ORIGINAL

ILLINOIS POLLUTION CONTROL BOARD
JUNE 29, 2010

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	) R08-9) (Rulemaking - Water)

REPORT OF PROCEEDINGS at the hearing of the above-entitled cause before the Marie Tipsord, Hearing Officer, taken before Rebecca A. Graziano, Certified Shorthand Reporter within and for the County of Cook and State of Illinois, at the Bilandic Building, Room N-505, Chicago, Illinois, commencing at the hour of 9:00 a.m. on the 29th day of June, A.D., 2010.

A P P E A R A N C E S

THE ILLINOIS POLLUTION CONTROL BOARD,

Ms. Marie Tipsord, Hearing Officer
Ms. Alisa Liu, Environmental Scientist
Mr. G. Tanner Girard, Acting Chairman
Mr. Thomas Johnson, Board Member
Ms. Carry Zalewski, Board Member
Mr. Gary Blankenship, Bord Member

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Appeared on behalf of the Metropolitan Water Reclamation District of Greater Chicago,

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BY: MR. ALBERT ETTINGER
MS. JESSICA DEXTER

Appeared on behalf of ELPC, Prairie Rivers Network, and Sierra Club,

MS. TIPSORD: Good morning, everyone. My name is Marie Tipsord, and I've been appointed by the Board to serve as hearing officer in this proceeding entitled, "Water Quality Standards and Effluent Limitations for the Chicago Area Waterway System and Lower Des River, Proposed Amendments to 35 IL Admin Code 301, 302, 303 and 304." The docket number is R08-9, sub docket B.

With me today to my immediate left is acting chairman, G. Tanner Girard. To his left is Board member Carry Zalewski, and to her left, Board member Gary Blankenship. To my far right is Board member Thomas Johnson. To my immediate right is Alisa Liu from our technical unit.

I also would like to take a moment to introduce to all of you, today we have three interns with us this summer, Alia Neilson, Shannon Bebe, and Carrie Peterson (phonetic). Alia and Shannon are at Kent, and Carrie is at U of I.

Although today is the first hearing in sub docket B, it is our 40th overall hearing in the R08-9 proceeding. This is, I'm sure, a record number of hearings. It's also been done at a very fast time frame for the Board. In other

cases where the Board's had this many hearings, it's been set over a ten-year period. This has been over two and a half. So we've all worked very, very hard, and I did want to take this opportunity to thank all of you for your hard work so far. And since we're in the first hearing on sub docket B, it looks like we may have more work to do.

There are a few housekeeping notes I want to put in the record. Exhibits in all of the sub dockets that we are going to have hearings in -- this one, sub docket B, sub docket C, and sub docket D -- where we have hearings, the exhibits will continue to be numbered sequentially.

That being the case, the first exhibit on today's docket will be given Exhibit Number 382. The first 381 exhibits, of course, will go across, in all probability, all four dockets. So to avoid having two number ones, two number twos, two number three hundreds, we're going to have to continue to sequentially number them. That is the same thing we are doing with the public comments. We are continuing to sequentially number the public comments.

The clerk's office and I are

consulting on comments that come in, and some comments are docketed in both sub dockets. For example, the IEPA filed a couple of things in two sub dockets. We've had other people file things in two sub dockets: The District, Ms. Alexander and the environmental groups. But when a member of the general public sends us a letter that's talking about both recreational use and disinfection, we've put a link in both sub docket A and sub docket B so that it will be in both sub dockets.

So we are making those calls. If you see that we have missed something, please don't hesitate to call John or I so that we can make sure that they're linked across the sub dockets that they need to be linked across. And I thank you in advance for that.

The subject of today's hearing is the Chicago Health Environmental Exposure and Recreation Study, known as C-H-E-E-R-S, CHEERS. And we will begin the testimony today with Dr. Samuel Dorevitch. And questions -- I understand the People are going to go first. Is that correct? They were filed by the Natural Resource Defense Counsel, Ann Alexander, on behalf of all the environmental

groups?

MS. ALEXANDER: That's correct.

THE COURT: And after we conclude with Dr. Dorevitch, if we are finished by the end of the day with Dr. Dorevitch today, we will not start the hearing until 1:00 o'clock tomorrow. Dr. Gorelick, for personal reasons, will not be available in the morning tomorrow morning, so we have agreed to start at 1:00 o'clock tomorrow to take care of that. It was a situation that arose at the last minute. And I appreciate Dr. Gorelick's attempts to be available, but he just can't be tomorrow morning.

Anyone may ask a follow-up question. You need not wait until your turn to ask questions. I do ask that you raise your hand, wait for me to acknowledge you, and after I've acknowledged you, state your name and whom you represent before you begin your question.

