Volume 10

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

Before The Honorable Vince Chhabria, Judge

EDWARD HARDEMAN,	)	
	)	
Plaintiff,	)	
	)	
VS.	)	**NO. C 16-00525 VC**
	)	
MONSANTO COMPANY,	)	
	)	
Defendant.	)	
	)	

San Francisco, California
Friday, March 8, 2019

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

For Plaintiff:

ANDRUS WAGSTAFF PC
7171 W. Alaska Drive
Lakewood, Colorado 80226
BY: AIMEE H. WAGSTAFF, ATTORNEY AT LAW
DAVID J. WOOL, ATTORNEY AT LAW

MOORE LAW GROUP
1473 South 4th Street
Louisville, Kentucky 40208
BY: JENNIFER MOORE, ATTORNEY AT LAW

(APPEARANCES CONTINUED ON FOLLOWING PAGE)

REPORTED BY: Marla F. Knox, RPR, CRR
Jo Ann Bryce, CSR No. 3321, RMR, CRR, FCRR
Official Reporters

APPEARANCES: (CONTINUED)

For Defendant:

WILKINSON WALSH ESKOVITZ LLP
2001 M Street, NW - 10th Floor
Washington, D.C. 20036
BY: BRIAN L. STEKLOFF, ATTORNEY AT LAW
RAKESH N. KILARU, ATTORNEY AT LAW
TAMARRA MATTHEWS JOHNSON, ATTORNEY AT LAW
JULIE RUBENSTEIN, ATTORNEY AT LAW
CALI COPE-KASTEN, ATTORNEY AT LAW

I N D E X

Friday, March 8, 2019 - Volume 10

E X H I B I T S

Friday - March 8, 2019 **8:21 a.m.**

P R O C E E D I N G S

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(Proceedings were heard out of presence of the jury:)

THE COURT: Hi, everybody. So you had something you wanted to talk about?

MR. STEKLOFF: Just a few things before Dr. Levine testifies so that I stay completely within the bounds of the various orders that --

THE COURT: Is Dr. Levine testifying first?

MR. STEKLOFF: No. Dr. Mucci is testifying first. I figured instead of on a short break, it was a better time to cover it.

There are really three things to cover, Your Honor. The first is I'm not re-visiting any of your rulings on the questions we proposed for Dr. Levine.

THE COURT: Okay.

MR. STEKLOFF: With respect to Dr. Arber, we had proposed a question we did not propose to Dr. Levine. You had allowed that question.

THE COURT: Yes.

MR. STEKLOFF: I want to -- I would like to ask that question, but replacing the word "pathologist" with "oncologist" for Dr. Levine, and I just wanted to make sure that was okay.

THE COURT: You have the same objection?

MS. MOORE: Yes, Your Honor. And given your ruling, we understand.

THE COURT: That's overruled. That's fine.

MR. STEKLOFF: Second, Your Honor -- and I don't want to overdo this -- but in the same timeframe that I'm asking these questions, I am going to shift to specific causation and Mr. Hardeman and probably a few questions about Dr. Weisenburger's differential methodology, so not his general causation opinions.

I'm sort of just flagging that maybe a little leeway -- I don't think I will be asking maybe really leading questions, but I do want to ask questions that are careful so that if they are too open-ended, I think they would be difficult. For example, Why don't you think Roundup was a causation of Mr. Hardeman's cancer, that could lead to a path that we don't want to go down. So sort of just flagging -- if it is okay, I would like some leeway on a little bit of leading so I'm careful.

THE COURT: I think that makes sense given that we want to cabin the testimony.

MS. MOORE: And we're fine with that in the answer, Your Honor. It depends on the question obviously.

THE COURT: Yeah, I mean, obviously once we get into the meat of it --

MR. STEKLOFF: Thank you, Your Honor.

And then we are not seeking to re-visit your ruling on Dr. Arber and BCL6, but I wanted to flag -- I wanted to raise the issue of -- I think you think that similar testimony would be appropriate from Dr. Levine in her report at page 23, and she --

THE COURT: Testimony similar to what I'm allowing for Dr. Arber?

MR. STEKLOFF: No. Sorry. Testimony -- testimony that you were precluding from Dr. Arber about the BCL6 gene mutation and its relationship to hepatitis C. And I have a copy of the report if it is easier, but in her report, Your Honor, on page 23 --

THE COURT: I'm sensing, by the way -- I'm going to pull it up. But I'm sensing that this may be one we need to spend a little more time talking about during a break because I want to bring the jury right in at 8:30 today.

MR. STEKLOFF: No problem.

THE COURT: Okay. What page did you say?

MR. STEKLOFF: 23, second-to-last page, Your Honor.

MS. MOORE: It is about Dr. Shustov, Your Honor.

THE COURT: Wow, Shustov said that in his report?

MS. MOORE: Your Honor, I actually don't know. I don't have Shustov's report with me. We haven't called him to testify in the case. The jury hasn't even heard Dr. Shustov's

name, so we don't see any relevance at all to bringing this up. I think it is another way to get in evidence that the Court has excluded.

THE COURT: Yeah, I mean, it appears from Dr. Levine's report -- in the way she describes Dr. Shustov's report -- that Dr. Shustov said something that was clearly wrong, and she is rebutting it; but nobody on behalf of the Plaintiff at trial has said that clearly wrong thing.

And so I don't -- it is not clear to me just from -- I'm only just glancing at this. It is not clear why -- again, it is not clear that there is anything for her to rebut in that regard.

MR. STEKLOFF: And I agree, Your Honor, that Dr. Weisenburger did not specifically mention the BCL6 gene, so it was a little different than what Dr. Shustov had in his report. Dr. Weisenburger did have a blowup of the -- of what he claimed to be a specific patient that was just like Mr. Hardeman who had specific genetic translocations that disappeared following antiviral treatment.

THE COURT: Yeah, but that sounds like you are arguing the same point that you were arguing about Dr. Arber. I will tell you -- I will look at this a little more closely, and we can continue this conversation maybe over the lunch break or something like that.

How long do you anticipate Dr. Mucci to take? You said

like an hour, hour and a half, something like that.

MS. MATTHEWS JOHNSON: That's where we are aiming for.

MS. WAGSTAFF: I have something I need to raise about Dr. Mucci.

THE COURT: Okay.

MS. WAGSTAFF: Last Friday we received an updated materials considered list. And as you recall, Dr. Mucci is providing testimony on epidemiology only. She has not offered throughout the entire litigation anything on the other two pillars; and her updated reliance list included the mechanistic studies and some studies on the other pillars of science.

This morning I talked to Monsanto's counsel to ask to what extent they are going to elicit testimony on these, and we think that any testimony related to a reliance or a consideration of mechanistic data or toxicology data to form her opinion or even to support her opinion is a new opinion that has not gone through the proper steps and should not be allowed this late in the game and was not disclosed previously. We think that is different than just updating your material list with new --

THE COURT: Well, I have pulled up her report.

MS. WAGSTAFF: Sure.

THE COURT: I'm -- it looks like she did go through the Bradford-Hill analysis. Am I right about that?

MS. WAGSTAFF: She did not do a Bradford-Hill

analysis.

THE COURT: Okay. I'm sorry.

MS. WAGSTAFF: She did not do a Bradford-Hill analysis. She did not do a weight of the evidence analysis, and she only opined on the epidemiology. She has stated that in the Johnson trial; and these articles on mechanistic data, the Bolognesi and the Paz-y-Mino, were added last Friday.

MS. MATTHEWS JOHNSON: Just to be clear, Dr. Mucci does not intend to offer an opinion on any mechanistic or animal studies. She did update her materials considered list. There have been updates across various litigations, just to be clear; and those were just notifying things she has read. There is some hepatitis C articles that are now on there. There is going to be no testimony from her at all about hepatitis of any sort, but these are materials that she has looked at.

As we explained, it is not a reliance issue. It is simply an issue of these are things that she has additionally looked at. Her testimony is going to be about epidemiology.

I do think in a prior case there was cross-examination on the question of whether she looked at other studies. If that comes up on cross-examination, her truthful answer would be Yes, I looked at these other studies. So I think that's the way that it would come out if it came out at all.

THE COURT: Okay.

MS. WAGSTAFF: So as long as it will not come out on direct that she has considered more than one of the pillars for opining her opinion, then I'm okay with that because I will not elicit that on cross.

MS. MATTHEWS JOHNSON: No. I think the issue is, as I said, she is not relying on anything else. So if we do -- are you saying she can't say she has looked at these studies at all? I want to make sure because we would need to instruct the witness if she has to actually say she actually didn't read the studies.

THE COURT: Well, I mean, I don't understand why that would come out on direct if she is coming out to -- if she is coming here to offer an opinion on the epidemiology.

MS. MATTHEWS JOHNSON: Okay. And she does have a view on epidemiology being the most important, so that is also part of her testimony.

THE COURT: Okay. All right.

There were problems on BART today, and we have one juror who is a few minutes late because of BART. So we will probably start in just four or five minutes. I will see you-all then.

MS. MOORE: Thank you, Your Honor.

(Recess taken at 8:30 a.m.)

(Proceedings resumed at 8:38 a.m.)

(Proceedings were heard in the presence of the jury:)

THE COURT: Good morning, everybody.

Okay. You have a little bit more, testimony, right? Why don't you go ahead and put that on.

MS. WAGSTAFF: Your Honor, Plaintiffs continue the deposition through their Monsanto corporate witness, Dr. William Reeves.

(Video was played but not reported.)

THE COURT: Is that it for Dr. Reeves?

MS. WAGSTAFF: I believe that is it for Dr. Reeves. And, your Honor, Plaintiffs would move into evidence Trial Exhibits 100, 505, 506, 508, 509, 510, 511, 512, 514 and 515.

MR. STEKLOFF: If I can just review them with counsel on a break.

THE COURT: Sure.

MR. STEKLOFF: I don't expect any issues. I think we would move in the exhibit that was shown in the latter portion, which I think was Exhibit 95.

THE COURT: Okay.

All right. Next witness.

MS. MOORE: Your Honor, Plaintiffs call Dr. Donna Farmer, another employee of Monsanto.

THE COURT: Go ahead.

(Video was played but not reported.)

MS. MOORE: Your Honor, Plaintiff would move to enter into evidence Trial Exhibit 454.

MR. STEKLOFF: No objection, Your Honor.

THE COURT: Okay. It will be admitted.

(Trial Exhibit 454 received in evidence)

MR. STEKLOFF: Just to be clear, it was the e-mail -- no objection, Your Honor.

THE COURT: Anything else from the Plaintiffs?

MS. WAGSTAFF: Your Honor, Plaintiff rests.

MR. STEKLOFF: Your Honor, we have a motion but we will reserve it for later.

THE COURT: That sounds fine.

Does Monsanto have any witnesses?

MS. MATTHEWS JOHNSON: Yes, we do, Your Honor. Monsanto calls Dr. Lorelei Mucci.

LORELEI MUCCI,

called as a witness for the Defendant, having been duly sworn, testified as follows:

THE CLERK: State your full name and spell your last name for the record.

THE WITNESS: My name is Lorelei Mucci, L-O-R-E-L-E-I, M-U-C-C-I.

DIRECT EXAMINATION

BY MS. MATTHEWS JOHNSON

Q. Good morning, Doctor.

A. Good morning.

Q. Would you please introduce yourself to the jury?

A. Yes, my name is Lorelei Mucci. I live in Boston,

Massachusetts. And I work at Harvard University at the School of Public Health.

Q. What is your profession?

A. I'm a cancer epidemiologist.

Q. Do you have some slides that describe your background and education?

A. Yes, I do.

MS. MATTHEWS JOHNSON: May we have permission to publish the first slide, Your Honor?

THE COURT: Go ahead.

BY MS. MATTHEWS JOHNSON

Q. Doctor, what is a cancer epidemiologist?

A. So an epidemiologist is one of the scientific disciplines of public health. Epidemiology focuses on trying to understand why diseases occur in humans, and so cancer epidemiology specifically focuses on trying to understand why cancer occurs in humans and how to prevent cancer from happening.

Q. Now, have you ever met a Dr. Beate Ritz?

A. I have not.

Q. Well, she was here last week and she testified, and she said that you were a "young colleague who had no training, no specialty in going out into the field or asking people about their work or their environmental exposures."

Let me ask you: Is that accurate?

A. No, that is not correct.

Q. Please explain.

A. So for the -- I have worked as on epidemiologist for the past 16 years and have been involved in a number of different studies collecting information from individuals participating in these studies. And most recently I'm leading a global study of prostate cancer patients where we are asking the patients about environmental exposures, what lifestyle factors they are engaged in, what medications they are taking and what their quality of life is. So I have been very engaged in collecting data from a range of different patient populations.

Q. Okay. And in this study is it across many countries? Is it just here in the United States or is it across many countries?

A. So this study is being conducted in the United States and in nine other countries around the world.

Q. Involving how many men?

A. So we are recruiting 5,000 men for this study.

Q. Tell us the different types of cancers that you have been involved with researching as a cancer epidemiologist.

A. I have been studying several different types of cancers throughout my experience. I have worked in the areas of breast cancer and prostate cancer. I have looked at colorectal cancer. Liver cancer. I have done some work also in childhood cancers, really several different cancer types.

Q. Let's take a step back a bit and talk about where you went

to school, where you grew up.

MS. MATTHEWS JOHNSON: And if we may, may we publish the next slide, please?

MS. WAGSTAFF: No objection, Your Honor.

THE WITNESS: So actually, I grew up in Boston, just outside of Boston. I attended for my bachelor's degree, Tufts University. I studied biology in Tufts, and I graduated in 1989. Afterwards, I moved out to Seattle for a few years where I worked in a research lab looking at doing experiments in cells.

I moved to Wyoming also for a year where I worked with the pathologist for the State of Wyoming. And then after coming back to Boston, I attended Boston University where I received my master's degree in epidemiology and biostatistics, and then I completed my doctoral degree in epidemiology at Harvard.

BY MS. MATTHEWS JOHNSON

Q. And did you do any postgraduate research and study?

A. Yes. So after completing my doctoral degree, it is pretty common to do what is called a postdoctoral fellowship. I spent time as a postdoctoral fellow at the Karolinska, which is one of the leading medical epidemiology institutes in Sweden.

Q. I think the jury has heard in Sweden they keep really, really accurate health records; is that correct?

A. Yes, they do. So they are able to track health, including cancer, in the population. And for cancer research in Sweden,

they have been studying cancer at a national level for about 60 years.

Q. So why did you go into this field of studying cancer?

A. So there were really both personal and professional reasons. From a professional perspective, you know, 16 million individuals around the world are diagnosed with cancer each year. It is really the leading cause of mortality in the world. So as a public health researcher, I wanted to have an impact on improving the health through reducing cancer incidence and trying to understand what the causes are.

On a personal level I have lost two grandparents to cancer. I have lost two aunts also to cancer, and have had several family members and friends who have been diagnosed with cancer, so both professionally and personally.

Q. You mentioned I think that you have -- I think a couple of jobs, if I'm not mistaken.

MS. MATTHEWS JOHNSON: May we publish the next slide?

THE COURT: Any objection?

MS. WAGSTAFF: No objection.

MS. MATTHEWS JOHNSON: So -- I'm sorry. Let's go back. Sorry about that. Thank you.

BY MS. MATTHEWS JOHNSON

Q. All right. Tell us what you do as an associate professor at Harvard.

A. So I have several different responsibilities as a faculty

member. One of them is teaching, so I currently teach a course on the epidemiology of cancer. I mentor our master students and doctoral students in cancer epidemiology, and then I'm also involved in research as well. And at the School of Public Health, I also am responsible for overseeing the cancer epidemiology and cancer prevention program.

Q. What is the Dana Farber Harvard Cancer Center?

A. So the Dana Farber Harvard Cancer Center is a center that is funded by the National Cancer Institute. It brings together seven different institutions from around the Boston medical area, including the Harvard School of Public Health. It also institutes, like, the Dana Farber Cancer Institute, Mass General Hospital. And the goal of this cancer center is to bring together researchers across all of the disciplines, so bringing together physicians, population science -- including epidemiology and basic science -- with the idea of trying to accelerate our understanding for cancer prevention and treatment of cancer.

Q. How long has it been around?

A. So it's one of the -- it is the oldest cancer center in the country. The idea of the cancer center started in 1947, and it was first funded by the National Cancer Institute in the 1980s. And it is currently also the largest cancer center in the country with more than 1,200 scientists and physicians that are part of this cancer center.

Q. So tell me about this idea of team science. What is team science?

A. So in cancer research now, we are breaking down what we call the silos. So people are working really across different disciplines together. So as an example, as an epidemiologist in my own research, I work very closely with physicians as well as basic scientists with the idea that people coming from these different points of view of cancer research can help inform each other and really provide the best science to tackle the questions, both in prevention and treatment. So the idea of working together, you are going to be much more productive and find new discoveries much more quickly than if you work just in isolation.

Q. So we are not going to go through your 300-plus published papers or the chapters that you have edited in textbooks, but just give us a brief overview of sort of the areas in which you have published.

A. Yeah. So the work I have done in cancer research really is in many different areas. You know, one of the areas that I have worked on is, as I said, trying to understand why cancer occurs. So it could be looking at things like physical activity or obesity or even inherited factors like family history or genetic factors.

I have also done some research -- once individuals are diagnosed with cancer -- trying to understand whether specific

factors, for example, looking again at physical activity. So once a person is diagnosed with cancer, looking at whether engaging in even regular physical activity -- walking briskly -- could actually lower the risk of different cancer types. And then also looking at quality of life and trying to understand after a person is diagnosed with cancer, how can we improve both survival from cancer but also quality of life for individuals.

Q. So you have been on the side where you have been the person writing the article and submitting it. Have you ever been on the other side? They've talked about peer reviewed. Have you ever been a peer reviewer?

A. Yes. So I currently am a peer reviewer for 40 different medical and cancer journals. In addition, I recently became the senior editor for a journal from an organization called the American Association for Cancer Research. It is the leading international research agency on cancer, and one of their journals is called Cancer Epidemiology, Biomarkers & Prevention. I just became the senior editor for that journal.

Q. Okay. I and going to read that one more slowly. So you are the senior editor of the cancer -- Journal of Cancer Epidemiology, Biomarkers & Prevention?

A. Correct.

Q. And as a senior editor, what is that role?

A. As senior editor our role is to first -- when a person

submits their manuscript to us, we review to see the quality of the science, to see whether it is a good fit for the people who have been reading our journal; and many articles actually at that point will get rejected and not sent out for a formal review by external people.

So we -- what we then do, if we decided it met a certain, you know, level of quality, we would then send it out to two or three independent experts for them to review; give critiques of the study. And then once we got that data back, as the senior editor, we would make a decision whether there is still sort of large potential gaps in the evidence or if we should -- if we think it is a good-quality study.

Q. Is it fair to say that not everything that is in draft form is ever going to make it into a publication?

A. Yes. Absolutely. That is absolutely correct.

Q. I would like to talk just briefly about some of your areas of research.

MS. MATTHEWS JOHNSON: We are up and running. Thank you so much.

BY MS. MATTHEWS JOHNSON

Q. Let's actually start at the bottom here. It says you are program chair for the Prostate Cancer Research Program. Just tell us just a little bit about what that is.

A. Yeah. So the U.S. Army actually is one of the big funders for cancer research. It first started in the 1980s with breast

cancer, and then the second program they funded research on was prostate cancer, which is an area that I do a lot of research in. And so currently the prostate cancer research program from the U.S. Army funds $100 million per year in research.

And serving on the programmatic committee, my role is to make funding decisions about grants that are submitted to our agency to review the quality and think about which are the ones that are going to have the biggest impact for patients. And then also to set what we say is the vision for the next year, what are the types of grants we want to fund. For example, a big area of interest for us is supporting young investigators early on in their careers. So I have just taken on as program chair of the committee.

Q. And what is the amount that the funding is? I'm sorry. I might have missed it.

A. Currently we are funding -- the U.S. Army funds $100 million in prostate cancer every year.

Q. Now, next I want to talk about a couple of studies: The Nurses' Health Study and the Health Professionals Follow-Up Study.

First tell us about the Nurses' Health Study. Is that a cohort study?

A. Yes. It is one of the earliest cohort studies. It has been going on for about 40 years. It was -- back in the 1970's, the investigators recruited 130,000 female nurses. The

idea of recruiting nurses was, first of all, they were interested in health and could provide good quality health information. These nurses had been followed regularly throughout these four decades with questionnaires and other types of ways of collecting information, also including linkage with cancer registries, to identify which of the women have developed different types of cancer.

Q. It says here you have served as an advisory board member. What are the duties of an advisory board member?

A. Yeah. So in epidemiology, especially with these cohort studies that go on for many years, it is pretty standard practice to set up external advisory boards. And this is bringing in scientists and researchers who are not directly involved in the study but can provide an independent evaluation and critique of how this study is being done and whether there is any problems that they see with the study, whether there is any potential ways that they can help improve the quality of the study.

Q. Now, the Health Professionals Follow-up Study, tell us about that one just briefly, please.

A. Yeah. So the Health Professionals Follow-up Study actually was developed as a companion study to the Nurses' Health Study. So this study includes all men. It started in the 1980s, and there were 50,000 men that were initially recruited. Again, these were veterinarians, optometrists and

dentists with the idea that these would be men who really cared about their health and also could provide very good-quality information about their health.

Q. And your role as a co-principle investigator is what?

A. So I am the lead -- one of the two lead investigators on this study, and I'm responsible for the overall scientific conduct of the study. So the quality of the data, getting funding to support the study, reviewing all of the research proposals as well as the research results coming out of the study, so I'm one of the two people responsible overall for this study.

Q. Now, you said the Nurses' Health Study happens to be all women. The Health Professionals Study happens to be all men. Now, is that information that you are getting out of those studies just apply to nurses or just apply to men who are dentists, for instance?

A. No, absolutely not. In fact, the results from these two cohorts have really provided important information that has led to new discoveries of the causes of cancer, for example, so they have relevance well beyond nurses and health professionals.

Q. Now, just tell us just a few things that you have learned just over the course of working with these studies.

A. Yeah. So one of the important findings that have come out of these two studies has been really establishing that regular

aspirin use is associated with a lower risk of colorectal cancer. That is now a finding that is accepted by the U.S. Preventive Service Task Force.

