ORIGINAL

ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:	)	
	)	
WATER QUALITY STANDARDS AND EFFLUENT LIMITATIONS FOR THE CHICAGO AREA WATERWAY SYSTEM AND THE LOWER DES PLAINES RIVER: PROPOSED AMENDMENTS TO 35 Ill. Adm. Code Parts 301, 302, 303 and 304	)	R08-09 (Rulemaking-Water)

REPORT OF PROCEEDINGS held in the above-entitled cause before Hearing Officer Marie Tipsord, called by the Illinois Pollution Control Board, taken before Laura Mukahirn, CSR, a notary public within and for the County of Cook and State of Illinois, at 160 North LaSalle Street, Room N-505, Chicago, Illinois, on the 30th day of June, 2010, commencing at the hour of 1:00 p.m.

A P P E A R A N C E S

MS. MARIE TIPSORD, Hearing Officer
MR. TANNER GIRARD, Chairman
MS. ALISA LIU, Member
MS. ANDREA MOORE, Member
MR. THOMAS E. JOHNSON, Member
MS. CARRIE ZALENSKI, Member
Appearing on behalf of the Illinois Pollution Control Board

HEARING OFFICER TIPSORD: Let's go on the record. I am going to be repetitious today, just so you all know. Be warned. Good afternoon. My name is Marie Tipsord and I've been appointed by the board to serve as a hearing officer in this proceeding entitled the Water Quality Standards and Effluent Limitations for the Chicago Area Waterway System and Lower Des Plaines River. Proposed amendments to 35 Ill. Admin. Code 301, 302, 303, and 304. This is Docket No. 08-9 and this is Subdocket B. With me today to my immediate left is acting chairman G. Tanner Girard, the presiding board member, to his left board member Carrie Zalewski, to her left board member Andrea Moore. To my far right is board member Thomas Johnson and to my immediate right is Alisa Liu from our technical staff.

Also today we have Shannon Bebe (ph.), Alia Nielsen, and Carrie Petersen, our summer interns this semester. Shannon and Alia are both from Kent and Carrie is from U of I.

Today's hearing is the second in Subdocket B, but it is the 41st overall hearing in this proceeding, day of hearings in this proceeding. As I noted yesterday, even though this is Subdocket B, we are going to continue to number the exhibits sequentially. So the first exhibit today will be given Exhibit No. 390, and we're doing the same thing with public comments. We are also -- If something comes in designated as R08-9, the clerk's office, in consultation with myself, is deciding which sub docket that should be docketed in and linked. So basically if you're going to file something and it needs to be in Sub Docket A, B, C, or D or all of them, just note it on your filing. There's no need to file two separate documents, one for Sub Docket A and one for Subdocket B. Let's try and save some trees. We can just go ahead and you can put it on your header that it's Sub Docket A and B, Sub Docket A, B, C, and D, whatever. And we'll docket it and we can link it -- once we scan it, we can link it that way. And that

will save us from having to have nine copies of the exact same thing in four different dockets. So just to give you a heads up. The subject of today's hearing is the Chicago Health Environmental Exposure and Recreation Study known as CHEERS. Yesterday we began with the testimony of Dr. Samuel Dorevitch and the questions from the Natural Resource Defense Council and the rest of the environmental groups and the people. Today we will conclude with Dr. Marc Gorelick and questions from the District. The testimony will be marked as an exhibit and entered as if read. Anyone may ask a follow-up question. You need not wait for your turn to ask questions. I do ask that you raise your hand and wait for me to acknowledge you. After I have acknowledged you, please state your name and whom you represent before you begin your questions. Please speak one at a time. If you're speaking over each other, the court reporter will not be able to get your questions on the record. Please note that any questions asked by a board member or

staff are intended to help build a complete record for the board's decision and not to express any preconceived notion or bias. I noted yesterday there's pending motions in Subdocket B for additional hearings and those are not yet ripe for decision. The Board will be making that decision, not the hearing officer. Also, in Subdocket A there are pending motions for leave to file replies. I actually had both parties -- two of the parties that filed those ask me yesterday. The Board has indicated we will take those with the case, which means we'll take those as we decide whether or not to proceed to first notice and what to proceed to first notice with in Subdocket A. So that's just to let everyone else know so I don't get another dozen phone calls. Also at the end of the day yesterday Albert Ettinger asked me about a status conference. I told him I thought it would be premature to schedule a status conference until the Board rules on the motion to hold additional hearings in Subdocket B. Once the Board rules on that, I

will do a hearing officer order that asks -- gives everybody some dates and let everybody get back to me about availability to do a status call to find out where we are as far as what additional hearings we might need to hold in the remaining subdockets. Obviously Subdocket A, right now we've had the final comments in, so that will not be one at this point to look at that we'll be talking about. And depending upon what the Board rules in this subdocket, we'll talk about potential hearing dates if the Board rules to have additional hearings. That is a contested motion, so I'm just trying to cover all my bases. I have no idea. I haven't read all of them yet.

With that, Dr. Girard.

CHAIRMAN GIRARD: Thank you. Good afternoon. Welcome to the hearing. What day is this? Forty-one?

HEARING OFFICER TIPSORD: Forty-one.

CHAIRMAN GIRARD: Day 41. I won't give a long speech, so let's get on with the testimony and questions. Thank you.

HEARING OFFICER TIPSORD: Anybody have anything before we begin?

MR. ANDES: Marie, I just want to go back and clarify for a moment the statement you made about Subdocket A and materials going with the case. Can you go over that again?

HEARING OFFICER TIPSORD: Sure. We have had, and I don't have the docket in front of me, so forgive me if I've missed someone. The Midwest Generation, Citgo PDV, and I think a third person filed a motion for leave to file a reply to the IEPA's final comments. They've attached their replies with the motions for leave to file so the Board will rule on the motions for leave to file. If the Board accepts the replies, then they'll be considered as part of the first notice batch. So it's just -- as I told Susan Franzetti yesterday, if they hadn't filed the reply with them, then the Board would have had to rule on the motion and give them an opportunity to file the reply if they were going to grant it. This way we can do

it all at once and save, again, hopefully save some papers by not sending out a board order to everybody on a procedural matter.

Anything else?

MS. WILLIAMS: I was just wondering if we had an estimate of what board meeting the motions will be ripe for decision approximately?

HEARING OFFICER TIPSORD: Subdocket B, the motions? Mr. Andes indicated to me yesterday that they would be filing motion for leave to file a reply. So depending upon when that's filed will depend upon when it's ripe.

Anything else? Are we ready to have Dr. Gorelick sworn in?

MS. ALEXANDER: Yes.

(Witness sworn.)

MS. ALEXANDER: And I have as Exhibit 389 Dr. Gorelick's prefiled testimony.

HEARING OFFICER TIPSORD: Actually it will be Exhibit 390.

MS. ALEXANDER: I never get these

right.

THE COURT: I've been handed the prefiled testimony of Marc Gorelick, M.D. If there's no objection, we will admit it as exhibit 390. Seeing none, it is Exhibit 390.

And then with that, Mr. Andes, I think we're ready to begin questions.

MR. ANDES: Thank you.

E X A M I N A T I O N

BY MR. ANDES:

Q. Good afternoon, Dr. Gorelick. Let's start with Question 1. How many of your peer-reviewed original research papers in clinical epidemiology involve epidemiological studies related to illness or public health risk?

A. Well, they all have to do with illness because they're all clinical medical studies. Many of them are related to diagnostic strategies, management strategies. So depending on exactly how you define public health risk, I would count seven of them as having to do with public health risk.

Q. Can you identify which ones those are? I don't know if we have a --

A. A couple of them are in the Exhibit 390. Did I get it right, testimony? Some recent studies, association between rainfall and pediatric emergency department visits for acute gastrointestinal illness, water use and acute diarrheal illness in children in the United States, ED visits for diarrheal illness increased after release of undertreated sewage, epiglottitis in children 1979 to 1992.

Q. I'm sorry. Was the 1992 one, is that in your CV?

A. Yes.

Q. Okay.

A. Effective ethnicity and race on use of pain medications in children with long bone fractures.

Q. What year was that?

A. 2003. Like I said, it depends a bit on how you define public health risk. All of these have to do with illness. Association between infant continuity of care and pediatric emergency departmentalization. That was 2004.

Q. I think that's six so far.

A. Emergency Department of Management of

sexual transmitted infections in U.S. adolescents. That's 2004 as well.

Q. Okay. Did any of those studies result in a conclusion of positive results? In other words, a positive correlation between a study factor and increased illness or public health risk? And, if so, how many of the studies yielded positive results?

A. Five of those, I would say, yielded positive results; that is, that we found that there was a positive correlation between one or more study factors and risk of illness.

Q. So does that mean then that the other two studies resulted in conclusion of negative results?

A. That's correct.

Q. Okay. Do you believe it -- and which two were those?

A. So there was the one I referred to about the effect of ethnicity and race in the use of pain medications in children.

Q. Is that the 1992?

A. That was 2003.

Q. Okay.

A. And it depends on how you define negative, because we often look at multiple risk factors. But the water use and acute diarrheal illness in children, that was 2010, we found some positive associations and some negative associations.

