

Exhibit 618

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION
NO. 7:23-CV-897

IN RE:)
)
CAMP LEJEUNE WATER LITIGATION)
)
)
This Document Relates to:)
ALL CASES)
-----)

VIDEOTAPED DEPOSITION OF
LISA A. BAILEY, PH.D.,
a witness herein, called by the Plaintiffs for
examination, taken by and before Ann Medis, RPR,
CLR, CSR-WA, and Notary Public in and for the
Commonwealth of Pennsylvania, via Zoom
Videoconference, at Keller Postman, 1101
Connecticut Avenue, NW, Suite 1100, Washington,
DC 20036, on Wednesday, July 9, 2025, commencing
at 9:31 a.m.

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* I N D E X *

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P R O C E E D I N G S

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THE VIDEOGRAPHER: We are now on the record. My name is David Campbell. I'm a videographer for Golkow, a Veritex Division. Today's date is July 9, 2025, and the time on the video monitor is 9:31 a.m. This deposition is being held at 1101 Connecticut Avenue, Northwest, Suite 1100, Washington, D.C. 20036. This is in the matter of in-house enhanced re Camp Lejeune water litigation this is in the United States District Court for the District of North Carolina Southern Division. The deponent today is Lisa Bailey.

The court reporter is Ann Medis, also with Golkow. Counsel, will you please identify yourselves for the record after which the reporter will please swear in the witness.

MR. SNIDOW: J.J. Snidow on behalf of the PLG.

MR. MICELI: David Miceli appearing by Zoom on behalf of PLG.

MR. MANDELL: Zac Mandell for PLG.

MR. SHERMAN: Dean Sherman. I'm a summer associate with Keller Postman.

1 MS. GRAVES: Raleigh Graves, litigation
2 assistant.

3 MS. ELLISON: Anna Ellison on behalf of
4 the United States.

5 MS. SILVERSTEIN: Kailey Silverstein on
6 behalf of the United States.

7 MS. PLATT: Elizabeth Platt on behalf of
8 the United States.

9 LISA A. BAILEY, PH.D.,
10 having been first duly sworn, was examined
11 and testified as follows:

12 EXAMINATION

13 BY MR. SNIDOW:

14 Q. Good morning, Dr. Bailey. Like I said,
15 I'm J.J. Snidow. I think you understand that I
16 represent the plaintiffs in this case.

17 A. Yes.

18 Q. Now, I'm not going to mark them all, but
19 for the record am I correct you prepared 25
20 different reports in this case?

21 A. Correct.

22 Q. And that's five for each of the
23 diseases; true?

24 A. Correct.

25 Q. So bladder cancer, kidney cancer,

1 leukemia, non-Hodgkin's lymphoma and Parkinson's
2 disease?

3 A. Yes.

4 Q. And five each?

5 A. Right.

6 Q. Am I correct that all the opinions that
7 you intend to offer in each of those cases is
8 contained in those reports?

9 A. Yes.

10 Q. Am I correct those reports contain all
11 the literature that you relied on?

12 A. Correct.

13 Q. So if I look at the materials considered
14 list, I'll see every piece of scientific evidence
15 that you relied on; is that true?

16 A. Correct.

17 Q. If I look in your report, I'll see the
18 full scope of the opinions; true?

19 A. Correct.

20 Q. Am I correct that in those reports, you
21 try to give an accurate account of the methodology
22 that you used?

23 A. Yes.

24 Q. No steps that you took that are not in
25 those reports; true?

1 A. Correct.

2 MS. ELLISON: Objection. Form.

3 BY MR. SNIDOW:

4 Q. Having reviewed all the evidence, the
5 science and the plaintiff-specific materials, is
6 there any Camp Lejeune plaintiff who you believe
7 experienced an increased risk of getting any
8 disease?

9 A. Based on my evaluation of the exposure
10 information for each of the plaintiffs and the
11 methodology in my report, I don't believe the
12 exposures were high enough for any of the
13 plaintiffs to be of concern for health effects.

14 Q. You say of concern. Was there any
15 increased risk for any of the plaintiffs?

16 MS. ELLISON: Objection. Form.

17 THE WITNESS: In terms of the
18 calculation, I calculated risks based on exposure,
19 individual exposure information. And the risks
20 fell within EPA's acceptable risk range or below
21 for each of the plaintiffs.

22 BY MR. SNIDOW:

23 Q. You did those risk assessments
24 individually; correct?

25 A. Correct.

1 Q. Have you ever seen a published risk
2 assessment done on an individual?

3 A. So site risk assessments and risk
4 assessments that are done for communities are done
5 on the community. They're done on a population.

6 You can use similar methodology for
7 individuals. It's commonly done, particularly in
8 specific causation analyses. You would want to
9 use a similar approach using similar regulatory
10 toxicity values, but with individual exposure
11 information, which is what I did in my report.

12 Q. Let me break that down. It sounds like
13 you have seen in the published literature that
14 people use risk assessments to evaluate the risk
15 to a population; true?

16 MS. ELLISON: Objection. Form.

17 THE WITNESS: Can you repeat the
18 question?

19 BY MR. SNIDOW:

20 Q. Sure. In the published literature,
21 people sometimes do a risk assessment for a
22 population; correct?

23 MS. ELLISON: Same objection.

24 THE WITNESS: I have seen in published
25 literature risk assessments for populations, yes.

1 BY MR. SNIDOW:

2 Q. In particular, even for Camp Lejeune,
3 there's a published risk assessment for Camp
4 Lejeune; true?

5 A. There is, yes.

6 Q. Sometimes they do it for particular
7 communities; is that fair?

8 A. Yes.

9 Q. You've seen that published in the
10 literature; correct?

11 A. I have.

12 Q. I understand you're saying that you've
13 seen risk assessments done for an individual in
14 litigation; true?

15 A. Correct.

16 Q. Have you ever seen a risk assessment
17 done for an individual in the published scientific
18 literature?

19 MS. ELLISON: Objection. Form.

20 THE WITNESS: I don't recall seeing it
21 in published literature. That doesn't mean it's
22 not a reasonable approach for a specific
23 causation.

24 BY MR. SNIDOW:

25 Q. I understand. Sitting here today, in no

1 way in your report do you cite any literature
2 where a scientist has conducted a risk assessment
3 for an individual; true?

4 MS. ELLISON: Same objection.

5 THE WITNESS: I am not aware of
6 something in the published literature. It's
7 possible that there is. But, again, it doesn't
8 mean it's not appropriate for a specific
9 causation.

10 BY MR. SNIDOW:

11 Q. Have you ever read the text of the Camp
12 Lejeune Justice Act?

13 A. I have not read the text.

14 Q. In preparing your report, were you ever
15 instructed to use the standard from that text?

16 MS. ELLISON: Objection. Foundation.

17 THE WITNESS: I was asked to do a risk
18 evaluation, evaluate the exposure information for
19 each of the plaintiffs. That's what I did.

20 BY MR. SNIDOW:

21 Q. Were you ever asked to determine whether
22 it was at least as likely as not that the
23 chemicals contributed to the plaintiffs' injuries?

24 MS. ELLISON: Same objection.

25 THE WITNESS: I was not asked to do that

1 specifically. I was asked to evaluate potential
2 exposures and potential risks for plaintiffs.

3 BY MR. SNIDOW:

4 Q. Excuse me, Dr. Bailey. I'm not trying
5 to cut you off.

6 In your reports, am I correct you do not
7 apply the as likely as not standard?

8 MS. ELLISON: Same objection.

9 THE WITNESS: That's not a term that I
10 use in my reports.

11 BY MR. SNIDOW:

12 Q. Do you agree that the Camp Lejeune site
13 has been remediated?

14 MS. ELLISON: Object to form.
15 Foundation.

16 THE WITNESS: That is not something that
17 I evaluated for my report.

18 BY MR. SNIDOW:

19 Q. I understand. But you've seen reference
20 to the cleanup at Camp Lejeune; correct?

21 A. That's not something that I looked at
22 for my report. It wasn't relevant to my report,
23 so I did not look at that.

24 Q. Do you agree that remediation was
25 appropriate given the concentration of chemicals

1 present at Camp Lejeune?

2 MS. ELLISON: Objection. Foundation.

3 THE WITNESS: I didn't specifically look
4 at the site as a whole in the context of
5 remediation. I was looking at individual
6 exposures to the contamination at the time. So I
7 didn't look at the site in terms of whether it
8 should be cleaned up or not.

9 BY MR. SNIDOW:

10 Q. You know one purpose of risk assessment
11 is to determine when remediation is appropriate?

12 A. Yes. That is one use of risk
13 assessment.

14 Q. You calculated that the risks to the
15 Camp Lejeune population were below acceptable
16 levels; true?

17 A. They were within the acceptable range or
18 below for cancer risk, yes.

19 Q. So in your view, remediation was not
20 necessary given the risks involved?

21 MS. ELLISON: Object to form.
22 Foundation.

23 THE WITNESS: Again, that's not
24 something that I looked at for my report. I
25 looked at individual exposure information and

1 potential risks that would be calculated using
2 EPA's standard methodology for individual
3 exposures. I was not looking at it as a
4 population. That's something that you would want
5 to consider at a population level for cleanup. It
6 was not what I did.

7 BY MR. SNIDOW:

8 Q. What is the background risk rate for
9 kidney cancer?

10 A. I have that in my report, but I have to
11 look at my report to tell you what it is. I don't
12 have it, off the top of my head.

13 (Bailey Exhibit 1 was marked.)

14 BY MR. SNIDOW:

15 Q. I'm going to mark as Exhibit 1 your
16 report for Terry Dyer. Here's your report for
17 Terry Dyer.

18 MR. SNIDOW: By agreement, one of these
19 for counsel.

20 MS. ELLISON: Thank you.

21 MR. SNIDOW: You're welcome.

22 BY MR. SNIDOW:

23 Q. Am I correct that this is a report that
24 you prepared for one of the plaintiffs in the Camp
25 Lejeune litigation?

1 A. Correct.

2 Q. And this is for bladder cancer?

3 A. This is for bladder cancer.

4 Q. Do you know what the background risk
5 rate for bladder cancer is?

6 A. It's in my report, and I will find it.
7 Slightly less than one in two for men, slightly
8 more than one in three for women.

9 Q. Your testimony is that the risk of
10 getting bladder cancer --

11 A. Sorry. I correct myself there. That is
12 on total cancer.

13 Q. Yes.

14 A. Let me see. For bladder cancer, it's
15 3.6 percent for men, 1.1 percent for women.

16 Q. What page is that on?

17 A. Page 16.

18 Q. Then you go on to report the background
19 cancer risk for all individuals at 40 percent;
20 correct?

21 A. Correct. That is the average background
22 cancer risk for all cancers combined.

23 Q. Just to be clear, that's not the risk of
24 developing one of the particular cancers at issue.
25 It's the risk of developing cancer generally;

1 correct?

2 A. Correct.

3 Q. Did you review any human epidemiology
4 yourself?

5 A. Yes, I did.

6 Q. Let me distinguish a couple of things.
7 You're aware there were a series of studies done
8 looking at Camp Lejeune in particular?

9 A. Yes.

10 Q. The Bove series?

11 A. Yes.

12 Q. Then there are studies that underpin
13 some of the risk assessments; is that fair?

14 A. That's correct.

15 Q. The Charbotel study, for example?

16 A. Correct.

17 Q. I understand in your report you discuss
18 the Charbotel study; true?

19 A. Not in this report.

20 Q. In the kidney cancer.

21 A. Yeah, in the kidney cancer report.

22 Q. But you don't discuss the series of
23 studies done on Camp Lejeune; true?

24 A. I do not discuss those in my report,
25 correct, only in the context of what Dr. Goodman

1 says in general about those studies.

2 Q. That was going to be my question.

3 In your report, you don't have any
4 opinions on the Camp Lejeune epidemiology; true?

5 A. I don't have opinions written in my
6 report about the Camp Lejeune epidemiology.

7 Q. For that you're relying entirely on
8 Dr. Goodman?

9 A. I'm relying on Dr. Goodman's
10 methodology, yes. I'm relying on her conclusions
11 for those studies.

12 Q. You're also aware that there is
13 epidemiology not underpinning the risk assessment,
14 not Camp Lejeune, but looking at water
15 contamination events at different parts of the
16 country; correct?

17 A. I'm aware of those, yes.

18 Q. You don't have any opinions on those
19 types of studies, do you?

20 A. Only in the context of some of my
21 discussions about some of those studies and the
22 rebuttals of the plaintiffs' experts.

23 Q. In your rebuttal, I think you again rely
24 on Dr. Goodman; correct?

25 A. I generally rely on Dr. Goodman;

1 correct. If there is something more specific
2 about the study that is important for exposure and
3 risk, I do -- I have looked at it in that context.

4 Q. Did you review the Camp Lejeune water
5 modeling?

6 A. I reviewed the expert reports of the
7 Camp Lejeune water modeling experts.

8 Q. Such as Dr. Maslia?

9 A. I looked at the expert reports of
10 Spilotopoulos and Dr. Hennet.

11 Q. Did you review the underlying water
12 modeling done by ATSDR?

13 A. I did not review the details of the
14 modeling. I'm aware of the modeling, but I did
15 not review the details of the modeling. It was
16 not what I was asked to do.

17 Q. Understood. That's what I'm trying to
18 get at. When you say you reviewed the details,
19 did you actually look at the ATSDR water modeling?

20 A. I looked at the water modeling results,
21 yes.

22 Q. You did? You're not offering any
23 opinions on the integrity of that water modeling;
24 true?

25 A. I did not do an evaluation of that

1 modeling, but I did review the opinions of
2 Dr. Spilotopoulos and Hennet who did review based
3 on that modeling.

4 Q. Of course. My only point is you,
5 yourself, are not offering any independent
6 opinions about the integrity of that water
7 modeling?

8 A. I did not review the water modeling, so
9 I'm not offering that opinion. That was not what
10 I was asked to do.

11 Q. To be fair, you're not an expert in
12 water modeling?

13 A. Correct.

14 Q. Do you agree that risk assessment is
15 ultimately based on results from either human
16 epidemiology or animal studies?

17 A. The toxicity values that EPA uses are
18 typically, yes, based on human or animal studies.

19 Q. In general, it's preferable to use the
20 human epidemiology when you have it; true?

21 A. I would not say that that's true. It
22 depends on the quality of the studies. EPA does a
23 lot of evaluation of those animal and epidemiology
24 studies and based on that information determines
25 whether the animal study is the best to derive a

1 toxicity value or a human study. And there are a
2 number of factors that go into that decision.

3 Q. All else equal in terms of study
4 quality, agree you should use human epidemiology?

5 A. That's a hypothetical question. So I
6 can't answer that just generally. And I think it
7 would be very difficult to say they're equal in
8 quality. They're very different studies. So I
9 don't think that is ever something that comes up.
10 I think all of the information needs to be
11 integrated.

12 Q. So you think there are times when you
13 should rely on the animal studies rather than the
14 human subjects?

15 MS. ELLISON: Objection. Form.
16 Foundation.

17 THE WITNESS: I'm saying that that's
18 what EPA has done. They sometimes rely on the
19 animal studies if -- based on a number of factors
20 and interpreting epidemiology data with the animal
21 data.

22 BY MR. SNIDOW:

23 Q. Do you agree that risk assessment is not
24 an exact science?

25 A. Risk assessment is an estimate of -- a

1 conservative estimate of potential adverse health
2 effects based on exposure information. So it's
3 not an exact science, but it is -- because of
4 that, it's very conservative.

5 Q. You say it's very conservative. Do you
6 agree that risk assessments can sometimes
7 underestimate the risk?

8 A. In general, EPA risk assessments do not
9 underestimate risk. They typically overestimate
10 risk based on conservative exposure assumptions
11 and conservative assumptions about the toxicity
12 chemical.

13 Q. I hear you on "in general." But you
14 agree it is possible for risk assessments to
15 underestimate the risk; true?

16 A. Again, that's a hypothetical. I would
17 need to look at the specific risk assessment, the
18 specific chemical and say whether I think this
19 might be underestimating risk. I have not seen a
20 situation where I thought the risk result was
21 underestimating risk.

22 Q. How do you know what the real risk is?

23 MS. ELLISON: Objection. Form.

24 THE WITNESS: Well, what I do know is
25 that the exposure information is often estimated

1 to be a very high estimate of possible exposure
2 information. The exposure parameters are
3 typically conservative. So you're assuming people
4 are spending a lifetime at the site, drinking a
5 large amount of water daily, maybe spending the
6 entire time in their home, things that would be
7 overly protective so that you're not missing a
8 possible risk.

9 BY MR. SNIDOW:

10 Q. You agree epidemiology studies the
11 distribution and occurrence of diseases across
12 populations?

13 A. Yes. That's typically what epidemiology
14 is.

15 Q. Risk assessment is distinct from
16 epidemiology; correct?

17 A. Risk assessment is different from
18 epidemiology, but it uses epidemiology.

19 Q. Of course. But it's a different
20 discipline?

21 A. They're related.

22 Q. In your report, you discuss various
23 reference values, like cancer slopes and
24 inhalation risks; correct?

25 A. Correct.

1 Q. Do you agree that those reference values
2 cannot give you an estimate of causation?

3 MS. ELLISON: Objection. Form.
4 Foundation.

5 THE WITNESS: So those risk values can
6 provide a good sense of whether the exposures are
7 high or low relative to what EPA considers
8 acceptable. So in that sense, they can be very
9 helpful for a specific causation.

10 BY MR. SNIDOW:

11 Q. Let me give a statement. You can tell
12 me if you agree or disagree.

13 Do you agree reference values have no
14 place in the estimate of causation?

15 MS. ELLISON: Objection to the form.

16 THE WITNESS: I don't agree with that.

17 BY MR. SNIDOW:

18 Q. Do you agree that risk assessment is not
19 a causation analysis at all?

20 MS. ELLISON: Object to the form.

21 THE WITNESS: I agree that there is a
22 place for risk assessment in specific causation
23 because it provides perspective about potential
24 exposures for individuals.

25

1 BY MR. SNIDOW:

2 Q. Do you agree that risk assessment is not
3 a causation analysis?

4 MS. ELLISON: Object to the form.

5 THE WITNESS: Risk assessments, risk
6 calculations by themselves are not a causation
7 analysis, but that's not what I did. That was one
8 part of my evaluation.

9 BY MR. SNIDOW:

10 Q. Besides doing a risk assessment, what
11 did you do to evaluate causation?

12 A. I looked at the margin of exposure,
13 which is looking at the point of departure that is
14 the basis of the toxicity values. So it's looking
15 at -- essentially looking at epidemiology as the
16 basis of the toxicity value.

17 If the toxicity value was not based on
18 the health endpoint of concern, I also looked at
19 epidemiology specific to that endpoint and
20 compared those exposure estimates from those
21 studies to the exposure estimate to the
22 plaintiffs. So you need to do all of those
23 things.

24 Q. Do you think that reference values can
25 be used as estimators of risk?

1 A. Reference values can be used to
2 provide -- to demonstrate whether exposures may be
3 low or high relative to what EPA considers health
4 protective.

5 Q. Let me ask it again. Do you agree that
6 reference values -- well, strike that.

7 I'll ask it this way. Agree or
8 disagree, reference values cannot be used as
9 estimators of risk?

10 A. So EPA has risk values for cancer and
11 they have reference values for noncancer.
12 Noncancer is not typically described -- noncancer
13 risks are technically not described as risks
14 because they're not calculated that way. So it's
15 a threshold. So it's a comparison value for
16 reference values. But they can be used to
17 determine whether potential exposures are high or
18 low relative to that value, which is what EPA
19 considers health protective.

20 Q. Agree or disagree, reference values
21 cannot be used as estimators of causation?

22 MS. ELLISON: Objection. Form.

23 THE WITNESS: Reference values can be
24 used as part of a causation analysis.

25

1 BY MR. SNIDOW:

2 Q. It sounds like you disagree with the
3 statement I read.

4 MS. ELLISON: Objection. Form.

5 THE WITNESS: Can you read the statement
6 again?

7 BY MR. SNIDOW:

8 Q. Sure. Reference values cannot be used
9 as estimators of causation.

10 MS. ELLISON: Same objection.

11 THE WITNESS: Reference values can be
12 used to provide perspective on causation.

13 BY MR. SNIDOW:

14 Q. Do you agree that EPA and ATSDR have
15 stated that risk assessments can't be used to
16 quantify the risk of cancer?

17 A. I need more context for that.

18 Q. Correct me if I'm wrong. I read your
19 report to be using risk assessment to quantify the
20 risk of cancer; true?

21 A. So I used risk assessment to provide
22 perspective on the exposures for the individual
23 plaintiffs and did a risk calculation based on
24 individual exposure information and EPA's toxicity
25 values. So in that context, they can be used.

1 Q. Right. But my question was: Is it your
2 belief that risk assessment values can be used to
3 quantify the risk of cancer?

4 A. So at a population level, those cancer
5 risk values are used to estimate the probability
6 that individuals in that population -- so if
7 they're all exposed in the same way that you're --
8 whatever the exposure assumptions are for that
9 calculation -- sorry.

10 Can you ask that question again?

11 Q. Can risk assessment values be used to
12 quantify the risk of cancer?

13 A. So it can be used to provide a risk
14 estimate. It's a theoretical estimation for a
15 population based on everyone being exposed the
16 same way, is what I was trying to say. So it's
17 theoretical in the sense that it's based on very
18 conservative exposure assumptions, considering
19 sensitive individuals within the population.

20 So it can provide perspective within the
21 population about whether that population may be at
22 risk if it's above ten to the minus four or below
23 ten to the minus six or within range. It's
24 helpful.

25 Q. Do you consider yourself to be an expert

1 on cancer?

2 MS. ELLISON: Objection. Form.

3 THE WITNESS: My expertise is in human
4 health risk assessment and toxicology where I do
5 have to think about cancer studies and
6 carcinogenic chemicals.

7 BY MR. SNIDOW:

8 Q. When you're speaking to scientists, do
9 you hold yourself out as an expert in cancer?

10 A. In cancer risk assessment.

11 Q. You do?

12 A. Yes. In risk assessment, yes.

13 Q. And you've done that before. You've
14 described yourself as an expert in cancer to other
15 scientists?

16 A. In human health risk -- in the context
17 of toxicology and human health risk assessment.
18 So understanding potential mechanisms of
19 carcinogenesis and evaluating risk.

20 Q. I truly understand that you do risk
21 assessment. I'm just saying: Do you hold
22 yourself out as an expert in cancer?

23 A. I think that's very general, so I can't
24 really answer that.

25 Q. How about kidney cancer?

1 A. Again, that's very general. I can't
2 answer that. There are lots of different areas
3 that should be considered in terms of being an
4 expert in cancer in general or kidney cancer in
5 general.

6 Q. Have you ever told another expert that
7 you're an expert in kidney cancer?

8 MS. ELLISON: Objection. Form.

9 THE WITNESS: I have not said that I'm
10 an expert in kidney cancer, but I have said that
11 I'm an expert in evaluating risk and exposure.
12 And those risk assessments often consider
13 chemicals that are carcinogenic and are -- some of
14 them have been shown to cause kidney cancer. So
15 in that context, yes.

16 BY MR. SNIDOW:

17 Q. You know what a nephrologist is; right?

18 A. Yes.

19 Q. It's a medical doctor which you're not;
20 correct?

21 A. Correct.

22 Q. They specialize in kidney cancer;
23 correct?

24 A. Correct.

25 Q. They are, of course, experts in kidney

1 cancer; correct?

2 A. Correct.

3 Q. That's not you; correct?

4 A. That's why I did not say that I was.

5 Q. The same for bladder cancer, have you
6 ever described yourself as an expert in bladder
7 cancer?

8 A. I'm not a medical doctor, so no.

9 Q. Leukemia?

10 A. I'm not a medical doctor, so I would not
11 generally say that I'm an expert in leukemia. But
12 in evaluating risk for chemicals that might cause
13 leukemia, yes.

14 Q. And the same for NHL, right, you've
15 never described yourself as an expert in
16 non-Hodgkin's lymphoma?

17 A. That's correct. But I have done risk
18 evaluations for chemicals that cause that.

19 Q. Of course. Have you ever described
20 yourself as an expert in neurodevelopmental
21 disorders?

22 A. I'm not a medical doctor, so, no, I'm
23 not an expert in that field.

24 Q. Same for Parkinson's specifically; true?

25 A. Correct, but again, risk evaluations

1 where I'm looking at chemicals and exposure to
2 those chemicals.

3 Q. Have you ever published any cancer
4 epidemiology studies?

5 A. I have not published a cancer
6 epidemiology study, no.

7 Q. Have you ever published any studies on
8 biologic mechanisms underlying cancer?

9 A. I have authored some weight-of-evidence
10 evaluations that consider mechanisms of cancer,
11 yes.

12 Q. I understand. But you've never
13 published, for example, an animal study on cancer?

14 A. I have not published an animal study,
15 no.

16 Q. Have you ever been a primary
17 investigator for an epi study?

18 A. I have not.

19 Q. How about for a clinical trial?

20 A. I have not.

21 Q. Ever served on an IARC advisory panel
22 for a carcinogen?

23 A. I have not.

24 Q. EPA?

25 A. I have spoken with EPA about carcinogens

1 when they're evaluating -- deriving toxicity
2 values. But I'm not on EPA panels.

3 Q. And never have been; correct?

4 A. I have not.

5 Q. Has any regulatory body asked you to
6 evaluate a carcinogen on their behalf?

7 A. No.

8 MS. ELLISON: Object to the form.

9 THE WITNESS: I correct that. I have
10 been. I did an evaluation for Health Canada on
11 naphthalene in indoor air.

12 BY MR. SNIDOW:

13 Q. Have you ever published a paper on
14 kidney cancer?

15 A. I don't believe I have.

16 Q. Bladder cancer?

17 A. I have not published a paper on bladder
18 cancer.

19 Q. Leukemia?

20 A. I am an author on a formaldehyde paper
21 that involves leukemia.

22 Q. Am I correct, in that paper, you
23 determined that formaldehyde likely does not cause
24 leukemia?

25 A. I would have look at the paper, but I

1 believe that the mechanisms -- I would have to
2 look at the paper. It was a while ago.

3 Q. We might look at it later.

4 Have you published on NHL?

5 A. I have not.

6 Q. You have published on trichloroethylene;
7 true?

8 A. I would have to look at my CV, but I
9 don't believe I have a published paper on
10 trichloroethylene.

11 Q. I thought it was produced to us, but
12 it's okay.

13 Have you ever published on
14 perchloroethylene?

15 A. As I sit here today, I don't recall
16 that.

17 Q. Benzene?

18 A. I don't recall a publication on benzene.

19 Q. Vinyl chloride?

20 A. No, I have not.

21 Q. Have you ever published a Bradford Hill
22 analysis?

23 MS. ELLISON: Object to the form.

24 THE WITNESS: I have considered Bradford
25 Hill criteria in my evaluations, but I have not

1 published on Bradford Hill, no.

2 BY MR. SNIDOW:

3 Q. Have you ever employed the equipoise
4 standard in one of your publications?

5 MS. ELLISON: Objection. Foundation.

6 THE WITNESS: As I sit here today, it's
7 not something that I recall.

8 BY MR. SNIDOW:

9 Q. The government is, of course,
10 compensating you for your expert work?

11 A. Correct.

12 Q. Have you totaled up the invoices that
13 you sent?

14 A. I haven't added them up, no, but I have
15 a sense of them.

16 Q. Maybe we can shortcut this. As far as I
17 can tell, Gradient has billed the government about
18 \$1.7 million so far. Is that approximately
19 correct?

20 A. That sounds correct.

21 Q. That's great. I'll just mark the
22 invoices as Exhibit 2. For the record, this is a
23 composite exhibit bearing a leading Bates-stamp of
24 BAILEY_USA_SUBPOENA_1, and it is a collection of
25 the invoices and government forms documenting the

1 contract agreement.

2 (Bailey Exhibit 2 was marked.)

3 BY MR. SNIDOW:

4 Q. Dr. Bailey, I'm not asking you to look
5 at every single page. Can you just verify that
6 this appears to be a collection in the back half
7 of the invoices that Gradient sent to the
8 government and the front half documentation
9 produced by the government for Gradient's
10 contracts?

11 A. Yes. This looks like our invoices.

12 Q. You can put that aside for now.
13 Did you discuss this case with any other
14 experts or the government?

15 A. Yes. Yes, I did.

16 Q. Who?

17 A. I have talked to Dr. Judy LaKind.

18 Q. Was counsel present for those
19 conversations?

20 A. Yes.

21 Q. Anyone else that you spoke to?

22 A. Not that I recall.

23 Q. Did you ever speak to Dr. Goodman?

24 A. I think early on for like logistics, but
25 no, I did not talk to Dr. Goodman.

1 Q. Dr. Goodman works for your company; am I
2 correct?

3 A. Correct.

4 Q. You're relying on her evaluation of the
5 epidemiology; correct?

6 A. Yes.

7 Q. But you did not speak to her about it?

8 A. I did not.

9 Q. How many times did you speak to
10 Dr. LaKind?

11 A. I don't know the exact number, but it
12 was a handful of times.

13 Q. You're relying on Dr. LaKind's opinions
14 about exposure for individual plaintiffs; true?

15 A. Correct.

16 Q. Did you take that from her reports, or
17 is there anything in conversations that you relied
18 upon?

19 MS. ELLISON: Just objection. Really
20 quick, Dr. Bailey, don't discuss anything that was
21 said between you and Dr. LaKind. That's
22 privileged. So to the extent that your answer
23 requires you to say anything about the substance
24 of your discussions, I'll instruct you not to
25 answer.

1 THE WITNESS: The question again,
2 please?

3 BY MR. SNIDOW:

4 Q. In your report you're relying on
5 exposure assessments performed by Dr. LaKind?

6 A. Correct.

7 Q. Did you get those exposure assessments
8 from her reports or from conversations with
9 Dr. LaKind or both?

10 MS. ELLISON: Same objection. I won't
11 do it while you're in the middle of a question.

12 THE WITNESS: It was mostly about
13 information about exposure transmitted to me
14 from -- through DOJ that would be in her report so
15 that we had that information early on to do a risk
16 evaluation.

17 BY MR. SNIDOW:

18 Q. Understood. So fair to say it's not
19 necessarily the numbers that are in her final
20 report, but DOJ transmitted to you the numbers
21 that eventually appeared there?

22 A. They are -- and if there was any
23 updates, of course, they would. We made sure that
24 everything was consistent in the final report.

25 Q. Were you asked to assume that

1 Dr. Goodman's analysis of the epidemiology is
2 correct?

3 MS. ELLISON: Again, objection.

4 Dr. Bailey, to the extent that answering
5 that question involves anything that you discussed
6 with the attorneys, I'll instruct you not to
7 answer.

8 MR. SNIDOW: I'll note just for the
9 record I am allowed to ask her if she was directed
10 to assume anything.

11 MS. ELLISON: Yes. If there are any
12 assumptions that you relied on that we provided to
13 you, you can answer, but limited to assumptions.

14 THE WITNESS: I was asked to rely on
15 Dr. Goodman's report, but I did also review her
16 methodology. And I agree with her methodology. I
17 was comfortable relying on her report.

18 BY MR. SNIDOW:

19 Q. Who asked you to rely on her report?

20 A. DOJ in the process of doing my
21 evaluation.

22 Q. What did you do to verify that her
23 methodology was correct?

24 A. Well, I generally know what the
25 methodology -- what one does in terms of doing

1 systematic review to determine whether the
2 evidence supports a potential association between
3 a certain chemical and a disease. I've been
4 involved in those evaluations myself. So I'm
5 familiar with the methodology, and it's consistent
6 with what I would do.

7 Q. When you say "the methodology," are you
8 talking about the weight-of-the-evidence
9 methodology?

10 A. Yes.

11 Q. You agree that's a pretty broad
12 methodology without a lot of rules to it; correct?

13 MS. ELLISON: Object to the form.

14 THE WITNESS: EPA does have a systematic
15 review guidance, yes.

16 BY MR. SNIDOW:

17 Q. You didn't do a systematic review of the
18 literature that Dr. Goodman reviewed, did you?

19 A. I did not do the systematic review, no.
20 Dr. Goodman did.

21 Q. And you agree when doing a
22 weight-of-the-evidence analysis, you definitely
23 need to review all the evidence; true?

24 A. Correct.

25 Q. So how do you know that she got the

1 weight of the evidence correct?

2 MS. ELLISON: Object to the form.
3 Foundation.

4 THE WITNESS: So I agree with her
5 methodology. I don't have any reason to doubt
6 that she looked at all of the available
7 literature. Her reports were quite large and
8 extensive and considered a lot of data, a lot of
9 epidemiology, animal data, mechanistic data and
10 the Camp Lejeune studies.

11 BY MR. SNIDOW:

12 Q. But in terms of the weight of the
13 evidence, you did not, I assume, review all the
14 evidence that Dr. Goodman reviewed?

15 A. Not to the extent that she did.

16 Q. I'll represent to you she has reports
17 for each of the diseases.

18 Did you read every page of those
19 reports?

20 A. I looked very carefully at those
21 reports, particularly at the tables at the end.

22 Q. Not really my question. She's got five
23 reports, hundreds of pages. Did you review every
24 page?

25 MS. ELLISON: Object to the form.

1 THE WITNESS: I did not review every
2 page, but I reviewed the key sections, the
3 sections that I know were relevant to my analysis.

4 BY MR. SNIDOW:

5 Q. You agree when doing a
6 weight-of-the-evidence analysis, you have to weigh
7 evidence, some more strongly and some less
8 strongly?