Another really important area of research that these two studies have participated in is helping to refine our understanding that regular physical activity and really just even -- as I mentioned, just brisk walking can lower the risk of several different types of cancer, including breast cancer, colorectal cancer and advanced prostate cancer.

There is other health outcomes we have looked at as well. So many, many important findings have emanated from these two studies.

Q. Doctor, let's turn to why you are here today. Why are you here today?

A. I was asked to provide an opinion on the epidemiological evidence on whether there is a causal association between exposure to glyphosate and non-Hodgkin's lymphoma risk.

Q. Now, to be clear, you have looked at many different kinds of cancer, risk factors for cancer; but you have not looked specifically at pesticides and NHL before becoming involved here; is that right?

A. No, I have not.

Q. Now, did you approach this question the same way that you approached these questions in your professional life in your career?

A. Yes.

Q. And how is that?

A. So I identified all of the available epidemiological studies on this topic of glyphosate exposure and non-Hodgkin's lymphoma, and then also looked at all of the epidemiology-related materials that looked at validation studies within this body of literature; reviewed each of them and looked at the strengths and potential weaknesses, and then evaluated my opinion based on all of the available epidemiology.

Q. And when you use that methodology -- and what you are about to tell the jury here today, is this the same thing that you would tell your colleagues back at Harvard?

A. Yes, it is.

Q. Is it the same things you would teach your students?

A. Yes.

Q. Let me ask you, Doctor, about what your opinion is.

MS. MATTHEWS JOHNSON: Is there any objection?

MS. WAGSTAFF: No objection, Your Honor.

BY MS. MATTHEWS JOHNSON

Q. What is your opinion, Doctor?

A. So based on my review of all of the epidemiology studies, there is no evidence of a causal association between glyphosate exposure and the risk of non-Hodgkin's lymphoma.

Q. And by "glyphosate" does that also include Roundup?

A. Yes.

Q. Do you hold this opinion to a reasonable degree of scientific certainty?

A. Yes, I do.

Q. Now, I would like to talk a little bit about epidemiology and the role of epidemiology in looking at causes of cancer.

How does epidemiology fit into the larger body of science and other things that people may look at in evaluating questions like whether something is a risk factor or could actually be a cause of cancer?

A. Right. Well, if we want to understand why cancer occurs in humans, the ideal population to study is human beings. So therefore, the epidemiology studies really are the highest level of evidence that we have in trying to understand any relationship between a risk factor and cancer risk.

Q. Now, there has been a lot of testimony that has already come in here over the past several days, and at times there has been an image up and causation is at the top, and there are three points underneath. One is epidemiology. One is mechanistic. The other says animal.

I just want to ask you, Dr. Mucci, do you agree with that image of causation?

A. No, I don't.

Q. And why is that?

A. So as I mentioned, you know, really if you want to

understand why cancer is occurring in humans, the best model -- the best level of evidence we have is studying populations of humans, the epidemiology studies. I think the studies that are done in animals or in cells can be helpful in two ways.

One is if there is no epidemiology studies that exist, you can identify potential hypotheses about potential relationships of exposures that you might want to then test in a human population. So that is one way we use these kind of animal studies and cell line studies.

The other way we can think of it is if we have several epidemiology studies that suggest -- that come together supporting strong evidence of a positive association, you can then look at mechanisms of why there might be this relationship between an exposure and disease. That can also be really helpful if we want to think about prevention. In order to think about prevention, we have to understand mechanism.

So those two bodies of science really can help in those two ways, but ultimately if we want to understand why cancer occurs in humans, we really need to study human beings.

Q. Okay. Now, we are going to now, I guess, talk about different types of epidemiology studies. I want to show you something that is in evidence.

MS. MATTHEWS JOHNSON: It is Exhibit 1467.

MS. WAGSTAFF: No objection.

\\\

BY MS. MATTHEWS JOHNSON

Q. Are you able to see that, Doctor?

A. Yes.

Q. Okay. Great. So this is from Dr. Ritz's Epi 200A class that she teaches at UCLA. She just taught it just the other week. And it is a table -- it says table 1, Validity for Etiologic Inference, According to Study Design.

So let's just pause right there. What is etiologic inference?

A. So etiology is the area of research where we are trying to understand causes. So in this case here that we are talking about trying to understand the causes of cancer, but more generally it is the types of studies that help identify the causes of disease.

Q. Near the top we have the Prospective Cohort Study. Do you agree with Dr. Ritz that the cohort studies are generally the most accepted in the scientific community?

A. Yes, I do.

Q. And in this case -- and we will dig into this in a moment -- thank you -- we have a cohort study. Is that cohort study AHS?

A. Yes, the Agricultural Health Study.

Q. And then down the line here, you have something called nested case control studies. But just to be clear, is a nested case control study something that is inside of a cohort study;

is that right?

A. Yes, it is. So none of the case control studies that have published on glyphosate and non-Hodgkin's lymphoma would be considered these nested case control studies.

Q. Okay. So if we have just general case control studies, do they belong -- where do they belong in relation to the nested case control studies?

A. Somewhere between probably the time series and cross-sectional studies.

MS. MATTHEWS JOHNSON: You will have to endure my penmanship, sorry.

BY MS. MATTHEWS JOHNSON

Q. So, Doctor, let's talk about some of the way -- the difference between the way a cohort study works and the way a case control study works. And did you do -- do you have an example that you -- to kind of run us through that difference.

A. Yes, I do.

MS. WAGSTAFF: No objection.

MS. MATTHEWS JOHNSON: If we can have the screen.

BY MS. MATTHEWS JOHNSON

Q. Okay. So if we are talking about a cohort study, just to give an example, how would we look at this question of tooth decay and drinking sugary versus non-sugary drinks for a cohort study?

A. Right. So the question -- the causal question we would be

asking here is, Does regular drinking of sugary drinks increase the risk of tooth decay in children, let's say.

Q. And so what happens as you go forward in time with a cohort study?

A. Right. So what we would then do in this situation if we wanted to do a cohort study is we would identify a group of children. At the start of the study, you would want all of the children to be free of any tooth decay. And then we would collect information about whether or not they regularly drank sugary drinks. For example, we could collect that data from a questionnaire.

Q. Okay. And so, again, my animation jumped ahead of me, but you are here in time. Nobody has tooth decay. You go forward in time and see who gets tooth decay and whether they eat sugary drinks or not.

A. Exactly. And there are several advantages in this kind of approach and this design that reduces or eliminates any potential specific types of bias in the study.

Q. Okay. So now a case control study, if we look here at the time marker is at present and then going backwards. Can you explain what we are seeing here?

A. Sure. So with a case control study, what we do would be first to identify the cases, what we call the cases. Those would be a group of children who already have tooth decay. The next step would then be -- and this can be some of the

challenges with case control study -- is to identify the right group of controls or people who don't have tooth decay. So they really should come from the same population that the cases came from, and that can be one of the challenges.

And then you would ask -- again, it could be through questionnaires -- ask the children to look -- think back in the past about whether or not they drank sugary beverages.

Q. Okay. So -- thank you very much.

So let's talk about the way case control studies and cohort studies can be the same, which is -- you mentioned questionnaires. Do you use questionnaires in case control studies and cohort studies?

A. Yes. It is probably the most common way in which we collect information on participants in these studies.

Q. And do you do interviews of people in case control studies and cohort studies?

A. Yes, we do.

Q. All right. So are you really gathering information from people in both of these kinds of studies?

A. Yeah. You are collecting information in both of the studies; although, you know, because people have been already diagnosed with a disease, sometimes the case control studies can cause problems since you're -- whether they have the disease or not could have some influence on the way they remember information.

MS. MATTHEWS JOHNSON: May we show the next slide, please?

BY MS. MATTHEWS JOHNSON

Q. All right. So in the course of looking at this question, NHL and Roundup, did you look at both case control and cohort studies?

A. Yes, I did.

Q. Okay. And did you consider it important to do that?

A. Absolutely. It's important to use the same approach in reviewing all of the literature and exactly in the same way with the same level of scrutiny.

Q. Okay. And just off top, is there a value to the case control studies?

A. Yes, there is.

Q. Okay. And are you here to testify today that AHS, the cohort study, is a perfect study with no flaws, no problems?

A. No, I'm not.

Q. So let's talk a little bit about just right now your overview of these two types of studies.

So first, tell us about your overall assessment of the case control studies?

A. Right. So for all of the case control studies that have looked at glyphosate non-Hodgkin's lymphoma, really we can describe these studies as exploratory. What I mean by that is none of these case control studies that have been published

really look specifically at the question of glyphosate and non-Hodgkin's lymphoma.

And that's really important because the way that you do the study, if you are looking at, you know, these studies we are looking at between 30 and 50 different pesticides, when you do that kind of study is different than if you are focused specifically on glyphosate. So that is one issue.

Second issue, the U.S. -- the studies that were done in the United States, as well as even the early Swedish study, really were in the early years soon after glyphosate was first introduced on the market. And the reason that is important is that cancer really -- all types of cancer take many, many years, if not decades, to occur after someone is exposed to a substance. So if you only have a short amount of time between when people in your study might theoretically first start using glyphosate and when the cancer cases were collected, you just really -- you are concerned that you don't have enough -- what we call -- latency period for the cancer to really occur.

Third -- the third issue with all of these studies is the small case numbers. And what I mean by that is not the total number of non-Hodgkin's lymphoma cases, but actually -- what is actually more important when we think about the power of a study is the number of cases that were exposed and the number of controls that were exposed. And those numbers were, for all the case control studies, were very small.

And then finally, really an important aspect of any epidemiology studies is this idea that you want to disentangle -- when you are looking at the association, the exposure, you are looking at from all of the other factors that people might be doing at the same time. You want to separate those things out. And so in this case, these studies did not properly adjust for the use of other pesticides in their analyses.

Q. Okay. So now just please give us, as I said, a brief overview of the Agricultural Health Study.

A. So as we talked about, I mean, this study did have some potential issues. However, there were a lot of strengths in the study as well.

First is the power of the study. Its overall size in terms of the number of exposed cases was tenfold or greater than the number of any of the exposed cases in the case control study, so really a much larger study. And the timeframe of when the cases were diagnosed, you could really start to look at whether being exposed for 20 or more years or 10 or more years led to cancer risk that some of the earlier studies could not do.

Secondly, the way they captured cancer in the Agricultural Health Study was by linking it together with cancer registry data. And why that was important was in cohort studies, you want to make sure that you are able to capture every case of

cancer that occurs. And using these cancer registries allows that to happen.

Third, because, you know, again, because this study wasn't exploratory, it was very focused on the hypothesis about glyphosate. They did a very careful adjustment and approach to adjusting for other pesticides.

And then finally, there is a number of validation studies that were done to assess the quality of the information that was being collected.

Q. So when you say "validation," I just want to make sure -- I want to put a pin in that. What does that mean when you say something is being validated?

A. So, you know, in this example, in the Agricultural Health Study, we have data that was being collected from questionnaires. We can then compare that information on the questionnaires with some sort of what we say "gold standard," and see how -- what the quality of the information is. And that's pretty important to assess and show that the way you are collecting data in your study is a good quality.

MS. MATTHEWS JOHNSON: May we show the next slide on the Agricultural Health Study?

MS. WAGSTAFF: No objection.

MS. MATTHEWS JOHNSON: No problem.

BY MS. MATTHEWS JOHNSON

Q. So we have looked at this before. The Agricultural Health

Study ran for years, and there are -- is it fair to say that there are a lot of publications, a lot of articles that came out of the Agricultural Health Study over those many years?

A. Yes. To date there have been more than 250 publications that have been published on this cohort.

Q. And then there is the cohort consortium, and I see two studies you are involved with; and the Agricultural Health Study is involved there as well; is that right?

A. So the National Cancer Institute has formed a consortium of all of the cancer epidemiology cohorts. There are now 40 cohorts, part of the consortium from 15 different countries. The Agricultural Health Study is one of the 40 cohorts included in this consortium.

Q. So I'm just going to show you now the findings from the two papers that related to glyphosate, one in 2005.

MS. WAGSTAFF: No objection.

BY MS. MATTHEWS JOHNSON

Q. And so in 2005, is it true that as a result of the 2005, there was no association between glyphosate exposure and all cancer incidence including NHL? Was that the finding in 2005?

A. Yes, it was.

Q. And then in 2018, was there another paper that made the same finding?

A. Yes. So in 2018 they actually had 11 to 12 additional years of information for whether cancer occurred. They had

more than ten times greater number of cases and exposed cases, so really a much more powerful analysis of this question. They found no association and no evidence of any dose response between glyphosate and cancer overall as well as for non-Hodgkin's lymphoma and any of the subtypes of non-Hodgkin's lymphoma.

Q. And did this paper from 2018 actually get an award?

A. Yes, it did. So the lead author of the study received Outstanding Research Paper by staff scientists from the director -- one of the directors of the National Cancer Institute.

Q. Okay. So next I want to talk about one of the publications that was early on, Alavanja 1996. It is -- if you want to turn to it -- we are not going to comb through it right now, but if you want to look at it --

MS. WAGSTAFF: Do you have a binder for me?

MS. MATTHEWS JOHNSON: Yes, we do need a binder. So sorry. She doesn't have one either. We are all going to get binders. Thank you.

May I approach the witness, Your Honor?

THE COURT: Sure.

BY MS. MATTHEWS JOHNSON

Q. We are not going to comb all the way through this paper, just to be clear. But if we look at -- it is Exhibit -- for the record -- Alavanja 1996, it is Exhibit 1021.

Doctor, just a couple things out of here. Is it, in your experience as an epidemiologist, common to publish a paper as a big study like this is getting underway?

A. Yes. This is very standard to present an overview of the study during the first couple of years of its conduct.

Q. Okay. And does it talk about the goals of the study, for instance?

A. Yes, it does.

Q. All right. And just some baseline information. Is there a table in there where they talk about pesticide use as the study is about to begin?

A. Yes, in table 1.

Q. Okay. And what was about the average number of years that people were already using pesticides at the time that the study started?

A. So on average in this cohort they were using for 23 years of pesticide exposure, and that is just the average use in the population. Some people were using actually for many more years than that.

Q. And what about days per year?

A. So on -- again, on average, they were using pesticides for about 15 days per year. But, again, that is the average, and a lot more people were using more than that.

Q. Okay. And then at the time -- and I know that this came out in a later publication -- but at the time these 50-plus

thousand people got involved in the Agricultural Health Study, what percentage of people were already using glyphosate?

A. So 75 percent of the participants at the very start of the study were already using glyphosate, so about three in four of the individuals.

Q. At the start?

A. At the start.

Q. And is there some discussion in here, even in these early years, about how to measure exposure? Can you tell us about the 200 families that they talk about in this study?

A. Yeah. So they were -- since the information on pesticide exposure was one of the important factors they were studying and they wanted to make sure that the quality of that data was really high, and so they used -- they recruited 200 farm families to be able to look at how well the data they are collecting from the questionnaires related to internal measures that are measured in urine. So urine is one way that we measure different compounds such as pesticides. So they could use these data to test the validity of the questionnaire data.

Q. Okay. So let's look at a little timeline.

THE COURT: Any objection?

MS. WAGSTAFF: No objection.

BY MS. MATTHEWS JOHNSON

Q. So first we see here 54,251 people do the first questionnaire when they sign up in the mid'-90s; is that right?

A. Yes, it is.

Q. Okay. And you have this arrow pesticide information going back. So is this the questions about pesticide use?

A. Yes, so exactly. So on -- at baseline at the start of the study they were asked not only whether they were currently using different pesticides, but also about what type of pesticides they used all the way back to the 1950s in some cases.

Q. And there is a cancer info arrow, and it is going forward. So just to be clear, what does that mean about the cancer information that this study was going to collect for this 54,000 people?

A. Yes, so -- so none of these individuals at the start of the study had cancer; and that is, again, one of the important features of a cohort study. So they were able to link all 54,000 individuals over time and identify in every case all of the cancer cases that occurred in this population.

Q. So let me ask you this: If 75 percent of these people had already reported glyphosate use, if any -- any of that group of 75 percent of those people had gotten any kind of cancer since that first questionnaire, was the study going to keep -- capture that data?

A. Yes. And also even for the 25 percent who were initially unexposed in both groups, all of the cases of cancer would be identified.

Q. Okay.

MS. MATTHEWS JOHNSON: May I go to the next slide?

MS. WAGSTAFF: No objection.

BY MS. MATTHEWS JOHNSON

Q. So I think you have already talked about this the cancer databases. Is this actually a legal requirement for doctors? They have got to report these cancers?

A. Yes. In all 50 states in the United States it is mandated, it is legally required, that physicians report every diagnosis of cancer. And that's the way that each state tracks the -- you know, how big the cancer burden is in their state. So it is legally required.

Q. Now, I would like to talk a little bit about questionnaires, just briefly.

MS. MATTHEWS JOHNSON: May we go to the next slide?

MS. WAGSTAFF: No objection.

BY MS. MATTHEWS JOHNSON

Q. So we have heard some testimony about these questionnaires that folks got when they came in to get their license application. Did you actually read Dr. Ritz's testimony?

A. Yes, I have.

Q. Okay. And there was a lot of conversation about people don't really want to do this. They come in. They just want to get their license and get out. In your experience with enrolling people in studies and your breadth of experience in

this area, do you agree with that?

A. No, absolutely not. If anything, the people who decide they want to be a part of a study, like a cohort study, are very committed to not only being a part of the study but really learning about their own health as well.

Just as a quick sidenote, being part of this Health Professionals Follow-up Study where people have been part of it for 30 years, when a participant dies, we often get notes from the family members telling them about how important being part of this cohort study has been in their life. So, if anything, I think there is good evidence to suggest the opposite; that people really want to be a part of the study.

Q. In terms of knowing whether people took it seriously and filled in the information accurately, were there actual articles written as they tried to make sure they had a good questionnaire or getting good information?

A. Exactly. You know, as we mentioned earlier, when you are collecting data from questionnaires, you do want to be, as an epidemiologist, thoughtful about whether the information that you are collecting is a good quality.

And so one way that you can look at this is by doing different validation studies. And so there have been several different validation studies to assess the quality of the information that has been collected, and all of these studies together have shown that the questionnaires have been able to

collect very good data on pesticides, including glyphosate.

MS. MATTHEWS JOHNSON: Go to the next slide.

MS. WAGSTAFF: No objection.

BY MS. MATTHEWS JOHNSON

Q. So we have talked about there is a first questionnaire. I just want you to explain just very briefly, the 4,000 people who returned a year later. What happened with that?

A. Yeah. So, you know, out of the 57,000 individuals who have filled out the first questionnaire, 4,000 of them had to come back about a year later to renew their pesticide application, you know, licenses. And so that was a natural experiment in which the investigators can say, Hey, let's use these 4,000 individuals since they are coming back, to allow us to assess the consistency of the information they provided on the first questionnaire. They basically gave them the same questionnaire they filled out at baseline, and then they could compare the answers and say -- you know, if they said they were ever smoking at the start of the study, did they still report they are ever smoking. If they ever used this pesticide, are they still saying they ever used that pesticide.

Q. And how good do they think the questionnaires were, running this test with the 4,000?

A. So they found really high concordance or agreement on the two questionnaires for the pesticides. And, in fact, for many of the pesticides, including glyphosate, the consistency of the

information was even higher than for factors such as physical activity, which we use commonly in studying epidemiology. So the data of quality was quite good for the pesticides, including glyphosate.

MS. MATTHEWS JOHNSON: Can we go to the next slide?

MS. WAGSTAFF: No objection.

BY MS. MATTHEWS JOHNSON

Q. All right. Now, there has also been some discussion about whether people would really want to do this. And so this is just -- just a snippet from the letter -- a letter that went out. And this is the letter that went with the questionnaire; is that right?

A. Yes, it is.

Q. Okay. If you can just read the first sentence of the second paragraph.

A. The study will give you information you may find helpful in making decisions for your health and the health of your family.

Q. And in your experience someone coming in and joining a study, are they going to want to provide good information?

A. Yes, absolutely.

Q. And do they maybe want to get good information as a result?

A. Absolutely. So, you know, given that there were concerns that farmers might be at increased risk for different diseases,

you know, it makes a lot of sense that people would really want to participate and give good quality data --

MS. WAGSTAFF: Your Honor, this starts to call for speculation.

THE COURT: Overruled.

THE WITNESS: So we know this from the cohort studies that I have been engaged in where, you know, people want to give accurate information because they care about their health. They care about things that are happening to their families.

BY MS. MATTHEWS JOHNSON

Q. So let's take a look at a question -- just one of the questions. We are not going to go through the whole questionnaire.

This is just one question. And going through it, was -- let me be clear here. This is about -- one question about Roundup. And just for the record, Jury is another name for a different brand of Roundup, correct?

A. Yes.

Q. Not a jury like a jury in a courtroom.

A. That's right.

Q. Okay. But there was a long list of pesticides; is that right?

A. Yes. There were data collected on 50 different pesticides on the questionnaire.

Q. Okay. And if you could just go across and just tell us

what they were asked about.

A. Right. So there were several different pieces of information collected. They first asked participants to report whether they had ever used glyphosate or -- in this case glyphosate -- but other pesticides. They asked how many years they had either personally mixed or applied the pesticide in an average year, how many days were the individuals applying the pesticide, and then finally they asked how far back did you first start using this pesticide so they could really get a cumulative estimate of the total number of days over a person's lifetime that they were using the pesticide.

Q. And was there eventually a second questionnaire?

A. Yes, there was. That questionnaire was asked about seven years after the first questionnaire.

Q. All right. And tell us how many people were interviewed, live by phone, in that follow up?

A. So there were data completed on the second questionnaire by 34,698 of the original participants.

Q. Let me just say right off top, 34,698 is definitely --

A. Yes.

Q. -- less than 57,310; is it not?

A. Yes, it is.

Q. Okay. So in your experience in doing this kind of work when you have gone out into the field to gather information, have there been times where you can't get back in touch with

everybody you got in touch the first time around?

A. Yes. Absolutely. One particular study that I worked on was a cohort of women from Sweden where only 70 percent of the women completed the second questionnaire.

Q. Okay. And so that meant you went from 100 percent down to 70 percent?

A. Yes.

Q. In that particular study?

A. Yes.

Q. All right. Were you still able to get useful data out of that study?

A. Yes. But, I mean, to be clear, when you don't have complete data, and you do have missing data for this, it is a reason to be concerned. So you want to assess are there any differences in the people who gave the second questionnaire than those who didn't. Is there any reason that this missing data might lead to some sort of bias.

