Exhibit 608

1 IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
2 SOUTHERN DIVISION
NO. 7:23-CV-897
3
IN RE:)
4)
CAMP LEJEUNE WATER LITIGATION)
5)
)
6 This Document Relates to:)
ALL CASES)
7 _____)
8
9
10
11 VIDEOTAPED DEPOSITION OF
12 HARRY P. ERBA, M.D., PH.D.,
13 a witness herein, called by the Plaintiffs for
14 examination, taken by and before Ann Medis, RPR,
15 CLR, CSR-WA, and Notary Public in and for the
16 Commonwealth of Pennsylvania, via Zoom
17 Videoconference, at 1100 L Street, Northwest,
18 Washington, DC, on Wednesday, July 23, 2025,
19 commencing at 9:05 a.m.
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25

A P P E A R A N C E S

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Jonathan Rasson, videographer

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P R O C E E D I N G S

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THE VIDEOGRAPHER: We are now the record. My name is Jonathan Rasson. I'm a videographer with Golkow, a Veritext Division. Today's date is July 23, 2025, and the time is 9:05 a.m. Eastern Daylight Time. This video deposition is being held in person at 1100 L Street, Northwest, Washington, DC, in the matter of Camp Lejeune Water Litigation, for the United States District Court for the Eastern Direct of North Carolina, Southern Division. The deponent is Dr. Harry Erba.

Will counsel please identify themselves.

MR. LEE: Good morning. My name is Randy Lee for the plaintiffs along with Pat Telan.

MS. MCKEEVER: Good morning. Traci McKeever for the United States.

MS. ADAMS: Jennifer Adams for the United States.

MR. O'HARE: James O'Hare, intern for the United States.

THE VIDEOGRAPHER: The court reporter today is Ann Medis and will now swear in the witness.

HARRY P. ERBA, M.D., PH.D.,
having been first duly sworn, was examined
and testified as follows:
EXAMINATION

BY MR. LEE:

Q. Good morning, Doctor. How are you doing today?

A. I'm fine. How are you, sir?

Q. Doing very well. Appreciate it. A broad question I don't typically ask in a deposition. I'm from Raleigh, and I saw that you're from Duke. I've dealt with them for 25 years. But we're here in Washington, D.C.

Is there any particular reason we're here versus you and I being in Raleigh or Durham?

A. I'm not sure. I go where I'm told to go.

Q. Fair enough. Fair enough.

A. Usually every day by my wife.

Q. Indeed. I've been married 40 years. I learned that about 30 years. So I'm in the same ship you are.

In terms of your appearance here today, I take it you're going to go home back to Durham after this, or are you staying in the area?

A. No. I'm going home.
Q. Excellent. Now, you've prepared five reports in this case.
A. That is true.
Q. You are there any other reports that you prepared in this case other than the five that we'll talk throughout the course of the day?
A. No.
Q. And they're five plaintiffs. Do you recall their names?
A. Yes.
Q. What are they for the record?
A. Connard, Amsler, Gleesing, Fiolek and Hill.
Q. Thank you. Just for the record, were you asked to look at -- let me back up.
Did you look at any other cases other than the five you just mentioned that are involved with the Camp Lejeune litigation?
A. No.
Q. When did you first become involved in this case?
A. I cannot remember the exact date actually.
Q. What's your best estimate?

A. 2023, late 2023.

Q. How did you become involved in this case? How did that happen?

A. A lawyer at the Camp Lejeune government office, DOJ, contacted me and asked if I would be interested.

Q. Based upon the information that you were kind enough to provide, it appears that this is the first matter you've been involved in as an expert; is that correct?

A. That is correct.

Q. And as it relates to that, what did you do to learn about how experts function? In other words, did you take a course some place? Did you look online to see how an expert functions in these types of matters?

MS. MCKEEVER: Objection to form.

BY MR. LEE:

Q. Do you understand the question?

A. I understand the question. I did not do anything to prepare to be an expert other than my 30 years as being an expert in leukemia.

Q. I imagine we'll discuss that throughout the course of the day.

In terms of the reports you drafted, you

were also kind enough to give us information concerning materials you considered.

Are the materials considered list that counsel was kind enough to provide to us, are those complete and up to date?

A. Yes. I believe we included more recently the manuscripts by Yu and Wang.

Q. How is it that you came to include the manuscripts by Yu and Wang?

A. They were presented to me -- not presented to me, but the references were told to me by lawyers at the DOJ.

Q. Did you review those documents?

A. I did.

Q. What, if anything, did the information contained in those manuscripts inform you of that you weren't already aware of?

MS. MCKEEVER: Objection to form.

THE WITNESS: The point of those manuscripts was that there is no safe level of benzene, just paraphrasing the conclusions that were made there in those two papers. And that I was not aware of, but we can talk more about my interpretation of those manuscripts as well.

BY MR. LEE:
Q. I imagine we will. Which one of those publications resulted first, if you know?
A. Which one?
Q. Which one was published first?
A. I believe it was Yu and then Wang was the subsequent one, I think.
Q. Did you read those publications in detail?
A. I did.
Q. Do you know what the cohort was? Let's talk about Wang.
A. I believe both cohorts were the UK Biobank.
Q. Were you familiar with the UK Biobank prior to receiving those publications?
A. Peripherally, yes. I knew it existed.
Q. How so?
A. The UK Biobank is often used in medical research looking at associations of genetics with diseases.
Q. Have you reviewed material from the UK Biobank in the past?
A. No.
Q. You say you were aware of it, but hadn't

reviewed materials.

How is it that you became aware that it existed prior to this litigation?

A. Prior to it, these are references made in other manuscripts that I've read.

Q. And that would be prior to your involvement in this litigation?

A. Yes.

Q. What is your opinion, if anything, related to the quality of the data that comes out of that particular biobank?

MS. MCKEEVER: Objection to form.

THE WITNESS: It's hard for me to speak to the quality. I don't have any knowledge of the auditing procedures that they do in that registry, in that biobank. So I'm not certain of the accuracy of the data and then also the analyses that are done with that data.

BY MR. LEE:

Q. Have you had occasion to review biobanks similar to the UK Biobank in your experience as a physician?

A. No, not specifically.

Q. What does that mean, "not specifically"?

A. So, for example, there are data for

clonal hematopoiesis mutations that are present as we age, and that was taken from, you know, large registries. There's the Swedish Registry for Leukemias, but I didn't specifically look at the data in those, just publications of leukemia experts.

Q. Now, I started talking about Wang briefly. Now I'm going to shift to Yu.

Do you recall the number of individual patients that were involved in the assessment prior to the publications of the Yu manuscript?

MS. MCKEEVER: Objection to form.

BY MR. LEE:

Q. Do you understand my question?

A. No, I do not.

Q. Do you know how many individuals they assessed or evaluated?

A. I can't remember the exact number. If I saw the paper, I could tell you, but I think it was over a hundred thousand.

Q. If I represented to you it was over 500,000, does that refresh your memory at all?

A. If you say so, I wouldn't be surprised.

Q. What impact, if any, does the fact that a study paper has large number of individuals who

are considered in that paper's analysis? What impact does size have from your perspective?

MS. MCKEEVER: Objection to form.

THE WITNESS: So the sample size in any study is important for determining the accuracy of the data coming out of it, but there are many other factors as well.

BY MR. LEE:

Q. What are the other factors?

A. The other factors would be the details of the demographics that were obtained in that study from the people who are in it, the auditing procedures that are used, the follow-up of the people, things like that.

Q. Obviously, looking at your CV, you've published quite a few articles and materials in your career. Tell me about auditing. What does that mean?

A. Tell you --

Q. Auditing. You said you used auditing procedures. What does that mean?

A. I'm a clinical trialist, so I develop, help develop new drugs for people with leukemia. And these studies are closely regulated by a number of government agencies, not the least of

which is the Food and Drug Administration.

So the quality of the data is incredibly important as we're talking about making new drugs available to people with cancer, the safety, the efficacy. And so that quality of the data is audited by the sponsor of the study, often an industry sponsor, and can be audited by the Food and Drug Administration as well.

Q. To the best of your knowledge, how much time did you spend reviewing the Wang and the Yu publications?

A. I read them, I believe, it was about an hour.

Q. Each?

A. Total.

Q. Do you have any criticisms of the methodology used in those two publications?

MS. MCKEEVER: Objection to form.

THE WITNESS: So as I said, I'm not an expert in registries, biobanking, but I've looked at their data and the conclusions that they were trying to make. And I did have some concerns about the conclusions, how strong they can make the conclusions based on the methodology.

BY MR. LEE:

Q. Explain those to me, those considerations or concerns.

A. My reading of the material, the way the assessments were made of exposures to benzene were based on the residential address of each of the participants, I believe, at the beginning of the registry when they actually entered into the registry. And that was between 2006 and 2010.

And they were grouped into certain geographic spaces. I'm not sure how those spaces were determined, but they were -- I think it was kilometer squared spaces, and they were grouped together so that they could correlate ambient atmospheric benzene that was -- I'm not sure how that was determined. I don't understand. I'm not an expert in determining how much benzene is in the air, but it was in each of those areas.

So my criticism comes from then the association of those people developing various diseases, not just leukemia, but cancers, cardiac disease. My problem in thinking about that is that I don't know how these squares were developed, so what's included in them, what's not excluded. Made me think of gerrymandering from

political situations.

But you don't know how they determine that. You don't know where in that kilometer space one of the subjects lives. Do they live near a gas station or some chemical plant?

You don't know if they've moved after that. You don't know if the person had a residence in that area which maybe was rural and might have less benzene and then moved to -- during the day spends most the day in -- it was UK, so in London where there might be, I assume, higher benzene exposure.

And I don't know if the registry followed them, because it was done over years. People move. So if they moved, did they follow them to a new area, then recalculate the benzene exposure. That I couldn't remember finding in the methodology. So that was my basic concern about the methodology.

Q. Follow-up questions. Do you know that none of the concerns that you just articulated -- are you certain that those are not addressed in the publications?

MS. MCKEEVER: Objection to form.

BY MR. LEE:
Q. Or are you speculating?
MS. MCKEEVER: Also, if you're asking him specific questions about the studies, I'm going to ask that you put them in front of him.
If you can answer without seeing the studies, you may do so.
THE WITNESS: Yeah, I can't remember specifically, but if I could think of those concerns, they probably did, too, and probably addressed them. But I'd have to look to see what their explanations were.
BY MR. LEE:
Q. You just don't recall?
A. I don't recall.
Q. Let's address your experience with designing studies. Have you in your review for this case, all the various publications that you've cited in your reports, some of which we'll talk about, have you come across any what you described as well-designed epi studies?
MS. MCKEEVER: Objection to form.
THE WITNESS: Well, designed?
BY MR. LEE:
Q. Epidemiological studies.

A. I don't participate in epidemiological studies. I don't remember being an author on any one like that.

Q. Let's follow up on that. Just to be clear, you've reviewed a number of studies that frankly relate to and involve epidemiology --

A. Yes.

Q. -- in your involvement in this case; is that fair?

A. That's fair.

Q. But as you sit here today, just so we're clear, you have no training as an epidemiologist; is that fair?

A. That is fair. I do not.

Q. And you wouldn't consider yourself to be an expert in epidemiology?

A. That is true.

Q. And you're not going to tell this court or a jury that you're an expert in epidemiology?

A. That is true.

Q. Is that fair?

A. Yes.

Q. Do you consider yourself an expert in interpreting epidemiology studies?

MS. MCKEEVER: Objection to form.

THE WITNESS: I'm not an expert in epidemiology, so I would not be on a short list of people to review an epidemiology paper. And I am on those short lists every day for leukemia papers. However, I do review scientific literature. I have to have some understanding of biostatistics in order to do that. So I understand some of the language.

But in terms of all of the methodology, I do not. I'm not an expert.

BY MR. LEE:

Q. So is it fair to say then that you will not contend in this litigation that you are an expert who should be called upon to assess and evaluate the strengths and weaknesses of the epidemiology studies?

MS. MCKEEVER: Objection to form.

THE WITNESS: I don't completely agree with that. I agree that you already have in this case for both plaintiffs and the government experts in epidemiology. And I've read some of those reports, obviously. Again, would I be asked to write one of those reports? No.

Can I look at the reports and look at the arguments being made and make a judgment for

1 myself as to the validity of the data? I can form
2 that opinion, scientific opinion about that.
3 BY MR. LEE:
4 Q. Have you ever been called upon to be an
5 editor for an epidemiology journal?
6 A. Never.
7 Q. We'll follow up on that in a few
8 moments.
9 In terms of the five reports that you
10 drafted in this case, again Connard, Amsler, Hill,
11 Fiolek and Gleesing, is it your opinion that none
12 of those five plaintiffs were harmed by the water
13 that they consumed at or around Camp Lejeune?
14 MS. MCKEEVER: Objection to form.
15 THE WITNESS: I was only asked to make a
16 determination of the diagnoses of leukemia in
17 these five people. As far as other harms that may
18 or may not have occurred from the alleged exposure
19 that may or may not have occurred at Camp Lejeune,
20 I cannot, you know, give an opinion on that.
21 So just on -- I can only give an opinion
22 on what I believe -- from what I know about the
23 biology of leukemia.
24 BY MR. LEE:
25 Q. Let me be clear then. You're not going

to come into this litigation and make a definitive statement that the five individuals whose names are now on the record were not harmed by the water they consumed at Camp Lejeune; true?

MS. MCKEEVER: Objection to form.

THE WITNESS: If the statement is as you said --

BY MR. LEE:

Q. Yes, sir.

A. -- and I have to sign the statement there was no harm, I cannot do that because it's outside my scope of expertise.

Q. So to be clear, you're not going to come to a courtroom in front of a jury or a judge or judges and make the statement that it is my opinion that none of the five individuals whose reports you drafted -- you're going to say they were not harmed by the water that they consumed at Camp Lejeune because that's beyond your area of expertise?

MS. MCKEEVER: Objection to form.

THE WITNESS: I believe you went just one step too far there. My area of expertise is in leukemia. I was retained by the government to give my expert opinion on the etiologies of

leukemia, the various types of leukemia, the treatments, the prognosis, the complications of therapy, life expectancy. So I do believe I -- I do believe the Department of Justice chose well. I'm an expert in leukemia. Outside of leukemia --

BY MR. LEE:

Q. We agree.

A. Thank you. I appreciate that.

Outside of leukemia, I will not make any statement about harm done to these people at Camp Lejeune by water, air, random gunfire, anything.

Q. Thank you. I appreciate that.

What do you know about Camp Lejeune? You're from North Carolina as I am. What do you know about that location?

A. I know that it is a large area that is on the coast bounded by one town that I'll be visiting soon, Jackson -- Jacksonville, North Carolina and made up of a large number of different sites inside of that.

Q. Are you visiting Jacksonville for professional reasons or personal?

A. I'll be traveling there for business reasons, I think a lecture.

Q. Have you spoken at the local hospital in

Jacksonville?
A. No, not yet.
Q. Do you know the name of it?
A. No.
Q. Do you know the name of any hospitals in that area?
A. I'm not really good at that, to be honest with you. I know a lot of hospital names, but not exactly where they are.
Q. How about Onslow Memorial Hospital, does that ring a bell?
A. Yes.
Q. Have you received patients from that area?
A. Yes.
Q. So as it relates to where that is logistically, you know it exists, but you don't know quite where; is that fair?
A. That is fair.
Q. What else do you know about Camp Lejeune? I want to put this in a time reference.
Prior to your involvement in this litigation, did you have any knowledge concerning the fact that there were allegedly contaminants in the water at Camp Lejeune during a certain

timeframe?

A. Yes, sir.

Q. How did you know that?

A. Television commercials and patients in our own practice.

Q. Help me with that. When you say "patients in our own practice," what do you mean by that?

A. We would -- we're a referral center for leukemia. And people -- I can't remember actual names of any of these. I wouldn't be able to share them with you anyways. But they would say that they were at Camp Lejeune just as they would come to me and say they worked in the rubber industry and whatever, yes.

Q. Again, I don't want those names. I appreciate HIPAA considerations and concerns.

But in your practice at Duke, did you come across any patients whose paperwork that you reviewed indicated that there was some concern about contaminated water and having an impact on their health outcome?

MS. MCKEEVER: Objection to form.

THE WITNESS: I don't recall any paperwork like that that came along with patient.

BY MR. LEE:
Q. Did you have any conversations with patients to the extent you can provide us with that information where, during their interaction with you, they were concerned that their outcome may have been related to consumption of water at Camp Lejeune?
MS. MCKEEVER: Objection to form.
THE WITNESS: I can't remember specific names of patients, but I do believe that there have been patients admitted to our service that I've heard were at Camp Lejeune.
BY MR. LEE:
Q. Let me follow up on that. Was there any connection or concern with respect to whether their disease outcome, whatever it might have been, was related to the water at Camp Lejeune?
MS. MCKEEVER: Objection to form.
THE WITNESS: Not that I remember, no.
BY MR. LEE:
Q. Are you familiar with the Camp Lejeune Justice Act?
A. Camp Lejeune?
Q. Lejeune Justice Act, are you familiar with that?

A. Not the details of it, no.
Q. But you have some familiarity?
A. I think that's why we're here.
Q. Tell me what you know about it.
A. Well, without having it in front of me --
Q. Was it ever front of you? Have you ever seen it?
A. The actual Act? If it was, I don't recall reading it, to tell you the truth.
Q. Is there any particular reason, for example, you in your research haven't looked to see what exactly is in the Justice Act?
MS. MCKEEVER: Objection to form.
THE WITNESS: There are many reasons why I wouldn't look at it. It doesn't impact on my care of the patients, and, you know, I have other things that occupy my time quite a bit.
BY MR. LEE:
Q. Subsequent to your involvement in the litigation, did you even think about looking at the Act to see what it said?
MS. MCKEEVER: Objection to form.
THE WITNESS: Did I think about looking at the Act? Boy, that's hard if I thought about

1 looking at the Act. I can't recall thinking about
2 looking at the Act, no.
3 BY MR. LEE:
4 Q. Do you think it might have been helpful
5 to at least know what the litigation was about?
6 MS. MCKEEVER: Objection to form.
7 THE WITNESS: I think it is helpful to
8 know what the litigation is about, and I have my
9 understanding of that.
10 BY MR. LEE:
11 Q. And what is your understanding?
12 A. My understanding is that there is
13 concern that the water supply at Camp Lejeune was
14 contaminated at two or three specific areas in
15 Camp Lejeune and that people may have been harmed
16 based on some of the chemicals that may have been
17 in that water based on modeling.
18 Q. Again, I know you're not an attorney;
19 correct?
20 A. I'm not?
21 Q. An attorney.
22 A. No. I am not an attorney.
23 Q. Do you have knowledge concerning whether
24 the Act provided a timeframe within which the
25 Marines and their family members could file a

lawsuit?

MS. MCKEEVER: Objection. Lack of foundation.

BY MR. LEE:

Q. Do you have any knowledge about that?

A. I do not.

Q. Do you have knowledge concerning what the applicable standard of care is that was articulated in that Act?

MS. MCKEEVER: Objection. Lack of foundation.

THE WITNESS: Does that mean I answer?

BY MR. LEE:

Q. You answer the question.

MR. LEE: For the record, counsel, this is just a discovery deposition. You can object to every question I've got. So if that will help us move along, then we'll just keep moving.

MS. MCKEEVER: He said he's never read it. So you're asking questions about something he said he's never seen. So that's why I'm objecting.

THE WITNESS: I've never seen it. Can you repeat the question?

BY MR. LEE:
Q. Sure. Do you have any understanding as to what the applicable standard of care is in this case?
A. I can honestly say that I have no understanding of that, yes.
Q. And just to be clear, as an expert in a legal matter, do you believe it would be appropriate for you as an expert to render opinions to know what the standard of care is that will be applied in this case?
MS. MCKEEVER: Objection to form.
THE WITNESS: My understanding of my role in this is to objectively look at the data and make a determination about potential etiologies of a person's leukemia, and I would leave, you know, the legal standards to you.
BY MR. LEE:
Q. Have you ever talked to any of your colleagues at Duke concerning their involvement in legal matters?
A. No.
Q. Do you have knowledge concerning whether or not any of your colleagues have been experts in cases involving medical malpractice, products

liability, anything of that nature?

A. I do not.

Q. Just so I'm clear then, did you communicate with legal counsel at Duke prior to being involved in this case to determine whether you could or could not serve as an expert?

A. I did not.

Q. So as we sit here today, you don't know whether or not Duke has certain guidelines, if you will, that are applicable to providers who practice at their facility related to whether they can or cannot provide legal assistance?

MS. MCKEEVER: Objection to form.

THE WITNESS: I am aware of the guidelines that I have in terms of outside activities which I need to take part in. When I got to Duke, I went to the Office of Conflict Management and asked what are the standards here at Duke. So I do know that. Not specifically legal. There were four.

Number one, that I do not say that I'm representing Duke, which I am not. Number two, that I be paid fair market value for whatever services I provide. Number three, that there be a contract between me and the people asking me for

my services. And number four, that I have complete control over my opinions and my statements aside from whoever is, you know, signing the contract or paying for the honorarium. Those are the four.

BY MR. LEE:

Q. So you did speak with, if you will, folks who address those kinds of issues?

A. Yes.

Q. Did you receive anything in writing from them concerning what their guidelines were?

A. Yes. Well, they're online.

Q. Have you looked at those recently?

A. Recently? No. I have not looked at them recently.

Q. I want to focus on the standard of care and your understanding of what it is.

Do you know what "more likely than not" means in the legal sense?

MS. MCKEEVER: Objection to form.

THE WITNESS: In the legal sense, no. I'm not a lawyer. I do not know. In the vernacular, more likely than not means that there's a 50/50 chance and you are just on the side of by whatever amount, 50.1 percent, that

it's as likely as not.
BY MR. LEE:
Q. Have you heard the phrase "as likely as not"?
A. As likely as not? I may have, yes.
Q. But you just don't recall?
A. I don't recall. And I don't know what that means legally.
Q. Have you heard the legal phrase "to a reasonable degree of medical certainty"?
A. Yes, I have.
Q. What does that mean?
A. That means that in rendering an opinion based on the facts before me, that that opinion is reasonable based on, you know, the data that I have.
Q. I'm going to change one word. Have you heard the phrase "to a reasonable degree of scientific certainty"? Do you understand what that means?
A. Yes.
Q. What does that mean?
A. That is something that, you know, I need to abide by in all of our clinical trials. The FDA actually is very strict on applying scientific

1 certainty, which includes not only knowing the
2 reported effect, but the probability of that
3 effect happening without the intervention, the
4 so-called null hypothesis.
5 So basically there needs to be a
6 statistical argument that the data that you're
7 looking at and the conclusion you're making is
8 likely to have occurred. It's not likely to have
9 occurred by chance.
10 Q. Do you have knowledge with respect to
11 whether or not Camp Lejeune has undergone any type
12 of cleanup related to chemical toxins?
13 A. I do not, no.
14 Q. So if I asked you whether remediation
15 occurred at Camp Lejeune within the last 10, 15
16 years, you have no knowledge?
17 A. No knowledge.
18 Q. Do you have any knowledge about military
19 institutions that have had remediation and/or
20 cleanup?
21 MS. MCKEEVER: Objection to form.
22 THE WITNESS: I don't have knowledge
23 about military institutions' cleanups, no.
24 BY MR. LEE:
25 Q. Do you have any knowledge about any

location ever being remediated as a result of toxins?

A. Yes.

Q. Tell me about what you know.

MS. MCKEEVER: Same objection.

THE WITNESS: Very little. What I read in the newspaper, clean up of -- what was it -- dioxin. I think it was dioxin in New Jersey. Does that ring a bell?

BY MR. LEE:

Q. Yes.

A. Minimal knowledge.

Q. In your clinical practice, what type of patients do you currently routinely treat?

A. I see people with acute myeloid and acute lymphoblastic leukemia, myeloid dysplastic syndromes, myeloproliferative neoplasms and aplastic anemia.

Q. Are you treating patients currently who have CLL or SLL?

A. A few.

Q. Are you trending away from patients who have those diagnoses, or is it just the nature of the results you receive?

A. There are other experts at Duke that are

specializing in that, more junior people. So we're trying to funnel those patients more towards those early investigators and away from older people. I've had tons -- I've had experience in CLL for my entire career, but at Duke we have different doctors who see them.

Q. How many hours a week are you actually in clinic?

A. I do two full days in clinic, Monday and Thursday. It goes from 8:00 until 6:00, so about 20 hours a week.

Q. How about the rest of your workweek at Duke?

A. The rest of my workweek at Duke is often online editing notes, looking at patient results, talking to referring doctors, doing clinical research. I'm the chair of the SWAB Leukemia Committee, an NCI-funded cooperative group. So I spend time developing clinical trials there.

I'm the co-chair of the NCI Precision of Medicine Initiative MyeloMATCH. That just started. I spend a lot of time on Zoom calls and answering emails about that and give lectures.

And those are the things I do when I'm not on service, meaning rounding in the hospital,

which is a full-time job for a week at a time. I do ten weeks every year on the inpatient service. It's a leukemia service.

Q. Are you a toxicologist?

A. I am not.

Q. What expertise, if any, do you have in toxicology?

A. The only toxins I deal with are the ones, unfortunately, I have to give to patients in chemotherapy.

Q. Is there a subspecialty defined as toxicology that you're aware of?

A. In medicine, yes.

Q. What type of training does a toxicologist in medicine receive, if you know?

A. I do not know.

Q. Just so the record is clear, you don't hold yourself out as an expert in toxicology; true?

A. That is true.

Q. And you will not do so in court?

A. That is true.

Q. In this case, there's been a lot of discussion about VOCs. What are VOCs?

MS. MCKEEVER: Objection to form.

THE WITNESS: VOCs are volatile organic chemicals. I believe that's what it stands for.
BY MR. LEE:
Q. What are they?
MS. MCKEEVER: Objection to form.
THE WITNESS: I do not know what they all are. I know some of them are involved in this litigation.
BY MR. LEE:
Q. Which ones?
A. Well, benzene is organic. It's volatile. So I would say that's one of them. TCE, PCE and vinyl chloride.
Q. What makes a chemical volatile?
MS. MCKEEVER: Objection to form.
THE WITNESS: My understanding of the term volatile in this situation is that at ambient temperatures, that the molecule can exist in the atmosphere.
BY MR. LEE:
Q. What do you know the metabolism of TCE?
MS. MCKEEVER: Objection to form.
THE WITNESS: I'm not a toxicologist. I know very little about that metabolism.

BY MR. LEE:

Q. Tell me what you know.

A. I know it's metabolized. Yeah, you know, I'm not an expert there. You know, I remember bits and pieces of data that I've, you know, read in Goodman's report.

Q. What do you remember?

A. Well, one of those chemicals, if it gets into the body, is exhaled. I think it's PCE. Which one did we say? PCE and TCE, they're exhaled without being changed. If they're absorbed in the body, they're metabolized and excreted.

Benzene can be found in the blood. That's pretty unusual. Usually in the setting of an acute exposure, it can be found in the blood. There are some metabolites that are specific for benzene. Some of those metabolites are known to be carcinogenic and cause DNA damage, and they can be found in the blood or the urine. Bits and pieces.

Q. You started talking about TCE, and you said you did know how it was metabolized. Now I want to use PCE.

Do you know how PCE is metabolized?

MS. MCKEEVER: Objection to form.
THE WITNESS: I do not know.
BY MR. LEE:
Q. Do you know how benzene is metabolized?
A. I know benzene is metabolized in the liver to other organic compounds, but that's all I know.
Q. What are the other organic compounds benzene is metabolized to?
A. I do not remember the names.
Q. How is vinyl chloride metabolized?
MS. MCKEEVER: Objection to form.
THE WITNESS: Excuse me?
BY MR. LEE:
Q. Vinyl chloride, how is it metabolized?
A. I do not know.
Q. Do you know whether the parent compound, TCE, whether or not the parent compound is a carcinogen?
A. Since I've already stated I'm not an expert in toxicology, I guess you'll understand my answer is going to be I don't know.
Q. Same answer, PCE?
A. That is true.
Q. Same answer for benzene?

