

Exhibit 149

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EXHIBITS: 1-12

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
No. 7:23-cv-00897

IN RE: CAMP LEJEUNE WATER
LITIGATION,

This Document Relates To:
ALL CASES

VIDEOCONFERENCED VIDEOTAPED DEPOSITION of
DAVID MADIGAN, Ph.D.

Wednesday, June 11, 2025
9:53 a.m.

Held at: Regus
100 Cambridge Street
Boston, Massachusetts

Megan M. Castro, RPR, CSR #152614
Court Reporter

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I N D E X

Witness	Page
DAVID MADIGAN, Ph.D.	
Examination by Attorney Sprayregen	5, 202
Examination by Attorney Miceli	158

E X H I B I T S

Number	Description	Page
Exhibit 1	Notice of Deposition of and Request for Production of Documents to David Madigan, Ph.D.	7
Exhibit 2	Expert Report of David Madigan, Ph.D., dated 3-16-25, with attachments	9
Exhibit 3	Deposition transcript of David Madigan, Ph.D., dated 11-14-19	15
Exhibit 4	Deposition transcript of David Savitz, Ph.D., dated 5-16-25	21
Exhibit 5	Cochrane Training, Chapter 10: Analysing data and undertaking meta-analyses	27
Exhibit 6	General Causation report of Peter G. Shields, M.D., dated 2-7-25	42
Exhibit 7	Excerpt from "Epidemiology and the Law"	53

P R O C E E D I N G S

- - -

THE VIDEOGRAPHER: We are now on the record. My name is Robert Martignetti. I am the videographer for Golkow. Today's date is June 11, 2025, and the time is 9:53 a.m.

This video deposition is being held in Boston, Massachusetts, In Re: Camp Lejeune Water Litigation. The deponent is David Madigan, Ph.D.

Counsel will be noted on the stenographic record. The court reporter is Megan Castro and will now swear in the witness.

- - -

DAVID MADIGAN, PH.D., first having been satisfactorily identified by the production of his driver's license and duly sworn by the Notary Public, testified under oath as follows in answer to examination by

ATTORNEY SPRAYREGEN:

- - -

Q. Good morning, Dr. Madigan.

A. Good morning.

Q. I introduced myself off the record, but

1 I will introduce myself again. My name is
2 Sharon Sprayregen. My colleague is
3 Marcus Tobin, and we represent the
4 United States.

5 This proceeding, even though we are not
6 in a courtroom is -- you are -- I will take
7 that back.

8 You are under oath, even though we are
9 not in a courtroom. You understand that,
10 right?

11 A. Yes.

12 Q. And you understand that a court
13 reporter is taking everything down, so we
14 should try not to speak over each other.
15 Right?

16 A. Yes.

17 Q. And if you don't understand a question,
18 please let me know. Okay?

19 A. Okay.

20 Q. And if you answer a question, I will
21 assume that you understood it. Is that fair?

22 A. Yes.

23 Q. And we can take a break any time you
24 like just as long as a question is not pending.

1 Is that fair?

2 A. Yes.

3 Q. Great.

4 Is there any reason why you can't give
5 complete and accurate and truthful testimony
6 today?

7 A. No.

8 (Exhibit 1, Notice of Deposition of and
9 Request for Production of Documents to
10 David Madigan, Ph.D., marked for
11 identification.)

12 BY ATTORNEY SPRAYREGEN:

13 Q. So I am showing you what we are marking
14 as Exhibit 1. Have you seen this document
15 before?

16 A. Yes.

17 Q. Have you reviewed the request for
18 production for documents? It is at the end.

19 A. Yes.

20 Q. Do you have any responsive materials to
21 produce?

22 A. No. I believe everything that was
23 asked for, you have it.

24 Q. My understanding is that you have an

1 additional invoice that hasn't yet been
2 produced. Is that correct?

3 ATTORNEY MICELI: That was -- short
4 answer is yes, May 28th you sent.

5 A. Okay.

6 BY ATTORNEY SPRAYREGEN:

7 Q. But nothing other than that additional
8 invoice, I take it?

9 A. Correct.

10 Q. Are you withholding any materials that
11 would be responsive?

12 A. No.

13 Q. I know you have served as an expert
14 witness before. Do you know how many times you
15 have been an expert witness?

16 A. Times?

17 Q. How many cases you have been hired to
18 be an expert witness for.

19 A. Over -- forever, in my life?

20 Q. In the last 10 years.

21 A. I don't know the answer, but maybe a
22 dozen.

23 Q. Only a dozen?

24 A. Different matters. I mean, I have

1 been, like, for example, I have done work in
2 talc litigation. There have been many, many
3 cases in that context, but it is one report,
4 basically.

5 Q. Understood. So when you say a dozen
6 matters, you are counting the talc litigations
7 as one matter. Is that right?

8 A. Exactly.

9 Q. Have you ever --

10 ATTORNEY SPRAYREGEN: Withdrawn.

11 BY ATTORNEY SPRAYREGEN:

12 Q. In most of these cases, have you
13 testified for the plaintiff?

14 A. Yes. Except I worked on an
15 intellectual property case some years ago, I
16 don't know when it was, for defendants.

17 Q. Would you say that was in the last
18 10 years?

19 A. Probably. I am not certain.

20 Q. Is that the only case where you have
21 been hired to work for defendants?

22 A. Yes. I have never been asked in any
23 other context.

24 (Exhibit 2, Expert Report of David Madigan,

1 Ph.D., dated 3-16-25, with attachments,
2 marked for identification.)

3 BY ATTORNEY SPRAYREGEN:

4 Q. I am showing you what we are marking as
5 Exhibit 2, which is titled "Comments on
6 Camp Lejeune Defendants' Reports," and dated,
7 if you look at the last page of the actual
8 report, before the exhibits, March 16, 2025.

9 Is this the report that you wrote for
10 this litigation?

11 A. Yes.

12 Q. Prior to preparation of this report,
13 did you review the reports of any of the U.S.'s
14 general causation experts?

15 A. Unless it is cited in here, no.

16 Q. So you cited the reports of
17 Dr. Goodman?

18 A. Right. I was asked to comment on the
19 reports of Dr. Goodman and Dr. Shields. Yes.

20 Q. Dr. Goodman wrote a number of reports.
21 Did you read multiple reports of Dr. Goodman's?

22 A. I focused on one of them -- I think it
23 might have been the kidney one -- and skimmed
24 the other ones, and they are very, very

1 similar.

2 Q. And you read the entirety of
3 Dr. Shields's report?

4 A. Yes.

5 Q. Did you review the report of
6 Dr. McCabe?

7 A. That doesn't ring a bell.

8 Q. Prior to preparation of this report
9 that is Exhibit 2, did you review the reports
10 of any of the plaintiffs' general causation
11 experts in this case?

12 A. I don't believe so.

13 Q. Did you review any of Dr. Bird's
14 reports in this case?

15 A. I don't believe so.

16 Q. Other than the reports of Dr. Goodman
17 and Dr. Shields, are there any other documents
18 related to this litigation that you reviewed to
19 write your report in this case?

20 A. I don't believe so. Unless there is
21 something referenced in here, no.

22 Q. Have you reviewed the 2017 ATSDR
23 assessment of the evidence?

24 A. I have seen that document, yes.

1 Q. Did you review any of Dr. Bove's
2 published studies concerning the population at
3 Camp Lejeune?

4 A. So same as -- I have seen -- not in
5 preparing this, but I have seen those
6 documents, those papers.

7 Q. So when you say you have seen those
8 documents, but not in preparation for preparing
9 your report, what was the context in which you
10 have seen those documents?

11 A. So I have -- I don't know -- over the
12 last, maybe, a year, consulted with the counsel
13 to my left. And in that context, he has asked
14 me to look at some things and he has asked me
15 some questions about them, so that is the
16 context in which I have seen the Bove papers.

17 Q. But you didn't review them in
18 preparation to write this report that you
19 submitted. Is that correct?

20 A. That is correct.

21 Q. Would you agree --

22 ATTORNEY SPRAYREGEN: Take that back.

23 BY ATTORNEY SPRAYREGEN:

24 Q. How do you define an observational

1 study?

2 A. So an observational study is -- they
3 come in different flavors. But a typical
4 observational study is you gather data by
5 observing people -- people, let's call it
6 people; it could be other objects, but it could
7 be people in the world. So you don't
8 intervene.

9 The difference between an observational
10 study and an interventional study is, in an
11 observational study, you just gather it. You
12 observe behavior, characteristics, et cetera,
13 in the world. You don't intervene.

14 That is the key difference between an
15 observational study and an interventional
16 study. I could go on at length, but.

17 Q. So you would agree with my definition
18 that an observational study is a type of study
19 in which researchers observe and analyze
20 outcomes without intervening or assigning
21 exposures to the study subjects?

22 A. That sounds right.

23 Q. And you have previously written in
24 expert reports submitted to courts that

1 observational studies have well-documented
2 limitations. Is that correct?

3 A. Yes.

4 Q. You have previously testified, and I
5 quote, There are some observational studies
6 that I will happily rely on, subject to
7 limitation. There are others that I feel are
8 fatally flawed.

9 Is that correct?

10 ATTORNEY MICELI: Object to the form.
11 Foundation.

12 A. I can't confirm that with certainty.
13 Maybe.

14 BY ATTORNEY SPRAYREGEN:

15 Q. Is that a statement that you would
16 agree with?

17 A. Say that again.

18 Q. There are some observational studies
19 that I will happily rely on, subject to
20 limitations. There are others that I feel are
21 fatally flawed.

22 ATTORNEY MICELI: Same objection.

23 A. Yes, I would make that statement today.

24 BY ATTORNEY SPRAYREGEN:

1 Q. And you have previously testified that,
2 in observational studies, the estimates can be
3 systematically biased, meaning that you
4 could -- that they could systematically be too
5 low or too high. Is that correct?

6 ATTORNEY MICELI: Object to the form.
7 Foundation.

8 A. Same answer, I don't recall saying
9 that, but that seems like that is a true
10 statement.

11 (Exhibit 3, Deposition transcript of David
12 Madigan, Ph.D., dated 11-14-19, marked for
13 identification.)

14 ATTORNEY MICELI: Just for the record,
15 it is interesting that we have this since the
16 deposition was subject to a protective order,
17 but it was not admitted into evidence in the
18 trials. So we will make that note and we will
19 have to investigate that further later.

20 ATTORNEY SPRAYREGEN: There are
21 provisions to mark parts of the deposition
22 confidential, and we can talk about that
23 afterward if you want.

24 ATTORNEY MICELI: But it is not that we

1 mark them. In the litigation, in the Taxotere
2 MDL litigation, there was a protective order
3 that made what you are using as Exhibit 3
4 protected. That was my concern. I understand
5 that we can agree. I am just making a note for
6 the record, but thank you.

7 ATTORNEY SPRAYREGEN: I understand. I
8 didn't understand that.

9 BY ATTORNEY SPRAYREGEN:

10 Q. Would you please turn to page 195?

11 A. Okay, I am there.

12 Q. I am not even there.

13 And do you see where it says, on
14 line 3:

15 "Question: Sure. What does bias means
16 in the context of an observational study?

17 "Answer: Basically, it means -- so
18 these studies are trying to effect -- trying to
19 estimate an effect size, right, the true causal
20 effect of an intervention. In this case,
21 Taxotere. So the -- you -- the bias would be
22 present if your observational study
23 systematically guessed too high -- estimated or
24 guessed too high or too low systematically. So

1 I'm not talking about sampling variability,
2 which is -- which is kind of white noise,
3 randomness. But if, systematically, it's --
4 you know -- it's -- it aims -- it gives you an
5 estimate that's too high or systematically too
6 low, that's bias.

7 "Question: Okay. Is that why bias in
8 observational studies is sometimes called
9 'systematic error'?

10 "Answer: Sure.

11 "Question: Are those terms synonymous
12 in terms of observational studies?

13 "Answer: Probably, I think -- yeah, I
14 think that is generally how people use the
15 phrase 'systematic error.'

16 "Question: And this idea of bias in
17 observational studies is something you have
18 published yourself on. Correct?

19 "Answer: Quite a bit.

20 "Question: Extensively. Right?

21 "Answer: Yep."

22 Did I read that correctly?

23 A. Yes.

24 Q. Was that your prior testimony?

1 A. Yes.

2 Q. I do the same thing. We will do our
3 best not to do that. Thank you.

4 Do you still agree with everything that
5 you testified that I just read?

6 A. Yes.

7 Q. And environmental-epidemiological
8 studies are observational studies. Would you
9 agree with that?

10 A. I think that is generally true, but I
11 guess you could have randomized studies that
12 could still be called epidemiological. But
13 generally, I think it is true.

14 Q. Would you agree that cohort studies
15 looking at the relationship between a chemical
16 exposure and a disease are observational
17 studies?

18 A. Yes, generally speaking, when people
19 use the term "cohort study," it is a type of
20 observational study.

21 Q. Would you also agree the case studies
22 looking at the relationship between a chemical
23 exposure and disease are observational studies?

24 A. Sure, insofar as they are -- a case

1 series is a study, yes, they are definitely
2 observational.

3 Q. And the human studies, as opposed to
4 the animal and mechanistic studies that
5 Dr. Goodman and Dr. Shields examined in their
6 reports, are observational studies. Is that
7 true?

8 ATTORNEY MICELI: Object to the form.

9 A. Yes, generally speaking, they did not
10 look at randomized studies; they looked at
11 observational studies.

12 BY ATTORNEY SPRAYREGEN:

13 Q. When they were looking at humans as
14 opposed to animals?

15 A. Yes.

16 Q. Would you agree that, before making a
17 causal determination, for example, that a
18 particular chemical can cause a disease,
19 epidemiologists need to consider the quality of
20 the studies?

21 ATTORNEY MICELI: Object to the form.

22 A. Sure, as a general matter, if you are
23 going to be drawing a causal conclusion, you
24 consider the design of the studies, the size of

1 the studies, if you will, the quality of the
2 studies before drawing a causal conclusion.

3 Q. Would you agree that each study must be
4 evaluated to determine whether its design is
5 appropriate, the study size is adequate, and
6 systematic bias has not influenced the observed
7 association?

8 ATTORNEY MICELI: Object to the form.

9 A. I mean, what you are describing is good
10 practice, that one, in general, would consider
11 those issues.

12 BY ATTORNEY SPRAYREGEN:

13 Q. Prior to your work in this case, had
14 you ever communicated with Dr. Savitz?

15 A. No.

16 Q. Prior to your work in this case, had
17 you -- did you know who he is?

18 A. Yes, I was familiar with the name.

19 Q. Had you read any of his published
20 articles or books prior to your work in this
21 case?

22 A. Probably. I can't be certain.

23 Q. You had never worked together. Is that
24 right?

1 A. That's right.

2 Q. And it is my understanding from your
3 materials considered list that you reviewed
4 Dr. Savitz's May 16, 2025, deposition in this
5 case. Is that right?

6 A. I don't remember the date, but I read
7 his deposition -- a deposition of Dr. Savitz.

8 (Exhibit 4, Deposition transcript of David
9 Savitz, Ph.D., dated 5-16-25, marked for
10 identification.)

11 BY ATTORNEY SPRAYREGEN:

12 Q. So Exhibit 4 is the transcript of
13 Dr. Savitz's deposition in this case.

14 Could you quickly review it and see if
15 this is what you were given to look at?

16 ATTORNEY MICELI: Object. But -- you
17 mean his May 16th deposition. Because he had
18 given one prior, just so we are clear.

19 ATTORNEY SPRAYREGEN: Thank you. I
20 appreciate that. I forgot, and you are
21 absolutely right.

22 ATTORNEY MICELI: All right. Thank
23 you.

24 A. What was the question? Is this the one

1 that I reviewed?

2 BY ATTORNEY SPRAYREGEN:

3 Q. Yes.

4 A. Yes.

5 Q. Can you turn to page -- of the
6 deposition, not of the paper -- 158.

7 A. Okay.

8 Q. You are always ahead of me.

9 And the very last line on page 158 is,
10 the middle of the question:

11 "You'd agree that it's important to
12 also consider the quality of the study when you
13 are looking for an association or trying to
14 infer causation?

15 "Answer: Right. Interpreting the
16 study -- you can't interpret the study results
17 without looking at the study methods. And, in
18 fact, you can argue that you should look at the
19 methods first to decide is this going to be an
20 informative study based on the quality of the
21 work. So if it is a good study, whatever it
22 finds it is worth paying attention to."

23 Did I read that correctly?

24 A. You did.

1 Q. Do you agree with Dr. Savitz's
2 testimony that I just read to you?

3 A. Yes. I mean, I agree with him that you
4 can argue that you should look at the methods
5 first. I don't think you absolutely have to
6 look at the methods first, but I don't think he
7 is saying that either. He is saying you can
8 argue that. But generally I agree with what he
9 said here.

10 Q. Then looking on page 159, starting at
11 line 16. Let me know when you are there.

12 A. I am there.

13 Q. Thanks.

14 So I will represent to you that this is
15 a reference to, I believe -- or I believe this
16 is a reference to one of Dr. Savitz's books.

17 The question, "Do you see where you
18 have a section, See the quality of the study's
19 finding and association?"

20 "Answer: Yes.

21 "And you state there, first of all,
22 epidemiological studies vary substantially in
23 their quality and hence vary in the confidence
24 that can be placed in their results. Right?

1 "Answer: That's correct.

2 "Question: And next you say, even when
3 findings are mixed across studies, some
4 supportive of an effect and others not, if
5 those that are methodologically strongest tend
6 to provide the most support for a potential
7 causal association, the overall weight of
8 evidence tips in that direction. Correct?

9 "Answer: That's correct, yes."

10 Did I read that correctly?

11 A. You did.

12 Q. Do you agree with what Dr. Savitz
13 testified to that I just read to you?

14 ATTORNEY MICELI: Object to the form.

15 A. I do. It is pretty vague that the
16 overall weight of evidence tips in that
17 direction. I don't quite know what that means.
18 But it is not unreasonable.

19 BY ATTORNEY SPRAYREGEN:

20 Q. Can you turn back to your report, which
21 is Exhibit 2?

22 A. Yes.

23 Q. Can you turn to page 2 and look at
24 paragraph 6?

1 A. Okay.

2 Q. Under the heading "Scope and Summary of
3 Opinions" is paragraph 6. And that paragraph 6
4 says, quote, "I have been asked to provide my
5 opinion, to a reasonable degree of scientific
6 certainty, regarding the purpose of and
7 methodological soundness of using meta-analyses
8 in an assessment of the health outcomes from
9 exposures to chemicals."

10 Did I read that correctly?

11 A. You did.

12 Q. So you are not opining in your report
13 on the relationship between TCE, PCE, benzene,
14 or vinyl chloride and any cancer or Parkinson's
15 disease. Is that correct?

16 A. That's correct, I am not.

17 Q. And you did not undertake a Bradford
18 Hill analysis. Is that correct?

19 A. That is correct, I did not.

20 Q. Can you please turn to page 6 of your
21 report.

22 A. Okay.

23 Q. Are you at page 6? You see where
24 paragraph 19 is?

1 A. I do.

2 Q. So at paragraph 19, you write,
3 "Meta-Analysis is the use of statistical
4 methods to summarize the results of multiple
5 independent studies. Per the Cochrane
6 Handbook, by combining information from all
7 relevant studies, meta-analyses can provide
8 more precise estimates of the effects of
9 health" -- excuse me -- "can provide more
10 precise estimates of the effects from chemical
11 exposure than those derived from the individual
12 studies included within a review."

13 Did I actually read that correctly?

14 A. I think so, yes, "the effects of health
15 effects." It is not the most beautiful
16 sentence.

17 Q. And in the sentences that I read is
18 footnote 12. Is that right?

19 A. Yes.

20 Q. And then, at the bottom of the page, in
21 footnote 12, you write, "The 'Cochrane
22 Collaboration'" -- and then you give a
23 website -- "is a global independent network of
24 researchers, professionals, patients, carers,

1 and individuals interested in health. It was
2 established in 1993 with the primary goal of
3 helping people make well-informed decisions
4 about healthcare by preparing, maintaining, and
5 promoting systematic reviews of healthcare
6 interventions. It plays a crucial role in
7 promoting evidence-based medicine and public
8 health practices worldwide." And then you cite
9 a study.

10 Did I read that correctly?

11 A. Yes.

12 Q. Do you consider the "Cochrane Handbook
13 for Systematic Reviews of Interventions" to be
14 authoritative?

15 A. Yes, generally speaking. It doesn't
16 mean that I agree with every last word in
17 there. But as a general matter, it is an
18 authoritative source.

19 (Exhibit 5, Cochrane Training, Chapter 10:
20 Analysing data and undertaking
21 meta-analyses, marked for identification.)

22 BY ATTORNEY SPRAYREGEN:

23 Q. So what we have marked as tab 5 is
24 chapter 10, "Analyzing Data and Undertaking

1 Meta-Analyses," from the website that you
2 listed in your report.

3 Does that seem -- does this look like
4 it would be chapter 10 from the website that
5 you listed in footnote 12 of your report?

6 ATTORNEY MICELI: Object to the form.

7 A. Yes.

8 BY ATTORNEY SPRAYREGEN:

9 Q. So on the first page, the first bullet
10 point says, "Meta-Analysis is the statistical
11 combination of results from two or more
12 separate studies."

13 Did I read that correctly?

14 A. You did.

15 Q. Do you agree with that statement?

16 A. Yes.

17 Q. The next bullet point says, "Potential
18 advantages of meta-analyses include an
19 improvement in precision, the ability to answer
20 questions not posed by individual studies, and
21 the opportunity to settle controversies arising
22 from conflicting claims. However, they have
23 the potential to mislead seriously,
24 particularly if specific study designs,

1 within-study biases, variation across studies,
2 and reporting biases are not carefully
3 considered."

4 Did I read that correctly?

5 A. Yes.

6 Q. Do you agree with bullet point 2?

7 A. Generally, yes. The second clause is,
8 "the ability to answer questions not posed by
9 individual studies."

10 I don't quite follow that.

11 But the rest of it, yes, I generally
12 agree with.

13 Q. Would you criticize a scientist who,
14 when considering a meta-analysis or when doing
15 a meta-analysis, didn't, and I quote from
16 bullet point 2, consider specific study designs
17 within study biases, variation across studies,
18 and reporting biases?

19 ATTORNEY MICELI: Object to the form.

20 A. Would I criticize?

21 BY ATTORNEY SPRAYREGEN:

22 Q. Would you think that that meta-analysis
23 was not properly conducted if the authors did
24 not do the things that Cochrane says should be

1 done?

2 ATTORNEY MICELI: Object to the form.

3 A. Yes, I mean, I generally agree. In the
4 context of a meta-analysis, you need to look
5 at -- it is only as good as the component
6 studies. You need to look at those studies and
7 assess them.

8 BY ATTORNEY SPRAYREGEN:

9 Q. So I believe you have written in
10 your -- this a direct quote from a report.

11 Quote, "A meta-analysis" --

12 ATTORNEY SPRAYREGEN: Withdrawn. I
13 should clarify that. Excuse me.

14 BY ATTORNEY SPRAYREGEN:

15 Q. This is a direct quote from a report
16 that you have written not in this case.

17 "A meta-analysis of poorly conducted,
18 biased, or otherwise uninformative studies does
19 not add to our base of knowledge of an issue.
20 Indeed, such an analysis presents a serious
21 risk of misleading with false or flawed
22 precision."

23 ATTORNEY MICELI: Object to the form.

24 BY ATTORNEY SPRAYREGEN:

1 Q. Is that a statement that you would
2 agree with today?

3 A. Generally, yes.

4 Q. Would you agree that, if the component
5 studies of a meta-analysis are biased, for
6 example, they all have biased measures of
7 exposure assessments, then the results of a
8 meta-analysis will be similarly biased?

9 ATTORNEY MICELI: Object to the form.

10 A. Not necessarily. So it depends. You
11 said specifically if the exposure measurements
12 are biased. So that might or might not lead to
13 bias in the effect size estimation. It
14 depends. So I don't think I could agree to
15 that in complete generality. I think it
16 depends.

17 Actually, can I add to my answer?

18 BY ATTORNEY SPRAYREGEN:

19 Q. Of course.

20 A. I am not entirely sure what -- the
21 term, "biased exposure measurements," is that
22 the phrase? What does that mean?

23 Q. If the assessment of someone's exposure
24 to a chemical is systematically wrong, for

1 example, the exposure assessment systematically
2 says that a person is exposed to more of the
3 chemical than they are, in fact, exposed to.

4 ATTORNEY MICELI: Object to the form.

5 A. I see. Yes, I would expect that would
6 probably translate into bias in the effect size
7 estimate, which is, I think, what actually
8 matters, I suppose.

9 But I am not sure it is absolutely sort
10 of mathematically one follows the other,
11 necessarily. Probably. In general, it would.

12 BY ATTORNEY SPRAYREGEN:

13 Q. So the problem might be my
14 inarticulateness. Could you go back the
15 Taxotere deposition. It is Exhibit 3.

16 A. Yes.

17 Q. And turn to page 121.

18 So on page 121, do you see, on line 19,
19 there is a question.

20 Do you see that?

21 A. I do.

22 Q. "Question: Do you also look at the
23 reliability of studies when conducting a
24 meta-analysis?"

1 "Answer: Absolutely, yeah, you
2 consider each of the trials individually that
3 you're including.

4 "Question: Okay. Would you agree that
5 it's not appropriate to blindly combine studies
6 and lump them into a meta-analysis and expect
7 it to yield truth?

8 "Mr. Miceli: Object to the form.

9 "Answer: Well, yielding truth is a
10 lofty goal, but, no, of course, you don't
11 blindly combine studies, whatever that means.

12 "Question: (By Mr. McRae) And if there
13 are concerns in the individual underlying
14 studies, then the meta-analysis will inherit
15 those concerns. Right?

16 "Mr. Miceli: Object to the form.

17 "Answer: Generally. I don't know what
18 you mean by 'concern' exactly, but -- but,
19 yeah, I mean, the meta-analysis embodies the
20 individual studies.

21 "Question: (By Mr. McRae) Okay.
22 Yeah. And performing a meta-analysis doesn't
23 cure those concerns. Right?

24 "Answer: So I don't know what I mean

1 by 'concern' exactly, but, you know, if there
2 is a fatal flaw, you know, a study that's
3 included in the meta-analysis, then the
4 meta-analysis inherits that flaw, whatever that
5 means.

6 "Question: Okay. If there are
7 concerns about bias in the individual studies,
8 will the meta-analysis inherit those concerns?

9 "Mr. Miceli: Object to the form.

10 "Answer: In general, yes."

11 Did I read that correctly?

12 A. You did.

13 Q. Do you agree with the testimony that
14 you gave that I just read to you?

15 ATTORNEY MICELI: Object to the form.

16 A. I do.

17 BY ATTORNEY SPRAYREGEN:

18 Q. What is heterogeneity in a
19 meta-analysis?

20 A. So generally speaking, that refers to
21 the differences between the effect sizes from
22 the component studies, if any.

23 Q. Can you please go back to the Cochrane
24 Handbook, which is Exhibit 5.

1 A. Okay.

2 Q. And turn to page 18.

3 A. Okay.

4 Q. And at the bottom of the page, you see
5 the box which says, "C62, ensuring
6 meta-analyses are meaningful (mandatory)"?

7 A. Sorry. Say again.

8 Q. Sure. I am on page 18, and there is a
9 box at the bottom of the page.

10 A. Yes, I am there.

11 Q. And then at the very -- the heading of
12 the box, if you will, it says, "C62, ensuring
13 meta-analyses are meaningful (mandatory)."

14 Do you see that?

15 A. I do.

16 Q. Then in that box, in the second column,
17 it says, "Meta-analyses of very diverse studies
18 can be misleading, for example where studies
19 use different forms of control."

20 Did I read that correctly?

21 A. Yes.

22 Q. And my understanding is that the word
23 "control" there refers to control populations.
24 Is that right?

1 ATTORNEY MICELI: Object to the form.

2 ATTORNEY SPRAYREGEN: I can withdraw
3 the question.

4 BY ATTORNEY SPRAYREGEN:

5 Q. What do they mean when they say -- when
6 studies use different forms of control?

7 ATTORNEY MICELI: Object to the form.

8 A. So they could mean the comparator.
9 Right? So you are studying an intervention of
10 some sort. They could mean, if different
11 studies compare the intervention with different
12 controls, that might or might not be a problem.
13 But it might be. So something -- certainly
14 something you would want to look at.

15 I guess they could mean statistical
16 control as well, like different statistical
17 adjustment methods in different studies.
18 Again, that is something that might or might
19 not be a problem, but you would want to look at
20 it.

21 They probably mean the former rather
22 than the latter, but I can't be certain.

23 BY ATTORNEY SPRAYREGEN:

24 Q. Can you tell me what you think they

1 probably mean?

2 ATTORNEY MICELI: Object to the form.

3 BY ATTORNEY SPRAYREGEN:

4 Q. You said they probably mean the former,
5 not the latter. What is the former?

6 A. The former meaning, they probably are
7 referring to, if the component studies in a
8 meta-analysis, let's say, they are -- all the
9 studies concern a specific intervention. But
10 one study compares it to one particular -- a
11 different intervention and another study -- let
12 me use letters.

13 So the intervention is called A, and
14 one study compares A versus B and a different
15 study compares A versus C. That might -- it
16 all depends, but that might be problematic.

17 I think that -- that would be my most
18 probable explanation for what they are meaning
19 there. I can think of other ones, but I bet
20 that is what they are thinking.

21 Q. Thank you.

22 And then turning a few pages to
23 page 20.

24 A. Sorry. Same document?

1 Q. Yes, we are staying with the same
2 document, the Cochrane in chapter 10,
3 "Analyzing Data and Understanding
4 Meta-Analyses."

5 A. Okay.

6 Q. Under Section 10.10.3, "Strategies For
7 Addressing Heterogeneity," the authors write,
8 "Review authors must take into account any
9 statistical heterogeneity when interpreting
10 results, particularly when it variation in the
11 direction of effect."

12 Did I read that correctly?

13 A. Yes.

14 Q. Do you agree with that statement?

15 A. I certainly agree with the first part,
16 "Review authors must take into account any
17 statistical heterogeneity when interpreting
18 results." That is perfectly reasonable.

19 "Particularly when there is variation
20 in the direction of effect," I don't know. Not
21 necessarily. There is -- you just should take
22 it into account, statistical heterogeneity,
23 period.

24 Q. On the next page, the authors talk

1 about strategies when there is heterogeneity.
2 And the first one is, "Check again that the
3 data are correct."

4 Do you agree with that?

5 A. That is not unreasonable, yes.

6 Q. The second one is, "Do not do a
7 meta-analysis. A systematic review need not
8 contain any meta-analyses. If there is
9 considerable variation in results, and
10 particularly if there is inconsistency in the
11 direction of effect, it may be misleading to
12 quote an average value for the intervention
13 effect."

14 Did I read that correctly?

15 A. You did.

16 Q. Do you agree with that statement?

17 A. Yes. It may be misleading, is what
18 they are saying here, to quote an average
19 value. Sure, it may be, but not necessarily.
20 It all depends.

21 Q. And then staying on page 21, the third
22 point is, "Explore Heterogeneity. It is
23 clearly of interest to determine the causes of
24 heterogeneity among results of studies. This

1 process is problematic since there are often
2 many characteristics that vary across studies
3 from which one may choose. Heterogeneity may
4 be explained by conducting subgroup analyses or
5 meta regression."

6 Did I read that correctly?

7 A. You didn't, actually.

8 You said "explained" rather than
9 "explored."

10 Q. That is a big one.

11 With the substitution of "explored" for
12 "explained," did I read that correctly?

13 A. Yes.

14 Q. Do you agree with the statement as
15 written?

16 A. So, "It is clearly of interest to
17 determine the causes of heterogeneity among
18 results of studies." Sure. Agree with that.

19 "This process is problematic." What
20 process? I am a little confused there.

21 "Since there are often many
22 characteristics that vary across studies from
23 which one may choose." That is a bit twisted.
24 I am not arguing against it. I am not entirely

1 sure what it means. I certainly agree with the
2 first sentence. It is clearly of interest to
3 determine the causes of heterogeneity.

4 Q. Do you agree with the third sentence,
5 "Heterogeneity may be explored by conducting
6 subgroup analyses or meta regression"?

7 A. Sure. In general, they are the kinds
8 of things that one can do when trying to
9 explore -- in the face of heterogeneity, you
10 are trying to understand it, and they are
11 absolutely reasonable things that one might do.

12 I guess they mean the process of
13 determining the causes of heterogeneity. That
14 is what I suppose is what they mean, now that I
15 read it again. But they say it is problematic.
16 I would say it can be challenging would be a
17 better word than "problematic."

18 Q. I agree with you, after you made that
19 comment that that sentence was not clear. I
20 was also most interested in the first and third
21 sentence.

22 A. Okay.

23 ATTORNEY SPRAYREGEN: I am going mark
24 Exhibit number 6.

1 (Exhibit 6, General Causation report of
2 Peter G. Shields, M.D., dated 2-7-25,
3 marked for identification.)

4 BY ATTORNEY SPRAYREGEN:

5 Q. So Exhibit 6 are the first 245 pages of
6 Dr. Shields's report, which, in the interest of
7 saving some trees, I stopped at page 245.

8 Could you turn please to page 38.

9 A. Okay.

10 Q. In the middle of the --

11 ATTORNEY SPRAYREGEN: Withdrawn.

12 BY ATTORNEY SPRAYREGEN:

13 Q. In the second full paragraph, 13 lines
14 down, there is a sentence that begins with
15 "Caution."

16 Do you see that?

17 A. Yes.

18 Q. The report says, "Caution is needed
19 when determining what type of studies are
20 combined (e.g., grouping cohort and
21 case-control studies together) and how
22 heterogeneous they are (one of the statistical
23 assessments)."

24 Did I read that correctly?

1 A. You did.

2 Q. Do you agree with that sentence?

3 A. "Caution is needed," dot, dot, dot.

4 Before going any further, caution is
5 always needed. It is kind of a nothing-burger.
6 I mean, caution is needed. Yes, I agree.

7 "When determining what type of studies
8 are combined." Sure.

9 Then the parenthetical example,
10 "Grouping cohort and case-control studies
11 together," not sure why he is highlighting
12 that. I mean, just caution is always needed
13 when conducting analysis, not just
14 meta-analysis.

15 And then caution is needed in terms of
16 how heterogeneous they are. Agreed.

17 Q. Then the next sentence is, "For
18 example, it is problematic to combine case
19 control and cohort studies."

20 Do you see that?

21 A. I see that.

22 Q. If that sentence read, "It is
23 problematic to combine case control and cohort
24 studies without also analyzing each

1 separately," would you agree with that
2 statement?

3 ATTORNEY MICELI: Object to the form.

4 A. That is kind of a non-sequitur then.
5 Right? You always want to examine the
6 individual studies, always. So there is no
7 need for, in this context, you analyze the
8 individual studies. You always look at the
9 individual studies.

10 BY ATTORNEY SPRAYREGEN:

11 Q. What I am talking about is doing a
12 separate forest plot or meta-analysis, if you
13 will, of the case-control studies and also a
14 separate analysis of the cohort studies before
15 determining that you will be putting them all
16 together in one meta-analysis.

17 ATTORNEY MICELI: Excuse me. Is that a
18 question?

19 BY ATTORNEY SPRAYREGEN:

20 Q. Would you agree that that is a proper
21 methodology to use when conducting
22 meta-analyses?

23 ATTORNEY MICELI: Object to the form.

24 A. So that is not what this says. Okay?

1 I hear what you said and I will answer. But
2 just so we are clear, that is -- all that is
3 being stated here is caution is needed. Right?

4 But to the point -- the question, since
5 you asked, you can do that. I am not opposed
6 to doing -- looking at the -- if there are case
7 control and cohort studies being combined in a
8 meta-analysis, it is not unreasonable to look
9 at them separately. You can. I wouldn't -- I
10 wouldn't say you have to do it in every case.

11 BY ATTORNEY SPRAYREGEN:

12 Q. Can you go back to your report, which
13 is Exhibit 2. Please turn to page 9.

14 A. Okay.

15 Q. And this concerns the sentences we have
16 been discussing. You write on page 9 --

17 A. Sorry. I am on the wrong page 9.

18 ATTORNEY MICELI: You are at page 9 of
19 Exhibit 2, now?

20 A. Yes, I am there.

21 ATTORNEY SPRAYREGEN: Correct.

22 ATTORNEY MICELI: I just want to make
23 sure I am following you as well.

24 ATTORNEY SPRAYREGEN: Yes, yes.

1 BY ATTORNEY SPRAYREGEN:

2 Q. You there?

3 A. Yes.

4 Q. So the third statement you make related
5 to -- that starts with Shields talking about --

6 ATTORNEY SPRAYREGEN: Withdrawn.

7 BY ATTORNEY SPRAYREGEN:

8 Q. The third, I think, full paragraph or
9 grouping on the page, if you will, says,
10 "Shields: States without citation: 'It is
11 problematic to combine case-control and cohort
12 studies.' Madigan: Many published,
13 peer-reviewed meta-analyses include both cohort
14 and case-control studies. Here are healthcare
15 examples."

16 And then you list three papers.

17 Did I accurately reflect what is on
18 page 9 of your report?

19 A. Yes.

20 Q. Are you aware that, in all three of the
21 studies you cite, the authors separately
22 analyzed the cohort and case-control studies?

23 A. No. It could be. I have no problem
24 accepting that, but I was not aware, or I

1 didn't remember.

2 ATTORNEY SPRAYREGEN: We have been
3 going, I think, for about an hour. Would you
4 like to take a break or keep going?

5 ATTORNEY MICELI: Whatever you like.

6 THE WITNESS: Happy to keep going for a
7 while.

8 ATTORNEY SPRAYREGEN: Do you know what?
9 I would like to take a 10-minute break.

10 THE VIDEOGRAPHER: The time is
11 10:52 a.m., and we are off the record.

12 (Recess taken at 10:52 a.m.)

13 (Recess ended at 11:11 a.m.)

14 THE VIDEOGRAPHER: The time is
15 11:11 a.m., and we are on the record.

16 BY ATTORNEY SPRAYREGEN:

17 Q. Can you turn to your report, page 6,
18 paragraph 19.

19 ATTORNEY MICELI: Are we done with
20 Shields for now?

21 ATTORNEY SPRAYREGEN: For now, but we
22 will be going back to that one.

23 ATTORNEY MICELI: Yes, I just want to
24 make sure I clip it back together.

1 You said page 9 of his report?

2 ATTORNEY SPRAYREGEN: I said page 6,
3 paragraph 19.

4 ATTORNEY MICELI: All right.

5 BY ATTORNEY SPRAYREGEN:

6 Q. So in paragraph 19, the fifth line
7 down, there is a sentence that says, "They" --
8 which is referring to meta-analyses -- "also
9 facilitate investigations of the consistency of
10 evidence across studies and the exploration of
11 differences across studies."

12 Do you see that?

13 A. I do.

14 Q. Did I read that correctly?

15 A. Yes.

16 Q. How do you --

17 ATTORNEY SPRAYREGEN: Withdrawn.

18 BY ATTORNEY SPRAYREGEN:

19 Q. You said you didn't do a Bradford Hill
20 analysis for this report. Right?

21 A. Correct.

22 Q. But you have done them in the past. Is
23 that right?

24 A. Yes.

1 Q. How do you use a meta-analysis when
2 evaluating consistency in a Bradford Hill
3 analysis?

4 ATTORNEY MICELI: Objection to the
5 form.

6 A. I don't understand the question. What
7 has Bradford Hill got to do with it?

8 BY ATTORNEY SPRAYREGEN:

9 Q. One of the considerations or factors,
10 whatever word we want to use, for criteria,
11 Bradford Hill is consistency. Right?