So it is a reasonable concern to have, and I think one of the important features of the investigators in this study was they tested in several different ways to see whether this missing data caused a problem here, similar to what we did in our study of Swedish women.

Q. Okay. So let's go to the next slide, if there is no objection. And, again, we are just looking at a few papers -- and we are not going to dive into each one of these -- but this

missing data question, was it something that people thought about and wrote articles about and tried to figure out?

A. Yes, they did. So one of the first things they did was to compare the people who completed the second questionnaire versus those who only completed the first questionnaire. And what was reassuring was when you looked at a range of different lifestyle factors and use of different other factors in the study, there really were no differences in the population. So that gives you some reassurance that this missing data might not cause problems, but then -- sorry.

Q. Then let me just ask. There has been a word that has been thrown out here over the past several days called "imputation." Are you familiar with that concept?

A. Yes, I am.

Q. Is that something you have ever used in your work?

A. Yes, it is.

Q. And so is imputation like guessing?

A. No, it isn't. It is a well-established method that epidemiologists and scientists use in our research to address missing data.

Q. Now, when Dr. Ritz was here last week, she talked about someone called Farmer Ted. And Farmer Ted was somebody who wasn't using Roundup during the first questionnaire and so he reported no use. And then he didn't fill out the next questionnaire. And so him -- but he became a Roundup user. So

you get lost, right. You get lost in the data because you are listed as not being a user. You don't fill out the second questionnaire. So then he might be missing.

Do you recall reading that in the testimony?

A. Yes, I do.

Q. So did Dr. Ritz's criticism about Farmer Ted change your confidence in the data from this study?

A. No, it did not.

Q. Okay. Well, why is that? Why is that?

A. So, first of all, it is important to remember that already at the first questionnaire at the start of the study, three-quarters, or 75 percent, of the individuals were already using glyphosate. And then on the second questionnaire for those who completed it, during additional seven years only 5 percent more, or a total of 80 percent, so only 5 percent started using it.

So when you think about the information on the people we didn't have data on, it was a really, really a small number of individuals. And when you have the potential for bias; but it is only occurring in a very, very small number of individuals, it really can't have any impact on the overall results of your study.

Q. Okay. So I want to understand. So 75 percent at the very start said they were using glyphosate. So if any of those people ever develop cancer, even if they didn't fill out the

second questionnaire, would that have been captured in this study?

A. Yes, it would.

Q. And what you are saying is there was an increase, a little bit of an increase, from 75 to 80 percent --

A. Yes.

Q. -- but that increase was small; is that right?

A. Yes. Exactly, yes.

Q. Okay. And just to be clear, there were second questionnaires from almost 35,000 people; is that right?

A. Yes, that's correct.

Q. And so did the folks in Andreotti actually look at just the 34,000? I just want to go to the article. This is from Andreotti 2018 -- where they only looked at the 34,698 people who actually filled out both questionnaire. Did they do that?

A. Yeah. So I think we talked about this study actually receiving an award, and I think the reason for this is that they did a very thoughtful analysis really across this study to look at whether bias from this missing data might have caused a problem. They looked at it in three different ways.

One of the ways they looked at it was, let's just look at the association between glyphosate use and non-Hodgkin's lymphoma in all 35,000 individuals where we have complete data, and they did -- they saw no association, no evidence of dose response. And, in fact, their findings from that analysis were

basically identical to the analysis where they used the data that was imputed. So it gives you, again, another reassurance that this method of imputation did not introduce any bias. And then you could really test that here by looking at all 35,000 people that had the complete data.

Q. So when you say "the complete data" for the 34,698 people, there is no imputation for 34,698 people, is there?

A. No, there is not.

Q. Because you have the two questionnaires?

A. Correct.

Q. So next in 2019 -- and there has been some discussion that there was criticism, right -- that there was criticism after Andreotti came out about imputation -- at some point did the authors write a letter in 2019 and say -- and actually go back and look at this information one more time?

A. Yes. So there was a letter -- and this is a pretty standard approach for having scientific discussions is when a study gets published, other outside people might write a letter raising concern about an issue in the study. So Sheppard and Shaffer wrote a letter raising concerns about the imputation. And so what was really nice to see again with the Agricultural Health Study investigators is they looked to see whether, if they did the imputation method differently, would they then see an association. But, in fact, when they did this new approach to imputation, again, they didn't see any association between

any glyphosate exposure and non-Hodgkin's lymphoma, and, therefore, concluded that the imputation method did not introduce meaningful bias in their study.

Q. So next I would like to talk about exposure.

MS. WAGSTAFF: No objection.

THE COURT: Before we go to that, this is probably a good time for our morning break or a morning break.

Remember the different schedule today, everybody, that we are stopping at 1:00 o'clock, and we will just take an extra morning break or two. And we will resume at ten after the hour. Thank you.

(Proceedings were heard out of presence of the jury:)

THE COURT: Why don't we knock out discussion of the Levine issue that you had raised. The upshot here is that I think -- I don't -- I think it is the same issue as Dr. Arber. I don't think that, you know, this response to Shustov comes in because it hasn't come in at the trial because his testimony hasn't come in at the trial. I don't understand how -- I can give you one more chance to explain if you want, but I don't understand how this is any different from how I ruled about Dr. Arber's testimony.

MR. STEKLOFF: Okay. I think the difference, Your Honor, is that -- I think at least part of the basis for your ruling about Dr. Arber was that this opinion was not disclosed. If we walk back through first --

THE COURT: Well, not only was it not disclosed, again, it was inconsistent with -- the implication of what you were proposing Dr. Arber to say was inconsistent with what he did disclose.

Anyway, go ahead.

MR. STEKLOFF: But I think -- I understand that. That's not an issue with Dr. Levine, I don't believe, because I think Dr. Levine very clearly says in her report that BCL6 is associated with the hepatitis C virus. She has literature that she cites is included in her reliance materials. And I will say it is also literature that demonstrates that once HCV is treated through antiviral therapy and there is a sustained viral response, that that does not mean that genetic mutations associated with HCV are automatically eliminated, and it specifically cites to BCL6.

THE COURT: And everything you just said, everything you just said is fine, I think.

MR. STEKLOFF: Right.

THE COURT: The only thing that I am precluding is the testimony that you look at -- when you look at Hardeman's slides that it -- that you see BCL6 mutations that are consistent with having had hepatitis C. That is the part that I'm not allowing.

MR. STEKLOFF: Understood, Your Honor. And if I can just try one more time.

The reason why I think that should be admissible is Dr. Weisenburger's testimony. So Dr. Weisenburger stepped down from the stand and walked through a chart demonstrating that there were translocations in a study that he said were eliminated when you looked at the 15 or so -- the 15 or so patients that were in that study. He said they have certain translocations. It was not BCL6. I think it was something called T14 and T16. This is at approximately page 1207 of the transcript.

He then I think -- I don't remember if he was still in the gallery or at his seat -- but he -- but following up on that discussion, at page 1210, he was asked, So once he was cured in 2006 of hepatitis C, what happened to any abnormal cells he may have had based on the data here?

And then I objected. It was overruled.

And then Dr. Weisenburger went on to say that specific mutations were eliminated.

THE COURT: I understand -- I understand the argument. The same concept applies as applied to Dr. Arber.

MR. STEKLOFF: Thank you, Your Honor.

THE COURT: Okay. Thank you.

(Recess taken at 10:05 a.m.)

(Proceedings resumed at 10:12 a.m.)

(Proceedings were heard out of the presence of the jury:)

THE COURT: Okay. You can go ahead and bring in the

jury.

(Pause in proceedings.)

(Proceedings were heard in the presence of the jury:)

THE COURT: Okay. You can resume.

MS. MATTHEWS JOHNSON: Thank you, Your Honor.

Q. Good morning, Dr. Mucci.

A. Good morning.

Q. Before we turn to exposure, I want to draw your attention to Andreotti 2018, Exhibit 1032, and if you could go to page -- the second page, "Statistical Analysis," please.

And I wanted to make sure that it was clear that there were some people who moved outside the state; and if they were documented to have moved outside the state, were they excluded from the analysis?

A. Yes, they were.

Q. And according to Andreotti 2018 under "Statistical Analysis," is it a few hundred people?

A. Yeah. 300 people were excluded from the study.

Q. So we were next going to go to the exposure method.

MS. MATTHEWS JOHNSON: May I show the next slide?

MS. WAGSTAFF: No objection, Your Honor.

MS. MATTHEWS JOHNSON: And while -- if we may have the screen, please.

Q. All right. So, first, tell us what does "exposure" mean in the context of AHS and pesticides?

A. Yeah. So in our epidemiology research, we want to try to estimate what the exposure is inside our body to different factors, including pesticides. So the exposure assessment is the way in which we tried best to use the questionnaire data to measure that internal amount of exposure.

Q. Okay. And --

MS. MATTHEWS JOHNSON: May I show the next slide?

MS. WAGSTAFF: No objection, Your Honor.

BY MS. MATTHEWS JOHNSON:

Q. So looking at the next slide, this is from Dosemeci. So we saw that there were publications about the exposure issue, and is there a Dosemeci approach to this or an equation or algorithm that's used?

A. Yeah. So this was the first algorithm that the AHS investigators used to try to estimate the best dose of exposure to pesticides, including glyphosate.

And in this --

Q. And we'll talk about it, I think, in a little bit --

A. Yeah.

Q. -- but I just wanted to make sure there was one approach.

And then what did Coble do in 2011?

A. Yeah. And just to kind of explain, so originally, you know, they were interested in looking beyond just the number of days or years somebody was using a pesticide, could additional information be included in that algorithm or in the model to

predict better the exposure. And so this was the first approach that the AHS investigators used.

And then about 10 years later, they actually improved this algorithm where they used those biomarkers or biological levels of the pesticides in the urine and compared it to the questionnaires. So they were actually even able to improve the algorithm for measuring the best estimate of exposure to the pesticides.

Q. So going next to another article or questions -- excuse me -- that were asked, were the folks in the AHS asked about how they applied pesticides?

A. Yes. So they were able to check all the different ways in which they applied pesticides, including whether they were using a hand spray gun or whether they were using an air blast, for example. So they could actually check multiple responses here with the idea that different ways in which you apply it might lead to different amounts of exposure inside the body.

MS. MATTHEWS JOHNSON: May I show the next slide?

MS. WAGSTAFF: No objection.

BY MS. MATTHEWS JOHNSON:

Q. And did they also ask about protective equipment?

A. Yes, they did. So, again, each person in the study could fill out all the ways they might use protective gear. So, for example, using goggles or wearing gloves or just reporting that they didn't use any type of protective gear. Again, with the

idea the more protective gear, the less exposure there would be inside the body.

Q. Now, was there a separate article by somebody else named DellaValle that asked the question about whether people were using any personal equipment at all?

MS. MATTHEWS JOHNSON: May I show the next slide? This is DellaValle.

MS. WAGSTAFF: This is the next slide?

MS. MATTHEWS JOHNSON: Yes. It is DellaValle.

MS. WAGSTAFF: No objection.

THE WITNESS: So --

BY MS. MATTHEWS JOHNSON:

Q. And this one -- go ahead, Doctor. Please.

A. So in this particular study, the Agricultural Health Study investigators presented information about how common it was, for example, to use protective gear.

And so from this study, what we could see was actually that less than half of the AHS participants were actually using any sort of protective gear when they were applying or mixing pesticides.

Q. So they looked at 20,000 farmers and they asked them this question. And just to make sure we're clear, this is a table from that article; right?

A. Yes, it is.

Q. And they're asking about personal protective equipment

when applying, and then they said "How many had an affirmative response?", which is I think a confusing way to put that, but what does that mean?

A. Right. So, you know, less than half were actually using protective gear and, therefore, more than half were not using the protective gear.

Q. Now, we talked a little bit about there's Dosemeci and Coble and these algorithms, and we are not doing the algorithms, but --

MS. MATTHEWS JOHNSON: May I go to the next slide?

MS. WAGSTAFF: No objection, Your Honor.

BY MS. MATTHEWS JOHNSON:

Q. Just tell us generally what they tried to do with this information that they got, what they were asking and what they tried to do with it.

A. Right. So they had all of these six different types of information that were collected from the questionnaires, and they built an algorithm or basically just a mathematical model that they could then compare and say, "Using these six factors, how much exposure is any participant getting from different pesticides?" And then they could actually compare it.

So essentially they included information in this algorithm on how many days they were mixing or applying, how many years were they mixing or applying, what method did they use for applying, did they use protective gear, did they personally

mix; and then, finally, did they mix -- fix any equipment with the idea, again, that you might get more exposure from that. And they put all of that information together and then could assign people as having no exposure to glyphosate, small amounts, moderate amounts, or very high exposure to glyphosate.

Q. And so in Andreotti 2018 where they're presenting all this different data, is there a set of data that is broken down into quartiles?

A. Yes. So they took all of the individuals in the study, and basically for those who -- the 80 percent who had ever used glyphosate, they divided them into four equal groups. And so then you could look at -- as I said, like looking at those who only had a low-level of exposure to glyphosate, those who had a moderate level, and those really who had the highest level.

Q. Okay. And so were there four levels that they had ultimately? So the quartiles is for four levels?

A. Exactly.

Q. Okay.

A. Yes.

Q. Now, when you look at the actual numbers of cases of NHL in each of those quartiles, is that data actually shown by number in the Andreotti 2018 paper?

A. Yes, it is.

Q. Okay.

MS. MATTHEWS JOHNSON: May I go to the next slide?

MS. WAGSTAFF: This is the next slide?

MS. MATTHEWS JOHNSON: Yes.

MS. WAGSTAFF: No objection, Your Honor.

BY MS. MATTHEWS JOHNSON:

Q. And just tell us here what we see.

A. So the way they divided the exposure data was into quartiles, and what that means is dividing people into four equal groups. So you can see in each of those who had exposure to glyphosate, there were all people -- there were the same number of people.

And then you can see at the bottom, those are the number of non-Hodgkin's lymphoma cases in each of the groups, including the group that had no exposure to glyphosate.

Q. And so in the lowest group there were -- in the group with no exposure to glyphosate, Andreotti 2018 reports 135 diagnoses; is that correct?

A. Yes, it is.

Q. And then what do they report for the low?

A. 113 cases of non-Hodgkin's lymphoma.

Q. And for the medium low?

A. 104.

Q. And for the medium high?

A. 112 cases.

Q. And for the high?

A. 111 cases.

Q. And as you look at this data, Doctor, what does that tell you?

A. Well, so what it would tell me if you look across the levels of exposure, you don't see any evidence of a higher number of cases or a higher incidence of non-Hodgkin's lymphoma in those who were exposed to the highest levels of glyphosate compared to those with the lowest exposure to glyphosate. So there's no evidence of a dose-response of any sort either.

Q. Okay. And breaking it down to another level, did Andreotti 2018 specifically provide numbers on diffuse large B-cell lymphoma?

A. Yes, they did.

Q. Okay. And so for those who had no exposure to glyphosate, how many diagnoses of DLBCL were there?

A. 27.

Q. And just so we're clear for the record, is the DLBCL number going to be part of the larger NHL number?

A. Yes. It's one of the subtypes of non-Hodgkin's lymphoma.

Q. Okay. So for the low category, how many?

A. There were 28 cases.

Q. And for the medium low, how many cases?

A. 23 cases.

Q. And for the medium high, how many?

A. 30.

Q. And for the high, how many?

A. 22 cases.

Q. And what does this data tell you?

A. So, again, there is no evidence of an increased risk of the diffuse large B-cell lymphoma with the highest quartile of exposure to glyphosate compared to those without any exposure. There's no evidence of any dose-response either.

Q. Now, there's been a lot of testimony sometimes looking at what we've come to learn is a forest plot. There's a dot, and a little line, and the line can cross the 1. But I want to be clear, just because there's a lower number of diagnoses in one group than another group, is that trying to say that it's good for you to use glyphosate?

A. No, absolutely not. The interpretation from the relative risks in the study really are that there's no association -- no evidence of a positive association and no protective association. There's just no difference in the risk of non-Hodgkin's lymphoma or this diffuse large B-cell in the highest groups versus the lowest groups.

Q. Now, let's take a step back. There is an article with the author's name is Koutros; is that right?

A. Yes.

Q. And were you able to take data from Andreotti 2018 and looking at the Koutros article look at what was the rate of NHL in the U.S. population?

A. Yeah. So at the time of the study, the rate of the

population -- the rate of non-Hodgkin's lymphoma was 1.07 percent.

Q. In the United States population?

A. Yes.

Q. Okay. And going all the way back and looking at the whole cohort, that's everybody in the AHS whose data was ultimately captured and included in Andreotti -- we know some people got excluded because they moved and stuff like that -- but if we go back and look at the rate of NHL in the whole cohort, what was that rate?

A. 1.06 percent.

Q. So, again, let me ask you. 1.06 is a tenth of a thousandth less than 1.07; is that right?

A. Yes, although I would say really there's no difference in the rate in those two populations.

Q. Okay. So that's where I was headed. So you're not here saying that it's a lower rate?

A. No.

Q. Okay. So with that difference, what would you say based on that data, Doctor?

A. So those data together with the mathematical analyses that were done in the Agricultural Health Study really show no evidence of an association between exposure to glyphosate and risk of non-Hodgkin's lymphoma and no evidence of an association for the risk specifically for diffuse large B-cell

lymphoma.

Q. So now I'd like to turn and just take a look at a few of the case-control studies.

MS. MATTHEWS JOHNSON: May we go to the next slide?

MS. WAGSTAFF: No objection.

BY MS. MATTHEWS JOHNSON:

Q. So we said at the very outset, Doctor, that you had looked at case-control studies also; is that right?

A. Yes. Correct.

Q. Okay. And you're not here saying that the case-control studies have no value; is that right?

A. No. I'm not saying that, no.

Q. And just let me say, in general, it's possible to look at these and what -- let me ask you. I'm not going to speak.

You tell me. What is the use of those case-control studies?

A. Right. So -- you know, so there had been an observation already back in the 1970s that farmers had an excess risk of non-Hodgkin's lymphoma, and so these early studies, these case-control studies, were exploratory trying to identify what is it about farming that might be leading this increased risk of non-Hodgkin's lymphoma.

So these early case-control studies, they were -- you know, as we talked, had some concerns for bias, but they generated hypotheses and they looked at -- you know, each of

the studies looked at 30 to 50 pesticides.

In those studies they actually saw several pesticides that had suggestively positive numbers, and these then could be things that could be then followed up in a well-designed study specifically addressing the hypothesis for that pesticide.

So really we think about in epidemiology there can be exploratory studies that help think about new hypotheses that we want to test in really well-designed studies.

Q. So if we take a look -- just briefly we're going to run through these because the jury has certainly seen them before.

But at the top here, you're asking a question, and so what are the two things that you're looking at or considering, among others, as you're looking at these studies?

A. So one of the things that I'm looking at is: Are the results properly adjusted for use of other pesticides? Since we know from these studies that people using glyphosate were also using other pesticides, so did the analyses presented in the study properly address for other pesticides and were those results statistically significant?

Q. Okay. And there's been a lot of talk about statistical significance, but is this about the whiskers not crossing the 1? Is that what that's about sort of?

A. Yes. It helps to assess the extent whether you have a chance finding or a false positive.

Q. Okay. And someone has slipped me a very important note,

and I'm going to have to go back one slide because this happens. This is why it's a team effort. Thank you.

I want to go back because we were talking about this issue of dose-response. And if you look here in the column of no glyphosate exposure, that column is white; and if you go over to the high level, it's red.

A. Yes.

Q. And I just want to ask you, do you remember from Dr. Ritz's testimony when she talked about the white paint can and the red paint can and how things can get so mixed up that everything is just all pink? Do you recall that?

A. Yes, I do.

Q. Do you agree that that was possible in this study?

A. No, I don't. So just more generally, when you collect information with questionnaires, you may be concerned that there might be some misclassification and that would lead to this concept. However, when you have data comparing people who don't use any pesticide versus people who are using very high levels of pesticide, you almost never get that kind of misclassification between those two extreme groups.

Another example of this is physical activity. You know, if you're running and training for a marathon -- right? -- you would be in this highest level of exposure, and then you have a group that's very sedentary and doesn't do any exercise, you can see that you're never going to misclassify somebody who's

running a marathon as somebody being completely sedentary and vice versa.

So while you might have a little bit of misclassification in these groups next to each other, the extreme comparisons are never going to have that type of misclassification.

Q. And so speaking from the sedentary couch end, you're essentially saying those kind of people don't typically claim to run marathons?

A. No, correct, and vice versa.

Q. Okay. Going back to the case-control studies. So now we're just going to go through them and just do a quick little overview.

So Hardell, when you looked at that study, did you see results that were properly adjusted for other pesticides and statistically significant?

A. No, I did not.

Q. What about in Eriksson?

A. No. And, again, what you can see, you know, part of this is they didn't do a proper adjustment for confounding. They did not have -- they had very small numbers of cases. They did not have statistically significant associations for these analyses properly adjusted.

Q. What about for Orsi? And Orsi, I think we have all heard, is the French hospital study I think is what people have been calling it.

A. Right. Correct. So the results were not properly adjusted or statistically significant.

Q. And let's talk about De Roos. Just so we're clear, De Roos is a few American studies that were put together; is that right?

A. Yes. It was a pooled analysis looking at the same time at 47 different pesticides, and the challenge with this study is there were only 36 exposed cases, and that study did not do a proper adjustment for confounding, and the result from the hierarchical model was not statistically significant.

Q. Okay. And so we're going to put a pin in that one. We need to pause on that one for just a moment because in De Roos there was a logistic regression that yielded a number that was statistically significant. So what is your concern about using the logistic and what is your concern about De Roos and the reliability of that number?

A. So in the epidemiology, the number -- as I mentioned earlier, the number of exposed cases is really important to the overall power of the study; and on average, you want to have about five exposed cases for every variable you put in your model.

In the logistic regression model, since they put in all 47 pesticides, you actually have less than one exposed case per pesticide in the model so you end up -- and the authors themselves thought to do the hierarchical model as a way of

trying to deal with the fact that they had so few exposed cases.

