SUPERIOR COURT OF CALIFORNIA

COUNTY OF ALAMEDA

BEFORE THE HONORABLE WINIFRED Y. SMITH, JUDGE PRESIDING

DEPARTMENT NUMBER 21

---oOo---

COORDINATION PROCEEDING SPECIAL TITLE (RULE 3.550) ROUNDUP PRODUCTS CASE THIS TRANSCRIPT RELATES TO: Pilliod, et al. vs. Monsanto Company, et al.	**JCCP No. 4953** **Case No. RG17862702** **Pages 4799 - 5054** **Volume 29**

Reporter's Transcript of Proceedings

Wednesday, May 1, 2019

Reported by: Kelly L. Shainline, CSR No. 13476, RPR, CRR
Stenographic Court Reporter

APPEARANCES OF COUNSEL:

For Plaintiffs:

THE MILLER FIRM, LLC
108 Railroad Avenue
Orange, Virgina 22960
(540)672-4224
BY: MICHAEL J. MILLER, ATTORNEY AT LAW
mmiller@millerfirmllc.com

BAUM HEDLUND ARISTEI & GOLDMAN PC
10940 Wilshire Boulevard, 17th Floor
Los Angeles, California 90024
(310) 207-3233
BY: R. BRENT WISNER, ATTORNEY AT LAW
rbwisner@baumhedlundlaw.com
PEDRAM ESFANDIARY, ATTORNEY AT LAW
pesfandiary@baumhedlundlaw.com

(APPEARANCES CONTINUED ON FOLLOWING PAGE)

APPEARANCES: (CONTINUED)

For Defendants:

EVANS FEARS & SCHUTTERT LLP
2300 W. Sahara Ave, Suite 950
Las Vegas, Nevada 89102
(702) 805-0290
BY: KELLY A. EVANS, ATTORNEY AT LAW
kevans@efstriallaw.com

HINSHAW
One California Street, 18th Floor
San Francisco, California 94111
(415) 362-6000
BY: EUGENE BROWN JR., ATTORNEY AT LAW
ebrown@hinshawlaw.com

GOLDMAN ISMAIL TOMASELLI BRENNAN & BAUM LLP
564 West Randolph Street, Suite 400
Chicago, Illinois 60661
(312) 681-6000
BY: TAREK ISMAIL, ATTORNEY AT LAW
tismail@goldmanismail.com

(Multiple other counsel present as reflected in the minutes.)

I N D E X

Wednesday, May 1, 2019

Wednesday, May 1, 2019 8:45 a.m.

P R O C E E D I N G S

---oOo---

(Proceedings commenced in open court out of the presence of the jury:)

THE COURT: Good morning.

MR. EVANS: So I think just the issue was raised yesterday --

THE COURT: No letter.

MR. EVANS: What's that?

THE COURT: No letter. You cannot use the letter.

And that's fine, I don't even want to hear about it, but you can make a record.

MR. MILLER: Your Honor has ruled. That's the end of it.

THE COURT: Yeah, done.

I just think that that's sort of an obscure reference to it because it's in a letter about an investigation about something else, and I think we would be in a trial within a trial about exactly what that means. I couldn't let it go. I mean I'd have to let the defendants then defend that. And then we're, I think, wasting time. And I'm not sure it's a real criticism, to be honest with you. I'm not sure what it

is. From that letter, I can't tell what it is.

MR. MILLER: Your Honor has ruled. Thank you.

THE COURT: Okay. Is that it?

MR. EVANS: That's it.

MR. WISNER: One thing, Your Honor.

THE COURT: Ten-minute breaks and a 40-minute lunch so we can hopefully have a little more time to get done with your witness today.

MR. EVANS: Yeah, and I think candidly -- and I shared the PowerPoint with Mr. Miller and, you know, we've talked about epidemiology once or twice so I think we're going to try to move through it pretty quickly today.

THE COURT: I'd check on your jurors, whether they're awake or not, to be honest with you at this stage of the game.

MR. EVANS: Yeah, we're going to move pretty quickly, Your Honor.

THE COURT: All right.

MR. WISNER: Yesterday there was a thing issued by the EPA, another report or document. I think they're going to file a motion to take judicial notice of it. The timing of it is suspect. But putting that issue aside, I just want to make sure that Dr. Mucci isn't going to talk about it. Because we're definitely

going to oppose --

MR. EVANS: She's not.

MR. WISNER: Very good.

MR. ISMAIL: So, Your Honor, there's a motion on file for judicial notice. This is not a thing from the EPA. It's, if you recall, some of the plaintiffs' witnesses were and even Mr. Wisner in his opening suggested, well, you know, maybe the EPA is going to change their mind from their last OPP report. And the issue had been pending. And yesterday they did indeed issue their --

THE COURT: Is this the final ruling on the reregistration?

MR. WISNER: Still interim.

THE COURT: Let me just take a look at it.

MR. ISMAIL: This is a courtesy copy. It has been filed. And it's in the context of an argument and it will not come up today.

MR. WISNER: Your Honor, we will oppose this. And just to give you a quick background, putting aside the timing issues and the fact that, you know, we were delaying this case for a few weeks -- almost a week and a half now, and conveniently this comes out right after we close and just before closings. Putting that issue --

THE COURT: Boy, the reach of Monsanto.

MR. WISNER: I know, snap their fingers, they get a report.

THE COURT: What are we saying here?

MR. EVANS: It's me, Your Honor.

THE COURT: Oh, is it you personally? I'm sorry, Mr. Wisner.

MR. WISNER: We can make light about it.

THE COURT: I'm not making light about it. I mean, come on.

MR. WISNER: For me it's concerning personally because the scope of corruption that I think is in the EPA, but that's a different issue.

The concern, Your Honor, is that if this does come in, we have to call back Dr. Portier to rebut it, just pure rebuttal. We also are going to have to --

THE COURT: Would he actually say -- I don't know what's in it, but would he actually say something he hasn't already said about the state of glyphosate and whether or not it is in fact carcinogenic? Or is it to remind the jury that that's how he feels?

MR. WISNER: No, no, it would be to respond to the statements in the document. It wouldn't be -- there's new statements in it.

THE COURT: Okay, I don't need to know what

you think you need to do on rebuttal. I'm just wondering whether or not --

MR. WISNER: We have to rebut it. And part of that rebuttal would also be playing the deposition of a person named Todd Rands at Monsanto. We didn't play it in our case in chief because it's largely 2018 stuff. But we have documents showing Monsanto's interactions with the EPA and intel -- intelligence about the EPA and the White House as it relates to this very issue. It opens up a very big can of worms. We'll put this all in a brief and get it to you right away because obviously we don't have much time.

THE COURT: Well, you have until Monday because when I leave here, I'm not bringing this with me.

MR. WISNER: Fair enough.

THE COURT: Yeah, that's not happening. So I would address it when I get back if your opposition is on file.

MR. WISNER: We'll have it on file, Your Honor.

THE COURT: Thank you.

MR. ISMAIL: Thank you.

THE COURT: We have 10 minutes.

(Recess taken at 8:49 a.m.)

(Proceedings resumed in open court in the presence of the jury at 9:03 a.m.)

THE COURT: Good morning, ladies and gentlemen.

ALL: Good morning.

THE COURT: We're going to continue on with defendant's case.

I just want to remind you that we're going to be leaving a little early today at 3:00 o'clock so we're taking short breaks, two 10-minute breaks, and lunch will be about 40 minutes, just to give you an idea what our day will look like.

So, Mr. Evans, you may continue.

MR. EVANS: Thank you, Your Honor, good morning.

Good morning, everyone.

Defense calls Dr. Lorelei Mucci.

THE COURT: Just stand up there.

THE CLERK: Raise your right hand, please.

LORELEI MUCCI,

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

THE WITNESS: Yes, I do.

THE CLERK: Thank you. Please be seated.

Would you state and spell your name for the

record.

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

DIRECT EXAMINATION

BY MR. EVANS:

Q. Good morning, Dr. Mucci. How are you?

A. Good morning. How are you?

Q. The good thing is you are the second-to-last witness that the jury is going to hear from. So Monday we'll have the last witness and then we'll wrap this thing up.

But you are an epidemiologist; is that right?

A. Yes, I am.

Q. And the jury has heard, give or take, 1,400 times the epidemiology in this case, a little exaggeration, so I'm going to try to move through this very quickly today but focus on some issues that I know that you looked at.

But before we do that, could you just introduce yourself to the ladies and gentlemen of the jury.

A. Sure. My name is Lorelei Mucci. I'm a cancer epidemiologist. And I live in Boston, Massachusetts.

Q. And I want to use your CV to talk about some

of your background.

MR. EVANS: May I approach, Your Honor?

THE COURT: Yes.

MR. EVANS: Permission to publish 6810?

MR. MILLER: No objection, Your Honor.

(Exhibit published.)

BY MR. EVANS:

Q. And, Dr. Mucci, you can look either at the one on the screen or the paper copy there, but I want to talk to you a little bit about that.

Let's just start with your educational background. Where did you go to school?

A. So I received a bachelor of science degree from Tufts University. And then I completed a master's of public health in epidemiology and biostatistics at Boston University. And then I received my doctor of science from Harvard University.

Q. And did you do a dissertation as part of your doctor work?

A. Yes, I did.

Q. And what was that on?

A. So the focus of my doctoral thesis was on the role of periodontal disease in cancer and cardiovascular disease.

Q. And do you teach students now?

A. Yes, I do.

Q. And do you have a favorite course that you like to teach?

A. Currently one of the courses that I'm leading is on the epidemiology of cancer. It introduces students to the basic concepts of cancer, trying to understand what are the major causes of different types of cancer and what are the major risk factors for cancer.

Q. And if you turn to the next page, where do you actually teach courses?

A. So I'm currently an associate professor at the Harvard School of Public Health which is located in Boston.

Q. And how long have you been there?

A. I have been on the faculty as primary faculty for the past nine years.

Q. And prior to that, where did you work?

A. So after I finished my doctor of science training, I did what's called a postdoctoral fellowship, it's additional training in cancer epidemiology, in Sweden at a place called the Karolinska Institute. Then I came back to Boston and where I was working at Brigham and Women's Hospital and Harvard Medical School.

Q. All right. And if you look down at the next

part of your CV there, it says hospital or affiliated institutions. Do you see that?

A. Yes.

Q. What are your positions there?

A. Right. So -- so the Harvard School of Public Health is one of seven different institutions that are part of a cancer center in Boston known as the Dana-Farber/Harvard Cancer Center. It brings together a thousand different people around these seven institutions who are focused on cancer research, and it's the oldest and largest cancer center in the country.

And so my role specifically there is as a leader for the program in cancer epidemiology.

Q. And just talk a little bit more about the Dana-Farber. What is the Dana-Farber/Harvard Cancer Center?

A. Yeah, so it was started actually initially in the 1950s. The idea was to bring together people doing research that I do, epidemiology, together with clinicians who do cancer research and basic scientists with the idea of bringing people together can help accelerate our understanding of why cancer occurs, how to prevent cancer from happening, and how to better treat cancer.

And so the Dana-Farber/Harvard Cancer Center was established. As I mentioned, the Harvard School of Public Health is there. Also some of the hospitals, Dana-Farber Cancer Institute which is the biggest cancer institute in the New England area, and with the goal again of working together to understand why cancer occurs and how to prevent it.

Q. So is it fair to say this is an interdisciplinary team that brings lots of different experts to the question of cancer and what's going on?

A. Yeah, exactly. And so actually the National Cancer Institute funds 50 cancer centers around the country. And the specific goal of the National Cancer Institute is, by bringing people together across different disciplines, we can work better together.

So I work very closely as leader of the cancer epidemiology program with oncologists, surgeons, and also basic scientists in the research that I do, as well as helping to support the research of all of the members in the cancer epidemiology program.

Q. All right. And if we continue down your CV, one of the sections here is major administrative responsibilities. And I want to talk, if you turn to the next page, the advisory board member on the Nurses' Health Study.

Could you tell the ladies and gentlemen of the jury what the Nurses' Health Study is and what your role was?

A. Sure. So the Nurses' Health Study was one of the really early cohort studies that was set up. And specifically it enrolled about 120,000 women who were nurses back in the 1970s. So it's a study that's been going on for about 40 years.

And the idea was that nurses could provide high-quality information about their health. And so these 120,000 women had been followed through our -- regularly with questionnaires. We link data in the cohort to cancer registries to find out who's developed cancer. And there's also a variety of blood-based and other types of biomarkers that we have in the study.

So my specific role is serving on the advisory board. And our responsibility is really to provide the investigators of the Nurses' Health Study with some critiques about potential problems going on with the study and then also to work with them to identify solutions and other aspects to provide just better -- our goal is to get better quality information from the cohort study.

Q. If you could turn to the next page. And just highlighting the Co-Principal Investigator Health

Professionals Follow-Up Study. What's the Health Professionals Follow-Up Study?

A. So the Nurses' Health Study is -- includes nurses and it's all women. And so in the 1980s we started an all-male cohort called the Health Professionals Follow-Up Study. It includes dentists, optometrists, veterinarians, again with the idea that these individuals could provide high-quality health information.

And actually the importance of studying cancer in men is that cancer is elevated in about for 30 or 35 different cancers in men. And so the idea was we enrolled 50,000 men. They've been followed every two years with questionnaires and to try to understand what the causes of cancer are.

Q. And is one of the issues you focused on prostate cancer?

A. Yes, it is.

Q. And what are you currently involved in with respect to that issue?

A. So prostate cancer, as you may know, it's the leading cause of cancer in men in 100 different countries around the world. And so the work that we're doing, both in the Health Professionals Follow-Up Study and others, is trying to understand whether they have a

history of prostate cancer, whether things like physical activity could lower the risk of developing prostate cancer, and then once a man has cancer, trying to understand whether there's factors that can improve survival and quality of life for the men.

Q. All right. So you've mentioned the Nurses' Health Study and the Health Professionals Follow-Up Study. Are there a number of different cohort studies going on now that are supported by the National Institutes of Health and the National Cancer Institute?

A. Yeah, so currently the National Cancer Institute funds 50 different cohort studies of cancer. They've actually put together a group called the Cohort Consortium which with the idea of pooling together these 50 cohort studies. And I serve as a leader of one of the working groups for this Cohort Consortium.

Q. Is the Agricultural Health Study, which the jury has heard about, is that part of this consortium of studies?

A. Yes, it is. It's one of the cohorts that are part of the Cohort Consortium.

Q. And is the Agricultural Health Study ongoing today?

A. Yes, it is. It's -- you know, one of the unique strengths of many of the cohort studies in this

consortium is that we're able to actively follow the individuals for cancer incidence and mortality. And that is one of the studies that's ongoing today.

Q. And as an advisory board member of the Nurses' Health Study, if you had issues or criticisms with that study, would that be something that you would communicate to the investigators and the other advisory board members?

A. Right. So that's one of the responsibilities that we have is to try to identify potential problems early and then work with the investigators to see whether those are in fact issues, and if they are, to work with them on solutions.

And so we meet every year to, you know, discuss progress. And then we're also in contact regularly through e-mails and telephone conferences as well.

Q. And go down to page 6 and just talk briefly about your roles as an ad hoc reviewer and the editorial boards.

A. Sure. So, you know, one of the ways that we share the results of the research we do is by publishing in medical journals. And each manuscript gets reviewed by other scientists, by peers. And so I serve on -- as a reviewer for all of the journals that are listed here.

And I review manuscripts for the quality of the science and the validity of the findings.

Q. How many different manuscripts have you reviewed? Do you have an idea? An estimate?

A. I couldn't even guess, but it's at least several hundred, if not more.

Q. And if you go to the top of the next page, the senior editor of *Cancer Epidemiology, Biomarkers and Prevention*, what is your role there?

A. Yeah, so one of the biggest international organizations in cancer is the American Association for Cancer Research, and they have several journals. And the *Cancer Epidemiology, Biomarkers and Prevention* is the leading cancer epidemiology journal that exists.

I joined currently this year as the senior editor for the journal and have a variety of responsibilities for everything from making final decisions about whether or not to accept manuscripts, also helping to set the scientific direction for the types of research that we want to be publishing on in this journal.

Q. I want to switch down now to talk about some of the grants that you've received. If you just look down at the bottom of page -- that same page, the past funded grants.

And let's not -- we don't need to pull it up specifically. But do you offer several pages here talking about the past history of grants that you and your institution have received?

A. Yes, I -- yes, I have.

Q. And just briefly tell the ladies and gentlemen of the jury what that process is in getting grants from governmental or other entities.

A. So all of the research that I do is funded either by government agencies like National Cancer Institute or actually the U.S. Army is one of the biggest funders of cancer research. Or also foundations support the research we do.

And put in what we call a grant application that describes the scientific aims of the study and how we're going to approach the design and the conduct of the study. So we submit those and it gets reviewed by peer reviewers.

Q. All right. And let's switch on to page 14. And do you currently have studies that are ongoing that are supported by grants?

A. Yes, I do. I have approximately over $10 million of research funding that supports the research that we do.

Q. And if you just look down at the bottom of

that page, just talk briefly about the one at the bottom there with respect to tumor and circulating markers as links between obesity and prostate cancer.

A. Yeah, so the National Cancer Institute funds large interdisciplinary collaborations. And the Dana-Farber/Harvard Cancer Center has a large what we call a program project that brings together epidemiologists, oncologists, basic scientists and to work in prostate cancer. And the project that I'm leading is on the role that obesity plays in prostate cancer.

Q. And if you turn to page 16, and I just want to talk briefly, this bridge project of MIT and Dana-Farber.

A. Uh-huh.

Q. So talk to us a little about that. And again this goes to this interdisciplinary nature of the work you're doing.

A. Yeah, so the Massachusetts Institute of Technology and the Dana-Farber/Harvard Cancer Center every year offer a grant mechanism with this idea of bridging together scientists who work in the field of population science which includes epidemiology together with basic science.

And so this particular project we received is

funded specifically to look both from the basic science perspective and from epidemiology to try to understand a specific aspect of prostate tumors.

Q. All right. And the jury's heard -- you're referring to it as basic science.

A. Yes.

Q. Or bench science.

A. Yes.

Q. They've heard about genotoxicity studies, they've heard about animal studies, et cetera. You're not actually here to talk about that today; correct?

A. No. I'm here to talk about the epidemiology.

Q. And that's the human data that you spent your career studying, epidemiology in cancer?

A. Yes, it is.

Q. Okay. And before you were contacted by attorneys in this case to look at NHL and Roundup, had you actually studied pesticides and Roundup before?

A. No, I hadn't.

Q. And had you focused on NHL before?

A. Very limited work on non-Hodgkin's lymphoma.

Q. Okay. And could you just describe the process you went through to prepare your opinions and to assess the issues before you came to testify today.

A. Yeah. So it was the same process that I would

take with any study that I would do on my own or for peer reviewing as well. And it's to review carefully all of the published epidemiology studies on Roundup in non-Hodgkin's lymphoma. Also to look at any of the studies that were published around the specific, you know, for example, cohort studies. So really looking at all of the evidence of the epidemiology studies and looking through each study and critically evaluating its strengths and its weaknesses.

Q. And just to be clear, have you decided you're just going to dismiss some studies because they are not done a certain way or they don't have statistical significance, for example?

A. No. It's really critical when you're trying to assess whether something is a risk factor for cancer to actually evaluate every single study. And, again, you may come to a decision that some studies may have more potential for bias than another study, but it's really critical to evaluate each study and take the evidence in total.

Q. And in offering your opinions today, are you going to offer those to a reasonable degree of scientific certainty?

A. Yes, I am.

Q. And is it to the same degree of scientific

certainty that you would teach your students?

A. Yes, it is.

Q. And that you would engage in when you're looking at all the other studies that you've been involved with?

A. Absolutely, yes.

Q. And I want to just go briefly to page 18 of the CV. And you list out here the courses you've had over time. And then you also talk about your advisory and supervisory responsibilities with respect to other students; correct?

A. Yes.

Q. And so just talk to us. Are you, in fact, a mentor? Do you have students who are coming up in epidemiology that you are sitting on their, for example, dissertation board or the equivalent?

A. Yes. So in addition to actually teaching courses and doing research, one of the other roles that I have is mentoring students. And over the past 15 years I've mentored about almost 80 graduate students or postdoctoral fellows in cancer, and many of whom now have gone on to be their own independent researchers and teachers.

Q. Turn to page 21, please.

And you actually list out these individuals

that you've mentored and taught and served as an advisor.

A. Yes, I do.

Q. Okay. And then if we go to -- we're just about to wrap this up, but if you look at the bibliography which is on page 36. And this lists the peer-reviewed articles that you've been an author on; correct?

A. Yes.

Q. And how many -- what are you up to now?

A. So close to 300 peer-reviewed research articles and letters to the editor.

Q. And have you also been an editor of a book?

A. Yes. In the past two years, I was an editor for two textbooks focused in the area of cancer.

Q. All right. And I think Mr. Miller here may have actually helped out your -- I don't know if you actually get any sort of a royalty from it, but it looks like he's got four or five copies of one of your textbooks. So I think he's going to ask you questions about that. But that's --

MR. EVANS: Can I borrow one?

MR. MILLER: Sure.

BY MR. EVANS:

Q. Is this one of your textbooks?

A. Yes, it's called the *Textbook of Cancer Epidemiology*. It's one of the textbooks that students use kind of all over the world to look at the epidemiology of cancer.

Q. And are you being compensated for your time?

A. Yes, I am.

Q. And how much is your hourly rate?

A. $350 per hour.

Q. And do you know roughly how many hours you spent on this particular case?

A. Approximately 40 to 50 hours.

Q. And you spent some additional time researching the issues and analyzing, talked about reading a bunch of articles and analyzing issues; did you spend additional time?

A. Yes, I have.

Q. And do you have an approximation of how much that is?

A. Perhaps, you know, several hundred hours over the course of time.

MR. EVANS: With that, Your Honor, I would proffer Dr. Mucci as an expert in cancer epidemiology.

THE COURT: Voir dire?

MR. MILLER: Yes, Your Honor. Thank you.

///

VOIR DIRE EXAMINATION

BY MR. MILLER:

Q. Good morning.

A. Good morning. It's nice to see you.

Q. How have you been?

A. Fine, thank you.

Q. Good. Did you have a safe trip in from Boston?

A. I actually came in from London.

Q. Okay. That's even farther.

Well, we've met before, of course.

A. Yes, we have.

Q. I just want to go to your qualifications. And I know you're an epidemiologist, and I'm not challenging the fact that you're an epidemiologist, Dr. Mucci.

There are epidemiologists who, before they were called to be litigation experts, studied Roundup; is that fair?

A. Yes.

Q. And you're not one of them; right?

A. I am not, no.

Q. And there are epidemiologists who, prior to being called in that capacity, have studied pesticides generally and their relationship to non-Hodgkin's lymphoma; that's true, isn't it?

A. Yes, it is.

Q. And you're not one of them?

A. No, I'm not. But I do have the training to be able to read through all of this literature and be able to critique it.

Q. Sure, sure. But I'm talking about before you became the expert that you agreed to become for Monsanto, you did not research Roundup; right?

A. That is correct, yes.

Q. And you did not research any pesticides in relationship to non-Hodgkin's lymphoma; that's also true, isn't it?

A. I didn't do my own research, no.

Q. And you talked about a lot of articles and a lot of books. And we're going to look at your book. I think we both know that. But none of your articles relate to the relationship between Roundup and non-Hodgkin's lymphoma; true?

A. That's true.

Q. None of them relate to the issue of pesticides and non-Hodgkin's lymphoma; that's also true?

A. Yeah, again that is true. However, I am able, with my training and my experience, to be able to critically evaluate this set of studies. And in addition as a peer reviewer, I've actually -- have

reviewed articles on the topic of pesticides and cancer and so have that background as well.

Q. And you've told us you sent letters to the editor, you count those as part of your publications; right?

A. Yes, I do.

Q. And you've never sent a letter to the editor criticizing any of the studies that have been published that we're intimately familiar with about Roundup and non-Hodgkin's lymphoma; you've never done that, have you?

A. No. And part of it is, you know, when you send in a letter to the editor, usually you would want to send it within a couple weeks after the study is published. This hasn't been an area of research that I particularly have focused on. So I wouldn't have sent in a letter to the editor on this topic.

Q. I'm just saying it's not your area of expertise, that's why you wouldn't have sent it in, right?

A. Well, again, although I don't study pesticides in cancer, I do have the background and training to be able to critically review these epidemiology studies.

Q. As a cancer epidemiologist, you're intimately familiar with the International Agency for Research on

Cancer; right?

A. Yes, I am.

Q. And you know that they invite specialists to sit on panels that are called monographs and they study issues of cancer; right?

A. Yes. And in fact I was invited to be part of one of the IARC panels.

Q. Well, and that's why I asked. You were not invited to be on the Monograph 112 issue of pesticides and non-Hodgkin's lymphoma; right?

A. That is correct.

Q. And I'm not -- you know, I'm not trying to insult you in any way. That's just not your area of expertise. That's why they wouldn't invite you; right?

A. Right. So again, you know, although it's not an area of research that I've focused on myself, my training, my experience being able to -- leading cohort studies, leading research in cancer, I'm able to really critically evaluate and understand all of the epidemiology studies in this particular case.

Q. But to be clear, the first time you critically evaluated the epidemiological studies on the issue of Roundup and non-Hodgkin's lymphoma was after the call from the Monsanto lawyers; right?

A. No, that's actually not completely the case.

As I mentioned, I have served as a peer reviewer of studies that have looked at the topic of pesticides and cancer. I also have close colleagues that work in this area as well that I collaborate closely with and understand their own research.

I have attended scientific meetings where there's been studies published and presented on pesticides and cancer. So although it's not an area of research that I haven't done myself, it's still an area that I feel that I have the expertise to understand and evaluate.

Q. Name one article you've reviewed on the issue as an editorial reviewer.

A. So one of the studies was some of the early work on dioxins in breast cancer that was being evaluated in a journal of the National Cancer Institute. That's one example.

I've also published -- worked as a peer reviewer on a variety of different other publications for the *Cancer Epidemiology, Biomarkers and Prevention*, *Cancer Prevention Research*. There's been several peer-reviewed process that I've done on this topic.

THE COURT: So, Doctor, if you could just slow --

THE WITNESS: Yeah.

THE COURT: -- down a little bit.

THE WITNESS: Sure, sorry.

THE COURT: The reporter is taking down --

THE WITNESS: Sorry, Your Honor.

THE COURT: -- everything you say.

THE WITNESS: Sorry.

MR. MILLER: This lady has been working hard for six weeks on this.

Q. You understand this case is not about breast cancer.

A. Yes, I do. It's on non-Hodgkin's lymphoma.

Q. It's not about dioxins; right?

A. Yes, I understand, but actually, you know, really some of these principles of epidemiology are common across all of the different types of studies. The issues around the quality of questionnaires, the quality -- the issues around confounding, these are all core common concepts we study in epidemiology.