9 A. Correct.

10 Q. Do you agree you can't do that without
11 actually reviewing evidence?

12 A. That's right. And that's what
13 Dr. Goodman did. She reviewed the evidence.

14 Q. I understand. But how do you know that
15 she weighed it correctly without reviewing it
16 yourself?

17 A. Because I agree with Dr. Goodman's
18 methodology, and I relied on her evaluation of
19 those data. I don't have any reason to doubt her
20 evaluation considering that she -- her methodology
21 is consistent with what I would do and what I have
22 done in other evaluations.

23 Q. Which is employ the
24 weight-of-the-evidence approach?

25 A. Yes.

1 Q. Which involves some degree of scientific
2 judgment. Wouldn't you agree?

3 A. Based on the evidence.

4 Q. Yes. And did you independently verify
5 that you agreed with Dr. Goodman's judgment?

6 A. I did not independently verify. But
7 again, I agree with her methodology. It was not
8 what I was asked to do.

9 Q. How many times have you testified in
10 depositions?

11 A. I believe seven.

12 Q. Have you ever testified at trial?

13 A. I have not.

14 Q. Obviously, this count -- well, there
15 shouldn't be for deposition. What depositions
16 have you given testimony in?

17 A. It's on my list of testimony, my
18 testimony list, which I believe you have. So I'd
19 have to look at that to list them all.

20 Q. Do you remember what the last one was,
21 the most recent one?

22 A. The most recent one, can you give me the
23 date for that one?

24 Q. Do you know approximately how many
25 reports you've written for litigation?

1 A. I have been involved in many reports for
2 litigation, some as the expert and some as support
3 for other experts in my 25 years of my career.

4 Q. Do you think it's more than a hundred?

5 A. As I sit here today, I don't know, but
6 it's possible.

7 Q. I was looking for a ballpark. Is a
8 hundred a reasonable estimate?

9 A. I would say between 50 and a hundred,
10 maybe not quite a hundred.

11 Q. How many times have you published an
12 article on behalf of Gradient?

13 A. I would have to look at my CV to tell
14 you how many publications I have while I was at
15 Gradient.

16 Q. You've published with Dr. Goodman;
17 correct?

18 A. I have, yes.

19 Q. That was done under the auspices of
20 Gradient?

21 A. That was while I was at Gradient, yes.

22 Q. Let me put it a different way. You
23 haven't published with Dr. Goodman in a situation
24 where you were both academics, for example?

25 MS. ELLISON: Object to the form.

1 THE WITNESS: Correct.

2 BY MR. SNIDOW:

3 Q. Have you ever been -- has Gradient ever
4 been paid for an article that you published?

5 A. Gradient has been compensated for my
6 time to evaluate any of the science that's part of
7 a publication.

8 Q. I think you've published that chrysotile
9 asbestos doesn't cause mesothelioma or lung
10 cancer; is that true?

11 A. I'd need to look at the publication that
12 you're talking about.

13 (Bailey Exhibit 3 was marked.)

14 BY MR. SNIDOW:

15 Q. I'll show you a document we'll mark as
16 Bailey Exhibit 3, which is a publication called
17 "Electricians' Chrysotile Asbestos Exposure From
18 Electrical Products and Risks of Mesothelioma and
19 Lung Cancer."

20 Dr. Bailey, do you see this is a
21 publication that you are one of the co-authors of?

22 A. Yes.

23 Q. So is Dr. Goodman?

24 A. Yes.

25 Q. And this was published in 2014?

1 A. Yes.

2 Q. That's when you were working -- one of
3 the years when you were working at Gradient; true?

4 A. Yes.

5 Q. And if you go to page 13, and in the
6 Conclusion section, last paragraph, it says, "We
7 conclude that epidemiology studies reporting an
8 increased risk of mesothelioma or lung cancer
9 among electricians, the most likely cause of lung
10 cancer is smoking, and the most likely cause of
11 mesothelioma is exposure to amphibole asbestos as
12 a result of renovation, demolition work or working
13 in close proximity to other skilled craft." True?

14 A. That is what it says.

15 Q. Did you produce this paper as a result
16 of compensation from an asbestos manufacturer?

17 A. I don't recall, so I'm going to read the
18 conflict of interest here.

19 It looks like we did not. We were not
20 compensated for this work. This was our own time,
21 but some of the work was done in the context of
22 litigation matters.

23 Q. By Dr. Goodman?

24 A. Dr. Goodman, yeah, that's what it says
25 here.

1 Q. The work you're referring to, it appears
2 Dr. Goodman was serving as an expert witness?

3 A. Yes.

4 Q. Do you know if that was in asbestos
5 litigation?

6 A. I would imagine it is. I'm assuming it
7 is just because this paper is about asbestos, and
8 that's what it's talking about, but I don't know
9 exactly what the litigation is that she's
10 referring to here.

11 Q. You are aware that Dr. Goodman has
12 served as an expert witness on behalf of asbestos
13 manufacturers?

14 A. I don't know the clients that
15 Dr. Goodman has testified on behalf of.

16 Q. You can put that to the side.
17 During your time at Gradient, you've
18 done work on a manganese?

19 A. Yes.

20 Q. That work was done on behalf of the
21 Manganese Interest Group?

22 A. Yes.

23 Q. Which I assume is a trade group for
24 folks who mine manganese?

25 A. They have interest in the use of

1 manganese.

2 Q. Some of your work was regarding whether
3 the manganese industry should be more regulated;
4 true?

5 A. That's not how I would characterize it,
6 no.

7 (Bailey Exhibit 4 was marked.)

8 BY MR. SNIDOW:

9 Q. I'm showing you Bailey Exhibit 4, which
10 is an article called "Potential Implications of
11 New Information Concerning Manganese Ohio
12 Community Health Effects Studies."

13 That's your name at the top?

14 A. Yes.

15 Q. You're the author on this paper?

16 A. Yes.

17 Q. This was published in 2021?

18 A. Yep.

19 Q. This was when you were working at
20 Gradient?

21 A. Correct.

22 Q. This paper Gradient was compensated for;
23 true?

24 A. I believe this is with the manganese
25 industry, yes.

1 Q. So you're publishing in the
2 peer-reviewed literature, but the Manganese
3 Interest Group is financing it; correct?

4 A. They are financing it, but, of course,
5 it's still based on science.

6 Q. Of course. Then at the bottom of the
7 abstract, do you see where it says, "These results
8 are important, particularly in determining whether
9 the study should influence regulatory reference
10 values related to manganese." Correct?

11 A. Yes. For this particular paper that is
12 what we did because there was concern that this
13 study might be considered for derivation of a
14 revised manganese reference value.

15 Q. The Manganese Interest Group didn't want
16 that to be revised; correct?

17 A. The Manganese Interest Group wanted us
18 to look at the science to see what the science
19 supported for a manganese value.

20 Q. You in this paper actually gave the
21 Manganese Interest Group the ability to comment on
22 your manuscript.

23 A. That's what it says here, yes.

24 Q. Is that appropriate, do you think, to
25 let an industry group comment on a peer-reviewed

1 publication?

2 MS. ELLISON: Object to the form.

3 THE WITNESS: I don't think it's
4 inappropriate as long as my evaluation is
5 consistent with the science, and that is always
6 what I do. So as long as the comments are
7 editorial in nature and not -- and don't conflict
8 with my opinion based on the science, then I don't
9 think it's inappropriate.

10 BY MR. SNIDOW:

11 Q. When you say "editorial in nature," do
12 you mean you didn't receive substantive comments
13 from the Manganese Interest Group?

14 A. Correct.

15 Q. You didn't?

16 A. Correct.

17 Q. Do you remember, what did they comment?

18 A. I don't remember, but I know that my
19 evaluation is based on the science, and they did
20 not influence my opinion based on the science.

21 Q. You've done work on naphthalene?

22 A. I have.

23 Q. And you argue that there's a threshold
24 for naphthalene?

25 A. Yes. We have a paper on that.

1 Q. You argued it should not be considered a
2 mutagenic carcinogen.

3 A. Naphthalene as a primary chemical is not
4 mutagenetic. So that's correct.

5 Q. And you argued that it should not be
6 considered a carcinogen in humans at all; true?

7 A. I would have to look at my paper, but I
8 don't believe that that was our conclusion.

9 Q. You don't believe that was your
10 conclusion?

11 A. I believe that we were looking at the
12 data to determine what exposure information was
13 available for naphthalene and what concentrations
14 may result in cancer in animals based on
15 naphthalene exposure and whether those
16 concentrations were high compared to what
17 occupational exposures are to naphthalene.

18 Q. You did this work on behalf of the
19 Naphthalene Research Committee?

20 A. Correct.

21 Q. Which I assume is a trade group for the
22 folks who deal with naphthalene?

23 A. Yes.

24 Q. They compensated Gradient for your work
25 on that; right?

1 A. Yes.

2 (Bailey Exhibit 5 was marked.)

3 BY MR. SNIDOW:

4 Q. I'll show you Bailey Exhibit 5, an
5 article called "Hypothesis-Based
6 Weight-of-Evidence Evaluation and Risk Assessment
7 for Naphthalene Carcinogenesis."

8 You're the first author on this; true?

9 A. Yes.

10 Q. Published in 2016; right?

11 A. Yes.

12 Q. This is when you were at Gradient;
13 correct?

14 A. Yes.

15 MS. ELLISON: Can we get copies?

16 MR. SNIDOW: I'm sorry.

17 BY MR. SNIDOW:

18 Q. If you to page 37, there's a section
19 called Discussion.

20 Do you see that?

21 A. Yes.

22 Q. And then do you see where the sentence
23 begins, "Our evaluation of human relevance" -- I'm
24 sorry. I said that so wrong.

25 Do you see where it says, "Our

1 evaluation of human relevance"?

2 A. On page 37?

3 Q. Yes.

4 A. Yes.

5 Q. It says, "Our evaluation of human
6 relevance suggests that low naphthalene metabolism
7 in human respiratory tissue is most consistent
8 with little to no toxicity or carcinogenic risk at
9 typical naphthalene environmental exposures."

10 Did I read that correctly?

11 A. You did. And "exposure" is important in
12 that sentence.

13 Q. So let me understand. You're not
14 disputing that naphthalene can cause cancer
15 humans; correct?

16 A. The evidence is that it can cause cancer
17 in animals. And so you would want to think about
18 that in the context of potential cancer in humans.

19 Q. Maybe I'm asking this the wrong way. I
20 read this sentence as you suggesting that
21 naphthalene probably doesn't cause cancer in
22 humans.

23 Is that the way you read it?

24 A. Let me read this again.

25 So at typical naphthalene environmental

1 exposures, the evidence suggests naphthalene is
2 not metabolized in human respiratory tissue to the
3 extent that it would cause toxicity and
4 carcinogenic risk at typical naphthalene
5 environmental exposures. At very high
6 concentrations, that's a different question.

7 Q. Understood. So you're saying at typical
8 levels of naphthalene exposure, it probably
9 doesn't cause cancer in humans?

10 A. Correct, based on my analysis.

11 Q. If you look at page 42 at the top
12 right-hand side, it says, "This paper was prepared
13 with financial support to Gradient from the
14 Naphthalene Research Committee." Correct?

15 A. Correct.

16 Q. It confirms that they're indeed a trade
17 group for naphthalene; correct?

18 A. Correct.

19 Q. It says that that group was given the
20 opportunity to comment on this manuscript as well;
21 right?

22 A. Correct, but not on the science. They
23 relied on our interpretation of the data.

24 Q. When you say "not on the science," I
25 mean, this is a paper that's published in a

1 scientific journal; right?

2 A. Correct.

3 Q. This is Critical Reviews of Toxicology?

4 A. Correct.

5 Q. Why does a trade group need to comment
6 on the manuscript?

7 A. For editorial, editorial comments they
8 had to make sure that we are sort of talking about
9 the chemicals in a way that makes sense in the
10 context of potential exposures to humans.

11 So we will look at the data and look
12 hard at the science and evaluate potential risks
13 to animals, how it might extrapolate to the
14 humans, and then we think about how that exposure
15 compares to typical exposures in the environment.

16 So they're funders of the manuscript.
17 They can look at the language and make sure that
18 it's -- editorial comments on the manuscript is
19 reasonable, but they did not comment on our
20 interpretation of the science.

21 Q. How do you define editorial? How are
22 you defining it here?

23 A. We have punctuation, grammar.

24 Q. So it's your testimony that the only
25 thing that the Naphthalene Trade Group did was

1 correct grammar and punctuation?

2 A. I don't remember all of it. I don't
3 remember the comments. I'd have to look back.
4 They might not even have done that. I don't
5 recall. I just know that they did not comment on
6 the science. They relied on our evaluation of the
7 science, which is the most important part of this
8 evaluation.

9 Q. You can put that one aside.

10 You've done work for Gradient on the
11 relationship between formaldehyde and leukemia?

12 A. Yes.

13 Q. And you dispute --

14 MS. ELLISON: Hold on a second.

15 (There was a pause in the proceedings.)

16 BY MR. SNIDOW:

17 Q. And you argued formaldehyde is not
18 causally associated with leukemia; correct?

19 MS. ELLISON: Sorry. I missed the
20 beginning of the question. Can you just ask it
21 again, please?

22 MR. SNIDOW: Sure.

23 BY MR. SNIDOW:

24 Q. You've done work for Gradient on
25 formaldehyde and leukemia?

1 A. Yes.

2 Q. And you published a paper on that?

3 A. Yes.

4 Q. In that paper you argued that
5 formaldehyde is not causally associated with
6 leukemia; correct?

7 A. I believe that was the conclusion, but
8 that was a long time ago.

9 Q. You did that work on behalf of the
10 Formaldehyde Council?

11 A. Yes.

12 Q. You agree that's an organization that
13 probably doesn't want a determination that
14 formaldehyde causes leukemia?

15 MS. ELLISON: Object to the form.
16 Foundation.

17 THE WITNESS: That organization wanted
18 our opinion about what the science says about
19 potential for formaldehyde to cause leukemia,
20 which is what we did.

21 BY MR. SNIDOW:

22 Q. They were paying for you; right?

23 A. They did support us, but our evaluation
24 was based on the science.

25 Q. Do you think they would have been

1 pleased if you determined their product caused
2 leukemia?

3 MS. ELLISON: Object to the form.
4 Foundation.

5 THE WITNESS: I'm not sure whether they
6 would have been pleased or not. That was not --
7 that had no bearing on the evaluation.

8 BY MR. SNIDOW:

9 Q. You again allowed them to review the
10 manuscript and provide comments?

11 A. I would have to look at the paper to see
12 what we did there.

13 (Bailey Exhibit 6 was marked.)

14 BY MR. SNIDOW:

15 Q. I marked as Bailey Exhibit 6 a paper
16 called Exposure to Formaldehyde -- a paper called
17 "Is Exposure in Air Causally Associated with
18 Leukemia?" You'll see at the top you are the
19 second author on the paper.

20 A. Yes.

21 Q. And Julie Goodman is the third author on
22 the paper?

23 A. Dr. Goodman is on the paper as well.

24 Q. If you will turn to page 616, if you see
25 the last paragraph there, you'll agree that your

1 conclusion was that formaldehyde does not cause
2 leukemia in humans; correct?

3 A. Where are you looking on 616?

4 Q. Bottom right, the last sentence right
5 before the Acknowledgments.

6 A. The conclusion is that it was weak in
7 comparison to more substantial weight of evidence
8 supporting the lack of causal association. So the
9 evidence is weak. That was our conclusion.

10 Q. The evidence for causation was weak?

11 A. Yes.

12 Q. You thought the evidence against
13 causation was stronger?

14 A. Correct.

15 Q. If you turn to the page 617, middle of
16 that paragraph on the left, it says, "The
17 preparation of this review was sponsored by the
18 Formaldehyde Council." Correct?

19 A. It does, yes.

20 Q. I guess I didn't ask this, but I assume
21 that is a trade group for people who deal with
22 formaldehyde; true?

23 A. Correct.

24 Q. It confirms that you provided them the
25 opportunity to review a draft of the paper;

1 correct?

2 A. Yes.

3 Q. I assume you don't remember the comments
4 they provided?

5 A. I don't remember the comments.

6 Q. Your testimony is it was entirely
7 editorial; right?

8 A. I know that their comments did not
9 change our opinions about the science.

10 Q. You've published an article stating that
11 the pesticide chlorpyrifos -- do you know how to
12 say that?

13 A. Chlorpyrifos.

14 Q. -- does not cause neurodevelopmental
15 harm; right?

16 A. I was an author on that paper.

17 Q. That was done on behalf of Dow Chemical?

18 A. I don't recall. It was a long time ago.
19 (Bailey Exhibit 7 was marked.)

20 BY MR. SNIDOW:

21 Q. I'll show you a document that I'll mark
22 as Bailey Exhibit 8 -- Bailey Exhibit 7. If you
23 look at the top, you'll see you're the third
24 author on this paper.

25 A. Yes.

1 Q. Dr. Goodman is again a co-author on this
2 paper; correct?

3 A. Yes.

4 Q. If you will look at the page ending in
5 899, it says that the paper was prepared with
6 financial support to Gradient by Dow AgroSciences;
7 right?

8 A. Yes.

9 Q. I assume that they are the manufacturer
10 of this pesticide?

11 A. I don't recall if they are, but I am
12 going to assume they are since they -- yes.

13 Q. At this time, this paper was done
14 because the EPA was considering putting in place
15 new ECELS?

16 A. I actually don't recall. I was very
17 peripherally involved in this paper. So I don't
18 recall the details of this, how this work came
19 about.

20 Q. Do you know whether Dow AgroSciences was
21 permitted to comment on this paper?

22 A. I don't know.

23 Q. You've done work for the national
24 petroleum institute?

25 A. I don't recall the national petroleum

1 institute.

2 MS. ELLISON: J.J., I don't know how
3 many more of these you have. We've been going
4 about an hour.

5 MR. SNIDOW: Do you mind like giving me
6 five minutes?

7 MS. ELLISON: Yes.

8 BY MR. SNIDOW:

9 Q. I'm sorry. Have you done work for the
10 American Petroleum Institute?

11 A. Yes.

12 Q. That's no fair.

13 MS. ELLISON: You were close.

14 BY MR. SNIDOW:

15 Q. Any other industry groups besides the
16 ones that we've gone through that I haven't
17 mentioned that you've done work for?

18 A. The only other group that I recall is
19 the American Chemical Council.

20 Q. They're a trade group for chemical
21 companies?

22 A. Correct.

23 Q. Have you ever published a paper funded
24 by industry where you determined that there was
25 strong evidence in favor of causation?

1 A. I don't recall that that was a
2 conclusion, but it's always based on the science.

3 Q. Of course. But as far as you can
4 recall, every time an industry group has asked you
5 to look at their chemical, your conclusion was
6 that it does not cause the disease in question?

7 MS. ELLISON: Object to the form.

8 THE WITNESS: That is not correct. It's
9 in the context of exposure information typically.
10 Some may cause a health effect at a high exposure
11 concentration, but then it's important to compare
12 that to what's a typical environmental exposure or
13 occupational exposure. So that part is very
14 important.

15 BY MR. SNIDOW:

16 Q. That's fair. But every time you've been
17 asked to evaluate whether a typical exposure
18 causes a particular disease, you've been asked by
19 an industry group who makes that chemical, your
20 conclusion has been not enough evidence of
21 causation; right?

22 MS. ELLISON: Object to the form.

23 THE WITNESS: Off the top of my head, I
24 have not -- I don't know that we have talked about
25 all of my evaluations today. But most

1 importantly, they're all based on the science.
2 And some of them may have concluded that high
3 exposures could cause a health effect, but at more
4 typical exposures, it's unlikely.

5 But that's sort of a broad answer. I
6 would need to look specifically at all of my
7 papers to see.

8 BY MR. SNIDOW:

9 Q. I understand. I'm asking you based on
10 your memory. Can you recall a time when you've
11 been asked by an industry group that makes a
12 certain chemical, hi, Dr. Bailey, please take a
13 look at the evidence and tell us whether our
14 chemical causes a certain disease at typical
15 exposures, that you've published a paper that
16 saying yes, it does?

17 MS. ELLISON: Object to the form.

18 BY MR. SNIDOW:

19 Q. Can you recall ever doing that?

20 A. Again, I feel like I would need to look
21 at everything. I've done evaluations where we may
22 have talked about chemicals at certain exposure
23 concentrations being potentially problematic in
24 terms of publishing.

25 Particularly talking about the papers

1 that you showed me today, I don't think I can
2 answer that because some of these are occupational
3 exposures where I didn't look at typical exposure
4 concentrations for the general population. So
5 it's a difficult question to answer without the
6 specifics.

7 Q. So, first, of all, I'm asking you based
8 on your memory. I understand you'd like to review
9 every single one of the papers.

10 Based on your memory, can you ever
11 recall publishing a paper about a chemical that an
12 industry group is involved with where you said,
13 yes, this is likely to cause a certain disease at
14 typical levels of exposure? Can you recall ever
15 doing that?

16 MS. ELLISON: Object to the form.

17 THE WITNESS: I can't recall that
18 specific conclusion as I sit here today, but
19 whatever the evaluation was, it's based on
20 science.

21 BY MR. SNIDOW:

22 Q. I understand. Have you ever been asked
23 by an industry group to look at the relationship
24 between their product and a particular disease and
25 published a paper determining that there's a

1 serious risk to human health from what that
2 industry was doing?

3 MS. ELLISON: Object to the form.

4 THE WITNESS: Can you repeat that
5 question?

6 BY MR. SNIDOW:

7 Q. Yeah. Let's take an example. The
8 formaldehyde people asked you to look at
9 formaldehyde and leukemia; right?

10 A. Correct.

11 Q. The asbestos people asked Dr. Goodman
12 and you to look at chrysotile asbestos and
13 mesothelioma and lung cancer; right?

14 A. Correct.

15 Q. Dow Chemical, it looks like, asked you
16 to look at the pesticide and neurodevelopmental
17 effects; right?

18 A. Um-hum.

19 Q. Each time you came out and said, in my
20 view of the science, I don't think that there's a
21 risk to human health at typical exposures; true?

22 MS. ELLISON: Object to the form.

23 THE WITNESS: Again, the conclusions in
24 these papers are -- that's what I would stand by.
25 Some of them are occupational. Some of them are

1 typical.

2 BY MR. SNIDOW:

3 Q. Let me ask a different way. Have you
4 ever been approached by a group like one of these
5 who produces a chemical that people are out there
6 saying might be linked to this disease at typical
7 levels and said, bad news for you, guys;
8 absolutely this is a huge public health problem?
9 Ever published anything like that?

10 MS. ELLISON: Object to the form.

11 THE WITNESS: So we're asked to look at
12 the science and to determine whether the science
13 supports an association between chemical exposures
14 and health effects. And sometimes at high
15 concentrations, there is an association. And then
16 we need to look at what more typical exposures
17 are.

18 So I would not start out with any
19 conclusion one way or the other. It's always
20 based on the science.

21 BY MR. SNIDOW:

22 Q. I get that, Dr. Bailey. But do you
23 remember my question.

24 My question was: Can you ever remember
25 publishing a paper like I described?

1 MS. ELLISON: Object to the form.

2 THE WITNESS: I think you asked me that
3 already, and I said that I have not published
4 anything where I stated that conclusion because
5 that was not what the science supported.

6 MR. SNIDOW: Break.

7 THE VIDEOGRAPHER: Off the record at
8 10:38.

9 (Recess from 10:38 a.m. to 10:52 a.m.)

10 THE VIDEOGRAPHER: Back on the record at
11 10:52.

12 BY MR. SNIDOW:

13 Q. I'm going to my switch topics, but just
14 a couple of follow-up questions to some of the
15 stuff we talked about, Dr. Bailey.

16 Have you worked with Dr. Goodman on
17 other projects for Gradient?

18 A. I have.

19 Q. When you worked on those other projects,
20 had you discussed your work with Dr. Goodman?

21 A. Yes.

22 Q. Gradient has billed, it looks like so
23 far, \$1.7 million to the government for this work.

24 MS. ELLISON: Object to form.

25 THE WITNESS: For my project, yes.

1 BY MR. SNIDOW:

2 Q. Are you aware that for Dr. Goodman's
3 project, it's about \$4 million?

4 A. I'm not aware of what her project
5 billed.

6 Q. Your testimony is that you and
7 Dr. Goodman have never once discussed Camp
8 Lejeune?

9 A. That's correct.

10 Q. Have you ever seen a publication that
11 uses a risk assessment to assess causation in a
12 population, in a population level?

13 A. Risk assessments are often used to
14 evaluate causation not typically in published
15 literature because we don't publish typically on
16 the individual.

17 Q. I'm asking about population.

18 A. Oh, population. Sorry.

19 Q. I understand that you've seen it done in
20 litigation. I'm asking about peer-reviewed
21 literature.

22 Have you ever seen a peer-reviewed
23 publication that uses risk assessment to assess
24 causation in a population?

25 MS. ELLISON: Object to the form.

1 THE WITNESS: As I sit here today, I
2 can't recall of a publication that assesses
3 causation in a population.

4 BY MR. SNIDOW:

5 Q. Using risk assessment?

6 A. Using risk assessment; right.

7 Q. Do you think that risk assessments for
8 an individual can be used to disprove causation?

9 MS. ELLISON: Objection to the form.

10 THE WITNESS: Sorry. Can you repeat
11 that?

12 BY MR. SNIDOW:

13 Q. Do you believe that risk assessments for
14 an individual can be used to disprove causation?

15 A. I think they are an important part of a
16 causation analysis for individuals. And so, yes,
17 they can be used to support causation or to
18 suggest that there is not a causal relationship.

19 Q. So let's make it concrete. So if you
20 have a person who is exposed to a certain
21 chemical, if the risk assessment shows a low
22 enough hypothetical increased risk, do you think
23 you can rule out the possibility that chemical
24 caused the disease?

25 MS. ELLISON: Object to the form.

1 THE WITNESS: I think that's one part of
2 the evaluation. You need to also consider the
3 epidemiology and compare the concentrations in the
4 epidemiology to the estimated exposures for the
5 individual.

6 BY MR. SNIDOW:

7 Q. Are you aware that Gradient is owned by
8 Blackstone?

9 A. Gradient is part of Geosyntec, and
10 Blackstone is, yeah, an investor.

11 Q. Do you know if Blackstone owns any
12 entities that manufacture any of the chemicals at
13 issue in this case?

14 A. I don't know.

15 Q. Are you a principal at Gradient?

16 A. Yes.

17 Q. Does that mean you have an equity stake
18 in the company?

19 A. Yes.

20 Q. Have you done work for a company called
21 Westlake?

22 A. I don't recall.

23 Q. Do you know if Gradient has?

24 A. I don't recall.

25 Q. Do you know if Gradient has to do any

1 monthly, quarterly or yearly reporting to
2 Blackstone?

3 A. I'm not familiar with the reporting that
4 goes on.

5 Q. Do you do revenue projections for
6 matters that you work on?

7 A. Yes.

8 Q. Have you done one for this case?

9 A. I typically do revenue projections for
10 all my projects combined.

11 Q. But do you think you -- do you split out
12 how much money -- excuse me -- how much Gradient
13 is going to probably bill for the Camp Lejeune
14 case?

15 A. That's typically not how we report it.
16 We report a lump sum of what we think our revenue
17 might be going forward.

18 Q. For all the matters you work on?

19 A. Yes.

20 Q. Do you have a target billing that you
21 are tasked to try to hit?

22 A. I think in general, yes, we do have a
23 target billing.

24 Q. What's your target?

25 A. I'm saying this off the top of my head

1 because I don't have the information in front of
2 me, but for principal level, it's around 750,000.

3 Q. Per year?

4 A. Yes.

5 Q. So roughly maybe half, maybe 40 percent
6 of what Gradient has billed the government so far
7 for your work?

8 A. 750,000 is half of the 1.5 roughly
9 million, yes.

10 Q. Let's look at your Dyer report, which I
11 think I marked as Exhibit 2. If you could turn to
12 page 8.

13 MS. ELLISON: I think it's my Exhibit 1,
14 just for the record.

15 MR. SNIDOW: Thank you.

16 BY MR. SNIDOW:

17 Q. If you go to page 8, you'll see that you
18 have a Conclusion section, and you say, "Based on
19 the results of my analysis described above, it's
20 my opinion to a reasonable degree of scientific
21 certainty that there's insufficient evidence to
22 conclude that Ms. Dyer's exposure to, TCE, PCE,
23 benzene, vinyl chloride and 1,2-tDCE from tap
24 water during the 14.5 years that she lived and
25 spent time at Camp Lejeune are causally associated

1 with her bladder cancer."

2 Did I read that approximately correctly?

3 A. Yes.

4 Q. Am I correct that you -- aside from
5 swapping out the years of time on Camp Lejeune and
6 the relevant disease, that is the exact same
7 conclusion that you reach for all 25 of the
8 plaintiffs that you evaluated?

9 A. I used similar language, but, of course,
10 it's based on the individual exposure evaluations
11 and risk evaluations.

12 Q. That's what I mean. It says Ms. Dyer's
13 exposure was 14.5 years; right?

14 A. Yes.

15 Q. So for other plaintiffs, you put in
16 different years; correct?

17 A. The years differ, but other things
18 differed as well, whether they were potentially
19 exposed during swimming, whether they worked at a
20 mess hall.

21 Q. I'm just talking about this conclusion.
22 My question is about your reports. I've read
23 them.

24 Am I correct that you have essentially
25 this paragraph, with the exception of the years,

1 the name and the disease, for every single one of
2 the plaintiffs that you looked at?

3 MS. ELLISON: Object to the form.

4 THE WITNESS: That paragraph is similar,
5 but the exposure evaluation and the evaluation for
6 each plaintiff is different.

7 BY MR. SNIDOW:

8 Q. If you go to page 21 of your report, if
9 you go down, do you see the paragraph right below
10 Margin of Exposure Estimate that begins "In some
11 cases"?

12 A. Yes.

13 Q. It says, "In some cases, it is also
14 helpful to compare plaintiff-specific exposure
15 information to exposure information from reliable
16 epidemiology studies." Correct?

17 A. Correct.

18 Q. That's helpful to do in support of a
19 causation analysis. I think you already told me
20 that; right?

21 A. Yes.

22 Q. So one thing you want to do is you want
23 to look at how much the plaintiff was exposed to
24 and see how much people in epidemiology studies
25 were exposure to; correct?

1 A. Also animal studies.

2 Q. Also animal studies. What you want to
3 see is are people in the epidemiology studies who
4 have similar exposures, do they have an increased
5 risk of disease; right?

6 A. Well, you want to look at epidemiology
7 studies that may or may not have reported an
8 association. You want to understand the exposure
9 in those studies and then compare that to the
10 exposure estimate for the plaintiff and see how it
11 compares.

12 Q. That's what I'm getting at. Let's say a
13 study reports an increased risk for a certain
14 disease, a certain exposure. You want to compare
15 that result to the exposure that the individual
16 has; correct?

17 A. Well, you want to look at the study.
18 The study may report something, but you'd want to
19 look at the study to see -- you want to look at
20 the results of the study. You may interpret the
21 study differently from what the study reports.

22 Q. Of course. But if you looked at the
23 study, you interpreted that this is a reliable
24 study, you'd want to look at the risk ratio for
25 the exposure category in the study and then

1 compare that to the individual exposure; correct?

2 A. That's generally what we do, yes.

3 Q. And if the individual had exposure that
4 corresponded to an exposure category in the study
5 that showed an increased risk, that would increase
6 the likelihood that you find a causal association;
7 right?

8 MS. ELLISON: Object to the form.

9 THE WITNESS: I would want to look at
10 the results of the study to see how I interpret
11 whether there's an increased risk or not. So I
12 don't take the conclusions of the authors at face
13 value. It's my interpretation of the studies.

14 BY MR. SNIDOW:

15 Q. So I assume that you did what I just
16 described in this case; right?

17 A. I looked at the -- I did what I
18 described.

19 Q. But you didn't actually read the
20 Aschengrau study; correct?

21 A. I did.

22 Q. It's not in your report.

23 A. The Aschengrau study is on my MCL.

24 Q. You read that?

25 A. I did.

1 Q. You compared the exposure levels of the
2 Aschengrau study to the exposure levels of the
3 people at Camp Lejeune?

4 A. I considered how the authors evaluated
5 exposure in that study. And I don't agree that
6 those exposures are comparable to exposures of
7 individuals in Camp Lejeune.

8 Q. Where do you say that in your reports?

9 A. There is -- actually, I think I do cite
10 it in my report because I think I --

11 Q. What you just said. Your testimony is
12 you went through the Aschengrau exposures and
13 compared that to the exposures of the people at
14 Camp Lejeune.

15 MS. ELLISON: Object to the form.

16 THE WITNESS: I did consider the
17 Aschengrau studies and the exposure information
18 that was reported in those studies. And I talk
19 about that in some of my rebuttals if the
20 plaintiff expert talked about Aschengrau.

21 So I don't know if that's the case for
22 Dyer. But I have talked about the Aschengrau
23 studies in my rebuttals in Section 9 of some of
24 the bladder cancer plaintiff reports.

25

1 BY MR. SNIDOW:

2 Q. Maybe I'm just asking this wrong. Let's
3 look at page 21 of your report again. You say,
4 "In some cases, it is also helpful to compare
5 plaintiff-specific exposure information to
6 exposure information from reliable epidemiology
7 studies." Correct?

8 A. Correct.

9 Q. Your testimony is you did that; right?

10 A. I did.

11 Q. For all of the epidemiology studies?

12 A. For all of the reliable epidemiology
13 studies.

14 Q. Which ones are reliable?

15 A. Aschengrau is not.

16 Q. How do you know that?

17 MS. ELLISON: Object to the form.

18 THE WITNESS: I have looked at the
19 Aschengrau study, and I understand how the
20 exposure information is reported in that study.
21 And it's not reliable for individual exposure
22 information.