Q. And, finally, McDuffie, which is also sometimes referred to as the Canadian study, what about McDuffie?

A. Yeah. So McDuffie, again, found no evidence of a properly adjusted statistically significant association.

Q. And just to be clear, McDuffie and Eriksson contain a 2-day and a 10-day purported dose-response, and what is the problem with those numbers, Doctor?

A. So in neither of the studies when they looked at those estimates of dose-response did they adjust for use of other pesticides, and that really is a problem since we've seen in these studies that the people using the most glyphosate are the ones who are also much more likely to be using other pesticides.

So if you don't adjust for other pesticides, you're not being able to disentangle whether an association you see is due to glyphosate or the fact that they're also using other pesticides or using other things farming practices.

Q. Okay. So I want to pause, and you mentioned something called a pooled analysis. We don't see pooled analysis over here on Dr. Ritz's chart, do we?

A. No.

Q. Okay. And do we see meta-analysis over here on Dr. Ritz's chart?

A. No.

Q. Okay. So just on meta-analysis, are you familiar with a paper called Zhang that was published within the past few weeks?

A. Yes, I am.

Q. Have you reviewed that paper?

A. Yes, I have.

Q. What is your opinion of it?

A. So the method that they used to combine in the meta-analysis the six studies was a flawed approach. There are many articles written about the appropriate way to do meta-analysis when you're looking at different levels of exposure. And I can describe it as in this study they mixed -- three of the studies only had ever versus never exposure, two of the studies had very limited estimates of dose-response, and then they had the AHS. So when you're doing that, you're mixing basically apples and oranges and pineapples all together, and it's just not a valid approach to doing meta-analyses.

Q. And let me ask you specifically about AHS, Andreotti, 50,000-plus person study. Did Zhang include all of AHS?

A. No, they did not. In fact, they only used a very small slice, less than 20 percent, of the full data in that study. And the importance of that is that the full power of the AHS was underestimated in that meta-analysis.

I think the other part about the meta-analysis to mention is that all of those case-control studies that did not do a proper adjustment for pesticide use, you're putting those odds ratios into the meta-analysis. So if you put flawed data into a meta-analysis, you're going to get flawed data out of the meta-analysis.

Q. So, for instance, De Roos, is De Roos part of Zhang?

A. Yes, it was.

Q. Okay. And so if De Roos is 35- to 40-year-old data before you put it in Zhang, is it still 35- to 40-year-old data once it's in Zhang?

A. Yes, absolutely.

Q. So next I just want to talk about the Andreotti study and ask the same question, results that are properly adjusted for other pesticides and statistically significant.

And here I want to talk about some of the testimony we've heard about some of these ratios being below 1. And I know you read Dr. Ritz's testimony where she said if it's .87, it's 13 percent protective, it is a negative association. Do you recall that, Doctor?

A. Yes, I recall that.

Q. Do you agree with that?

A. No, absolutely not. In fact, that's not the correct interpretation of that data. When we look at the results from a study, not only do you want to look at that relative risk

number but also the confidence intervals around that because that gives you a range of values that are consistent with your data.

And when you look at that full set of numbers, the proper interpretation and what the interpretation of the authors themselves was was that there was no association.

Q. And as you look at the data overall, Doctor --

MS. WAGSTAFF: No objection.

BY MS. MATTHEWS JOHNSON:

Q. -- what is your finding with regard to the rate of NHL in the general population versus the rate of NHL in the AHS study?

A. Right. So if we were concerned that glyphosate increased the risk of non-Hodgkin's lymphoma, given the fact that 80 percent of the Agricultural Health Study participants were using glyphosate, then you would expect to see the rates of non-Hodgkin's lymphoma higher than the general population but, in fact, that's not what we see at all. The rates of non-Hodgkin's lymphoma in the Agricultural Health Study are the same as that of the general population.

Q. And did you use all of this data -- AHS, case-control studies -- to reach your opinion?

A. Yes, I did.

Q. And what is your opinion about the causal association between Roundup and NHL?

A. Based on my evaluation of all of the epidemiological

studies, there's no evidence of a causal association between glyphosate and non-Hodgkin's lymphoma and no evidence of any dose-response.

MS. MATTHEWS JOHNSON: May I just have one moment, Your Honor?

THE COURT: Sure.

(Pause in proceedings.)

BY MS. MATTHEWS JOHNSON:

Q. And are all of those opinions, Doctor, held to a reasonable degree of scientific certainty?

A. Yes, they are.

MS. MATTHEWS JOHNSON: We tender the witness, Your Honor.

MS. WAGSTAFF: Thank you, Your Honor. Just one second while I get organized.

(Pause in proceedings.)

CROSS-EXAMINATION

BY MS. WAGSTAFF:

Q. All right. Does everyone have their binders?

A. Yes.

Q. Okay. Good morning, Dr. Mucci.

A. Good morning.

Q. My name is Aimee Wagstaff.

And you just testified that you're a cancer epidemiologist; right?

A. Yes.

Q. Okay. You're not an environmental epidemiologist; right?

A. No, I'm not.

Q. Okay. You're a molecular epidemiologist; right?

A. Well, actually, molecular epidemiology is one of the tools I use in my own research to study cancer, but I am a cancer epidemiologist.

Q. And before we get into the substance of your opinions, let's talk a little bit about how you got involved in researching the link between Roundup and cancer. Okay?

Until Monsanto called you and asked you to serve as an expert witness for the company, you'd never researched glyphosate; right?

A. No, I had not.

Q. And until Monsanto called you to serve as an expert witness, you'd never researched Roundup; right?

A. That's correct.

Q. Okay. And, in fact, until that phone call, you'd never investigated any pesticide; correct?

A. I had not done my own research on pesticides, but I've certainly read the literature on a range of different pesticides as they relate to cancer.

Q. Okay. So you'd never investigated any pesticide before Monsanto called you; right?

A. So just to clarify, I have not done my own research but I

have -- I read a number of publications on the topic of pesticides and cancer.

Q. Okay. And Monsanto's lawyer published to the jury that you have over 300 published papers; is that right?

A. Yes, it is.

Q. And none of those relate to Roundup; correct?

A. That's correct.

Q. None of those relate to any pesticides; is that correct?

A. That is correct, yes.

Q. And none of those relate to non-Hodgkin's lymphoma; is that correct?

A. No, that's not correct. I have published some studies on non-Hodgkin's lymphoma. I've also been involved in -- as editor for a textbook on cancer epidemiology, including a chapter on non-Hodgkin's lymphoma.

Q. Okay. And the jury has already heard a parties' stipulation that Monsanto is paying you for your time here today to give an opinion to the jury on whether or not exposure to Roundup causes non-Hodgkin's lymphoma; right?

A. Yes. I've been paid for my review of all the evidence, to write an expert report, and to give my opinion on the evidence of the epidemiology studies.

Q. Okay.

MS. WAGSTAFF: And, Ms. Melen, if we could put up -- oh, I'm sorry.

Can we turn on the -- I'm sorry. It was habit. Can we turn on the --

Q. So I want to make sure that I have your opinion correct Your opinion is that there is no evidence of causal association between Roundup and non-Hodgkin's lymphoma; right?

A. Yes, that's correct.

Q. And this was a slide that you made; correct?

A. Yes, it is.

Q. Okay. It's not that there's a weak association? Your opinion is there is no evidence of any association; is that right?

A. So --

MS. MATTHEWS JOHNSON: Objection. Misstating the testimony.

THE COURT: Overruled.

THE WITNESS: So, no, my statement is there's no evidence of a causal association.

BY MS. WAGSTAFF:

Q. Okay.

A. And just to clarify, in our studies sometimes we see statistical associations, but those statistical associations can be due to bias or confounding. So my opinion is that there's no evidence of a causal association.

Q. Okay. Fair enough.

And your opinion also is that there is no evidence of any

dose-response related to exposure to Roundup and non-Hodgkin's lymphoma; right?

A. So, again, just to clarify, there's no evidence of a causal association of a dose-response.

Q. Okay. So you think the evidence shows a dose-response?

A. No. Again, just to clarify what my opinion is, my opinion is that there's no evidence of a causal association between doses of glyphosate and the risk of non-Hodgkin's lymphoma.

Q. Okay. No evidence whatsoever?

A. So, again, no evidence of a causal association.

Q. And you work for the Harvard T.H. Chan School of Public Health; right?

A. Yes, that's correct.

Q. Okay. And John Henshaw is the current president of the Harvard Chan School of Public Health; right?

A. I'm not sure who that is. Dean Michelle Williams is the head of the Harvard T.H. Chan School of Public Health.

Q. So you're not familiar with Dr. Henshaw?

A. No, I'm not.

Q. Okay. And, Dr. Mucci, this isn't the first time that you've said that there's no risk of a cancer from a chemical despite what the scientific literature says; is that right?

MS. MATTHEWS JOHNSON: Objection to the form.

THE COURT: Overruled.

THE WITNESS: I'm not sure what you're referring to

specifically.

BY MS. WAGSTAFF:

Q. Okay. Isn't it true that in 2008 you were under a congressional investigation for saying that a toxic chemical was not a cancer risk even though the available scientific evidence refuted those statements?

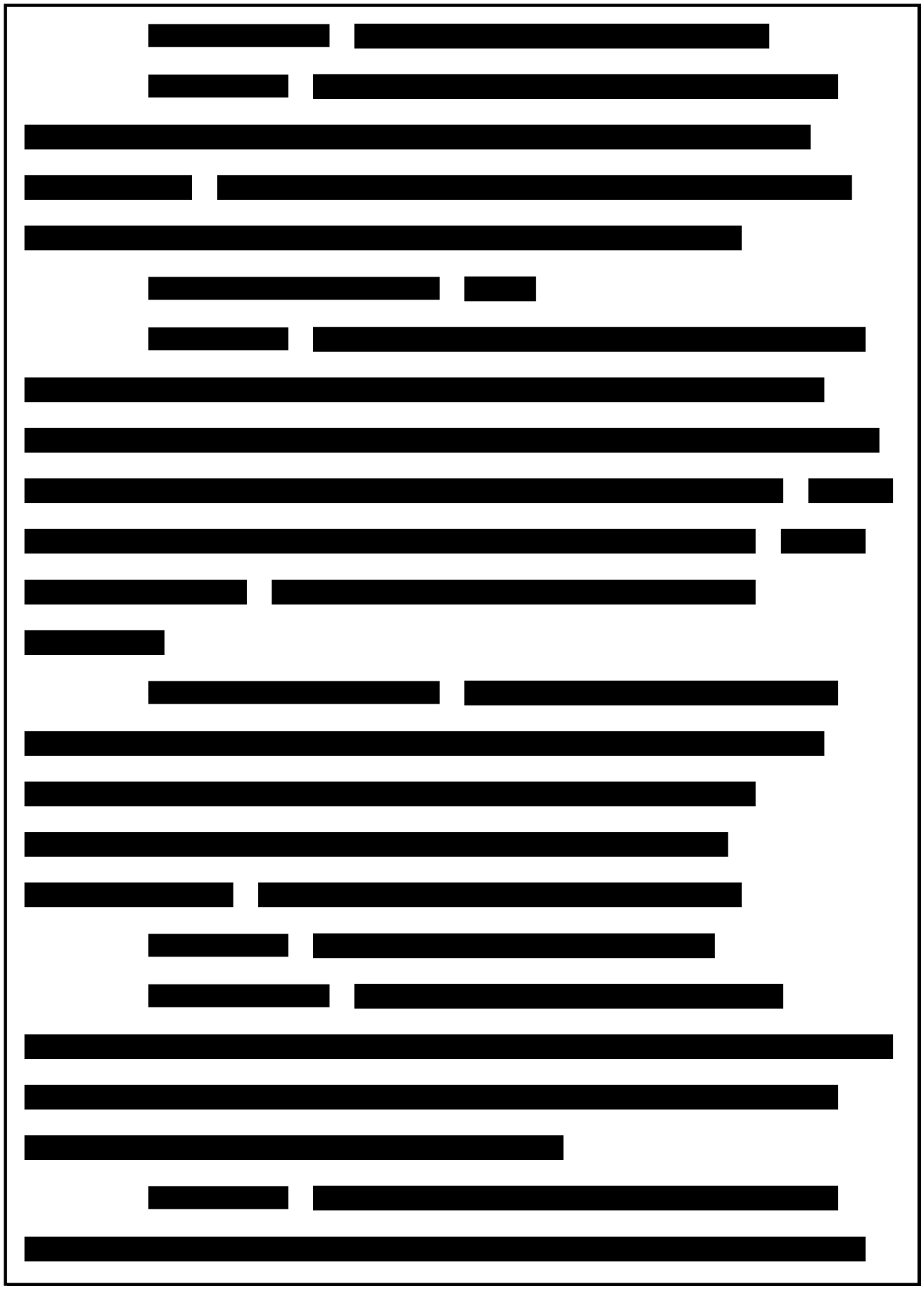
MS. MATTHEWS JOHNSON: Objection, Your Honor. May we have a sidebar briefly?

THE COURT: Sure.

(The following proceedings were heard at the sidebar:)

[redacted]

SIDEBAR



[redacted]

(The following proceedings were heard in open court:)

BY MS. WAGSTAFF:

Q. All right. Dr. Mucci, were you a member of the acrylamide EPA panel?

A. Yes, I was.

Q. All right. And I've handed you a letter that is dated March 13th, 2008, and it is from the United States House of Representatives Committee on Energy and Commerce. Do you see that?

A. Yes, I do.

Q. And it's written by Chairman John Dingell and Chairman Bart Stupak, the Subcommittee of Oversight and Investigations. Do you see that?

A. Yes, I do.

Q. And have you seen this letter before?

A. I have not, no.

Q. All right. And so this letter, if I can direct you to the second page, paragraph 5. And this is a letter setting forth a congressional investigation; is it not?

A. So I'm not sure what this letter is since I've never seen

it before, but I could tell you a little bit about the -- that committee and also my past research; but, you know, I have not seen this letter previously.

Q. Sure. And in paragraph 5 it says "Lorelei Mucci." Is that you?

A. Yes, it is.

Q. Okay. And it says -- and this is some congressmen writing to the -- looks like the EPA and stating that -- it says at the beginning (reading):

"In reviewing this matter, we note that a number of EPA panels assessing the human health effects of toxic chemicals" --

Let me put this on the Elmo.

Congress says (reading):

"In reviewing this matter, we note that a number of EPA panels assessing the human health effects of toxic chemicals" --

THE COURT: I'm going to interject.

MS. WAGSTAFF: Okay.

THE COURT: If you're going to ask questions about this document, you need to describe it accurately.

MS. WAGSTAFF: Okay.

THE COURT: This is not Congress saying anything.

MS. WAGSTAFF: All right.

THE COURT: This is an individual member of

Congress -- two individual members of Congress saying something. So I need you to describe this accurately or I will cut off the line of questioning.

MS. WAGSTAFF: Okay. Sure.

Q. So this is two members of Congress asking the EPA, and they state (reading):

"In reviewing this matter, we note that a number of EPA panels assessing the human health effects of toxic chemicals have included individuals alleged to have pecuniary interests in the chemical industry."

Do you see that? Did I read that correctly?

A. Let's see...

(Witness examines document.) And could you define "pecuniary"? I'm not familiar with that word.

Q. Financial interest.

A. That would be absolutely incorrect. I had no financial interest in the study of acrylamide that was formed in the formation of food. There was absolutely no financial interest that I had.

Q. Okay. And it says, "We note, for example, the following," and it lists nine people, and. Then we go to Number 5, and you had told me that that is you, Lorelei Mucci, and it says (reading):

"Lorelei Mucci sits on the EPA acrylamide panel, but has made the following statements, each of which can be

refuted with the available scientific evidence, prior to her selection on the panel."

Do you see that?

A. Yes, I do. And, again, if I could clarify the work that I've done on this topic of acrylamide, that may be helpful in giving some context for this.

Q. Sure. Absolutely. I just want to get through this paragraph.

And so the two members of Congress tell the EPA that your statements, which can be refuted with the available scientific evidence, are as follows (reading):

"One, there is little evidence of an association between acrylamide from any specific baked or fried potato product and cancer risk; two, the levels of acrylamide individuals are generally exposed to through food do not appear to increase the risk of cancer; and, three, the intake of acrylamide, no matter how much is consumed, is not a breast-cancer risk factor."

Did I read that correctly?

A. Yes, you have. And so, again, if I could provide some context.

Q. Sure.

A. I was a post-doc in 2002 in Sweden when the Swedish Food Administration first found that acrylamide, which is a compound that was formed naturally during cooking practices -- so, for

example, baked potato products and breads have levels of acrylamide -- and so as a post-doctoral fellow, I did research using a number of both case-control and cohort studies investigating whether the amount of acrylamide that people were consuming in their diets increased the risk of several different cancers, including breast cancer.

These particular quotes are coming from the manuscripts that I had published on this topic. Those reports were funded by actually the U.S. Army Breast Cancer Program and the National Cancer Institute. There was no suspicious funding at all in any of the studies, and these particular quotes come from the publications.

And, in fact, now -- you know, this letter was written in 2008 -- in 2019 it's generally accepted by most scientists that the amount of acrylamide that people are exposed to in diet is not a risk factor for cancer, and that's the current state of evidence in 2019.

Q. Okay. Well, I don't want to get into a side trial of whether or not acrylamide is cancerous or not, but based -- back to this letter, these two congressmen were saying that your statements could be refuted by available scientific evidence. Did I read that correctly?

A. Yes. While you read that correctly, actually, again, as I've said, even back then and now, the totality of evidence in the epidemiology studies does not support associations.

In fact, the reason I was asked to serve on this expert panel was because I'd published in the epidemiology literature looking at dietary acrylamide and cancer risk. So that's, in fact, the reason I was asked to serve as an expert panel member.

Q. And, actually, this letter was written, I think we just agreed, on March 13th of 2008; right?

A. Yes. Correct.

Q. And in 1994, actually part of the available scientific evidence on acrylamide was that IARC had found acrylamide to be a probable carcinogen?

MS. MATTHEWS JOHNSON: Objection, Your Honor.

THE COURT: I think it's time to move on. That question is stricken.

BY MS. WAGSTAFF:

Q. Okay. So now let's talk about the opinions you're going to give the jury today.

You're not here to give any opinions about Mr. Hardeman; is that correct?

A. That's correct.

Q. You're not here to give -- you haven't reviewed his medical records; is that correct?

A. I have not.

Q. You have not -- you have no opinion on his exposure history; correct?

A. I've not looked at his records. I'm not commenting on that, no.

Q. And I mean you don't know if he sprayed 1 day or 100 days or 1 year or 26 years; right?

A. No, and that information isn't relevant to reviewing the epidemiology studies.

Q. Okay. And you're not an oncologist; correct?

A. No, I'm not.

Q. And you're not a hematologist; right?

A. No, I'm not.

Q. And you're not a pathologist; right?

A. No. But, again, I'm a cancer epidemiologist, and it gives me the background and expertise to be able to review the scientific evidence on this topic.

Q. Okay. And you're not a hematopathologist; right?

A. No, I'm not.

Q. And so your only opinion today is on whether or not exposure to Roundup can cause non-Hodgkin's lymphoma; right?

A. Based on the epidemiology, yes.

Q. Okay. And that's great. I wanted to move into that.

So to be clear, you're not here to offer any opinion whatsoever on the animal studies?

A. I actually have reviewed the animal studies -- some of the animal studies and some of the genotoxic information --

MS. WAGSTAFF: Objection, Your Honor.

THE COURT: You can continue your answer.

THE WITNESS: -- and that information doesn't change my opinion about whether or not glyphosate causes non-Hodgkin's lymphoma.

BY MS. WAGSTAFF:

Q. But you are not relying on that information for your opinion? I want to be crystal clear to the jury. Your opinion is based solely on the epidemiological literature?

A. No, it's -- again, I have considered some of the animal studies and the genotox studies, and those studies in fact even strengthen my opinion that there's no evidence of a causal association.

Q. All right. And on March 1st, which was just six days ago, we got notice that you reviewed some of the cell studies; is that correct?

A. Well, so, you know, during my review of the epidemiology studies, I had done -- as well as reviewing some authoritative reports, I was very familiar with the animal studies and the genotox studies, and I have since reviewed in detail some of those publications. And, again, the evidence from there actually strengthens my opinion that there is no evidence of a causal association.

Q. All right. I'm sorry. I didn't think this would be that -- that you would have given the answer that you're relying on animal studies and cell studies because I'd never

heard that opinion before.

Could you turn to your testimony --

MS. MATTHEWS JOHNSON: Objection, Your Honor.

THE COURT: Overruled.

BY MS. WAGSTAFF:

Q. Could you turn to your testimony that you gave last -- you should have a book on your testimony.

A. Could you give me some information on where to find it, please?

Q. It's the -- I'm looking for my book actually.

So if you could turn to the testimony that you gave last summer, July 31st, 2000 --

A. I'm sorry. Which book?

Q. July 31st. It says "Expert Reports."

THE COURT: I think you need to give her a tab maybe.

THE WITNESS: I have two books and there's many tabs.

BY MS. WAGSTAFF:

Q. Okay. One is your testimony.

THE COURT: Okay. Why don't you figure out which tab it's at.

MS. WAGSTAFF: Six.

THE COURT: Okay.

BY MS. WAGSTAFF:

Q. There's an index that labels it. So in --

A. (Witness examines documents.)

Q. Are you there?

A. Yes, I am.

Q. Okay. If you could go to page 4318, please.

A. (Witness examines document.)

Q. Actually, that's the wrong cite, so I will... I will come back to that. All right.

So moving on. Sorry, I wasn't anticipating that response.

So you are not here to give any opinion on whether or not Roundup causes tumors in mammals; is that correct?

A. Again, as it relates to my overall opinion that there's no causal association in humans, it was one piece of the evidence that I used in making that assessment.

MS. WAGSTAFF: Your Honor --

THE COURT: Why don't we take a five-minute break. The jury will return at five minutes after the hour.

(Proceedings were heard out of the presence of the jury:)

THE COURT: Okay. And, Dr. Mucci, you should stay in the room.

THE WITNESS: I'm sorry. Should I stay up here or --

THE COURT: It doesn't matter where you stay, but you should stay in the room.

So I don't really understand what's going on here. We had a discussion about this this morning, and Ms. Wagstaff did not ask her if she had read any of the animal studies. Ms. Wagstaff did not ask her if she had read any of the

mechanistic studies. The only thing Ms. Wagstaff asked her was "You're only offering an opinion on the epidemiology."

