Exhibit 10

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION	)	MDL No. 2741
THIS DOCUMENT RELATES TO ALL CASES	)	Case No. 16-md-02741-VC

TUESDAY, JANUARY 23, 2018
CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER

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VIDEOTAPED DEPOSITION of LORELEI A. MUCCI, ScD, held at the offices of Cetrulo LLP, 2 Seaport Lane, Boston, Massachusetts, commencing at 9:01, on the above date, before Maureen O'Connor Pollard, Registered Merit Reporter, Realtime Systems Administrator, Certified Shorthand Reporter.

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VIDEOGRAPHER:

CHRISTOPHER COUGHLIN,
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INDEX

EXHIBITS

PROCEEDINGS

THE VIDEOGRAPHER: We are now on the record. My name is Chris Coughlin, and I'm a videographer for Golkow Technologies. Today's date is January 23, 2018, and the time is 9:01 a.m.

This video deposition is being held in Boston, Massachusetts, In Re: Roundup Products Liability Litigation, United States District Court, Northern District of California, MDL number 2741, Case Number 16-md-02741-VC.

The deponent is Dr. Lorelei Mucci.

Will counsel please identify yourselves and state whom you represent.

MS. WOOL: David Wool of Andrus Wagstaff for the plaintiffs.

MR. TRAVERSE: Jeffrey Travers, The Miller Firm, for the plaintiffs.

MR. LASKER: Eric Lasker, Hollingsworth LLP, for Monsanto.

THE VIDEOGRAPHER: The court reporter is Maureen O'Connor, and she will now swear in the witness.

MR. LASKER: Let me clarify, do we

have anyone on the phone? We don't have anything set up, so maybe we don't.

LORELEI A. MUCCI, ScD,
having been first duly identified and sworn, was examined and testified as follows:

EXAMINATION

BY MR. WOOL:

Q. Good morning, Dr. Mucci.
A. Good morning.
Q. How are you doing this morning?
A. Fine. How are you?
Q. Doing well.

So we are here to talk about your supplemental report, is that your understanding?

A. Yes.
Q. I'm going to go ahead and hand you what I've marked as Exhibit 32-1.

(Whereupon, Exhibit Number 32-1, Supplemental Expert Report of Lorelei A. Mucci, ScD, MPH, was marked for identification.)

MR. WOOL: Which is your supplemental report that you authored pursuant to PTO 34 in this litigation, is that correct?

Page 6

A. Yes.
Q. And if you don't know the pretrial order number, that's fine.
A. Okay.
Q. And does this report along with the original report that you authored contain all of your opinions on the Andreotti study that was just published, or is soon to be published in 2018?
MR. LASKER: Objection to form.
A. It's based on my opinion in reading the most recent publication, as well as additional readings I've done, yes.
BY MR. WOOL:
Q. Okay. Let me go ahead and hand you what I've marked as Exhibit 2.
(Whereupon, Exhibit Number 32-2, Andreotti, et al article, Glyphosate Use and Cancer Incidence in the Agricultural Health Study, was marked for identification.)
BY MR. WOOL:
Q. Which is the study in question.
And so I guess my question is, does this supplemental report, which is Exhibit 1,

Page 7

together with your original report contain all of the opinions that you intend to offer relevant to Exhibit 2 that you have in front of you?
MR. LASKER: Objection to form.
A. There may be additional -- I tried to keep my report brief, and as such there may be specific topics I didn't cover. I raised the most important topics, and those are enclosed in my supplemental report.
BY MR. WOOL:
Q. As you sit here today, are there any opinions that you are aware of that you intend to offer about Exhibit 2 that are not contained in either Exhibit 1 or your original expert report?
A. I'll have to hear the questions and then -- it's not clear to me. There are additional readings that I've done since I submitted my report, and those are included in the information that you all have received. And there's a little bit more that I've learned about the topic, but the major points are covered in the supplemental report.
Q. When you say since you submitted your

Page 8

report, are you referring to Exhibit 1?
A. My supplemental report, Exhibit 1, yes.
Q. I just want to clarify.
All right. And did anybody help you in drafting Exhibit 1 other than, say, advice that you received from counsel?
A. No.
Q. You didn't receive any help from a grad student?
A. No.
Q. Did anybody summarize any articles for you?
A. No.
Q. Nobody -- okay.
And you said you had read a couple of new articles since you submitted that report, correct?
A. Yes.
Q. And were those provided to us pursuant to your notice of deposition?
A. I'm sorry, I don't understand the question.
Q. Let me clarify that.
Do you recall offhand what additional

Page 9

materials you reviewed since submitting that report?
A. I've read a study, for example, published by Benbrook describing trends in glyphosate use over time. There's papers like that that I felt were relevant to my understanding of the epidemiology literature, particularly with respect to the Agricultural Health Study.
Q. Okay. And have you read any of the plaintiffs' depositions that were taken?
A. Yes.
Q. Which ones did you read?
A. I've read through Dr. Ritz and Dr. Neugut.
Q. Just those two?
A. Yes.
Q. And any of the plaintiffs' expert reports?
A. Yes.
Q. Do you recall which expert reports?
A. Yes. I read through Dr. Ritz, and I skimmed through Dr. Neugut. And I can't recall the other ones that I've skimmed through.
Q. That's fine.

Page 10

Okay. So let's talk about, I guess we'll call it the Andreotti study, is that fair?
A. Yes.
Q. Exhibit 2.
A. Yes.
Q. Okay. So that study contained information on both private and commercial applicators, correct?
A. Yes.
Q. And there was a separate questionnaire issued at enrollment for each subset, correct?
MR. LASKER: Object to the form.
A. I'm sorry, I don't understand the question.
BY MR. WOOL:
Q. Okay. Have you reviewed the questionnaires that the cohort members were given at enrollment?
A. Yes.
Q. And do you recall if there was a separate questionnaire for private applicators and a different one for commercial applicators?
A. I don't recall that, no.
Q. Fair enough.
And following enrollment, everybody

Page 11

who was contained within the cohort received a follow-up questionnaire at an approximate five year interval, is that correct?
A. I'm sorry, could you restate the question?
Q. So the cohort members were given a questionnaire at enrollment, right?
A. Yes.
Q. And then there was a follow-up questionnaire that was given at an approximate five year interval?
A. Yes.
Q. And enrollment occurred in the early '90s, correct, approximately?
A. I just want to confirm. So enrollment was between 1993 to 1997.
Q. Okay. And then follow-up occurred starting in approximately 1999?
A. Yes.
Q. To about 2005, correct?
A. Yes.
Q. And are you aware -- strike that.
Do you know what percentage of respondents filled out their questionnaires in, say, 1999 as opposed to, say, 2000, 2001, 2002,

Page 12

etcetera?
A. No, that information is not provided.
Q. Would that be important for you to know?
A. The information that was provided in the Andreotti study describes a five year time period, and so that provided sufficient information that on average the cohort filled out the questionnaire five years between baseline and follow-up.
Q. Is that information you would want to know? To clarify, would you want to know when the cohort members filled out their follow-up questionnaire?
MR. LASKER: Objection to the form.
A. As I said, I think there's sufficient information that's provided in the methods from Andreotti, et al describing that it was a five year time period between the baseline questionnaire and the enrollment questionnaire.
BY MR. WOOL:
Q. So as you sit here today, when a cohort member filled out their questionnaire is not a piece of information you would be interested in?

Page 13

MR. LASKER: Objection to form.
A. While it is important to understand the timing of the questionnaire, I think there's enough information that's provided in Andreotti, et al to give a sense of the timing of the baseline and follow-up questionnaire being five years.
BY MR. WOOL:
Q. Okay. And in the follow-up questionnaire, the cohort was asked to report the number of days a pesticide was used in the most recent year, correct?
A. Yes.
Q. And that answer was used to determine three metrics that are used in the Andreotti study?
MR. LASKER: Objection to form.
A. Could you clarify, three metrics?
BY MR. WOOL:
Q. So the follow-up questionnaire was used to determine ever-never use along with the enrollment questionnaire, correct?
A. Yes.
Q. It was used to determine lifetime days of use?