Q. Do you believe that it's possible for an epidemiological study to support a conclusion that a certain factor does not or likely does not contribute to increased illness or public health risk?

A. Well, I would say I would not think that it -- that a certain factor does not because we don't -- I mean studies, epidemiologic studies don't prove something one way or another. We simply assess a likelihood. So can it support a conclusion that a concern factor likely does not? Yes. And that's typically a negative result. We would say that it is unlikely that there's an association, and we would define what we mean by unlikely.

Q. And am I right that in the two studies you identified, the one on water use and the one on ethnicity, the studies concluded that certain factors likely did not contribute to increased risk?

A. Correct.

Q. And you agreed with those conclusions?

A. Correct.

MS. ALEXANDER: Can I ask a quick follow-up on that? Were you also involved in a study concerning use of CAT scans?

DR. GORELICK: Yes.

MS. ALEXANDER: And did you reach a negative conclusion? Were there negative results in that study ultimately?

DR. GORELICK: That was a study where we weren't looking at risk of illness, per se. It was a method of diagnosing head injury and looking at factors that predicted whether or not a head injury was present to try to determine who needs to get a CAT scan and who doesn't. And we identified that some of those factors were positively associated with having an injury that would show up on CAT scan and some of those factors were not associated with having an injury that showed up on CAT scan.

MS. ALEXANDER: How many participants were there in that study?

DR. GORELICK: About 42,000.

MS. ALEXANDER: And were there prior studies of that same subject?

DR. GORELICK: Oh, yes.

MS. ALEXANDER: How many about.

DR. GORELICK: At least eight or ten. And of smaller, usually -- those other studies anywhere between 500 and a couple of thousand children.

MS. ALEXANDER: And did -- ultimately did these studies support a conclusion, this 42,000 person study, together with these eight or ten other studies, then support a conclusion essentially that a particular risk did not exist and the CAT scan procedure was not necessary?

DR. GORELICK: Right. So, again, we would identify, for example, that if a child had -- give an example of an actual finding from that study. Child had dizziness, and children with dizziness were no more likely to have a positive CAT scan than children who did not have dizziness. There was a large number of subjects we were able to calculate

the difference between the kids who did and didn't have dizziness. And we were able to say that those numbers were very similar within a margin of error. The margin of error in our study of 42,000 was much smaller than the margin of error in the other studies. But because there was a consistent pattern across those studies of children with a -- at risk factor not being more likely to have the head injury we were interested in, taken together they supported a conclusion that it was unlikely that children with dizziness would have a positive CAT scan. We couldn't conclude that the risk is zero, but we concluded that it was very small.

MS. ALEXANDER: Okay. Thank you.

BY MR. ANDES:

Q. Dr. Dorevitch testified that the CHEERS study used the perspective cohort design. Do you agree with that testimonial?

MS. ALEXANDER: Can we clarify what you mean by agreed? Do you mean you agree that he testified that he used that method or is he agreeing that that method is

appropriate?

MR. ANDES: Is it your understanding that the study did use the perspective cohort design?

DR. GORELICK: Yes. That's my understanding.

BY MR. ANDES:

Q. And have you ever been involved in a study that used that design?

A. Yes.

Q. Can you tell me which studies?

A. Well, multiple of them. But to give one example of the study of the CAT scans that we just discussed. That was a prospective cohort study.

Q. And are you aware that the currently applicable EPA microbial water quality criteria for recreational use are based on the results of past perspective cohort studies?

MS. WILLIAMS: I'm going to object unless you can clarify what criteria you're talking about.

MR. ANDES: I was referring to the EPA recommended criteria for recreational use.

MS. WILLIAMS: Illinois EPA?

MR. ANDES: I'm sorry. U.S. EPA.

MS. WILLIAMS: Can you give a date?

MR. ANDES: 1986, I believe.

THE WITNESS: Right. So there were, among other studies, there were -- there are some experimental studies, there are -- I'm sorry -- prospective cohort studies, some case control studies. So a variety of study designs are used and have been applied in looking at the associations between recreational water use and illness. There's always -- when you look at epidemiologic studies, you know, the ideal would be to do an experiment, but we can't experiment on humans really unfortunately. So we've come up with a number of types of epidemiologic studies to try to get around the fact that we can't do a controlled experiment, completely controlled experiment like you can on animals, for example. And so of those, the prospective cohort study is one type and that's generally considered, of those less than perfect studies, to be the gold standard

for this type of epidemiological study.

BY MR. ANDES:

Q. In your recent study entitled Association Between Rainfall and Pediatric Emergency Department Visits for Acute Gastrointestinal Illness, did you recommend that a cohort follow-up study be conducted to assess community wide incidences of disease?

A. Yes.

Q. In Dr. Dorevitch's testimony it was stated that the CHEERS study followed the basic study format used for U.S. EPA's NEEAR study, the National Epidemiological and Environmental Assessment of Recreational Water Study. Is that your understanding as well?

A. Yes. The NEEAR study uses, among other things, prospective cohort of epidemiologic proportion.

Q. Now, are you aware of how EPA -- U.S. EPA intends to use data from the NEEAR study in developing recreational water quality standards?

A. I'm sorry. Am I aware of how they're planning on using it?

Q. Well, I guess first question is are

you -- Is it your understanding EPA will be using information from that study in setting standards?

A. I would assume they would use data from that study and other available studies, sure. It's why it was commissioned.

Q. In Dr. Dorevitch's testimony, he stated that the design and protocols of the CHEERS study as well as the quality of data collected and its analysis and interpretation had been reviewed and endorsed by a panel of recognized leaders in the fields of water microbiology and health from the U.S. Centers For Disease Control and Prevention, U.S. EPA, and others. Is that consistent with your understanding?

A. Yes. That would be sort of standard for studies that are funded, for example, by National Institute of Health, CDC, EPA, other government, quasi-government organizations foundations as they go through a peer-review process where it gets reviewed and vetted by experts like that. And I give them credit because this study funded by the Water Reclamation District would not have had to go through that process. They could fund whatever they want. But they chose to, in

fact, have that kind of peer review which I think is -- gives it a similar level of scrutiny to other funded studies.

Q. Have you been involved in any studies that have gone through similar process with review by personnel from the CDC, U.S. EPA, other agencies?

A. Well, yes. I am involved and have been involved in several studies that are funded by CDC or the National Institute of Health and so on. And so, again, that's part of the peer review process of applying for those grants in the first place.

Q. Does that include any of the seven studies we discussed earlier?

A. The CAT scan study that I mentioned, that was funded by the Health Bureau of the Department of Health and Human Services; currently involved in two ongoing studies, have not been published yet, one of health effects of climate change that was funded by the CDC and reviewed by them. Also looking at a study of intraabdominal injury in children who have been injured funded by the CDC. And several of the other studies funded by NIH and other agencies.

Q. And those studies have or are going through similar peer review processes?

A. Right. As I said, that's part of the grant application and review process.

Q. As to the interim technical report, Dr. Dorevitch testified that that report provided interim summaries of key data elements including preliminary results of water quality and observation of recreational use of the CAWS during the last three recreation seasons. Is that your understanding as well?

A. That's what I saw included in the interim technical report, yes.

Q. Have you ever been involved in an epidemiological study that analyzed differences among study subjects which you call confounding factors? And, if so, can you explain how, summarily, how the studies address the confounding factors?

A. Sure. So probably the most, one I'll remember best because it's the most recent one, is the study I listed in my testimony: The Water Use and Acute Diarrheal Illness in Children which has just been published in a journal called Epidemiology

of Infection. And so in that study we took children who were coming into our emergency department for acute diarrheal illness and matched them with children who were coming in for other reasons: Sprains, cuts, colds, that kind of thing. And we asked them a series of questions about their water use to try to see if there was an association between the kind of water they used for drinking and whether they were sick or not. We recognize that there are other things about people who come in to the emergency department for diarrheal illness as opposed to other problems that might also explain some of those differences. So among the other questions that we asked in our survey were, you know, number of other children at home, whether other people at home were sick, did they go to day care or school, because we know that's a risk factor for being sick. We looked the race and ethnicity, we looked at age by matching the children who came in with somebody of the same age, so we knew that that wouldn't be different between them. The time of year, because we know that illness varies by time of year. So we'd enroll people on the same day or within a day of each other so that that wasn't a

difference between them. So those are all things that we thought, you know, people who come in -- because people come into the emergency department for a whole bunch of reasons, and why would somebody with diarrhea come in to the emergency department? It might be because they were really sick, it might be because they don't have access to a doctor or they don't have insurance or whatever other things. And those -- All might influence their risk of being sick on the one hand and the kind of water they use on the other. So that's what we mean by confounding factors, and those are among the ones that we looked at in that particular study.

Q. As to the NEEAR study being conducted for EPA, are you aware of what confounding factors they are looking at?

A. Yeah. They're looking at a number of the same ones I just mentioned. So this is one publication from the NEEAR study from the Environmental Health Perspective 2006.