MS. MATTHEWS JOHNSON: That's right.

THE COURT: And so it seems to me that all of those answers were inappropriate, and I thought we had established very clearly this morning that such answers would be inappropriate.

So I think at this point probably, I mean, I'll listen -- if Ms. Wagstaff wants it, I think it would probably be appropriate for me to instruct the jury that the jury is only to consider Dr. Mucci's testimony about the epidemiology, and that all of her prior responses about the animal studies and about genotoxicity will be stricken and should be disregarded.

MS. MATTHEWS JOHNSON: Well, let me just say first, Your Honor, we were very clear about on direct examination exclusively talking --

THE COURT: Yes, but Ms. Wagstaff did not ask if she'd read the animal literature. She asked "Are you offering an opinion on anything other than the epidemiology studies?" And the answer to that, of course, is no.

MS. MATTHEWS JOHNSON: And to be clear --

THE COURT: But the answer that was given was, "Well, actually, I've read the animal studies and I've read the genotox studies, and they actually support my opinion."

MS. MATTHEWS JOHNSON: Well, let me say first,

Your Honor, I want to take full responsibility if there was any miscommunication with the witness. So let me take, first, full responsibility there.

Second, I want to say I do believe Ms. Wagstaff's question was "You have not looked at anything but the epidemiology?" Maybe this is a question of reading back, but --

THE COURT: I don't think so.

MS. MATTHEWS JOHNSON: Okay.

THE COURT: I mean --

MS. MATTHEWS JOHNSON: And maybe there was confusion on the front end.

Certainly what I think would be potentially appropriate is for the witness to be able to clarify, with Ms. Wagstaff leading the witness through it, that "Your opinion is about epidemiology. You are not relying on any genotox or animal studies," because the reliance question is correct in terms of the reliance.

So I would -- that would be our submission, that Ms. Wagstaff be able to lead the witness through that with a clear understanding that the fact that things have been read is not sufficient to make it a reliance matter particularly given at the posture that we are here at trial.

THE COURT: I mean, I would think it would be appropriate to strike all the prior testimony if that's what the plaintiff wants.

MS. WAGSTAFF: Your Honor, I'd actually like and think a curative instruction is necessary. I raised this prior to the testimony knowing this was going to be an issue. They added the reliance materials last week. I was very careful in my questions. I did everything we discussed.

And now she's muddied the water to the point where I think we need a curative instruction. And I will ask her further questions on it, but I do think the answers need to be struck, and I think your idea of a curative instruction is appropriate.

THE COURT: Okay. And so the curative instruction should be simply for me to say that Dr. Mucci is only permitted to offer an opinion here on the epidemiology?

MS. WAGSTAFF: And not on the animal studies or the cellular studies, yes.

THE COURT: Okay. That's fine.

MS. WAGSTAFF: Thank you.

THE COURT: I'll do that. Okay.

Do you want to go ahead and bring the jury back in?

(Proceedings were heard in the presence of the jury:)

THE COURT: Okay. Welcome back.

So there were -- you heard a series of questions and answers about Dr. Mucci's review of animal studies, toxicology literature, and cellular literature. Dr. Mucci is only here permitted to testify about the epidemiological literature, and so I am striking all of the testimony about the toxicology

literature and the cellular literature and instructing you to disregard it.

You can continue.

BY MS. WAGSTAFF:

Q. All right. Back to where we were. Dr. Mucci, to be clear, you're not here to offer any opinion on whether Roundup causes tumors in mammals; right?

A. No, I'm not.

Q. And, Dr. Mucci, you're not here to offer any opinion on whether Roundup causes malignant lymphomas in mice?

A. No, I'm not.

Q. And you're not here to offer an opinion on whether there's a --

THE COURT: I think we've established that so you can move on now.

MS. WAGSTAFF: All right.

Q. And, Dr. Mucci, regarding the cellular data, you're not here to offer any opinion on whether or not Roundup or glyphosate is genotoxic or causes oxidative stress; right?

A. No, I'm not.

Q. All right. And, Dr. Mucci, you have written a book on cancer epidemiology; right?

A. Yes, I have.

Q. And is this your book?

A. Yes. It's one of them.

Q. Okay. And I'd like to hand you a few pieces. I have photocopied portions I'm going to ask you about?

MS. WAGSTAFF: May I approach, Your Honor?

THE COURT: Sure.

(Pause in proceedings.)

THE WITNESS: Thank you.

BY MS. WAGSTAFF:

Q. All right. So this book was written -- it looks like this was just published last year; is that right?

A. Yes. Correct.

Q. Okay. And so this is pretty recent. These are your pretty recent views; is that right?

A. Yes, it is.

Q. Okay. And so if you turn to the first page, which is page 111. It should be the first page after the cover page. Did I photocopy that right?

A. No. I don't have 111 here.

Q. You don't have page 111? It says "Chapter 6, Concepts in Cancer"?

A. It's not the first page, though.

Q. Oh.

A. So I don't have 111. Sorry.

Q. Okay. Well, we can do this on here then.

You have "Concepts in Cancer Epidemiology and Etiology"; right?

A. Yes.

Q. Okay. And can you tell the ladies and gentlemen of the jury what "etiology" means?

A. So etiology, as I mentioned earlier, is understanding why cancer occurs.

Q. So you have a section on etiology, which is cause -- it's causation of cancer; right? That's just what you described?

A. It's looking at the definition of the cause.

Q. Okay. And if you can turn to page 127, which I hope I included --

A. Yes.

Q. -- there's a "Causal Inference in Epidemiology." I just wanted to orient you to the page. Do you see that?

A. Yes, I do.

Q. Okay. And so then if you turn to the next page, this section of your book is discussing ways to infer causation from epidemiology; is that right?

A. Yes.

Q. And this was published last year, and this is your book; right?

A. Yes, it is.

Q. Okay. And one of the ways that you can infer causation from epidemiology is something looks like called the Bradford-Hill causation analysis; right?

A. Yes. These are a set of guidelines that the authors

Bradford and Hill put together as a guide for assessing causation. It's one of the ways that we think of it.

Q. Okay. And it's my understanding you did not do a Bradford-Hill analysis with respect to the epidemiology in this case; is that right?

A. Yeah, that's correct. And, again, these are a set of guidelines and this is one way in which we assess causation in epidemiology studies, but I did not apply a formal Bradford-Hill analysis here.

Q. Okay. Without getting into the other way that your book says, your book only lists two ways in this section on how to infer causality; correct?

A. Actually, that's not exactly correct. There are two tables here; but if you look throughout the textbook, there's many different ways in which we evaluate whether or not there's a cause. So these are two of the tables, but there are many different approaches we use and that are described here in this textbook.

Q. Sure. Sure. But this section, which is "Causal Inference in Epidemiology," there's only two manners; right?

A. Again, so this is -- this is part of the approach that's described in this particular chapter, but it's not the complete way in which we think about causation. Again, these are guidelines we do use, that can be used, but I did not do a formal Bradford-Hill analysis.

Q. And you didn't do an informal one either; right?

A. Actually, if you look at my report, I do discuss some of the criteria. In fact, in terms of these guidelines, really the only one that scientists agree on as necessary is temporality. So there's actually nine guidelines here. The only one that all scientists agree on is that there has to be temporality, meaning that the exposure has to happen before the disease. The others are, again, a set of guidelines that can be used.

Q. Okay. Excellent. And I'm glad you brought up your report.

The jury heard you talk a lot about the Andreotti 2018 paper, the AHS paper?

A. Yes.

Q. Do you remember that?

A. Yeah. It was one of the studies I referred to in my report.

Q. Yeah. And you spent a lot of time walking the jury through that study. Do you remember that?

A. Yes, I do.

Q. Okay. And what was the date that that study was published?

A. I believe it was published in 2018.

Q. Okay. And what was the date you gave your expert report in this matter?

A. I provided two expert reports.

Q. Your first one.

A. I don't remember the date of that report.

Q. Okay. If you look to the book where it has your testimony -- are you in that book? -- the first page -- the first tab should be your expert report.

A. Yes. So the first expert report was July of 2017.

Q. Okay. So you actually formed your opinions and provided a written report that is 70 -- well, 71 -- 72 pages, typed pages, prior to that publication even being published; right?

A. Well, the first Agricultural Health Study publication had come out.

Q. Sure.

A. We also had a draft version of an updated analysis within the Agricultural Health Study that hadn't been published yet but using the same methodology. So there were actually -- while there wasn't two formal publications, there were two manuscripts from the Agricultural Health Study that I describe in the report.

Q. Sure. So Andreotti hadn't been published yet and wasn't available yet when you submitted your report in this case; is that right?

A. Right. That's correct.

Q. Okay. And you're only here to testify about epidemiology; right?

A. Yes, that's correct.

Q. Okay. And if we can go back to your book in a moment, but you would agree that a chemical can cause cancer in humans even when the epidemiology is considered limited or inadequate? Would you agree with that?

A. Not necessarily. I don't agree with that. I think the definition -- I would think you would want to have the context specific. I think it would really depend on the compound and the exposure.

Q. Sure. So let's turn to page 107 in your book, which hopefully I copied correctly.

So this is a chart that's in your epidemiology -- or cancer epidemiology book. And you would agree -- tell me when you're there, Dr. Mucci.

A. I'm sorry. I don't think I have -- I don't know if I have this here.

(Witness examines document.) Oh, here. Yes.

Q. Do you have it?

And you would agree that these are chemicals that are known to be human carcinogens; is that correct?

A. They're labeled as Group 1 by IARC, yes.

Q. And you consider them to be human carcinogens; right?

A. These are considered by IARC to be human carcinogens. I haven't looked formally at all of these pesticides. I haven't reviewed the evidence for these.

Q. Well, in your book on the page before, it states --

MS. MATTHEWS JOHNSON: Objection. Could you --

THE COURT: I don't know how to rule because I haven't heard the question.

MS. MATTHEWS JOHNSON: I'm sorry.

BY MS. WAGSTAFF:

Q. On the page before you actually state that a Group 1 IARC classification is the benchmark for an identification of human carcinogens; right?

A. Yes, that's written there.

Q. Okay. So you would agree, then, with me that these are human carcinogens?

A. So, again, I -- these are from IARC Group 1 classification. I haven't looked at each of these currently so I wouldn't want to say one way or the other about this set of pesticides here.

Q. Okay. So the --

A. Or chemicals here. Sorry.

Q. Okay. So IARC has classified these as a Group 1 carcinogen, and it's your --

MS. MATTHEWS JOHNSON: Objection, Your Honor.

THE COURT: Overruled.

BY MS. WAGSTAFF:

Q. -- and it's your opinion that a Group 1 classification is the benchmark for a human carcinogen; is that right?

A. Again, it's one of the important ways that we think about causation in cancer.

Q. Sure. And so some of these have -- you'll see right here, and this is a chart in your book, and it's labeled "Group 1, Agents with Less Than Sufficient Evidence in Humans" -- that's epidemiology; right?

A. Yes, it is.

Q. -- "But With Strong Mechanistic Evidence"; right?

A. Yes, that's correct.

Q. And the mechanistic evidence is sort of the cellular data; right?

A. Yes, that's correct.

Q. And you're not here today to give any opinion on the mechanistic evidence of glyphosate causing and Roundup; correct?

A. No, I am not.

Q. So in this chart there are several times when the epidemiology is inadequate, and then this is the animal study section; right? The third column?

A. Yes, it is.

Q. And you're not giving any opinion on the animal studies today?

A. No, I'm not.

Q. And then this column on the far right is the mechanistic evidence. So there are scenarios whereby the human evidence is

either inadequate or limited but it's still considered to be a human carcinogen; correct?

A. Again, this is the list of Group 1 agents, which I think is different than glyphosate, for example. However, I haven't reviewed these specific agents here with respect to their carcinogenicity.

Q. Sure. But this is your book and you have stated that this classification right here is the benchmark for a human carcinogen; right?

A. And, again, just to be clear, I said it's one of the benchmarks --

Q. One.

A. -- that's used for causation. And, again, these are classified as Group 1 carcinogens, but I haven't reviewed these in detail.

Q. Okay. Thank you.

All right. I'd like to talk a little bit about some of the slides that you used. You put up -- first of all, would you agree that there is exposure misclassification in the AHS?

A. So in epidemiology, whether it's a case-control or a cohort study, we are always concerned about misclassification. The more important thing to think about is how much and did it lead to bias.

So while there may be some misclassification, as I described earlier, it seems highly unlikely that there's

misclassification between those in the highest group versus those in the no exposure.

Q. So, yes, you would agree that there is exposure misclassification in the AHS?

A. So, again, I think it's a more complicated answer than just yes or no. There may be some but it's very unlikely in those extreme levels of the highest versus no exposure.

Q. Okay. And if you could turn to, I think it's the book that's right in front of you, and if you could turn to what I believe is 1011, please. And let me know when you get there.

A. (Witness examines documents.) Yes.

Q. Okay. So this is the initial Agricultural Health Study questionnaire; right?

A. Yes, it is.

Q. And you made a slide about this?

A. Yes, I did.

Q. Because you think it's important; right?

A. Yes. It provides information on the way that the exposure dose in the study was created, yes.

Q. Okay. And so this questionnaire, which the jury hasn't seen in total, is 22 pages. It's pretty dense; right?

A. Yes. While that's true, actually, you know, the investigators themselves think that it would take on average 25 minutes. So it's a fairly standard length questionnaire for an epidemiological study.

Q. Okay. And of the questionnaire, you pulled out these two questions to show the jury; right?

A. These -- well, actually, I believe that we pulled out more than just these two questions actually.

Q. Okay. But you did pull out these two questions as being important to show the jury; right?

A. Yes. Correct.

Q. And this questionnaire related to how many chemicals?

A. So this questionnaire collected information on 50 different chemicals -- pesticides.

Q. Okay. So name two of the pesticides. We know glyphosate was one of them; right?

A. Malathion, 2,4-D.

Q. Okay. Let's just -- we can do 2,4-D and glyphosate; right?

So let's say that I use a hand spray gun. You see this first one is "How do you personally apply pesticides?" Do you see that?

A. Yes, I do.

Q. Okay. And this is Number 16 in this questionnaire that you pulled out; right?

A. Yes. Correct.

Q. So let's say that I am a farmer and I use a hand spray gun -- do you see that? That's an option?

A. Yes, I do.

Q. -- to spray glyphosate, but let's say I use a gas canister for 2,4-D. How do I answer this question?

A. Well, so actually you would mark all of the options that apply to you in the way in which you personally apply the pesticides. You would actually fill out both of those.

Q. But it's a bubble question so how do the people know which one applies to glyphosate and which one applies to 2,4-D?

A. Yeah, so, actually, that is a really good question, and you might be worried that because they were asking this general question for pesticides, that it might lead to some measurement error in the dose.

However, I think the investigators actually looked at that in both the Dosemeci and Coble approaches to this algorithm. They looked to see whether the fact that they had kind of just these general comments for all pesticides, whether they could still get an accurate dose of different specific pesticides.

So I agree that, while it could be a potential for concern, that the AHS investigators actually tested to see whether it might lead to measurement error; and, in fact, actually they found that they could get good estimates of exposure with this kind of information.

Q. Okay. So the answer is that the investigators wouldn't have any way to know which one related to glyphosate and which one related to 2,4-D; right?

A. Yes. While that's correct, they applied these measures to

all the pesticides. But, again, it didn't end up making any difference in the estimate of the exposure.

Q. Okay. And so, then, let's look down at the next question that you found was important to show the jury. The next question talks about protective equipment do -- you generally wear when you personally handle pesticides. Do you see that?

A. Yes. Correct.

Q. And, once again, it's talking about 50 pesticides?

A. Yes, it is.

Q. Okay. So let's say that when I use 2,4-D, that's known to cause cancer -- I don't know if it is or not, but let's say that it is -- so I wear face shields and goggles. Then let's say with glyphosate I wear leather gloves. And you mentioned malathion. Let's say with malathion I wear a respirator and a gas mask. How do I fill this out?

A. Right. So, again, the question asks the participants to fill out all of the things that apply to them when they're using pesticides; and for this particular set of information, what was kind of more important was whether or not they ever used any sort of personal equipment or not. That was one of the factors that went into the algorithm.

And, again, I understand that this raises concern about whether asking the question this way might lead to some problems in the assessment of the exposure; but, again, the investigators investigated -- so, first of all, there's two

things.

One, the investigator assessed compared to the biomarker in the urine how well it did at estimating exposure. The other factor is in the Andreotti study they looked at both this algorithm that used things like protective gear and how they applied for the exposure and then also just used the cumulative number of days of exposure. So they said, "Well, if we're worried about measurement error, let's just look at the cumulative exposure without this information." And, again, the results were identical.

Q. Okay. So, once again, the investigators wouldn't have any way to know which protective equipment applied to which chemical; right?

A. Yes. While that's correct, it actually doesn't have an effect on the estimate of internal dose.

Q. Why would the investigators ask questions that don't matter?

A. That actually isn't true. This question actually does matter.

Q. Okay.

A. Because they actually showed in the algorithm having information on whether they used protective gear or the method in which they applied more generally in pesticides actually provided more accurate information about the internal exposure for specific pesticides. So it actually does really matter.

Q. Okay. And you've mentioned a few times now using urine to test the glyphosate. I think I've heard you mention that a few times.

A. Yes.

Q. You're not here to give an opinion on whether or not testing glyphosate levels in urine is an appropriate way to test glyphosate levels; right?

A. No, I'm not.

Q. Okay.

All right. Next I'd like to turn to another chart that you made. And you made this chart; right?

A. Yes, I did.

Q. And your overall view is that cohort studies seem to be better than case-control studies; right?

A. Yeah. And as we discussed earlier, it's not just my view but, in fact, it's actually a standard view of epidemiologists that cohort studies are more -- have more validity than case-control studies.

Q. Okay. And you put up here -- you decided to bring up this that Dr. Ritz had showed the jury; right?

A. Yes.

Q. Okay. And you would agree with me, though, while this could be a general principle, you actually have to look at the specific study; right?

A. Absolutely.

Q. So you can't just make some bright-line rule that cohorts trump all case controls; right?

A. It's correct that you want to look -- in epidemiology you want to look at the individual studies, and actually that's what this particular figure is. It's the summary of all of the case-control studies and the cohort study. Those look to the topic.

Q. Okay. So these are your factors on how you would summarize the case-control studies versus the Agricultural Health Study; is that right?

A. These are some of the highlights of some of the issues in the studies.

Q. Well, these are your highlights that you decided to show the jury; right?

A. These are strengths and limitations that not only I saw when I reviewed the epidemiology studies but, in fact, these are some of the issues that the authors themselves, when they wrote their studies, described.

Q. Okay. So let's just look at a few of them, if you will. You say that the case-control studies are -- well, let me just say -- let me just make sure I understand your chart.

These four under case-control studies, you view these as negative qualities; correct?

A. Yes.

Q. Okay. And these four under the Agricultural Health Study,

you view these as positive qualities; right?

A. Yes, I do.

Q. So you say that the case-control studies in this case should not be trusted because they are exploratory; right?

A. So, actually, that's not what I said. What I said was they have value because of these earlier findings that farming increased the risk of non-Hodgkin's lymphoma. So they're not without any value; however, each of the studies were exploratory. They were not looking at the specific hypothesis that glyphosate increased the risk of cancer. They were looking at 30 to 50 pesticides.

I think another important fact that I haven't mentioned is glyphosate in some of them -- there were many, many pesticides that turned out as positive. So, again, it's this idea that these provide hypothesis to test in a more well-designed analysis.

Q. Okay. And you had mentioned that there were 250 studies that have come from the AHS; right?

A. Yes, that's correct.

Q. Give or take a few?

A. Yes.

Q. But only two that relate to glyphosate and Roundup; right?

A. Yes, that's correct.

Q. And the first one was in 2005?

A. Yes.

Q. And the second one was in 2018; right?

A. Yes, that's correct.

Q. Okay. So if you could turn to -- I'm looking at the -- stay with the same binder that you're at, please, and if you could turn to the first tab, which I think is Exhibit 100.

And you've seen -- tell me when you're there, Dr. Mucci.

A. (Witness examines document.) Yes, I'm here.

Q. All right. If you'll take a moment to look over that document; or if you've seen it, we can --

A. Yes, I'm familiar with this document.

Q. Okay. So this is a document July -- let me get a clean copy out. Sorry.

This is in July of 2000 -- I'm sorry -- of 1997. I made a note on it so I'm covering it up.

And it's written by John Acquavella; right?

A. Yes, it is.

Q. And who is John Acquavella?

A. John Acquavella is an epidemiologist who formerly was an employee of Monsanto.

Q. Okay. So when he wrote this, Dr. Acquavella was actually an employee of Monsanto; right?

A. I'm not sure if he was at the time or not.

Q. Okay. And it's written prior to any results coming out regarding glyphosate and non-Hodgkin's lymphoma; right?

A. Yes, it is.

Q. And it's to the Communication Subcommittee, and it looks like he was asked to provide some background thoughts on "epidemiology and Agricultural Health Study that you could use to build positive messages." Do you see that?

A. Yes, I see that.

Q. Okay. And then he goes on to say (reading):

"The limitations of the AHS can be illustrated by comparison with the hypothetical ideal study."

Did I read that right?

A. Yes, it does.

Q. (reading)

"The ideal study would have the following characteristics..."

Correct?

A. Yes, that's correct.

Q. Okay. And then he lists -- Dr. Acquavella lists a few of those characteristics; right?

A. Yes, he does.

Q. Okay. And then he goes on to sort of give a little summary fashion of each one; right?

A. Yes, he does.

Q. And what he says is (reading):

"Most of the diseases to be studied in the AHS have scant reasoning to link them putatively to pesticide exposure."

Did I read that right?

A. Yes.

Q. (reading)

"Thus, much of the research can be termed exploratory."

Right?

A. Yes, that is what he said there.

Q. And that's not unusual in epidemiology but it is unusual on this big of a scale; right?

A. Yeah. And so that is, in fact, what he said; however, just to be clear, in the case of glyphosate, actually this was a very hypothesis-driven analysis in the Agricultural Health Studies because there were these exploratory studies -- case-control studies that had some suggestive findings. And so, in fact, the study of glyphosate and non-Hodgkin's lymphoma really doesn't refer to what he's saying here.