Page 14

A. Yes.
MR. LASKER: Object to form.
BY MR. WOOL:
Q. And the follow-up questionnaire was also used to determine the intensity of weighted lifetime days of use?
MR. LASKER: Object to form.
A. The information for both questionnaires was integrated into the lifetime, weighted lifetime intensity measure, yes.
BY MR. WOOL:
Q. So if a cohort member had not used glyphosate prior to enrollment, ever-never use for that member would be calculated from the follow-up questionnaire, correct?
MR. LASKER: Object to the form.
A. I'm sorry, I don't understand the specific question.
BY MR. WOOL:
Q. Okay. So, for example, if a cohort member had never used glyphosate at or prior to enrollment -- right?
A. Yes.
Q. -- the ever-never use that's calculated in Andreotti would be dependent upon,

Page 15

I guess, both enrollment and then the follow-up questionnaire, right?
MR. LASKER: Object to the form.
A. Both pieces of information were integrated in determining ever-never exposure as well as the intensity measures as well.
BY MR. WOOL:
Q. And so if a cohort member did not use glyphosate at enrollment or in the year prior to follow-up, the follow-up questionnaire would show that member as never having used glyphosate, correct?
MR. LASKER: Object to the form.
A. I'm sorry, could you repeat the question?
BY MR. WOOL:
Q. Yes.
So if somebody enrolled in the AHS study --
A. Yes.
Q. -- and they did not use glyphosate prior to enrollment --
A. Yes.
Q. -- and then they did not use glyphosate prior to the follow-up year, the

Page 16

results of Andreotti would show that participant as never having used glyphosate?
MR. LASKER: Objection to form.
A. So just to -- so if a person had -- so the information on ever-never use gets updated across time because you have these two points of information, and so the information on ever-never exposure is based on the baseline questionnaire, and then it's updated information on the follow-up questionnaire, which is a pretty standard epidemiological approach to integrating a time varying exposure.
BY MR. WOOL:
Q. And I think I've asked this, but the follow-up questionnaire only inquired as to the previous calendar year of use of a pesticide, correct?
MR. LASKER: Object to form.
A. Yes. The follow-up questionnaire asked about the prior year of use, which is actually a pretty standard epidemiological approach to asking follow-up questionnaires. You like to give a reference time point for participants to answer whether or not they have participated in an exposure.

Page 17

BY MR. WOOL:
Q. So if somebody had used glyphosate after enrollment but did not use glyphosate in the calendar year immediately preceding follow-up, would the follow-up questionnaire have captured that glyphosate use?
MR. LASKER: Objection to form.
A. While that particular individual would have been classified as being unexposed at both time points, that would represent likely a very unlikely scenario, a very low proportion of participants.
BY MR. WOOL:
Q. And --
A. And would suggest actually that the majority of their person time actually was spent as unexposed, which would be appropriate, since they would have only used a very short window of time between the baseline questionnaire and the follow-up questionnaire.
Q. Okay. And I believe you said that that -- strike that.
How were lifetime days of use calculated in the Andreotti study?
A. The information that was used to

Page 18

calculate lifetime days of use included the number of years an individual was using glyphosate and the number of days of use per year that it was being used.

Q. And in determining the number of days per year of use for the -- strike that.

So it is a combination of the days of use reported in both the enrollment questionnaire and at follow-up, correct?

A. So again, it's a time varying exposure, so the information sort of gets -- they're at -- you have the baseline information, and then it gets updated again based on the follow-up information. So it's sort of a -- the way the questionnaires were -- the data from the questionnaires were integrated in terms of the number of days of use and the lifetime days allows this time varying exposure to be calculated.

Q. Now, you just used the term "time varying exposure."

A. Yes.

Q. What do you mean by that term?

A. It means, there are some things in epidemiology that are fixed, someone's sex,

Page 19

someone's genetic susceptibility. There are other things where the exposures can vary over time, smoking for example, someone may be smoking at one time point and then may stop smoking at the second time point, so things that can -- whose exposure the prevalence can vary over time is a time varying exposure.

Q. All right. And the Andreotti study also calculated intensity weighted lifetime days of use?

A. Yes.

Q. Correct?

Okay. And how is the intensity score calculated, if you recall?

A. So the intensity -- there are several publications, actually, which nicely show the method by which the Agricultural Health Study used different information on the use of protective gear, information on the type of spraying, whether they personally mixed. And there are a number of really -- one of the strengths of the Agricultural Health Study is the fact that it uses validated algorithms to calculate this weighted intensity data and show that it has a very good validity.

Page 20

So while I don't -- I couldn't tell you the exact formula, I do know in reading the epidemiology literature on this topic that they really used a validated algorithm for calculating the intensity weighted days.

Q. What do you mean by "validated algorithm"?

A. The approach that the Agricultural Health Study took was to compare the information from the questionnaire algorithm versus a biological marker to compare how well, and there was a first formula that was used, and then it was actually revised based on additional information on how well it predicted the urinary markers.

Q. Okay. Now, if you look at Exhibit 2, at the top of the second page, on the right-hand column the authors state that "the intensity score was derived from an algorithm based on literature-based measurements and information provided by the applicator, specifically whether the participant mixed or applied pesticides, prepared pesticide related equipment, used protective equipment, and application method used."

Page 21

Are you following me?

A. Yes. That's the -- I was just referring to -- so that was the -- based on the algorithm that Dr. Coble had examined and then had -- so it was based -- there was an earlier algorithm they had developed which was used actually in the first Agricultural Health Study, and then they've actually refined this algorithm, and this is what was used in this updated publication of Andreotti, et al. And so it actually -- the way that they tested whether the updated algorithm improved the information on intensity weighted was using urinary based biomarkers, so it's listed by Coble, et al.

Q. And the authors state the algorithm was based on literature-based measurements, correct?

A. Yes. So I believe that was based on the Dosemici algorithm. But again, so they started -- used that as a starting point, and then they further refined it based on their own questionnaire and tried to really optimize the intensity weighted measure within the Agricultural Health Study.

Q. And is that what they mean when they

Page 22

say literature-based measurements?
MR. LASKER: Objection to form.
A. I'm not sure what they mean by literature-based measurements. But what I believe in reading all the past publications, and if you read the Coble publication, it describes in detail the approach that they took starting with this baseline algorithm, and then refining the algorithm using additional components from the questionnaire, and then they tested that within the Coble study to compare it for two of the pesticides, compared and show that the algorithm -- the new algorithm actually improved the prediction with the biomarker compared with the older algorithm.
So I'm not sure specifically what they meant there by the literature base, but if you read through the Coble study that's, in fact, the process they used.
BY MR. WOOL:
Q. Okay. And in calculating the intensity score, they also based that calculation upon information provided by the applicator, correct?
A. It was the information that was

Page 23

provided in the first and second questionnaires.
Q. Okay. And specifically whether the participant mixed or applied pesticides?
A. There were a variety of factors actually. That was one of the factors, but there were a variety of factors that went into the algorithm.
Q. And one of those was whether the applicator used protective equipment, correct?
A. Yes. There were actually several features, though. What was interesting to see in the Coble study was the importance of including these multiple measures in the intensity weighted algorithm.
Q. And the questionnaire simply asked whether personal protective equipment was used when mixing, correct?
MR. LASKER: Object to the form.
A. I'm sorry, I don't recall the specific wording of the questionnaire.
BY MR. WOOL:
Q. Let me ask this.
Do you recall whether the questionnaire asked whether personal protective equipment was used specifically for mixing or

Page 24

applying glyphosate?
A. I'm sorry, I don't remember the exact wording of those questions.
Q. Is the use of personal protective equipment something that could affect exposure?
MR. LASKER: Objection to form.
A. In the Coble publication, that really describes in detail the algorithm. That's one of the factors that's used in the algorithm. And because it's felt that it's one of several factors, that may influence the actual intensity of the exposure. So it is, in fact, one of many variables that goes into the algorithm.
BY MR. WOOL:
Q. And do you know if the questionnaire asked whether somebody used personal protective equipment generally for applying all pesticides?
A. I'm sorry, if you have the questionnaire I could take a look at it. I just don't recall the specifics of how the questions were asked.
Q. And I think the last part, and I might be mistaken on this about the intensity score, is that it weighed the application method used by the applicator, is that correct?

