:4 110:21 245:6 259:19 298:7,11
snuff 345:10		speakers 51:1,3 160:19 261:10 285:12 293:1 322:6	speaking 10:18 223:21 288:4 289:15 303:14 315:2	standardization 152:16
soak 133:8		speaks 287:15	speaking 10:18 223:21 288:4 289:15 303:14 315:2	standards 68:17,20 68:21 69:19 247:7 251:18 298:9
soaking 133:16		spec 175:3	speaking 10:18 223:21 288:4 289:15 303:14 315:2	standpoint 52:19 141:8
societies 103:2		special 264:14,19	speaking 10:18 223:21 288:4 289:15 303:14 315:2	Stanford 221:5
software 31:15		species 125:22 126:7,14 181:4 182:15 269:9 277:10,15,17	speaking 10:18 223:21 288:4 289:15 303:14 315:2	start 4:14 8:3 30:12 42:21 44:7,7 46:6 68:16 88:9,15 106:2 110:4,14 183:22 192:20 220:4,14 262:4 316:11 322:11
soil 107:16 115:18		specific 16:2 30:9	speaking 10:18 223:21 288:4 289:15 303:14 315:2	standard 14:16 78:4 110:21 245:6 259:19 298:7,11
sold 168:22 187:7 190:2 193:22 216:22			speaking 10:18 223:21 288:4 289:15 303:14 315:2	standardization 152:16
solely 263:2			speaking 10:18 223:21 288:4 289:15 303:14 315:2	standards 68:17,20 68:21 69:19 247:7 251:18 298:9
solicit 13:1 200:16 209:7			speaking 10:18 223:21 288:4 289:15 303:14 315:2	standpoint 52:19 141:8
soliciting 200:22			speaking 10:18 223:21 288:4 289:15 303:14 315:2	standpoint 52:19 141:8
solid 19:15 23:4			speaking 10:18 223:21 288:4 289:15 303:14 315:2	Stanford 221:5
Solomon 94:20,21			speaking 10:18 223:21 288:4 289:15 303:14 315:2	start 4:14 8:3 30:12 42:21 44:7,7 46:6 68:16 88:9,15 106:2 110:4,14 183:22 192:20 220:4,14 262:4 316:11 322:11
solubility 182:10			speaking 10:18 223:21 288:4 289:15 303:14 315:2	started 163:19 164:17 172:22 173:6,17 177:15 180:5 200:3 204:1 311:22
soluble 182:2			speaking 10:18 223:21 288:4 289:15 303:14 315:2	starting 56:8 103:7 119:9 172:3 301:17
solution 79:6 177:9 177:10			speaking 10:18 223:21 288:4 289:15 303:14 315:2	state 10:17 106:16 110:16 113:6
solutions 54:17 116:6 247:3,4 326:1			speaking 10:18 223:21 288:4 289:15 303:14 315:2	
solve 44:6,16 73:17 129:1			speaking 10:18 223:21 288:4 289:15 303:14 315:2	

121:4 168:11 211:7 260:8,22 266:19 291:13 311:22 stated 231:13 247:20 248:6 275:1 324:7 statement 8:4 24:16 40:16 63:14 155:2 222:18 223:7,16 223:20 224:3 255:19 259:8,11 261:8 285:6 297:6 314:8 322:17,21 323:19 335:18 336:10 338:4 statements 230:12 314:2 states 38:6 57:14 117:14 119:5 129:14 136:22 140:2 147:7 152:22 153:15 154:9,15 163:3 166:3 171:18 173:3,8,13,15,17 183:8 187:14 188:20 192:9 199:10 202:10 204:18 230:4 233:15 249:16 256:9 292:15 state-based 191:4 state-of-the-art 270:21 Station 221:5 statistical 269:16 280:3 statistically 280:2 statisticians 82:17 status 336:14 statute 260:3,12 statutes 17:9 stay 28:9 steal 89:15 step 131:1 138:12 213:13 257:22 329:2	Stephen 2:8,14 232:17 stepped 185:7 stepping 68:1 steps 83:10 121:9 135:6,17 146:21 192:21 214:1 253:17 326:6 344:5,6 Steve 7:16 62:9 84:14 93:16 94:17 94:21 106:3 108:4 110:20 115:3 122:13 146:13 150:10 156:6 157:18 160:21 203:13 Steven 2:5,13 227:11,17 Steve's 156:19 stimulate 20:12 stimuli 278:19 stock 195:21 stole 47:13 89:14 stomach 302:2 stone 334:2 stool 110:7 stop 104:12,14 109:19 122:4 222:9 255:12 stop-go 138:13 store 129:11,13 stores 129:16 150:19 stories 161:13 186:22 204:2 story 77:7 161:5,12 166:6 strain 135:16 strangely 252:18 strategic 71:3 80:15 94:5 strategically 192:20 strategy 3:7 36:20 43:9,19 47:12 62:21 70:17,19 83:20 87:14 88:13 88:19 103:5	117:17 149:1 150:8 192:13 256:15 stratifying 268:7 272:17 street 340:8 strength 189:6 strengthened 267:13 strengths 295:9,10 stress 131:22 stresses 27:18 strictly 210:21 striving 24:4 strong 19:19 22:8 23:2,5 27:4 34:14 76:13 151:1 194:17 277:15 strongly 235:18 236:14 