So just because I haven't published myself on Roundup and non-Hodgkin's lymphoma doesn't necessarily mean -- and in fact, actually given all my training and experience as a cancer epidemiologist, I have more than sufficient expertise to evaluate this body of evidence.

Q. Did you -- do you know what the InterLymph organization is?

A. Yes, I do actually. My former mentor was one of the founding investigators of InterLymph.

Q. So was Dr. Weisenburger. Are you aware of that?

A. No, I wasn't.

Q. You're not a member of the InterLymph, are you?

A. No. I haven't done much research in specifically -- in lymphoma and non-Hodgkin's lymphoma. But I have several colleagues who have.

Q. Some epidemiologists are also medical doctors; right?

A. Yes, they are.

Q. And you're not one of them?

A. No. I'm a Ph.D. scientist.

Q. And of course you've read Dr. Ritz's deposition in this case; right?

A. Yes, I have.

Q. She is a medical doctor as well as an epidemiologist; you're aware of that?

A. She has a medical degree but I understand has not practiced in medicine. So I think that is an important distinction.

Q. Some of the experts we've heard from in the last six weeks are oncologists; right? Cancer doctors?

A. Yes.

Q. You're not one of them?

A. No, I'm not.

Q. Okay. Some of them are hematologists, blood cancer doctors; right?

A. I'm not sure. I haven't followed every expert that you've presented. So I'm not sure.

Q. I see, that's fair. I'm sorry. I'll be more clear.

You're not a hematologist?

A. No. I'm a cancer epidemiologist, which is, I think, the most relevant thing in looking at the epidemiology studies of cancer.

Q. And to be clear, you chatted about this with Mr. Evans, you're not a toxicologist; right?

A. I'm not.

Q. And you did not look at, at least by the time you formed your opinions and first testified for Monsanto, any opinions about toxicology; right?

A. I -- I mean, I don't think that's exactly clear. As part of my initial evaluation, I did, for example, read some of the report -- regulatory reports that were put out and that talked about some of the toxicology.

But I'm not a toxicologist. I'm not here to

talk about the toxicology. What I'm here to talk about are the epidemiology studies.

Q. Ma'am, when you testified at the *Johnson* trial, do you remember saying you had not reviewed the toxicology; right?

MR. EVANS: Your Honor, is this going to qualifications?

THE COURT: No. Sustained. That's an objection.

MR. EVANS: Yes.

MR. MILLER: I'm sorry. I didn't hear, Your Honor.

THE COURT: I said he objected that that does not go to qualifications about her testimony in the *Johnson* trial?

MR. MILLER: Just whether or not she looked at the toxicology literature before she ever testified in trial, is the question.

THE COURT: Sustained. Sustained.

MR. MILLER: We'll move on. I'll come back to that later.

Q. Now you are an epidemiologist; right?

A. Yes, I am.

Q. And there are certain kinds of epidemiologists called occupational epidemiologists; right?

A. Yes, there are.

Q. And you're not one of them?

A. No, I'm not.

Q. Okay. Certain epidemiologists are environmental epidemiologists; right?

A. Yes, that's correct.

Q. And you're not one of them?

A. No, I'm not.

Q. And did you tell them on that first phone call you're not an occupational epidemiologist?

A. I'm sorry?

Q. When the Monsanto lawyers called, did you tell them that?

A. I can't recall.

Q. All right. Now, within epidemiology, you do have an area of specialty; right?

A. Yes, cancer epidemiology.

Q. Prostate cancer; right?

A. Prostate cancer is one of the areas that I've studied. But actually I've published on bladder cancer, breast cancer. I've done a little bit of work on lymphoma, kidney cancer, colorectal cancer. I've studied several different types of cancer.

Q. No, I didn't say you hadn't studied other types of cancer. Let me be fair. Your primary

interest, it's all over your CV, is prostate cancer; right?

A. It's one of the cancers that I focus on, yes.

Q. Okay. Well, let's just take a look.

MR. MILLER: Can I have the ELMO, please. Thank you.

MR. EVANS: Again, Your Honor, does this go to qualifications? I object.

MR. MILLER: Well, I think it does.

THE COURT: Overruled. Let him ask the question.

MR. MILLER: Let me back that out. Wrong way.

(Exhibit published.)

BY MR. MILLER:

Q. This is your CV, 2014, 2015, 2013. I mean, you do a lot of prostate cancer research.

A. I'm sorry. It's prostate.

Q. I know I'm saying it wrong. I'm sorry. You know a lot more about it than I do. Prostate. I apologize. Sorry.

A. Yes.

Q. And prostate cancer has nothing to do with this case; you'll agree?

A. No, it doesn't. And that is true. However, the -- first of all, the principles of the research that

I do in prostate cancer and the approach that I take to the study of all the cancers that I do research on is the same approach that I took in looking through the epidemiology cases here.

Also as I mentioned, I am leader of the cancer epidemiology program at the Dana-Farber/Harvard Cancer Center. I work closely with researchers in all sorts of different cancer types including lymphoma.

I also am a co-investigator currently of a project that's funded by the American Institution for Cancer Research on trying to understand precursors for multiple myeloma. It's involving a new cohort study of 50,000 individuals.

So, again, I'm just adding that was one of the things we didn't talk about, but it goes to show that I am really looking at a broad range of cancers in the research I do.

Q. I promised Mr. Evans I'll do my best to get you out of here today. You've got to help me. You've got to answer my questions. Okay.

My question was: Do you remember it? Your specialty, your primary focus is prostate cancer; that's true?

A. That's not correct actually.

Q. It's not --

MR. EVANS: Objection, Your Honor.

THE COURT: Sustained.

Counsel, why don't we save that for cross-examination?

BY MR. MILLER:

Q. Now, you talked about your funding, the National Cancer Institute; right?

A. Yes.

Q. You're also funded by the Bayer Corporation, aren't you?

A. So one of the newest projects that we have started is a global registry of prostate cancer patients. We're recruiting 5,000 men with advanced prostate cancer, meaning they have metastatic disease already. And one of the drugs that's used for treatment of men who have metastatic prostate cancer is from Bayer. So Bayer has been one of the funders of this particular study.

Q. So the answer is, yes, you're funded by Bayer Corporation?

A. Well, I'm actually not personally funded, but the research study that I'm working on is funded. So I don't receive direct funding from them, but the research product is funded by Bayer in part.

Q. You did not mention on your CV but you've been

invited to lecture by the American Chemical Association?

A. American Chemical Society, yes.

Q. Excuse me.

And they pay for you to go places and you give them lectures --

A. No, that's not correct actually. So the American -- when I was doing specific research in the topic of known as acrylamide, I was invited as a guest speaker to the American Chemical Society.

So I wasn't funded by them. I wasn't a paid speaker. It was very different. You know, every year the American Chemical Society has a research conference just like the American Association for Cancer Research. So I attended as a guest speaker.

Q. So have you ever been asked to be on the Scientific Advisory Panel of the Environmental Protection Agency in looking at issues about pesticides and non-Hodgkin's lymphoma?

A. Not on pesticides but on another topic.

Q. Now, you told us that you think you've been paid about $40,000 by Monsanto?

A. No. I said with respect to this specific case, I've worked about 40 to 50 hours.

Q. It's more like $200,000 Monsanto has paid you to be an expert; right?

A. For this particular case, it's been about 40 to 50 hours. I haven't -- throughout the entire time that I've worked on this topic, I've worked several hundred hours and given a rate of $350.

I haven't added up all the amount. But it's been several hundred hours that I've worked on this particular set of litigation.

Q. It was $100,000 last June. Do you remember that?

A. Yes, I do.

Q. And you've been busy since last June with this, haven't you?

A. I can tell you I've worked several hundred hours reviewing all of the epidemiology studies, being an expert witness, providing expert reports. There's been several hundreds of hours of work that I've put into this topic.

MR. MILLER: Your Honor, limited to general epidemiology, I have no further questions at this time.

THE COURT: You may proceed, Mr. Evans.

I'm not sure what general epidemiology is.

MR. EVANS: She was offered as cancer epidemiology, Your Honor.

Do you have an objection to that?

MR. MILLER: General cancer epidemiology, no

objection, Your Honor.

THE COURT: I just wanted to understand what the modifier meant. Thank you.

MR. MILLER: Sure.

DIRECT EXAMINATION (RESUMED)

BY MR. EVANS:

Q. All right, Dr. Mucci, did you work with me to prepare a PowerPoint presentation to hopefully expedite your testimony today?

A. Yes, I did.

MR. EVANS: And, Your Honor, I've shared that with counsel. And I think I've got a copy that I can hand up to you.

MR. MILLER: I have no objection, Your Honor.

(Demonstrative published.)

BY MR. EVANS:

Q. So let's just start definitionally about what epidemiology is. And so let's talk about that.

What do you -- when you're looking at epidemiology, what are you actually looking at?

A. So epidemiology is the study of why disease happens in humans, is the simplest definition.

Q. Okay. And are you looking at individual patients in epidemiology studies?

A. We're looking at populations of patients, yes.

Q. But within a different -- within a study, you're actually looking at what happens with individuals?

A. Exactly, yes.

Q. Okay. And do you -- let's go to the next slide.

(Demonstrative published.)

BY MR. EVANS:

Q. Could you just, at a very high level, tell the ladies and gentlemen of the jury what your opinion is after you reviewed all the epidemiology, all the research you've done on this topic, what your opinion is.

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

Q. And you were asked a bunch of questions about, I guess, whether you had the expertise to comprehend the studies that you were actually looking at.

Did you understand what you were looking at?

A. Yes, I did.

Q. And do you feel confident that -- in your opinion?

A. Absolutely. The principles of epidemiology that I use in my own research are the same principles in

these set of case-control and cohort studies I've evaluated. So I absolutely am confident in my opinion.

Q. And when you look at epidemiology and you're looking at whether one thing is associated with or related to or causative of a condition or a disease, are the principles the same whether you're looking at one thing versus another?

A. Yes, absolutely.

Q. And when you're teaching your students about looking at evaluating epidemiology, do those same principles apply whether you're looking at prostate cancer or breast cancer or NHL?

A. Yes, absolutely.

Q. And whether you're looking at, you know, something that may be related to prostate cancer versus something that may be related to NHL?

A. Yes.

Q. Is there anything unique or complicated about this set of epidemiology for a Ph.D. scientist as yourself to analyze this set of epidemiology versus the science that exists in other situations?

A. No. And in fact, actually, you know, this particular set of studies, they're not occupational studies per se. They're not environmental studies. They're studies of cancer in populations of individuals.

And it's the same principles I would use in my own research and the same principles I would teach my students.

Q. Now let's go to the next slide.

(Demonstrative published.)

BY MR. EVANS:

Q. And just explain what is being demonstrated here with respect to the pyramid or the triangle of different types of epidemiology.

A. Right. So these are the five different types of study designs that are used to study populations of individuals. And it's well established in epidemiology that there's -- there's a ranking in terms of which studies have the highest level of validity and least susceptible to bias.

And so this shows a pyramid of the studies at the top have the highest validity, the least amount of bias, and then as you go down, you get more concerns about bias.

Q. And with respect to this issue about whether Roundup is associated with or causative of NHL, are there randomized control trials that look at that issue?

A. No, there are not.

Q. So is the highest -- on your chart here, the highest type of epidemiology we have is the cohort

studies?

A. Yes. It's not only just in this set of studies, but actually all of epidemiology, it's well established that cohort studies, because of the way they're designed and conducted, they're less susceptible to bias so they have a higher level of validity.

Q. And when you talked about those 50 studies that the National Institutes of Health and National Cancer Institute are studying the different populations around the world, nurses and dentists and et cetera, are they all cohort studies?

A. Yeah. They're all cohort studies as part of the Cohort Consortium.

Q. And are those inexpensive, short-term, you know, sort of passing studies that you can do in a week or a month?

A. No. You know, as I mentioned, like the Nurses' Health Study is a study that's been going on for 40 years. It's generated literally thousands of publications. These are studies that become richer as they go on in time. And so they're studies that are invested in because they provide such high-quality information.

Q. All right. Let's talk a little bit more about -- let's talk a little bit more about cohort

study.

MR. EVANS: Next slide.

(Demonstrative published.)

BY MR. EVANS:

Q. And just explain to the ladies and gentlemen of the jury about a cohort study and what you're trying to show here.

A. So the idea of a cohort study is to take, you know, a group of people, of individuals, who at the start of the study don't have the disease you're interested in.

So in this particular example, we're looking at whether coffee could be a risk factor for heart disease. And so at the start of the study, none of the individuals have heart disease. You collect data on coffee, whether or not they're drinking coffee, and then over time you see which individuals do and do not develop heart disease.

Q. And in a perfect world, if we had a time machine, how would you actually want to do this study?

A. Right. So in -- so in epidemiology we often talk about this idea of a time machine. So the idea is that if we could take a group of people where everybody drank coffee and then follow them forward in time and you see a certain number of them develop heart disease.

And then what you'd like to be able to do is send that same group of people back in time and they live the exact same life that they lived before, but the only difference is that they're not drinking coffee. And then what you can do is then look at the incidence of heart disease in that population.

So if you see a higher rate of heart disease when that group of people were drinking coffee versus when they weren't, that would suggest that it was a cause of heart disease.

Q. And since we all don't have a flux-capacitor-driven DeLorean to jump in a time machine --

A. Uh-huh.

Q. -- how do you actually analyze this issue?

A. Right. And so -- so what we do in -- in epidemiology study and cohort studies is that the group -- you want the group who's not drinking coffee to represent the group who did and the only difference is that they were drinking coffee or not drinking coffee. And then you can compare the rates of heart disease in those two groups.

Q. And why is it that researchers, epidemiologists like yourself generally think the cohort studies are higher level of evidence than, for example,

case-control studies?

A. Right. So as I mentioned on -- when we were talking about the pyramid, cohort studies, because the way we're collecting the data, we're collecting information on the entire cohort of people. There's not selection forces that go into that group of individuals. They're just less susceptible to bias in the way we design the study and conduct the study.

Q. Okay. Now let's look at the case-control study and talk a little bit about what goes on in a case-control study.

A. Right. So in a case-control study, they're often done to be efficient because, you know, it does take time for heart disease, for example, to develop. What the investigator would do is first identify a group of people who have heart disease. And then to identify a population of people who don't have heart disease but, if they did, would have gotten into your study too. That's kind of one of the important principles. And then you go and ask them to think about what they -- whether or not they drank coffee in the past.

Q. And are there concerns particular case-control studies that you have to be sensitive to when you're evaluating them?

A. Yeah, so there are more potential issues, you

know, we worry about with case-control studies. There's more things that can go wrong which is why they're considered to be a lower level of validity.

You know, as an example, some of the early case-control studies, not only just in this set of studies, but more generally some of the early studies, you know, you have to identify cases and get them into your study pretty soon after they get diagnosed with the disease because there's also a risk they may die before you get to them.

And if -- and some of the earlier case-control studies would include, since the people already died by time -- by the time they started to do the study, they included -- since they didn't -- weren't able to give information themselves, they included surrogates or proxies. And that can be a problem.

Q. So instead of actually using the person who has the condition you're studying, you'd ask, you know, a relative or a spouse or something like that?

A. Exactly. And the problem with that is that that information can be, in many settings, less reliable.

Q. And the jury has heard about the classification of glyphosate from IARC and talked with -- about this what limited evidence by IARC

actually means.

And here it says that a causal interpretation is considered by the working group to be credible, but chance, bias, or confounding could not be ruled out with reasonable confidence.

What does that mean to you?

A. I think what I take from this, the most important thing was that in looking at the epidemiology studies of the working group found those studies to be -- they were concerned that there was bias or confounding that might be the reason you're seeing a positive association in some of the earlier studies, and they couldn't rule out whether those were an issue.

Q. Now, when you talk about chance, what is -- in epidemiology, when you talk about chance, what does that mean?

A. So I think the way we talk about chance in epidemiology is like flipping a coin and seeing how many times you get heads. So, you know, in -- you know, there's 50 percent chance that you're going to get heads or tails.

But let's say you flip the coin 10 times. Just by chance, you might get six heads. And then that the odds ratio that you would get of whether or not you're going to get heads on your coin flip is actually

1.5. But we know actually there's just as equally likely a chance that you're going to get heads versus tails. So but because of small numbers, the small number of times we flip the coin, just by chance we got a positive association where it was more likely to get heads.

But with larger numbers, if we flip the coin a hundred times or a thousand times, on average we're going to get much closer to 50 percent heads and 50 percent tails.

Q. And then they talk about bias or confounding. And what are bias and confounding in epidemiology studies that you have to be sensitive to and look for?

A. Right. So bias is a large class of things can go wrong in studies. It can -- it's things that give you the wrong answer. It gives you the wrong relative risk answer. There's many different forms of bias. I've talked a little bit about the proxy bias, but there's other types of bias as well.

Confounding instead is a specific type of bias. And I think an example, it might be easier to understand, so some of the early case-control studies that looked at coffee and heart disease found that coffee drinkers had about a twofold increased risk of heart disease compared to nondrinkers.

But actually it wasn't the coffee that was causing the heart disease. It was the fact that the coffee drinkers were more likely to be smoking cigarettes. And so it was the fact that coffee drinkers tend to be smoking. And if you don't appropriately adjust for the confounding, you get a positive association that's not a causal association.

So that's the idea of confounding. It's a mixing of facts.

Q. And to go back to your opinion, you talk about no evidence of a causal association. Is that what you're referring to when you're talking about in this particular case?

A. Right, exactly. And so as epidemiologists, when we're looking at all of the evidence, if we see a statistical association, the first question we want to ask is: Is that statistical association due to bias, confounding, or chance? And so if you can rule those out, then you can look at whether or not an association is causal.

So my decision about whether there's a causal association or not is in consideration of all the bias and confounding.

Q. All right. And in this particular case if you actually look at the bias and confounding and the

statistical significance, do you believe there is evidence of a causal association between Roundup and NHL?

A. No. And in fact, actually I think the working group was concerned about bias and confounding in some of the earlier studies they relied on.

Since that time, we now have a number of additional analyses and publications that have come out that show that some of those earlier studies were subject to bias and confounding. And when you take those into account, there is no evidence of a causal association.

Q. All right. And let's talk about one such study, the Hohenadel study. Can you just tell the ladies and gentlemen of the jury briefly about that.

A. Yeah. So this is the same case-control study from Canada that Dr. McDuffie had published on. In this particular study, they were trying to address this issue of confounding. They wanted to disentangle the fact that people who might be using Roundup were also using other types of pesticides.

So this is one approach that we take in epidemiology to look at whether confounding might be present, is what we call stratifying or looking at, you know, trying to tease out the effect of one pesticide on

non-Hodgkin's lymphoma from another.

Q. So what do they do here with respect to -- and again this is the same data in the McDuffie study that the jury has heard about it?

A. Yes, it is.

Q. All right. So what do these researchers do?

A. Right. So maybe I can go back to the coffee example, though, first.

So in the study of coffee and heart disease, the way to get rid of the confounding due to smoking is just to look at people who never smoked. And then there's no way that smoking could be a confounder.

They did the same thing here, which is to say, in the individuals who were -- and specifically here they were looking at whether malathion might be a confounder of the association with glyphosate.

So what they did was to look at individuals who were only using glyphosate, only using malathion, or both, and comparing that to people who were not using either of those pesticides and to see whether -- where the increased risk might be.

And so that's what they -- that approach that they took.

Q. And so what were the results?

A. And so what you can see from this table

here --

Q. Actually, if you want to --

MR. EVANS: So is it okay if she stands, Your Honor, and points to it?

THE COURT: That's fine.

THE WITNESS: And so here, this is the -- this is the odds ratio and 95 percent confidence interval for non-Hodgkin's lymphoma for those only using malathion, for only using glyphosate, or using both.

And what you can see in the group, so this is where malathion could not be a confounder. You essentially see no association between glyphosate and non-Hodgkin's lymphoma. And the only reason there might have been a positive association was because of confounding by malathion.

BY MR. EVANS:

Q. Now, if the jury has heard that in another study malathion did not show an increased risk for NHL, does that mean that it should not have been controlled for in this study?

A. No. I mean, I think this is one of the important factors as epidemiologists is that we know confounding is something we need to look at specifically in each study. What -- whether malathion or something else might be a confounder in one study but not in

another, it actually happens all the time. It's confounding is something we look at specifically in a study.

The other thing about confounding it's one of the biases we can actually look at, see if it's present, and do something about it.

Q. What do you mean do something about it?

A. Well, so in this particular example and the example I gave on smoking -- or sorry -- coffee and heart disease, you could do the stratification, right, and so in the group only using glyphosate there's no confounding by malathion.

The other way we do it is using what we call a mathematical model where we adjust for other things including, in this case, other pesticides.

Q. All right. Now let's look -- we're not going to go into each one of these studies. Again, the jury has heard about these studies numerous times.

But at a -- just at a level looking at case-control studies that have analyzed the ever-versus-never use of glyphosate, could you just talk about these four studies?

A. Right. So there's been a number of publications, but they sort of boil -- the case-control studies boil down to these four --

Q. Just if I can interrupt.

A. Sure.

Q. So, for example, the Hardell 2002, you've got on your slide here includes the Hardell 1999. So actually two different publications. I think the jury probably saw both of them.

A. Right.

Q. But they're actually looking at the same data?

A. Exactly. And since all of the data that was in the 1999 study of Hardell is part of this updated one, you'd only want to look at the more current of the studies. And so that's what this data is here.

Q. And so when you look at the Hardell 2002 report and you adjust, what do you end up with?

A. Right. So what you can see here, first of all, this was based on eight exposed cases and eight exposed controls. So that idea of the flipping of the coin, you worry that chance might have played a role. And why you can see that is the large width of the 95 percent confidence interval.

So there's no evidence of a significant increased risk, but it's also not -- it's not a study that provides much information because it's really such a small study.

Q. And then let's talk about Eriksson briefly and

Orsi.

A. Right. So Eriksson had a different set of cases and controls than did Hardell, but it was still based in Sweden. Again, when you adjust for other pesticides, you see no significant association with non-Hodgkin's lymphoma.

It had 29 exposed cases, 18 exposed controls, so still a pretty small study.

Q. Now, small study, both of them, but they have a positive point estimate. It's above 1. Does that -- to you as a cancer epidemiologist, what do you do with that information?

A. Right. So although the number is above 1, what I also want to look at is the width of the confidence interval. And it's this idea of there's so much kind of uncertainty in what the actual number is. Again, it's that idea of flipping the coin.

So it's something that I'm going to look at and something I'm going to think about because I'm looking at all the studies, but it's not very informative just because the sample size is so small.

Q. And Orsi, another small study?

A. Yeah. So Orsi, also very small study, as all three of these studies were not designed specifically to look at glyphosate, they were looking at many different

pesticides at the same time. But it only had 12 exposed cases and 24 exposed controls.

The other issue with Orsi is that they did not adjust for other pesticides. So this relative risk here is not adjusted for other pesticides.

Q. And then the jury has heard about NAPP. And talk a little bit about NAPP and what's included within NAPP.

A. Right. So NAPP includes the publications -- the earlier publications that included the Canadian data from McDuffie. Also that Hohenadel was the same data set. And then also all of the U.S. case-control studies that were done including the publication from Dr. De Roos.

And the NAPP study kind of a little bit different from these earlier studies because it was specifically addressing the hypothesis of whether glyphosate was associated with non-Hodgkin's lymphoma, and the reason that's important is that the way they sought to analyze the data was specific for glyphosate.

Q. All right. And it's larger, the number of cases there are more than the prior ones.

A. Yeah, so much, much larger. You can see, you know, five to ten times larger than these individual studies with 113 exposed cases.

Q. And when you look at NAPP, it includes both McDuffie and the De Roos data; right?

A. Yes.

Q. And the jury has heard about the De Roos 2003 study separately. But when you look at it as part of the overall study in NAPP, what are the results?

A. Right. So it's, as I mentioned, the earlier publications, including Dr. De Roos' study, weren't specifically looking at Roundup. They were looking -- in that particular study they were looking at 47 different pesticides. The approach they took was to put all of the 47 pesticides into these mathematical models.

And the challenge with that earlier study was there were only 36 cases exposed to Roundup. And if you have 47 different pesticides, you're going to have some pesticides for which there's no exposed cases, and that can cause a problem in your analysis.

Q. And what's that called in epidemiology?

A. We call that a sparse data bias. And what happens is because you have very few to no cases in specific cells, it can lead to your estimates what we say as being unstable and so it can lead to spurious associations or getting the wrong answer.

Q. So you, as a cancer epidemiologist, would --

you think it's more important to look at the earlier De Roos 2003 study or the study when it's actually looking at glyphosate as part of the larger group of cases?

A. Right. So -- and the reason that I -- so that looking at the approach that was taken in the NAPP study was the correct approach that we do in terms of adjusting for confounding. That's kind of the standard epidemiology approach where you look at a specific exposure and disease and try to identify what are the specific confounders in this set of data for that exposure and disease.

Q. And what were the results of the NAPP analysis?

A. So, again, you can see there's no evidence of a significant increased risk when you adjust for other pesticides.

Q. And that point estimate is actually below 1.

A. I'm not -- I wouldn't interpret it that way. I would actually say there's essentially no association.

Q. Okay. Now, let's go to the next slide.

(Demonstrative published.)

BY MR. EVANS:

Q. And you've added here -- what did you add?

A. So these are the two most recent set of

epidemiology publications. The first is Andreotti which is the most recent analysis of the cohort, the Agricultural Health Study. And then second is the publication by Leon, and that was an analysis that included not only Agricultural Health Study but also two studies from Europe.

Q. All right. And let's talk a little bit about each of those. And the jury has again heard numerous times about the Agricultural Health Study so we're not going to go into details here.

But at a high level, just again summarize what the AHS did.

A. Right. So, I mean, the AHS, the Agricultural Health Study was initially put together to try to look at the potential health effects of pesticides and other farming practices.

They recruited 50,000 individuals who, at the start of this study, did not have cancer. And then they followed -- they collected information on pesticide use from questionnaires. And then they have followed them prospectively forward over time to see which individuals developed cancer, including non-Hodgkin's lymphoma, and which ones remain cancer-free.

Q. And, again, is that study methodology the same methodology as other cohort studies like the Nurses'

Health Study or the Professional Health Workers Study that you've talked about and you've been involved in?

A. Yes, it is.

Q. And those studies we're going to talk about in a minute. But did those cohort studies have people who fall out of the study over time?

A. Yes, they do. You know, it's one of the important issues in a cohort study is to try to monitor, follow up of all the individuals in your study. That's one of the things that we try to do, yes.