Please speak one at a time. If you are speaking over each other, the court reporter will not be able to get your questions on the record. Please note that any question 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.

A couple other housekeeping things. First of all, I note there has been a motion by the District to have additional hearings in sub docket B. We have received two responses. Obviously, that is something the Board will take up and won't be discussed today at this hearing.

Also, Ms. Alexander, we talked off the record. I want to get on the record what you would like to do. You had pre-filed Dr. Gorelick's testimony in both sub docket A and sub docket B. Since there are no more hearings in sub docket A currently scheduled, would you like that to be entered as a public comment?

MS. ALEXANDER: We have no objection to that being a public comment. We simply filed it because the technical reports had been filed in sub docket A.

MS. TIPSORD: And I think that's it for housekeeping. Dr. Girard?

MR. GIRARD: Good morning, and welcome to hearing day 40 in this rulemaking. The Board is certainly impressed with the time and effort that all the participants are putting into this

rulemaking, and it will make for a better rule because of all your hard work. So thank you for that. Let's get on with the testimony and questions. Thank you.

MS. TIPSORD: Thank you. Does anyone else have anything preliminary before we start? With that, Mr. Andes, we'll have your witness sworn in.

MR. ANDES: I believe he's already been sworn in.

MS. TIPSORD: In the general docket. But since this is a new sub docket, let's start over by swearing him in, just so there's no question.

(Witness sworn.)

MS. TIPSORD: I also want to welcome -- I know there's some other students from Kent here today observing. I want to welcome all of you.

MR. SULSKI: IEPA has an intern here, too, Kim.

MS. TIPSORD: Hi, Kathleen. Welcome.

MR. SULSKI: Kim.

MS. TIPSORD: Kim. Sorry. I'm telling you, names are not with me today.

Having the witness sworn in, could we enter his testimony?

(Document tendered.)

MS. TIPSORD: If there's no objection, I will enter the pre-filed testimony of Samuel Dorevitch as Exhibit Number 382. Seeing none, it's Exhibit 382.

(Document marked as Exhibit No. 382 for identification.)

MR. ARMSTRONG: Good morning, Dr. Dorevitch.

DR. DOREVITCH: Good morning.

MR. ARMSTRONG: My name is Andrew Armstrong for the People of the State of Illinois on behalf of the Illinois Attorney General's office. This is Elizabeth Wallace.

MS. WALLACE: Good morning.

DR. DOREVITCH: Good morning.

MR. ARMSTRONG: Starting with pre-filed question number one, regarding your testimony that the information presented in the CHEERS interim technical report, quote, "Should not be viewed in answers to primary study questions," end quote, what purpose does this report serve?

DR. DOREVITCH: The purpose of the report is to update the Pollution Control Board of the state of the CHEERS research study.

MR. ARMSTRONG: Have you developed similar internal reports with incomplete -- I'm sorry. Let me ask the question B first.

Are the findings in the interim technical report accurate and statistically reliable?

DR. DOREVITCH: The findings of the report, as it says in the report, are preliminary. There has been data analysis that's taken place since then, and is continuing to take place, and that the final report submitted on August 31st would be considered the definitive word on all of those analysis.

MR. ARMSTRONG: Then moving to the question I was just going to ask, have you developed similar interim reports with incomplete or inconclusive findings for other research projects, such as CHEERS?

DR. DOREVITCH: I'm not sure there is another research project like CHEERS. But yes, I have developed reports -- interim progress reports

from other projects and for CHEERS as well.

MR. ARMSTRONG: And have you filed those interim reports in rulemaking proceedings before?

DR. DOREVITCH: There are interim reports that are filed that go to our external peer review. There was a summary of recruitment that was filed by the District about a year ago, May of 2009, in which I summarized the number of people recruited into each group and projections for the number of people in the study at the time its completed. And that was filed with the Board.

MR. ANDES: I believe, just to interject, it was filed on July 14th, 2009.

MR. ARMSTRONG: And what was your impetus for developing this interim technical report? Who made the decision to develop the report?

DR. DOREVITCH: Well, I think the impetus was that there was concern certainly on my part, and on the part of the researchers, that the window of opportunity was closing for our research to impact the rulemaking process. So although the final results are not ready, I thought it would be

helpful to let the Board know this is where we're at, this is what needs to be done, here's a timeline for wrapping up the project.

MR. ARMSTRONG: Question number two, are you aware of the MWRDGC press release entitled, "Study Confirmed Chicago Waterways Not Harmful to Recreational Users," dated May 12th, 2011?

DR. DOREVITCH: I am aware of that.

MR. ARMSTRONG: I'd like to -- since we'll be talking about it, I'd like to put it into the record right now.

(Document tendered.)