Page 25

MR. LASKER: Objection to form.
A. I'm sorry, I don't understand the question.
BY MR. WOOL:
Q. Did the intensity score incorporate the specific application method used in applying pesticides, if you recall?
A. I believe that it did, yes. There were several factors that went into the intensity weighted score. If you have the publication by Coble, et al we could take a look and look at specifically, but I believe that is the case.
Q. We might get to that in a little bit.
So in effect what the authors of Andreotti did with the follow-up questionnaire was use the last year of use, and use the information gathered from that to determine the previous five years of use, is that fair?
A. So the -- as I'd mentioned previously, it's pretty standard in an epidemiological questionnaire to provide some sort of reference year. And so the way the information on ever-never was assessed, as well as the days and years of use was updated, so you have

Page 26

information that was the baseline, and then it was updated with the second questionnaire.

Q. So based on the second questionnaire and the answers that were given in that questionnaire, did the authors use those answers to essentially predict what the use would have been for the five years prior to the questionnaire?

MR. LASKER: Objection to form.

A. I'm not sure I understand specifically your question. Are you trying -- could you clarify your question?

BY MR. WOOL:

Q. I can clarify it.

So at follow-up, the follow-up questionnaire, we agreed, only asked about the year immediately prior to follow-up, correct?

A. Correct.

Q. And did the authors use that information to predict what the use would have been for the years between enrollment and follow-up?

A. The -- if somebody was using glyphosate at the enrollment questionnaire and then not using glyphosate at the follow-up

Page 27

questionnaire, and they talked about the year prior, then that person would have been classified appropriately as exposed up until the second questionnaire, and then would be assigned as unexposed from the year before and going forward. Does that make sense?

So the information -- yeah, so I think -- yeah. I'm not sure if I'm answering the question specifically.

Q. If I use glyphosate for -- let's say five times a year for the year immediately prior to enrollment --

A. Yes.

Q. -- in calculating my lifetime days of use, how would the authors use that information?

MR. LASKER: Objection to form.

A. So I think you would have to also account for the baseline information. So again, what we're thinking about is a follow-up forward in time, so they would use that information, they use the information on the baseline questionnaire up until, and then updated the information based on the follow-up questionnaire which is, again, like standard epidemiological approach that you would take for looking at an

Page 28

exposure that may or may not vary over time.

BY MR. WOOL:

Q. Okay. And if we turn to, I believe, Page 3 of the Andreotti study. Actually, sorry, Page 4, Table 2.

The quartiles that are provided are based on the intensity weighted lifetime days of glyphosate use, correct?

A. Yes.

Q. And quartile 1 being the least amount of use, correct?

A. So the way the quartiles are formed, it divides those who were exposed, it divides those groupings into four equal groupings. So, yes, the quartile 1 would be those who have used glyphosate but have less use, and quartile 4 would be the ones who are using glyphosate with the most use.

Q. And quartile 2 and 3 would be -- would show increasing use?

A. Correct.

Q. Okay. Now, would you expect to see some random error in a cohort of this size?

A. I'm sorry, with respect to what?

Q. With respect to the exposure

Page 29

information that was provided by the cohort members.

A. I'm sorry, could you clarify what you mean by "random error"?

Q. You've heard the term random error before?

A. As an epidemiological concept, random error in terms of chance, or random error in terms of misclassification?

Q. In terms of either.

MR. LASKER: Objection to form.

A. Have I -- so I guess, I think, in my mind random error is a vague term, so I think if you could ask me specifically what type of error you're referring to when you ask me if there's random error.

BY MR. WOOL:

Q. With respect to chance, what does random error mean to you as an epidemiologist?

A. Random -- the role of chance implies that you have a -- there's a true measure of the relative risk, and then based on random sampling you might get a certain distribution around that true relative risk. And the larger study that you have, and the larger number of cases you

Page 30

have, as we have here, then that -- the likelihood that random error is playing a role actually decreases substantially.

Q. So if I understand your answer correctly, the larger the study the less the likelihood of random error, correct?

MR. LASKER: Objection to form.

A. There's actually several factors that go into whether or not you think random error is playing a role, or the role of chance. So the size of the study, the number of cases, the number of exposed cases, all of those are factors that go into the role of changes. So the larger the study, the more cases you have, and the higher the problems of exposed cases you have, all of those will lower the likelihood, and this is the case here we have in Andreotti.

BY MR. WOOL:

Q. Do you know if the participants in the cohort were allowed to take their questionnaires home prior to filling them out?

A. I'm sorry, I don't know that answer.

Q. Do you know if they were allowed to cross-reference their purchase records?

A. I'm sorry, I don't know that answer.

Page 31

Q. Do you think that the data would have been more reliable if they had been allowed to cross-reference their purchase records?

A. I'm not sure one way or the other. What I do know was given the way the questionnaire was given, there was actually some validation studies that were done to show the information the way they provided it was highly reliable. So there was a sample of about 4,000 of the participants who happened, because of the regulations of the applicators came back a year after they had filled out the baseline questionnaire, and then they filled out the same information, and then there was a reliability study and said how reliable was the information they gave a year ago with what they gave now, and that actually showed high reliability.

So I think -- I'm not sure what they had done and whether they were able to take the questionnaire home, but what I do know is based on the way the questionnaire was given the results seemed to be very reliable in reporting of glyphosate.

Q. And the study that you described in your answer, that is the Blair 2002 study, if

Page 32

I'm not mistaken, is that correct?

A. I believe it was Blair 2001.

Q. Blair 2001?

A. Yes.

Q. And are there any other validation studies that you're relying upon that you believe indicates that the answers given at enrollment were accurate?

A. Yes, there was another nice publication. Again, one of the really nice things about the Agricultural Health Study is that there are so many publications they've done looking at the potential for bias, and I think the Agricultural Health Study, in particular, is a really nice example of epidemiology.

But another study they did was to compare when different pesticides came on the market, and then sort of did a -- you know, did anybody report using glyphosate or other pesticides prior to when they actually had come on the market. So again, that's another kind of test of the reliability of the data. And that actually also showed very low likelihood of people reporting a number of these pesticides, including glyphosate, before they ever came on

Page 33

the market. So that's another kind of proof of principle that the information is quite reliable.

Q. Do you have any experience collecting occupational data, such as pesticide exposures, for any of your own publications?

MR. LASKER: Object to the form.

A. While I haven't collected information on pesticides exposure, I've been involved in multiple, multiple studies collecting a wide array of data. There are a number of commonalities in the collection of epidemiological data, so I'm very familiar with the principles of epidemiology data collection.

BY MR. WOOL:

Q. So for any of those studies that you just described, did any of these studies involve occupational exposures?

A. I'm sorry, could you clarify the question?

Q. Did they involve exposures to a chemical of some sort that somebody was exposed to during the course of their occupation?

A. I'm sorry, which studies are you referring to?

Page 34

Q. You just said that you had been --
A. My own studies.
Q. Yes.
A. Sorry.
So again, as I said, I have not been involved in the collection of occupational data. However, I have been involved in a wide array of epidemiological risk factors. Each of these have a number of common principles. I think the reliability of information is valid, whether it's a dietary factor or occupational factor or body mass index. So reliability is a well standard epidemiological principle for assessing the quality of exposure information.
Q. Have you ever been involved in the design of a questionnaire for occupational exposure studies?
A. As I had just mentioned, I haven't been involved in studies of occupational based exposures. However, I have been involved in multiple -- design of multiple questionnaires in a range of study populations.
Q. Have you ever been involved in the validation of any questionnaires relevant to occupational exposures?

Page 35

MR. LASKER: Object to the form.
A. As I've said, I haven't been involved in the design or validation. However, there are some very common principles of assessing the quality of data collection, and I think I can -- although I haven't been involved in the design or specific validation of pesticides, I can look at the epidemiology literature, I can look at the study of Blair 2001 and Hoppin that show the quality of the occupational -- or the pesticide data that was collected in the Agricultural Health Study seemed to be very reliable.
Q. Okay. And the questionnaires asked about -- strike that.
The Agricultural Health Study questionnaires didn't actually evaluate exposure, did they? They asked about use of a pesticide and used some other factors, like whether protective equipment was worn, etcetera, to sort of determine exposure, right?
MR. LASKER: Objection to form.
A. I'm not sure what you mean by "exposure."
BY MR. WOOL:
Q. Well, so the Andreotti study

Page 36

determined the exposure by looking at the frequency of glyphosate use, correct?
MR. LASKER: Objection to form.
A. The Andreotti study used a wide array of factors, including the number of years of use, the number of days of use, the different use of protective gear. There are a number of factors in the algorithm that went into this classification of intensity of days use, weighted intensity days use.
BY MR. WOOL:
Q. Do you recall whether the questionnaire asked specific questions about the methods of glyphosate application?
A. I'm sorry, I don't recall that.
MR. LASKER: Objection to form.
BY MR. WOOL:
Q. Do you know whether the methods of application can determine actual pesticide exposure?
MR. LASKER: Objection to form.
A. I'm sorry, I'm not -- that's not my -- necessarily my area of expertise. Again, I'm not sure how the specific questions on glyphosate were collected on the questionnaire.