Q. All right. So I'm going to have to talk louder or we're going to have to move more quickly because we've got some jurors who are tired. So...

A. Yes, yes, I know.

Q. All right. Let's go to the next slide.

(Demonstrative published.)

BY MR. EVANS:

Q. And, again, with respect to questionnaires and AHS, what was actually done?

A. Right. So the questionnaires collected data on 50 different pesticides, whether they had ever used the pesticide, how often they used the pesticide, and ways in which they used it, how they applied it, whether they used protective gear.

Q. And, again, the first questionnaire is

answered by how many folks?

A. So the first questionnaire was answered by 57,000 individuals.

Q. And the second questionnaire, was that actually performed by telephone?

A. Yes, it was. It was collected on average about five years after the first questionnaire. And it was completed by 34,000 individuals.

Q. All right. And, again, the jury has seen the overall results of both the 2005 De Roos publication with respect to there being no association with glyphosate exposure and cancer including NHL, and the 2018 publication by Andreotti which came to the same result. So we don't need to spend more time on that.

What I want to focus on, though, is there have been a number of criticisms that the jury has heard about regarding the AHS. And with respect to that, have you looked at those issues that have been evaluated and criticisms of AHS?

A. Right. So absolutely. And I think there is, you know, there's potential biases in both the case-control and the cohort study.

One of the advantages we have with the cohort studies is that the investigators looked at many of these different issues in different types of valid --

what we call validation studies or approaches to try to see whether the bias was there or the issue was there and, if so, could they correct it in some way.

MR. EVANS: Your Honor, perhaps it is a good time to take a break.

THE COURT: We can take a break now. I was going to take a break in about five or ten minutes anyway.

MR. MILLER: Sure.

THE COURT: So why don't we take a break for ten minutes. We're going to resume at around 20 after the hour. Thank you.

As soon as the jurors leave, you can step down, Dr. Mucci.

THE WITNESS: Thank you, Your Honor.

(Jury excused for recess.)

(Proceedings continued out of the presence of the jury:)

MR. EVANS: Your Honor, I would like just to make for the record. I objected at the time, but I said it was not going to qualifications. Mr. Miller should not be referring to the *Johnson* case when cross-examining the witness. That specifically violates a motion in limine. He said it twice. And I object and I think it's improper.

MR. MILLER: There's no way we can be hamstrung for cross-examining the witness without talking about her prior testimony.

MR. EVANS: You can ask about prior testimony --

THE COURT: You can ask about her prior testimony, but don't mention the *Johnson* case specifically.

MR. MILLER: I won't mention it by name, fine, Your Honor.

THE COURT: Or the *Hardeman* case.

MR. ISMAIL: Or just reference to trial.

THE COURT: Just reference to her trial work, and I think you're fine.

MR. WISNER: Should we do it by date? Is that better?

MR. ISMAIL: Exactly. That's the way we did it.

THE COURT: You can do it by date, I think that's fine. But just specifically mentioning *Johnson* or *Hardeman* would be inappropriate.

MR. EVANS: It doesn't need to be referenced to trial. Just to prior testimony on X date.

MR. MILLER: That's fine.

THE COURT: Okay, 10 minutes.

(Recess taken at 10:11 a.m.)

(Proceedings resumed in open court in the presence of the jury at 10:25 a.m.)

THE COURT: Mr. Evans, you may proceed.

MR. EVANS: Thank you, Your Honor.

Q. All right. Dr. Mucci, we left off talking about the AHS data evaluation process over the course of time.

You mentioned something that I think is important, which is, in a cohort study that's going on over decades of time, is it a good thing that people are raising issues and identifying things that the study needs to be potentially looking at?

A. Right. It's part of the scientific processes in epidemiology that we, throughout the course of a study, try to assess what might go wrong in a study and try to prevent it from happening or fix it halfway through the study. So absolutely. Very important.

Q. And one of the issues the jury has heard about is, again, the number of folks who did not respond to the second questionnaire; right?

A. Yes.

Q. Okay. And, again, is there a way that you can prevent people from no longer participating in a study?

A. I'm sorry. You mean prevent them from not

participating?

Q. Yes, for falling out of the study. Sorry.

A. Right. Sorry.

So there are a number of ways that we try to make sure that we get as high of a number of the participants that can do follow-up, for example, by sending newsletters out, having regular contact.

So there's a number of ways in which you try to make sure that we get as much complete follow-up as possible.

Q. But if someone decides, "Hey, I'm just not going to participate," what do you do about that?

A. Well, I think, you know, there's nothing really you can do in terms of losing them, but you can assess whether having them not be a part of the study leads to a bias or any sort of problems.

Q. And with respect to that issue in the Agricultural Health Study, was there an assessment of the impact of this 35, 40 percent of people who did not participate in the second follow-up?

A. Yeah, they did. They looked at it a number of different ways in these particular publications here. They looked to see whether the people who did or did not answer the second questionnaire were different in some ways. And actually on many different factors they sort

of were the same. And so there wasn't as much -- but you wouldn't have the concern there would be bias.

They also looked to see whether the analysis results would differ depending on whether you included them or didn't include them. And again the results were the same.

So they looked at it a number of different ways and did not see any issue from the people that were lost.

Q. And so the jury has heard about, for example -- we're now looking at the middle road here with respect to imputation, whether it's accurate or not. The jury has heard about Andreotti 2018 that they actually just looked at the people who had actually responded to both questionnaires.

A. Right. Exactly.

Q. And was there an increased risk when you just looked at the people who had actually answered both the questionnaires?

A. No. There was still no evidence of an association.

Q. So even if you don't consider the individuals who didn't participate in the second group, there was not an increased risk?

A. Exactly. And, you know, again, one of the

strengths of this -- the Agricultural Health Study is they're saying, hey, look, this could be a problem, let's look at this, let's see if it's going to cause a problem, let's see in our analysis it results in anything. And no matter how they looked at, they kept getting the same answer, which was there was no association between Roundup and non-Hodgkin's lymphoma.

Q. And the jury has heard some issues regarding whether the questionnaires gathered enough information about, for example, the products being used or over what period of time or maybe protective equipment issue.

Did the authors, investigators actually look at those types of issues?

A. Yes, they did. They -- they looked at how well the questionnaires captured information about internal dose of Roundup exposure to see whether the way they collected the questionnaire could provide a valid estimate of the dose of Roundup. And in fact, they showed throughout these multiple studies that the questionnaire data did a very good job in estimating the dose of exposure.

Q. And with respect to the issue that the jury has heard about with respect to misclassification, right, I think we've heard about this in the context of the number of users of Roundup or glyphosate over time

went up; is that right?

A. Over time it has gone up, yes.

Q. And does that fact mean that somehow there's going to be some terrible misrepresentation of who's using what and there's going to be some kind of -- I think I heard about the analogy of mixing paint.

A. Right.

Q. How does that all play out?

A. Right. So, you know, again, in both case-control and cohort studies, one of the things that we always think about is how well we've measured the exposure, in this case Roundup.

And you might have some little bit of error between groups. But I think one of the strengths of this particular study is that you have about 20 percent of individuals who never used glyphosate. And then you have 20 percent of the individuals used a very high and more than 100 cumulative days of exposure.

And so I think an example of misclassification is -- I do a lot of research on physical activity in cancer, and you might have someone who can't remember whether they exercised, you know, two hours or three hours in a week. But you aren't going to misclassify people who are getting almost no physical activity versus those who are running 10 miles a day. You're not

going to get that misclassification at the extreme ends of things.

So it's the same analogy here. You're not going to have somebody who's used glyphosate for more than 100 days in their lifetime reporting actually that they've never used it, and vice versa. So you're not worried about that misclassification at the extreme categories.

Q. What about the Farmer Tom example the jury has heard about where you've got an individual who potentially, you know, "Okay, I answered no on the first questionnaire."

A. Uh-huh.

Q. "And I started to use Roundup. And then I stopped using it before I answered the second questionnaire."

Is that a concern -- first of all, is that a concern that the investigators in the study were sensitive to?

A. So the way that the investigators, you know, address the potential issue actually is in what we call our latency analyses where they looked and said let's look at to see -- you know, with cancer, cancer takes really many years, if not decades, to occur. So from the time you start getting exposed to something and when

a cancer occurs can be decades.

So what they asked was let's look at 15 years between when somebody was using Roundup and when non-Hodgkin's lymphoma occurred. And in that particular analysis, none of the people would have been like this Farmer Tom because it would only be relying on that first questionnaire. And again they saw no association with glyphosate.

Q. All right. So just to be clear, if you're looking at a person who, on the first questionnaire, answered what?

A. They answered either yes or no that they were using it.

Q. And that's the only data point going forward?

A. Right. Because then what you're doing is to say 15 or more years later, is there an elevated risk of non-Hodgkin's lymphoma. And so that analysis is only relying on the baseline questionnaire. And again you don't see any evidence of a positive association.

Q. And is this issue about misclassification, you know, is that an issue that first came up after the Andreotti study was -- or article was actually published?

A. No. It's a topic that the Agricultural Health Study investigators have been thinking about and doing a

variety of validation studies for really over the past, you know, 15, 20 years.

Q. And that's the Dosemeci, the Coble, and the DellaValle different studies?

A. Absolutely, yes.

Q. And so this is not an issue that's new that they just somehow, "Oh, I just missed that"?

A. That's correct.

Q. Anything else -- again, you've helped prepare these slides. Anything else you want to talk about on this particular slide?

A. No. I think this -- the only thing I would add is this is just a highlight of some of the studies were done, but there was actually many, many other publications that looked at different issues of bias within the Agricultural Health Study.

Q. And you reviewed all of those?

A. Yes, I did.

Q. And is your opinion that the results of the Agricultural Health Study are important, reliable information or somehow they're invalid?

A. Yeah, they're based on all of these different approaches to validation. The quality of the data collected in the Agricultural Health Study specifically on Roundup and non-Hodgkin's lymphoma is as valid -- it

is valid -- as valid as the cohort studies that I work on.

Q. Okay. And with respect to this slide, what are you trying to demonstrate here?

A. Right. So I think if we were concerned that, you know, there might be some potential for bias in the Agricultural Health Study, another way to look at whether there's bias present is just simply to compare the incidence of non-Hodgkin's lymphoma in a group of individuals using Roundup in the cohort compared to the general population of individuals from Iowa and Minnesota. And when you make that comparison, what you can see is that the incidence rates are the same.

Q. So if you just look at people within the AHS study -- and they're following those people through the cancer registry?

A. Yes.

Q. So they're actually collecting all of the individuals who are in the study whether they get cancer or not?

A. Correct.

Q. Not relying upon them to respond to the -- some kind of questionnaire, but they actually can go out and get the data?

A. Right. So each of the cancer registries in

the United States, it's mandated by law that each cancer case gets reported to these cancer registries. So you basically get almost complete follow-up for cancer incidence using these cancer registries.

Q. And who's obligated to report it, the patient or the doctor?

A. The doctors are.

Q. So it's not just incumbent upon a patient who is diagnosed with cancer to somehow register the cancer with the cancer registry, the physician is actually required?

A. Exactly, yes.

Q. Okay. Now let's look at the Leon study the jury has heard about. Let's talk a little bit about what it is and what the results were.

A. So this is one of the latest publications on the topic. It started as a consortium of prospective cohort studies of agricultural health workers.

This particular analysis combines the data from three cohort studies. So one of them was the Agricultural Health Study. The second was a cohort from -- of farmers from Norway. And the third was a cohort from France. And these individuals, they have information on glyphosate and non-Hodgkin's lymphoma.

Q. And was this study adjusted for other

pesticide use?

A. Yes, it is. Each of the analyses that were done, the results were adjusted for other pesticides.

Q. And what were the results of the Leon study?

A. So in this analysis in one of the strings that they had, you know, 16 years of follow-up of these 300,000 individuals. So large number of individuals diagnosed with non-Hodgkin's lymphoma.

And in this analysis, they found no evidence of a positive association between non-Hodgkin's lymphoma and ever use of glyphosate.

Q. And just to come to this slide, then, if you add the cohort studies to the prior case-control studies, is that the body of epidemiology that you looked at?

A. Yes, it is.

Q. Okay. And of that, what part of it did IARC have at the time they actually did their analysis back in 2015?

A. Right. So the analysis that IARC did would have only included these first three results from the case-control studies. They did not have access to the results from the North American Pooled Project results or the two cohort analyses.

Q. But they did have access to McDuffie and

De Roos, though; correct?

A. Yes, they did. But, again, those specific publications weren't focused on Roundup. They were focused on looking at a broad range of pesticides. And the advantage of North American Pooled Project was it was a specific hypothesis about glyphosate and non-Hodgkin's lymphoma. So the design of the analysis and the actual analysis itself was specifically targeted at looking at the question of glyphosate and non-Hodgkin's lymphoma.

Q. And you, as a cancer epidemiologist at the Harvard School of Public Health, when you look at that data set, what is your conclusion about whether that is evidence of a causal relationship between Roundup and non-Hodgkin's lymphoma or not?

A. So I think given how many additional cases we have through these updated analyses and given the approaches to thinking about adjustment for other confounders, based on all of that evidence there is no evidence of a causal association between glyphosate and non-Hodgkin's lymphoma.

Q. All right. Now, the jury has heard something about dose-response. And have you looked at that issue?

A. Yes, I did.

Q. First of all, explain briefly to the jury what

this issue of dose-response is.

A. Right. So, again, you know, if you think about the analogy of physical activity and cancer risk, the idea would be that the more physical activity you're engaging in, the lower your risk of different cancers or the lower your risk of heart disease.

So it's this idea that you might have increased or decreased risk for higher levels of the specific exposure that you're looking at.

Q. I really would like you not to talk anymore about exercise or weight --

A. Okay, sorry.

Q. -- in talking about different medical conditions. I'm just joking.

A. Sure.

Q. All right. So when you look at all this evidence, what do you look at, all these studies?

A. So in each of these studies, there was some estimate of dose-response. I think one of the challenges was that some of them were adjusted for use of other pesticides and then some of the results were not.

Q. All right. And if you look at the McDuffie results, were those adjusted or not?

A. They were not adjusted. So the

ever-versus-never comparison was adjusted but the dose-response was not.

Q. What about in the Eriksson study?

A. No. Again the dose-response analysis was not adjusted for other pesticides.

Q. And, again, the De Roos 2005, that's the initial Agricultural Health Study article; correct?

A. Yes.

Q. Those results.

And were those adjusted?

A. Yes, they were. So this is the relative risk, 95 percent confidence interval for the highest exposure which was about 57 lifetime days of exposure compared to those never using it, and it was adjusted.

Q. Okay. And so you're taking the highest exposure group and comparing them to the no exposure group?

A. Yes.

Q. And that's just based upon the people who actually in 2005 had responded and filled out the questionnaire?

A. Exactly, yes.

Q. And so there's no imputation?

A. Right.

Q. There's no people dropping out?

A. Right. Correct.

Q. Is there a Farmer Tom or Ted issue at that point in time?

A. No, there's not.

Q. This is just looking at people who, in the initial questionnaire, answered what their usage was?

A. Yes.

Q. And those who said I use it the highest group versus the no group?

A. Yes.

Q. And was there an increased risk?

A. No, there was no evidence of a positive association.

Q. All right. And the NAPP study that you looked at, the jury has seen this I think several times.

But did it look at this issue about extended usage and whether there's an increased risk?

A. Yes. It looked at three different measures. They had three different measures of dose that they presented in the NAPP study.

Q. And what do those different measures of exposure show?

A. So what you can see here, so the first measure is the one that's analogous to both Eriksson and De Roos, and that's the cumulative number of days that

somebody was using glyphosate compared to those never using it. Again you see no association for those in the highest dose versus those who never used it, adjusted for other pesticides.

Q. And what about the 3.5 years?

A. Again, so this is -- this is a little bit different measure. This is simply just asking not only just about the number of years they were using the product. And, again, what you can see is there's no association.

Q. And with respect to the 1.77, and I think that is in the self-responders group.

A. Yes.

Q. Do you remember that?

A. Yes.

Q. Versus the self-responders plus the proxy.

A. Yes, correct.

Q. And why did you put that on your slide there?

A. Because it was one of the three measures of dose that they looked at, and it is borderline statistically significant.

Q. All right. And so when you look at those three results in that study, what's your takeaway as a cancer epidemiologist?

A. Right. Well, I think for me the measure of

dose-response that is the most meaningful is the lifetime number of days that someone is exposed.

You know, for example, if you're looking at somebody in the greater than two days per year, let's say they've used it three days in one year versus, you know, three days in 20 years, that's a very different amount of exposure.

So the dose-response that's most meaningful is the one that's integrating information not only of the number of days per year, but the number of overall years they've been using it.

So, for me, adjusting for other pesticides there's no evidence of a dose-response.

Q. And with the two days per year or to fit in that category, you could be a person who actually used it three times in one year and that would be it?

A. Correct.

Q. Versus if you're looking at a person who, for example, used it three times in three years, that would be nine total days?

A. Correct.

Q. They would then be in the highest category?

A. Yes.

Q. Is that fair?

A. Yes.

Q. Okay. Now let's look at the NAPP June of 2016. Have you looked at that?

A. Yes, I have.

Q. And it doesn't actually report out specific numbers like most all the other studies; correct?

A. Right. So what it did, you can't get the exact numbers, it just presents figures looking at the -- you know, compared to the never uses, the lower dose, and then the higher dose.

And then what's nice about that analysis, though, was they present the unadjusted for other pesticides and then also adjusted for other pesticides, you can see whether or not there was confounding present.

And I think there were 15 different dose-response analyses they presented in that particular set of slides. And in none of them was there any evidence of a significant dose-response.

Q. And in the Andreotti update study, do they also look at dose-response?

A. Yes, they looked at dose-response in a couple of different ways.

Q. And how did they look at it?

A. So first they looked at, just as they did with the De Roos 2005, the cumulative number of days of

exposure. And so this particular set of results here is comparing those who had used glyphosate for more than 108 days over their lifetime compared to those who were never users, and they also had a dose-response measure that integrated information on use of protective gear.

Q. And with respect to the comparison between those who used it the most and the highest quartile versus those who didn't use it at all, was there an increased risk?

A. No, there was no evidence of an association at all.

Q. All right. And now the jury has also -- we can just go on to the DLBCL. They've also heard about DLBCL.

And did you look at that specifically to see what the epidemiology was regarding the issue about whether Roundup is not only associated or not associated with the risk of NHL in general, but DLBCL, which is a subtype?

A. Yes, I did.

Q. And what did your analysis reveal?

A. So here you can see these are the odds ratios for ever-exposure to Roundup and risk of non-Hodgkin's lymphoma. And then in Andreotti, it's comparing the top quartile to never-use.

And as you can see, for all three of the cohort study -- I'm sorry -- all three of the case-control studies, there's no evidence of a positive association between Roundup and risk specifically of DLBCL.

Again, when you look at Andreotti, there's no evidence of a positive association at all.

And then the study of Leon reported on DLBCL and found a borderline significant increased risk of Roundup and the specific subtype.

One of the things, however, was the data they included in Leon from the Agricultural Health Study was actually less recent than the current Andreotti study. So they only had follow-up for cancer incidence through I think it was 2009, 2010. Whereas the Andreotti had two additional years of follow-up.

And why that's important is DLBCL is a relatively rare subtype so having more cases just gives you a little more power.

So I took the results from Andreotti on DLBCL and integrated and replaced the results they had there in Leon. And when we do that, you can see there's again no evidence of a positive association using the most up-to-date AHS data.

Q. And, again, when you say there's no evidence

of positive association, even though there's a point estimate above 1, does that mean that there's evidence or not?

A. No, again, what you want to do is not only to look at the point estimate but also the 95 percent confidence interval. You need to look at how much certainty, and I think you can sort of see here in the result from Eriksson, because it was based on relatively few cases, you have a lot of uncertainty in what the actual estimate is in that study.

You can see kind of tighter confidence intervals in the bigger studies, but still based on smaller numbers of cases. So you get -- you have to look not only at the point estimate but the confidence interval as well.

Q. Now, I wanted to go back and I forgot to talk about this for a minute.

If the jury heard from Dr. Nabhan that in looking at dose-response issues you don't have to even consider confounding, would you agree or disagree with that, if that's what they heard?

A. I would disagree.

Q. Why?

A. So in epidemiology when you're looking, for example, at dose-response and you see an association,

the first thing you need to ask is could bias or confounding have led to that dose -- apparent dose-response. Again, a statistical association does not mean a causal association. So you first want to rule out that there's bias and confounding.

And so that's why it's incredibly important to always adjust for confounding. And in fact, actually there's many examples where you get a dose-response because of confounding. Because those who are in the highest group of the exposure are much more likely, for example, to be exposed to other pesticides even more so than those in the lower level of exposure.

Q. And the whole issue about whether you have to adjust for other pesticides when you're looking at this issue, do you think that's important or is that something that, you know, only a rookie would do or someone who's sort of making core baseline epidemiology mistakes?

A. No. In fact, it's very critical. You know, confounding in epidemiology is one of the core issues we worry about. Again, we can't do the time machine. And the reality is people who -- I know you don't like the physical activity example -- but people who are, you know, physically active, they're less likely to smoke and they're more likely to eat a healthy diet and they

are more likely to go regularly to the physicians.

And so confounding is something as an epidemiologist we're concerned about. And the good thing about it is there's something we can actually do with it in our mathematical model. So it's always something that we should be concerned about. And we should look within a study to see if confounding is present.

Q. Now, the jury has heard about some meta-analyses including one by Zhang. She was the first author on it.

But did you look at all the meta-analyses?

A. Yes, I did.

Q. And what is your view of the significance of meta-analyses or if they have issues?

A. Right. So I think just more generally with a meta-analysis, I think as an epidemiologist we think that the quality of the meta-analysis is based on the quality of the data going into it. So this idea if you put garbage into the meta-analysis, you're going to get garbage out.

Q. And just more basically, what is a meta-analysis?

A. Right. So a meta-analysis is where we take the data from each individual study, so the relative

risk from each study, and then we weight -- and then we come up with a summary relative risk from those data, and the weights of each study is based on its overall size. So a larger study is going to contribute more to the summary relative risk than a smaller study would.

Q. Now, is a meta-analysis the same thing as a pooled analysis?

A. No, it's not.

Q. And you talked about the NAPP study, for example. Is that a meta-analysis or a pooled analysis?

A. So the NAPP is a pooled analysis. And the advantage there is that you can combine the different studies and take a common approach for the analysis.

And so in this case, they were able to adjust consistently for confounding in the same way across the studies. That was something you wouldn't be able to do if you were just to do a meta-analysis of those studies.

Q. And did the meta-analyses that have been done with respect to this issue of Roundup exposure and whether it's related to non-Hodgkin's lymphoma, did they use only adjusted data?

A. No. None of the meta-analyses used only adjusted data. They included also unadjusted results as well.

Q. And you got another point here about combining

different exposure levels. What does that mean?

A. Right. So in -- in the -- in the methodology for doing a meta-analysis, you don't want to mix, you know, apples and oranges. You don't want to mix, for example, if you just have ever-versus-never in some studies and then you have dose-response in the others, it's not valid approach to mix those different types of exposure levels. And that's something that Zhang did in their meta-analysis.

Q. All right. Let's look. The jury has seen the top part of this which is the summary, I believe, that one or more of their witnesses showed with respect to the epidemiology.

First of all, do you have some thoughts about whether this is a proper way of analyzing the issue overall about whether Roundup is associated or causes non-Hodgkin's lymphoma?

A. No. This is not a valid approach that we take in epidemiology looking at the results of studies in this way. We don't -- we just wouldn't do that.

Q. Well, you look at results; right?

A. We do look at the results, but it's improper to present a summary plot this way.

Q. Why?

A. Because it's very misleading.

Q. Why?

A. So, first of all, what you can see is that on this graph you're presenting different pieces of data from the same study. So you're essentially double-dipping.

MR. EVANS: Your Honor, could she stand up and point?

THE COURT: Certainly.

THE WITNESS: So -- so the first thing is it's not a valid approach to present multiple results from the same study when you're looking at a summary plot like this.

So, in this example, we have two results from De Roos 2003. And then you also have Hardell 1999, you have two results there. So you're presenting multiple levels of data from the same study.

BY MR. EVANS:

Q. All right. And, for example, the De Roos study looks like there's the 2003, they're presenting two different data sets there or results there; correct?

A. Exactly, yes.

Q. And what's wrong with that?

A. Well, it just gives you a misleading impression that those results have more importance than they actually do because you're double-counting, you're

double-dipping.

Q. All right.

A. So --

Q. Go ahead.

A. No, I was going to say so another problem is, you know, within the same study they're presenting both the adjusted and unadjusted estimate, and if you're concerned about confounding, which we are in these studies, you should always rely on the most adjusted estimate from the data. And it wouldn't -- it's not valid to present the unadjusted estimate in that case.

Q. And below the red line there, there's a listing of the meta-analysis. Again, what is the issue you have with that?

A. Right. Well, if you're going to present the meta-analyses, then you shouldn't present the individual data. So, you know, it's just not really helpful to present the meta-analyses when you actually have the actual data present.

Q. Is it a double-counting issue again?

A. Again, it's a double-counting issue, yes.

Q. And does it include the NAPP 2015 numbers?

A. No, it does not.

Q. Or the most recent Leon study?

A. No, it does not.

Q. And what about with respect to the Andreotti study, does it present all the Andreotti data?

A. No, it doesn't. It really is -- it's cherrypicking. It's really picking just a very small subset of the full data that was available from that cohort.

Q. Now, have you done your own --

A. Shall I sit down?

Q. Yeah, if you'd like.

A. Thanks.

Q. Have you done your own assessment and plotting in meta-analysis of the data?

A. Yes, I have.

Q. And why don't you explain to the ladies and gentlemen of the jury what you have here.

A. Right. So I took the most current analysis from each of the case-control and cohort studies. Here I took the same approach that we should take which is I only counted each study once, and I present also the most adjusted estimate for each of the analyses.

Q. All right. Now I don't see, for example, the McDuffie study up there. Why not?

A. Well, the McDuffie study is one of the studies that's included in NAPP. So NAPP, again, I think is a higher quality approach to the McDuffie and the

U.S.-based studies. So that is the study that I'm presenting here.

Q. And you've got the Hardell study up there?

A. Yes. The Hardell 2002 publication which also included the 1999 data.

Q. And the Hardell data -- and what's the weight there? You've got the percentage there. What does that mean?

A. Right. So -- so as I mentioned earlier with a meta-analysis, studies that are larger because of the number of exposed cases in the study are going to contribute more to the estimate of the relative risk from the meta-analysis than smaller studies would.

So in this case, the analysis from Leon 2019, because of the large number of exposed cases, contributes a larger proportion of the weight. And that's also the size of the dot -- the size of the relative risk is larger and it's reflective of the relative contribution of that study to the meta-analysis.