338:11 struck 307:7 314:4 structure 19:6 23:6 166:18 179:5,6,7 186:15 279:18 struggle 26:19 27:19 79:4 students 315:6,15 315:16 studied 62:16 296:6 studies 49:7 65:4 113:10 119:5 177:18 181:17 182:15 224:21 225:5,15 228:16 230:19 231:1,6 238:1 240:22 241:17 245:13,17 249:12 250:1,3,5 250:11,21 251:17 251:21 253:11 255:5,14 264:22 265:1 267:8 268:15,16,18,20 269:5,7,14,16 270:6 271:1,5,6,8 271:18 274:7 275:6,7 276:4,11 277:4 278:10	280:4,11,16 282:16 288:11,13 289:1,7 290:5,9,11 290:15,22 291:1 292:1 295:12 299:22 300:20 301:5 302:10,22 303:5,7 304:2,4,11 309:8,11 310:13 311:13 313:8,15 314:20 318:14 322:7 323:11 333:17 study 64:6 112:15 225:19 255:16 268:9 270:17 274:6 277:12 278:4,6,11 279:3,5 279:9,12 288:17 288:20 289:5,10 290:6 295:9 301:3 305:2 308:21 310:16 311:18 312:13 315:3,7 335:19 336:11 stuff 165:11 326:3 sub 8:15 221:10 229:12 230:1 231:13 235:18 245:9 246:3 249:21 252:16 259:16 286:1 287:18 288:7 299:18 311:18 319:21 321:5 332:7 subcommittee 1:18 3:16 9:15 220:17 224:15 227:17 252:12 254:20 subcommittee's 225:8 subcutaneous 277:5 301:20 subject 229:14 266:2 282:2 284:20 subjected 17:12	subjective 27:17 submission 289:12 submit 11:14 251:3 251:12 261:15 320:7 343:5,8,12 submitted 8:22 111:2 145:8 220:21 251:20 261:17 265:20 324:15 subscription 50:13 subsequent 264:4 280:20 284:22 285:2 310:22 subsequently 171:10 268:16 substance 165:20 184:6,7 233:9 297:10 substances 244:16 substantial 59:14 substantially 125:17 270:2 287:3 substantiate 224:16 substantiating 267:17 substitute 189:6 194:4 248:12 substitution 183:18 193:21 216:15 sub-committee 9:12 24:14 54:4 221:17 225:14 230:17 232:19 236:11,18 237:3,18 238:5 249:9 250:21 252:4,15 254:7 259:3,13 261:22 262:8,20 263:7,12 263:15 265:12,15 266:15 270:15 275:11 281:3,13 288:1,5 307:8 312:2,20 313:21 318:12 320:21 321:3 324:18 329:8 330:4,19
--	--	---	--	--

sub-committee's 230:15 252:19 258:18,22 259:10 331:6	89:11 113:16 Sundlof 2:8 7:15,16 150:11 155:13,16 161:4 185:17 187:3 188:5 197:16 202:21 209:16 210:4 211:1 212:16 216:2 298:3,17,21	surely 328:9 surface 83:3 131:20 surfaces 184:8 Surgeon 247:20 surprisingly 190:16 surrogate 167:10 surrounding 277:17 surveillance 20:20 123:11 124:6 149:2 152:16,18 184:18,22	196:3 199:3,18 226:20 267:9 279:18 322:8,9 325:6 systematic 280:9 systematically 192:21 203:6 systemic 274:21 systems 70:3,4 85:21 87:16 192:1 267:8	133:21 134:12,14 134:16,20 135:18 139:17 141:4 165:13 244:11 256:8 288:19 talent 27:15 talented 48:4 talk 38:12 39:19 42:3 55:16 79:17 86:8 88:18 106:6 106:22 145:5 161:17 174:12 181:13 186:5,11 192:11 222:6 253:15 294:5 talked 37:21 40:3 50:6 54:21 58:17 65:11 76:12 79:15 83:21 89:10 91:5 118:14 122:21 150:18 187:4 205:15,17 218:15 262:14 300:19 327:16 talking 38:4,9 53:22 77:22 101:19 122:3 126:11 148:13 152:13 184:2 212:22 299:19 301:9 307:22 310:16 311:9 talks 55:1 66:7 tandem 140:17 Tarantino 264:15 target 52:20 55:6 66:16 73:11,15 84:20 97:20 154:3 targeted 63:21 127:16 task 43:16,17 47:10 47:11 52:22 81:11 90:1,2 122:22 127:19 159:13,14 159:20 191:15 tasks 43:13 84:5 99:4 taste-test 164:6
succeed 51:11 success 59:17 290:11 successes 12:1 successful 75:1 84:17 103:6 142:2 202:14 successfully 189:17 suddenly 138:4 201:14 sufficient 19:22 230:8 231:2 270:10 284:14 sufficiently 273:6 sugars 219:3 suggest 196:15 202:16 238:7 259:13 267:12 278:8 279:2 280:13 293:16 suggested 197:16 287:21 313:8 suggestion 198:6 325:1 331:15 suggestions 11:12 41:12 95:17 208:2 209:8 292:9 suggests 192:19 238:17 256:3 275:22 285:7 suit 233:3 256:13 suitable 144:1 sulfate 187:12 sulfotransferases 266:22 summarize 280:15 303:20 344:14 summary 120:22 202:21 230:4 summer 51:11 86:2	super 93:17 supercede 319:21 