Page 37

BY MR. WOOL:
Q. Okay. Do you know if the AHS study examined the correlation between the methods of application and the prevalence of non-Hodgkin's lymphoma?
MR. LASKER: Objection to form.
A. I'm sorry, I don't understand your question.
BY MR. WOOL:
Q. So the AHS study gathered information about the method of application, correct?
MR. LASKER: Which study?
MR. WOOL: Sorry, the Andreotti study, my apologies.
MR. LASKER: Start again.
BY MR. WOOL:
Q. So the Andreotti study collected data on the method of application, correct?
A. By "method," you mean whether it was aerial spraying?
Q. Correct.
A. Yes.
Q. And do you know if the Andreotti study looked at the correlation between that information and the prevalence of non-Hodgkin's

Page 38

lymphoma in the study population?
A. I don't recall reading any specific study looking at that, no.
Q. Okay.
A. But actually, you know, I think what the study by Coble showed actually was that they developed -- and following up on the publication of Dosemici, is that this algorithm that they developed and tested in a number of different studies that have been published by authors involved in the Agricultural Health Study show this updated algorithm that integrated multiple pieces of information into the algorithm really seemed to perform the best in terms of predicting exposure to glyphosate, or the intensity of exposure to glyphosate.
Q. And in the Andreotti study, the cohort members were selected because they applied for licenses to use restricted use pesticides, is that correct?
A. I believe that they were -- let me just refer to it. Yes, they were seeking licenses to apply restricted use pesticides when they were enrolled.
Q. And what is a restricted use

Page 39

pesticide?
A. I'm not familiar with that term. I'm not sure what they mean by that specifically.
Q. Okay. Let's turn to Page 7 of your report, which is Exhibit 2, and in the second paragraph you note that "potential limitations of the study" -- which is the Andreotti study, which is Exhibit 1 in this deposition -- "include the possibility of non-differential misclassification of glyphosate-based herbicide exposure."
Did I read that correctly?
A. Yes.
Q. And just so we're clear, how would you define non-differential misclassification?
A. In this particular context what I mean is that if there is measurement error in glyphosate exposure, it's unrelated to the outcome of non-Hodgkin's lymphoma. And that's one of the strengths of a cohort study.
In contrast, a differential misclassification can occur sometimes in case-control studies because the reporting of the information on the exposure may be influenced by the outcome itself. It's a

Page 40

measure of recall bias.
Q. And it's your opinion that non-differential exposure misclassification is a potential limitation of the Andreotti study, correct?
A. What I said is in epidemiology, it's a standard approach. We want to say if we see a finding that's null, we want to try to understand whether bias confounding or chance were playing a role. One factor that we might be concerned about is non-differential misclassification because it would tend to bias a finding to the null.
Q. Okay. And if we turn to Page 3 of your report, I believe you actually talk about that potential limitation.
A. Yes.
Q. Now, is it your opinion that some exposure misclassification did occur in the Andreotti study?
A. It's possible that there is some misclassification, non-differential misclassification of glyphosate-based exposure. However, there's a number of lines of data that would suggest that the amount of

Page 41

misclassification is probably not large, and that's -- as I'd mentioned earlier, it's based on the Hoppin publication, based on the Blair 2001 publication showing the very reliable information. It's based on the algorithm developed by Coble and showing the validation with urinary biomarkers. So all of these would suggest that while there -- if there is -- it's important not only to know if there is misclassification, but the extent of the misclassification, so if there is misclassification it's likely to be small.
Q. So as you sit here today, can you tell me whether there was some misclassification in the Andreotti study?
A. While I can't necessarily say definitively yes or no if there is misclassification, it would -- the true relative risk would actually have been more protective than what we observed in the study which -- you know, so again, what I can say definitively is that non-differential misclassification did not hide a positive association between glyphosate-based herbicides and NHL risk, so that I can say.

Page 42

Whether there is some non-differential misclassification I can't exclude, but it would not have led to a true relative risk being a positive association in this study.

Q. So if some non-differential misclassification did occur, is it your opinion that the true relative risk would be even lower than what's reported?

A. It's not my opinion, it's actually a standard epidemiological principle. So if you have -- as I've shown in my figure 1 in my report, it's a mathematical relationship. If you have a relative risk that you observe that's less than 1, and you have non-differential misclassification, then the true relative risk would actually be even smaller than 1, than what you observed away from 1. So it's just a mathematical relationship. So it's not my opinion, but it's actually an epidemiological principle.

Q. And so if, just to be clear, if some exposure of misclassification did occur, then the true relative risk reported in the Andreotti study would, in fact, be lower than what is reported, which I think you point out as .86?

Page 43

A. Yes.

Q. Okay. And you discuss some of the validation studies that show that the cohort provides reliable information?

A. Yes.

Q. And it is on the basis of some of those validation studies that you are able to surmise that the percent of exposure misclassification was low, I think -- strike that, actually.

Okay. You cited to the 2001 Blair paper to support the proposition that exposure misclassification was limited in the Andreotti study, correct?

A. Yes.

Q. Okay. Let's go ahead and take a look at this.

I'm marking Blair 2001 study as Exhibit 3.

(Whereupon, Exhibit Number 32-3, Blair, et al article, Reliability of Reporting on Life-Style and Agricultural Factors by a Sample of Participants in the Agricultural Health Study from Iowa, was marked for identification.)

Page 44

BY MR. WOOL:

Q. Okay. Just briefly, can you explain what Blair did to determine the extent of exposure misclassification?

A. Yes. So there were data available from about 4,000 of the participants who filled out a baseline questionnaire in the Agricultural Health Study who actually came in a year later and filled out the same exact questionnaire, and so the authors compared how reliable the information was between those two questionnaires. And reliability is an established methodology for assessing the quality of epidemiological data from questionnaires. So they compared the exact agreement between these two questionnaires.

Q. Okay. If you turn to Page 95, Table 1.

A. Yes.

Q. You will see that they have what they describe as a comparison of dichotomous responses on pesticide use between first and second questionnaires, correct?

A. Yes.

Page 45

Q. And they actually break down how individual pesticides or herbicides fared in terms of exact agreement, correct?

A. Yes.

Q. And Table 1 examines ever-never use, is that correct?

A. Yes.

Q. And for glyphosate, the exact agreement between the first and second questionnaire is 82 percent, is that correct?

A. Yes.

Q. Okay. And what is the kappa statistic measuring?

A. So the kappa statistic takes into account the role that chance might play in the fact that two people say the same thing on the two different questionnaires. So, you know, if -- with glyphosate you have fairly high prevalence of the exposure and therefore just by chance you may have two people saying they used glyphosate on the two different questionnaires, so the kappa statistic basically adjusts for the prevalence of the exposure in leading to concordant answers.

Q. And further down in Table 1 they

Page 46

provide these same calculation using method of application, correct?
A. Yes.
Q. And, for example, the exact agreement with hand-spraying on application is 72 percent, correct?
A. Yes.
Q. And depending on what type of application method was used, there are kind of a range of different figures for exact agreement, correct?
A. Yes, yes. So they ranged from 72 percent up to 99 percent.
Q. Now, does the Blair paper indicate to you that use of a pesticide in any given year can be used to determine -- strike that.
Is it your opinion that the Blair paper demonstrates that use of a pesticide in any given year can accurately predict the frequency of pesticide application in another year?
MR. LASKER: Objection to form.
A. So what this tells us is about the reliability of the quality of the information that's provided. It doesn't -- it gives you

Page 47

some sense of what the quality of epidemiological data is. That's what this paper is telling us.
BY MR. WOOL:
Q. And when you say "quality," does that include whether the information is reliable?
A. Exactly, yes.
Q. Now if you turn the page over to Page 96, and you look at Table 2, Table 2 is telling us the agreement between the days per year of pesticide use mixed and applied, correct?
A. It tells us a number of different measures, including years mixed, days per year, and decade first applied, yes.
Q. Okay. And if we look at glyphosate and the days per year mixed or applied, the exact agreement provided by Blair 2001 is 53 percent, correct?
A. Actually that's the years mixed or applied is 53 percent.
Q. I'm sorry, yes.
A. Yes. And while that is true, if you look further in the text, what's important to note is that 90 percent of the subjects gave