Q. And I notice that, for example, you don't have the Andreotti study on here. Why not?

A. Right. So they -- I didn't include that because the Andreotti study was included in the Leon publication. So I don't want to double-dip.

Q. So, again, when you have pooled results, both NAPP and Leon, you're presenting the overall pooled result; right?

A. That's correct.

Q. And that's different from meta-analysis?

A. That is correct, yes.

Q. You're doing a meta-analysis here?

A. Yes, I am.

Q. And the Eriksson study, it looks like it's got about 6 percent of the total weight.

A. Yes.

Q. The Hardell number is, you know, less than 2 percent total.

Where's the actual point estimate? I can't see it from here. My glasses aren't too good.

Okay.

A. So, and again, it's because the Hardell study only had eight exposed cases, it's not contributing that much to the overall weight of the meta-analysis.

Q. And when you do a meta-analysis of all of the studies on this issue, what's the overall result?

A. Right. So what you can see here is when you look at the association between ever-exposure to Roundup and risk of non-Hodgkin's lymphoma, there's no evidence of a positive association. So the summary meta-analysis

relative risk was essentially 1.0.

Q. So it's .99 --

A. Yes.

Q. Again, I know it's not different than one statistically, but it's no increased risk; is that what it was?

A. There's no -- no association.

Q. And now this meta-analysis you did includes Orsi, and that's, we know, unadjusted data; right?

A. That's correct.

Q. And if you take Orsi out, what happens to the results?

A. Really essentially almost identical results so the confidence interval just gets a little bit wider because it's one less study, but essentially again if you include -- and I excluded Orsi because it was unadjusted, but there's no association at all, no evidence of a positive association.

Q. Doctor, we're almost done here. But the last point here, just in looking at all of the data that the -- that's available to your review, how does it compare to the data that was available to IARC's review?

A. Right. So when IARC reviewed all of the case-control and cohort studies that were available, the total number of exposed cases, so non-Hodgkin's lymphoma

cases exposed to glyphosate, was 207.

Now with the updated analyses that we have from the Agricultural Health Study, from Leon, we have a total of 1,086 exposed additional cases. So for a total of about 1,200.

So we have more than three -- actually more than five times the number of exposed cases additionally now than we did when IARC reviewed the data.

Q. And when you look at all the epidemiology that you looked at, you look at all the different studies regarding NHL and whether it's related to Roundup, what is your opinion again?

A. Right. And can I just say one more thing with respect to the other?

Q. Sure.

A. The other thing that we have, you know, IARC could not rule out bias or confounding in those early set of studies they looked at.

What we know, for example, from NAPP was there was confounding due to use of other pesticides in those early case-control studies. They actually analyzed it and tested that. So that was information also that IARC would not have had, based on the results. So...

Q. When you look at the entire weight of the evidence, you look at all the studies, are you just

disregarding and not paying attention to studies you don't like?

A. No. I looked at all of the epidemiology studies, all of the case-control and cohort studies.

Q. And when you look at all of that study -- all of those different studies, you, as a cancer epidemiologist, what's your opinion about whether there's a causal relationship between Roundup and NHL?

A. Right. Based on all of this epidemiology evidence, there is no evidence of a causal association between Roundup and non-Hodgkin's lymphoma.

Q. And, again, I asked you this earlier, but is that opinion to the same degree of reasonable certainty that you would have in your work outside this courtroom?

A. Yes, it is.

Q. Same degree of scientific certainty that you would teach your students?

A. Yes, it is.

Q. Thank you very much.

A. Thank you.

MR. EVANS: Pass the witness.

THE COURT: Cross-examination.

MR. MILLER: Thank you, Your Honor.

Have a sip of water and then we'll start.

THE WITNESS: Thank you.

CROSS-EXAMINATION

BY MR. MILLER:

Q. Doctor, I want to get to a couple of points. I want to thank everybody for their patience and I'll try to keep this moving.

I just want to talk about how you got here and not Ellen Chang. You know who Ellen Chang is; right?

A. Yes. We were doctoral students together.

Q. Right. At Harvard?

A. Yes.

Q. Okay. And before Monsanto called you, they called Dr. Chang, didn't they?

A. I don't know one way or the other if they did.

Q. Well, you know Dr. Chang, sponsored by Monsanto, did a meta-analysis of this very issue, that is -- right?

A. Yes, she did.

Q. Okay. And her meta-analysis funded by Monsanto was published in a peer-reviewed journal; that's right, isn't it?

A. Yes, it is.

Q. Okay. And so let's look at it.

MR. MILLER: If I can have the ELMO.

It's Exhibit 2107.

(Counsel confer off the record.)

BY MR. MILLER:

Q. This is -- let's get a point of reference. Okay.

This is Dr. Chang; right?

A. Yes, it is.

Q. Whom you went to graduate school at Harvard with?

A. Yes.

Q. Who did a meta-analysis published by -- on this very issue that was funded by Monsanto; you're aware of that, we just talked about that?

A. Yes.

Q. So -- and you never wrote -- you've written letters to the editor, but you've never written a letter to the editor criticizing the findings of Dr. Chang; right?

A. No. I actually wasn't familiar with the study until I started working on this case.

Q. One of her findings -- and we'll go back to the rest of them later, but one of her findings was -- this is on page 12 -- blow it up so we can all see it -- a meta-analysis for the association between any use of glyphosate and the risk of what kind of lymphoma?

A. B-cell lymphoma.

Q. Based on two studies was what?

A. A relative risk of 2.0 and a 95 percent confidence interval of 1.1 to 3.6.

Q. Statistically significant doubling of the risk of B-cell lymphoma was the result of Dr. Chang's analysis; right?

A. Yes. This is the result from that analysis, but it did not include the updated data -- there's a lot of data missing from this particular meta-analysis that we have now.

Q. We're going to look at all the data, believe me. I'm trying to get you out at 3:00 o'clock, but we've got to look at it.

But Dr. Chang, who was funded by Monsanto, reports that, "Hey, not only did I find a doubling of the risk for diffuse large B-cell, but the other meta-analysis by Schinasi and Leon found a doubling of the risk as well"; that's true, isn't it?

A. She does report that, yes.

Q. Okay. And then after she reported that, Monsanto called you and asked you to be an expert in this case; right?

A. I'm not sure of the timing of -- of when this study was reported and when I was asked to be a part of this case.

Q. Let's take a look.

(Counsel confer off the record.)

MR. MILLER: Permission to approach, Your Honor?

THE COURT: Yes.

MR. MILLER: This is a copy of what we've marked Exhibit 3134.

A copy for the Court.

And I hope to God I have one more copy. Yes, I do.

Permission to publish, Your Honor?

THE COURT: Any objection?

MR. EVANS: Your Honor, if this is being offered to the witness to refresh the date, I think you could do that without publishing it.

MR. MILLER: Well, it's about bias, Your Honor. It goes to bias. It goes to the contract, and this will explain to the jury how she got involved.

MR. EVANS: I don't have any objection.

MR. MILLER: All right.

(Exhibit published.)

BY MR. MILLER:

Q. You remember receiving this letter from the Hollingsworth firm -- that's a law firm, there are several members of it here -- asking you to be an expert for Monsanto; right?

A. Yes.

Q. Okay. And by the way, the money that we've talked about, it goes to you, not Harvard; right?

A. That's correct.

Q. You're not here on behalf of Harvard?

A. No, I'm not.

Q. You're not here on behalf of the Dana-Farber Institute?

A. No, I'm not.

Q. All right. So, Dr. Mucci, regarding the Roundup litigation, this letter confirms that on behalf of the Hollingsworth firm that Monsanto retained you to provide expert consulting services for the purposes of assisting the Hollingsworth firm in representing Monsanto in connection with potential or actual litigation against Monsanto; right?

A. Yes, that's what it says. Yes.

Q. Okay. Right.

And you wonder why they didn't retain Dr. Chang instead of you?

A. I don't know. I didn't speak with Dr. Chang about this.

Q. But you come in here and criticize studies that have been funded by Monsanto. Why is that?

A. I'm sorry, I don't understand your question.

MR. EVANS: Objection, Your Honor. Misstates her testimony.

THE COURT: Well, overruled. Her answer will stand.

BY MR. MILLER:

Q. And you never talked to Dr. Chang about it?

A. No, I haven't.

Q. So since January of 2016, they've been paying you $350 an hour; right?

A. Yes, that's correct.

Q. And that's what we call portal to portal?

A. I'm sorry, I don't understand your question.

Q. The moment you leave Boston until you get here until you get back; right?

A. I'm not -- sorry, I'm sorry, I don't understand your question.

Q. Well, your hours, are you paid only for the time in the courtroom or --

A. Oh, I see. Yes. No. When I'm traveling, because I'm away from my responsibilities in Boston, I'm paid an amount for being here in person.

Q. Let's talk about your funding by Bayer. Let me ask you to look at this if I could. Exhibit 3132 -- no, 3122. Excuse me.

MR. MILLER: Thank you, Your Honor.

Permission to publish, Your Honor?

THE COURT: Any objection?

MR. EVANS: No objection.

(Exhibit published.)

BY MR. MILLER:

Q. Who is this a picture of?

A. So this is the executive committee of the global cohort study that I mentioned. It's a new cohort of 5,000 men who have prostate cancer that we're recruiting from around the world.

Q. Called Ironman?

A. Yes, that's correct.

Q. Which one of these fellows is from Bayer?

A. None of them.

Q. Okay. Who are they?

A. So as I mentioned, this is the executive committee. The person on the left is Jake Vincent. He heads the -- an organization called the Prostate Cancer Clinical Trials Consortium.

Paul Villanti, who is one of the leaders of a foundation called Movember. It's a men's health charity for growing mustaches.

Phil Kantoff, who is the head -- he's the chairman of medicine at Memorial Sloan Kettering Cancer Center.

Dan George, who's the head of prostate cancer at Duke University.

And then myself.

And we serve on the executive committee.

Q. Okay. So how long -- so Bayer funds this project with two other pharmaceutical companies?

A. Yes, and then together with a partnership with Movember. So these pharmaceutical companies and Movember have come together to fund this project.

Q. Depending on the results, Bayer may use it for commercial application?

A. I couldn't say one way or the other. But they are one of the funders, yes.

Q. And I just want to point out, you're a professor at Harvard, we talked about it. But it's at the T. Chan School of Public Health, that's your subdivision; right?

A. It's the Harvard School of Public Health, yes.

Q. Yeah. It's called the T. Chan School of Public Health?

A. T.H. Chan School of Public Health.

Q. Excuse me, I'm sorry. Thank you.

All right. We'll move on from that one.

One more point on that. You work with Stacey Simmons from Bayer on the project and Joseph Germino?

A. Germino.

Q. Excuse me. I'm sorry to mispronounce his name.

And how long have you been working with those two fellows?

A. Right. So Stacey has been part of the project since its inception. She also -- one of the leaders of our diversity working group. We're trying to recruit about 30 percent of our participants who are African-American, Latino, and so she's one of the members of the diversity working group.

And then Joe has also basically been there since the beginning.

And these types of partnerships between academics, foundations, and, you know, pharmaceutical companies are really critical to be able to do the type of research that we're doing and are pretty common actually.

Q. Okay. Now, I heard you this morning with Mr. Evans criticize the meta-analyses that were done in this case. You agree, though, in your book on cancer, you say -- and I can hand you a copy of the book if you want.

A. Yeah, sure. That would be helpful.

Q. Sure. Sure. I don't want to be unfair.

MR. MILLER: Your Honor, do you want a copy?

THE COURT: Sure.

BY MR. MILLER:

Q. I'm just going to turn real quick to page 127 of your book, and in spite of the criticisms you gave today about meta-analysis, and I'm on the bottom right side of the page there, in your book you say meta-analysis has provided important widely accepted data even when derived from observational data; right?

A. Yes --

Q. That's true, isn't it?

I'm sorry.

A. Yes, it can be, but as I said earlier, the quality of the meta-analysis is dependent on the quality of the studies going into it. And so if you have data that are unadjusted, for example, it's going to lead to a bias result. And I think that's sort of some of the issues we talked a little bit earlier in the chapter, and in fact, you know, for observational epidemiology studies the role of meta-analysis can be --

THE COURT: If you can just slow down --

THE WITNESS: Oh, sure.

THE COURT: -- just a bit.

THE WITNESS: Sorry.

///

BY MR. MILLER:

Q. Slow down and just answer the question that we're talking about. We'll get you out of here quicker.

A. Right. Yeah. No. I'm trying to just give you a complete answer.

I mean, I think it's, you know, meta-analyses can be useful to summarize the results of studies, but they are -- they can be flawed. And it really depends on the quality of the data going in.

MR. MILLER: All right. You can turn that back on, please.

Thank you.

Q. We can go into this some more in detail, but I wanted to get to it before lunch. You said that this was a misleading chart that the plaintiffs had put in; right?

A. It is -- it's very misleading, yes. That's the reason that I spoke.

Q. Dr. Mucci, you know the plaintiffs didn't prepare this chart.

A. I don't know who prepared the chart. But I know it was presented during -- and that the plaintiffs had commented on it.

Q. It comes out of Dr. Zhang's published article. Are you aware of that?

A. That's actually not correct. That particular figure does not come from the article.

Q. Excuse me.

(Document published.)

BY MR. MILLER:

Q. We blew this up a while back so everybody can see it.

A. Yes, I can see it.

Q. This is Dr. Zhang's article.

A. But that figure doesn't come from Dr. Zhang's article. That figure refers -- says that it was derived from her study. That figure she didn't present in the publication, however.

Q. Well, we're going to go through Dr. Zhang's article, as you might imagine, in some pretty good detail after lunch. And I apologize to everybody for that. But we kind of have to. You're an epidemiologist.

So you put up your own meta-analysis that you've never published; right?

A. I have never published that meta-analysis, no.

Q. Never even attempted to get that published?

A. I have not tried to have it published, no. I just -- actually because the Leon study just came out a few weeks ago, I -- I just ran these analyses recently.

Q. Not published; right?

We can agree?

A. Yes.

Q. Okay. You said that randomized case-controls were the top of the pyramid of the hierarchy of studies; right?

A. It's randomized control studies.

Q. Right?

A. Randomized control trials, yes.

Q. Yes. Ma'am, I'm sorry if I misspoke. Yes.

So that would be in this example if we took 5,000 people and said: Here, you spray Roundup once a week for five years. And you 5,000 people spray water for five years. And we'll go back and look and see what the incidence of non-Hodgkin's lymphoma is in the two groups.

That would be a randomized control?

A. Correct.

Q. And that would be unethical to do that with Roundup, wouldn't it?

A. The reason it would be unethical is that with a randomized trial you want to show that there's a benefit and there's no reason to think that Roundup protects you against cancer. So that's the reason we wouldn't do that study.

Q. If you tried to propose that study to the ethics board at Harvard, they would reject it as unethical?

A. I'm not sure what they would do. But I can tell you what -- you wouldn't do a study, no matter what the substance was, if you don't think there's going to be a benefit of the substance, you're not going to do a randomized trial.

Q. All right. Let's go back to your book. You have a copy there.

Now you told us that IARC got it wrong in this case, or do you agree with them?

A. So what I agree about was based on the epidemiology studies they had available, that they were limited, that there was concern that bias and confounding might explain some of the results. That's the part that I agree on.

As I showed earlier, IARC just didn't have access to all of the data that we have available now.

Q. You and I've had this conversation before; right? About IARC and your book?

A. We have, yes.

Q. Tell the ladies and gentlemen of the jury how many times you cite IARC in your book.

A. I couldn't tell you the exact number. It's

probably about 400 times. And actually since we had last talked, I realized, you know, the other thing that IARC does is it publishes global statistics on cancer. In each of our chapter in the textbook, we talk about the number of new cases of different cancers, the number of deaths from cancer, each specific trends, all of that data is IARC as well.

So what I haven't done is said how many of my IARC references are because we have all these global statistics in the textbook. But I think that's actually a large proportion of it.

Q. You know and I know that your book is on Kindle; right?

A. Yes.

Q. And it's searchable on Kindle?

A. Yes.

Q. And I searched it, and there were 475 references to IARC in the book.

A. Right. And again what I was trying to explain to you is that a lot of those references are because we're citing the number of bladder cancer cases, the number of colorectal cancer deaths, the number of how the each specific patterns look for these different cancers and all of that data comes from IARC.

Q. Sure, because it's an eminently reliable and

leading agency on causes of cancer in the world; that's the truth?

A. It's one of the important cancer agencies that exists. It's also an incredibly important source of cancer statistics.

Q. And you also -- we Kindled up -- cited Dennis Weisenburger eight times in the book, didn't you?

A. Yeah. He was a coauthor on several of the early case-control studies of different cancers.

Q. And I don't want to be unkind, but Dr. Weisenburger has never cited you; you're aware of that, right?

A. I couldn't say.

Q. All right. So you put up a slide --

You agree that you only cited the EPA twice in the book?

A. I -- I -- I didn't count -- I didn't go through Kindle and look at the references.

Q. You didn't cite EFSA at all, whoever they are?

A. I couldn't tell you. Sorry.

Q. European Food Commission?

A. No, I couldn't tell you if we cited them or not.

Q. We can Kindle it up, but will you accept my representation that it's not there?

A. Okay.

Q. And for IARC, you put --

THE COURT: Kindle it up?

MR. MILLER: Did I do something wrong? I'm sorry, Judge.

THE COURT: No, I'm sorry. I didn't mean to --

MR. WISNER: It's a new verb.

THE COURT: I've never seen anything be Kindled before, but that's fine.

MR. MILLER: Yeah, it's a new world. I don't understand it very well myself.

Q. Okay. You put up this definition in your PowerPoint with Mr. Evans about what IARC said here; right?

A. Yes.

Q. But in your book on page 129, you say -- this is terrible highlighting -- but agent is probably carcinogenic to humans. That's what a 2A means.

A. What -- that is what a 2A means. What I put up was actually what the working group had noted about the epidemiology.

Q. We could get out of here before 3:00 o'clock.

The truth is they found it to be probably carcinogenic to humans and you agree?

A. I -- what I agree about with respect to what IARC said was at the time that IARC did their analysis of the case-control studies, they couldn't rule out that bias and confounding led to some of the associations that they did, and that's what I agree with.

Q. Okay. Agree. 2A equals probable human carcinogen. That's what it means; right?

A. That's the label that IARC uses for 2A in their classification.

Q. Human carcinogen.

And just to look at -- I'm doing a terrible job.

(Counsel confer off the record.)

BY MR. MILLER:

Q. Probable human carcinogen. I mean, that's what we've known now. We've been here for six weeks, that's what 2A means; right?

A. That is the definition of IARC's 2A, yes.

Q. And the nice part about IARC, I mean, in a lot of cases juries got to be are they going to believe the plaintiffs' experts, are they going to believe the defense experts, but we got 17 people invited from around the world who come for free, they don't charge a penny, and they look at this stuff for weeks, and this is the conclusion they reached. Right?

A. And again --

Q. Is that true?

A. It is true. And but just to be clear, though, the -- the IARC data now that they relied on was 10 or more years old now.

We have so much more epidemiology that IARC didn't have. And so I think -- I couldn't say what IARC would conclude now. But looking at all of the totality of the epidemiology, all those concerns that there was bias and confounding we actually see now in -- in the updated results. And when you take it all together now, there is no evidence of a causal association. And you can rule out the bias and confounding issues.

Q. Are you finished?

A. Yes.

Q. Okay. All right.

One of the studies that you did, quite famous for, ejaculation frequency and risk of prostate cancer. Do you remember that study?

A. Yeah, risk of prostate cancer.

Q. Okay. I've got a copy for you. I want to talk about how you determine association of causation in your own work; okay?

MR. MILLER: Permission to publish, Your Honor?

THE COURT: Any objection?

MR. EVANS: No objection, Your Honor.

(Document published.)

BY MR. MILLER:

Q. Okay. This is -- and again, prostate -- if I pronounce it wrong, I apologize. That's an area you spend a lot of time in; right?

A. It's one of the cancers I study, yes.

Q. And what you tell in this study, Dr. Rider and Dr. Mucci, is that in a nutshell men who ejaculate 21 times a month have less risk of prostate cancer; is that right?

A. That's what our -- our study found that men who had more frequent ejaculations had a lower risk of prostate cancer. The prostate, one of its rules it's producing seminal fluids that's used in ejaculation.

Q. Okay. And it's 19 percent, that's the difference between men who don't ejaculate 21 times a month than men who do; right?

A. Yes.

Q. And on that 18 percent difference -- which is a lot less than 200 percent, we can agree; right?

A. Yes.

Q. Okay.

You decided that that was strong evidence of a

beneficial role of ejaculation in preventing prostate cancer; right?

A. It's one -- you know, it was a large prospective cohort. We looked at a variety of potential biases and confounding. And our conclusion was it was the strongest evidence to date.

Q. Sure. And it's an 18 percent change?

A. Yes.

Q. Okay. And then a study on whole milk and prostate cancer, you concluded 12 percent was a significant risk even though it wasn't even statistically significant. Do you remember that?

A. I'd love to take a look at the study.

Q. Yes, ma'am. I'll hand up a copy.

Exhibit 3129, here you go.

A. Thank you.

MR. MILLER: Permission to publish?

MR. EVANS: No objection.

MR. MILLER: Okay.

(Exhibit published.)

BY MR. MILLER:

Q. So whole milk and its relationship to prostate cancer, generally the title; right? That's what the issues were?

A. Yes.

Q. All right. And going to the highlighted area here, it was -- sorry -- yeah, it was 12 percent, not statistically significant; right?

A. So actually that number that you're looking at looks at the total dairy intake. I think the result that we were really focused on was, if you look at the title, it's around whole milk consumption in fatal cancer which we found a relative risk of 1.49 and the higher risk of fatal cancer 2.17 in the survival analysis.

Q. Okay. The 1.29 --

A. I'm sorry, 1.49.

Q. Yeah, 1.49. But it wasn't statistically significant. It was .97 to 2.28?

A. And then if you look at the next line in the survival analysis, whole milk intake remained associated with risk of progression to fatal disease with diagnosis hazard ratio of 2.17.

Q. You wouldn't want to sit here and tell this jury that scientists, real scientists in the real world, don't use a data because the confidence interval goes below 1?

A. No, right. I mean, I think -- and I don't think I've said that. But actually just -- I just want to be clear that the title focuses in specifically on

our finding on whole milk, not total dairy.

Q. Right. But you did tell the lawyers for Monsanto that your primary interest was in prostate cancer when they called or -- no?

A. I -- I honestly can't recall what I spoke about. But, you know, as I've talked about, really I have a lot of broad interests in cancer epidemiology.

Q. Let's go back to your book if we could. Let's go back to page 128. What you thought was important about going from association to causation.

I'm at page 128. Let me know when you're there. Are you there?

A. Yes.

Q. Okay. All right. So what you said was:

> "Repeated demonstration of an association of similar direction and magnitude in several studies, undertaken by different investigators in different population groups, increased confidence in a genuine causal basis but cannot conclusively establish this."

Did I read that correctly?

A. Yes.

Q. And that's what we have here. We have Hardell in Sweden, we have De Roos in America, we have Canada

studies, we have different populations, all of the associations going in the same direction. Whether you agree with the studies or not, that's what we have.

A. Yeah, actually in the -- you know, that final meta-analysis showed that they do go all in the same association which is that there's no association. When you adjust for other confounders and you present that summary of all of the estimates, they are aligned and they're converging that there is no association. So I do agree with that.

Q. Okay. And you go on in your textbook to say:

> At this stage both biologic and epidemiologic considerations should be taken into account in interpreting the results of empirical studies.

Did I read that correctly?

A. Yes, you did.

Q. And you never did that here. You never looked at the biological considerations, you only looked at the epidemiology.

A. So --

Q. Yes or no?

A. I -- I -- let me explain. When you -- when you see no association in the epidemiology studies, it's not really informative what you might or might not see

in the biological studies. I mean, the way that biology or experimental studies might contribute to a body of evidence is if there is no epidemiology, or if you do see a positive association, try to understand what the mechanism is, why it might occur. In this particular case, none of the epidemiology studies together show evidence of a positive association.

Q. To Dr. Mucci?

A. No. Actually I -- you know, I took the same strategy that IARC took when they did their meta-analysis in summarizing the results of all the study. I just took -- what I took are the most adjusted estimates from each of the study, the most up-to-date data, not results that were published 10, 20 years ago.

Q. We're going to look at the data after lunch. And one of us is cherrypicking. I think we can agree on that; right?

A. Yes.

Q. Okay. We'll find out after lunch.

But to answer my question, you never did a Bradford-Hill analysis on this data; yes or no?

A. No, I didn't, but actually a Bradford-Hill analysis is sort of old-fashioned in epidemiology. It's one -- it's a set of guidelines we look at it, but we don't really use it now in epidemiology.

Q. Bradford-Hill analysis isn't used in epidemiology now? Did I hear that right?

A. It's -- it's -- it's -- it's a fairly old-fashioned approach. It's one of the -- one of the ways that we look at criteria for causation, but it's actually -- it's -- it's -- it's a little bit out of date.

Q. This book was published in 2018?

A. Yes. And actually, so you can see we talk about the Bradford-Hill because it has in the past been used so often. But then you can see on the next pages we go through discussing a process of causal inference which doesn't refer to Bradford-Hill.

Q. Let's look at the Bradford-Hill criteria which apparently was not out of date in 2018 when you published your book, and take a look at it.

And we went through this with Dr. Portier and we went through it with Dr. Nabhan and with Dr. Weisenburger, but I want to go through it with you even though you didn't do it.

A strong association is more likely to be causal. That's true, isn't it?

A. It -- a strong association when there's no confounding or bias, then it is more likely to be true. But if there is confounding or bias, that's not the

case.

Q. Okay. So if in the ejaculation study, 18 percent is strong evidence, what is 100 to 200 percent seen in these case-control studies here? Can we agree it's stronger?

A. No. Actually when you look at all of the epidemiology studies, they show no association actually for glyphosate and non-Hodgkin's lymphoma.

Q. According to Dr. Mucci?

A. Again, I'm -- I've just presented the results from each of the case-control and cohort studies that were most adjusted for other pesticides and are the most up-to-date data.

Q. Consistency. What you report in your book is an association is more likely to be, what, causal; right?

A. Yes.

Q. When it is observed in different population groups; that's true, isn't it?

A. Again, so all of these -- and in fact in the Bradford-Hill criteria, when he published this now 54 years ago, one of the things he said is you first need to rule out that any observations that you have are not due to bias or confounding, that you want to say -- you want to rule out cause and effect. And if you can't

do that, then you shouldn't be applying these criteria.

So that's one of the things also that's said in Bradford-Hill.

Q. I understand that's what you're saying now. I'm looking at what you published in your book.

Can I go now to specificity? Specificity in this case means the association is not found with all manners of cancer. It's only found with non-Hodgkin's lymphoma.