supplement 221:14 supplied 166:2 supplier 163:12 suppliers 247:1 supplies 62:13 187:21 supply 59:1 66:12 68:4,15 157:10 175:14,15 185:3 185:20 191:7,8 193:11 199:22 201:14,14 209:17 212:5 249:7 support 19:11,12 35:17 59:11 76:13 224:15 229:1 230:20 231:12 237:17 244:12,16 244:20 249:5,21 268:12 270:1 supported 59:16 supporting 261:16 supportive 28:22 supports 19:7 42:10 290:12 suppose 322:14 supposed 82:3 166:22 216:9 sure 28:11 52:18 94:20 99:7 100:13 152:3 159:15 218:17 243:9 248:15 261:3 272:12 298:3 303:21 319:18 323:6 328:8 334:2 339:16 344:4	survey 201:20 203:19 survival 67:1 survive 22:6 susceptibility 257:5 267:2 susceptible 291:5 293:8,10,20 suspect 208:13 314:21 sustained 26:6 Sutton 193:3,7,8 197:4 Suttons 199:21 swab 131:6 143:17 swabbing 133:6 swill 188:12 switch 123:11 switched 219:3 symbol 200:5,7 symbolizes 203:9 sympathetic 37:21 symposia 49:21 50:21 51:3,16 symposium 101:13 symptoms 110:6 syndrome 183:9 185:10 synergies 84:11 synergistic 84:9 181:18 synergy 156:10 synthesis 178:10 synthetic 178:18 syrup 196:20 system 86:1 112:5 145:11 154:22	table 3:1 37:1 38:16 39:1 67:3,4 92:10 215:12 218:14 263:20 265:19 318:21 table-ware 240:18 tackle 46:9 61:5 73:3 91:15 207:16 tackled 44:14 tainted 174:2 take 19:5 27:16 28:6 30:3 31:13 46:5 55:10 62:7 65:18 71:21 73:7 75:22 81:1 83:6 88:8 89:3 90:14 92:8 122:9 123:2 124:3 128:5 130:18 135:3 136:7 137:21 139:13 141:11 146:1 147:13 153:20 154:16 192:21 200:21 216:11 234:4,10 255:13 317:12 320:12 322:11 326:6 328:8 329:1 taken 80:16 92:2 110:7 145:1 191:10 252:4,6 255:21 259:13 268:3 315:19 takes 113:1 121:14 124:18 132:16	

teaching 292:3	275:2	201:9 226:4	theoretical 53:11	33:12 34:16,19
Tech 141:3	tend 130:11 309:15	288:21	theory 147:22 204:9	38:15 39:15 40:11
technical 327:5	tenets 24:19	tests 127:2,2 187:19	217:16	40:21 43:8 46:1
technique 128:11	tension 66:7	201:6,11,20	therapeutic 77:9	47:21 50:17 51:10
128:18	tenure 34:19	Texas 13:18 119:13	therapeutics 6:7	53:19 55:9 56:8
techniques 32:2	ten-fold 133:11	th 189:17 202:14	48:19	59:7,10 62:8 63:3
58:18 124:6	term 321:16,20	233:19 264:10	therapy 45:17	64:22 67:5,11
130:20 133:1	terms 18:15 27:21	265:19 272:17	theses 24:21	69:11 71:8 72:3
135:2 203:20	31:14 33:10 37:8	294:18 308:11	They=re 81:8	73:11 74:22 76:7
299:21 300:9	50:17 52:14 54:13	335:4	thing 49:11 51:2	79:19 82:1 83:8,12
technological	56:17 58:6 68:3	thank 8:2 10:22	65:13 72:5 93:19	83:18 84:2 86:2
146:16	69:1 74:4 76:8	11:1 12:7 28:5,8	99:12 119:8	88:7 91:9,16 92:5
technologies 2:17	96:1 97:8,18 99:22	29:9 39:11 47:17	120:20 126:8	92:19 93:6,14,18
32:1 45:10,21 93:3	100:10 101:9	60:1,6 85:13 88:4	128:14 129:13,13	93:19 94:2 95:12
96:6 123:17 156:8	105:10 107:4,16	88:12,15 94:20	132:21 134:9	95:15 98:8,10,15
159:17 239:5,13	110:11 114:19	105:16 106:5	138:22 142:8	98:18,20 99:5,9,9
239:19	125:5 135:7	145:5,10 147:12	179:1 199:19	100:18,19 101:11
technology 13:22	146:21 148:9	160:19 161:4	204:4,10 208:11	102:3 103:6,16
14:9 18:18 26:13	152:4 155:2	203:10,12 209:11	214:5 247:21	109:15 117:2
27:1,2 65:12 66:13	158:19 205:2	210:10 219:22,22	255:1 288:19	129:7 145:9
100:1 106:9,20	219:16,18 253:10	221:9 227:6,10,12	300:1 305:6	148:16 150:15
107:6,11,13,14	271:14 276:9	227:14,15 232:6,7	325:22	151:21 152:8,9,14
108:6 109:11	282:15 283:9	232:12,13,19	things 23:21 24:6	154:2,11 155:14
110:22 114:18	290:21 295:1	234:16,17,18,21	30:1 47:6 49:16	156:19 157:6,19
124:7 128:8	337:11	235:3 238:22	52:5 59:7 61:3	159:13 160:5,9,13
136:16 140:3,11	terrain 78:3	239:1,6,8 242:16	65:22 67:19,21	165:2 166:5,14
140:14 141:9,11	terrific 145:8	242:17 247:11	71:20 81:13,22	174:11 177:6
143:9,10 144:2	160:20 344:16	248:9,11,11,17	85:20 89:9,17 94:1	179:1 185:5,14,16