Q. Can we get copies of that?

MS. ALEXANDER: That's the --

DR. GORELICK: This is one of the NEEAR -- you asked for publications from the

NEEAR study.

MR. ANDES: It's possible that's been put into evidence.

MS. ALEXANDER: I don't know if we have it on the record, but I have no problem marking it.

DR. GORELICK: They mentioned a number of the same confounders: Age, race, ethnicity, gender --

MS. ALEXANDER: Why don't I just get this marked for the record. I'd like to offer this to be marked as Exhibit 391, and we will get you copies. I only have this one. I guess I should pass it along to Fred.

HEARING OFFICER TIPSORD: Okay. I will reserve then Rapidly Measured Indicator -- If there's no objection, we will reserve Exhibit 391 for Rapidly Measured Indicators of Recreational Water Quality are Predictive of Swimming Associated Gastrointestinal Illnesses, Timothy Wave, Rebecca Caldren, et al., as authors from January 2006 Environmental Health Prospectus.

DR. GORELICK: While you're at it, you

asked about studies from the NEEAR -- so here is another one. You might as well enter it at the same time.

HEARING OFFICER TIPSORD: Is there no objection to 391 being used for that article?

MS. WILLIAMS: I don't have an objection to the exhibit, but I just want to make clear for the record that the Agency needs to have copies of every exhibit as part of what we submit to the U.S. EPA when a rulemaking is final. So as long as counsel agrees to make sure we are given copies of anything that does not have enough copies for us to get today I have no objection.

MS. ALEXANDER: We will absolutely make sure.

HEARING OFFICER TIPSORD: And I would note, too, that anything that is entered as an exhibit we can scan and have available very quickly as well.

MS. WILLIAMS: Would you prefer that we request with the clerk which ones we don't have?

HEARING OFFICER TIPSORD: I'm just

saying if you miss one, that's another way for you to get them because I understand the predicament you're in, so.

MR. ANDES: I would like to see copies at this time if I can.

MS. ALEXANDER: Sure.

HEARING OFFICER TIPSORD: The second article is High Sensitivity of Children to Swimming Associated Gastrointestinal Illnesses - Results Using a Rapid Assay of Recreational Water Quality, same authors; looks like Timothy J. Wade, Rebecca Caldron. This is May 3 -- May 2008, copyright Lippenpot, Williams, and Wilkes. If there is no objection, we'll reserve Exhibit No. 392 for this article. Seeing none, we'll reserve 292.

MS. ALEXANDER: So while he's reviewing, you can resume testimony.

THE WITNESS: Can I have it back so I can finish answering your question?

MR. ANDES: I'm sorry. I didn't know you didn't have any copies.

MS. ALEXANDER: I didn't know those

would be presented today. My apologies.

DR. GORELICK: So you asked about what confounding factors they looked at. Things that they thought to consider were age, sex, race, contact with animals, contact with other persons with diarrhea, number of other visits to the beach, any other chronic illnesses, digging in the sand, consumption of raw meat, fish, or undercooked eggs, use of nose plugs. So those are, at least in these two published studies so far from the NEEAR, that's what they've looked at.

BY MR. ANDES:

Q. I'll ask you a question then based on an exhibit we used yesterday. And I do not recall what number. This was the list of 19 potential confounders.

HEARING OFFICER TIPSORD: 388.

BY MR. ANDES:

Q. Dr. Gorelick, this is a list of potential confounding factors that have been identified as potentially significant in the CHEERS study. Am I correct that a lot of the same factors are listed here as were identified in the NEEAR

studies?

A. Yes. Many of them are the same.

Q. Thank you.

MS. ALEXANDER: Can I ask a follow-up question? Dr. Gorelick, have you ever been involved in an epidemiological study in which socioeconomic status was considered a confounding factor?

DR. GORELICK: Yes.

MS. ALEXANDER: And when you considered socioeconomic status, did you ask participants individually what their income was?

DR. GORELICK: We've done it several ways. But the best way to do it is to actually find out what their household income is. Sometimes people use, for example, zip code and you can look at the median income for that zip code. So if I live in zip code 53213, I know what the average household income is. But, of course, not everybody in that zip code has the same -- people live on one side of the town versus the other, people who have different incomes. So that tends to

reduce the amount of information you have. And so, again, a study that we're currently finishing writing up looking at bottled water use. We actually asked them about their income so that we didn't get -- would have a better sense of what their socioeconomic status was.

BY MR. ANDES:

Q. Were you asking them in a private setting?

A. Yes. In a written survey we asked them.

Q. Not at a public beach?

A. They were in the emergency department. They had to check a box on a form.

Q. Okay. We have a series of questions about various possible confounding factors. And rather than go through each of them individually, I'll try to ask these all as one question and let you respond. And I think these are Questions 20 through 27.

We've identified a number of possible confounding factors including year of enrollment, season, gender, age, race, or ethnicity,

water activity, duration of activity, and post-activity behavior.

And the question is whether you've been involved in studies that have looked at these confounding factors; and, if so, if you could explain how they were addressed.

A. Sure. With the exception of the last two, duration of activity and post activity and behavior, I guess those were not relevant to the studies we were doing. I have been involved in studies that have examined all of the others as confounders. And, again, one study in which we looked at all of those was the study of water and diarrheal illness that I just referred to.

So, you know, again, the concept of confounding is if I try to compare people who either, for example, use one waterway versus another or people who come to the emergency department for diarrhea versus for something else, there are a lot of things about those people that are different. One of them might be the thing I'm interested in in our study, the type of water they drink. But there are lots of other things that might be different about them that could also explain whether they got

sick. And so if I simply compared everybody in one group with everybody in the other, I might find that they were different with regard to, say, what kind of water they drank. But it wasn't -- They were also -- it was actually all the other things that are related to water that they drank. For example, we found in our study that minority of patients are more likely to drink bottled water. So we also know that in our area that's -- they're also more likely to get sick. So if I attributed it to the water, it might not be because of the water. It might be because of their racial ethnicity. So in order to be able to account for that in an epidemiologic study, two things have to happen: First is they have to think of that confounder in the beginning. There are a lot of things I might think about. Of course, there's limits practically of how many questions I can ask. So there may be things I think about, but I think, well, I'm not really sure that's so important and not ask about it. But I have to think about it. I have to ask about it and collect the information on it. And then I have to, when I analyze that data, do it in a way that takes into account those differences. And the most common way

for doing that is a mathematical modeling technique. It's called logistic regression modeling. And what that allows me to do is to say if I take all of the other things into account that I asked about: Age, race, how many kids at home are sick, et cetera, and I just want to look at the water use, what's the effect of just the water use? That does a pretty good job of adjusting to the confounding. It, of course, don't do anything about confounders that I didn't think about and ask about and/or include in my model. And it also -- it's -- although it's a very good technique and it's certainly the gold standard and I use it all the time, I also recognize that it doesn't completely eliminate confounding. It is just a model. So there's always the possibility of some residual confounding even if we do that. But that's the general way that I and others who are involved in these, including, as I understand, the CHEERS study will be addressing these confounders.

Q. Okay. Is it accurate to say that you start out with a list, a broad list, of possible confounding factors that you draw based on your own judgment and experience, an then you narrow that

down based on consideration of various factors? Say, including, let me suggest, biological plausibility would be one thing you would consider in determining whether something is likely to be confounding factor or not?

A. Sure. So that's one of the things you might take into account in generating your list. Some of it is what's already been published in the literature, what other people have found. It's a little tricky. So let's say I think of 20 things and I ask about 20 things. And I think, gee, 20 things is a lot to include in a model, because in one of the issues that comes up is the more things you try to include in your models, the more margin of error you introduce into your results. Sometimes it becomes -- and you -- sometimes if it overwhelms the model, you cannot even run it. So you have to be careful there. On the other hand, what is frequently done, and I'm guilty of having done this myself, recognizing the controversy, is it's tempting to look at a confounder and say, well, in our study population, it didn't look like that matters. Because, for example, if I looked at time of year, people seem to get sick at about the same

rate at different times of year. So I'm not going to include that in my model because I don't think it's a problem. The issue there is it's not a simple yes, no, or there's -- these factors can interact with each other. And the problem with confounding is it can make it look like there's an association that's not really there or it can make it look like there's not an association that's really there. If in my raw data I just look and I say people seem to get sick as often in May as in August, I'm not going to include that in my model. That, in itself, might have been confounded. And so there's a lot of controversy in this statistical epidemiologic literature about how you do that. In general it is recommended that if you have the sample size to include confounders you should include them even if that first pass that what we call the uni-varied analysis, one variable at a time, doesn't seem to suggest something for that very reason. So, again, there's practicalities of -- I mean there's considerations of practicality, how many questions can you ask, how many things can you include in your model. Sometimes you have to make those choices. But it's generally considered

more rigorous and better to include things that might make sense even if your first pass suggested it doesn't.

Q. And in terms of the, say, if we focus on the studies identified earlier in health risk, could each of those look at confounding factors?