23 BY MR. SNIDOW:

24 Q. I think maybe I'm asking this the wrong
25 way.

1 Do you see the sentence begins, "In some
2 cases"?

3 A. Yes.

4 Q. Will you please show me in your report
5 where you did the comparison that's described in
6 that sentence?

7 A. Sure. Section 8. Section 8 describes
8 epidemiology in animal studies relevant to bladder
9 cancer, and I looked at studies in -- for that
10 section, I looked at epidemiology studies and
11 animal studies that had exposure information and
12 compared those to the plaintiffs' exposure.

13 Q. So where is Aschengrau?

14 A. Aschengrau was not a study that I
15 consider reliable. So I did not consider it here.

16 Q. Where do you say that? Where do you say
17 I read Aschengrau; it's not reliable, so I didn't
18 cite it here?

19 A. For this section I relied on
20 Dr. Goodman's evaluation of all of the data.
21 Dr. Goodman does not consider Aschengrau in her
22 evaluation. But I did look at Aschengrau in the
23 context of my rebuttals, my rebuttal section, and
24 also in the context of some of the rebuttals that
25 I reviewed from other plaintiff experts.

1 Q. Did you review Moore 2010?

2 A. I did review Moore 2010.

3 Q. Did you review all the studies from
4 Woburn, Massachusetts?

5 A. I have looked at those.

6 Q. You don't discuss any of those here, do
7 you?

8 A. Well, I was not asked to discuss the
9 individual epidemiology studies that Dr. Goodman
10 considered in her report. So I relied on her
11 evaluation of those studies. I agree with her
12 methodology. I looked at some of the studies that
13 had specific exposure information, epidemiology
14 studies with specific exposure information, and
15 then compared that to the plaintiffs' exposures,
16 the reliable epidemiology studies.

17 Q. Did you defer to Dr. Goodman's
18 interpretation of what studies were reliable?

19 A. I used Dr. Goodman's report for a
20 summary of reliable studies, yes. But I agree
21 with her methodology.

22 Q. I understand you agree with her
23 methodology. Just to be clear, her methodology is
24 employing the weight-of-the-evidence approach;
25 right?

1 MS. ELLISON: Object to the form.

2 THE WITNESS: She did a systematic
3 review of the available information.

4 BY MR. SNIDOW:

5 Q. That absolutely requires scientific
6 judgment to determine what studies are reliable or
7 not; right?

8 A. Yes.

9 Q. And my question is this: Did you defer
10 to Dr. Goodman's determination about what's
11 reliable, or did you individually read each of
12 these EPA studies and assess whether you thought
13 they were reliable?

14 MS. ELLISON: Object to the form.

15 BY MR. SNIDOW:

16 Q. Which one?

17 A. In general, in terms of an overall
18 evaluation of potential causation for a chemical
19 exposure and health effects, I relied on
20 Dr. Goodman's systematic review. There were
21 individual studies within her evaluation that also
22 had exposure information. I considered those
23 studies more carefully for my Section 8 and other
24 studies that were not reliable in the context of
25 my rebuttal in Section 9.

1 BY MR. SNIDOW:

2 Q. Do you agree that epidemiology studies
3 provide the primary methodology for demonstrating
4 a causal relationship?

5 A. Epidemiology studies are one set of data
6 that you'd want to consider.

7 Q. But do you agree they're the primary
8 method?

9 A. I don't. I think that you need to look
10 at epidemiology, animal studies and mechanistic
11 data and integrate all of that information.

12 Q. So you disagree?

13 MS. ELLISON: Object to the form.

14 THE WITNESS: I agree that epidemiology
15 needs to be considered certainly in the context of
16 animal data and mechanistic data.

17 BY MR. SNIDOW:

18 Q. Did you do your own independent
19 literature search to find the epidemiology
20 literature?

21 A. I did not.

22 Q. So the universe of epidemiology
23 literature you considered was limited to
24 Dr. Goodman's review?

25 A. Yes, it was. And again, I agree with

1 her methodology.

2 Q. Well, you know what a literature review
3 is; right?

4 A. Of course.

5 Q. That's where you go on PubMed or
6 something similar and try to collect all the
7 literature on a certain topic; right?

8 A. Yes.

9 Q. You didn't do that?

10 A. That's not what I was asked to do for my
11 evaluation.

12 Q. Did you copy and paste any sections of
13 your report for one plaintiff into another?

14 A. Some of the general sections I did, yes.

15 Q. Do you agree that an individual's risk
16 varies based on different factors including age,
17 sex, race, lifestyle, family history?

18 A. Yes. That is part of what is important
19 for whether someone may have a health effect or
20 not.

21 Q. Your risk assessments that you performed
22 here do not take into account the plaintiff's age;
23 correct?

24 A. They do.

25 Q. They do?

1 A. Yes.

2 Q. How does it take into account the
3 plaintiff's age?

4 A. Well, for example, Amsler, child, the
5 risk assessment for Amsler considers age-dependent
6 adjustment factors that EPA recommends, and I used
7 those.

8 Q. That's fair. That's specifically for
9 children; correct?

10 A. Yes.

11 Q. But for the plaintiffs here who are
12 exposed as adults, your risk assessment does not
13 consider their age; correct?

14 A. Well, I didn't apply those adjustment
15 factors for the adults, so it does consider their
16 age.

17 Q. I think we're talking past each other.
18 Whether the plaintiff was 20 when exposed, 50 when
19 they got the disease, or whether the plaintiff was
20 35 when exposed, 70 when they got the disease,
21 your risk assessment would come out the same way;
22 correct?

23 MS. ELLISON: Object to the form.

24 THE WITNESS: So I followed EPA's
25 standard methodology for evaluating risk. And

1 there are risks that you -- risk calculations that
2 you conduct for adults and risk calculations that
3 you conduct for children. So I conducted the risk
4 evaluations for the adults as adults.

5 BY MR. SNIDOW:

6 Q. Again, do you remember my question
7 though? The risk calculation that you do you for
8 adults doesn't depend on their age; correct?

9 MS. ELLISON: Object to the form.

10 THE WITNESS: EPA does not consider a
11 specific age for individuals other than children
12 versus adults.

13 BY MR. SNIDOW:

14 Q. That was my only question. Your risk
15 assessment that you did did not depend on the
16 person's adult age; correct?

17 MS. ELLISON: Object to the form.

18 THE WITNESS: EPA's standard risk
19 approach for adults is to consider -- actually, I
20 take that back, because we did consider body
21 weight that may vary for different ages. So we
22 considered I believe -- if the body weight was
23 slightly different for a younger adult versus an
24 older adult, that might have gone into the
25 calculation.

1 BY MR. SNIDOW:

2 Q. How about gender, did you take that into
3 account in your risk assessment?

4 A. Specifically for the calculations, we
5 would consider the gender. For a default exposure
6 assumption, it's typically based on the more
7 conservative sex, either male or female, in terms
8 of body weight -- in terms of body weight
9 specifically.

10 Q. So it doesn't vary based on the person's
11 sex? You used one for everyone?

12 A. I would have to look at Dr. LaKind's
13 report to see what we used for some of the
14 plaintiffs. But I know that body weight was
15 something that was considered based on the age of
16 the individual.

17 Q. I'm not asking about body weight. Age
18 and body weight are different; correct? Sex and
19 body weight are different.

20 You understand those are different
21 concepts; right?

22 MS. ELLISON: Object to the form.

23 THE WITNESS: I think you asked me about
24 sex. I was answering body weight, with body
25 weight based on different concepts.

1 BY MR. SNIDOW:

2 Q. Maybe I'm not asking this concretely
3 enough. Let's take two plaintiffs. They have the
4 exact same facts except one is a female and one is
5 male. Your risk assessment would come out
6 identically for both of them?

7 MS. ELLISON: Object to the form.

8 THE WITNESS: The risk calculation would
9 come out to be -- it depends on whether the
10 male -- the woman or the man. There are other
11 factors that are important for that calculation.
12 How were they each individually exposed?

13 BY MR. SNIDOW:

14 Q. Assume for me all of that is the same.
15 They were on base the same amount of time. They
16 did the exact same activities. Every single thing
17 that you considered about their experience was the
18 same, except one is a male, one is a female.

19 Your risk assessments is going to come
20 out to be the exact same for both of them;
21 correct.

22 MS. ELLISON: Object to the form.

23 THE WITNESS: It may not depending on
24 the body weight. So I would have to actually run
25 a calculation to see how different it might be.

1 BY MR. SNIDOW:

2 Q. Assume that they weigh exactly the same.
3 The only difference is their gender. Your risk
4 assessment would come out exactly the same for
5 them; true?

6 A. If they weighed exactly the same and
7 they had the same activities, same time period.
8 We are assuming that they're living in the same
9 location, that they were both healthy Marines at
10 the time, ingested similar amounts of water.
11 You'd have to consider all those things.

12 Q. Correct. If you did and the only
13 variation was gender, the risk assessment would
14 come out exactly the same; correct?

15 A. The risk calculation would be similar,
16 yes.

17 Q. Same answer for race; true?

18 MS. ELLISON: Object to the form.

19 THE WITNESS: It would, but you have to
20 remember that the toxicity values applied in those
21 calculations do consider potentially sensitive
22 subpopulations. So the calculation may be
23 conservative -- is generally conservative because
24 those subpopulations were considered.
25

1 BY MR. SNIDOW:

2 Q. I understand. But again, I think it's
3 easier if we just make it concrete.

4 You've got two individuals. Assume one
5 is Caucasian. One is African-American. They have
6 the exact same body weight, the same exposures,
7 the same all the facts that you describe your
8 report. Your risk assessment will come out
9 exactly the same for both of them; correct?

10 A. The risk calculation -- if everything is
11 exactly the same, that would be the risk
12 calculation, and it would be a conservative
13 estimate.

14 Q. Same answer for family history; correct?

15 A. The risk calculations could be -- could
16 come out to be the same. Again, you'd have to
17 make sure everything is exactly the same, the
18 assumptions you're making, the conservative
19 assumptions you're making. But again, this is
20 only one part of the risk evaluation, of the
21 specific causation evaluation I should say.

22 Q. I get it. I'll make it concrete.
23 You've got two plaintiffs. One has got no family
24 history of cancer. One has got a ton of family
25 history of cancer. Assuming they had the same

1 weight, exposure, all the things I ticked through,
2 all else equal except family history, your risk
3 assessment will still come out the same for both
4 of them; right?

5 A. The risk calculation portion of the
6 specific causation analysis might come out to be
7 the same, but that's not the only thing that you
8 would think about.

9 Q. I know. But you agree that the cancer
10 risk for someone with a substantial family history
11 is not at all the same as someone who doesn't have
12 a family history; correct?

13 MS. ELLISON: Object to the form.

14 BY MR. SNIDOW:

15 Q. Sorry. Dr. Bailey, listen to my
16 question. I know you're not trying to be
17 difficult. But you certainly agree --

18 MS. ELLISON: J.J., she was just
19 answering your question. She began answering. So
20 I'd ask that you let her finish. Then you can ask
21 whatever follow-up questions you have.

22 BY MR. SNIDOW:

23 Q. Do you agree that the cancer risk for
24 someone with a family history of cancer is not the
25 same for someone who doesn't have a family history

1 of cancer?

2 A. In general, if there's a family history
3 of cancer, there's a possibility that there's
4 increased risk for an individual -- for an
5 individual whose family has a history of cancer.
6 But that doesn't mean that the -- that has nothing
7 to do with the exposure evaluation piece of it.
8 That's a separate analysis.

9 So, yes, familial connection is an
10 important part of the specific causation analysis.
11 And the exposure evaluation is also an important
12 part of the exposure analysis.

13 Q. Did you do any assessment of smoking
14 exposure for each plaintiff?

15 A. I did not.

16 Q. Did you do any assessment of exposures
17 to any other risk factors for each plaintiff?

18 A. I did not.

19 Q. Did you do any assessment of the cancer
20 risk any of the plaintiffs would have experienced
21 from smoking?

22 A. I have not.

23 Q. Did you do any assessment of the cancer
24 risk that any of the plaintiffs would have
25 experienced from any other risk factors?

1 A. I did not. That was not what I was
2 asked to do.

3 Q. Did you do any assessment of any
4 protective traits that any of the plaintiffs might
5 have had?

6 A. What do you mean by protective traits?

7 Q. Whether they're in good shape, whether
8 they had no family history, anything like that.

9 A. I did consider in the context of
10 uncertainty factors for variability within the
11 human population. I did consider that some of the
12 plaintiffs were healthy Marines at the time of
13 exposure. That was something that I did consider.

14 Q. But you made that assumption across the
15 board; correct?

16 A. That's an assumption that's important
17 for the noncancer population. So that would have
18 been the Parkinson's disease patients, plaintiffs.

19 Q. Again, I think we're talking past each
20 other.

21 Did your assumption about whether
22 they're healthy or not vary between plaintiffs?

23 A. For plaintiffs that were civilians, I
24 did not do that adjustment for the Parkinson's
25 disease patients -- plaintiffs. Excuse me.

1 Q. You, yourself, did not create any
2 exposure measurements for the individual
3 plaintiffs; Dr. LaKind did that?

4 A. That's correct. Dr. LaKind did the
5 exposure calculations.

6 Q. She provided you the daily exposure
7 doses; true?

8 A. Correct.

9 Q. That takes into account -- sorry. And
10 she provided you the daily exposure
11 concentrations; correct?

12 A. Yes.

13 Q. And just to clarify, the daily exposure
14 doses, that's for the oral and dermal exposures;
15 true?

16 A. Correct.

17 Q. The daily exposure concentration, that's
18 for inhalation; true?

19 A. Correct.

20 Q. From that, she provided you with an
21 ultimate measure of average daily dose; correct?

22 A. Yes.

23 Q. So just in concrete terms, the number
24 that Dr. LaKind provided to you is the average
25 daily dose of the chemicals that each of the

1 plaintiffs was exposed to; right?

2 A. Yes.

3 Q. Dr. LaKind did not provide you a measure
4 of the cumulative amount of the chemicals that the
5 plaintiffs were exposed to; correct?

6 A. That's correct. That was the part I
7 did.

8 Q. And her metric that she provided to you
9 does not account for intensity of exposure; true?

10 A. The metric that she provided is an
11 estimate of the exposure concentrations from the
12 water that the plaintiffs may have been exposed to
13 at that time.

14 Q. Let me ask a different way. If someone
15 had two years of exposure at a thousand micrograms
16 and two years at zero, that would get treated the
17 same way as someone who had a thousand micrograms
18 for four years; correct?

19 MS. ELLISON: Object to the form.

20 THE WITNESS: Can you say those numbers
21 again?

22 BY MR. SNIDOW:

23 Q. Someone had two years of a thousand
24 micrograms and two years of zero, you treat that
25 the same as someone who had a thousand micrograms

1 for four years?

2 A. That is the way the EPA does the risk
3 calculations, yes.

4 Q. That's the number that Dr. LaKind
5 provided to you?

6 A. Well, I would say that's a hypothetical.
7 So in terms of the amount that you're providing to
8 me, I don't know how that compares to any of the
9 plaintiffs. In terms of micrograms, that's not
10 how we report doses. It's milligram per kilogram
11 day or microgram per meter cubed. So I don't know
12 what the 1000 is. But EPA does have that
13 assumption that it's exposure times time.

14 Q. Average exposure?

15 A. Yes.

16 Q. Dr. LaKind provided to you -- you said
17 this, but I'll say it again -- with daily exposure
18 concentrations; right?

19 A. Yes.

20 Q. That's expressed in what unit?

21 A. Microgram per meter cubed.

22 Q. And that unit does not depend on the
23 weight of the person; correct?

24 A. Correct. That is how EPA does that
25 calculation.

1 Q. So regardless if someone weighs 80
2 pounds or 250 pounds, their daily exposure
3 concentration, all else equal, will be the same;
4 true?

5 A. That's correct, but it is based on --
6 EPA did consider that, and it is based on
7 assumptions that the inhalation rates that they
8 assume for those toxicity values are comparable
9 for construction workers and children, so the
10 people in the population that you think might have
11 a higher exposure, sort of a higher inhalation
12 rate.

13 So EPA does consider that, and that's
14 why microgram per meter cubed is justified.

15 Q. Let me just break this down. Daily
16 exposure doses is one measure of exposure
17 Dr. LaKind provided you; right?

18 A. Daily exposure concentrations.

19 Q. I'm actually talking about daily
20 exposure doses for the oral and dermal. That's
21 one measure that she provided?

22 A. Daily exposure dose does not sound like
23 the right...

24 Q. Turn to page 3 in your report. Go down
25 to the last bullet.

1 A. Yes, yeah. That is what -- sometimes we
2 say average daily dose. That is how she reported
3 it.

4 Q. That's one measure of exposure that she
5 provided to you; right?

6 A. Yes.

7 Q. You think that's a valid measure of
8 exposure; correct?

9 A. Correct, for the day, yes.

10 Q. The other measure that she provided you
11 is daily exposure concentrations; right?

12 A. Correct.

13 Q. That's for the inhalational?

14 A. Yeah.

15 Q. The first one, DED, that one does
16 explicitly take into account the individual's
17 weight; true?

18 A. Correct.

19 Q. Because it's a per kilogram basis;
20 correct? The other one, daily exposure
21 concentration, does not explicitly take into
22 account a person's weight; correct?

23 A. Correct. And that's consistent with
24 EPA's approach.

25 Q. I get it.

1 A. And they just have provided good
2 justification for why that is reasonable.

3 Q. My question is just if someone said an
4 exposure calculation must vary based on someone's
5 weight, you'd disagree with that; right?

6 A. For the oral dose, it would.

7 Q. But not for the inhaled dose?

8 A. Not for inhalation because the toxicity
9 values are very conservative, and EPA has
10 discussed how they're protective of a number of
11 age ranges and inhalation rates within the
12 population.

13 Q. Based on Dr. LaKind's exposure metrics,
14 you then made certain assumptions to calculate the
15 lifetime average daily dose; correct?

16 A. Yes.

17 Q. You assume an exposure frequency; right?

18 A. Yes.

19 Q. And an exposure duration; correct?

20 A. Yes.

21 Q. And an averaging time?

22 A. Right.

23 Q. And for exposure frequency, you assume
24 365 days a year; right?

25 A. For exposure pathways where it would be

1 everyday. So for drinking water, yes.

2 Q. That's what we're talking about here;
3 right?

4 A. We're talking about other pathways, too,
5 inhalation from showering.

6 Q. Is it your testimony that you varied the
7 exposure frequency by plaintiff?

8 A. For certain pathways, yes, depending on
9 what their exposures were. For drinking water,
10 no, that's daily.

11 Q. You also made an assumption about
12 averaging time?

13 A. The averaging time for cancer risk
14 calculations are 70 years. That's standard.

15 Q. That's what you said, 25,550 days?

16 A. Yes.

17 Q. Then for exposure duration, you used the
18 number of years the plaintiffs spent on base;
19 true?

20 A. Correct. Depending the exposure
21 pathway, some of those did vary. Swimming was not
22 every day. Working in the mess hall was not every
23 day. Those exposure durations were slightly
24 different.

25 Q. Then based on that, you ultimately

1 calculated what you term LADDs, which means
2 lifetime average daily doses; true?

3 A. Correct.

4 Q. That's for oral and dermal exposure;
5 correct?

6 A. Yes.

7 Q. And for inhalational exposure, you
8 calculated lifetime average daily exposures; true?

9 A. Correct.

10 Q. You did not calculate total micrograms
11 of exposure?

12 A. I did not.

13 Q. You did not calculate, say, other mass
14 units, right; no total milligrams, no total
15 nanograms, no cumulative exposure expressed in
16 terms of the mass of the chemicals; true?

17 A. Correct.

18 Q. You also did not calculate total
19 microgram per liter months of exposure?

20 A. I calculated cumulative exposures, so
21 this would be a concentration in air over time.
22 So I did do similar calculations for my Section 8
23 comparisons to epidemiology.

24 Q. Your testimony is you calculated
25 microgram per liter months of exposure?

1 A. No. Micrograms per meter cubed years or
2 PPM years of inhalation exposure. So cumulative
3 for the epidemiology inhalation studies for
4 Section 8, not microgram per liter month for
5 water.

6 Q. Let's do the ingestion first. For
7 ingestion, you did not calculate microgram per
8 liter months of exposure?

9 A. I didn't calculate that specifically,
10 but I did look at the concentration over time.

11 Q. You know what an area under the curve
12 calculation is; right?

13 A. Yes.

14 Q. And you agree that the unit microgram
15 per liter months is an area under the curve
16 metric; true?

17 A. Yes.

18 Q. For the ingestion exposure, you did not
19 calculate an area under the curve metric for any
20 of the plaintiffs; true?

21 A. I did a calculation described in my
22 report here where it's microgram -- milligram per
23 kilogram day is the concentration that Dr. LaKind
24 calculated based on microgram per liter. And then
25 I take that. So it's based on microgram per liter

1 of water, how much water was ingested, and then
2 divided by the body weight for a day.

3 Then I take that, which has the
4 microgram per liter in it, and multiply by the
5 exposure frequency and exposure duration, and
6 that's where the months come in. So it's in my
7 calculation, but I don't specifically report
8 microgram per liter months. But I do consider the
9 number of months or years.

10 Q. Understood. You don't specifically
11 report microgram per liter months of exposure for
12 the plaintiffs; true?

13 A. I don't report that, but it's in my
14 calculation.

15 Q. Or micrograms per liter years; correct?

16 A. Again, I don't report that, but it's in
17 my calculation. You can back that out of my risk
18 calculation.

19 Q. But you didn't do that, did you?

20 MS. ELLISON: Object to the form.

21 THE WITNESS: It was not something I
22 needed to do for my risk evaluation because I
23 wanted to compare to toxicity values from EPA that
24 are reported in milligram per kilogram day or risk
25 per milligram per kilogram day.

1 BY MR. SNIDOW:

2 Q. Are you capable of doing those
3 calculations?

4 A. Yes.

5 Q. You're capable of expressing an area
6 under the curve pretty easily; true?

7 A. Yes. I'm capable of calculating the
8 microgram per liter month concentration.

9 Q. You calculated average daily exposure;
10 true?

11 A. Yes.

12 Q. Did you do any calculation of total
13 cumulative exposure for ingestion?

14 A. Are we talking ingestion or inhalation?

15 Q. Ingestion.

16 A. I did -- the cumulative part of the
17 calculation is in my risk calculation. It's part
18 of my risk calculation. So the days, years are in
19 there. So I don't report the cumulative values
20 the same way that you're asking, the microgram per
21 liter month, but it's part of my calculation.

22 Q. But you don't report the total
23 cumulative exposure for ingestion, do you?

24 A. I didn't report that because I didn't
25 need that for my risk calculations. But again,

1 it's within my calculation. But that's not an
2 endpoint for my calculation because that's not
3 useful for comparison to toxicity values that EPA
4 provides.

5 Q. You're aware that ATSDR says that
6 there's sufficient evidence that TCE at Camp
7 Lejeune causes bladder cancer; true?

8 A. That is what they conclude in their
9 public health assessment.

10 Q. And you disagree with that?

11 A. I relied on Dr. Goodman's report in
12 addition to EPA's reports, IARC for conclusions on
13 PCE.

14 Q. You know that IARC classifies PCE as a
15 possible carcinogen; right?

16 A. Yes.

17 Q. You know that's based on bladder cancer
18 epidemiology; right?

19 A. I would want to look at the IARC
20 monograph for PCE, but I believe that there is
21 some uncertainties with the bladder cancer
22 studies, the epidemiology bladder cancer studies
23 that EPA and IARC both talk about in their
24 evaluations.

25 Q. But ATSDR says there's sufficient

1 evidence for causation for PCE and bladder cancer;
2 right?

3 MS. ELLISON: Object to the form.

4 THE WITNESS: ATSDR does make that
5 conclusion in their public health assessment.

6 BY MR. SNIDOW:

7 Q. Dr. Goodman disagrees; right?

8 A. Dr. Goodman's conclusions are that
9 there's not enough evidence for an association.

10 Q. And you went with Dr. Goodman over
11 ATSDR; right?

12 MS. ELLISON: Object to the form.

13 THE WITNESS: I looked at Dr. Goodman's
14 report. I looked at EPA's report and IARC. So I
15 considered all of that information.

16 BY MR. SNIDOW:

17 Q. So just out of curiosity what did you do
18 to determine Dr. Goodman was correct about this
19 over ATSDR?

20 MS. ELLISON: Object to the form.

21 THE WITNESS: Well, again, I am
22 confident in Dr. Goodman's methodology. She
23 considers many epidemiology studies, animal
24 studies, the reliability of those studies. So I
25 don't have any reason to disagree with her

1 conclusion.

2 But then I also looked at EPA's
3 conclusion for PCE and bladder cancer and IARC's
4 conclusion for PCE and bladder cancer, and they
5 are not conclusive that there is a causal
6 association for PCE and bladder cancer.

7 BY MR. SNIDOW:

8 Q. Did you review the PCE and bladder
9 cancer literature yourself?

10 A. That was not what I was asked to do for
11 my evaluation. But I needed to understand
12 Dr. Goodman's conclusion based on methodology I
13 agree with and Agency conclusions.

14 Q. So that's a no, you didn't consider the
15 PCE and bladder cancer epidemiology?

16 MR. SNIDOW: Object to the form.

17 THE WITNESS: I looked at the PCE
18 epidemiology studies that are relevant to my
19 Section 8.

20 BY MR. SNIDOW:

21 Q. Okay. So let's do that. Let's look at
22 Section 8. Am I correct in Section 8.2 on page 43
23 you cite precisely one study looking at PCE and
24 bladder cancer?

25 A. It is one study that reported inhalation

1 concentrations of PCE, an occupational study, and
2 also looked at incidence of bladder cancer in that
3 population.

4 Q. So I assume that's the only study that
5 that's ever looked at PCE and bladder cancer?

6 A. I looked at any study that had exposure
7 information, and this is the one epidemiology
8 study that had exposure information and looked
9 specifically at bladder cancer in humans.

10 Q. Did you review any other studies looking
11 at PCE and bladder cancer?

12 A. If I had, I would have cited it here.

13 Q. And there aren't any others; correct?

14 A. That's correct. This was the one study
15 that had exposure information. If there were more
16 than one, I would have considered it.

17 Q. So before deciding to agree with
18 Dr. Goodman over ATSDR, you reviewed one study on
19 the relationship between PCE and bladder cancer?

20 MS. ELLISON: Object to the form.

21 THE WITNESS: So again, I rely on
22 Dr. Goodman's report because I agree with her
23 methodology. I don't have any reason to believe
24 that her conclusions are incorrect. And it's not
25 inconsistent with EPA's conclusions and IARC's

1 conclusions.

2 BY MR. SNIDOW:

3 Q. The only reason I entered this, I asked
4 you if you did any independent evaluation of this,
5 and you said you did.

6 I'm just asking: Did you do anything
7 besides read the Hadkhale 2017 study to
8 independently verify that Dr. Goodman's conclusion
9 was correct?

10 MS. ELLISON: Object to the form.

11 THE WITNESS: I specifically said that I
12 reviewed the studies in Section 8, which is what I
13 did and what I confirmed with your later
14 questions.

15 BY MR. SNIDOW:

16 Q. You agree there's one study cited there?

17 A. There's one study that looked at
18 exposure information, and that's why I looked at
19 it. If there were more, I would have cited it
20 here.

21 Q. I assume when we look at Hadkhale 2017,
22 it's going to show evidence that PCE does not
23 cause bladder cancer?

24 A. I'm would want to look at that study to
25 see exactly what the conclusion was, although I

1 can probably read it here.

2 Hadkhale reported no significant
3 associations and no trends between bladder cancer
4 and PCE occupational exposure to PCE inhalation
5 exposure at concentrations as high as 87.55 PPM
6 years. So that's what Hadkhale -- that summarizes
7 the information from Hadkhale for PCE.

8 Q. You are an epidemiologist, yes?

9 A. I review epidemiology studies often for
10 my human health risk assessments.

11 Q. You do not hold yourself out as an
12 epidemiologist?

13 A. Epidemiology is something I have to look
14 at all the time. I don't have a degree in
15 epidemiology, but I look at epidemiology often in
16 my work.

17 Q. When you are speaking to other
18 scientists, do you describe yourself as an
19 epidemiologist?

20 A. I describe myself as a toxicologist,
21 human health risk assessor.

22 Q. So no, not an epidemiologist?

23 A. I don't use the word epidemiologist, but
24 I certainly need to consider epidemiology in my
25 evaluations.

1 Q. Do you consider yourself an expert in
2 epidemiology?

3 A. I have to review epidemiology for many
4 of the evaluations that I do.

5 Q. So you know how to read it. You know
6 the basic principles; true?

7 A. Correct.

8 Q. So to be a confounder, you agree that a
9 variable needs to be correlated both with the
10 relevant exposure and the outcome of interest?

11 A. So confounding is not something that I
12 talk about in my report. But I generally
13 understand what confounding is because I have to
14 consider it for my evaluations.

15 Q. So is what I said correct?

16 A. Can you repeat it?

17 Q. Yeah. To be a confounder, a variable
18 needs to be correlated both with the relevant
19 exposure and the outcome of interest.

20 A. That's generally how we talk about
21 confounding.

22 Q. It's not enough for it just to be
23 correlated with the outcome of interest; true?

24 A. This is not something that I talked
25 about in my report. I would want to look at

1 Dr. Goodman's general discussion of epidemiology
2 before I -- and discussion of confounders before I
3 agree to that.

4 (Bailey Exhibit 8 was marked.)

5 BY MR. SNIDOW:

6 Q. I'll mark this as Exhibit 8. I'm going
7 to draw a diagram for you here. Exposure. Other
8 variable.

9 I'm showing you Exhibit 8. What I'm
10 trying to describe here is in a situation where
11 the exposure is correlated with another variable,
12 that in turn is correlated with the outcome,
13 that's a confounding situation; correct?

14 A. Yes.

15 (Bailey Exhibit 9 was marked.)

16 BY MR. SNIDOW:

17 Q. I'll mark this as Exhibit 9. What I'm
18 trying to describe here is a situation where the
19 exposure is not correlated with the other variable
20 or the other variable is correlated with the
21 outcome of interest, that is not a confounding
22 situation; true?

23 A. In the general sense, yes. I would
24 probably need specific...

25 Q. Of course. But that's generally

1 correct?

2 A. Yeah. I mean, that's very simple, but
3 yes.

4 Q. So do you know what the risk factors are
5 for Parkinson's disease?

6 A. That's not something that I discussed in
7 my report, so it's not something that I can opine
8 on.

9 Q. Do you agree that knowing what the risk
10 factors are for a certain disease would be helpful
11 in determining if there's potential for
12 confounding?

13 A. What I was asked to do was to look at
14 whether the exposures to the individual chemicals
15 at the site were potentially related to the
16 plaintiffs' health effect. That's what I did.

17 I did not consider risk factors,
18 potential confounding. That is something that
19 you'd want to think about in a specific causation
20 analysis. But my part of the specific causation
21 analysis was just the risk calculations and
22 whether the exposure information could have led to
23 health effects.

24 Q. Do you know what nondifferential
25 exposure misclassification is?

1 A. I have heard of that. It's not
2 something that I had to think about for my report.

3 Q. Do you agree that it will bias results
4 in a study toward the null?

5 A. My understanding is that depending on
6 how the results are reported, it can bias toward
7 or away from the null. That's true.

8 Q. How about for a dichotomous exposure and
9 dichotomous outcome, do you agree that
10 nondifferential exposure misclassification will
11 produce bias toward the null in that situation?

12 A. When there's individual exposure groups,
13 it can -- it may bias toward or away from the
14 null.

15 Q. You know what the term dichotomous is;
16 right?

17 A. So that would be like an ever versus
18 never.

19 Q. Yep.

20 A. Often that is considered -- well, I'm
21 not going to answer that because that's not
22 something that I am familiar enough about to
23 answer, to opine on here. It was not part of my
24 evaluation.

25 Q. You do know though what bias toward the

1 null is; true?

2 A. Yes.

3 Q. That means that the result will be
4 dampened?

5 A. There's a potential that the result is,
6 yes, lower.

7 Q. Moving lower, yes. It will make an epi
8 result appear weaker than it is in reality; true?

9 MS. ELLISON: Object to the form.

10 THE WITNESS: That's generally what bias
11 towards the null means, that term, yes.

12 BY MR. SNIDOW:

13 Q. In doing a risk assessment, do you agree
14 the ultimate output is increased probability of a
15 certain disease?

16 A. The output is what the risk might be,
17 the calculated theoretical risk might be for a
18 population exposed, everyone exposed the same way.
19 And the risk calculation is what the risk
20 calculation is based on exposure information. And
21 then you determine whether that's potentially a
22 problem.

23 Q. I'm just asking about units. It's
24 expressed in units such as a theoretical one extra
25 cancer in a population of a million; true?

1 MS. ELLISON: Object to the form.

2 THE WITNESS: Yes. It can be reported
3 that way.

4 BY MR. SNIDOW:

5 Q. Or one in a thousand, whatever it is;
6 correct?

7 A. Right.

8 Q. My question is though: It's not a --
9 you know what relative risk is; right?

10 A. Yes.

11 MS. ELLISON: Object to the form.

12 BY MR. SNIDOW:

13 Q. Risk assessments don't produce relative
14 risks?

15 A. Correct. It's a different type of risk
16 calculation.

17 Q. Epidemiology sometimes produces relative
18 risks; true?

19 A. Correct.

20 Q. But the risk assessment is going to
21 produce theoretical risk in absolute terms;
22 correct?

23 A. It's the calculation that's based on
24 exposure information for the plaintiff, and it's
25 based on epidemiology studies that do report

1 relative risks. So they are connected.