Q. Sure. So in 1997 before any of the results were known about what the data would show, Dr. Acquavella, who's an epidemiologist at Monsanto, was telling people that the AHS was an exploratory study?

A. No. So, again, to be clear, the Agricultural Health Study collected data on many different exposures and many different outcomes. However, the analysis that was done specifically on glyphosate and non-Hodgkin's lymphoma was a very hypothesis-driven study that was following up on some of the

results from exploratory studies. So you can't describe that particular set of studies on glyphosate and cancer as exploratory as was written here.

Q. Okay. So he doesn't separate out glyphosate in this paper, does he?

A. No, he does not.

Q. In fact, he says the AHS in total; right?

A. Well, he actually follows it up and says much of the research is exploratory; but, again, that's not relevant for this set of studies that was done in the Agricultural Health Study on glyphosate.

Q. Sure. And then it says (reading):

"The downside for industry and agriculture in this approach is that exploratory research tends to yield uncertain findings."

And you would agree with that; right?

A. Well, so that is the issue and, indeed, some of the early case-control studies that looked at so many pesticides did yield some findings that had uncertain validity. And, again, the importance of undertaking whether it's a case-control or cohort study, a very hypothesis-driven analysis, that's going to give you the most certain findings.

Q. Sure. And then he says (reading):

"This energizes pesticide opponents, may cause the public to dictate a market change, and typically makes the

manufacturer adopt a defensive stance."

A. I'm sorry, I couldn't comment on that particular statement as an epidemiologist.

Q. Okay. Fair enough.

(reading)

"It would have been preferable if the AHS had a limited scope and focused more detail on a few worthy questions."

Do you see Dr. Acquavella saying that in 1997?

A. Yes, I see that. And, in fact, actually, I would really disagree as a cancer epidemiologist. All of the cohort studies that I mentioned earlier that are part of this NCI cohort consortium, one of their value is the fact that they collect detailed information on a range of exposures and can look at their association with a range of the cancers.

So, actually, I actually disagree with his statement there because one of the values is you can take with all of this information but do a very hypothesis-driven analysis and design of the study. So even though all the data has been collected, you can still take a very focused look at the data. So I actually really disagree with the comment by Dr. Acquavella here.

Q. Okay. And then Dr. Acquavella goes on to talk about the exposure assessment. And, again, this is in 1997 prior to any data being finalized with respect to glyphosate. And

Dr. Acquavella says (reading):

"The exposure of the assessment in the AHS will be inaccurate."

A. That is what he says. And I can understand. He also says later that usage does not necessarily mean exposure, and that's actually one of the strengths of the fact that the AHS investigators developed this algorithm where they use the information not only about cumulative days of exposure and years of exposure, but also use of positive -- protective gear and the way in which they applied.

So, you know, as I said earlier, you can always worry about misclassification; however, one of the strengths of the AHS was the investigators in multiple ways wanted to assess the quality of the pesticide use, including glyphosate, and actually showed after this memo came out that the quality of glyphosate data and the algorithm used for glyphosate was actually highly valid.

Q. Okay. And then Dr. Acquavella goes on to say (reading):

"Inaccurate exposure classification can produce spurious results."

Do you see that?

A. Yes, I do.

Q. Okay. And then he states (reading):

"In a study of this size, there will be some, perhaps many, spurious exposure-disease findings due to exposure

misclassification."

Did I read that correctly?

A. Yes. And, in fact, that is -- that is standard in epidemiology. If you do have a lot of misclassification of your exposure, you're going to get a spurious finding. However, that's not the case here of glyphosate and non-Hodgkin's lymphoma.

Q. Okay. So you don't agree with Dr. Acquavella's 1997 statement that the AHS was exploratory?

A. The Agricultural Health Study itself collected many, many different pieces of data. What is not exploratory, however, is the actual hypothesis-driven two studies that have been published looking at glyphosate and cancer risk. Those are not exploratory at all.

Again, as I explained, cohort studies collect -- one of their strengths is they collect a lot of exposure information, a lot of different outcome information, in which to look at a range of different hypotheses. So it's actually a strength.

Q. Okay. So you don't agree with Dr. Acquavella's 1997 statement that the AHS is exploratory? Yes or no.

A. No, I don't agree with that.

Q. And you don't agree with Dr. Acquavella's 1997 statement that the exposure assessment in the AHS will be inaccurate?

A. While I agree that we should always, as epidemiologists, be concerned whether it's a case-control or a cohort study

about the quality of the exposure information, it's not the case here.

And that's one of the advantages we have now in 2019, is so many studies have been done to assess the quality of the data on glyphosate and other pesticides in this cohort. So while in 1997 at the beginning you might have been concerned about it as a problem, now in 2019, given all of the studies that have looked at this, we know it's not a problem.

Q. Okay. So to be clear, you do not agree with Dr. Acquavella's 1997 statement that the exposure assessment in the AHS will be inaccurate?

A. Again --

Q. Yes or no.

A. -- it's -- it's --

Q. You either agree with it or you don't.

A. Well, in 2019 given all of the studies that have been done, no, I don't agree with it.

Q. Okay. And one difference between when Dr. Acquavella made these statements in 1997 and as you sit here today testifying to the jury is we know the results now with respect to glyphosate and non-Hodgkin's lymphoma; right?

A. That actually isn't the reason that I say that. The reason --

Q. I'm not asking you if that's the reason. I'm saying --

A. Yes, that is true. Yes, in 2019 we have the two results.

Q. Okay.

A. However, we also have all of these other studies that have looked at the quality of the data.

Q. And you testified next that case controls were bad because they had "early years" is what you wrote there.

A. Well, so this --

Q. Hang on. There's no question yet on the table.

A. Okay.

Q. You're not here to testify or give any opinion on how long it takes to develop non-Hodgkin's lymphoma after exposure to glyphosate or Roundup; right?

A. I wouldn't agree with that completely. I think there -- as a cancer epidemiologist, one of the critical factors we think about is the latency period, what is the amount of time in which it might take for when an exposure first happens and when cancer develops; and having read a lot about the epidemiology of non-Hodgkin's lymphoma and specifically some of these studies, I can get a sense about the amount of time it takes for these kind of things to happen so...

Q. Okay. And you would defer to a doctor who has spent 40-plus years investigating the causes of cancer with respect to the latency issue of how long it actually takes; right?

A. I'm not sure. I'd have to know who this person was or what the qualifications were. But, again, you know, we know, even as an example, with respect to non-Hodgkin's lymphoma, in

World War II there was a huge atomic bomb in Japan that happened and they have followed the survivors of that bomb to see who develops cancer. And that particular study shows, even in this population highly, highly exposed to radiation through the bomb, that you don't see non-Hodgkin's lymphoma develop until at least 10 or more years. You don't see a dose-response.

Q. Okay. And next is small numbers; right?

A. Small numbers of cases, yes.

Q. And that's sort of related to power over here; correct?

A. Yes, it is.

Q. Those are the same thing? Power is the same thing as small numbers; right?

A. Well, small numbers of exposed cases is one of the aspects that contributes to the power of a study.

Q. Okay. And, you know, I've been trying to explain this for a while, but I think that one of your charts actually shows it really well.

You made this chart; right?

A. Yes, I did.

Q. And I just want to make sure I understand this. When you're looking at a chart like this, you have two numbers. You have 11,000 --

A. Yes.

Q. -- and then you have 22; right?

A. Yes, that's correct.

Q. So when you are describing a cohort, you would list the 11,000 number; right?

A. No. And, again, just to be clear, what you would want to first say is what's the overall size of the cohort, how many cancer cases have occurred in total, and how many of the cases had the exposure. So all of those three components are really critical to the power of a study.

Q. Sure. And so when you are, though, describing the size -- when you say -- I think that the jury has heard some numbers thrown around about the Agricultural Health Study and they've been between 50,000 or 80,000 depending on if you include the spouses -- you're using this top-line number; right?

A. No. So, again, just to be clear -- well, maybe I don't understand your question specifically.

Q. Well, when you look at the number, the case-control number is identified as Dr. Ritz identified it, 51 McDuffie; right?

A. Those are the exposed cases.

Q. Yeah. So this is the number down here at the bottom of your chart?

MS. MATTHEWS JOHNSON: Objection, Your Honor. She's showing a different cancer.

BY MS. WAGSTAFF:

Q. I'm just hypothetically talking about how to understand the apples-to-oranges comparison and power between cohort and

case controls.

A. Yeah. So --

Q. There are different numbers that you're looking at. So when AHS has 50,000 people and McDuffie has 51, that's not really a fair comparison, is it?

A. Well, that's not the comparison you would actually want to make.

Q. Okay. Right.

A. In this case you have 51 exposed cases of non-Hodgkin's lymphoma. In the Agricultural Health Study, they had more than 400 exposed cases of non-Hodgkin's lymphoma. So even when you just -- that's the apples-to-apples comparison, and what you can see is that there are more than eight times exposed cases in the Agricultural Health Study as there are in McDuffie.

Q. Okay. And so, then, the last one that you say is bad about the case-control studies is that they fail to properly adjust for other pesticides; right?

A. Yes.

Q. Okay. And then you say that the Agricultural Health Study properly adjusts for other pesticides. So, once again, these two are kind of linked together; right?

A. Yes. Correct.

Q. Okay. And I think one example that you gave, and this is actually your chart -- and, again, these are your cases that you pulled out. You made this chart; right?

A. Yes.

Q. First of all, you showed the jury to make it onto your chart, the cases had to fit two criteria; right?

A. Sorry. I don't understand your question.

Q. To make it onto your chart -- you made this chart; right?

A. Yes, I did.

Q. Okay. To make it onto this chart -- or to get a guess in this chart, I guess, because you wrote "no, no, no, no, no," you would have to be properly adjusted for other pesticides and statistically significant; right?

A. Yes, that's correct.

Q. Is it your opinion that you ignore data that's not statistically significant?

A. So that really depends on the context. So in some cases -- you don't -- first of all, you never ignore any data, but you interpret the data potentially differently depending on the context.

Q. Okay. So you should not ignore data that's not statistically significant; right?

A. In some -- again, it's really context dependent.

Q. So should you ignore data that is not adjusted for other pesticides?

A. Well, again, you should never -- and let me restate what I said. We never should ignore any of the data; and in coming to my opinion about this topic, I didn't ignore any data.

However, when you see a result of a study that's not properly adjusted for other pesticide use, it raises concern that the finding you have, even if it's statistically significant, is not biased.

So -- and just to be clear, just because something is statistically significant does not mean it's a causal association. So, again, just to be clear, I would not ignore any of the data. However, if a result from a study is not properly adjusted for other confounders and it does see a positive association, that makes me -- that gives me a lot of concern about the results of that study.

Q. Okay. Well, let's look at De Roos. This is De Roos 2003; right?

A. Yes, it is.

Q. Because there is also a De Roos 2005?

A. Yes. De Roos 2005 is the first Agricultural Health Study Cohort publication.

Q. Okay. And De Roos 2005 is not on either one of these charts; is that right?

A. No. Although if we put it on the second chart, there would still not be a positive -- a statistically significant association properly adjusted because the AHS De Roos 2005 is properly adjusted for other pesticides but it's not -- no statistically significant finding.

Q. Okay. So I wrote "2003" on there just so we wouldn't get

confused. Is that fair?

A. Yes.

Q. And the jury heard, it seems like forever ago but it was just Wednesday, from Dr. Weisenburger. Do you know who Dr. Weisenburger is?

A. Yes, I do.

Q. Okay. And so I'm going to put up here for you, I believe this is the De Roos 2003 paper, and it is in your book as Exhibit 451. Tell me when you're there.

A. I'm here.

Q. All right. And so you testified earlier -- well, let's go back to your chart.

You say that -- the De Roos 2003 paper, you just told the jury that it's not properly adjusted for other pesticides; is that right?

A. Yes, that's correct.

Q. And what happened in De Roos 2003 is that the authors did a hierarchical regression?

A. Yes.

Q. And they did a logistical regression; right?

A. Yes, they did.

Q. Okay. So let's -- and the other case-control studies -- Hardell, Eriksson, Orsi, McDuffie -- they all did logistical regressions as well?

A. They did logistical -- logistic regression but did not

properly adjust for other pesticides --

Q. Sure.

A. -- just to be clear.

Q. Sure. Sure. And I'm just talking right now about the differences between hierarchical regression and logistical regression. Okay? I'm not throwing the confounding thing on there yet.

So the only case-control study that's involved in this case that did a hierarchical regression is De Roos 2003; is that right?

A. Yes, it is. And I can explain why that was important to do, and --

Q. We'll get to that in just a minute because they heard a lot about it from Dr. Weisenburger --

A. Okay.

Q. -- who was an author on the paper as well; and maybe when I'm walking you through this, you can tell us why it was important. Okay?

A. Okay.

Q. So in your opinion, the De Roos 2003 hierarchical regression is not statistically significant; is that right?

A. That's correct.

Q. Okay. I thought I had these pretty closely memorized, but it is .9; right?

A. Yes.

Q. Okay. And .9 is pretty darn close to statistically significant; right?

A. Yes. While that's true, the bigger concern here is the approach for adjustment for potential confounding. So that's why for that particular set of data, I gave the statement of no.

And if I could just add to that, the proper adjustment for confounding that included the datasets in De Roos also included McDuffie. Actually, in that analysis, the pooled analysis of those studies, that properly adjusted for use of other pesticides did not show any evidence of an association.

Q. Are you talking about the NAPP study?

A. Yes, I am.

Q. Okay. So we'll get to the NAPP study in a minute. And just to remind the jury, the NAPP study took De Roos 2003 and pooled it with Eriksson.

But let's just --

A. No. Not with Eriksson. With McDuffie.

Q. Yeah, with McDuffie.

So let's just stay on De Roos 2003 for a minute. Okay? Because based on your table, we should be looking at the hierarchical. But, again, since it's a .9, you're not really telling the jury they should ignore a .9; right?

A. No. And, again, just to be clear, my concern with this particular study is not only that particular confidence

interval, but also the fact that -- the approach that they took for adjusting. When you have only 36 exposed cases, adjusting, whether you're using logistic or hierarchical, putting 47 pesticides into a model with only 36 cases can cause a lot of problems.

Q. Okay. So let's just look at this table, if you will. This is the table from De Roos 2003. And, again, this is the only study we've looked at that has done a hierarchical regression. Okay? So there it is right there.

And then we just discussed that all the other studies did a logistical regression; right?

A. Yes.

Q. Okay. And so if you go all the way down, these are all of the chemicals that they adjusted for; right?

A. Yes, it is.

Q. So the De Roos 2003 adjusted for all these chemicals. You get down here to glyphosate. I put a little mark so I could find it easily. There you go.

And so you've got -- you can -- these first ones you don't really have to pay attention to for purposes of our question and answer, but the logistical regression is right here (indicating), 2001 -- or 2.1. And there's the hierarchical; right?

A. Yes, it is.

Q. And those numbers actually were put up here by Dr. Ritz

last week. Okay?

And so what you're telling the jury is that you should pay attention to the hierarchical over the logistical; right?

A. Well, so, again, just to be clear, the authors themselves were concerned with the fact that they had a limited number of exposed cases for several of these pesticides so they took this approach of hierarchical regression, which -- because they had so few exposed cases in many of these settings.

So the authors themselves thought the hierarchical approach would provide a more appropriate adjustment, but still you're concerned, given there are only 36 exposed cases in both of these cases, it's not a proper adjustment. The proper adjustment was the way that -- of these data was the NAPP study.

And so, I mean -- and we're not also -- you know, something else that we could talk about with the study, it's not just the proper adjustment for confounding or lack thereof or the statistical significance. In this particular study, this was the study where they didn't even have close to 10 years of potential latency. They had 45 percent of their controls and 35 percent of their cases actually had died before they started the study. So the data on exposures didn't even come from them. It came from next of kin.

So there are actually a lot of problems with this particular study beyond just the statistical significance and

lack of proper adjustment.

Q. So, Dr. Mucci, I appreciate your answer, and we are on kind of a clock here, and I think I asked you just if you were telling the jury if this is the number we should use. So I'm sure that your counsel will come back on redirect and --

A. Right.

Q. -- and give you --

A. And -- and --

Q. Hang on. Let me get to my next question.

THE COURT: Well, wait a minute. She's explaining to you that she doesn't think it's a number worth using for a variety of reasons, and she has a right to answer that question.

MS. WAGSTAFF: Okay.

THE COURT: So go ahead.

THE WITNESS: Right. You know, exactly.

So I think when we look at each study, we're not just looking at the number. We're not looking at the relative risk or the confidence interval only. We want to think about everything that went into the quality of the study. We want to see is there evidence of misclassification or not, did they do a proper adjustment for confounding.

In this case the fact that so many of the cases and so many controls had already died when the study was done and there were proxies and there was another publication that

actually showed that there was bias introduced by the fact that it wasn't the actual respondents who gave the data, so you can't just look at any one number in isolation, you really need to think about the entire study when you come to your opinion about the quality and whether or not to use a specific number in your analysis.

BY MS. WAGSTAFF:

Q. And you more artfully said what I was asking you before. You can't just go off of a chart like this to determine when a study is good or bad?

A. That's absolutely true; however, in this case in that particular table that I gave you, it describes all of the problems with those case-control studies.

I absolutely agree there are some cases of very well-conducted, well-analyzed case-control studies. There are some examples of poorly done cohort studies. In this body of literature, however, unfortunately the published case-control studies have a number of potential limitations and issues. They raised some hypotheses to be tested in more well-designed studies, including, for example, the pooled analysis, which did a proper adjustment for confounding.

So I absolutely agree with you. You can't make generalities, but in this particular set of literature, the cohort study quality is much, much more valid than the case-control studies.

Q. Back to what I was asking you about, we are back to the hierarchical and logistical. And my understanding of the hierarchical, how it differs from the logistical, is that certain assumptions are made about chemicals and are weighted based on certain factors; is that correct?

A. So that's one of the differences.

Q. Okay. And so one of the factors -- actually the jury heard from one of the authors of this study, Dr. Weisenburger; but the authors also put in here in table 1 sort of a weight that they were giving each chemical; is that right?

A. Yes, it is.

Q. And the weight that they gave glyphosate, it looks like is .3; is that right?

A. Yes, it is.

Q. And so that weight is factored into the hierarchical regression, right?

A. Yes, it is.

Q. And that is a very important part of the hierarchical regression, right?

A. It is one of the parts that goes into it. You can see from all of the columns in the other table, all of these pieces of information went into the matrix that was used for assessing in the hierarchical.

Q. Sure.

A. So it is one of the factors.

Q. I mean, it is a pretty important one. The .3, it says it is the carcinogenic potential, right?

A. Yes, correct.

Q. The authors are guessing -- educatedly [sic] guessing -- but guessing on certain factors that are going on in the world, the probability that something is a carcinogen, right?

A. No. The way they came up with this specifically was based on information that came from the EPA and from IARC.

Q. Okay. In 2003 when this was -- when this was done with respect to glyphosate only -- I'm not talking about the other 46 chemicals -- with respect to glyphosate, IARC had not made a ruling on glyphosate, right?

A. No, they hadn't.

Q. And so if you look at the -- how you weighted glyphosate, it talks about exactly what you just said, right?

A. Yes.

Q. Okay. So it talks about the carcinogenic probability, which is, again, this last column, right?

A. Yes.

Q. Okay. It says, The value is created by combining the classifications from the IARC Monograph program on the evaluation of carcinogenic risk to humans and the EPA integrated risk information system?

A. Yes, that's correct.

Q. So they do some sort of analysis based on what the EPA has

said about the chemical and what IARC has said about the chemical?

A. That's what it says, yes.

Q. And then it gives you -- it says 1.0, .9. It goes all the way down -- I'm not going to read them all the way down. But it goes all the way down and gives it a different weight for this column based on what the two entities had said, right?

A. Yes, that's what it says.

Q. Okay. When this paper was published, it was a .3. Glyphosate was a .3. And that was accurate for 2003, right, as far as we know?

A. Yeah. As far as we know, yes.

Q. Okay. And since 2003, IARC has ruled that glyphosate is a probable carcinogen, right?

A. That's the classification they have labeled it.

Q. Okay. So it says right here .6, a probable human carcinogen in one assessment. Okay. So we know that it would at least --

MS. MATTHEWS JOHNSON: Objection to the incomplete reading.

THE COURT: Sustained.

BY MS. WAGSTAFF

Q. And unclassifiable in the other.

MS. MATTHEWS JOHNSON: I object to foundation for this question, "unclassifiable in the other."

THE COURT: You can answer the question if you know how to.

THE WITNESS: Right. I don't think that's the case in this set of studies since EPA actually did make a classification, which was that it was not a carcinogen.

BY MS. WAGSTAFF

Q. Okay. So let's see. Where would that be then on here?

A. It's actually not clear from the way they have labeled these where it would fall in that particular setting.

Q. But it is clear that it wouldn't be a .3?

A. Actually, it is not clear. I couldn't tell you since it is not clear, but it doesn't fit .3. It doesn't fit, perhaps, some of the others, so it's not clear where it would go into.

Q. Okay. Well, let's look .3 is not assessed by IARC or EPA IRIS or deemed unclassifiable in one or both assessments. So it wouldn't fit .3 anymore.

A. Again, it is not clear where it would fit into any of them actually.

Q. Sure. We know it wouldn't fit .3 because IARC has now -- the first sentence of .3 is not assessed by IARC. We know that that's not true anymore, right?

A. Again, so it was assessed by IARC. It is just not clear to me, based on the way the authors defined this, where it would actually go. So I couldn't say one way or the other where it would fit.

Q. Sure. I understand you can't make an opinion on where it would fit, but you can at least agree that it would no longer be a .3?

A. Again, I couldn't tell you what it would be because it doesn't fit into any of these particular categories.

Q. Okay. So the fact that the first sentence of .3 says, Not assessed by IARC, you can't agree with me that now that's changed?

A. I appreciate that it has changed; but, however, it is not clear to me where they would have categorized glyphosate in this particular example.

Q. Okay. Let's just assume that it is no longer a .3 because IARC has assessed it, okay. Let's just assume that. This number is no longer correct, right?

A. Again, it's unclear, even if it did change, how it would change the estimate here. We don't have that kind of information available, so you couldn't say one way or the other how it would affect the relative risk estimate.

Q. Okay. So it would change it. I mean, it is a factor. It is .3. Is it your testimony that that -- this column right here of the carcinogenic probability, is it your testimony that that doesn't -- if that number changes, it doesn't matter?