Page 48

responses actually within one category of agreement. I think that's really an important feature about -- you know, while it's true that we may in epidemiology be unable to tell with complete specificity the exact number of days that somebody has used glyphosate or the number of years they've applied, what this tells us here is that we're able to appropriately rank people as either high, low, or not exposed.
And so I think that's an important feature as well. So it's not only what's the exact agreement in terms of the number of years mixed, but also, you know, was it -- if the categories were so disparate, then you're right, then you might be a little bit more concerned about that percent agreement.
But the fact in the text where it says 90 percent of subjects give responses within one category of agreement, that's really important additional information. It suggests we can appropriately rank people as high, low, or no exposed.
Q. Okay. And if you look down below Table 2, for years mixed or applied, the categories are 1 or less, 2 to 5, 6 to 10, 11 to

Page 49

20, 21 to 30, and more than 30, correct?
A. Yes.
Q. Okay. And if we go down in Table 2 to days per year mixed or applied, for glyphosate the exact agreement reported in Blair is 52 percent, correct?
A. Yes. And we have the same point below, which is that although it's -- the exact agreement is 52 percent, that the categories within one -- 90 percent of the responses were within one category of agreement.
Q. And the categories for the days per year of usage are less than 5, 5 to 9, 10 to 19, 20 to 39, 40 to 59, and 60 to 150 -- I'm sorry, and more than 150, correct?
A. Correct. So what this tells us, then, is that although the exact agreement of somebody, for example, filling out 60 to 150 is 52 percent, it's highly unlikely that somebody who used 60 to 150 would then on the second questionnaire report less than 5. So I think the fact that you have 90 percent agreement within one category is a really important feature of this study.
Q. But somebody could report, say, 150

Page 50

uses a year and then drop down to 40 years -- sorry, 40 uses per year --
A. But that --
Q. -- and that would be one category apart, correct?
A. Oh, I see what you're saying. It's possible, but we don't know exactly what the difference was. We don't know the exact value, because it's such a broad range there.
Q. Okay. Right. And so just what I want to clarify is that the days per year mixed or applied exact agreement figure is not telling us that somebody might have used glyphosate one more day per year, it's telling us that they are in a different category, correct?
A. I'm sorry, I don't understand.
Q. Sorry, that was my fault. The question was not clear at all.
And so what I'm asking is, the exact agreement percentage does not -- is not looking strictly at whether or not there's a slight variation in agreement, it is, in fact, looking at whether or not somebody is in a different category, correct?
A. I'm sorry, I still don't understand

Page 51

specifically your question.
Q. The percentage of agreement is based on which category a cohort member falls into, correct?
MR. LASKER: Objection to form.
A. So in the case of days per year, the percent exact agreement of 52 percent suggests, then, that 52 percent of participants reported being in the same category of days per year of use on both questionnaires. And then the follow-up is that 90 percent of the subjects were within one category of exposure.
So again, you know, these are categories of exposure, and suggesting that we're able with this questionnaire to appropriately rank people, and that's really the goal of epidemiology.
BY MR. WOOL:
Q. And what is the known rate of error for predicting frequency of glyphosate use using this method in the Blair study?
MR. LASKER: Objection.
A. I'm sorry, I don't understand your question.
BY MR. WOOL:

Page 52

Q. Okay. Let's go to Page 7 of your expert report. And you state in the second sentence of the second paragraph, "However, validation studies" -- are you there?
A. Yes.
Q. Okay. "However, validation studies within the Agricultural Health Study show that these licensed applicators have been shown to be able to provide reliable self-reported information in this cohort." And then your cite to that is this Blair study that we're looking at in Exhibit 3.
A. Yes, that's what I say in my report, yes.
Q. Are there any other cites or studies that you rely upon to validate this opinion?
MR. LASKER: Objection to form. Asked and answered.
A. As I had mentioned earlier, although I didn't cite it here, another piece of information that's quite helpful is the publication by Hoppin which looked at comparing, particularly for the baseline questionnaire, when people reported when they first started using different pesticides, the authors compared

Page 53

those -- they wanted to know what -- if it was an issue that people were reporting starting use of pesticides prior to when they came on the market, which would suggest they were an incorrect response. So that was another piece of information that shows the reliability of the information on exposure.
BY MR. WOOL:
Q. Okay. Can you turn to Page 98 of the Blair article, please? Now, at the top of the right-hand column, the authors note that "Although the reliability" --
A. I'm sorry, you said at the top of the right-hand --
Q. Top of the right-hand column on Page 98.
A. Yes.
Q. The authors note that "Although the reliability of reported pesticide use among farmers is as good as, for many other factors, assessed by questionnaires in epidemiological research and better than for some variables it is important to assess affects of potential misclassification on estimates of relative risk. If the level of agreement between the first and

Page 54

second interview is considered a measure of non-differential misclassification, we can calculate affects on relative risk. For example, if the true relative risk was 4.0 in non-differential misclassification for ever-never handled individual pesticides is as in Table 1 (from 79 percent to 88 percent agreement), the calculated relative risk would range from 2.0 to 2.6."

Did I read that correctly?

A. Yes, that is what it says. But I think one important thing to remember is also that the effect on the relative risk is also going to be a function of the prevalence of the exposure.

Q. So what do you mean by that, just so I'm clear?

A. So if you -- if the prevalence of the exposure is much lower, and you have the same sort of agreement, you're going to see more distortion in the relative risk than you would with an exposure that's more common such as with glyphosate, because the rare -- an exposure is the more sensitive it is going to be to misclassification on an absolute scale.

Page 55

Q. Okay. I just want to make sure I understand what you're saying correctly.

You were saying that for more commonly used pesticides that are not rare, that the effect on the relative risk is not going to be as sensitive?

A. I can't recall which year it was, but I know Blair has another publication about misclassification where the authors show the effect of the amount of misclassification on the relative risk as a function of the prevalence of the exposure. I just don't recall specifically what year that was.

Q. I think 2011 maybe.

A. Yes. Possibly, yes. So I think that kind of shows the -- how those things are interrelated with each other.

Q. Do you believe that it is impossible for non-differential exposure misclassification to conceal a true positive association?

MR. LASKER: Objection to form.

A. Could you ask the question again?

BY MR. WOOL:

Q. Yes. Do you believe that it is impossible for non-differential

Page 56

misclassification to conceal a true positive association?

MR. LASKER: Objection to form.

A. I'm sorry, the words are straightforward, but I'm still not understanding what you're asking.

BY MR. WOOL:

Q. Is it possible that in the Andreotti study exposure misclassification could conceal a true positive association?

A. It's highly unlikely. And the reason that I say that is that given the odds ratio that was estimated in Andreotti, et al was less than 1, that makes it highly, highly, highly unlikely that misclassification would mask a positive association. And that's based on standard epidemiology principles.

Q. So are you saying in effect that while misclassification could bias the result towards the null it could not, say, jump across 1?

A. That's not just based on what I'm saying, it's based on standard epidemiology principles mathematically. Like if you have a very small study, a very small study, which we don't have here in Andreotti, by chance it is

Page 57

possible that you might have something like that. But in this case of Andreotti, et al where chance is very unlikely to have -- to do this, mathematically non-differential misclassification is going to bias a true relative risk towards the null. Therefore, given the observed relative risk that we see in Andreotti, et al, it's highly, highly unlikely that it's masking a true positive association.

Q. Now, if we go back to Table 2 --

A. Of --

Q. -- of the Blair article, Exhibit 3. And again, we look at the days per year mixed or applied figure for glyphosate.

A. Sorry, days per year, or the years per --

Q. The days per year in the middle of Table 2 --

A. Yes.

Q. -- which is reported again as 52 percent, would you expect the accuracy of -- or strike that.

In the questionnaires that were given in Andreotti, et al, those questionnaires asked about the last year of use, correct?