A. Some of them did. You know, as I mentioned earlier, there are different types of epidemiologic studies, sort of a -- almost a hierarchy. So, again, the best thing to do would be to be a completely controlled experiment. That's how you could get the best evidence that this causes that. You take genetically identical rats and you subject some of them to one thing and some of them to another. But we can't take genetically identical humans and randomly subject them to things that might be harmful. So we figure out ways to try to get at the answer. Prospective cohort study is one. That's sort of the top of the pyramid recognizing limitations that I just mentioned of confounding, for example. Some of these studies that we did are what are called ecological studies where you're really only looking at one factor. You recognize that there might be confounding, but you don't take

it into account. The reason is because they're easy to do and they're often the first pass to see if there's an interesting question. So an example of that that might sound familiar to you all is studies that look at people who live in Finland where they eat a the lot of fish don't have a lot of heart disease. People who live in another country where they don't eat a lot of fish have heart disease. So, yes, there are a lot of differences between Finland and Mexico other than how much fish they eat. But when you look at a bunch of countries over that, you say, maybe there is something to this fish hypothesis. I should do more rigorous studies to address that. So some of the studies that I've been involved in are ecological studies where we very deliberately do not look at confounding factors as a way of saying, gee, are we on to something here. You had mentioned, for example, the rainfall study. That was an ecological study. We would not look at confounding on that because we didn't measure those. But the question is are we on to something here? Should we do a more rigorous prospective cohort study to figure out whether there's something to it and that's in fact what we're currently doing.

Q. You're referring to the study, the association between rainfall and pediatric emergency department visits?

A. Yes. The one you had asked about previously.

Q. Okay. So in that study, the study team did not consider confounding factors, but recommended a follow-up prospective cohort study to look at those issues; is that correct?

A. Correct.

Q. So when that study concluded -- well, did that study conclude that there was a significant association between rainfall and pediatric emergency visits for acute GI illness?

A. Yes.

Q. And that was a conclusion sufficient to recommend a follow-up study to confirm the results; is that correct?

A. That's right.

Q. In the other epidemiological studies you've been involved in, can you estimate how many confounding factors have been included? Is there a range?

A. Yeah. I mean sometimes it's as few as

two or three. Sometimes it's seven or eight. When we did our study of CAT scans -- because we had -- the number of confounders you look at is somewhat depends on the sample size. So we looked at about 35 factors in that study in a model because we had 42,000 patients. So we were able to do that.

Q. And in that study, in terms of how you address those factors, was that where you would have utilized the logistic regression analysis?

A. That's right.

Q. And that's the way you would address those factors to determine whether they influence the results you were seeing?

A. That's correct.

Q. Is that the maximum number of confounding factors you've addressed in a study?

A. Yes.

Q. In his testimony, Dr. Dorevitch stated that the analysis of health risks of an incidental contact water recreational activities including consideration with the multiple factors must be considered when describing relationships between key variables would be conducted in the future. Is that your understanding?

A. My understanding is yes, they're going to do logistic regression and other analyses to adjust for that.

Q. So that would account for differences such as age, underlying health conditions, the other factors that are listed on that page that I gave you earlier?

A. Again, to the best degree possible with logistic regression modeling which is good, but not perfect, yes.

Q. Have you ever been involved in an epidemiological study that addressed information bias?

A. You have a few questions here about bias, and bias is -- so, again, the best way to determine whether A causes B is to do a perfectly controlled experiment. And in that situation then you could come up with an incorrect result. You could find some -- you could conclude that A causes B when it doesn't really, mostly due to just statistical chance. You know, you happen to, by bad luck, pick five rats that were kind of unusual. So in an epidemiologic study we also have the problem of chance error, but then there's the problem of

what we call systematic error. One form of that is confounding, we've already talked about, and another is bias. So bias is where there is something about the way that your study is either designed or conducted that is giving you the wrong information, the wrong inputs, and, therefore, you get the wrong output. So one form is information bias. I ask people questions. I don't get the right answer. When that happens, I might draw false conclusion. If people tell me, for example, that they don't fall in the water when they do, I might conclude that people don't get sick from falling in the water because they didn't know they fell in the water. If people tell me they didn't go have a hamburger at, pick your favorite place that doesn't cook its hamburgers well enough, after they went to the river, but they did, I'll have the wrong information. So every study has the potential for -- every epidemiologic study has the potential for information bias. The question is how likely is it, what do you do to minimize it? And unlike confounding, you can't really in general do anything about it after the fact. All you can do is wring your hands and say this could have crept in. And

that's one of the factors that you could call attention to and say every epidemiologic study has a little section about the limitations of the study. One of our limitations is this. So one way of minimizing information bias, for example, is to, when you're doing a survey type of study, is to do a prior study where you validate that or you use a survey that somebody else has validated. So to the best of your ability you say, if I ask the question in this way, am I going to get accurate information? And there are a variety of ways of doing that kind of validation. But that would be one way of doesn't prevent information bias, but it gives you some assurance that at least the data that you're collecting is reasonably accurate. So, for example, in our study of water use and diarrheal illness, we did a prior study validating a survey about the water use and then we used that validated survey in our subsequent prospective study. Again, it's not a guarantee that the information we got is correct, but it's a step towards minimizing that information bias.

Q. So to the extent that the CHEERS study, for example, used questions derived from the

NEEAR study questionnaire, that would provide some assurance that those were questions that had been previously validated?

A. Again, that would be a helpful step.

MS. ALEXANDER: Follow-up question on bias. Is it your view that -- is bias in a recreational water study more likely to overestimate or underestimate risk as a general matter?

DR. GORELICK: Well, one of the things about bias is that it's often difficult to predict the direction, but sometimes you can. In information that's just bad information, people are -- to the extent that people are kind of guessing about things. So you ask them, you know, if I ask you how much -- did you drink coffee this morning? You'd probably give me a good answer. If I said did you drink coffee last Wednesday, how much? You might not give me a great answer. If I asked you a year ago, you probably won't have a clue, but you make something up. You might say, well, I usually have two cups a day, so you'd say two cups. And to the

extent people sort of just generally misremember things and tend to go towards an average, that will always tend to underestimate risk.

So most forms of this bias, especially information bias, will tend to underestimate risk and lead you to estimate a lower association or no association when there's really one there because all the people who go swimming or all the people who go in the CAWS answer pretty much the same way as all the people who go here because they're all just kind of remembering badly.

MS. ALEXANDER: Are you aware of any research that addresses the question as to whether races are likely to be over or underestimated?

DR. GORELICK: Well, specifically with regards to recreational water there is a study that was published in 1998, I believe, called Review of Epidemiologic Studies on Health Effects From Exposure to Recreational Water, and it was published in the International Journal of Epidemiology, 1998.

This was a review of the --

MS. ALEXANDER: Let me get this marked as 393. I'd like to offer that.

HEARING OFFICER TIPSORD: I've been handed Review of Epidemiological Studies on Health Effects From Exposure to Recreational Water, International Journal of Epidemiology, 1998. And I'm having a hard time finding authors. Annette Pruss (ph.). If there is no objection, we will mark this as Exhibit 393.

Seeing none, it's Exhibit 393.

DR. GORELICK: So this is a review of the existing studies and their study designs and potential sources of bias in these types of studies. And they go through reasons why you might have bias. And some of these -- so, for example, not controlling for confounders may under or may overestimate the effect. But the most common types of errors, the use of indicators for assessing water quality and the methods of exposure assessment as well as selection of unrepresentative study populations. So

selection bias. All of those will tend to underestimate. So their conclusion is that most of these studies will, in fact, tend to underestimate the risk rather than overestimate the risk.

BY MR. ANDES:

Q. Dr. Gorelick, if you ask people when they come out of the water whether they've been dunked in the water, they're pretty likely to remember fairly accurately at that point. Am I right?

MS. ALEXANDER: Do you mean if you ask them immediately after or if you ask them five days after?

MR. ANDES: I said when they come out of the water or within a half an hour after they come out of water, when they're at the beach. They're fairly likely to remember if they've fallen in the water. Am I correct?

DR. GORELICK: So in terms of what we call recall bias, did they remember it? Yes. They'd probably more likely remember it than if you asked them later.

BY MR. ANDES:

Q. And if we're asking people within, say, two to three days after going in the water whether they had gotten sick, acute gastrointestinal illness, for example, in the last two of to three days, fairly likely to remember if that's occurred?

A. All right. So one form of information bias which I started to talk about was called recall bias. Did you remember correctly. There are other forms of information bias. And information bias just means that the information you're getting is biased. It's wrong. Another type is what's called, for example, social -- has the same social desirability bias. When people are asking questions especially face to face, you might answer in a way that you think that person wants to hear. You might avoid embarrassing answers, for example. And to the extent to which what happens, again, can be hard to measure. That's not affected so much by the time since. That's affected by other factors. So, for example, there's literature out there that suggests that -- and I didn't do these studies. I'm just quoting them. That women are more likely to answer in a socially desirable way than men. It may be different at different ages. It may be different --

it's shown to be different in different racial and ethnic groups. It may have do with, for example, your -- what you're doing. You might be embarrassed to admit that you fell in if you think of yourself as a really good kayaker, for example. So those kinds of things also enter into -- it's another source of information bias. It's not going to be affected by whether or not, you know, you ask them right away or five days later.