A. For?
Q. Benzene.
A. Benzene is the parent compound.
Q. Is it a carcinogen?
A. Directly?
MS. MCKEEVER: Objection to form.
THE WITNESS: I know that IARC considers it a human carcinogen.
BY MR. LEE:
Q. How about the metabolites of benzene, whatever they are?
A. Whatever they are, they are involved in the carcinogenesis, yes, some of them.
Q. But you don't know which ones?
A. No.
Q. Same question, vinyl chloride.
MS. MCKEEVER: Objection to form.
BY MR. LEE:
Q. Carcinogen?
A. What do I know about that? Again, I'm not a toxicologist, so I would rather not, you know, give an opinion on that.
Q. Do you know what the chemical structure of PCE is?
A. I do not, no.

Q. Same answer for TCE?
A. No. I do not know. Ask me benzene.
Q. Do you know benzene?
A. I do know benzene.
Q. What is the structure?
A. Benzene is a six-carbon aromatic ring.
Q. Do you have any training in volatile organic compound exposure reconstruction?
MS. MCKEEVER: Objection to form.
THE WITNESS: Again, I'm not an expert in this, so I do not know.
BY MR. LEE:
Q. Are you an expert in risk assessment?
A. No. I'm not an expert in risk assessment.
Q. I've read some of your materials online. If a patient asks you what causes CLL, what do you tell them?
A. We don't know.
Q. Same question, AML.
MS. MCKEEVER: Objection to form.
THE WITNESS: If a patient asks what causes AML, I talk to them about the things that we know cause AML, and that would be inherited genetic syndromes that are associated with

1 developing AML. Many times the DNA repair
2 enzymes. I will talk to them about,
3 unfortunately, the chemotherapy and radiation
4 treatments that we give to patients can lead to
5 AML and myeloid neoplasms.
6 I would tell them that there are other
7 myeloid neoplasms that can turn into AML like
8 aplastic anemia and myeloproliferative neoplasms.
9 And in terms of environmental exposures, the only
10 one that I'm aware of is benzene.
11 BY MR. LEE:
12 Q. When you say you're aware of, what do
13 you mean by that?
14 A. What I mean by that is that in textbooks
15 that I reference, benzene is often listed as a
16 known leukemogenic -- an agent known to be
17 associated with the development of leukemia,
18 specifically acute myeloid leukemia and
19 myelodysplasia syndrome, myelodysplastic syndrome.
20 For the others, I've never seen them
21 listed in any textbooks or articles I read as part
22 of my usual job.
23 Q. Do you know whether TCE has recently
24 been banned?
25 MS. MCKEEVER: Objection to form.

THE WITNESS: I do not know.
BY MR. LEE:
Q. Again, just so I'm clear then, did you do any independent research on any of the volatile organic compounds that you and I have been talking about thus far in preparation for forming your opinions in this case?
A. No, I did not.
Q. Have you in your either involvement in this case or in your practice as a physician ever looked at the EPA website for any reason?
A. No, I have not.
Q. Just so we're clear, EPA is the Environmental Protection Agency?
A. Yes, sir.
Q. Do you know what the EPA does, by any chance, any knowledge, the name, Environmental --
A. Yeah.
Q. -- Protection Agency?
A. Yes.
Q. Do you know whether they have determined as part of their role that certain chemicals and compounds should not be produced anymore because of the research that that organization has done? Are you familiar with that?

A. I am not.
MS. MCKEEVER: Objection to form.
BY MR. LEE:
Q. Just so I'm clear, to the extent that EPA has banned TCE and is limiting the use of PCE, you have no knowledge about that?
MS. MCKEEVER: Objection to form.
BY MR. LEE:
Q. Is that fair?
A. Other than what you just told me.
Q. This is the first time you've heard that; fair?
A. Yes.
Q. In your role as an expert and, obviously, I've seen your CV and we'll talk about that in a moment, you've given lectures from the time?
A. Yes.
Q. In some of those lectures, are you called upon to disclose any conflicts of interest that you have either before giving the lecture or during the process of it?
A. Every time.
Q. Explain that for the record so the court understands what that means.

A. So it's important that when you're rendering an opinion, you tell people, you know, what are potential conflicts of interest. People usually refer to these -- think of these only as financial conflicts of interest, which I think is absurd. There are other potential conflicts. But financial conflicts of interest. So especially in my line of work where I do studies of new drugs for people with leukemia, but I also as a leukemia expert am a consultant to pharmaceutical companies, I'm a speaker about drugs I've helped develop so that I can educate other clinicians and get honoraria from those sponsors, those are potential conflicts of interest.

Even the research support that goes directly to Duke I will claim as a conflict of interest because some small fraction of it supports my salary.

Q. Do you routinely do that before you actually, if you will, give the presentation, or is that included in the PowerPoint?

A. It's the second slide after the title slide in every one of my presentations and for many of the CME programs that I do that are, you know, CME programs, the sponsor will ask for that

information and publish it in a book ahead of time or online.

Q. Just so it's clear for the court, CME is continuing medical education; correct?

A. Yes.

Q. I understand this is the first time you're being involved in litigation.

As an expert, do you have an opinion concerning whether there are certain cases you wouldn't review because you have a conflict of interest?

MS. MCKEEVER: Objection to form.

THE WITNESS: I can't think of any offhand, no.

BY MR. LEE:

Q. Let me help with a couple. If you were asked to review a case involving a colleague at Duke who's on staff and you were asked to review that case, would you review it?

A. No.

Q. Because?

A. I don't review cases like that.

Q. Is that because of a potential conflict?

A. No.

Q. Why wouldn't you review it?

A. Are you talking about -- can I ask for clarification? It's about malpractice or a problem?

Q. Malpractice.

A. Malpractice. Okay. So I, in general, have made it a rule not to get involved in malpractice. And the major reason for that is that the medical record often does not accurately reflect everything that goes on between a doctor and a patient that can get lost in translation, especially years later if there's a bad outcome.

So I typically do not -- I have not gotten involved in any malpractice suit for either a plaintiff or a physician.

Q. I want to make sure the record is clear. This is the first time you've been involved in any case as an expert, or have you been involved in other scenarios?

A. First time. Last time.

Q. Fair enough. With respect to conflicts of interest, you indicated that -- you said it could be economic, but there are multiple other kinds of conflicts. You mentioned and I saw in your CV that you currently have a relationship with three companies, I believe.

A. More than that, but yes.

Q. Fair enough. I only remember three. I apologize for that.

Are any of those companies to your knowledge involved in the production of any of the compounds or chemicals involved in this litigation?

MS. MCKEEVER: Objection to form.

THE WITNESS: I do not know the entire portfolio of any of those companies. And specifically I doubt that any of those companies are directly making those compounds, but I don't know. Could they be byproducts of their production process? Could be, but I do not know.

BY MR. LEE:

Q. You listed quite a few epidemiology reports or studies, I should say, in your materials considered list.

Did you review all of those in their entirety?

A. The ones I listed I did, yes.

Q. Were there any other epidemiology studies that you reviewed but didn't include on your MCL or materials considered list?

A. No.

Q. Same question with respect to toxicology studies.

A. No. That's it.

Q. So correct me if I'm wrong. Is it fair to say then that the entirety of the materials that you reviewed would be included on either your materials considered list, your references or supplemental materials considered list?

A. That's correct.

Q. Is that fair?

A. Yes.

Q. So when you were educating yourself and identifying materials to consider, based upon the last response, there were no other articles that you reviewed that should have been included on your list; is that fair?

A. I don't know about the words should have been included on that list. But there are no other articles that I included. I would say that I did not believe in rendering my opinion that I needed -- that were specifically about these five patients and their leukemias -- that I needed any other information about the specific toxins to render my opinion about their leukemia. And that was what I was asked to discuss.

Q. Fair enough. I'll follow up on that. But just so I'm clear, you're able to today give your complete and final opinions with respect to the topics you're going to talk about; correct?

MS. MCKEEVER: Objection to form.

THE WITNESS: I don't understand the question.

BY MR. LEE:

Q. Are you able to give your complete, full and final opinions concerning the five individuals whose cases you reviewed? You're going to give your full and final opinions here today?

MS. MCKEEVER: Same objection.

THE WITNESS: I'm going to argue with the word "final." There may be more data that comes in that I'm not aware of. But based on the data that I have, the opinion that I put in that reports was my final opinion for that report.

BY MR. LEE:

Q. Thank you for that classification. I appreciate that.

So as we sit here today, based upon the information you have reviewed, are you able to give complete opinions with respect to the five clients that we're here to talk about?

A. I am able to give my complete opinion about other leukemia, the specific type of leukemia and my opinion about the potential relationship between that leukemia and an exposure that may have occurred decades ago, yes.

Q. You mentioned a name earlier. The name came up quite often in your reports, Dr. Goodman.

Who is Dr. Goodman?

A. Dr. Goodman is an expert for the Department of Justice on epidemiology and toxin exposures. I don't know all of her qualifications. When I read the report, I passed over those quickly.

Q. Fair enough. Have you met Dr. Goodman?

A. Personally, no. I do remember seeing her on at least one Zoom call.

Q. I'm not entitled to know -- if your attorney was on the call, she's going to object to me asking questions about that.

You were on one Zoom call with Dr. Goodman?

A. At least one.

Q. It could have been two?

A. It could have been two.

Q. Could it have been three?

A. No.
Q. What do you know about her background?
A. I know she included her background in her report, and I don't remember any of the details of it.
Q. Is Dr. Goodman an M.D.?
A. No, I do not believe. I have to look at the report again, but I don't believe she's an M.D.
Q. So to be clear, as we sit here today, you don't recall any specific details about Dr. Goodman's background, training and experience?
MS. MCKEEVER: Objection to form.
THE WITNESS: I know she has extensive experience in epidemiology and toxicology. I do not remember any of the details.
BY MR. LEE:
Q. Are you deferring to Dr. Goodman's opinions in certain areas in this litigation?
A. So it depends on what certain areas you're talking about. I am not an expert in toxicology, epidemiology. So yes, I do have to look at her reports to help form my opinion in each of these cases.
Q. Did you compare Dr. Goodman's

background, training and experience to the experts who were identified by the plaintiffs?

A. I did not.

Q. Help me then understand how you made a decision with respect to which experts' opinions you were going to, if you will, defer to given you don't have expertise of the toxicologists or epidemiologists.

How did you compare the two, if you will, teams of experts to determine whose opinions you were, in essence, going to defer to?

MS. MCKEEVER: Objection to form.

THE WITNESS: So this is a common question that I would get every day in my own practice, right. There are experts in leukemia and whose opinions would I defer to and consider. And I do that on the basis of their experience, not based on their training, in other words, where they went to college, where they went to medical school. It's their experience that they bring to the table and specifically their experience in taking care of patients with leukemia.

In this regard -- I shouldn't keep saying the word "honestly" because this is all honest.

BY MR. LEE:

Q. We hope so.

A. Yes, sir, it is. In this regard, quite frankly, I felt that if the plaintiffs hired certain experts and the DOJ hired certain experts, that those people had been fully vetted as experts. And I am not in any position having not met them and spoken to them directly to say who's a better expert than another expert. I would not try to make a determination of who was a better expert, quote-unquote better.

Q. Are you aware of the names any of the plaintiffs' epidemiologists?

A. I'm aware of their names, yes.

Q. Help me understand how you made the decision in this case. I understand how you function in the medical arena. In this case where this is the first matter you've been involved in and you said perhaps the last, how did you decide to go with epidemiologist A and not epidemiologist B?

MS. MCKEEVER: Objection to form.

THE WITNESS: So I want to first state that my opinions in these cases is based on my knowledge of leukemia.

BY MR. LEE:

Q. Fair.

A. And the specific details of the reports from all of these experts was -- they're less important to me than my knowledge of leukemias. Having said that, when I read Dr. Goodman's report and read some of the plaintiffs' reports, there was one thing that struck me. And that is scientific accuracy, as you stated earlier.

Dr. Goodman was very careful in her report as to what things were -- she felt were scientifically accurate based on estimates of hazard ratios, relative risk with confidence intervals, whereas quite frequently in the other expert reports, those confidence intervals were dismissed as not as important because the totality of the data shows trends.

And that kind of reasoning would be completely discounted if I were trying to get a drug approved. So I'm bringing it back to what I do. I felt more comfortable with Dr. Goodman's opinions.

Q. Are you aware that Dr. Dr. Goodman was deposed in this case, gave a deposition?

A. Am I aware? I'm sorry.

Q. That Dr. Goodman gave a deposition in this case.

A. I'm aware that she gave a deposition.

Q. Have you read her deposition?

A. I have not.

Q. Just to be clear then, you don't know whether or not her opinions stood up under the scrutiny of a direct examination in a deposition; is that fair?

MS. MCKEEVER: Objection to form.

THE WITNESS: That will have to be fair that I'm not aware of the deposition. So I can't even begin to answer your question about stood up or not stood up.

BY MR. LEE:

Q. Did you review the depositions of Dr. Bailey?

A. Dr. Bailey, no.

Q. Dr. LaKind?

A. No, I did not.

Q. Dr. McCabe?

A. I did not.

Q. Do you know Dr. Bailey?

A. No, I do not.

Q. Were you on any Zoom calls with Dr. Bailey?

A. No, no. I'm bad at names. On one call there was Dr. Goodman and one other person. I think it was LaKind and not Bailey, but I could be mistaken. It was one of those two.

Q. Do you know Dr. Bailey's background, training and experience?

A. I do not.

Q. Do you have specific knowledge with respect to whether or not Dr. Bailey has certain degrees, know anything about that?

A. I know nothing about that.

Q. Same question with respect to Dr. LaKind, do you know Dr. LaKind's background, training and experience?

A. I do not.

Q. Same question, Dr. McCabe. Do you know Dr. McCabe's background, training and experience?

A. I do not.

Q. In your reports, you made reference to Dr. Bailey and Dr. LaKind and that you were relying upon and frankly made reference to some of their content of their reports.

A. I remember in one report I did do that.

There might have been others, but I definitely did one.

Q. Why did you do that?

MS. MCKEEVER: Objection to form.

THE WITNESS: Why did I do that? I felt that their data supported my opinion that I had already formed in this case. So I put those specifics in there. The case was Mr. Connard.

BY MR. LEE:

Q. Make sure I'm clear. I think I heard you. You already formed an opinion?

A. Yes.

Q. And Dr. Bailey's information was simply confirming the opinion you already had?

A. It supported the opinion that I had.

Q. Fair to say if her opinion didn't support your conclusions that you have already, you wouldn't have included it? Fair?

MS. MCKEEVER: Objection to form.

THE WITNESS: Can we speak about the specific example?

BY MR. LEE:

Q. Sure, absolutely.

A. So the specific example was with Mr. Connard, and it was my -- when I reviewed it,

I felt that the latency between the time of his exposure and the development of a new onset pancytopenia leukemia was outside the window where we would expect chemotherapy, albeit different, to cause leukemia. And I extrapolated from that data.

That was the basis of my opinion. The latency was longer than we have seen with other chemotherapies. And I can quote articles and chemotherapy if you'd like.

I did include in my report the details of the exposure that was calculated by Dr. Bailey because at least in the data that we have, she felt that the level of exposure was minimal and associated with a very low risk of developing -- a lower risk of developing AML, the ambient, the natural risk of developing AML. So it supported the conclusion that I had already come to.

Q. So to be clear then, you already had your conclusion, and Bailey's information simply supported the conclusions you already had; is that fair?

A. This is true for all five of my opinions. I based my opinion on my knowledge of leukemia because I am not an epidemiologist. I'm

not a toxicologist. I'm not a risk assessor. I'm a leukemia specialist who knows something about the biology of these diseases.

Q. So it's fair to say then that you already reached your conclusions and opinions. You really didn't need the exposure data with respect to Mr. Connard; is that fair?

MS. MCKEEVER: Objection to form.

THE WITNESS: Fair to say did I really not need it? I would say that's true, yeah.

BY MR. LEE:

Q. Is that true in all five cases?

A. Yes. Definitely true in all five cases.

Q. Is that to a reasonable degree of medical certainty?

MS. MCKEEVER: Objection to form.

THE WITNESS: Yes.

BY MR. LEE:

Q. And you'll say that in court?

A. Yes, I will. That's what I wrote in my report.

Q. My question was different. My question was: You didn't need the exposure data to reach your conclusion that you already concluded; is that fair?

MS. MCKEEVER: Objection to form.
BY MR. LEE:
Q. Make sure we're saying the same thing.
A. You know, when I make conclusions about my patients and what I do in clinical practice, I use the totality of the data that I have. And so all I can say is that when I read these five cases, based on my knowledge of the biology of acute leukemia and chronic lymphocytic leukemia, I did not believe it was more likely than not that these cancers were due to that exposure that occurred decades ago.
Not being an expert in toxicology and how the water modeling was done, to come up with those exposures, you know, I'm not qualified as an expert to make any judgment about how those calculations were done. Did they support my argument? They did. This is similar to what I would do in a manuscript. Where I'm writing a paper that supports what I am thinking, I will include it. If it doesn't support what I am saying, I would discuss it.
Q. To be clear, I'll repeat my question one more time.
A. Yes. Your question is did I need the

exposure data? I should let you say it, but you said it multiple times.

To form my opinion in these five cases, I didn't actually need the exposure data; that is correct.

Q. You did not?

A. I did not. I'm sorry. I did not need the exposure data as to the levels. The exposure data was the presumed exposure that occurred during certain periods of time. That I did need.

Q. Explain that. I don't know what you mean by that.

A. Again, what I know about leukemia that is due to DNA damaging agents is that there is a latency between that exposure and the development of that type of leukemia. And in the two cases of the acute leukemias, they were not consistent. The development of leukemia was not consistent with the time of exposure. They differed in the two cases, Amsler and Connard, but they didn't support that exposure that long ago led to the leukemia decades later.

Q. You mentioned water modeling.

A. I mentioned?

Q. Water modeling.

A. Yes.
Q. What is water modeling?
MS. MCKEEVER: Objection to form.
THE WITNESS: I have no clear understanding of what water modeling is. I am not a toxicologist or a water engineer.
MR. LEE: Counsel, what was wrong with that last question I asked?
MS. MCKEEVER: It was very vague, very broad. "What's water modeling" could mean anything.
BY MR. LEE:
Q. Did you understand my question?
A. I understood your question.
Q. Thank you. We'll move on.
So just to be clear, in terms of risk assessment, you're not a risk assessor, so you're not going to render opinions concerning the quality of the risk assessments that were done in this case; fair?
A. The quality of -- yes, that is fair.
Q. I'm going to ask you an unfair question. Would you agree that risk assessment is not an exact science?
A. I'm not an expert in risk assessment.

So I am not certain exactly how people come up with these relative risks. Would I say it's not an exact science? Nothing is an exact science. So I would have to agree with that.

MS. MCKEEVER: Doctor, we've been going a little over an hour. Are you okay?

THE WITNESS: I'm good.

MR. LEE: Let's take a five-minute break.

THE VIDEOGRAPHER: The time 10:16, and we are off the record.

(Recess from 10:16 a.m. to 10:27 a.m.)

THE VIDEOGRAPHER: The time is 10:27, and we are back on the record.

BY MR. LEE:

Q. Doctor, I have some follow-up questions for you. Are you currently the editor of any peer-reviewed journals?

A. No, I'm not. I'm an ad hoc editor, reviewer of papers, but not an editor.

Q. Are any of those again papers or publications, general articles? What are you referring to?

A. Publications and journals.

Q. Which journals, which ones?

A. Journal of Clinical Oncology and then a number of other random requests I get.

Q. Are any of those journals the type that involve issues related to carcinogenesis?

A. Those journals may have articles in them on carcinogenesis, both preclinical data and maybe even some epidemiologic data, yes.

Q. Are you called upon -- I know they can call upon whomever they want, but are you typically a go-to person when folks are looking at issue related to cancer, carcinogenesis?

A. No, I am not.

Q. What areas of expertise do you have? Everyone has an areas of expertise. What is yours?

A. Taking care of people with acute leukemia, developing new drugs. I've been involved in the development and FDA approval of a drug that's added to chemotherapy for patients with FLT3 ITD mutated AML that has shown to improve the survival of patients with leukemia with that subtype. So it's really a new drug development and also in the day-to-day clinical practice of taking care people with acute leukemia.

Q. I just want to tie this area down, make sure I'm clear. Have you published or peer reviewed any research cases focused specifically on environmental causes of hematologic cancers such as CLL?

A. I have not.

Q. Same question, AML.

A. I have not.

Q. ARL?

A. I have not.

Q. SLL?

A. No, I have not.

Q. How about NHL?

A. No, I have not.

Q. Are you familiar with epidemiologic or case control methodologies used to assess environmental exposure to carcinogens?

A. In general, I'm familiar with the types of methodology that are used in epidemiology in population-based case-control cohort studies. I generally understand those methodologies.

Q. Do you publish on those methodologies?

A. I have not.

Q. I asked you earlier about toxicology generally. Now I'm going to ask you a couple of

1 questions about environmental toxicology.
2 Do you consider yourself to be an expert
3 in environmental toxicology?
4 A. I am not.
5 Q. Are there any journals that you're
6 familiar with that focus on hematologic
7 carcinogenesis?
8 A. Focus on it?
9 Q. Yes, sir.
10 A. No, I'm not aware.
11 Q. Have you ever been an editor of a
12 peer-reviewed journal?
13 A. No, I have not.
14 Q. Have you had any experience conducting
15 animal studies?
16 A. I believe I know the question you're
17 asking. So I don't think you're interested in my
18 work on lampbrush chromosomes in amphibians in the
19 1970s because I really would like to go on and on
20 about that.
21 Q. I'll tell you what. Tell me a little
22 bit about that.
23 A. You're very kind. It did make the cover
24 of Nature.
25 Q. It did? Fair enough.

A. No, sir. I have not been involved in animal toxicology studies.

Q. Fair enough. Looking at your reports --

A. Can I qualify that a little bit?

Q. Please.

A. I have to have some knowledge of animal toxicology studies because as an investigator of new drugs, I am required to review the investigator brochure on every new drug that I'm investigating. And so there's going to be in vitro studies, and there's going to be the animal toxicology studies.

So I am familiar with some of the nomenclature and methods that are used for medicines, but not specifically toxins. But, no, I've never done those studies myself.

Q. Thank you. You mentioned IARC in one or two of your reports. What is IARC?

A. It is an independent -- it's an international independent review committee looking at the strength of evidence related to, I believe, environmental toxins. And I can't remember what it stands for.

Q. Have you ever served on an IARC advisory panel?

A. I have not.
Q. How about an EPA advisory panel?
A. I have not.
Q. Any regulatory body, have you ever served on any regulatory body?
A. I don't think you mean this, but I'm a member of the leukemia steering committee of the National Cancer Institute. But I don't think it's a regulatory body. I'm sorry. May I add?
Q. Please, absolutely.
A. In terms of regulatory bodies for drug company studies, I've been on an independent review committee of a drug that became FDA approved in 2018 for older patients with AML. And then I've been the chair of data safety and monitoring committees for at least two other drugs that did not become FDA approved.
Q. In your reports, you made reference to the American Cancer Society website and that you looked at certain information.
Why did you use that website?
A. I did not use it because it's an authoritative source.
Q. You anticipated my next question. Thank you.

A. I apologize for that.
Q. That's okay.
A. You can ask anyways, and I'll have an answer ready for you. I did not use it as an authoritative source. I used it because, as I mentioned, for chronic lymphocytic leukemia, I don't know of any environmental exposure that has been clearly shown to be associated with CLL, SLL, that's accepted to the point of being in textbooks.
But I was curious as to what laypeople might hear from an established source like the American Cancer Society. So I went to that website just to see what they listed to make sure I wasn't missing something in the public domain.
Q. Thank you. Are there any authoritative websites that you would make a reference to as it relates to specifically CLL?
A. Are there websites that relates to CLL? I can't think of anything in terms of websites, no. Many of the websites are direct to patient or institutional telling you about CLL. There are a lot of those out there, the Mayo Clinic, MD Anderson, things like that.
Q. Doctor, you shared with us that your

focus is taking care of patients, obviously, while you were at Duke.

Does your involvement currently involve investigating the cause of those patients' cancers?

A. No, it does not.

Q. Has your role throughout your career ever involved investigations relating to the cause of cancer?

A. I'm pausing because I'm going way back. Before I was a doctor, I was a laboratory investigator. So I want to make sure I'm being complete. But, no, none of those salamanders got cancer. But, no, there were no animal studies. I wasn't involved in any studies in the cause of cancer.

Q. In your entire career?

A. In my entire career.

Q. You mentioned community work with SWOG. What does that stand for?

A. It stands for the Southwest Oncology Group. That one I know.

Q. It's fair to say that you've never worked as a researcher studying how environmental chemicals cause cancer?

A. That is true.
Q. You mentioned earlier that you treat patients with chemotherapeutic agents that can cause DNA damage. Did I hear that correctly?
A. That is correct.
Q. What is that mechanism?
A. It depends on the drug. Each of these chemicals have different mechanisms by which they cause DNA damage. So there are broad classes. Alkylating agents that will change the structure of nucleotides leading to DNA damage during DNA replication. Topoisomerase 2 inhibitors can cause it again by inhibiting that enzyme that's involved in unwinding DNA at the time of replication and can lead to cancer.
Each of the chemotherapies work differently. There are tubulin inhibitors that block mitoses. So it depends on the drug.
Q. Is it fair to say that based on your prior answer, you said that benzene causes DNA damage; is that correct?
A. That is correct.
Q. Do we know how?
A. We know how it causes DNA damage. The metabolites of the drug -- of benzene will -- how

it specifically causes DNA damage, you know, no, I'm not going to say because I'm not certain. I could not give an educated discussion of that.

Q. Thank you. Just a follow-up.

Do you know whether or not TCE is known to cause DNA damage?

A. TCE known to cause DNA damage? I know it was in Dr. Goodman's report. She went through the Bradford criteria for causation of cancers. I just cannot remember.

Q. You don't know one way or the other; is that fair?

A. That's fair. I would have to look at report again to remind myself. It's not something I kept in my mind.

Q. And it's not something you had knowledge of before this litigation?

A. Definitely not.

Q. Same question. I'll make it clear. Do you know whether or not PCE --

A. No.

Q. -- causes DNA damage?

A. I do not know for certain. I'm assuming it does, but I do not know that. I do not know the mechanism by which it causes that. I want to

be more specific about that.

Q. Let me follow up then. Is it your opinion that TCE does cause DNA damage?

A. It's that these volatile organic compounds can cause DNA damage at certain concentrations, levels of exposure, yes. In vitro, by the way.

Q. Let me follow up on that. The drugs that you utilize to provide care for patients who have various types of leukemia, you indicated that at least some of them cause DNA damage; correct?

A. Correct.

Q. Is there a level of administration of those drugs where they don't cause DNA damage?

A. So that data is hard to find. It's something we clearly are concerned about in terms of trying to make chemotherapy safer for patients. There are a number of studies that suggest that less exposure of certain chemotherapy drugs was associated with a lower chance of getting leukemia, and I believe some of the best data was breast cancer, a series of breast cancer in people.

So there did appear to be a dose-response curve or dose-response that helps to

link the agent with the development of cancer. But is there a minimum amount? I'm not aware of that?

Q. So in other words, regardless of the level of the medication that you're administering to patients to provide care for them, you anticipate and expect that there will be DNA damage?

MS. MCKEEVER: Objection to form.

THE WITNESS: If I give an agent that I know causes DNA damage, the way it works is by causing DNA damage. So I clearly expect it's going to cause DNA damage, or else I wouldn't have given it to them.

BY MR. LEE:

Q. That's as clear as one can state it.

Just so we're clear, you have an understanding -- if I misstate this, correct me, that -- benzene causes DNA damage. Are you able to articulate using the same rationale you and I just talked about with the chemotherapeutic agents that benzene, because we know it causes DNA damage, can cause DNA damage at any level?

MS. MCKEEVER: Objection to form.