145:22 146:12,16	terrorism 218:12	253:5,6,19,22	96:7 97:10 98:21	185:20 191:13
147:22 149:8	terrorist 210:19	254:6,13 258:2,3	100:13 103:8	192:4,18 193:8,19
153:20 154:16	211:22	260:17,18,20	107:10 126:16	197:15 198:7
156:13 157:12,13	test 24:21 109:19	261:6 262:16	131:2 132:5	199:1 200:19
157:15 158:10	115:1,10,17	265:7 281:7,14,17	138:10 144:15	201:7 202:13
309:13 314:5	123:10 124:17	281:19 292:21	148:18 163:11	203:18,21 204:5
tee 208:4	127:9 129:6 158:6	297:3 298:3 299:1	164:21 168:18	207:1,20 208:2,6
teeth 19:1	183:10 184:14	312:20 341:14,22	174:5,11 176:3	208:21 209:13
teleconferences	187:16 198:20	343:17 345:17,21	181:15 183:20	212:16 213:13
263:22 265:18,18	288:21,22	346:2	205:20 206:13	214:18,18 216:16
telephone 1:13 9:22	testament 165:2	thankfully 274:2	208:1,11,22 213:6	217:5,8,19,21
264:3	tested 118:16	thanks 38:21 39:13	213:12 214:6	218:20 219:20
tell 4:6 41:10 44:1	166:10	40:6,8,9 59:21	215:2,13 216:14	236:17 238:17
56:19 148:7 161:5	testing 114:20 116:2	61:15 65:4 122:19	216:21 218:6,22	253:13 262:2,5
172:9 243:7	116:2,9,22,22	147:14 185:15	219:16 299:3,16	275:13 276:3
281:22 334:1	123:5,6,10,14	203:16 205:6	300:10 302:20	281:22 283:11
temporal 272:12	124:19 125:1,2,4,5	249:8 264:15,19	307:7 321:4	285:12 287:11,21
temporary 263:7	128:6 129:2	265:13 281:2	323:17 330:21	289:18 291:3
ten 82:14 139:5	143:19,22 173:15	340:17,17	344:3,7	292:7 294:8
274:17,18,19,21	173:17 195:3	themes 40:12 41:22	think 15:5 29:10	295:19 296:9

299:4 300:2,16,21 302:6,20 303:5 306:11 307:6,19 312:1,5 313:12 314:19 315:16,20 318:6,18,18 319:11 320:9 321:5,11,18,22 322:8 323:6 324:15,19 325:6 326:15 327:11,14 327:17 328:5,7,12 328:13,20,22 329:11,20,21 330:2 331:19 333:4 334:19 335:14,16 336:4,5 336:8,12,19 337:5 337:9,10,11 338:2 338:14,18,20,21 339:4,5 340:1,10 340:12,15 341:4,7 344:2,9,20,21,22 345:7 thinking 44:8 61:20 62:4 85:9 101:8 105:11 107:5 141:10 154:11 186:16 192:13,20 199:20 202:1 203:5,22 208:10 209:6 215:10 236:22 238:8 314:1 319:9 320:1 third 31:18 55:22 69:6 153:14 177:7 thorough 66:21 228:20 230:13 244:20 245:4 293:19 thought 25:7 66:11 85:11 90:5 91:5 166:11 168:17 170:22 205:16 294:1 313:16 323:8 thoughtful 39:12 229:15 239:2	281:21 321:6 341:20 thoughts 29:3 89:4 89:6 92:8,11 103:9 157:18 261:11 thought-out 102:10 thousand 35:19 thousands 129:15 129:15,15 172:7 threat 32:14,20 194:13 200:13 threats 185:18 203:7 three 13:13 15:7 35:14 41:4,15 42:19 55:9 70:1 95:21 104:3,17 121:14 132:8 134:13,20 141:4 162:15,19 163:11 165:13 172:18 222:6 258:17 275:3 Throckmorton 2:9 7:20,21 205:9 212:20 213:13 214:13 215:7 thrombogenic 278:19 throughput 32:3 through-put 138:21 146:9,17,19 throw 138:18 278:22 thrown 115:15 thunder 47:13 89:14 thyroid 204:4,5,8 208:3,18 214:9 215:1 thyroids 205:11 tie 334:6 tight 88:10 222:4 tightly 274:6 tilapia 216:17 till 337:6 time 4:11 6:7 20:18 27:14 38:18 39:11	39:21 40:1 42:20 48:1 54:12 69:6 75:10 77:19 85:10 88:12 98:4 104:10 104:12,14 117:11 119:7,15 120:7 123:10 124:15 126:17 132:17,20 134:14,17 135:7 136:7 137:1 138:7 139:13,15 145:13 146:9 148:8 160:17 163:5 169:22 172:8 174:7 188:2 217:16,21 219:4 222:7,10,14 233:11 235:17 248:10 254:14 257:9,16 258:8 265:7 275:15 282:2,5 291:2 311:10 312:19 314:22 320:1 324:22 329:13 336:17 344:9 timeline 343:12 timely 95:2 331:13 331:15 times 28:1 167:8 188:16 193:21 204:1 215:13 262:14,15 288:18 336:14 342:22 time-frame 118:8 119:16,20 290:10 time-line 307:5 time-lines 71:10 time-table 73:22 time-tables 44:20 timing 91:11 tireless 281:3 tissues 179:21 today 9:13 15:7,10 16:20 24:17 26:21 33:13 38:10 41:6,9 45:11 47:6 52:16 53:22 54:7,11,13	84:10 88:11 96:1 160:14 186:22 190:5 224:11 226:8,22 227:7 234:19 236:4 