2 Q. I get they're connected. I'm just
3 talking the ultimate output.

4 The ultimate output is going to be in
5 absolute terms; correct?

6 MS. ELLISON: Object to the form.

7 THE WITNESS: I don't know what you mean
8 by absolute terms.

9 BY MR. SNIDOW:

10 Q. Like one in a thousand, one in a
11 million.

12 A. That is what the calculation comes out
13 to be, yes, but you have to interpret that number
14 with other information.

15 Q. So how big does that number need be for
16 you to look at it and say that's big enough to say
17 that there's causation in this individual case?

18 A. Well, you wouldn't look at just the risk
19 calculation by itself, but if the risk calculation
20 comes out to be something well above ten to the
21 minus four, you would -- you would want to
22 understand the exposure information better. And
23 you'd want to understand whether you made
24 conservative assumptions about the exposure
25 information. And often that is the case. And

1 then you'd want to potentially think about whether
2 that's a realistic exposure.

3 So if something is within ten to the
4 minus six, ten to the minus four, that's
5 considered a target risk range for EPA, not very
6 much of a concern. Above that, you would want to
7 think about the very conservative exposure
8 estimates that went into the calculation and think
9 about whether you might want to adjust some of
10 those.

11 Q. Maybe I'll try to make this concrete.
12 In your report, for all 25 plaintiffs you conclude
13 that your risk assessments make you confident that
14 there's not causation; right?

15 A. So my risk calculations provide
16 perspective on the exposure information estimated
17 for a plaintiff.

18 Q. What ten to the minus would make you
19 find causation or be concerned about causation?

20 MS. ELLISON: Object to the form.

21 THE WITNESS: It would not be just that
22 calculation.

23 BY MR. SNIDOW:

24 Q. I understand it wouldn't be.

25 MS. ELLISON: One second. Sorry. The

1 court reporter -- can we all just slow down a
2 little bit.

3 MR. SNIDOW: Sorry.

4 BY MR. SNIDOW:

5 Q. Let me say I get it that you did a risk
6 assessment; correct? You did a margin of exposure
7 analysis; correct?

8 A. Um-hum.

9 Q. Did I miss anything else?

10 A. Comparison of epidemiology.

11 Q. Right. That's kind of baked into your
12 margin of exposure, isn't it?

13 A. No, because the margin of exposure is
14 specific to the toxicity value point of departure.
15 The epidemiology section considers the endpoint of
16 concern and compares the exposure in those studies
17 that are for the endpoint that we're talking
18 about.

19 Q. Did I miss anything besides those three
20 things?

21 A. Those are the three things that I
22 considered for my exposure evaluation, which is
23 only part of a specific causation analysis.

24 Q. For your exposure evaluation, the
25 calculated risk was ten to the minus one, so

1 10 percent.

2 Would that raise concerns for you?

3 A. Well, that's a hypothetical question.
4 That's not a risk I calculated for any of the
5 plaintiffs. So the plaintiffs' risks were well
6 below that. So in your hypothetical example, that
7 would be something that could be considered high.

8 Q. How about ten to the minus two?

9 A. That's well above ten to the minus four,
10 so again hypothetical. Not something I calculated
11 for any of these plaintiffs. But in the
12 hypothetical example, that would be considered
13 high. But you'd also want to consider other
14 information because it's a conservative estimate
15 of risk.

16 Q. Ten to the minus three, would that be
17 concerning?

18 A. It's getting closer to the ten to the
19 minus four. Again, you have to think about -- at
20 that point, you'd probably not need to be careful
21 and think about the exposure assumptions that
22 you're considering and whether they're very
23 conservative or not.

24 Q. Then at ten to minus four, no concern?

25 A. At ten to the minus four, I don't think

1 there's a concern because that's a conservative
2 estimate of risk based on EPA's exposure
3 assumptions and very conservative toxicity values,
4 particularly if you're using a linear no threshold
5 approach, which is what we do for risk
6 calculations. And that's a very conservative
7 approach.

8 So my opinion is it is not. It's very
9 low compared to 40 percent in cancer risk in the
10 population. A ten to the minus four is
11 .01 percent. So it's very low.

12 Q. Have you ever seen a published risk
13 assessment performed to calculate an individual
14 person's chance of getting a disease?

15 A. I believe you asked me that earlier, and
16 I said I've not seen publications that reports
17 that. It's not typically in the published
18 literature. But I have seen those evaluations.

19 Q. Done by Gradient?

20 A. Some of them done by Gradient, yes.

21 Q. Anyone else?

22 A. I don't usually look at expert reports
23 for other companies.

24 Q. So sitting here today, can you think of
25 anyone other than Gradient who's ever done a risk

1 assessment to calculate an individual person's
2 risk of getting a disease?

3 A. As I sit here today, I can't recall one,
4 but it's certainly something that is done often in
5 specific causation evaluations where you want to
6 get a sense of what the exposure is. It's very
7 useful.

8 Q. Where have you seen it done?

9 MS. ELLISON: Object to the form.

10 THE WITNESS: It doesn't matter whether
11 I've seen it done or not.

12 BY MR. SNIDOW:

13 Q. That's what I'm asking you.

14 A. I know that it's an evaluation that's
15 useful because it provides information. It
16 provides perspective on what the exposure
17 estimates are for an individual and how that
18 compares to what considers EPA considers safe. So
19 I don't need to see it anywhere else. I know from
20 my experience that it's useful.

21 Q. That's fair. I'm just asking. You said
22 you know it's not in place.

23 Have you ever seen it done by anyone
24 except Gradient?

25 MS. ELLISON: Object to the form.

1 THE WITNESS: I don't think it's
2 relevant to my evaluation because I know it's an
3 important part of the question --

4 BY MR. SNIDOW:

5 Q. Is that a "no"?

6 A. -- regarding exposure.

7 Q. Is that no, you've never seen it done?

8 MS. ELLISON: Object to the form.

9 THE WITNESS: I know it's an important
10 part of my evaluation. I have not seen other
11 expert reports outside of Gradient, but that
12 doesn't mean it's not a useful evaluation.

13 BY MR. SNIDOW:

14 Q. Dr. Bailey, I appreciate you're trying
15 to answer my question. I do think I'm asking it
16 pretty concretely.

17 My question is: Besides Gradient, have
18 you ever anywhere, anywhere seen a risk assessment
19 performed to calculate the individual person's
20 risk of getting a disease?

21 MS. ELLISON: Same objection.

22 THE WITNESS: I have not seen a specific
23 evaluation, but that doesn't mean it's not a
24 useful evaluation. I don't know where I would
25 have the opportunity to.

1 BY MR. SNIDOW:

2 Q. Have you ever seen anyone other than
3 Gradient use a risk assessment to disprove
4 causation?

5 A. Again, I've only worked on Gradient
6 expert reports where we have done that kind of
7 evaluation, and these are reasonable approaches
8 for expert reports. So I have not seen other
9 reports, but that doesn't mean they don't exist.
10 It just means I haven't seen them. I don't know
11 how I would have an opportunity to see them.

12 Q. So the answer is no, sitting here today,
13 you can't point to anyone other than Gradient
14 who's ever done a risk assessment to disprove
15 causation?

16 MS. ELLISON: Object to the form.

17 THE WITNESS: Again, doing a risk
18 assessment -- doing a risk assessment for
19 causation is a very reasonable approach to
20 providing perspective on exposure. I would not
21 have an opportunity to see whether other experts
22 did that type of evaluation. So I can't answer
23 that question.

24 But I know from my experience and my
25 expertise that it is reasonable, provides

1 perspective on what the exposures are.

2 MR. SNIDOW: Move to strike.

3 Nonresponsive.

4 BY MR. SNIDOW:

5 Q. My question is: Have you ever seen it
6 done? Have you seen it, or have you not seen it?

7 MS. ELLISON: Object to the form.

8 THE WITNESS: I've seen it done in
9 Gradient expert reports. I have not seen it done
10 in other expert reports because I have not seen
11 those reports.

12 BY MR. SNIDOW:

13 Q. Or anywhere else. You've just never
14 seen it anywhere in the world, peer-reviewed
15 literature, expert reports, website, anyone other
16 than Gradient ever done an individual risk
17 assessment to calculate an individual's risk of
18 getting a disease, have you?

19 MS. ELLISON: Object to the form.

20 THE WITNESS: Individual risk
21 assessments are not published typically. They're
22 typically done for litigation, and the reports
23 that I've looked at at Gradient, I have seen it.
24 I have not seen other reports.

25 So I have not seen it, but it doesn't

1 mean it doesn't exist. I just haven't seen it in
2 other expert reports, and it wouldn't be something
3 published in the literature. So the answer is no,
4 but there's a good reason why.

5 BY MR. SNIDOW:

6 Q. The answer is no, never seen it done
7 outside of Gradient; correct?

8 MS. ELLISON: Object to the form.

9 THE WITNESS: Correct, but there's a
10 good reason why. I think I explained it.

11 BY MR. SNIDOW:

12 Q. Did you calculate the relative risk
13 ratios for exposure to any of the chemicals in any
14 of the diseases?

15 A. That's not how you view a risk
16 evaluation for an individual. You would want to
17 look at the individual exposure information and
18 calculate a risk based on that exposure
19 information and EPA's toxicity values. Relative
20 risks are done for populations in epidemiology
21 studies, not for an individual.

22 Q. You say that's now you do it. How did
23 you learn to do an individual risk assessment to
24 determine an individual's risk of getting a
25 disease?

1 A. I've been doing risk assessments for 25
2 years. So I know how to do risk assessments.

3 Q. For an individual, like where do I go?
4 You said that's not how it's done. Where do I go
5 to see how it's done?

6 A. I think it's fairly straightforward.
7 The risk assessments that are done for population,
8 you use exposure information based on what might
9 be the most sensitive individual in that
10 population. When you do something for an
11 individual, you look specifically at exposure
12 information for that individual, when they were
13 exposed and the specific timeframe and activities.

14 So it's logical that you would want to
15 use exposure parameters specific to an individual
16 to do an individual risk calculation.

17 Q. Did you calculate relative risk ratios
18 for any of the disease and chemical combinations
19 at issue here?

20 A. I did not do relative risk. I did risk
21 calculations based on EPA's approach.

22 Q. Dr. Bailey, your view, correct me if I'm
23 wrong, is that there is a threshold dose for
24 carcinogens?

25 A. I think that there is likely a threshold

1 for many carcinogens because of repair mechanisms
2 and detoxification mechanisms that we have in our
3 bodies to deal with chemicals.

4 Q. So is that, yeah, you think there's a
5 threshold dose for carcinogens?

6 A. I think that it is possible, yes, that
7 there is a threshold dose for carcinogens because
8 of the mechanisms that we have in our bodies to
9 deal with toxic exposures.

10 Q. What's the threshold dose for TCE and
11 kidney cancer?

12 A. So in my report, I talk about how a
13 threshold is very likely. It's biologically
14 plausible because we have these mechanisms in our
15 bodies to deal with chemical exposures,
16 detoxification, DNA repair mechanisms.

17 It's very difficult to determine what
18 that level is. And so EPA, because it's very
19 difficult to determine those thresholds, uses the
20 linear no threshold approach. But what my point
21 is is that because it's very likely that there is
22 a threshold, as you get down to very low
23 concentrations, that linear no threshold approach
24 is a conservative estimate because you're now --
25 you're drawing a line below what the threshold --

1 it's very difficult to know what that threshold
2 is, which is why EPA use the linear no threshold
3 extrapolation, and I agree with that.

4 But it doesn't mean that that threshold
5 doesn't exist. It likely does. It's biologically
6 plausible, and that's my point in my report.

7 Q. So what's the threshold dose for TCE and
8 kidney cancer?

9 A. I don't know.

10 Q. How about TCE and NHL?

11 A. I don't know, but I didn't use a
12 threshold for my calculations.

13 Q. Fair enough. How about TCE and
14 leukemia?

15 A. As I said, it's difficult to determine
16 what those thresholds are, but they likely exist.
17 It just makes sense. Biologically plausible that
18 you're going to have some level of repair or
19 detoxification that happens.

20 And then once those systems are
21 overwhelmed, then you start to see an increase.
22 But that's where the threshold is. And what that
23 is for each chemical is not easy to determine, but
24 they're biologically plausible.

25 Q. Well, in your report, you're actually a

1 little stronger; right? You say that it's not
2 biologically plausible for there to be a
3 threshold; right?

4 A. I'm saying it's not biologically
5 plausible for their -- get the language here.

6 Q. Page 20. Because before you were
7 telling me you think it's biologically plausible
8 that there is a threshold; right?

9 A. Yes.

10 Q. But in your report, you actually say it
11 the other way. You see in the middle of the
12 paragraph, page 20, "And, therefore"?

13 A. Yes.

14 Q. You say, "It's not biologically
15 plausible that there's no threshold."

16 A. Let me read this. I'm saying that the
17 concept that there's no threshold below which
18 increased cancer risk is unlikely is not
19 biologically plausible. So the concept that
20 there's no threshold is not biologically
21 plausible. In other words, the concept that there
22 is a threshold is biologically plausible.

23 Q. I know. But you're saying because that
24 there's not one, it's not even biologically
25 plausible; right?

1 A. Yes, because of DNA repair mechanisms
2 and detoxification mechanisms that exist in the
3 body.

4 Q. So what authority says it's not even
5 biologically plausible to believe that carcinogens
6 don't have a threshold dose?

7 A. So I'm not basing it on an authority.
8 I'm basing it on my understanding of the science.
9 I have a lot of years of experience before I even
10 started in consulting understanding the mechanisms
11 of DNA damage repair, mutagenesis. And it's just
12 not biologically plausible from my understanding
13 of the science to not have -- to not have a
14 threshold.

15 (Bailey Exhibit 10 was marked.)

16 BY MR. SNIDOW:

17 Q. I'm going to show you a document that
18 I'll mark Exhibit 10. So this is the Federal
19 Reference Manual on Scientific Evidence, Third
20 Edition.

21 Have you ever seen this before?

22 A. I might have. I don't recall.

23 Q. If you could go to page 670.

24 MS. ELLISON: I'll just note for the
25 record that pages 651 through 656 are missing, so

1 it's not the complete chapter.

2 MR. SNIDOW: I'm going to do excerpts
3 for stuff. If there is -- actually, I should say
4 this.

5 BY MR. SNIDOW:

6 Q. Dr. Bailey, I'm showing you an excerpt
7 here. If there's material from this or basically
8 any other large document that we've excerpted that
9 you want to read, let me know. I'll have Raleigh
10 print it and you can take a look on a break.
11 We've been killing a lot of trees. I'm trying to
12 cut down on that a little bit. I think though on
13 this one, you might not, but --

14 MS. ELLISON: And, J.J., for the record,
15 can you note when one of the reports or papers is
16 incomplete just so that Dr. Bailey and I are both
17 aware that it's an incomplete document for the
18 record?

19 MR. SNIDOW: Of course.

20 MS. ELLISON: Thank you.

21 BY MR. SNIDOW:

22 Q. Do you see at the top of page 670 it's
23 talking about NOEL levels?

24 A. I see that.

25 Q. You know what that is; right?

1 A. Yes.

2 Q. No effect level?

3 A. Yes.

4 Q. It says, "This analysis does not apply
5 to substances that exert toxicity by causing
6 mutations leading to cancer. Theoretically, any
7 exposure at all to mutagens may increase the risk
8 of cancer, although the risk may be very slight
9 and not achieve medical probability." Correct?

10 A. That's what it says, yes.

11 Q. I assume that you disagree with that?

12 A. I don't have the rest of the paragraph
13 here.

14 Q. Go to the previous page.

15 A. The previous page is 657.

16 Q. Do you want to see it?

17 A. Sure.

18 Q. Put this one aside.

19 MR. SNIDOW: Raleigh, if you wouldn't
20 mind printing -- just print this entire chapter
21 from the reference manual.

22 MS. GRAVES: What chapter is that?

23 MR. SNIDOW: It begins on page 633.

24 BY MR. SNIDOW:

25 Q. We'll take a look at this in a second.

1 But suffice it to say you don't agree
2 that any exposure at all to mutagens may increase
3 the risk of cancer, do you?

4 A. So from a public health perspective, EPA
5 does calculate a risk all the way down to zero
6 using their linear no threshold approach. What is
7 the year of this report?

8 Q. Dr. Bailey, I'll give you the full copy.
9 In your report, you say that the concept of the no
10 threshold dose for carcinogens is not even
11 biologically plausible; correct?

12 A. Correct.

13 Q. This is saying the opposite; right?

14 MS. ELLISON: Objection. She's asked to
15 see the full document. Until she has time to
16 review it, I don't think these questions are
17 appropriate.

18 (Bailey Exhibit 11 was marked.)

19 BY MR. SNIDOW:

20 Q. Let's do another one. I'll show you a
21 document that I'll mark as Exhibit 11. This is
22 from ATSDR. You see this is from their -- this is
23 from the Public Health Guidance Manual.

24 If you could turn to page 8, do you see
25 in the middle of the paragraph it says, "ATSDR

1 does not have an acceptable cancer risk range"?

2 A. That's what it says.

3 Q. Do you see where it says, "Health
4 assessors should avoid using phrases such as
5 within the acceptable cancer risk range"?

6 A. It does say that. This is in the
7 context of a public health assessment where you're
8 talking about health of the community. So it's
9 not a general guideline for individual risk
10 assessments. It's a guideline for public
11 assessments.

12 Q. Remember earlier when I asked how you
13 figured out how to do individual risk assessments
14 and you said, well, just look at how you do it for
15 populations?

16 MS. ELLISON: Object to the form.

17 BY MR. SNIDOW:

18 Q. That was your testimony, wasn't it?

19 A. It is a similar calculation, yes.

20 Q. Do you agree this is about how to do it
21 for populations; right?

22 A. This is about populations, yes,
23 conservative estimates for individuals in those
24 populations.

25 Q. It says, "Avoid using phrases such as

1 within the acceptable cancer risk range." Right?

2 A. It does say that for a population
3 because you need to understand individuals, all
4 the individuals in that population. Although it
5 is a conservative estimate, I think you would want
6 to be careful to have that type of conclusion in a
7 public health assessment for a community. That's
8 different. That's a health decision.

9 For individual risk assessments where
10 you're looking at individual exposure information,
11 that's a different type of evaluation where you're
12 a looking specifically at an individual, what
13 their exposures might have been, how much water
14 they might have ingested, based on their own
15 discussions about that. So that's different.

16 The public health assessment looks at a
17 community where everyone is exposed similarly for
18 sensitive individuals in the population and where
19 the exposure assumptions are very conservative.
20 It might not apply to an individual. I think this
21 statement is because the risks that come out of
22 these calculations for a community are overly
23 conservative. So you wouldn't want to make that
24 general statement for a community.

25 Q. You're going to have to break that down

1 for me. You said these estimates are
2 conservative; true?

3 A. Yes. They are typically conservative.

4 Q. Let's just be clear what that means.
5 That means when you're doing risk assessments for
6 a population, it's going to give you, if anything,
7 an overly high estimate of the risk; correct?

8 A. Yes.

9 Q. ATSDR says don't call any of these
10 numbers the acceptable cancer risk range when
11 you're doing it for a population; correct?

12 A. That's what they're saying for a public
13 health assessment, yes.

14 Q. Why does it matter -- why does that
15 change if you're doing a risk assessment for an
16 individual?

17 A. I think you want to -- for an individual
18 you're looking specifically at the exposure
19 information for that individual. And so you're
20 sort of looking at a more refined risk calculation
21 for that individual. So that's how it's
22 different.

23 Q. Can you point me to any peer-reviewed
24 publication that says that when you're talking
25 about an individual risk assessment, it's okay to

1 talk about acceptable cancer risk?

2 A. It doesn't have to be in peer-reviewed
3 literature for me to from my own background and
4 expertise know that that's reasonable. This is a
5 range that EPA considers acceptable and often will
6 regulate to ten to the minus four.

7 So in my mind, because EPA -- in my
8 expertise and from my experience, EPA has
9 determined that that's a cancer risk that's
10 considered within their target range and
11 acceptable, that that would provide perspective
12 about an individual exposure if that risk falls
13 below ten to the minus four or at ten to the minus
14 four for an individual and you have exposure
15 information for that individual, specific to that
16 individual that provides perspective and can
17 demonstrate that exposures for that individual are
18 low.

19 MR. SNIDOW: Move to strike.
20 Nonresponsive. Let me ask it again.

21 BY MR. SNIDOW:

22 Q. Is there any peer-reviewed literature
23 that says when you're doing individual risk
24 assessments, you're allowed to talk about
25 acceptable cancer risk ranges?

1 A. There's no peer-reviewed literature that
2 says that, but it's logical.

3 Q. Can you point to me any document outside
4 of Gradient that says that you should use that
5 kind of language when doing an individual risk
6 assessment?

7 A. Well, as an expert in the field and as
8 an expert in health risk assessment and
9 toxicology, I know that it's a reasonable
10 approach. I don't need to find an article that
11 says that it is. It's logical scientifically, my
12 perspective.

13 Q. Any authority you can point to?

14 MS. ELLISON: Object to the form.

15 THE WITNESS: I don't think an authority
16 on my evaluation is relevant. I think my
17 expertise in human health risk assessment is
18 what's relevant.

19 BY MR. SNIDOW:

20 Q. Let's to go Tab --

21 MS. ELLISON: J.J., I don't know if
22 you're in the middle of a topic, but just flagging
23 that it's been about ten over the hour.

24 MR. SNIDOW: Yeah. Break now is good.

25 THE VIDEOGRAPHER: Off the record at

1 12:11.

2 (Recess from 12:11 p.m. to 12:33 p.m.)

3 THE VIDEOGRAPHER: Back on the record at
4 12:33.

5 (Bailey Exhibit 12 was marked.)

6 BY MR. SNIDOW:

7 Q. Dr. Bailey, I'm going to show you a
8 document that I'll mark as Exhibit 12. These are
9 EPA's Guidelines for Carcinogen Risk Assessment.
10 It's an excerpt. You've seen this document
11 before?

12 A. I have.

13 Q. If you look on the back page, which is
14 3-24, do you see where it says, "For effects other
15 than cancer, reference values have been described
16 as being based on the assumption of biological
17 thresholds"?

18 A. I see that.

19 Q. That's referring to the fact that for
20 cancer, the reference values are based on the
21 assumption that there is a threshold?

22 A. For cancer, there's an assumption
23 threshold that there's not a threshold.

24 Q. For cancer, there's the assumption that
25 there's not a threshold?

1 A. Yes.

2 Q. You think that assumption is
3 biologically not plausible?

4 A. I think it's biologically not plausible;
5 correct?

6 MS. ELLISON: J.J., just to confirm,
7 this is actually 3.3.4. I'll just note for the
8 record the entirety of Section 3.3.4 is not here.

9 MR. SNIDOW: Yep.

10 BY MR. SNIDOW:

11 Q. Then it says, "The agency's more current
12 guidelines for these effects...do not use the
13 assumption, citing difficulty of empirically
14 distinguishing a true threshold from a
15 dose-response curve that's nonlinear at low
16 doses."

17 Did I read that correctly?

18 A. That's correct.

19 Q. What that is saying is even for
20 noncancer, the EPA is moving away from assuming a
21 threshold; correct?

22 A. Let me read this. I don't think that's
23 what it says. I think it just says that it's
24 difficult to empirically distinguish a true
25 threshold dose-response curve nonlinear at low

1 doses.

2 Q. Do you see where it says, "The more
3 current guidelines do not use this assumption"?

4 A. The current guidelines for non -- for
5 other effects other than cancer do use reference
6 values.

7 Q. Let's read it again. "For effects other
8 than cancer, reference values have been described
9 as being based on the assumption of biological
10 thresholds." Correct?

11 A. Right.

12 Q. So that's saying for noncancer effects,
13 we assume that there is a threshold; correct?

14 A. Correct.

15 Q. For those effects; correct?

16 A. Correct.

17 Q. Then it goes on to say the more current
18 guidelines for those effects do not use this
19 assumption; correct?

20 A. I would want to look at those guidelines
21 because they still use thresholds. They use
22 reference values for noncancer. So I don't know
23 what that means without looking at the reference
24 documents in that sentence.

25 Q. You can put that one aside. While he's

1 getting that, you testified earlier that it's
2 difficult to determine what the threshold is;
3 correct?

4 A. For carcinogens, yes.

5 Q. Why is that?

6 A. Because there are mechanisms that are
7 important for determining or sort of defining what
8 that threshold might be. And for some chemicals
9 we're still trying to understand those mechanisms.
10 And then we're often looking at that information
11 in animals and then extrapolating that to humans.
12 So there's a lot of information that goes into
13 understanding what the threshold might be. And so
14 they're difficult to determine empirically.

15 (Bailey Exhibit 13 was marked.)

16 BY MR. SNIDOW:

17 Q. Let me show you a document that I will
18 mark as Exhibit 13. This is from the National
19 Academy of Sciences, 1977. You agree the National
20 Academy of Medicine is a reputable organization?

21 A. Yes.

22 Q. Can you turn to page 54 in this excerpt.

23 MS. ELLISON: Just for the record, this
24 not a complete excerpt.
25

1 MR. SNIDOW: You're welcome to a
2 standing objection.

3 MS. ELLISON: Thank you.

4 MR. SNIDOW: You're welcome to note it.

5 MS. ELLISON: Appreciate it. I'll take
6 it.

7 BY MR. SNIDOW:

8 Q. Do you see in the middle of page it
9 says, "With respect to carcinogenesis, it seems
10 plausible at first thought it has often been
11 argued that threshold must exist below which even
12 the most toxic substance would be harmless"?

13 A. Yes.

14 Q. Then about three lines later, it says,
15 "There is no scientific basis for such estimations
16 of safe doses in connection with carcinogenesis."

17 A. That is what it says. It also says,
18 "Unfortunately, a threshold cannot be established
19 experimentally that is applicable to the total
20 population." And that's what I'm saying.

21 Q. Well, you're saying there is a threshold
22 or just that you can't estimate it?

23 A. That there is a threshold that's
24 difficult to estimate.

25

1 Q. You think -- do you have any authority
2 that says that, that there's a threshold for
3 genotoxic carcinogens?

4 A. I mean, in my expert opinion, so I am --
5 with my 25 years of experience, beyond that
6 actually, meaning grad school, I did a lot of work
7 on DNA damage repair mutagenesis. So there is
8 mechanisms that our bodies use to deal with
9 exposures at low concentrations and, that
10 information is clear in the science.

11 So just understanding what types of
12 mechanisms are involved in dealing with sort of
13 detoxification and DNA repair, that you would have
14 to be above those concentrations. The
15 concentrations sort of overwhelm those mechanisms.
16 That's where the threshold would be, and that
17 makes biological sense based on the science.

18 Q. Any peer-reviewed publications that you
19 can point to that says that genotoxic carcinogens
20 have a threshold?

21 A. Well, I do cite several articles in my
22 report that talk about the biological plausibility
23 of a threshold for carcinogens.

24 Q. It's one thing to say it's biologically
25 plausible that there is a threshold. It's another

1 thing to say, as you do, that it's not
2 biologically plausible to have a no threshold
3 theory; right? Those are different.

4 MS. ELLISON: Object to the form.

5 THE WITNESS: Can you repeat that?
6 Because I'm not sure that they're different.

7 BY MR. SNIDOW:

8 Q. In your report, you say -- you know what
9 the non-threshold model is; correct?

10 A. Yes.

11 Q. It's what the EPA uses.

12 A. A linear extrapolation.

13 Q. Yes. You think that that's not even
14 biologically plausible to do; correct?

15 A. I understand why EPA does it. It's a
16 public health decision that they have made. It's
17 not consistent with what's biologically plausible
18 in terms of science.

19 Q. I'm asking you: What peer-reviewed
20 publication says that?

21 MS. ELLISON: Object to the form.

22 THE WITNESS: I don't think I need a
23 peer-reviewed publication that specifically says
24 that. I know from my own expertise in the field
25 that it makes sense. It's biologically plausible

1 that there would be. And this -- what you just
2 put in front of me here says it seems plausible
3 that a threshold must exist below which even the
4 most toxic substances would be harmless.

5 Unfortunately, a threshold cannot be
6 established experimentally that is applicable to a
7 total population. So I feel like that sentence --
8 those two sentences sort of acknowledge that there
9 is one, but we just can't determine what it is,
10 which is exactly what I'm saying.

11 BY MR. SNIDOW:

12 Q. I'm just saying it sounds like no
13 peer-reviewed literature. Any other document that
14 I could point to that says, look, the idea that
15 there's not a threshold for genotoxic carcinogens,
16 that's just not biologically plausible?

17 MR. SNIDOW: Object to the form.

18 BY MR. SNIDOW:

19 Q. Anything, any authority.

20 A. I think that you can interpret some
21 discussions about thresholds and non-thresholds as
22 it being possible or that it is biologically
23 plausible that there isn't one, but we can't
24 determine what it is. So because of that, the
25 linear no threshold is the approach for public

1 health decisions.

2 Q. Any specific authority you can give me?

3 A. I think I answered the question that it
4 doesn't need to be specifically stated. I think
5 my understanding of the science and the way the
6 science is discussed in reports, Agency reports,
7 including the one you just put in front of me,
8 suggests that there is a threshold, but we just
9 can't determine what it is.

10 It's biologically -- of course, it's
11 biologically plausible that there would be. We
12 have ways to deal with chemicals in our body. And
13 once those mechanisms are saturated and no longer
14 functional, then that's where the threshold would
15 be. But it's not easy empirically to determine
16 what that is. It doesn't mean it doesn't exist.

17 (Bailey Exhibit 14 was marked.)

18 BY MR. SNIDOW:

19 Q. Let's do another one. Marking
20 Exhibit Bailey 14, which is an excerpt.

21 You're familiar with NIOSH?

22 A. Yes.

23 Q. Are they a pretty reputable
24 organization?

25 A. Yes.

1 Q. Can you go to the page that's marked 19.
2 Do you see where it says, "For carcinogen risk
3 assessment, NIOSH generally treats exposure
4 response as low-dose linear unless a nonlinear
5 mode of action is clearly established"?

6 Did I read that correctly?

7 A. Where is that?

8 Q. Second paragraph down. It begins, "For
9 carcinogen risk assessment..."

10 A. Yes. I see say that.

11 Q. You see the last sentence there, "In
12 general, whether the model forms are linear or
13 nonlinear, any nonzero exposure to a carcinogen is
14 expected to yield some excess risk of cancer."
15 Correct?

16 A. In that calculation, we're using a
17 linear low-dose extrapolation. You would
18 calculate a risk, but that didn't mean that
19 there's a risk of health effect. You then have to
20 look to see what that number is compared to what
21 EPA considers de minimis.

22 Q. It says whether it's linear or
23 nonlinear; correct?

24 A. It does say whether it's linear or
25 nonlinear.

1 Q. It says, "Any nonzero exposure to
2 carcinogens is expected to yield some excess risk
3 of cancer." Correct?

4 A. In the application of the nonlinear
5 threshold, that is how the calculation comes out.
6 I don't think that's saying that there's no
7 threshold. It's just saying that when you use a
8 linear no threshold approach, you're calculating a
9 risk even at very low concentrations. You could
10 be below the threshold. I think the two are
11 not -- the two are different.

12 So is it biologically plausible to not
13 have a threshold? I don't think it's biologically
14 plausible to not have a threshold. Does EPA use a
15 linear extrapolation and calculate risk above
16 zero? Yes, but that's a health decision because
17 we don't understand what's going on at very low
18 concentrations. So they're using a conservative
19 approach.

20 Q. You keep saying when you're doing a
21 linear model. Do you see where it says whether
22 it's linear or nonlinear?

23 A. Yes.

24 Q. So it's not just when you're doing a
25 linear model; correct?

1 MS. ELLISON: Object to the form.

2 THE WITNESS: I think there are other
3 shapes of the curve that can happen below a
4 threshold. So it may be super linear. So it may
5 be not a straight line. But the assumption is
6 that it's there in the straight line.

7 BY MR. SNIDOW:

8 Q. You think that there's a threshold dose
9 for TCE in cancer?

10 A. I have looked at the mechanisms of TCE,
11 and I believe that there is likely a threshold for
12 TCE carcinogenesis, but I don't know what it is.

13 Q. Put aside what it is. I know you can't
14 tell me that.

15 What's the best evidence you have that
16 there is a threshold for TCE?

17 A. I understand how TCE is metabolized.
18 And there are likely downstream metabolites that
19 are responsible for the carcinogenesis of TCE.
20 And I have an understanding of when those
21 metabolites are likely generated, and they're not
22 until higher exposure concentrations.

23 Q. So what are the metabolites of TCE?

24 A. I could not name them, off the top of my
25 head, but I do know that TCE is metabolized to

1 different -- many different types of metabolites,
2 particularly at higher exposure concentrations
3 when the detoxification mechanisms are not active.

4 Q. So like can you name one of these
5 metabolites that have convinced you that there is
6 a threshold for TCE?

7 A. Not off the top of my head. I'd have to
8 look at some of my evaluations on that.

9 Q. How about in your report?

10 A. I don't talk about that in my report.

11 Q. Walk me through it again. How does it
12 work? So you know that TCE has some unknown
13 metabolites; right? That's the first step.

14 A. There are known metabolites.

15 Q. It's got metabolites?

16 A. Yes.

17 Q. You don't know what they are?

18 A. I have written about them, and I've
19 looked at them. I just can't name them as I sit
20 here right now.

21 Q. Walk me through -- it's got metabolites.
22 How do I get from that to, well, there might be
23 some safe level of TCE?