THE WITNESS: I cannot agree to that

statement.
BY MR. LEE:
Q. Why?
A. Why? So it depends on the system. Are we talking about in vitro experiments? Are we talking about animal experiments? Are we talking about human data? The reason why these things are different is when you expose cells to these chemicals, you know, you know exactly what is the dose you're giving those cells and for how long those cells are being exposed. So you have that information.
When you're talking about exposure of people to toxins, then it's going to depend on the route by which it gets into the body, the way it's metabolized by the body, the person's ability to repair DNA damage because, fortunately, we have DNA repair mechanisms in all of our cells. It's going to depend on the ability of the drug -- of the cell to pump out the toxin. So there's a multiple ABC cassette proteins called multidrug resistance proteins that pump toxins out of cells.
Fortunately, God thought about all of this before we came onto the land, gave us all these things in our cells to protect our DNA. And

1 those are the major things, metabolism and what
2 the cell does to get rid of it and repair DNA
3 damage.
4 Q. Thank you. Let's start with
5 preclinical. What did the preclinical studies
6 reveal, to the extent you know, as it relates to
7 whether or not -- I'm talking just about
8 benzene -- you're going to have a response at very
9 low levels of benzene?
10 A. I'm not aware -- I don't know that data
11 specifically, about how low a level. Like one
12 molecule in a Petri dish I don't know.
13 Q. Fair enough. So that's where I wanted
14 to go, figure out what your knowledge base is. So
15 as it relates to preclinical assessment and
16 evaluation of what those papers show, do you have
17 any knowledge of what the data has revealed thus
18 far preclinical?
19 MS. MCKEEVER: Objection.
20 THE WITNESS: Any knowledge -- I gave
21 you some knowledge. Beyond that, no, I do not
22 know details.
23 BY MR. LEE:
24 Q. What's the basis of that knowledge? In
25 other words, have you reviewed papers, or is that

1 something you recall from the distant past?
2 MS. MCKEEVER: Objection to form.
3 THE WITNESS: I've read it in textbooks
4 mostly.
5 BY MR. LEE:
6 Q. Textbooks?
7 A. Before this, yes, textbooks.
8 Q. When is the last time you read a
9 textbook?
10 A. That I --
11 Q. Reviewed a textbook, yes. Is that
12 something common? I'm asking because a lot of
13 people don't use textbooks anymore.
14 A. I know. It's disappointing because I
15 spent a lot of time writing that last chapter in
16 Hoffman's 7th Edition. They just asked me to do
17 the 8th edition. I'm trying to get done with this
18 so that I can actually go onto that project.
19 Q. Understood.
20 A. That's too much information I know.
21 You're right. I mean, textbooks are falling out
22 of favor. Everything is online, but the thing
23 about textbooks is that the textbook is written by
24 authorities in the area, and they are peer
25 reviewed before they are published in detail. So

they were authoritative sources of information. They just, you know, become obsolete very quickly as medicine moves on.

Q. I can't help it. With that response, I got to go there.

Is it fair to say that when a textbook gets published in the press, it's already two years behind?

MS. MCKEEVER: Objection to form.

THE WITNESS: I'm sorry?

BY MR. LEE:

Q. When a textbook is published, it's already about two years behind what's occurring on the cutting edge?

A. In my experience in these textbooks that I've been involved in, I would say that's a reasonable estimate, yes. It takes a couple years to --

Q. To get to press?

A. To get to press, yes.

Q. So as it relates to if one really wants to be current, on the cutting edge, isn't it about going on online and reviewing certain, if you will, potential authoritative cites to be up to date and current?

MS. MCKEEVER: Objection to form.

THE WITNESS: If I was talking to another leukemia doctor who was talking to me about leukemia and they weren't doing that, I wouldn't be talking to them. It would be a fellow that I would be training.

So in terms of your question, yes, if you're going to be practicing in that area, you should be reading the up-to-date information. That's why we have continuing medical education.

BY MR. LEE:

Q. And that's what you teach your fellows and residents who are going to be the physicians of the future; true?

A. That is true.

Q. So I want to go back to my question about preclinical.

What specific knowledge, information do you have about what the preclinical data shows as it relates to the levels at which benzene is carcinogenic?

MS. MCKEEVER: Objection to form.

THE WITNESS: And I think I answered that. I don't have any detailed information or knowledge.

BY MR. LEE:
Q. Appreciate it.
MR. LEE: Is it time?
MS. MCKEEVER: 10:48. You want a couple more questions?
THE WITNESS: Yes, please.
MS. ADAMS: First time I've heard a witness ask for more questions.
MR. LEE: Indeed. We're having so much fun.
BY MR. LEE:
Q. This is a broad question. I apologize. Is being male a risk factor for someone eventually developing CLL?
A. Risk factor? Yeah, there are a number of demographic features. And men are more likely to have CLL than women.
Q. What's the distinction between a risk factor and cause?
A. That's an important question. A risk factor in my mind indicates only that there is a certain demographic feature that is associated with that disease. So we'll talk about chronic lymphocytic leukemia as an example, age, obesity, family history, smoking.

1 There are a number of things where you
2 look at a CLL population and you will see that
3 that CLL population is more likely to be older,
4 more likely to have smoking, family history.
5 Those things are potential risk factors. Those
6 things say nothing about cause.
7 Q. So to be clear, simply being a risk
8 factor does not mean that that risk factor causes
9 leukemia?
10 MS. MCKEEVER: Objection to form.
11 THE WITNESS: It depends on the risk
12 factor. So I didn't mention some for acute
13 lymphoblastic leukemia, acute myeloid leukemia.
14 There are some situations where I am going to be
15 able to be a lot more certain, more than this
16 50/50, a lot more certain that that exposure
17 caused the leukemia through a known mechanism.
18 BY MR. LEE:
19 Q. Obesity, age, gender are not, if you
20 will, causative demographic findings?
21 A. They are not causative. I agree with
22 that.
23 Q. What is a differential diagnosis?
24 A. A differential diagnosis is when a
25 patient has a symptom or a sign, and that's all

you know. And there are a number of things on a list that can cause that symptom. So a differential diagnosis is just that list. And what you learn to do as a clinician is prioritize your differential diagnosis by refining it with additional information that moves a certain diagnosis higher or lower on the list.

Q. In this case, do you make a distinction between a differential diagnosis and a differential etiology?

A. I do.

Q. Help me with the distinction.

A. A differential diagnosis is that -- I only know of diagnostic codes, ICD-10 codes now. So a differential diagnosis is CLL, AML, ALL. They might be on differential diagnosis of a person showing up with a high white count. So that's a differential diagnosis.

A differential etiology is, quite frankly, something that I haven't considered until this case, different causes, a differential etiology. And that would be listing -- making that same list of potential causes of the cancer based on what you know about the person.

Q. What methodology do you use to evaluate

1 whether -- let's speak about Mr. Connard --
2 whether his exposure to VOCs contributed to
3 development of his disease?
4 A. So the methodology I used was reviewing
5 his medical record and the diagnosis of the acute
6 myeloid leukemia and first determining if there
7 was anything in particular about that disease that
8 would specifically say, oh, gee, that must have
9 been due to an exposure. We can talk about
10 another case where I think I can be more certain.
11 In his case, you know, I looked at the
12 diagnosis. Everything about his diagnosis is
13 something that we see on a daily basis on our
14 inpatient service, a man his age with acute
15 myeloid leukemia showing up with new onset
16 pancytopenia.
17 Remind me of the question. What
18 things -- what methodology did I use in
19 determining differential etiology?
20 Q. Correct.
21 A. So in his case then, I know that there
22 are certain things that we know are associated
23 with developing acute myeloid leukemia, family
24 history in regards to certain genetic diseases
25 that are associated with developing leukemia,

prior chemotherapy, aplastic anemia, environmental exposures.

In determining the etiology of his, the methodology that I used was, number one, what is my knowledge of leukemia that develops after other DNA damaging agents. And the best example of that is a person at a very specific point in time gets chemo or gets radiation.

Q. It's time. We'll come back.

A. May I finish?

Q. I want to make sure you finish your response because it is 10:55.

A. I appreciate that, sir.

And so what I know -- so I extrapolate from that data that I know of. Being an AML expert, I've had to review this data for chemotherapy. Bone marrow transplants cause leukemia. MOPP chemotherapy for Hodgkin's cause leukemia.

The best data that we have is when a person has been exposed to chemo for one disease and lives long enough to see if they're going to get another disease. I mean, if they all die of the first disease, you're not going to know. So it's very specific situations like breast cancer

and Hodgkin's disease. That's where the best data comes from, lymphomas and breast cancer, because people live a long time after that immediate exposure. And you have long-term follow-up.

So my knowledge of that is that the median time to development of a myeloid neoplasm like AML is somewhere between five and seven years, pretty uncommon sooner than 12 years with typical DNA damaging -- 12 months I should say with typical DNA damaging agents and very uncommon after 15 years.

In fact, the MOPP data for Hodgkin's disease showed an increasing rise of AML starting at two years and plateauing at 10 years and then no increase after that. So that's the data I have for DNA damaging agents that I give.

In terms of toxicology, not being an expert, I did rely on the reports of Goodman and IARC that showed that for the highest exposures, the high exposure to benzene where there was a statistically significant increase in the risk of AML, that those exposures occurred -- those cancers occurred 10 to maybe 15 years later, but after that, they didn't see it. These were people without cancer. So you would expect that they

1 were followed longer.
2 So those are the two pieces of
3 information that I relied upon in terms of latency
4 that helped me determine that in Mr. Connard's
5 case, that it was very possible that this was just
6 a de novo AML.
7 MR. LEE: Go off the record.
8 THE VIDEOGRAPHER: The time is 10:57,
9 and we are off the record.
10 (Recess from 10:57 a.m. to 11:16 a.m.)
11 THE VIDEOGRAPHER: The time is 11:16,
12 and we're back on the record.
13 BY MR. LEE:
14 Q. Doctor, we're back on the record. I'm
15 going to pick up where we left off and ask some
16 general questions about methodologies that we were
17 discussing, differential diagnoses and different
18 etiology. Fair?
19 A. Yes.
20 Q. You mentioned earlier Bradford
21 considerations. Some call them Bradford criteria.
22 But I'll call them considerations. What are the
23 Bradford Hill considerations?
24 A. I read them in Goodman's report and one
25 of the other reports from the plaintiffs. And I

1 don't remember exactly all of them, but there's a
2 list of, again, I'm guessing six to eight that
3 have to do with different features that will speak
4 to causality of, you know, an agent with a disease
5 we'll say. I can't remember all of the names of
6 them, but there are several.
7 Q. So in follow-up, is it fair to say then
8 the Bradford Hill considerations are not
9 considerations that you were aware of prior to the
10 prior to this litigation?
11 A. That is exactly correct.
12 Q. Did you utilize in your determination of
13 causation the Bradford Hill considerations?
14 A. Thank you. No. Specifically I didn't
15 go through Bradford Hill considerations. What I
16 did do in my methodology is look at similar kinds
17 of issues, like, you know, plausibility, you know,
18 characteristics of leukemia, you know, different
19 criteria, but, no, not Bradford Hill.
20 Q. Plausibility, what does that mean?
21 A. To me it means that is it plausible that
22 there is even a possibility of a linkage between
23 this and cancer. So if we know that agent causes
24 DNA damage and cancers are due to DNA damage, then
25 you can -- it might be plausible to assume that

that agent may have something to do with that cancer. But, of course, then you have to fulfill all the other criteria.

Q. What are the other criteria? I'm talking about your methodology.

A. My methodology?

Q. Yes, sir. That's what we're talking about now.

A. In my methodology, it was specifically the type of leukemia because they are all different. It was the genetics, in one case very importantly the genetics of that leukemia. It was the latency between the potential exposure and the developing of that leukemia. Those were the major ones.

Q. Any others? Any other minor ones?

A. I guess I'll include plausibility, but from a point of view of just is it plausible that this person could have just developed leukemia because it's bad luck. Most cases of leukemia are idiopathic. So, for example, if one of the cases was a two year old that developed chronic lymphocytic leukemia, I'd be very concerned either the diagnosis was wrong or maybe there was an association.

But in none of the cases did I see any demographic features that said to me it wasn't plausible that this person had leukemia just because people get leukemia.

Q. I'm going to reverse that a little, make sure that I'm on the same page.

To what extent did you consider or weigh the fact that the allegations are that all five individuals who you're here to talk about were exposed to chemicals that we know and we think are genotoxic?

MS. MCKEEVER: Objection to form.

THE WITNESS: I clearly considered that, you know, this whole case is about the exposure that those people had at that point in time to some level that was calculated I would say, not actually directly measured, my understanding, based on this water modeling.

So based on those calculations, there was some level of exposure at that period of time. And now I've been asked to comment on, okay, now that these people show up with leukemia, and was it, you know -- did I take into account that they had had the exposure? Absolutely. The latency was very important. And in one case, it was -- I

1 would say it was critically important.
2 BY MR. LEE:
3 Q. How did you take into consideration the
4 fact that they were exposed to known, if you will,
5 DNA toxins?
6 A. So I took it into consideration because,
7 again, I don't know the exact level of exposures.
8 I know that that's what this whole case is about,
9 is that there's been the alleged exposure of these
10 people at that point in time. So that's all I
11 really know. And I'm not a toxicologist, not an
12 epidemiologist. So how did I take it into
13 account?
14 Say the question one more time. I want
15 to make sure I'm answering your question.
16 Q. Sure. I appreciate that.
17 How did you, if at all, take into
18 consideration the fact that -- let's just use one
19 individual at a time -- let's just use Amsler --
20 Ms. Amsler was exposed to toxins when on base at
21 Camp Lejeune?
22 MS. MCKEEVER: Objection to form.
23 THE WITNESS: So there was the potential
24 for this alleged exposure during the time she was
25 on base, and now at the age of 60, she develops

acute lymphoblastic leukemia. If I had seen -- I did take into account that exposure in terms of plausibility. And if that exposure had -- if she had been on base one to three years before and developed that leukemia, I would be hard pressed to say that something happened to her.

I would be hard pressed to disagree with something happened at that time in her life. I don't know about exposures. I'm not an expert there. But while she was there, something happened in her body that led to her getting leukemia when she did.

BY MR. LEE:

Q. When you're using the word "plausible," explain to me what you mean by it in the context that you're using it.

A. Plausible, to me it just means any one of these five people who presented to my clinic with the characteristics of their leukemia, would I consider -- would I think it's plausible that they just like most of our patients that have leukemia because they're going to develop leukemia. There was nothing different about those five people that suggested to me that their presentation was so outside the norm that it must

have been due to something that maybe we don't know.

And the reason why this is important is it comes up all the time in our practice. In our practice, everyone wants to know why me. Very common question. Why did I get this? It's not like lung cancer where you can point to smoking or mesothelioma and asbestos. In this case, it's people know that there are environmental exposures. They might not know of the data that supports that agent causing leukemia, but everyone knows about radon in homes, let's say, or benzene or Chernobyl radiation. And they'll ask. Hey, I got all these x-rays, CAT scans. Did that cause my leukemia? Very upon common question.

And the only thing I can say to those people is that we know that in those situations, yes, where you were exposed to something that many people are exposed to, but why you got leukemia, I don't know. I don't know that that agent was causative. There's nothing about your disease that tells me that that agent was causative, that event.

Q. In the discussion that you just gave, the example you gave, have you ruled out -- you

used the word radon -- that as a potential cause, or are you saying you just you don't know?

A. I just don't know.

Q. Would it be included in the differential etiology?

A. All these things would be included. Living is included. Every exposure that we have.

Q. Give me Dr. Erba's definition of the word "plausible."

MS. MCKEEVER: Objection. Asked and answered.

THE WITNESS: Plausible means that in this person -- I'm not talking about etiology. I'm talking about was there something about this person's presentation that says to me that something must have caused their disease. Can I give you examples?

BY MR. LEE:

Q. Absolutely.

A. Thank you for that. A 20 year old developed AML and three family members have leukemia. Then we find a RUNX1 mutation. I know it's the RUNX1 mutation of the family. That's pretty easy.

A patient gets, like a patient I'm

1 treating now, breast cancer therapy with dose
2 stents, Adriamycin and cyclophosphamide and just
3 as she's recovering from that a year later, she
4 comes in for routine blood counts and they were
5 normal the month before and now her white count is
6 a hundred thousand and she has acute myeloid
7 leukemia with a KMT2A rearrangement. It was the
8 chemotherapy that caused it.
9 How certain am of that? Certain enough
10 to say to the team that was taking care of her in
11 the hospital watch when the genetics comes back.
12 She's going to have a KMT2A rearrangement, and
13 when I'm wrong, which I sometimes am wrong, but
14 I've been wrong recently, it's a different genetic
15 change that was caused by it.
16 So those are situations where I can say,
17 yeah, I am really certain about what may have
18 caused that person's leukemia. Otherwise, I can't
19 tell, you know, this is just random chance that
20 people are getting leukemia or is it any of the
21 things that we're exposed to in this life that are
22 doing it. I just have no idea.
23 Q. What is your definition of biological
24 plausibility?
25 A. Biological?

Q. Plausibility, if you have.
A. I don't have one.
Q. To what extent does your definition of plausibility incorporate considerations of mechanistic considerations?
MS. MCKEEVER: Objection to form.
THE WITNESS: It's like the Bradford Hill criteria. You know, there has to be in my mind some mechanism by which that event would be causing something that can lead to cancer. So, yeah, that would be included.
BY MR. LEE:
Q. Are you an expert on the mechanistic nature, the manner in which benzene causes, if you will, DNA damage?
A. I am not an expert in the mechanism by which it causes damage DNA damage. I know that exposure to benzene causes DNA damage. That's all I know.
Q. Do you have any knowledge or expertise with respect to the mechanism, of any, if you will, carcinogenic toxin that causes any DNA damage?
MS. MCKEEVER: Objection to form.
THE WITNESS: Some, yes, toxins,

environmental toxins. I'd have to think of, you know, inhibition of topoisomerase 2 by certain chemotherapy drugs. That can cause cancer. That can cause leukemia, yes.

BY MR. LEE:

Q. The environmental toxins that are at issue in this case, do you have any knowledge with respect to the manner in which the toxins act mechanistically to cause DNA damage?

MS. MCKEEVER: Objection to form.

THE WITNESS: I don't have knowledge of exactly how, no.

BY MR. LEE:

Q. We've talked generally about your methodology. Is there any publication, website, textbook that you can refer me to that lays out the methodology you just described?

A. Not that I know of. I mean, you're asking if any. What I laid out to you, you know, was clinical reasoning. So most of it comes from experience. But is there a textbook somewhere that discusses this kind of thing? Sure. It might exist. I don't know.

Q. If it does exist, said textbook, you don't know anything -- you can't point me to it?

A. That's correct.

Q. So what we're really saying is we're talking about Dr. Erba's methodology with respect to the manner in which you address the causation issue in these cases?

MS. MCKEEVER: Objection to form.

THE WITNESS: I believe that's why I was specifically hired by the Department of Justice as a leukemia expert in, you know, diagnosing and treating leukemia.

BY MR. LEE:

Q. I agree. I just wanted to make sure that's on the record.

A. Okay.

Q. Just so we're clear, you've already given us your methodology. Anything you want to revise about that or add to it, or are you comfortable with the responses you've given so far?

A. I can't remember if I left out anything specific in my methodology. But, you know, you speak of methodology like, you know, an airline pilot has a method of making sure we all don't crash tomorrow. So they check off things. I don't have a checkoff box like that. So if I left

something off the list, I left something off the list that I was considering in my head. But, yeah, this is my clinical opinion.

Q. Again, I want to be clear on this topic. If I wanted to reproduce the methodology, the approach you're taking, frankly I need to talk to you because there's no publication I can go to to, if you will, educate myself about the methodology?

MS. MCKEEVER: Objection to form.

THE WITNESS: The methodology, there may be a way of -- there may be something out there. But again, my opinion was not just based on this is what I think of years of experience. This is what I know about the biology of these diseases, you know, based on published reports of, you know, these types of cancers.

So I'm trying to separate the data that I actually used with whatever methodology you want to call it. That is published. And I reference some of those papers in my materials considered. But, you know, a stepwise approach, no, you'd have to do like 30 years of clinical care of patients to come up with that. And it will be different for somebody else.

BY MR. LEE:

Q. You mentioned radon. What is that?

A. It's an element. It's radioactive. I think it's in cement walls. It's in the ground. There are radioisotopes all around us right now, and they all have different path links of decay. Again, I'm not an expert. I'm talking in big generalities. I'm Italian. I'm using my hands. I apologize for that.

But there's no specific -- I don't have any specifics about that. So it's a radioactive element that has been implicated in the possible cause of cancers, but I do not -- I am not an expert in the data that supports that or doesn't support that.

Q. I want to close the loop on this topic. There's no peer-reviewed causation framework document that you can refer me to if I wanted to recreate the manner in which you assess these cases?

MS. MCKEEVER: Objection to form.

THE WITNESS: Again, I think I answered this. The methodology and what order I considered things, no. But, as I said, the basis of my opinion is based on my knowledge of the biology of

each of these diseases, and that's well published.
BY MR. LEE:
Q. Thank you. Appreciate the clarification.
Is exposure to radiology films and the radiation associated with those studies a risk factor for leukemia?
A. I believe -- again, I'm not an expert on this, but we do -- I try to limit, you know, radiation exposure because -- and we tell people how much exposure they're getting with each scan now because we know that it's a risk factor for cancers in general and specifically leukemia.
Q. Again, based on that response, cancers in general, to your knowledge, does exposure to, if you will, the radiation associated with the various studies, whether they're x-rays, MRIs, whatever, can that lead to multiple different types of cancers, not just leukemia?
MS. MCKEEVER: Objection to form.
THE WITNESS: MRI, magnetic resonance imaging, I'm not certain it's been linked to any cancer at this point, although people do talk about the electrical fields of our body. I'm not sure that we've ever seen anything like that.

But with radiation exposure, yes, radiation exposure has been linked to multiple different types of cancers besides leukemia.

BY MR. LEE:

Q. How about CT scans?

A. Yes, CT scans, yes. There was a study done -- may I?

Q. Please.

A. The one I remember is x-rays of people with ankylosing spondylitis who got a lot of x-rays to their spine, and they had a higher risk of developing AML. Maybe your next question is going to be how do I know that? In a textbook. I never read the original publication. But it fit with my framework of things in the environment may cause DNA damage and leukemia.

Q. Fair enough. Your colleagues, radiologists, based upon your knowledge, skill, training, experience and education, are they not at an increased, if you will, risk for the various types of cancers including leukemia because they're exposed to radiation frequently?

MS. MCKEEVER: Objection to form.

THE WITNESS: So our radiology colleagues wear appropriate shielding to make sure

that they don't get exposed. They wear badges to look at the amount of exposure they're getting. We have really definite information about how much exposure they're getting. And there is to my knowledge -- I'm not an expert in radiation exposure, but these people are allowed to continue to work as I was because I wore these badges as a laboratory scientist. You're allowed to continue to work if you are a receiving a certain level of radiation because it is considered safe.

BY MR. LEE:

Q. Tell me about these badges. What are you referring to so the court is clear on that?

A. These are -- I don't know how they -- they pick up decay in x-rays. So they get processed. Every month you turn in your badge. They process it in the black box down the hall somewhere, and they get back an estimated exposure. And it's like you're told if you've been exposed to a safe amount of radiation or not.

Q. Just so we're clear on this topic, you don't disagree -- I'm going to make a statement -- you agree that a single type of carcinogen can cause multiple types of cancers?

MS. MCKEEVER: Objection to form.

1 THE WITNESS: So that is my knowledge.
2 I'm a leukemia specialist and really focusing on
3 that. But I know that certain exposures can cause
4 different types of cancers. It may be different
5 elements in that. For example, cigarette smoke
6 has benzene and has been associated with leukemia.
7 Cigarette smoke has a lot of other things
8 associated with lung cancer, but cigarette smoking
9 has been linked to both of those as well as
10 bladder cancer. So, yes, there's an exposure in
11 the environment that can lead to multiple cancers.
12 BY MR. LEE:
13 Q. To that end, do you have knowledge with
14 respect to whether or not benzene acts in the bone
15 marrow?
16 A. Acts in the bone marrow? I would assume
17 that where it's doing its damage is in the bone
18 marrow. That's where, you know, blood is formed.
19 Q. Just so the court is clear, when you say
20 you assume it acts in the bone marrow, the reason
21 you say that is why? What's the basis of that?
22 A. Our hematopoietic stem cells are
23 circulating throughout our body all the time. So
24 where the exposure actually occurs, I don't know
25 that anybody has actually worked that out. It

could be as it's passing through the liver or the heart. I don't know.

Q. However, you would reasonably expect that benzene acts on the bone marrow because that's where most of the activity, if you will, of the hematopoietic system is. Is that a true statement?

A. That's a true statement.

Q. You agree with that.

A. I agree with that.

Q. Earlier today you mentioned you spoke with a couple of other experts. You recall Dr. Goodman. You don't recall the second one.

Did any expert instruct you to include certain information in your reports?

MS. MCKEEVER: Objection. I'm going to instruct you not to answer any conversations about -- that you had with other experts based on privilege.

BY MR. LEE:

Q. In terms of your reports, did anyone other than an expert instruct you or an attorney what to include in your reports?

A. Did anyone other than an attorney --

Q. Correct.

A. -- instruct me? No.

MS. MCKEEVER: Objection to form.

BY MR. LEE:

Q. Your reports, did everything you include, were those independent decisions that you made to include that data, or did someone else influence your decision?

A. No. That was all mine.

Q. Do you know who Dr. Shields is?

A. I know his first name. Peter Shields, yes.

Q. Who is he?

A. He's also -- I don't know his training, but I believe an epidemiologist, toxicologist. I don't know. They're the same right now today for me because they're not leukemia doctors.

Q. Do you have any knowledge with respect to whether Dr. Shields might, in fact, be an oncologist?

A. I do believe he is an oncologist, yeah.

Q. Do you remember anything about his -- well, did you review any of his reports?

A. Can I -- I can't recall right now. There are a lot of names. Do you have my materials list?

Q. Sure, I do. We're going to come to that in a few.

But as it relates to Dr. Shields, he gave a deposition as well. Do you remember having access to his deposition by any chance?

A. No. I didn't see his deposition.

Q. Doctor, I'm going to identify some exhibits for the record now. You'll have access to your reports if you like.

(Erba Exhibit 1 was marked.)

BY MR. LEE:

Q. I'm going to hand you what will be identified as Exhibit No. 1, which will be the notice of deposition. I'm going to hand it to madam court reporter first. I'm just going to run through this pretty quickly.

Exhibit 1 I've represented to you is a notice of deposition. Have you seen that document before?

A. I have.

(Erba Exhibit 2 was marked.)

BY MR. LEE:

Q. Exhibit No. 2. I'm going to represent to you that Exhibit No. 2, which I'm reading the caption for, says Defendant United States of

America Responses and Objections to Plaintiffs' Notice of Deposition and Request for Production of Documents to Dr. Harry P. Erba.

Is that what's in front of you, Exhibit No. 2?

A. Yes.

Q. To your knowledge, have you seen that document before?

A. No. I don't remember seeing this document before.

(Erba Exhibit 3 was marked.)

BY MR. LEE:

Q. Exhibit No. 3, do you recognize Exhibit No. 3?

A. I do recognize this, yes.

Q. And what is it, sir?

A. I'm sorry?

Q. What is it?

A. It's my curriculum vitae. It's missing something.

Q. It's not a complete copy?

A. It's not a complete copy, no.

Q. In terms of the copy you provided to your counsel, is there anything else that you would want to add, any recent publications that

you're proud of that we need to talk about?
A. There are two things. And one of them I have given to counsel, and that is up until I moved to Duke, I was keeping a list of all of my CME lectures that I gave up until June of 2018. So they may be able to provide that to you.
The second is I haven't bothered to update this. I think I mentioned it in passing, but I was recently awarded the membership in the Clinical Excellence Society at Duke.
Q. Congratulations.
A. That, and 25 cents gets you a cup of coffee.
Q. For the record, I didn't say that.
A. I did.
(Erba Exhibit 4 was marked.)
BY MR. LEE:
Q. Exhibit No. 4 will be a copy of Dr. Erba's invoices. And we received an additional supplemental production of an invoice today. I have a couple questions about that just if we can.
Based on the supplement that was given to us, which basically is an invoice dated 7/22/25, would that exhibit be a relatively

complete copy of your current invoices?