That is specificity, isn't it, Dr. Mucci?

A. Yeah, but there's other examples of, for example, smoking increases the risk of about 10 different cancers. So whether something's specific or not isn't necessarily important.

And I understand this is what our textbook showed and we felt it was important because in the past this has been a way in which epidemiologists have tried to assess causation. But what you can see and what we do now in the modern era of epidemiology is a more thorough approach to the process of causal inference.

Q. Since 2018?

A. Again, we actually -- we have presented this for completeness. We think it's important to present on something that people have used in the past, but it's -- it's -- it's not something that we use now.

Q. All right. Let's go to gradient. This is what you published last year in 2018.

Gradient. That criterion refers to the presence of an exposure response relationship.

Right?

A. Yes.

Q. (Reading from book:)

If the frequency or intensity of the outcome increases when an exposure is more intense or lasts longer, then it is more likely that the association...

-- is what, ma'am?

A. Is causal. And, again, if you can rule out bias and confounding.

Q. That's been well-known in epidemiology since Bradford-Hill that the association is dose-dependent, it's more evidence of causality; isn't that true?

A. Yes, but it's not relevant in this particular set of cases because you don't see evidence of dose-response.

Q. According to Dr. Mucci.

All right. So let's keep going.

Plausibility. An association is more likely to be causal when it is

biologically plausible.

You didn't look at that issue; that's true, isn't it?

A. In this per -- I focused on the epidemiology studies, that's correct.

Q. Answer my question. It's true you did not look at biological plausibility?

A. I -- you know, just to be clear, I am familiar with the biological plausibility. I didn't review each of the individual studies on the basic science. That -- that part is true.

Q. Yeah, I mean, before you come in here and testify that Roundup doesn't cause cancer, wouldn't a fair-minded scientist want to do the Bradford-Hill analysis and look at the biological plausibility; isn't that reasonable?

A. So, actually -- so, again, just to be clear, the Bradford analysis was a set of guidelines put forth over 50 years ago. It's not something that we, as epidemiologists, today rely on. What we do is we evaluate all of the epidemiology studies and assess whether bias or confounding could explain associations.

You know, if we consistently saw association that we thought we could rule out bias or confounding, then it would be important to look at biological

plausibility. But given that epidemiology is talking about humans and given that the studies don't show an association, it's not meaningful to look at biological plausibility.

Q. Let's look at what you said in 2018.

Experimental evidence. Experimental evidence exists, then the association is more likely to be causal.

That's true, isn't it?

A. This is -- that is one of the criteria that Bradford-Hill specified, yes.

Q. You didn't look at any experimental evidence in mice. You didn't look at any experimental evidence in rats. That's true?

A. Again, I looked at -- I'm familiar with those. I just didn't look at the specific studies.

Q. The other criteria that you thought was important enough to put in your book in 2018 is analogy.

The existence of an analogy, for example, if a drug causes birth defects and another drug could have the same effect could strengthen the belief that the association is causal.

Right?

A. That's what analogy is, yes.

Q. Sure. And other pesticides are know to cause non-Hodgkin's lymphoma. You said so yourself; right, Doctor?

A. There -- there is evidence of positive associations with other pesticides.

Q. So we have an analogy here; right? True?

A. Except for the fact that there is no evidence of a positive association in the epidemiology studies. So therefore none of these criteria would hold.

Q. According to Dr. Mucci?

A. No. Again, this is just -- I'm just presenting -- what I presented were all of the actual results from the actual studies. I just provided an overview with my meta-analysis. But I didn't present -- these are the actual current data that exist today.

Q. Which you've never published, and if you tried to publish, it would be rejected within 60 seconds; you know that?

MR. EVANS: Objection. Argumentative.

THE COURT: Sustained. Stricken.

BY MR. MILLER:

Q. Let's look at what you said in 2018.

Criteria for inferring causation -- this is on the topic of not -- of Bradford-Hill not being the modern way since 2018.

Quote:

Criteria for inferring causation from epidemiologic investigations have been proposed over the years, by several authors, including MacMahon, Pugh, Ipsen. This is back in the 1960s. United States Surgeon General. Sir Austin Bradford Hill (1965), the IARC (1987) and others.

In spite of differences in emphasis, a similar set of principles has been invoked by most authors. Sir Bradford Hill advocated the nine widely used criteria listed in 6-3 to distinguish causal from noncausal association.

That's where science truly is today; isn't it, Doctor?

A. That is -- that paragraph really just summarizes what's been used over time. I'm not sure exactly what your question is.

Q. Well, my question is the Bradford-Hill criteria is alive and well in 2019 outside of this courtroom, isn't it?

A. Actually, I mean, again, we don't have to argue about this particular topic, but I think if you look in the next set of the textbook, it would go into a

lot of detail about the process of causal inference.

I think it's important to specifically present the Bradford-Hill here, but it wasn't -- it's not something that's really used that much now.

Q. Believe me, I would love to go through this whole book with you, but I'm trying to get you out of here by 3:00. These folks want to get some sunshine. So let's sort of keep moving. All right.

The importance of IARC, just look at page 565, you cite them just on this one page.

MR. MILLER: Can you get the auto focus, somebody.

Q. IARC. IARC. IARC. You cited them for dyes. You cite them for water. You cite them for pharmaceuticals. You cite them for drugs and herbal products.

They are an important source in your view of information about what causes cancer; that's got to be fair.

A. Yeah, they -- they actually are one of many important sources of information.

Q. Strong associations are less likely to be attributable to residual confounding; that's true, isn't it?

A. Not necessarily. It really depends on the

specific exposure and disease that you're looking at.

Q. Let's look at your book, page 250.

Talking about the environmental exposure of tobacco, and you say this is strength of association relative risk of two are less likely attributable to residual confounding than modest association relative risk 1.2 and which strengthens the evidence of causality; right?

A. So I haven't had a chance to look at this topic recently. But it can be. But I could give you an example. I know we didn't want to talk anymore about physical activity, but I actually did a study on physical activity and lung cancer risk, and found that those who are engaging in regular physical activity -- or not engaging in regular physical activity were about twice as likely to be diagnosed with lung cancer as those who were regularly physically active.

The problem was that the people who were the most physically active were also a lot more likely to smoke. And so when I carefully adjusted for smoking, that association completely disappeared and there was no association between physical activity and lung cancer.

So while in many cases it may be the case that a strong association is not due to confounding, there are many other cases where it is. And the thing about

confounding is you just need to look at it within each study to see if it's present or not.

Q. A strong association is 1.7?

A. Again, so I agree in some cases that may be the case. But there's many, many other examples in cancer epidemiology where confounding can lead to such a strong association.

Q. We're making some progress.

You use proxy responders in your studies, don't you?

A. Rarely. I have in the past but rarely.

Q. The answer is, yes, you have used in the past proxy responders?

A. I have -- I think there was only one study in fact that used proxies.

Q. So I want to look now at the De Roos study and your chart for De Roos. Where was that?

De Roos isn't on your study. It's not on your PowerPoint, is it?

A. So actually De Roos I included as part of the NAPP results, as well as McDuffie, because it's the most up-to-date analysis that exists of those studies.

Q. All right. Let's take a look at it even though it didn't make it onto your chart, okay.

MR. EVANS: Objection, Your Honor.

Argumentative.

THE COURT: Overruled.

BY MR. MILLER:

Q. Here's a copy, Doctor. 1588.

MR. MILLER: Permission to publish -- we've already published it, Your Honor.

1588, we'll put it up on the screen.

(Exhibit published.)

BY MR. MILLER:

Q. All right. Now, you've looked at this before; right?

A. Yes, I have.

Q. Just to reorient us, this is a study by Dr. De Roos, Dr. Weisenburger, Dr. Blair; right? Among others.

A. Yes, correct.

Q. And you agree all three of them have more expertise and more experience in investigating pesticides and non-Hodgkin's lymphoma than you do; fair?

A. Yes, they do.

Q. Okay. And unlike you, they did a study and it was peer-reviewed and published; right?

A. Yes.

Q. Okay. And in this peer-reviewed published study in 2003 that did not make your PowerPoint, let's

go to Table 3, and let's look at the glyphosate. And on the logistic regression -- now I've looked at a lot of studies. I bet you can imagine. You use logistic regression all the time.

A. Yes.

Q. Under the logistic regression, they found a statistically significant doubling of the risk for people that were exposed to glyphosate.

A. That's what they found, yes.

Q. Okay. And you never wrote a letter to the editor criticizing this paper?

A. I was not familiar with this study in 2003.

Q. I understand.

A. 15, 16 years ago.

Q. Right. It wasn't your area of expertise?

A. That wasn't the reason. I just -- it wasn't a study that I looked at.

Q. And let's go, if we can, to page 7 of this study, bottom right. I want to blow up that paragraph that starts "glyphosate."

What these scientists who studied the issue say glyphosate commercially sold as Roundup is commonly used herbicide in the United States on both crops and on noncrop land. Association of glyphosate where non-Hodgkin's lymphoma was observed in another

case-control, but the estimates were based on only four exposed cases.

That's the 99 Hardell study; correct?

A. Yes, it is.

Q. Okay. And then a recent study across a large region of Canada found an increased risk of non-Hodgkin's lymphoma associated with glyphosate use that increased by the number of days used per year; right?

A. Yes.

Q. That's the Eriksson study?

A. That was McDuffie.

Q. I'm sorry. You're right, that's the Canada study.

So now we have, as you discussed in your textbook, different populations from different parts of the world all showing a positive association?

A. Right. And again the other thing that my textbook talks about is when you see a positive association, you need to rule out confounding and bias. And what we know from some of these same authors -- I know Dr. Weisenburger is part of the NAPP, so is Dr. Zhang, I think, is part of the NAPP, that there was residual confounding, that the approach that they took in this study wasn't the right approach to take.

Q. I've been dying to ask you this. Dr. Weisenburger is the author of the NAPP. Can we agree he knows more about the NAPP than Dr. Mucci?

A. Absolutely. And that's why it's interesting to see the approach that they took with that particular analysis where they took a very thoughtful approach for adjusting for confounding whereas in this case they were adjusting for 47 different pesticides when they only had 36 cases.

Q. And the way science is built, science is built upon prior science; right?

A. Yes, it is.

Q. And so Dr. De Roos and Dr. Weisenburger and Dr. Blair, the independent scientists they were, did they write, quote:

> These few suggestive findings provide some impetus for further investigation into the potential health effects of glyphosate even though one review concluded that the active ingredient was noncarcinogenic and nongenotoxic.

You see that?

A. Yeah. And actually I do agree with that. There was concern in these studies that were now 15 and 16 years old that there were some positive associations.

And so the impetus was, for example, in putting together the NAPP, the case-control study where it was a very hypothesis-driven approach and appropriate adjustment for confounding, and that's one of the studies they did.

Q. Are you finished?

A. Yes.

Q. Let's go look at the footnote 50. Okay. Let's look at, yeah, footnote 50.

The study that they cite as showing the other way is written by Dr. Williams. Did Monsanto send you the deposition of Bill Heydens, vice president of Monsanto, who admitted ghostwriting the Williams article? Did they send you that information?

A. No.

MR. EVANS: Objection, speculation.

THE COURT: I'm sorry. I can't hear you.

MR. EVANS: I said objection, speculation.

THE COURT: Overruled. She can answer.

THE WITNESS: No.

BY MR. MILLER:

Q. You don't know anything about the ghostwriting issue in this case?

A. No, I don't.

Q. So like in your case, would you allow someone to write an article, like Bayer, and then just hand it

to you and have you put your name on it?

MR. EVANS: Objection, Your Honor. Speculation.

THE COURT: Sustained. And irrelevant.

BY MR. MILLER:

Q. Do you write your own articles?

A. Yes, I do.

Q. Okay. All right. So that is the study in 2003 by -- let me make sure we have one, two, three, four, five, six, seven scientists in a peer-reviewed journal.

Go, if we could, please, to page 8, bottom left, where it says second -- you see that.

MR. MILLER: Blow that up so we can all read that.

(Document published.)

BY MR. MILLER:

Q. They say -- and, again, this is the study that looked at 44 different pesticides and only found an association statistically significant with four of them; right? We can go back to the table if you don't remember.

A. I'm sorry. Could you --

Q. Yeah, so let's go back to the table. Let's orient this comment if we could.

This is the study in 2003 that looked at 44 different pesticides, herbicides; right?

A. 47, yes.

Q. Yeah, 47, I'm sorry.

And only found a statistically significant risk in four of them, one of them being Roundup; right?

A. That's what the study found, yes.

Q. All right. Let's go back then to page 8. And where the authors say --

MR. MILLER: Do we have that up --

(Document published.)

BY MR. MILLER:

Q. Second, the fact that there were few associations suggest that the positive results we observed, that is for Roundup and three others, are not likely due to -- are not likely to be due to what, Doctor?

A. Systemic recall bias or selection bias.

And I -- I think that was a reasonable concern. It doesn't address confounding, but it's a reasonable thing to say.

Q. Let's move on.

Excuse me, Doctor. One more thing we want to talk about. Let's go to the top of that same paragraph on page 8.

What they say here is the pooled study of multiple --

A. I'm sorry, I don't see where you are.

Q. It's on the top left.

A. Yes.

Q. This pooled study of multiple agriculture pesticides provides an opportunity to estimate the effect for each specific pesticide. That's true, isn't it?

A. That's what they say, yes.

Q. And it's adjusted for use of other pesticides; right?

A. They did an adjustment for other pesticides. But as I talked about earlier, really the concern is when you're putting in more variables into your model than you actually have exposed cases, it's leading to what's called a sparse data bias. And you can get a lot of instability or you can get the wrong answer.

And actually you can worry about that and you can say, well, maybe it is or maybe it's not a problem. But they actually looked at it with the NAPP, and when they do an appropriate adjustment for confounding, that's when you see no association using the same data they use here from De Roos.

Q. Sparse data bias is not a criticism that

appears anywhere in the literature about this study; you know that to be true, right?

A. I couldn't say whether it doesn't exist at all, but I can say that as an epidemiologist it's one of the concerns that we have. And again, we can have an argument about it, but actually they tested this specifically in the NAPP analysis where they only adjusted for three other pesticides. And then you all of a sudden see no association. So it goes to this idea in fact there was a sparse data bias. It led to kind of a spurious association when there wasn't really one that existed.

Q. Before you knew you were coming in here today, did you get anything to show us where people complained about sparse data bias in the DeRoos study?

A. No, but, you know, sparse data bias is something we as epidemiologists worry about. And again, like -- again we could say in the hypothetical but here we have the results of the NAPP analysis where they did a very thoughtful and appropriate adjustment for confounding.

Throwing 47 variables into a model where you only have 36 exposed cases, you can get the sense of what might go awry with something like that.

But we actually have the data in NAPP to show

that when you do an appropriate adjustment for confounding, there is no association. In the NAPP that included this particular study, there is no association.

MR. MILLER: Why don't we do this. Why don't we talk about NAPP the minute we get back from lunch and let these good folks have a break.

THE COURT: That's fine.

Ladies and gentlemen, we're going to take 40 minutes for lunch so we'll be resuming at 12:40. Thank you.

(Recess taken at 11:58 a.m.)

(Proceedings resumed in open court in the presence of the jury at 12:44 p.m.)

THE COURT: Mr. Miller, you may resume.

MR. MILLER: Thank you, Your Honor.

Q. Likely neither one of us had lunch so I'm not going to bother to ask if you had a good lunch.

Now let's get back to work and try to get this done.

I promised the jury we'd start out with the NAPP study after lunch, and we will.

But before we do, just to be clear, you did not look at Al Pilliod or Alberta Pilliod's medical records, and you're not here to say whether Roundup was a substantial contributing factor in causing either of

their cancers; correct?

A. I haven't looked at their records.

Q. Okay. I just want to make sure we all understood that. Okay.

So the answer is you're not here to say whether or not Roundup was a substantial factor in causing their cancers; right?

A. I'm here -- yeah. I'm here specifically about the epidemiology, yes.

Q. I understand. I understand. And, okay, let's go back to work.

MR. MILLER: If we can turn on the overhead.

Q. And so this is one that you walked through with Mr. Evans in your direct examination; right?

A. Yes.

Q. And this is the NAPP. And you told the jury that there was no association; right?

A. Correct.

Q. Okay. Now, Exhibit 2082, what's already been shown to the jury, is a June 2015 NAPP presentation in Ontario. You've reviewed it, haven't you?

A. Yes, I have.

Q. Okay. And Dr. --

MR. EVANS: Do you have a copy, counsel?

(Counsel confer off the record.)

BY MR. MILLER:

Q. Do you want a copy, Doctor?

A. Yes, please.

Q. Sure. Here you go.

A. Thank you.

Q. Yes, ma'am.

MR. MILLER: And, Your Honor, here you go.

Q. You've reviewed this before, haven't you, Doctor?

A. Yes, I have.

Q. Okay. And while you showed the jury no association, in this first presentation of the NAPP data, they showed and Dr. Weisenburger told us this was the most relevant data.

MR. ISMAIL: Objection -- sorry.

MR. EVANS: Objection, Your Honor. It misstates prior testimony.

MR. MILLER: I'll restate.

MR. EVANS: Mr. Ismail wanted to make an objection for me.

MR. ISMAIL: My apologies.

MR. MILLER: Let me restate.

MR. EVANS: He usually just elbows me.

MR. MILLER: I've been there, believe me.

Q. Dr. Weisenburger, again let's orient

ourselves, he's one of the authors of this; right?

A. Yes, he is.

Q. And Dr. Blair is one of the authors of this; right?

A. Yes, he is.

Q. And you're aware that Dr. Blair has been deposed in this case and said under oath recently, a year ago, that he still believes Roundup is a probable human carcinogen; have you been shown that depo?

A. I haven't looked at the deposition.

Q. Did you ask for it?

A. I did not.

Q. And the Monsanto lawyers didn't share it with you?

A. I haven't looked at it.

Q. Okay. Okay. All right.

Here's what Dr. Weisenburger and Dr. Blair said in their NAPP study, that -- now we're looking at diffuse large B-cell in this case for a particular reason. But for statistical significant increased risk shows a 2.49 statistically significant; right?

A. That result is, yes.

Q. 150 percent increased risk; right?

A. The result is 2.49 there, yes.

Q. And I'm not making light of the importance of

your ejaculation study, it's important, I'm sure. You know, prostate cancer is a serious thing. But you show an 18 percent increased risk there and thought that was very important; right?

A. It was a finding that we reported on, yes.

Q. I mean, Dr. Rider, your coauthor, flew to New Orleans to present that information; right?

A. She did, yes.

Q. And both of you have been interviewed in the press about it?

A. Yes, we have.

Q. It's important information. It's an 18 percent risk. This is 150 percent increased risk; isn't it?

A. That's what is presented in this earliest set of slides. But the, you know, updated analysis that present subsequently don't show the same finding.

Q. You complained about our data not being adjusted. Let's take a look and see.

Odds ratio, that's what OR stands for; right?

A. Yes.

Q. Adjusted for age, sex, state/province, lymphatic or hematopoietic cancer in a first-degree relative, use of proxy respondent, use of any personal protective gear, use of 2,4-D -- that's another

pesticide, isn't it?

A. Yes, it is.

Q. And adjusted for Dicamba; that's another pesticide?

A. Yes.

Q. And adjusted for malathion?

A. Yes.

Q. And so this data is adjusted, prepared by, I think you'll agree Aaron Blair and Dr. Weisenburger, you've already agreed know more on this pesticide and non-Hodgkin's lymphoma relationship than you do; right?

A. They've published on the topic.

Q. Sure.

A. Yes.

Q. Sure.

A. So but, you know, again this is one of the sets of data. If you look kind of in the next set of slides, I think looking at the cumulative exposure, there you actually see no association for DLBCL.

Q. The data you showed Mr. Evans shows no association, but the PowerPoint that Dr. Weisenburger presented in Ontario shows 150 percent increased risk?

A. Right. And then the same presentation two slides later when you look at DLBCL for the cumulative lifetime days of exposure, there you can see there's no

association for DLBCL.

Q. And the authors would know which data is the most important; right?

A. Well, I -- there's three sets of data that they presented here, three different measures of dose-response, and that's the one that's highlighted here.

Q. Did you read the draft manuscript that is awaiting approval to be published by these authors?

A. Yes, I reviewed a draft from four years ago.

Q. Okay. 2085. Let's take a look at it.

Indulge me for one second, excuse me. There it is. All right. And I have a copy.

Here you go, Doctor.

A. Thank you.

MR. MILLER: Your Honor.

And counsel.

Permission to publish, Your Honor?

THE COURT: Any objection?

MR. EVANS: Yeah, it's unpublished, Your Honor.

MR. MILLER: Your Honor, she reviewed it.

MR. EVANS: She reviewed it, but it doesn't mean you can show it to the jury. You have this -- sidebar?

THE COURT: Sidebar.

(Sidebar held but not reported.)

BY MR. MILLER:

Q. All right. Let's review this together. Okay. This is what the authors put in a draft manuscript.

Now you've written draft manuscripts; right?

A. Yes, I have.

Q. Part of the process is authors get together and they write a paper and share it among themselves; right?

A. Yes, they do.

Q. And then they decide whether or not it's publication worthy and then they'll submit to a journal; right?

A. Yeah, that's generally the process. I'm not sure where in the process this particular version is. But, yeah, that is generally the process.

Q. Right. Yeah, but just the general process.

And then the reviewers will comment, right, and they'll either recommend, accept it, or reject it for the journal?

A. Right. Or revise.

Q. Or revise, sure.

And so you reviewed this. And this is a draft manuscript of the NAPP; right?

A. It's -- yes.

Q. And I just want to make sure we understand. There's one, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve authors of this; right?

A. Yes.

Q. Including Dr. Blair we've talked about. Dr. Pahwa, Dr. McLaughlin, Dr. Weisenburger; right?

A. Yes.

Q. And what they say -- what this paper -- if you go to page 2.

A. Page 2?

Q. Yes, please. Do you have it?

A. Yes.

Q. Okay. Read the third bullet point down. What these 13 authors say about what this paper adds to the scientific literature. Read it out loud, please.

A. So subjects who ever used glyphosate had elevated odds ratios for non-Hodgkin's overall and for all subtypes except follicular lymphoma.

Q. All right. Keep going, please.

A. Significant or nearly significant risks of NHL overall were observed --

Q. Excuse me, Doctor, I'm sorry to interrupt. Slower for her, please.

Significant?

A. Or nearly significant risks of NHL overall were observed for greater than two days per year -- it gives an odds ratio -- and greater --

Q. What's the odds ratio?

A. 2.42, 95 percent confidence interval 1.48-3.96. And greater than seven lifetime days odds ratio 1.55, 95 percent confidence interval 0.9 to 2.44 of glyphosate use with some difference in risk by subtype.

Q. Okay. So what these 13 authors got together and ran this manuscript by, looked at all the data from Ontario, looked at the data from South America presentation, looked at all of it. The data that Monsanto's lawyers want to show the jury, the data I want to show the jury; right?

A. Uh-huh.

Q. And they looked at all of it and they said, quote:

> Significant or nearly significant risk of non-Hodgkin's lymphoma overall were observed for greater than two days' use.

A. Right. And that is the unadjusted estimate. For some reason they decided to highlight there. It's not the adjusted estimate.

Q. Well, these 13 scientists spend their lives studying pesticides and they believe that's the most appropriate data to put in their manuscript; right?

MR. EVANS: Objection. Foundation, speculation.

THE COURT: Sustained.

BY MR. MILLER:

Q. They say significant or nearly significant risk of non-Hodgkin's lymphoma were observed for greater than two days per year, odds ratio 2.42, that's 142 percent increase risk; right?

A. That's the relative risk estimate, yes.

Q. Statistically significant?

A. Yes.

Q. Okay.

A. Right.

Q. And that's a dose-response greater than two days' use?

A. So a dose-response assumes there's no confounding present in the analyses. And actually the authors themselves say in the discussion adjusting for several pesticides 2,4-D, Dicamba, malathion, was a useful way to attempt to disentangle the effect of glyphosate from other pesticides on NHL risk.

And actually in the PowerPoint presentation,

you can see what happens to all of the dose-response. All in 15 different analyses in August 2015 presentation, all of those dose-response, when you adjust for the confounding, disappear. You can have dose-response that appears to be there, but in this case it was all due to confounding.

Q. They got that data and looked at that data and that's what they reported as an important point. What this paper adds --

A. Right.

Q. -- is that there is a significant -- what these authors say this papers adds --

A. Right, but this paper --

Q. Wait, wait. Let me finish.

THE WITNESS: Judge, sorry.

THE COURT: One voice at a time. So we can just start with the question and then an answer.

THE WITNESS: Sure.

THE COURT: Thank you.

THE WITNESS: I apologize.

MR. MILLER: Thanks.

Q. Okay. What this paper adds, what these 13 authors say about the NAPP data, not what Alberta Pilliod's lawyers say and not what Monsanto's lawyers say, but what these 13 authors say is that significant

or nearly significant risk of non-Hodgkin's lymphoma overall were observed for greater than two days per year odds ratio 2.42; right? If they're right, that's 142 percent increased risk.

A. Right. And, again, that is the result that they focused on was not adjusted for other pesticides. I'm not sure why they decided here to put that.

But also this manuscript has not been published as written. We don't know what any revisions have been made. We don't know who wrote that specific comment or if all the authors had approved that. We just don't actually know, given this manuscript, where it was in the publication.

And so actually we actually don't know if one author said that or if all the authors agreed to it actually because it's just a draft manuscript.

Q. Let's look at page 12. Okay? This is what these 13 authors -- so to be clear, though, let's go back to page 1. There's not one author on this document, there's 13; right?

A. Right. And so when I read a manuscript and I'm the first author, I'll write the title page, I'll put all the coauthors who are going to be part of the study, and then I write the draft of what I'm going to write. Then I submit it to my coauthors and they

critique it and give comments and it goes back and forth.

I can't tell you whom among this author list that is on this study has or has not commented because we don't know. It's not a published study. And, you know, the fact that it's four years old, you wonder if it didn't get accepted yet because the authors have decided to highlight unadjusted numbers when they actually have adjusted data and actually talk about confounding being present.

Q. Since you don't know, let's not guess. Is that fair?

A. I think that's fair.

Q. Okay. Let's turn to page 12 and see what we do know from these 13 authors.

Would you please read the paragraph that starts "Our results."

A. Sure. And but just to be clear again, since we don't know if the 13 authors have commented on this draft or not, all we can say is that one author wrote this. I think -- I think we agree to that.

Q. Do you want me to read it, or are you going to read it?

A. No, I'm happy to read it. I just want to make it, you know, clear. I think this is the part about

science that you go back and forth in a manuscript, and we just don't know who has or hasn't commented on this job.