Q. There is some speculation, correct, in terms of determining, well, how were they thinking about what's socially desirable? Well, because, and we talked about this yesterday, one might say -- well, someone might want to report that they got sick because then there'd be certain requirements imposed. Or they might say, I don't want to report I'm sick because I don't want to be limited in my access to the water body.

A. That's exactly right. So we know that there's plenty of literature showing that that happens. How it happens in a particular study or particular individual is often difficult to predict, which is why bias is such a problem. Because you can speculate either way. All you know is it does

happen. It happens in every study. And so you try to think about, well, if it happened in this study, what effect would it have? And to the extent that the way that you're collecting your information is subject to that kind of bias, the less strong, regardless of all the other elements of the study design, how carefully conducted, how large the study, when one is, first of all, as a peer reviewer reviewing the study; and, second of all, as a person reading this published study and using results of it, you know, again, there's epidemiologic studies that are not yes or no. They don't prove anything. They prove something more or less likely. Some of that is statistical likelihood, some of that is methodological likelihood. So if I read a study and I say, gee, they were asking people these questions. I might think about how this happened, you know. If they ask a year later, I'm not going to trust the results as much as if I asked right away. Is there the potential for social desirability bias? Did they try to address it at all? That's going to affect the results. So there's always some speculation. But one has to recognize it's always -- it happens in every study, it's always

possible, and you can't really do anything about it after the fact except try to minimize it by either asking the questions in ways that are less prone to it or something like that.

MS. ALEXANDER: And a quick follow-up on that. In the situations where you really can't address it through your analysis, do you generally acknowledge that bias in your study write-up?

DR. GORELICK: Yes. That would be the kind of thing that goes in that limitations section.

MS. ALEXANDER: And one other question regarding recall bias associated with questions regarding getting wet. You were asked the question earlier whether someone -- there was likely to be recall bias when a participant is asked whether they fell in the water upon getting out of the water. Is it your view that there could be recall bias when a participant is asked after a trip of several hours whether they got wet to a lesser degree?

DR. GORELICK: Well, sure. I mean if,

you know, because getting wet, falling in the water is pretty traumatic. You remember that. If somebody splashed you with the paddle, and the person in the back splashed you in the front. If it happened at the beginning of the trip, you might forget it by the end. So I mean those are all things to consider in these sorts of studies.

BY MR. ANDES:

Q. And recognizing the final report?

A. Correct.

Q. As to the studies, the seven epidemiological studies on health risks we talked about. Can you give us a sense of what the size of the population studied was in terms of a range, sort of smallest to largest?

A. Smallest, probably a couple of hundred subjects, up to, as I said, about 42,000.

Q. Okay. And in terms of margin of error, what kinds of margins of error did you identify in those studies? I don't know if that's a range again or --

A. Oh, sure. I mean the margin of error is related to the size of the study. The larger the

study, the smaller the margin of error. It also -- it -- Well, it's related not only to the total number of subjects, but also to how many have the thing that you're interested in. So, for example, with our study of 42,000 subjects looking at head injury, there are only a few hundred that had head injury. Because, fortunately, most kids who hit their heads do okay. That's the good news. That's why I like my job. But -- So when we're trying to estimate, for example, things about the kids with head injury, our margin of error is bigger. When we're trying to estimate things about the kids without head injury, the margin of error is smaller because there were very, very many more of them. There are other things besides the sample size that enter into the margin of error including how much variability there is in the population you're studying. So if you're looking at, for example, a very narrow age range or very narrowly defined population where they're much more similar to each other, you can have a smaller margin of error with a given sample size. Because just by sampling them, there's not that much difference. If you have a very diverse population from which you're sampling,

there's going to be more margin of error for a given sample size because there is more variability and you're more likely to pick a, quote, bad or unrepresentative sample with a given number because there's just so much more variation in there.

Q. Okay.

MS. ALEXANDER: Follow-up on that. In determining how much significance to attach to a study with a larger margin of error, would you consider previous research? And if so, how.

DR. GORELICK: Yeah. So, you know when you're designing a study and you're figuring out how many people do I need to enroll in this study, there is always the practical things of how many can I enroll. How many people are out there who recreate on the CAWS or how many people are out there who hit their heads, or how many people are out there with some rare disease. Sometimes you're constrained by that. There's also a practicality of how much money do I have to do the study, because these cost a lot of money. But really from a scientist's

perspective, how many people do I need, that means is how big a margin of error are you willing to accept? So couple of things to consider: One is how serious is it? Okay. If it's something where you're talking about people dying, you'd rather have a small margin of error because that's pretty significant and a small difference might be really important. If you're talking about, you know, somebody having a rash, you might accept the larger margin of error. If there's already things in the literature that you can compare to, because, again, no one study can prove anything. You're trying to take the totality of the evidence out there. So frequently you're not the first study to do something. You might be trying to confirm a prior study. Well, if another study found that -- or two other studies found this and I'm trying to confirm it, I might accept a larger margin of error, because I'm just trying to show it's in the same ballpark. Now we have a third or a fourth or a tenth study that's showing a similar thing.

So the novelty of it, you know, whether there's other evidence to support it, whether or not you're interested in subpopulations within your study. Because if you are, then you have to take that into account when you design your study because the margin of error for the whole study, it's going to be bigger for each subgroup. And the smaller the subgroup, the wider the margin of error. So those are all things that you have to take into account: Prior evidence, importance of the outcome, what it's proposing to be used for. So in clinical decision making, I'm trying to decide whether to order a test for a specific patient. I can accept the wider margin of error, because I can take a lot of other factors into account at that level. I can take into account their preferences, what else I know about them that's going to influence the risk, and so on. If I want to do something that's going to result in a guideline for everybody to use in clinical decision-making or a policy or a law, I want

smaller margins of error because I'm not -- there's not much of an allowance for that individual variation. So many clinical studies have much smaller sample sizes with larger margins of error because the context that we're going to use those results in. When we did our CAT scan study, we were -- there were already a bunch of studies out there. They were all relatively small with wide margins of error. We wanted to be able to find something that was consistent with them but could be large enough that it could, when added to those others and showing consistency in results, potentially drive a guideline; wouldn't do it by itself, but consistent with the existing literature.

HEARING OFFICER TIPSORD: Mr. Harley, you have a follow-up?

MR. HARLEY: I wanted to ask a follow-up. By the way, my name is Keith Harley. I'm an attorney with the Chicago Legal Clinic. About the influence of the severity of the impact in determining the margin of error. And you mentioned that if

there were the risk of people dying that you would want to actually define a much smaller, more precise margin of error. Did I characterize your testimony correctly?

DR. GORELICK: Yes. So the -- You can look at severity in a couple of ways. One is the severity for an individual person. Dying is worse than a rash. You know there's severity on a population basis. If it's something that may not be very severe but could potentially affect very large numbers of people, that margin of error you might want to be smaller. Because a, quote, minor illness over thousands of people, you know, so it causes you to miss a day of work, for example. So if I miss a day of work it's not a huge deal, but if thousands of people miss a day of work, that's a big economic impact. So I might want to find something that would cause a small reduction in that because lots of people involved. So there's individual severity and there's social severity, if you will. Does that make sense?

MR. HARLEY: Yes. Thank you. In

terms of severity and potential health outcomes for children, what are the potential outcomes of GI illness?

MR. GORELICK: So most GI illness is limited, doesn't need to be treated, goes away on its own over a period of days. It's a symptomatic burden. Most of -- and currently we've just put an application to do a study of intervention to reduce the severity of GI illness. The primary justification for that is in the end economic and social because on average children with gastroenteritis miss typically three days of daycare and parents of those children miss a day or two of work. So, you know, people don't tend to die of gastrointestinal illness. But it has a morbidity to it in the form of symptoms. They feel bad, they buy more diapers, they're -- or hopefully not in diapers if they're older; missing school, missing work, and there's a big economic impact.

MR. HARLEY: Are children more susceptible to negative outcomes of GI

illness than adults?

DR. GORELICK: Children who get the same infection. So, for example, a rotavirus is one common cause of gastrointestinal illness. Children with that infection will tend to have a more severe illness than adults with that same infection, if that's what you're asking. In terms of how long they're sick or how severe their symptoms are, likely that short-term complications such as lactose intolerance, there aren't a whole lot of long-term complications.

MR. HARLEY: What about respiratory infections? What would be some of the impacts or the severity of the impacts of respiratory infection for children?

DR. GORELICK: So, I mean, again, on average, children with respiratory -- otherwise healthy children with respiratory infections will tend to have a more severe illness than an otherwise healthy adult in the form of their likelihood of being hospitalized, the duration of their symptoms, the severity of their symptoms and so on.

MR. HARLEY: And what are the --

DR. GORELICK: I'm putting the caveat in there. And the same is true of GI illness, otherwise healthy. Adults are more likely to have other health problems. An adult with cancer is going to be probably sicker than an otherwise healthy child. But if you take a healthy 35-year-old adult and a healthy five-year-old child, the five-year-old child is probably going to be sicker.