12 A. Right.

13 Q. How do you view the use of
14 meta-analyses when determining whether or not
15 the consistency factor in Bradford Hill is met?

16 ATTORNEY MICELI: Object to the form.

17 A. I mean, I suppose, first of all, in
18 terms of doing -- you are calling it Bradford
19 Hill -- a Hill analysis; Bradford is his middle
20 name. So he calls it Bradford Hill, always
21 strikes me as odd.

22 So in a Hill analysis, the consistency,
23 like, doesn't -- there is no -- you can do a
24 Bradford Hill analysis without doing a

1 meta-analysis. Right? There is no particular
2 need to do -- one might, one might not. So,
3 like, one doesn't go with the other,
4 necessarily.

5 So that is why I am kind of struggling
6 a bit here. Like, if you asked me the question
7 without mentioning Bradford Hill, maybe it
8 wouldn't make any difference to my answer.

9 Just in the context of a situation
10 where you have got multiple studies addressing
11 the same question, an obvious thing to do is to
12 look at the consistency -- an obvious and
13 necessary thing to do is to look at the
14 consistency of the findings in those studies.

15 And the process of meta-analysis sort
16 of services that. So, for example, one
17 typically does a forest plot. Once you do the
18 forest plot, you immediately get some insight,
19 not the only tool, but you get some insight
20 into the consistency across the studies. None
21 of that has anything to do with Bradford Hill,
22 though, in my mind.

23 You might do that in the context of a
24 Hill analysis, but you might not.

1 BY ATTORNEY SPRAYREGEN:

2 Q. When you have done a Hill analysis and
3 you are evaluating the consistency of
4 associations across studies, have you ever used
5 a meta-analysis?

6 ATTORNEY MICELI: Object to the form.

7 A. Probably. I am struggling to pull an
8 example out of my head. Maybe.

9 BY ATTORNEY SPRAYREGEN:

10 Q. As you sit here today, you can't think
11 of an example. Is that correct?

12 A. An example where I was doing a Hill
13 analysis and, as part of that, I did a
14 meta-analysis? Is that the question?

15 Q. As part of your evaluation of the
16 consistency factor or criteria, you used a
17 meta-analysis in some way.

18 A. My memory is just not that good. I may
19 have. Entirely possible I have. I just can't
20 recall sitting here this minute.

21 Q. But I just want to make sure I
22 understand, sitting here right now, you can't
23 recall ever using a meta-analysis in
24 conducting -- when examining the consistency

1 criteria in a Bradford Hill analysis?

2 A. I can't recall with accuracy.

3 I may have done one in -- I published
4 work related to ovarian -- asbestos talc and
5 ovarian cancer. May have done a meta-analysis
6 there. I just can't remember.

7 Q. Is there a particular paper or
8 litigation that you are thinking of?

9 A. It is a paper. It is a published
10 paper.

11 Q. What is the title of the paper?

12 A. It is paper number 184 in my CV. It is
13 called, "Evidence that cosmetic talc is a cause
14 of ovarian cancer."

15 ATTORNEY MICELI: Which number was
16 that?

17 A. 184.

18 You understand, I am not saying I know
19 for a fact there is a meta-analysis in it.
20 There might or might not be. I can't remember.
21 I have done meta-analysis in this context. I
22 may have included it in that paper. I just
23 can't recall.

24 BY ATTORNEY SPRAYREGEN:

1 Q. You may have included it when
2 evaluating the consistency criteria?

3 A. It is possible. I just can't remember.

4 Q. Any others?

5 ATTORNEY MICELI: Object to the form.

6 A. Not that I can recall here. I have not
7 published very many Hill analyses. So no, not
8 that I can recall, to answer your question.

9 BY ATTORNEY SPRAYREGEN:

10 Q. When you have seen others evaluate the
11 consistency criteria, in doing a Bradford Hill
12 analysis, have you seen other researchers use
13 meta-analyses?

14 ATTORNEY MICELI: Object to the form.
15 Foundation.

16 A. I am sure I have. But I know what your
17 next question is going to be. So which ones?
18 I just don't recall.

19 ATTORNEY SPRAYREGEN: I am going to
20 introduce Exhibit number 7.

21 Which one was 6?

22 THE WITNESS: 6 was the Shields report.

23 (Exhibit 7, Excerpt from "Epidemiology and
24 the Law", marked for identification.)

1 BY ATTORNEY SPRAYREGEN:

2 Q. So Exhibit number 7 is a chapter from
3 Dr. Savitz's book, "Epidemiology and the Law."

4 Have you read that book?

5 A. I don't have this book. I may have
6 looked at it over the years. I don't recall.
7 I am aware of the book.

8 Q. Can you please turn to page, of the
9 book, 111.

10 A. Okay.

11 Q. If you look at the first full
12 paragraph, it says -- it starts with,
13 "Another."

14 Do you see that?

15 A. I do.

16 Q. "Another feature of meta-analysis that
17 can be problematic concerns the extraction of
18 selected results from each study in an effort
19 to produce comparable findings. Epidemiology
20 studies typically produce an array of findings
21 that collectively contribute to an
22 understanding of the relationship between
23 exposure and disease. They may use different
24 exposure metrics, control for different

1 factors, or apply different analytic methods,
2 all within the same study. Scrutiny of the
3 array of findings within a study is often of
4 great value and that ability is lost when only
5 isolated results are considered. The decision
6 about which findings to extract from each study
7 also leaves room for inconsistent, arbitrary
8 selection across studies, i.e., cherry-picking.
9 The desire for simplicity is understandable and
10 it is simpler to summarize an entire study with
11 one number. But the cost of that simplicity
12 can be a substantial loss of information and a
13 misleading result."

14 Did I read that correctly?

15 A. You did.

16 ATTORNEY MICELI: Object to the form.
17 I think you said "epidemiology" and it is
18 "epidemiologic," but I don't think it makes a
19 difference to how you read it.

20 ATTORNEY SPRAYREGEN: Thank you.

21 BY ATTORNEY SPRAYREGEN:

22 Q. With that substitution, did I read it
23 correctly?

24 ATTORNEY MICELI: Yes.

1 A. Yes.

2 ATTORNEY SPRAYREGEN: Thank you. I
3 actually had a hard time seeing it.

4 ATTORNEY MICELI: Wait until you get
5 older.

6 BY ATTORNEY SPRAYREGEN:

7 Q. Do you agree with that paragraph that
8 Dr. Savitz wrote?

9 ATTORNEY MICELI: Object to the form.
10 Foundation.

11 (Pause.)

12 A. It feels a little -- I basically agree
13 with it. In the component studies, if there
14 are different statistics summarizing an effect
15 size, that can be interesting and, yes, it is
16 lost when you do a meta-analysis. But by
17 definition, you extract one effect size out of
18 a paper. That is true.

19 But it is important, for example, to
20 be, when you are doing a meta-analysis, to be
21 consistent about which statistic you pull from
22 papers, and -- so I think that is in the spirit
23 of what he is saying here.

24 Have I answered the question? I

1 generally agree with that.

2 BY ATTORNEY SPRAYREGEN:

3 Q. Right. You said specifically that you
4 generally agree with it, and then you noted two
5 specific things that you agree with. Is that
6 correct?

7 A. Two things?

8 ATTORNEY SPRAYREGEN: Withdrawn.

9 Could you read back Dr. Madigan's
10 answer?

11 (The prior testimony was then read back
12 as follows:

13 "Answer: I basically agree with it.
14 In the component studies, if there are
15 different statistics summarizing an effect
16 size, that can be interesting and, yes, it is
17 lost when you do a meta-analysis. But by
18 definition, you extract one effect size out of
19 a paper. That is true.

20 But it is important, for example, to
21 be, when you are doing a meta-analysis, to be
22 consistent about which statistic you pull from
23 papers, and -- so I think that is in the spirit
24 of what he is saying here.

1 Have I answered the question? I
2 generally agree with that.")

3 BY ATTORNEY SPRAYREGEN:

4 Q. So in that answer, one of the things
5 you said was, "It is important to be consistent
6 about which statistic you pull from papers of
7 the component studies."

8 That is a statement you agree with?

9 A. Yes.

10 Q. And if --

11 ATTORNEY SPRAYREGEN: Withdrawn.

12 BY ATTORNEY SPRAYREGEN:

13 Q. What is publication bias?

14 A. Sorry. Are we --

15 Q. We are moving on.

16 A. So publication bias usually refers to
17 the notion that some studies are done that
18 don't get published and, therefore, might not
19 be available for a meta-analysis. And insofar
20 as those unpublished studies are different from
21 the published studies, that is a concern.

22 Different systematically. I don't mean
23 different from -- just random differences. I
24 mean just what I said. If they differ

1 systematically, that is a concern.

2 Q. Would you agree that studies with
3 positive findings are more likely to be
4 published than studies that do not have
5 positive findings?

6 ATTORNEY MICELI: Object to the form.

7 ATTORNEY SPRAYREGEN: I understand. I
8 am trying to think of a better way to phrase
9 the positive results.

10 BY ATTORNEY SPRAYREGEN:

11 Q. But I think you know what I am getting
12 at.

13 Studies that show an effect in some way
14 are more likely to be published than studies
15 that show a lack of an effect?

16 A. I am obviously aware that people say
17 that. Maybe. I don't know. I don't have any
18 hard data to establish that one way or another.
19 But it may be true.

20 Q. Have you heard of the NCI cohort
21 studies of benzine?

22 A. I read about them in at least one of
23 the reports.

24 ATTORNEY SPRAYREGEN: So I believe we

1 are now marking Exhibit 8.

2 (Exhibit 8, Chapter 8 of
3 "Trichloroethylene, Perchloroethylene,
4 Benzene, Vinyl Chloride, and
5 trans-1,2-Dichloroethylene Exposure and
6 Leukemia Risk" by Julie E. Goodman, Ph.D.,
7 dated 2-7-25, marked for identification.)

8 ATTORNEY MICELI: This is a very
9 limited portion of her report.

10 BY ATTORNEY SPRAYREGEN:

11 Q. Exhibit 8 is an except of Dr. Goodman's
12 report and includes the table of contents as
13 well as the chapter on leukemia.

14 Can you please turn to page 79.

15 A. I am sorry. Is this a Goodman report
16 that I have seen?

17 Q. So this --

18 A. Sorry.

19 Q. So I am not sure if anyone is going to
20 object to my making this statement. As I said,
21 Dr. Goodman wrote a number of reports. One of
22 her reports was this title, "Trichloroethylene,
23 Perchloroethylene, Benzene, Vinyl Chloride, and
24 trans-1,2-Dichloroethylene Exposure and

1 Leukemia Risk."

2 And Exhibit 8 is the -- and it includes
3 the table of contents. And then if you go
4 to -- it is chapter 8, and if you go to the --
5 in the table of contents, the chapter 8 that
6 says "Benzine and Leukemia," Exhibit number 8
7 is all of chapter 8 from the Goodman leukemia
8 report.

9 A. Got it. Thank you.

10 ATTORNEY MICELI: Let me just object to
11 the incomplete exhibit. And I don't object to
12 the representation. It appears to be table of
13 contents and Section 8, chapter 8, whatever you
14 want to call it, of Dr. Goodman's -- at least
15 part of chapter 8 of her report. Leukemia
16 report.

17 BY ATTORNEY SPRAYREGEN:

18 Q. I believe I got the page wrong. It is
19 on page 78.

20 (Pause.)

21 Q. My bad. Staying on page 79, in the top
22 paragraph, the third line down. The National
23 Cancer Institute-Chinese Academy of
24 Preventative Medicine NCI-CAPM study, and then

1 there is a cite, "Cohort had a wide variety of
2 occupations, allowing for an evaluation of a
3 wide range of benzene exposures."

4 Did I read that correctly?

5 A. You did.

6 Q. You said you had heard of the NCI
7 studies before?

8 ATTORNEY MICELI: Object to the form.

9 A. Just in the context of either Shields
10 or Goodman. I can't remember which one.

11 BY ATTORNEY SPRAYREGEN:

12 Q. Understood. Thank you.

13 And then, if you turn to page 78, the
14 second paragraph is talking about the Pliofilm
15 process.

16 It says, "In these studies, workers
17 were evaluated in the 'Pliofilm' process during
18 which natural rubber was dissolved and refined
19 benzene and processed by being spread out on a
20 conveyor belt system," and then it gives a
21 number of studies.

22 "This cohort included workers exposed
23 to benzene for at least one day between 1940
24 and 1975. Studies of the Pliofilm cohort are

1 of particularly high quality because the
2 participants were exposed to a wide range of
3 benzene exposure levels and had minimal
4 occupational coexposures to other potential
5 carcinogens," and then there is a cite to ATSDR
6 2024a.

7 Did I read that correctly?

8 A. Yes.

9 Q. So in reading Dr. Shields's and
10 Dr. Goodman's reports, was it your impression
11 that the NCI cohort study and the Pliofilm
12 studies were high quality studies?

13 ATTORNEY MICELI: Objection to the
14 form.

15 A. I don't recall.

16 BY ATTORNEY SPRAYREGEN:

17 Q. So if these studies -- this is a
18 hypothetical. If these studies evaluated but
19 didn't publish results on kidney cancer because
20 such result were null, that could lead to
21 publication bias in a meta-analysis. Is that
22 right?

23 ATTORNEY MICELI: Object to the form.
24 Foundation.

1 A. It all depends. I mean -- just that.
2 It might or might not introduce bias. It
3 might.

4 (Exhibit 9, Article entitled "A
5 retrospective cohort study of
6 cause-specific mortality and incidence of
7 hematopoietic malignancies in Chinese
8 benzene-exposed workers" dated 2015, marked
9 for identification.)

10 ATTORNEY MICELI: Are we done with 8,
11 for now?

12 ATTORNEY SPRAYREGEN: Not quite.

13 BY ATTORNEY SPRAYREGEN:

14 Q. And looking back in Exhibit 8, that is
15 the Goodman chapter on leukemia, when
16 discussing the NCI studies, she mentioned that
17 the Linet 2015 was one of those studies.

18 It is on page 79. Is that right?

19 A. Sorry. What I am tripping over here is
20 I see the reference on page 79 to Linet. But
21 your question is?

22 Q. My question was, the Linet paper, the
23 2015 paper that I introduced as Exhibit 9,
24 is -- or I will represent -- I asked if you saw

1 the reference to --

2 ATTORNEY SPRAYREGEN: Withdrawn.

3 BY ATTORNEY SPRAYREGEN:

4 Q. I am trying to just say that the Linet
5 paper that I introduced as Exhibit 9 is the one
6 that is referenced in Dr. Goodman's report.
7 But there is no title in her report. So it
8 does say Linet 2015 when talking about the NCI
9 studies.

10 So my question was just, did she talk
11 about the Linet 2015 when she talked about the
12 NCI studies?

13 ATTORNEY MICELI: Object to the form.
14 Foundation. I will stipulate that she cites to
15 Linet, et al., 2015, 2019, and 2020. We don't
16 know that Exhibit 9 is the -- only 2015
17 paper --

18 ATTORNEY SPRAYREGEN: Thank you.

19 ATTORNEY MICELI: -- by Linet, but it
20 is a Linet 2015 paper.

21 ATTORNEY SPRAYREGEN: Thank you.

22 BY ATTORNEY SPRAYREGEN:

23 Q. And the title of Exhibit 9 is, "A
24 retrospective cohort study of cause-specific

1 mortality and incidence of hematopoietic
2 malignancies in Chinese benzene-exposed
3 workers."

4 Is that right?

5 A. Yes.

6 Q. If you turn page 2189. It is table 2.

7 A. Okay.

8 Q. There are some lines that are
9 highlighted.

10 Do you see that?

11 A. I do.

12 Q. Table 2 says, "Relative risk of
13 mortality among Chinese benzene-exposed versus
14 unexposed workers following up during 1972 to
15 1999 by or according to cause of death."

16 Is that correct?

17 ATTORNEY MICELI: Object to the form.

18 A. You read that correctly, yes.

19 BY ATTORNEY SPRAYREGEN:

20 Q. And among the causes of mortality that
21 are investigated is esophagus with a code of
22 150. Right?

23 A. I see that.

24 Q. Stomach with a code of -- or excuse

1 me -- an ICD-9 code of 151.

2 A. I see that.

3 Q. Colon/rectum with an ICD-9 code of 153
4 and 154. Right?

5 A. Yes.

6 Q. Liver with an ICD-9 code of 155, 156.
7 Right?

8 A. Yes.

9 Q. Pancreas with an ICD-9 code of 157.
10 Yes?

11 A. Yes.

12 Q. Lung with an ICD code of 162. Right?

13 A. Yes.

14 Q. Female breast with an ICD-9 code of
15 174. Right?

16 A. Yes.

17 Q. Uterus with an ICD-9 code of 182.
18 Right?

19 A. Correct.

20 Q. And bladder with an ICD-9 code of 188.
21 Right?

22 A. Yes.

23 Q. So this paper does not appear to look
24 at kidney cancer but does look at a number of

1 other cancers. Is that right?

2 A. That appears to be the case.

3 Q. So if these authors didn't publish any
4 results on kidney cancer, but, in fact, had
5 done a study and saw that they had null
6 results, would that lead -- could that lead to
7 publication bias that would affect a
8 meta-analysis?

9 ATTORNEY MICELI: Object to the form.
10 Foundation.

11 A. So there are several studies in here
12 that are null. So the proposition seems a
13 little improbable.

14 But if a study is excluded from an
15 meta-analysis because it is, quote/unquote,
16 null, whatever that means, but if a study is
17 excluded from a meta-analysis because of its
18 findings, that the analyst doesn't like it,
19 that is a problem.

20 BY ATTORNEY SPRAYREGEN:

21 Q. I am focusing on something else.

22 A meta-analysis only looks at published
23 studies. Right?

24 A. Not always, but in many cases, yes.

1 Q. When meta-analyses only looked at
2 published studies, if published studies are
3 more likely to have findings, could the
4 meta-analyses be biased?

5 ATTORNEY MICELI: Object to the form.

6 A. So if it is the case that the
7 unpublished studies are systematically
8 different, higher estimate or lower estimate,
9 for example, if they are systematically
10 different from the published studies, that
11 could be a problem.

12 BY ATTORNEY SPRAYREGEN:

13 Q. Okay. And you are not agreeing to the
14 fact that studies with positive or some effect
15 are more likely to be published than studies
16 with no effect. Is that correct?

17 ATTORNEY MICELI: Object to the form.

18 A. I have seen people say that. I do not
19 know if that is true or not.

20 ATTORNEY SPRAYREGEN: You can put that
21 aside.

22 ATTORNEY MICELI: When you say "put
23 that aside," 8 and 9, or just 9?

24 ATTORNEY SPRAYREGEN: 8 and 9.

1 ATTORNEY MICELI: Okay. Thank you.
2 Just trying to keep mine in order.

3 ATTORNEY SPRAYREGEN: Understood. And
4 very good practice, given this deposition.

5 (Exhibit 10, Article entitled "Occupational
6 benzene exposure and risk of kidney and
7 bladder cancers: A systematic review and
8 meta-analysis" dated 2024, marked for
9 identification.)

10 ATTORNEY MICELI: Is this 10, or 10 and
11 11? Because it looks like there is a
12 supplemental table.

13 ATTORNEY SPRAYREGEN: This is
14 Exhibit 10. I am just including the
15 supplemental table as part of the exhibit.

16 ATTORNEY MICELI: Okay. Is this the
17 only supplemental table? Just so we know
18 whether or not it is a complete. You are the
19 master of your exhibit, don't worry. We will
20 worry about it later.

21 ATTORNEY SPRAYREGEN: I believe the
22 exhibit has all of the supplemental tables,
23 though I will be focusing on one of them.

24 ATTORNEY MICELI: Okay. Thank you.

1 ATTORNEY SPRAYREGEN: At least that was
2 the intention.

3 BY ATTORNEY SPRAYREGEN:

4 Q. So Exhibit 10 is a paper by
5 Seyyedsalehi. Do you know how to pronounce
6 that, by the way?

7 ATTORNEY MICELI: No, but we can go
8 with Salehi if you want.

9 ATTORNEY SPRAYREGEN: Seyyedsalehi.

10 BY ATTORNEY SPRAYREGEN:

11 Q. It is a paper by Seyyedsalehi entitled,
12 "Occupational benzene exposure and risk of
13 kidney and bladder cancers: A systematic
14 review and meta-analysis," as well as the
15 supplemental tables to that article.

16 Did I read the title of the paper
17 correctly?

18 A. Yes.

19 Q. So based on the title of the paper, it
20 examines occupational exposures, not drinking
21 water studies. Does that sound right?

22 A. That seems to be the case.

23 Q. If occupational exposures to benzene
24 are higher than the levels at Camp Lejeune,

1 then this study may not be applicable to a
2 causal determination of whether benzene at the
3 levels at Camp Lejeune can cause kidney cancer.
4 Is that right?

5 ATTORNEY MICELI: Object to the form.

6 A. Not necessarily. It depends on the
7 nature of the association between benzene
8 exposure and cancers as to whether the
9 statement you made is true or not.

10 BY ATTORNEY SPRAYREGEN:

11 Q. Would you agree that the paper is not,
12 in itself, sufficient to determine that benzene
13 at levels of Camp Lejeune can cause kidney
14 cancer?

15 ATTORNEY MICELI: Object to the form.
16 Foundation.

17 A. I have no idea. I don't know what the
18 levels are at Camp Lejeune, and I don't know
19 what the occupational levels are. I don't know
20 if it makes any difference that they are
21 different, if they are different.

22 BY ATTORNEY SPRAYREGEN:

23 Q. Can you turn to page 6. Ignore the
24 highlighting in the first column. And in the

1 second column on page 6, in the paragraph
2 continued from the first column at the very
3 bottom, do you see that some wording is
4 highlighted?

5 A. (Witness pointing.)

6 Q. No. Yes.

7 A. Okay.

8 Q. The highlighted wording, which was done
9 by me, in the paragraph continuing from the
10 first column on page 6 is, "Furthermore, our
11 meta-analysis revealed significant differences
12 in kidney cancer risk within the industry of
13 employment with a higher risk in studies
14 conducted in the chemical industry. This
15 observation suggests that individuals working
16 in this sector might be exposed to higher
17 levels of benzene directly compared with other
18 job titles. However, this result can be due to
19 chance because of multiple comparisons."

20 Did I read that correctly?

21 A. You did.

22 Q. Would you agree that this sentence is
23 saying that levels of benzene may have an
24 effect on the results?

1 ATTORNEY MICELI: Object to the form.

2 A. Yes, it is a speculation. He is
3 just -- I guess he is saying that the kidney
4 cancer risk varied across industries. And then
5 he speculates that the industries in which the
6 risk is higher, maybe there were higher
7 exposures. That is how I read this.

8 Q. I want you to turn to the supplement
9 now.

10 I want to go to table 4 of the
11 supplement.

12 ATTORNEY SPRAYREGEN: And to answer
13 your question earlier, Dave, I believe this is
14 all of the tables because, as you can see,
15 table 4 is at the end.

16 ATTORNEY MICELI: Right. Okay.

17 BY ATTORNEY SPRAYREGEN:

18 Q. Are you at table 4?

19 A. I am.

20 Q. And table 4 of the supplement is
21 titled, "Results on dose response
22 relationship." Is that correct?

23 A. Yes.

24 Q. And then it is divided between cancer

1 types. The top four studies are kidney and
2 then the bottom studies are bladder. Is that
3 right?

4 A. Yes.

5 Q. And only one of those studies gives an
6 actual number in terms of dose detail rather
7 than describing the dose as low, medium, or
8 high. Is that correct?

9 Or low, slash, medium, high?

10 A. The Vlaanderen study gives information.
11 It is not numbers. I agree with you there.
12 But they describe low as, I presume, that is
13 thirtile, that is first third, and then the
14 second third, and then the third third, but it
15 is not a number in terms of parts per million
16 per month or whatever.

17 Q. Right. So what I am referring to is
18 that the Wong study describes medium as 25 to
19 100 PPM months and high as over 100 PPM months.

20 Do you see that?

21 A. I see that.

22 Q. And what I am saying is the Wong study
23 is the only study that gives an actual dose
24 detail of numbers rather than simply referring

1 to low, medium, or high.

2 A. Yes. But I just wanted to point out
3 that the Vlaanderen gives a little more
4 information than just low, medium, high.

5 Q. Would you agree that the only study
6 that gives dose numbers is the Wong study?

7 A. Yes.

8 Q. I wasn't trying to be difficult. I
9 understand that you need to be precise.

10 As we have just discussed, the high
11 dose is over 100 PPM months. Right?

12 ATTORNEY MICELI: Object to the form.

13 A. That is what it says here. I am not
14 familiar with this study.

15 BY ATTORNEY SPRAYREGEN:

16 Q. It also says here, understanding that
17 you are not familiar with the study, that the
18 medium dose is 25 to 100 PPM months. Right?

19 A. That appears to be the case, it is 25,
20 underscore, 100, which a bit odd. But I assume
21 that means 25 to 100.

22 Q. Do you know how these exposures
23 compared to the exposures to benzene at
24 Camp Lejeune?

1 A. I do not.

2 Q. This is a hypothetical.

3 If the people who were living at
4 Camp Lejeune were exposed to much lower doses
5 of benzine than those with occupational
6 exposures, would you agree that this
7 meta-analysis may not provide information on
8 whether -- may not be applicable to a causal
9 determination of whether those at
10 Camp Lejeune -- whether the benzine at
11 Camp Lejeune --

12 ATTORNEY SPRAYREGEN: Withdrawn.

13 BY ATTORNEY SPRAYREGEN:

14 Q. I will start over.

15 If the levels in the Wong study and the
16 levels in all of the other studies of
17 occupational exposures are much higher than the
18 levels at Camp Lejeune, would you agree that
19 this study may not be applicable to a causal
20 determination of whether benzine at the levels
21 of Camp Lejeune could cause kidney cancer?

22 ATTORNEY MICELI: Object to the form.
23 Foundation.

24 A. Not necessarily. It depends on the

1 nature of the relationship between the exposure
2 and the outcome.

3 BY ATTORNEY SPRAYREGEN:

4 Q. When you say it depends on the
5 nature --

6 ATTORNEY SPRAYREGEN: Withdrawn.

7 Can you read back Dr. Madigan's last
8 answer?

9 (The prior answer was then read back as
10 follows:

11 "Answer: Not necessarily. It depends
12 on the nature of the relationship between the
13 exposure and the outcome.")

14 BY ATTORNEY SPRAYREGEN:

15 Q. You say, "It depends on the nature of
16 the relationship between the exposure and the
17 outcome."

18 What do you mean by that?

19 A. So, for example, it is not the case
20 that there is necessarily a linear relationship
21 between dose and risk in every context. It can
22 be nonlinear. It can be a threshold effect.
23 It can be that exposure above some level gives
24 you a certain risk and then it doesn't increase

1 with more exposure. That is possible.

2 So I can't answer the question in any
3 kind of generality. I have not looked at the
4 nature of the relationship between benzene
5 exposure and kidney cancer.

6 Q. Do you know of any --

7 ATTORNEY SPRAYREGEN: Withdrawn.

8 BY ATTORNEY SPRAYREGEN:

9 Q. But given what you just said about the
10 fact that there could be a threshold or it
11 could be a linear relationship or it could be
12 some other increasing, I believe you said,
13 relationship, and if I mischaracterized your
14 testimony, please let me know.

15 A. Nonlinear.

16 Q. Nonlinear.

17 If there could be a threshold effect, a
18 nonlinear relationship, or a linear
19 relationship, in any one of those situations,
20 would someone who had less exposure to benzene
21 be more likely to get kidney cancer?

22 ATTORNEY MICELI: Object to the form.
23 Foundation.

24 A. You are kind of outside of my expertise

1 here. I don't know. Is that possible with
2 certain kinds of exposures? I don't know.

3 BY ATTORNEY SPRAYREGEN:

4 Q. You can put that aside, thanks.

5 Can you please go back to the Cochrane
6 chapter on meta-analyses, which is Exhibit 5.

7 A. Okay.

8 Q. And can you turn to page 10, please.

9 A. Okay.

10 Q. In the middle of the page, you see
11 where there is a heading 10.4.4.3, "Validity of
12 methods of meta-analysis for rare events."

13 A. I see that.

14 Q. So the first paragraph under that
15 heading says, "Simulation studies have revealed
16 that many meta-analytical methods can give
17 misleading events for rare events, which is
18 unsurprising given their reliance on asymptotic
19 statistical theory. Their performance has been
20 judged suboptimal either through results being
21 biased, confidence intervals being
22 inappropriately wide, or statistical power
23 being too low to detect substantial
24 differences."

1 Did I read that correctly?

2 A. You did.

3 Q. Can you explain this statement to me?

4 A. So what they are stating -- I don't
5 know whether I agree with it or not.

6 But so with very rare events, just in
7 general, there can be issues with the
8 statistical theory that underlies a statistical
9 test. Actually, forget meta-analysis, just in
10 general. In very rare events, the theory, the
11 mathematics underlying some of the statistical
12 methods, it requires an asymptotic, which is
13 meaning behavior of the method as the sample
14 size goes to infinity. With very rare events,
15 sometimes these theoretical properties can be
16 off. Let's put it that way.

17 That is the first sentence.

18 Do you want me to keep going?

19 Q. Yes, please.

20 A. Then the statement here is "Their
21 performance" -- by which I think the authors
22 mean meta-analysis with rare events -- "has
23 been judged" -- passive voice -- "has been
24 judged suboptimal." I don't quite know what

1 that means.

2 I guess the results being biased, I
3 don't know why rare events would necessarily
4 result in bias.

5 "Confidence intervals being
6 inappropriately wide." Okay. That will be in
7 the conservative direction. "Or a statistical
8 power being too low." Sure. If you have rare
9 events, your power is diminished the rarer the
10 outcome as a general matter. So that does make
11 sense, that very rare events, you will have
12 reduced power. It might or might not be too
13 low in a particular context.

14 How am I doing? Am I answering the
15 question?

16 Q. So it sounds like there are some
17 statements in here you agree with and some you
18 either disagree with or you are not sure you
19 agree with. Is that correct?

20 ATTORNEY MICELI: Object to the form.

21 A. It is very imprecise, it is very
22 hand-wavy kind of stuff. But let me just say
23 that.

24 BY ATTORNEY SPRAYREGEN:

1 Q. What I thought they were saying -- and
2 you are the statistician and I am not -- is
3 that, with rare events, there may not be an
4 observation in the study because the event is
5 so rare.

6 Is that what they were saying or is
7 that wrong?

8 ATTORNEY MICELI: Object to the form.

9 A. I think it is a little more general
10 than that. So that is certainly -- you know,
11 if you do a study -- forget meta-analysis again
12 for a second. If you do a study, a cohort
13 study and the event of interest does not occur
14 on either arm, you have nowhere to go. You
15 can't make any kind of inference from that.

16 But in situations where there are very
17 small numbers of events, like one-on-one arm
18 and -- I shouldn't do this because it all
19 depends. But if you have got a study in which
20 there is one event in one arm and two events in
21 the other arm, that can be -- can be, not
22 always, but it can be problematic in terms of
23 the mathematics underlying some of the
24 statistical methods.

1 BY ATTORNEY SPRAYREGEN:

2 Q. I also thought that they were saying
3 that, when there were rare events, the studies
4 would have large heterogeneity in results. Is
5 that correct?

6 ATTORNEY MICELI: Object to the form.

7 BY ATTORNEY SPRAYREGEN:

8 Q. Or could have large heterogeneity in
9 terms of results.

10 ATTORNEY MICELI: Same.

11 A. No. Not necessarily.

12 And also, generally, you will have wide
13 confidence intervals, in general. It all
14 depends. In general, if you have got rare
15 events, you will have wide confidence
16 intervals. So you are unlikely to have,
17 certainly, statistical heterogeneity --
18 statistically significant heterogeneity.

19 BY ATTORNEY SPRAYREGEN:

20 Q. So going back to Cochrane, what in that
21 paragraph do you agree with?

22 ATTORNEY MICELI: You are talking about
23 the first paragraph of 10.4.4.3?

24 ATTORNEY SPRAYREGEN: Yes, thank you.

1 A. Okay. So let's go through it.

2 So simulation studies have revealed
3 that many meta-analytical methods can give
4 misleading results for rare events. I neither
5 agree or disagree with that. I have not seen
6 those studies. He is just stating -- they. I
7 shouldn't say "he." They.

8 That is a statement of fact:
9 Simulation studies have revealed. I would need
10 to see those studies.

11 And then there is an opinion that is
12 unsurprising given their reliance on asymptotic
13 statistical theory. I understand what is
14 behind that, but, again, I have not seen the
15 studies.

16 "Their performance has been judged
17 suboptimal." Again, I kind of neither agree
18 nor disagree. I don't know what -- maybe they
19 are explaining suboptimal with the rest of
20 sentence, so let me interpret it that way.

21 "Their performance has been judged suboptimal,
22 either through results being biased."

23 So that, I believe, is referring to
24 those simulation studies, which I am not

1 familiar with. I don't know what studies they
2 are talking about.

3 So do those studies show that
4 meta-analysis with rare events can lead to
5 biased results? Maybe. I don't know.

6 "Confidence intervals being
7 inappropriately wide." Again, yes, wide.
8 Because when you have got rare events, you will
9 have wider intervals than if you don't have
10 rare events. But I don't know about the
11 inappropriate. That comes from the simulation
12 studies, presumably.

13 And then statistical power being too
14 low, that is a more general statement. Sure,
15 if you have got rare events, you will have
16 diminished power. That is a true statement.

17 Q. Can you turn to page 24 of the same
18 exhibit.

19 A. Okay.

20 Q. Page 24 of the Cochrane chapter on
21 meta-analysis. In a meta-analysis, can you
22 tell me, what is a summary estimate?

23 A. That would usually refer to the --
24 usually, when you do meta-analysis, you produce

1 an estimate of some effect. That would be
2 referred to as the summary estimate that
3 summarizes the information from the component
4 studies.

5 Q. What is the confidence interval around
6 the summary estimate in a meta-analysis?

7 A. So there is a notion in statistics of a
8 population, and you are trying to estimate some
9 characteristic of the population, an effect
10 size, typically in the context of
11 meta-analysis.

12 So there is a true -- conceptually,
13 there is a true effect size that I don't know,
14 you don't know, but it exists conceptually. So
15 there are mathematical and statistical methods
16 that can associate an interval with a summary
17 estimate -- or any estimate, but I would say a
18 summary estimate -- such that that interval has
19 the property that, with probability, say,
20 95 percent, doesn't have to be, but, say, with
21 probability 95 percent, in a particular
22 tactical sense, that interval contains the true
23 value.

24 Q. So in the Cochrane chapter on

1 meta-analysis, page 24, heading 10.10.4.2,
2 "Interpretation of random effects
3 meta-analysis," the authors write, "The summary
4 estimate and confidence interval from a random
5 effects meta-analysis referred to the centre of
6 the distribution of the intervention effects
7 but do not describe the width of the
8 distribution. Often the summary estimate and
9 its confidence interval are quoted in isolation
10 and portrayed as a sufficient summary of the
11 meta-analysis. This is inappropriate. The
12 confidence interval from a random effects
13 meta-analysis describes uncertainty in the
14 location of the mean of systematically
15 different effects in the different studies. It
16 does not describe the degree of heterogeneity
17 among the studies, as may be commonly believed.
18 For example, when there are many studies in a
19 meta-analysis, we may obtain a very tight
20 confidence interval around the random-effects
21 estimate of the mean effect even when there is
22 a large amount of heterogeneity."

23 Did I read that correctly?

24 A. Yes.

1 Q. Do you agree with this paragraph?

2 ATTORNEY MICELI: Object to the form.

3 A. It is technically correct. So the
4 confidence interval pertains to the mean of the
5 effects, the true effects corresponding to each
6 of the component studies. So it is technically
7 correct.

8 BY ATTORNEY SPRAYREGEN:

9 Q. Do you agree with the statement that
10 often the summary estimate and its confidence
11 interval are quoted in isolation and portrayed
12 as a sufficient summary of the meta-analysis
13 and this is inappropriate?

14 A. I disagree with the statement "this is
15 inappropriate." It is what it is.

16 It is certainly inappropriate if people
17 make incorrect statements about what it is.
18 But to my mind, the confidence interval is the
19 key quantity. It gives you your uncertainty
20 around the estimate of the true average effect.

21 Q. When discussing meta-analyses, do you
22 think authors should provide additional
23 information in describing the results beyond
24 the summary estimate and the confidence

1 interval around the summary estimate?

2 ATTORNEY MICELI: Object to the form.
3 Foundation.

4 A. Sure. I think it is very useful, for
5 example, to provide a measure of heterogeneity,
6 as is commonly done with meta-analysis.

7 BY ATTORNEY SPRAYREGEN:

8 Q. What is a forest plot?

9 A. So it is a commonly used graphical
10 device in meta-analysis where you show -- on
11 the vertical axis is or are the component
12 studies. And then for each study, you show the
13 95 percent confidence interval for the effect
14 in that study. And so you plot that for the
15 different studies.

16 And then, typically, at the bottom, you
17 plot the meta-analytic point estimate and
18 confidence interval.

19 So it is a visual device that is very
20 useful, summarizes the meta-analysis.

21 Q. So that was my next question.

22 Would you agree that a forest plot
23 provides useful information when looking at a
24 meta-analysis?

1 A. I would.

2 ATTORNEY SPRAYREGEN: We have been
3 going for an hour and I am about to move on to
4 a new topic. So I think it would be good to
5 take a break now.

6 THE VIDEOGRAPHER: The time is
7 12:14 p.m. and we are off the record.

8 (Recess taken at 12:14 p.m.)

9 (Recess ended at 12:31 p.m.)

10 THE VIDEOGRAPHER: The time is
11 12:31 p.m., and we are on the record.

12 BY ATTORNEY SPRAYREGEN:

13 Q. As I mentioned when we were off the
14 record, I am going to be moving back to the
15 Savitz deposition that occurred in May in this
16 case, which is Exhibit 4.

17 Can you take that out, or it looks like
18 you already have it out.

19 A. Yes.

20 Q. Thanks.

21 Can you please turn to page 42.

22 A. Okay.

23 Q. And so I am going to start in the
24 middle of 42 when I read the testimony. But

1 can you just see that this is an answer that
2 Dr. Savitz gives, and it is starting at the
3 bottom of page 41, at line 19.

4 And that answer continues over.

5 A. Okay.

6 Q. So in his testimony, in response to a
7 question, Dr. Savitz said, "A relative risk of
8 1.1 that goes from 1.05 to 1.15, and that's
9 statistically significant, I would say it's a
10 very small increased risk but measured very
11 precisely."

12 Did I read that correctly?

13 A. You read it correctly.

14 Q. I think what there is supposed to be is
15 the words "with a confidence interval" in
16 there. So I think it should say, or it would
17 be more clearer if it said, "A relative risk of
18 1.1 with a confidence interval that goes from
19 1.05 to 1.15 and that is statistically
20 significant, I would say it is a very small
21 increased risk but measured very precisely."