Q. Let me know when you're ready to read.

A. Our results are lined with findings from epidemiology studies of other populations that found an elevated risk of --

THE COURT: Slow down, please.

THE WITNESS: Sorry.

BY MR. MILLER:

Q. Slow down.

A. -- an elevated risk of non-Hodgkin's lymphoma for glyphosate exposure and with a greater number of days per year of glyphosate use. As --

Q. That's dose-response, isn't it?

A. That is referring to one of the dose-response analyses. And it's referring specifically to a meta-analysis by Schinasi that was problematic because it didn't include only adjusted numbers.

As well as the meta-analysis of glyphosate use and NHL risk.

Q. Okay. So what they're telling us, these 13 authors, or one or two or three, a collection of them that are working on this draft, is that our results are aligned with findings from other epidemiological studies

of other populations that found an elevated risk for non-Hodgkin's lymphoma.

That's what they think their data shows; right, Doctor?

A. That's what -- that's what they've written. But actually we have the results -- I'm -- I'm -- we have the results of the adjusted analysis which actually are not aligned with find -- potential findings. So essentially, you know, we -- I am not sure why they've highlighted the unadjusted numbers here. It's a little confusing.

Q. Well, you think all 13 of these scientists got it wrong or do you think one of them got it wrong and hadn't shared it with the other 12 yet?

A. I couldn't say.

Q. As well as meta-analysis. You and I have talked, there's several meta-analyses, and all of them show a statistically significant increased risk; that's the truth, isn't it?

A. That is true. And they're also all including unadjusted estimates in their meta-analysis.

Q. The Chang and Delzell --

A. Yes.

Q. -- is unadjusted?

A. Yes.

Q. We'll look at that in a minute. All right.

A. And they also don't include all of the updated cohort data that we have now.

Q. Like the Zhang article that we're going to talk about in a minute; right?

A. I'm sorry, like the Zhang?

Q. The Zhang article. You've read the Zhang article?

A. Yes, I have.

Q. And that's the new data that you've been referring to, isn't it?

A. No. The new data that I'm referring to are Andreotti which was published three years after this draft manuscript, as well as the Leon cohort study which was just published a few months ago.

Q. Which shows a statistically significant increased risk for diffuse large B-cell lymphoma; true?

A. I actually don't -- it's -- it's -- it's probably borderline significant. I'm not going to argue with that. But it also didn't include the most up-to-date AHS data. And as I showed, when you include that data it goes from 1.36 to 1.21 and not significant.

Q. How come so many people are getting this wrong, Dr. Mucci?

MR. EVANS: Objection. Argumentative.

THE COURT: That is sustained.

BY MR. MILLER:

Q. All right. Let's go back to page 5.

I think you told us this data was unadjusted.

A. The data that they highlighted is unadjusted. But their -- their -- they do have some adjusted results in this manuscript.

Q. Okay. The assessment of limited evidence of epidemiological studies was based on case --

A. I'm sorry?

Q. I'm sorry. I'm at page 5. Excuse me. I'm sorry. Top of paragraph.

A. Okay.

Q. Are you with me?

A. Yes.

Q. And what it says there is that the assessment of limited evidence from epidemiological studies was based on case-control studies in the United States, Canada, and Sweden that reported increased risk of non-Hodgkin's lymphoma that persisted after what? After adjustment for other pesticides. That's what it says; right?

A. That's in the ever/never and that -- that is true. But the -- the results of the dose-response from those same case-control studies unfortunately were not

adjusted for other pesticides.

Q. So -- okay. All right. Let's move on.

Let's go back to page 12. We were talking about what these 13 authors concluded, and I'm looking back at that same paragraph again, quote:

From an epidemiologic --

A. I'm sorry, I don't see where you're at.

Q. Yeah, we're back at the same paragraph we were at before, about two-thirds of the way down page 12.

A. Yeah.

Q. Okay. Let me know when you're there.

A. Yeah.

Q. What they say is, quote:

From an epidemiological perspective, our results were supportive of the IARC evaluation of glyphosate as a probable human carcinogen; right?

A. That's what they've stated, yes.

Q. Okay. So if someone were to tell this jury that the NAPP study didn't support IARC, these authors don't agree with that, do they?

A. Well, again, just to be clear, we're not sure which of the authors have written this draft manuscript --

MR. EVANS: So objection, foundation, Your Honor. But she's answered.

THE COURT: Okay. Thank you. Go ahead.

BY MR. MILLER:

Q. You can answer.

A. So I just think that's important to be clear about.

Secondly, the comparison they're making is based on unadjusted estimates, but then the authors later on in this manuscript actually say that their results show that confounding due to use of other pesticides made a difference. And they actually talk about it in the results section as well. They say that the results were attenuated.

Q. Now, I want to talk to you about --

THE COURT: Counsel, have a seat.

MR. MILLER: I want to pull up an exhibit here. Bear with me. My box is getting smaller.

Q. All right. You work at the Harvard T.H. Chan School of Public Health?

A. Yes, I do.

Q. And they put out news alerts about medical news, don't they?

A. Yes, they do.

Q. Okay. Let's talk about a couple of them.

MR. MILLER: We're going to look at Exhibit 3126. I have a copy for everyone.

Your Honor, I've redacted some in response to an MIL.

Permission to publish?

MR. EVANS: That's fine. No objection.

MR. MILLER: ELMO on, please.

(Exhibit published.)

BY MR. MILLER:

Q. Now I want to talk about what your lawyer says about these issues.

That's where you work; right, the Harvard T.H. Chan?

A. Yes, it is.

Q. School of Public Health; right?

A. Yes.

Q. All right. So they put out news. And they said probable carcinogenic herbicide, they're talking about Roundup, aren't they?

A. You know, the title is cut out so I can't see. But, yes, they later go on to talk about glyphosate, yes.

Q. Sure. Glyphosate was deemed a probable carcinogenic hazard by IARC in 2014. Actually, 2015; right?

A. That's correct.

Q. Okay. It was March.

U.S. EPA, FDA, and the World Health Organization have declared it probably isn't, but a professor at your school, Alice Lu, says in an August 17, 2018 article in the *Atlantic* that he trusted IARC findings as it has long been what?

A. As has long been recognized as the only agency that looks at environmental chemicals and their carcinogenicity.

Q. He said that although the herbicide has been on the consumer market since 1974, safety data has only recently become available.

And it's true; isn't it?

A. I'm not sure what he meant by safety data. So I'm not sure what he meant by safety data.

Q. He says, quote, the reason that IARC took so long is because of lack of data, he said. They had to weigh the validity of the risk before coming to the conclusion. That's what IARC does; right?

A. I'm sorry. What is your specific question?

Q. That's what IARC does, they weigh the evidence and then come to a conclusion --

A. Yes.

Q. -- and important enough for your school to report on it; right?

A. Yes, you know, I'm not sure what year this

press release came out. But we often, when news comes out from something like EPA or IARC or other agencies, we will report on things that may have public health significance. So I think, you know, at the time this was a comment based on that IARC finding.

Q. And let's cut to the chase. I mean, you know that the State of California has declared Roundup a known human carcinogen?

A. So based on Proposition 65, it's sort of an automatic thing that when IARC comes out with a classification, that it automatically puts a label. It doesn't do its own independent evaluation. It's just relying on the results of IARC.

Q. You never wrote to the State of California, the scientists here, to say, no, you got this wrong?

A. About?

Q. Roundup being a known cause of cancer.

A. I have not, no.

Q. Okay. And what we looked at before, that wasn't the only time that your school has published information about this important finding by IARC; right?

Let's take a look. It's not a memory game. I don't want to be unfair.

Exhibit 3127.

MR. MILLER: I have one for you counsel.

Q. This is again from the Harvard T.H. Chan School of Public Health?

A. Yes.

MR. MILLER: Permission to publish, Your Honor?

MR. EVANS: I object as hearsay, Your Honor.

MR. MILLER: We just looked at one.

THE COURT: Pardon me?

MR. MILLER: We just looked at one, Your Honor.

MR. EVANS: Not down this road.

(Sidebar held but not reported.)

THE COURT: Sustained.

BY MR. MILLER:

Q. You reviewed this before; right?

A. I'm not sure if I've looked at it before.

Q. Do you remember me coming to Boston and taking your deposition?

A. I'm sorry, I don't remember looking at this previously.

Q. I was hoping you'd remember me. Oh, this. All right.

Well, suffice to say it's been more than one occasion when your school has published the importance of this IARC finding?

A. So just to clarify. What they've done is to summarize the findings of IARC. I'm not sure when these two pieces were actually put on the website. But it's pretty standard, as I mentioned, when there's findings that come out on specific compounds that may have relevance for public health for the School of Public Health's website to talk about it.

In just looking at this particular piece, it's just simply highlighting what was said in IARC. It's not making any specific conclusion about it.

And, again, IARC's review of the epidemiology was that it was limited. We now have so much more evidence. None of that evidence was noted in either of these websites. So I'm assuming these were published some time ago.

Q. Sure. We're going to get to the Zhang article in a bit. But Dr. Zhang reported -- and that's one of the more recent studies you're talking about, right, the Zhang?

A. No. Actually when I look at the epidemiology, I don't rely on a meta-analysis. I rely on the original epidemiology studies themselves.

The two more recent studies that I'm talking about are the Agricultural Health Study and the Leon three cohort studies.

Q. But you said in your book: Meta-analysis provide an important widely accepted data even where derived from observational data; remember?

A. Right. But also in this, if you tell me the page I can read the exact text, but we also said meta-analyses have their limitations which are well recognized. If you put in unadjusted estimates into a meta-analysis, you're going to get a bias estimate out of your meta-analysis. And that's something we've also commented on this textbook as well.

Q. How many years have you been an epidemiologist?

A. For more than 15 years.

Q. Have you ever seen a perfect study?

A. I have not -- you know, there -- there are studies that have more strengths and more weaknesses. However, when we know that there's confounding, confounding is one of the biases we're concerned about. If you put into your meta-analysis a bias estimate, you are going to get a bias estimate out of that meta-analysis.

So in terms of reviewing the epidemiology studies, it's actually more critical to actually review each of the individual studies rather than relying on the -- a meta-analysis.

Q. And that's why it's so important to be an environmental or occupational epidemiologist because they know about exposures in the field; right?

A. So the exposure data that was collected in this study is the same type of exposure information I use in my own epidemiology studies. It was primarily from questionnaire data.

So as an epidemiologist, I'm -- I'm well trained in being able to evaluate the quality of data that comes from questionnaires.

Q. Let's take a look at this, maybe short-circuit some of this. This is Exhibit 2131. This is an article that I think you reviewed before.

By 95 scientists saying they agree with IARC. Do you remember looking at that?

A. Yes, I do.

Q. Okay. And we published it before, and I'll put it back up on the easel.

Differences in the carcinogenic evaluation of glyphosate between IARC and European Food Safety; right?

A. Yes.

Q. And 95 scientists, including Dr. Portier who we heard from it seems like forever ago now, Dr. De Roos who's one of the authors of the AHS 2005 study right?

A. And also the Andreotti 2018 study.

Q. Right. Who said she agrees with IARC that it's a probable human carcinogen?

A. So this -- I can -- I can see this was published soon after IARC came out, but it was well before the updated results. So she -- all of these authors didn't have access to the cohort results from the Agricultural Health Study, didn't have access to the three new cohort studies. And so they're basing their evaluation on older data.

So now in 2019 we have much more updated results with more than five times the number of exposed cases. We have a lot more information now than they had even three years ago when they published this letter.

Q. So they published this in 2016 about the same time you were being hired by Monsanto's lawyers; right?

A. Yes.

Q. Okay. And what these 95 scientists tell us is the most appropriate and scientifically based evaluation of the cancers reported in humans and laboratory animals as well as the supportive mechanistic data is that glyphosate is what?

A. A probable human carcinogen.

Then in the next line, what you can read is they say on the basis of this conclusion and in the absence of evidence to the contrary, we now have --

Q. Finish the sentence: It is reasonable to conclude --

A. Right.

Q. -- that glyphosate formulations, that's Roundup; right?

MR. EVANS: Objection, Your Honor.

THE COURT: Wait. You can't interrupt her. And you have to allow her to finish and then ask your next question.

MR. MILLER: Yes.

THE WITNESS: So I think, you know, they were aligned with -- you know, they had -- they didn't have the data now. And so that is a very important point there. In the absence of evidence to the contrary. We now have so much more data than they had when they wrote this.

And that's how science works. You can have a hypothesis. You can look at a set of data and come to a certain conclusion, which IARC said was limited because they couldn't rule out bias or confounding.

Now there's so much more epidemiology data that supports no causal association between non-Hodgkin's lymphoma and glyphosate.

So, again, it's really critical that they wrote that because it goes to this point. With revised

data, they may -- many of these authors might not have agreed with what they wrote here. I couldn't say one way or the other, but there is substantial evidence to the contrary.

Again, one is showing that there was confounding in the early case-control studies; and secondly, we have much more data from cohort studies which is a more reliable source of information.

Q. Finished?

A. Yes.

Q. Okay. On the basis of this conclusion, in the absence of evidence to the contrary, it is reasonable to conclude that glyphosate formulations -- you understand that to be Roundup?

A. Yes.

Q. What's the surfactant in Roundup?

A. What is a surfactant?

Q. What is the surfactant in American Roundup?

A. I'm not sure.

Q. Didn't look into that, did you?

A. I didn't. But, you know, in all of these studies, what they were reporting on was the formulation. So, you know, we were studying in these human studies the effect of Roundup on non-Hodgkin's lymphoma in the case-control and cohort studies.

Q. Something else you didn't look into, you didn't look into the laboratory animal data or the supportive mechanistic data; right?

A. Again, I -- you know, I'm familiar with it. I didn't review each of the individual studies. But I am familiar with what those studies show.

Q. You wrote your report without looking at any of that; let's just be honest.

A. No. Again, I haven't looked at each specific study from that, but I am familiar with that. I've looked at the regulatory reports. And then in each of the epidemiology, they often focus on the mechanistic and -- and experimental studies.

Q. The takeaway from this, and Dr. Mucci, is you think these 95 doctors would come out and say they don't believe this anymore; is that the takeaway?

A. So I couldn't -- I couldn't tell you what the specific authors would say. However, they did specifically say in the -- without -- let me read the exact words of what they said.

In the absence -- I can't find where specifically you were looking at.

On the basis of this conclusion in the absence of evidence to the contrary.

And now we have the updated analysis from

Agricultural Health Study. We have the cohort study of Leon which pooled together three prospective cohorts. We also have actually a revised analysis with NAPP of the initial case-control studies. That is data to the contrary.

Q. Well, we can go into a really wonky discussion about AHS that I'm sure would put everybody to sleep.

But isn't it fair to say -- we can talk about exposure misclassification, loss to follow-up. But at the end of the day, Dr. Blair and Dr. De Roos, both authors of the AHS study that you rely on so much, have concluded that Roundup is a probable human carcinogen; that is the truth, isn't it?

MR. EVANS: Objection, Your Honor. Foundation.

THE COURT: Speak up.

MR. EVANS: Objection, Your Honor. Foundation.

THE COURT: Sustained.

BY MR. MILLER:

Q. Let's go back and look at it. All right. Let's go back to Exhibit Number 2131.

Anneclaire De Roos, that's the author of the AHS, one of them?

A. She's one of them, yes.

Q. And she signed a letter with 95 scientists; right? She signed that in 2016; right?

A. Yep. Yep.

Q. Okay. In 2016, Dr. De Roos, author of that AHS study, in a peer-reviewed journal stated: The most appropriate and scientifically based evaluation of the cancers reported in human and laboratory animals as well as the supportive mechanistic data is that glyphosate is a probable human carcinogen; right?

A. That is what they wrote. And in addition to the part about it being absence of evidence to the contrary earlier, and they also comment on the fact that they agree with IARC that the epidemiology studies were at the time limited because they couldn't rule out bias or confounding.

So they say earlier on the other side that specific thing. And so to that point, we now have all this updated evidence showing in fact their concern about confounding was rightly so.

Q. We have an hour and a half left. We're going to get to new evidence.

But based on this, and you raised an excellent point, it says on the basis of this conclusion and in the absence of evidence to the contrary, it is reasonable to conclude that glyphosate formulation

should also be considered likely human carcinogen.

Ma'am, are you aware that Monsanto never did studies on the formulation to determine whether it was carcinogenic?

A. I couldn't say one way or the other.

Q. Wouldn't you want to know?

MR. EVANS: Objection, Your Honor.

THE COURT: Sustained.

BY MR. MILLER:

Q. Would knowledge of that issue, if there were such studies, would you want to read them?

MR. EVANS: Objection, Your Honor.

THE COURT: Overruled. You can answer.

THE WITNESS: So in my review of all of the epidemiology studies, those are -- that's what I would have focused on. It wasn't -- as we've talked about already, I didn't look at detail at the mechanistic studies or the experimental studies.

And the reason is that if you want to understand why cancer happens in humans, you want to study people. You don't want to study animals. You don't want to study cells.

There's many examples where you might see in one specific mouse model or one specific cell line when you give really high doses of a substance, it can lead

to cancer, it can lead to changes. Whether that's relevant or not to humans is -- it's not always the case.

So in fact when you want to understand what causes cancer in humans, epidemiology studies are the thing that are the most important. So that's what I would have focused on.

BY MR. MILLER:

Q. Monsanto had a full-time employed epidemiologist; are you aware of that?

A. I -- I assume you're talking about Dr. Acquavella.

Q. Dr. John Acquavella.

A. Yes, I'm familiar with him, yes.

Q. To be a fair and impartial expert on this, did you talk to Dr. Acquavella about this before you came in here?

MR. EVANS: Objection, Your Honor.

THE COURT: Sustained.

So, Doctor, if you would just, when you hear "objection," don't say anything --

THE WITNESS: Yes.

THE COURT: -- until I've ruled on it.

THE WITNESS: Okay.

///

BY MR. MILLER:

Q. Did you review Dr. Acquavella's deposition?

A. No, I did not.

Q. Did you ask to review Dr. Acquavella's deposition?

A. No, I didn't ask, no.

Q. So back to my original question. We sort of got off on a tangent. The takeaway is -- and if we have to get wonky, we will -- but that Dr. Blair and Dr. De Roos, authors of the Agricultural Health Study, in 2016 said Roundup is a probable human carcinogen?

A. Just to be clear, I think Dr. Blair was not a coauthor of the Andreotti study.

Q. I didn't say Andreotti. I said the Agricultural Health Study of 2005; right?

A. Correct. He wasn't -- he was part of the 2005 publication but was not part of the 2018.

Q. Okay, so the answer is, yes, it's true that Dr. De Roos and Dr. Blair, who were the authors of the 2005 AHS study, have said in 2016 Roundup is a probable human carcinogen, that's true; right?

A. And that's -- they said they're -- they're aligned with what IARC said, which is that the epidemiology evidence was limited because they couldn't rule out bias or confounding. So they also said that.

And they also said in the absence of data to the contrary, which we actually have so much more data now.

Q. At some point, the Court is going to want to take an afternoon break. These folks deserve it. And then we're going to get to that data after that break. That's the way I'm timing it. Okay.

All right. Dr. Blair wrote a study about the confounding problems and exposure misclassification in epidemiological occupation.

A. Yes, he did.

Q. And you reviewed it?

A. Yes, I have.

Q. Okay. Let's take a look at it. It's Exhibit 1676.

MR. MILLER: I have a copy for everyone. I'll hand those out.

Q. Now, let's orient ourselves to time and place.

MR. MILLER: Put that up on the screen. 1676.

(Exhibit published.)

BY MR. MILLER:

Q. All right. Dr. Blair; right? Yeah?

A. Yes.

Q. Okay. And he's writing in a paper about issues regarding confounding exposure misclassification

in epi studies of occupation; right?

A. Yes.

Q. And let's just sort of go to page 7. And this is -- to put this in context, it's 2007 he wrote this; right?

A. Yes, he did.

Q. Which is two years after the Agricultural Health Study in 2005; right?

A. Yes, it is.

Q. Okay. So two years after he co-wrote the Agricultural Health Study with Dr. De Roos, he writes this paper in peer-reviewed literature. And please turn with me to page 7.

He writes, along with his fellow scientists in the conclusion.

MR. MILLER: Blow that up.

(Exhibit published.)

BY MR. MILLER:

Q. We believe of the two of the major methodologic issues raised in epidemiologic studies of occupational exposures, that is confounding and exposure misclassification, the latter is a far greater concern.

Right?

A. That's what he says, yes.

Q. And exposure misclassification is -- I know

you don't like the analogy, but it's the Farmer Tom, Farmer Ted, that's exposure misclassification, isn't it?

A. That can be one form of misclassification, yes.

Q. And he tells us that is a greater concern than confounding; true?

A. So -- so that is what he says. However, I think there's a couple of important issues. One is with confounding, you can look to see whether confounding is present in a given study.

Q. Well --

A. And so this may be a general statement. But actually for each of the studies we have here, you can look to see whether confounding is present, first of all.

And in many of the case-control studies, they did show confounding was present. So it may be a general statement that they may be concerned about that. But in this particular body of literature, you can see that confounding was a big issue.

The other thing is what they're talking about with respect to misclassification is using job matrices or saying you've worked as a farmer, you've worked as a welder, you've worked in this occupation. How likely are you to be exposed to different things? That's very

different than the epidemiology studies we have which is based on questionnaires.

Q. Finished?

A. Yeah.

So I just want to be clear. I think this is an important study that he talks about in usual occupational cohorts. But this particular publication doesn't have a lot of relevance to this set of epidemiology studies that we're looking at.

Q. This is from the author of AHS, two years after AHS. Let's go on and see what else he says here.

Quote: It is rare to find substantial confounding in occupational studies or in other epidemiological studies for that matter.

It's what he says?

A. It is what he says. And, again, you know, I think having this type of publication can be very helpful in the context of occupational epidemiology, but when we think about confounding, we want to look specifically at each -- each publication. And in fact, I think some of the early case-control studies including Dr. Blair comment on confounding as by other pesticides.

Q. He goes on to tell us: Even by risk factors that are strongly related to the outcome of interests, malathion, 2,4-D Dicamba, that's what he's talking

about, even by risk factors that are strongly related to the outcome, he simply doesn't see a problem with confounding; right?

MR. EVANS: Objection. Foundation, Your Honor.

THE COURT: Overruled.

THE WITNESS: So he does -- he's talking about again in the topic of something very general. But then in his draft manuscript of which he's a coauthor for NAPP, he actually highlights the problem with confounding in this particular topic of glyphosate non-Hodgkin's lymphoma. And they talk specifically about the importance of adjusting for the other pesticide use because it is a confounding.

So, again, as a general statement in occupational studies, he said this. It's not really relevant to this set of epidemiology studies.

BY MR. MILLER:

Q. You haven't read Dr. Blair's deposition?

A. I have not. But I can read this particular -- I can read all of this body of evidence and say this particular focus here was not really relevant to the epidemiology studies that we have.

Q. What he says here is the direction of the bias is largely predictable, that is, a bias of a relative

risk towards the null; right?

A. When you have a yes-no exposure, yes.

Q. And all of us are amateur epidemiologists now, we know bias towards a null means it gets rid of a possible association?

A. If there is substantial misclassification. You know, one of the strengths, if you want to talk about the Agricultural Health Study, was they looked at so many different validation studies and showed actually that the questionnaire data had relatively little misclassification. So I think that's an important consideration here.

Q. Okay. And, yep, I forgot to read that one.

In addition, the magnitude of the relatively small amounts of misclassification -- just a little bit of misclassification -- can be sufficient to lead to an interpretation of no effect.

A. In yes-or-no comparisons. But, again, if we think about the Agricultural Health Study, it's very unlikely you're going to misclassify somebody who's been using glyphosate for 100 or more days in their lifetime as never exposed and vice versa. That kind of misclassification is not going to be happening.

Q. While we're talking about exposure, you know in Andreotti that there are four quartiles of exposure;

right?

A. Yes. And then the fifth group is never exposure.

Q. Okay. And the highest quartile of exposure, that means somebody's been exposed a lot; right?

A. For 100 or more days in their lifetime.

Q. Okay. And you didn't -- have you read Dr. Phalen's deposition? He was here yesterday.

A. No, I have not.

Q. So you don't know whether or not the plaintiffs were in the highest quartile of use?

A. I don't know.

Q. Okay. All right.

Let's go quickly to the Eriksson study.

MR. MILLER: And whenever Your Honor wants to take a break, we can do it now or later.

THE COURT: Why don't we do it now, just for 10 minutes. We're running out of time.

(Recess taken at 1:39 p.m.)

(Proceedings resumed in open court in the presence of the jury at 1:52 p.m.)

BY MR. MILLER:

Q. All set, Doc?

A. Yes.

Q. Okay, great.

One of the things that's been an area of controversy, and just to kind of generally orient you, is I think you've said before -- correct me if I'm wrong -- that you don't think there was an exponential increase in the use of the glyphosate during the AHS study.

A. So just to be clear, what I was commenting on, there was not an exponential increase in the age of participants because so many were already ever exposed to glyphosate at the start of the study.

Q. And I think you said about 75 to 80 percent.

A. So 75 percent at the start of the study were already using glyphosate.

Q. And that's important to know that you believe the AHS to be such a valid study; that's fair, isn't it?

A. It's -- the fact that you have such a high prevalence of the exposure really makes for a powerful study because you have a sufficient number of exposed cases.

Q. But it wasn't 75 percent. It was only 35 percent. Are you aware of that?

A. I'm sorry. 35 percent in the Agricultural Health Study?

Q. At the start of the study, yes, ma'am.

A. Based on the baseline questionnaire.

Q. Yes, ma'am.

A. Yep.

Q. Only 35 percent.

A. Or the first year questionnaire.

Q. Right. Only 35 percent, not 75 percent; right?

A. Well, but that was a -- you know, if you look at the entire set of 50,000 individuals, what they reported on the first questionnaire was actually three-quarters of them were using glyphosate at some point.

Q. Right. Not 75 percent.

A. No, three-quarters is 75 percent.

Q. Excuse me?

A. Three-quarters is 75 percent.

Q. You're saying 75 percent were using Roundup when the AHS started?

A. They had ever been exposed to glyphosate, yes.

Q. Let's take a look at Exhibit 3056.

MR. MILLER: Thank you.

Q. A couple things I wanted to point out about this study, if I could.

You've seen this before, Doctor? It's on your reliance list.

A. Yes, I have.

MR. MILLER: Permission to publish?

MR. EVANS: No objection.

MR. MILLER: All right. Do we have this for the screen might be a better way, Exhibit 3056.

(Exhibit published.)