Page 58

MR. LASKER: Objection to form.
A. No, that's not correct. It was -- in the follow-up questionnaire it referred to the last year farmed.
BY MR. WOOL:
Q. Okay. The last year farmed.
A. Yes.
But this particular -- I'm sorry to interrupt you. But this particular reliability study actually looked at the baseline questionnaire, not the follow-up questionnaire.
Q. Okay.
A. Do you think it might be appropriate for a quick break?
Q. Absolutely. We can take a break right. Now.
A. That would be awesome.
THE VIDEOGRAPHER: Going off the record. The time is 10:03.
(Whereupon, a recess was taken.)
THE VIDEOGRAPHER: Back on the record. The time is 10:17.
BY MR. WOOL:
Q. All right. So we were talking about the Blair paper briefly before we went off the

Page 59

record, right?
A. The Blair 2001?
Q. The Blair 2001 paper.
A. Yes.
Q. And the Blair paper only examined the exact agreement between enrollment questionnaires, correct?
A. It looked specifically at the baseline questionnaire, yes, the reliability of the information in the baseline questionnaire.
Q. Are you aware of any papers that have looked at the follow-up questionnaire?
A. In terms of the reliability?
Q. Yes.
A. I'm not familiar, no.
Q. And this Blair paper only looked at two years of questionnaire data, correct?
MR. LASKER: Objection to form.
A. I believe actually the questionnaires were completed one year apart.
BY MR. WOOL:
Q. One year apart.
So one questionnaire, and then a questionnaire the next year, correct?
A. Correct.

Page 60

Q. All right. Let me ask you this. Do you consider the AHS to be a null study?
MR. LASKER: Objection to form.
Which study are you talking about?
BY MR. WOOL:
Q. I'm sorry, the Andreotti study. I keep saying AHS.
Do you consider the Andreotti study to be a null study?
MR. LASKER: Objection to form again.
A. I find the findings on non-Hodgkin's lymphoma, that there's no association between glyphosate-based herbicides and the risk of non-Hodgkin's lymphoma, or any of the non-Hodgkin's lymphoma subtypes.
BY MR. WOOL:
Q. You do not consider it to be a negative study?
MR. LASKER: Objection to form.
A. I'm not sure what you mean specifically by "negative study." What I would say about this is that the data suggests there's no association between glyphosate-based herbicides and the risk of non-Hodgkin's lymphoma.

Page 61

BY MR. WOOL:
Q. Do you believe that glyphosate-based herbicides have a protective effect?
A. I do not believe that, based on the epidemiological evidence in this study, nor in the totality of the epidemiology evidence, would it suggest either a positive or inverse association.
Q. All right. You're familiar with the concept of imputation?
A. Yes.
Q. Okay.
A. In the context of epidemiological studies.
Q. Right. I should have clarified.
A. Yes.
Q. And in this study, was it 37 percent of the population, I think, that was lost to follow-up?
MR. LASKER: Objection to form.
A. So just to clarify, when we talk about lost to follow-up, there's different connotations in epidemiology. We don't -- we haven't lost to follow-up in terms of what happened in terms of disease outcomes, but

Page 62

37 percent of the participants who filled out the baseline questionnaire did not fill out the second questionnaire.
BY MR. WOOL:
Q. In any of your own publications, have you ever had 37 percent of a cohort be lost to follow-up?
MR. LASKER: Objection to form.
A. Well, I haven't -- in the cohort studies that I've worked on, we haven't had 37 percent of our participants not complete a second questionnaire. I actually have been involved in a cohort study where I -- while I didn't use the follow-up questionnaire, that particular follow-up questionnaire, more than 30 percent of the individuals did not fill out a second questionnaire. It was the Swedish mammography cohort. So I worked with their baseline questionnaire, but that particular cohort had a second questionnaire 30 percent of the participants did not complete. And they took an approach very similar to what was done with Andreotti, et al in terms of doing multiple imputation, comparing multiple imputation to complete case assessment, and did a variety of

Page 63

things to assess whether the amount of missing data might influence the results.
Q. Do you believe the Andreotti study would be more reliable if fewer than 30 percent had been lost to follow-up?
A. Well, it's interesting. In epidemiology we should be concerned when we see that 37 percent of the participants did not complete the second questionnaire. I definitely believe that's a valid concern. What's reassuring, however, are the different approaches that the authors, the Andreotti authors, took in their publication to assess whether such an amount of missing data might influence the results.
In addition, there's a publication by Heltshe which describes the methodology of the imputation for the study. They also did a number of assessments of the quality of imputation which suggest that it actually didn't influence the results. And finally there's another publication by Montgomery.
What we're really concerned about is whether the association between glyphosate and non-Hodgkin's lymphoma is different in those who

Page 64

did fill out the second questionnaire and those who didn't. So all of those things together, I think one should be concerned about this, but multiple nodes of evidence suggest that it didn't lead to a substantial bias in this study.
Q. Do you believe that -- or strike that.
Can you explain briefly how the authors imputed -- or strike that. Let's actually take a look at the Heltshe study real quick. We will mark this as Exhibit 4.
(Whereupon, Exhibit Number 32-4, Heltshe, et al article, Using multiple imputation to assign pesticide use for non-responders in the follow-up questionnaire in the Agricultural Health Study, was marked for identification.)
BY MR. WOOL:
Q. And in the abstract the authors note that "To assess the imputation procedure, a 20 percent random sample of participants was withheld for comparison. The observed and imputed prevalence of any pesticide use in the holdout dataset were 85.7 percent and 85.3 percent respectively." Correct?

Page 65

A. Yes.
Q. And if you turn to Page 412, in the right-hand column. I think it's actually highlighted in your copy.
A. Yes.
MR. LASKER: Okay. Thank you.
BY MR. WOOL:
Q. Okay. And the highlighted portion, I believe, in your copy starts with "In pesticides with the highest prevalence have the largest standard errors, while rarely used pesticides have very little variability."
Is that what's highlighted in yours?
A. That is what is highlighted. I'm just trying to see what they're referring to here. What information -- standard error. The estimates of the standard error, so the variability around the mean, which makes sense, yes.
Q. So, and am I correct that the more prevalent a pesticide is used, what the authors are saying is there will be a larger standard error with that pesticide compared to a pesticide that is not used frequently?
A. It actually refers to they're slightly

Page 66

higher than the true standard error.
Q. Okay.
A. But that's different than the relative error. That concept of the standard error is different than the relative error, so it's not really describing how well the imputation procedure worked.
Q. Okay. And how is the standard error different than the relative error?
A. Well, the standard error, you know, we say the mean or the estimated prevalence is 40 percent, and then we have sort of a distribution of what we think the true expected prevalence is. The relative error compares what was actually observed in that 20 percent holdout versus what was predicted based on the imputation, so that relative difference in the estimate.
So the standard error doesn't give you a sense of whether the information is a valid or not imputation, just giving you -- it's like in a 95 percent confidence interval around an odds ratio, that is comprised of the standard error around the odds ratio. It gives you a sense of the distribution.

Page 67

Q. And you would consider glyphosate to be a highly used pesticide, correct?
A. Yes, it is a highly -- the prevalence is quite high. But again, that doesn't -- what that comment in the second column on Page 412 does not imply that because the prevalence is high the relative error -- there's no -- if you look, actually, in table -- where did I see it? This is different than what I had downloaded.
Oh, here. So Figure 2 here is a figure showing the relative errors, which is a better -- is really what you want to look at when you want to assess how well the imputation worked. And there, actually, you can see that there doesn't really seem to be a relationship between the prevalence of the pesticide and the distribution of the relative errors, and that is reassuring actually.
Q. Okay. Now, on the same page that you're on, Page 414.
MR. LASKER: Okay. I'm there.
BY MR. WOOL:
Q. In the right-hand column, the first full paragraph reads, "A key assumption of any imputation is that missingness is independent of

Page 68

the unobserved outcome of interest or unobservable confounders (i.e., missing at random). The reduction of bias and increase in precision from multiple imputations is dependent on the covariates associated with both non-response and the endpoint variable and factors associated with non-participation, which were included in our imputation model. For our imputation analysis, the 'outcome' of interest is the missing pesticide use itself," and they cite to Montgomery, et al, which shows that "there is little evidence for selection bias in Phase 2 of the AHS. However missing at random is an untestable assumption without additional data; thus it is possible that non-responders differ from responders in variables we have not measured."
Did I read that correctly?
A. Yes, you read that correctly.
Q. Okay. So what is the untestable assumption that they're talking about in that section?
A. It's this concept of the data being missing at random, meaning that the reason that the data are missing is not related to some