22 Do you agree?

23 A. I agree that the word "confidence
24 interval" should be sort of in there for this

1 to make sense. So that agree with and I agree
2 that it is statistically significant.

3 It would be.

4 But I don't agree, in an absolute
5 sense, that it is very small increased risk or
6 that it is measured very precisely. They are
7 absolute judgments. Relative risk of 1.1 might
8 not be very small in some contexts. And ditto
9 with the confidence interval. So I am
10 uncomfortable with the absolute
11 characterization of the relative risk and the
12 confidence interval.

13 Q. You anticipated my next question.

14 In the context of environmental-
15 epidemiology studies dealing with exposures,
16 would you agree that a relative risk of 1.1
17 with a confidence interval that goes from 1.05
18 to 1.15 that is statistically significant, is a
19 very small increased risk but measured very
20 precisely?

21 A. No. It is too absolute. It would all
22 depend on the seriousness of the risk,
23 et cetera. That might or might not be -- like,
24 I don't know what very small means, actually,

1 in general.

2 But making a qualitative statement like
3 that without any context, even though you
4 provided a little context, which is
5 environmental-epidemiology, but even in that
6 context, I wouldn't characterize that as very
7 small, in an absolute sense.

8 Q. Do you know of environmental-
9 epidemiology studies that characterize a
10 relative risk of 1.1 as something other than
11 small?

12 ATTORNEY MICELI: Object to the form.

13 A. Not off the top of my head. I don't
14 know of studies off the top of my head that
15 call it small or call it big or call it
16 anything.

17 BY ATTORNEY SPRAYREGEN:

18 Q. In environmental-epidemiology studies,
19 are there risk estimates that you would call
20 big?

21 A. Maybe in a particular context. I don't
22 know. I mean, but what I would not say is that
23 a relative risk of 1.2 is big or small or
24 somewhere in between. It depends on the

1 context.

2 It is like saying the number 11 is a
3 big number. That doesn't make any sense. It
4 all depends on the context.

5 Q. Are you aware, as you sit here today,
6 of any environmental-epidemiology studies where
7 the risk estimate is 1.2 that have
8 characterized that risk estimate as large?

9 ATTORNEY MICELI: Object to the form.

10 A. Not sitting here this minute. No.
11 There could well be. I can't pull that out of
12 my head.

13 BY ATTORNEY SPRAYREGEN:

14 Q. Can you give me an example of a context
15 in which a risk estimate of 1.1 is considered
16 high?

17 A. If I have an increased risk of
18 10 percent of dying in the next 60 seconds, I
19 would call that high.

20 Q. Can you give me a context in a
21 peer-reviewed journal in which a risk estimate
22 of 1.1 is considered high?

23 ATTORNEY MICELI: Object to the form.

24 A. Like, I don't have these -- I don't

1 have studies like that in my head. I can't
2 give you one off the top of my head. I could
3 study the issue and see what I could find.

4 BY ATTORNEY SPRAYREGEN:

5 Q. So I am going to ask you to go to the
6 Shield report, which is Exhibit number 6, I
7 believe.

8 A. Okay.

9 Q. I am also going to ask you to keep your
10 report handy because I am going to go back and
11 forth between those.

12 A. Okay.

13 Q. So turning to the Shields report on
14 page 2, do you see the table of contents?

15 A. I do.

16 Q. Do you see that the section
17 "Methodological approaches to causation
18 inference" starts on page 29 and it goes
19 through page 62?

20 A. I see that.

21 Q. Turning to your report, page 7, let me
22 know when you are there.

23 A. I am there.

24 Q. You are fast.

1 So heading number 5 in your report is
2 "Comments on the Defendants' Reports Related to
3 Meta-Analysis." Is that right?

4 A. Yes.

5 Q. And then the first comment you have on
6 Dr. Shields is the quote --

7 ATTORNEY SPRAYREGEN: Withdrawn.

8 Strike that.

9 BY ATTORNEY SPRAYREGEN:

10 Q. So paragraph 24 says, "Dr. Shields
11 raises a series of general concerns about
12 meta-analyses that are entirely nonspecific
13 and, in fact, could be raised about essentially
14 any statistical analysis. While it could be
15 the case that a particular analysis is flawed,
16 centuries of statistical research and practice
17 coupled with a rigorous peer-review process
18 have led scientists and policy makers to rely
19 extensively on statistical analyses in general
20 and meta-analyses in particular. Here are some
21 examples of Dr. Shields's nonspecific
22 criticisms, well-established scientific
23 methodology, and my comment in rebuttal."

24 Did I read that correctly?

1 A. You did.

2 Q. Your first -- the first criticism you
3 have of Dr. Shields is -- would you agree that
4 you are critiquing each of these statements of
5 Dr. Shields?

6 A. Yes, I am basically -- the point in
7 paragraph 24 that I made is that he is making
8 very nonspecific comments, and then I am
9 showing examples of these and adding commentary
10 as to why they are examples of the point I am
11 trying to make.

12 Q. So the first nonspecific comment of
13 Dr. Shields that you point out is referring to
14 "meta-analyses are thought to increase
15 statistical power and precision, although this
16 does not necessarily make the results
17 reliable." Is that right?

18 A. That is the statement from
19 Dr. Shields's report, yes.

20 Q. The second statement from Dr. Shields's
21 report that you address is, "It can be argued
22 that using studies from different populations
23 makes the results more generalizable, but this
24 cannot be assumed." Right?

1 A. Yes.

2 Q. The third statement from Dr. Shields's
3 report that you address is, "The diversity of
4 study populations and methods might increase
5 cautious interpretation." Is that right?

6 A. Yes.

7 Q. The fourth statement of Dr. Shields's
8 that you address is, "In some cases, these
9 types of studies are mixing apples and
10 oranges." Correct?

11 A. Yes.

12 Q. The fifth statement of Dr. Shields that
13 you address is, "The inclusion and exclusion
14 criteria are critical to evaluate and can be
15 subject to great subjectiveness." Correct?

16 A. Correct.

17 Q. And the sixth statement of Dr. Shields
18 that you address is, "Meta-analyses are also
19 subject to publication bias." Right?

20 A. Right.

21 Q. Can you now turn to Dr. Shields's
22 report and go to page 37.

23 A. Okay.

24 Q. And this is in the methodology section

1 because it is between pages 29 and 62. Is that
2 right?

3 A. Yes.

4 Q. And do you see the paragraph that
5 starts at the end of the page, "Pooled
6 Studies."

7 Do you see that?

8 A. I do.

9 Q. So the second sentence in that
10 paragraph is, "They are thought to increase
11 statistical power and precision, although this
12 does not necessarily make the results reliable.
13 It can be argued that using studies from
14 different populations makes the results more
15 generalizable, but this cannot be assumed and
16 the diversity of study populations and methods
17 might increase cautious interpretation. In
18 some cases, these types of studies are mixing
19 'apples and oranges.' These inclusion and
20 exclusion criteria are critical to evaluate and
21 can be subject to create subjectiveness. They
22 are also subject to population bias."

23 After I corrected myself, did I read
24 that correctly?

1 A. Yes.

2 Q. In this one paragraph in the
3 methodology overview section of Dr. Shields's
4 report are the first six statements that you
5 criticize Dr. Shields for. Is that right?

6 A. They are the first six statements that
7 I highlighted in that section of my report,
8 yes.

9 Q. As nonspecific statements?

10 A. Right.

11 Q. And turning back to your report.

12 The seventh nonspecific statement of
13 Dr. Shields is, "Different meta-analyses for
14 the same research question might have different
15 results because, for example, the inclusion and
16 exclusion criteria differ which leads to
17 inclusion of different studies, different
18 models, and combining different types of
19 studies." Is that correct?

20 A. You read it correctly, yes.

21 Q. The eighth criticism you have of
22 Dr. Shields or the eighth nonspecific statement
23 of Dr. Shields is, "It is not uncommon that
24 different computer models provide different

1 results, weakening the usefulness of the
2 meta-analysis process." Right?

3 A. Yes.

4 Q. And the ninth nonspecific statement of
5 Dr. Shields that you highlight is, "Different
6 models can be applied, with strength and
7 weaknesses, but the highest level of evidence
8 is when multiple methods corroborate each
9 other." Is that right?

10 A. Yes.

11 Q. The tenth nonspecific statement of
12 Dr. Shields that you highlight is, "The process
13 does not reduce bias and confounding of
14 individual studies, and all of the studies may
15 be subject to the same bias and/or
16 confounding." Is that correct?

17 A. Yes.

18 Q. And in the eleventh nonspecific
19 statement of Dr. Shields that you highlight is,
20 noting that he states without citation, "It is
21 problematic to combine case-control and cohort
22 studies." Is that correct?

23 A. Yes.

24 Q. The twelfth nonspecific statement of

1 Dr. Shields that you highlight is -- that he
2 states without citation, "Including many small
3 and/or low quality studies does not necessarily
4 provide a more reliable risk estimate, and the
5 results may not be any better than the lower
6 quality studies it represents." Is that
7 correct?

8 A. Yes.

9 Q. And the thirteenth nonspecific
10 statement of Dr. Shields that you highlight is,
11 "But in the real-world application, for example
12 the clinical setting, meta-analyses can be done
13 but decision-making is based on context, for
14 example relying more heavily on the highest
15 quality studies such as randomized studies or
16 large cohort studies with biomarkers."

17 Is that correct?

18 A. Yes.

19 Q. And the fourteenth nonspecific
20 statement of Dr. Shields that you highlight is,
21 "The most useful information is the overview
22 and how the study results vary (e.g., as in the
23 forest plot)."

24 Is that correct?

1 A. Yes.

2 Q. Do you see the second full paragraph on
3 that page?

4 A. I do.

5 Q. Then the -- I believe it is the fourth
6 sentence down, starts with "Different
7 meta-analyses." Is that right?

8 A. I see that.

9 Q. So in the report, it says, "Different
10 meta-analyses for the same research question
11 might have different results because, for
12 example, the inclusion and exclusion criteria
13 differ, which leads to inclusion of different
14 studies, different models, and combining
15 disparate types of studies. Different models
16 can be applied with strengths and weaknesses,
17 but the highest level of evidence is when
18 multiple methods corroborate each other. It is
19 not uncommon that different computer models
20 provide different results, weakening the
21 usefulness of the meta-analysis process. The
22 process does not reduce bias and confounding of
23 individual studies, and all of the studies
24 maybe be subject to the same bias and/or

1 confounding. Caution is needed when
2 determining what type of are combined (e.g.,
3 grouping cohorts and case-control studies
4 together) and how heterogeneous they are (one
5 of the statistical assessment). For example,
6 it is problematic to combine case control and
7 cohort studies. Including many small and/or
8 low quality studies did not necessarily provide
9 a more reliable risk estimate and the results
10 may not be any better than the lower quality
11 studies it represents. The reliance on
12 meta-analyses depends on the context. For
13 example, regulatory and review analyses might
14 rely heavily on meta-analyses for regulation to
15 follow precautionary principles. But in the
16 real-world application, for example, the
17 clinical setting, meta-analyses can be done but
18 decisionmaking is based on context. For
19 example, relying more heavily on the highest
20 quality studies such as randomized studies or
21 large cohort studies with biomarkers. I note
22 that the U.S. preventative task force
23 methodology in Cochrane reviews rely heavily on
24 the meta-analysis process but there are

1 rigorously applied inclusion and exclusion
2 criteria."

3 Did I read all of that correctly?

4 A. There is one. You said "review
5 analysis," which it should have been "review
6 agencies."

7 Q. Thank you.

8 With that correction, did I read the
9 Dr. Shields report correctly?

10 A. Yes.

11 Q. That whole paragraph is in the
12 methodology section. Right?

13 A. Yes.

14 Q. And your critiques of Dr. Shields, or
15 all of the nonspecific statements that
16 Dr. Shields makes that you highlight, or I
17 should say --

18 ATTORNEY SPRAYREGEN: Withdrawn.

19 BY ATTORNEY SPRAYREGEN:

20 Q. And the sixth through fourteenth of
21 Dr. Shields's statements that you highlight are
22 all in this one paragraph in the methodology
23 section. Is that right?

24 A. That appears to be the case, yes.

1 ATTORNEY SPRAYREGEN: I am going to
2 move on to another exhibit.

3 (Exhibit 11, Chapter 1 through 6 of
4 "Trichloroethylene, Perchloroethylene,
5 Benzene, Vinyl Chloride, and
6 trans-1,2-Dichloroethylene Exposure and
7 Kidney Cancer" by Julie E. Goodman, Ph.D.,
8 dated 2-7-25, with attachments, marked for
9 identification.)

10 BY ATTORNEY SPRAYREGEN:

11 Q. What has just been marked as Exhibit 11
12 are chapters 1 to 6 of Dr. Goodman's kidney
13 cancer report, then the attachments in table C
14 and then attachment D.

15 Is this the report that you said you
16 reviewed in more detail than the others?

17 A. Yes.

18 Q. In your report, on page 13,
19 paragraph 25, you write, "In each of her
20 reports, Dr. Goodman raises similar nonspecific
21 concerns."

22 Then you noted that, in the excerpts of
23 Dr. Goodman's report, you have added the
24 emphasis. Is that right?

1 A. Yes.

2 Q. The first statement from Dr. Goodman's
3 report that you note is, "One issue with
4 meta-analyses is that they may result in
5 'over-inclusiveness.'"

6 A. Conclusiveness.

7 Q. I am going to start over, and I
8 appreciate that.

9 The first statement of Dr. Goodman's
10 that you note is, and I quote, "One issue with
11 meta-analyses is that they may result in
12 'over-conclusiveness,' or the appearance that
13 results are more precise and conclusive than
14 they actually are (Lash et al. 2021). Also,
15 because meta-analysis methods cannot correct
16 the biases in the underlying study-specific
17 results, these biases carry over to the
18 meta-analysis results. When pooling studies
19 with similar biases, individual study CIs and
20 P-values 'tighten' to yield even stronger
21 pooled values resulting in this
22 over-conclusiveness."

23 After I made your correction, did I
24 read it correctly?

1 A. Yes.

2 Q. And then the next statement of
3 Dr. Shields that you highlight --

4 A. Goodman.

5 Q. Thank you.

6 The next statement of Dr. Goodman that
7 you highlight is, "In addition, all systematic
8 reviews and meta-analyses are subject to
9 potential publication bias."

10 Is that correct?

11 A. Yes.

12 Q. And the third statement of Dr. Goodman
13 that you highlight is, "Underrepresentation of
14 null findings can bias the results of a
15 systematic review or meta-analysis away from
16 the null."

17 Is that correct?

18 A. Yes.

19 Q. So in Dr. Goodman's kidney cancer
20 report, please turn to page 7.

21 A. Okay.

22 Q. This is the "Principles and
23 Methodology" chapter of her report. Is that
24 right?

1 A. Yes.

2 Q. Then please turn to page 13, which is
3 in the "Principles and Methodology" chapter.
4 Is that correct?

5 A. Okay, yes.

6 Q. The first full paragraph on page 13,
7 which is in the section --

8 ATTORNEY SPRAYREGEN: Withdrawn.

9 BY ATTORNEY SPRAYREGEN:

10 Q. And do you see, on page 12, there is a
11 heading that says, "Systematic Reviews in
12 Meta-Analyses."

13 Do you see that?

14 A. I do.

15 Q. On page 13, the first full paragraph on
16 page 13 is, "One issue with meta-analysis is
17 that they may result in over-conclusiveness or
18 the appearance that results are more precise
19 and conclusive than they actually are (Lash et
20 al. 2021). Also because meta-analysis methods
21 cannot correct the bias in the underlying study
22 specific results these biases carry over to the
23 meta-analysis results when pooling studies with
24 similar biases, individual studies CIs and P

1 values quote tighten to yield even stronger
2 pooled values resulting in this
3 over-conclusiveness."

4 Did I read that correctly?

5 A. Yes.

6 Q. That is the first statement of
7 Dr. Goodman's that you note. Correct?

8 A. Yes.

9 Q. And then the next paragraph, the first
10 sentence, in your second critique of
11 Dr. Goodman -- sorry. The first sentence is
12 your second critique or statement of
13 Dr. Goodman's that you highlight. Is that
14 right?

15 A. Yes.

16 Q. Then the last sentence of that same
17 paragraph -- or I should say the second full
18 paragraph on page 13 is --

19 ATTORNEY SPRAYREGEN: Withdrawn.

20 BY ATTORNEY SPRAYREGEN:

21 Q. The second-to-last sentence in that
22 paragraph that we have just been discussing is,
23 "Underrepresentation of null findings can bias
24 the results of a systematic review or a

1 meta-analysis away from the null."

2 Right?

3 A. Yes.

4 Q. So all three of the statements that you
5 highlight from Dr. Goodman are in her
6 methodology chapter. Is that correct?

7 A. The three that you covered.

8 Q. Yes.

9 A. There are others.

10 Q. Yes. And then under those three that
11 we just discussed, you write, "These are
12 hypothetical concerns that may or may not have
13 any relevance to a specific meta-analysis.
14 Dr. Goodman. For the most part, Dr. Goodman
15 fails to raise any of these concerns in the
16 context of any specific meta-analysis
17 discussed. In some instances, she repeats some
18 of these generic concerns without explaining at
19 any level of detail how they apply in the
20 specific analyses she cites."

21 Did I read the paragraph from page 13
22 of your report correctly?

23 A. You did. And for the record, there is
24 a stray "Dr. Goodman" in there that should be

1 deleted.

2 Q. Thank you, I wasn't sure how to handle
3 that.

4 So can you now turn back to
5 Dr. Goodman's report and go to page 51.

6 This is her chapter on TCE and kidney
7 cancer. Right?

8 A. Yes.

9 Q. Then turning to page 55 in this chapter
10 on kidney cancer. Let me know when you get
11 there, please.

12 A. Yes.

13 Q. Dr. Goodman writes --

14 A. Where are you?

15 Q. Sorry, thank you.

16 I am sorry. I am in the very last
17 paragraph that starts on page 55 and continues
18 over to 56.

19 A. Okay.

20 Q. Dr. Goodman writes, "All of the pooled
21 and meta-analyses incorporated, some of the
22 cohort and case-control study studies reviewed
23 here and were limited by the underlying
24 limitations of the analyzed studies as

1 described in section 6.1.1 and attachment C
2 table C1. As these analyses were conducted
3 several years ago, none included more recent
4 studies published in the last decades, e.g.,
5 Mitchellec, et al. 2019. Most notably, pooling
6 or averaging results across studies could not
7 overcome the critical limitations of
8 nonspecific and indirect exposure
9 characterization and uncontrolled and residual
10 confounding."

11 Did I read that correctly?

12 A. You did.

13 Q. So please turn to page 51 of her
14 report, which is the section she just referred
15 to, 6.1.1.

16 And you see that it says -- excuse me,
17 are you there?

18 A. Yes.

19 Q. I should know that by now.

20 So 6.1.1 says, "Study population." Is
21 that right?

22 Excuse me. 6.1.1.1 -- I think I left
23 out the last point 1 -- is study population?

24 A. Yes, but didn't she refer to 6.1.1?

1 Q. 6 point -- she did. She referred to
2 6.1 -- I was going to go through subheadings of
3 6.1.1.

4 A. Fine.

5 Q. But you have pointed out -- I was
6 trying to save a little bit of time.

7 But you are correct. Everything that I
8 am going through is in section 6.1.1, and that
9 is the section that she just referred to that I
10 just read.

11 Is that right?

12 A. Yes.

13 Q. Thank yo.

14 So section 6.1.1.1, "Study population,"
15 would you agree -- and you can read it -- that
16 Dr. Goodman discusses the strengths and
17 limitations of the studies?

18 ATTORNEY MICELI: Object to the form.

19 A. Sure. It is a kind of a summary of
20 characteristics of the studies, in summary
21 form. Like most studies, many studies,
22 et cetera.

23 And she is looking at some specific
24 issues, like loss to follow up, participation

1 rates, and so on.

2 Q. Moving on to the next subsection is
3 6.1.1.2 with the heading "Exposure Assessment."
4 Is that right?

5 A. Yes.

6 Q. And you can see, she spends more time
7 discussing exposure assessment than she does
8 any of the other issues within section 6.1. Is
9 that right?

10 A. It is longer, yes, there is more text.

11 Q. And the second paragraph, the first
12 sentence says, "The most critical limitation of
13 all of the cohort and case-control studies was
14 the manner by which exposures were estimated."
15 Is that right?

16 A. That is what she wrote, yes.

17 Q. And would you then -- take as much time
18 as you need to read the section -- agree that
19 she goes on to critique the ways in which
20 exposure is assessed in the literature
21 examining TCE and kidney cancer?

22 A. Yes. I mean, it is longer but similar
23 to the previous section. So she is making
24 statements, sometimes specific comments, about

1 particular studies and, at other times, just
2 making general comments about the studies.

3 Q. Would you say the same thing for her
4 discussion of outcome assessment and for
5 covariants considered, which are sections
6 6.1.1.3 and 6.1.1.4 respectively?

7 A. Same answer, it is not like she is
8 giving some general comments about the studies
9 that are included. Yes.

10 Q. And then can you turn to table C, which
11 is the next stapled packet in this exhibit.

12 A. Okay.

13 Q. Would you agree that, in table C,
14 Dr. Goodman discusses the specific strengths
15 and weaknesses of the kidney cancer
16 epidemiology studies?

17 ATTORNEY MICELI: Object to the form.

18 ATTORNEY SPRAYREGEN: I will rephrase
19 the question. I appreciate that.

20 BY ATTORNEY SPRAYREGEN:

21 Q. Would you agree in that table --

22 ATTORNEY SPRAYREGEN: Withdrawn.

23 BY ATTORNEY SPRAYREGEN:

24 Q. You see that table C.1 is kidney cancer

1 epidemiology study quality assessment?

2 A. Yes.

3 Q. Would you agree that, in table C.1,
4 Dr. Goodman looks at the study population and
5 notes -- for each of the studies listed, she
6 notes, in study population, the strengths and
7 weaknesses; in exposure assessment, the
8 strengths and weaknesses; in outcome
9 assessments, the strengths and weaknesses; in
10 the covariants considered, the strengths and
11 weaknesses; and in temporality, the strengths
12 and weaknesses?

13 A. She did, yes, those specific
14 characteristics, she looked at those for every
15 study, yes.

16 Q. Sorry. I cut you off. I didn't mean
17 to. I was going to say the same thing that you
18 said.

19 And she looked at those strengths and
20 weaknesses of study population, exposure
21 assessment, outcome assessment, covariants
22 considered, and temporality for each one of the
23 listed kidney cancer epidemiology studies. Is
24 that right?

1 ATTORNEY MICELI: Object to the form.

2 A. Yes, she considered -- she calls
3 them -- others to do, too.

4 She called them quality factors. She
5 considered specific quality factors for each of
6 the studies. They are not the same as the
7 issues that I highlighted on page 13 of my
8 report.

9 BY ATTORNEY SPRAYREGEN:

10 Q. So as I understand your report, you are
11 critiquing Dr. Goodman for saying,
12 nonspecifically, that the underlying studies
13 have biases. Is that incorrect?

14 ATTORNEY MICELI: Object to the form.

15 A. Well, I mean, if you look at, on my
16 report page 13, for example -- not for example,
17 let's just go through it.

18 So Dr. Goodman raises a concern about
19 over-conclusiveness. I didn't see anything in
20 here that speaks to that issue. I don't see
21 anything in attachment C, for example, that
22 speaks to that issue.

23 The second one concerns publication
24 bias. Same thing, I don't see anything in

1 table C that discusses publication bias in the
2 context of specific studies.

3 And then, thirdly, underrepresentation
4 of null findings that she talked about, again,
5 I don't see anything in here that speaks to
6 that generic concern, nonspecific concern.

7 BY ATTORNEY SPRAYREGEN:

8 Q. You say -- I am looking at the bottom
9 of page 13, right above paragraph 26, but it
10 might be said somewhere else as well.

11 Or she says, "All of these
12 meta-analyses are limited by the underlying
13 limitations in the individual studies they
14 included. Averaging results across studies
15 cannot overcome the critical limitations of
16 nonspecific and indirect exposure
17 characterization and uncontrolled and residual
18 confounding, which is present in most of these
19 studies."

20 Are you quoting from Dr. Goodman there?

21 A. Yes, I believe so.

22 Q. Would you agree that Dr. Goodman
23 specified the problems with the exposure
24 characterization and uncontrolled and residual

1 confounding in her report and in her tables of
2 the component studies?

3 A. So yes and no. She clearly does talk
4 about exposure assessment study by study,
5 strength and weaknesses.

6 She talks about covariants considered,
7 but it is, in some cases -- actually, most
8 cases, she points out what the covariants were
9 that were included and then covariants that did
10 not control for are considered, and then she
11 lists other covariants.

12 But there is no evidence that these
13 other factors are of any relevance to these
14 studies. It is just generic concerns, did
15 not -- I am looking at one here in particular,
16 the Dagg study on page C-3, did not control for
17 or consider smoking.

18 Okay. Is that of any relevance here?
19 Is that a problem in this particular study?

20 Q. What I was focusing on is your
21 criticism -- or is the fact that she says,
22 "Because meta-analyses cannot correct for the
23 biases in the underlying study-specific
24 results, these biases carry over to the

1 meta-analysis results."

2 And would you agree that she was
3 pointing out the underlying problems in the
4 component studies?

5 ATTORNEY MICELI: Object to the form of
6 the question.

7 A. Some. Yes, she is doing some of it in
8 this appendix, yes, I agree.

9 BY ATTORNEY SPRAYREGEN:

10 Q. Thank you. I am going to move on.

11 You can put that aside, and I do not
12 believe I am coming back to it.

13 A. Okay. Lunch break?

14 ATTORNEY SPRAYREGEN: Should we go off
15 the record?

16 ATTORNEY MICELI: How long have we been
17 going?

18 THE VIDEOGRAPHER: 45.

19 ATTORNEY MICELI: I am happy to stay on
20 record. You said lunch break, so why don't we
21 go off the record and discuss.

22 THE VIDEOGRAPHER: The time is
23 1:16 p.m., and we are off the record.

24 (Recess taken at 1:16 p.m.)

1 (Recess ended at 1:56 p.m.)

2 THE VIDEOGRAPHER: The time is
3 1:56 p.m., and we are on the record.

4 BY ATTORNEY SPRAYREGEN:

5 Q. Earlier today, you testified that you
6 have not reviewed the plaintiffs' experts'
7 general causation reports. Is that right?

8 A. That's right. The plaintiffs' -- yes,
9 that's right, yes.

10 Q. So you are not offering any opinions on
11 the plaintiffs' experts' use of meta-analyses
12 in their general causation reports. Is that
13 right?

14 A. That's right, I am not.

15 Q. Do you know what the plaintiffs'
16 experts' qualifications are?

17 A. I do not.

18 Q. So you don't know whether any of the
19 plaintiffs' experts are qualified to offer
20 opinions on the reliability of meta-analyses.
21 Is that right?

22 ATTORNEY MICELI: Object to the form.

23 A. Actually, Dr. Savitz is a plaintiffs'
24 expert. Right? I am aware of his

1 qualifications. Other than that, no. Now ask
2 the question, sorry.

3 BY ATTORNEY SPRAYREGEN:

4 Q. You were right. I should have said any
5 of the plaintiffs' experts other than
6 Dr. Savitz. So I will rephrase the question.

7 So you have no opinions on whether any
8 of the plaintiffs' experts, other than
9 Dr. Savitz, are qualified to review the
10 reliability of meta-analyses.

11 Is that right?

12 A. That's right.

13 Q. What issues would make a meta-analysis
14 reliable?

15 ATTORNEY SPRAYREGEN: Excuse me.
16 Strike that.

17 BY ATTORNEY SPRAYREGEN:

18 Q. What issues would make a meta-analysis
19 unreliable?

20 A. I mean, in short, a meta-analysis is as
21 good as its component studies. So the general
22 concerns that arise around observational
23 studies, they all apply to meta-analysis. And
24 then, over and above that, then, in the

1 specific context of meta-analysis,
2 heterogeneity is certainly a significant
3 concern, and comparability across the studies
4 is a very important issue.

5 Q. Would you agree that there are articles
6 published in the peer-reviewed literature that
7 have incorrect conclusions?

8 ATTORNEY MICELI: Object to the form.

9 A. In complete generality, I am sure there
10 are.

11 BY ATTORNEY SPRAYREGEN:

12 Q. Would you agree that there are articles
13 published in the peer-reviewed literature that
14 come to the exact opposite conclusion from each
15 other?

16 A. Well, certainly there are examples of
17 articles in the literature where one study
18 shows -- I will stick to the context of
19 epidemiology. I am very aware of examples
20 where one study, for instance, shows a
21 statistically significant finding in one
22 direction and a study, a different study of the
23 same issues shows a statistically different
24 finding in the other direction.

1 That happens for sure.

2 Q. You have given presentations with
3 examples in which two different studies look
4 that same exposures, I think to a particular
5 drug, and the outcome -- and --

6 ATTORNEY SPRAYREGEN: Withdrawn.
7 Strike that.

8 BY ATTORNEY SPRAYREGEN:

9 Q. You have given presentations with
10 examples in which two different studies look at
11 the same exposure, I believe it is a particular
12 drug, and the same outcome, meaning disease,
13 and come to different conclusions. Is that
14 right?

15 A. That's right. It was what I was
16 talking about, where one is statistically
17 significant in one direction and a different
18 study of essentially the same issue is
19 statically significant in the opposite
20 direction.

21 I have used lots of examples like that
22 in talks.

23 (Exhibit 12, Article entitled "Reference
24 Guide on Epidemiology", marked for

1 identification.)

2 BY ATTORNEY SPRAYREGEN:

3 Q. So Exhibit 12 is the reference manual
4 on scientific evidence. And I am only going to
5 have you look at one definition there. Can you
6 please turn to page 582. I have even
7 highlighted it. So let me know when you are
8 there.

9 A. I'm there.

10 ATTORNEY MICELI: I am just going to
11 object to the use of it. This is a -- I will
12 let you try to establish whether or not he has
13 ever reviewed this before, but I am going to
14 have a foundational objection.

15 ATTORNEY SPRAYREGEN: Okay.

16 BY ATTORNEY SPRAYREGEN:

17 Q. So the highlighted quote on page 582 is
18 a definition, and it says, "The power of a
19 study is the probability of finding a
20 statistically significant association of a
21 given magnitude (if it exists) in light of the
22 sample sizes used in the study. The power of a
23 study depends on several factors: The sample
24 size; the level of alpha (or statistically

1 significance) specified; the background
2 incidence of a disease; and the specified
3 relative risk that the researcher would like to
4 detect."

5 Did I read that correctly?

6 A. You did.

7 Q. Would you agree with this definition
8 that I just read?

9 ATTORNEY MICELI: Object to the form.

10 A. It is not in -- it is a specific
11 definition in the context where one is
12 computing a relative risk. So that doesn't
13 cover, for example, a hazard ratio or a risk
14 difference, so it is an odd one. It is --
15 specifically, it is the definition for relative
16 risk.

17 But that said, yes, I agree with that.
18 That is correct.

19 BY ATTORNEY SPRAYREGEN:

20 Q. Turning to your report, page 5,
21 paragraph 17.

22 ATTORNEY MICELI: Page 5?

23 ATTORNEY SPRAYREGEN: Page 5,
24 paragraph 17.

1 BY ATTORNEY SPRAYREGEN:

2 Q. This is a paragraph in which you
3 discuss power. Right?

4 A. Yes.

5 Q. I think I actually know the answer to
6 this, but I am asking you for help. Where in
7 this paragraph does your discussion consider
8 the fact that a study needs a larger number of
9 observations when the disease it is studying is
10 more rare?

11 A. Well, I mean, I guess the comment four
12 lines from the bottom, "as the size of the
13 effect you are trying to measure decreases, so
14 does the trial's power."

15 Q. That is what I was thinking. But you
16 with agree --

17 ATTORNEY SPRAYREGEN: Withdrawn.

18 BY ATTORNEY SPRAYREGEN:

19 Q. That is what I was thinking.

20 Would you agree with the statement that
21 a study needs a larger number of observations
22 when a disease it is studying is more rare?

23 A. As a general matter, yes. Maybe there
24 are exceptions, but generally speaking, yes.

1 Q. Turning back to page 4 of your report.
2 You see paragraph 14?

3 A. I do.

4 Q. You write, "Often researchers report a
5 point estimate along with a related '95 percent
6 confidence interval.' The 95 percent
7 confidence interval represents the range of
8 hypothetical effects that are not rejected by
9 the data given a stated significance level.
10 More informally, a 95 percent confidence
11 interval represents a range of plausible values
12 for the true risk ratio. When the confidence
13 interval includes 1, it is a mistake for
14 researchers to conclude definitively that there
15 is no true effect. In fact, the data in such
16 circumstances may be far more compatible with
17 the existence of an effect than with an absence
18 of an effect. For example, a point estimate of
19 1.2 with a 95 percent confidence interval that
20 ranges from .87 to 1.66 indeed includes 1 as a
21 plausible value for the rate ratio. However, a
22 70 percent confidence interval in the example
23 goes from 1.01 to 1.42. In other words, even
24 though the rate ratio is not statistically

1 significant with 70 percent confidence, the
2 true risk ratio exceeds 1 (more specifically,
3 with 70 percent confidence, the true rate ratio
4 is between 1.01 and 1.42)."

5 Did I read that correctly?

6 A. You did.

7 Q. Have you ever come to a conclusion in a
8 litigation based on studies in which the point
9 estimate was significant at a 70 percent
10 confidence interval?

11 A. Come to a conclusion? I mean, for
12 example, I often noted, in work I have done in
13 litigation, whether something is statistically
14 significant or not. So at the 70 percent
15 level, that result would not be statistically
16 significant.

17 I don't know about conclusion.

18 Q. Have you ever published any papers in a
19 peer-reviewed journal in which you use a
20 70 percent confidence interval to determine a
21 relationship between two variables?

22 A. I may have -- it's the two-determiner
23 relationship between two variables. The last
24 kind of clause of the question sort of threw me

1 for a loop. So I think the first part of the
2 question was -- correct me if I'm wrong, the
3 first part of the question was have I ever
4 computed a 70 percent confidence interval. I
5 may have. I don't know. I would have to look.

6 But it was the next part of your
7 question, to conclude or to determine that an
8 association exists?

9 Q. Between two variables.

10 A. I don't determine these things. I
11 describe the statistical evidence.

12 Q. You say you may have used a 70 percent
13 confidence interval in an article you have
14 personally published or coauthored. Is that
15 what you are testifying to?

16 A. Could be. I don't know. Could have.

17 I know your next question. No, I can't
18 point to a specific paper.

19 My point is, there is nothing
20 sacrosanct about a 95 percent interval. I have
21 certainly computed 90 percent intervals. I
22 have computed 99 percent intervals, for sure.
23 Have I ever done a 70? I don't know.

24 Q. So I have personally seen 90, 95, and

1 99. But I've never personally seen 90, and I
2 am not --

3 A. 70.

4 Q. I have never seen 70. Excuse me.
5 Thank you.

6 So I was asking, not so much -- so my
7 question is about what is done in the
8 literature. So I will rephrase that.

9 It is not -- so I am really asking
10 about what you have seen in the literature and
11 whether studies are published using a
12 70 percent confidence interval.

13 A. I can't point to a specific example.
14 There is no reason why that shouldn't be true.
15 But these numbers are completely arbitrary.
16 You can show or publish any -- you could do a
17 30 percent confidence interval. There is
18 nothing right or wrong about any one level
19 there. It is what it is.

20 Q. Sorry. I didn't mean to interrupt you.

21 The convention, I think you testified,
22 is to use 95, 99. And then -- is 95 or 99. Is
23 that right?

24 A. I have seen 90 quite frequently.

1 Q. So the convention is 95, 99, and
2 sometimes 90. Is that right?

3 ATTORNEY MICELI: Object to the form.

4 A. The convention? I will agree with you
5 that certainly -- by far and away, the most
6 common is 95 percent. Do people sometimes use
7 90? I have seen it. Do people use 99? I have
8 seen it. And then adding the point that these
9 numbers are, it's a so-what, I can show you an
10 88 percent confidence interval. There is
11 nothing wrong with that.

12 BY ATTORNEY SPRAYREGEN:

13 Q. In which context have you seen a
14 90 percent confidence interval used?

15 A. It is often used for interactions where
16 people generally apply -- often, not always,
17 sometimes apply a lower level of threshold for
18 statistical significance. Actually, I have
19 seen 80 percent in that context.

20 Q. Can you tell me a little bit more about
21 that context? I don't understand what you are
22 saying. But I am sure that is due to my lack
23 of knowledge, not the way you are saying it.

24 A. In certain kinds of statistical

1 analyses, in particular, something called a
2 regression, there one looks at the relationship
3 between a so-called dependent variable and an
4 outcome and predictor variables, or covariants.

5 When there is more than one covariant,
6 a question sometimes arises which is, is there
7 an interaction? Does the effect of the
8 covariants -- do they depend on -- does the
9 effect depend on each other, of the covariants.

10 So in that context, there is
11 statistical procedures to test whether an
12 interaction is present or not. You can
13 quantify the interaction. You can estimate it.

14 And there, sometimes, you could apply a
15 95 percent level of confidence to assess is
16 there an interaction or not. But it is not
17 uncommon for people to apply a lower level
18 because there is less power for interactions.
19 The power is greatly diminished when you are
20 looking at an interaction. So I have certainly
21 seen 90 percent in that context, and I have
22 seen 80 percent in that context.

23 Q. So other than when looking at an
24 interaction effect, have you seen the use of a

1 90 percent confidence level?

2 A. 90?

3 Q. Yes.

4 A. Sure.

5 Q. When else?

6 A. I don't know. I have seen -- it is
7 common enough to see 90 percent confidence
8 intervals.

9 Q. Have you ever seen it in
10 environmental-epidemiology studies?

11 A. I don't recall. I just don't know one
12 way or another.

13 No. Actually, you asked me, have I
14 seen. I don't remember.

15 Q. You served as an editor --

16 ATTORNEY SPRAYREGEN: Strike that.

17 BY ATTORNEY SPRAYREGEN:

18 Q. Have you served as an editor of any
19 epidemiology journals?

20 A. I am on the editorial board of a
21 journal called "Therapeutical Innovation and
22 Regulatory Science." That is largely about
23 epidemiology.

24 I have served on the editorial board of

1 the "International Journal of Occupational and
2 Environmental Health." That is basically
3 epidemiology.

4 I served as a senior associate editor
5 for something called "Advances in Disease
6 Surveillance." That is basically epidemiology.

7 That is about it. That is it, I think.

8 Page 30.

9 Q. I am on 31. That would explain why I
10 am not seeing it. I also had some of them
11 highlighted.

12 Where is the title that included the
13 phrase "Advances in Disease Surveillance"?

14 A. Right there.

15 ATTORNEY MICELI: Six from the bottom.
16 BY ATTORNEY SPRAYREGEN:

17 Q. And of these three journals, which, if
18 any, dealt with environmental exposures?

19 A. Certainly the "International Journal of
20 Occupational and Environmental Health" did.

21 The other two, possibly not. I
22 don't -- maybe the "Advances in Disease
23 Surveillance." I don't remember.

24 Q. As an editor of the "International

1 Journal of Occupational and Environmental
2 Health," do you know if the journal has
3 criteria related to statistical significance
4 for determining whether or not an article will
5 be published?