BY MR. MILLER:

Q. All right. And this is a study by, who else, Aaron Blair and others about what's going into the AHS study; right?

A. Yes.

Q. And to orient us all, it was done in 1999; right? This was published in 1999; right?

A. This was published in 1999.

Q. Yes. And what they're talking about is characteristics of pesticide use in a pesticide applicator cohort, the AHS study; right?

A. Yes.

Q. Okay. And just to put it in context, the first paragraph on the left, please.

MR. MILLER: And blow that up so we can all read it together. Yeah.

(Exhibit published.)

BY MR. MILLER:

Q. Data on recent and historic pesticide use and pesticide applicator and farm characteristics were

collected at this point from 35,000 people; right?

A. Yes.

Q. Okay. And if we go to the introduction section, we want to look at something there before we leave this page. 1999, these scientists tell us specific agriculture agents that might be responsible for the excess risk of cancer, and they relate several forms of cancer, the one we're interested in hematopoietic. Do you see that?

A. Yes.

Q. Among male farmers have not been clearly identified, but the strongest link to date is with what?

A. Hematopoietic system cancers.

Q. And the strongest link to date is with pesticides; right?

A. I'm sorry? Okay. Sorry.

Q. Have not been clearly identified?

A. Yes, the strongest link to date is with pesticides, yes.

Q. Okay. And that was in 1999, Dr. Blair; right?

A. Yes.

Q. If we could please go to Table 2. It's on page -- page number, yeah, that page, 174.

And look, it tells us pesticide use and medium number of applications made last year by state and

license type; right?

A. Yeah. So it's referring to specifically the use of pesticides in the prior year.

Q. Right. Percentage of population use and indicated pesticide last year. Glyphosate was only 33 percent in Iowa; right?

A. Yes. So 33 percent of the respondents were -- had used glyphosate in the prior year.

Q. I thought you said under oath it was 75 percent?

A. So 75 percent of individuals at some point during their lifetime had ever used glyphosate.

And that's one of the strengths of the way that the Agricultural Health Study collected information was they weren't asking only what are you currently using, but what's your lifetime exposure. And that's the way in epidemiology we collect exposure data. We don't only want to know what are you doing now, but what did you do in the past so you can get an estimate of someone's lifetime exposure to this.

Q. Let's take a look at Table 6.

What Dr. Blair tells us in Table 6 is that for these people, 76 percent of them in Iowa are wearing chemical-resistant gloves, aren't they? Right?

A. Yes.

Q. You --

A. So I didn't -- I haven't looked at this publication for a while. So I just need to orient myself a little bit.

Q. Take your time. I mean, 76 percent use chemical-resistant gloves. And you don't know whether my clients were ever warned or not to use chemical-resistant gloves; that's something outside your area of expertise?

A. Right. I know -- you know that I -- actually I know from the updated full cohort that only about 50 percent of the participants were using any form of protective gear.

So, you know, I'm not sure what the 77 -- 6 percent is specifically referring to, but I do know in the full cohort less than half were actually using any form of protective gear.

Q. It says here 47 percent were using face shields or goggles here?

A. Right. Again like so, you know, when we look at the full cohort of data, we know that less than half of them were using some form of protective gear.

Q. 30 -- 29.8 percent are wearing boots, apron, waterproof pants; right?

A. Again, yes. What I can tell you, though, is

less than half of the cohort was using protective gear in the full 50,000 individuals.

Q. Pretty hard to generalize this to the home gardener that doesn't know using this stuff --

(Simultaneous colloquy.)

THE WITNESS: Well, actually, no, and I can --

THE COURT: I'm sorry. Hold on.

THE WITNESS: Yeah, sorry.

MR. EVANS: Objection, Your Honor. Relevance. Argumentative.

THE COURT: Sustained.

MR. MILLER: We'll move on.

Q. Last study before we get to the new studies. The Eriksson study. Let's go over it real quick. I apologize, I know we've been over it a lot. But real quick. Let's see if you agree or disagree with these scientists.

MR. MILLER: Thank you.

Your Honor, here is yet another copy of Eriksson.

(Exhibit published.)

BY MR. MILLER:

Q. All right. It's been published before, Exhibit 1703.

You've seen this, Doctor; right?

A. Yes, I have.

Q. Okay. All right. And this is a peer-reviewed paper; right?

A. Yes, it is.

Q. Published in *International Journal of Cancer*. It's a prestigious cancer journal; right?

A. Yes, it is.

Q. By four scientists; right?

A. Yes.

Q. Who study this issue, pesticide and non-Hodgkin's lymphoma?

A. Yes.

Q. Okay. And what they did in 2008, look at page 3.

MR. MILLER: Blow up that top left paragraph, please.

(Exhibit published.)

THE WITNESS: I'm sorry. Page 3?

BY MR. MILLER:

Q. Yes, please.

A. The top?

Q. We're going to look at the top left paragraph.

A. Okay.

Q. And it's talking about latency periods there. For glyphosate it had an odds ratio of 2.26.

Statistically significant; right?

A. It's actually 2.81.

Oh, sorry, 2.26, yes.

Q. I just want to get it accurate.

A. Yep.

Q. And you expect -- I mean, when we study cancer, we expect whatever the DNA hit is, it's going to show up after 10 years; right?

A. Yeah, I mean, with cancer you'd want to look at longer latencies and, you know. So this particular number here unfortunately was not adjusted for other pesticides, but, you know, when you don't adjust for pesticides, this is the relative risk that they observed.

And what you can see from the Table 7 is when you adjust for other pesticides for ever-versus-never exposure that relative risk -- not this one specifically because they didn't present that data -- but it attenuates substantially showing confounding.

Q. I don't mean to interrupt you. Are you finished?

A. Yes.

Q. These scientists, four of them who studied this issue in a peer-reviewed journal, show a statistically significant increased risk over doubling;

right?

A. The relative risk is 2.26.

Q. And you have rightfully so put on your résumé all the times you've sent letters to the editor?

A. Yes.

Q. You didn't send a letter to the editor on this one, did you?

A. No, I did not.

Q. Just quick, and we'll leave this. I know what your conclusions are. They didn't adjust their data correctly, but let's look what these scientists say on page 6, top left.

These scientists tell us glyphosate was associated with a statistically significant increased risk, increased odds ratio for lymphoma in our study, and the result was strengthened by a tendency to dose-response effect; right?

A. Yes, that's what they say.

Q. All right. They go on to the last sentence over there on the right side, these scientists say, quote, furthermore our earlier indication of an association between glyphosate and non-Hodgkin's lymphoma has been considerably strengthened.

Right?

A. Yes. And they also -- you know, it's

interesting because they also in this kind of highlight the issue of confounding that existed in the study.

Q. You think this data is confounded and this jury shouldn't consider it, but IARC thought this data was important and used it as part of the reason they concluded Roundup is a probable human carcinogen; true?

A. Right. So actually, though, you know, IARC did rely on this data and they also said they couldn't rule out bias or confounding. The authors themselves also note the point of confounding that many individuals that use MCPA earlier are now also exposed to glyphosate, and this is probably why the multivariate analysis does not show any significant odds ratios for these compounds.

So, again, they're kind of -- I don't know why they didn't focus on the adjusted findings or why they didn't adjust for other pesticides in all of their analyses. But I think, yeah, IARC did include this and it is one of the ones I considered as well. But the important thing is that IARC said that they couldn't rule out that the prior studies were not due to bias or confounding. And that was what IARC said.

Q. IARC said it's a probable human carcinogen?

A. And they also said they couldn't rule out the epidemiology was due to bias or confounding. And we can

actually see in this study the role that confounding played in the multivariate analysis.

Q. I also like to bring it back to an expert's own research. In your paper where you reported an 18 percent protective effect for 21 times or more ejaculating in prostate, you didn't rule out every confounder?

A. No, that is -- that's true. But we actually looked at I think 20 different potential confounders. We looked -- did several sensitivity analyses, we did subgroup analyses.

I think you're right. I think it is an important thing that we should never rely only on one study alone but really look at the totality of the evidence.

And specifically here, you know, they actually looked at whether there's confounding or not only in one of their analyses, and they actually showed in their own data that there was substantial confounding.

Q. Let's look at this new data which you speak. Okay?

Hot off the press, 2019. It's probably as new as data is going to get, isn't it?

A. I'm not sure which study you're referring to.

Q. Zhang. Let's look at it.

The jury knows this well. And I apologize going over the same stuff, believe me I do.

But I'm here, Exhibit 2233.

MR. MILLER: It's new data, Your Honor.

Now, permission to publish?

MR. EVANS: No objection.

(Exhibit published.)

BY MR. MILLER:

Q. Okay. Let's reorient -- it's been a long trial and we've had a couple long breaks. But just to sort of cut to the chase, this is a manuscript, peer-reviewed, published; right?

A. Yes.

Q. These scientists are scientists who deal with exposure and pesticide issue; right?

A. Yes.

Q. Okay. And you know there's such a thing as a Scientific Advisory Panel for the Environmental Protection Agency; right?

A. Yes. I actually served as an advisor on one of those panels.

Q. But not for pesticides?

A. No, but it was for chemicals.

Q. Okay. You know Dr. Zhang --

A. I don't know Dr. Zhang.

Q. Let me finish my question.

A. Okay. All right.

Q. Do you know that Dr. Zhang was on the Scientific Advisory Panel for the EPA on this issue of pesticides; right?

A. I don't know that, no.

Q. Well, let's go to the back. Okay. Here you go. Let's go to page 33. Look at the declaration of interests.

MR. MILLER: If we could blow that up, please. Page 33. Yeah, 33.

(Exhibit published.)

BY MR. MILLER:

Q. Declaration of interest. And responsible authors put their declaration of interest or conflicts in papers; right?

A. Yes.

Q. Okay. And what these authors are telling us is they have no financial conflicts or interests to declare; right?

A. That's correct.

Q. They don't work for Monsanto, they don't work for me, they're scientists; right?

A. Yes.

Q. And they're scientists who were tapped,

Dr. Zhang, Dr. Taioli, and Dr. Sheppard, to serve on the Science Review Board of the United States Environmental Protection Agency Scientific Advisory Panel; right?

A. For glyphosate, yes.

Q. Met for a couple weeks in Washington, D.C.?

A. Okay, yes.

Q. Actually Crystal City. But okay.

So these scientists go from the Scientific Advisory Panel and they come back to their respective offices, one of them, Dr. Zhang, right here at the University of California Berkeley; right?

A. Yes.

Q. And they do -- let's go back to the front page -- exposure to glyphosate-based herbicides and the risk of non-Hodgkin's lymphoma, a meta-analysis and supporting evidence; right?

A. Yes.

Q. Now so I don't want to be unkind, but unlike you, they did look at the animal data, they did look at the cell data, they looked at the toxicological data; right?

A. Yes, they looked at all of it.

Q. Okay. And go to page 2 if we could.

All right. Look at where these folks are from. Peer-reviewed journal. We're again page 2,

please.

MR. MILLER: Blow up that top part.

(Exhibit published.)

BY MR. MILLER:

Q. Just to put this in context, we've got Berkeley, right? Right down the road here. University of Washington. And Mount Sinai, New York. These are some pretty heavy-hitting scientific spots, aren't they?

A. They're -- yes.

Q. And these are respected scientists?

A. You know, I'm not familiar with any of the scientists, but they're from good universities.

Q. Okay. Now let's go to the bottom of that page and look at the "We concluded" -- I'm sorry.

> We conducted a new meta-analysis and included the most recent update to the AHS cohort published in 2018.

That's that Andreotti study you've been talking about so much; right?

A. Yes, it is.

Q. And along with five case-control studies; right?

A. Yes.

Q. So they took the Andreotti data, which is AHS number 2?

A. Yes.

Q. And they mixed the highest quartile of that in with the case-control studies in some scientific fashion -- these are legitimate scientists.

And let's go to the next page. Let's go to the last sentence in that first paragraph.

MR. MILLER: Highlight that.

(Exhibit published.)

BY MR. MILLER:

Q. Overall in accordance with evidence from experimental animal and mechanistic studies, our current meta-analysis of human epidemiological studies -- that's what you've been talking about; right? Human epidemiological studies suggest a compelling link between exposures to glyphosate-based herbicides and the increased risk for non-Hodgkin's lymphoma.

That's what these three scientists reported in a peer-reviewed journal; right?

A. That is what they reported, yes.

Q. And you've been an expert for Monsanto for two and a half years by this point in time; right?

A. Yes.

Q. You didn't send a letter to the editor to *Mutation Research* and say, hey, these three got it wrong?

A. Yeah. And there's actually a reason for that. As, you know, I think there's a reason for me not to get involved in these current set of studies and write letters to the editor because of the ongoing litigation. So I feel as a scientist, it's my responsibility to not give public comment given that I am part of this litigation. So actually I don't think it's appropriate for me to write a letter in this context.

Q. You could say -- let me finish, let me finish.

You could say: Dear Editors, although I am a retained expert for Monsanto, I am also a scientist and I think this is flat wrong. And say the reasons why.

A. Right.

Q. You could do that if you wanted to.

A. I actually disagree. I don't think that would be a reasonable thing to do. I felt personally that I would not do that.

I can say, you know, about this, this -- the quality of the meta-analysis, any meta-analysis, relies on the quality of the data. Three of the six studies included in this were based on unadjusted data. They didn't -- they were dose-response that were not adjusted for other pesticides.

If you're going to put bias data into the meta-analysis, you're going to get bias data out of the

meta-analysis.

Q. So you think Dr. Zhang from Berkeley, Dr. Taioli from Mount Sinai, and the other doctor from University of Washington, they just really didn't understand how correctly to do this study?

A. Actually, unfortunately in this case, that is the case. You know, it's standard in meta-analyses also, you never want to mix ever-versus-never with dose-response in the same meta-analysis. That's just not a valid methodology for doing meta-analysis.

It's not just me saying this. This is epidemiology textbooks write this. You want to -- if -- you can look at ever-versus-never and all those studies, and then you can look at all the studies looking at dose-response. But you should never mix them.

But, secondly, the quality of the meta-analysis relies on the validity of the studies going into it. You have three of the six studies that were biased because of confounding.

Q. Are you finished?

A. Yes.

Q. Name one scientist in the world that has written to this peer-reviewed journal and said these folks have got it wrong?

A. I -- I couldn't say if anybody has or has not.

Q. Well, they haven't, you know that.

A. I actually don't know that. I -- you know, this study just came out. Sometimes it can take some period of time for letters to come out.

But I can tell you as an epidemiologist this is not the right approach to take with a meta-analysis.

Q. Let's take a look at page 6.

What these three scientists tell us in the last sentence in the top part here, they go:

> Here we evaluated all the published studies on the carcinogenicity of glyphosate-based herbicides and present the first meta-analysis to include the most recently updated AHS cohort. We also discussed lymphoma-related results from studies of glyphosate-exposed animals as well as mechanistic consideration to provide supporting evidence for our analysis of the studies of human exposures to glyphosate.

That's what they did; right?

A. That's what they say that they did. But just to be clear, you know, they didn't have the results of Leon when they did this meta-analysis. So the Leon results are not included here.

Q. That's what they say they did? You don't believe they did what they just told us they did?

A. Well, I'm just -- I just want to be clear that they didn't have access to the results from Leon because Leon was published after this came out. So they actually didn't evaluate what we have now as all of the available human studies.

Q. Right. Leon was published the day I was picking the jury, just introducing myself to these folks. And it showed a statistically increased risk of diffuse large B-cell lymphoma; right?

A. Using an older version of the Agricultural Health Study data. And actually we don't know if it was statistically significant. I would agree that it's probably borderline significant.

Q. I don't mean to interrupt. Did Leon get it wrong or did they get it right?

A. So to this point here looking at non-Hodgkin's lymphoma in total, there was no association overall in that study of relative risk. I think it was 0.95. That wasn't integrated into this meta-analysis here.

Q. Of course it wasn't. But this is a 2019 meta-analysis. And there's a reason the rest of us are interested in diffuse large B-cell lymphoma, and Leon showed a statistically significant increased risk of it;

right?

MR. EVANS: Objection. Hearsay.

THE WITNESS: We don't know that it was statistically significant.

BY MR. MILLER:

Q. Well, we're going to look at it.

Let's finish looking at Zhang.

MR. EVANS: Too much rapid fire, Your Honor.

THE COURT: You have to speak loud. Louder.

BY MR. MILLER:

Q. Page 21 if we could, please.

All right. Look at the last sentence in the first paragraph. They have some pretty harsh criticisms of Andreotti; right?

MR. MILLER: Highlight that sentence.

(Exhibit published.)

BY MR. MILLER:

Q. These three scientists say, quote, as we discuss further in the next paragraph this approach, referring --

A. I'm sorry, I don't see where you are.

Q. I'm sorry. I'm on page 21.

A. 21 of the manuscript, not 21 of the --

Q. 21 at the very bottom.

MR. WISNER: The very bottom?

MR. MILLER: Yeah. Yeah.

MR. EVANS: Bates number?

MR. MILLER: 21.

THE COURT: Bates 22.

MR. MILLER: Bates 22. Let's get it right.

BY MR. MILLER:

Q. 21. All right.

That's what I'm trying to do. Okay. All right.

Are you on the right page?

A. Yes.

Q. Now, talking about Andreotti, these three scientists --

A. I'm sorry.

MR. EVANS: Objection.

(Counsel confer off the record.)

BY MR. MILLER:

Q. Are you there? You were on the -- okay. There it is.

Ready?

A. I'm sorry. What's showing up here is different than what I'm seeing here.

Q. That's not fair to you or anybody else. I want you --

MR. MILLER: May I approach, Your Honor?

THE COURT: The last sentence of the first paragraph.

BY MR. MILLER:

Q. Yeah, the last sentence of the first paragraph on this page.

A. Classification.

Q. Well, if you see it, that's what I want to ask you about.

MR. EVANS: Page 21 on the bottom, Bates number.

THE COURT: Page 21 in the bottom right, the Bates number, last sentence, first paragraph.

BY MR. MILLER:

Q. Are you there?

A. Yeah. I just want to -- I'm sorry, I'm sorry --

(Simultaneous colloquy.)

THE WITNESS: Is it page 21 here or page 21 here?

BY MR. MILLER:

Q. That's a legitimate question. 21 on the very bottom, very right.

A. I'm sorry, which 21 though? Which page 21? Because there's two. There's a publication here --

(Simultaneous colloquy.)

BY MR. MILLER:

Q. You're pointing to it.

A. There's also a page number here.

Q. It's confusing. I apologize. Don't ask me why. Are we all oriented?

THE COURT: It's on the screen.

THE WITNESS: Yes.

BY MR. MILLER:

Q. Okay. Okay.

Blow up that whole paragraph.

(Exhibit published.)

BY MR. MILLER:

Q. What that paragraph is talking about is the Andreotti; right?

A. Yes.

Q. And what these three scientists say, and I apologize for the confusion getting there, but, quote:

> As we discuss further in the next paragraph, this approach -- talking about Andreotti -- effectively bakes into the results the null hypothesis of no increased risk of non-Hodgkin's lymphoma due to glyphosate risk.

That's a pretty strong criticism, isn't it?

A. I'm really -- I'm really sorry. Like I'm --

I'm just -- I'm trying to figure out where you are in this. I'm just trying to figure out where on the paper. So the top of page 21?

Q. Yes, ma'am.

A. Okay. As we discussed, yes.

Q. And by baking in the results of the null hypothesis, the thing is set up to show null results?

A. Right. So actually, you know, so these same authors had written a letter to the editor after Andreotti was first published, and they actually criticize the imputation method for not integrating information on the cancer outcome.

And so in a response, Andreotti said we don't think this would have led to bias, and in fact then they did an updated algorithm using the cancer outcome information that actually showed that approach had no effect and they still see no association.

So, you know, I'm not sure if this got published before Andreotti's response to this concern, but actually Andreotti themselves in their data showed that using this updated algorithm didn't have any effect on the associations.

Q. It would be unfair for me to drag this out and have you come Monday. I don't want to do that. But I need some help. I'll ask questions and you'll have to

answer them and we'll move on.

A. Right. No, I think -- I was just trying to -- it's -- I was just trying to clarify that this -- what they've written here, they actually wrote in a letter to the editor, Andreotti addressed it and showed actually their concern was -- was not a concern. There was no issue.

Q. Let's look at what they say in February 2019 on the next paragraph.

MR. MILLER: Blow it up, please.

(Exhibit published.)

BY MR. MILLER:

Q. Here's what these three scientists from Mount Sinai, Berkeley, and University of Washington say:

> Because of the non-Hodgkin's lymphoma outcome information was not used in the imputation procedure, the exposure -- and they quoted -- imputation method used in AHS '18 report can be better named exposure simulation.
>
> All right.
>
> This term gives a much more accurate understanding of the impact of imputation on the data of the risk estimates because when exposure is simulated in a model that

does not take the NHL outcome into account, the uncertainty of the imputed exposure behaves like a classical measurement of error, thus will bias the effect estimate towards the null.

A. Right. Yeah, so that's -- yeah, that is what they -- they said here. That is what they wrote essentially in this letter to the editor after Andreotti was published.

And then Andreotti subsequently has published -- and I'm not sure the timing of the response with this particular publication. But what they showed, we said, all right, well, if -- let's concerned -- let's test it in our data. So they did an updated imputation and used the outcome information and actually showed that the association was still null, there was no evidence of association.

So, you know, I know this was a concern here in this published study. But Andreotti, et al., actually directly addressed it in a peer-reviewed letter to the editor with updated results showing that this imputation was not flawed.

Q. Let's keep going in this study, try to wrap it up. Try to give Monsanto a couple minutes.

Page 27 in the bottom, bottom right. Okay.

Summary of glyphosate-based herbicide and non-Hodgkin's lymphoma association in humans. Do you see that?

A. Yes.

Q. So these three scientists, February, peer-reviewed journal, say overall the results from our new meta-analysis employing *a priori* hypothesis -- tell the ladies and gentlemen what an *a priori* hypothesis is.

A. It would be, you know, specifying what a hypothesis was and then doing an analysis based on that hypothesis.

Q. And their *a priori* hypothesis was the people who are exposed more would have more risk of non-Hodgkin's lymphoma; right?

A. Yeah, and that is what they hypothesized and -- but only three of the six studies they included actually had dose-response and all -- and two of those three dose-response studies were not adjusted for other pesticides.

So unfortunately, like, that was their hypothesis, but given the data they had, they couldn't directly address the hypothesis that they had.

Q. Including the updated AHS 2018 study, one, demonstrated a significantly increased non-Hodgkin's lymphoma risk in highly glyphosate-based herbicide-exposed individuals; right, that's what they

found?

A. That's what they reported, yes.

Q. Yeah. Ever-use, 41 percent increase?

A. That's what they reported, yes.

Q. Right. And going back to your study, 18 percent change in men's risk of prostate, you thought that was very important. That was strong evidence. This is stronger.

A. It's actually not stronger, again, because of the concern of the confounding that existed in three of the six studies they used in the meta-analysis.

Q. Let's look at middle paragraph if we could, the last sentence on this page, and I'll get close to wrapping it up.

> To investigate causal inference regarding association between glyphosate exposure and non-Hodgkin's lymphoma, we discuss briefly whether or not the association identified from the epidemiology study could be supported by further experimental animal and mechanistic studies.

That's what they say?

A. Yes.

Q. Because that's what good scientists do under

the Bradford-Hill criteria; right?

A. Right. But if -- if the totality of the evidence does not support a causal association in humans, then whether or not something is or is not in the experimental or mechanistic studies isn't really relevant.

Q. Well, but they thought it was. They went ahead and looked at it; right?

A. They did look at it, yes.

Q. But you did not?

A. I did not, no.

Q. Okay. Let's go to page 34, the very bottom right. And if we could, middle of that first paragraph.

> The totality of the evidence from six studies of glyphosate-exposed mice support this association in humans.

That's what these three scientists said in February 2019 in a peer-reviewed paper; right?

A. That's what they said, yes.

Q. The overall evidence from human, animal, and mechanistic studies presented here supports a compelling link -- not just a link, a compelling link -- between exposures and glyphosate-based herbicides and increased risk for non-Hodgkin's lymphoma.

Right?

A. That is what it said. But, again, it's using the same results that IARC raised concerns about being due to bias and confounding. And so I don't agree with this statement here based on the human data.

Q. Oh, yeah, we've got to talk about this. This AHS study that you talk about, I want to ask you about how accurate the pesticide applications were. Point in fact, there was a study on that very issue, wasn't there?

A. I'm not sure which one you're talking about.

Q. It's on your reliance list. And it's Exhibit 4219, Reliability of Reporting on Lifestyle and Agricultural Factors by a Sample of Participants in AHS from Iowa?

A. Yes.

Q. Okay. You've read that, haven't you?

A. Yes, I have.

MR. MILLER: Permission to publish?

Q. But before I do, just so we can orient the ladies and gentlemen of the jury, what happened was there's this quirk in Iowa where they had 4,000 people who had filled out a pesticide application, then a year later filled one out again.

A. Yes.

Q. And then who else but Dr. Blair and others

went back and looked at how accurate these two applications were; right?

A. Yes.

Q. Okay. Let's take a look at it.

(Counsel confer off the record.)

BY MR. MILLER:

Q. All right. So what they did is Dr. Blair, Reliability of Reporting on Lifestyle; right?

A. Yes.

Q. And AHS?

Okay. And what they tell us is there was a sort of unique quirk. Enrollment and completion of the questionnaire from '94 through '96. After initiation of the study, the Iowa legislature changed procedures regarding the pesticide certification for private applicators, allowing annual training as an alternative to the exam; right?

A. Yes.

Q. So they had two options then. They got an application from 4,000 people. They got another application a year later.

A. Questionnaire, yes.

Q. I'm sorry. Questionnaire.

A. Yes.

Q. And what they found was in this study --

comparison of dichotomous responses, meaning they said something different a year later; right?

A. No. Comparison -- dichotomous means just they looked at the ever-versus-never. So they compared did they agree -- if they said they had ever used it on the first questionnaire and did they also say ever on the second questionnaire.

Q. Right. Only 82 percent of them -- oh, I'm sorry. Yeah, 82 percent was with the percent with exact agreement; right?

A. Yes, that's correct.

Q. Okay. 18 percent said something else a year later; right?

A. Right. But, yeah, and actually that they go on to say specifically that that level of agreement is similar to those generally found for factors typically used in epidemiological studies such as tobacco use and actually higher for things like physical activity.

Q. I have to focus in. It gets worse.

Comparison of multi-response questions on pesticide use between first and second questionnaires; right?

A. Yes.

Q. Okay. Years mixed reply for glyphosate, only 53 percent were in agreement with what they said the

year before?

A. Yeah, so the exact agreement was 53 percent, but later on I think what was really important to see was that 90 percent of the individuals were only within one category difference.

So, again, that idea, the misclassification on the extreme group, the highest exposure versus never exposure, that's not misclassified. There's a little bit of misclassification in the doses, but 90 percent of the participants were within one category of several categories.