Page 69

factor of interest here.
Q. Now, is it your opinion that this imputation method used in Andreotti has general acceptance within the epidemiological community?
A. The use of imputation is a common procedure in epidemiology, yes. However, what I think is important, as Andreotti has done, is to evaluate whether it's worked or not worked. So while it is accepted, it's also accepted by epidemiologists that we should do our best to understand whether the multiple imputation approach has given us a valid estimate of the missing data.
Q. And have you used an imputation model in any of your own publications?
A. Yes.
Q. Have you used this imputation model?
MR. LASKER: Objection to form.
A. I wouldn't have used this specific multiple imputation model because this was specified specific -- you want to -- what you want to do with multiple imputation is think about what you're trying to predict, and you want to use the covariates and the relationship of those covariates to best predict the missing

Page 70

data. So the approach in the study where I've used multiple imputation was very different than this. But it's still -- it's using a similar strategy which they have done here.
BY MR. WOOL:
Q. Could baseline exposure of misclassification impact the accuracy of the imputation?
MR. LASKER: Objection to form.
A. In what context? I'm sorry.
BY MR. WOOL:
Q. Insofar as it provides a reliable outcome.
MR. LASKER: Objection to form.
A. I'm sorry, could you ask specific -- a more specific question? I'm not sure I understand what you're asking.
BY MR. WOOL:
Q. As I understand, the Heltshe is looking at, among other things, sort of the validity of the imputation model, correct?
A. Yes.
Q. Okay. And could a measurement error in baseline glyphosate use impact the validity of the model as it's used in Andreotti, et al?

Page 71

MR. LASKER: Objection to form.
A. Are you asking more generally, or did it in this particular case?
BY MR. WOOL:
Q. Could it.
A. I guess it may or may not. It would be hard to predict, because it would rely on a number of factors. So it might, but it may not as well.
I think here in this specific example what's really nice to see is that the imputation methodology performed well in predicting use of glyphosate in this study.
Q. Now, if you turn back, I think, to Table 3, you'll see that Table 3 gives us a number of figures for the various pesticides at use, or at issue in the Andreotti study, correct?
A. Yes.
Q. And three of the calculations that Table 3 provides are reference Brier scores, Brier score, and Brier skill score, correct?
A. Yes.
Q. Now, what is a reference Brier score?
A. Well, what these three metrics were

Page 72

used for here was to say how well -- did the imputation approach do a better job, was it more predictive than if you just used the model or just looked at what the actual observed prevalence was. And so these three values here are used to say did the imputation add more information than if you just used the actual observed data.
So it's a measure of should you just do simple -- a simple approach, or should you do this much more complicated approach. So that's what the Brier score is being used for here.
Q. And have you ever calculated a Brier score in any of your own publications?
A. I have not used the Brier score, no.
Q. Were you familiar with the Brier score before this litigation?
A. Although I wasn't familiar with this particular score, I'm very familiar with prediction modeling in different strategies people use to assess how well predicted model adds information compared to sort of a baseline model. So I wasn't familiar with this specific measure, but could easily understand why it's being used here.

Page 73

Q. And so what does the reference Brier score for glyphosate indicate?
A. So again, you know, what we're really interested here in this table is the Brier skill score because it gives us a sense, compared to the reference Brier, how much additional information the multiple imputation model did in proving the accuracy in the prediction. So what it tells us is that the imputation model gave almost a 10 percent improvement in the prediction of the imputed data compared to just relying on this simple model. So, and that is compared to some of the other pesticides, for example, benomyl where it doesn't look like the imputation added much more information than if you just used the simple model.
So does that answer your question?
Q. Yeah, I think it answers it well enough.
Do you believe that maintaining a high rate of follow-up is integral to ensuring study validity?
MR. LASKER: Objection to form.
A. Yeah. As an epidemiologist, our goal is to optimize the amount of follow-up, because

Page 74

that would ensure that there's no issue of a selection bias being introduced. But at the same time, just because you might not have all of the participants in your study completing the second questionnaire, it doesn't necessarily imply that a bias has resulted. It's important to evaluate whether a bias has resulted, but it doesn't necessarily mean that it has occurred.
BY MR. WOOL:
Q. In terms of the non-responders in Andreotti, is it possible to rule out selection bias?
A. There are multiple nodes of evidence that suggest that selection bias is not likely to be a big concern here, and, you know, I think we have that data from the Andreotti publication itself where they looked at a number of sensitivity analyses. We have that in the Montgomery study which looked at the -- a number of factors in those who did and did not complete the second questionnaire. They also tried to assess the potential role of selection bias in a number of exposure/outcome relationships. And then also from Heltshe as well.
So I think all of these pieces of

Page 75

information would suggest that it's very unlikely that selection bias would have led to a bias in this Andreotti study.
Q. But you can't definitively rule out selection bias having occurred in the Andreotti study, correct?
MR. LASKER: Objection to form.
A. Well, as an epidemiologist where we never would be able to completely rule anything out, I think again what's really important here is that there's multiple nodes of evidence showing whether this bias existed, and all of these different nodes of evidence suggest that the bias is very unlikely to have occurred in this Andreotti study.
MR. LASKER: Just for clarification, are you saying nodes or modes?
THE WITNESS: Nodes.
MR. LASKER: That's what I thought, I wanted to clear it up.
BY MR. WOOL:
Q. We talked about a high rate of follow-up just a second ago, right?
A. (Nodding in the affirmative).
Q. Okay. Is there any agreement within

Page 76

the field of epidemiology as to what constitutes a high rate of follow-up?
MR. LASKER: Objection to form.
A. I wouldn't -- I mean, I think it's very context specific. And again, our goal is to try to have as high follow-up as possible. If that doesn't occur, then it's also important as an epidemiologist to evaluate the potential for bias, which Andreotti has done specifically here. And also not only Andreotti, et al, but also the many other publications that have relied on the Agricultural Health Study second questionnaire have also done -- looked at this issue as well in the context of the exposure and the outcome they were looking at.
BY MR. WOOL:
Q. Would you consider a 37 percent loss in follow-up to be a high rate of follow-up?
MR. LASKER: Objection to form.
A. I would say, again, it is a -- we would be concerned just as we would be concerned with any amount of missing data. However, just because there is that amount of missing data doesn't mean necessarily bias occurred.
And I think as we've just talked

Page 77

about, these authors and many of the other authors in the Agricultural Health Study have evaluated the impact of bias. Because you're right, as an epidemiologist we should be concerned. However, it's really reassuring to see from multiple studies, multiple lines of evidence, the way they've looked at the potential for bias in multiple ways, all of these analyses suggest that selection bias did not result in any -- in the study of Andreotti, et al and glyphosate and NHL risk analysis.
BY MR. WOOL:
Q. Would it be reasonable for an epidemiologist to put less weight on a study due to a 37 percent loss in follow-up?
MR. LASKER: Objection to the form.
A. Again, that's a very general comment. And what I would want to know is -- so we can think of it it's almost like a Bayesian approach. A priori if I heard there was 37 percent missing data, that would raise my concern. However, if I see that the authors, and multiple authors have looked at this question in multiple ways, and there doesn't seem to be a bias occurred, my posterior

Page 78

probability then would be based on all this information that a bias is unlikely to have happened.

So while it is something to think about and to be concerned about, there are standard approaches we can take as epidemiologists to investigate whether a bias indeed occurred. And in this case, and again from all of these different pieces of data that we've talked about, it doesn't seem that the 37 percent missing data has resulted in any substantial bias in this study. And I think --

BY MR. WOOL:

Q. Okay. So in your capacity as a peer reviewer, have you ever come across a study where 37 percent of the cohort was lost to follow-up?

MR. LASKER: Objection to form.

A. As I mentioned, this wasn't necessarily in the context of peer review. But as I've mentioned, I had previously collaborated on the Swedish mammography cohort study, and there -- and that's an NCI-funded cancer epidemiology cohort, they published literally hundreds of publications, and they have

Page 79

30 percent of their participants did not complete the second questionnaire. They did multiple imputation, they compared it, just as Andreotti did, to the complete case assessment, they did a variety of assessments to see whether the participants who completed both questionnaires differed from those who only completed one, so I -- there are well-established epidemiology studies, cohort studies that do have large amounts of missing data.

BY MR. WOOL:

Q. And is it possible that the loss in follow-up in the Andreotti study is related to exposure status?

MR. LASKER: Objection to form.

A. I'm not sure I understand what you mean. Because what you're really concerned about is not whether the missing data is related to the exposure status, but really whether the missing data on the exposure is also differentially related to the outcome. That's where the selection bias would occur.