244:2 248:10 254:15 256:3 281:10 283:1 today's 27:5 252:16 told 198:1 222:17 tolerance 304:16 tomato 118:16 127:12 129:6 130:6,9,17 131:7 143:14 156:2 tomatoes 91:1 112:16 113:18 117:20 118:10,11 118:15,19 119:6 122:5 129:9,12,18 130:7,18 131:16 132:9 133:13,15 138:5 155:9 tomorrow 16:21 ton 195:1,2 tool 120:16 145:21 146:1 150:2 152:14,15 154:7 toolbox 150:2 tools 50:12 80:2,4 80:16 82:22 83:1,4 83:16 106:13 118:6 153:22 156:22 301:2 too-good-to-be-tr... 201:18 top 36:5 40:19 44:10 45:4 46:4,11 46:20 58:4 139:9 139:19 214:21 304:21 topic 10:9 104:1 146:8 292:3 297:21 topics 3:7 8:18 10:3 54:10 88:13 342:12 344:15 topology 62:17	top-down 78:18 159:16 Torti 2:10 6:10,10 29:15 39:19 40:6 60:3,12 62:6 66:9 71:12 84:10 85:16 86:9 90:11,19 91:9 94:7 96:16 102:12 104:18,22 159:10 189:20 207:11 292:20 299:2 312:17 339:13 345:17 total 180:22 totality 103:4 256:1 272:4 306:16 totally 298:8 317:8 touch 43:11 67:6 84:18 207:18 touches 59:4 tough 81:20 toxic 197:19 233:9 255:7 257:4 toxicity 165:14 181:10 182:11 224:21 274:21 279:4 toxicogenetic 308:13 toxicological 2:7 7:10 294:10 295:2 toxicologists 165:9 198:1 toxicology 4:20 7:11 181:17 250:8 264:20 toxins 6:3 trace 119:9 246:13 traceability 155:8 155:17 traced 118:19 119:13 traces 319:8 trace-back 117:16 124:11 125:20 126:18 158:19 163:19 trace-backs 135:3
---	---	---	--	---

153:13	trigger 210:18	turtles 126:6	unable 251:14	297:12 313:10
tracing 114:3	triggered 210:14	Twaroski 264:16	258:15	undertake 119:5
118:11,12	trillion 65:16,17	two 4:16,16 11:19	unacceptably	undertaken 43:14
track 58:21	trouble 75:7 303:11	35:1,19 36:17	224:19	250:22
tracked 56:12	306:9 337:17	47:11 53:3 73:9	unbelievably 67:13	underway 35:1 87:7
129:20	trout 177:19	77:8 81:8 99:21	67:14	87:22 302:12
tracking 123:13	true 12:19 58:14	100:15,15 105:2,9	uncertainties	unfolding 88:2
trade 67:15 211:8	167:10 238:10	118:19 132:8	231:20 269:21	unfortunately
traditionally 82:8	276:15	134:20 135:2,6	273:17 277:17	25:17 139:8
tragically 198:14	truly 33:13	136:17 139:14	294:4 318:7	155:22 156:1
trained 235:13	trust 173:14 249:5	151:18 152:12	330:17,18 331:21	uniform 130:4
training 6:13 18:1	253:3	162:21 165:4	331:22 332:2	Union 155:19 229:6
transcriber 10:16	try 53:1 66:3 82:11	177:7 178:2	uncertainty 185:9	254:2 255:11,18
transferred 169:3	84:15 97:13 98:5,9	186:22 199:11	230:7 270:14	unique 16:9 48:6,6
transformation	101:15 105:6	203:17 221:16	273:21 274:5,12	186:21
13:9,11	108:4 111:16	222:7 240:22	274:17 275:1,8	unit 193:20 194:6
translate 278:17	117:10,17 122:20	263:12 283:5,17	284:14 286:15	United 38:6 57:13
translational 5:5	122:21 123:1	284:5,6 286:18	287:6 296:15	129:14 136:22
26:1	133:5 135:4 151:8	306:9 316:13	308:9 326:5 330:3	140:2 166:3
transmit 317:13	200:17 217:12	317:6,10,17 318:2	uncovered 271:17	171:18 173:3,8,13
320:5 331:5	262:9 316:19	319:9 323:11,16	uncovering 185:9	183:7 187:14
333:14	336:6	328:5 329:17	underline 275:10	188:20 192:9
transmitted 136:5	trying 28:18 34:4	339:8 342:4,7,21	underlying 249:12	199:10 202:10
340:4	39:6 49:13 68:3	344:7	331:12	204:17 233:14
transparency 19:13	80:10 86:21 97:7	two-fold 263:2	undermines 224:22	249:16 252:9
222:22	101:15 113:2	two-part 104:6	underpin 268:3	256:9
transparent 21:19	140:10 151:5	Tyl 270:16 271:1,5	underscore 15:11	units 162:9
27:20 222:20	195:20 211:21	271:10 276:3	underscores 255:2	universally 175:8
254:21	293:17 326:11	type 124:19 138:14	understand 20:22	university 4:19 5:4
transparently 251:1	334:15 337:4,5	142:5 144:7,8	51:17 59:13 63:5	5:22 13:18 99:20
transport 217:3	tubes 177:6,7	187:20 263:19	63:18 72:13 80:7	180:10 221:5
travel 223:12	tubing 96:6	types 82:21 117:15	81:4 83:5 153:4,12	235:11 281:11