Q. I don't want to interrupt you. Are you done?

It says dates per year mixed replied, only 52 percent said the same thing on the second survey as they said on the first one.

A. Right, but I think what is more reassuring in the study is again that 90 percent had agreement within one category. So, again, that extreme misclassification you might be worried about just wasn't present in this study.

Q. 62 percent -- only 62 percent remember what decade they started using it; right?

A. Again, the exact agreement was 62 percent, but within plus or minus. It's sort of analogous to if you were filling out a food frequency questionnaire, how

many times are you eating carrots, you might say on one questionnaire it was twice a week and another questionnaire it's three times a week. But that's very -- that's a very little misclassification compared to never eating carrots or eating them, you know, 10 times a week.

So there was a little bit of misclassification, but it was in one category.

Q. You don't think that's shaky data?

A. That isn't -- that -- those types of data, as the authors themselves said, were on par with other epidemiological factors such as tobacco use. And actually concordance was higher for pesticides than things like diet and physical activity which we as epidemiologist use quite often in our analyses.

Q. And again I want to apologize. I don't want to spend a lot of time on this. But you believe the AHS study very important and it's part of your opinions; right?

A. All of the epidemiology studies are part of my opinion.

Q. But the AHS is a big part of your opinion?

A. It's -- again, I looked at all of the epidemiology studies, the case-control and the cohort studies.

Q. The reason I bring it up is because Harvard experts wrote a peer-reviewed paper about how good the AHS data would be before the AHS results came out. You're aware of that, aren't you?

A. Yes, I am.

Q. It's called the Gray study, isn't it?

A. Yes, it is.

Q. And the Gray study, they were pretty critical and predictive about what was going to come out of that AHS study; right?

A. So -- so, yes, this was a study -- yes, please, go ahead.

Q. I was waiting for you to finish.

A. I would love to see a copy.

Q. All right. Exhibit 0362.

You and I have been through this before, haven't we?

A. Yes, we have.

Q. Let's try to make it quick for everybody. But in a nutshell --

MR. MILLER: Permission to publish, Your Honor?

MR. EVANS: No objection.

THE COURT: Granted.

(Exhibit published.)

BY MR. MILLER:

Q. This is, to put it in context, it was published in a peer-reviewed journal, 2000; right?

A. Yes, correct.

Q. Okay. And this is from the Center of Risk Analysis at Harvard University School of Public Health; right?

A. Yes. Some of the coauthors were based at Harvard.

Q. Sure. These are Harvard professionals before the results come out telling us the criticisms they have of the data we're going to get out of AHS; right?

A. Right. So they -- you know, and this is what we do in epidemiology is we think about the critiques, the concerns we might have about the data.

And one of the strengths was that the Agricultural Health Study investigators -- and this was published five years before the first De Roos 2005 publication and 19 years before the Andreotti study.

Since this came out, there were multiple attempts at validating and addressing the concerns that they raised, as well as concerns that advisory board members raised.

So, you know, this is a reasonable thing for epidemiologists to do and an important thing to do.

Q. And let's look at it. Before you were hired as this litigation expert, before the AHS data came out, these Harvard experts looked at what kind of data we could expect from AHS; right?

A. They raised concerns, yes.

Q. Yes, ma'am.

And so let's look at page 6, the bottom far right. Or at the top, the first sentence. What these Harvard scientists tell us, if you go to the very top sentence, please. There you go.

Quote: The low and variable response rate to the supplemental questionnaires seriously affect the quality of the AHS.

Right?

A. That's what they say, yes.

Q. That's that 17,000 we talked about that never returned the second questionnaire?

A. Right. And, again, like -- it is a really reasonable concern to have that it could lead to bias. And I think one of the strengths of the Agricultural Health Study is they looked within their data and said did it actually cause a problem.

And that's what the real strength is. Let's be concerned about it. Let's look at it in our data. But in this case, it didn't lead to any bias.

Q. Well, this is what they said, if I could, please, the next sentence.

> Steps have been taken to increase response rate, but the rate of nonresponse remains substantial.

And that's true, that's what happened, 37 percent never filled out the second questionnaire.

A. Right. Exactly. And, again, I think it's -- it's absolutely reasonable to have been concerned, but when they wrote this, they didn't actually have the data from the Agricultural Health Study. They didn't know -- they were concerned, but they didn't know specifically if it would or would not impact it. And they looked at it and found it didn't have an impact at all.

Q. Well, let's see what they say here.

In the prospective cohort study, low response rates to questionnaire designed to obtain information on subject identifiers, exposures, and baseline disease status will clearly diminish the statistical power and may create what?

A. Bias.

Q. Yeah, that's what happened.

A. This is what they raised concerns about. And, again, rightly so. It was appropriate to be concerned. But one of the strengths -- they didn't have the results

that we have now. The Agricultural Health Study, they looked at in their own data, they've done validation studies.

So, again, these are reasonable concerns I would have as an epidemiologist before I have the findings. But the strength we have now 19 years later are all the validation studies that were done on this cohort and all of the analysis to try to tease out and address whether bias was present.

Q. They warned in the year 2000, quote:

If low response rates occur with the follow-up questionnaires, the potential for bias will increase, partly from misclassification of subjects. And we've heard about that from experts here. Misclassification. That's that pink paint stuff, isn't it?

A. That they were concerned about misclassification, yes.

Q. All right. Go to page 13 if we can. I'm going to move on, but the middle paragraph, pesticide use.

These scientists from Harvard:

However, there are still serious questions about the quality of pesticide use data that are being collected in the AHS.

All right. That's what Harvard scientists

said in the year 2000; right?

A. Right. They also talk about -- in the sentence before that, they approach sensible. But I think they raise concerns. And they -- and, again, these are things as epidemiologists we do worry about. Whether it's a case-control or cohort study, we want to know is the quality of the information we're collecting valid.

And again it's something to be concerned about. But the AHS investigators throughout several studies have shown that the quality of information they got from the questionnaires was highly valid and allowed them to correctly classify individuals as being exposed or not exposed.

Q. They warn -- if we could, on page 15, bottom right again, the bottom paragraph.

These details are important because if pesticides cause chronic diseases such as cancer, the biological meaningful measure exposure may be a cumulative dose figure that accounts for farming practices or even decades ago. That's that we talked about right?

A. Yes.

Q. All right. I think we probably explored that enough.

Let's do this. I want to give the floor back to Monsanto's counsel. I think we can agree on some things or agree that we don't agree.

I want to see who you agree with and who you don't agree with, okay? Let's take a look if we could. Put that up.

State of California. Glyphosate is known to the State of California to cause cancer. Do you agree or disagree?

A. Again, just to clarify --

MR. EVANS: So, counsel, can I see what you're going to show, please.

MR. MILLER: Oh, I'm sorry.

Great. Okay, perfect. Thank you.

MR. EVANS: Okay.

MR. MILLER: Okay?

MR. EVANS: Yeah, no objection.

BY MR. MILLER:

Q. Okay. Do you agree or disagree?

A. I just want to clarify. California didn't do its own evaluation about glyphosate. They're relying solely on IARC. And so it's an automatic procedure when IARC comes out with a certain classification, the State of California, through Proposition 65, makes this classification.

So, again, the IARC data was based on studies that now are 10 years older or more. They didn't have what they have now. So I do not agree that the epidemiology studies support a causal association so I would disagree with the statement.

Q. The next one up. IARC. Glyphosate is probably carcinogenic to humans. Group 2A. Do you agree or disagree?

A. What I agree about with IARC was the fact that they said the epidemiology data were limited because they couldn't rule out bias or confounding. So that part of the IARC classification, I actually do agree that at the time the data they had, they couldn't rule out bias or confounding.

So I'm not sure where to tell you to put my X there, but there's parts of that I agree with based on the data they had at the time.

Q. I'll put you down for agree?

A. Maybe just leave it blank.

Q. Let's put it down for both; is that fair? Agree and disagree?

A. Maybe we could just leave it blank.

Q. Okay. Let's leave it blank. Okay.

Let's go to the 94 scientists' letter we looked at where they said glyphosate is a probable human

carcinogen. Do you agree with them or not?

A. Right. Again, I do not agree with this. Again, it was based on what they had in IARC as well so there was no new data. All of these things were relying on the same old studies that we -- that they had at the time. So there's nothing new there.

Q. Do you disagree?

A. I disagree.

Q. Okay. The McDuffie study, 2001, showed a dose-response two days per year or more of doubling the risk, statistically significant.

Do you agree with that finding or disagree?

A. I'm not sure you could say it is the finding that they had, right. Whether it's a causal association or statistically significant association is a different question.

But I think what we know by the analysis of the NAPP where we had McDuffie and the U.S. studies, you could see that confounding underlies the positive association. So I don't think this is a causal association. It is a statistically significant association, but we know it's due to confounding.

Q. Do you want us to put you down for agree or disagree on that one?

A. Well, again, I think it's -- what am I

agreeing to? I think it's just unclear what you're asking me to agree to.

Q. That Dr. McDuffie and her fellow scientists, in a peer-reviewed journal, found a dose-response relationship for two days per year or greater of doubling of the risk, statistically significant, and that's a valid scientific association.

A. It's -- it's -- it's the statistical association, but we now know from the same authors that published this study that that dose-response was due to confounding.

Q. Put you down as agree or disagree? It's up to you.

A. Again it's not quite as straightforward. It is the statistical association they had.

Q. And turning it into causation you won't have to do the Bradford-Hill criteria which of course you didn't do; right?

A. I'm -- I'm not sure how to answer the specific -- I think you could leave it blank because it's not an easy question to ask -- answer.

Q. We'll leave it blank then. Sure.

Hardell, 2001. Those scientists say glyphosate is a risk factor for non-Hodgkin's lymphoma.

Do you agree or disagree?

A. Disagree.

Q. I'll put you down for disagree.

De Roos, 2003, with Dr. Weisenburger, with Dr. Blair. A doubling of the risk, statistically significant increased risk that's adjusted for 44 pesticides.

Is that scientifically valid information in your view or not?

A. It is not. It was adjusted for 47 pesticides.

Q. 47, you're absolutely right. I apologize.

So do you want to be put down as a disagreer?

A. Again, it's complicated, right? Because it is a statistically significant finding, but it's not the appropriate approach to adjusting for confounding. And the NAPP study that includes both McDuffie and De Roos found a relative risk for ever-exposure to glyphosate non-Hodgkin's lymphoma of no association.

So that's -- that's the result I'd like to comment on, not -- not these that we know are either due to confounding or due to a poorly adjusted estimate.

Q. And, again, the NAPP author, one of them Dr. Weisenburger who is an expert here in this case; right, we agree?

A. Yes.

Q. You tell me. Do you want to put nothing there

for De Roos, agree or disagree? It's up to you, Doctor.

A. I just -- again, I'll leave it blank.

Q. Let's leave it blank. Okay.

De Roos, 2005, the study authors Aaron Blair and Anneclaire De Roos, agree that glyphosate is a probable human carcinogen.

Do you agree with them or not?

A. I'm not exactly sure what you're saying here. Specifically in the 2005 study they said this?

Q. It's pretty clear to me. Study authors, you know what we mean by study authors.

A. No, I understand. In the actual publication they said this?

Q. It looks pretty clear and I didn't say that.

A. Right. So I think that's what's confusing -- confusing. Did they say this in the De Roos 2005 publication? Or is this at some other point that they've said this?

Q. In his deposition, if you read it, Dr. Blair says under oath that it's a probable human carcinogen.

You didn't read it?

MR. EVANS: Your Honor, I'm just going to object. You've got a reference -- anyway, I think it's misleading and I object.

THE COURT: I'm going to sustain that

objection.

BY MR. MILLER:

Q. You didn't read Dr. Blair's deposition?

A. No, I didn't.

Q. Hypothetically if Dr. Blair testified under oath that it's still a probable human carcinogen and De Roos signed a letter with 94 scientists that said it's a probable human carcinogen, do you agree or disagree with them?

A. Again, I would have to understand the context with which they're saying this. And they didn't say that in the De Roos 2005 publication.

Q. Who was the chair of the IARC committee that found Roundup a probable human carcinogen?

A. Dr. Blair.

Q. You don't want to put an answer down there for 5, it's okay with me, just tell me.

A. Again, I think because I think it's misleading to say that in De Roos 2005 that they said that. They didn't say that.

Q. Misleading? Where does it say it says it in the article. I don't say --

(Simultaneous colloquy.)

THE WITNESS: Because you said the source --

THE COURT: We can only have one voice at a

time.

MR. EVANS: I'm going to object. There's a reference on there to a source. And then something from that which --

THE COURT: No speaking objection.

Your last question was argumentative. Why don't we move on to a different question.

BY MR. MILLER:

Q. Sure.

What's misleading about that sentence?

A. Because you're giving a source of De Roos 2005 in which they -- they -- they didn't say that specifically.

Q. Aaron Blair has never said that?

A. Not in DeRoos 2005 which is the source that you list for that particular statement.

Q. Leave it blank?

A. Leave it blank.

Q. Okay. Eriksson 2008. Let me know if I'm misleading here. Quote:

Glyphosate was associated with a statistically significant increased risk for lymphoma with a dose-response greater than 10 lifetime days, statistically significant increased risk.

Do you agree with that or not?

A. And, again, that was the statistically significant finding that they had in a study which we know is confounded. So, again, it's sort of very similar to the McDuffie study and the De Roos study. They were statistically significant, but you can't say that something is causal if you can't rule out bias and confounding. IARC alone said that as well.

Q. Leave it blank? Or --

A. Leave it blank.

Q. Let's go to Schinasi and Leon, the meta-analysis 2014. And we looked at this earlier when we started our cross-examination. The strongest relationships were seen with diffuse large B-cell a doubling of the risk, statistically significant.

Can we put you down as agreeing with them or disagreeing?

A. Again, I mean, I think it's the same as Eriksson, it's the same as De Roos. This is -- this is the association they found, but it is biased.

Q. Well, speaking of bias, let's see if you agree with Chang and Delzell who were funded by Monsanto who reported statistically significant positive meta relative risk for B-cell lymphoma.

Do you agree that that's true or not?

A. That -- again, it's the -- it's the same --

it's the same issue that you keep highlighting, which are these are indeed the relative risks that these studies found, but they don't address the issue with confounding that we know was present in some of these earlier studies.

And so it's the same issue with these other studies. It's just because something is statistically significant finding doesn't mean there's a causal association.

Q. Last one on that chart. I've been reminded. We had a disagreement about Leon. It will take two seconds. But last one.

Zhang, you wanted the new information. 2019, Dr. Zhang and Dr. Taioli say there is a compelling link between exposures of Roundup and increased risk for non-Hodgkin's lymphoma.

Do you agree with them or not?

A. Right. And just to -- just to be clear, although the Zhang publication is 2019, except for the AHS it doesn't include any new data. It's all the earlier case-control studies.

Q. Put you down for an agree or disagree?

A. I think it's a biased result so I disagree with that finding.

Q. And just because we disagree on Leon, give me

one second and I'll be done.

Exhibit 2984.

MR. MILLER: A copy for everyone.

Q. This is a large study, again came out while here in Oakland. You reviewed this; right?

A. Yes, I did.

Q. And just cut to the chase. All right. If you would please turn with me to page 8.

Just to orient ourselves. The jury has looked at this before.

Diffuse large B-cell; right?

A. Yes.

Q. Glyphosate; right?

A. Yes.

Q. Ever/never use?

A. Yes.

Q. Statistically significant increased risk 36 percent?

A. Actually, we don't know specifically if this is statistically significant. It could be borderline. I will give you that.

Q. Twice the risk of prostate cancer in your ejaculation study; right?

A. I'm sorry?

Q. Well, you have an 18 percent is a big deal in

that study. This is twice that. It's 36 percent; right?

A. The relative risk is 1.36, yes.

MR. MILLER: Please have a safe trip back to Boston. Thank you for your patience.

Everyone, thank you for your patience.

MR. EVANS: I have till 3:00 o'clock, Your Honor?

REDIRECT EXAMINATION

BY MR. EVANS:

Q. I just want to make sure that the jury is clear with respect to this last back-and-forth.

And just to be clear, when you say you can either agree -- you don't think you should agree or disagree on this, I just want to make sure.

So the McDuffie study, it actually reports out what is on here; correct?

A. Yes, correct.

Q. So you're not disagreeing that's in the study?

A. No, I'm not disagreeing with that part.

Q. Okay. But is that study -- those results, are they adjusted or not adjusted?

A. They're not adjusted for other pesticides.

Q. So is that a confounded result?

A. Yes.

And actually the reason we know that is in the NAPP study itself, we see that the results were confounded in McDuffie.

Q. And the 94 scientists letter, I forget which ones you actually answered or not, but the 94 scientists letter here, you talked about that that doesn't include the most recent data post 2016; correct?

A. Correct.

Q. So I'm just going to write next to that "not updated." Is that correct?

A. Correct.

Q. And you talked about IARC. Now, again, that's what IARC says?

A. Yes.

Q. I mean, that is their classification.

A. Yes, correct.

Q. You agree with that classification, you think that it is a probable human carcinogen?

A. No, I don't. And, again, their -- their statement there was that the evidence was limited. We have so much more evidence now. So I disagree with that statement.

Q. We already talked about California.

And Hardell, again, 2001, is that -- I think there's a 2002 Hardell study and 1999.

A. Correct.

Q. But, again, we talked about whether that was adjusted or not?

A. Right, correct. And it was not adjusted.

Q. So that's confounded.

And De Roos 2003, we talked about De Roos 2003. That's actually brought into the NAPP study; correct?

A. Correct.

Q. And that's one thing I want to talk to you just briefly about is you were asked questions and he showed you data from the June 2015 NAPP report; correct?

A. Correct.

Q. And you know in fact there was an August 2015 NAPP report; right?

A. Yes, correct.

Q. And you know there was a 2016 NAPP report?

A. Yes, correct.

Q. And what we talked about earlier were the data that actually superseded --

A. Yes.

Q. -- what Mr. Miller showed you?

A. That's correct.

Q. Okay. Now, you also were asked questions about a draft of a report; right?

A. Yes.

Q. And again that was four years ago. Has it actually been published?

A. It hasn't. And actually the 2015 draft manuscript was actually before the 2016 updated analyses.

Q. Exactly.

A. Yeah.

Q. And so four years later, whatever the status of that draft is, you have no idea whether it's anywhere close to what any of those authors currently think?

A. That's correct.

Q. Dr. Weisenburger was here and Mr. Ismail actually cross-examined him, and the ladies and gentlemen of the jury heard that progression of the data from 2015 June through August into 2016. So I think they have a clear understanding of that.

But you understand the 2016 data is the last data that's actually been presented?

A. That's correct.

MR. MILLER: I object. I know we're in a hurry, but I'm objecting.

THE COURT: Overruled, but --

BY MR. EVANS:

Q. All right. Now, De Roos 2003, that's been

12 years. Is that 12 years before the actual NAPP analysis?

A. Yes, it is.

Q. Okay. And, again, this is adjusted for 44 pesticides. And when you're talking about that, it's not that that's -- you're not disagreeing that's what that report in 2003 stated?

A. Right.

Q. But do you think that's a proper adjustment for confounding?

A. No, it's not. And in fact actually that's specifically why those authors did the follow-up in NAPP. They said since we're focused on glyphosate, let's do the appropriate adjustment for confounding for glyphosate.

Q. And so this you have to actually look at NAPP. Okay.

Now, De Roos 2005, and again we've all -- we looked repeatedly at the conclusion of the De Roos 2005 AHS study; correct?

A. Correct.

Q. Did that find a statistically significant or any increase in the risk of NHL with respect to Roundup use?

A. No. It found no association for any of the

dose-response measures or for any of the cancers including non-Hodgkin's lymphoma. There was no association.

Q. So with respect to the source here, De Roos 2005, not -- or no association.

Now, the statements here, study authors Blair and De Roos agree that glyphosate is a probable human carcinogen, you've already stated -- do you agree with that or not? Assuming that's what they say, do you agree with that or not?

A. I don't agree with that statement, no.

Q. Now, Eriksson 2008, again is that confounded, unadjusted?

A. That's an unadjusted -- that's -- association.

Q. And Schinasi and Leon, same thing. Is that we talked about I think the shorthand term was garbage-in, garbage-out?

A. Right. In fact, actually IARC specifically addresses Schinasi raising concerns and they did their own meta-analysis because Schinasi, for some reason, included unadjusted data even though there was adjusted data available.

Q. Is that confounded?

A. Confounded, yes.

Q. Chang and Delzell, did that include unadjusted

data?

A. It included unadjusted data, yes.

Q. Confounded?

A. Yes.

Q. What about Zhang?

A. Yes. Three of the six studies were unadjusted for other pesticides.

Q. I just wanted to be clear on that.

Now, your book, you're one of the editors. You literally wrote the textbook on epidemiology that gets taught at Harvard; correct?

A. Yes.

Q. And talked about the Bradford-Hill. You remember talking about that? And you said that's kind of an outdated model.

A. Yes.

Q. But if you look actually at the Bradford-Hill, and I don't want to talk about whether it's outdated or not, what is the first criteria that is being talked about there?

A. Sorry. Could you refer to what page?

Q. 128.

A. Strength.

Q. Strength association?

A. Yes.

Q. And what's the second one?

A. Consistency.

Q. Now, if you look at -- we can pull up the page 23.

Is this the most current analysis of all the epidemiologic data?

A. Yes, it is.

Q. Is there any association from all of the epidemiology when you put it all together, is there any increased association with respect to the use of Roundup?

A. No. In fact, actually there's absolutely no association. It's almost the null value.

Q. Okay. And so if you were to do a Bradford-Hill analysis and look at the first criteria, which is strength association, it's zero.

A. That's correct.

Q. Is there any strength at all?

A. No strength at all.

Q. And the consistency, which is the number 2 one --

A. Right. Yeah, but they're actually fairly consistent in showing no association.

Q. But is there a consistent increased risk?

A. No evidence of a consistent increased risk.

Q. Okay. And Bradford-Hill, you talked about earlier. Did the authors Bradford and Hill, did they actually talk about the importance of controlling for confounding?

A. Yeah. Actually they said before you look at any of these nine points, first you have to say is the association that I observed, can we explain in a way due to bias and confounding. That's absolutely the first thing you need to do.

Q. And why is it that statistical significance doesn't overcome bias and confounding?

A. Right. Because you can essentially get a statistically significant finding because you have bias or because you have confounding.

So even if you have a study of 100,000 individuals, it can -- bias can lead to a statistically significant finding that's not causal.

Q. So the jury has heard about the analogy between if you're looking at smoking and cigarettes and match use; right?

A. Right.

Q. Okay. You could have a -- well, I'll ask you. Could you have a statistically increased risk of lung cancer from match use that would be statistically significant?

A. No. So you're asking the question --

Q. Okay.

A. No, maybe I'm not understanding your question.

Q. Well, I'm just saying if you did a study, if you didn't control --

A. For matches.

Q. No. If you did not control for cigarette smoking --

A. Right.

Q. -- could you have a statistically significant increased risk of lung cancer from lighting a match?

A. Yes, exactly, absolutely.

Q. Okay. And even though it's statistically significant, would it be absolutely wrong?

A. Absolutely wrong, yes.

Q. Okay. And so you have to -- well, do you have to look at confounding and adjusting for confounders and potential biases, you have to look at that before you even look at the statistical significance?

A. Absolutely. In fact, actually the interpretation of statistical significance and confidence interval is only valid if you can rule out bias and confounding.

Q. You talked about the evolution of science.

A. Yes.

Q. And you were shown, for example, 2003 De Roos study that we know over the course of 15 or 12 years ends up in the NAPP study.

A. Right.

Q. Okay. You were also -- talked about some of the early raising of issues concerning AHS; right?

A. Yes.

Q. And was there an evolution of those issues over time that were addressed and reanalyzed and now we have the data?

A. Yes.

Q. And are you relying upon the current data today for your opinion?

A. Yes, I am. All of the studies that have been done to date.

Q. And what is, again, your analyzing all the current data, what is that opinion?

A. Right. Based on all of the epidemiology studies, there is no evidence of a causal association between Roundup and non-Hodgkin's lymphoma.

MR. EVANS: All right. Thank you, doctor.

THE WITNESS: Thank you.

MR. MILLER: Just one question.

THE COURT: Is there something brought up on redirect --

MR. MILLER: Yes.

THE COURT: -- that wasn't addressed?

MR. MILLER: Well, I mean, it's all been addressed.

THE COURT: One question. One.

MR. MILLER: Okay.

RECROSS-EXAMINATION

BY MR. MILLER:

Q. Drs. Zhang and Taioli did an analysis of all the current data and found compelling evidence of the association between Roundup and non-Hodgkin's lymphoma in 2019; right?

A. It was, first of all, a bias analysis. Three out of the six studies they included were confounded. It was an analysis done in 2019, but it was still a biased analysis.

MR. MILLER: No further questions, Your Honor.

THE COURT: All right. Thank you.

All right. You may be excused. Thank you, Dr. Mucci.

So, ladies and gentlemen, we'll be coming back on Monday at 9:00 a.m. We'll get started with our final witness from the defense.

So I want to thank you for your time and attention. And just again remind you please don't talk

about the evidence with anyone. Don't talk about anything you've heard in the courtroom. Don't consider any of the evidence until you've heard all of it, including my instructions, which will be the legal framework for considering the evidence when you do deliberate.

So juror amnesia. Leave this all right here. Okay? And have a good, very long break.

(Jury excused to return Monday, May 6, 2019.)

(Proceedings continued in open court out of the presence of the jury:)

THE COURT: I'm going to give this back to you. I kept everything else, but I think I have enough copies of that.

THE WITNESS: Thank you so much.

MR. WISNER: Your Honor, I have the joint jury instructions where they currently stand with all your rulings and separated by sections.

THE COURT: That's fine. I appreciate that.

(Proceedings adjourned at 3:03 p.m.)

State of California)
)
County of Alameda)

I, Kelly L. Shainline, Court Reporter at the Superior Court of California, County of Alameda, do hereby certify:

That I was present at the time of the above proceedings;

That I took down in machine shorthand notes all proceedings had and testimony given;

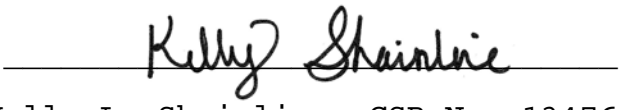
That I thereafter transcribed said shorthand notes with the aid of a computer;

That the above and foregoing is a full, true, and correct transcription of said shorthand notes, and a full, true and correct transcript of all proceedings had and testimony taken;

That I am not a party to the action or related to a party or counsel;

That I have no financial or other interest in the outcome of the action.

Dated: May 1, 2019



Kelly L. Shainline, CSR No. 13476