6 A. It would be very unusual for a journal
7 to have such a criterion. It would be weird.

8 To answer your question, though, is I
9 don't know, I don't remember.

10 Q. In your prior work as an expert
11 witness, you have emphasized that your results
12 were statistically significant at a 95 percent
13 confidence level. Is that right?

14 A. "Emphasized"? I have certainly
15 testified that a given result in a given
16 context is either statistically significant or
17 it is not statistically significant. And by
18 convention, that is 5 percent -- or 95 percent.

19 Q. Has a court ever excluded part of your
20 opinion because you relied on results that were
21 not statistically significant?

22 A. No, I don't think so.

23 Q. What about in the Abilify litigation?

24 A. I don't think so. Show me if you want

1 to, but I don't think so.

2 Q. We can come back to that.

3 Are you familiar with the term
4 "confidence interval ratios"?

5 A. Somewhat. It is not a very common
6 term, but I believe it is referring to the
7 ratio between the top and the bottom.

8 Q. Of the confidence interval?

9 A. Yes, I'm sorry. You know what I mean,
10 other side of the interval.

11 Q. You said it is not very common. Is
12 that right?

13 A. That's right. I have seen it, but it
14 is not something that I encounter all the time.

15 Q. In your opinion, is that benchmark
16 better than applying a 95 percent level of --

17 ATTORNEY SPRAYREGEN: Withdrawn.

18 BY ATTORNEY SPRAYREGEN:

19 Q. In your opinion, is that benchmark
20 better than applying statistical significance?

21 ATTORNEY MICELI: Object to the form.

22 A. A benchmark? You are comparing apples
23 and oranges there.

24 So a confidence interval ratio is a

1 number. It is just the top of the interval
2 divided by the bottom of the interval. It is a
3 measure of the width of the interval.

4 Statistical significance is what it is.
5 It is, is the P-value bigger than .05, yes or
6 no? So they are incomparable. They are just
7 two different things.

8 Q. So my understanding is that a
9 confidence interval ratio is used to measure
10 the precision of the estimate. Right?

11 ATTORNEY MICELI: Objection to the
12 form.

13 ATTORNEY SPRAYREGEN: Withdrawn.

14 BY ATTORNEY SPRAYREGEN:

15 Q. I mean, is that correct?

16 A. It is a measure of the precision.

17 You can also just look at the width of
18 the interval. But sure, it is a kind of a
19 measure of -- a big, wide confidence interval,
20 the ratio tends to be bigger than a smaller
21 tends to be.

22 Yes. I will leave it at that.

23 I have nothing against confidence
24 interval ratios. It just it is what it is.

1 One number divided by another number.

2 Q. Are you familiar with confidence
3 interval ratios used in epidemiological
4 studies?

5 A. I have seen people provide or describe
6 confidence interval ratios in many contexts.
7 Presumably in -- I can't give you a specific
8 one, but I am sure I have seen it in
9 epidemiology in general.

10 Q. Why would someone ever use a confidence
11 interval ratio rather than just showing
12 confidence intervals?

13 ATTORNEY MICELI: Object to the form.

14 A. That would be bad practice, in my view.

15 BY ATTORNEY SPRAYREGEN:

16 Q. What would be?

17 A. Not to show -- to show a ratio without
18 showing the interval. Give you an example. So
19 one confidence interval can go from 2 to 8.
20 That is a confidence interval ratio of 4. A
21 different confidence interval can go from .5 to
22 2. Also 4.

23 They are completely different creatures
24 from each other. So it would be irresponsible

1 to show a confidence interval ratio in
2 isolation.

3 Q. What is your current position?

4 A. As of today, I am the provost and
5 senior vice president for academic affairs at
6 Northeastern University, and I am also a
7 professor.

8 Q. I understood that you may be retiring.
9 Is that right?

10 A. Not quite. I am stepping down as
11 provost at the end of this month. I will
12 continue as a professor.

13 Q. So you will be back here for the
14 beginning of the fall semester. Is that
15 correct?

16 A. I am actually going to be on
17 sabbatical, but.

18 Q. But after your sabbatical, you will
19 then be returning to Northeastern. Is that
20 right?

21 A. Yes.

22 Q. Why are you stepping down?

23 A. I have done a five-year term, and I
24 declined to do a second five-year term. I have

1 had enough.

2 Q. You are not a medical doctor. Is that
3 right?

4 A. That's correct.

5 Q. And you are not a toxicologist. Right?

6 A. I am not.

7 Q. And you are not an epidemiologist. Is
8 that right?

9 A. I am an expert in epidemiology at this
10 point. I think I have worked in epidemiology
11 for north of 20 years.

12 Q. Have you ever been qualified by a court
13 as an expert in epidemiology?

14 A. Yes, often.

15 Q. Which courts have qualified you as an
16 expert in epidemiology?

17 A. I can't tell you that. You will have
18 to check the record, but it has happened
19 repeatedly.

20 Q. Can you give me any cases in which you
21 have been qualified, not as a biostatistician
22 or a statistician, but as an epidemiologist by
23 a court?

24 A. No, not sitting here this minute. I

1 can find out. I can find that information for
2 you.

3 But I have certainly been qualified as
4 an expert in statistics and epidemiology.

5 Q. Have you --

6 ATTORNEY SPRAYREGEN: Withdrawn.

7 BY ATTORNEY SPRAYREGEN:

8 Q. And you can't give me the name of even
9 one of the cases right now?

10 A. Of course I can't.

11 Q. Do you have any publications concerning
12 kidney cancer, bladder cancer, leukemia,
13 non-Hodgkin lymphoma, or Parkinson's disease?

14 A. This is going to take me a minute.

15 (Pause.)

16 A. I don't believe I have any papers about
17 those cancers. But I have many papers that
18 look at, like, lots of different examples,
19 methodology papers that illustrate the
20 methodology using examples. So I am sure there
21 are cancer outcomes in some of those papers,
22 but I have not written any papers about those
23 cancers.

24 Q. Have you written any papers about

1 Parkinson's disease?

2 A. Sorry. That is not a cancer.

3 No, I don't think so.

4 (Court reporter clarification.)

5 Q. Have you ever served as an expert
6 witness in a case involving environmental
7 exposures to chemicals?

8 A. I don't believe so.

9 Q. Have you published any papers or
10 co-authored any papers in peer-reviewed
11 journals concerning environmental exposures?

12 A. I don't think so.

13 Q. In your expert report, on paragraph 3,
14 the first sentence, "Much of my research
15 concerns statistical and epidemiological
16 methods for assessing effects of exposures such
17 as drugs, medical devices, and chemicals."

18 Did I read that correctly?

19 A. You did.

20 Q. Which chemicals were you referring to
21 there?

22 A. That is a good question.

23 I may have just been referring to my
24 work in this present context.

1 Q. By "this present context," do you mean
2 the Camp Lejeune litigation?

3 A. Yes, and the consulting that I did for
4 Mr. Miceli recently.

5 Q. I just want to be clear, you are
6 talking about the Camp Lejeune litigation and
7 consulting for the Camp Lejeune litigation. Is
8 that right?

9 A. I believe that is the context.
10 Mr. Miceli had asked me to look at a number of
11 issues in recent times. I believe they are
12 connected with this litigation.

13 Q. So sitting here today, you don't
14 believe you have done any research concerning
15 statistical and epidemiological methods for
16 assessing the effects of exposures and
17 chemicals other than in the context of the
18 Camp Lejeune litigation. Is that right?

19 ATTORNEY MICELI: Object to the form.
20 Foundation.

21 Let me just ask you to rephrase it in
22 the context of environmental exposure to
23 chemicals because you can see his work in drug
24 litigation, and drugs are chemicals. That is

1 the basis of my objection.

2 ATTORNEY SPRAYREGEN: I understand what
3 you are saying.

4 Could you read back his two prior
5 answers as well as what Dave just said?

6 I see what you are saying. I just
7 think I was phrasing it in terms of what he had
8 said.

9 ATTORNEY MICELI: Okay.

10 ATTORNEY SPRAYREGEN: So that is why I
11 was asking her to read it back to me.

12 ATTORNEY MICELI: Yes.

13 (The prior testimony was then read back
14 as follows:

15 "Question: Which chemicals were you
16 referring to there?

17 "Answer: That is a good question.

18 I may have just been referring to my
19 work in this present context.

20 "Question: By 'this present context,'
21 do you mean the Camp Lejeune litigation?

22 "Answer: Yes, and the consulting that
23 I did for Mr. Miceli recently.

24 "Question: I just want to be clear,

1 you are talking about the Camp Lejeune
2 litigation and consulting for the Camp Lejeune
3 litigation. Is that right?

4 "Answer: I believe that is the
5 context. Mr. Miceli had asked me to look at a
6 number of issues in recent times. I believe
7 they are connected with this litigation.

8 "Question: So sitting here today, you
9 don't believe you have done any research
10 concerning statistical and epidemiological
11 methods for assessing the effects of exposures
12 and chemicals other than in the context of the
13 Camp Lejeune litigation. Is that right?")

14 BY ATTORNEY SPRAYREGEN:

15 Q. Can you answer the question that the
16 court reporter just read back?

17 A. Sure.

18 It is a little murky, actually, because
19 you introduced the word "methods" in there. So
20 have I done studies of downstream effects of
21 chemical exposures, outside of recent work that
22 I have done for Mr. Miceli? I can't point to
23 anything. I may or may not have.

24 Method is a little different because I

1 have done a lot of work on methodology that is
2 applicable in environmental situations.

3 ATTORNEY SPRAYREGEN: Can you read back
4 his last answer?

5 (The prior testimony was then read back
6 as follows:

7 "Answer: Sure.

8 It is a little murky, actually, because
9 you introduced the word 'methods' in there. So
10 have I done studies of downstream effects of
11 chemical exposures, outside of recent work that
12 I have done for Mr. Miceli? I can't point to
13 anything. I may or may not have.

14 Method is a little different because I
15 have done a lot of work on methodology that is
16 applicable in environmental situations.")

17 BY ATTORNEY SPRAYREGEN:

18 Q. What are the downstream effects that
19 you were just referring to?

20 A. I mean studies that consider is there
21 an association between this particular chemical
22 exposure and that particular health outcome.

23 Q. When you look at the particular
24 chemical exposure and the particular health

1 outcome, what are the chemicals that you are
2 studying?

3 ATTORNEY MICELI: Object to the form.

4 A. So the work that I have done of that
5 type in recent times -- well, actually, I am
6 not referring to any chemicals in particular.

7 BY ATTORNEY SPRAYREGEN:

8 Q. You just said you had done a number of
9 studies about particular chemical exposures and
10 how they relate to particular health outcomes.

11 A. No, no.

12 Q. I misunderstood you?

13 A. Yes, sorry.

14 I am saying -- I am interpreting -- so
15 the question you asked me a couple of minutes
16 ago, right, was have I worked on methods for,
17 dot dot dot.

18 And that kind of threw me for a loop a
19 bit because I have worked on methods that
20 absolutely have applicability in environmental
21 epidemiology. So a different question is, have
22 I worked on studies of the effects of chemical
23 exposures.

24 Q. Thank you. What is your answer to the

1 question of have you worked on studies --

2 A. Not -- sorry. Go ahead.

3 Not that I recall, except in the
4 context of recent work for Mr. Miceli.

5 Did we get there?

6 Q. I think so.

7 So have you written any papers
8 published in peer-reviewed journals that
9 concern TCE, PCE, benzene, or vinyl chloride?

10 A. No, I have not.

11 Q. Do you have any support staff or
12 graduate students who assisted with your work
13 on this case?

14 A. No.

15 Q. And I believe we discussed earlier that
16 the last invoice that was produced is from
17 February 23, 2025. Is that right?

18 A. Sounds right, yes.

19 ATTORNEY MICELI: I informed you before
20 this deposition that there is one additional
21 one that we received May 28th in the amount of
22 \$16,400 that we need to produce to you. I can
23 produce that to you electronically today.

24 ATTORNEY SPRAYREGEN: I appreciate

1 that. I just couldn't remember.

2 ATTORNEY MICELI: Okay.

3 BY ATTORNEY SPRAYREGEN:

4 Q. Did you do anything in preparation for
5 today's deposition?

6 A. I had a call with, actually, the two
7 lawyers here to my left yesterday evening.

8 Q. Is that the only call that you had in
9 preparation for today's deposition?

10 A. Might have been one more. I think
11 there was one short one last Friday, I think it
12 was.

13 Q. And how long was the call yesterday
14 evening?

15 A. 15 minutes.

16 Q. Have you had any communications with
17 other experts in this case?

18 A. I don't believe so, no.

19 Q. Have you received any compensation in
20 connection with your work in this case?

21 A. Yes.

22 Q. Do you know how much you have been paid
23 to date?

24 A. No. Whatever the invoices were paid.

1 Whatever they are.

2 Q. Is your compensation in this matter in
3 any way dependent on the outcome of the case?

4 A. No.

5 Q. What percentage of your annual income
6 is earned from performing expert services work?

7 ATTORNEY MICELI: Object to the form.

8 A. In the last year, say, 2024, something
9 like 10 or 15 percent. I don't have an exact
10 number.

11 BY ATTORNEY SPRAYREGEN:

12 Q. Is that representative of the last five
13 years?

14 A. Probably, yes. It has ebbed and flowed
15 a bit, but it is in that kind of range.

16 Q. As an expert witness, have you ever
17 offered opinions on general causation that a
18 court has excluded?

19 A. I don't think so. Actually, I think,
20 in Abilify, I was excluded from offering an
21 opinion about medical causation, which I didn't
22 do and never would do.

23 Beyond that, there is nothing that I
24 can recall.

1 Q. What about Accutane?

2 A. Right. So there, I did a power
3 calculation that a judge took issue with.

4 Q. What about Alsartan?

5 ATTORNEY MICELI: Valsartan?

6 BY ATTORNEY SPRAYREGEN:

7 Q. Valsartan.

8 A. I have no recollection.

9 Q. What about Taxotere?

10 A. He would know better than I will. But
11 I -- wasn't there an issue -- I don't recall.
12 I really just don't recall sitting here at this
13 minute.

14 Q. What about in re: Incretin-based
15 therapies?

16 A. There, yes, I had some opinions
17 excluded. The issue there was, I wrote a
18 report on what turned out not to be the most
19 recent data. I wasn't provided with the most
20 recent data, and the court, not unreasonably,
21 said you need to use the most recent data. I
22 didn't know there was such data.

23 ATTORNEY SPRAYREGEN: Can we go off the
24 record?

1 THE VIDEOGRAPHER: The time is
2 2:41 p.m., and we are off the record.

3 (Recess taken at 2:41 p.m.)

4 (Recess ended at 3:04 p.m.)

5 THE VIDEOGRAPHER: The time is
6 3:04 p.m., and we are on the record.

7 BY ATTORNEY SPRAYREGEN:

8 Q. Dr. Madigan, you remember we were
9 talking about paragraph 3 of your report
10 earlier?

11 A. Yes.

12 Q. So I am just going to read the first
13 sentence from paragraph 3 again.

14 "Much of my research concerns
15 statistical and epidemiological methods for
16 assessing the effects of exposure such as
17 drugs, medical devices, and chemicals."

18 Did I read that correctly?

19 A. Yes.

20 Q. And when you write "chemicals" there,
21 is it your testimony, that refers to your work
22 on the Camp Lejeune litigation and any
23 Camp Lejeune consulting you have done?

24 A. Nothing else comes to mind when I look

1 at my CV, so yes, that is what I am referring
2 to.

3 Q. When were you first contacted to work
4 on this report?

5 ATTORNEY MICELI: Let me impose an
6 objection. I don't think I need to instruct my
7 witness not to answer, but you are talking
8 about this report? Because he talked about
9 consulting beforehand.

10 ATTORNEY SPRAYREGEN: That is what I
11 was trying to ask, but yes.

12 ATTORNEY MICELI: Okay. Thank you.

13 A. Couple months ago.

14 BY ATTORNEY SPRAYREGEN:

15 Q. So the report is dated March?

16 A. I mean, a couple of months before that.
17 I worked on this on and off for a couple of
18 months. So, yes. What is the date?

19 ATTORNEY MICELI: March 16th is the
20 date on your report.

21 A. So I don't know exactly, but I would
22 guess January, something like that.

23 BY ATTORNEY SPRAYREGEN:

24 Q. What were you asked to do?

1 A. So I was asked --

2 ATTORNEY MICELI: Object to the form.

3 And do not state anything that you
4 discussed with myself or other members of the
5 plaintiffs' leadership group.

6 A. So I was asked, as it says in my
7 report, I was asked to provide opinions with
8 regard to the purpose and methodological
9 soundness of using meta-analysis in an
10 assessment of the health outcomes from
11 exposures to chemicals.

12 I was also asked to make comments
13 specifically on the reports of Dr. Shields and
14 Dr. Goodman.

15 BY ATTORNEY SPRAYREGEN:

16 Q. Did you have any questions about what
17 you were asked to do?

18 A. Not that I can recall.

19 Q. Did you ask for any materials?

20 A. I don't think so.

21 Q. Approximately how long did it take you
22 to draft this report?

23 A. That would be the most recent invoice.
24 So 20 hours. Less than 20 hours. I don't

1 know, around about 20 hours I would guess.

2 Q. If you had more time, would you have
3 done anything differently?

4 A. No.

5 Q. Are there any materials you would have
6 liked to have seen?

7 A. No.

8 Q. Are there any materials you asked for
9 and did not get?

10 A. No.

11 ATTORNEY SPRAYREGEN: I have no other
12 questions.

13 THE WITNESS: Thank you very much.

14 ATTORNEY MICELI: I have a few.

15 I am going to have a few follow-up
16 questions. I am not going to take very long.

17 But I am going to flip my exhibits over
18 because I think I am going to have to grab some
19 of them along the way.

20 EXAMINATION

21 BY ATTORNEY MICELI:

22 Q. Before we get started, Dr. Madigan, can
23 you, for the benefit of somebody who may review
24 this deposition at a later date, can you just

1 summarize for us your educational background
2 and your work as a statistician? And I would
3 say going back to when you were at Rutgers.

4 A. Sure.

5 So my education, I have a bachelor's
6 degree in mathematics from Trinity College
7 Dublin. That was in 1984. And then I have a
8 Ph.D. in statistics also from Trinity College
9 Dublin. That is 1990.

10 I then served as a professor of
11 statistics -- a tenured professor of statistics
12 at four different major research universities.
13 And I have had, in addition, in between some of
14 those academic appointments, I have also worked
15 in industry, as people call it, outside of
16 academia, but as a statistician.

17 Q. Can you tell us which institutions you
18 are referring to?

19 A. Sure.

20 Q. And the positions held.

21 A. Sure.

22 So my first academic appointment was as
23 a tenure-track assistant professor of
24 statistics at the University of Washington in

1 Seattle, which is one of the top institutions
2 in the country in statistics.

3 I received tenure there and became an
4 associate professor.

5 At that point, I left the academy and
6 worked for AT&T Labs as a research statistician
7 for a period. Then I did some other things.

8 And then returned to an academic
9 position as a full professor of statistics at
10 Rutgers.

11 While I was at Rutgers, I also served
12 as the director of the institute of
13 biostatistics, which I was in what was then
14 called the department of statistics. So
15 separately, Rutgers had an institute for
16 biostatistics, and I directed that.

17 So that work involved -- was extensive
18 interactions with basically pharma in the
19 New Jersey area. There is a lot of pharma
20 companies located there.

21 Then I moved from Rutgers to Columbia
22 University in New York City, where I stayed
23 for, I don't know, 14 years or something. So I
24 was a full professor, tenured professor of

1 statistics at Columbia.

2 I was the chair of the Columbia
3 department of statistics, which is one of the
4 oldest statistics departments in the country.
5 I did that for five years.

6 During that time, actually beginning at
7 Rutgers and continuing at Columbia, I was one
8 of the founders of a significant project, a
9 public/private partnership called OMOP, the
10 Observational Medical Outcomes Partnership,
11 which is a partnership between the pharma
12 industry and the FDA. I was one of the PIs.

13 That evolved into something called
14 OHDSI. I was one of the founders of OHDSI,
15 O-H-D-S-I, which is Observational Healthcare
16 Data Sciences and Informatics, which is a major
17 worldwide collaboration focused on epidemiology
18 and generating evidence from large-scale
19 healthcare data.

20 Throughout all of this time, I have
21 done extensive consulting -- there is a list on
22 my CV -- with companies on statistical matters,
23 many of them within the pharmaceutical
24 industry, but there is also other clients in

1 other sectors.

2 Should I go on?

3 Q. Let me pick up because you left off at
4 Columbia. And were you the dean of arts and
5 sciences there?

6 A. That's right. So I served a term --
7 actually, I served two terms as the chair of
8 the department of statistics. And then I
9 became the so-called executive vice president
10 for arts and sciences and the dean of the
11 faculty of arts and sciences.

12 So Columbia University -- it is not
13 uncommon. Columbia University, basically,
14 there is the arts and sciences, which is 27
15 academic departments and about 50 centers and
16 institutes. And then there is, from my
17 perspective, everything else, which is the
18 business school, the law school, the medical
19 school. The little things like that.

20 So I ran the arts and sciences for five
21 and a half years.

22 Q. Okay. And then you came here to
23 Boston?

24 A. Then I came here to Boston as the

1 provost and professor of statistics at
2 Northeastern.

3 Q. I think you said this before, but I
4 want to make sure it is clear again for the
5 judge who may read this or we will be able to
6 include it in a brief.

7 But as far as the hierarchy at
8 Northeastern, you are currently the provost and
9 you came here as the provost, and who ranks
10 above you in the pecking order at the
11 university?

12 A. The president.

13 Q. Only the president?

14 A. Yes. So I am basically number two.

15 Q. Okay. And then in the private industry
16 side, where have you worked?

17 A. So a long time ago, I worked in Ireland
18 with software companies and also as a
19 consultant for KPMG doing statistical work back
20 in the 1980s.

21 Q. Way back then.

22 A. Way back then.

23 (Laughter.)

24 A. Before some people in the room were

1 born, no doubt.

2 Then when I left the University of
3 Washington, I went to AT&T Labs, which was
4 basically a part of Bell Labs, is what it
5 amounts to, to do statistical research. I was
6 there for a while. Then I was involved in a
7 startup in New York City.

8 Q. Have you ever worked as a consultant to
9 the FDA?

10 A. So I have had extensive interactions
11 with the FDA over a very long period of time.
12 So I mentioned OMOP, the Observational Medical
13 Outcomes Partnership. That was a partnership,
14 a public/private partnership that lasted for --
15 went on for about five years.

16 It was -- the chair of the advisory
17 board for that project -- it was basically
18 pharma money and FDA oversight and leadership
19 and some academics involved.

20 So the chair of the advisory committee
21 was the head of CDER, which is the drug branch
22 of the FDA.

23 Q. Center for Drug Evaluation and
24 Research?

1 A. Yes, Janet Woodcock. So I worked very
2 closely with her during those years.

3 I served on an FDA -- one of the FDA
4 advisory committees. So the FDA maintains a
5 set of committees, outside -- external
6 committees.

7 Q. Make sure you slow down for the court
8 reporter.

9 A. FDA maintains a set of committees of
10 experts that advise them on matters like
11 approval or nonapproval of a drug or a device.

12 So I served a term on -- a three-year
13 term on an advisory committee.

14 Following that, I served three years as
15 a consultant to the FDA in related matters.

16 I also served on a subcommittee of a
17 science board at the FDA.

18 Actually, apropos nothing, yesterday I
19 conducted a fireside chat with the most recent
20 commissioner of the FDA.

21 Q. Who is that?

22 A. Rob Califf.

23 Q. Have you ever worked as a consultant to
24 the department of defense?

1 A. I don't think so.

2 Q. Have you ever done any work
3 reevaluating or reassessing the evidence
4 concerning anthrax for the United States
5 government?

6 A. Yes.

7 Q. Can you tell us about that?

8 A. Sure. So for about a 10-year period
9 after 9-11, when anthrax was a significant
10 concern -- perhaps still is.

11 Q. If you are near it, it is a big
12 concern.

13 A. Indeed.

14 I worked as a consultant for the
15 Centers For Disease Control on what their AVIP,
16 their Anthrax Vaccine Investigational Program.
17 And it was to do with -- so there is an anthrax
18 vaccine that was actually approved in the
19 1950s, and there were concerns about the safety
20 of that vaccine. It was an old-fashioned
21 vaccine. So I did a lot of work with the CDC
22 over an extensive period on that matter, I
23 would say, just to keep it short.

24 Q. Were you rerunning data for them?

1 A. Yes.

2 Q. We have talked about your time at
3 Washington, Bell Labs, Rutgers, Columbia,
4 Northeastern, your work with OHDSI, OMOP, CDC,
5 and this collaboration with pharmaceutical
6 companies.

7 Is all of the work that you were doing
8 in that regard statistics -- statistical, or
9 biostatistical work?

10 A. And epidemiological. So statistics and
11 epidemiology.

12 Q. In that career that we have reviewed,
13 that portion of it, how long has it spanned?

14 A. 1990, I guess. 35 years.

15 Q. And part of that has been working with,
16 as a consultant, the United States government,
17 the Food and Drug Administration, and the
18 Centers For Disease Control?

19 A. Yes.

20 Q. I know this is clear because the
21 federal judge who will be reviewing this is an
22 employee of the United States government. But
23 that is the same government that Ms. Sprayregen
24 is here representing today?

1 A. I believe so.

2 Q. Thanks for that. That is the
3 background stuff I wanted to go over.

4 I wanted to start, because you have
5 made reference to the peer-review process a
6 couple of times today, and it is probably going
7 to come up in some of my questions, but could
8 you explain for the purposes of the court what
9 the peer-review process is, how it plays into
10 publications, and, as a scientist, how do you
11 rely upon the peer-review process?

12 A. Sure.

13 So that peer-review process is of
14 central importance, not just in the
15 United States, but globally, in research. In
16 science, for sure, but also outside of science.

17 So the basic kind of paradigm is, if I,
18 as a researcher, if I do a study or I develop a
19 new method for something, in order to
20 communicate that to the world, the process is
21 to seek to publish it in a journal.

22 And the more influential journals are
23 certainly all peer-reviewed. So the basic way
24 it works is you write up your work, you send it

1 to a relevant journal. The journal -- it will
2 go to the editor, typically an academic, not
3 always. It goes to the editor of the journal.
4 The editor does typically what is called a desk
5 review. So the editor might reject it on the
6 spot as not of interest, or maybe immediately
7 sees some flaw in the work.

8 But assuming that it is of interest and
9 it seems plausible, the editor actually
10 typically would hand it to an associate editor
11 who seeks peer reviewers for the paper, so
12 typically blinded. So you, as the author, you
13 don't know who these reviewers are. So they
14 seek some of your peers, fellow experts in the
15 field, send them the paper, typically more than
16 one. Sometimes as many as five or six.

17 And then those -- typically, unpaid.
18 Those peer reviewers assess the work for its
19 correctness, to some extent, although that
20 remains the responsibility of the author. But
21 they -- it's a quality review.

22 All going well, which is maybe
23 10 percent of the time in a top journal --
24 actually, there is often some iteration.

1 Sometimes the reviewers will suggest changes.
2 Then it goes back to the reviewers.

3 But all going well, the process ends
4 with the reviewers writing reports for the
5 editor, and then the editor reads those reports
6 and says, yes, this is publishable in my
7 journal or, no, it is not publishable in my
8 journal.

9 I have served on every last piece of
10 that. So I obviously have been an author. I
11 have served as a peer reviewer constantly. It
12 has got to be thousands of times.

13 I have served as an associate editor,
14 and then I have also served as the
15 editor-in-chief on a couple of journals,
16 including "Statistical Science," which is
17 arguably the top journal in statistics.

18 Q. When you publish -- and I know that you
19 can't speak for every publication that has ever
20 been submitted.

21 But generally speaking, when you are
22 submitting to a peer-reviewed journal, do you
23 have to set out the objective of your study?

24 A. Yes, generally speaking.

1 Q. Do you have to set out the methodology
2 by which you conducted the study?

3 A. Yes. Certainly, if the genre is
4 mathematics, then maybe not. You might publish
5 a paper that proves a theorem.

6 But if it is a clinical study, a study
7 of the impacts of a chemical, then, yes, there
8 is a background section, there is a methods
9 section, there is a results section, discussion
10 section.

11 Q. Do you set out the strengths and
12 weaknesses of the study as well?

13 A. Typically, in the discussion section,
14 any journal will insist that you make clear
15 what the limitations of the study are.

16 Q. We have heard some mention about biases
17 and confounders to studies.

18 Are biases and confounders the types of
19 things that get discussed when you are
20 discussing strengths and weaknesses of a study?

21 A. Sure. Absolutely.

22 Q. Do some, most, or all studies have
23 strengths and weaknesses?

24 A. Certainly all clinical studies have

1 strengths and weaknesses.

2 Q. Thank you for correcting. All clinical
3 studies have strengths and weaknesses.

4 When you are reviewing, not as a peer
5 reviewer, but when you are reading a clinical
6 study or an observational study, is reviewing
7 the strengths and weaknesses part of your
8 critical review of that piece?

9 A. Absolutely.

10 Q. The fact that a study has some
11 weaknesses or potential weaknesses, does that
12 make it fatal to rely upon that piece of
13 evidence when drawing conclusions on causation?

14 ATTORNEY SPRAYREGEN: Objection to
15 form.

16 A. No. Every study has weaknesses.

17 BY ATTORNEY MICELI:

18 Q. In your view, does the peer-review
19 process -- or is the peer-review process, in
20 part, in place to deal with identifying and
21 making sure that weaknesses in the study are
22 included within what gets published?

23 A. Yes, absolutely.

24 Q. I want to look at Exhibit 5 with you

1 for a second. That is the Cochrane.

2 And I am going to be kind of jumping
3 around because Ms. Sprayregen was pretty
4 thorough in what she went through, but I am
5 going to have some questions on some of the
6 things that she mentioned.

7 This is the Cochrane chapter 10,
8 training chapter, "Analyzing Data and
9 Undertaking Meta-Analyses."

10 First of all, on the first page in the
11 bottom right corner, it says 1/102. Does
12 that -- I take that to mean 1 of 102 pages?

13 A. Yes.

14 Q. But if you flip to the back, we have
15 got 52 of 102. Correct?

16 A. Yes.

17 Q. On the last page.

18 If we go to page 18 of 102, you were
19 asked, at the bottom the page here, there is
20 this box that is 10 point -- or excuse me, C62,
21 "Ensuring meta-analyses are meaningful
22 (mandatory)."

23 There was some language that was
24 reviewed with you.

1 You were asked by Ms. Sprayregen, what
2 do they mean by "control" in this sentence on
3 the right-hand side in the box, the first three
4 lines -- two and a half lines.

5 Do you recall that?

6 A. I do.

7 Q. As we sit here today, I mean, I know
8 that you gave your best interpretation, but can
9 you answer what the authors meant by the words
10 they chose?

11 A. No, I can't. I can offer, as I did,
12 what I think they might be thinking of. But,
13 no. You need to ask them.

14 Q. You gave your best interpretation of
15 what they may have meant. But if she wants to
16 know what the authors meant, she can either
17 just read it or go and ask the authors?

18 ATTORNEY SPRAYREGEN: Objection.

19 A. Yes.

20 BY ATTORNEY MICELI:

21 Q. With regard to Section 10.10.3, which
22 is on page 20 of 102, there was a discussion
23 about heterogeneity. And my question for you
24 is, you were asked some questions earlier today

1 about heterogeneity of studies that are
2 aggregated or put into meta-analyses.

3 Do you recall those questions?

4 A. Yes.

5 Q. Is heterogeneity a know -- I don't know
6 what the right term is.

7 Is heterogeneity a known issue with
8 meta-analyses that you have to be aware of when
9 conducting a meta-analysis?

10 A. Yes, it is something that you need to
11 consider when performing a meta-analysis.

12 Absolutely.

13 Q. Are there tests for heterogeneity?

14 A. Yes. Statistical tests.

15 Q. Right. If we -- statistical tests.

16 You were asked about page 21, line 3.
17 There is things you can do and one of them is
18 explore heterogeneity.

19 A. Yes.

20 Q. And is that something that is done
21 regularly in meta-analyses that get published
22 in the peer-reviewed scientific literature?

23 A. Yes. I mean, it is good practice,
24 always, when doing a meta-analysis to report

1 heterogeneity and to look at heterogeneity and
2 discuss it.

3 Q. And although heterogeneity --

4 ATTORNEY MICELI: Well, let me strike
5 that.

6 BY ATTORNEY MICELI:

7 Q. Can heterogeneity be so great that it
8 causes you to give less credence or less weight
9 to a meta-analysis?

10 A. Yes, I mean, it is a continuum. Right?
11 There is actually a statistic. One of the
12 statistics that people use, I use, to measure
13 heterogeneity is called I-squared. And it
14 varies from 0 percent to 100 percent.

15 And so there is no magic line above X,
16 you know, thou shalt not do a meta-analysis.
17 There is no such X.

18 But it becomes more of a concern
19 certainly the closer to 100 percent you are.

20 Q. Okay. But that is a known concern --
21 not to say concern.

22 Heterogeneity is a known factor in
23 meta-analyses that people in your profession
24 and in your field have to be aware of and look

1 to when reviewing meta-analyses?

2 A. Absolutely.

3 Q. And the fact that there is some
4 heterogeneity within a meta-analysis or the
5 studies included within meta-analysis does not
6 render the meta-analysis unworthy of relying
7 upon it for what it demonstrates?

8 ATTORNEY SPRAYREGEN: Objection to
9 form.

10 BY ATTORNEY MICELI:

11 Q. Is that a fair statement?

12 A. I mean, there is always some
13 heterogeneity. I mean, if you are doing a
14 meta-analysis of a few studies that are
15 identical, that would be bizarre. So there is
16 always some heterogeneity. So it really is
17 just a question of degree.

18 Q. I think you may have answered this
19 earlier.

20 But is there anything improper about
21 including observational studies of different
22 type, like a cohort study or cohort studies and
23 case-control studies in a single or a combined
24 meta-analysis?

1 A. No. It is -- I cite to examples in my
2 report. It is something I have done. It is
3 perfectly reasonable to include cohort studies
4 and case-control studies in a meta-analysis, in
5 my mind, in my view.

6 Q. You were asked about publication bias
7 during Ms. Sprayregen's questioning.

8 Is publication bias something that is
9 discussed -- regularly discussed within the
10 limitation section of a peer-reviewed
11 scientific article?

12 A. Yes. Certainly when it is relevant, it
13 is often discussed.

14 Q. Can publication bias be tested for?

15 A. Sure. There is a standard statistical
16 test called EGGER test, that is not the only
17 one, but it is a widely used statistical test
18 to assess the presence of publication bias.

19 Q. So the fact that somebody just alleges
20 publication bias or suggests publication bias
21 does not render a scientific journal article
22 unworthy of belief or worthy of being relied
23 upon.

24 ATTORNEY SPRAYREGEN: Objection to

1 form.

2 BY ATTORNEY MICELI:

3 Q. Is that fair?

4 A. I think that is fair, yes.

5 Q. I want to look at your report with you.

6 And I want to look at paragraph 19. I
7 think it is on page 6.

8 A. Yes.

9 Q. This is the -- I want to find exactly
10 where we are talking about.

11 Ms. Sprayregen went over this paragraph
12 with you that begins with "Meta-analysis." I
13 am going to read down through where you
14 reference footnote 13.

15 "Meta-analysis is the use of
16 statistical methods to summarize the results of
17 multiple independent studies. Per the Cochrane
18 Handbook, by combining information from all
19 relevant studies, meta-analyses can provide
20 more precise estimates of the effects of health
21 effects from chemical exposure than those
22 derived from individual studies included within
23 a review. They also facilitate investigations
24 of the consistency of evidence across studies,

1 and the exploration of differences across
2 studies."

3 Did I read that correctly?

4 A. Yes.

5 Q. Because you were asked about the use of
6 the word "consistency" there, and there were
7 some questions concerning consistency in
8 meta-analyses and consistency concerning a Hill
9 analysis, is it necessary to conduct a Hill
10 analysis on consistency before doing a
11 meta-analysis of multiple studies?

12 A. No.

13 Q. Okay.

14 A. These are just different things.

15 So in the context of meta-analysis,
16 nothing to do with Hill, in the context of
17 meta-analysis, the issue of consistency is
18 something that one needs to look at.

19 Q. Is that how you were using the term
20 "consistency" here in paragraph 19 of your
21 report?

22 A. Yes.

23 Q. I just want to make sure there wasn't
24 any confusion that it was somehow necessary to

1 do a Bradford Hill -- or excuse me -- a Hill
2 analysis on consistency alone.

3 A. No.

4 Q. The fact that those same two words are
5 used in your paragraph 19 and as a Hill
6 consideration are totally separate?

7 A. Yes, they are unrelated in my mind.

8 Q. Okay.

9 A. Actually, just -- that is not quite
10 right when I said they were unrelated.

11 When doing a Hill analysis, one of the
12 things one does is look at consistency. That
13 could be -- it could not, not necessarily, but
14 it could be in the context of a meta-analysis.
15 So they are not completely unrelated. But
16 certainly here, in paragraph 19, where I am
17 talking about consistency, any mention of Hill
18 analysis is basically a red herring here.

19 Q. Okay.

20 I am done with number 5. I am going to
21 go to Exhibit number 7 with you, which is
22 "Epidemiology and the Law" authored by David
23 Savitz and Stephen G. Schwarz.

24 There we are, at the very bottom.

1 You had mentioned earlier today that
2 you are familiar with Dr. Savitz?

3 A. He is very eminent. He is one of the
4 top epidemiologists in the country.

5 Q. If you could, I know -- if we could
6 turn to page 108 of this. Actually, what I
7 want to do first is turn all the way over to
8 page 111. There is a paragraph that
9 Ms. Sprayregen read to you on page 111 that is
10 part of the section that begins on page 109,
11 "Disadvantages of relying on meta-analysis to
12 synthesize evidence."

13 Do you recall that paragraph that is
14 the first full paragraph on page 111?

15 A. Yes.

16 Q. I want you to turn with me to page 108
17 and 109, which is one page earlier, and there
18 is a section 2 called, "Rationale for
19 conducting meta-analyses."

20 Do you see that?

21 A. I see that.

22 Q. In this, the first paragraph begins --
23 and I am going to read about halfway through
24 this paragraph.

1 "An increasingly popular approach to
2 examining a set of studies addressing the same
3 question is through a systematic review that
4 generally culminates is what is referred to as
5 a meta-analysis. The product of a
6 meta-analysis is often a pooled estimate of the
7 association between exposure and disease,
8 combining the results from a series of studies
9 into a single number, the pooled relative risk
10 or odds ratio. The intention, of course, is
11 that the pooled estimate is the most accurate
12 indicator of the effect of exposure on disease
13 risk because it is based, not on the data from
14 an single study, but on the combined data from
15 a number of different studies."

16 Did I read that correctly?

17 A. Yes.

18 Q. Do you agree with that?

19 A. Yes.

20 Q. Is one of the benefits or -- rather
21 than -- can you just explain to the Court what
22 the benefit of doing a meta-analysis is in the
23 context of multiple underpowered studies?