MR. HARLEY: In terms of respiratory infection, what are some of the potential health outcomes for a child as a result of developing respiratory infection?

DR. GORELICK: Well, acutely, their -- unlike gastrointestinal infections, respirator infections do have some risk of mortality. Fortunately quite low, but some of them can be fairly severe. Again, there is the risk of hospitalization, duration of symptoms. Long-term outcomes, there is some association between some respiratory infections and the development of asthma, for

example. And that seems to be something that is, if not unique, that's far more common in young children than it is in adults.

MR. HARLEY: What about ear infections and the severity of ear infections in children in terms of health outcome?

DR. GORELICK: So, again, most ear infections are relatively minor. But children with repeated ear infections are at risk of hearing loss requiring surgery in the form of tubes to prevent ear infections, and rarely infections of the bone of the skull next to the ear that can cause more severe outcomes.

MR. HARLEY: Is a child who recreates in waters with elevated levels of pathogens at greater risk of developing gastrointestinal illness?

DR. GORELICK: There is a higher risk in children from recreation. One of the NEEAR studies that we entered, I think it was 392, it's called High Sensitivity of Children to Swimming Associated Gastrointestinal Illness, was one of the studies that showed

that. There are a few things about GI illness in children in recreation. One factor is they just are more likely to, with regard to swimming at least, go in the water for longer. But with regard to all forms of this, if they're exposed to water, they proportionately swallow more water than adults do. So if your risk of getting sick is related, in part, to how much of something you ingest, their risk is increased. They're also more susceptible to those infections because of relative lack of immunity to those pathogens. And so there is two reasons why children are at higher -- at least two reasons why children are at higher risk of recreational water associated illness than otherwise healthy adults would be.

MR. HARLEY: So just to wrap this up, Doctor. If you were evaluating the potential health outcomes of children recreating in waters that are undisinfected, you would want to have more precise margin of error.

DR. GORELICK: More precise -- well, more precise than what?

MR. HARLEY: As opposed to less precise.

DR. GORELICK: Right. So I think the point is that if you have a group that's at a special risk such as children, you'd want to be able to say as much as possible about them in the form of having a narrow enough margin of error that when you establish your result, a clinically important difference. So, for example, if the risk -- say I would be interested in knowing if they were 50 percent more likely to be sick if they were on this waterway than that. Because that's important. There are a lot of kids. We talked about the health outcomes. So a 50 percent increase would be an important increase to know about. You need to design your study so that the margin of error for that group of children is sufficient so that if there is really a 50 percent increase, you would identify it as opposed to saying, gee, we found a 50 percent increase, but it's not statistically significant because our margin of error is too wide; and, therefore, we

would conclude that there's no association. All you can really conclude is there is no association within that margin of error, but that margin of error includes the thing that you think important, then that's not sufficiently large. I hope that makes sense.

MR. HARLEY: Thank you, Doctor.

MS. ALEXANDER: While we're on the subject, I have some follow-ups regarding sensitive populations.

Would you say, as a general matter, that both young children and pregnant women would be considered sensitive populations from an immunological standpoint?

DR. GORELICK: They have both been considered to be susceptible populations with regard to environmental risks of infectious diseases.

MS. ALEXANDER: Are you aware of scientific literature that backs up that conclusion for both populations?

DR. GORELICK: Yes.

MS. ALEXANDER: I'm showing you an article by Charles Gerba, et al., entitled

Sensitive Populations - Who is At Greatest Risk. Have you seen that before?

DR. GORELICK: Yes, I have.

MS. ALEXANDER: Are you aware that Mr. Gerba was one of the district's witnesses in this proceeding?

DR. GORELICK: Yes.

HEARING OFFICER TIPSORD: I've been handed Sensitive Populations - Who is At Greatest Risk, International Journal of Food Microbiology from 1996. The authors are Charles Gerba, Joan Rose, and Charles Hobbs. I'm assuming you want this marked as an exhibit?

MS. ALEXANDER: Yes, we do. I'm sorry. Exhibit 394.

HEARING OFFICER TIPSORD: If there's no objection, we'll mark as Exhibit 394. Seeing none, it's Exhibit 394.

MS. ALEXANDER: And what did Gerba, et al, conclude in this article concerning sensitive populations?

DR. GORELICK: Again, they were looking specifically at waterborne and

foodborne illness, intestinal enteric illness. And their conclusion, based on reviewing of the literature and other things, is that the sensitive populations are the very young, pregnant women, the elderly, and immunocompromised individuals.

MS. ALEXANDER: And did he indicate whether -- what percentage of the population did he indicate were immunocompromised approximately?

DR. GORELICK: He estimated about 20 percent of the population would fall into one of those categories.

MS. ALEXANDER: Did they estimate that would likely increase or decrease in the future?

DR. GORELICK: Increase.

BY MR. ANDES:

Q. Now, when -- Let me clarify something. We just talked about immunocompromise. You're not saying immunocompromised people are 20 percent of the population?

A. High risk subpopulations are 20 percent.

Q. And as to the immunocompromise such as people on cancer drugs, et cetera, I'll ask you the question I've asked several other medical doctors here: If an immunocompromised person came to you and said I'd like to go kayaking in a water body with bacteria levels, would you suggest they not do that?

A. As I mentioned the last time I testified, I would like to be able to advise them that they should be able to go recreate in the waterways, that they should not be placed at high risk.

Q. That didn't really answer my question.

A. I would advise them that the water was probably dangerous for them and that's a shame.

MS. ALEXANDER: Which water are you referring to?

DR. GORELICK: The water in the river.

MS. ALEXANDER: The river at issue in this proceeding?

DR. GORELICK: Correct.

MS. ALEXANDER: Okay. I have a few more follow-ups.

HEARING OFFICER TIPSORD: I actually

have a follow-up. Then you would, that same population, you would feel comfortable telling them it's okay to recreate in Lake Michigan?

DR. GORELICK: You know, fortunately we have some monitoring. So I, you know, the level of risk in the water body is going to be associated with the water quality. So my understanding is other -- depending on where you are in Lake Michigan and what the weather conditions and so on, there are times when they could recreate there and there are times when they could not.

HEARING OFFICER TIPSORD: Thank you.

MS. ALEXANDER: I also wanted to follow up by showing you an article also with Dr. Gerba as an author entitled risk of waterborne illness via drinking water in the United States. Have you seen this?

DR. GORELICK: Yes.

MS. ALEXANDER: I'd like to have this marked as Exhibit 395.

HEARING OFFICER TIPSORD: Risk of Waterborne Illness Via Drinking Water in the

United States, Springer 2008, authors are Kelly A. Reynolds, Christina D. Mina, and Charles Gerba. If there is no objection we'll mark this as Exhibit 395.

MS. WILLIAMS: Can we get some foundation about why a drinking water article is relevant?

MS. ALEXANDER: It's the same line of questioning generally concerning who constitutes a sensitive population for immunological purposes.

MR. ANDES: I have to raise one general concern which is I think we're getting very close to direct testimony here. I'm almost done with my questions and counsel for the proponent here has been asking more questions than I have. My concern is we're getting direct testimony in through follow-up questions, which I don't think is legitimate.

MS. ALEXANDER: I think asking more questions that you have is a bit of a stretch. And this question regarding sensitive populations has come up very directly, and we're responding to it very

directly. I don't have a lot more. I just want him to address the issue that was addressed in testimony today and repeatedly in both the testimony of Dr. Gorelick and Dr. Dorevitch, this question of who is a sensitive population. It is critical to this proceeding, and I want to get complete testimony on the record about it. And it's not going to take much longer.

MR. ANDES: That's not -- I didn't ask questions about that. So you're --

MS. ALEXANDER: They are in your prefiled questions about it.

MR. ANDES: I haven't asked that question here.

MS. ALEXANDER: Well, it's in your prefiled questions.

MR. ANDES: How is it a follow-up question to anything I've asked?

MS. ALEXANDER: It's a follow-up question to things that you presented to this panel that you're going to be asking. And I think that this is a little bit more discussion than really is required for an

additional three minutes of questioning.

HEARING OFFICER TIPSORD: I'm going to allow the questioning. I think it is in response to questions that were asked yesterday. I understand it's probably closer to direct testimony than cross-examination, however, this is a rulemaking process, everything relevant is allowed. And since we did have direct questions to Dr. Dorevitch yesterday about what he considered a sensitive population, I think it important to find out what Dr. Gorelick thinks is a sensitive population. And I understand the experts don't necessarily agree. And with that, I'm going to mark Exhibit 395 and enter it into the record. And go ahead.

MS. ALEXANDER: And, Dr. Gorelick, what was concluded in this article that we've just marked as Exhibit 395 concerning who constitutes a sensitive population?

DR. GORELICK: Similar to the other article: The elderly, the very young, chronically ill, people with immuno suppressive therapies and pregnant women.

And, again, they estimate 20 to 25 percent of the total population, and, similarly, we have a table breaking that down.

MS. ALEXANDER: Okay. And the last item I'd like to show you is this article here from the CDC. Have you even this before?

DR. GORELICK: Yes.