24 MS. ELLISON: Object to the form.

25 THE WITNESS: So this is not something

1 that I talked about in my report, so I don't
2 want -- I'm not going to opine on the details of
3 my understanding of the threshold. But I do know
4 from looking at the science for TCE that there is
5 likely a threshold, and it's based on metabolism.
6 That's all I can say about that for now as I sit
7 here without looking in my analysis.

8 BY MR. SNIDOW:

9 Q. Well, can you give me any authority
10 saying that there is a threshold for TCE?

11 A. I don't know if there's an authority
12 that says that, but based on my review of the
13 science, I believe there is.

14 Q. So no authority saying TCE probably has
15 a threshold?

16 MS. ELLISON: Object to the form.

17 THE WITNESS: I consider myself an
18 authority on or an expert in the area of
19 evaluating TCE toxicity and mechanistic
20 information and risk assessment. So based on my
21 expertise.

22 (Bailey Exhibit 15 was marked.)

23 BY MR. SNIDOW:

24 Q. I'm going to show you a document that I
25 will mark as Exhibit 15. This is another excerpt.

1 This is from the European Chemicals Agency.

2 MS. ELLISON: I think you said this, but
3 just to make sure that the court reporter got it,
4 this is another excerpt, so not the entire
5 document that J.J. just handed the witness.

6 MR. SNIDOW: That's correct.

7 BY MR. SNIDOW:

8 Q. Could you turn to page 2. Do you see in
9 the kind of middle of the page there's a sentence
10 that begins "Trichloroethylene"?

11 A. Okay.

12 Q. Do you see where it says,
13 "Trichloroethylene is a non-threshold carcinogen"?

14 A. Yes.

15 Q. Do you disagree with that; right?

16 A. I do.

17 Q. Could you go to page 4. It says
18 Characterization of Risk.

19 A. Yes.

20 Q. It says, "Trichloroethylene is
21 considered to be a genotoxic carcinogen."

22 I think you agreed with that so far;
23 right?

24 A. Trichloroethylene is a carcinogen, and
25 its metabolites have been shown to be genotoxic.

1 Q. Then it says, "No threshold can be
2 determined below which exposure would be safe."
3 Right?

4 A. That is what this says. That's not what
5 I agree with.

6 Q. I know. You can put this one aside.
7 Did you review -- you're aware that the
8 EPA has banned TCE; right?

9 A. Under Tosca, it has banned TCE for
10 certain uses of TCE. Well, based on uses of TCE I
11 should say.

12 Q. I don't know what that means. You know
13 that EPA has banned TCE; correct?

14 MS. ELLISON: Object to the form.

15 THE WITNESS: In the Tosca rule, it's
16 banning TCE based on certain uses of the chemical,
17 and many of them are occupational uses.

18 BY MR. SNIDOW:

19 Q. Put aside what evidence was compiled in
20 support of the ban. I'm asking: The EPA banned
21 trichloroethylene entirely; true?

22 A. They banned the uses of TCE in
23 occupational settings. That's what they did.

24 (Bailey Exhibit 16 was marked.)
25

1 BY MR. SNIDOW:

2 Q. I'm going to show you a portion of
3 their -- an excerpt of their risk assessment,
4 which I'll mark as Exhibit 16.

5 Have you reviewed their risk evaluation
6 for TCE?

7 A. Yes.

8 Q. If you could turn to the bottom of page
9 237.

10 A. Okay.

11 Q. Do you see where it says Human Studies?

12 A. Yes.

13 Q. And it's talking TCE exposure and
14 neurogenerative disorders?

15 A. Yes.

16 Q. It cites the Bove 2014a, 2014b and
17 Goldman 2012?

18 A. Yes.

19 Q. You don't cite those in your report;
20 right?

21 A. They are likely on my MCL, but I did not
22 talk about them in -- I may have talked about -- I
23 may have referenced them in the context of some of
24 my rebuttals.

25 Q. So you think that you did reference the

1 Goldman 2012 study?

2 A. I'd have to look at my Parkinson's
3 disease reports to see if I did, but I have looked
4 at it for the rebuttals of the plaintiffs'
5 experts.

6 Q. You can put this one aside for now.
7 Do you have Exhibit 1 in front of you?

8 A. I can get it in front of me. I do.

9 Q. If you go to page 4, you quote the
10 background lifetime cancer risk for all cancers
11 combined at 40 percent.

12 A. Yes.

13 Q. And then do you see you state that one
14 times ten to the negative four is .0001 percent
15 probability?

16 A. Right.

17 Q. Then you add that to the 40 percent?

18 A. That is the way to think about it, yes.

19 Q. You are not taking into account the
20 specific background risk from for bladder cancer;
21 right?

22 A. Not in this calculation, but you could
23 do that.

24 Q. You did not?

25 A. I did not, but you could easily add that

1 low percent to whatever the risk is for bladder
2 cancer.

3 Q. Well, you'd also have to figure out what
4 the risk is for bladder cancer specifically;
5 right?

6 A. I think I have some discussion of that
7 in my report.

8 Q. You do. Am I correct that for each of
9 the diseases, you simply added one times ten to
10 the negative six to the overall background risk
11 for cancer in the general population?

12 A. Just to provide some perspective on how
13 low these numbers are. It was not part of my
14 calculation. It was just illustrative.

15 Q. In your risk assessment, you used cancer
16 slope factors and inhalation risk units to
17 calculate risk; right?

18 A. Yes. Those are the values that I used
19 for the risk calculations.

20 Q. Those are based on a single disease
21 endpoint; true?

22 A. They're often based on the most
23 sensitive endpoint based on all the data that EPA
24 has evaluated, yes.

25 Q. So for a certain chemical, the cancer

1 slope factor and inhalation risk unit could be
2 based on kidney cancer; right?

3 A. Yeah.

4 Q. Or leukemia?

5 A. Yes.

6 Q. Or some random cancer like liver cancer;
7 right?

8 A. That is one cancer that it has been
9 based on after EPA looks at all cancers.

10 Q. Then you took the cancer slope factor
11 and applied it to other cancers?

12 A. I applied it to a cancer risk
13 calculation because it's the most sensitive and
14 it's protective of all the other cancers that EPA
15 looked at. So it's a general cancer risk value
16 that EPA uses to determine cancer risk in general.
17 So it includes everything that they looked at.

18 Q. But, for example, I think you know the
19 cancer slope factor for kidney cancer -- strike
20 that.

21 The cancer slope factor for
22 trichloroethylene is based on kidney cancer;
23 correct?

24 A. One of them is based on kidney cancer.

25 Q. The cancer slope factor is based on

1 kidney cancer?

2 A. There are three cancer slope factors for
3 TCE.

4 Q. There are plaintiffs that you reviewed
5 who were exposed to TCE and developed, say,
6 leukemia; correct?

7 MS. ELLISON: Object to the form.

8 THE WITNESS: There are several
9 plaintiffs who have leukemia, and I looked at
10 exposures for all of the chemicals to see where
11 the risks came out.

12 BY MR. SNIDOW:

13 Q. And to determine the cancer risk for
14 leukemia plaintiffs, you used the cancer slope
15 factor for TCE that was based on kidney cancer;
16 right?

17 A. So I used the cancer slope factor that
18 EPA derives based on looking at all of the
19 information for TCE, including studies that looked
20 at the potential for leukemia risk following
21 exposure to TCE. So those studies have been
22 considered by the Agency.

23 But the Agency determined that kidney
24 cancer was the most sensitive endpoint. And
25 non-Hodgkin's lymphoma was another endpoint that

1 they used to calculate a TCE risk value.

2 Q. I may have missed asking this wrong. So
3 you've got two plaintiffs. One has got bladder
4 cancer and one's got leukemia; right? And they've
5 got exactly the same everything except for that.

6 Your cancer slope calculation for them
7 will come out exactly the same?

8 MS. ELLISON: Object to the form.

9 THE WITNESS: I use the cancer slope
10 factor that EPA uses that considers leukemia as a
11 potential endpoint for TCE. So the leukemia
12 studies are within their evaluation, their
13 systematic review. And they don't calculate a
14 leukemia slope factor because there's not enough
15 information to suggest that there's an
16 association. So the calculation -- the number
17 that they derive is based on where they see --
18 from reliable epidemiology studies and animal
19 studies where they see an association. And that's
20 what they use to calculate their cancer values.

21 BY MR. SNIDOW:

22 Q. I'm not trying to be difficult,
23 Dr. Bailey. You remember my question; right?

24 My question was: Assume you've got two
25 plaintiffs. They've got different cancers.

1 Everything else is equal. Your cancer slope
2 calculation is going to come out the same for
3 them; correct?

4 MS. ELLISON: Object to the form.

5 THE WITNESS: It would. And for the
6 leukemia plaintiff, it would be a very
7 conservative estimate because there's no evidence
8 to support an association between TCE exposure and
9 leukemia. So it would be a very conservative risk
10 for cancer in general for that plaintiff.

11 BY MR. SNIDOW:

12 Q. So that's a yes, it's going to come out
13 the same; correct?

14 A. It will come out the same, but you have
15 to interpret it differently.

16 Q. Same answer for if you had a bladder
17 cancer patient and a kidney cancer patient. With
18 respect to TCE, your analysis is going to come out
19 exactly the same for them; right?

20 MS. ELLISON: Object to the form.

21 THE WITNESS: So this is a hypothetical
22 question. I would have to consider -- of course,
23 in my evaluation I considered lots of other
24 things, the exposure, different exposure
25 information for the plaintiffs, the areas where

1 they lived, the exposure frequency, duration, the
2 activities. All of that would be part of my
3 calculation.

4 BY MR. SNIDOW:

5 Q. I understand. I'm asking you -- I'm
6 basically asking how your formula works. And your
7 formula does not change based on the specific
8 cancer type; is that correct?

9 A. For TCE, it would because there are
10 three cancer values for TCE. So NHL would be
11 different from kidney cancer, or if liver cancer
12 was one that we're evaluating, it would be
13 different.

14 But if there is no toxicity value that
15 EPA derived for a certain endpoint, I don't use it
16 because there isn't one. But it doesn't mean that
17 they didn't look at it. It means that they looked
18 at it, and the endpoint that they -- the value
19 that they derived is based on the most sensitive
20 endpoint protective of all cancers.

21 Q. You agree that individual tumor types
22 should be considered separately; right?

23 A. Well, you'd want to consider that in the
24 epidemiology studies, which is what I do in my
25 Section 8.

1 Q. Because different tumor types are --
2 involve different cell types; right?

3 A. In terms of -- I mean, that is something
4 that you'd want to consider in interpreting the
5 data for when you're doing a weight-of-evidence
6 evaluation and looking at all of the data.
7 Certainly that would be something that would be
8 important. I would imagine medical experts look
9 at that as well.

10 Q. And also because different tumors often
11 have different mechanisms of action?

12 A. That I can't answer because that's a
13 hypothetical. I'm not looking at a particular
14 chemical. I don't know the specifics of what
15 you're asking me.

16 Q. You don't know the different mechanisms
17 of action between PCE and TCE seen between kidney
18 cancer and bladder cancer?

19 MS. ELLISON: Object to the form.

20 THE WITNESS: That's a very general
21 question. There are proposed mechanisms for
22 different chemicals that may be associated with
23 certain diseases. There are different proposed
24 mechanisms. And I can't answer that here without
25 doing an evaluation of the data.

1 BY MR. SNIDOW:

2 Q. Do you agree leukemia and kidney cancer
3 have different risk factors?

4 A. I don't know. I would have to look at
5 the risk factors for each of them to see what they
6 are and compare them.

7 Q. You didn't do that before writing your
8 report?

9 A. That was not something that was part of
10 my evaluation.

11 Q. Same answer for bladder cancer, NHL,
12 kidney cancer, Parkinson's, you're not aware of
13 the different risk factors for them?

14 A. That's not something that I did in my
15 report. My report was focused on the exposure
16 piece of the specific causation analysis.

17 Q. Do you agree that kidney cancer and
18 leukemia have different causes?

19 MS. ELLISON: Object to the form.
20 Foundation.

21 THE WITNESS: That's not something that
22 I wrote -- that my report discusses. So I'd have
23 to look at the different causes of the different
24 cancers to tell you if they're different.
25

1 BY MR. SNIDOW:

2 Q. Before writing your report, you didn't
3 look into what does cause kidney cancer, did you?

4 A. That was not something that I was asked
5 to do for this report because my report is based
6 on the exposure piece of the specific causation
7 analysis, not the risk factors.

8 Q. Same answer, you didn't look into
9 different causes for bladder cancer, NHL,
10 leukemia, Parkinson's disease?

11 MS. ELLISON: Object to the form.
12 Foundation.

13 THE WITNESS: I did not look at those
14 because they're not -- that was not part of my
15 evaluation. That was not what I was asked to do.

16 BY MR. SNIDOW:

17 Q. In your report, you estimate various
18 margins of exposure; correct?

19 A. Correct.

20 Q. I just want to be clear on that
21 methodology. So first you define a POD; is that
22 right?

23 A. Yes.

24 Q. And that means point of departure;
25 correct?

1 A. Correct.

2 Q. And that's the exposure level at which
3 there is either no risk or a very, very, very,
4 very, very low risk; right?

5 A. Yes, based on the toxicity values.

6 Q. Well, I think it's actually based on the
7 animals and human epi; right?

8 A. That's what I mean, the studies that are
9 the basis of the toxicity values, yes.

10 Q. That's what I wanted to clarify.

11 So the point of departure, correct me if
12 I'm wrong, is you look at either the animal
13 literature or the human epidemiology, and you
14 determine the point at which there's no risk or
15 extraordinary de minimus risk; right?

16 A. No. That is not the point of departure
17 for my margin of exposure section. It's based
18 specifically on the study that EPA used to derive
19 the toxicity value.

20 Q. Let's look at page 41 of Exhibit 1. Do
21 you see where it says Plaintiff-Specific Margins
22 of Exposure?

23 A. Yes.

24 Q. It says, "As discussed in Section 3, the
25 exposure levels at which health effects are

1 predicted to be associated with no or a very low
2 response from animal or human studies are the
3 starting point, (i.e., points of departure) used
4 to derive regulatory toxicity criteria."

5 Did I read that correctly?

6 A. Yes.

7 Q. Sometimes that's derived from animal
8 studies; true?

9 A. The point of departure that EPA used to
10 derive the regulatory toxicity criteria specific
11 number, sometimes it's from animal studies, and
12 sometimes it's from epidemiology.

13 Q. And you agree that human data are the
14 preferred point of departure?

15 A. I think I answered this earlier. It's
16 something that you would want to look at in
17 combination with animal data, with mechanistic
18 data. And then based on all of that information,
19 integrating all of that information, you determine
20 and EPA has determined whether the animal data or
21 the human data are best for derivation of the
22 toxicity value.

23 (Bailey Exhibit 17 was marked.)

24 BY MR. SNIDOW:

25 Q. Showing you Exhibit 17, not an excerpt

1 this time. That's your name on the top right,
2 right, Lisa Bailey?

3 A. Yes.

4 Q. This is an evaluation of methyl
5 methacrylate that you did?

6 A. Okay.

7 Q. Yes?

8 A. Yes.

9 Q. I believe again just in the study, you
10 also determined that there was not human risk at
11 low levels of exposure?

12 A. This one was very a long time ago. I
13 would have to review this study again to tell you
14 what the conclusion was.

15 Q. Turn to page 9 -- Section 9, page 231.
16 Do you see the last paragraph there beginning
17 "Human data"?

18 A. Yes.

19 Q. It says, "Human data are often
20 recommended as the preferred point of departure
21 when setting occupational exposure standards."
22 Right?

23 A. Often recommended, yes.

24 Q. I think I asked you in general if that
25 was true before, and you said, well, not

1 necessarily.

2 Do you agree it's often recommended?

3 MS. ELLISON: Object to the form.

4 THE WITNESS: I think it is often
5 recommended, but it has to be -- it still has to
6 be in the context of a systematic review of all of
7 the information. Sometimes it comes out to be an
8 epidemiology study, and sometimes it doesn't. If
9 the data integration suggested an epidemiology
10 study is reliable and sufficient for a
11 calculation, then it will be used. If it isn't,
12 then the animal data will be used.

13 BY MR. SNIDOW:

14 Q. Do you agree that using animal data
15 creates some uncertainty about whether the results
16 are applicable to humans?

17 A. There is some uncertainty, yes, and it's
18 usually dealt with by doing conservative
19 extrapolations, using conservative assumptions for
20 the extrapolation from animals to humans.

21 Q. First you have to extrapolate from
22 animals to humans; correct?

23 MS. ELLISON: Object to the form.

24 THE WITNESS: I don't know if that's the
25 first step. I'd have to look at the evaluation.

1 Sometimes there's something else you need to do
2 first with the animal data before extrapolating to
3 humans.

4 BY MR. SNIDOW:

5 Q. It's certainly one of the things you do;
6 right?

7 A. Yes.

8 Q. Put this one aside. If you go back to
9 the report, in your report, I believe you define
10 the point of departure as the exposure level
11 that's associated with a 1 percent increased risk.

12 A. It depends on the chemical. And you'd
13 have to get that from the EPA toxicological
14 profile. And they report what the risk is for the
15 point of departure. So that's what I start with.
16 If it's 1 percent, I start with that. If it's
17 something else, I'll start with that.

18 Q. For TCE you agree you started with 1
19 percent?

20 A. I'd have to look at the appendix.

21 Q. Do you have E-1 there?

22 A. Yes. That is what I started with.

23 Q. 1 percent?

24 A. Yes.

25 Q. And I think it's your testimony that 1

1 percent is a de minimus risk?

2 A. No.

3 Q. No?

4 A. This is the risk that was reported in
5 the study that's associated with this particular
6 dose, milligram per kilogram data. This is the
7 highest level of exposure from the study. It's
8 where they started.

9 Q. I know, but you say you have this
10 equation. You have a POD.

11 A. Yes.

12 Q. It ultimately is going to give you the
13 exposure that leads to a 1 percent increased risk;
14 right?

15 A. That's the -- that is the number that
16 comes out of EPA's dose-response evaluation. It's
17 a conservative estimate. It's based on modeling
18 and looking at confidence intervals around that
19 modeling and estimating where the 1 percent risk
20 would fall using conservative assumptions.

21 Q. My only question though is: The POD
22 that you're modeling is 1 percent increased risk;
23 correct?

24 MS. ELLISON: Object to the form.

25 THE WITNESS: It is because that's the

1 starting point for the point of departure for the
2 toxicity value.

3 BY MR. SNIDOW:

4 Q. And that's one in a hundred; right?

5 A. 1 percent is one in a hundred.

6 Q. If you go back to page 41 of your
7 report, at the top you define the point of
8 departure as the levels at which health effects
9 are predicted to be associated with no or a very
10 low response for animal or human studies?

11 A. Yes. That's how they're defined by EPA.
12 That's their starting point.

13 Q. So 1 percent is no or very low response?

14 MS. ELLISON: Object to the form.

15 THE WITNESS: That is a low starting
16 point for a point of departure.

17 BY MR. SNIDOW:

18 Q. A cancer risk of one in a hundred?

19 MS. ELLISON: Object to the form.

20 THE WITNESS: So that is a number that
21 comes out of EPA's derivation of the toxicity
22 value. And again, it's based on conservative
23 modeling, conservative confidence intervals around
24 that model. And it's estimating where on that
25 model a 1 percent risk would be. And then that's

1 the starting point. Then that's where they
2 then -- they do the linear extrapolation from that
3 point.

4 BY MR. SNIDOW:

5 Q. I'm just saying 1 percent increased risk
6 is in no way a de minimus risk; correct?

7 MS. ELLISON: Object to the form.

8 THE WITNESS: Well, the de minimus risks
9 that EPA uses for a population is ten to the minus
10 six or lower.

11 BY MR. SNIDOW:

12 Q. So 1 percent is, what, 5,000 times above
13 that?

14 A. But that's not what they use for
15 evaluating risks. They use a linear extrapolation
16 from that point, which is why I did both. I
17 looked at the comparison to the point of departure
18 and I calculated risks.

19 Q. You keep -- I don't think you're doing
20 it intentionally. My only question is: Do you
21 consider a 1 percent absolute increased risk of
22 cancer to be de minimus?

23 MS. ELLISON: Object to the form.

24 THE WITNESS: Mathematically it's not
25 equal to the ten to the minus six, but I'm using

1 it in a different way here. And I'm comparing
2 that point of departure, which is a conservative
3 estimate, to the exposures for the plaintiff, and
4 they're well below that starting point, which is
5 one part of my analysis.

6 BY MR. SNIDOW:

7 Q. This is in absolute terms, not relative
8 terms; right?

9 MS. ELLISON: Object to the form.

10 THE WITNESS: It is a direct comparison
11 of the exposure for the plaintiff estimated based
12 on conservative estimates of the exposure in
13 comparison to the estimated point of departure for
14 the toxicity value that EPA used, yes.

15 BY MR. SNIDOW:

16 Q. You don't know what the relative risk
17 for a certain cancer that will correspond to this
18 1 percent increased risk is, do you?

19 A. I would have to look at the study to
20 see -- I think there's a way you can do that. I
21 don't know, off the top of my head, how it
22 compares to the exposure information from the
23 study where the relative risk was X.

24 Q. We're going to look at that, I promise.
25 My only question is: You didn't

1 calculate it; right?

2 A. I calculated risks based on EPA's method
3 to provide some perspective on the exposure. I
4 did not do relative risk calculations for a
5 population. That's an epidemiology study
6 calculation. It wouldn't make sense to do that
7 here.

8 Q. Once you calculated the POD, you then
9 created what you call a margin of exposure; right?

10 A. Yes.

11 Q. As I understand it, if the individual
12 experienced exposure to amounts associated with 1
13 percent, then their margin of exposure would equal
14 1.0; correct?

15 A. Yes.

16 Q. If they were exposed to amounts that
17 were below 1 percent, then their margin of
18 exposure would be greater than one; correct?

19 A. Yes. If you're comparing it to the
20 concentration that's the basis of the 1 percent,
21 yes, it would be lower than -- greater than nine.

22 Q. Conversely, if they were exposed to
23 concentrations that were greater than the risk
24 associated with 1 percent, their margin of
25 exposure would be less than one?

1 A. If their exposure was greater than the
2 point of departure that I looked at -- again, this
3 is a hypothetical question. None of my margins of
4 exposure came out to be less than one. They were
5 all well above one. If it was greater than the
6 point of departure, then it would come out to be
7 less than one.

8 Q. And then if you look at page 22 of your
9 report, you say that, "If the margin of exposure
10 is greater than one, that provides support that
11 adverse health effects would not be expected for
12 the individual."

13 A. That provides some additional support,
14 yes. You wouldn't want to do it -- only do this
15 calculation. You'd want to look at other things
16 as well, as I did.

17 Q. So if it was -- let's say it's .9. Why
18 does having an increased risk of cancer on the
19 order of 0.9 percent, why does that provide
20 support there's no adverse health effects?

21 MS. ELLISON: Object to the form.

22 BY MR. SNIDOW:

23 Q. That's a huge increased risk, isn't it?

24 MS. ELLISON: Same objection.

25 THE WITNESS: So again, that's

1 hypothetical. Nothing came out to be .9.
2 Everything was well above one for the plaintiffs
3 here. But as I said, you want to look at the risk
4 calculation that's plaintiff specific, see where
5 that falls relative to the EPA's acceptable range
6 of ten to the minus six, ten to the minus four,
7 and also look at a margin of exposure. That's one
8 part of the evaluation. Nothing came out to be
9 .9.

10 BY MR. SNIDOW:

11 Q. I understand. But in your report, you
12 don't provide any other ratios besides MoE greater
13 than one; right? You don't say it needs to be ten
14 times. It needs to be hundred times. You say if
15 the margin of exposure is greater than one, that
16 provides support that adverse health effects would
17 not be expected; right?

18 A. You also have to look at the other parts
19 of my evaluation. So you'd want to look at the
20 risk calculation and also look at the epidemiology
21 comparison I did in Section --

22 Q. Let's stay focused on the MoE.

23 MS. ELLISON: Just the talking over,
24 please.

25

1 MR. SNIDOW: I'm not trying to.

2 MS. ELLISON: I know.

3 BY MR. SNIDOW:

4 Q. We've talked about the risk assessment.
5 I promise we'll talk about the epidemiology.
6 Right now I want to talk about the margin of
7 exposure. Okay?

8 A. That's what we're talking about.

9 Q. You did this analysis because you
10 thought it informed your causation opinion;
11 correct?

12 A. Yes, in the context of the other
13 information, not by itself.

14 Q. I want to talk about why it's in here at
15 all. How does it follow that if the MoE is
16 greater than one, that means adverse health
17 effects would not be expected?

18 A. I didn't say that they are not expected.
19 I said it provides support that adverse health
20 effects would not be expected meaning that it's
21 additional support in combination with the risk
22 calculation and with the Section 8.

23 Q. Why does that provide support at all?
24 Why does it provide any support at all for the
25 proposition there's no adverse health effects if

1 you've got an MoE of 1.0 if .9 percent absolute
2 increased risk of cancer?

3 A. I'm confused about the hypothetical. My
4 margins of exposure are higher than that. So if
5 you calculate something that's well above one,
6 that provides support that the exposure for the
7 plaintiffs is well below EPA's starting point for
8 the toxicity value, the level that EPA considers a
9 no effect level or a very low effect level.
10 That's the point of margins of exposure.

11 Q. You're really not suggesting that a 1
12 percent absolute risk is a no effect level, are
13 you?

14 MS. ELLISON: Object to the form.
15 Foundation.

16 THE WITNESS: It's the point of
17 departure that EPA starts with.

18 BY MR. SNIDOW:

19 Q. A risk of one in a hundred?

20 A. Again, you need to look at that in
21 combination with the risk calculation which do not
22 come out to be one in a hundred. They come out to
23 be much lower than that.

24 Q. Let's look at page -- just down a little
25 bit, you say, "If the plaintiffs' exposures are

1 well below exposures where effects have been
 2 observed in epidemiology or toxicology studies,
 3 even if there is a risk calculation greater than
 4 U.S. EPA's targets, these results provide support
 5 the individual exposures are not likely to be
 6 associated with the health effect of concern."

7 You wrote that; right?

8 A. Let me read it. Yes. That's why you
 9 want to look at both of the results from the
 10 margin of exposure calculation and the cancer
 11 calculation, the cancer risk calculation. But
 12 again, that's not what happens with the
 13 plaintiffs. All of the risks are within EPA's
 14 targets. So that's not something that I think
 15 about.

16 Q. I'm asking about your methodology now.
 17 You chose to say if MoE is greater than one;
 18 right? You wrote that sentence?

19 MS. ELLISON: Object to the form.

20 THE WITNESS: That sentence I wrote,
 21 yes.

22 BY MR. SNIDOW:

23 Q. I'm asking you: Why does that follow?

24 MS. ELLISON: Object to the form.

25 THE WITNESS: I think I explain it in my

1 report. It means that the exposure for the
2 individual is lower than the starting point for
3 the cancer toxicity value, the conservative
4 starting point that EPA uses to derive the
5 toxicity value. So if you're lower than that, it
6 provides support that the exposures are lower than
7 what's been observed in the literature.

8 BY MR. SNIDOW:

9 Q. You then did plaintiff-specific margins
10 of exposure for all 25 plaintiffs; right?

11 A. Yes.

12 Q. Have you ever seen that done in the
13 scientific literature?

14 A. Yeah.

15 Q. For individuals?

16 A. No, not for individuals. I mean, it's
17 commonly done. EPA did margins of exposure for --
18 in the Tosca risk evaluations.

19 Q. So you've seen it done for populations;
20 right?

21 A. Yes.

22 Q. Have you ever seen a peer-reviewed
23 publication that calculates the margins of
24 exposure for an individual?

25 A. There are not typically publications for

1 individuals. But I have seen it done in the
2 context of expert reports that are looking at
3 individual causation analysis.

4 Q. Were those expert reports written by
5 Gradient?

6 A. The ones that I've looked at, yes,
7 because I work at Gradient.

8 Q. Well, you say that, but how many
9 litigations have you been involved?

10 A. Many.

11 Q. During those litigations, do you
12 sometimes review expert reports from other people?

13 A. Sometimes.

14 Q. You did here; right?

15 A. Yes.

16 Q. And you often, I'm sure, review expert
17 reports from people who are on the same side of
18 litigation as you do?

19 A. Not often.

20 Q. You did here; right?

21 A. Not an evaluation that was similar to
22 mine.

23 Q. I know. But you review other expert
24 reports; correct?

25 A. I do review other expert reports.

1 Q. In the course of your entire career,
2 have you ever seen anything in the published
3 literature or an expert report where someone does
4 a margin of exposure calculation for an individual
5 person?

6 A. Yes. I've seen expert reports where
7 that's done.

8 Q. Oh, really? Outside of Gradient.
9 Sorry.

10 MS. ELLISON: Object to the form.

11 THE WITNESS: I have not looked
12 at reports -- I can't recall looking at a report
13 outside of Gradient where -- I may have. I've
14 been doing this for a very long time. It's
15 certainly a very reasonable approach.

16 BY MR. SNIDOW:

17 Q. You apply this analysis to noncancer and
18 cancer endpoints; correct?

19 A. I do.

20 Q. And have you seen it done for cancer
21 endpoints even with respect to a population?

22 A. As I sit here right now, I can't recall
23 when that has been done. But again, it's
24 certainly a reasonable approach to consider where
25 the starting point is for derivation of the

1 toxicity value and compare that to what the
2 exposure is for an individual.

3 It gets at the question that I'm asking,
4 is this exposure something that is of concern for
5 human health. You have to look at it.

6 Q. But just to clarify, whether we're
7 talking about an individual or even a population,
8 you can't recall ever seeing a margin of exposure
9 analysis done for cancer; correct?

10 MS. ELLISON: Object to the form.

11 THE WITNESS: I have seen it done for
12 individuals or populations.

13 BY MR. SNIDOW:

14 Q. In a Gradient expert report?

15 A. Yes.

16 Q. Any other place?

17 A. I can't recall right now, but again,
18 it's a reasonable approach. It's something that
19 you should look at as a risk assessor, someone who
20 is trying to answer the question about whether
21 exposures are elevated or not. It's an important
22 part of the analysis.

23 Q. Let's walk through exactly how you
24 derived the margin of exposure for TCE and bladder
25 cancer. So look at Exhibit 1, page 22.

1 A. Yes.

2 Q. You say, "If the plaintiffs' exposures
3 are well below exposures where effects have been
4 observed in epidemiology or toxicology studies,
5 even if there's a risk calculation greater than
6 USA EPA's targets..."

7 Then I think we've discussed the rest of
8 the sentence; right?

9 A. Yes.

10 Q. Let me just focus on the first part.
11 What if the relevant exposure simply has not been
12 evaluated in an epidemiology study? Would you
13 still say that the fact that the plaintiffs'
14 exposures are below the levels that have shown
15 results indicates no causation?

16 MS. ELLISON: Object to the form.

17 THE WITNESS: I don't know what you mean
18 by relevant exposure.

19 BY MR. SNIDOW:

20 Q. You know what a dose-response is; right?

21 A. Yes.

22 (Bailey Exhibit 18 was marked.)

23 BY MR. SNIDOW:

24 Q. Let me just draw it and I'll show you.

25 The dots, I'm going to use this to mean the levels

1 of exposure that have been shown to increase risk
2 in the epi. Okay?

3 A. Risk for what endpoint?

4 Q. For whatever you want.

5 A. The endpoint is important.

6 Q. Cancer.

7 A. Okay.

8 Q. My star down there is what you're
9 calling here the plaintiffs' exposure, which is
10 less than demonstrated in the epidemiology; right?

11 A. There are no numbers on here.

12 Q. I'm just trying to figure out what
13 you're saying.

14 A. I'm not sure what you're asking me. I'm
15 sorry.

16 Q. You say -- it's in the second half of
17 the sentence. You're referring to where
18 effects -- exposures where effects have been
19 observed in epidemiology or toxicity studies;
20 right?

21 A. So this is specific to the study related
22 to the toxicity value that EPA had derived.
23 That's what this margin of exposure calculation is
24 based on. It's based on the toxicity value that
25 EPA derives and the endpoint associated with that

1 toxicity value. Those are the effects.

2 Q. You see you refer to exposures where
3 effects have been observed in epidemiology
4 studies; right? Do you see that?

5 A. Yes.

6 Q. I'm telling you this is what I'm trying
7 to represent with the dots. Those are exposures
8 that have been demonstrated in the epidemiology
9 studies.

10 A. Yes.

11 Q. You say, "If the plaintiffs' exposures
12 are well below those levels, that means that
13 there's not likely to be a health concern."

14 I'm asking you, can you explain to me
15 why that is true?

16 A. Because that is -- those are the points
17 where effects have been observed in studies. So
18 if exposures for the plaintiffs is well below
19 effects that have been or concentrations or doses
20 where effects have been identified, then you can
21 say that the exposures are well below what we know
22 and what we have seen causes this health effect
23 for this particular chemical.

24 Q. How do you know it doesn't also cause
25 this health effect at the lower exposures that

1 weren't examined in the epi?

2 A. So the study was used to derive a point
3 of departure, and then EPA does a linear
4 extrapolation from that point all the way down.
5 It does calculate a risk down here, but these are
6 very low exposure estimates. So EPA does the best
7 that they can with the information that's
8 available.

9 Most of the studies that we have are at
10 doses that are well above exposures in a
11 population. So then they use that information and
12 apply conservative estimates to determine a way to
13 provide some perspective on whether there might be
14 a risk at this very low concentration.

15 (Bailey Exhibit 19 was marked.)