24 A. So an underpowered study of an issue,

1 that there was an association between an
2 exposure and an outcome. An underpowered
3 study, in general, leaves you, once it is
4 conducted, it doesn't have much power. It
5 leaves you in a state of ignorance. You
6 conduct such a study and you might find a
7 slightly elevated increased risk or decreased
8 risk, whatever it might be. But because it
9 lacks, generally, is not statistically
10 significant. It leaves you in a state of not
11 being sure.

12 So the beauty of meta-analysis is, and
13 the reason why it is such a widely used
14 powerful tool, the reason -- one of the reasons
15 why meta-analysis is so useful is you can take
16 several such studies -- they don't have to be
17 underpowered, but you can take several
18 underpowered studies, and by combining them
19 using meta-analytic techniques, you end up with
20 a powerful analysis, statistically powerful.
21 Meaning that, if indeed there is, let's say, an
22 elevated risk, there is a high chance that the
23 meta-analysis will find it.

24 Q. Is the tool that you just described,

1 the meta-analysis, recognized in the field of
2 statistics and biostatistics as a valid and
3 reliable tool for estimating risk and/or cause?

4 A. Absolutely.

5 Q. I mean, how long have meta-analyses
6 been around?

7 A. 1950s, I think.

8 Q. You have been, you said, 35 years you
9 have been in the field?

10 A. Yes.

11 Q. You have been a professor at four large
12 research universities?

13 A. Yes.

14 Q. Throughout that entire course of being
15 a professor, have you taught on the utility and
16 usefulness of meta-analyses?

17 A. Many, many times.

18 Q. Have you utilized meta-analyses in your
19 work that you have done with the federal
20 government?

21 A. Yes. Certainly in the context of the
22 OMOP project, for example, with the FDA. That
23 was meta-analysis all over the place.

24 Q. Have you used, in your professional

1 career, meta-analyses to analyze information
2 and data for pharmaceutical companies?

3 A. Absolutely.

4 Q. Have you used meta-analyses in drawing
5 conclusions and rendering opinions that have
6 been accepted and approved in the United States
7 federal court system?

8 A. Federal court system? I believe so. I
9 am not certain of the federal versus state.

10 Q. Sure.

11 Let me give you one example. Do you
12 recall doing one of the TAX 316 and the TAX 301
13 study?

14 A. I sure do.

15 Q. Was that meta-analysis allowed in your
16 testimony in the Taxotere litigation?

17 A. Yes.

18 Q. Have you done it in other state courts?

19 A. I have certainly done meta-analysis
20 many times in -- as part of my testimony in
21 litigation.

22 Q. Let's go to page 109. I don't want to
23 read the entire section here, but the last full
24 paragraph on page 10 that starts, "By pooling."

1 A. Yes.

2 Q. It says, "By pooling the results across
3 studies, the fluctuation in findings due to
4 random error is minimized, which is why the
5 confidence interval becomes narrower. The
6 weighted average gives large studies more
7 credit and small studies less credit, smoothing
8 out differences that would otherwise be
9 distracting from the overall pattern."

10 Did I read that correctly?

11 A. You did.

12 Q. Do you agree with that statement?

13 A. Yes.

14 Q. That is all I have on that one.

15 I don't know why I have this question
16 right here, but since it is here, I am going to
17 go ahead and ask it.

18 You have been shown parts of reports
19 from different experts, but two from
20 Dr. Goodman, one a leukemia risk -- or a
21 leukemia report and another a kidney cancer
22 report.

23 Are you offering any disease-specific
24 opinions in your rebuttal report?

1 ATTORNEY SPRAYREGEN: Objection to
2 form.

3 A. No.

4 BY ATTORNEY MICELI:

5 Q. So if we looked at your report, in
6 page 2, section 2, paragraphs 6 and 7, this
7 says, "Scope and Summary of Opinions."

8 And you have gone over paragraph 6 and
9 you can read paragraph 7.

10 Is this the extent of your -- the
11 top -- what is listed in paragraph 6 and
12 paragraph 7 and the comments with regard to the
13 opinions of Dr. Shields and Dr. Goodman, is
14 that the extent of your opinions in this case?

15 A. Yes.

16 Q. I am probably going to come back to
17 this.

18 Because you have been shown a number
19 of -- some publications that deal with
20 particular diseases and set out certain
21 comments about diseases, and you have shown
22 table 2 and I believe it was the -- I am not
23 going to go there right now, I may come back to
24 it.

1 Was it necessary for you to look at --
2 in rendering the opinions that you have on the
3 validity of meta-analyses and the comments you
4 make concerning -- the general comments you
5 made concerning Dr. Shields's and Dr. Goodman's
6 reports, was it necessary to investigate the
7 specific data on any disease, whether it is any
8 of the four cancers or Parkinson's disease
9 involved in the first round of the Camp Lejeune
10 litigation?

11 ATTORNEY SPRAYREGEN: Objection to
12 form.

13 A. No.

14 BY ATTORNEY MICELI:

15 Q. Let me go to Exhibit number 9, which
16 was the Linet, et al. And I know that it
17 wasn't necessary for you to review this one,
18 but I want to look at it with you just quickly.
19 And go to -- are you there with me? I bet it
20 is going to be at the bottom again.

21 (Discussion off the record.)

22 BY ATTORNEY MICELI:

23 Q. With regard to the Linet, et al., case,
24 can you flip to page 2189? That was the

1 table 2 in this study.

2 A. Yes.

3 Q. This is the relative risk of mortality
4 among Chinese benzene-exposed versus unexposed
5 workers follow-up during 1972 through 1999 by
6 cause of death.

7 A. Yes.

8 Q. You were asked some questions
9 concerning kidney cancer, which was not
10 included on this chart, and you were asked
11 about publication bias.

12 Do you remember those questions?

13 A. Yes.

14 Q. And there was some questions about
15 publication bias being impacted because they
16 didn't include kidney because it may have
17 either been at the null or below.

18 Do you recall that suggestion?

19 A. I do.

20 Q. I want you to look at the line for
21 stomach cancer. Do you see it?

22 A. I do.

23 Q. And if you go over to the right, it
24 says RR is 1.0. Is that the null?

1 A. That is the null.

2 Q. So the authors of this study
3 included -- it included cancers that included
4 the null. Correct?

5 A. For sure, in a very kind of extreme
6 definition of null. So a very rigid definition
7 of null. So that 1 on stomach is -- the
8 estimated odds ratio is precisely 1. And,
9 obviously, it is not statistically significant.
10 That's is -- if that isn't null, I don't know
11 what is.

12 But there are several others here, like
13 the very next one -- actually, no.

14 Say the liver, two down. That is --
15 the estimated risk there is 1.2. But it is
16 absolutely -- it is not statistically
17 significant.

18 Q. It didn't achieve statistical
19 significance?

20 A. It did not.

21 So there is a mix here. There is one
22 that is truly, by anyone's definition, a null
23 study. And then there are others that did not
24 reach statistical significance that perhaps

1 some individuals are calling null are also
2 included.

3 Q. So the suggestion that the authors may
4 have not included studies or findings that
5 crossed the null -- were at or crossed below
6 the null and, therefore, this study was somehow
7 tainted by publication bias, would seem to be
8 contradicted by this table?

9 ATTORNEY SPRAYREGEN: Objection to
10 form.

11 You can answer.

12 A. Yes. I remember being asked a
13 hypothetical, but it seems like an improbable
14 hypothetical to me.

15 BY ATTORNEY SPRAYREGEN:

16 Q. Is that because of what is actually
17 shown?

18 A. Precisely.

19 Q. Let's drop down to leukemia.

20 It has the 204 -- the ICD codes are 204
21 to 208.

22 A. Yes.

23 Q. And that relative risk is 2.8, it is
24 1.6 to upper bound 5.5 in the confidence

1 interval?

2 A. Yes.

3 Q. So that finding does achieve
4 statistical significance?

5 A. Absolutely.

6 Q. Okay. That is all I wanted to show on
7 that one.

8 The next article I wanted to show you
9 was Exhibit 10. This is the Seyyedsalehi?

10 ATTORNEY TUBIN: Somebody somewhere
11 knows.

12 BY ATTORNEY MICELI:

13 Q. Seyyedsalehi. You were asked some
14 questions specifically about this and in the
15 chart that follows about the Wong study?

16 A. Right.

17 Q. I just wanted to make clear that you
18 did not have to review this study or the Wong
19 study to offer the opinions that you give in
20 your rebuttal report. Is that correct?

21 A. That's correct.

22 Q. But you did give us an explanation
23 about linear versus nonlinear relationship
24 between dose and disease or effect.

1 When you were answering those
2 questions, I thought I heard you say that that
3 was outside of your expertise. Did I hear you
4 correctly?

5 A. Yes, I have no knowledge of the nature
6 of any dose-response relationship between
7 benzine and kidney or bladder cancer. I have
8 no knowledge about that.

9 Q. You didn't review anything to offer
10 that opinion in your rebuttal report?

11 A. Correct.

12 Q. So you did not -- well, you don't offer
13 a medical or a scientific causation opinion in
14 any portion of your rebuttal report, do you?

15 A. I do not.

16 Q. When you were going through your
17 report, and I wanted to go to page 7,
18 section 5, of your report. This is, I think --
19 actually, it is not that.

20 It is when we were talking about
21 Dr. Shields's opinions and Dr. Goodman's
22 opinions.

23 And those would be paragraphs 24 and
24 25. And as you were going through those with

1 Ms. Sprayregen, she was asking you your next
2 opinion would be, and then she would read from
3 your report, and you would say yes.

4 I want to make sure that I understood
5 you correctly that, when you were saying yes to
6 Ms. Sprayregen, you were saying she read your
7 report correctly?

8 A. Yes. I think more specifically, what
9 Ms. Sprayregen did was, Dr. Goodman's opinion
10 number 1 -- or statement. I can't recall
11 exactly the word you used -- number 1 was, and
12 you would read it. And the question was, is
13 that number 1? And I would answer yes. Then,
14 is this number 2? And I would answer yes.

15 So I think what you are making sure
16 is -- I am glad you are doing it. I think you
17 are making sure that that is what I was
18 agreeing to, not the actual statement by
19 Dr. Goodman.

20 Q. You were agreeing that Ms. Sprayregen
21 was reading it correctly, not that the
22 substance of what she was reading was correct?

23 A. Exactly.

24 Q. That is what I want to make sure of for

1 whoever reads this later.

2 I don't know if I need to ask this. I
3 think you may have.

4 (Pause.)

5 Q. Concerning the -- I am going to go back
6 to Exhibit 10.

7 Excuse me. No, I apologize. 11.
8 Dr. Goodman's report. I believe it was
9 attachment C to her report that Ms. Sprayregen
10 reviewed with you.

11 A. Yes.

12 Q. Table C1. And she went through
13 strengths and weaknesses that Dr. Goodman
14 attempts to include in her attachment C.

15 And with regard to covariants
16 considered -- or covariants not considered, is
17 there any reason to believe that the
18 covariants, one, were relevant to the outcome
19 of the study that she is citing to?

20 A. Not that I am aware of.

21 Q. Is there any reason --

22 ATTORNEY MICELI: Or let me strike that
23 and I am going to ask it differently.

24 BY ATTORNEY MICELI:

1 Q. In your review of Dr. Goodman's report,
2 does she ever analyze how the unaddressed
3 covariants skew the results in a way that is
4 adverse to the DOJ's position?

5 A. Not that I am aware of.

6 Q. Okay. Does she address the covariants,
7 the weaknesses in the covariants, or the ones
8 that were not addressed, does she address how
9 they would be disproportionately affecting one
10 group or another to skew the results of the
11 studies?

12 ATTORNEY SPRAYREGEN: Objection to
13 form.

14 A. I don't believe so. She makes a
15 statement repeatedly, like, did not control or
16 consider smoking, and I am sure she is
17 factually correct.

18 But the issue is, does it matter in
19 this context? Is it actually a confounder?

20 BY ATTORNEY MICELI:

21 Q. When you say that, in your report, at
22 paragraph 24 concerning Dr. Shields, and 25
23 concerning Dr. Goodman, you mention that they
24 both make general statements or criticism but

1 they don't have specific examples.

2 Can you explain to the Court what you
3 mean by that?

4 A. Well, some of the concerns that I
5 mentioned -- sorry -- that they raise as
6 general concerns, like, for example, with
7 Dr. Goodman, just as an example, she says,
8 "Meta-analysis may result in
9 over-conclusiveness."

10 Q. What paragraph?

11 A. Sorry. Page 13 of my report,
12 paragraph 25.

13 Q. Right.

14 A. To the best of my knowledge, she
15 doesn't examine that issue in the context of
16 any of the studies in her report. It is just,
17 here is a general concern.

18 There are other concerns, like, for
19 example, unmeasured confounding, where, in the
20 appendix C or whatever it is that we were just
21 looking at, she lists things that weren't
22 measured.

23 But who is to say that they were a
24 confounder? To be a confounder means it

1 actually has to be related to both the outcome
2 and the exposure, and she doesn't provide
3 evidence of that. So they are very kind of
4 general concerns.

5 Q. Does she provide any evidence or any
6 explanation to whether or not it affects the
7 outcome or the exposure?

8 ATTORNEY SPRAYREGEN: Objection to
9 form.

10 A. I don't believe so.

11 BY ATTORNEY MICELI:

12 Q. So I want to try to summarize this to
13 bottom line it for the court.

14 The fact that she addressed general
15 concerns like one issue with meta-analyses is
16 that they may result in over-inclusiveness, she
17 states that concerning any --

18 A. Conclusiveness.

19 Q. Conclusiveness, thank you. I heard
20 somebody else make that same mistake earlier
21 today.

22 Let me rephrase that.

23 One issue is meta-analyses that they
24 may result in over-conclusiveness.

1 She states that as a concern for
2 meta-analyses globally. Is that fair?

3 A. Yes.

4 Q. Okay. Does she ever address how
5 over-inclusiveness has impacted any particular
6 study that is relied upon by plaintiffs'
7 experts?

8 A. I don't believe so.

9 Q. Did you find it in her report?

10 A. No.

11 Q. Would the same hold true for the
12 general concerns of meta-analyses that are
13 addressed by Dr. Shields?

14 A. Yes.

15 Q. In the first instance on page 7 of your
16 report, paragraph 24, opinion number 1
17 regarding Shields, "Meta-analyses are thought
18 to increase statistical power and precision,
19 although this does not necessarily make the
20 results reliable."

21 Did I read that correctly?

22 A. Yes.

23 Q. Does that seem to contradict Exhibit 7,
24 the Savitz publication, that states the very

1 purpose of meta-analyses are to pool results to
2 give statistical power?

3 ATTORNEY SPRAYREGEN: Objection to
4 form.

5 You can answer.

6 A. Yes. I mean, it is the "are thought to
7 increase statistical power."

8 No. They increase statistical power
9 and precision. That is what meta-analyses do.
10 That is the point, or one of the points of
11 doing a meta-analysis.

12 And then the second clause, "This does
13 not necessarily make the results reliable."
14 That is a strawman.

15 BY ATTORNEY MICELI:

16 Q. And for Dr. Shields, with his general
17 criticisms about meta-analyses, does he
18 demonstrate in his report, and that you have
19 reviewed, any situation where the concerns he
20 has about meta-analyses have somehow resulted
21 in inaccurate findings in the meta-analyses
22 that are relied upon by plaintiffs' experts?

23 A. I don't believe so.

24 Q. Okay. That is all I have on that one.

1 ATTORNEY SPRAYREGEN: Object to form.
2 Too late.

3 ATTORNEY MICELI: But it is on the
4 record. It is good.

5 Now, if we can take a five-minute
6 break. I think I might be done.

7 THE VIDEOGRAPHER: The time is
8 4:02 p.m., and we are off the record.

9 (Recess taken at 4:02 p.m.)

10 (Recess ended at 4:06 p.m.)

11 THE VIDEOGRAPHER: The time is
12 4:06 p.m., and we are on the record.

13 ATTORNEY MICELI: I have nothing
14 further. Sorry. I should have said that.

15 CONTINUED EXAMINATION

16 ATTORNEY SPRAYREGEN: Would you be able
17 to read back the last question that was asked
18 of Dr. Madigan and his response?

19 (The pending question was then read
20 back as follows:

21 "Question: And for Dr. Shields, with
22 his general criticisms about meta-analyses,
23 does he demonstrate in his report, and that you
24 have reviewed, any situation where the concerns

1 he has about meta-analyses have somehow
2 resulted in inaccurate findings in the
3 meta-analyses that are relied upon by
4 plaintiffs' experts?

5 "Answer: I don't believe so.")

6 BY ATTORNEY SPRAYREGEN:

7 Q. How would you know --

8 ATTORNEY SPRAYREGEN: Withdrawn.

9 BY ATTORNEY SPRAYREGEN:

10 Q. You have mentioned that you haven't
11 read the reports of the plaintiffs' experts.
12 Is that right?

13 A. Plaintiffs' experts, no.

14 Q. Yes, the plaintiffs' experts.

15 Dr. Bird?

16 A. That was a question about Dr. Shields.

17 Q. The question asked if any of his
18 critiques were problematic in the meta-analyses
19 replied upon by the plaintiffs' experts.

20 A. I see. Okay. I took that to mean the
21 meta-analyses that were included in
22 Dr. Shields's report.

23 I missed that completely.

24 Q. I just wanted to clarify that you are

1 not opining on whether or not the meta-analyses
2 that the plaintiffs' experts used were done
3 correctly. Is that right?

4 ATTORNEY MICELI: Object to the form.

5 A. That's right. I haven't looked at
6 those reports. I don't know what meta-analyses
7 they are relying on.

8 I misinterpreted that question to mean
9 what was addressed in Dr. Shields's report.

10 BY ATTORNEY SPRAYREGEN:

11 Q. Do you know what any of the confounders
12 that need to be controlled for in epidemiology
13 studies on the relationship between benzene and
14 kidney cancer?

15 ATTORNEY MICELI: Object to the form.

16 A. That is not something I have looked at.
17 It would also, I think, just depend on the
18 context of the study. It is not just in the
19 abstract, an exposure and an outcome. It is
20 also, in the context of a particular study,
21 something might be a confounder or it might not
22 be a confounder.

23 BY ATTORNEY SPRAYREGEN:

24 Q. You had mentioned --

1 ATTORNEY SPRAYREGEN: Strike that.

2 BY ATTORNEY SPRAYREGEN:

3 Q. You had mentioned -- do you know which
4 confounders need to be controlled for when you
5 are looking at the relationship between a
6 chemical exposure and bladder cancer?

7 ATTORNEY MICELI: Object to the form.

8 A. No, I don't. It is not something I
9 have looked at.

10 BY ATTORNEY SPRAYREGEN:

11 Q. Do you know what confounders need to be
12 controlled for when you are looking at the
13 relationship between a chemical exposure and
14 any of the types of leukemia?

15 ATTORNEY MICELI: Same objection.

16 A. Same answer. I don't know. It would
17 depend also on the context, the particular
18 study, the particular subjects.

19 BY ATTORNEY SPRAYREGEN:

20 Q. The same answer for NHL?

21 A. Yes.

22 Q. And the same answer for Parkinson's
23 disease?

24 ATTORNEY MICELI: Same objection.

1 A. Yes, same answer.

2 BY ATTORNEY SPRAYREGEN:

3 Q. So when you were saying that
4 Dr. Goodman talks about confounders earlier, do
5 you recall when Mr. Miceli asked you some
6 questions about that?

7 A. Yes.

8 Q. How do you know whether or not the
9 confounders that she controls for are needed or
10 not?

11 ATTORNEY MICELI: Object to the form.

12 A. I don't. She lists -- it is more of
13 the confounders she doesn't -- the covariants
14 that she lists that were not included in the
15 analysis. So she lists something like smoking,
16 for instance.

17 So I don't know if smoking is a
18 confounder. It would depend on the particular
19 context of the study. She makes no claim that
20 it actually matters. She just lists a laundry
21 list of things that are -- covariants that
22 weren't included. That is what she does.

23 BY ATTORNEY SPRAYREGEN:

24 Q. But if smoking is a risk factor for

1 kidney cancer, would you agree that that is a
2 variant that should be included in a study?

3 ATTORNEY MICELI: Object to the form.

4 A. No. Unless it is also related to the
5 exposure. Just to be related to the outcome
6 doesn't make it a confounder. Or just to be
7 related to the exposure doesn't make it a
8 confounder. It needs to be related to both.

9 BY ATTORNEY SPRAYREGEN:

10 Q. So if smoking related to both the
11 exposure and the disease, would that need to be
12 controlled for?

13 A. Maybe. It depends.

14 ATTORNEY SPRAYREGEN: I don't have
15 anything else.

16 ATTORNEY MICELI: Nothing further here.

17 THE WITNESS: Thank you very much.

18 THE VIDEOGRAPHER: The time is
19 4:12 p.m. This deposition has concluded, and
20 we are off the record.

21 (Whereupon, at 4:12 p.m., the
22 deposition was adjourned.)
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ATTACH TO DEPOSITION OF: DAVID MADIGAN, Ph.D.
CASE: IN RE: CAMP LEJEUNE WATER LITIGATION
DATE TAKEN: 06/11/2025

ERRATA SHEET

PAGE	LINE	CHANGE	REASON

I have read the foregoing transcript of my deposition and except for any corrections or changes noted above, I hereby subscribe to the transcript as an accurate record of the statements made by me.

Executed this ____ day of _____, 20__.

DAVID MADIGAN, Ph.D.

CERTIFICATE

Commonwealth of Massachusetts
Suffolk, ss.

I, Megan M. Castro, Registered
Professional Reporter and Notary Public in and for
the Commonwealth of Massachusetts, do hereby
certify:

That DAVID MADIGAN, Ph.D., the witness
whose deposition is hereinbefore set forth, was
duly sworn by me and that such deposition is a
true record of the testimony given by the said
witness.

IN WITNESS WHEREOF, I have hereunto set
my hand on June 26, 2025.



Megan M. Castro
Registered Professional Reporter
Certified Shorthand Reporter No. 152614

My Commission expires:
July 22, 2027

0	1.42. 130:23	11-14-19 3:16	159 23:10
0 176:14	1.6 192:24	15:12	16 10:8 21:4
00897 1:5	1.66 130:20	111 2:8 54:9	23:11
05 140:5	1/102 173:11	182:8,9,14	16,400 151:22
06/11/2025	10 3:20 4:9	11:11 47:13,15	162 67:12
208:3	8:20 9:18	12 4:18 26:18	16797 209:17
1	27:19,24 28:4	26:21 28:5	16th 21:17
1 3:11 4:13 7:8	38:2 47:9 70:5	110:10 126:23	156:19
7:14 107:3,12	70:10,10,14	127:3	17 128:21,24
114:23 130:13	71:4 80:8	121 32:17,18	174 67:15
130:20 131:2	95:18 153:9	126 4:18	18 35:2,8
173:12 191:7,8	166:8 169:23	12:14 91:7,8	173:18
195:10,11,13	173:7,20	12:31 91:9,11	182 67:17
200:16	186:24 193:9	13 42:13	184 52:12,17
1,2 4:3,15 60:5	196:6	107:18 110:2,6	188 67:20
60:24 107:6	10.10.3 38:6	110:15,16	19 25:24 26:2
1-12 1:2	174:21	111:18 112:21	32:18 47:18
1-209 1:1	10.10.4.2 88:1	119:7,16 120:9	48:3,6 92:3
1.0. 190:24	10.4.4.3 80:11	179:14 198:11	179:6 180:20
1.01 130:23	84:23	14 130:2	181:5,16
131:4	100 1:17 75:19	160:23	1940 62:23
1.05 92:8,19	75:19 76:11,18	15 3:15 152:15	195 16:10
93:17	76:20,21	153:9	1950s 166:19
1.1 92:8,18	176:14,19	150 66:22	185:7
93:7,16 94:10	102 173:12,15	151 67:1	1972 66:14
95:15,22	173:18 174:22	152614 1:20	190:5
1.15 92:8,19	107 4:13	209:18	1975 62:24
93:18	108 182:6,16	153 67:3	1980s 163:20
1.2 94:23 95:7	109 182:10,17	154 67:4	1984 159:7
130:19	186:22	155 67:6	1990 159:9
1.2. 191:15	10:52 47:11,12	156 67:6	167:14
1.42 131:4	11 1:15 4:13	157 67:9	1993 27:2
	5:6 70:11 95:2	158 3:5 22:6,9	1999 66:15
	107:3,11 196:7		190:5

1:16 122:23,24 1:56 123:1,3	2024 4:12 70:8 153:8 2024a 63:6 2025 1:15 5:6 10:8 21:4 151:17 209:15 2027 209:20 204 192:20,20 20530 2:15 208 192:21 21 3:17 39:21 175:16 2189 66:6 189:24 22 209:20 23 151:17 24 86:17,20 88:1 97:10 98:7 194:23 197:22 200:16 245 42:5,7 25 75:18 76:18 76:19,21 107:19 194:24 197:22 198:12 26 120:9 209:15 27 3:19 162:14 28th 8:4 151:21 29 96:18 100:1 2:41 155:2,3	3 3 3:15 15:11 16:3,14 32:15 121:16 145:13 155:9,13 175:16 3-16-25 3:14 10:1 30 133:17 137:8 301 186:12 31 137:9 312-741-5220 2:9 316 186:12 35 167:14 185:8 37 99:22 38 42:8 3:04 155:4,6	4:06 202:10,12 4:12 207:19,21 5 5 3:4,19 27:19 27:23 34:24 80:6 97:1 128:20,22,23 138:18 141:21 172:24 181:20 194:18 5-16-25 3:18 21:9 5.5 192:24 50 162:15 500 2:8 51 113:5 114:13 52 173:15 53 3:23 55 113:9,17 56 113:18 582 127:6,17
2 2 3:13 9:24 10:5 11:9 24:21,23 29:6 29:16 45:13,19 66:6,12 96:14 141:19,22 182:18 188:6,6 188:22 190:1 195:14 2-7-25 3:22 4:4 4:16 42:2 60:7 107:8 2.8 192:23 20 37:23 143:11 157:24 157:24 158:1 174:22 208:20 2015 4:8 64:8 64:17,23 65:8 65:11,15,16,20 2017 11:22 2019 65:15 114:5 202 3:4 202-676-6531 2:15 2020 65:15 2021 108:14 110:20	4 4 3:17 21:8,12 74:10,15,18,20 91:16 130:1 141:20,22 404-915-8886 2:4 41 92:3 42 3:21 91:21 91:24 45 122:18 4:02 202:8,9	6 6 3:21 4:13 24:24 25:3,3 25:20,23 41:24 42:1,5 47:17 48:2 53:21,22 72:23 73:1,10 96:6 107:3,12 115:1 179:7 188:6,8,11	

<p>6.1 115:2 6.1. 116:8 6.1.1 114:1,20 114:24 115:8 6.1.1. 114:15 115:3 6.1.1.1 114:22 115:14 6.1.1.2 116:3 6.1.1.3 117:6 6.1.1.4 117:6 60 4:1 95:18 62 96:19 100:1 64 4:5</p>	<p style="text-align: center;">8</p> <p>8 4:1,1 60:1,2,2 60:11 61:2,4,5 61:6,7,13,13,15 64:10,14 69:23 69:24 141:19 80 134:19 135:22 87 130:20 877.370.3377 1:22 88 134:10</p>	<p>133:22,22 134:1,6 135:15 138:12,18 139:16 99 132:22 133:1,22,22 134:1,7 9:53 1:16 5:6</p>	<p>abstract 204:19 academia 159:16 academic 142:5 159:14,22 160:8 162:15 169:2 academics 164:19 academy 61:23 160:5 accepted 186:6 accepting 46:24 account 38:8 38:16,22 accuracy 52:2 accurate 7:5 183:11 208:17 accurately 46:17 accutane 154:1 achieve 191:18 193:3 actual 10:7 75:6,23 195:18 actually 26:13 31:17 32:7 40:7 56:3 81:9 93:24 108:14 110:19 121:7 123:23 129:5 134:18 136:13 142:16 148:18</p>
<p style="text-align: center;">7</p>	<p style="text-align: center;">9</p>	<p style="text-align: center;">a</p>	
<p>7 3:11,23 53:20 53:23 54:2 96:21 109:20 181:21 188:6,9 188:12 194:17 200:15,23 70 4:9 130:22 131:1,3,9,14,20 132:4,12,23 133:3,4,12 78 61:19 62:13 78701 2:9 79 60:14 61:21 64:18,20 7:23 1:5</p>	<p>9 3:13 4:5 45:13,16,17,18 46:18 48:1 64:4,23 65:5 65:16,23 67:1 67:3,6,9,14,17 67:20 69:23,23 69:24 189:15 9-11 166:9 90 132:21,24 133:1,24 134:2 134:7,14 135:21 136:1,2 136:7 917.591.5672 1:22 95 87:20,21 90:13 130:5,6 130:10,19 132:20,24</p>	<p>a.m. 1:16 5:6 47:11,12,13,15 abilify 138:23 153:20 ability 28:19 29:8 55:4 able 163:5 202:16 above 78:23 120:9 124:24 163:10 176:15 208:16 absence 130:17 absolute 93:4,7 93:10,21 94:7 absolutely 21:21 23:5 32:9 33:1 41:11 150:20 171:21 172:9 172:23 175:12 177:2 185:4 186:3 191:16 193:5</p>	

<p>149:8 150:5 152:6 153:19 161:6 162:7 165:18 166:18 169:9,24 176:11 181:9 182:6 191:13 192:16 194:19 197:19 199:1 206:20 add 30:19 31:17 added 107:23 adding 98:9 134:8 addition 109:7 159:13 additional 8:1 8:7 89:22 151:20 address 98:21 99:3,8,13,18 197:6,8 200:4 addressed 197:8 199:14 200:13 204:9 addressing 38:7 50:10 183:2 adequate 20:5 adjourned 207:22 adjustment 36:17</p>	<p>administration 167:17 admitted 15:17 advances 137:5 137:13,22 advantages 28:18 adverse 197:4 advise 165:10 advisory 164:16,20 165:4,13 affairs 142:5 affect 68:7 affecting 197:9 affects 199:6 afterward 15:23 agencies 106:6 aggregated 175:2 ago 9:15 114:3 150:16 156:13 163:17 agree 12:21 13:17 14:16 16:5 18:4,9,14 18:21 19:16 20:3 22:11 23:1,3,8 24:12 27:16 28:15 29:6,12 30:3 31:2,4,14 33:4 34:13 38:14,15</p>	<p>39:4,16 40:14 40:18 41:1,4 41:18 43:2,6 44:1,20 56:7 56:12 57:1,4,5 57:13 58:2,8 59:2 72:11 73:22 75:11 76:5 77:6,18 81:5 82:17,19 84:21 85:5,17 89:1,9 90:22 92:22,23 93:1 93:1,4,16 98:3 115:15 116:18 117:13,21 118:3 120:22 122:2,8 125:5 125:12 128:7 128:17 129:16 129:20 134:4 183:18 187:12 207:1 agreed 43:16 agreeing 69:13 195:18,20 ahead 22:8 151:2 187:17 aims 17:4 al 65:15 108:14 110:20 114:5 189:16,23 alleges 178:19</p>	<p>allowed 186:15 allowing 62:2 alpha 127:24 alsartan 154:4 amanda 2:3 amemiller 2:5 america 2:17 amount 88:22 151:21 amounts 164:5 analyses 3:20 25:7 26:7 27:21 28:1,18 35:6,13,17 38:4 39:8 40:4 41:6 44:22 46:13 48:8 49:14 53:7,13 69:1,4 80:6 89:21 97:12,19 97:20 98:14 99:18 101:13 103:12 104:7 104:10 105:12 105:13,14,17 108:4,11 109:8 110:12 112:20 113:21 114:2 120:12 121:22 123:11,20 124:10 135:1 173:9,21 175:2 175:8,21</p>
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

176:23 177:1 179:19 180:8 182:19 185:5 185:16,18 186:1,4 189:3 199:15,23 200:2,12,17 201:1,9,17,20 201:21 202:22 203:1,3,18,21 204:1,6 analysing 3:20 27:20 analysis 4:12 25:18 26:3 28:10 29:14,15 29:22 30:4,11 30:17,20 31:5 31:8 32:24 33:6,14,19,22 34:3,4,8,19 37:8 39:7 43:13,14 44:12 44:14,16 45:8 48:20 49:1,3 49:19,22,24 50:1,15,24 51:2,5,13,14,17 51:23 52:1,5 52:19,21 53:12 54:16 56:16,20 57:17,21 58:19 63:21 68:8,15 68:17,22 70:8	71:14 73:11 77:7 80:12 81:9,22 83:11 86:4,21,21,24 87:6,11 88:1,3 88:5,11,13,19 89:12 90:6,10 90:20,24 97:3 97:14,15 102:2 104:21 105:24 106:5 108:15 108:18 109:15 110:16,20,23 112:1,13,16 122:1 124:13 124:18,20,23 125:1 157:9 175:9,11,24 176:9,16 177:4 177:5,6,14,24 178:4 179:12 179:15 180:9 180:10,11,15 180:17 181:2 181:11,14,18 182:11 183:5,6 183:22 184:12 184:15,20,23 185:1,23 186:15,19 198:8 201:11 206:15 analyst 68:18	analytic 55:1 90:17 184:19 analytical 80:16 85:3 analyze 13:19 44:7 186:1 197:2 analyzed 46:22 113:24 analyzing 27:24 38:3 43:24 173:8 animal 19:4 animals 19:14 annual 153:5 answer 5:19 6:20 8:4,21 15:8 16:17 17:10,13,19,21 22:15 23:20 24:1,9 28:19 29:8 31:17 33:1,9,17,24 34:10 45:1 50:8 53:8 57:10,13 58:4 74:12 78:8,9 78:11 79:2 92:1,4 117:7 129:5 138:8 147:17,22 148:4,15 149:4 149:7 150:24 156:7 174:9	192:11 195:13 195:14 201:5 203:5 205:16 205:20,22 206:1 answered 56:24 58:1 177:18 answering 82:14 194:1 answers 147:5 anthrax 166:4 166:9,16,17 anticipated 93:13 anyone's 191:22 apologize 196:7 appear 67:23 appearance 108:12 110:18 appearances 2:1 appears 61:12 68:2 76:19 106:24 appendix 122:8 198:20 apples 99:9 100:19 139:22 applicability 150:20 applicable 72:1 77:8,19 149:2
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>149:16 application 103:11 105:16 applied 102:6 104:16 106:1 apply 55:1 112:19 124:23 134:16,17 135:14,17 applying 139:16,20 appointment 159:22 appointments 159:14 appreciate 21:20 108:8 117:19 151:24 approach 183:1 approaches 96:17 appropriate 20:5 33:5 approval 165:11 approved 166:18 186:6 approximately 157:21 apropos 165:18 arbitrary 55:7 133:15</p>	<p>area 160:19 arguably 170:17 argue 22:18 23:4,8 argued 98:21 100:13 arguing 40:24 arises 135:6 arising 28:21 arm 83:14,17 83:20,21 array 54:20 55:3 article 4:5,9,18 64:4 70:5 71:15 126:23 132:13 138:4 178:11,21 193:8 articles 20:20 125:5,12,17 arts 162:4,10 162:11,14,20 asbestos 52:4 aside 69:21,23 80:4 122:11 asked 7:23 9:22 10:18 12:13,14 25:4 45:5 50:6 64:24 136:13 146:10 148:5 150:15 156:24 157:1,6,7,12,17</p>	<p>158:8 173:19 174:1,24 175:16 178:6 180:5 190:8,10 192:12 193:13 202:17 203:17 206:5 asking 129:6 133:6,9 147:11 195:1 assess 30:7 135:15 169:18 178:18 assessed 116:20 assessing 145:16 146:16 148:11 155:16 assessment 11:23 25:8 31:23 32:1 105:5 116:3,7 117:4 118:1,7 118:21,21 121:4 157:10 assessments 31:7 42:23 118:9 assigning 13:20 assistant 159:23 assisted 151:12 associate 87:16 137:4 160:4 169:10 170:13</p>	<p>association 20:7 22:13 23:19 24:7 72:7 127:20 132:8 149:21 183:7 184:1 associations 51:4 assume 6:21 76:20 assumed 98:24 100:15 assuming 169:8 asymptotic 80:18 81:12 85:12 at&t 160:6 164:3 atsdr 11:22 63:5 attach 208:1 attachment 107:14 114:1 119:21 196:9 196:14 attachments 3:14 4:17 10:1 107:8,13 attempts 196:14 attention 22:22 attorney 3:4,5 4:22 5:20 7:12 8:3,6 9:10,11</p>
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

10:3 12:22,23 14:10,14,22,24 15:6,14,20,24 16:7,9 19:8,12 19:21 20:8,12 21:11,16,19,22 22:2 24:14,19 27:22 28:6,8 29:19,21 30:2 30:8,12,14,23 30:24 31:9,18 32:4,12 34:15 34:17 36:1,2,4 36:7,23 37:2,3 41:23 42:4,11 42:12 44:3,10 44:17,19,23 45:11,18,21,22 45:24 46:1,6,7 47:2,5,8,16,19 47:21,23 48:2 48:4,5,17,18 49:4,8,16 51:1 51:6,9 52:15 52:24 53:5,9 53:14,19 54:1 55:16,20,21,24 56:2,4,6,9 57:2 57:8 58:3,11 58:12 59:6,7 59:10,24 60:8 60:10 61:10,17 62:8,11 63:13 63:16,23 64:10	64:12,13 65:2 65:3,13,18,19 65:21,22 66:17 66:19 68:9,20 69:5,12,17,20 69:22,24 70:1 70:3,10,13,16 70:21,24 71:1 71:3,7,9,10 72:5,10,15,22 74:1,12,16,17 76:12,15 77:12 77:13,22 78:3 78:6,14 79:7,8 79:22 80:3 82:20,24 83:8 84:1,6,7,10,19 84:22,24 89:2 89:8 90:2,7 91:2,12 94:12 94:17 95:9,13 95:23 96:4 97:7,9 106:18 106:19 107:1 107:10 110:8,9 111:19,20 115:18 117:17 117:18,20,22 117:23 119:1,9 119:14 120:7 122:5,9,14,16 122:19 123:4 123:22 124:3 124:15,17	125:8,11 126:6 126:8 127:2,10 127:15,16 128:9,19,22,23 129:1,17,18 134:3,12 136:16,17 137:15,16 139:17,18,21 140:11,13,14 141:13,15 144:6,7 146:19 147:2,9,10,12 148:14 149:3 149:17 150:3,7 151:19,24 152:2,3 153:7 153:11 154:5,6 154:23 155:7 156:5,10,12,14 156:19,23 157:2,15 158:11,14,21 172:14,17 174:18,20 176:4,6 177:8 177:10 178:24 179:2 188:1,4 189:11,14,22 192:9,15 193:10,12 196:22,24 197:12,20 199:8,11 201:3	201:15 202:1,3 202:13,16 203:6,8,9 204:4,10,15,23 205:1,2,7,10,15 205:19,24 206:2,11,23 207:3,9,14,16 austin 2:9 author 169:12 169:20 170:10 authored 145:10 181:22 authoritative 27:14,18 authors 29:23 38:7,8,16,24 46:21 68:3 81:21 88:3 89:22 174:9,16 174:17 191:2 192:3 available 58:19 avenue 2:8 average 39:12 39:18 89:20 187:6 averaging 114:6 120:14 avip 166:15 aware 46:20,24 54:7 59:16 95:5 123:24 125:19 175:8
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