MS. ALEXANDER: I'd like to have this marked as 396.

HEARING OFFICER TIPSORD: I've been handed Water Recreation and Disease Plausibility of Associated Infections, Acute Effects, Sequelae and Mortality, Kathy Ponn, World Health Organization in 2005.

We'll mark that as Exhibit 396 if there is no objection.

Seeing none, it's Exhibit 396.

MS. ALEXANDER: And, Dr. Gorelick, what does the WHO conclude about who constitutes a sensitive population?

DR. GORELICK: So, again, based on all of the existing literature concluded that similar list of groups, as I just mentioned:

Those with various immuno suppression, pregnancy, and age.

MS. ALEXANDER: Is it your opinion that it is well-established in the literature that young children and pregnant women constitute sensitive populations?

DR. GORELICK: Yes. I would say that that it is well established.

HEARING OFFICER TIPSORD: Can I have you clarify young children? Under six, under ten?

DR. GORELICK: This particular study from this high sensitivity of children, associated illness I mentioned, looked at ten years and younger. So within that group whether there's a higher higher risk group is a little unclear. There's not a lot of kids ages one, two, and three who are out on boats. But, in general, the younger the child the less immunity they have to these things and the more likely they are to get sick when exposed to them.

MS. ALEXANDER: Lastly, I wanted to present to you an article entitled Water

Ingestion During Swimming Activities in a Pool, and ask you is this a research that supports the conclusion that children are more likely to swallow water during recreational activities than adults?

DR. GORELICK: That they swallow more water.

MS. ALEXANDER: Yes. I'd like to present this as Exhibit 397.

HEARING OFFICER TIPSORD: If there's no objection, this is an article by Alfred Dufor, Otis Evans, Thomas Payner, and Riccardo Kantu (ph.), and this is from 2006. If there's no objection, we'll mark this as Exhibit 397.

MR. ANDES: The only comment I'll make is I'm pretty sure this and at least one of the Gerba studies we submitted as exhibits earlier just --

HEARING OFFICER TIPSORD: I think you're correct.

MR. ANDES: I'm pretty sure we submitted them already.

HEARING OFFICER TIPSORD: I think

you're correct. I think this one, in particular, rang a bell. But just to be on the safe side, we'll go ahead and mark it as Exhibit 397.

MS. ALEXANDER: My apologies if it's already in there. Can you summarize briefly what this study concluded?

DR. GORELICK: They had people of various ages swimming in a pool that had a chemical indicator in it so that they can -- instead of asking how much water they swallowed, they could actually measure by getting urine samples how much water they had swallowed. And in the -- they were asked to swim for 45 minutes or more, and the children swallowed on average 37 milliliters which is about an ounce, and the adults swallowed a little bit less than half of that or 60 milliliters. So about twice as much for the nonadults as the adults.

MS. ALEXANDER: Thank you.

BY MR. ANDES:

Q. So these studies are all about

swimming activities?

A. This particular one is about swimming, yes.

Q. And the studies you've submitted here so far seem to be primarily either drinking water or ingestion during swimming, correct?

A. Depends on which one -- what are you referring to? Which studies are you referring to?

Q. The Reynolds, Mena, Gerba studies, Risk of Waterborne Illness Via Drinking Water?

A. Correct.

Q. This one is Water Ingestion During Swimming Activities in a Pool?

A. Right.

Q. To your knowledge, is there anything here that deals with secondary contact specifically?

A. Well, most of these are concluding susceptibility to waterborne pathogens. So if there's exposure to a pathogen, are they at greater risk of getting sick. This swimming study about the swimming pool suggests also that children are more likely to be exposed because they swallow water. So two separate questions. You could -- one could postulate that being in water in a pool isn't the

same as being water falling out of a boat, although you could argue they might be. But in terms of the underlying susceptibility to being sick from a waterborne pathogen. If there's Germ X in the water and you're exposed to it, how likely are you to get sick? That shouldn't matter whether it's drinking, swimming, fishing, or anything. That's an immunologic phenomenon that shouldn't vary depending on what the source of that waterborne pathogen is.

Q. So that would stay the same but the exposure levels could differ?

A. Right. So one line of arguments is that these are populations that are at higher risk of because of who they are. If they have the exact same amount of water exposure, they'd be at higher risk. There's also a line of argument that shows, at least the one setting where it was feasible to do, because I don't know of anybody who's done a study where they intentionally tip people out of boats to see how much they swallow. Although one could, in theory, do that. But if you put people in a pool with chemical marker, that children swallow more water so their exposure is higher. And even if the exposure is the same, they're at higher risk.

So these studies that are related to drinking water, for example, are relevant because they're not about how much water you get in or how you get exposed. It's if it gets into you in any way, shape, or form, are you more likely to get sick from it? And are you more likely to get more severely sick from it.

Q. Are you more likely than another population to get a more severe infection?

A. Correct.

Q. Okay. Which doesn't deal with the issue of differing exposure scenarios and whether you're more likely to get -- and whether you are more or likely less to get sick in a given scenario?

A. What it deals with is if you have a given exposure, however you get it, you're more likely to get infected. And if you get infected, you're more likely to have severe illness.

Q. Now, are all those studies dealing with both issues: A, you are more likely to be infected, and more likely to having a severe infection?

A. There's a combination of those.

Q. And as to the different, quote, sensitive, unquote populations we're talking about,

the risks are different. Would one say that immunocompromised adult --

A. You couldn't lump them all together.

Q. An immunocompromised adult would not be more likely to swallow -- more likely to swallow more water than an otherwise healthy adult?

A. Not being someone who takes care of adults, I don't know the answer to that. I can imagine reasons why that would be true, but it would be speculation.

Q. Could be more or less. But there's nothing in here indicating the exposure scenarios --

A. Correct, correct. The exposure scenario is looking just the children. The immunologic risk is looking at all of them. But those immunologic risks are going to be different. So a pregnant woman is going to have a certain immunologic risk, someone with cancer on chemotherapy will have a different increased risk, a child will have a different increased risk.

Q. Okay.

HEARING OFFICER TIPSORD: Let's take a ten-minute break if you're done with that line of questioning.

(Short break taken.)

HEARING OFFICER TIPSORD: Are we ready to go back on the record? Back on the record, Mr. Andes.

BY MR. ANDES:

Q. Couple of follow-up questions, Dr. Gorelick. Some of the reports from the NEEAR study have been introduced. Are you aware of subsequent paper from the NEEAR study looking at risks from ingestion on the beaches of sand by children versus ingestion of water?

A. I have not seen that.

Q. Okay. We will make a copy of that report. We will file a copy of that report with the Board looking at risks from sand ingestion versus water ingestion.

Also, and this is something we could ask Dr. Dorevitch to talk about. But there is a further report that will be made available in the NEEAR future from the CHEERS study that will be relevant. This study, Dr. Gorelick -- and you haven't seen it yet, so you can't really react to it. But assume for a moment this study, this report will specifically look at risks in terms of what are

the exposures, primary and secondary contact, in a pool, a person swimming in a pool, a person kayaking in a pool, people sort of quasi fishing in a pool versus doing all those things in an actual water body. I assume that would be a relevant -- that information would be relevant to looking at the exposure scenarios and the amount of ingestion and the effect that would have on risk.

MS. ALEXANDER: Is that a question?

BY MR. ANDES:

Q. Would that be relevant in looking at what the bottom line risks are here, particularly because some of the studies we're talking about specifically relate to swimming. So if we had a report that dealt with exposure scenarios to swimming, kayaking, et cetera, direct comparisons including pool versus river, is it your sense that would be relevant information here?

A. I guess I'm a little bit unclear about what you're saying the study would look at. So I'll just tell you it says if you're kayaking in a pool, which I don't know who does that, but let's say you're doing it for experimental purposes. You have someone kayaking in a pool, they get exposed to "X"

amount of water. But if they're kayaking in a river they're exposed to "Y" amount of water?

Q. Right. And the same for, say, direct contact children and adults.

A. Boy, I'm -- I assume one is doing it for a reason. I'm just having trouble figuring out how that would fit in.

MS. WILLIAMS: Relevant to what? I don't understand your question.

DR. GORELICK: It's a little hard for me to figure out from what you're asking without actually seeing it and being able to comment on it to know how I would use that information, how one would use that information in regard to, I assume, you mean in regard to the CHEERS study?

MR. ANDES: Well, to clarify, I can certainly ask a question of Dr. Dorevitch to explain what that report is going to be.

HEARING OFFICER TIPSORD: Go ahead.

MR. ANDES: Dr. Dorevitch, could you explain?

DR. DOREVITCH: Sure.

HEARING OFFICER TIPSORD: And I note

that Dr. Dorevitch was sworn in yesterday and he's still under oath.

DR. DOREVITCH: I didn't know I've been under oath this whole time. It never goes away. Will I be released from this oath at some point?