16 BY MR. SNIDOW:

17 Q. Let's look at Tab J, which I'll mark as
18 Exhibit 19. This is the high risk toxicological
19 review for TCE from the EPA, which I think you
20 reviewed this.

21 A. Yes.

22 Q. If you could go to page 5-140.

23 MS. ELLISON: I can't recall if you
24 said, but for the record, this is not a complete
25 copy.

1 MR. SNIDOW: It's not a complete copy.
2 I think we got the full chapter this time.

3 MS. ELLISON: Thank you.

4 MR. SNIDOW: You're welcome.

5 BY MR. SNIDOW:

6 Q. If you will go to actually first on page
7 5-139, it's talking about Dose-Response Analyses:
8 Human Epidemiologic Data; right?

9 A. Yes.

10 Q. In the middle of the page, it says, "The
11 Charbotel 2006 study was selected as the sole
12 basis for the derivation of inhalation unit risk
13 estimate for kidney cancer." Correct?

14 A. Yes.

15 Q. Did you read the Charbotel study?

16 A. I have looked at the Charbotel study for
17 a number of projects, yes.

18 MS. ELLISON: Also, just for the record,
19 what was handed to Dr. Bailey is not a complete
20 copy of the chapter. I believe there is a
21 complete copy if you want to enter it as an
22 exhibit. I don't know if it matters for your
23 purposes.

24 MR. SNIDOW: No.

25

1 BY MR. SNIDOW:

2 Q. We're on page 5-140. So TCE and kidney
3 cancer, you agree that the Charbotel study forms
4 the sole basis for the inhalation unit risk;
5 right?

6 A. For kidney cancer.

7 Q. For kidney cancer. And the inhalation
8 unit risk then gets transformed into the cancer
9 slope; correct?

10 A. Inhalation unit risk is the cancer --
11 yes. Then that is used to derive the OR kidney
12 slope factor.

13 Q. For kidney cancer there's not any other
14 epidemiology that all of that is based on other
15 than Charbotel; correct?

16 A. Charbotel is the basis of the toxicity
17 value, yes.

18 Q. If you see on page 5-140, it shows the
19 results for Charbotel 2006; right?

20 A. Yes.

21 Q. And the exposure categories are
22 nonexposed, low, medium and high; true?

23 A. Um-hum.

24 Q. The odds ratios are 1.62, 1.15 and 2.16;
25 right?

1 A. Yes.

2 Q. This is based on factory workers in
3 France; correct?

4 A. Yes.

5 Q. This is renal cell carcinoma and not any
6 of the other cancers at issue in this case;
7 correct?

8 A. I would have to look at the study. Yes,
9 RCC is what it says here, yes.

10 Q. In the Charbotel, the dose-response
11 wasn't totally linear; correct?

12 A. I would have to look at the model data
13 to tell you whether it's linear.

14 Q. Well, you can just see from it; right?
15 It's 1.62, 1.5, 2.16.

16 A. Yes.

17 MS. ELLISON: Object to the form.

18 THE WITNESS: I mean, those numbers go
19 down, but there's also some variability. I mean,
20 the important number is the top number where the
21 risk is significant.

22 BY MR. SNIDOW:

23 Q. Well, you need all the results to model
24 the dose-response curve; do you not?

25 A. Yes.

1 Q. EPA did that here; right?

2 A. Yes.

3 Q. Even though the 1.62 and 1.5 are not
4 statistically significant; correct?

5 A. They did. You have to look at all the
6 data for a dose-response curve.

7 Q. That's right. And even though this
8 dose-response curve not monoatomic; true?

9 A. That is true.

10 Q. Then EPA based on those three results
11 extrapolates the linear regression model down to
12 zero; true?

13 A. Correct, based on the modeling of that
14 data.

15 Q. And you have reviewed the Charbotel
16 study, so you know that the PPM years in the low,
17 medium and high categories are higher than they
18 were at Camp Lejeune; correct?

19 MS. ELLISON: Objection. Foundation.

20 THE WITNESS: I would have to compare
21 the PPM years. I did that in my -- by looking at
22 the margins of exposure for the kidney cancer
23 plaintiffs. So that would be the comparison.

24 BY MR. SNIDOW:

25 Q. So these are higher than are at Camp

1 Lejeune?

2 A. Yes.

3 Q. Nowhere in the Charbotel study were
4 people exposed to the levels of TCE that the
5 people at Camp Lejeune were exposed to; right?

6 MS. ELLISON: Objection to the form.
7 Foundation.

8 THE WITNESS: The inhalation exposure
9 concentrations are higher than those at Camp
10 Lejeune just based on my margins of exposure,
11 which are high.

12 BY MR. SNIDOW:

13 Q. I'm asking something else. It's not as
14 if in Charbotel they looked at low levels and
15 found no effect; right?

16 MS. ELLISON: Object to the form.

17 THE WITNESS: EPA typically relies on
18 worker studies of higher exposure concentrations
19 because often they're more reliable in terms of
20 exposure information for the chemical of concern
21 and the health effects of concern. So sometimes
22 that's what EPA needs to do and often, does that
23 often with occupational studies for derivation of
24 toxicity values. The exposures are higher than
25 what people are exposed to in the population.

1 BY MR. SNIDOW:

2 Q. So how does it follow from Charbotel
3 that people exposed to lower exposures are not at
4 increased risk?

5 MS. ELLISON: Object to the form.
6 Foundation.

7 THE WITNESS: Because, I mean, even if
8 the 253 and 62 PPM year, that's not a significant
9 risk.

10 BY MR. SNIDOW:

11 Q. We just talked about this. The EPA
12 treats these numbers as real. They're using this
13 to model everything you did in your report with
14 respect to RCC and TCE; right?

15 A. Yeah. Exposures lower than those would
16 be less likely to have health effects.

17 Q. Sure, less likely. But why is below
18 this no risk?

19 MS. ELLISON: Object to the form.

20 BY MR. SNIDOW:

21 Q. How do you know that in cumulative
22 exposure categories below the ones in Charbotel
23 there's not an increased risk?

24 A. It's based on all of the information
25 that EPA looks at, including the animal data,

1 mechanistic data and this Charbotel study. It
2 uses the exposure information from the Charbotel
3 study and assumes that there is some risk higher
4 than zero all the way down to zero. So anything
5 above zero you do calculate something.

6 And then that number, and this is a
7 conservative derivation of the toxicity value
8 because it's based on conservative modeling of
9 that data, and then that is compared to what EPA
10 considers a safe level of exposure.

11 Q. Two more.

12 A. Go for it.

13 Q. Your POD, the level at which there's no
14 or de minimus risk; right?

15 A. The POD is not equivalent to de minimus
16 risk. EPA considers the POD -- that's the
17 starting point. It is what it is. It's the
18 starting point of derivation of the toxicity
19 value. Then you use that to calculate risk. And
20 if the risks are -- based on the linear
21 extrapolation from that point, if the risks are
22 ten to the minus six, then it's de minimus based
23 on the toxicity value. It's conservative, a
24 conservative estimate based on Charbotel's study.

25 Q. Even though there's increased risk of

1 every exposure category in Charbotel?

2 MS. ELLISON: Object to the form.

3 THE WITNESS: There's increased risk at
4 the highest exposure, which is a significant
5 exposure, and it's well above the exposures in
6 the -- for the plaintiffs.

7 MR. SNIDOW: Take a break.

8 THE VIDEOGRAPHER: Off the record at
9 1:40.

10 (Recess from 1:40 p.m. to 2:33 p.m.)

11 THE VIDEOGRAPHER: Back on the record at
12 2:33.

13 BY MR. SNIDOW:

14 Q. Dr. Bailey, did you calculate what
15 Ms. Dyer's exposure was in terms of micrograms per
16 liter month of TCE?

17 A. I took Dr. LaKind's exposure estimates,
18 which were milligram per kilogram day. I did
19 start with a microgram per liter concentration. I
20 then took that and multiplied by months or years
21 or the exposure duration. So that calculation is
22 within my risk calculation. So I don't report
23 microgram per liter months, but it's part of the
24 calculation that I do.

25 Q. If I changed Dyer to any of the other 24

1 plaintiffs, you do not report microgram per liter
2 month of TCE for any of them; true?

3 A. I don't report that, but again, I didn't
4 because it's not comparable to EPA's toxicity
5 values, but it is -- I considered all of those
6 parameters in my calculations.

7 Q. If I changed TCE to any of the other
8 chemicals, same answer; you considered it, but you
9 don't report those values, do you?

10 A. I don't report microgram per liter
11 month, right, but it's part of my calculation.

12 Q. Now, you mentioned that for TCE, there
13 is no cancer slope for bladder cancer
14 specifically.

15 A. EPA does not have the cancer slope
16 factor for bladder cancer; correct.

17 Q. For that reason, you used the kidney
18 cancer slope factor?

19 A. I used all of them combined. So I used
20 some of kidney cancer, liver cancer and
21 non-Hodgkin's lymphoma, so a very conservative
22 estimate.

23 Q. That's what I was going to say. You
24 said that's conservative. Given that there is no
25 cancer slope for bladder cancer, how do you know

1 that it isn't steeper than for the other cancers?

2 A. Because EPA considered any study that
3 looked at TCE exposure in bladder cancer. And if
4 they thought that the studies were reliable enough
5 to derive a toxicity value, they would have. And
6 then if that was less sensitive or resulted in a
7 higher risk than NHL or kidney cancer, they would
8 have used it. But they didn't because it was not
9 the most sensitive endpoint, that or the data were
10 not -- did not suggest that there's an
11 association.

12 Q. But you don't actually know what the
13 slope of the TCE dose response curve looks like
14 for bladder cancer, do you?

15 MS. ELLISON: Object to the form.

16 THE WITNESS: Well, it's not something
17 that EPA calculated because the data are not
18 reliable enough to do that type of calculation.
19 The data don't support -- EPA did not conclude
20 that TCE is a bladder carcinogen.

21 BY MR. SNIDOW:

22 Q. If you were trying to calculate the risk
23 of melanoma, do you think it would be appropriate
24 to use the kidney cancer slope?

25 A. From what chemical?

1 Q. TCE, PCE.

2 A. Yes. What I'm looking at specifically
3 is whether there's a cancer risk for exposure to
4 TCE for all cancers that EPA considered. And if
5 melanoma was something that was found to be
6 associated with TCE, then would be considered.

7 Q. Even though the causes are just so very
8 different; right?

9 MS. ELLISON: Object to the form.

10 THE WITNESS: You would look at that as
11 one part of the evaluation, and you would also
12 look at are there any epidemiology studies that
13 specifically looked at melanoma and TCE. And you
14 look at that and you look to see what those
15 exposures might be. And if they're available,
16 then you can do that comparison. And I did that
17 in my Section 8.

18 BY MR. SNIDOW:

19 Q. How many people did you have helping you
20 with this report?

21 A. So I have one person who is my main risk
22 person who sets up the spreadsheets and
23 essentially works through the risk calculations.
24 So that's one key person.

25 I have another person who's more -- her

1 focus is more on the hazard piece, so the
2 toxicology, the epidemiology. So she provides
3 support. And they each have people that provide
4 support to them.

5 Q. Do you know how many people total?

6 A. The main people would be those two plus
7 a few more that I know have looked at the risks
8 and looked at plaintiff-specific information, and
9 then maybe three or four that also looked at the
10 hazard information, that section.

11 Q. So maybe six or seven total?

12 A. Roughly, yeah. I don't recall the exact
13 number.

14 Q. Do you have Exhibit 2 in front of you?

15 A. Yes.

16 Q. If you could turn to the page with
17 Bates-stamp ending 149.

18 MR. SNIDOW: I think you guys have a
19 copy of this somewhere.

20 MS. ELLISON: Yeah. Thank you.

21 BY MR. SNIDOW:

22 Q. Are you there?

23 A. Yep.

24 Q. So that's you at the top there,
25 Elizabeth Bailey. That's one.

1 A. Yes.

2 Q. Then Mary Hixon.

3 A. Yes.

4 Q. Anna Engle?

5 A. Yep.

6 Q. So that's three. Then six copy editors.

7 A. Yes. They were not involved in the
8 evaluation. They were copy editors. So they were
9 looking for grammatical errors, sentence
10 structures, spelling fix. They were the copy
11 editors.

12 Q. So up to nine total?

13 A. I would not count the copy editors as
14 individuals who worked on my report in terms of
15 any part of the evaluation.

16 Q. I'm just trying to get a sense of who's
17 touched this report. So that's nine people so
18 far?

19 A. For the copy editors, I had 25 reports,
20 so I had a lot of copy editors.

21 Q. Then if you go down, it looks like
22 there's Jiayang Chien.

23 A. Yes.

24 Q. So ten so far?

25 A. Five or six are the main people. Then

1 the copy editors if you want to add them would be
2 around ten.

3 Q. And then three associates, what were
4 they doing?

5 A. So Dan is a library person. So he would
6 be looking for literature that we asked him to
7 look for. Same for Rebekah. Catalina helps with
8 the risk piece.

9 Q. So 13 so far. Then the next page, it
10 looks like we've got five more with one repeat.

11 A. Yeah. Again, copy editors mostly.
12 Sarah is the library person again looking for
13 literature for us. Copy editing and library
14 staff, whoever is available will be used for that.
15 But they're not at all involved in the analysis.
16 Janet was one of the people that helped Jiayang
17 with the risk spreadsheets.

18 Q. So 17 people listed on this one invoice;
19 right?

20 A. If you're counting all of the copy
21 editor or library people.

22 Q. What are the library people doing
23 exactly?

24 A. So if we have a study that we need to
25 look at, they will get it for us. Sometimes they

1 need to be purchased, and they will purchase them
2 for us and get them to us.

3 Q. Do they read it?

4 A. No.

5 Q. They just pull it?

6 A. Yes.

7 Q. And it takes them this many hours to do
8 that?

9 A. So it depends on how many we're asking
10 them to look at or to find. Sometimes there's a
11 very long list of articles that we need them to
12 get.

13 Q. Do you read all the articles yourself?

14 A. I read all of the key articles for my
15 analysis, yes.

16 Q. Well, you said all the key articles.
17 Are you a hundred percent sure that you read every
18 article that's listed in your report?

19 A. I can't say I read every single article
20 on my MCL from cover to end, but the documents
21 that I cite in my report -- I cited some very
22 large like Agency documents. I would not have
23 read those from cover to cover because they're
24 not -- the sections are not all relevant.

25 But I look at -- I look at the entirety

1 of the report. I look at -- and for publications
2 I would look at tables. I look at the key
3 information. Sometimes I don't look at the
4 background information because it's not as
5 relevant. But, yes, I do look at all of the
6 studies.

7 Q. I understand you haven't read them cover
8 to cover. Is it your testimony that you looked at
9 every single study in your materials considered
10 list, or did you delegate some of it?

11 A. No. I put eyes on all of the documents.

12 Q. You did?

13 A. Yes.

14 Q. Every single one?

15 A. Yes.

16 Q. Do you agree that risk assessment does
17 not produce an estimate of risk for a specific
18 cancer type?

19 A. Risk assessment can be used to provide
20 perspective on certain cancer types if the cancer
21 of concern is also the basis of the toxicity value
22 that's used for the risk calculation. So it can
23 be. It depends.

24 Q. Well, you don't in your report produce
25 any specific risk estimates for a specific type of

1 cancer, do you? It's cancer generally.

2 A. That's the first part of the
3 calculation. But then I look at studies that also
4 look at the specific cancer and the exposures in
5 those studies.

6 Q. Epi studies?

7 A. Yeah, and some of the animal studies.

8 Q. You agree that human epidemiology can
9 tell you what the risk is for a particular type of
10 cancer; correct?

11 MS. ELLISON: Object to form.

12 THE WITNESS: Human epidemiology studies
13 are useful in providing perspective on whether --
14 on what exposures might -- what exposures are
15 reported in the literature to be associated with
16 certain health effects. So you'd want to look at
17 that in the context of the other information.

18 BY MR. SNIDOW:

19 Q. Do you agree that the Bove series of
20 studies produced relative risk ratios for all of
21 these diseases?

22 MS. ELLISON: Object to the form.
23 Foundation.

24 THE WITNESS: The Bove study did report
25 relative risks.

1 BY MR. SNIDOW:

2 Q. How many Bove studies were there?

3 A. I don't recall, off the top of my head.
4 I'd have to look at my MCL to see how many.

5 Q. And you think you read them all?

6 A. I have looked at them, and I mostly
7 looked at the tables, yes.

8 Q. All the Camp Lejeune epi you read?

9 MS. ELLISON: Object to form.
10 Foundation.

11 THE WITNESS: Like I said, I look at --

12 MS. ELLISON: Sorry. Just let me say
13 the objection.

14 Sorry. Could you repeat your question,
15 J.J.?

16 BY MR. SNIDOW:

17 Q. You think you read all the Camp Lejeune
18 epidemiology?

19 A. I have looked at the Camp Lejeune
20 studies.

21 Q. If you go to page 42 of your report, you
22 see there's a paragraph that begins "Although
23 Dr. Goodman..."

24 A. Um-hum.

25 Q. It ends with Goodman 2025?

1 A. Yes.

2 Q. Do you disagree with me that this is the
3 only thing in all of your 25 reports that you say
4 about the Camp Lejeune epidemiology?

5 MS. ELLISON: Object to the form.

6 THE WITNESS: I am citing Dr. Goodman
7 for her evaluation of the Camp Lejeune studies
8 because she did an extensive evaluation of those
9 studies in her report, and I agree with her
10 methodology. So that is how I talk about those
11 studies.

12 BY MR. SNIDOW:

13 Q. My question though is: This is it;
14 right? This is the only statements that you make
15 about the Camp Lejeune epidemiology in all 25 of
16 your reports?

17 A. I might have discussed some of the Camp
18 Lejeune epidemiology studies in the rebuttal
19 sections, but that would be report specific, and I
20 don't recall.

21 Q. Do you want to take a look?

22 A. For this one, I guess I could take a
23 look. It only speaks to one of the plaintiffs.
24 So I do talk about in Section 9 the one bullet
25 where Dr. Hatten, Longo and Bird refer to Camp

1 Lejeune studies. And I'm generally providing the
2 same statement that I did early on based on
3 Dr. Goodman's review of those studies.

4 Q. So that's it; right? That's all you did
5 on that?

6 A. That is what I did for my report, yes,
7 because that is...

8 Q. You said before all of the literature
9 that you reviewed is in your materials considered
10 list; right?

11 A. Yes.

12 Q. So let's look at page 51. Do you see
13 where it says Bove?

14 A. Yes.

15 Q. And you've got one Bove study; correct?

16 A. I do. This is my reference list. This
17 is not the MCL.

18 Q. These are the references. These are
19 ones we discussed; right?

20 A. In my report, but that's not my MCL.

21 Q. In your report, you say, "I did
22 not" -- excuse me -- page 42. You say, "I did
23 consider exposure estimates from those studies
24 because of the methodological limitations of the
25 studies, e.g., high likelihood of exposure

1 misclassifications as discussed by Dr. Goodman."
2 Right?

3 A. Correct.

4 Q. Besides high likelihood of exposure
5 misclassification, what are the other
6 methodological limitations in the six Camp Lejeune
7 studies?

8 A. Well, I think that is by itself a major
9 uncertainty, which is why I highlighted it here,
10 particularly in the context of what I'm doing
11 because it's very important to understand how
12 individuals were exposed. And we don't have that
13 information for the individuals in the Bove
14 studies.

15 Q. Any others besides that that you can
16 tell me?

17 A. Off the top of my head, no, because
18 that's what Dr. Goodman described. But that is a
19 very key limitation to interpretation of those
20 studies, is the -- we don't have the exposure
21 information for each of the individuals. But I
22 did rely on Dr. Goodman's evaluation of the other
23 limitations.

24 Q. And it's your testimony we don't have
25 exposure information for individuals in any of the

1 Camp Lejeune epidemiology?

2 MS. ELLISON: Object to the form.

3 THE WITNESS: So in epidemiology
4 studies, for the people with the various diseases,
5 we don't have individual exposure information for
6 those people and for those study participants.

7 BY MR. SNIDOW:

8 Q. That's your testimony, that's your
9 understanding, is that there's no individual
10 exposure information in any of the Camp Lejeune
11 epidemiology?

12 A. Correct.

13 Q. And you verified that by reading the
14 studies, I assume?

15 A. Yes. I have a general understanding of
16 the studies, and I know that there's not
17 individual exposure information for the study
18 participants.

19 Q. You know that?

20 A. Those studies were not done with
21 individual exposure information for each of the
22 plaintiffs -- sorry -- each of the study
23 participants.

24 Q. Am I correct that if we look through all
25 of your reports, I'm going to find this exact

1 same boilerplate language about the Camp Lejeune
2 epidemiology?

3 MS. ELLISON: Object to the form.

4 THE WITNESS: So it's not boilerplate
5 language. It's a discussion of Dr. Goodman's
6 conclusions based on her evaluation of the Camp
7 Lejeune studies. It's different depending on the
8 endpoint. And as I mentioned before, I do agree
9 with her methodology for evaluating those studies,
10 but it's not boilerplate language.

11 BY MR. SNIDOW:

12 Q. It's not identical in every single one
13 your reports?

14 A. No.

15 Q. It's not?

16 A. No, because there's a different
17 discussion about the conclusions for each
18 endpoint.

19 Q. You mean it changes like bladder cancer
20 to kidney cancer?

21 A. Well, that's one thing, but also the
22 context of whether the risks were -- this one says
23 statistically null and close to one. Some of them
24 say something different depending on the endpoint.
25 They don't all say statistically null and close to

1 one.

2 Q. Am I correct sitting here today, besides
3 exposure misclassification, you can't identify any
4 limitations of the Camp Lejeune epidemiology?

5 MS. ELLISON: Object to the form.

6 THE WITNESS: I know there are other
7 limitations, but I'm not going to guess what they
8 are. Dr. Goodman talks about them. But
9 certainly, as I already indicated, exposure
10 misclassification is key. We need to understand
11 how much people were exposed to.

12 BY MR. SNIDOW:

13 Q. Can you get Exhibit 10.

14 A. Okay.

15 Q. If you could turn to page 657.

16 MS. ELLISON: And just stating again for
17 the record I don't believe this is a complete copy
18 of the document.

19 MR. SNIDOW: I thought we had.

20 MS. ELLISON: No. We gave her a
21 complete version of the toxicological review.

22 BY MR. SNIDOW:

23 Q. You can go down to footnote 67,
24 Dr. Bailey. Do you see where it says, "In terms
25 of general causation, accurate exposure assessment

1 is important because its true effect can be missed
2 because of the confounding caused by cohorts that
3 often include workers with little exposure to the
4 putative offending agents thereby diluting the
5 actual effect."

6 A. I do see that sentence.

7 Q. Any reason to disagree with that?

8 A. I would need to look at this example
9 here. I want to read this again.

10 Yes. I think that's saying essentially
11 what I was saying, that accurate exposure
12 assessment is important.

13 Q. Right. It gives the reason why accurate
14 exposure assessment is important; right?

15 MS. ELLISON: Object to the form.
16 Foundation.

17 THE WITNESS: That's an example of one
18 reason why you would want to make sure you have
19 correct exposure information, for missing things
20 or for just estimating something wrong.

21 BY MR. SNIDOW:

22 Q. It doesn't say that part though; right?
23 It says --

24 A. It doesn't need to. I think that's --

25 Q. I'm just asking what it says. It

1 doesn't say anything except because you can miss a
2 true effect; correct?

3 A. You can miss a true effect, but you can
4 also incorrectly say that there is an effect
5 because of confounding.

6 Q. It's talking about exposure
7 misclassification there; right?

8 A. It's talking about accurate exposure
9 assessment being important.

10 Q. What it's saying is you've got a cohort
11 and it's got workers with little exposure. That's
12 going to dilute the effect that you'll observe for
13 the workers that had higher exposure; correct?

14 MS. ELLISON: Object to the form.

15 THE WITNESS: I mean, that is one reason
16 that you would want to make sure you have exposure
17 information, but the opposite is also true. You
18 could be assuming that people are exposed to much
19 higher concentrations than they actually were.
20 It's just important -- it's an uncertainty. You
21 need to have exposure information for study
22 participants in order to have a good analysis of
23 whether the exposures are related to the health
24 effects that are being reported.

25 (Bailey Exhibit 20 was marked.)

1 BY MR. SNIDOW:

2 Q. Let's look at -- give me Tab 2, which I
3 will mark as Exhibit 20.

4 Dr. Bailey, this is your expert report
5 that you prepared in the Mousser case. I'll give
6 this to you. And this is a kidney cancer case;
7 correct?

8 A. Yes.

9 Q. And if you will turn to page 38, if you
10 look at the bottom of the -- do you see the
11 paragraph that says "Trichloroethylene"?

12 A. Yes.

13 Q. And it says, "Dr. Goodman concluded that
14 the epidemiology evidence provides support for an
15 association between kidney cancer and very high
16 occupational TCE exposures, more than 335 parts
17 per million years based on Charbotel."

18 Did I read that correctly?

19 A. Yes.

20 Q. So you're deferring to Dr. Goodman's
21 opinion that TCE can cause kidney cancer at high
22 exposures; correct?

23 A. Correct.

24 Q. Based on the Charbotel study; correct?

25 A. Right.

1 Q. Then it says, "Mr. Mousser's exposure
2 estimates are well below 335 parts per million
3 years." Correct?

4 A. Yes.

5 Q. Tell me, how does it follow that just
6 because Mr. Mousser's exposure was less than the
7 exposures in Charbotel, that that means
8 Mr. Mousser was not at an increased risk?

9 A. So I would need to look at the other
10 parts of my evaluation. So I also -- so I
11 actually compared the exposure concentrations for
12 Mr. Mousser to the 335 PPM years. That's my
13 margin of exposure calculation, which is in
14 Section 7. And so he was 200fold below the
15 exposure information -- the exposure estimates
16 for -- for TCE I have a separate margin of
17 exposure range. It was 200 to 506,000fold lower
18 than that 335 PPM year estimate that's considered
19 to be a concentration where there may be health
20 effects. So that's one thing.

21 I also did a risk calculation for
22 Mr. Mousser.

23 Q. Just before you do that, that's
24 ultimately going to bottom out in Charbotel;
25 right?

1 MS. ELLISON: Object to the form.

2 THE WITNESS: Excuse me?

3 BY MR. SNIDOW:

4 Q. For TCE and kidney cancer you did a risk
5 assessment; right?

6 A. I did a risk calculation.

7 Q. That's going to rely on cancer slope
8 factors and the IERs; right?

9 A. Right.

10 Q. All of that is ultimately based on three
11 endpoints in Charbotel; correct?

12 A. It's based on the dose-response
13 evaluation of the Charbotel study that EPA -- yes,
14 that EPA used.

15 Q. Three endpoints; right?

16 A. It's based on -- no. For kidney cancer
17 it's just based on kidney cancer, kidney cancer
18 endpoint, not the other -- you mean concentration.

19 Q. I mean three actual results, low
20 exposure, medium exposure, high exposure in
21 Charbotel. That's it. Everything you did with
22 respect to Mr. Mousser and kidney cancer is based
23 on that?

24 MS. ELLISON: Object to the form.

25 THE WITNESS: No, because at the end,

1 that's what I used to calculate his risk, but
2 that's based on EPA and Dr. Goodman and the other
3 agencies doing a full evaluation of all of the
4 available data for kidney cancer and determining
5 that the Charbotel study is the best study to use
6 to evaluate risk.

7 So it's a study that's used -- in the
8 end, it's the study that's used, but it's used in
9 the context of a lot of other available
10 information that was looked at to come to the
11 decision that the Charbotel was the best, most
12 representative study for risk evaluation.

13 BY MR. SNIDOW:

14 Q. Did you do an independent review of
15 other studies looking at TCE and kidney cancer?

16 A. I did not do that for my report.
17 Dr. Goodman did.

18 Q. She told you the other ones weren't very
19 good; right?

20 MS. ELLISON: Object to form. She was
21 still answering the question. So I'd just ask
22 that you let her finish it. Thank you.

23 THE WITNESS: I agree with Dr. Goodman's
24 methodology. She did look at a lot of studies
25 related to TCE and kidney, cancer including animal

1 studies and mechanistic studies.

2 (Bailey Exhibit 21 was marked.)

3 BY MR. SNIDOW:

4 Q. Let's do Tab K. Mark as -- put this one
5 to the side. Mark as Exhibit 21 the Charbotel
6 study.

7 You recognize this as Charbotel; right?

8 A. Yes.

9 Q. You've reviewed this in doing your
10 report; right?

11 A. I have looked at this study, yes.

12 Q. Let us start with -- if you will go to
13 page 778. If you look at the bottom right-hand
14 column, do you see where it says, "An expert
15 performed"?

16 A. Um-hum.

17 Q. It says, "An expert performed the
18 exposure assessment by using information from the
19 occupational questionnaires (a questionnaire
20 devoted to the screw-cutting industry and a
21 general one for any other jobs) and the task
22 exposure matrix for the screw-cutting tasks."
23 Right?

24 A. Yes.

25 Q. So that's how they evaluated TCE

1 exposure in Charbotel; correct?

2 A. They used a job matrix, yes, job
3 exposure matrix.

4 Q. All based on a questionnaire about where
5 people worked? Yes?

6 A. It does look like a questionnaire, an
7 occupational questionnaire was used, but the idea
8 that they have information about the different
9 tasks that people did or do and what the exposures
10 are for those types of tasks.

11 Q. And in your view, that is a high quality
12 exposure metric?

13 A. It is based on -- I mean, sometimes
14 there are epidemiology studies, occupational
15 studies that look at exposures with personal
16 monitoring, and those are good estimates of
17 exposure.

18 But job matrix is a very common way to
19 look at exposure information in occupational
20 studies. And ultimately the exposure information
21 that goes into the job matrix is based on
22 monitoring of workers in those tasks. So it is
23 something that's commonly used in epidemiology.

24 Q. You agree that's going to lead to some
25 exposure misclassification?

1 A. I can't say that for sure for this
2 report. I don't know. I mean, I would have to
3 look at -- Dr. Goodman would be the one to opine
4 on that. That's not something that I talked about
5 in my report.

6 Q. Let's walk it through. What the authors
7 are trying to figure out is how much TCE these
8 employees were exposed to; true?

9 A. Yes. The authors yes.

10 Q. You want number to be as accurate as
11 possible; correct?

12 A. Correct.

13 Q. In an ideal world, you can have like a
14 little badge or something and you would monitor
15 exactly how much TCE people are exposed to; right?

16 A. Right.

17 Q. They don't have that in Charbotel, do
18 they?

19 A. That's right.

20 Q. Instead, they went and sent out a
21 questionnaire and said, where did you work in the
22 factories and how long did you work there; right?

23 MS. ELLISON: Object to the form.
24 Foundation.

25 THE WITNESS: I don't know the exact

1 questions that were asked, but it was developed
2 from a questionnaire. But it's also common to
3 gather exposure information in that way for
4 epidemiology studies, and EPA considered that when
5 they chose this study as a reliable study.

6 BY MR. SNIDOW:

7 Q. You have an independent opinion that
8 Charbotel provides the best exposure estimates for
9 the risk of kidney cancer from TCE; right?

10 MS. ELLISON: Object to the form.

11 BY MR. SNIDOW:

12 Q. You're not just relying on EPA. That's
13 your opinion?

14 MS. ELLISON: Object to form.

15 THE WITNESS: So I am relying on EPA's
16 evaluation of the studies to determine which of
17 the studies best reflect what exposures might be
18 associated with TCE. I'm relying on EPA's
19 evaluation and Dr. Goodman's evaluation.

20 BY MR. SNIDOW:

21 Q. To state the obvious, using a
22 questionnaire is not going to give you a perfectly
23 accurate estimate of the exact amount of TCE that
24 workers were exposed to; correct?

25 MS. ELLISON: Object to the form.

1 THE WITNESS: Using a questionnaire will
2 give you an estimate of the exposure. But it's
3 not a personal monitor, so it's not exact, no.
4 But it is the way that they did the evaluation
5 here. And a lot of times the epidemiology studies
6 that we have, we do what we can with the
7 information that is available and EPA has
8 determined. And this is a very common way to look
9 at exposure in epidemiology studies.

10 BY MR. SNIDOW:

11 Q. Yep. Another way would be a
12 questionnaire about where people live; correct?

13 MS. ELLISON: Object to form.

14 THE WITNESS: Another way to do what?

15 BY MR. SNIDOW:

16 Q. Another valid way of trying to get an
17 exposure when you don't have personal monitoring,
18 you can ask people where they live?

19 A. So that's different. I think for
20 occupational studies, it's common to use an
21 exposure matrix when you know that people are
22 exposed to a certain chemical, but you're not sure
23 what it is. Where people lived is very different
24 because there's a lot of additional other things
25 that you'd want to consider for where someone

1 lives.

2 Q. If you go to page 781 at the bottom, it
3 defines the dose tertiles that's used in
4 Charbotel, right, and it says, "The cumulative
5 dose tertiles defined on controls' exposure were 1
6 to 150 parts per million years." Correct?

7 A. Correct.

8 Q. That is an area under the curve
9 measurement; correct?

10 A. PPM years is cumulative, yes.

11 Q. That does not take into account
12 someone's weight; right?

13 A. No. This is just inhalation
14 concentration.

15 Q. Correct. That's a perfectly valid way
16 of doing exposure estimates for inhalation; true?

17 A. For inhalation, yes.

18 Q. Just to be clear, the cancer slope is
19 ultimately going to be based on the IUR; correct?

20 A. The cancer slope factor does based on
21 off of the IUR using a PBPK model that does that
22 extrapolation and accounts for body weight.