A. There's another invoice, number 18, that for some reason -- I emailed it just yesterday, and it didn't make it.

Q. Do you recall how much that would be for?

A. $4,500.

Q. Looking at Exhibit No. 4, the first page, I'm looking at an entry that says Flight Durham to D.C. And the date on that -- you've got Uber charges as well, and it's invoice number 13.

Is that what that says at the top?

A. Um-hum.

Q. That trip to D.C., what was the purpose?

A. It was to meet with the DOJ lawyers.

Q. And there's a separate invoice that would have been, if you will, submitted to the DOJ for the actual time you were here for that meeting?

A. Yes. It would be somewhere in here. I have it on invoice number 11, if you're asking.

Q. Fair enough. I appreciate that. I'm going to apologize. I don't know the names of all the DOJ attorneys. But if you can glance through this, are there some communications with specific

DOJ attorneys? I'm not entitled to know what you talked about. Are those included within your invoices you've submitted?

A. Yeah. On the invoices I submitted, sometimes I -- I don't always list all of the DOJ. In fact, I never do. I might have Tracy's name here. No. I don't even have that. So I say it different ways, the DOJ attorneys, the leukemia team, yeah. I don't know in each of those meetings -- I cannot remember who was present or not present.

Q. Fair enough. I'm looking at invoice 15. It says Federal Courthouse. What's that for?

A. I met with -- I went to -- I think that that was the federal courthouse in Raleigh, and I drove there twice. And again, it was for, you know, meeting with the DOJ lawyers.

Q. Fair enough. That confused me a little bit. Appreciate that.

So looking at these documents now, are you able to determine at least based on materials you've submitted when you first became involved in this case?

A. When I first --

Q. Datewise when you first submitted an

1 invoice is probably the best way.
2 A. So that would be invoice number 1. I
3 think the date on that was 20 -- where is that
4 one? There's number 2.
5 Q. Just go to invoice 2.
6 A. Here it is HPE001, invoice on March 19,
7 and it was, as I said -- I was recalling 2023. So
8 October 29, 2023.
9 Q. Yes.
10 (Erba Exhibit 5 was marked.)
11 BY MR. LEE:
12 Q. You can put that aside. Go to
13 Exhibit 5. Doctor, you haven't seen this document
14 before I'll represent to you. If you look at the
15 bottom right-hand corner of that document first
16 page, can you read what that says, the name?
17 A. It says Bailey_USA_Subpoena and a number
18 49.
19 Q. Can you turn to page number 3 in that
20 document, just the third page. Let me know when
21 you are there.
22 If you look at that document near the
23 bottom, it has a -- it says Funding Details.
24 Do you see that?
25 A. Yes, I do.

Q. What's the bottom number when it says current.

A. 1.7 million.

Q. Can you say the total amount, please.

A. $1,762,459.75.

Q. I will represent to you that this is information we received in a request for the invoices for Dr. Bailey and that this was represented consistent with what you have produced as it relates to invoices. This is the amount that she or her -- Gradient and Dr. Bailey, had billed up until this date. And the date at the very top, I need to go up top and confirm for the record, but her deposition was a couple of weeks ago.

That number, over $1.7 million, you and I discussed earlier about potential conflicts of interest or bias. Obviously, you're new to this process.

What is your initial thought with respect to seeing someone who has billed $1.7 million plus in this litigation?

MS. MCKEEVER: Objection to form.

THE WITNESS: You're asking for my initial thought?

BY MR. LEE:
Q. Yes, sir.
A. She must be quite an expert and she did a lot of work.
Q. Do you know who employs Dr. Bailey?
A. At the time of all this work, it looks like the Department of Justice did, the federal government, but I don't know in general who does.
Q. Are you familiar with a corporation called Gradient?
A. I remember Gradient because I recently looked at in preparation for today the Goodman report, and Goodman had Gradient on her front page, title page.
Q. Did you note that it said she's a principal of Gradient? Do you know what that means?
A. No.
Q. Do you have any knowledge about Gradient other than what you just communicated to me?
A. I do not.
Q. So to be clear, are you aware of whether or not entities have publicly stated that Gradient is a biased company that will defend industry clients with nonobjective science?

MS. MCKEEVER: Object to form and foundation.

THE WITNESS: To answer your question, I'm not aware of any specific allegations for or against Gradient.

BY MR. LEE:

Q. So it's fair to say you haven't done any research concerning Gradient, who owns them or what their relationship is with other corporations?

MS. MCKEEVER: Objection to form.

BY MR. LEE:

Q. Fair?

MS. MCKEEVER: Same objection.

THE WITNESS: I haven't done any separate research, no.

BY MR. LEE:

Q. Are you familiar with a company called Blackstone that is a private equity entity?

A. I am not.

Q. Are you familiar with a company called Geosyntec?

A. I am not.

Q. I will represent to you that Gradient, who's affiliated with both Dr. Bailey and

Dr. Goodman, is owned by Geosyntec. I've represented to you that Blackstone is a private entity company that owns Geosyntec that owns Gradient. I will also represent to you that Blackstone owns entities that produce some of the chemicals involved in this case. That's for point of information.

So we have two experts, Bailey and Goodman, who work for an entity that is ultimately affiliated with the company that produces some of the very VOCs that we're talking about today.

Would you agree with me that there is an economic interest that a producer of some of these VOCs have with some of the experts who have testified in this case?

MS. MCKEEVER: Objection to form and foundation.

THE WITNESS: You did a bunch of represents in the --

BY MR. LEE:

Q. I did.

A. -- specific question. The specific question is?

Q. Do you agree that there's an economic relationship between a private equity company that

manufactures some of these VOCs and some of the experts that are involved in this case?

MS. MCKEEVER: Same objections.

THE WITNESS: Based on what you said about, you know, these companies, you know, this one, they worked for this one and then it's owned by this one and this one. These relationships, there may be some kind of economic relation that I don't understand.

BY MR. LEE:

Q. Fair enough. When you and I talked earlier about what you do when you are presenting at conferences, you inform individuals if, in fact, there's even a perception of a conflict; true?

MS. MCKEEVER: Objection to form.

BY MR. LEE:

Q. True?

A. Yes.

Q. Why do you do that?

A. I do that so that people can put in context my statements and opinions into and how it may be -- if they believe it's being influenced by any of those financial interactions.

(Erba Exhibit 6 was marked.)

BY MR. LEE:
Q. I want to identify now Exhibit No. 6. Doctor, I've handed you a document that's identified as Exhibit No. 6. You haven't seen this before. Top right corner, what is the name of that company at the top right?
A. Gradient.
Q. Top right there's a total invoice number. Do you see that number?
A. Top right?
Q. That's highlighted in orange.
A. Yes.
Q. What is that number?
A. $78,127.37.
Q. That number is actually less than the number you saw for Dr. Bailey; is that correct?
A. That is correct.
Q. Turn to page 2. Do you see that highlighted section at the bottom there?
A. I do.
Q. What number is highlighted?
A. The billings to date totals $4,321,996.36.
Q. Go back to page 1. At the top left, who is the principal that's listed there?

A. Top left, Julie Goodman.

Q. So is today the first time that you were informed that Julie Goodman has billed at least at the date of this particular invoice, Goodman and her colleagues with Gradient, and this does not include Dr. Bailey, in excess of $4 million in this case?

MS. MCKEEVER: Objection to form and foundation.

THE WITNESS: This is the first time I've seen this, yes.

BY MR. LEE:

Q. In excess of $4 million is a lot of money. Do you agree with that?

MS. MCKEEVER: Objection to form.

THE WITNESS: You know, "a lot of money" has to be put into perspective, sir. You know that. I read Dr. Goodman's report. It was incredibly detailed. She reviewed an incredible amount of material. The number of tables in there was staggering. She did the Bradford Hill analysis for four different chemicals. And she had people, associates, obviously, that also work with her to support her work. So I would assume that she was billing for the work that she needed

to do to give her expert opinion in this case.
BY MR. LEE:
Q. You reviewed the reports you mentioned, Dr. Goodman. Did she in any of those reports mention the name Geosyntec, that company?
A. I would have to look at them again. I don't remember.
Q. Same question, Blackstone. Do you recall seeing the name Blackstone?
A. I do not recall.
Q. In your review of the materials you've seen, do you recall any statement at least in those reports that either Dr. Bailey or Dr. Goodman had a potential conflict of interest?
MS. MCKEEVER: Objection to form.
THE WITNESS: I didn't see any documents like that regarding outside interests, conflict of interest, things like that.
BY MR. LEE:
Q. You can put the document aside.
A. All of them?
Q. Yes, please.
I'm going to shift gears and ask you a few general questions and then skip into some nuances related to the cases themselves.

I want to make sure I tie down your thoughts in terms of risk assessments. Do you have any knowledge concerning how regulatory agencies use risk assessments?

A. No, I do not. Regulatory agencies that we're talking about here, Environmental Protection?

Q. Yes.

A. Toxins. No, I do not.

Q. In your review of the documents prepared by Dr. LaKind and Dr. Bailey, did you note whether or not they took into consideration individual risk factors, such as age, sex, race, lifestyle?

MS. MCKEEVER: Objection to form.

THE WITNESS: I read a lot of reports. I would have to look at them again. I didn't review them before this meeting. So I can't answer that question.

BY MR. LEE:

Q. Do you have knowledge with respect to whether or not, and I'll just use one, age should be taken into consideration when one is making a determination as it relates to a risk assessment?

MS. MCKEEVER: Objection to form.

THE WITNESS: Age is a consideration

when you're talking about leukemia. As I mentioned, if a patient, a person with CLL that was diagnosed at age 2, that would be an outlier. But age is a risk factor for leukemia, yes.

BY MR. LEE:

Q. Do you know whether or not the age of the patient was taken into consideration by Dr. Bailey and Dr. LaKind when they did their evaluations and assessments?

A. I would again have to review the reports. Again, they were lengthy reports. I don't remember that. I do know from my report what I quoted was not their assessment of risk factors for leukemia, but their assessments of the water modeling and potential exposures.

Q. Do you know whether or not there were reports that were, if you will, submitted to counter the reports of Dr. Bailey or Dr. LaKind?

A. I do not know.

Q. So when you say you took into consideration their findings, were there any other reports that you reviewed that addressed the same issues?

MS. MCKEEVER: Objection to form.

THE WITNESS: Not that I recall.

BY MR. LEE:
Q. Let me just break that down. As it relates to Dr. LaKind, you reviewed Dr. LaKind's report?
A. Yes.
Q. Is Dr. LaKind a he or a she?
A. I don't recall.
Q. Same question.
A. Am I supposed to be able to determine that by her first name or his first name? Because that's a loaded question, sir.
Q. It is.
A. One we're allowed to ask in this new administration.
Q. On the record I just did.
A. I'm sorry for that, sir.
Q. For the record, was Dr. Bailey -- do you know whether or not he or she took into consideration certain demographics of these particular clients, specifically the five we're here to talk about today?
A. I can't recall, you know, that detail.
Q. So just to close the issue on exposure measurements, you did not make an effort to conduct or perform any exposure measurements for

the individual plaintiffs because they're outside of your area of expertise?

MS. MCKEEVER: Objection. Form.

THE WITNESS: I did not make any attempt to do that because it is way outside my experience and my expertise and my ability to understand, you know, the details of water modeling and toxicology. But again, I based on my opinions in my report based on my knowledge of leukemia specifically.

BY MR. LEE:

Q. So as it relates to the units of measurement when they were assessing, "they" being -- let's talk about one provider, Dr. Bailey. When Dr. Bailey was doing her estimates and calculations, do you know the units of measure that she was using?

A. I do.

MS. MCKEEVER: Objection. Form.

THE WITNESS: I know from my report it was .00033, but you're not asking that. The units of measure, I've seen two different units of measure for benzene in some of these reports, which led to my again saying, boy, I really am not an expert here. But one of them was parts per

billion -- parts per million, not billion, parts per million dot years in her report.

BY MR. LEE:

Q. Do you know whether they used any units of measure that included microgram per liter month?

A. That's what I cannot recall. I've seen that measurement, for example, in the Wang paper. I saw that measurement and was trying to figure out the relationship. I did do that somehow. How did I do that? There was something in the paper that led me to think I could maybe equate those. But again, since I'm not an expert in how those measurements are done, I didn't feel comfortable saying that I know, you know, how they relate to each other.

Q. Have you ever in your professional experience interacted with someone who performs risk assessment?

A. Other than my insurance broker.

Q. I figured you'd go there. Other than your insurance broker.

A. Couldn't resist, sir. No, I have not.

Q. Do you know whether or not it's common for someone to assess risk for an individual who

1 already has in this case an unknown diagnosis?
2 MS. MCKEEVER: Objection to form.
3 BY MR. LEE:
4 Q. I'll rephrase that for you.
5 Based on what you know about risk
6 assessment, and you shared with me what your
7 knowledge is, intuitively as a clinician, do you
8 think it's appropriate to do a risk assessment
9 with someone who already has a condition?
10 MS. MCKEEVER: Objection to form.
11 THE WITNESS: The way you're asking that
12 question leads me to think I really don't know
13 much about risk assessments, because the way
14 you're asking the question makes it seem like I am
15 supposed to say no, that's not reasonable. But I
16 don't know.
17 BY MR. LEE:
18 Q. A patient comes into your practice has
19 cardiovascular disease.
20 A. Now we're talking my language.
21 Q. And a family history of cardiovascular
22 disease. Do you talk to that patient about their
23 risk of cardiovascular disease?
24 A. Yes.
25 Q. What do you tell them?

A. I look at the known risk factors for cardiovascular disease including family history, smoking, diabetes, hypertension, hyperlipidemia. There are various models out there. Here again, I'll say since I am not an expert in cardiology, I do not do those calculations for my patients.

Q. For a patient who had a heart attack, what's the chance of that individual having another heart attack, if you know?

MS. MCKEEVER: Objection.

THE WITNESS: I actually don't know.

BY MR. LEE:

Q. I'm going to reverse that question a little bit. Individual presents to your practice and they have AML. You've told us that patients will ask you what caused it; is that correct?

A. That is correct.

Q. And what do you tell them? Assuming you don't have any other known causes, what do you tell them?

A. We don't know.

Q. In your discussions with a patient who has AML, do you have a conversation with them concerning their risk for having contracted AML?

A. In my conversations with patients who

have AML, do I have a discussion about their risks for why they got leukemia? Yes.

Q. How does that go? What exactly does it involve?

A. It usually begins and ends with, you know, you're older. Your family had leukemia. You were a smoker and if they've had these other things. But it's really age and family history. I usually don't bring up smoking. I don't want to blame -- leukemia is so common, I don't want to blame it on their smoking. Maybe it was, but I don't know.

I know there's benzene in tobacco smoke, but I don't want to say to the person, you got leukemia because you smoked too much. And part of the reason for that is that's not why they're there. They might want to know. They're curious. But they want to know what I'm going to do about their leukemia. So the conversation is really moving away from why did I get it to what are we going to do now.

Q. In those conversations you have with individuals who are in your practice, do you discuss relative risk of them having contracted AML as an example?

MS. MCKEEVER: Objection to form.
THE WITNESS: I don't use the term relative risk, no.
BY MR. LEE:
Q. Do you know what relative risk means?
A. I'm assuming it means relative to some other population, yes.
Q. Why don't you have that conversation with them?
MS. MCKEEVER: Objection to form.
THE WITNESS: I don't have that conversation with them because, you know, it varies by every age. I guess to qualify my last answer, I could say by age, I know the incidence of AML goes up by age, and we have some estimates by age. But in terms of other relative risks in terms of tobacco or family history, we don't really have -- I don't have really good data in my mind to share with them.
BY MR. LEE:
Q. If I use the phrase hazard identification, does that mean anything?
A. Hazard ratios, but hazard identification, no.
Q. I'll move on. Are you familiar with the

phrase "substantial contributing factor"?
A. It's not a phrase I use often.
Q. For example, in a patient you're providing for, would you agree with me, and let's talk CLL, that the patient can have multiple potential causes or etiologies of his or her CLL?
MS. MCKEEVER: Objection to form.
THE WITNESS: I don't agree with that because I don't know the etiology of CLL in any of our patients.
BY MR. LEE:
Q. In any of your CLL patients, you don't know the etiology?
A. That is correct. It varies, but I don't know.
Q. In your clinical experience over the years, decades of providing care for CLL patients, has there ever been a patient, CLL, where you were able to definitively determine the cause of his or her CLL?
MS. MCKEEVER: Objection to form.
THE WITNESS: No.
BY MR. LEE:
Q. Why?
A. Because there is no known cause of CLL.

Q. Because there's no known cause, does it stand to reason there could be multiple contributing causes that led to the CLL?

MS. MCKEEVER: Objection to form.

BY MR. LEE:

Q. Does that make sense?

A. There are contributing causes, multiple contributing causes? Again, I don't know that. I know there are risk factors. There are demographics, but I don't know that there are multiple contributing causes.

The current theory that I'm aware of, and this is theoretical, not proven, not accepted by everyone, but the theory that is out there right now based on utilization of immunoglobulin variable region genes. There are about a hundred of them. It turns out in CLL patients, it's a very restricted number of variable region genes that are seen in the clones of patients and the disease that those patients have, which has suggested to experts in the field, CLL experts, that CLL is due to some kind of aberrant reaction against a very common thing in the environment or actually something that's already in our body. But other than that, there is really no known

cause, etiologic agent of CLL.

Q. Following up on your description, you said that it could be related to something in the environment.

A. Yes.

Q. As a potential etiology.

A. As a potential.

Q. Does it stand to reason that you can't rule out an environmental toxin being that environmental element that you're describing in your description? True?

MS. MCKEEVER: Objection to form.

THE WITNESS: I'm ruling that out because I use the word commonly found in our environment. And, you know, there are other -- the agents that are thought to be commonly involved in our environment are many. They don't know which ones they are.

BY MR. LEE:

Q. Question. Given that we don't -- I'm using your words -- don't know the etiology or cause of CLL, are you saying it's impossible for an environmental toxin to be the cause of CLL?

MS. MCKEEVER: Objection to form.

THE WITNESS: I'm clearly not saying

it's impossible.
BY MR. LEE:
Q. So just to follow up on that, would you agree that you cannot definitively rule out environmental toxin exposure as being the cause of CLL?
MS. MCKEEVER: Objection to form.
THE WITNESS: All I can say is my understanding of the IARC report is that there is no definitive proof that CLL is caused by benzene specifically. And I don't know of any scientific evidence of a particular toxin causing CLL. That's all I can say.
BY MR. LEE:
Q. Does lack of definitive proof mean that there's definitively no evidence, if you will? It simply hasn't been discovered yet?
MS. MCKEEVER: Objection to form.
THE WITNESS: So I would have to answer, no, you can't equate those two things. There are lots of miracles that happen that make me think God exists, but I don't know that God exists. I mean, there's no proof that God exists. So that's my faith. But that's it.

BY MR. LEE:

Q. Would you agree that medicine in the timeframe that you've been involved in medicine has evolved over time?

A. It clearly has evolved over time.

Q. In those many decades that you've been practicing as a provider, would you agree that there are now, if you will, diagnoses that you and others can make whereas when you first started practicing, the thought was we don't know the etiology? Would you agree with that?

A. I have to think of an example of a diagnosis that we make now where we now know the etiology that we didn't know before. I have to turn that question around. I'm just -- it's a convoluted question.

So the diagnosis we have now that now we know that there was an etiology of it, but before we didn't, that's what you're saying?

Q. Let me change the question a little bit. Would you agree -- I'm going to go way back now -- hand washing before surgical procedures wasn't always common in medical practice?

A. Yes.

Q. Morbidity and mortality in and around

1 surgical procedures was astronomically high?
2 A. Yes.
3 Q. Once it was determined that providers
4 simply washing his or her hands before going into
5 the OR, the infection rate, morbidity and
6 mortality rates went down; true?
7 A. True. From textbooks I know that.
8 Q. There you go. Would you agree that
9 that's an example of the medical field advancing
10 and moving forward and determining the etiology of
11 why those patients were having issues postop?
12 MS. MCKEEVER: Objection to form.
13 BY MR. LEE:
14 Q. That's common knowledge to you and other
15 physicians; correct?
16 MS. MCKEEVER: Objection to form.
17 BY MR. LEE:
18 Q. So that's where my question comes from.
19 Would you agree that fortunately as providers move
20 forward, we're able to, if you will, continues to
21 advance science and make diagnoses that we
22 couldn't make before?
23 A. I definitely agree with that, that we're
24 going to be able to make diagnoses that we
25 couldn't make before. That's a diagnosis. What

you're asking me to say is that is it possible that sometime in -- maybe I shouldn't put the words in your mouth, but is it possible that sometime in the future, since we're talking about hand washing, is it possible sometime in the future that we're going to learn, let's cut to the chase, that VOCs cause CLL? Is that possible?

And I would say anything is possible, not impossible. But given the question that we're asking, I cannot think of a methodologic way that we are going to be able to solve that question in the future and not being completely conjecture at this point.

Q. Let me go back to your comment that we don't know what causes CLL.

Was there a time when you were practicing where some of the causes of AML that we know now are causes weren't known to be an etiology?

A. Yes. As an example, we know family history is important, and over time we've learned specific genetic changes that are inherited. In fact, I worked with a physician who discovered RUNX1 was inherited in families that developed AML back in the 1990s.

Q. What is your understanding of the definition of cancer slope factor?

A. Cancer?

Q. Cancer slope factor, S-L-O-P-E factor. Do you have any knowledge about that?

A. Cancer slope factor, no, none.

Q. So to the extent you read that in Dr. Bailey's report, you just don't remember that?

A. I don't remember that.

Q. Again, an unfair question I'm going to ask to make sure the record is clear.

Are you aware that Dr. Bailey calculated cancer risk for chemical disease combinations where no be established cancer slope factor exists?

MS. MCKEEVER: Objection to form.

THE WITNESS: I don't remember that statement. I don't know what cancer slope factor means.

BY MR. LEE:

Q. So just so I'm clear, to the extent one can calculate a cancer slope factor for a given VOC and a cancer, you know nothing about that?

MS. MCKEEVER: Objection to form.

THE WITNESS: I don't know -- I don't

want to opine. I hate that term. I don't want to give an opinion on cancer slope factor in any question because I don't even know what that means.

BY MR. LEE:

Q. Fair enough. You mentioned Dr. Bailey's report in at least one, I think several of your expert reports, and you stated that her comment was that her estimates were conservative.

A. Her?

Q. Her estimates for exposure were conservative. Do you remember that language?

A. I remember that language, and I believe I took it from her report.

Q. What's the basis for you agreeing that her estimates were conservative?

MS. MCKEEVER: Objection to form.

THE WITNESS: So I have no basis for making that independent assessment since I'm not an expert.

BY MR. LEE:

Q. So just to follow up on that, you didn't actually go behind her comment stating that it's conservative to determine whether her statement in her report was, in fact, valid; true?

MS. MCKEEVER: Objection to form.

THE WITNESS: As answered, no, I did not do any further investigation to see if her comment was, you know, valid.

BY MR. LEE:

Q. Do you recall in your report you cited Dr. Bailey's conclusion that any plaintiff with an estimated cancer risk below one times ten to the minus four cannot prove causation?

MS. MCKEEVER: Objection to form.

THE WITNESS: That was in my report. I do remember that being in my report.

BY MR. LEE:

Q. You cited her statement. So you agree with her statement or you were simply cutting and pasting?

MS. MCKEEVER: Object to form.

THE WITNESS: The statement again was?

BY MR. LEE:

Q. Her statement was related to estimated cancer risk factors, and she said anything below one times ten to the minus four cannot prove causation. That was her statement. You copied it.

MS. MCKEEVER: Objection to form.

THE WITNESS: So my interpretation of that separately -- I did copy it. It comes from her report. But why did I think that that was correct? I mean, I could look at my report, but I believe my next statement in that report was because the baseline incidence of acute myeloid leukemia is four per hundred thousand, how could we say something that may have increased your risk by one in ten to the minus four actually cause that person's leukemia. That was the basis.

Again, it's based on my knowledge of the incidence of AML, not the calculations that Dr. Bailey did. And as I said that report, I had already formed my opinion based on the latency between the exposure and the diagnosis. So her opinion supported mine.

But not being an expert, all I could do was accept that calculation and felt it supported my general conclusion. But without it, I would have made the same conclusion.

BY MR. LEE:

Q. Are you familiar with the ATSDR?

A. Yes.

Q. What is it?

A. I don't remember what it stands for.

It's been in a number of the papers. I haven't reviewed it independently.

Q. So to the extent that ATSDR has explicit language that instructs individuals doing risk assessments not to use their data in a certain fashion, you know nothing about that; is that fair?

MS. MCKEEVER: Objection to form.

THE WITNESS: No. I don't know anything about their recommendation.

BY MR. LEE:

Q. Fair enough. So to the extent that Dr. Bailey utilized an approach that the ATSDR said not to use for the risk assessment, you have no knowledge about that?

MS. MCKEEVER: Objection to form.

THE WITNESS: I have no knowledge.

BY MR. LEE:

Q. Do you have knowledge with respect to whether or not the EPA data that's available that looks at risk range for various cancers, do you know whether that's applicable to contaminated sites and whether they need to clean them up or not versus individual risk factors? Do you know one way or the other?

A. I do not. As I mentioned earlier, I'm aware and grateful that the EPA exists. How they do their work, I'm not sure. I leave it to those experts.

Q. As it relates to whether or not Dr. Bailey was using their data incorrectly, you have no opinion on that?

MS. MCKEEVER: Objection to form.

THE WITNESS: I have no opinion.

BY MR. LEE:

Q. Do you know whether or not the EPA has an opinion on whether or not there's a threshold model applicable to carcinogens?

A. I have not read the details of the EPA about whether they have a threshold model for it, who hold that and who doesn't hold that.

Q. Same question. ATSDR, do you know whether or not ATSDR has an opinion or papers on that topic?

A. I am not aware of that. I'm aware of my own feelings about that. But I'm not an expert, so I'm sure you don't care.

Q. I'll accept when you say you're not an expert, and we'll move on.

A. Thank you.

Q. Dr. LaKind, what exactly did Dr. LaKind do in this case? You said you read her report. What is her role?

MS. MCKEEVER: Objection to form.

THE WITNESS: I don't know her methodology or exactly what she did.

BY MR. LEE:

Q. Are you aware of the fact that an expert addressed issues related to the shower model?

A. I don't know what that model is, no.

Q. So to the extent shower modeling data was included in a report or an report that's included in your materials considered list, you just don't remember?

MS. MCKEEVER: Objection to form.

THE WITNESS: I don't remember that part of her report, no.

BY MR. LEE:

Q. I'll just close the loop with one more question on this topic. In terms of water modeling and shower models, there's no point in me asking more questions. You know nothing about shower modeling?

A. Are you talking about shower, like a shower?

Q. Yes.

A. Now I think I know what you're talking about there. Sorry. Maybe it's my hearing. I thought it was some kind of weird engineering modeling thing.

I think the shower modeling is there's something in the water, and when you have a shower, it gets aerosolized, and there's some kind of model about how much of that volatile chemical then might be in that air that they're breathing in the shower.

I know nothing about how those calculations are done because I'm not an expert.

Q. Fair enough. Then as it relates to whether or not the shower flow rates, the rate at which the water was coming out of the shower and the impact that had on, if you will, the VOCs, you have no knowledge about that?

MS. MCKEEVER: Objection to form.