176:24 196:20 197:5 axis 90:11	based 22:20 27:7 71:19 103:13 105:18 131:8 154:14 183:13	120:21 122:12 126:11 139:6 144:16 145:8 146:9,11,14 148:4,6,9 151:15 152:18 168:1 186:8 188:22 196:8 196:17 197:14 199:10 200:8 201:23 203:5	190:4 194:7 204:13 best 18:3 174:8 174:14 198:14 bet 37:19 189:19 better 41:17 59:8 103:5 105:10 139:16 139:20 154:10 beyond 89:23 153:23 bias 16:15,21 17:6,7,16 20:6 31:13 32:6 34:7 58:13,16 63:21 64:2 68:7 82:4 99:19 100:22 102:13,15 104:22,24 109:9,14 110:21 111:23 119:24 120:1 178:6,8,14,18 178:20,20 190:11,15 192:7
b	bash 2:7 basic 168:17,23 basically 9:4 16:17 56:12 57:13 98:6 137:2,6 160:18 162:13 163:14 164:4,17 181:18 basis 147:1 beautiful 26:15 beauty 184:12 beginning 142:14 161:6 begins 42:14 179:12 182:10 182:22 behalf 2:5,10 2:17 behavior 13:12 81:13 belief 178:22 believe 7:22 11:12,15,20 23:15,15 30:9 59:24 61:18 70:21 74:13 79:12 85:23 96:7 104:5	believed 88:17 bell 11:7 164:4 167:3 belt 62:20 benchmark 139:15,19,22 benefit 158:23 183:22 benefits 183:20 benzene 4:2,8 4:10,14 60:4 60:23 64:8 66:2 70:6 107:5 benzine 25:13 59:21 61:6 62:3,19,23 63:3 66:13 71:12,23 72:2 72:7,12 73:17 73:23 76:23 77:5,10,20 79:4,20 151:9	bet 37:19 189:19 better 41:17 59:8 103:5 105:10 139:16 139:20 154:10 beyond 89:23 153:23 bias 16:15,21 17:6,7,16 20:6 31:13 32:6 34:7 58:13,16 63:21 64:2 68:7 82:4 99:19 100:22 102:13,15 104:22,24 109:9,14 110:21 111:23 119:24 120:1 178:6,8,14,18 178:20,20 190:11,15 192:7 biased 15:3 30:18 31:5,6,8 31:12,21 69:4 80:21 82:2 85:22 86:5
b 3:9 37:14 bachelor's 159:5 back 6:7 12:22 24:20 32:14 34:23 45:12 47:22,24 57:9 57:11 64:14 78:7,9 80:5 84:20 91:14 96:10 101:11 113:4 122:12 130:1 139:2 142:13 147:4 147:11,13 148:16 149:3,5 159:3 163:19 163:21,22 170:2 173:14 188:16,23 196:5 202:17 202:20 background 128:1 159:1 168:3 171:8 bad 61:21 141:14 base 30:19			

biases 29:1,2 29:17,18 108:16,17,19 110:22,24 119:13 121:23 121:24 171:16 171:18 big 40:10 94:15 94:20,23 95:3 140:19 166:11 bigger 140:5,20 biomarkers 103:16 105:21 biostatistical 167:9 biostatistician 143:21 biostatistics 160:13,16 185:2 bird 203:15 bird's 11:13 bit 17:19 40:23 50:6 76:20 115:6 134:20 150:19 153:15 bizarre 177:15 bladder 4:11 67:20 70:7 71:13 75:2 144:12 194:7 205:6 blinded 169:12	blindly 33:5,11 board 136:20 136:24 164:17 165:17 book 54:3,4,5,7 54:9 books 20:20 23:16 born 164:1 boston 1:18 5:8 162:23,24 bottom 26:20 35:4,9 73:3 75:2 90:16 92:3 120:8 129:12 137:15 139:7 140:2 173:11,19 181:24 189:20 199:13 bound 192:24 bove 12:16 bove's 12:1 box 35:5,9,12 35:16 173:20 174:3 bradford 25:17 48:19 49:2,7 49:11,15,18,19 49:20,24 50:7 50:21 52:1 53:11 181:1 branch 2:14 164:21	break 6:23 47:4 47:9 91:5 122:13,20 202:6 breast 67:14 brief 163:6 bryson 2:2 bullet 28:9,17 29:6,16 burger 43:5 business 162:18 <hr/> c <hr/> c 5:1 37:15 107:13 114:1 117:10,13 119:21 120:1 121:16 196:9 196:14 198:20 c.1 117:24 118:3 c1 114:2 196:12 c62 35:5,12 173:20 calculation 154:3 califf 165:22 call 13:5 61:14 94:15,15,15,19 95:19 152:6,8 152:13 159:15 called 17:8 18:12 37:13	52:13 119:4 135:1,3 136:21 137:5 160:14 161:9,13 162:9 169:4 176:13 178:16 182:18 calling 49:18 192:1 calls 49:20 119:2 cambridge 1:17 camp 1:8 5:8 10:6 12:3 71:24 72:3,13 72:18 76:24 77:4,10,11,18 77:21 146:2,6 146:7,18 147:21 148:1,2 148:13 155:22 155:23 189:9 208:2 cancer 4:15 25:14 52:5,14 61:23 63:19 67:24 68:4 72:3,14 73:12 74:4,24 77:21 79:5,21 107:7 107:13 109:19 113:7,10 116:21 117:15 117:24 118:23 144:12,12,21
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

145:2 187:21 190:9,21 194:7 204:14 205:6 207:1 cancers 4:11 68:1 70:7 71:13 72:8 144:17,23 189:8 191:3 capm 61:24 carcinogens 63:5 career 167:12 186:1 carefully 29:2 carers 26:24 carolina 1:4 carollton 2:3 carry 108:17 110:22 121:24 case 9:15,20 11:11,14,19 16:20 18:21,24 20:13,16,21 21:5,13 30:16 42:21 43:10,18 43:23 44:13 45:6,10 46:11 46:14,22 68:2 69:6 71:22 76:19 78:19 91:16 97:15 102:21 105:3,6 106:24 113:22	116:13 145:6 151:13 152:17 152:20 153:3 177:23 178:4 188:14 189:23 208:2 cases 1:10 8:17 9:3,12 68:24 99:8 100:18 121:7,8 143:20 144:9 castro 1:20 5:13 209:5,17 causal 16:19 19:17,23 20:2 24:7 72:2 77:8 77:19 causation 3:21 10:14 11:10 22:14 42:1 96:17 123:7,12 153:17,21 172:13 194:13 cause 4:6 19:18 52:13 64:6 65:24 66:15 72:3,13 77:21 185:3 190:6 causes 39:23 40:17 41:3,13 66:20 176:8 caution 42:15 42:18 43:3,4,6 43:12,15 45:3	105:1 cautious 99:5 100:17 cdc 166:21 167:4 cdcr 164:21 center 164:23 centers 162:15 166:15 167:18 central 168:14 centre 88:5 centuries 97:16 certain 9:19 20:22 36:22 78:24 80:2 134:24 186:9 188:20 certainly 36:13 38:15 83:10 84:17 89:16 125:2,16 132:21 134:5 135:20 137:19 138:14 144:3 168:23 171:3 171:24 176:19 178:12 181:16 185:21 186:19 certainty 14:12 25:6 41:1 certificate 209:1 certified 209:18	certify 209:8 cetera 13:12 93:23 115:22 chair 161:2 162:7 164:16 164:20 challenging 41:16 chance 73:19 184:22 change 208:5 changes 170:1 208:16 chapter 3:19 4:1,13 27:19 27:24 28:4 38:2 54:2 60:2 60:13 61:4,5,7 61:13,15 64:15 80:6 86:20 87:24 107:3 109:23 110:3 112:6 113:6,9 173:7,8 chapters 107:12 characteristic 87:9 characteristics 13:12 40:2,22 115:20 118:14 characterizati... 93:11 114:9 120:17,24
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

characterize 94:6,9 characterized 95:8 chart 190:10 193:15 chat 165:19 check 39:2 143:18 chemical 18:15 18:22 19:18 26:10 31:24 32:3 73:14 148:21 149:11 149:21,24 150:9,22 171:7 179:21 205:6 205:13 chemicals 25:9 145:7,17,20 146:17,23,24 147:15 148:12 150:1,6 155:17 155:20 157:11 cherry 55:8 chief 170:15 chinese 4:8 61:23 64:7 66:2,13 190:4 chloride 4:2,14 25:14 60:4,23 107:5 151:9 choose 40:3,23	chose 174:10 circumstances 130:16 cis 108:19 110:24 citation 46:10 102:20 103:2 cite 27:8 46:21 62:1 63:5 178:1 cited 10:15,16 cites 65:14 112:20 citing 196:19 city 160:22 164:7 civil 2:14 claim 206:19 claims 28:22 clarification 145:4 clarify 30:13 203:24 clause 29:7 131:24 201:12 clear 21:18 41:19 45:2 146:5 147:24 163:4 167:20 171:14 193:17 clearer 92:17 clearly 39:23 40:16 41:2 121:3	clients 161:24 clinical 103:12 105:17 171:6 171:24 172:2,5 clip 47:24 closely 165:2 closer 176:19 coauthored 132:14 cochrane 3:19 26:5,21 27:12 27:19 29:24 34:23 38:2 80:5 84:20 86:20 87:24 105:23 173:1,7 179:17 code 66:21,24 67:1,3,6,9,12 67:14,17,20 codes 192:20 coexposures 63:4 cohort 4:6 18:14,19 42:20 43:10,19,23 44:14 45:7 46:11,13,22 59:20 62:1,22 62:24 63:11 64:5 65:24 83:12 102:21 103:16 105:7 105:21 113:22	116:13 177:22 177:22 178:3 cohorts 105:3 coleman 2:2 collaboration 26:22 161:17 167:5 colleague 6:2 collectively 54:21 college 159:6,8 colon 67:3 columbia 2:15 160:21 161:1,2 161:7 162:4,12 162:13 167:3 column 35:16 72:24 73:1,2 73:10 combination 28:11 combine 33:5 33:11 43:18,23 46:11 102:21 105:6 combined 42:20 43:8 45:7 105:2 177:23 183:14 combining 26:6 101:18 104:14 179:18 183:8 184:18
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

come 13:3 125:14 126:13 131:7,11 139:2 168:7 188:16 188:23 comes 86:11 155:24 coming 122:12 comment 10:18 41:19 97:5,23 98:12 129:11 commentary 98:9 comments 10:5 97:2 98:8 116:24 117:2,8 157:12 188:12 188:21 189:3,4 commission 209:19 commissioner 165:20 committee 164:20 165:13 committees 165:4,5,6,9 common 134:6 136:7 139:5,11 commonly 88:17 90:6,9 commonwealth 209:2,7 communicate 168:20	communicated 20:14 communicati... 152:16 companies 160:20 161:22 163:18 167:6 186:2 company 1:22 comparability 125:3 comparable 54:19 comparator 36:8 compare 36:11 compared 73:17 76:23 compares 37:10,14,15 comparing 139:22 comparisons 73:19 compatible 130:16 compensation 152:19 153:2 complete 7:5 31:15 70:18 125:9 completely 133:15 141:23 181:15 203:23	component 30:5 31:4 34:22 37:7 56:13 57:14 58:7 87:3 89:6 90:11 121:2 122:4 124:21 computed 132:4,21,22 computer 101:24 104:19 computing 128:12 conceptually 87:12,14 concern 16:4 33:18 34:1 37:9 58:21 59:1 119:18 120:6,6 125:3 151:9 166:10 166:12 176:18 176:20,21 198:17 200:1 concerning 12:2 144:11 145:11 146:14 148:10 166:4 180:7,8 189:4 189:5 190:9 196:5 197:22 197:23 199:17 concerns 33:13 33:15,23 34:7	34:8 45:15 54:17 97:11 107:21 112:12 112:15,18 119:23 121:14 124:22 145:15 155:14 166:19 198:4,6,18 199:4,15 200:12 201:19 202:24 conclude 130:14 132:7 concluded 207:19 conclusion 19:23 20:2 125:14 131:7 131:11,17 conclusions 125:7 126:13 172:13 186:5 conclusive 108:13 110:19 conclusiveness 108:6,12,22 110:17 111:3 119:19 198:9 199:18,19,24 conduct 180:9 184:6 conducted 29:23 30:17 73:14 114:2
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>165:19 171:2 184:4</p> <p>conducting 32:23 40:4 41:5 43:13 44:21 51:24 175:9 182:19</p> <p>confidence 23:23 80:21 82:5 84:13,15 86:6 87:5 88:4 88:9,12,20 89:4,10,18,24 90:13,18 92:15 92:18,23 93:9 93:12,17 130:6 130:7,10,12,19 130:22 131:1,3 131:10,20 132:4,13 133:12,17 134:10,14 135:15 136:1,7 138:13 139:4,8 139:24 140:9 140:19,23 141:2,6,10,12 141:19,20,21 142:1 187:5 192:24</p> <p>confidential 15:22</p> <p>confirm 14:12</p>	<p>conflicting 28:22</p> <p>confounder 197:19 198:24 198:24 204:21 204:22 206:18 207:6,8</p> <p>confounders 171:17,18 204:11 205:4 205:11 206:4,9 206:13</p> <p>confounding 102:13,16 104:22 105:1 114:10 120:18 121:1 198:19</p> <p>confused 40:20</p> <p>confusion 180:24</p> <p>Congress 2:8</p> <p>connected 146:12 148:7</p> <p>connection 152:20</p> <p>conservative 82:7</p> <p>consider 19:19 19:24 20:10 22:12 27:12 29:16 33:2 121:17 129:7 149:20 175:11 197:16</p>	<p>considerable 39:9</p> <p>consideration 181:6</p> <p>considerations 49:9</p> <p>considered 21:3 29:3 55:5 95:15,22 117:5 118:10,22 119:2,5 121:6 121:10 196:16 196:16</p> <p>considering 29:14</p> <p>consistency 48:9 49:2,11 49:15,22 50:12 50:14,20 51:3 51:16,24 53:2 53:11 179:24 180:6,7,8,10,17 180:20 181:2 181:12,17</p> <p>consistent 56:21 57:22 58:5</p> <p>constantly 170:11</p> <p>consultant 163:19 164:8 165:15,23 166:14 167:16</p>	<p>consulted 12:12</p> <p>consulting 146:3,7 147:22 148:2 155:23 156:9 161:21</p> <p>contacted 156:3</p> <p>contain 39:8</p> <p>contains 87:22</p> <p>contents 60:12 61:3,5,13 96:14</p> <p>context 9:3,23 12:9,13,16 16:16 30:4 44:7 50:9,23 52:21 62:9 78:21 82:13 87:10 93:14 94:3,4,6,21 95:1,4,14,20 103:13 105:12 105:18 112:16 120:2 125:1,18 128:11 134:13 134:19,21 135:10,21,22 138:16 145:24 146:1,9,17,22 147:19,20 148:5,12 151:4 180:15,16 181:14 183:23</p>
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

185:21 197:19 198:15 204:18 204:20 205:17 206:19 contexts 93:8 141:6 continue 142:12 continued 73:2 202:15 continues 92:4 113:17 continuing 73:9 161:7 continuum 176:10 contradict 200:23 contradicted 192:8 contribute 54:21 control 35:19 35:23,23 36:6 36:16 42:21 43:10,19,23 44:13 45:7 46:11,14,22 54:24 102:21 105:3,6 113:22 116:13 121:10 121:16 166:15 167:18 174:2 177:23 178:4	197:15 controlled 204:12 205:4 205:12 207:12 controls 36:12 206:9 controversies 28:21 convention 133:21 134:1,4 138:18 conveyer 62:20 corner 173:11 correct 8:2,9 12:19,20 14:2 14:9 15:5 17:18 24:1,8,9 25:15,16,18,19 39:3 45:21 48:21 51:11 57:6 66:16 67:19 69:16 74:22 75:8 82:19 84:5 89:3,7 99:10 99:15,16 101:19 102:16 102:22 103:7 103:17,24 108:15 109:10 109:17 110:4 110:21 111:7 112:6 115:7 121:22 128:18	132:2 140:15 142:15 143:4 173:15 191:4 193:20,21 194:11 195:22 197:17 corrected 100:23 correcting 172:2 correction 106:8 108:23 corrections 208:15 correctly 17:22 22:23 24:10 25:10 26:13 27:10 28:13 29:4 34:11 35:20 38:12 39:14 40:6,12 42:24 48:14 55:14,23 62:4 63:7 66:18 71:17 73:20 81:1 88:23 92:12,13 97:24 100:24 101:20 106:3,9 108:24 111:4 112:22 114:11 128:5 131:5 145:18 155:18 180:3 183:16 187:10	194:4 195:5,7 195:21 200:21 204:3 correctness 169:19 corresponding 89:5 corroborate 102:8 104:18 cosmetic 52:13 cost 55:11 counsel 5:11 12:12 counting 9:6 country 160:2 161:4 182:4 couple 150:15 156:13,16,17 168:6 170:15 coupled 97:17 course 31:19 33:10 144:10 183:10 185:14 court 1:3,20 4:21 5:12 6:12 138:19 143:12 143:23 145:4 148:16 153:18 154:20 165:7 168:8 183:21 186:7,8 198:2 199:13 courtroom 6:6 6:9
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

courts 13:24 143:15 186:18 covariant 135:5 covariants 117:5 118:10 118:21 121:6,8 121:9,11 135:4 135:8,9 196:15 196:16,18 197:3,6,7 206:13,21 cover 128:13 covered 112:7 crate 100:21 creatures 141:23 credence 176:8 credit 187:7,7 criteria 49:10 51:16 52:1 53:2,11 99:14 100:20 101:16 104:12 106:2 138:3 criterion 138:7 critical 99:14 100:20 114:7 116:12 120:15 172:8 criticism 98:2 101:21 121:21 197:24	criticisms 97:22 201:17 202:22 criticize 29:13 29:20 101:5 critique 111:10 111:12 116:19 critiques 106:14 203:18 critiquing 98:4 119:11 crossed 192:5,5 crucial 27:6 csr 1:20 culminates 183:4 cure 33:23 current 142:3 currently 163:8 cut 118:16 cv 1:5 52:12 156:1 161:22	173:8 183:13 183:14 186:2 189:7 date 5:5 21:6 152:23 156:18 156:20 158:24 208:3 dated 3:14,16 3:18,22 4:4,8 4:12,16 10:1,6 15:12 21:9 42:2 60:7 64:8 70:8 107:8 156:15 dave 74:13 147:5 david 1:14 2:2 3:3,12,13,16,18 5:9,15 7:10 9:24 15:11 21:8 181:22 208:1,22 209:9 day 62:23 208:19 deal 172:20 188:19 dealing 93:15 dealt 137:18 dean 162:4,10 death 66:15 190:6 decades 114:4 decide 22:19	decision 55:5 103:13 decisionmaki... 105:18 decisions 27:3 declined 142:24 decreased 184:7 decreases 129:13 defendant 2:17 defendants 9:16,21 10:6 97:2 defense 165:24 define 12:24 definitely 19:1 definition 13:17 56:17 57:18 127:5,18 128:7,11,15 191:6,6,22 definitively 130:14 degree 25:5 88:16 159:6 177:17 deleted 113:1 demonstrate 201:18 202:23 demonstrates 177:7
	d 3:1 5:1 107:14 161:15 dagg 121:16 data 3:20 13:4 27:20,24 38:3 39:3 59:18 130:9,15 154:19,20,21 154:22 161:16 161:19 166:24		

department 2:12 160:14 161:3 162:8 165:24 departments 161:4 162:15 depend 93:22 135:8,9 204:17 205:17 206:18 dependent 135:3 153:3 depends 31:10 31:14,16 37:16 39:20 64:1 72:6 77:24 78:4,11,15 83:19 84:14 94:24 95:4 105:12 127:23 207:13 deponent 5:9 deposition 1:14 3:11,15,17 5:7 7:8 15:11,16 15:21 21:4,7,7 21:8,13,17 22:6 32:15 70:4 91:15 151:20 152:5,9 158:24 207:19 207:22 208:1 208:15 209:10 209:11	deps 1:23 derived 26:11 179:22 describe 75:12 88:7,16 132:11 141:5 described 114:1 184:24 describes 75:18 88:13 describing 20:9 75:7 89:23 description 3:10 design 19:24 20:4 designs 28:24 29:16 desire 55:9 desk 169:4 detail 75:6,24 107:16 112:19 detect 80:23 128:4 determination 19:17 72:2 77:9,20 determine 20:4 39:23 40:17 41:3 72:12 131:20 132:7 132:10 determiner 131:22	determining 41:13 42:19 43:7 44:15 49:14 105:2 138:4 develop 168:18 device 90:10,19 165:11 devices 145:17 155:17 dichloroethyl... 4:3,15 60:5,24 107:6 differ 58:24 101:16 104:13 difference 13:9 13:14 50:8 55:19 72:20 128:14 differences 34:21 48:11 58:23 73:11 80:24 180:1 187:8 different 8:24 13:3 35:19 36:6,10,11,16 36:17 37:11,14 54:23,24 55:1 56:14 57:15 58:20,22,23 69:8,10 72:21 72:21 88:15,15 90:15 98:22	100:14 101:13 101:14,17,17 101:18,24,24 102:5 104:6,9 104:11,13,14 104:15,19,20 125:22,23 126:3,10,13,17 140:7 141:21 141:23 144:18 148:24 149:14 150:21 159:12 177:21 180:14 183:15 187:19 differently 158:3 196:23 difficult 76:8 diminished 82:9 86:16 135:19 direct 30:10,15 directed 160:16 direction 24:8 24:17 38:11,20 39:11 82:7 125:22,24 126:17,20 directly 73:17 director 160:12 disadvantages 182:11 disagree 82:18 85:5,18 89:14
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

discuss 122:21 129:3 176:2	disproportion... 197:9	177:13 180:10 181:11 183:22	102:12,19 103:1,10,20
discussed 76:10 112:11,17 151:15 157:4 171:19 178:9,9 178:13	dissolved 62:18	186:12 195:16 201:11	106:9,14,16,21 107:12,20,23 108:2,9 109:3 109:6,12,19 111:7,11,13 112:5,14,14,24 113:5,13,20 115:16 117:14 118:4 119:11 119:18 120:20 120:22 123:23 124:6,9 155:8 157:13,14 158:22 182:2 187:20 188:13 188:13 189:5,5 194:21,21 195:9,19 196:8 196:13 197:1 197:22,23 198:7 200:13 201:16 202:18 202:21 203:15 203:16,22 204:9 206:4
discusses 115:16 117:14 120:1	distracting 187:9	doj's 197:4	draft 157:22
discussing 45:16 64:16 89:21 111:22 116:7 171:20	distribution 88:6,8	dose 74:21 75:6 75:7,23 76:6 76:11,18 78:21 193:24 194:6	drawing 19:23 20:2 172:13 186:4
discussion 117:4 129:7 171:9,13 174:22 189:21	district 1:3,4 2:15	doses 77:4	drinking 71:20
disease 18:16 18:23 19:18 25:15 54:23 126:12 128:2 129:9,22 137:5 137:13,22 144:13 145:1 166:15 167:18 183:7,12 187:23 189:7,8 193:24 205:23 207:11	ditto 93:8	dot 43:3,3,3 150:17,17,17	driver's 5:17
diseases 188:20 188:21	diverse 35:17	doubt 164:1	
disparate 104:15	diversity 99:3 100:16	downstream 148:20 149:10 149:18	
	divided 74:24 140:2 141:1	dozen 8:22,23 9:5	
	division 2:14	dr 5:22 10:17 10:19,19,20,21 11:3,6,13,16,17 12:1 19:5,5 20:14 21:4,7 21:13 23:1,16 24:12 42:6 54:3 56:8 57:9 60:11,21 61:14 63:9,10 65:6 78:7 92:2,7 97:6,10,21 98:3,5,13,19,20 99:2,7,12,17,21 101:3,5,13,22 101:23 102:5	
	dmiceli 2:4		
	doctor 143:2		
	document 1:9 7:14 11:24 37:24 38:2		
	documented 14:1		
	documents 3:12 7:9,18 11:17 12:6,8 12:10		
	doing 29:14 44:11 45:6 49:18,24 51:12 53:11 56:20 57:21 82:14 122:7 163:19 167:7 175:24		

<p>drop 192:19 drug 126:5,12 146:23 164:21 164:23 165:11 167:17 drugs 145:17 146:24 155:17 dublin 159:7,9 due 73:18 134:22 187:3 duly 5:17 209:11 dying 95:18</p>	<p>170:5,5,13,15 editorial 136:20,24 education 159:5 educational 159:1 effect 16:18,19 16:20 24:4 31:13 32:6 34:21 38:11,20 39:11,13 56:14 56:17 57:15,18 59:13,15 69:14 69:16 73:24 78:22 79:17 87:1,9,13 88:21 89:20 90:13 129:13 130:15,17,18 135:7,9,24 183:12 193:24 effects 26:8,10 26:14,15 88:2 88:5,6,12,15,20 89:5,5 130:8 145:16 146:16 148:11,20 149:10,18 150:22 155:16 179:20,21 effort 54:18 egger 178:16</p>	<p>eighth 101:21 101:22 either 23:7 62:9 80:20 82:18 83:14 85:22 138:16 174:16 190:17 electronically 151:23 elevated 184:7 184:22 eleventh 102:18 embodies 33:19 eminent 182:3 emphasis 107:24 emphasized 138:11,14 employee 167:22 employment 73:13 encounter 139:14 ended 47:13 91:9 123:1 155:4 202:10 ends 170:3 ensuring 35:5 35:12 173:21 entire 55:10 185:14 186:23</p>	<p>entirely 31:20 40:24 51:19 97:12 entirety 11:2 entitled 4:5,9 4:18 64:4 70:5 71:11 126:23 environmental 2:14 18:7 93:14 94:5,8 94:18 95:6 136:10 137:2 137:18,20 138:1 145:6,11 146:22 149:2 149:16 150:20 epidemiologic 55:18 epidemiologi... 18:7,12 23:22 141:3 145:15 146:15 148:10 155:15 167:10 epidemiologist 143:7,22 epidemiologi... 19:19 182:4 epidemiology 3:23 4:18 53:23 54:3,19 55:17 93:15 94:5,9,18 95:6 117:16 118:1 118:23 125:19</p>
<p>e</p>			
<p>e 3:1,9 4:4,16 5:1,1 60:6 107:7 e.g. 42:20 103:22 105:2 114:4 earlier 74:13 123:5 151:15 155:10 174:24 177:19 182:1 182:17 199:20 206:4 earned 153:6 eastern 1:4 ebbed 153:14 editor 136:15 136:18 137:4 137:24 169:2,3 169:4,5,9,10</p>			

126:24 136:10 136:19,23 137:3,6 141:9 143:9,10,13,16 144:4 150:21 161:17 167:11 181:22 204:12 errata 208:4 error 17:9,15 187:4 esophagus 66:21 esquire 2:2,3,7 2:12,13,13 essentially 97:13 126:18 establish 59:18 127:12 established 27:2 97:22 estimate 16:19 17:5 32:7 69:8 69:8 86:22 87:1,2,6,8,17 87:17,18 88:4 88:8,21 89:10 89:20,24 90:1 90:17 95:7,8 95:15,21 103:4 105:9 130:5,18 131:9 135:13 140:10 183:6 183:11	estimated 16:23 116:14 191:8,15 estimates 15:2 26:8,10 94:19 179:20 estimating 185:3 estimation 31:13 et 13:12 65:15 93:23 108:14 110:19 114:5 115:22 189:16 189:23 evaluate 53:10 99:14 100:20 evaluated 20:4 62:17 63:18 evaluating 49:2 51:3 53:2 evaluation 51:15 62:2 164:23 evening 152:7 152:14 event 83:4,13 83:20 events 80:12,17 80:17 81:6,10 81:14,22 82:3 82:9,11 83:3 83:17,20 84:3 84:15 85:4	86:4,8,10,15 evidence 11:23 15:17 24:8,16 27:7 48:10 52:13 102:7 104:17 121:12 127:4 132:11 161:18 166:3 172:13 179:24 182:12 199:3,5 evolved 161:13 exact 125:14 153:9 exactly 9:8 33:18 34:1 156:21 179:9 195:11,23 examination 3:4,5 5:19 158:20 202:15 examine 44:5 198:15 examined 19:5 examines 71:20 examining 51:24 116:21 183:2 example 9:1 19:17 31:6 32:1 35:18 43:9,18 50:16 51:8,11,12 56:19 57:20 69:9 78:19	88:18 90:5 95:14 101:15 103:11,14 104:12 105:5 105:13,16,19 119:16,16,21 128:13 130:18 130:22 131:12 133:13 141:18 185:22 186:11 198:6,7,19 examples 46:15 97:21 98:9,10 125:16,19 126:3,10,21 144:18,20 178:1 198:1 exceeds 131:2 except 9:14 60:11 151:3 208:15 exceptions 129:24 excerpt 3:23 53:23 excerpts 107:22 excluded 68:14 68:17 138:19 153:18,20 154:17 exclusion 99:13 100:20 101:16 104:12 106:1
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

excuse 26:9 30:13 44:17 66:24 114:16 114:22 124:15 133:4 173:20 181:1 196:7 executed 208:19 executive 162:9 exhibit 3:11,13 3:15,17,19,21 3:23 4:1,5,9,13 4:18 7:8,14 9:24 10:5 11:9 15:11 16:3 21:8,12 24:21 27:19 32:15 34:24 41:24 42:1,5 45:13 45:19 53:20,23 54:2 60:1,2,11 61:2,6,11 64:4 64:14,23 65:5 65:16,23 70:5 70:14,15,19,22 71:4 80:6 86:18 91:16 96:6 107:2,3 107:11 117:11 126:23 127:3 172:24 181:21 189:15 193:9 196:6 200:23	exhibits 1:2 4:21 10:8 158:17 existence 130:17 exists 87:14 127:21 132:8 expect 32:5 33:6 expert 3:13 8:13,15,18 9:24 13:24 123:24 138:10 143:9,13,16 144:4 145:5,13 153:6,16 expertise 79:24 194:3 experts 10:14 11:11 123:6,11 123:16,19 124:5,8 152:17 165:10 169:14 187:19 200:7 201:22 203:4 203:11,13,14 203:19 204:2 expires 209:19 explain 81:3 137:9 168:8 183:21 198:2 explained 40:4 40:8,12	explaining 85:19 112:18 explanation 37:18 193:22 199:6 exploration 48:10 180:1 explore 39:22 41:9 175:18 explored 40:9 40:11 41:5 exposed 4:8 32:2,3 62:22 63:2 64:8 66:2 66:13 73:16 77:4 190:4 exposure 4:3 4:10,15 18:16 18:23 26:11 31:7,11,21,23 32:1 54:23,24 60:5,24 63:3 70:6 71:12 72:8 78:1,13 78:16,23 79:1 79:5,20 107:6 114:8 116:3,7 116:20 118:7 118:20 120:16 120:23 121:4 126:11 146:22 149:22,24 155:16 179:21 183:7,12 184:2	199:2,7 204:19 205:6,13 207:5 207:7,11 exposures 13:21 25:9 62:3 71:20,23 74:7 76:22,23 77:6,17 80:2 93:15 116:14 126:4 137:18 145:7,11,16 146:16 148:11 148:21 149:11 150:9,23 157:11 extensive 160:17 161:21 164:10 166:22 extensively 17:20 97:19 extent 169:19 188:10,14 external 165:5 extract 55:6 56:17 57:18 extraction 54:17 extreme 191:5 f face 41:9 facilitate 48:9 179:23
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

fact 22:18 32:3 52:19 68:4 69:14 79:10 85:8 97:13 121:21 129:8 130:15 172:10 177:3 178:19 181:4 199:14 factor 49:15 51:16 176:22 206:24 factors 49:9 55:1 119:4,5 121:13 127:23 factually 197:17 faculty 162:11 fails 112:15 fair 6:21 7:1 177:11 179:3,4 200:2 fall 142:14 false 30:21 familiar 20:18 76:14,17 86:1 139:3 141:2 182:2 far 130:16 134:5 163:7 fashioned 166:20 fast 96:24 fatal 34:2 172:12	fatally 14:8,21 fax 1:22 fda 161:12 164:9,11,18,22 165:3,3,4,9,15 165:17,20 185:22 feature 54:16 february 151:17 federal 167:21 185:19 186:7,8 186:9 feel 14:7,20 feels 56:12 fellow 169:14 female 67:14 field 169:15 176:24 185:1,9 fifth 48:6 99:12 find 96:3 144:1 144:1 179:9 184:6,23 200:9 finding 23:19 125:21,24 127:19 193:3 findings 24:3 50:14 54:19,20 55:3,6 59:3,5 68:18 69:3 109:14 111:23 120:4 187:3 192:4 201:21 203:2	finds 22:22 fine 115:4 fireside 165:19 first 5:15 22:19 23:5,6,21 28:9 28:9 38:15 39:2 41:2,20 42:5 49:17 54:11 72:24 73:2,10 75:13 80:14 81:17 84:23 97:5 98:2,2,12 101:4,6 108:2 108:9 110:6,15 111:6,9,11 116:11 132:1,3 145:14 155:12 156:3 159:22 173:10,10 174:3 182:7,14 182:22 189:9 200:15 five 142:23,24 153:12 161:5 162:20 164:15 169:16 202:5 flavors 13:3 flaw 34:2,4 169:7 flawed 14:8,21 30:21 97:15 flip 158:17 173:14 189:24	flowed 153:14 fluctuation 187:3 focused 10:22 161:17 focusing 68:21 70:23 121:20 follow 29:10 105:15 115:24 158:15 190:5 following 45:23 66:14 165:14 follows 5:18 32:10 57:12 78:10 147:14 149:6 193:15 202:20 food 167:17 footnote 26:18 26:21 28:5 179:14 force 105:22 foregoing 208:14 forest 44:12 50:17,18 90:8 90:22 103:23 forever 8:19 forget 81:9 83:11 forgot 21:20 form 14:10 15:6 19:8,21 20:8 24:14
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

28:6 29:19 30:2,23 31:9 32:4 33:8,16 34:9,15 36:1,7 37:2 44:3,23 49:5,16 51:6 53:5,14 55:16 56:9 59:6 62:8 63:14,23 65:13 66:17 68:9 69:5,17 72:5 72:15 74:1 76:12 77:22 79:22 82:20 83:8 84:6 89:2 90:2 94:12 95:9,23 115:18 115:21 117:17 119:1,14 122:5 123:22 125:8 128:9 134:3 139:21 140:12 141:13 146:19 150:3 153:7 157:2 172:15 177:9 179:1 188:2 189:12 192:10 197:13 199:9 201:4 202:1 204:4,15 205:7 206:11 207:3 former 36:21 37:4,5,6	forms 35:19 36:6 forth 96:11 209:10 foundation 14:11 15:7 53:15 56:10 63:24 65:14 68:10 72:16 77:23 79:23 90:3 146:20 foundational 127:14 founders 161:8 161:14 four 75:1 129:11 159:12 185:11 189:8 fourteenth 103:19 106:20 fourth 99:7 104:5 frequently 133:24 friday 152:11 full 42:13 46:8 54:11 104:2 110:6,15 111:17 160:9 160:24 182:14 186:23 further 15:19 43:4 202:14 207:16	furthermore 73:10 g g 3:22 5:1 42:2 181:23 gather 13:4,11 general 3:21 10:14 11:10 19:22 20:10 27:17 32:11 34:10 41:7 42:1 81:7,10 82:10 83:9 84:13,14 86:14 94:1 97:11,19 117:2,8 123:7 123:12 124:21 129:23 141:9 153:17 184:3 189:4 197:24 198:6,17 199:4 199:14 200:12 201:16 202:22 generality 31:15 79:3 125:9 generalizable 98:23 100:15 generally 17:14 18:10,13,18 19:9 23:8 27:15 29:7,11 30:3 31:3	33:17 34:20 57:1,4 58:2 84:12 129:24 134:16 170:21 170:24 183:4 184:9 generating 161:18 generic 112:18 120:6 121:14 genre 171:3 georgia 2:3 getting 59:11 give 7:4 26:22 80:16 85:3 95:14,20 96:2 141:7,18 143:20 144:8 176:8 186:11 193:19,22 201:2 given 21:15,18 70:4 79:9 80:18 85:12 126:2,9 127:21 130:9 138:15 138:15 209:12 gives 17:4 62:20 75:5,10 75:23 76:3,6 78:23 89:19 92:2 187:6 giving 117:8
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>glad 195:16 global 26:23 globally 168:15 200:2 go 13:16 32:14 34:23 45:12 50:3 61:3,4 71:7 74:10 80:5 83:14 85:1 96:5,10 99:22 113:5 115:2 119:17 122:14,21 141:19,21 151:2 154:23 162:2 168:3 169:2 173:18 174:17 181:21 186:22 187:17 188:23 189:15 189:19 190:23 194:17 196:5 goal 27:2 33:10 goes 81:14 92:8 92:18 93:17 96:18 116:19 130:23 169:3 170:2 going 19:23 22:19 41:23 43:4 47:3,4,6 47:22 53:17,19 60:19 81:18 84:20 91:3,14</p>	<p>91:23 96:5,9 96:10 107:1 108:7 115:2,8 118:17 122:10 122:17 127:4 127:10,13 142:16 144:14 155:12 158:15 158:16,17,18 159:3 168:6 169:22 170:3 173:2,5 179:13 181:20 182:23 187:16 188:16 188:23 189:20 194:16,24 196:5,23 golkow 1:22 5:5 golkow.com 1:23 good 5:22,23 20:9 22:21 30:5 51:18 70:4 91:4 124:21 145:22 147:17 175:23 202:4 goodman 4:4 4:16 10:17,19 10:20 11:16 19:5 60:6,15 60:21 61:7 62:10 64:15</p>	<p>107:7,20 109:4 109:6,12 111:11 112:5 112:14,14,24 113:13,20 115:16 117:14 118:4 119:11 119:18 120:20 120:22 157:14 187:20 188:13 195:19 196:13 197:23 198:7 206:4 goodman's 10:21 60:11 61:14 63:10 65:6 107:12,23 108:2,9 109:19 111:7,13 113:5 189:5 194:21 195:9 196:8 197:1 government 166:5 167:16 167:22,23 185:20 grab 158:18 graduate 151:12 graphical 90:9 great 7:3 55:4 99:15 176:7 greatly 135:19</p>	<p>grossman 2:2 group 157:5 197:10 grouping 42:20 43:10 46:9 105:3 guess 18:11 36:15 41:12 74:3 82:2 129:11 156:22 158:1 167:14 guessed 16:23 16:24 guide 4:18 126:24</p>
h			
<p>h 3:9 161:15 half 162:21 174:4 halfway 182:23 hand 82:22 169:10 174:3 209:15 handbook 26:6 27:12 34:24 179:18 handle 113:2 handy 96:10 happened 143:18 happens 126:1 happily 14:6,19</p>			