BY MR. WOOL:

Q. So I guess my question should be, do

Page 80

you know if lost in follow-up in AHS is related to outcome status or -- strike that.

Can you definitively rule out that loss in follow-up in the Andreotti study is related to outcome status?

MR. LASKER: Objection to form.

A. While -- in the approach, one of the approaches that -- there are a couple of different approaches that would suggest that is not the case. In the sensitivity analysis Andreotti, et al looked at first just the individuals who had filled out both questionnaires, so the complete case, so where selection bias wouldn't have caused a problem. And when you look at the relative risk estimates for the association between glyphosate and NHL risk there and compare it to the imputation, the findings are very, very similar, very, very similar.

Also, when they say well, let's just look at the baseline questionnaire, when they do that, again the results of that baseline questionnaire compared to the follow-up questionnaire, very, very similar. So both of those strategies would suggest that such a bias

Page 81

did not lead to any bias of the results.

BY MR. WOOL:

Q. What does the concept of -- or what does external validity mean within the field of epidemiology?

A. So external validity refers to generalizability, meaning can you take the findings in this one cohort study and extrapolate that to other populations.

Q. Do you believe that you can extrapolate the results of the Andreotti study to other populations?

A. There's no reason for me to suggest -- there's no inclination to me to suggest why that would not be the case, why an underlying relationship between glyphosate and NHL risk would differ in this population versus another population.

And in fact, actually there was a really nice editorial that accompanied Andreotti, et al by Ward, Elizabeth Ward, suggesting, actually, that the Agricultural Health Study in many ways is an excellent population to look at the association between glyphosate and NHL risk.

Page 82

Q. Now, what about the concept of internal validity as it relates to the larger field of epidemiology?
A. Yes, internal validity is what we've been talking about already. It's thinking about the concepts of whether bias confounding or chance might explain an observed association.
Q. And is internal validity a necessary prerequisite to establish external validity?
A. Certainly. Well, I mean, really you wouldn't want to generalize a bias finding to a different population, so that's what that concept means.
Q. So I guess yes, internal validity is a necessary prerequisite to external validity?
MR. LASKER: Objection to form.
A. Well, you need to have a study to be internally valid to say anything meaningful about the observed association, regardless of generalizability. But that's the case for every epidemiological study, you want to make sure that bias confounding and chance have not -- are not explaining the observed association that you have, which, you know, again, has been nicely investigated here in Andreotti, et al.

Page 83

BY MR. WOOL:
Q. Now, in your supplemental expert report you completed a meta-analysis, correct?
A. Yes. What I did was to do an updated meta-analysis where I, as you can see from Figure 2 in my supplemental report, I looked at point estimates from four different studies.
Q. And one of those studies was Pahwa, et al, 2016?
A. Yes. Was it -- yeah, Pahwa 2016.
Q. Would it be improper to exclude that study?
A. Would it be improper to exclude that study?
Q. Yes, in the meta-analysis.
A. I'm sorry, I don't understand your question.
Q. If I were to -- I guess, if a meta-analysis did not include the Pahwa study, would you consider that to be a flawed meta-analysis?
A. Well, I think in -- what you would do in a meta-analysis is to evaluate -- you would want to go through an understanding of all of the available epidemiological studies that meet

Page 84

the criteria for the meta-analysis that you're performing, so it would be very unclear why you would exclude Pahwa here.
Q. Okay. And in the Andreotti study, they evaluated the cohort at 20 years, correct?
MR. LASKER: I'm sorry.
A. I'm sorry, I don't understand your question.
BY MR. WOOL:
Q. Let me just go to Table 3, I think that is little bit more clear.
MR. LASKER: Where are you?
MR. WOOL: Table 3 of Andreotti.
MR. LASKER: Just get myself organized here.
Page 6?
MR. WOOL: Yes.
BY MR. WOOL:
Q. And what is the right-hand column showing us?
A. So in this table the authors presented data on intensity weighted days of exposure of glyphosate and cancer risk, and in the right column is looking at an analysis lagging -- or introducing a latency to look at longer term

Page 85

effects of glyphosate-based herbicides.
MR. LASKER: Just for the record, I don't know if this is intended or not, this Exhibit 32-2 does not include the supplemental table. I don't know if you intended it not to, but we don't have it.
MR. WOOL: It should have.
MR. LASKER: It should have. We don't have it.
MR. WOOL: Well --
MR. LASKER: You won't ask those questions.
MR. WOOL: It is what it is at this point.
BY MR. WOOL:
Q. So staying in the right-hand column, for the 20 year lag and looking at non-Hodgkin's lymphoma, what are the figures in the parenthesis telling us?
A. I'm sorry, in the parenthesis, those are 95 percent confidence intervals. Is that what you're referring to?
Q. Yes.
And so what is the upper figure telling us in those parenthesis?

Page 86

A. I'm sorry, I don't understand what you're referring to.
Q. If we look at the first quartile in the parenthesis we see a range of .91 to 1.64, correct?
A. Yes.
Q. Okay. What is the 1.64 telling us?
A. That's the upper bound of the 95 percent confidence interval.
Q. And what -- you said upper bound or upper --
A. That's the upper bound of the 95 percent confidence interval.
Q. What does the upper bound mean in the field of epidemiology?
A. So it gives you -- so we're estimating what you think to be the relative risk, and then you have some uncertainty around that estimate. The amount of uncertainty is a function of the number of cases, the prevalence of the exposure, so this gives you a range of values that are consistent. Although you would think that the range of values are more consistent with the point estimate than the -- either the lower or upper bound. But to me what that tells you when

Page 87

you look at the 20 year lagged analysis, there's no association between glyphosate-based herbicides and risk of non-Hodgkin's lymphoma with 20 -- even if you lag 20 years of exposure.
Q. Okay. But the upper bound for all quartiles with a 20 year lag for non-Hodgkin's lymphoma are above 1, correct?
MR. LASKER: Objection to form.
A. Well, that is correct. The other way to look at this is that all of the lower bounds of the 95 percent confidence intervals are below 1, because when you look at the overall association here, this really is telling us there's no association between glyphosate-based herbicides, assuming a 20 year lagged analysis, and the risk of NHL.
I actually have -- I don't know if it's helpful, but in my supplemental report we also looked at the 15 -- I'm sorry, I don't have those numbers specifically, but there was no association either with assuming a 10 year, a 15 year, or a 5 year lag, which we see also in this Table 3.
BY MR. WOOL:
Q. And am I correct that for your

Page 88

meta-analysis, you did not include the results with the 20 year lag?
A. That information was not available for all of these studies, so this particular meta-analysis simply looks at the ever-never exposure that was available from each of the publications.
My goal wasn't to -- my goal was really just to give sort of an information about what the totality of the epidemiology is saying to us. You know, there is caveats, as I've said previously, that we can come up with a meta relative risk estimate, but it doesn't adjust for any potential biases or confounders that have not been taken into account here.
Q. Just so I'm clear, you're not saying that -- strike that. I understand your answer.
Okay. I think that's it for right now.
MR. WOOL: If you have any questions?
MR. LASKER: None. You don't have an option. We're done.
A. Thanks so much.
THE VIDEOGRAPHER: This concludes the January 23, 2018 deposition of Dr. Lorelei

Page 89

Mucci. Going off the record. The time is 10:55.
(Whereupon, the deposition was concluded.)

COMMONWEALTH OF MASSACHUSETTS)
SUFFOLK, SS.)

I, MAUREEN O'CONNOR POLLARD, RMR, CLR, and Notary Public in and for the Commonwealth of Massachusetts, do certify that on the 23rd day of January, 2018, at 9:01 o'clock, the person above-named was duly sworn to testify to the truth of their knowledge, and examined, and such examination reduced to typewriting under my direction, and is a true record of the testimony given by the witness. I further certify that I am neither attorney, related or employed by any of the parties to this action, and that I am not a relative or employee of any attorney employed by the parties hereto, or financially interested in the action.

In witness whereof, I have hereunto set my hand this 5th day of February, 2018.

____

MAUREEN O'CONNOR POLLARD, NOTARY PUBLIC
Realtime Systems Administrator
CSR #149108

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ACKNOWLEDGMENT OF DEPONENT

I, ____________________________, do Hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____
LORELEI A. MUCCI, ScD DATE

Subscribed and sworn
To before me this
______ day of _________________, 20____.
My commission expires: _______________

____
Notary Public

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