travelled 69:3	Tuesday 252:14	123:9 149:12	153:16 172:3	315:5
travels 346:1	tumor 291:15	290:16 303:5	181:16 182:9	unpublished 315:21
treat 77:16	tumors 5:2	Typhimurium	192:1 206:11	unrelated 311:21
treated 199:2	turn 10:14,17,20	126:22	221:19 223:2	unsuspected 32:10
treating 81:7	54:20 55:5,5 63:12	typically 126:2	228:7 237:5 258:1	untuned 334:3
treatment 5:2 77:10	105:12 146:4	290:14 301:17	285:20 291:6	unusual 290:7
tree 142:4	165:19 195:21	typing 109:6 118:7	305:2 306:4 313:9	un-contaminated
tremendous 302:8	218:1	typo 187:5	313:10 322:13	210:2
340:17	turned 163:12	typo 187:5	345:20	update 3:5 39:20
trial 45:15 82:2	164:22 165:20	T5000 141:18	understandable	40:5 86:6 90:12,13
300:4	170:17		270:17	91:12,17 94:16
trials 82:4,6,10,16	turning 91:2 159:11	U	understanding 18:4	updated 111:5
82:17 164:13	turns 168:20 169:8	ultimate 35:13	36:13 45:18 61:20	229:8
300:11	211:16	ultimately 21:17	61:22 75:5 77:8	upgrade 82:12
tried 41:2 42:14	turn-key 144:6	87:4 107:7,17	78:1,12 97:9 167:4	upgrading 327:7
143:11,18 326:18	turtle 111:20	114:16 115:15	181:21 231:16	upper-most 293:18
		un 204:11		

urate 176:12,13	102:7 146:5 277:1	267:10 296:12	vitalize 37:16	234:14 239:7
urge 227:3 240:8	330:3 343:21	300:18 301:19	vitro 278:17	241:12 258:19
242:12 244:6	usefulness 103:14	various 33:4 77:1	vivo 278:13,17,19	275:10 303:19
251:1	uses 139:6 141:19	97:21 156:10	vocabulary 341:2	312:3 313:1,5
urged 250:21	167:14 224:17	168:5 171:15	volume 131:13	317:21 319:11
urgency 345:21	297:15	219:6 290:16	190:8 194:8 205:2	328:1 330:14
urgent 170:7	usually 300:1	vast 172:16	volumes 129:8	331:2 332:11
urges 249:10 252:2	utility 230:20 231:7	Vector-Borne 5:15	voluntarily 226:10	334:1 337:14
255:11	270:8	Vegas 163:12	von 2:1 11:2 12:3,7	338:10 341:22
urinary 309:9 310:2	utilize 156:12	vegetables 149:10	28:11,14,17 29:9	344:3 345:17
urine 182:1,5,22	157:15	149:12	34:16 38:21 39:2,7	wanted 41:5 43:22
308:22 309:10,16	utilized 149:13	vehicle 117:21	39:13 67:10 75:22	53:8 71:4 89:5
315:11,18	244:21	venued 233:16	86:11 265:2	127:19 129:4
Urvashi 2:19	U.S 1:1	verification 22:3	vote 234:19 316:12	137:16 202:17
253:20 254:1		verify 149:3	334:15,16,20	206:10 235:22
USDA 106:18 147:2	V	versions 332:7	335:5 338:4 339:4	237:6 312:19
170:19	validate 21:22 25:2	versus 210:21	339:5	322:2 338:6
USDA-regulated	25:7 95:6 194:12	277:19,20 307:4	voting 9:16 334:4	341:12 344:13
111:22	validated 17:11	308:6	vulnerabilities	wanting 168:9
use 8:14 20:3,9	22:19 27:8 32:12	vertical 33:4	192:8 218:8	wants 150:22 342:4
26:14 45:14 53:2	78:2 123:18	vested 254:5	vulnerability 193:9	ware 184:8
53:19 62:2 74:8	136:11 279:12	veterinary 2:3 5:17	200:11,20 267:10	warranted 270:17
76:2,19 78:5 82:12	validating 93:4	7:14 161:8 177:19	vulnerable 276:13	Washington 1:9
93:4 108:13 109:9	validation 17:22	viable 247:8		224:7 236:6
109:11,13 113:7	19:14 22:13 77:13	vice 243:10	W	wasn't 57:2 153:9
128:12 135:22	124:17	view 12:13 68:6,7	W 2:2	156:1 215:18
136:2 137:18	valuable 93:7 95:2	77:18 324:11	waiting 234:11	293:4 294:15
140:11 145:20,22	95:8 99:5 189:8	343:18	320:18	306:2 310:21
149:11,16 150:5	209:6	viewed 273:21	walk 161:14 193:1	328:8
164:7 175:20	value 93:18 167:18	290:6	193:17 195:6	watch 80:12
187:18 192:9,14	174:17 190:17	viewpoints 227:22	196:14 340:7	water 84:13 107:17
197:17 200:18	192:10 273:8	views 286:5 336:15	Wal-Mart 68:9,10	115:18 120:10
207:5 229:11	302:8	vigor 224:14	wand 79:6	217:2 298:20
239:10 240:17,21	values 268:5 273:9	vigorous 266:3	want 16:19 45:7	way 17:2,19 27:3
247:14 249:18	294:12	vine 130:11	47:17 49:17 54:20	28:17 29:21 43:21
254:5 255:20	Vandenberg 1:19	violation 124:5	59:5 66:10 72:1	44:12 54:9,22 61:3
256:21 257:15	221:18 281:10	216:10	74:9 75:21 80:4	61:22 62:16 66:20