<p>happy 47:6 122:19 hard 56:3 59:18 hazard 128:13 head 51:8 94:13,14 95:12 96:1,2 164:21 heading 25:2 35:11 80:11,15 88:1 97:1 110:11 116:3 health 25:8 26:9,14 27:1,8 137:2,20 138:2 149:22,24 150:10 157:10 179:20 healthcare 27:4 27:5 46:14 161:15,19 hear 45:1 194:3 heard 59:20 62:6 171:16 194:2 199:19 heavily 103:14 105:14,19,23 held 1:17 5:7 159:20 help 129:6 helping 27:3 hematopoietic 4:7 64:7 66:1</p>	<p>hereinbefore 209:10 hereunto 209:14 herring 181:18 heterogeneity 34:18 38:7,9 38:17,22 39:1 39:22,24 40:3 40:17 41:3,5,9 41:13 84:4,8 84:17,18 88:16 88:22 90:5 125:2 174:23 175:1,5,7,13,18 176:1,1,3,7,13 176:22 177:4 177:13,16 heterogeneous 42:22 43:16 105:4 hierarchy 163:7 high 15:5 16:23 16:24 17:5 63:1,12 75:8,9 75:19 76:1,4 76:10 95:16,19 95:22 184:22 higher 69:8 71:24 73:13,16 74:6,6 77:17 highest 102:7 103:14 104:17</p>	<p>105:19 highlight 102:5 102:12,19 103:1,10,20 106:16,21 109:3,7,13 111:13 112:5 highlighted 66:9 73:4,8 101:7 119:7 127:7,17 137:11 highlighting 43:11 72:24 hill 25:18 48:19 49:2,7,11,15,19 49:19,20,22,24 50:7,21,24 51:2,12 52:1 53:7,11 180:8 180:9,16 181:1 181:1,5,11,17 hired 8:17 9:21 hodgkin 144:13 hold 200:11 hour 47:3 91:3 hours 157:24 157:24 158:1 human 19:3 humans 19:13 hypothetical 63:18 77:2 112:12 130:8 192:13,14</p>	<p>i i.e. 55:8 icd 67:1,3,6,9 67:12,14,17,20 192:20 idea 17:16 72:17 identical 177:15 identification 7:11 10:2 15:13 21:10 27:21 42:3 53:24 60:7 64:9 70:9 107:9 127:1 identified 5:16 identifying 172:20 ignorance 184:5 ignore 72:23 illustrate 144:19 immediately 50:18 169:6 impacted 190:15 200:5 impacts 171:7 importance 168:14 important 22:11 56:19</p>
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>57:20 58:5 125:4 impose 156:5 imprecise 82:21 impression 63:10 improbable 68:13 192:13 improper 177:20 improvement 28:19 inaccurate 201:21 203:2 inappropriate 86:11 88:11 89:13,15,16 inappropriately 80:22 82:6 86:7 inarticulate... 32:14 incidence 4:7 64:6 66:1 128:2 include 28:18 46:13 163:6 178:3 190:16 196:14 included 26:12 34:3 52:22 53:1 62:22 114:3 117:9</p>	<p>120:14 121:9 137:12 172:22 177:5 179:22 190:10 191:3,3 191:3 192:2,4 203:21 206:14 206:22 207:2 includes 60:12 61:2 130:13,20 including 33:3 70:14 103:2 105:7 170:16 177:21 inclusion 99:13 100:19 101:15 101:17 104:12 104:13 106:1 inclusiveness 108:5 199:16 200:5 income 153:5 incomparable 140:6 incomplete 61:11 inconsistency 39:10 inconsistent 55:7 incorporated 113:21 incorrect 89:17 119:13 125:7</p>	<p>increase 78:24 98:14 99:4 100:10,17 200:18 201:7,8 increased 92:10,21 93:5 93:19 95:17 184:7 increasing 79:12 increasingly 183:1 incretin 154:14 independent 26:5,23 179:17 indicator 183:12 indirect 114:8 120:16 individual 26:11 28:20 29:9 33:13,20 34:7 44:6,8,9 102:14 104:23 108:19 110:24 120:13 179:22 individually 33:2 individuals 27:1 73:15 192:1 industries 74:4 74:5</p>	<p>industry 73:12 73:14 159:15 161:12,24 163:15 infer 22:14 inference 83:15 96:18 infinity 81:14 influenced 20:6 influential 168:22 informally 130:10 informatics 161:16 information 26:6 55:12 75:10 76:4 77:7 87:3 89:23 90:23 103:21 144:1 179:18 186:1 informative 22:20 informed 27:3 151:19 inherit 33:14 34:8 inherits 34:4 innovation 136:21 insight 50:18 50:19</p>
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

insist 171:14 insofar 18:24 58:19 instance 125:20 200:15 206:16 instances 112:17 institute 61:23 160:12,15 institutes 162:16 institutions 159:17 160:1 instruct 156:6 intellectual 9:15 intention 71:2 183:10 interaction 135:7,12,13,16 135:20,24 interactions 134:15 135:18 160:18 164:10 interest 39:23 40:16 41:2 42:6 83:13 169:6,8 interested 27:1 41:20 interesting 15:15 56:15 57:16	international 137:1,19,24 interpret 22:16 85:20 interpretation 88:2 99:5 100:17 174:8 174:14 interpreting 22:15 38:9,17 150:14 interrupt 133:20 interval 87:5 87:16,18,22 88:4,9,12,20 89:4,11,18 90:1,13,18 92:15,18,24 93:9,12,17 130:6,7,11,13 130:19,22 131:10,20 132:4,13,20 133:12,17 134:10,14 139:4,8,10,24 140:1,2,3,9,18 140:19,24 141:3,6,11,18 141:19,20,21 142:1 187:5 193:1	intervals 80:21 82:5 84:13,16 86:6,9 132:21 132:22 136:8 141:12 intervene 13:8 13:13 intervening 13:20 intervention 16:20 36:9,11 37:9,11,13 39:12 88:6 interventional 13:10,15 interventions 27:6,13 introduce 6:1 53:20 64:2 introduced 5:24 64:23 65:5 148:19 149:9 investigate 15:19 189:6 investigated 66:21 investigational 166:16 investigations 48:9 179:23 invoice 8:1,8 151:16 157:23	invoices 152:24 involved 160:17 164:6 164:19 189:9 involving 145:6 ireland 163:17 irresponsible 141:24 isolated 55:5 isolation 88:9 89:11 142:2 issue 30:19 96:3 108:3,10 110:16 119:20 119:22 125:4 126:18 154:3 154:11,17 175:7 180:17 183:24 197:18 198:15 199:15 199:23 issues 20:11 81:7 115:24 116:8 119:7 124:13,18 125:23 146:11 148:6 iteration 169:24
			j
			janet 165:1 january 156:22

<p>jersey 160:19 job 73:18 johnson 2:13 journal 95:21 131:19 136:21 137:1,19 138:1 138:2,6 168:21 169:1,1,3,23 170:7,8,17,22 171:14 178:21 journals 136:19 137:17 145:11 151:8 168:22 170:15 judge 154:3 163:5 167:21 judged 80:20 81:23,24 85:16 85:21 judgments 93:7 julie 4:4,16 60:6 107:7 july 209:20 jumping 173:2 june 1:15 5:6 209:15 justice 2:12</p>	<p>kellerpostma... 2:10 key 13:14 89:19 kidney 4:10,15 10:23 63:19 67:24 68:4 70:6 71:13 72:3,13 73:12 74:3 75:1 77:21 79:5,21 107:7,12 109:19 113:6 113:10 116:21 117:15,24 118:23 144:12 187:21 190:9 190:16 194:7 204:14 207:1 kind 17:2 43:5 44:4 50:5 79:3 79:24 82:22 83:15 85:17 115:19 131:24 140:18 150:18 153:15 168:17 173:2 191:5 199:3 kinds 41:7 80:2 134:24 know 6:18 8:13 8:14,21 9:16 12:11 17:4 20:17 23:11 24:17 33:17,24</p>	<p>34:1,2 38:20 47:8 52:18 53:16 59:11,17 65:16 69:19 70:17 71:5 72:17,18,19 76:22 79:6,14 80:1,2 81:5,24 82:3 83:10 85:18 86:1,5 86:10 87:13,14 93:24 94:8,14 94:22 96:22 113:10 114:19 123:15,18 127:7 129:5 131:17 132:5 132:16,17,23 136:6,11 138:2 138:9 139:9 152:22 154:10 154:22 156:21 158:1 160:23 167:20 169:13 170:18 174:7 174:16 175:5,5 176:16 182:5 187:15 189:16 191:10 196:2 203:7 204:6,11 205:3,11,16 206:8,17 knowledge 30:19 134:23</p>	<p>194:5,8 198:14 known 175:7 176:20,22 knows 193:11 kpmg 163:19</p>
I			
			<p>labs 160:6 164:3,4 167:3 lack 59:15 134:22 lacks 184:9 language 173:23 large 84:4,8 88:22 95:8 103:16 105:21 161:18 185:11 187:6 largely 136:22 larger 129:8,21 lash 108:14 110:19 lasted 164:14 late 202:2 laughter 163:23 laundry 206:20 law 3:24 53:24 54:3 162:18 181:22 lawyers 152:7 lead 31:12 63:20 68:6,6</p>

86:4 leadership 157:5 164:18 leads 101:16 104:13 leave 140:22 leaves 55:7 184:3,5,10 lecresha 2:13 lecresha.a.jo... 2:17 led 97:18 left 12:13 114:22 152:7 160:5 162:3 164:2 lejeune 1:8 5:8 10:6 12:3 71:24 72:3,13 72:18 76:24 77:4,10,11,18 77:21 146:2,6 146:7,18 147:21 148:1,2 148:13 155:22 155:23 189:9 208:2 length 13:16 letters 37:12 leukemia 4:3 60:6,13 61:1,6 61:7,15 64:15 144:12 187:20 187:21 192:19	205:14 level 78:23 102:7 104:17 112:19 127:24 130:9 131:15 133:18 134:17 135:15,17 136:1 138:13 139:16 levels 63:3 71:24 72:3,13 72:18,19 73:17 73:23 77:15,16 77:18,20 license 5:17 life 8:19 light 127:21 liked 158:6 likely 59:3,14 69:3,15 79:21 limitation 14:7 116:12 178:10 limitations 14:2,20 113:24 114:7 115:17 120:13,15 171:15 limited 60:9 113:23 120:12 line 16:14 22:9 23:11 32:18 48:6 61:22 92:3 175:16 176:15 190:20	199:13 208:5 linear 78:20 79:11,18 193:23 lines 42:13 66:8 129:12 174:4,4 linet 64:17,20 64:22 65:4,8 65:11,15,19,20 189:16,23 list 21:3 46:16 161:21 206:21 listed 28:2,5 118:5,23 188:11 lists 121:11 198:21 206:12 206:14,15,20 literature 116:20 125:6 125:13,17 133:8,10 175:22 litigation 1:8 2:14 5:9 9:2 10:10 11:18 16:1,2 52:8 131:8,13 138:23 146:2,6 146:7,12,18,24 147:21 148:2,3 148:7,13 155:22 186:16 186:21 189:10	208:2 litigations 9:6 little 40:20 56:12 68:13 76:3 83:9 94:4 115:6 134:20 148:18,24 149:8,14 162:19 liver 67:6 191:14 living 77:3 llc 2:2 located 160:20 location 88:14 lofty 33:10 long 6:24 122:16 152:13 157:21 158:16 163:17 164:11 167:13 185:5 longer 116:10 116:22 look 10:7 12:14 19:10 21:15 22:18 23:4,6 24:23 28:3 30:4,6 32:22 36:14,19 44:8 45:8 50:12,13 54:11 67:23,24 119:15 126:3 126:10 127:5 132:5 140:17
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>144:18 146:10 148:5 149:23 155:24 172:24 176:1,24 179:5 179:6 180:18 181:12 189:1 189:18 190:20 looked 19:10 54:6 69:1 79:3 118:14,19 188:5 204:5,16 205:9 looking 18:15 18:22 19:13 22:13,17 23:10 45:6 64:14 90:23 115:23 120:8 121:15 135:20,23 198:21 205:5 205:12 looks 68:22 70:11 91:17 118:4 135:2 loop 132:1 150:18 loss 55:12 115:24 lost 55:4 56:16 57:17 lot 149:1,15 160:19 166:21 lots 126:21 144:18</p>	<p>low 15:5 16:24 17:6 75:7,9,12 76:1,4 80:23 82:8,13 86:14 103:3 105:8 lower 69:8 77:4 103:5 105:10 134:17 135:17 lump 33:6 lunch 122:13 122:20 lung 67:12 lymphoma 144:13</p> <hr/> <p style="text-align: center;">m</p> <hr/> <p>m 1:20 209:5 209:17 m.d. 3:22 42:2 made 16:3 41:18 72:9 98:7 108:23 168:5 189:5 208:18 madigan 1:14 3:3,12,14,16 5:10,15,22 7:10 9:24 15:12 46:12 155:8 158:22 202:18 208:1 208:22 209:9 madigan's 57:9 78:7</p>	<p>magic 176:15 magnitude 127:21 maintaining 27:4 maintains 165:4,9 major 159:12 161:16 make 14:23 15:18 27:3 45:22 46:4 47:24 50:8 51:21 82:10 83:15 89:17 93:1 95:3 98:11,16 100:12 124:13 124:18 157:12 163:4 165:7 171:14 172:12 180:23 189:4 193:17 195:4 195:24 197:24 199:20 200:19 201:13 207:6,7 makers 97:18 makes 55:18 72:20 98:23 100:14 106:16 197:14 206:19 making 16:5 19:16 60:20 94:2 98:7</p>	<p>103:13 116:23 117:2 172:21 195:15,17 malignancies 4:7 64:7 66:2 mandatory 35:6,13 173:22 manner 116:14 manual 127:3 march 10:8 156:15,19 marcus 2:13 6:3 marcus.o.tubin 2:16 mark 15:21 16:1 41:23 marked 4:21 7:10 10:2 15:12 21:9 27:21,23 42:3 53:24 60:7 64:8 70:8 107:8,11 126:24 marking 7:13 10:4 60:1 martignetti 2:20 5:4 massachusetts 1:18 5:8 209:2 209:7 master 70:19</p>
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

materials 7:20 8:10 21:3 157:19 158:5,8	116:22 118:16 119:15 124:20 129:11 131:11	measures 31:6	30:17 31:5,8
mathematical 87:15	133:20 139:9 140:15 146:1	mechanistic 19:4	32:24 33:6,14 33:19,22 34:3
mathematically 32:10	147:21 149:20 156:16 173:12	medical 143:2 145:17 153:21 155:17 161:10 162:18 164:12 194:13	34:4,8,19 35:6 35:13,17 37:8 38:4 39:7,8 40:5 41:6 43:14 44:12,16
mathematics 81:11 83:23 159:6 171:4	174:2,7 175:23 176:10 177:12 177:13 185:5 198:3 201:6 203:20 204:8	medicine 27:7 61:24	44:22 45:8 46:13 48:8 49:1,14 50:1 50:15 51:5,14 51:17,23 52:5 52:19,21 53:13 54:16 56:16,20 57:17,21 58:19
matter 9:7 19:22 27:17 82:10 129:23 153:2 166:22 197:18	meaning 15:3 37:6,18 81:13 126:12 184:21	medium 75:7,9 75:18 76:1,4 76:18	55:17,23 56:5 56:16 57:13 57:17,21 58:19 59:1,14 60:1 60:15 61:5,14 61:17,23 62:5 62:19,21 63:13 64:16 66:16,20 65:17,21 66:19
matters 8:24 9:6 32:8 161:22 165:10 165:15 206:20	meaningful 35:6,13 173:21	members 157:4	63:21 68:8,15 68:17,22 69:1 69:4 70:8 71:14 73:11 77:7 80:6,12 80:16 81:9,22 83:11 85:3 86:4,21,21,24 87:6,11 88:1,3 88:5,11,13,19 89:12,21 90:6 90:10,17,20,24 97:3,12,20 98:14 99:18 101:13 102:2 103:12 104:7 104:10,21 105:12,14,17
mccabe 11:6	means 16:15,17 24:17 33:11 34:5 41:1 68:16 76:21 82:1 93:24 198:24	memmiller 2:3	
mcrae 33:12,21	meant 174:9,15 174:16	memory 51:18	
mdl 16:2	measure 90:5 129:13 140:3,9 140:16,19 176:12	mention 171:16 181:17 197:23	
mean 8:24 20:9 21:17 23:3 27:16 30:3 31:22 33:18,19 33:24 36:5,8 36:10,15,21 37:1,4 41:12 41:14 43:6,12 49:17 58:22,24 64:1 78:18 81:22 88:14,21 89:4 94:22	measured 92:10,21 93:6 93:19 198:22	mentioned 64:16 91:13 164:12 173:6 182:1 198:5 203:10 204:24 205:3	
	measurements 31:11,21	mentioning 50:7	
		met 49:15	
		meta 3:20 4:12 25:7 26:3,7 27:21 28:1,10 28:18 29:14,15 29:22 30:4,11	

105:24 108:4	204:1,6	15:6,14,24	137:15 139:21
108:11,15,18	method 81:13	19:8,21 20:8	140:11 141:13
109:8,15	148:24 149:14	21:16,22 24:14	146:4,10,19
110:12,16,20	168:19	28:6 29:19	147:9,12,23
110:23 112:1	methodologi...	30:2,23 31:9	148:5,22
112:13,16	25:7 96:17	32:4 33:8,16	149:12 150:3
113:21 120:12	157:8	34:9,15 36:1,7	151:4,19 152:2
121:22 122:1	methodologi...	37:2 44:3,17	153:7 154:5
123:11,20	24:5	44:23 45:18,22	156:5,12,19
124:10,13,18	methodology	47:5,19,23	157:2 158:14
124:20,23	44:21 97:23	48:4 49:4,16	158:21 172:17
125:1 157:9	99:24 101:3	51:6 52:15	174:20 176:4,6
173:9,21 175:2	105:23 106:12	53:5,14 55:16	177:10 179:2
175:8,9,11,21	106:22 109:23	55:24 56:4,9	188:4 189:14
175:24 176:9	110:3 112:6	59:6 60:8	189:22 193:12
176:16,23	144:19,20	61:10 62:8	196:22,24
177:1,4,5,6,14	149:1,15 171:1	63:13,23 64:10	197:20 199:11
177:24 178:4	methods 22:17	65:13,19 66:17	201:15 202:3
179:12,15,19	22:19 23:4,6	68:9 69:5,17	202:13 204:4
180:8,11,15,17	26:4 36:17	69:22 70:1,10	204:15 205:7
181:14 182:11	55:1 80:12,16	70:16,24 71:7	205:15,24
182:19 183:5,6	81:12 83:24	72:5,15 74:1	206:5,11 207:3
183:22 184:12	85:3 87:15	74:16 76:12	207:16
184:15,19,23	99:4 100:16	77:22 79:22	middle 22:10
185:1,5,16,18	102:8 104:18	82:20 83:8	42:10 49:19
185:23 186:1,4	108:15 110:20	84:6,10,22	80:10 91:24
186:15,19	145:16 146:15	89:2 90:2	milberg 2:2
189:3 198:8	148:11,19	94:12 95:9,23	milberg.com
199:15,23	149:9 150:16	115:18 117:17	2:4,5
200:2,12,17	150:19 155:15	119:1,14 122:5	million 75:15
201:1,9,11,17	171:8 179:16	122:16,19	mind 50:22
201:20,21	metrics 54:24	123:22 125:8	89:18 155:24
202:22 203:1,3	miceli 2:2 3:5	127:10 128:9	178:5 181:7
203:18,21	8:3 14:10,22	128:22 134:3	

<p>mine 70:2 minimal 63:3 minimized 187:4 minute 47:9 51:20 95:10 143:24 144:14 154:13 202:5 minutes 150:15 152:15 mischaracteri... 79:13 misinterpreted 204:8 mislead 28:23 misleading 30:21 35:18 39:11,17 55:13 80:17 85:4 missed 203:23 mistake 130:13 199:20 misunderstood 150:12 mitchellec 114:5 mix 191:21 mixed 24:3 mixing 99:9 100:18 models 101:18 101:24 102:6 104:14,15,19</p>	<p>money 164:18 month 75:16 142:11 months 75:19 75:19 76:11,18 156:13,16,18 morning 5:22 5:23 mortality 4:6 64:6 66:1,13 66:20 190:3 move 91:3 107:2 122:10 moved 160:21 moving 58:15 91:14 116:2 multiple 10:21 26:4 50:10 73:19 102:8 104:18 179:17 180:11 183:23 murky 148:18 149:8</p> <p style="text-align: center;">n</p> <p>n 3:1 5:1 name 5:4 6:1 20:18 49:20 144:8 narrower 187:5 national 61:22 natural 62:18</p>	<p>nature 72:7 78:1,5,12,15 79:4 194:5 nci 59:20 61:24 62:6 63:11 64:16 65:8,12 near 166:11 necessarily 31:10 32:11 38:21 39:19 50:4 72:6 77:24 78:11,20 82:3 84:11 98:16 100:12 103:3 105:8 181:13 200:19 201:13 necessary 50:13 180:9,24 189:1,6,17 need 19:19 30:4 30:6 39:7 44:7 50:2 76:9 85:9 116:18 151:22 154:21 156:6 174:13 175:10 196:2 204:12 205:4,11 207:11 needed 42:18 43:3,5,6,12,15 45:3 105:1 206:9</p>	<p>needs 129:8,21 180:18 207:8 neither 85:4,17 network 26:23 never 9:22 20:23 133:1,4 153:22 new 91:4 160:19,22 164:7 168:19 nhl 205:20 ninth 102:4 noise 17:2 non 44:4 144:13 nonapproval 165:11 nonlinear 78:22 79:15,16 79:18 193:23 nonspecific 97:12,21 98:8 98:12 101:9,12 101:22 102:4 102:11,18,24 103:9,19 106:15 107:20 114:8 120:6,16 nonspecifically 119:12 north 1:4 143:11 northeastern 142:6,19 163:2</p>
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>163:8 167:4 notably 114:5 notary 5:18 209:6 note 15:18 16:5 105:21 108:3 108:10 111:7 noted 5:11 57:4 107:22 131:12 208:16 notes 118:5,6 notice 3:11 7:8 noting 102:20 notion 58:17 87:7 null 63:20 68:5 68:12,16 109:14,16 111:23 112:1 120:4 190:17 190:24 191:1,4 191:6,7,10,22 192:1,5,6 number 3:10 10:20 41:24 52:12,15 53:20 54:2 55:11 60:21 61:6 62:21 67:24 75:6,15 95:2,3 96:6 97:1 129:8,21 140:1 141:1,1 146:10 148:6 150:8</p>	<p>153:10 163:14 181:20,21 183:9,15 188:18 189:15 195:10,11,13 195:14 200:16 numbers 75:11 75:24 76:6 83:17 133:15 134:9</p>	<p>90:2 94:12 95:9,23 115:18 117:17 119:1 119:14 122:5 123:22 125:8 127:11 128:9 134:3 139:21 141:13 146:19 150:3 153:7 157:2 202:1 204:4,15 205:7 206:11 207:3 objection 14:22 49:4 63:13 127:14 140:11 147:1 156:6 172:14 174:18 177:8 178:24 188:1 189:11 192:9 197:12 199:8 201:3 205:15,24 objective 170:23 objects 13:6 observation 73:15 83:4 observational 12:24 13:2,4,9 13:11,15,18 14:1,5,18 15:2 16:16,22 17:8 17:12,17 18:8 18:16,20,23</p>	<p>19:2,6,11 124:22 161:10 161:15 164:12 172:6 177:21 observations 129:9,21 observe 13:12 13:19 observed 20:6 observing 13:5 obtain 88:19 obvious 50:11 50:12 obviously 59:16 170:10 191:9 occupational 4:10 63:4 70:5 71:12,20,23 72:19 77:5,17 137:1,20 138:1 occupations 62:2 occur 83:13 occurred 91:15 odd 49:21 76:20 128:14 odds 183:10 191:8 offer 123:19 174:11 193:19 194:9,12 offered 153:17</p>
	<p>o</p>		
	<p>o 5:1 161:15 oath 5:18 6:8 object 14:10 15:6 19:8,21 20:8 21:16 24:14 28:6 29:19 30:2,23 31:9 32:4 33:8 33:16 34:9,15 36:1,7 37:2 44:3,23 49:16 51:6 53:5,14 55:16 56:9 59:6 60:20 61:10,11 62:8 63:23 65:13 66:17 68:9 69:5,17 72:5 72:15 74:1 76:12 77:22 79:22 82:20 83:8 84:6 89:2</p>		

<p>offering 123:10 153:20 187:23 ohdsi 161:14 161:14 167:4 okay 6:18,19 8:5 16:11 17:7 22:7 25:1,22 33:4,21 34:6 35:1,3 38:5 41:22 42:9 44:24 45:14 54:10 66:7 69:13 70:1,16 70:24 73:7 74:16 80:7,9 82:6 85:1 86:19 91:22 92:5 96:8,12 99:23 109:21 110:5 113:19 117:12 121:18 122:13 127:15 147:9 152:2 156:12 162:22 163:15 176:20 180:13 181:8 181:19 193:6 197:6 200:4 201:24 203:20 old 166:20 older 56:5 oldest 161:4 omop 161:9 164:12 167:4</p>	<p>185:22 once 50:17 184:3 ones 10:24 37:19 53:17 197:7 opining 25:12 204:1 opinion 25:5 85:11 138:20 139:15,19 153:21 194:10 194:13 195:2,9 200:16 opinions 25:3 123:10,20 124:7 153:17 154:16 157:7 186:5 187:24 188:7,13,14 189:2 193:19 194:21,22 opportunity 28:21 opposed 19:3 19:14 45:5 opposite 125:14 126:19 oranges 99:10 100:19 139:23 order 15:16 16:2 70:2 163:10 168:19</p>	<p>original 4:21 outcome 78:2 78:13,17 82:10 117:4 118:8,21 126:5,12 135:4 149:22 150:1 153:3 184:2 196:18 199:1,7 204:19 207:5 outcomes 13:20 25:8 144:21 150:10 157:10 161:10 164:13 outside 79:24 148:21 149:11 159:15 165:5 168:16 194:3 ovarian 52:4,5 52:14 overall 24:7,16 187:9 overcome 114:7 120:15 oversight 164:18 overview 101:3 103:21</p>	<p>155:2,3,4,6 202:8,9,10,12 207:19,21 packet 117:11 page 3:2,10 10:7 16:10 22:5,9 23:10 24:23 25:20,23 26:20 28:9 32:17,18 35:2 35:4,8,9 37:23 38:24 39:21 42:7,8 45:13 45:16,17,18 46:9,18 47:17 48:1,2 54:8 60:14 61:18,19 61:21 62:13 64:18,20 66:6 72:23 73:1,10 80:8,10 86:17 86:20 88:1 91:21 92:3 96:14,18,19,21 99:22 100:5 104:3 107:18 109:20 110:2,6 110:10,15,16 111:18 112:21 113:5,9,17 114:13 119:7 119:16 120:9 121:16 127:6 127:17 128:20</p>
		p	
		<p>p 5:1 108:20 110:24 140:5 p.m. 91:7,8,9 91:11 122:23 122:24 123:1,3</p>	

128:22,23 130:1 137:8 173:10,17,18 173:19 174:22 175:16 179:7 182:6,8,9,10,14 182:16,17 186:22,24 188:6 189:24 194:17 198:11 200:15 208:5 pages 1:1 37:22 42:5 100:1 173:12 paid 152:22,24 pancreas 67:9 paper 22:6 52:7 52:9,10,11,12 52:22 56:18 57:19 64:22,23 65:5,17,20 67:23 71:4,11 71:16,19 72:11 132:18 169:11 169:15 171:5 papers 12:6,16 46:16 56:22 57:23 58:6 131:18 144:16 144:17,19,21 144:22,24 145:9,10 151:7 paradigm 168:17	paragraph 24:24 25:3,3 25:24 26:2 42:13 46:8 47:18 48:3,6 54:12 56:7 61:22 62:14 73:1,9 80:14 84:21,23 89:1 97:10 98:7 100:4,10 101:2 104:2 106:11 106:22 107:19 110:6,15 111:9 111:17,18,22 112:21 113:17 116:11 120:9 128:21,24 129:2,7 130:2 145:13 155:9 155:13 179:6 179:11 180:20 181:5,16 182:8 182:13,14,22 182:24 186:24 188:8,9,11,12 197:22 198:10 198:12 200:16 paragraphs 188:6 194:23 parenthetical 43:9 parkinson's 25:14 144:13	145:1 189:8 205:22 part 38:15 51:13,15 61:15 70:15 112:14 132:1,3,6 138:19 164:4 167:15 172:7 172:20 182:10 186:20 participants 63:2 participation 115:24 particular 19:18 37:10 50:1 52:7 82:13 87:21 94:21 97:15,20 117:1 121:15 121:19 126:4 126:11 135:1 149:21,22,23 149:24 150:6,9 150:10 188:20 200:5 204:20 205:17,18 206:18 particularly 28:24 38:10,19 39:10 63:1 partnership 161:9,10,11 164:13,13,14	parts 15:21 75:15 187:18 passive 81:23 past 48:22 patients 26:24 pattern 187:9 pause 56:11 61:20 144:15 196:4 paying 22:22 pce 25:13 151:9 pecking 163:10 peer 46:13 95:21 97:17 125:6,13 131:19 145:10 151:8 168:5,9 168:11,13,23 169:11,18 170:11,22 172:4,18,19 175:22 178:10 peers 169:14 pending 6:24 202:19 people 13:5,5,6 13:7 17:14 18:18 27:3 59:16 69:18 77:3 89:16 134:6,7,16 135:17 141:5 159:15 163:24 176:12,23
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>percent 87:20 87:21 90:13 95:18 130:5,6 130:10,19,22 131:1,3,9,14,20 132:4,12,20,21 132:22 133:12 133:17 134:6 134:10,14,19 135:15,21,22 136:1,7 138:12 138:18,18 139:16 153:9 169:23 176:14 176:14,19</p> <p>percentage 153:5</p> <p>perchloroeth... 4:2,14 60:3,23 107:4</p> <p>perfectly 38:18 178:3</p> <p>performance 80:19 81:21 85:16,21</p> <p>performing 33:22 153:6 175:11</p> <p>period 38:23 160:7 164:11 166:8,22</p> <p>person 32:2</p> <p>personally 132:14,24</p>	<p>133:1</p> <p>perspective 162:17</p> <p>pertains 89:4</p> <p>peter 3:22 42:2</p> <p>ph 1:22</p> <p>ph.d. 1:14 3:3 3:12,14,16,18 4:4,16 5:10,15 7:10 10:1 15:12 21:9 60:6 107:7 159:8 208:1,22 209:9</p> <p>pharma 160:18 160:19 161:11 164:18</p> <p>pharmaceutical 161:23 167:5 186:2</p> <p>phillips 2:2</p> <p>phrase 17:15 31:22 59:8 137:13</p> <p>phrasing 147:7</p> <p>pick 162:3</p> <p>picking 55:8</p> <p>piece 170:9 172:8,12</p> <p>pis 161:12</p> <p>place 172:20 185:23</p> <p>placed 23:24</p>	<p>plaintiff 9:13</p> <p>plaintiffs 2:5 2:10 11:10 123:6,8,11,15 123:19,23 124:5,8 157:5 200:6 201:22 203:4,11,13,14 203:19 204:2</p> <p>plausible 130:11,21 169:9</p> <p>plays 27:6 168:9</p> <p>please 6:18 16:10 25:20 34:23 42:8 45:13 54:8 60:14 79:14 80:5,8 81:19 91:21 109:20 110:2 113:11 114:13 127:6</p> <p>pliofilm 62:14 62:17,24 63:11</p> <p>plot 44:12 50:17,18 90:8 90:14,17,22 103:23</p> <p>point 28:10,17 29:6,16 39:22 45:4 76:2 90:17 98:6,10 98:13 114:23</p>	<p>115:1 130:5,18 131:8 132:18 132:19 133:13 134:8 143:10 148:22 149:12 160:5 173:20 201:10</p> <p>pointed 115:5</p> <p>pointing 73:5 122:3</p> <p>points 121:8 201:10</p> <p>policy 97:18</p> <p>pool 201:1</p> <p>pooled 100:5 108:21 111:2 113:20 183:6,9 183:11</p> <p>pooling 108:18 110:23 114:5 186:24 187:2</p> <p>poorly 30:17</p> <p>popular 183:1</p> <p>population 12:2 87:8,9 100:22 114:20 114:23 115:14 118:4,6,20</p> <p>populations 35:23 98:22 99:4 100:14,16</p> <p>portion 60:9 167:13 194:14</p>
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>portrayed 88:10 89:11</p> <p>posed 28:20 29:8</p> <p>position 142:3 160:9 197:4</p> <p>positions 159:20</p> <p>positive 59:3,5 59:9 69:14</p> <p>possible 51:19 53:3 79:1 80:1</p> <p>possibly 137:21</p> <p>postman 2:7</p> <p>potential 24:6 28:17,23 63:4 109:9 172:11</p> <p>power 80:22 82:8,9,12 86:13,16 98:15 100:11 127:18 127:22 129:3 129:14 135:18 135:19 154:2 184:4 200:18 201:2,7,8</p> <p>powerful 184:14,20,20</p> <p>ppm 75:19,19 76:11,18</p> <p>practice 20:10 70:4 97:16 141:14 175:23</p>	<p>practices 27:8</p> <p>precautionary 105:15</p> <p>precise 26:8,10 76:9 108:13 110:18 179:20</p> <p>precisely 92:11 92:21 93:6,20 191:8 192:18</p> <p>precision 28:19 30:22 98:15 100:11 140:10 140:16 200:18 201:9</p> <p>predictor 135:4</p> <p>preparation 10:12 11:8 12:8,18 152:4 152:9</p> <p>preparing 12:5 12:8 27:4</p> <p>presence 178:18</p> <p>present 2:19 16:22 120:18 135:12 145:24 146:1 147:19 147:20</p> <p>presentations 126:2,9</p> <p>presents 30:20</p> <p>president 142:5 162:9 163:12 163:13</p>	<p>presumably 86:12 141:7</p> <p>presume 75:12</p> <p>pretty 24:15 173:3</p> <p>preventative 61:24 105:22</p> <p>previous 116:23</p> <p>previously 13:23 14:4 15:1</p> <p>primary 27:2</p> <p>principles 105:15 109:22 110:3</p> <p>prior 10:12 11:8 17:24 20:13,16,20 21:18 57:11 78:9 138:10 147:4,13 149:5</p> <p>private 161:9 163:15 164:14</p> <p>probability 87:19,21 127:19</p> <p>probable 37:18</p> <p>probably 9:19 17:13 20:22 32:6,11 36:21 37:1,4,6 51:7 153:14 168:6 188:16</p>	<p>problem 32:13 36:12,19 46:23 68:19 69:11 121:19</p> <p>problematic 37:16 40:1,19 41:15,17 43:18 43:23 46:11 54:17 83:22 102:21 105:6 203:18</p> <p>problems 120:23 122:3</p> <p>procedures 135:11</p> <p>proceeding 6:5</p> <p>process 40:1,19 40:20 41:12 50:15 62:15,17 97:17 102:2,12 104:21,22 105:24 168:5,9 168:11,13,20 170:3 172:19 172:19</p> <p>processed 62:19</p> <p>produce 7:21 54:19,20 86:24 151:22,23</p> <p>produced 8:2 151:16</p> <p>product 183:5</p>
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>production 3:11 5:16 7:9 7:18 profession 176:23 professional 185:24 209:6 209:18 professionals 26:24 professor 142:7 142:12 159:10 159:11,23 160:4,9,24,24 163:1 185:11 185:15 program 166:16 project 161:8 164:17 185:22 promoting 27:5 27:7 pronounce 71:5 proper 44:20 properly 29:23 properties 81:15 property 9:15 87:19 proposition 68:12 protected 16:4</p>	<p>protective 15:16 16:2 proves 171:5 provide 24:6 25:4 26:7,9 77:7 89:22 90:5 101:24 103:4 104:20 105:8 141:5 157:7 179:19 199:2,5 provided 94:4 154:19 provides 90:23 provisions 15:21 provost 142:4 142:11 163:1,8 163:9 public 5:18 27:7 161:9 164:14 209:6 publication 58:13,16 63:21 68:7 99:19 109:9 119:23 120:1 170:19 178:6,8,14,18 178:20,20 190:11,15 192:7 200:24 publications 144:11 168:10 188:19</p>	<p>publish 63:19 68:3 133:16 168:21 170:18 171:4 publishable 170:6,7 published 12:2 17:18 20:19 46:12 52:3,9 53:7 58:18,21 59:4,14 68:22 69:2,2,10,15 114:4 125:6,13 131:18 132:14 133:11 138:5 145:9 151:8 172:22 175:21 pull 51:7 56:21 57:22 58:6 95:11 purpose 25:6 157:8 201:1 purposes 168:8 put 69:20,22 80:4 81:16 122:11 175:2 putting 44:15</p>	<p>144:3 qualitative 94:2 quality 19:19 20:1 22:12,20 23:18,23 63:1 63:12 103:3,6 103:15 105:8 105:10,20 118:1 119:4,5 169:21 quantify 135:13 quantity 89:19 question 6:17 6:20,24 16:15 17:7,11,16,20 21:24 22:10 23:17 24:2 32:19,22 33:4 33:12,21 34:6 36:3 44:18 45:4 49:6 50:6 50:11 51:14 53:8,17 56:24 58:1 64:21,22 65:10 74:13 79:2 82:15 90:21 92:7 93:13 101:14 104:10 117:19 122:6 124:2,6 131:24 132:2,3 132:7,17 133:7</p>
		q	
		<p>qualifications 123:16 124:1 qualified 123:19 124:9 143:12,15,21</p>	