A. Again, since -- what I would like to see is the actual data. I would like to see if they reran this hierarchical how it would affect -- I don't think any of us could speculate how

it would change. However, what we do know -- and probably what is more important in the studies notwithstanding the limitations of these studies -- is we actually have the more appropriate adjustment than either the logistic or hierarchical, which is the pooled analysis from the NAPP study.

Q. Okay. But you -- but I was just asking you about this because you told the jury that this was the number you should -- that they should pay attention to, is the hierarchical.

MS. MATTHEWS JOHNSON: Objection to the misstatement of testimony.

THE COURT: Sustained.

BY MS. WAGSTAFF

Q. Okay. Let's actually look -- the jury has heard about it from one of the authors; Dr. Weisenburger. Let's actually look at *De Roos* 2005. If you will --

THE COURT: Maybe, before we turn to that, maybe now would be a good time for our last break before we finish the trial day.

Why don't we resume at ten minutes after the hour?

(Proceedings were heard out of presence of the jury:)

THE COURT: You might want to stick around for just a second because I want to raise the issue of the discussion of this chart from her book. It seems to me that Ms. Wagstaff was doing fine on this issue of toxicology and the cell studies

before she got to this chart.

Now, I think that once she got to this chart, that opens the door -- it is unfair to Dr. Mucci to preclude her from saying what she knows about toxicology and the cell studies after using this chart where her book identifies some substances that were classified as Class 1 carcinogens without adequate evidence from cancer studies in humans.

I mean, that is the kind of thing we were discussing at the beginning of the trial day this morning that would open the door to allow Dr. Mucci to say what she knows about toxicology and cell studies. And I think -- as applied to the discussion she had about this chart with Ms. Wagstaff -- I think now she has the right to say, Yes, there are some carcinogens that -- where there is inadequate epidemiological evidence, but it has been concluded that they are carcinogens from the other evidence; but here is why I don't believe that could possibly be the case with glyphosate.

I think that's fair game now.

MS. WAGSTAFF: So, Your Honor, if you will remember -- because I grappled over how to get this chart in front of her without bringing up IARC -- and if you look back at --

THE COURT: I'm not talking about IARC.

MS. WAGSTAFF: I understand that.

THE COURT: I think it was appropriate to introduce IARC in the way that you did.

MS. WAGSTAFF: Okay. So one thing that I will say is that I actually don't -- it is not -- I'm okay with her talking about how sometimes when people look at the carcinogenicity of a chemical, you should look at all three. I'm okay with her saying that. And I'm even okay with her testifying that sometimes she did.

I don't think she can say in this case, though, that she looked at all three with respect to glyphosate or Roundup because that wasn't her opinion. That is not what she did.

And so if she wants -- if her counsel on redirect wants to say that, Yeah, that this one, pick any one, areca nut had inadequate and sufficient -- it was genotoxic and explain why that is, I think that is appropriate. But I don't think that she can then -- that opens the door for her to then say, Oh, I looked at --

THE COURT: I don't agree. I think the way -- the way you did this -- and the problem is this line of questioning combined with my earlier curative instruction really creates a misimpression about Dr. Mucci's opinion. And I think she has the right to explain, Yes, the areca nut, there is not adequate epidemiological evidence, and here is why, and here is why we still think that it is carcinogenic. But I don't think that I have now looked at the -- at this, that and the other thing and in the toxicology area, in the cell data area, and it doesn't -- it doesn't change my opinion on the epidemiology in

this case.

I think that's -- you went too far down the road. And it's not fair to leave that misimpression about her testimony now. So I'm -- I will allow -- if you choose to go down that road, I will allow that now on redirect. And I will even say, you know, I previously instructed you to disregard that testimony; but Dr. Mucci has an opportunity to explain the discussion during cross-examination about this chart.

MS. WAGSTAFF: And I assume, then, I can cross-examine her on the mechanistic studies and the animal studies. If she does that, it opens the door --

THE COURT: Of course.

MS. WAGSTAFF: -- I can ask her whatever I want about those.

THE COURT: Of course, yeah. Okay. Be back in a few minutes.

(Recess taken at 12:07 p.m.)

(Proceedings resumed at 12:12 p.m.)

MS. WAGSTAFF: Your Honor, may I seek clarification on something prior to the jury coming in?

THE COURT: Sure.

MS. WAGSTAFF: All right. So with respect to the page in the book we were just talking about, the Bradford-Hill page, I would --

THE COURT: The Bradford-Hill page?

MS. WAGSTAFF: I'm sorry, not the Bradford-Hill page.

THE COURT: The one I was just talking about was page 107.

MS. WAGSTAFF: Right. That's what I meant. Sorry, Your Honor.

THE COURT: Okay.

MS. WAGSTAFF: So these are the IARC classifications.

THE COURT: Yes.

MS. WAGSTAFF: You obviously know that. In Portier's cross-examination, Monsanto designated testimony where they defined what "limited" meant by IARC, asked him if he agreed with that definition of IARC. Portier said that he did. It is page 331.

And so if we are going to go down this path, I think that I should be allowed to ask questions on what these mean in terms of limited, inadequate, sufficient, genotoxicity. I think if we are going down that path, and Monsanto is going to ask Dr. Mucci questions on it, that I should be able to, on recross, follow up with that.

THE COURT: I don't think so. I mean, you say if we are going down the path. You are the one who took us down the path.

MS. WAGSTAFF: Sure.

THE COURT: And she -- I think she has the opportunity to explain why she views glyphosate differently than the areca

nut, for example, based on all of the materials she has reviewed. And I don't think we need to get into what these IARC definitions are.

MS. WAGSTAFF: Okay. I mean, they are already in the case. They are in evidence through Dr. Portier, so --

THE COURT: Okay. I don't think -- I think under 403, that's not a road we are going to continue to go down. She just has an opportunity to clarify her testimony with respect to this chart.

All right. Go ahead and bring them in.

(Proceedings were heard in the presence of the jury:)

THE COURT: You can continue.

BY MS. WAGSTAFF

Q. All right, Dr. Mucci. Are you ready?

A. Yes.

Q. Just to re-orient where we were prior to our break, we were talking about the *De Roos* 2003 and the two logistical versus hierarchical numbers, right?

A. Yes.

Q. Okay. And this first number, which is the logistical regression, that actually shows a statistically significant doubling of the risk, and it is adjusted for other -- for 47 other pesticides.

A. So you said -- there were a lot of different statements in that statement. So I just want to be clear that --

Q. It is statistically significant?

A. Yes. While that is statistically significant, it does not imply a doubling of the risk. Again, this isn't the proper approach for adjustment for confounding here. So a doubling of risk would suggest causality; here what we see is a statistical association. It wasn't a proper adjustment for confounding.

Q. So what does 2.1 mean? Doesn't that mean a doubling of the risk?

A. Again, just to be clear, a doubling of the risk would infer causality. That number is 2.1. However, that is not evidence of a causal association. That is not an appropriate adjustment for other pesticides.

Q. I understand -- I understand your opinion that 2.1 is not causality in this instance and with this case, but I'm asking you, 2.1 means -- an epidemiologist would call that a doubling of the risk, right?

MS. MATTHEWS JOHNSON: Objection. Asked and answered.

THE COURT: Overruled.

THE WITNESS: Again, just to be clear, the relative number is 2.1. When you put it into the words of saying it's a doubling of risk, that implies causality. In this case, again, this is a statistical association. It is not a causal association.

BY MS. WAGSTAFF

Q. Sure. And I understand that. But I'm saying outside of

this courtroom, if you were talking to your epidemiology colleagues back in Boston, would you call this a doubling of the risk?

A. In this particular case, no, I would not. And the reason is that it is not a causal association.

Q. Okay. But let's say it is not glyphosate. Let's say it's -- let's go up here to a different one that has 2.4. Is that a doubling of the risk?

A. So, again just to be clear, I have not studied that particular pesticide. I would -- there are the same limitations with this data set. The issues not only with confounding but proxy bias, the really short latency of this study, I would not say that is a doubling of risk. I haven't studied that particular pesticide, so it is really -- I'm just trying to be helpful --

Q. Sure.

A. -- and say that it is really context dependent. And when you use the words like "doubling the risk," again, that implies causality.

Q. Okay. And I haven't said anything about causality and what that number means. Those are your words. I'm just asking if epidemiologists refer to a 2.1 odds ratio as doubling of the risk?

A. Again, in some settings they might.

Q. Okay.

A. And then other settings they might not. It would really depend on the greater context. As epidemiologists, we are not looking at solely just one number. We are looking at the totality of a study.

Q. Okay. Have you ever in your entire -- I think you said you have been an epidemiologist for 16 years?

A. Yes, I have.

Q. Have you ever referred to a 2.1 odds ratio as doubling of the risk?

A. In certain settings, yes. But perhaps in other settings I might not have.

Q. Okay. So *De Roos* was one of the authors in this paper, right?

A. Yes, she was.

Q. And Dr. De Roos did the next paper which is *De Roos* 2005, right?

A. Yes, that's correct.

Q. And I think that that is Number 451, please.

And this is the first agricultural --

A. No, I'm sorry. 451 I think is still the case-control study.

Q. 528.

All right. Are you there?

A. Yes, I am.

Q. Okay. And so this is two years after the study we just

looked at, right?

A. Well, it was two years in terms of publication, but the case control -- the cases in controls were created in the 1980s and early 1990s, just to be clear.

Q. Sure. Yes. Sure. This is a paper that deals with the Agricultural Health Study data, right?

A. Yes, it does.

Q. So this paper does not deal with the data that we just looked at, right?

A. It is a separate study, yes.

Q. Okay. Completely new set of data. However, in this study the authors describe the previous results in landscape, right? If you turn to page 53.

A. I'm sorry. My copy of the article is very blurry. It is very hard to read.

Q. I have got it pulled up -- I actually have a clean copy.

MS. WAGSTAFF: May I approach?

THE COURT: Sure.

THE WITNESS: Thank you.

BY MS. WAGSTAFF

Q. 53 on the left-hand column -- and I'm sorry if it is blurry. That wasn't my -- and this is under the Discussion section, but it starts with -- if you look on my screen, you can kind of get a -- kind of get a feel for where I am.

Do you see that, Dr. Mucci?

A. Yes, I do.

Q. Okay. So in this 2005 report, study, Dr. De Roos is reporting sort of on the lay of the land with respect to the case controls, right?

A. Yes, she is.

Q. Okay. And so she talks about all of the case controls really that the jury has learned about. She talks about *Hardell* and *Eriksson*, right?

A. Yes.

Q. And then she talks about how *Hardell* then pooled it with another *Hardell* 2002, right?

A. Yes.

Q. And then she goes on and she talks about a more extensive study conducted across a large region of Canada found an elevated risk of NHL associated with glyphosate use more frequent than two days. You are familiar with that study, right?

A. Yes, I am.

Q. That is the *McDuffie* study.

And then she talks about her own study, right? The next one is her own study.

A. Yes, it is.

Q. This is the data she chose to put in a later study with respect to sort of how people should remember her study, right?

A. Yes, it is.

Q. Okay. So Dr. De Roos, two years later, decides to tell people, Increased NHL risk in men was associated with having ever used glyphosate, and she gives the logistical regression numbers, right?

A. Yes, she does.

Q. And she says, After adjustment for commonly used pesticides in a pooled analysis of National Cancer Institute-sponsored case control conducted in Nebraska, Kansas, Iowa and Minnesota; is that right?

A. That's what she --

Q. And she cites her own paper, right?

A. Yes.

Q. Okay. Next, let's talk about the *Zhang* study. I think you mentioned the *Zhang* study that came out a month ago or so.

A. Yes.

Q. Okay. And you understand -- you have read this study, right?

A. Yes, I have.

Q. It came out, I think, March 6th -- or February 6th?

A. It came out recently, yes.

Q. February 5th.

And this is a meta-analysis.

A. Could you tell me where in the book it is, please?

Q. 554. Take a moment to --

A. I'm there.

Q. Okay. So this is the most recent data that we have on non-Hodgkin's lymphoma and exposure to Roundup, right?

A. This is the most recent publication, but it is actually, you know, using data that had been accumulated over time. So just to be clear, again.

Q. Sure. And this is a meta-analysis, right?

A. Yes, it is.

Q. And there were other meta-analysis done with respect to Roundup and non-Hodgkin's lymphoma, right?

A. Yes, that's correct.

Q. And did you review those other meta-analyses?

A. Yes, I have.

Q. So you reviewed the Chang meta-analysis?

A. Yes.

Q. You reviewed the Schinasi meta-analysis?

A. Yes, I have.

Q. And you reviewed the one by IARC?

A. I have, yes.

Q. Okay. And so this one is a little different than the other three, right?

A. Yes, it is.

Q. And this one is a little different because they actually did sort of a dose response how to use meta-analysis, right?

A. No. Actually, that's not really correct. In fact, what they did was sort of a hodgepodge of results. Three of the six

studies did ever-never. Two of the remaining studies had some measure of dose response using unadjusted for pesticides. And then there was one clear dose response. So it wasn't clearly a dose response analysis.

Q. Okay. So -- so the *Zhang* authors looked at the high use -- the high-exposure people, right?

A. No. Again, just to be clear, three of the six studies didn't have dose response to present. So in those they were only looking at ever versus never exposure.

Q. Okay. But some of them -- some of the analysis they did were with respect to the high-exposure people; is that fair?

A. Well, the highest in those particular studies, yes.

Q. Sure.

A. But, again, just to be clear, two of those three studies that had information on dose response were not adjusted for other pesticides, and that's an important factor in any meta-analysis.

Q. Sure. Okay. So unlike -- and the three previous meta-analyses -- Chang, Schinasi and IARC -- did not do those high-exposure analyses, right?

A. No. They focused on ever versus never exposure.

Q. So this was sort of a new analysis done, right?

A. It was new, but it was not a correct methodology. This isn't an appropriate way of combining results from studies. It is not appropriate to mix the results from different categories

of exposure. We don't do this in epidemiology.

Q. Okay. And so what the *Zhang* authors found was -- and it says, Accepted Manuscript across here. I'm sorry if that is a little confusing to read. I will highlight it.

But what the *Zhang* authors found was, Overall in accordance with the evidence from experimental animals and mechanistic studies, our current meta-analysis of human epidemiological studies suggests a compelling link between exposures to glyphosate based-herbicide -- and Roundup is a glyphosate based-herbicide, right?

A. Yes, it is.

Q. Okay. An increased risk for NHL, right?

A. That is what it said. However, what they have come up with is a biased analysis combining data including results that were not adjusted for other pesticides.

And let me be clear, as an epidemiologist when we review the studies, we review the independent epidemiological literature. We look at the quality of the data going into those studies. And as I discussed earlier, there were many flaws, including the fact that they were not adjusted properly for other pesticides.

So I think when you take into account the results of a meta-analysis, you have to think about what was the quality of the studies going into it.

MS. WAGSTAFF: Okay. Give me just one minute, and I

may be finished.

(A brief pause was had.)

BY MS. WAGSTAFF

Q. I have one last set of questions for you, Dr. Mucci.

I want to return back to sort of the bio-monitoring opinion that you gave today with respect to testing urine or testing Roundup and/or glyphosate in the urine. Do you remember those?

A. Yes, I do.

Q. Okay. And did the bio-monitoring studies look at the level of exposure in urine to quantify dose?

A. They were using it, I believe, to help inform on the ability of the algorithm to appropriately classify people as either high or low exposure to different pesticides.

Q. Okay.

A. So not to necessarily give a specific dose, and I think there were some concerns of whether you could use the urine levels to give a specific dose, but generally to quantify people as either having high levels of exposure to different pesticides or low levels of exposure.

Q. Okay. And you would agree if glyphosate is not rapidly excreted through urine, then that method would not be very accurate?

MS. MATTHEWS JOHNSON: Objection. Outside the scope of direct.

THE COURT: Sustained.

MS. WAGSTAFF: No further questions, Your Honor.

THE COURT: Ms. Johnson.

REDIRECT EXAMINATION

BY MS. MATTHEWS JOHNSON

Q. Good afternoon, Dr. Mucci.

A. Good afternoon.

MS. MATTHEWS JOHNSON: May I have the ELMO, please?

BY MS. MATTHEWS JOHNSON

Q. I'm going to show you *De Roos* 2003, and we are going to go to table 1. I know some time was spent on this, Doctor; but I just wanted to give you an opportunity to explain why you said what you said concerning the fact that one cannot be sure now in 2019 what weighting glyphosate would have based on this note?

A. Right. So to be clear, the U.S. EPA has said there is no association with glyphosate. So we have evidence from that. And now we have evidence from IARC around the classification of 2A. So the problem is that doesn't fit into any of the classifications that they have described here. So it doesn't fit into 0.1. It doesn't fit into 0.3. It doesn't fit into 0.5. It doesn't fit into 0.6, and so it is not clear where you would put those -- that compound glyphosate now with the classification from IARC.

Q. Right. And to get as high -- just to be clear, if

Dr. Ritz had testified that this classification should be .8 or .9, probable in one assessment and possible in another, probable in both, do you agree that that could be a classification?

A. No. In fact, absolutely not because the EPA was classifiable; and it was not listed as a possible human carcinogen.

Q. Thank you.

I'm going to stick with the ELMO, and next we are going to take a look at *De Roos* 2005. And so you were asked about *De Roos* 2005 and what it said about earlier studies.

Just to be clear: What is the finding of Anneclaire De Roos and the fellow authors in 2005 about glyphosate? What is the finding of this study?

A. So based on the results of the cohort analysis, there was no evidence of an association between glyphosate and non-Hodgkin's lymphoma and no evidence of a dose response.

Q. Okay. And within this study, they do talk about prior studies; and they start at the top talking about their finding here. Provided evidence of no association between glyphosate exposure and NHL incidence.

Is that correct?

A. Yes, correct.

Q. And then Ms. Wagstaff went through some of the discussion of the prior studies, but she stopped. She stopped right here

actually. And can you tell us what the very next sentence is that appears.

A. These previous studies were retrospective in design and thereby potentially susceptible to recall bias of exposure reporting.

Q. And then what is the -- let me highlight it for you first -- okay.

A. Our analysis of the AHS cohort had a prospective design which should largely eliminate the possibility of recall bias.

Q. And then in Alavanja 1996 -- and we are not going to go back to that on the ELMO -- but was there a discussion of the cohort studies there as well?

A. Yes, there were.

Q. What did Alavanja 1996 say about that? If you want to go to your binder --

A. I'm sorry. I actually --

Q. It is going to be in the black binder.

A. Yep.

MS. MATTHEWS JOHNSON: One moment, please, Your Honor.

(A brief pause was had.)

THE WITNESS: Dr. Alavanja, that is the 1996?

BY MS. MATTHEWS JOHNSON

Q. Exactly. Yes. And if you can go -- I believe you are going to see it on the second page. There is a study about cohort studies. It is on the right-hand side of the page.

Did you find it?

A. Yes.

Q. Perfect.

MS. MATTHEWS JOHNSON: Okay. Can we call it up here? Is it possible to get Alavanja 1996?

BY MS. MATTHEWS JOHNSON

Q. And if you can just read what it says about the prior cohort studies, Doctor.

A. Just under Prospective Cohort Study, that part here?

Q. No, I'm sorry. They are talking about the prior case-control studies. I apologize.

A. Sorry.

Q. I'm saying the wrong thing. I should be saying case-control studies. I apologize for that.

A. I have it here.

In case-control studies, nondifferential misclassification due to inaccurate recall of exposure history would be expected to underestimate the true risk while better recall on the part of cases; i.e., case recall bias, could bias estimates in either direction. In cohort studies -- is that enough?

Q. Yes. And then if you go to the next -- we are on the ELMO now. If you can just go to the next page, I'm directing them there now. Oh, she switched the ELMO -- I'm sorry.

THE CLERK: Do you need the ELMO?

MS. MATTHEWS JOHNSON: If we can go back to the

screen. Sorry about that.

BY MS. MATTHEWS JOHNSON

Q. Yes. If we can go back to this -- exactly. What page were you reading from, Doctor?

A. Top of page 363.

Q. Okay. If we can go forward one page at a time on the screen that I'm looking at -- stand by for one moment.

Okay. Then the top of page 363, where are we, Doctor?

A. I'm sorry.

Q. Which column were you reading from?

A. I was reading from the top left column.

Q. Okay. And if we can put that on the main screen as well, do we have the right thing called up here, Doctor?

A. Yes, correct.

Q. Okay. Yes, in case-control studies.

Okay. So is this reflecting some of your concerns about the case-control studies, doctor?

A. Yes, that was one of the concerns that they raised.

Q. In the -- in the course of planning for the AHS study?

A. Absolutely, yes.

Q. Okay. Thank you so much for your patience on that.

So, next, I would like to look at your textbook. And I will need the ELMO again.

So Ms. Wagstaff talked to you about the textbook, a couple pages out of it. That has several chapters; does it not?

A. Yes, it does.

Q. In fact, is Chapter 27 a chapter on non-Hodgkin's lymphoma?

A. Yes, it is.

Q. And in there is there a risk factor summary -- that is table 27-1 -- in that textbook?

A. Yes, there is. We provided a summary risk factor for all of the cancers in the textbook.

MS. WAGSTAFF: Counsel, what page is that?

MS. MATTHEWS JOHNSON: That is going to be page 655 for the record.

BY MS. MATTHEWS JOHNSON

Q. This is of your textbook -- textbook of cancer epidemiology; is that right, Doctor?

A. Yes, that's correct.

Q. Chapter 27?

A. Yes.

Q. Table 27-1, page 655.

And if we go up just a little bit here, we have description of -- it says here, Well-confirmed risk factors at the top?