THE WITNESS: As you're saying the question, knowing a little bit about physics and flow of water through, you know, tiny pipes, you know, I could imagine like in blood vessels, you get turbulent blood flow, it might make a difference. But how it would be calculated in or

1 considered in these models as a factor, I am not
2 aware of any of that.
3 BY MR. LEE:
4 Q. So to close the loop on this topic, you
5 don't know whether or not Dr. LaKind used flow
6 rates in her calculations that were less than half
7 of the actual flow rates? You don't know one way
8 or the other.
9 MS. MCKEEVER: Objection to form.
10 BY MR. LEE:
11 Q. Is that fair?
12 A. I stated I do not know.
13 Q. As a scientist, do you have any thoughts
14 on the impact it would have to be using flow rates
15 that are half of what they should be?
16 MS. MCKEEVER: Objection to form.
17 THE WITNESS: So is a scientist, I would
18 have concerns about using data that was not
19 correct. Again, Dr. LaKind practices in an area
20 that I don't, and if she had a reason to -- I
21 think it's she -- had a reason to consider a lower
22 flow rate than what you're quoting should have
23 been the flow rate, she may have had some good
24 reason. But I am not expert enough to defend one
25 flow rate over another. But I'm sure -- I would

imagine it wasn't arbitrary. But again, I don't know.

BY MR. LEE:

Q. Does the phrase margin of exposure analysis mean anything to you?

A. No, not really.

Q. We'll move on.

Do you have an opinion in this case with respect to whether or not the VOCs in this case had synergistic effects on other VOCs?

MS. MCKEEVER: Objection to form.

THE WITNESS: Do I have an opinion on whether -- so you're talking about mixtures of these chemicals?

BY MR. LEE:

Q. Yes, sir.

A. So it's not just benzene coming out or TCE or PCE. You put them together. They'd be synergistic?

Q. Yes, sir.

A. I do have an opinion on that. And I think Dr. Goodman discussed it in her report. I have a separate opinion based on my experience for that. You would think at first glance that if you have two chemicals that cause a problem, that you

1 would have at least additive effects, if not
2 synergistic effects.
3 But actually, the data doesn't support
4 that. Again, I have to stick with what I know.
5 So if you don't mind, I'll give you an example of
6 toxins I deal with. The treatment of AML has been
7 the same since 1973, one of the standard
8 treatments, of two drugs, daunorubicin and
9 cytarabine. Those drugs are given by intravenous
10 injection three days for one, seven days for
11 another.
12 There's preclinical data that shows that
13 the ratio of those two drugs when administered in
14 tissue culture to cells can have different effects
15 based on the ratio anywhere from synergistic to
16 additive to actually antagonistic.
17 Interesting model because we don't know
18 what we're doing. This is 1973 when Yates
19 published the paper and we're just squirting in
20 these drugs. It's like, oh, wow, we're curing
21 some people. We're excited. But then you get the
22 data. So a drug company said we're going to test
23 this hypothesis. So we are going to pick the
24 magical ratio of those two drugs and put it in a
25 liposome because that way we know it's delivered

to the cancer cell in that liposome. And that drug was developed. I was an investigator with that drug. It's called CPX351.

When they did the experiment in mice, it turned out to be more effective when they had the magical ratio, but more importantly, when we participated in the study of people with leukemia, older people who had a poor prognosis who got standard seven and three chemotherapy -- that's how we usually give the drugs -- were the same two drugs in the magical molar ratio, higher response rate and a higher cure.

So in that case, we're working towards taking advantage of that data that there was a synergistic effect, to your point. But that preclinical data, I'll remind you, also showed that there were antagonistic ratios. And what we knew about the concentrations of those two drugs is they vary over the time of the administration. So there appears a time that patients and mice in the experiments were getting antagonistic.

Taking from Dr. Goodman's report, I agreed with some of her conclusions about being careful about that association of mixtures being synergistic based on, again, the relative amounts

because that resonated with what I was thinking with chemotherapy drugs. The mechanism of action, these two drugs, daunorubicin and cytarabine, have a completely different mechanism of action. So if the mechanism by which those drugs, those volatile organic chemicals cause damage is different, they could potentially be antagonistic.

So thank you for allowing me to be long-winded once. I feel like I was in my educator role. I felt more comfortable there for about three seconds. I would say that I can't agree with you that the mixtures will always be synergistic in their effect, to answer your questions finally.

Q. So your answer would be the same if I asked you whether they were additive?

A. Yes. Can I go again?

Q. We can do that after lunch. But as it relates to -- you mentioned the mechanism of action, MoE, was similar or the same in that scenario from what you described, would you anticipate that they might be additive?

A. No. There's still other features about the ratio of these two drugs to each other, length of exposures, were the exposures the same at the

exact same time. There's so many things we don't know.

Q. To your knowledge, have there been publications related to VOCs and whether there were, in fact, additive, synergistic or inhibitory? Did you review any of that literature?

A. I did not review any of that literature.

Q. So it stands to reason you will not be opining at trial with respect to what, if any, interaction would occur between the VOCs?

A. I am hoping that at the trial, I am asked to opine on leukemia. So to answer your question, sir, no, I will not give an opinion on that at trial.

MR. LEE: Go off the record for a moment.

THE VIDEOGRAPHER: The time 12:38 and we're off the record.

(Recess from 12:38 p.m. to 1:35 p.m.)

THE VIDEOGRAPHER: The time is 1335 and we're back on the record.

BY MR. LEE:

Q. Good afternoon, Doctor. We're back from lunch. Hopefully, you are doing well.

A. I am. Hope you are, too.
Q. I am. Outstanding. When is the last time you did some online research related to your involvement in this case?
A. Online research, boy, I think it was during when I was reviewing Connard's records. It was a while ago.
Q. You know I can't resist. When you say it's a while ago, what does that mean?
A. Well, I'd have to look at my invoice of when I actually finalized Connard's record. So I would say I signed the records in April. So I would up until April.
Q. So to the extent there might have been additional publications related to some issues in this case, that's not something you would have reviewed?
A. No. I wouldn't be -- first of all, I wouldn't be looking for those because they're outside of what I do on a daily basis. So, no, I wouldn't have known about them.
Q. When you were preparing your reports, did you do any online research?
A. Yes. I looked for, you know, manuscripts that supported some of my opinions.

Q. Did you look at any manuscripts that did not support your opinions?

A. I'll qualify how I said it. I looked for manuscripts that were important for me formulating important decisions, and those were specifically on the causes of acute leukemia in Amsler, the acute leukemia in Connard and CLL, and I looked in general, not specifically saying, hey, what supports my opinion.

Q. And we've already covered your MCL. All those materials are included in that materials considered list?

A. Yes.

Q. When you say you looked in general, do you recall what your search terms might have been?

A. So for Amsler, it was KMT2A therapy related, acute lymphoblastic leukemia. Those would be two that come to mind that I could remember those searches back then.

And then for Connard, it was on specifically -- I was staying in my lane. So I looked at the risk of developing acute myeloid leukemia after exposure to various chemotherapies. So I would type in the disease, like Hodgkin's knowledge disease, and chemotherapy and AML,

1 something like that.
2 For CLL, it was a very general search
3 like CLL pathogenesis, etiologies, things like
4 that.
5 Q. Do you recall using any phrases
6 specifically that would have included TCE or PCE?
7 A. No. I never did that.
8 Q. How about benzene?
9 A. No.
10 Q. How about EPA?
11 A. No, I did not.
12 Q. ATSDR?
13 A. No, I did not.
14 Q. IARC?
15 A. I had the IARC manuscript. I'm trying
16 to figure out how I had that, but I had it. I
17 didn't search any further on other manuscripts. I
18 think it was the most recent one from 2018.
19 Q. You're not sure how you got that
20 manuscript?
21 A. Other than it being -- it was referenced
22 in Goodman's report. So that may be, you know,
23 why I looked at it because it some details about
24 benzene.
25 Q. Hard copy or electronic?

A. It was electronic. I'm just making sure. Did I actually made a copy of it? No. It was just on my separate hard derive.

Q. I'm going to introduce a few exhibits now in the interest of time. You're asked several times to take a look at the reports, so we'll introduce those.

Connard will be 7. 8 will be Amsler. 9 will be Hill. 10 will be Fiolek. 11 will be Gleesing.

(Erba Exhibits 7 - 11 were marked.)

BY MR. LEE:

Q. Doctor, I've handed you five documents, and I indicated the names of those, at least the names as I understood them, and perhaps how I pronounced them may or may not have been accurate.

Having said that, have you seen these documents before?

A. I have.

Q. For the record, can you describe them.

A. These are the final draft reports -- I'm sorry -- final reports on the five cases I was asked to review.

Q. Earlier you said that as it relates to doing additional research, after you completed

these reports, you have not done any additional research specifically related to this case?

A. That is true. Hold on. I think I mentioned earlier that the only additional research were the papers that were indicated to me by Department of Justice by Yu and Wang. That was additional after the report. Sorry. I misspoke.

Q. No, that's fair. Let me rephrase then.

Have you done any independent additional research?

A. No, sir.

Q. Thank you. I'm not entitled to anything that you communicated to counsel about. Given that this is the first case you've been involved in, help me understand the process you went through to begin drafting the report.

A. So I can't remember all the details, but the counsel, the DOJ --

Q. Again, I'm not entitled to know anything you talked to them about. Fair enough?

MS. MCKEEVER: Do you understand?

THE WITNESS: Yeah. I think I understand. But you're asking how did I know to put in things like specifically executive summary qualifications?

BY MR. LEE:

Q. Yes, sir.

MS. MCKEEVER: You cannot discuss any communications we had. Those are privileged conversations. If you can answer without disclosing privileged information, you may do so. If you cannot, then I instruct you not to answer.

THE WITNESS: All legal stuff, but let me make an attempt at it.

I had never prepared an expert report. And the Department of Justice gave me some guidance on what kinds of things should go into an expert report, qualifications, you know, things like that.

BY MR. LEE:

Q. Were there any materials -- let's just talk specifically about one case at a time -- with respect to Mr. Connard, who is a representative of Steven Matthew Connard, have you seen a deposition of Mr. Connard, by any chance?

A. I did.

Q. Was it an actual video, or was it the written transcript?

A. No, the written.

Q. Was there any material that you've asked

for that you have not received related to the Connard matter?

A. Yes.

Q. What is it?

A. I would have found interesting to have a record of blood counts before he was diagnosed with AML.

Q. Why?

A. Those blood counts could give me an indication of when the disease process may have actually started.

Q. And the diagnosis that Mr. Connard had was what?

A. Acute myeloid leukemia.

Q. What benefit would it have been to have the information available to you that you described?

A. Again, I'm extrapolating from my knowledge of etiology of acute myeloid leukemia from other DNA damaging agents. And his diagnosis was made nearly 20 years after he left Camp Lejeune. That's when the diagnosis was made.

It is possible in people who develop acute myeloid leukemia to have a related disorder prior to that called myeloid dysplastic syndrome

which may have been caused by the same types of toxins that we're talking about. Benzene exposure is linked to myeloid dysplastic syndrome. And that would have shown up, could have shown up I should say, earlier in terms of low blood counts.

But I discounted that based on the little bit of data I had in the record.

Q. In your current practice, is it common for you to be the original person making a diagnosis or is it simply as a consultant?

A. I'm the consultant typically.

Q. So what percentage of the cases you currently have were you the individual who actually made the initial diagnosis of leukemia?

A. Can I qualify your question? The diagnosis is suspected by multiple different other doctors, typically primary care, emergency room physicians based on abnormal blood counts. The diagnosis is confirmed after a person sees a blood specialist and has a bone marrow biopsy done.

Q. Do you actually perform bone marrow biopsies nowadays, or you let the residents and fellows handle that?

A. Yeah, I do not any longer. I still think I'm incredibly good at doing them. My

advanced practice practitioner thinks I'm full of baloney. But I was trained how to do them. I know how to do them.

I should say those are posterior iliac crest bone marrow biopsies taken from here. This is the most typical biopsy we do because you get a core biopsy, a piece of bone marrow, you get an aspirate. You get two different samples, both of them important.

When we cannot get a sample from the posterior iliac crest, we can do a sternal aspiration. And for obvious reasons, no else wants to do that except the old guy. So they give it to me to do. So I do those and I've done one in the last two weeks.

Q. Does the old guy do pediatrics as well?

A. No. This old guy does not do pediatrics.

Q. So what's the age range you currently provide care for?

A. So typically 18 years old is the cutoff.

Q. Was pediatrics ever within your wheelhouse, so to speak?

A. It is in a way because there's this period of time between 18 and 25 kind of young

adults where they may be seen by a pediatrician or and adult oncologist, and we can sometimes share the care of those parents.

Q. In your current practice at Duke -- how long have you been at Duke now?

A. Seven years, since July of 2018.

Q. In the seven years you've been at Duke, have you signed a death certificate and stated what the cause of death was?

A. Yes.

Q. What's the most recent occurrence that you recall?

A. Boy, it's been in the last year because typically this is a death that occurred at home, not in the hospital where a resident might sign that. So I would say within the past year.

Q. In the Connard case, you reviewed certain materials related to cause of death; is that correct?

A. That's true.

Q. Again, you can refer to your report. What was listed on the death certificate as it related to the cause of death?

A. Acute myeloid leukemia.

Q. And do you agree with that particular

notation on the death certificate?

A. I'd like to give more than a "yes" or "no" answer. The patient clearly had acute myeloid leukemia. He would not have had complications of chronic graft versus host disease if he didn't have acute myeloid leukemia, which likely led to his increased -- which led to his susceptibility to infections, which led to his hospitalization during which he died.

The reason -- so in that sense, it seems to be related. On the other hand, he did not have active acute myeloid leukemia at the time of death. And actually, I am not certain we actually know the cause of death. I speculated on it in my report.

Q. That's where I wanted to go.

A. Okay.

Q. You used the phrase you speculate in your report.

A. I did.

Q. Why?

A. So I speculated in my report because Mr. Connard was the first case I had as an expert witness. And I was all over this case as what's my job as a medical doctor. And I read through

the entire case. And I know that a part of the opinion that both sides want is the relationship of the acute myeloid leukemia to the potential for exposure at Camp Lejeune. I understand that.

But as I was writing my first report, I couldn't help but be an internist and think about my patients the way I normally do. I'm often asked to determine cause of death as a serious adverse event in a clinical trial of acute leukemia drugs. Quite frankly, that was the phone call I had this morning about a cause of death to determine what was the likely cause of death.

And even though that patient I'm talking about had acute myeloid leukemia, I did not say that was the cause of death. The proximal -- so we talk about the proximate cause of death -- what was that. And in this case, I'm not certain what the proximate cause of death was except I'm certain it wasn't active acute myeloid leukemia.

Q. Did you have any information that the attending physician who signed the death certificate didn't have when you formulated your opinion that you said you speculated on?

MS. MCKEEVER: Objection to form.

THE WITNESS: I don't know what

information that physician had who signed the death certificate. I'm not even sure which resident, was it a resident or the attending who signed it. In a hospital setting, it's often the resident who may be on call that evening and have, what do you call it, limited knowledge of the details of the case and they put a form in front of them that has to be filled out quickly so that the patient's body can be delivered to either autopsy or a funeral home.

So I would give my opinion that there's often not a lot of speculation and decision making about what to specifically put on that form.

BY MR. LEE:

Q. So let me try to understand what you just said over the course of the last five minutes.

You agreed that as a result of having acute AML, that the patient had a stem cell transplant?

A. I agree with that.

Q. Stem cell transplant in this instance led to graft versus host disease?

A. I agree with that.

Q. Which put the patient at risk for a

1 myriad of complications?
2 A. I agree.
3 Q. The ultimate cause of death, in your
4 opinion, was due to what?
5 A. Again, I don't know. An autopsy wasn't
6 done. That would have been incredibly helpful.
7 And I understand why a resident who is peripheral
8 to the case might have just said, oh, this patient
9 has had acute myeloid leukemia, and that's why
10 they're in the hospital, complications of the
11 treatment for that.
12 In my opinion, based on very sparse
13 documentation, incredibly sparse, and as I pointed
14 out in my report, sometimes contradictory with
15 lines crossed through certain terms, I was faced
16 with how many years later, 30 years, 25 years
17 later to determine why this person who was ready
18 to be discharged -- everyone thought he was doing
19 great, so we'll just get this CAT scan done -- why
20 all of a sudden he dropped dead, quite frankly, to
21 say it medically, sudden death. And that's what I
22 would call this. He had sudden death. I would
23 use a term like heart attack. That assumes that
24 there was ischemia to the heart. That wasn't the
25 case.

Q. Fair enough. Would you agree with me that patients who have graft versus host disease are at increased risk for sudden death?

MS. MCKEEVER: Objection to form.

THE WITNESS: I'm not going to agree to that, no.

BY MR. LEE:

Q. Have you reviewed the literature on that topic?

A. Excuse me?

Q. Have you reviewed the literature on that topic?

A. I have not reviewed the literature on the specific term sudden death as a cause of death in long-term survivors of AML.

Q. Long-term survivors of AML who have graft versus host disease, do they tend to have certain, if you will, complications and outcomes that you're aware of in your practice?

A. Yes.

MS. MCKEEVER: Objection to form.

BY MR. LEE:

Q. What are some of those?

A. Well, as in this case, the most important of which are infectious complications

which led to his hospitalization. That's what this hospitalization was. He had multifocal pneumonia, and this was due to chronic graft verse host disease and profound immunosuppression. Even though he was off immunosuppression, his immune system was weakened by the transplant. And then he had this chronic graft versus host disease.

He got a lot of immunosuppressive treatments for that. So infection was the reason for the hospitalization. I don't know the reason for the sudden death other than my speculation.

Q. So going back to the fact you said this is the first case that you reviewed in your, I'll call it, your new profession, just to see what your reaction is, your new endeavor.

A. I appreciate your sense of humor, Mr. Lee.

Q. Now having reviewed five cases, would you have speculated?

MS. MCKEEVER: Objection to form.

THE WITNESS: Pardon?

BY MR. LEE:

Q. Would you speculate today as it relates to cause of death now that you've reviewed in total five cases and not just the first one?

MS. MCKEEVER: Objection to form.
THE WITNESS: I can't help but speculate. This didn't make any sense to me. It didn't make any sense to the doctors. And there had to be a reason why this patient died.
BY MR. LEE:
Q. But as you sit here today, you don't know why?
A. No, I do not know.
Q. Fair?
A. That is fair.
(Erba Exhibit 12 was marked.)
BY MR. LEE:
Q. Doctor, take a few minutes to familiarize yourself with this document. I'm going to represent to you I anticipate or expect that you have not seen it before.
A. That is correct. I'm not a transplant -- I don't practice transplant medicine.
Q. Take a look at the abstract. Take a look at the bottom as to where it's from.
A. It's published in a very reputable journal Circulation, American Heart Association. It's an up-to-date reference, April 16, 2024. I

1 am looking here at the authors, and I guess what
2 stands out to me about this is without looking up
3 any of these names or any of the other names on
4 the panel, I don't recognize any transplant
5 doctors. So I'm assuming that these were mostly
6 cardiologists. But I'd have to look at each of
7 the people that they're referencing on these
8 committees.
9 Q. Fair enough.
10 A. But it appears to be a reputable -- it's
11 a reputable journal.
12 Q. I'm going to apologize on the record for
13 about what I'm to do because it's not something
14 you typically are asked to do in your profession.
15 I'm going to ask you to turn to the next page.
16 I'm going to read something into the record.
17 Under Figure 1, on the right side, if
18 you look at the second to last complete sentence.
19 Let me know when you're there, it begins with,
20 "Late complications."
21 A. Yes.
22 Q. I'm going to read this into the record.
23 Tell me if it's correct or that I read it correct.
24 "Late complications during the survivorship period
25 are often related to chemotherapy, radiation and

corticosteroid treatments. These typically manifest as cardiovascular diseases, secondary malignancies, lung disease and endocrinopathies."

I'm going to skip now to the next page on the left side, the paragraph above the statement that says, "Incidence of short and long-term cardiovascular complications in adult and pediatric populations." I'm going to read the last sentence. It begins with, "Common late effects."

Do you see that?

A. Yes.

Q. Common late effects include cardiovascular disease, secondary malignancies, chronic lung disease, fatality, gonadal failure, and other endocrinopathies such as metabolic syndrome diabetes.

Did I read that correctly?

A. Yes. I think it's frailty.

Q. Frailty. I apologize.

A. It's okay. But yes.

Q. Thank you for that correction.

Next paragraph below the one that I just read from incorrectly there, appreciate that, says, "Various cardiovascular complications

1 associated which HSCT" -- what is HSCT?
2 A. Hematopoietic stem cell transplantation.
3 Q. -- "can occur during inpatient
4 hospitalization and years after transplantation."
5 They have a table reference. "The incidence and
6 the risk of complications of HSCT are linked to
7 several factors, including therapies received
8 before the transplantation process, the type of
9 transplantation (autologous versus allogeneic),
10 the conditioning regimen, comorbid conditions and
11 age of the patient."
12 Did I read that correctly?
13 A. Yes.
14 Q. Next page, please. Under the right-hand
15 side column, it says Patient-Specific Factors.
16 Second paragraph, "Older age at transplantation is
17 linked to nearly all post-HSCT cardiovascular
18 complications, including arrhythmias and heart
19 failure. The risk of heart failure in recipients
20 greater than 55 years of age is four times greater
21 compared with recipients less than or equal to 19
22 years of age."
23 Did I read that correctly?
24 A. You did.
25 Q. One final page. I want to take you back

to page 1115. It will be the third page in. And on the left-hand side, last paragraph, the area is titled Incidence of Acute Complications. Adult Recipients the title there in that particular subsection. It says, "New onset arrhythmias are the most frequent cardiovascular complications associated with HSCT, occurring in 2 percent to 10 percent of adult recipients." I'll stop there.

Doctor, broadly speaking, to be clear, you haven't read this article, but have you come across anything similar to this?

A. Yes. This is clearly laid out in textbooks, but it's also been laid out in multiple publications. And if I may, quite frankly, this is why my 30 years of clinical research has been aimed at developing new therapies for people with acute leukemia, to try to avoid some of these complications of transplant that are necessary to potentially cure the disease.

Q. So as it relates to whether patients who have undergone, if you will, these stem cell transplantation procedures, do you have an opinion with respect to whether or not said patients are at risk for cardiovascular, if you will, complications?

MS. MCKEEVER: Objection. Form.

THE WITNESS: Based on my review of the literature, this paper being one of them, these patients are at risk for specific cardiovascular complications. Again, I like how this was written based on their own characteristics, the preparative regimen, the treatments they've used before, their age, many other factors. But it's a true statement.

BY MR. LEE:

Q. Did Mr. Connard's age having undergone stem cell transplantation put him at a higher risk for cardiovascular manifestations and complications?

A. Well, he was an adult. So compared to pediatrics, yes. But he wasn't an 80 year old either. But he received a very -- he actually received, as I remember from my report -- I could look it up -- but I'm pretty sure it was a reduced intensity conditioning regimen, so not very high doses of chemotherapy, and he didn't receive radiation either.

Q. When someone says a patient dies of sudden death in a hospital, do you remember or recall what that differential diagnosis includes

from your experience as a physician? And we'll take you back to when you were in residency training as well.

A. Yes. In fact, as I said, my day-to-day practice is leukemia, but I'm an attending on the inpatient service for various patients with leukemia. So quite frankly, unfortunately, some of our patients die suddenly in the hospital.

So there's a differential diagnosis that we have to consider when a patient dies, which means they are not conscious anymore. They cannot sustain a circulation. So I do recall the differential diagnosis of that.

Q. Would that differential include a sudden unanticipated unexpected cardiac arrhythmia?

A. Yes.

Q. Can you rule that out in Mr. Connard?

A. I can't completely exclude it, but if I may, if that's the case, the documentation was horrible and not what I would have expected from a major teaching institution and from an anesthesiologist.

Q. So I think I heard you say that the documentation was poor.

A. Yes.

Q. So just so the record is clear, you can't rule out a sudden unanticipated, if you will, cardiac arrhythmia?

MS. MCKEEVER: Objection to form.

THE WITNESS: As I said, without all of the records, I cannot rule that out. And if I may say so, typically at least now -- I'm not sure about 1980, but at least now, when there is a rapid response required, code blue as many people call it, there will be a nurse assigned to taking notes and keeping track of exactly what's doing, what drug were being given, what's the rhythm show when the patient gets a shock, when somebody showed up at the bedside, all of these things, and someone is keeping time.

I wasn't privy. If that occurred, I didn't have any of that documentation. So that documentation may be somewhere, but if you're asking me can I rule out the possibility that the documentation is there and there was arrhythmia, no, I can't rule that out because I never saw it.

BY MR. LEE:

Q. So just to close the loop on the issue of the cause of death of Connard, given your statement that you'd be speculating, again in

retrospect, should you put a differential diagnosis down versus speculating?

MS. MCKEEVER: Objection to form.

THE WITNESS: In my opinion, a differential diagnosis is always speculation, because, as I mentioned, you have a list of things that are possible until you come up with the diagnosis. One of the reasons I practice in leukemia is the diagnosis is very exact based on biology of the disease.

But in getting outside of my area for cardiovascular disease, you originally asked the question, do I have a differential diagnosis of sudden death, which is what this -- that's what this patient had. He was alive, and suddenly he was dead.

I have a differential diagnosis. And with the limited records I have, all I'm left to do is to speculate what kinds of things cause one of the things that was clearly documented, which was pulseless electrical activity. That was there. It was crossed out. And I have other reasons to believe that that was actually the case.

BY MR. LEE:

Q. I'm going to move on rather than continue to speculate. But just to be clear, have you seen death certificates where providers have indicated complications related to past history of AML and stem cell transplantation?

A. Yes, I have.

Q. Would that have been a better statement, in your opinion, on the death certificate?

MS. MCKEEVER: Objection to form.

THE WITNESS: It's an interesting question because in terms of cause of death on a death certificate, sudden death is no other way of saying dead. And that's not going to carry much weight in terms of a diagnosis. So you're forced to put something there.

I think it's interesting -- speculation, sir -- I think it's interesting that acute myeloid leukemia was put there as opposed to ventricular arrhythmia, massive pulmonary embolism, tension pneumothorax, which all of my differential might discuss. Instead of dealing with what was there with that patient, whoever filled that out said, gee, he's dead and all I know he had was AML.

When a death certificate is filled out,

the way -- if you read the rules of how it should be filled out, you always start with the proximate cause, and then number two and number three and number four are due to this, that and the other.

Yes. Acute myeloid leukemia should definitely have been on that death certificate. I believe it should have been there because I could not rule out that it didn't cause the proximate cause of death. But I think the problem in this case is they didn't know what the proximate cause of death was. All they were doing is speculating, but not as much as I did 20 years later.

BY MR. LEE:

Q. Let's move on to the Connard case briefly, if we can. I appreciate your helping me out. You can put that aside.

A. Can I keep it?

Q. You can keep it as long as you like, sir, absolutely. I've got an extra one if you want one.

Looking at the Connard report, can you turn to page 15, please. Can you read the conclusion for me?

A. "Based on my review of this case, I reached the following conclusion concerning

Mr. Connard's case to reasonable degree of medical certainty."

Q. What does that mean, reasonable degree of medical certainty, in this case?

A. In this case, putting all of the data I had together, and again what formed my opinion was the leukemia he had and the latency between his known diagnosis, the new onset pancytopenia, and the prior exposure to the best of my medical certainty and given how common leukemia is in general, I could not say that there was a causal connection with his exposure.

Q. If you were asked to quantify the percentage chance that your statement was correct, could you quantify it?

MS. MCKEEVER: Objection to form.

THE WITNESS: I would say -- I can't give an exact number, no. But because I can list other things in this patient's life that could have contributed to his increased risk of developing AML, it would have been hard for me to say one was more likely than another.

The fact that his mother was a smoker and I believe Mrs. Connard was a smoker, you know -- and remember this was back in the '60s

before the surgeon general's report, people were exposed to indoor concentrations of benzene that may have been higher than ambient levels anywhere else.

I just couldn't tell that this one exposure, inhalation exposure 20 years earlier was the cause of this leukemia when there were other features of this man's life that could have also contributed to why he was one of four out of a hundred thousand people every year who get leukemia. AML I should say.

BY MR. LEE:

Q. Next page, on page 16, I promise I'm almost done with this one, read number two into the record.

A. Number two?

Q. Yes, please.

A. "Mr. Connard's death, although possibly related to the complications associated with his AML treatment was not directly caused by his AML, which had been in remission for nearly a decade prior to his death."