23 Q. Then it looks like they've classified
24 these workers into low, medium and high cumulative
25 doses; true?

1 A. Right.

2 Q. Then if we go over and look at the
3 results, it says the table that was reprinted in
4 IRIS EPA that we were looking in the bottom right,
5 Table 6?

6 MS. ELLISON: What page are you on?

7 MR. SNIDOW: 782 at the top, Table 6,
8 bottom right.

9 THE WITNESS: Yes, I see that.

10 BY MR. SNIDOW:

11 Q. If we look at low, that's 1 to 150 parts
12 per million years?

13 A. Yes.

14 Q. And the adjusted odds ratio there is
15 above 1.0; true?

16 A. The first number is, but the confidence
17 interval includes one, so it's not statistically
18 significant.

19 Q. That doesn't mean you just ignore it;
20 right?

21 A. It means that it's not significant, so
22 you don't know whether there is an association or
23 not. It suggests that there may not be an
24 association. It's not statistically significantly
25 elevated.

1 Q. If you look in the bottom, it says, "A
2 significant trend was also identified between
3 cumulative dose and RCC risk." Right? Bottom
4 left of 782.

5 A. Yes. That's what it says.

6 Q. And that is statistically significant?

7 A. Just barely, below .05, yes.

8 Q. Just barely. This is the paper that the
9 EPA uses to calculate -- to create the
10 dose-response curve for TCE?

11 A. Yes.

12 MS. ELLISON: Object to the form. Just
13 let me object.

14 BY MR. SNIDOW:

15 Q. So what that means is in a statistically
16 significantly way, the higher the TCE, the higher
17 the kidney cancer risk; true?

18 MS. ELLISON: Object to form.

19 THE WITNESS: So the higher the TCE
20 exposure concentration, the higher the risk
21 calculation will be. That doesn't necessarily
22 mean that there's a concern for health effects.

23 BY MR. SNIDOW:

24 Q. I don't follow. You have to explain
25 that one.

1 A. Can you ask your question again? I'm
2 not sure I understand your question.

3 Q. The statistically significant
4 dose-response trend means the higher the TCE
5 exposure, the higher the risk of kidney cancer?

6 A. It means that there is an increase of
7 risk with increasing doses, yes.

8 Q. Now, where in Charbotel does it suggest
9 that exposures below 335 parts per million don't
10 increase the risk of kidney cancer?

11 A. So that is something that I relied on
12 from Dr. Goodman's report and her interpretation
13 of this study. So I'm not going to say where it
14 says 335 PPM year in this study. But her
15 evaluation of the study and those exposure
16 estimates are the basis of that cutoff point.

17 Q. You don't have any independent opinion
18 on whether there's a risk of kidney cancer from
19 TCE below 335 parts per million years?

20 A. Well, based on my report, there is
21 likely to be -- that's the threshold. That's the
22 concentration where you're likely -- where it's
23 possible to see kidney cancer following that TCE
24 exposure.

25 Q. That's the threshold?

1 A. That's the high concentration. Based on
2 the Charbotel study, that's what comes out of that
3 study. Based on Dr. Goodman's review of that
4 study, that high concentrations of TCE, 335 PPM,
5 greater than 335 PPM year in the occupational
6 studies will -- can result in kidney cancer.

7 Q. You understand that a threshold means
8 the exposure below which there's not an increased
9 risk; right?

10 A. Yes.

11 Q. So your testimony is 334 parts per
12 million years of TCE, no increased risk of kidney
13 cancer?

14 A. The Charbotel study supports that levels
15 between 335 PPM year as Dr. Goodman describes in
16 her report are not expected to result in an
17 increased risk of kidney cancer.

18 Q. Show me that in Charbotel. That was my
19 question.

20 MS. ELLISON: Object to form.

21 BY MR. SNIDOW:

22 Q. I know what you say in your report. I
23 know what Dr. Goodman says in her report. I'm
24 asking you. You guys say that, but where is that
25 in Charbotel?

1 MS. ELLISON: Object to form.
2 Foundation.

3 THE WITNESS: So that is something that
4 Dr. Goodman would be able to answer. That's not
5 something that I did, that I evaluated for my
6 report. I rely on Dr. Goodman's analysis. I rely
7 on her methodology. I know that she looked at
8 that exposure information and came to her
9 conclusion.

10 BY MR. SNIDOW:

11 Q. Go to page 777 of Charbotel, the front
12 page. Do you see at the bottom, in the abstract,
13 there's a sentence that says, "This study
14 suggests"?

15 A. Yes.

16 Q. It says, "This study suggests an
17 association between exposures to high levels of
18 TCE and increased risk of RCC." Correct?

19 A. Correct.

20 Q. That's the 336 parts per million years
21 result?

22 A. I think that this is referring to the
23 high dose of the three.

24 Q. I do, too. So 336; right?

25 MS. ELLISON: Object to form.

1 Foundation.

2 BY MR. SNIDOW:

3 Q. Or 335, I guess.

4 A. Yes. That actually is here, that 335
5 PPM years. I see that now.

6 Q. Then turn to the front again, 777. The
7 next sentence says, "Further epidemiological
8 studies are necessary to analyze the effect of
9 lower levels of exposure." Correct?

10 A. That is what it says.

11 Q. Dr. Goodman has interpreted Charbotel to
12 establish a threshold at below 335 parts per
13 million; correct?

14 MS. ELLISON: Object to form.
15 Foundation.

16 THE WITNESS: So the 335 PPM year does
17 come from the high dose where it's statistically
18 significant. The epidemiology study reports the
19 results of the study. It's often a conclusion in
20 epidemiology studies or other studies that
21 additional studies are necessary to analyze
22 effects or other exposure concentrations or other
23 types of studies could be done.

24 That doesn't mean that there are effects
25 at lower concentrations. That just means that it

1 would be helpful to be able to look at a study
2 that looks that low. But that's not what we have.

3 What we have and what we often have for
4 epidemiology studies are high exposure
5 concentrations where there is an effect. Then EPA
6 does what they can with that information and
7 extrapolates using very conservative exposure
8 estimates down to much lower concentrations.

9 BY MR. SNIDOW:

10 Q. So you agree though, like you said, it
11 would be helpful to look at studies that looked at
12 lower levels of TCE exposure and then see whether
13 they showed an increased risk of kidney cancer?

14 A. It's always helpful to have more
15 information.

16 Q. Especially when the study authors are
17 saying you need further studies to analyze the
18 data; right?

19 MS. ELLISON: Object to form.

20 THE WITNESS: The authors of these types
21 of publications will often say additional
22 information would be helpful.

23 BY MR. SNIDOW:

24 Q. So did you do that? Did you look at
25 studies looking at lower levels of TCE to see if

1 there's a link with kidney cancer?

2 MS. ELLISON: Object to form.

3 THE WITNESS: There are no studies that
4 are this reliable that look at levels that low.

5 BY MR. SNIDOW:

6 Q. My question was: Did you read any?

7 MS. ELLISON: Object to form.
8 Foundation.

9 THE WITNESS: So Dr. Goodman would have
10 reviewed those studies and considered those
11 studies in her report. If that was a study that
12 had exposure information and I thought it was
13 relevant for me to look at, which I would have if
14 that study existed, then I would have looked at
15 it. But that study doesn't exist.

16 BY MR. SNIDOW:

17 Q. Can you tell me any studies that you
18 looked at to see if they were reliable?

19 MS. ELLISON: Objection. Form.

20 THE WITNESS: I looked at the studies
21 that Dr. Goodman cites in her report. I looked at
22 the studies that she cited and talked about in her
23 report. I looked specifically at ones that have
24 exposure information. And that's what I looked
25 at.

1 BY MR. SNIDOW:

2 Q. Did you review the Andrew 2022 study?
3 Sorry if I asked this earlier. Forgive me if I
4 already did. Did you review Andrew 2022?

5 A. I don't recall Andrew 2022.

6 Q. So I'm going to mark as Exhibit 23 --
7 MS. ELLISON: 22 maybe?

8 MR. SNIDOW: Isn't Charbotel 22?

9 MS. ELLISON: I have it as 21.

10 MR. SNIDOW: You guys are right. I'm
11 marking as Exhibit 22 Andrew.

12 (Bailey Exhibit 22 was marked.)

13 BY MR. SNIDOW:

14 Q. Here's Andrew 2022. And just put it
15 next to Charbotel for a second and confirm that it
16 came out 16 years after Charbotel.

17 A. 2022 is, yes, 16 years later.

18 Q. Have you read this study?

19 A. This is not a study I'm familiar with.

20 Q. Do you want to take a second to read it?

21 A. I can look at the abstract. I think it
22 would take me a while to read it all and interpret
23 the study. I can read the abstract to start.

24 Q. Start by reading the abstract. If you
25 want to go off the record and read it, that's

1 totally fine.

2 MS. ELLISON: If she reviews it, we'll
3 be on the record. We're not going to have her
4 review anything off the record. That's what you
5 all have been doing in all depositions.

6 MR. SNIDOW: That's my policy. Your
7 policy is my policy.

8 MS. ELLISON: We're on the same page.

9 THE WITNESS: Am I reading the whole?
10 BY MR. SNIDOW:

11 Q. Start with the abstract. If you need a
12 second, I will let you read it. There's only a
13 few portions I want to go through.

14 A. Okay.

15 Q. So if you will look at page 4, you'll
16 see Section 3.3 says Trichloroethylene in New
17 Hampshire?

18 A. Yes.

19 Q. It reports the mean median -- mean and
20 median groundwater TCE levels; right?

21 A. Yes.

22 Q. And the median TCE levels was
23 135 micrograms per liter?

24 A. Yes.

25 Q. And you agree that's within the range of

1 Camp Lejeune contamination levels?

2 A. The median concentration is, but the
3 range that is being shown here is much higher.

4 Q. And you agree this is orders of
5 magnitude less concentration than the folks in
6 Charbotel were exposed to; correct?

7 A. So this is drinking water versus
8 inhalation. So it's a different -- that's why I
9 can't do a direct comparison.

10 Q. Just in terms of straight concentration,
11 a microgram per liter is a part per billion;
12 correct?

13 A. Microgram per liter is a part per
14 billion in water. It's a very different analysis
15 for air. And it's a different route. You're
16 ingesting versus inhaling. So it's different.

17 Q. If you go to page 5, do you see it
18 reports increased risk in the 50th to 75th
19 percentile?

20 A. Yes, but I also see that there's a
21 decreased risk in a greater than 75th percentile,
22 which is interesting.

23 Q. Dr. Bailey, you haven't read this at
24 all; right?

25 A. I'm looking at the table. I'm looking

1 at the results.

2 Q. In considering -- doing your analysis of
3 any of the 25 people, you never read this report;
4 right?

5 A. I did not read this report. I'm looking
6 at it now for the first time.

7 Q. If you turn to the Conclusions, page 9,
8 it says, "In summary, we observed an increased
9 risk of kidney cancer associated with estimated
10 TCE exposure." And then the last thing, it says,
11 "A study of heightened cancer surveillance for
12 members of the public with a history of TCE
13 exposure is warranted." Right?

14 A. That's what it says.

15 Q. I assume you agree that is entirely
16 under the threshold at 335 parts per million years
17 for TCE; right?

18 A. 335 parts per million years is an
19 inhalation concentration. This is a drinking
20 water concentration. I would say that this study
21 does not conclusively say that there's an
22 increased risk considering that a higher dose
23 showed a decreased risk. So I don't think this is
24 a reliable study.

25 Q. I want to make a record on this. You

1 read the abstract; correct?

2 A. I did. And I'm also looking at the
3 data.

4 Q. Hold on. You read the abstract. I
5 showed you the table and the conclusion; correct?

6 A. I can go read the study if you would
7 like.

8 Q. Hold on. I want to actually get to a
9 process point with you, which is you are willing
10 to testify that this is an unreliable study
11 without having read it?

12 MS. ELLISON: So if you want her to read
13 the study --

14 MR. SNIDOW: No. She didn't have to
15 offer that. She could have asked to read it.

16 MS. ELLISON: You're asking her
17 questions about the study, J.J. So either ask her
18 questions and give her time to review or don't ask
19 questions. But don't ask questions and then say
20 you have no idea what's in that study.

21 MR. SNIDOW: Okay.

22 BY MR. SNIDOW:

23 Q. You can put that one aside.

24 Did you read the Moore 2010 study?

25 A. I have looked at the Moore 2010 study.

1 Q. Is that a reliable study?

2 A. That is a study that EPA did consider in
3 its evaluation for TCE but ultimately decided that
4 the Charbotel study was a more reliable study for
5 quantitative estimates of risk for TCE.

6 (Bailey Exhibit 23 was marked.)

7 BY MR. SNIDOW:

8 Q. I'll mark this as Exhibit 23. This is
9 the Moore 2010 study.

10 If you will look at page 2, the end of
11 the abstract, it says, "These findings provide the
12 strongest evidence to date that TCE exposure is
13 associated with increased renal cancer risk."

14 A. That's what the authors of the study
15 concluded.

16 Q. And where in your kidney cancer report
17 do you discuss this study?

18 A. So I do not discuss this study because I
19 relied on the toxicity value that EPA calculated
20 that's based on the Charbotel study. So that's
21 the study that I briefly talk about in my report.
22 Dr. Goodman did talk about this study in her
23 report.

24 Q. Break this down. Before we were
25 talking, you said you did a risk assessment. You

1 looked at the MoEs and then you compared the
2 plaintiffs' exposure to reliable epidemiology;
3 correct?

4 A. Yes.

5 Q. Is Moore 2010 one of the pieces of
6 epidemiology that you compared the plaintiffs'
7 exposure to?

8 A. So I did not compare the exposure
9 information from Moore because of EPA's
10 interpretation of the Moore study in the context
11 of the Charbotel study where they concluded that
12 the Charbotel study was more reliable
13 quantitatively. So I used that study for
14 comparison.

15 Q. So is that a no, you didn't do any
16 comparisons with Moore?

17 MS. ELLISON: Object to form.

18 THE WITNESS: I did a comparison for the
19 Charbotel study because that's the one that EPA
20 relied on after reviewing both of them.

21 BY MR. SNIDOW:

22 Q. Let's go to the results on page 6,
23 middle of the page. Do you see where it says "For
24 TCE exposure"?

25 A. Yes.

1 Q. It says, "For TCE exposure, ORs" -- you
2 know that means odds ratio; right?

3 A. Um-hum.

4 Q. -- "were significantly elevated for all
5 exposure indices and was strengthened after
6 analyses were restricted to a high confidence
7 assessment." Correct?

8 A. That's what it says. I don't see
9 confidence intervals there.

10 Q. Go to page 13. You see that they do
11 cumulative PPM years?

12 A. Yes.

13 Q. It looks like they've broken it into
14 less than 1.58 PPM years and more than 1.58 PPM
15 years; right?

16 A. Yes.

17 Q. And both odds ratios are above 1.0?

18 A. Yes.

19 Q. And the result for more than 1.58 parts
20 per million years is statistically significant;
21 correct?

22 A. It is.

23 Q. This is, what, two orders of magnitude
24 less than the exposures in Charbotel?

25 A. If you're comparing to the 335,

1 mathematically it is lower. But I would have to
2 look to see how that compares to the plaintiffs'
3 exposures. I did calculate -- let's see. I could
4 see how that compares. But the bottom line is
5 that EPA did look at this study, and with the
6 information from the study in addition to the
7 Charbotel study decided that the Charbotel study
8 was a better study to derive a quantitative
9 toxicity value.

10 So EPA did not think that this exposure
11 estimate was reliable enough to derive a risk
12 value. So that's the basis of my comparison to
13 Charbotel.

14 Q. So that's a no, you didn't look to see
15 if any of the plaintiffs at Camp Lejeune had
16 exposures of more than 1.58 parts per million
17 years?

18 MS. ELLISON: Object to form.

19 THE WITNESS: I did not. I relied on
20 the Charbotel study, which is the study that EPA
21 determined was more reliable for a quantitative
22 estimate of exposure and risk and dose-response
23 evaluation.

24 BY MR. SNIDOW:

25 Q. Now, the EPA didn't say Moore is an

1 unreliable study. You're not testifying to that?

2 A. EPA said that the Charbotel study was
3 more reliable for deriving a quantitative risk
4 value.

5 Q. To do risk assessments; correct?

6 A. For risk assessments.

7 Q. That's why I keep going back to this.
8 You did risk assessments. You did the MoEs. Then
9 you did the comparison to epidemiology that was
10 deemed reliable by you or Dr. Goodman; right?

11 MS. ELLISON: Object to form.

12 BY MR. SNIDOW:

13 Q. Correct?

14 A. I did that comparison, yes.

15 Q. I'm not talking about the first one.
16 I'm talking about the last one where you said you
17 compared to epidemiology.

18 Why didn't you compare the exposures of
19 the plaintiffs to the results of Moore 2010?

20 A. Because I was comparing to -- I already
21 have a comparison to a reliable epidemiology study
22 that EPA determined to be more reliable than the
23 Moore study based on the exposure information, and
24 ultimately that is what I'm doing.

25 I'm comparing exposure information in

1 the study to exposure information for the
2 plaintiffs. And it makes sense to me to use what
3 the Agency is considering to be a more reliable
4 study for exposure, and that's Charbotel.

5 Q. You can put this one to the side for a
6 moment.

7 Did you review the Parker and Rosen
8 study looking at people in Woburn, Massachusetts?

9 A. I don't recall looking at that specific
10 study for my report.

11 Q. So you didn't do any comparisons with
12 the results from Woburn, Massachusetts?

13 A. I did not do any comparison to Woburn,
14 Massachusetts drinking water. I believe it was a
15 drinking water study.

16 Q. Let us -- can you go to your report for
17 Mousser, which I think is marked as Exhibit 20.

18 MS. ELLISON: 20, yeah.

19 BY MR. SNIDOW:

20 Q. Go to page 39.

21 A. Okay.

22 Q. And this is the section where you're
23 evaluating the link between PCE and kidney cancer;
24 right?

25 A. This is where I look at -- let me read

1 this. I'm pointing to studies that looked at
2 possible associations between PCE exposure and
3 kidney cancer, yes.

4 Q. And you don't cite any?

5 MS. ELLISON: Object to form.

6 THE WITNESS: So I looked for reliable
7 studies in Dr. Goodman's report, and there are no
8 epidemiology studies, reliable epidemiology
9 studies that report exposure information for PCE,
10 and also looked at kidney cancer. But I do point
11 to the animal studies that do look at that.

12 BY MR. SNIDOW:

13 Q. So did you do an independent review of
14 the literature to look for links between PCE and
15 kidney cancer?

16 MS. ELLISON: Object to form.

17 THE WITNESS: I did not do an
18 independent review. That's not what I was asked
19 to do. I relied on Dr. Goodman's review. And
20 again, I agree with her methodology and her
21 systematic review approach.

22 BY MR. SNIDOW:

23 Q. You say that Mr. Mousser's PCE exposure
24 estimates are well below those reported in the
25 animal bioassays; right?

1 A. Yes.

2 Q. Then you point out that his exposure is
3 less than the animals got; right?

4 A. Yes.

5 Q. Now, it's quite common in animal studies
6 to give them much higher doses than humans would
7 realistically be exposed to; true?

8 A. That is true.

9 Q. The reason for that is because -- well,
10 one reason is because you are ethically allowed to
11 experiment on animals, but you can't do that on
12 humans; true?

13 A. Yes. You can give animals. You can't
14 do experiments with humans in a laboratory.

15 Q. So how does it follow that just because
16 the animals had higher doses, that means humans at
17 lower doses aren't at an increased risk?

18 A. So for the PCE studies, Dr. Goodman's
19 report on those studies indicates -- this is what
20 I'm reading from my report -- that there are no
21 significant increases or trends in kidney tumors
22 in two-year chronic animal bioassays at
23 concentrations as high as 1,072 milligram per
24 kilogram day or 600 PPM inhalation. So there were
25 no effects in the animals even at those high

1 exposure concentrations.

2 So I think that that suggests that in
3 humans at doses well below where you're not seeing
4 effects in animals, you're not likely to see
5 effects in humans.

6 Q. Did you read those animal studies?

7 A. I have looked at the results of the
8 animal studies as Dr. Goodman reported them in her
9 report.

10 Q. So is that a no, you didn't review them
11 yourself?

12 A. I reviewed -- for the animal studies, I
13 relied on Dr. Goodman's summary of the exposure
14 information for the animal studies.

15 I don't have any reason to disagree with
16 her tabulating of the exposure information from
17 those studies. And I actually did have some
18 people in my group check to make sure that that
19 exposure information was tabulated correctly in
20 her report.

21 Q. I'm not trying to be cute. But like
22 this is an expert report. This is a paper. I'm
23 asking you the animal studies.

24 Did you review this, like Dr. Goodman's
25 version of this, or did you review the animal

1 studies? You, yourself.

2 MS. ELLISON: Object to form.

3 THE WITNESS: So I reviewed the results
4 from Dr. Goodman's report. I don't have any
5 reason to believe that she entered the
6 information, the exposure information from the
7 animal studies incorrectly, but we did check to
8 make sure that that information was entered
9 correctly and that those exposure concentrations
10 did result in no significant increase.

11 BY MR. SNIDOW:

12 Q. But did you read the animal studies?
13 Did you read them?

14 MS. ELLISON: Object to form.

15 THE WITNESS: I have looked at those
16 studies in the past. I did not look at -- I
17 didn't read those studies recently, but I have
18 looked at them, and I have looked at the results
19 of those studies.

20 BY MR. SNIDOW:

21 Q. Can you name me any of them?

22 MS. ELLISON: Object to form.

23 THE WITNESS: I can't name them, off the
24 top of my head, but if I looked at Dr. Goodman's
25 report, I can tell you who the authors are.

1 BY MR. SNIDOW:

2 Q. Do you have the Terry Dyer report?

3 MR. SNIDOW: Break? How long have we
4 been on?

5 THE VIDEOGRAPHER: Off the record at
6 3:38.

7 We've gone 4 hours, 37 minutes.

8 (Recess from 3:38 p.m. to 3:53 p.m.)

9 THE VIDEOGRAPHER: Back on the record at
10 3:53.

11 BY MR. SNIDOW:

12 Q. Dr. Bailey, I asked you if you talked to
13 Dr. Goodman. You said no.

14 Do you know if your team spoke to
15 Dr. Goodman's team?

16 A. I don't believe that the teams were
17 allowed to talk to each other.

18 Q. So did you and Dr. Goodman pull the same
19 articles in the literature review with your
20 librarians?

21 A. Dr. Goodman pulled the studies that she
22 thought were important. And then that information
23 was transmitted to DOJ, and then that list of
24 studies and those studies were transmitted to me.

25 Q. And then your team pulled them again?

1 A. Yeah. We pulled them from the file that
2 came from DOJ in the studies.

3 Q. But remember on the invoice for the
4 librarians. Were they actually pulling material
5 from publicly-available sources, or were they just
6 opening a packet from DOJ with Dr. Goodman
7 materials, do you know?

8 A. They were not involved in that. So they
9 would have been pulling maybe risk specific
10 studies that I was interested in looking at or --
11 yeah, I think that's what they were pulling. They
12 were pulling different studies. I don't recall
13 the exact studies that they pulled, but...

14 Q. Now, if I understood correctly, you were
15 relying pretty heavily on the EPA in choosing to
16 rely on Charbotel; right?

17 A. Yes. I was relying on EPA's evaluation
18 of all of the data and Dr. Goodman's.

19 Q. You're aware that the EPA has banned TCE
20 at levels lower than 335 parts per million;
21 correct?

22 A. So they have banned TCE based on worker
23 exposures, based on occupational exposures. And
24 in terms of the exposure concentration, I don't
25 know exactly what the exposure concentrations are

1 for those workers, but they did risk calculations
2 based on exposure estimates for the workers and
3 then determined that there should be a ban on TCE
4 based on how the risk calculations came out for
5 the workers.

6 Q. So I want to quickly go through for
7 bladder cancer. If you could turn to the Dyer
8 report, which I think was Tab 1.

9 A. Yep.

10 Q. Go to page 30. I want to talk about how
11 the PODs were calculated for PCE.

12 A. Okay. I'm on page 30.

13 Q. You cite a source there, US EPA 2012b
14 and c.

15 A. Yes.

16 Q. And that's the IRIS assessment?

17 A. That's the IRIS assessment.

18 Q. Did you review the IRIS assessment when
19 putting together your report?

20 A. Yes.

21 Q. You're aware that the PCE cancer slope
22 is derived from animal studies?

23 A. It is derived from animal studies and
24 liver cancer at the endpoint.

25 Q. So the cancer slope and IUR that you

1 used ultimately are not based on human
2 epidemiology; true?

3 A. They are in the sense that EPA reviewed
4 any available epidemiology for PCE and health
5 effects associated with exposure to PCE in those
6 studies and determined that the animal data for
7 liver cancer is the most reliable for deriving a
8 toxicity value in consideration of the
9 epidemiology on the animals.

10 Q. The cancer slope is not based on human
11 epidemiology, is it?

12 MS. ELLISON: Object to the form.

13 THE WITNESS: The cancer slope factor
14 is based -- is calculated based on an animal
15 study, but that animal study was chosen in the
16 context of reviewing a lot of other information,
17 not just that one animal study.

18 BY MR. SNIDOW:

19 Q. Right. I understand they considered a
20 lot of other information. But they eventually
21 created the cancer slope factor in the IUR using
22 the results from a study on rats in liver cancer;
23 correct?

24 A. Yes, as protective of all cancers for
25 humans.

1 Q. Then you ultimately used that IUR and
2 that cancer slope factor derived from the liver
3 cancer rat study to calculate the risk of bladder
4 cancer in humans?

5 A. I calculated a cancer risk from the
6 exposures in humans. You can apply that to
7 bladder cancer because EPA considered that data in
8 deriving its toxicity value and landed on liver
9 cancer in animals as being the most conservative,
10 most protected.

11 Q. You think that that is a better
12 methodology, for example, than looking at the
13 epidemiology linking PCE to bladder cancer?

14 A. So it's one part of my evaluation. It's
15 a conservative estimate of cancer risk for PCE,
16 but then I also looked at the epidemiology in
17 Section 8 where there is a study that looked at
18 PCE exposure and bladder cancer. So I did both.

19 Q. What's the study that looked at -- no.
20 I understand. We'll get there in a moment. I
21 want to go through the steps you have to go
22 through to do that.

23 First you have to use the liver cancer
24 rat study in order to create a dose response model
25 for the rats; correct?

1 A. That is what EPA did, yes.

2 Q. Then the EPA has to extrapolate that
3 from rats to humans; correct?

4 A. They do extrapolate that from rats to
5 humans.

6 Q. Then when you're doing the IUR, you have
7 to create a slope that lets you extrapolate from
8 high to low exposures; correct?

9 A. The IUR is typically a straight down
10 line from the point of departure down to the point
11 of origin.

12 Q. Then to get the ingestion risk, you have
13 to turn the IUR into a cancer slope; correct?

14 A. Correct. And they used the PBPK model
15 to do that extrapolation.

16 Q. Those steps that I just described were
17 how you calculated the increased risk from PCE;
18 right?

19 A. So those steps are what EPA used to
20 derive the toxicity values for PCE. Then I used
21 those toxicity values to calculate risk.

22 Q. You did say that you looked at some
23 epidemiology for bladder and PCE; correct?

24 A. Yes.

25 Q. That's the Hadkhale study?

1 A. Correct.

2 Q. Then if you turn to page 43 of your
3 report.

4 A. Yes.

5 Q. You say, "I relied on Hadkhale 2017,
6 which is the only bladder cancer epidemiology
7 study that Dr. Goodman evaluated that reported
8 exposure estimates for PCE."

9 Then you say, "Hadkhale reported no
10 significant associations and no trends between
11 bladder cancer and PCE inhalation exposures at
12 concentrations as high as 87.55 PPM years."
13 Right?

14 A. Yes.

15 Q. Did you verify whether that is true?

16 A. Yes. I looked at the Hadkhale study.

17 Q. So when we look at it, we're not going
18 to find any significant associations or trends
19 between bladder cancer and PCE all the way up to
20 87.55 PPM years; right?

21 A. So I looked at significant associations
22 and trends. So there might have been a
23 significant association, but if there's no trend,
24 then it's not considered significant. So it would
25 be like a non-monotonic dose response or

1 something. So I looked at both of those,
2 significant and trend.

3 Q. That's what you're trying to say here,
4 is that you only -- this says reported no
5 significant associations and no trends; right?

6 A. Yes. I'm saying I looked at both of
7 those things. They're both important.

8 Q. That's what you meant by putting and "no
9 trends" in parentheses?

10 A. Yes.

11 MS. ELLISON: Object to form.

12 BY MR. SNIDOW:

13 Q. That's what you meant?

14 A. This particular study -- they don't
15 always report trends, but this particular study
16 reported associations, confidence intervals so you
17 can get an idea whether it's significant or not
18 and also trends. So I wanted to make it clear
19 that I looked at the trends in addition to whether
20 the association was significant or not.

21 Q. So you, it sounds like, agree that
22 Hadkhale did report significant associations
23 between PCE and bladder cancer; right?

24 A. I'd like to look at Hadkhale to tell you
25 what they concluded.

1 (Bailey Exhibit 24 was marked.)

2 BY MR. SNIDOW:

3 Q. Let me show you Exhibit 24. Here you
4 go. And this is the Hadkhale article that you
5 were referencing in your report; right?

6 A. This is not -- this is the Hartwig.

7 MR. SNIDOW: Sorry. We'll leave this as
8 24 though.

9 MS. ELLISON: Okay.

10 (Bailey Exhibit 25 was marked.)

11 BY MR. SNIDOW:

12 Q. This we'll mark as 25. So this is the
13 Hadkhale study that you're referencing in your
14 report?

15 A. Yes.

16 Q. This is the only PCE epidemiology
17 bladder cancer study you discuss in your report;
18 right?

19 A. It's the only one I had exposure
20 information, so yes.

21 Q. We'll come back to that. If you go on
22 page 1739 at the bottom.

23 A. Yes.

24 Q. It's talking about an American study
25 that observed an increased risk of bladder cancer

1 among those exposed to the trichloroethylene at
2 the highest exposure level. Then it goes on to
3 say, "The study observed a dose-response
4 relationship with exposures to trichloroethylene."

5 And if you look at footnote 12, you'll
6 see that's the Zhao study.

7 A. Yes.

8 Q. Did you review that one?

9 A. I don't recall reviewing that study.

10 Q. If you go to page 1745, at the
11 conclusion at the end, it says, "The study
12 provides evidence of an association between
13 occupational exposure to," and then it mentions
14 perchloroethylene and bladder cancer risk; right?

15 A. I'm sorry. Where again are you?

16 Q. 1745, last paragraph, right at the end.
17 The study provides evidence of an association
18 between occupational exposure to
19 trichloroethylene, some other chemicals that
20 aren't relevant here, and bladder cancer risk.
21 Right?

22 A. That's what the authors concluded, yes.

23 Q. Right. And you and Dr. Goodman
24 interpreted this study to show no bladder cancer
25 risk up to 87.55 PPM years; right?

1 A. For perchlorethylene, I believe.

2 Q. That's one of the chemicals we just went
3 through; right?

4 A. Yes. But you weren't specific about
5 that for 87.5. So that would be specific to
6 perchlorethylene. Let me just look and see if
7 that's correct. Yes.

8 Q. So you have interpreted the study to
9 find no association between PCE and bladder cancer
10 even though the study authors said they got one?

11 MS. ELLISON: Object to form.

12 THE WITNESS: So I don't rely on the
13 author's interpretation. I look immediately at
14 the results of the analysis. And what I'm seeing
15 is for perchlorethylene, the trend is there's no
16 significant trend. And that's because although
17 there's a significant reported risk in the middle
18 range, there is not -- it actually significantly
19 decreased at the higher range.

20 So it doesn't reliably suggest that
21 there's an increased risk if you consider the
22 trends and the fact that it's -- the risk goes up
23 and then goes down.

24 BY MR. SNIDOW:

25 Q. You agree that bladder cancer is more

1 common in males than females?

2 A. I don't recall if that's true.

3 Q. Go to page 1744. Do you know where the
4 PCE results are there?

5 A. I see the PCE results.

6 Q. Statistically significant trend for the
7 males?

8 A. There is not a statistically significant
9 trend for the males at the highest dose.

10 Q. Do you see P for trend?

11 A. I do see a trend, but there is not --
12 it's not statistically significant. So you need
13 to look at both of those things, is it
14 statistically significant and a trend. It goes up
15 and then goes down in terms of significance.

16 Q. In terms of significance, but not in
17 terms of the risk ratios.

18 A. Right, but you have to interpret the
19 ratios in the context of the confidence intervals.
20 And if the confidence interval includes one, then
21 you can't say whether there's an association or
22 not because it's not statistically significant.

23 So I interpreted that that data to
24 suggest that at 87.55 PPM, there's not an
25 increased -- plus .05 is borderline. I don't even

1 know if it's considered statistically significant.
2 That's borderline for the trend.

3 Q. So you interpreted the study as no
4 association at any level between PCE and bladder
5 cancer?

6 A. Up to 87.55.

7 Q. Yes, even though the authors say they
8 found an association between PCE and bladder
9 cancer?

10 MS. ELLISON: Object to form.

11 THE WITNESS: The authors made that
12 conclusion, but I made my conclusion based on my
13 review of the data, which is reasonable.

14 BY MR. SNIDOW:

15 Q. Again, you didn't write this study;
16 right?

17 A. I did not author the study.

18 Q. For TCE and bladder cancer, if you go to
19 page 25 of your report, it looks like you again
20 relied on the Hadkhale study.

21 A. On page 25 of my report, I don't believe
22 I'm talking about Hadkhale there. 25 of my
23 report? Which report are we looking at?