258:1 260:1,2	285:22 286:1	Virginia 5:22 141:3	86:9 88:16 93:20	68:2 69:9,15 78:2
262:22 263:11	290:1,21 294:7	virtually 143:1	96:12,14 100:2,19	78:3 84:8 85:20
268:19,20 270:2	301:8 307:6	viruses 142:6,7	105:6 106:6,14	89:3 104:15
270:18 271:1	Vandenburg 274:2	visibility 75:3	107:5,19 108:6,14	115:14 123:6
277:5 278:2	variability 268:6	visible 27:16 59:19	108:20 110:3	124:12 125:3
279:11 280:4,11	272:15,21,22	vision 34:8,11,14	112:15 117:21	129:20 131:17
288:17 290:5	274:18,19	39:22	122:4,9 145:17	147:9 151:13
296:5,10 297:11	variable 140:17	visit 68:9 221:20	146:11 150:5,17	154:21 156:22
299:20 321:19	variation 308:14	293:21	152:6 155:4	157:16 159:6,12
used-by 115:14	variations 308:15	visited 172:6	204:13 207:9	167:4 168:1 172:9
useful 101:10 102:6	variety 184:19	visits 172:7	208:11 219:18	190:3 201:17

202:20 208:4 212:5,5 213:20 273:4 285:15 295:7 302:6 310:4 317:15 318:6 ways 47:19 55:9 71:13 81:9 82:10 157:17 158:9 159:18 163:20 199:4 206:7 279:19 300:7 318:4 336:1 weak 200:10 weaker 191:3 wealth 66:2 web 170:12 208:16 website 168:8,8 173:10 175:4 343:7 web-site 61:9 Wednesday 225:10 week 77:22 79:17 99:10 111:14 119:19 121:14 135:4,4 216:3 238:6 252:14 253:2 331:16,17 332:22 333:16 weekend 179:22 weeks 38:2 155:17 162:15,19 165:5 170:2 172:15 195:19 244:3 weight 166:19 170:5 183:20 216:22 217:1,4,6 231:4,5 245:22 256:1 269:22 270:4 273:14 274:15 285:6 295:5 338:21 340:22 Weiss 2:15 232:14 232:15 233:2 welcome 4:4 8:7 89:8 103:9 185:10 209:9 220:15 228:16 243:18 247:3 253:14	261:20 welcomed 34:20 welfare 244:1 well-being 246:20 well-constructed 19:21 well-documented 228:22 well-done 96:10 well-established 245:15 well-framed 25:8 well-intentioned 233:22 well-lit 24:5 well-stated 83:9 well-thought 101:7 well-validated 139:22 went 114:6 117:1 164:9 220:10 264:22 338:7 weren't 179:15 we'll 24:11 38:9 60:12,19 61:13 74:8,8 86:18,20 88:8 89:3 91:22 98:14 100:8,17 104:8,8,11,12,14 122:17 142:17 160:11 161:13 181:13 227:10,10 232:14 242:18,22 248:18 262:2,5,9 285:16 329:16,17 we're 17:22 31:8 34:4 39:18 41:13 46:12 47:6 49:12 50:9,15,20 51:10 52:20 53:13,14,22 54:3,10,15,17 59:10,11,16 64:19 65:3,6 68:21 69:17 73:5,6 74:1,2 75:7 75:11 78:17 80:3 82:3,11 86:21 89:1 92:21 93:4 95:8,22 97:5,6 98:17	101:21 105:11 106:15 110:21 116:13,21 118:1 118:10 119:9,10 120:3,7 122:12,14 122:16 123:13,14 124:5 125:19 127:4,6,7 133:17 138:18 140:14 141:3,15 142:19 143:4 146:18,22 152:3,10 154:12 160:13 161:17 173:12,18 186:19 188:19 189:20 200:15,16,22 201:20 202:2 205:20 208:5 209:7 217:8,9,14 260:19 286:10 287:9 297:19 301:3,9 303:21 306:5 307:14,19 308:4,17 309:8 311:9 314:22 324:4,14 325:5 329:21 333:8 334:15 337:16 339:12 344:15 we've 29:17 30:1 37:3 40:7 42:4 43:14,20 44:3 45:2 46:8 49:19 50:14 52:22 58:17 59:10 72:15 74:1 82:21 87:16 91:13,14 92:2 97:6 103:6 108:19 111:8 114:5 116:15 119:18 132:13 138:4,6,7,8,22 139:1 140:10 145:21 146:5 150:3,17,18 154:10,14 161:20 167:21 171:11 176:4 185:17 186:1 188:8	191:18 202:22 205:15 206:20 218:3 290:10 318:3 319:18 324:15 329:12 332:20 333:4 335:10 337:9 340:1,2 wheat 163:13 165:21,22 166:22 187:5,7 211:15 wheel 279:20 white 33:7 56:14 177:8 320:7 wholly 189:7,9 who've 209:1 wide 61:11 78:17 184:18 258:2 273:6 296:12,14 widely 164:2 207:3 wide-spread 256:20 widget 128:12 wild 215:17 WILLIAM 2:7 Willie 193:3,6,8 197:4 199:21 willing 27:14 100:6 willingness 16:2 window 217:16,17 win-win 147:9 Wisconsin 99:20 wise 216:15 wish 10:10 254:6,13 withstanding 275:15 woken 138:4 women 2:16 77:16 235:2,5 237:8,10 239:16 241:9 242:15 291:11 292:12 293:1,13 women's 6:18 241:19 wonder 220:6,13 wonderful 11:13 281:20 wondering 86:6 218:13	word 135:8 139:16 