Q. Anything else you want to revise? Based on our conversations, is that what you're trying to communicate?

A. It's true as stated. He did not have AML at that point. It is definitely possible that the complications he had from the treatment of AML led to an event that caused his sudden death.

Q. Thank you. We'll turn now to the Amsler report. Again, feel free to look through the whatever you'd like to in that report to refamiliarize yourself. I have a couple of broad questions.

In this report, you refer several times to Dr. Goodman and then Dr. Shields and their respective reports. For example, on page 17, next to the last paragraph.

A. Second to last -- in the whole page?

Q. Correct, page 17. I'm sorry.

A. Yes.

Q. With respect to their -- I'm referring specifically to Dr. Goodman and Dr. Shields -- information related to epidemiological evidence, did you review the papers that Dr. Goodman and Dr. Shields referenced in their reports --

A. No.

Q. -- or is it just relying upon -- I apologize.

A. I apologize for answering.

Q. -- their statements in the reports? I'm trying to understand.

A. So for making this statement, I reviewed the -- now I can remember what IARC stands for. So I reviewed the report on benzene specifically regarding, you know, that report. The report I reviewed was only talking about benzene and not all four as I said in this.

On the other hand, it didn't mention the other three, but it only was discussing benzene. That was the only one I looked at. And so I looked at the IARC report. I looked at Julie Goodman's report and Peter Shields' report, but that's all.

Q. I want to follow up on that. As you know, their reports were quite extensive.

A. Yes, they were.

Q. And they made reference to literally thousands of publications as you know.

A. Yes.

Q. When they made -- again I apologize. When Dr. Goodman and Dr. Shields made specific reference to certain publications and sections that you quoted, did you go back and look at those publications yourself or rely upon their

representations concerning the reports?

A. I relied on that their representation plus the summary in the IARC report.

Q. You mean you didn't read those thousands of articles?

A. No. But since you asked the question, she had very nice tables in there listing the levels of support and some of the problems with each of them. Not all of them, as I remember, actually stating that benzene was associated with leukemia. But the bulk of the evidence says that exposure to benzene has been associated with leukemia and is a known carcinogen, leukemogenic agent. I have a day job.

Q. Turn to page 20, please.

A. 23?

Q. Turn 20. Let's talk about the conclusions in this section. Can you read starting with "Based on my review of this case."

A. "Based on my review of this case, I have reached the following conclusions concerning Ms. Amsler's case to a reasonable degree of medical certainty. Any exposure Ms. Amsler may have had to the water supply at Camp Lejeune was not responsible for the development of her ALL."

Q. Continue, please.

A. "As of today, Ms. Amsler is likely cured of ALL. The risk of relapse is less than 5 percent at most. Her risk of nonrelapse mortality related to the bone marrow transplant is low because she did not receive total body irradiation, has minimal evidence of chronic graft versus host disease" and at this point -- I didn't say that here, but parenthetically -- at this point "is unlikely to develop anthracycline-induced cardiomyopathy since she received doxorubicin (Adriamycin) five years ago.

"Ms. Amsler has not endured any toxicity that would preclude her from returning to a normal life and from pursuing her chosen career."

Q. How old is Ms. Amsler, if you know?

A. She was 60 years old at the time of diagnosis as I remember. Let me go back and just make sure. There are five people here. Yeah. She was 60 years old at the time of diagnosis, and that was 2020. So she's 65 now, 64 actually.

Q. I want to ask a broad question about, if you will, latency. What is latency? What is a latency period when you're talking about leukemia?

A. So latency in general is the period of

time between a causative agent and the development of a disease itself. So that's the period of time.

Q. Is the latency period for ALL the same as AML?

A. It depends. These are very different diseases. So by latency we are assuming we know the cause. There are only very specific situations where we know the cause. And I would say depending on the type of AML, the type of ALL, the latencies could be very different.

Q. Let's shift back a moment to Mr. Connard and his AML. What type of AML did he have, and what was the latency?

A. So the classification of AML has undergone various changes since the 1970s and '80s. So at the time, I believe he was said to have an M0 acute myeloid leukemia, which is an undifferentiated form of AML.

Today we are more likely to classify AML by the cytogenetic and mutational changes. All of our classification systems have moved towards cytogenetic and mutational data. He had monosomy 7, which has been associated with a subtype of AML with adverse risk. We don't have a mutational

analysis.

Q. As it relates to the latency and the percentage of those individuals who will be expected to have AML more than 10 years after the exposure, what is the percentage, if you know?

MS. MCKEEVER: Objection to form.

THE WITNESS: I don't know. All I can say in general is monosomy 7 is seen after known leukemogenic exposures and nontherapy related disease.

BY MR. LEE:

Q. So when you say nontherapy related, what does that mean?

A. In cases where we don't know the cause, the patient did not have chemotherapy, radiation. Then one study I quoted -- it was the Danish registry I believe -- was 18 percent, 18 percent of patients with AML will have monosomy 7 who were not therapy related.

Q. And as it relates to the onset of I guess -- I just want to make sure I'm clear then. What is your opinion with respect to whether or not someone can have the onset of AML 25 years after an exposure?

MS. MCKEEVER: Objection to form.

THE WITNESS: My opinion is that a person could have exposure to a known leukemogenic agent and 20 years later, 25 years later, 30 years later, if they live to a hundred, can develop AML. However, based on my review of the literature, saying that those cases are related to that exposure is problematic.

BY MR. LEE:

Q. Why?

A. The data doesn't support in the people who have lived 20, 30 years, we see a plateau in the incidence of AML. There's a median, but then there a plateau after in many of the studies. Not all of the studies had that granular detail.

Q. How about ALL, same question?

MS. MCKEEVER: Same objection.

THE WITNESS: In ALL after known leukemogenic agents, and in that case, there's typically -- the case of Ms. Amsler, those exposures, the subtype that she has, the short latency is one to three years.

BY MR. LEE:

Q. Are there any situations in the subtypes that Ms. Amsler has where a certain percentage can be seen outside of that tight window you just gave

me from one to three yours?

MS. MCKEEVER: Objection to form.

THE WITNESS: I am certain that someone has 3.1 years out from that treatment, but I have never seen this type of leukemia after exposure to topo 2 inhibitors, topoisomerase 2 inhibitors 20 years, 20-plus years later. I've never seen that.

BY MR. LEE:

Q. So as it relates to the environmental toxins TCE, PCE, do you have an opinion with respect to whether or not a patient can be exposed to one of those agents and go on to develop leukemia 20 years out?

MS. MCKEEVER: Objection to form.

THE WITNESS: Are we back to Amsler?

BY MR. LEE:

Q. Absolutely. Please.

A. So we're back to Amsler. In Amsler's case, based on the biology of the acute lymphoblastic leukemia she has, I am certain, as I said in my report, that any potential exposure she had 20 years prior or whatever did not cause her disease.

Q. You used the word "certain." What does that mean quantitatively?

A. Close to a hundred percent.
Q. To a reasonable degree?
A. That's a pretty reasonable degree of medical certainty. I wish most of my decisions in medicine were that certain.
Q. Do you have knowledge with respect to whether or not exposure to environmental toxins and radiation can lead to an increased rate of leukemia, 30, 40, 50 years out?
MS. MCKEEVER: Objection to form.
THE WITNESS: I am aware of -- I'm trying to think of the data that I know as a nonepidemiologist because I don't review this literature. The only thing I'm coming up with from my involvement in this case and things I reviewed is the Bove report on incidence of acute myeloid leukemia specifically. And that was, you know, years after, a long time after, 20-plus years after the time at Camp Lejeune or Camp Pendleton. That was the comparison. I'm aware of that.
(Erba Exhibit 13 was marked.)
BY MR. LEE:
Q. I'm going to hand you now what is going to be listed as Exhibit No. 13.

1 Doctor, I've handed you a document
2 that's been identified as Exhibit No. 13. Take a
3 few moments to take a look at it. It's an NIH
4 Public Access document. The title is "The
5 incidence of leukemia, lymphoma and multiple
6 myeloma among atomic bomb survivor 1950 to 2001."
7 Have you seen this particular
8 publication and/or the material related to
9 survivors of the atomic bombs?
10 A. I'm aware of the studies being done,
11 many of them sponsored by, as it says here, the
12 National Cancer Institute following what our
13 government did in Japan in World War II. So I'm
14 aware that that was done. This specific reference
15 I have not seen.
16 Q. Take a few moments to familiarize
17 yourself with it. I'm going to ask you a couple
18 of broad questions and then take you to some
19 specific lines of inquiry.
20 A. So I've been able to read the abstract.
21 Q. One or two just brief questions. I'm
22 going to ask you about your knowledge first. That
23 may address all the questions that I have.
24 Would you agree that the bombs, and
25 there were two, were dropped over 70 years ago

1 currently?
2 A. Yes.
3 Q. I know you haven't had a chance to look
4 at this in great detail, but based upon your
5 knowledge and training, are you aware that there
6 is literature that has been published? I'm going
7 to ask you to take a look at Table 4. It's on
8 page 35.
9 A. Page 35.
10 Q. It's Table 4. Take a few moments to
11 familiarize with that document, please. If you
12 look at the very top of Table 4, I'll just read
13 what it says. You can continue to look at it.
14 I'm going to ask you a couple of questions about
15 what this table represents.
16 It says, "Observed and fitted excess
17 cases of leukemia other than CLL or ATL by time
18 period and age of exposure with category-specific
19 ERR estimates."
20 A. Yes.
21 Q. Looking at the left side, can you see
22 that the initial follow-up was in 1950 to '55?
23 Again, the bombs were dropped in '45, '47. I was
24 looking at the period. The period just to
25 familiarize yourself is the left side. If you

just look at those years --

MS. MCKEEVER: I think you're on the wrong table.

BY MR. LEE:

Q. I'm on Table 4. I might need to look at the one you were looking at. That might have been more interesting.

A. Okay.

Q. Again, I want to move along. But based upon the information from the atomic bomb studies, would you agree with me that this describes the excess occurrence of certain types of leukemia more than 50 years after the individuals in this case were exposed to known toxins?

MS. MCKEEVER: Objection to form.

THE WITNESS: So again, given that I'm not an expert in these calculations and I'm not prepared to argue or defend the different modes of looking at excess risk, especially when one of the titles of Table 6 was the Preferred Model, that's the author's opinion, obviously, there's a way of modeling this that's preferred over a prior one. And the prior modeling, according to what they said, didn't show this. And now with their preferred modeling, they showed that there is an

excess risk.

So within the confines of just looking at the data that they are providing in these numbers without knowing how these calculations are done, it would support what you said, although that is the age of exposure. And now I'm looking at the number of years afterwards. So based on that, as you said, you know, 20 years, plus years, there were more observed cases than expected using this modeling.

BY MR. LEE:

Q. Again, I'm not just saying 20 years. I'm saying 50 years out.

A. 50 years, yeah.

Q. You made reference to Table 6. Look at the top of Table 6.

A. Actually, I'm sorry, I was looking at Table 3 before. But it was the same thing, preferred modeling. Yes, Table 6.

Q. We can move on from that. I wanted to address Table 6. I had used that in another case.

A. I've got Table 6.

Q. Fair enough. Going back to Table 4, that's the one I want to know what you looked at earlier when we were trying to get to Table 4.

Let's make sure I address your comment.

Your statement, and I'm going to ask you to base this response not just on the chart, but based upon your knowledge to the extent you're aware outside of this litigation, do you have knowledge concerning whether or not there's an increased rate of cancer in Japan separate and apart from what I'm showing you in this document?

MS. MCKEEVER: Objection to form.

THE WITNESS: No, I do not.

BY MR. LEE:

Q. So the first time you had knowledge concerning the fact that individuals who had the atomic bomb dropped on them have an excess rate of leukemia is looking at this document?

MS. MCKEEVER: Objection to form.

THE WITNESS: I've never reviewed this. So, yeah, I had no other knowledge of that.

BY MR. LEE:

Q. But you're not disputing the numbers. Obviously, you're giving your qualifiers in your answer, but you're disputing the information contained in this document?

MS. MCKEEVER: Objection. Lack of form and foundation.

THE WITNESS: I'm disputing that -- I'm not an expert in this kind of analysis at all. Since World War II there have been multiple changes that have occurred in the Japanese society that could also be linked to an increased risk of leukemia aside from those estimates. And I don't know how that kind of information was included.

And so this is a group of authors taking one exposure and using some complicated model to look at expected versus observed rates. As a nonepidemiologist, as I said at the beginning of the day, I am not expert to make any kind of knowledgeable or educated comment about this. I take it -- I take what you're saying, that this is one manuscript that supports what you are saying.

BY MR. LEE:

Q. That's fair. Just to make sure I heard what you just said, the comments you made with respect to concerns you have about the exhibit I just handed you, those are the same concerns and considerations you have with respect to the work that was done by Bailey and LaKind in this case; true?

MS. MCKEEVER: Objection to form.

THE WITNESS: So I don't know how to

answer this question. I came into this case as a leukemia expert. I am not any of those other things, epidemiologist, toxicologist. And the opinions I formulated are based on my knowledge of the biology of these diseases. That's the only thing I can firmly stand on.

BY MR. LEE:

Q. Take a look at the first page of the document I just handed you.

A. This?

Q. Before you respond to my next question, to be clear, the critique of the manner in which this exhibit was presented to you and the information contained therein, your comments concerning the fact you're not an expert on the topic or how they conducted, if you will, the analysis, that's the exact same thing you can say with respect to the work that was done by Dr. Bailey; true?

MS. MCKEEVER: Objection to form and lack of foundation.

THE WITNESS: I've already said I'm not an expert in epidemiology. So the details of their analyses are, you know -- I know they did analyses, but I --

BY MR. LEE:

Q. Who is "they"?

A. I'm sorry. Everyone did analysis, Shields, LaKind, Goodman. Everyone did analyses in an area where they're an expert where they may or may not have had some kind of conflict in making their analysis. And that's why I felt it very important when I was called into this case to actually discuss the leukemia and not specifically any of these other things that I am not expert in.

Q. Fair. Doctor, have you -- at Duke I know a number of professors do have relationships with universities and institutions abroad.

Have you had relationships?

A. I guess you'd have to define relationships.

Q. Sure. Professional interaction, studies, communications.

A. Yes, yes. We've been investigators on the same trials.

Q. A number of experts of your caliber and experience have actually traveled to Japan, China, various locations to give lectures.

Have you done that, sir?

A. Recently I went to Japan, yes.

Q. Look at the very bottom of this document. I should say I'm looking specifically at the names that are listed and the institutions where these folks currently work.

For example, I'm going to look at the names. First we've got the incidence. Then you've got the list of the locations where the individuals reside. You'll see, for example, one of the locations is Division of Cancer and Epidemiology Genetics, the National Cancer Institute, Maryland USA.

Do you see that?

A. I see that.

Q. Do you know anything about that particular entity, location or who those individuals would be as it relates to their knowledge, skill and experience?

MS. MCKEEVER: Objection to form.

THE WITNESS: I have no knowledge. I said this at the beginning of -- no. I said that for the transplant paper. For this paper as well. I don't know, you know, who those people are, what their credentials are and how I would as a leukemia doctor decide how expert they are or what conflicts they might have.

BY MR. LEE:
Q. Thank you. Are you familiar with the National Cancer Institute?
A. Excuse me?
Q. Are you familiar with the National --
A. Yes, I am.
Q. What do you know about the National Cancer Institute?
A. It is a government -- it is funded by the United States government and at risk of losing some of its funding, unfortunately, in the near future or now that supports the evaluation of the causes of cancer, the diagnosis of cancer, the treatments of cancer.
Q. Thank you. I appreciate that. We're going to move on now to the next exhibit. You can put that one aside if you'd like. It's going to be the Bruce Hill expert report.
A. I made a mistake earlier. I was given two copies of Fiolek. So I apologize for doing that.
Q. You don't have Mr. Hill?
A. No.
(There was a discussion off the record.)
THE WITNESS: I have it now.

BY MR. LEE:

Q. So the record is clear, what percentage of CLL cases are idiopathic?

A. To my knowledge, virtually a hundred percent.

Q. What percentage of AML cases are idiopathic?

A. This is an estimate, but I would say about 80 percent. Those aren't therapy related or related to myeloid neoplasms. And then there's familial. Roughly, depending on how you add up those numbers, about 80 percent are idiopathic.

Q. What percentage of ALL cases are idiopathic?

A. It's going to be higher than that. It's going to be like 90 percent, if not more.

Q. Understanding you're not an epidemiologist, isn't one of the purposes of epidemiology research to identify causes of idiopathic, if you will, diseases?

MS. MCKEEVER: Objection to form.

THE WITNESS: I would say one of the purposes of epidemiology is to find associations between something in a person's life, environmental exposures or other things, and a

disease.
BY MR. LEE:
Q. I appreciate that. So associations. How does one determine the cause of a disease?
MS. MCKEEVER: Objection to form.
THE WITNESS: So the cause of a disease -- I'm trying to formulate an answer for that.
We know that cancer is due to genetic damage in a person's lifetime that leads to the uncontrolled growth and behavior of a group of cells. So it's, you know, the genetic basis of cancer, carcinogenesis. And so the -- you can extrapolate from that things that we know are going to cause in a person DNA damage can lead to cancer.
BY MR. LEE:
Q. How does a physician like yourself distinguish between a spontaneous occurrence in terms of DNA versus something caused by a toxin?
A. The only way I know of doing that is a clear temporal relationship with a very specific subtype. That's why Ms. Amsler's case is so important in this case, because her exposure was far removed from the typical one to three years

for topoisomerase 2 inhibitors or neonatal.

But to answer your question, what complicates this matter completely is that recent evidence shows that as soon as we are formed in our mother's womb, we are already beginning to mutate. And you can see this and you can follow these mutations. So as we're sitting here, we're all accumulating mutations.

So do I know that it's a specific cause? I do not know. Do I know that these mutations can occur by chance? Absolutely. These mutations can occur by chance. That's why we have DNA repair enzymes to correct these mistakes, but these things can fail.

Q. I want to make sure I'm understanding. The bottom line is that -- and I'm going to paraphrase. I apologize -- there's no way currently, the current state of knowledge to distinguish between a spontaneous occurrence as it relates to DNA damage and damage that occurs as a consequence of an environmental toxin?

MS. MCKEEVER: Objection to form.

THE WITNESS: I think that's what this case is all about, is how to make that determination. And we're making it based on these

calculations of levels of exposure and, you know, what the literature says that we're discussing here.

So as I tell my patients, there is no way that I can tell when they come to me with leukemia without one of those known risk factors that it wasn't something in their life that caused it.

BY MR. LEE:

Q. So let me boil down what you just said in my mind. You correct me when I'm wrong. The bottom line is we have DNA damage in a number of these cases, the five that we're talking about. Let's just talk about these five. The question is what caused it. Was it spontaneous, or was it a toxin? Is that your opinion as to why we're here?

MS. MCKEEVER: Objection to form.

THE WITNESS: Say that again. Was it spontaneous, or was it --

BY MR. LEE:

Q. Or was it caused by a toxin or some other cause.

MS. MCKEEVER: Same objection.

THE WITNESS: I can't tell the difference between a spontaneous and a toxin. I

1 just can't tell that this exposure that we're
2 talking about caused any of these except in one
3 case for sure it did not, Ms. Amsler.
4 BY MR. LEE:
5 Q. Say that again.
6 A. The biology of Ms. Amsler's disease is
7 not consistent with exposure to a substance 20
8 years ago leading to it. But you asked a much
9 more general question.
10 Q. I did.
11 A. You asked if any of those other four
12 people came into my clinic and they asked me why I
13 got it, was this just bad luck or was it a bad
14 Chick-fil-A sandwich or whatever it might be, I
15 can't tell the difference between those.
16 I am not an expert on determining
17 whether duration and levels of exposure are
18 significant enough or substantial enough to
19 actually cause in a person enough DNA damage to
20 cause leukemia. And for that, both sides of this
21 table have expert witnesses, and hopefully you're
22 not relying on me.
23 Q. Thank you. What is MBL?
24 A. Monoclonal B-cell lymphocytosis.
25 Q. Can MBL be caused by an environmental

toxin?

MS. MCKEEVER: Objection to form.

THE WITNESS: You're asking the hypothetical can it be? I guess it could be. Do we know that it is? We do not know that it is. It's pretty common though.

BY MR. LEE:

Q. What's pretty common?

A. MBL.

Q. Do all patients -- I'm going to use the word "all" -- patients who have MBL go on to develop leukemia?

A. No. As far as we know, that is not true. And there are other examples of that. I'm in my education mode. I'm sorry. Pre-leukemia, myeloid dysplastic syndrome may or may not turn into acute myeloid leukemia. Monoclonal gammopathy of unknown significance may or may not turn into multiple myeloma. Sorry. I'm going fast.

But there are these pre-leukemic conditions that may or may not turn into those other cancers. And there are risk factors for determining what's the likelihood of each of those things happening.

Q. Turning our attention now to Bruce Hill, you do have that in front of you now?

A. Yes.

Q. I'm going to skip to the summary once again in the interest of time. Can you read the conclusion or begin reading it?

A. "Based on my review of this case, I have reached the following conclusions concerning Mr. Hill's case to a reasonable degree of medical certainty. Number one, Mr. Hill has at least two demographic features associated with a greater risk for development of CLL, male gender and obesity. Although relatively young at the time of diagnosis, not unusual to present after age 50."

Q. Stop for a moment. Just so we're clear, you have listed three demographic findings or features, to use your word, male gender and obesity. But those are risk factors.

A. Risk factors.

Q. And they don't, to your knowledge, cause CLL?

A. That is true.

Q. You indicated he was relatively young at the time of diagnosis. What is the age range that you typically will see a patient with CLL present?

A. Can I refer --

Q. Please, please.

A. The median age is 70, but I actually address that in my notes on Mr. Hill and his age based on registry data. 7.4 percent of CLL patients on the registry data are between the ages of 45 and 54. And I helped to publish data looking at new regimens for people with CLL. And in one study, the median age was 56. But 60 percent of the patients were less than the age of 60.

When you set up a criteria in a study that you're only going to study younger patients, then a higher percentage will be younger. So the point I was making is that this age is not causing me any alarm in saying why did this guy get CLL.

Q. So let me make sure I understand. Less than 10 percent of patients who have CLL are at the age that Mr. Hill was when he had his diagnosis confirmed; is that fair?

A. Yes.

Q. Does that based upon your knowledge, skill, training, experience and education lead you to look at other potential causes of CLL that you might not look at in an older person where you

talked numerous times today about you have these genetic mutations that occur?

Does it give you different perspective in the younger group versus the octogenarians as an example?

MS. MCKEEVER: Objection to form.

THE WITNESS: I would answer that, no, it does not give me a different perspective because I know of no causative agents for CLL in general. As I said, if he was a two year old, that would worry me. Then I would think most likely the diagnosis was wrong. It wasn't CLL. So that would make me think about it.

So getting on that continuum, the younger you are, would I think about it? Sure. I would think about it and then move on because we don't know of any causative agents for CLL.

BY MR. LEE:

Q. So when you're doing your assessment and evaluation of a case, if I'm hearing you correctly, in the setting that you're in when you're at Duke, the fact that it's a younger patient, 45 to 55, your assessment and evaluation is the same as someone who is 60-plus years old?

A. For CLL, that is true.

Q. Can you read the very last -- below four, below number four, can you read that last paragraph on page 26, please?

A. "Therefore, I believe it is highly unlikely that any potential exposure to the organic chemicals in the water supply at Camp Lejeune caused the CLL, kidney disease or hepatic steatosis."

Q. What does the phrase "highly unlikely" mean?

A. Highly unlikely to me means that based on my knowledge of what we know about the chemicals that have been studied and that may have been in the water supply, you know, that there's nothing about this person that tells me that his disease was caused by that exposure many years ago. Highly unlikely. You want a percentage? It's way over 50 percent, 80 to 100.

Q. Thank you for anticipating my question. I want to make sure I understood the distinction to the extent there is one between a reasonable degree of medical certainty and highly unlikely.

MS. MCKEEVER: Objection to form.

BY MR. LEE:

Q. You've got both in this document the

same page. I want to understand what you mean by that. These are your words; right?

A. Yeah. To me they mean the same thing. When I'm saying a reasonable degree of medical certainty in this case, I think it's highly unlikely. I mean, they're the same thing for me.

Q. And to be clear, that's your understanding of the standard that you're applying in this case regardless of what the legal standard is; fair?

MS. MCKEEVER: Objection to form.

THE WITNESS: As mentioned, I am not a legal expert. So the legal standard and these terms that are being used I will leave for you to discuss.

BY MR. LEE:

Q. Next exhibit, Robert J. Fiolek, do you have that in front of you, sir?

A. Yes, sir.

Q. If you can turn to the conclusions on page 27, can you read the introductory paragraph before you get to number one.

A. "Based on my review of this case, I have reached the following conclusions concerning Mr. Fiolek's case to a reasonable degree of

medical certainty."

Q. Can you read the next full sentence under number one, please?

A. "Mr. Fiolek has at least four factors associated with a greater risk for the development of CLL: advanced age, male gender, European ancestry and obesity."

Q. So I'm clear, we can move along, you've listed advanced age and European ancestry, which are ones that aren't necessarily included in all of your reports.

Just so I'm clear, those are risk factors?

A. So I meant European ancestry. I should have qualified it as unlike Mr. Hill, not African-American.

Q. So these are, again just so I'm clear --

A. I'm sorry. And not Asian. The Asian population has a very low incidence.

Q. Fair enough. Advanced age, male gender, European ancestry with the correction you mentioned and obesity are risk factors that you've included, but they are not causative reasons for, if you will, diagnosis of CLL?

A. That is what I stated, yes.

MS. MCKEEVER: Randy, if we can take a short break in the next few minutes. It doesn't have to be right this minute, but soon. Thank you.

MR. LEE: Appreciate it.

BY MR. LEE:

Q. Next page, 28. Just read the first sentence. Then we'll take a break. I'm going to have follow-up questions.

A. "Therefore, I believe it is highly unlikely that any potential exposure to the VOCs in the water at Camp Lejeune in the 1960s caused Mr. Fiolek's CLL or bladder cancer."

Q. Are you an expert with respect to the etiology of bladder cancer?

A. No, I am not.

Q. What's the basis for the opinion that the VOCs did not contribute to a cause of his bladder cancer if you're not an expert in bladder cancer?

A. So my basis of that is again just as an oncologist from review of the literature.

Q. What literature did you review?

A. I mean textbooks. I shouldn't say literature.

MR. LEE: Let's take a break.

THE VIDEOGRAPHER: The time is 1500, and we are off the record.

(Recess from 3:00 p.m. to 3:14 p.m.)

THE VIDEOGRAPHER: The time is 1514, and we are on the record.

BY MR. LEE:

Q. Doctor, we're back on the record. I want to follow up on the last sentence you read into the record. I will share with you it caught me a little off guard. In the Fiolek report, we're on page 28. Let me know when you're there.

A. I'm here.

Q. And you read that into the record, and your conclusion was it's highly unlikely that any exposures to the VOCs in the water at Camp Lejeune in the '60s caused Mr. Fiolek's CLL or bladder cancer.

You indicated that you reviewed some textbooks or a textbook. What textbook did you review?

A. The Oncology -- textbook of Oncology.

Q. Who is the author? Are you one of the authors on that?

A. No. I'm not one of the authors.

Q. Who is the author? Educate me so I can find it.

A. I usually use the hematology textbook. So it was something I went to just for this.

Q. If it comes to you later, let me know. The reason I ask is because you stated time and time again your role in this case is as the leukemia specialist. So my conclusion was that if I looked up the word leukemia specialist in the dictionary, I'd see your face. Now you're saying bladder cancer is not caused by the VOCs.

So is it just the textbook, or is there anything else you're relying upon?

MS. MCKEEVER: Objection to form.

THE WITNESS: So in part of this discussion, so he has bladder cancer.

BY MR. LEE:

Q. Yes, sir.

A. And so I probably could have done a better way of phrasing this than what I did. As I said earlier in the report, and I probably shouldn't have paraphrased it so bluntly, in relationship to his CLL, he never received an alkylating agent that has been associated with getting bladder cancer. He never received

chlorambucil. He never received cyclophosphamide.