A. Yes.

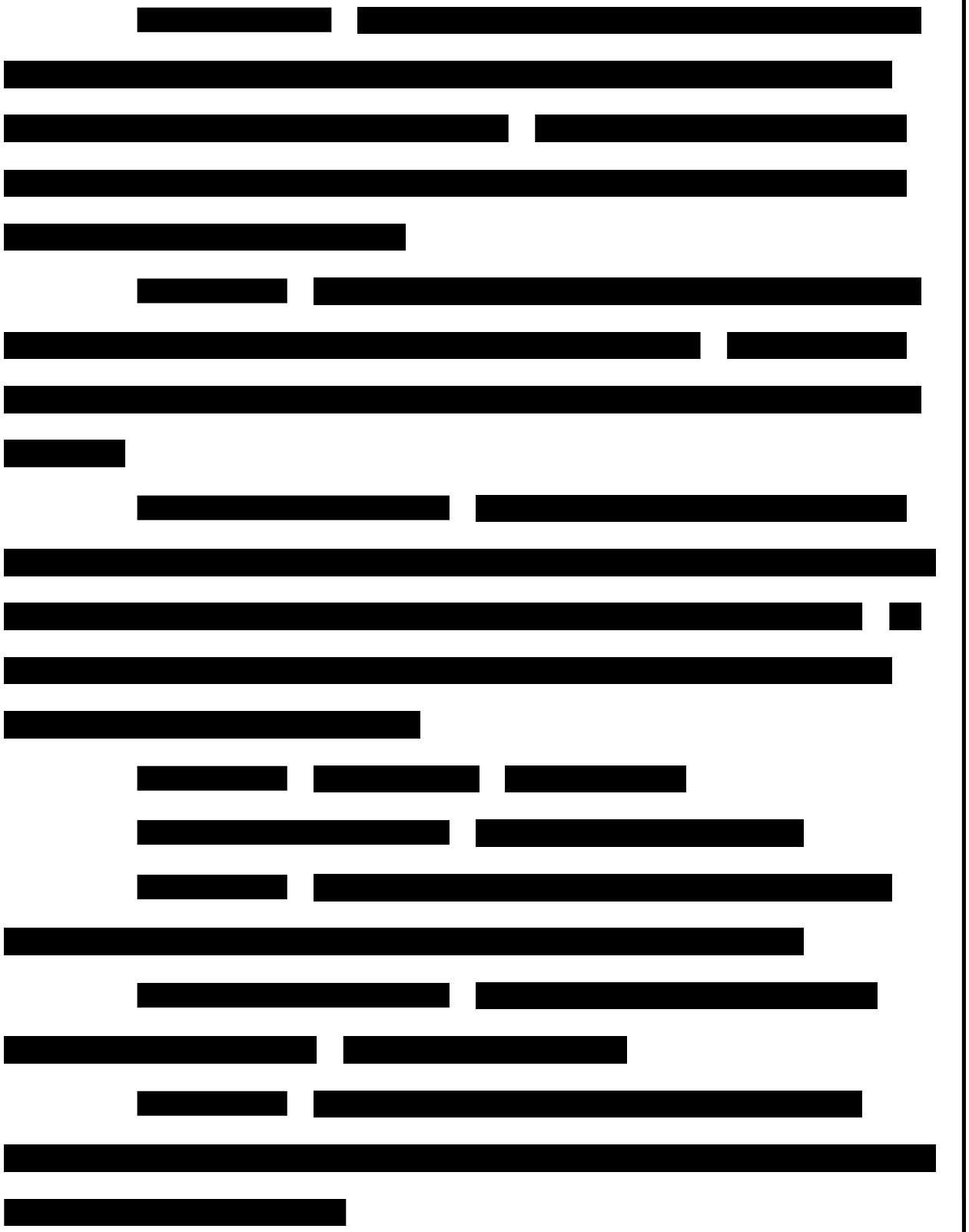
Q. If we go all the way to the top, Epidemiology of non-Hodgkin's lymphoma NHL subtypes risk factor summary?

MS. WAGSTAFF: Objection, Your Honor. Can we do a

SIDEBAR

sidebar? Can we take that off the screen?

(The following proceedings were heard at the sidebar:)



[redacted]

(Sidebar ended.)

(The following proceedings were heard in open court:)

BY MS. MATTHEWS JOHNSON

Q. So table 27-1 from your textbook of cancer epidemiology, page 655, has a table Epidemiology of non-Hodgkin's lymphoma, NHL subtypes, risk factor summary.

Do you list well-confirmed risk factors, Doctor?

A. Yes, we do.

Q. And included in that -- can we go down here where it says where there is weak, if any, relationship exists based on substantial data?

A. Yes.

Q. Okay. And what is listed there?

A. Pesticides --

Q. Okay.

A. -- solvents, blood transfusions and vaccinations.

Q. Okay. And among pesticides -- is glyphosate a pesticide?

A. Yes, it is.

Q. And in your textbook you have stated that weak, if any, relationship exists based on substantial data; is that correct?

A. Yes, correct.

Q. And is that what is in your textbook also what you have been studying and looking at here in this case?

A. Yes, it is.

Q. Thank you.

Now, Doctor, I just want to confirm here -- after the cross-examination and the questions that you received on cross-examination -- what is your opinion concerning the existence of any dose response for glyphosate or Roundup and any risk of NHL?

A. You know, in thinking about this, all of the studies that have published on dose response, we have the results of two case-control studies where you are -- they were not adjusted for other pesticides. So there is concern that the results of those studies might have bias. When you look at the results from the two Agricultural Health Study, where they took a proper adjustment for confounding as well as all of the other issues that we looked at and showed strength of the study, there is no evidence of a dose response between glyphosate exposure and non-Hodgkin's lymphoma or for any of the NHL subtypes.

Q. And what is your observation of the rate of NHL in the general population as opposed to the cohort of AHS?

A. Right. So, again, when we compared the rate in the general population, it was 1.07 percent. When we looked at it in the Agricultural Health Study, where 80 percent of the

people were exposed to glyphosate, the rate was identical. It was 1.06 percent.

Q. And what is your opinion on whether there is a causal association between Roundup and NHL?

A. My opinion is there is no evidence of a causal association between glyphosate and risk of non-Hodgkin's lymphoma in humans.

Q. And do you still hold that opinion to a reasonable degree of scientific certainty?

A. Absolutely, yes.

MS. MATTHEWS JOHNSON: One moment, please, Your Honor.

(A brief pause was had.)

MS. MATTHEWS JOHNSON: We have no further questions.

THE COURT: Anything on recross?

MS. WAGSTAFF: No questions, Your Honor.

THE COURT: Okay. You can step down, Dr. Mucci.

THE WITNESS: Thank you, Your Honor.

MR. STEKLOFF: We have Dr. Levine.

THE COURT: Let's do 15 minutes with Dr. Levine, yeah.

MR. STEKLOFF: We will grab here, and we call Dr. Alexandra Levine.

THE COURT: Okay.

ALEXANDRA LEVINE,

called as a witness for the Defendant, having been duly sworn, testified as follows:

THE CLERK: State your full name and spell your name for the record.

THE WITNESS: My name is Alexandra Mary Levine A-L-E-X-A-N-D-R-A. Mary, M-A-R-Y. L-E-V, as in "V-I-C-T-O-R," I-N-E.

DIRECT EXAMINATION

BY MR. STEKLOFF

Q. Good afternoon, Dr. Levine.

A. Good afternoon.

Q. I think we have about 15 minutes, so we are going to try to at least get through some of your background today. Okay?

A. Okay.

THE COURT: I figure you have been waiting so long, we might as well give you a chance to --

THE WITNESS: I appreciate it.

BY MR. STEKLOFF

Q. Dr. Levine, can you please tell the jury -- just explain to the jury a little bit about who you are.

A. I am a hematologist/oncologist right now at the City of Hope. That means I take care of patients who have cancers of the blood system: Leukemia, lymphoma, Hodgkin's disease, multiple myeloma, things of that sort. I primarily am a clinician now. I see patients, and I have followed those patients for decades, many of them.

Q. And -- bless you -- you mentioned hematologist and

oncologist. And the jury has heard these terms. But just to remind them, can you explain what a hematologist is?

A. Sure. A hematologist is somebody who specializes in diseases of the blood, and these could be non-cancerous kinds of things like anemia, and an example.

An oncologist is somebody who takes care of cancer of all types theoretically. A hematologic oncologist is somebody who specializes in cancers of the blood system, and that's what I do.

Q. And how does non-Hodgkin's lymphoma fit into that?

A. Non-Hodgkin's lymphoma is a type of malignancy of the blood system. That is my specific area of research and interest. And most of my patients do have non-Hodgkin's lymphoma.

Q. In your over 40 years, how many patients -- have you treated thousands of treatments with non-Hodgkin's lymphoma?

A. Yeah, I have treated thousands. At a time I was at the county hospital -- the big county hospital in Los Angeles -- I was in charge of the lymphoma service there for decades. I was in charge of all of the patients with lymphoma there and supervised their care. We had a weekly clinic where we saw about a hundred patients a week, most of them were lymphoma patients or leukemia, acute leukemia or non-Hodgkin's lymphoma. I would go over all of those cases with the interns and residents, the student doctors, if you will; but I was

ultimately responsible.

I was also the chairman of the hematology department for a number of decades. I was responsible for making the schedule, and it was important for me to be on service taking care of the patients while hospitalized. I did that purposefully six months out of the year.

So I have a lot of experience. I have seen many, many, thousands of patients with non-Hodgkin's lymphoma.

Q. And are you still treating patients with non-Hodgkin's lymphoma today?

A. Yes, I am.

Q. Okay. So we are -- in a moment we will walk through all of your -- through your academic work and your clinical work.

On this slide I just wanted to flag next to MD, you also have an MACP. Can you please explain to the jury what that is?

A. Yes. That stands for Master of the American College of Physicians. And it is an honorary position. This is the largest society that is directed toward physicians who are primarily internal medicine doctors. Hematology is a subspecialty. Oncology is a subspecialty of internal medicine. And I was elected a master, which is the most prestigious level of designation for that American College of Physicians.

Q. So can you, please, using this slide, just walk the -- walk the jury through your academic background.

A. Yes. First I graduated undergraduate right here at

Berkeley, at UC Berkeley. That was in 1966.

I then went to medical school at USC School of Medicine. That was important to me. That was part of the county hospital, and my heart was really in that county hospital. I wanted to be there.

Q. Can I stop you there for a moment? Why is it that you went into medicine?

A. When I was very young, in junior high school and even in grammar school, I said I wanted to be a doctor. And I have no idea really why I said it at that time, but will always feel blessed in the sense that somehow I did. Nobody in my family has ever been a doctor. I just said that.

Now that I'm older, I know very well why I went into this. I like people. I love people. I like to deal with people. I can communicate with people. I care about people. Medicine allowed me to spend my life with people who were in some sort of difficulty.

And the other thing that really I like is I like challenges. I like difficulties. And I like to figure out the answers to those problems. And combining medicine allowed me to deal with people who are in trouble who I might be able to help and allowed me a challenge to see what I could do to try to help as well.

Q. And so can you now explain to the jury what you did after getting your medical degree at USC, what the next step was in

terms of your internship and residency?

A. The next step after receiving an MD degree -- you aren't really licensed at that moment. You need another year of -- theoretically called apprenticeship. We call that an internship. So I was an intern in internal medicine at the county hospital. I then became a resident in internal medicine. That's the next step in training, also at the county hospital. And that is called the LA County USC Medical Center.

Q. Then it looks like you went on to have a fellowship at hematology and oncology at Emory University. Can you explain why you chose to focus on hematology and oncology at that time?

A. It is a long story. I will shorten it. Basically it was a tremendous challenge to me. Patients with cancer were a real -- there was a real possibility to find answers and to help people. Some of those cancers were curable. That meant that there was hope. There was hope for the patients. There was hope for me.

I like the challenge. And I like the fact that I believe that that field was going to change in the years ahead. And it allowed me to be in a field that was going to move and change and become hopefully better than it was when I started.

Q. And then after you left Emory, did you continue to focus on hematology as a fellow at -- back again at USC?

A. Yes. So that was the training in Emory; turned out to be primarily general oncology, and I wanted more training

specifically in hematologic oncology.

Q. Okay. So let's now turn to your clinical experience. And when we are talking about clinical experience, are we focusing here on your care and treatment of patients?

A. Yes.

Q. And can you explain first -- you touched on this a little bit at the outset -- but can you, just on a high level, explain the work that you did at USC between 1977 and 2006 and your various positions during that time?

A. Yes. I finished my fellowship. And as soon as I did, I became an assistant professor of medicine; and I was given the responsibility of being the director of the hematologic neoplasia service at the county hospital, overseeing the patients who had non-Hodgkin's lymphoma, but also leukemia, myeloma and other such diseases. And I continued that -- in that position until I left USC at the end of 2006.

At a certain point USC opened a cancer hospital at that -- that was the USC Norris Cancer Hospital. I will get to that in a moment.

Before that I was an interim chief at the division of medical oncology for a year. From 1991 to 2006, I was chief of the division of hematology.

When USC opened the Norris Cancer Hospital, I became the deputy clinical director of the cancer center in general. That means both the clinical aspects and the clinical research

aspects that were going on at that comprehensive cancer center. I became medical director of the Norris Cancer Hospital in 1996, and I did that until I left USC in 2006 at the end of December.

I then went to City of Hope. I became chief medical officer at the City of Hope. I was in that administrative job for ten years. And in January of 2017 I was almost 74 years old. I was tired of the administrative aspects. I wanted to concentrate and just go back and keep taking care of my patients, but I left the job as chief medical officer and right now I'm a professor at City of Hope; and I am a hematologist oncologist clinical care, taking care of patients.

Q. And we have heard a little bit that you were the chief medical officer, but as the chief medical officer from 2007 to 2016 -- first of all, did you hire Dr. Weisenburger?

A. Yes, I did.

Q. And also were you responsible -- I mean, technically did all of the doctors at City of Hope during that time period -- whether they were oncologists, pathologists or any other type of doctor -- report to you?

A. Yes. All of the doctors reported to me. I was responsible for the quality of their care. I was responsible for the patient satisfaction related to their care. I was responsible for their teaching activities. And I was also responsible for overseeing their clinical research activities.

Q. And even though you had a lot of administrative responsibilities during that time -- during that entire time period, were you still also -- bless you -- taking care of patients who had cancer?

A. I was always taking care of patients. I can't -- I have to always take care of patients.

Q. And you mentioned that you -- you became a professor and stepped down as chief medical officer in 2017. How regularly are you seeing patients now?

A. My regular clinic is one full day a week. People get ill, and that usually ends up being about two days a week. I had three different calls from patients this morning. So it's -- it's not a full-time job, but it's a two-day a week full-time job and then all the calls and issues that come up in the meantime.

Q. And are you seeing patients with non-Hodgkin's lymphoma almost every week?

A. Yes, every week.

Q. And are you seeing patients with diffuse large B-cell lymphoma almost every week?

A. Almost every week.

Q. And is that in your practice the most common or one of the most common forms of non-Hodgkin's lymphoma?

A. I'm considered a specialist in non-Hodgkin's lymphoma, and doctors from other places in the city or the country or even

the world will send me patients with non-Hodgkin's lymphoma. So my practice is very much specialized in that area.

Q. Now, during your career, have you also taught medical students or fellows or residents about hematology, oncology, non-Hodgkin's lymphoma, and other issues?

A. Yes. Teaching is an important part of my job. I have been teaching since I started as an intern, really. I have continued to teach to the present time. Still teach at USC, even though I'm not officially employed at USC at this point. I give lectures to the community -- to just community members. I give lectures to medical students, to interns, to residents, to physicians. I speak at conferences and so forth. So I do a lot of teaching.

Q. And I see -- we have talked about USC and City of Hope. There is also a reference here to a Claremont Graduate University School of Community and Global Health. Can you just briefly describe what that is?

A. Yes. I'm an adjunct professor there. That means I'm not officially employed there, but I teach there and am considered an adjunct part of their faculty.

Q. And at City of Hope, you also have the title of Melinda and Norman Payson, Professor of Medicine?

A. Yes. It is an honorary kind of thing. It is a named professorship. And that means the Payson family donated money to the City of Hope for specific use in lymphoma research and

gave a title to my role in that regard.

Q. And as part of the teaching that you have done again for now over 40 years, have you taught specifically about non-Hodgkin's lymphoma?

A. Definitely.

Q. Have you taught about some of the causes of non-Hodgkin's lymphoma?

A. Yes, I have.

Q. Have you also been involved in research during your career?

A. Yes.

Q. And the jury has heard a lot about peer-reviewed articles, but we see here you have published over 300 peer-reviewed articles?

A. That's correct.

Q. Have you published articles about non-Hodgkin's lymphoma?

A. Yes, I have.

Q. Have you published articles about some of the causes of non-Hodgkin's lymphoma?

A. Yes, I have.

Q. And now -- I think it will be Monday -- but are we going to talk about hepatitis C on Monday? Are we going to talk about hepatitis C on Monday?

A. Yes.

Q. And have you published articles about hepatitis C?

A. Yes, I have.

Q. Including the relationship between hepatitis C and non-Hodgkin's lymphoma?

A. Yes, I have.

Q. Okay. It also -- we have -- for reference on the slide -- that you have been involved in over 70 book chapters.

Can you just explain -- the jury just saw a book chapter, or a book -- but can you just explain very briefly what that means, the difference between a book chapter and a peer-reviewed article?

A. A peer-reviewed article is very, very carefully reviewed by external experts in the field who look -- and they are looking for any defect, anything that might not ring true in the article. It must be approved before it is published.

A book chapter is less intensive in the sense of peer review. Somebody will be asked to edit a book. I have done that as well. And let's say the book is on lymphoma, and they will -- the editor will then call somebody who has expertise in a given type of lymphoma or treatment of lymphoma or a certain cause of lymphoma and ask if you will write such a chapter. And I have agreed to do that about 70 times at this point. It takes a lot of time to write those chapters, and I decided at a certain point that I would agree to write only one a year, and so that's what I did.

Q. And if we can get through this slide, I think we have

covered the fact that your research has really focused on the treatment and causes of lymphoma; is that fair?

A. Correct.

Q. And it's included lymphomas caused by infectious organisms such as HIV, HTLV1 and hepatitis C. Is that also correct?

A. Yes.

Q. And then we have -- there is a reference here at the bottom that you were a member of the board of Scientific Councilors in two different five-year periods associated with the National Cancer Institute. Maybe to wrap up today, can you just please explain what your role was when you were a member of that board?

A. The board of Scientific Councilors is an honorary position as well. Scientists and physicians are chosen from around the country to come to the National Cancer Institute itself and to review the research being done by the scientist at the NCI to determine whether their science is optimal or whether their science needs to be changed in some way or discussed in some way.

So we review the scientists and doctors who work and do research at the National Cancer Institute. I was asked to do that on two occasions. Each one was a five-year term.

Q. And the National Cancer Institute, I think the jury has heard, that is associated with the National Institutes of Health, correct?

A. It is within the National Institutes of Health, the institute specifically designated to study cancer, its causes, its treatment, and so forth.

Q. Based on your participation in this board -- I mean, are they looking for leaders in the country on cancer and lymphoma and related issues?

A. Yes, they are looking for leaders in those areas who might come to look in an objective way at the science done by their own scientists at the National Cancer Institute.

MR. STEKLOFF: Your Honor, I'm happy to keep going or --

THE COURT: I think this is probably a great place to stop.

And so we are breaking for the weekend, so I will just remind everybody, once again, you have to be very careful not to speak with anybody about this or to expose -- be exposed to any information about this, any media reports.

If you learn that you have been exposed to something or somebody else has been exposed to something that they shouldn't have been, please let us know right away. Don't do any of your own independent research, all of my admonitions.

And we will resume at 8:30 sharp on Monday morning. Thank you.

(Proceedings were heard out of presence of the jury:)

THE COURT: If there is anything that anybody needs to

talk about this afternoon, it will have to be later.

MS. WAGSTAFF: I don't think Plaintiffs have anything.

MS. MOORE: We don't, Your Honor. We just have to tender the 454. It has been redacted since the version we gave to the Court originally. It has already been admitted today.

THE COURT: Okay. All right.

So -- but everybody needs to stay in the courtroom for five minutes before leaving. Theresa will let you know when you can leave because, as I have said in the past, we need to give the jurors a chance to ride the elevator down and all that before people leave.

Okay. So we will see you -- you have got some filings due I think on Sunday. You wanted to talk about --

MR. BRAKE: The next go of the trial.

THE COURT: I have thought about it a little bit more. I guess my inclination is the same as the one I expressed earlier which is that I think it would be fine to kind of -- you know, assuming we don't have a mistrial in this one -- that we kind of press the pause button a little bit after this verdict and after the March verdict in the State court.

So I would be comfortable pushing this trial back a -- the Stevick trial back a little bit in other words. If there is a mistrial in this case, we would try this case again in May.

MR. BRAKE: Understood. If that's Your Honor's ruling, that's Your Honor's ruling. I have talked to the

leadership team. I have talked to counsel for Monsanto. Most importantly talked to my clients, Christopher and Elaine Stevick. We are all in concordance to go forward on May 6. I'm not trying to argue with you. I'm telling you what our position is and what we have discussed amongst ourselves.

THE COURT: I didn't realize that was everybody else's preference. So then what I would say is as of now, full steam ahead. I'm not sure the exact date would be May 5 or 6th or the one we identified.

MR. BRAKE: May 6th.

THE COURT: In the May/June timeframe we will -- most likely can work something out.

MR. BRAKE: Of course. In order to prepare and have witnesses here, it is going to be important for us to know sooner rather than later the exact day Your Honor wants to start.

THE COURT: Understood.

MR. BRAKE: As I understand what you are saying now is it is going to be in that timeframe, but we don't know for sure.

THE COURT: As of now I think you can operate on the assumption it will be in the May/June timeframe, but I can't give you a precise date right now.

MR. BRAKE: Understood. Yes, sir. Thank you very much.

MR. STEKLOFF: Your Honor, I think the record is well preserved. Just so there is no ambiguity, the motion that I reserved at the end of Plaintiff's case is a directed verdict motion. We don't have to hear it now, but I just wanted that to be on the record.

THE COURT: Got it. We will see you Monday morning. I assume we will have some stuff to talk about Monday morning, so everybody make sure to be here right at 8:00 o'clock.

MS. WAGSTAFF: Thanks. Have a good weekend.

THE COURT: You too.

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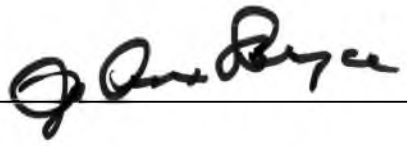
CERTIFICATE OF REPORTERS

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

DATE: Friday, March 8, 2019



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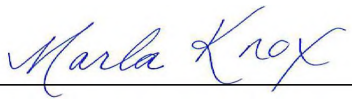

Marla F. Knox, RPR, CRR
U.S. Court Reporter