<p>135:6 138:8 145:22 147:15 147:17,20,24 148:8,15 150:15,21 151:1 174:23 177:17 183:3 187:15 195:12 202:17,19,21 203:16,17 204:8 questioning 178:7 questions 12:15 28:20 29:8 157:16 158:12 158:16 168:7 173:5 174:24 175:3 180:7 190:8,12,14 193:14 194:2 206:6 quickly 21:14 189:18 quite 17:19 24:17 29:10 64:12 81:24 133:24 142:10 181:9 quote 14:5 25:4 29:15 30:10,11 30:15 39:12,18 68:15 97:6 108:10 111:1</p>	<p>127:17 quoted 88:9 89:11 quoting 120:20 <hr/> r <hr/> r 5:1 raise 112:15 198:5 raised 97:13 raises 97:11 107:20 119:18 ran 162:20 random 58:23 88:2,4,12,20 187:4 randomized 18:11 19:10 103:15 105:20 randomness 17:3 range 62:3 63:2 130:7,11 153:15 ranges 130:20 ranks 163:9 rare 80:12,17 81:6,10,14,22 82:3,8,11 83:3 83:5 84:3,14 85:4 86:4,8,10 86:15 129:10 129:22</p>	<p>rarer 82:9 rate 130:21,24 131:3 rates 116:1 rather 36:21 40:8 75:6,24 141:11 183:20 ratio 128:13 130:12,21,24 131:2,3 139:7 139:24 140:9 140:20 141:11 141:17,20 142:1 183:10 191:8 rationale 182:18 ratios 139:4 140:24 141:3,6 reach 191:24 read 10:21 11:2 17:22 18:5 20:19 21:6 22:23 23:2 24:10,13 25:10 26:13,17 27:10 28:13 29:4 34:11,14 35:20 38:12 39:14 40:6,12 41:15 42:24 43:22 48:14 54:4 55:14,19,22 57:9,11 59:22</p>	<p>62:4 63:7 66:18 71:16 73:20 74:7 78:7,9 81:1 88:23 91:24 92:12,13 97:24 100:23 101:20 106:3,8 108:24 111:4 112:21 114:11 115:10 115:15 116:18 128:5,8 131:5 145:18 147:4 147:11,13 148:16 149:3,5 155:12,18 163:5 174:17 179:13 180:3 182:9,23 183:16 186:23 187:10 188:9 195:2,6,12 200:21 202:17 202:19 203:11 208:14 reading 63:9 172:5 195:21 195:22 reads 170:5 196:1 real 103:11 105:16 really 133:9 154:12 177:16</p>
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

reason 7:4 133:14 184:13 184:14 196:17 196:21 208:5 reasonable 25:5 38:18 41:11 178:3 reasons 184:14 reassessing 166:3 rebuttal 97:23 187:24 193:20 194:10,14 recall 15:8 51:20,23 52:2 52:23 53:6,8 53:18 54:6 63:15 136:11 151:3 153:24 154:11,12 157:18 174:5 175:3 182:13 186:12 190:18 195:10 206:5 received 151:21 152:19 160:3 recent 114:3 146:11 148:6 148:21 149:11 150:5 151:4 154:19,20,21 157:23 165:19	recently 146:4 147:23 recess 47:12,13 91:8,9 122:24 123:1 155:3,4 202:9,10 recognized 185:1 recollection 154:8 record 5:4,12 5:24 15:14 16:6 47:11,15 91:7,11,14 112:23 122:15 122:20,21,23 123:3 143:18 154:24 155:2,6 189:21 202:4,8 202:12 207:20 208:17 209:12 rectum 67:3 red 181:18 reduce 102:13 104:22 reduced 82:12 reevaluating 166:3 refer 86:23 114:24 reference 4:18 23:15,16 64:20 65:1 126:23 127:3 168:5	179:14 referenced 11:21 65:6 referred 87:2 88:5 114:14 115:1,9 183:4 referring 37:7 48:8 75:17,24 85:23 98:13 139:6 145:20 145:23 147:16 147:18 149:19 150:6 156:1 159:18 refers 34:20 35:23 58:16 155:21 refined 62:18 reflect 46:17 regard 157:8 167:8 174:21 188:12 189:23 196:15 regarding 25:6 200:17 registered 209:5,18 regression 40:5 41:6 135:2 regularly 175:21 178:9 regulation 105:14	regulatory 105:13 136:22 regus 1:17 reject 169:5 rejected 130:8 relate 150:10 related 11:18 46:4 52:4 97:2 130:5 138:3 165:15 199:1 207:4,5,7,8,10 relates 1:9 relationship 18:15,22 25:13 54:22 74:22 78:1,12,16,20 79:4,11,13,18 79:19 131:21 131:23 135:2 193:23 194:6 204:13 205:5 205:13 relative 66:12 92:7,17 93:7 93:11,16 94:10 94:23 128:3,12 128:15 183:9 190:3 192:23 relevance 112:13 121:13 121:18 relevant 26:7 169:1 178:12 179:19 196:18
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

reliability 32:23 123:20 124:10 reliable 98:17 100:12 103:4 105:9 124:14 185:3 200:20 201:13 reliance 80:18 85:12 105:11 relied 138:20 178:22 200:6 201:22 203:3 rely 14:6,19 97:18 105:14 105:23 168:11 172:12 relying 103:14 105:19 177:6 182:11 204:7 remains 169:20 remember 21:6 47:1 52:6,20 53:3 62:10 136:14 137:23 138:9 152:1 155:8 190:12 192:12 render 177:6 178:21 rendering 186:5 189:2 repeatedly 143:19 197:15	repeats 112:17 rephrase 117:18 124:6 133:8 146:21 199:22 replied 203:19 report 3:13,21 9:3,24 10:8,9 10:12 11:3,5,8 11:19 12:9,18 24:20 25:12,21 28:2,5 30:10 30:15 42:1,6 42:18 45:12 46:18 47:17 48:1,20 53:22 60:9,12,15 61:8,15,16 65:6,7 96:6,10 96:13,21 97:1 98:19,21 99:3 99:22 101:4,7 101:11 104:9 106:9 107:13 107:15,18,23 108:3 109:20 109:23 112:22 113:5 114:14 119:8,10,16 121:1 128:20 130:1,4 145:13 154:18 155:9 156:4,8,15,20 157:7,22	175:24 178:2 179:5 180:21 187:21,22,24 188:5 193:20 194:10,14,17 194:18 195:3,7 196:8,9 197:1 197:21 198:11 198:16 200:9 200:16 201:18 202:23 203:22 204:9 reporter 1:20 4:21 5:12 6:13 145:4 148:16 165:8 209:6,18 209:18 reporting 29:2 29:18 reports 10:6,13 10:16,19,20,21 11:9,14,16 13:24 19:6 59:23 60:21,22 63:10 97:2 107:20 123:7 123:12 157:13 170:4,5 187:18 189:6 203:11 204:6 represent 6:3 23:14 64:24 representation 61:12	representative 153:12 representing 167:24 represents 103:6 105:11 130:7,11 request 3:11 7:9,17 requires 81:12 rerunning 166:24 research 97:16 101:14 104:10 145:14 146:14 148:9 155:14 159:12 160:6 164:5,24 168:15 185:12 researcher 128:3 168:18 researchers 13:19 26:24 53:12 130:4,14 residual 114:9 120:17,24 respectively 117:6 response 74:21 92:6 194:6 202:18 responsibility 169:20
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

responsive 7:20 8:11 rest 29:11 85:19 result 55:13 63:20 73:18 82:4 108:4,11 110:17 131:15 138:15 198:8 199:16,24 resulted 201:20 203:2 resulting 108:21 111:2 results 22:16 23:24 26:4 28:11 31:7 38:10,18 39:9 39:24 40:18 54:18 55:5 59:9 63:19 68:4,6 73:24 74:21 80:20 82:2 84:4,9 85:4,22 86:5 89:23 98:16,23 100:12,14 101:15 102:1 103:5,22 104:11,20 105:9 108:13 108:17,18 109:14 110:18 110:22,23	111:24 114:6 120:14 121:24 122:1 138:11 138:20 171:9 179:16 183:8 187:2 197:3,10 200:20 201:1 201:13 retiring 142:8 retrospective 4:6 64:5 65:24 returned 4:22 160:8 returning 142:19 revealed 73:11 80:15 85:2,9 review 4:11 10:13 11:5,9 11:13 12:1,17 21:14 26:12 38:8,16 39:7 70:7 71:14 97:17 105:13 106:4,5 109:15 111:24 124:9 158:23 168:5,9 168:11,13 169:5,21 172:8 172:18,19 179:23 183:3 189:17 193:18 194:9 197:1	reviewed 7:17 11:18,22 21:3 22:1 46:13 95:21 107:16 113:22 123:6 125:6,13 127:13 131:19 145:10 151:8 167:12 168:23 170:22 173:24 175:22 178:10 196:10 201:19 202:24 reviewer 170:11 172:5 reviewers 169:11,13,18 170:1,2,4 reviewing 167:21 172:4,6 177:1 reviews 27:5,13 105:23 109:8 110:11 right 6:10,15 9:7 10:18 13:22 16:19 17:20 20:24 21:1,5,21,22 22:15 23:24 26:18 33:15,23 35:24 36:9 44:5 45:3 48:4 48:20,23 49:11	49:12 50:1 51:22 57:3 63:22 64:18 66:4,22 67:4,7 67:12,15,18,21 68:1,23 71:21 72:4 74:16 75:3,17 76:11 76:18 97:3 98:17,24 99:5 99:19,20 100:2 101:5,10 102:2 102:9 104:7 106:12,23 107:24 109:24 111:14 112:2 113:7 114:21 115:11 116:4,9 116:15 118:24 120:9 123:7,8 123:9,13,14,21 123:24 124:4 124:11,12 126:14,15 129:3 133:18 133:23 134:2 137:14 138:13 139:12,13 140:10 142:9 142:20 143:3,5 143:8 144:9 146:8,18 148:3 148:13 150:16 151:17,18
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>154:2 162:6 173:11 174:3 175:6,15 176:10 181:10 187:16 188:23 190:23 193:16 198:13 203:12 204:3,5 rigid 191:6 rigorous 97:17 rigorously 106:1 ring 11:7 risk 4:3,10 30:21 60:6 61:1 66:12 70:6 71:12 73:12,13 74:4 74:6 78:21,24 92:7,10,17,21 93:5,7,11,16,19 93:22 94:10,19 94:23 95:7,8 95:15,17,21 103:4 105:9 128:3,12,13,16 130:12 131:2 183:9,13 184:7 184:8,22 185:3 187:20 190:3 191:15 192:23 206:24 rob 165:22</p>	<p>robert 2:20 5:4 role 27:6 room 55:7 163:24 round 189:9 rpr 1:20 rr 190:24 rubber 62:18 rutgers 159:3 160:10,11,15 160:21 161:7 167:3</p> <hr/> <p style="text-align: center;">s</p> <hr/> <p>s 3:9 5:1 161:15 sabbatical 142:17,18 sacrosanct 132:20 safety 166:19 salehi 71:8 sample 81:13 127:22,23 sampling 17:1 satisfactorily 5:16 save 115:6 saving 42:7 savitz 3:18 20:14 21:7,9 24:12 56:8 91:15 92:2,7 123:23 124:6,9 181:23 182:2</p>	<p>200:24 savitz's 21:4,13 23:1,16 54:3 saw 64:24 68:5 saying 15:8 23:7,7 39:18 52:18 56:23 57:24 73:23 74:3 75:22 83:1,6 84:2 95:2 119:11 134:22,23 147:3,6 150:14 195:5,6 206:3 says 16:13 25:4 28:10,17 29:24 32:2 35:5,12 35:17 42:18 44:24 46:9 48:7 54:12 61:6 62:16 66:12 76:13,16 80:15 97:10 104:9 110:11 114:16,20 116:12 120:11 121:21 127:18 157:6 170:6 173:11 187:2 188:7 190:24 198:7 scale 161:18 school 162:18 162:18,19</p>	<p>schwarz 181:23 science 136:22 165:17 168:16 168:16 170:16 sciences 161:16 162:5,10,11,14 162:20 scientific 25:5 97:22 127:4 175:22 178:11 178:21 194:13 scientist 29:13 168:10 scientists 97:18 scope 25:2 188:7 scrutiny 55:2 seattle 160:1 second 29:7 35:16 39:6 42:13 62:14 73:1 75:14 83:12 98:20 100:9 104:2 111:10,12,17 111:21 116:11 119:23 142:24 173:1 201:12 seconds 95:18 section 2:14 23:18 38:6 61:13 96:16 99:24 101:3,7 106:12,23</p>
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

110:7 114:1,14 115:8,9,14 116:8,18,23 171:8,9,9,10,13 174:21 178:10 182:10,18 186:23 188:6 194:18 sections 117:5 sector 73:16 sectors 162:1 see 16:13 21:14 23:17,18 25:23 32:5,18,20 35:4,14 42:16 43:20,21 48:12 54:14 64:20 66:10,23 67:2 73:3 74:14 75:20,21 80:10 80:13 85:10 92:1 96:3,14 96:16,20 100:4 100:7 104:2,8 110:10,13 114:16 116:6 117:24 119:19 119:20,24 120:5 130:2 136:7 146:23 147:6 182:20 182:21 190:21 203:20	seeing 56:3 137:10 seek 168:21 169:14 seeks 169:11 seem 28:3 192:7 200:23 seems 15:9 68:12 71:22 169:9 192:13 seen 7:14 11:24 12:4,5,7,10,16 53:10,12 60:16 69:18 85:5,14 132:24 133:1,4 133:10,24 134:7,8,13,19 135:21,22,24 136:6,9,14 139:13 141:5,8 158:6 sees 169:7 selected 54:18 selection 55:8 semester 142:14 send 168:24 169:15 senior 137:4 142:5 sense 82:11 87:22 93:1,5 94:7 95:3	sent 8:4 sentence 26:16 41:2,4,19,21 42:14 43:2,17 43:22 48:7 73:22 81:17 85:20 100:9 104:6 111:10 111:11,16,21 116:12 145:14 155:13 174:2 sentences 26:17 45:15 separate 28:12 44:12,14 181:6 separately 44:1 45:9 46:21 160:15 sequitur 44:4 series 19:1 97:11 183:8 serious 30:20 seriously 28:23 seriousness 93:22 served 8:13 136:15,18,24 137:4 145:5 159:10 160:11 162:6,7 165:3 165:12,14,16 170:9,11,13,14 services 50:16 153:6	set 165:5,9 170:23 171:1 171:11 183:2 188:20 209:10 209:14 setting 103:12 105:17 settle 28:21 seventh 101:12 several 68:11 114:3 127:23 184:16,17 191:12 seyyedsalehi 71:5,9,11 193:9,13 shalt 176:16 sharon 2:12 6:2 sharon.v.spra... 2:16 sheet 208:4 shield 96:6 shields 3:22 10:19 11:17 19:5 42:2 46:5 46:10 47:20 53:22 62:9 96:13 97:6,10 98:3,5,13 99:12,17 101:5 101:13,22,23 102:5,12,19 103:1,10,20 106:9,14,16
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

109:3 157:13 188:13 197:22 200:13,17 201:16 202:21 203:16 shields's 11:3 42:6 63:9 97:21 98:19,20 99:2,7,21 101:3 106:21 189:5 194:21 203:22 204:9 short 8:3 124:20 152:11 166:23 shorthand 209:18 show 59:13,15 86:3 90:10,12 133:16 134:9 138:24 141:17 141:17 142:1 193:6,8 showing 7:13 10:4 98:9 141:11,18 shown 187:18 188:18,21 192:17 shows 125:18 125:20,23 side 139:10 163:16 174:3	signature 209:17 significance 128:1 130:9 134:18 138:3 139:20 140:4 191:19,24 193:4 significant 73:11 84:18 92:9,20 93:2 93:18 125:2,21 126:17,19 127:20 131:1,9 131:14,16 138:12,16,17 138:21 161:8 166:9 184:10 191:9,17 similar 11:1 107:20 108:19 110:24 116:22 similarly 31:8 simpler 55:10 simplicity 55:9 55:11 simply 75:24 simulation 80:15 85:2,9 85:24 86:11 single 177:23 183:9,14 sit 51:10 95:5 174:7	sitting 51:20,22 95:10 143:24 146:13 148:8 154:12 situation 50:9 201:19 202:24 situations 79:19 83:16 149:2,16 six 101:4,6 137:15 169:16 sixth 99:17 106:20 size 16:19 19:24 20:5 31:13 32:6 56:15,17 57:16 57:18 81:14 87:10,13 127:24 129:12 sizes 34:21 127:22 skew 197:3,10 skimmed 10:23 slash 75:9 slightly 184:7 slow 165:7 small 83:17 92:10,20 93:5 93:8,19,24 94:7,11,15,23 103:2 105:7 187:7	smaller 140:20 smoking 121:17 197:16 206:15,17,24 207:10 smoothing 187:7 software 163:18 somebody 158:23 178:19 193:10 199:20 someone's 31:23 somewhat 139:5 sorry 35:7 37:24 45:17 58:14 60:15,18 64:19 111:11 113:15,16 118:16 124:2 133:20 139:9 145:2 150:13 151:2 198:5,11 202:14 sort 32:9 36:10 50:15 92:24 131:24 sound 71:21 soundness 25:7 157:9 sounds 13:22 82:16 151:18
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

source 27:18	speculation	64:12,13 65:2	148:14 149:3
spanned	74:2	65:3,18,21,22	149:17 150:7
167:13	spends 116:6	66:19 68:20	151:24 152:3
speak 6:14	spirit 56:22	69:12,20,24	153:11 154:6
170:19	57:23	70:3,13,21	154:23 155:7
speaking 18:18	spot 169:6	71:1,3,9,10	156:10,14,23
19:9 27:15	sprayregen	72:10,22 74:12	157:15 158:11
34:20 129:24	2:12 3:4 4:22	74:17 76:15	167:23 172:14
170:21,24	5:20 6:2 7:12	77:12,13 78:3	173:3 174:1,18
speaks 119:20	8:6 9:10,11	78:6,14 79:7,8	177:8 178:24
119:22 120:5	10:3 12:22,23	80:3 82:24	179:11 182:9
specific 4:6	14:14,24 15:20	84:1,7,19,24	188:1 189:11
28:24 29:16	16:7,9 19:12	89:8 90:7 91:2	192:9,15 195:1
37:9 57:5 64:6	20:12 21:11,19	91:12 94:17	195:6,9,20
65:24 108:16	22:2 24:19	95:13 96:4	196:9 197:12
110:22 112:13	27:22 28:8	97:7,9 106:18	199:8 201:3
112:16,20	29:21 30:8,12	106:19 107:1	202:1,16 203:6
115:23 116:24	30:14,24 31:18	107:10 110:8,9	203:8,9 204:10
117:14 118:13	32:12 34:17	111:19,20	204:23 205:1,2
119:5 120:2	36:2,4,23 37:3	117:18,20,22	205:10,19
121:23 125:1	41:23 42:4,11	117:23 119:9	206:2,23 207:9
128:10 132:18	42:12 44:10,19	120:7 122:9,14	207:14
133:13 141:7	45:11,21,24	123:4 124:3,15	sprayregen's
187:23 189:7	46:1,6,7 47:2,8	124:17 125:11	178:7
198:1	47:16,21 48:2	126:6,8 127:2	spread 62:19
specifically	48:5,17,18	127:15,16	squared 176:13
31:11 57:3	49:8 51:1,9	128:19,23	ss 209:3
128:15 131:2	52:24 53:9,19	129:1,17,18	staff 151:11
157:13 193:14	54:1 55:20,21	134:12 136:16	standard
195:8	56:2,6 57:2,8	136:17 137:16	178:15
specified	58:3,11,12	139:17,18	stapled 117:11
120:23 128:1,2	59:7,10,24	140:13,14	start 77:14
speculates 74:5	60:10 61:17	141:15 144:6,7	91:23 108:7
	62:11 63:16	147:2,10	168:4

<p>started 158:22</p> <p>starting 23:10 92:2</p> <p>starts 46:5 54:12 96:18 100:5 104:6 113:17 186:24</p> <p>startup 164:7</p> <p>state 23:21 157:3 184:5,10 186:9,18</p> <p>stated 45:3 130:9</p> <p>statement 14:15,23 15:10 28:15 31:1 38:14 39:16 40:14 44:2 46:4 58:8 60:20 72:9 81:3,20 85:8 86:14,16 89:9 89:14 94:2 98:18,20 99:2 99:7,12,17 101:12,22 102:4,11,19,24 103:10,20 108:2,9 109:2 109:6,12 111:6 111:12 129:20 177:11 187:12 195:10,18 197:15</p>	<p>statements 82:17 89:17 98:4 101:4,6,9 106:15,21 112:4 116:24 197:24 208:17</p> <p>states 1:3 2:17 6:4 46:10 102:20 103:2 166:4 167:16 167:22 168:15 186:6 199:17 200:1,24</p> <p>statically 126:19</p> <p>stating 81:4 85:6</p> <p>statistic 56:21 57:22 58:6 176:11</p> <p>statistical 26:3 28:10 36:15,16 38:9,17,22 42:22 80:19,22 81:8,8,11 82:7 83:24 84:17 85:13 86:13 87:15 97:14,16 97:19 98:15 100:11 105:5 132:11 134:18 134:24 135:11 138:3 139:20 140:4 145:15</p>	<p>146:15 148:10 155:15 161:22 163:19 164:5 167:8 170:16 175:14,15 178:15,17 179:16 191:18 191:24 193:4 200:18 201:2,7 201:8</p> <p>statistically 84:18 92:9,19 93:2,18 125:21 125:23 126:16 127:20,24 130:24 131:13 131:15 138:12 138:16,17,21 184:9,20 191:9 191:16</p> <p>statistician 83:2 143:22 159:2,16 160:6</p> <p>statistics 56:14 57:15 87:7 144:4 159:8,11 159:11,24 160:2,9,14 161:1,3,4 162:8 163:1 167:8,10 170:17 176:12 185:2</p>	<p>stay 122:19</p> <p>stayed 160:22</p> <p>staying 38:1 39:21 61:21</p> <p>stenographic 5:12</p> <p>stephen 181:23</p> <p>stepping 142:10,22</p> <p>stick 125:18</p> <p>stipulate 65:14</p> <p>stomach 66:24 190:21 191:7</p> <p>stopped 42:7</p> <p>strategies 38:6 39:1</p> <p>strawman 201:14</p> <p>stray 112:24</p> <p>street 1:17</p> <p>strength 102:6 121:5</p> <p>strengths 104:16 115:16 117:14 118:6,8 118:9,10,11,19 171:11,20,23 172:1,3,7 196:13</p> <p>strike 97:8 124:16 126:7 136:16 176:4 196:22 205:1</p>
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>strikes 49:21 stronger 108:20 111:1 strongest 24:5 struggling 50:5 51:7 students 151:12 studies 12:2 14:1,5,18 15:2 16:18 17:8,12 17:17 18:8,8 18:11,14,17,21 18:23 19:3,4,6 19:10,11,20,24 20:1,2 23:22 24:3 26:5,7,12 28:12,20 29:1 29:9,17 30:6,6 30:18 31:5 32:23 33:5,11 33:14,20 34:7 34:22 35:17,18 36:6,11,17 37:7,9 39:24 40:2,18,22 42:19,21 43:7 43:10,19,24 44:6,8,9,13,14 45:7 46:12,14 46:21,22 48:10 48:11 50:10,14 50:20 51:4 54:20 55:8</p>	<p>56:13 57:14 58:7,17,20,21 59:2,4,13,14,21 62:7,16,21,24 63:12,12,17,18 64:16,17 65:9 65:12 68:11,23 69:2,2,7,10,14 69:15 71:21 73:13 75:1,2,5 77:16 80:15 84:3 85:2,6,9 85:10,15,24 86:1,3,12 87:4 88:15,17,18 89:6 90:12,15 93:15 94:9,14 94:18 95:6 96:1 98:22 99:9 100:6,13 100:18 101:17 101:19 102:14 102:14,22 103:3,6,15,15 103:16 104:14 104:15,23,23 105:3,7,8,11,20 105:20,21 108:18 110:23 110:24 113:22 113:24 114:4,6 115:17,20,21 115:21 116:13 117:1,2,8,16</p>	<p>118:5,23 119:6 119:12 120:2 120:13,14,19 121:2,14 122:4 124:21,23 125:3 126:3,10 131:8 133:11 136:10 141:4 148:20 149:10 149:20 150:9 150:22 151:1 171:17,22,24 172:3 175:1 177:5,14,21,22 177:23 178:3,4 179:17,19,22 179:24 180:2 180:11 183:2,8 183:15,23 184:16,18 187:3,6,7 192:4 197:11 198:16 204:13 study 4:6 13:1 13:2,4,10,10,11 13:15,16,18,18 13:21 16:16,22 18:19,20 19:1 20:3,5 22:12 22:16,16,17,20 22:21 27:9 28:24 29:1,16 29:17 34:2 37:10,11,14,15</p>	<p>54:18 55:2,3,6 55:10 61:24 63:11 64:5 65:24 68:5,14 68:16 72:1 75:10,18,22,23 76:5,6,14,17 77:15,19 83:4 83:11,12,13,19 90:12,14 96:3 99:4 100:16 103:22 108:16 108:19 110:21 113:22 114:20 114:23 115:14 118:1,4,6,15,20 121:4,4,16,19 121:23 125:17 125:20,22,22 126:18 127:19 127:22,23 129:8,21 168:18 170:23 171:2,6,6,12,15 171:20 172:6,6 172:10,16,21 177:22 183:14 183:24 184:3,6 186:13 190:1 191:2,23 192:6 193:15,18,19 196:19 200:6 204:18,20 205:18 206:19</p>
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

207:2 study's 23:18 studying 36:9 129:9,22 150:2 stuff 82:22 168:3 subcommittee 165:16 subgroup 40:4 41:6 subheadings 115:2 subject 14:6,19 15:16 99:15,19 100:21,22 102:15 104:24 109:8 subjectiveness 99:15 100:21 subjects 13:21 205:18 submitted 12:19 13:24 170:20 submitting 170:22 suboptimal 80:20 81:24 85:17,19,21 subscribe 208:16 subsection 116:2	substance 195:22 substantial 55:12 80:23 substantially 23:22 substitution 40:11 55:22 sufficient 72:12 88:10 89:12 suffolk 209:3 suggest 170:1 suggestion 190:18 192:3 suggests 73:15 178:20 suite 2:8 summarize 26:4 55:10 159:1 179:16 199:12 summarizes 87:3 90:20 summarizing 56:14 57:15 summary 25:2 86:22 87:2,6 87:16,18 88:3 88:8,10 89:10 89:12,24 90:1 115:19,20 188:7 supplement 74:8,11,20	supplemental 70:12,15,17,22 71:15 support 24:6 151:11 supportive 24:4 suppose 32:8 41:14 49:17 supposed 92:14 sure 16:15 17:10 18:24 19:22 31:20 32:9 35:8 39:19 40:18 41:1,7 43:8,11 45:23 47:24 51:21 53:16 60:19 82:8,18 86:14 90:4 113:2 115:19 125:9 126:1 132:22 134:22 136:4 140:18 141:8 144:20 148:17 149:7 159:4,19,21 163:4 165:7 166:8 168:12 168:16 171:21 172:21 178:15 180:23 184:11 186:10,14 191:5 195:4,15	195:17,24 197:16 surveillance 137:6,13,23 swear 5:13 sworn 5:17 209:11 synonymous 17:11 synthesize 182:12 system 62:20 186:7,8 systematic 4:11 17:9,15 20:6 27:5,13 39:7 70:7 71:13 109:7,15 110:11 111:24 183:3 systematically 15:3,4 16:23 16:24 17:3,5 31:24 32:1 58:22 59:1 69:7,9 88:14
			t
			t 3:9 tab 27:23 table 60:12 61:3,5,12 66:6 66:12 70:12,15 70:17 74:10,15

74:18,20 96:14 107:13 114:2 117:10,13,21 117:24 118:3 120:1 188:22 190:1 192:8 196:12 tables 70:22 71:15 74:14 121:1 tactical 87:22 tainted 192:7 take 6:6,23 8:8 12:22 38:8,16 38:21 47:4,9 91:5,17 116:17 144:14 157:21 158:16 173:12 184:15,17 202:5 taken 47:12 91:8 122:24 155:3 202:9 208:3 talc 9:2,6 52:4 52:13 talk 15:22 38:24 65:10 121:3 talked 65:11 120:4 156:8 167:2 talking 17:1 44:11 46:5	62:14 65:8 84:22 86:2 126:16 146:6 148:1 155:9 156:7 179:10 181:17 194:20 talks 121:6 126:22 206:4 task 105:22 taught 185:15 tax 186:12,12 taxotere 16:1 16:21 32:15 154:9 186:16 tce 25:13 113:6 116:21 151:9 technically 89:3,6 techniques 184:19 tell 36:24 86:22 134:20 143:17 159:17 166:7 temporality 118:11,22 tend 24:5 tends 140:20 140:21 tenth 102:11 tenure 159:23 160:3 tenured 159:11 160:24	term 18:19 31:21 139:3,6 142:23,24 162:6 165:12 165:13 175:6 180:19 terms 17:11,12 43:15 49:18 75:6,15 83:22 84:9 147:7 162:7 test 81:9 135:11 178:16 178:16,17 tested 178:14 testified 5:18 9:13 14:4 15:1 18:5 24:13 123:5 133:21 138:15 testifying 132:15 testimony 7:5 17:24 23:2 34:13 57:11 79:14 91:24 92:6 147:13 149:5 155:21 186:16,20 209:12 tests 175:13,14 175:15 texas 2:9	text 116:10 thank 16:6 18:3 21:19,22 37:21 55:20 56:2 61:9 62:12 65:18,21 70:1 70:24 84:24 106:7 109:5 113:2,15 115:13 122:10 133:5 150:24 156:12 158:13 172:2 199:19 207:17 thanks 23:13 80:4 91:20 168:2 theorem 171:5 theoretical 81:15 theory 80:19 81:8,10 85:13 therapeutical 136:21 therapies 154:15 thing 18:2 50:11,13 117:3 118:17 119:24 things 12:14 29:24 41:8,11 57:5,7 58:4 132:10 140:7 160:7 162:19
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

171:19 173:6 175:17 180:14 181:12 198:21 206:21 think 10:22 17:13,14 18:10 18:13 23:5,6 26:14 29:22 31:14,15 32:7 36:24 37:17,19 46:8 47:3 51:10 55:17,18 56:22 57:23 59:8,11 81:21 83:9 89:22 90:4 91:4 92:14,16 114:22 126:4 129:5 132:1 133:21 137:7 138:22,24 139:1 143:10 145:3,12 147:7 151:6 152:10 152:11 153:19 153:19 156:6 157:20 158:18 163:3 166:1 174:12 177:18 179:4,7 185:7 194:18 195:8 195:15,16 196:3 202:6 204:17	thinking 37:20 52:8 129:15,19 174:12 third 39:21 41:4,20 46:4,8 61:22 75:13,14 75:14,14 99:2 109:12 thirdly 120:3 thirteenth 103:9 thirtile 75:13 thorough 173:4 thou 176:16 thought 83:1 84:2 98:14 100:10 194:2 200:17 201:6 thousands 170:12 three 46:16,20 112:4,7,10 137:17 165:12 165:14 174:3 threshold 78:22 79:10,17 134:17 threw 131:24 150:18 tight 88:19 tighten 108:20 111:1 time 5:6 6:23 47:10,14 56:3	91:6,10 115:6 116:6,17 122:22 123:2 139:14 155:1,5 158:2 161:6,20 163:17 164:11 167:2 169:23 202:7,11 207:18 times 8:14,16 117:1 146:11 148:6 150:5 168:6 170:12 185:17 186:20 tips 24:8,16 title 52:11 60:22 65:7,23 71:16,19 137:12 titled 10:5 74:21 titles 73:18 tobin 6:3 today 7:6 14:23 31:2 51:10 95:5 123:5 142:4 146:13 148:8 151:23 167:24 168:6 174:7,24 182:1 199:21 today's 5:5 152:5,9	together 20:23 42:21 43:11 44:16 47:24 105:4 took 154:3 203:20 tool 50:19 184:14,24 185:3 top 61:21 75:1 94:13,14 96:2 139:7 140:1 160:1 169:23 170:17 182:4 188:11 topic 91:4 torts 2:14,14 totally 181:6 toxicologist 143:5 track 159:23 training 3:19 27:19 173:8 trans 4:3,15 60:5,24 107:6 transcript 3:15 3:17 15:11 21:8,12 208:14 208:17 translate 32:6 trees 42:7 trial's 129:14 trials 15:18 33:2
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>trichloroethyl... 4:1,13 60:3,22 107:4 trinity 159:6,8 tripping 64:19 true 15:9 16:19 18:10,13 19:7 56:18 57:19 59:19 69:19 72:9 86:16 87:12,13,22 89:5,20 130:12 130:15 131:2,3 133:14 200:11 209:12 truly 191:22 truth 33:7,9 truthful 7:5 try 6:14 127:12 199:12 trying 16:18,18 22:13 41:8,10 59:8 65:4 70:2 76:8 87:8 98:11 115:6 129:13 156:11 tubin 2:13 193:10 turn 16:10 22:5 24:20,23 25:20 32:17 35:2 42:8 45:13 47:17 54:8 60:14 62:13</p>	<p>66:6 72:23 74:8 80:8 86:17 91:21 99:21 109:20 110:2 113:4 114:13 117:10 127:6 182:6,7 182:16 turned 154:18 turning 37:22 96:13,21 101:11 113:9 128:20 130:1 twelfth 102:24 twisted 40:23 two 28:11 57:4 57:7 83:20 126:3,10 131:21,22,23 132:9 137:21 140:7 147:4 152:6 162:7 163:14 174:4 181:4 187:19 191:14 type 13:18 18:19 42:19 43:7 105:2 150:5 177:22 types 75:1 99:9 100:18 101:18 104:15 171:18 205:14</p>	<p>typical 13:3 typically 50:17 54:20 87:10 90:16 169:2,4 169:10,12,15 169:17 171:13</p> <hr/> <p style="text-align: center;">u</p> <hr/> <p>u.s. 2:12 105:22 u.s.'s 10:13 unaddressed 197:2 uncertainty 88:13 89:19 uncomfortable 93:10 uncommon 101:23 104:19 135:17 162:13 uncontrolled 114:9 120:17 120:24 under 5:18 6:8 25:2 38:6 80:14 112:10 underlies 81:8 underlying 33:13 81:11 83:23 108:16 110:21 113:23 119:12 120:12 121:23 122:3 underpowered 183:23,24</p>	<p>184:2,17,18 underreprese... 109:13 111:23 120:3 underscore 76:20 understand 6:9 6:12,17 16:4,7 16:8 41:10 49:6 51:22 52:18 59:7 76:9 85:13 119:10 134:21 147:2 understandable 55:9 understanding 7:24 21:2 35:22 38:3 54:22 76:16 140:8 understood 6:21 9:5 62:12 70:3 142:8 195:4 undertake 25:17 undertaking 3:20 27:20,24 173:9 unexposed 66:14 190:4 uninformative 30:18</p>
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>united 1:3 2:17 6:4 166:4 167:16,22 168:15 186:6 universities 159:12 185:12 university 142:6 159:24 160:22 162:12 162:13 163:11 164:2 unmeasured 198:19 unpaid 169:17 unpublished 58:20 69:7 unquote 68:15 unreasonable 24:18 39:5 45:8 unreasonably 154:20 unrelated 181:7,10,15 unreliable 124:19 unsurprising 80:18 85:12 unusual 138:6 unworthy 177:6 178:22 upper 192:24 usdoj.gov 2:16 2:16,17</p>	<p>use 17:14 18:19 26:3 35:19 36:6 37:12 44:21 49:1,10 49:13 53:12 54:23 123:11 127:11 131:19 133:22 134:6,7 135:24 141:10 154:21 176:12 176:12 179:15 180:5 used 51:4,16 90:9 126:21 127:22 132:12 134:14,15 140:9 141:3 178:17 181:5 184:13 185:24 186:4 195:11 204:2 useful 90:4,20 90:23 103:21 184:15 usefulness 102:1 104:21 185:16 using 16:3 25:7 51:23 98:22 100:13 133:11 144:20 157:9 180:19 184:19 usually 58:16 86:23,24</p>	<p>uterus 67:17 utility 185:15 utilized 185:18</p> <hr/> <p style="text-align: center;">v</p> <hr/> <p>v 2:12 vaccine 166:16 166:18,20,21 vague 24:15 valid 185:2 validity 80:11 189:3 valsartan 154:5 154:7 value 39:12,19 55:4 87:23 130:21 140:5 values 108:20 108:21 111:1,2 130:11 variability 17:1 variable 135:3 variables 131:21,23 132:9 135:4 variant 207:2 variation 29:1 29:17 38:10,19 39:9 varied 74:4 varies 176:14 variety 62:1 vary 23:22,23 40:2,22 103:22</p>	<p>veritext 1:22 versus 37:14,15 66:13 186:9 190:4 193:23 vertical 90:11 vice 142:5 162:9 video 5:7 videoconfere... 1:14 videographer 2:20 5:3,5 47:10,14 91:6 91:10 122:18 122:22 123:2 155:1,5 202:7 202:11 207:18 videotaped 1:14 view 49:13 141:14 172:18 178:5 vinyl 4:2,14 25:14 60:4,23 107:5 151:9 visual 90:19 vlaanderen 75:10 76:3 voice 81:23 volume 1:1</p> <hr/> <p style="text-align: center;">w</p> <hr/> <p>wait 56:4</p>
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>want 15:23 36:14,19 44:5 45:22 47:23 49:10 51:21 61:14 71:8 74:8,10 81:18 138:24 146:5 147:24 163:4 172:24 179:5,6 179:9 180:23 182:7,16 186:22 189:18 190:20 195:4 195:24 199:12</p> <p>wanted 76:2 168:3,4 193:6 193:8,17 194:17 203:24</p> <p>wants 174:15</p> <p>washington 2:15 159:24 164:3 167:3</p> <p>water 1:8 5:9 71:21 208:2</p> <p>wavy 82:22</p> <p>way 51:17 59:8 59:13,18 71:6 81:16 85:20 134:23 136:12 153:3 158:19 163:21,22 168:23 182:7 197:3</p>	<p>ways 116:19</p> <p>weakening 102:1 104:20</p> <p>weaknesses 102:7 104:16 117:15 118:7,8 118:9,11,12,20 121:5 171:12 171:20,23 172:1,3,7,11,11 172:16,21 196:13 197:7</p> <p>website 26:23 28:1,4</p> <p>wednesday 1:15</p> <p>weight 24:7,16 176:8</p> <p>weighted 187:6</p> <p>weird 138:7</p> <p>went 164:3,15 173:4 179:11 196:12</p> <p>whereof 209:14</p> <p>white 17:2</p> <p>wide 62:1,3 63:2 80:22 82:6 84:12,15 86:7,7 140:19</p> <p>widely 178:17 184:13</p> <p>wider 86:9</p> <p>width 88:7 140:3,17</p>	<p>withdraw 36:2</p> <p>withdrawn 9:10 30:12 42:11 46:6 48:17 57:8 58:11 65:2 77:12 78:6 79:7 97:7 106:18 110:8 111:19 117:22 126:6 129:17 139:17 140:13 144:6 203:8</p> <p>withholding 8:10</p> <p>witness 3:2 5:13 8:14,15 8:18 47:6 53:22 73:5 138:11 145:6 153:16 156:7 158:13 207:17 209:9,13,14</p> <p>wong 75:18,22 76:6 77:15 193:15,18</p> <p>woodcock 165:1</p> <p>word 27:16 35:22 41:17 49:10 92:23 148:19 149:9 180:6 195:11</p>	<p>wording 73:3,8</p> <p>words 92:15 130:23 174:9 181:4</p> <p>work 9:1,21 20:13,16,20 22:21 52:4 131:12 138:10 145:24 146:23 147:19 148:21 149:1,11,15 150:4 151:4,12 152:20 153:6 155:21 156:3 159:2 160:17 163:19 166:2 166:21 167:4,7 167:9 168:24 169:7,18 185:19</p> <p>worked 9:14 20:23 143:10 150:16,19,22 151:1 156:17 159:14 160:6 163:16,17 164:8 165:1,23 166:14</p> <p>workers 4:8 62:16,22 64:8 66:3,14 190:5</p> <p>working 73:15 167:15</p>
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>works 168:24 world 13:7,13 103:11 105:16 168:20 worldwide 27:8 161:17 worry 70:19,20 worth 22:22 worthy 178:22 write 11:19 12:18 26:2,21 38:7 45:16 88:3 107:19 112:11 130:4 155:20 168:24 writes 113:13 113:20 writing 170:4 written 13:23 30:9,16 40:15 144:22,24 151:7 wrong 31:24 45:17 61:18 83:7 132:2 133:18 134:11 wrote 10:9,20 56:8 60:21 116:16 154:17</p>	<p style="text-align: center;">y</p> <p>yeah 17:13 33:1,19,22 year 12:12 142:23,24 153:8 165:12 166:8 years 8:20 9:15 9:18 54:6 114:3 143:11 153:13 160:23 161:5 162:21 164:15 165:2 165:14 167:14 185:8 yep 17:21 yesterday 152:7,13 165:18 yield 33:7 108:20 111:1 yielding 33:9 yo 115:13 york 160:22 164:7</p>
x	z
<p>x 3:1,9 176:15 176:17</p>	<p>zina 2:7 zina.bash 2:10 zoom 2:7,13</p>