In relationship to the drugs he did get for CLL, ibrutinib, ibrutinib, there was one series from the Ohio State group, I think it was Jennifer Woyach, where they felt -- they looked at bladder cancer and they had five cases of bladder cancer, as I remember, before them. All had received a cyclophosphamide-based regimen. So it was really hard to say it was related to ibrutinib because they had all gotten chemotherapy before.

And then just in terms of the risk of bladder cancer, people with CLL are at higher risk of other cancers. We send them for dermatologic evaluations. We send them for GI evaluation. Bladder cancer is very unlikely. So to be more specific about what I do feel I can comment on, in relationship to the knowledge that he has CLL and got this treatment, those things weren't related to the bladder cancer.

Q. Fair enough. As I read this sentence, it refers to potential exposures to VOCs in the water at Camp Lejeune in the '60s caused the CLL or bladder cancer.

So are you revising that?

MS. MCKEEVER: Objection to form.

THE WITNESS: As I stated, I could have worded it better. I should have said CLL or in turn his bladder cancer, but I didn't say it that way.

BY MR. LEE:

Q. Fair enough. Are you saying that we should remove the word VOCs and bladder cancer in the same sentence?

A. I'm saying that I am not an expert to comment on the direct cause of VOC with bladder cancer. I'm not going to remove VOC from the CLL.

Q. Fair enough. But as it relates -- I want to make sure I tie this up and move on. I apologize.

So you do not hold the opinion, and correct me if I'm wrong, that you're in a position to state that there is no relationship between the VOCs and the bladder cancer in Mr. Fiolek?

MS. MCKEEVER: Objection to form.

THE WITNESS: I reviewed -- the only thing I reviewed -- I'm not an expert in this. I did in the course of my review for the CLL review the latest publication by Bove on the incidence of cancers. And as I recall that paper, the only cancer that was associated with being at Camp

Lejeune, not specifically VOCs, but being at Camp Lejeune was leukemia and myeloid dysplastic syndrome and, I believe, polycythemia vera, another myeloid neoplasm.

So, yes, I am not an expert. So you can take that opinion with a large grain of salt maybe or definitely, but it wasn't included as a risk in that Bove report.

BY MR. LEE:

Q. Which Bove report are you referring to?

A. It's on the one on the incidence. It's the one -- I'd have to look at the two of them, because the one on the incidence clearly had the subtypes of leukemia in there. So there were two, one on mortality and one on incidence.

So to your point, I need to retract that statement. One of those Bove reports did not, as I remember, list bladder cancer.

Q. Let me make sure I'm clear. When we initially began this comment relating to what you relied upon or reviewed, you said a textbook, the name of which you don't recall right now. Now you've added the Bove paper.

Help me understand what it is you're relying upon to render the opinion that

Mr. Fiolek's bladder cancer was not caused by the VOCs.

MS. MCKEEVER: Objection to form.

THE WITNESS: I'm going to come back to that. I should not have made that comment about VOCs directly and bladder cancer because I am not an expert in that. So that is a misstatement. And this really should have read as -- and as I pointed out in my discussion in terms of his CLL, having CLL and the treatment he got for CLL, I don't know of those as risk factors for bladder cancer.

So I should have included in here caused Mr. Fiolek's CLL which in turn would have caused his bladder cancer as opposed to "or bladder cancer" because to your point, I agree with you. The way it reads, it makes it look like I am in a position to make a comment about VOCs causing bladder cancer, and I am not.

BY MR. LEE:

Q. Thank you for the clarification. Again, I'd like to refer now to Mr. Joseph Gleesing. By now you know what I'm going to ask you to do. Let's go to conclusions.

But before we do that, I want you to go

1 up to the paragraph above, the paragraph that
2 begins Dr. McCabe. Read that into the record,
3 please.
4 A. "Dr. McCabe addresses the evidence
5 citing the effects of volatile organic compounds
6 on the immune system. Immune dysfunction is
7 hypothesized to be a contributing factor for the
8 development of neoplasia (cancer) in general due
9 to decrease in immunosurveillance. However, not
10 all cancers are associated with deficiencies in
11 our immune system. For example, congenital
12 immunodeficiencies are not associated with CLL.
13 Immunosuppressive therapy with drugs such as
14 calcineurin inhibitors, methotrexate and
15 azathioprine is associated with subsequent
16 development of skin cancers and myeloid neoplasms,
17 but again not CLL. There is no clinical data to
18 suggest the immune injury of any kind is a cause
19 of CLL.
20 "Furthermore, Mr. Gleesing had no
21 evidence of an autoimmune disorder or
22 immunodeficiency syndrome prior to the diagnosis
23 of CLL. The pathogenesis of CLL is unknown, but
24 the current favored hypothesis suggests an
25 exaggerated response to autoantigens or common

environmental antigens."

Q. Thank you very much. I want to focus on first Dr. McCabe. Do you know Dr. McCabe? To be clear, you don't?

A. No.

Q. You know nothing about his background, training and experience?

A. That is correct.

Q. I want to focus now on the issue of the immune system and whether various toxin can impact the immune system.

Do you have an opinion with respect to whether or not -- let's start with benzene -- benzene has an impact on the immune system?

MS. MCKEEVER: Objection to form.

THE WITNESS: I'm not a toxicologist. I've read some of the reports that I have. I would need them in front of me to recall the details. So I don't have a firm opinion on that.

BY MR. LEE:

Q. You don't have a firm opinion, what does that mean?

A. It means that I have not reviewed the literature myself, and I'm not an expert to make that determination. That's all.

Q. Based on your knowledge, skill, training, experience and education, do you have an opinion on whether or not the immune system is impacted by genotoxic we'll start with chemotherapeutic agents?

MS. MCKEEVER: Objection to form.

THE WITNESS: I would say I think of specific examples where a toxin can cause a problem in the lymphoid system, but not CLL.

BY MR. LEE:

Q. And I'm focusing just on the immune system and not CLL. I'm just focusing on that aspect for now.

So to be clear then, based upon your knowledge, skill and experience as a clinician for decades, you would agree that toxins can impact the immune system?

MS. MCKEEVER: Objection to form.

THE WITNESS: I believe that there's evidence that specific toxins -- I don't know all of them, but specific toxins have been known to impact on the immune system, and this is clear from my practice.

BY MR. LEE:

Q. And do you have knowledge with respect

to whether or not the toxins would increase the rate of mutagen formation either in the bone marrow or in the periphery?

MS. MCKEEVER: Objection to form.

THE WITNESS: We're talking about these toxins in general. So I am not certain how these drugs would actually cause the immunodeficiency. I'm not an expert in that, so no.

BY MR. LEE:

Q. Let's refer specifically to some of the drugs and medications you use in your practice.

A. Thank you.

Q. Looking specifically at the medications and drugs that you have knowledge of, would any of those -- you can put them on the record -- in your opinion lead to an increased rate of mutagen formation in either bone marrow or the periphery?

A. So I would answer that saying any of those toxins in an in vitro assay causing mutagenesis, I don't know. If you're asking me do I know that things we use in our practice, do they affect the immune system? Clearly those exist.

If you're asking me specifically to then say that these agents do that damage by directly damaging DNA, that I am not willing to say because

I know that some of these agents are very specific and targeted to things other than the DNA that causes the cells not to work.

Q. Let's talk about epigenetics. What does that mean? That statement, what does that mean in your practice? I know that's a commonly used phrase nowadays in the practice of medicine.

What does epigenetics mean to you?

A. Epigenetics is the field that looks at changes that are present basically in the chromatin structure, transcription of genes and post-transcriptional modification of MASON RNA, messenger RNA and post-translational modification of proteins, in other words, that can change the ultimate expression of a gene.

Saying it differently, epigenetic changes may be involved in the development of cancers that are not due to direct DNA damage.

Q. Do you have knowledge concerning whether or not some of the various medications that you are using and/or studying, in fact, have epigenetic manifestations?

MS. MCKEEVER: Objection to form.

THE WITNESS: That I'm using in my setting?

BY MR. LEE:

Q. Yes.

A. Absolutely, yes.

Q. Explain that. If you're talking to a layperson in Walmart or at church, how would you explain that?

A. So we know that the pathogenesis of leukemia can be due to changes in the proteins that are directing gene expression. So, for example, currently I'm a clinical investigator on a group of drugs that target a protein called menin. Menin is involved in the pathogenesis of leukemia because when there are certain genetic changes, those genetic changes will signal the leukemogenic gene expression profile through menin.

By making an inhibitor against menin, you can block that epigenetic change in the chromatin structure and shut down the genes that promote leukemia and actually upregulate the genes that promote normal development. And so that's just one recent example.

There are others with IDH inhibitors in acute promyelocytic leukemia, arsenic and ATRA and in MDS and AML using hypomethylating agents like

azacitidine and decitabine. So there are a whole class of drugs in that area.

Q. So if I ask questions outside of the area of expertise you have, specifically asking about environmental toxins, is it fair to say you don't have an opinion concerning whether TCE, PCE or any other environmental toxin might, in fact, cause issues with the immune system and also epigenetics?

MS. MCKEEVER: Objection to form.

BY MR. LEE:

Q. Is that fair, or can you go there?

A. I was going to say I'm happy by the end of this day that you're getting an idea of my knowledge and lack thereof in certain areas. And so that is exactly true. I can't talk to you about environmental toxins and how they affect epigenetic modulation of gene expression.

Q. Thank you for the classification concerning the drugs that you do work with.

I want to close the loop in our conversations concerning Mr. Gleesing. Can you read -- look at the Conclusion, IX. Can you read that first paragraph, please?

A. "Based on my review of this case, I have

reached the following conclusions concerning Mr. Gleesing's case to a reasonable degree of medical certainty. Mr. Gleesing has at least three factors associated with a greater risk for development of CLL: male gender, European ancestry" -- by that I'm paraphrasing here. I did not mean -- I meant not Asian, not African -- "and obesity. There is insufficient data in the literature to implicate VOCs such as those found in the water at Camp Lejeune in the development of CLL." Clearly this is my opinion. That's a paraphrase.

"Despite the epidemiologic available data, CLL has no known cause. It is my opinion, therefore, that Mr. Gleesing's CLL was highly unlikely to be related to or caused by his exposure to any contaminants in the water at Camp Lejeune 35 years earlier."

Q. Read the next one, next paragraph as well, please.

A. "Mr. Gleesing achieved an MRD negative complete remission of his CLL that has been durable for 4.5 years without any therapy, and there are effective therapy options if the CLL does recur. In light of this and his other

unrelated medical problems, it is unlikely his life expectancy has been shortened by the diagnosis of CLL."

Q. What is the basis for your opinion stated here that it's unlikely that his life expectancy has been shortened by the diagnosis of CLL?

A. I want to go back to then my details about Mr. Gleesing. In terms of his diagnosis, he had low expression of CD38. He also had on further evaluation, he had no -- he had 13Q which is associated with a more favorable prognosis, but he did have on a peripheral blood sample demonstrated unmutated IGHV3-30 gene sequence. So the unmutated status has been associated with a worse prognosis.

But he did not have P53 mutation that has been associated with it. That really drives the prognosis in CLL. It's a model. He's had an excellent response to therapy. And the therapy he's had was time limited. So he has not had continuous BTK inhibitors like ibrutinib or acalabrutnib or zanubrutnib. He hasn't had therapy venetoclax therapy. He hasn't had CAR T-cell. So there are many treatments that are

coming. So it's very hard to predict this survival from his CLL based on what will be coming soon.

Q. Is there any article, textbook or what have you you can refer me to that addresses issues related to life expectancy after a patient is diagnosed with CLL?

A. No, not that I can remember.

Q. Have you published on the topic of life expectancy?

A. I have not.

Q. We talked earlier about various organizations and guidelines.

Are you familiar with the Institute of Medicine, IoM?

A. I am.

Q. Did you review any of their guidelines or publications at any point during your involvement in this case?

A. I did not.

Q. I'm going to move to the next topic. You can put that one aside unless you have another comment.

A. Can I add to my discussion?

Q. Absolutely.

A. So the only thing I would add to that is when he actually started treatment, he had features that did not necessarily require treatment. So he did not have bone marrow failures. So he didn't have stage 3 or 4 disease at the time. So his stage was Rye stage 2 because he had a palpable splenomegaly. So that's another feature that's associated with a better prognosis.

And although I will just say right from the start I am not a cardiologist, he has predating all of this two vascular problems and a number of metabolic reasons for vascular disease. He has hypertension, hyperlipidemia, pre-diabetes, and that shows up with hepatic steatosis. So he has those problems.

And then the dilated ascending aortic aneurysm that's not related to the treatment of CLL all of a sudden got bigger, from 4.3 to 4.8 centimeters, but the follow-up was stable. So when I looked at his medical record and how well he did with treatment and when he was treated at stage 2 for his disease and the number of options we have and then related that to his other co-morbidities, it was my opinion that he was just as likely, I would say, to die of other things

1 than just of CLL.
2 But of course, we're very bad at
3 predicting the future for any of us because I
4 could drop dead on the way to the airport.
5 Q. We hope not.
6 A. We hope not, too. My clinic hopes I'm
7 there tomorrow.
8 Q. You mentioned a topic I wanted to talk
9 about and I forgot. So thank you. Hepatic
10 steatosis, what, if anything, is the difference
11 between hepatic steatosis and fatty liver?
12 A. I will preempt maybe a future question.
13 I am not a liver expert, but I play one every day
14 on the medicine service and all my patients.
15 Fatty liver is a diagnosis that can be
16 made with certainty by a liver biopsy, which is
17 almost never done for just fatty liver. It's
18 typically a diagnosis made by the appearance of
19 the liver on an ultrasound or a CT scan. Fatty
20 liver just means that the appearance on the
21 ultrasound or CT looks like there's fat in there.
22 It is associated with alcohol ingestion,
23 but there's nonalcoholic fatty liver or fatty
24 liver disease. When you start getting enough
25 inflammation in the liver from that fat, that's

what they call steatohepatitis, because the hepatitis, the -itis stands for inflammation. So you can have fatty liver without the inflammation or it can progress. The metabolic syndromes of hyperlipidemia, especially diabetes and obesity, put you at higher risk of that.

And now fatty liver has become, from what I remember a liver specialist telling me recently, the number one cause for cirrhosis, end-stage liver disease in the United States based on obesity and diabetes that's prevalent in our population.

Q. So you're distinguishing the two for me?

A. Fatty liver and -- what was the other term you used?

Q. Hepatic steatosis.

A. Hepatic steatosis, those are the same. Steatosis means fatty and hepatic is liver, so a fancy way of saying fatty liver. That's what doctors do. We change the names to keep everybody confused. Steatohepatitis is the one that is different and associated with a progression to cirrhosis.

Q. Thank you very much. Do you have anything else to add at that particular client?

A. No.

(Erba Exhibit 14 was marked.)

BY MR. LEE:

Q. I'm going to hand you a document. We've talked about it. We going to identify these for recordkeeping purposes. You and I talked at the very beginning about the Yu study and also the Wang Study. I'm going to remind you that's number 14.

Have you seen this document or at least the content of this document? You may have seen it online.

A. I'm just making sure this is the same one I reviewed. Yes.

Q. That's the only question I had.

A. Except I got the dates wrong. The Wang article came out first before the Yu article.

Q. I was not going to hold that against you.

A. It's okay. I never mind saying I was wrong about something.

(Erba Exhibit 15 was marked.)

BY MR. LEE:

Q. I'm handing you Exhibit 15. Are you familiar with that document?

A. This is clearly the one that came out first.

Q. Just so the record is clear, what is that document?

A. This is the publication by Wang, "Long-Term Exposure to Low Concentrations of Ambient Benzene and Mortality in a National English Cohort."

(Erba Exhibit 16 was marked.)

BY MR. LEE:

Q. I'm handing you what's been identified as Exhibit 16. Look at that document for a moment. I don't believe you've seen it before.

A. I have not.

Q. You'll note that the principal author's name is on the document. Do you see the name?

A. The first author is Julie Goodman.

Q. To your knowledge, is that the same Dr. Goodman we've been talking about all day?

A. The only knowledge I have of that is I see that she's at Gradient. So I would say it is likely.

Q. Take a moment to look at that. I only have a very brief questions. In one of your reports, you commented on the Cohn study, C-O-H-N.

A. Yes.
Q. The Cohn study was drinking water contamination and the incidence of leukemia and NHL.
Do you remember that document, the Cohn study?
A. I remember that very short three-page, four-page article. I would have to look at the details.
Q. You and I will look at that in a moment. But you do recall the Cohn study?
A. Yes.
Q. You did look at it yourself at some point?
A. Yes. I looked at it myself.
Q. Do you recall what your critique was of the Cohn study, as to whether it was a valid study or not?
MS. MCKEEVER: Objection.
THE WITNESS: I did critique the study in relationship to this case. If allowed I would like to go back to my notes.
BY MR. LEE:
Q. Please do.
A. Can I go back to my notes?

Q. You can. Before you do, let me hand you the Cohn study itself. That may help us. That will be the next exhibit.

(Erba Exhibit 17 was marked.)

THE WITNESS: This one I talked about. I know one of these papers had it, and so I want to get to it because I did have thoughts about it as a nonexpert. Well, I'm having trouble. I know I discussed it. Here it is. Yeah.

So it was in my response to -- that's where I reviewed it, was in my response to Dr. Laber. So I have it here.

BY MR. LEE:

Q. What was your critique of the Cohn study?

A. So I said there are several methodological issues with this population-based study that limit applicability of the conclusions to this case (in my opinion as a nonepidemiologist). First the authors could not adjust their models for all known risk associated with a higher incidence of CLL. They were able to comment on age and gender, but had no -- I'll just summarize -- no data on obesity and family history. They had self-reported ethnicity, but we

1 know that there's a potential effect of how
2 ethnicity is reported in these when you ask
3 people, you know, what their ethnicity is.
4 It is conceivable that the regions of
5 higher volatile organic chemical exposures also
6 had higher prevalence of other demographic
7 characteristics associated with CLL. A
8 multi-varied analysis including all known risk
9 factors would be required to conclude that the VOC
10 exposure was the cause of the CLL. Since the
11 reported relative risks are so close to unity, an
12 imbalance in other known risk factors could
13 potentially affect the conclusions. The incident
14 cases of primary leukemia and lymphoma were
15 collected between '79 and '87.
16 So now I think I moved on because CLL
17 may be included in the lymphomas. But the first
18 time that the VOC levels were actually measured
19 were '84 to '85. So it may be reasonable to
20 assume that the water supply was contaminated
21 prior to the first round. So mandatory water
22 testing. However, additional cases were not
23 collected after '87. So this is an exposure, and
24 then very quickly, within two years, '87, that's
25 when they're looking at the reports of CLL,

leukemias and lymphomas.

If the exposure to VOC contamination of the New Jersey water supply was responsible for the reported higher incidence of CLL in this cohort, these people likely already had MBL, and that is my opinion, given the natural history of MBL and the progression to CLL reviews by a colleague of mine, Shanafelt. Given the limited timing of the collection of leukemia cases from the New Jersey State Cancer Registry, this analysis does not allow us to conclude that an exposure to VOCs may cause the CLL decades later as in this case, which I stand by that conclusion.

Although the authors point out that the geographic regions evaluated the study did not exhibit major population influx during '70 to '80, there was no attempt to evaluate each reported case of cancer with time of residency in one of the New Jersey counties. So I felt in my mind, when I read this paper not as an epidemiologist, I found the conclusions weak.

I go on to talk about CLL would have been included in the low grade lymphoma. So maybe that's where it was included. The relative risk of developing low grade lymphoma is numerically

higher with TCE but not increased. Again, getting to those confidence intervals. The relative risk was numerically lower with the higher TCE exposures compared to lower, which is not what I'd expect in a dose and risk assessment, linearity or nonlinearity, showing a causal relationship.

The relative of risk of CLL was numerically but not statistically higher even at the higher levels of TCE. And there was no relationship between CLL and the PCE. In fact, the relative risk of CLL was numerically lower with exposure to PCE than without.

I went on for two paragraphs as a nonepidemiologist but reading the data that was before me to try to make a conclusion about how strong this data is showing an association between those drugs and the development of CLL decades later.

Q. Anything else?

A. I'll turn the page.

Q. I'm going to ask a question, but I don't want to cut you off.

A. No. I didn't say anything extra.

Q. Let's go back to the exhibit that I handed you that said Global Epidemiology that was

authored by Gradient employee Julie Goodman. If you can look at page number 7, let me know when you're there.

A. Yes.

Q. If you look at the bottom right, it says Ecological Studies. Can you read that full paragraph that goes onto the next page at the top. Then we'll talk about it.

A. "Three ecological studies examining the potential association between PCE exposure and NHL were identified, as shown in Table 4," which is on the next page. "All ecological studies are of low quality with respect to study design, exposure measurements, exposure levels and confounders with one exception. Cohn evaluated three exposure levels. As presented in Table 7, most of the associations between PCE and NHL from the ecological studies are null. The only exception is Cohn, which reported increased risk of NHL in males have PCE concentrations ranging from 0.1 to 5 parts per billion, but not in males exposed to greater than 5 parts per billion PCE or in females at any exposure indicating a lack of dose-response."

Q. Now, did Dr. Goodman conclude that the

Cohn study was, in fact, a well-run ecological study?

MS. MCKEEVER: Objection to form and lack of foundation.

THE WITNESS: No, I don't think she concluded that. Sorry about that. She never says that in here. She says there's an exception to the other ecological studies that were of low quality because of those confounders. She doesn't say why the Cohn analysis is an exception except for one thing, exposure levels.

So she doesn't say there that she thought the study design was great, the exposure measurements were fantastic and confounders were accounted for. In fact, if she said that in this paper, as a person who can read some scientific literature, I'd have to disagree with that conclusion independently. So that's all she said, that it included the three exposure levels.

BY MR. LEE:

Q. Did she say the other papers were low quality?

A. She said the other papers were of low quality, yes.

Q. She said the Cohn study was one

exception?

MS. MCKEEVER: Objection to form.

THE WITNESS: She said -- the quote is with respect to study design, blah, blah, blah, with one exception. Cohn specifically evaluated three exposure levels. And that was one of the four criteria that she commented on the low quality studies.

So we would have to ask Dr. Goodman if she felt that making up -- evaluating exposure levels would make up for the deficiencies in the other three, which she didn't assess. I'm not Dr. Goodman, but her conclusion here is the same as what I think I said in my report.

There was only one exception in the Cohn report, that the PCE and NHL in general -- so we don't even know CLL, high grade lymphomas, diffuse large B-cell lymphoma, all the different types. But if you lump them all together, that the null hypothesis, in other words, the confidence intervals overlapped one.

The only exception in that report was males at PCE concentrations that were below 5. But then she makes the point, which I agree with, but not in males exposed to higher levels of PCE.

So there's a lack of dose-response. She doesn't go on to say I think this undermines my conclusion about PCE. But in my mind, if you're talking about a toxin causing something, the higher the level of exposure, the higher the risk you should have.

BY MR. LEE:

Q. Let's take a look at the Cohn study real quickly, if we can. In the interest of time, we'll move on.

You, obviously, reviewed it and you've talked about at least in one of the reports your assessment, evaluation of the Cohn study. I just want to make sure that the record is clear as it relates to some of the statements that have been made about Cohn and what this study itself represents.

You can look at page 557.

A. Yes.

Q. Above Data Analysis, if you would, you commented on the timeframe and what have you. If you can read the last sentence into the record above Data Analysis.

A. "Misclassification of the '84 to '85 data should be low, at levels greater than 5 parts

per billion, particularly since many verification samples were taken from systems contaminated above the 5 parts per billion."

Q. What does misclassification mean?

A. Again, you'd have to ask the authors, but I would say in this case, that they felt that their estimates of the exposures or the levels was accurate at above 5 parts per billion, especially at levels greater than 5 parts per billion. So that's where they really thought they should see the best data, at levels greater than 5 parts per billion because most of the verification samples showed that were most accurate -- that's what I'm reading -- were above 5 parts per billion.

Q. Stepping back from the study, what does the word "misclassification" mean when you're looking at epidemiology studies?

A. I don't look at epidemiology studies, but I am assuming that what it meant was that since she's talking about the levels -- or he, sorry, Perry -- is talking about the levels of exposure or the levels in the water supply, that it's unlikely that they misclassified the data to a lower level or a higher level, that they were certain -- they were relatively certain of what

they were saying. It was really, really low or .1 to 5 or 5 or greater. They were happy with their data, in other words.

May I?

Q. Please, absolutely.

A. Which makes me again wonder why at that level, where they were so certain of the level of exposure and it was the highest, that's where they didn't see a relationship.

(Erba Exhibit 18 was marked.)

BY MR. LEE:

Q. I'm going to hand you the next exhibit, which is going to be Exhibit No. 18. This will be very brief.

Based on my recollection of the studies, you made reference to this particular publication and this article; did you not?

A. Yes.

Q. I don't remember which one of the studies or I should say reports she did. You're welcome to find it. You may recall. What is the title and who is the second author?

A. "Evaluation of Acute Nonlymphocytic Leukemia and its Subtypes with Updated Benzene Exposure and Mortality Estimates: A Lifetable

Analysis of the Pliofilm Cohort," and the second author is Julie Goodman.

Q. If you'll look down to the bottom left, it says from Gradient. And then below that, the next paragraph, what does that say?

A. "This work was funded by the American Petroleum Institute."

Q. To your knowledge, does the American Petroleum Institute manufacture benzene?

MS. MCKEEVER: Objection to form.

THE WITNESS: The only thing I know about petroleum products is that benzene is found in petroleum products. I don't believe -- well, is found in petroleum. I know that from the IARC report. And the other thing I know from the IARC report is benzene is what was put in unleaded gas to help prevent knocking, that knocking sound that an engine might make, which I don't understand because I'm not an expert in car mechanics either.

So that's all I know about it. So I know that benzene is somehow related to petroleum production.

BY MR. LEE:

Q. When you have an article that's funded by an organization that manufactures and/or has a

product that is the subject of the publication, in your mind, does that raise questions about, if you will, the purpose of that particular article?

MS. MCKEEVER: Objection to form and foundation.

THE WITNESS: So this is something I always have to take into account because every single one of the manuscripts that I've been involved in in the drug development have been -- not every one, but many of the major developments I've been involved in that have led to drug approvals have been funded by a pharmaceutical company. And we have to state whether there are conflicts of interest.

Here this statement is, number one, individual professional views are those of the author and may not necessarily reflect the views of API -- I'll just abbreviate it -- and the author's report no conflicts of interest.

So, you know, when these reports are made by any investigators and any author, unless there is evidence of malpractice in medicine or misconduct in reporting, we take the authors at their word that they didn't receive any kind of, you know, inducement, honoraria directly from the

American Petroleum Institute.
BY MR. LEE:
Q. I've represented to you earlier in this deposition that Dr. Goodman works with Gradient who is owned by Geosyntec, owned by Blackstone, a manufacturer of various toxins or affiliated with organizations and businesses that manufacture them.
When one works for an organization that produces some of the very compounds and chemicals that are at issue in a case, in your opinion, does that at least raise some questions about bias or conflict?
MS. MCKEEVER: Objection to form and foundation.
THE WITNESS: So what I didn't hear you say because I don't know what those industries are, any of them.
BY MR. LEE:
Q. That's fair.
A. I didn't hear American Petroleum Institute and how it relates to any of those three.
Q. I did not; correct.
A. So that I don't know. And I don't know

what those other -- what any of those corporations do. And so I guess I would have to say reading this, I wouldn't even have suspected a conflict of interest because I'm just not aware of that.

Q. When you say you wouldn't suspect a conflict of interest, what do you mean by that?

A. A misstatement. I should always consider that there's -- whenever you're hearing someone's opinion, they're up at the podium, they've written a paper, you have to wonder where is that opinion coming from. And there may be a financial conflict of interest. But there may be many other conflicts of interest that I could afterwards discuss, negative conflicts of interest, why a company really made somebody mad and they went around saying bad things about their product. It goes both ways.