The study, I don't remember the exhibit number, but one of the papers that Dr. Gorelick just talked about Dufor 2006, the swimming pool study; people, adults and children, were in a swimming pool. Cyanuric acid a tracer of swimming pool exposure was measured in the pool water and in the urine samples of children and adults who used the pool and they were able to calculate how much water people swallowed while swimming. And like Dr. Gorelick said, children swallow about twice as much as adults in a swimming pool while swimming. The university conducted a similar study where, in fact, people in canoes and kayaks were in park district pools with cyanuric acid in them which is the standard. That's in all outdoor swimming pools. And some

capsized, some didn't. And then, again, we collected urine samples and were able to calculate how much water people swallowed during limited contact activities like canoeing and kayaking and also simulated fishing as well as swimming. So that provides some basis for comparing how much water people swallow during limited contact recreation versus full contact recreation. And I think the point that Dr. -- that Mr. Andes was making about swimming pool versus river is that the questionnaires that the study participants answered at the pool were identical to the ones that were answered in the Maimster (ph.) study of rivers and Lake Michigan. So that it is possible to differentiate when people are in a protected environment like a swimming pool with life guards all around, do they -- if they're canoeing or kayaking behave different? Did they capsize more or less often? Did they swallow more or less water? And, again, the same questions that Dufor asked about do you -- are children more likely to swallow

water or do they swallow more water than adults. Those are the research questions that that study addressed.

DR. GORELICK: So one question one could look at, for example, if you asked people in the pool where you could actually measure. This gets to that validation question. So if they say they swallowed "X" amounts of water, you could see if they're answering that accurately and you could potentially identify how much information bias you have in the larger study. Recognizing that my guess is it's not enormous numbers of people that went kayaking in the pool. I don't know what the sample size is. But it's -- they measure urine. And does that include children as well as adults?

DR. DOREVITCH: It was -- there were 685 people in the study across all recreational activities. And, yes, it was children and adults.

DR. GORELICK: So it included kayaking and simulated fishing?

DR. DOREVITCH: Right. All the activities -- well, swimming there weren't small, small children, but there were small children that were in canoes and kayaks.

DR. GORELICK: I hope they were wearing life jackets.

DR. DOREVITCH: They were wearing life jackets.

MEMBER JOHNSON: I'm interested in the simulating fishing. Were there simulated fish?

DR. DOREVITCH: There were little rubber fishies that they could cast and reel in. And every five minutes they were to change the lure and -- just like real life. In order to simulate the hand-mouth action they had snacks and drinks and as potential ways that -- as potential routes of exposure where getting water on your hands from fishing it can get in somebody's mouth. So that was the extent of the rubber fishies in the pool.

BY MR. ANDES:

Q. Let's go back to the seven

epidemiological studies we've been discussing. Did any of those address the clustering issue?

A. Yes.

Q. And how did they do that?

A. So the clustering issue, as I said in my testimony, it's a little bit of an obscure technical issue. But we went through the fact that you have to determine your sample size for study and that's based on a number of factors, how big or small a difference you want to be able to say something about, how willing you are to accept different types of mistakes that you can make. So when you do a study you might -- for example, you can make a mistake in one direction by finding in your study that something is associated with something else, in reality it's not. So you have a false positive result. I think there's something, an association that doesn't really exist, or you could falsely conclude the other way. You could do your study and say, gee, this doesn't look like it's associated with that. In reality, it is, but you fail to find it. And conventionally we accept more of a risk of the latter; that is, we're more willing to not find something that's really there or

underestimate the risk than we are to overestimate the risk. That's just scientific convention. But the other thing that enters into your sample size when you put it into your formula is how you do your sampling. So if it's truly a random sample -- so I do a poll and I call 1,000 people at random. The -- there's one formula for the sample size. If I, instead, sample groups of people, so instead of, for example, calling and asking one person I call and ask everybody in a household, or I go to a school and I sample everybody in a classroom, that's called clustering. People who are within a household or within a classroom are more likely to be similar to each other than the whole population is. And that affects the statistical power of my study. And I have to account for that in the analysis. So, for example, if I, in this study, if I go out and at an event and I say, okay, there is 100 people out there all for the same event. And I'm going to sample all of them, there are more things about them that are more similar to each other both clinically and statistically than if I picked 100 people at random out on the river. And you have to account for that in the analysis. And the way it's generally done is

when you do your model, the logistic regression model I talked about, there is a technique called -- one way there are several -- it's called a generalized estimating equation, and it gets very technical. But the idea is that it's taking into account the fact that I haven't really sampled 100 individual people. I sampled a group of 100 people who were all out there for an event. And those are different things.

Q. So then if the question is asked, if it's noted here in the information gathered that those people were all flatwater kayaking, then that factor is taken into account?

A. That could be accounted for.

Q. Okay.

A. And the general effect -- so for a given sample size, 1,000, 10,000, whatever, if there's clustering, it reduces the power of the study for that same sample size. So 10,000 completely independent study subjects is different from ten cluster -- 100 clusters of 100 study subjects.

Q. And the effect just depends on the specific situation?

A. Exactly.

Q. Okay. As to the issue of missing data, have you addressed -- that issue is noted in your testimony. How has that issue been addressed in the studies we're talking about, the seven studies that you've done?

A. Well, there are a number of ways with dealing with missing data. And, actually, I wrote an article on different ways of dealing with missing data and the effects that it has and biases it can introduce depending on how you deal with it. The most common way to deal with it is just to ignore it. Say we studied 10,000 people and there were 500 of them that didn't answer the question, so we'll just drop them. And when it's a really tiny percentage that might not matter, but even -- but it will still matter a little bit. It just won't matter a ton. If it was 5,000 it would make a big difference. So the most common way is just to forget about them. Don't have the information, I can't use them. And that generally introduces some degree of bias and, again, it reduces your effective sample size because -- for two reasons: People who don't answer the question may be different for the

people who did answer the question. So if you just don't include them you have a biased idea of what's going on. And the second is you thought you had 10,000 subjects and really you have 9,500. It's not a huge difference, but all these things add up. So first you account for your clustering and you do logistic regression with 20 co-variants and you have 500 people with missing data. Each of those eats away a little bit at your power and bit by bit increases the margin of error in the study. So you get bias and you get reduction of power.

Q. And the specific -- I'm sorry. The specific amount of uncertainty created really is going to depend on the numbers in terms of how many pieces of missing data?

A. It depends on the numbers. It also depends on why it's missing. So if it's missing completely at random, I lost the paper, then it doesn't introduce as much bias. If it's missing because, for example, I talked about social desirability bias there. Some people don't want to answer a question because they may not feel comfortable answering it. So they leave that piece of information out. Let's say it's the people who

swallowed the most water. I don't want to admit to this person that I swallowed a bucket of water, so I'm just not going to fill it out. Then you think there's less water being swallowed than there is. Those kinds of things can creep in. Data are very rarely missing completely at random. It's usually because of something about the piece of information. People at extremes tend to not answer as one example. Or it's tied with the thing you're looking at. So how much bias you get depends on how many people don't answer question and why they didn't answer the question.

Q. And you could, in terms of whether it's random or not, that's something you could assess?

A. It's hard to assess.

Q. You could assess is it always the same question?

A. Right.

Q. Does it seem like there are similarities in the people who are not answering that question?

A. Right.

Q. Other similarities, those -- some

aspects that could help you --

A. That's right.

Q. -- get a beat on it?

A. That's right. In general when you try to do that, the power to find that difference is relatively small. So you might go, gee, it doesn't look like there's a big difference and conclude that it's missing at random and it truly isn't. And, again, I've published on this and I've done simulation study that showed that. So missing data is a problem. So one way of dealing with it is just to ignore it. One way of dealing with it is to try to figure out what it would have been if they'd answered the question which definitely sounds like cheating. And I've actually long been a skeptic of that approach, but I've come around. There are, again, highly technical ways of trying to figure out what that information would have been if they'd answered the question and doing what they call imputing that data. I know they didn't fill it in, but if they filled it in it would have been a seven. And then you can put that in and that helps in your analysis.

So those are a couple of ways that

people deal with missing data.

Q. Okay.

A. They all have their problems. The best way to do it is just to avoid it.

Q. All right. I should go back for one moment in terms of the specific reporting discussed by Dr. Dorevitch. Just to note, I think I said this before but I want to be clear, that as soon as that report is final we will submit it to the docket and Subdocket B.

With that, I think I have no more questions.

HEARING OFFICER TIPSORD: Are there any other questions for Dr. Gorelick? Thank you very much. I think that's all the business we have today. And as I said earlier, I'll do a hearing officer order once the Board rules on the motion for Subdocket B and we'll set up a conference call at that point. Thank you everyone. Have a wonderful day.

(Which were all the proceedings had.)

* * * * * *

STATE OF ILLINOIS)
) SS.
COUNTY OF COOK)

I, LAURA MUKAHIRN, being a Certified Shorthand Reporter doing business in the City of Chicago, Illinois, County of Cook, certify that I reported in shorthand the proceedings had at the foregoing hearing of the above-entitled cause. And I certify that the foregoing is a true and correct transcript of all my shorthand notes so taken as aforesaid and contains all the proceedings had at the said meeting of the above-entitled cause.

Laura Mukahirn

LAURA MUKAHIRN, CSR
CSR NO. 084-003592