24 Q. Dyer, Tab 1.

25 A. Page 25?

1 Q. Sorry. I wrote this down wrong. In
2 your assessment of TCE and bladder cancer, you did
3 not mention the Hadkhale study at all, did you?

4 A. Where are we talking about in my report?

5 Q. 5.1.1.

6 A. I'm referring to Dr. Goodman's review of
7 all of the epidemiology, which would include
8 Hadkhale. And then I'm relying on the ATSDR, EPA
9 and IARC for that. But Hadkhale -- what's the
10 date for Hadkhale? 2017. So it wouldn't have
11 been discussed in IARC, and it wouldn't have been
12 discussed in 2012 for EPA.

13 Dr. Goodman did consider it, and ATSDR
14 might have considered it. I don't know what the
15 cutoff was for studies for ATSDR in 2019.

16 Q. One of the things you did is you said
17 you compared the plaintiffs' exposure to exposure
18 in the relevant epidemiology; right?

19 A. Yes.

20 Q. The reliable epidemiology. It looks
21 like you guys agree that Hadkhale is reliable;
22 right?

23 MS. ELLISON: Object to form.

24 THE WITNESS: So it is a study. It was
25 one study that looked at exposure information.

1 It's an occupational study. Dr. Goodman includes
2 in it her report as a reliable study to be
3 considered for all -- in the context of all of the
4 other information.

5 BY MR. SNIDOW:

6 Q. Did you do any comparison of any of the
7 plaintiffs' TCE exposure and the bladder cancer
8 results in the Hadkhale study?

9 A. Yes.

10 Q. You did. Show me.

11 A. In Section 8. 3.1.

12 Q. I think maybe this is where I wanted to
13 go. If you look at the Hadkhale study on
14 Tab -- excuse me -- on page 1740 at the top.

15 A. Yes.

16 Q. You've got a statistically significant
17 result at 129.5 parts per million?

18 A. Yes.

19 Q. You've got borderline --

20 A. At greater at 129.5.

21 Q. Borderline statistically significant
22 result at 32.8 parts per million?

23 A. Yes.

24 Q. The authors interpret the study as
25 finding association between TCE and bladder

1 cancer?

2 A. That's the author's interpretation, yes.

3 Q. And you interpreted it as not finding an
4 association?

5 A. Let me read what I said here. So I
6 described the Hadkhale study as reporting
7 statistically significant associations between TCE
8 exposure and bladder cancer. Then I talk about
9 the limitations in the study.

10 Further, there are limitations in the
11 study including self-reported occupational history
12 to estimated exposures and also lack of adjustment
13 for smoking. But even so, I did look at the
14 lowest concentration in that range and compared
15 the lowest concentration in that range to the
16 plaintiffs just to provide some perspective about
17 how much lower -- even if you look at this study
18 and the exposure information in the study, how
19 does it compare to the exposure estimates for the
20 plaintiffs. So that's what I did.

21 Q. You did that even though this is relying
22 upon self-reported occupational history; right?

23 MS. ELLISON: Object to the form.
24 Foundation.

25 THE WITNESS: I did do that comparison

1 because it was the only study that looked at
2 exposures, occupational exposures to these
3 chemicals and bladder cancer. And it still
4 provides some perspective on this study in the
5 context of how it compares to the plaintiffs.

6 If we were talking about exposures that
7 were much higher, then you'd want to look more
8 carefully at this. But what I'm saying here is
9 the exposures are below even the lowest exposure
10 in this study, and there's uncertainty for the
11 study because of the smoking.

12 BY MR. SNIDOW:

13 Q. Because of what?

14 A. Of the smoking, potentially confounded
15 by smoking.

16 Q. Can you cite to me any scientific
17 evidence suggesting that TCE exposure is
18 correlated with smoking?

19 A. I can't cite scientific evidence
20 specifically, but in general, it's my
21 understanding that bladder cancer is a risk factor
22 for -- smoking is a risk factor for bladder
23 cancer. But I don't have any of the studies at
24 the tip of my tongue.

25 Q. Do you know whether 12 to 86 part per

1 million years is a realistic exposure for Marines
2 at Camp Lejeune?

3 MS. ELLISON: Object to form.
4 Foundation.

5 THE WITNESS: I can't answer that
6 question. I need more information about what do
7 you mean by realistic.

8 BY MR. SNIDOW:

9 Q. Could Marines have gotten to that level
10 of exposure?

11 MS. ELLISON: Object to form.

12 THE WITNESS: I don't know. I would
13 need to understand where that number comes from.

14 BY MR. SNIDOW:

15 Q. Well, it comes from what we were just
16 looking, at Hadkhale at 1740 for PCE.

17 A. We're talking about PCE then.

18 Q. No. Sorry. For TCE. Do you see in the
19 middle -- oh, for PCE. Sorry. See in the middle
20 13.6 to 87.55?

21 A. Yes.

22 Q. Did you do any calculations of whether
23 any of the Marines would have fallen into that
24 exposure category?

25 A. Well, I did compare the exposure

1 estimates for the Marines, and they were all below
2 that. So they would have been below, any of the
3 Marines that had bladder cancer.

4 Q. I think you compared it to 87. Did you
5 compare it to 13?

6 A. So I compared it to -- I actually did an
7 adjustment. I took the 87.55 PPM, which is an
8 occupational exposure, and adjusted it for
9 something that would be more continuous. So it's
10 the lower number, 21 PPM years. And none of the
11 plaintiffs were above that.

12 Q. I think I still don't understand. You
13 did something with the 87.55 result. Did you do
14 any comparisons with the 13.6 to 87.55 result?

15 A. I did not because looking at that data
16 as a whole, I conclude that the 87 -- that
17 there's -- that the study did not find -- does not
18 support an increased risk of bladder cancer for
19 PCE exposures up to 87.55 PPM years.

20 So based on my interpretation of the
21 data, based on the fact that there's not a
22 significant trend and the higher exposure group,
23 there's not a significant confidence interval, I
24 used the highest exposure estimate from that
25 range.

1 Q. You said before you did review the
2 Aschengrau study.

3 A. Yes.

4 Q. Did you compare any exposures from the
5 Camp Lejeune plaintiffs to the exposures that the
6 Aschengrau subjects experienced?

7 A. I did not because the Aschengrau study
8 does not provide individual exposure information.

9 MS. ELLISON: Is there another copy, by
10 any chance?

11 MR. SNIDOW: Yeah.

12 MS. ELLISON: Thank you.

13 BY MR. SNIDOW:

14 Q. If you go to page 291, in the bottom
15 right, the conclusion is, "We found evidence for
16 an association between PCE-contaminated public
17 drinking water and leukemia and bladder cancer."
18 Right?

19 A. That's what it says.

20 Q. And then it said, "Thus, its
21 carcinogenic potential is a matter of public
22 health concern." Right?

23 A. That is what the study -- that's what's
24 written there.

25 Q. You disagree with that. You don't think

1 that PCE at the levels here are a public health
2 concern?

3 MS. ELLISON: Object to form.
4 Foundation.

5 THE WITNESS: So this study looked at
6 different areas of PCE contamination and sort of
7 ranked them based on higher or lower
8 concentrations and reported what they reported.
9 But there's no discussion in this paper about the
10 specific exposure concentrations, the specific
11 levels of PCE in drinking water that people were
12 exposed to or for the individuals who had bladder
13 cancer.

14 BY MR. SNIDOW:

15 Q. If you look at page 289, do you see in
16 the middle where they're talking about relative to
17 liver dose?

18 A. 289. First column, second column?

19 Q. Left-hand column.

20 A. Yes.

21 Q. Second to last paragraph, relative to
22 liver dose estimates?

23 A. Yep.

24 Q. That's a measure of exposure; right?

25 A. It's a relative measure of exposure.

1 You're looking at different areas and saying this
2 is higher, this is the next. It's a method that
3 you can use to rank areas in terms of which might
4 be higher than the other. But it's not an actual
5 concentration that they're estimating.

6 Q. Well, they actually do give a cumulative
7 dose in absolute numbers; right? The 90th
8 percentile among exposed controls were 27.1 and
9 44.1 milligrams?

10 MS. ELLISON: Object to form.

11 THE WITNESS: So that's 90th percentile
12 among exposed controls. This was, I believe, the
13 amount that is going into the home. Again, it's
14 not a concentration. It's a mass amount.

15 And they calculate that and then sort of
16 rank each of the areas based on that total mass
17 that's going into the house. That's not a water
18 concentration. It's not something that you can
19 use to calculate a dose for individual people.
20 It's not something that you can use to say even
21 what the water concentration was. It's just total
22 mass. It's best used for sort of ranking
23 different areas.

24 (Bailey Exhibit 26 was marked.)
25

1 BY MR. SNIDOW:

2 Q. I'll show you Exhibit 26. Did you
3 review what ATSDR said about the Aschengrau study?

4 A. I probably did, but I would like to look
5 at what they said.

6 Q. I assume you've reviewed the ATSDR
7 summary of the evidence. This one is an excerpt.
8 You said you have seen this before?

9 A. I have looked at the ATSDR report, yes.

10 Q. If you look at page 89, do you see
11 they're talking about Aschengrau?

12 MS. ELLISON: Just for the record, I
13 will just say that this excerpt only contains
14 pages 1, 89 and 96 and nothing else.

15 BY MR. SNIDOW:

16 Q. If you need other parts of it,
17 Dr. Bailey, I'm happy to print one for you.

18 Do you see where it says Exposure
19 Duration Information in that column?

20 A. Yes.

21 Q. It says, "Note: High exposure (greater
22 than 90th percentile) was in range of Camp Lejeune
23 drinking water levels." Right?

24 A. That is what it says here.

25 Q. Yes. ATSDR seems to think that you can

1 use this to get a sense of exposure; right?

2 MS. ELLISON: Object to form.

3 THE WITNESS: I'm would like to see
4 where they determine that based on my read on
5 Aschengrau. I'm not seeing water concentrations
6 or water levels in this study or certainly not
7 directly related to the individuals who had health
8 effects in this study.

9 BY MR. SNIDOW:

10 Q. So if you go to page 285, look at the
11 top.

12 MS. ELLISON: Of Aschengrau?

13 MR. SNIDOW: Um-hum.

14 THE WITNESS: Yep.

15 BY MR. SNIDOW:

16 Q. Do you see where it says, "A large
17 proportion had been installed in the five towns of
18 the upper Cape Cod area"?

19 A. Yes.

20 Q. It says, "Typical concentrations in
21 affected lines in one town, Falmouth, range from
22 1600 to 7750 micrograms per liter"?

23 A. I do see that. That's a large range,
24 and it's much higher than levels at Camp Lejeune.

25 Q. Well, you were just saying that they

1 don't report them at all; right? You were wrong
2 on that.

3 A. Well, what they don't do is -- what you
4 don't know is what specifically is going into each
5 of the homes where these people are living. What
6 you only have from the study is the total mass.
7 This is just generally talking about typical
8 concentrations in affected lines.

9 There's nothing in this study that
10 directly connects the exposure in the
11 concentration of water to the individual who might
12 have been ingesting that water and the amounts
13 they were ingesting. So you can't connect,
14 directly connect the exposure concentration, the
15 level in the water, to the people who had bladder
16 cancer.

17 Q. Any idea why ATSDR might have used it to
18 compare directly to the Camp Lejeune levels?

19 MS. ELLISON: Objection. Foundation.
20 Form.

21 THE WITNESS: I don't know why they did
22 that.

23 BY MR. SNIDOW:

24 Q. You can put this one aside.

25 (Bailey Exhibit 27 was marked.)

1 BY MR. SNIDOW:

2 Q. I need to mark an exhibit. I will mark
3 as Exhibit 27 the report for Richard Sparks. This
4 is a report that you did for one of the
5 Parkinson's disease plaintiffs; correct?

6 A. Yes.

7 Q. And when you were reviewing the
8 epidemiology for Parkinson's and TCE, if you go to
9 page 39, it looks like you reviewed one study.

10 A. I considered all studies that reported
11 exposure information of the chemical that I was
12 looking at and the disease of concern. And
13 Solomon was the only one that had an inhalation --
14 an epidemiology study that also had inhalation
15 exposure information.

16 Q. Did you read any other studies looking
17 at TCE and PD?

18 A. I have looked at other studies related
19 to -- I looked at some of the animal studies
20 related to TCE and PD.

21 Q. How about human epidemiology?

22 A. If there was no exposure information
23 specifically described in the study, I didn't
24 review it carefully. I didn't review it in the
25 context of my report. So I reviewed sort of the

1 overall -- Dr. Goodman's overall review of those
2 studies that did not include exposure information.
3 Again, I agree with her methodology and her
4 conclusions about whether the chemical exposures
5 are related to Parkinson's disease.

6 But I specifically reviewed the studies
7 that looked at the exposure information because
8 that's what I did here in my Section 8.

9 Q. For one study; right?

10 A. If there were more than one, I would
11 have looked at all of them.

12 Q. You would have?

13 A. Yes.

14 Q. So you reviewed Goldman 2012?

15 A. Goldman 2012 is a study that I did look
16 at in the context of some of the rebuttals for the
17 Parkinson's disease experts, plaintiffs' experts.

18 Q. Do you want to show me that?

19 A. I don't believe it is in this report.

20 Q. This is a Parkinson's report; right?

21 A. If the plaintiff expert didn't talk
22 about the Goldman study, I did not talk about it
23 because the Goldman study is a drinking water
24 study. I would like to look at the Goldman study
25 if you have it. I have looked at it. But just to

1 refresh my memory.

2 Q. I do. And just so you know, it's not a
3 drinking water study. I really am curious as to
4 whether you have ever seen it.

5 A. Yeah.

6 MS. ELLISON: Objection to form.

7 (Bailey Exhibit 28 was marked.)

8 BY MR. SNIDOW:

9 Q. I'll mark it as Exhibit 28. This is
10 Goldman 2012. So you think you read this one?

11 A. So there were several Goldman studies.
12 I'm not sure if this is the one that I'm thinking
13 of or a different one. I believe there's a
14 different one that I may be thinking of.

15 Q. So did you review this one or not sure?

16 A. This one I don't recall looking at. I
17 did review a Goldman study, but this is not the
18 one that I'm thinking of.

19 Q. This is an occupational study; correct?

20 A. I would have to review it.

21 Q. Can you just confirm for me that in your
22 Parkinson's report, either in Section 8 or your
23 rebuttals to plaintiff experts, that you don't
24 discuss this study?

25 MS. ELLISON: Just to be clear, the only

1 report that's in front of her is the Sparks report
2 for Parkinson's, not the other four reports.

3 THE WITNESS: So I did not look at this
4 specific study. And I would have to look to see
5 whether Dr. Goodman reviewed this study. But it's
6 possible that she included this in her evaluation.
7 And EPA certainly would have considered this study
8 in its evaluation for TCE -- are we talking about
9 TCE? Yes, TCE -- and perc, particularly in the
10 most recent Tosca risk evaluation.

11 BY MR. SNIDOW:

12 Q. My question is just: Do you discuss
13 this paper?

14 A. I'd have to look at my references, but I
15 don't believe that I did because it was not
16 something that came up as a reliable study that
17 should be considered here.

18 Q. When you say "came up," you mean on
19 Dr. Goodman's analysis?

20 A. Based on Dr. Goodman's analysis of all
21 of the available information, yes.

22 (Bailey Exhibit 29 was marked.)

23 BY MR. SNIDOW:

24 Q. I'll mark as Exhibit 29 Goldman 2023.
25 Do you know whether you reviewed this study?

1 A. I did review this study.

2 Q. You did. Okay. You don't discuss it
3 anywhere in your report though; is that correct?

4 A. I don't discuss this in my report
5 because it sort of falls under the category of
6 Camp Lejeune studies that Dr. Goodman talks about
7 in her report. And there are limitation to those
8 studies as I summarize in my report.

9 Q. So this one is not Bove; right? This is
10 a different author?

11 A. Correct.

12 Q. What are the limitations of this one?

13 A. Let me look. So Dr. Goodman looked at
14 this study in the context of other Camp Lejeune
15 studies that looked at -- she looked at this study
16 that looked at Parkinson's disease. I don't
17 recall if there were other ones that looked at
18 Parkinson's disease.

19 But her conclusion was there's no
20 consistent associations reported between either
21 working or living at Camp Lejeune and TCE, PCE,
22 benzene or vinyl chloride exposures at Camp
23 Lejeune and Parkinson's disease. And that study
24 was included in her evaluation.

25 Q. Do you see the conclusions of Goldman

1 2023 here on the front?

2 A. Yes.

3 Q. It says, "The study's findings suggest
4 that the risk of PD is higher in persons exposed
5 to TCE and other VOCs in water four decades ago."
6 Right?

7 A. That's what the study concludes. That's
8 what the authors of the study conclude. That's
9 not what Dr. Goodman concludes about the Camp
10 Lejeune studies.

11 Q. So you'd go with Dr. Goodman over the
12 actual authors of Goldman 2023?

13 MS. ELLISON: Object to the form.

14 THE WITNESS: I rely on Dr. Goodman's
15 evaluation of all of the available information.
16 She doesn't rely on just one study. She looks at
17 all of the available information and integrates
18 all of that information, including study quality,
19 and reaches the conclusion that there is no
20 association -- the best available science does not
21 suggest that there's an association between TCE
22 and Parkinson's disease.

23 So that's what I rely on. And I agree
24 with her methodology.

25 MR. SNIDOW: Take a quick break.

1 THE VIDEOGRAPHER: Off the record at
2 4:35.

3 (Recess from 4:35 p.m. to 4:50 p.m.)

4 THE VIDEOGRAPHER: Back on the record at
5 4:50.

6 (Bailey Exhibit 30 was marked.)

7 BY MR. SNIDOW:

8 Q. Dr. Bailey, I'm going to show you a
9 document that I'll mark as Exhibit 30. This is
10 your report in the Connard case. If you'll look,
11 just confirm this is a leukemia plaintiff.

12 A. Yes.

13 Q. If you'll go to page 37 in Section 8, do
14 you see the section -- and it's on 36 as well --
15 you discuss the Talibov study?

16 A. Yes.

17 Q. Am I correct that's the only
18 epidemiology study that you mention looking at the
19 link between TCE or PCE and leukemia?

20 A. So that is one of the studies, and I
21 believe it may have been the only one of TCE and
22 the PCE that looks at specifically at -- there
23 were a number of leukemias. I can't remember if
24 it was leukemia in general or AML, acute myeloid
25 leukemia, that we looked at in this study. I

1 think it's just leukemia in general. This is what
2 it says in my report.

3 Q. This is the only epidemiology study you
4 cite?

5 A. Yes, in this section. And so it must
6 have been the only epidemiology study that had
7 exposure information for TCE and PCE and also
8 looked at leukemia specifically.

9 Q. And in Talibov, what was their measure
10 of exposure based on?

11 A. I don't recall. I'd have to look at the
12 study.

13 Q. But you chose that one to discuss
14 because it had the best measurement of exposure?

15 A. It was -- based on my report, it looks
16 like it was the only one that had inhalation
17 exposure information for these chemicals and also
18 looked at that endpoint.

19 Q. Did you review the Cohn 1994 study?
20 Have you?

21 A. I'm familiar with that study.

22 Q. You don't talk about it even though it
23 looked at the link between trichloroethylene and
24 leukemia; correct?

25 MS. ELLISON: Object to form.

1 Foundation.

2 THE WITNESS: I have talked about that
3 study in the context of the rebuttals, I believe.
4 And let me check my Section 9.

5 So I do talk about Dr. Gondek's
6 reference to that study. And then I talk about
7 Dr. Goodman's conclusion about the study. So I
8 relied on her evaluation of the Cohn study and
9 where she also says that EPA concluded that the
10 evidence for that study was not robust or
11 conclusive for an association between TCE exposure
12 and childhood leukemia.

13 BY MR. SNIDOW:

14 Q. Did you do any comparison of any
15 plaintiff exposures to the exposure in the Cohn
16 study?

17 A. I did not.

18 Q. Do you know what the exposure levels
19 were in the Cohn study?

20 A. Since EPA considered this to not be a
21 very robust or conclusive study, I did not
22 consider the exposure information in the Cohn
23 study.

24 Q. So it's a no, you don't know what the
25 exposure was?

1 A. Off the top of my head, I don't. But
2 it's also not considered a robust study. So it's
3 not really relevant.

4 Q. In your report, you don't describe any
5 of the strengths and limitation of the Cohn study,
6 do you?

7 A. I don't specifically describe the
8 strength or limitations, but Dr. Goodman does in
9 her report, and EPA does as well, and concluded
10 that the evidence was not robust or conclusive
11 based on that study.

12 Q. I don't mean to be rude.
13 Do you know whether the EPA is actually
14 talking about the Cohn study in that sentence?

15 A. Dr. Goodman is talking about how the
16 Cohn study was considered in EPA's toxicological
17 profile within which EPA concluded that the
18 evidence was not robust or conclusive.

19 Q. Right. But you made it seem that the
20 EPA said that the Cohn study was not robust and
21 conclusive. You have no evidence of that, do you?

22 MS. ELLISON: Object to form.

23 THE WITNESS: So if I could look at the
24 EPA toxicological profile and find its discussion
25 of the Cohn study, I could point to where EPA

1 concludes that the evidence was not robust or
2 conclusive. But I don't have any reason to
3 believe that that's not true if I wrote that in my
4 report and Dr. Goodman states it in her report.

5 BY MR. SNIDOW:

6 Q. You think that you independently
7 reviewed the Cohn study?

8 A. I likely looked at whether that was --
9 before I wrote that in my report, I'm quite
10 certain that I would have checked to make sure the
11 EPA said that.

12 Q. I understand that you reviewed the EPA
13 writeup. Did you review the Cohn study itself and
14 do your own evaluation about whether it was a
15 reliable study?

16 MS. ELLISON: Object to form.

17 THE WITNESS: I have looked at the Cohn
18 study but mostly in the context of how Dr. Goodman
19 describes the study and also EPA's conclusion
20 about the study.

21 BY MR. SNIDOW:

22 Q. Put that aside. I'm going to mark as
23 Exhibit 30 the Connard report.

24 If you'll turn to 37, do you see that
25 you discuss -- I'm sorry -- the two Rinsky

1 studies, 1981 and 1987?

2 A. Yes.

3 Q. Those are benzene studies?

4 A. Yes.

5 Q. And in your report, you compare exposure
6 of the plaintiffs to the exposures in the Rinsky
7 study?

8 A. Yes, I do, in the context of my margin
9 of exposure because the toxicity value for benzene
10 is based on those studies.

11 Q. Do you know what the exposure in those
12 two studies was based on?

13 A. I'm not sure what you mean by what the
14 exposure was based on.

15 Q. Do you remember Charbotel used an
16 occupational survey; right?

17 A. Yes.

18 Q. Do you know how they measured exposure
19 in the two Rinsky studies?

20 A. I don't recall how they measured
21 exposure, but it is an epidemiology study that EPA
22 relied on for its evaluation for benzene.

23 MR. SNIDOW: Give me Tab 4.

24 (Bailey Exhibit 31 was marked.)

25

1 BY MR. SNIDOW:

2 Q. I will mark this as Exhibit 31. This is
3 a report that you did for plaintiff Fiolek. If
4 you'll look and confirm this is a report on NHL.

5 A. Yes.

6 Q. If you go to page 4 -- 40, you state
7 there that ATSDR concluded there's sufficient
8 evidence for causation for TCE exposure in NHL;
9 correct?

10 A. ATSDR did reach that conclusion.

11 Q. And Dr. Goodman said that she thought
12 that the scientific evidence did not support a
13 causal association; right?

14 A. Yes. That's what Dr. Goodman concluded.

15 Q. And you relied on Dr. Goodman on that;
16 correct?

17 A. Yes. I relied on her systematic review
18 of the available information for that possible
19 relationship.

20 Q. Am I correct you reviewed only one
21 epidemiology study looking at the link between TCE
22 and NHL, and that's the Raaschou-Nielsen study?

23 A. So what this is talking about here is
24 the Raaschou-Neilsen study is the basis of the
25 toxicity -- the NHL toxicity value for TCE. So by

1 comparing -- by doing a margin of exposure for TCE
2 for the NHL toxicity value, I'm doing a comparison
3 to that study, yes. So I'm relying on the study
4 that EPA relied on.

5 Q. And you're aware that that study did
6 find an association between TCE and NHL?

7 MS. ELLISON: Object to the form.
8 Foundation.

9 THE WITNESS: So it is the basis of
10 EPA's toxicity value for NHL. So at some level,
11 EPA is saying there's an exposure to TCE that can
12 result in non-Hodgkin's lymphoma. That's based on
13 EPA's evaluation. But then you used that
14 information to do a risk calculation.

15 And then if you're well below the
16 concentration in the study or particularly if you
17 calculate a risk that's within EPA's or below
18 EPA's acceptable risk range, then it provides
19 support that those exposures are not of concern
20 for this health effect.

21 BY MR. SNIDOW:

22 Q. So just to break that down, EPA does
23 rely on Raaschou-Nielsen; correct?

24 A. To derive its NHL toxicity value for
25 TCE.

1 Q. For TCE. You though don't think TCE is
2 causally linked with NHL; correct?

3 MS. ELLISON: Object to form.
4 Foundation.

5 THE WITNESS: So EPA based on their
6 evaluation of the data concludes that -- let me
7 see where they have the conclusion, specifically
8 what they say.

9 BY MR. SNIDOW:

10 Q. Go in the middle of page 40 under TCE.
11 It's the sentence following ATSDR.

12 A. EPA, ATSDR, IARC concluded that
13 epidemiology studies suggest a causal relationship
14 between TCE exposure and NHL, yes.

15 Q. So to recap, ATSDR says there's
16 sufficient evidence; right?

17 A. Yes.

18 Q. EPA says that the study suggests a
19 causal relationship; right?

20 A. EPA says that.

21 Q. So does ATSDR; right?

22 A. ATSDR says that.

23 Q. So does IARC; right?

24 A. IARC does say that.

25 Q. Dr. Goodman says no; right?

1 A. Yes. And that's based on her review of
2 the information, and it's also based on a review
3 of more current information.

4 Q. You decided to accept her view over that
5 of ATSDR, EPA and IARC; right?

6 MS. ELLISON: Object to form.

7 THE WITNESS: So I'm not -- in my
8 calculation or evaluation of potential risk for
9 the plaintiffs here that have NHL, I'm not -- that
10 particular conclusion from Dr. Goodman's report
11 does not factor into my analysis because I still
12 used EPA's toxicity value that's based on NHL to
13 calculate a risk. And I still compare the studies
14 that look at NHL and TCE. And I compare the
15 exposure information.

16 So I'm still looking at those studies in
17 the context of the exposure information from those
18 studies to the exposure information for the
19 plaintiffs regardless of Dr. Goodman's conclusion
20 or the Agency's conclusion. I'm still considering
21 that exposure information and EPA's toxicity
22 value.

23 BY MR. SNIDOW:

24 Q. If you go to page -- if you could pull
25 out the Mousser report, which is Exhibit 20. Go

1 to page 42. On page 42, you have some criticisms
2 of Dr. Smith, Dr. Cooper and Dr. Del Pizzo.

3 A. Yes.

4 Q. And then in the second paragraph you
5 say, All three experts make these conclusions
6 without providing a robust analysis of the best
7 available scientific information relevant to
8 potential specific causation -- specific causal
9 association to exposure to these chemicals and
10 kidney cancer. Right?

11 A. That is what I wrote.

12 Q. What's the best scientific available
13 information on that topic?

14 A. So for this particular part of my
15 report, I think I am talking about their reference
16 to -- sort of this general reference to increased
17 levels of exposure, substantial levels of exposure
18 without providing a basis for why they consider it
19 substantial. There's no comparison to what EPA
20 considers an elevated concentration of exposure,
21 an elevated dose or an elevated inhalation
22 concentration. There's no comparison.

23 It's just based on Dr. Reynolds' total
24 mass and then a conclusion that this is
25 significant and substantial without really saying

1 anything about why they think it's significant and
2 substantial.

3 Q. So when you say the best available
4 scientific information there, what are you
5 referring to?

6 A. I'm referring to EPA's toxicity values
7 that provide a perspective on what the exposure
8 concentrations are that are associated with a risk
9 of ten to minus four, ten to minus six. I'm
10 talking about all of the studies that Dr. Goodman
11 looked at in her report. That's what I'm talking
12 about. So a systematic review of the available
13 information that EPA did and that Dr. Goodman did.

14 Q. On page 43 you criticize three of the
15 plaintiffs' experts for relying on the Camp
16 Lejeune studies.

17 MS. ELLISON: Object to form.

18 THE WITNESS: Yes. I point out that
19 there are methodological limitations in those
20 studies, particularly the exposure information.

21 BY MR. SNIDOW:

22 Q. Again, you're just repeating the
23 criticisms of Dr. Goodman there?

24 MS. ELLISON: Object to form.

25 THE WITNESS: I'm relying on

1 Dr. Goodman's interpretation or conclusions about
2 those studies, but particularly pointing out the
3 exposure piece, which is uncertain. And it's an
4 important part of my evaluation, the exposure for
5 the individuals.

6 BY MR. SNIDOW:

7 Q. Do you know how exposure was done in the
8 Camp Lejeune studies, how it was measured?

9 MS. ELLISON: Object to form.
10 Foundation.

11 THE WITNESS: I would have to look at
12 those studies, but I believe it's based on the
13 concentrations in the water.

14 BY MR. SNIDOW:

15 Q. And how should they have done it?

16 MS. ELLISON: Object to form.
17 Foundation.

18 THE WITNESS: So those studies are not
19 the best available science for evaluating
20 potential associations between the chemicals and
21 the health effect. So what they should have done
22 is looked at a more systematic review of all of
23 the information and used the best available
24 science similar to what EPA did.

25 They could have used EPA's toxicity

1 values that are more reflective of the best
2 available science.

3 BY MR. SNIDOW:

4 Q. I'm talking about the Camp Lejeune
5 epidemiology in particular. The one criticism
6 that you've given me is there's exposure
7 misclassification; right?

8 MS. ELLISON: Object to form and
9 foundation.

10 THE WITNESS: For those studies, yes.

11 BY MR. SNIDOW:

12 Q. I'm asking: How should they have done
13 their exposure classification that would have done
14 it better?

15 MS. ELLISON: Object to form and
16 foundation.

17 THE WITNESS: I think that those types
18 of studies are -- drinking water studies are --
19 they're sort of difficult studies to get reliable
20 exposure information, particularly for one
21 chemical for individuals. So in terms of what
22 they should have done, I think it's difficult to
23 say for drinking water studies.

24 Again, Dr. Goodman would be the one to
25 answer that kind of question for that particular

1 epidemiology study, but there are many other
2 studies they could have considered.

3 MR. SNIDOW: No further questions.

4 MS. ELLISON: We don't have any
5 questions either.

6 THE VIDEOGRAPHER: Anybody on Zoom have
7 questions? Off the record July 9, 2025 at
8 5:09 p.m.

9 (Whereupon, at 5:09 p.m., the taking of
10 the instant deposition ceased.)
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1 COMMONWEALTH OF PENNSYLVANIA)

2 COUNTY OF ALLEGHENY) SS:

3 C E R T I F I C A T E

4 I, Ann Medis, RPR, CLR, CSR-WA and
5 Notary Public within and for the Commonwealth of
6 Pennsylvania, do hereby certify:

7 That LISA A. BAILEY, PH.D., the witness
8 whose deposition is hereinbefore set forth, was
9 duly sworn by me and that such deposition is a
10 true record of the testimony given by such
11 witness.

12 I further certify the inspection,
13 reading and signing of said deposition were not
14 waived by counsel for the respective parties and
15 by the witness.

16 I further certify that I am not related
17 to any of the parties to this action by blood or
18 marriage and that I am in no way interested in the
19 outcome of this matter.

20 IN WITNESS WHEREOF, I have hereunto set
21 my hand this 22nd day of July, 2025.

22 
23

24 _____
Notary Public
25

COMMONWEALTH OF PENNSYLVANIA) E R R A T A
COUNTY OF ALLEGHENY) S H E E T

I, LISA A. BAILEY, PH.D., have read the foregoing
pages of my deposition given on July 9 , 2025, and
wish to make the following, if any, amendments,
additions, deletions or corrections:

Page	Line	Change and reason for change:
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In all other respects, the transcript is true and
correct.

LISA A. BAILEY, PH.D.

_____ day of _____, 2025.

Notary Public

GOLKOW, a Veritext Division
One Liberty Place
1650 Market Street, Suite 5150
Philadelphia, Pennsylvania 19103
877.370.3377

July 22, 2025

Anna Ellison, Esquire
U.S. Department of Justice
1100 L Street, NW
Washington, DC 20005
Re: Deposition of LISA A. BAILEY, PH.D.
Notice of Non-Waiver of Signature

Dear Ms. Ellison:

Please have the deponent read her deposition transcript. All corrections are to be noted on the Errata Sheet.

Upon completion of the above, the Deponent must affix her signature on the Errata Sheet, and it is to then be notarized.

Please forward the signed original of the Errata Sheet to John J. Snidow, Esquire for attachment to the original transcript, which is in his possession.

Please return the completed Errata Sheet within 30 days of receipt hereof.

Sincerely,

Ann Medis, RPR, CLR, CSR-WA

cc:

John J. Snidow, Esquire

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS

COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

Veritext Legal Solutions is committed to maintaining the confidentiality of client and witness information, in accordance with the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), as amended with respect to protected health information and the Gramm-Leach-Bliley Act, as amended, with respect to Personally Identifiable Information (PII). Physical transcripts and exhibits are managed under strict facility and personnel access controls. Electronic files of documents are stored in encrypted form and are transmitted in an encrypted

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