Q. It does. Same publication, if you can turn to page 416 under Discussion.

A. Yes.

Q. If you'll look at the second paragraph and if you would be so kind as to read that paragraph into the record.

A. "Leukemia is one of the most common cancers caused by industrial chemicals and

environmental agents according to U.S. EPA. One possible mechanism by which benzene may cause leukemia is via genotoxic effects of its metabolites acting alone or in concert on the pluripotential hematopoietic stem cells which result in chromosomal changes. Acute nonlymphocytic leukemia is considered to be the leukemia subtype most relevant to benzene exposure."

And acute nonlymphocytic leukemia is basically the same as AML.

Q. So that first sentence that you read, do you agree or disagree with the statement "leukemia is one of the most common cancers caused by industrial chemical and environmental agents according to the U.S. EPA"?

A. So I agree as it is written, it is correct. I will tell you that as a leukemia specialist, and they are not, I would have worded that in a different way to just cite the evidence that I do know of, which is what they end with, that acute nonlymphocytic leukemia is a leukemia subtype most relevant to benzene exposure. But AML being a subtype of leukemia, they didn't say anything wrong. It just is incomplete.

Q. Have you heard of or read anything about an organization called the Benzene Task Force?

A. I have not.

Q. Do you have any knowledge with respect to the fact that the American Petroleum Institute, which we've referenced in this particular publication, helped direct efforts of the Benzene Task Force to get favorable benzene regulations from U.S. governmental agencies?

MS. MCKEEVER: Objection to form.

THE WITNESS: No. I am not aware of that. I just have to smile. Am I aware of weird things happening in the government? Please. I'm sorry. I just had to say that because, otherwise, I'm on camera with a smile and they're wondering what I'm smiling about.

BY MR. LEE:

Q. Did you reference at any point a publication by Debra Glass, G-L-A-S-S, do you recall?

A. That name seems familiar. I'd have to look at one of my reports to see if it was included in there.

(Erba Exhibit 19 was marked.)

BY MR. LEE:

Q. The next exhibit will be 19.

A. Yes. I know it's in one of my reports. Wonder if it was -- Connard is my guess.

Q. When you're ready, I just have one or two questions. Then I'll move on. Take your time.

A. I just want to get the report here. Here we go. So if I can explain. Sometimes I don't --

Q. Please do. Please do.

A. -- I don't recall these things because, again, I was asked to give my opinion about the etiology, diagnosis, treatment and outcomes for various types of leukemia that all have different natural histories.

Having said that, as I became involved in the case, the Department of Justice asked me to look at some of the other expert reports and asked my opinion, what do I think about that. So I would end up commenting about something that another expert had in their report that I hadn't seen before.

So that's why it doesn't come top of mind. But now I see it's in my rebuttal to

Dr. Gondek's report. So now I'm ready.

Q. Looking at the Glass study in front of you, under Results, can you read into the record the first full sentence, please?

A. First full sentence --

Q. And the Results on the fourth page.

A. The Results in the abstract. "Matched analyses showed that the risk of leukemia was increased at cumulative exposures above 2 parts per million years and with intensity of exposure of highest exposed jobs over .8 parts per million."

Q. Next sentence.

A. "The risk increased with higher exposures for the 13 case sets with greater than 8 part per million years exposure. The odds ratio was 11.3 with confidence intervals at 2.85 through 45." Quite wide, in my opinion, but that's parenthetical. "The risk of leukemia was not associated with the start date or duration of employment."

Q. What year was this published, if you look at the bottom?

A. 2003.

Q. So based upon what you just read, is it

fair to say even in 2003, very low levels of exposure to benzene was associated with the onset of leukemia?

MS. MCKEEVER: Objection to form.

THE WITNESS: I'm sorry. One more time.

BY MR. LEE:

Q. Certainly. This was a publication in 2003, one that you referenced in one of your reports.

Is it fair to say just looking at what we have here that very low levels of benzene even in 2003 was shown to have an association with the onset of leukemia?

A. Yes.

MS. MCKEEVER: Same objection.

BY MR. LEE:

Q. The answer is?

A. So that's her conclusion, yes.

Q. Of the study?

A. Of the study. But that's actually not how I used -- I was asked to comment on the entirety of the study, and to me it was important. And again, this relates to my opinion in the Connard case specifically -- that's where I'm reading from, the Connard case specifically

where -- you asked me the question how did I determine my methodology for determining that this person's leukemia was not likely to be caused -- I'm just going to say not likely to be caused by this exposure.

Not being an expert in levels, I have to rely on my knowledge of latency between chemotherapy and an exposure. So the only thing I said in this report is that, in parentheses, Dr. Glass and colleagues showed that the risk of leukemia is associated with exposure within 15 years of diagnosis. The association with exposure prior to this period is weak.

This further supports my opinion that Mr. Connard's development of AML nearly 20 years after his departure from Camp Lejeune indicates that his AML was not caused by any chemicals in the water at Camp Lejeune. That's how I responded to this paper specifically.

Q. Thank you for that clarification. Can you turn to three pages from the back of this document. It doesn't have a number on it. I apologize for that.

A. Yes.

Q. And if you'll look at the top left-hand

side, the sentence that begins "Over a working lifetime." Let me know when you're there.

A. Yes. The sentence starts with what?

Q. "Over a working lifetime."

A. Here it is in the paragraph, yes.

Q. Can you read that to the end of that paragraph.

A. "Over a working lifetime, this could amount to cumulative exposure up to several hundred parts per million years. In our study, the risk of leukemia was increased at all cumulative exposures above 1 part per million year with a strong exposure response relationship. There was no evidence of a threshold."

Q. So again, in this publication based on what you just read, is it fair to say at least this author stated explicitly there was no evidence of a threshold?

MS. MCKEEVER: Objection to form.

THE WITNESS: I'm willing to agree with what you said. This author used some methodology to state that there was no evidence of -- I shouldn't say it that way -- that maybe the cumulative exposures that had been implicated in the risk are higher, and she said at all

cumulative exposures above 1 part per million per year. So she actually qualifies this study.

And, in my opinion, since you're asking about levels of exposure, when I read the Wang paper where they talk specifically about AML, both of them, Yu and Wang, although they say there's no level of exposure that's safe, when I look at the curves that are there, again just looking at data in front of me as a scientist, to me it looks like there's a clear threshold.

So to me these all say the same thing, that there is some level of exposure, and I don't know how to calculate that because I'm not an expert.

BY MR. LEE:

Q. Fair enough. You agree that in 2003, the paper that you referenced says that the risk of leukemia was increased at all cumulative exposures above 1 part per million year; correct?

Did I read that correctly?

A. Yes.

Q. You can look at the Yu or the Wang studies. Do you remember the level at which they indicated that if there was a threshold, what that number was?

A. In one paper -- and again I get the papers mixed up, but one paper, it was 0.18 parts per billion year, and the other one -- this is what confused me -- is around -- the other paper, the other paper that said there was no threshold, but when I looked at the curve, it seemed to cross unity at around .5 micrograms per cubic meter. So that they used different values.

So to me, it did seem to be a threshold. And anticipating your question just because I know you're going to ask it, these are two numbers. So if you ask me which number is higher, I know which number is higher. But these are completely different methodologies.

Q. To be clear, I don't want to misstate what you said, you recall one of the papers indicated that the threshold, to the extent there was one, was 0.18 parts per billion?

A. Per billion.

Q. Thank you, sir.

A. Seems pretty close to what one of the calculations said for Mr. Connard, which I believe in the Bailey report was .00033 parts per million, which would be 0.18 -- 0.33 parts per billion. So by that point, just as a scientist looking at

numbers, again, yeah, it looks like it's over that threshold.

But we are comparing atmospheric levels of benzene to water contamination and models of, as I heard, shower modeling of inhalation and trying to equate these. I think it's just very difficult as a scientist but not as an expert.

(Erba Exhibit 20 was marked.)

BY MR. LEE:

Q. I'll hand you the next exhibit. I'm going to move quickly here. Take a few moments to familiarize yourself with the exhibit. It's Exhibit No. 20.

A. I'm sorry. I was looking feverishly for the journal. I looked at everything except where it was listed as science.

Q. Are you ready?

A. I am ready.

Q. Who does it appear this publication was published by, which organization?

A. I'm sorry?

Q. Which organization would it appear that this publication --

A. Several organizations are listed here, Division of Cancer, Epidemiology and Genetics at

the NCI, School of Public Health at UC Berkley, Chinese Center for Disease Control, New York Blood Center, School of Public Health at UNC. I hear they're pretty good. Peking Union Medical College, SAIC-Frederick, and Center for Cancer Research. I'm sorry. My comment about UNC was their leukemia group is very good.

Q. I agree. Turn to the discussion right above the References, to the next to the last page, page 3. This will be brief. I just want to continue to address a couple issues.

A. Page?

Q. 3.

A. Yes.

Q. Do you see right above References?

A. Yes.

Q. And you'll look at -- beginning on the far right, there's a sentence begins -- that says, "Finally, genetic." Do you see that?

A. Yes.

Q. Read that into the record, please.

A. "The present study showed that total blood cell count, granulocyte, lymphocyte B-cells and platelets significantly declined with increasing benzene exposure and were lower in

1 workers exposed to benzene at air levels of 1 part
2 per million or less compared to controls."
3 Q. Thank you. Now, I'm going to skip down
4 to the very end, the last sentence which, "Finally
5 genetic variation." Let me know when you're
6 there. I'm sorry. The next to the last sentence.
7 I apologize.
8 A. "Finally, genetic variations in
9 myeloperoxidase" -- that's what MPO is -- "and
10 NQO1" -- which I don't know -- "conferred
11 susceptibility to benzene-inducing lowering of
12 white blood cell counts."
13 Q. Continue, please.
14 A. "Although confirmation of these findings
15 and other studies is needed, these data provide
16 evidence that benzene causes hematologic effects
17 at or below 1 part per million, particularly among
18 susceptible subpopulations."
19 Q. What year was this publication as best
20 you can tell?
21 A. 2005. 2004. I'm sorry.
22 Q. Again, confirmation even in 2004 for the
23 study we just looked at, Glass, and then as
24 science has continued to evolve with the Yu and
25 the Wang studies, now we're now at parts per

billion; is that fair?

MS. MCKEEVER: Objection to form.

THE WITNESS: Again, I'm not an expert in this. I cannot look at the methodologies that were used for assessing hematotoxicity. Do I know from textbooks that benzene has been associated with an effect on the bone marrow causing decreased blood counts and even aplastic anemia? I know that. But I am not an expert in the levels.

You're giving me a paper to look at. You're pointing out to me specific sentences to read that suggest that based on this analysis, that it is levels above one part per million that was associated with lower blood counts. So as it's written, it is true based on these authors. I don't consider what we're doing here a thorough review of the literature, and I am not capable of making that thorough review.

BY MR. LEE:

Q. It's not.

A. Because I'm not an editor.

Q. Fair enough.

MR. LEE: Let's go off the record for a moment.

THE VIDEOGRAPHER: The time is 1619 and we are off the record.

(Recess from 4:19 p.m. to 4:34 p.m.)

THE VIDEOGRAPHER: The time is 1634, and we're back on the record.

(Erba Exhibit 21 was marked.)

BY MR. LEE:

Q. I'll hand you the next exhibit, 21. Take a few minutes to look at that document, please.

A. Okay.

Q. Do you know any of the authors?

A. I do not, no.

Q. Can you tell me based on what we have in front of you what year it was published and where the authors are from based upon the information contained in the document?

A. So they're from UC Berkley. It's published in the Occupational Environmental Medicine. I don't know much about that journal, but it was published in 2022.

Q. Thank you. Can you read the title please into the record?

A. "Benzene-associated immunosuppression and chronic inflammation in humans: A systematic

review."

Q. Then can you look at the conclusions on that page and read that into the record.

A. The conclusion to the abstract is, "To the best of our knowledge, this is the first comprehensive review of benzene's immunotoxicity in humans. Based on results obtained from this review, we propose two potential immunotoxic mechanisms of how benzene induces leukemia/lymphoma: One, cancer invasion caused by proinflammatory cytokine production, and, two, cancer promotion via impaired immunosurveillance. Further studies will be required to confirm the connection between benzene exposure and its effects on the human system."

Q. Based upon the conclusions, do you have any knowledge or information related to the topic that they're describing that's any different than what you already told us today?

A. No, I do not, including this article about how they did this search. So, no, I don't.

Q. Is anyone in your department to your knowledge looking at issues related to benzene-associated immunosuppression?

MS. MCKEEVER: Objection to form.

THE WITNESS: Is there anything in my department?

BY MR. LEE:

Q. Anyone in your department at Duke.

A. There may be, but I don't know.

Q. You don't know. Fair enough.

We commented earlier about your knowledge concerning some of the hemotoxic agents that you use for therapeutic purposes.

To your knowledge, are any of the fellows or other attendings looking at immunosuppression and some of the medications or treatments modalities that are being used at Duke?

MS. MCKEEVER: Objection to form.

THE WITNESS: I don't have a thorough knowledge of all of the research being done at Duke regarding drugs, toxins, immunosuppression and cancer.

BY MR. LEE:

Q. But the knowledge you do have, you don't know whether other colleagues are or are not looking at issues related to immunosuppression and therapeutic regimen?

MS. MCKEEVER: Same objection.

THE WITNESS: As stated, I don't have

that knowledge. I would be shocked if somebody isn't getting grant support to do such a thing. But I don't know who or what exactly they're doing.

(Erba Exhibit 22 was marked.)

BY MR. LEE:

Q. Next Exhibit 22. Doctor, you have the exhibit in front of you. Can you take a few moments to review it, please.

A. Yes. Okay.

Q. I'm going to ask you to read a couple of items into the record. Before we do that, do you recognize the names of any of the authors?

A. I do.

Q. Which one or ones do you recognize?

A. I recognize Rory Shallis and Steven Gore.

Q. How do you recognize those names?

A. Steven Gore graduated from Yale around the same time I did. I didn't know him then. But he became a leukemia specialist. And so I've known him for his work in leukemia developing new drugs, and I know him personally as well. We work very closely together. He's moved to the NCI in the investigational drug branch. So I'm on

conference calls with him every week in this precision medicine initiative called MyeloMATCH. So I know a lot about Steve on a personal level as well.

Rory Shallis is a more junior investigator. And I have helped him get involved in MyeloMATCH, and he's going to be leading one of the clinical trials in adverse risk AML with P53 mutations.

Q. And what university again was this publication out of?

A. It's out of Yale University.

Q. A decent academic institution?

A. It was when I went there. I assume it's continued.

Q. In the abstract, can you read the first two sentences in the record, please?

A. "Most clinicians recognize adult therapy-related leukemias following cytotoxic chemotherapy and radiation, environmental regulatory agencies evaluate exposure to 'safe levels' of leukemogenic compounds. Benzene represents the most notorious leukemogenic chemical. Used in the production of ubiquitous items such as plastics, lubricants, rubbers, dyes,

and pesticides, benzene may be responsible for the higher risk of acute myeloid leukemia among automobile, janitorial, construction and agricultural workers. It is possible that ambient benzene may contribute to many cases of 'de novo' AML, not arising out of germline predispositions. In this appraisal of the available literature, we evaluate and discuss the association between chronic low-dose and ambient exposure to environmental benzene and the development of adult AML."

Q. If you can turn to the next page, please. Under section -- actually look at the bottom left-hand side, if you would. Last paragraph, the sentence that begins with "Benzene damages DNA," do you see that?

A. Yes.

Q. Can you read that into in the record please to the end of that paragraph.

A. "Benzene damages DNA via benzene-related oxidative stress and aryl hydrocarbons receptor dysregulation."

Q. Continue, please.

A. "For benzene-induced DNA damage to participate in leukemogenesis, current theory

assumes damage to critical genes in progenitor or stem cells. Such stem cells may remain quiescent until further leukemogenic genetic dysregulation occurs."

Q. What does it mean when it says "such stem cells may remain quiescent until further leukemogenic genetic dysregulation occurs"? What does that mean to you as a clinician?

A. So what that means is that there may be some inciting event and that other events are required to actually produce the phenotypic expression of neoplasia to actually cause cancer. We know this to be true that leukemia is just one of many cancers where we've been able to define the -- we call it the autogeny, how the cancer develops based on the acquisition of mutations over time. This includes colon cancer and many others.

Q. On the next page, top right side of the same page, number three, can you read that full sentence into the record.

A. "The evolution of disease classification of myeloid malignancies during the previous seven decades, and the failure of most epidemiological studies to include bona fide hematologists among

the research teams severely confound understanding of the exposure-disease relationship between cumulative benzene exposure and risk of myeloid neoplasms."

Q. What do you interpret that to mean?

MS. MCKEEVER: Objection to form.

THE WITNESS: What do I -- my first impression, pure Steve Gore. I'm sorry. I have to say that. He's very, like me, very opinionated, and he shares his opinion whenever he can. And he's quite outspoken. I love how he says, the failure of most epidemiologic studies to include bona fide hematologists among research teams severely confound understanding of exposure-disease relationship, getting to the criticism that there seemed to be these two camps, epidemiologic studies and then hematologists who understand the disease process itself.

BY MR. LEE:

Q. Page 12, please. I had to laugh at that comment as well.

A. I appreciate that.

Q. Under number eight, the sentence that begins, "The detection of statistically significant increases," can you read that into the

record to the end of that paragraph and then the very first --

A. Which paragraph? The first paragraph. I got it. And the first sentence of the next paragraph?

Q. "The detection of statistically significant..."

A. "The detection of statistically; significant increases in the risk of AML when compared with arbitrary exposure tranches should not be considered demonstration of an exposure threshold below which benzene exposure is safe. Such broad conclusions would be routed in data based on small sample sizes and likely benzene exposure underestimates, especially for older studies."

Q. Read the next paragraph first sentence only.

A. "What is more likely is an additive, though not necessarily linear, effect of cumulative benzene exposure."

Q. What do you interpret those sentences to mean?

MS. MCKEEVER: Objection to form.

THE WITNESS: So my interpretation of

those are again the opinion of the senior author on this paper, Dr. Steve Gore, who I know pays very close attention to anything that comes out with his name on it. So those conclusions to me are typical of a very strong opinion that Dr. Gore may have.

Having said that, what he is trying to say is basically the absence of data does not mean the -- the absence of data confirming causality should not be interpreted as the absence of causality.

BY MR. LEE:

Q. Do you agree with that statement?

A. The absence of data confirming the existence of God should never be interpreted as evidence that God does not exist. So the statement is obvious but meant to be argumentative and meant to incite discussion and present a point of view in this review paper, not original research.

Q. Under number nine, same page on the right side near the bottom, the sentence begins "One meta-analysis found." Can you read that through to the beginning of the next page first sentence.

A. One meta-analysis found nonsignificant elevations in risk for CML when assessing all studies, so an M relative risk -- I'm not sure what the M stands for. Modified. I don't know -- 1.23 confidence intervals overlap one, but reported a stronger association with studies which started follow-up of subjects after 1970 where the relative risk increased and the confidence intervals did not overlap one.

Q. Page 13, please.

A. Am I going to be allowed to make comments of these statements at some point?

Q. Let me back up. Make comments on the one you just read, sure.

A. So the comment I would have on this is that one of the things -- there have been these very interesting studies done in leukemia where people try to make assumptions based on subset analyses. So they start breaking down the whole group.

And by so doing or putting certain contributions on it, they try to make an argument that would support their position. So they find the position. They rig the data. They look at the data that will end up supporting their

position.

So I get concerned when I say okay, this meta-analysis didn't see anything, but, you know, within the specific -- you do a meta-analysis to get rid of all of that heterogeneity between studies. They say, okay, the meta-analysis didn't show anything. But now I'm going to focus you over here on these studies showing that there was an association. So this is a flaw.

It's the reason why we do meta-analysis, which are flawed in and of themselves because of the number of assumptions they make. But I object to -- he's trying to make a point here, but I don't necessarily agree with him.

Q. But again, the two authors that you articulated that you know are well respected clinicians in your academic arena; true?

A. They very well represented leukemia doctors, not epidemiologists.

Q. Thank you for that correction. Appreciate it. Page 13 again, in the Conclusion section, if you drop down to the sentence that's near the bottom that begins with, "There may be." Can you read that?

A. "Benzene is an omnipresent carcinogen,

consequent to its natural occurrence and its prevalent use as an industrial solvent."

Keep going?

Q. Please.

A. "Increasing evidence supports leukemogenicity of chronic, low-lose benzene exposure. Individuals employed in the manufacturing (specifically shoe, rubber, painting) automotive, janitorial, construction or agricultural industries are repeatedly identified as having an increased risk of developing AML or MDS. There may be no safe levels of benzene exposure. It is possible that ambient benzene may contribute to many cases of de novo AML, not arising out of germlike mutations. This speculation allows for the term de novo AML to be considered not only inaccurate, but perhaps even obsolete."

Q. What do you interpret that to mean?

MS. MCKEEVER: Objection to form.

THE WITNESS: I interpret it to mean exactly as number ten says, that this is the conclusion these authors are making based on this data that is worthy of consideration and discussion, but not definitive.

It also makes me wonder about -- so what they're saying here, in thinking about their conclusion, is that these authors picked benzene as being notorious for causing leukemia. It's in every textbook. So they picked that. And we know there's this baseline rate of leukemia. We all develop -- we develop, you know, leukemia in some incidence.

So they're saying they want to go to the extreme of saying it's benzene that we're all ingesting and all taking in that is causing the ambient rate, the natural rate of de novo AML. That is their assumption.

To that I would argue I disagree. I think it's the cosmic rays that we're exposed to. No, wait a second. I think it's the radon. Wait a second. No. I think it's living next to Chernobyl. No. I think it's -- there are so many things that are detrimental to the bone marrow and hematopoietic cells. There's no wonder that those cells are in the bone marrow where they're protected to the degree possible from radiation. There's no -- it's why hematopoietic stem cells have multidrug resistance proteins pumping out chemicals. We can't live without blood. And God

has done its best to protect blood for decades in our body.

But it's a fallible situation. So this is an argument actually that I might actually say to a patient in a different form that we don't know why you got de novo AML, but something caused DNA damage, and it could have been just a mistake or it could have been, you know, just -- it could have been something ambient in the environment that caused it, that somehow got through every one of your defense mechanisms to protect that hematopoietic stem cell, metabolism, excretion, multidrug resistance, DNA repair enzymes.

To me it seems a little unlikely that one molecule that you breathe in is going to do that. But to their point, they're saying it's the ambient level. Well, to that point I would come back to there are many other things that we're exposed to. Living on this earth is a dangerous thing. It leads to death in all of us.

And I would point out that we're mutating ever since we are a fetus. And they're not breathing benzene. But we're exposed to many things. So I love the discussion in this paper because it's thought provoking in terms of why do

we get cancer. But I don't look at this and say, this is why Mr. Connard got cancer. It's an interesting argument.

BY MR. LEE:

Q. Anything else?

A. I am pretty certain I went on too long as it is. So I will finish there.

Q. Turning back to the names of the authors on the paper that you have in front of you, if you look at the names of the authors, the third author, what's her name?

A. Nicole Deziel.

Q. Do you know her?

A. No, I do not.

Q. If you look below that, it tells you.

A. Yeah. She's in the department of environmental health sciences at the School of Public Health.

Q. So does that mean there weren't just physicians involved, but, obviously, other professionals as well?

A. Yes, it does. There is one or two. The other person is cancer outcomes, public policy and effectiveness research. It doesn't quite speak to environmental health.

If I may, I know nothing about Nicole Deziel other than she works at an excellent university and was probably hired there for good reason. But it is, like Steve Gore's opinion, one person's view of the literature. That's why I relied on the IARC data so much, because when you look at all of the experts that wrote that report, they're from all over the world in different disciplines. So it's more of a consensus than one person's opinion who I don't know.

Q. Thank you.

You've talked about the body's ability to fix mistakes, mutations. I'll call them mistakes since that's the phrase you used.

A. Yes.

Q. Would you agree that benzene presence can increase the risk of mistakes occurring in bone marrow?

A. Can increase the?

Q. Increase the risk of mistakes for DNA damage.

A. I agree that from the papers, the textbooks I've read and the few papers I read on the subject that, yes, benzene exposure at some level in vitro in animal models can cause DNA

damage in the bone marrow.

Q. And would you agree that knowing there's an increase will cause damage in the bone marrow as you said, but does it increase the rate at which these mistakes will occur?

MS. MCKEEVER: Objection to form.

THE WITNESS: I can say that only in in vitro studies can they show where they have a control population, control cell dish, that's not getting benzene and one getting benzene, that there is going to be more mutations in that group. But all of the human data I think is flawed. It's difficult to determine. That's the whole point here, if there's a difference in these two populations.

BY MR. LEE:

Q. So just to be clear, preclinical studies and evaluations have demonstrated that increased benzene -- you used the Petri dish example -- lead to increased occurrence of, if you will, mutations, mistakes, DNA damage; true?

A. True.

Q. If I had the same question about TCE, are you able to provide a response, or is that beyond the scope?

A. I am not. That's beyond my scope.
Q. Do you have an opinion based upon your knowledge, skill, training and experience with respect to whether or not benzene can inhibit the immune system's ability to fix the mistakes that occur in patients?
MS. MCKEEVER: Objection to form.
THE WITNESS: So I have no knowledge of that. I'm trying to understand how the immune system would fix the mistake. Could it get rid of the cell with the mistake? Maybe that's what you meant. And that's what immune surveillance is. So it's theorized that that is the mechanism. Even in the last paper you sent, you showed me, that was one of the theories. We proposed two potential mechanisms, and one of them is to impair immunosurveillance which there's been -- that's clearly a theory that's out there in cancer biology.
BY MR. LEE:
Q. Do you have an opinion with respect to whether that theory is valid?
A. I definitely have an opinion about whether things that damage the immune system can lead to AML, because that is a known risk factor

in one of the books I cited that I took part in in the International Consensus Conference, that immunosuppressive therapies that suppress the immune system that aren't known to cause DNA damage do lead to a higher risk of developing AML and MDS. So I have to believe that.

Q. Doctor, I appreciate your patience. Those are all the questions I have. Thank you very much.

MS. MCKEEVER: If we could just take a short break, I'll make a decision.

THE VIDEOGRAPHER: The time is 1700, and we are off the record.

(Recess from 5:00 p.m. to 5:10 p.m.)

THE VIDEOGRAPHER: The time is 1710. We're back on the record.

MS. MCKEEVER: Dr. Erba, I have no questions. I'm finished.

THE VIDEOGRAPHER: This concludes the video deposition. The time is 1710, and we are off the record.

(Whereupon, at 5:10 p.m., the taking of the instant deposition ceased.)

COMMONWEALTH OF PENNSYLVANIA)
COUNTY OF ALLEGHENY) SS:

C E R T I F I C A T E

I, Ann Medis, RPR, CLR, CSR-WA and Notary Public within and for the Commonwealth of Pennsylvania, do hereby certify:

That HARRY P. ERBA, M.D., PH.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by such witness.

I further certify the inspection, reading and signing of said deposition were not waived by counsel for the respective parties and by the witness.

I further certify that I am not related to any of the parties to this action by blood or marriage and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 2nd day of August, 2025.

_____
Notary Public

COMMONWEALTH OF PENNSYLVANIA) E R R A T A
COUNTY OF ALLEGHENY) S H E E T

I, HARRY P. ERBA, M.D., PH.D., have read the foregoing pages of my deposition given on July 23, 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.

_____
HARRY P. ERBA, M.D., 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

August 2, 2025

Traci C. McGeever, Esquire
U.S. Department of Justice
1100 L Street, NW
Washington, DC 20005
Re: Deposition of HARRY P. ERBA, M.D., PH.D.
Notice of Non-Waiver of Signature

Dear Ms. McGeever:

Please have the deponent read his deposition transcript. All corrections are to be noted on the Errata Sheet.

Upon completion of the above, the Deponent must affix his signature on the Errata Sheet, and it is to then be notarized.

Please forward the signed original of the Errata Sheet to Randy L. Lee, 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:

Randy L. Lee, 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.

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

fashion to authenticated parties who are permitted to access the material. Our data is hosted in a Tier 4 SSAE 16 certified facility.

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