189:21 287:12,13 314:9 330:15 worded 283:6 words 45:8 189:2 238:7 260:3 304:20 335:15 342:5 345:16 word-smithing 331:20 work 11:20 13:2 23:15 24:12 25:19 47:5 70:1 79:4 83:6,16 86:21 87:22 89:22 98:13 99:7 100:9 107:14 107:15 132:6 139:6 141:18 144:9 151:1 154:21 158:21 159:3 206:10 221:11 229:13 237:17 239:21 242:7 246:22 262:14 286:2 312:21 317:16 325:8 340:14 341:11,12 343:21 345:9 worked 51:22 60:21 83:10 139:12 235:14,15 341:15 341:17,19 workforce 47:12 workgroup 200:17 working 2:13 69:12 70:20 75:11 80:3 90:7,8 93:9 138:7 141:3,15 143:5 149:4 168:16 175:1 176:5 177:17 205:21 218:4 220:22 224:2,6 286:10 288:1 307:14 works 136:8,16,19 143:15,16 183:2 190:11
---	--	--	---	--

workshop 155:4	x 273:13	235:1,3,4 239:3	1500 174:1	30,000 219:10
world 12:14 14:10	<hr/> Y <hr/>	<hr/> \$ <hr/>	16 163:10 264:2,5	31 1:7 340:5
25:21 26:12 27:21	Yale 235:13,14	\$1 195:22	264:11 308:12	339 3:18
30:18 32:15,18	year 11:18,19 25:15	\$1.20 194:21	332:7	34 180:20,21
36:3 50:5 65:13	35:1,19,19 41:11	\$12 65:15,17	161 3:12	35 233:13
69:4 86:1 123:19	56:12 74:20 86:19	\$2,500 141:5	17 139:22	37 131:19
136:21 183:17	87:6 88:20 89:1,3	\$50 196:1	17.6 196:6	<hr/> 4 <hr/>
189:21 200:8	92:2,5,7 94:4,15	\$6 195:2	18 195:9 233:20	4 3:2 57:9 335:5
208:12 244:2	94:15,19 100:6	\$87 196:11	1858 188:11	4,000 50:15
246:3 247:16	113:8 117:14	<hr/> 0 <hr/>	1890 188:17	40 3:5
292:19 314:7	161:7 162:17	0.18 195:16,17	1923 189:16	45 139:17,18
world's 14:16	166:6,6 174:19	01 142:1	1997 190:12	<hr/> 5 <hr/>
world-wide 32:19	178:22 190:7	0157 110:17 114:21	<hr/> 2 <hr/>	5 270:3 273:12
67:15,16 229:4	191:14,16 192:4	0157:H7 115:2	2 43:5 172:17	295:4
244:22	199:11 227:2	125:6 158:3	2,000 35:18 50:14	50 128:14 163:3
worn 321:17	229:8 264:12	<hr/> 1 <hr/>	50:15	195:5,17
worrisome 213:11	273:13 342:13,22	1 43:4 273:13 331:7	2/3 166:18	50,000 169:10,18
worry 335:7	years 12:4 13:12,13	331:8	2:00 221:21	50/50 179:12
worst 97:15	14:15 15:7 35:14	1,000 48:2 128:13	20 36:5 189:18	53,000 172:16
worth 56:9 299:4	82:14,14 132:8	128:18	202:15 265:20	59 3:6
wouldn't 120:15	139:6 162:21	1,450 117:13	200 36:7 214:21	<hr/> 6 <hr/>
322:16	172:17 188:21	1,531 126:20	2000 57:1	6 57:10
wrap 122:15	193:3 195:20	1:00 10:13 220:2,4	2001 55:18 218:15	60 162:9
wrapped 299:9	202:11 215:15	1:03 220:11	2006 114:21	63 181:4
wrestle 15:10	228:6 236:2 310:6	1:1 179:8	2007 56:12,16 162:4	64 181:1
wrestle 15:10	310:10 315:4,12	10 51:15 88:8	214:22 233:2	<hr/> 7 <hr/>
write 319:12 320:8	345:4	130:13,15 133:21	2008 1:7 56:19	70 179:10
320:14 323:9	yeses 334:21,22	264:4	117:18	<hr/> 8 <hr/>
324:5 330:1	yesterday 79:15	100 14:15 81:18,19	2009 3:7 8:18 88:13	8,000 188:15
332:21	84:12 85:1	130:13,15 139:9	155:5	8.9 195:12,15,17
writers 51:16,17	yet-to-born 14:6	188:21 202:11	203 3:13	196:8
101:13	yield 250:11 274:1	101 105:22	21 11:5	8:00 1:9
writes 71:20	287:7	105 3:10	220 3:14	800 36:11 170:15
write-up 65:15	yielded 251:17	11 55:18 104:13	24 132:15,17,18	85 167:3
145:8	yields 22:11 252:22	171:6	225:13	88 3:7
writing 222:3	York 188:12,16	12 3:3 233:2	26.5 196:7	<hr/> 9 <hr/>
written 71:16 74:7	204:1 215:12	12,000 162:16	262 3:16	9/11 218:6
220:20 223:6	young 14:6 50:21	12:04 220:10	28 3:4 246:5	9:45 88:9
225:9 228:18	307:12 337:8	13 163:6 188:16	281 3:17	90 73:1
261:17 282:8	younger 310:4,9	13,000 172:17	295 57:13	91 56:12
316:10 318:11	youngest 310:5	132 170:14	<hr/> 3 <hr/>	92 3:8
wrong 90:6 117:1	<hr/> Z <hr/>	14 133:22 190:11	3 43:7	95 272:18 294:19
148:18 254:18	zero 177:15	147 3:11	3,000 162:17	
327:20	zoonoses 84:18	15 162:5 236:2	3.7 196:12	
wrote 262:15 332:8	Zoonotic 5:15	150 50:13	3:13 346:4	
342:3	Zuckerman 2:15		30 179:9	
WTO 65:21				
<hr/> X <hr/>				

99 126:1