MS. TIPSORD: I've been handed a Metropolitan Water Reclamation District of Greater Chicago press release dated may 12th, 2010, entitled, "Study Confirmed Chicago Waterways Not Harmful to Recreational Users." If there's no objection, I'll admit that as Exhibit 383. Seeing none, it's Exhibit 383.

(Document marked as Exhibit No. 383 for identification.)

MR. ARMSTRONG: Dr. Dorevitch, were you consulted in the preparation of this release?

DR. DOREVITCH: No, I was not.

BY MR. ANDERSON:

Q. Do you agree with the statement in this release that your study has confirmed that Chicago waterways are not harmful to recreational users?

MR. ANDES: Can you identify the specific statement that's being referred to?

MR. ARMSTRONG: The title of the press release, "Study Confirms Chicago Waterways Not Harmful to Recreational Users."

MR. ANDES: So you're asking him whether he agrees with the headline?

MR. ARMSTRONG: To the extent the headline is a statement in the press release, I'm asking if he agrees with that statement.

DR. DOREVITCH: I don't agree.

MR. ARMSTRONG: For question C, I'm just trying to identify exactly where in the press release this is.

(Counsel peruses document.).

MR. ARMSTRONG: In the first paragraph of the press release, the press release states that the CHEERS study, quote, "Reveals that there are no increased health risks for recreational users in the

inland Chicago area waterway system, compared to swimmers in Lake Michigan, and there is essentially no greater health risk to individuals who canoe or kayak in the CAWS and have water splashed on them than those recreating in other bodies of water."

So that's two different statements. I believe the first is from the first paragraph, and the second would be the first paragraph of the second page. Are those statements both accurate?

DR. DOREVITCH: I'd say those statements are not grounded in the title of the report.

MR. ARMSTRONG: Question 2D, this refers to a quote taken from the second to last paragraph on the second page. The press release states that, quote, "After 21 days, the illness rate among unexposed participants was actually higher than for the two water-exposed groups." Is this statement accurate?

DR. DOREVITCH: I think that information comes from an earlier analysis than what appears in the technical report. And again, I'd say that isn't grounded in the interim technical report.

MR. ANDES: If I can provide some documentation as to that issue?

MR. ARMSTRONG: Mm-hmm.

MR. ANDES: Okay. We have an excerpt from an earlier draft of the technical report, which we can admit it as an exhibit.

MS. TIPSORD: And just to clarify, it's an excerpt from an earlier draft? It's not a part of the report now?

MR. ANDES: Right.

(Document tendered.)

MS. TIPSORD: I have been handed, "Draft. Do not distribute. Chapter One, Occurrence of Illness Among Study Participants." If there's no objection, we'll admit this as Exhibit 384. Seeing none, it's Exhibit 384.

(Document marked as Exhibit No. 384 for identification.)

MR. ARMSTRONG: And if I could just ask about this draft. How many drafts of the technical report are there?

DR. DOREVITCH: Well, there's one technical report. In the development of the technical report, there were multiple drafts. I

couldn't tell you how many, but different sections went through, two, three, four drafts.

MR. ARMSTRONG: In the development of the technical report, were drafts exchanged between your research group and MWRD?

DR. DOREVITCH: Drafts were exchanged between my research group and our internal reviewers. In other words, there are people within UIC who are not conducting the research, but are sort of consultants to the project. The analyses in the draft reports would go back and forth among the project team consultants, and I update the District about once a month on the status of the project.

So some of the information that went to the internal reviewers was included in an update to the District. It wasn't exactly presented as, "This is the draft technical report."

MR. ANDES: If I can ask to follow up, and I think we can provide some information here as to the basis for the statement.

Dr. Dorevitch, in the table that's included in the exhibit -- first, am I correct to say that this is data which reflects a full 21 days of questioning?

DR. DOREVITCH: Yes.

MR. ANDES: And can you describe the three groups? And when it discusses in the table of three groups, can you describe for us who the groups are?

DR. DOREVITCH: The three groups are the group of participants who engaged in limited contact water recreation on the CAWS, and that's referred to as the CAWS group. There's a group that engages in limited contact water recreation in general use waters, and that's called the GUW -- G-U-W -- group, and then there are people who engage in outdoor recreation on approximately the same times and same places as the previous two groups, but they don't have water contact, and that is called the unexposed group, and it's noted as the UNX group.

MR. ANDES: And in this table, which reflects incidents of illness per thousand person days, is the incidents numbers for the unexposed group higher than for the two water recreating groups?

DR. DOREVITCH: It is.

MR. ANDES: So that's 6.37 versus 5.45

and 5.59. Am I correct?

DR. DOREVITCH: Yes, that's correct.

MR. ANDES: Thank you.

MR. ETTINGER: Can I just follow up? Was that statistically significant?

DR. DOREVITCH: I don't remember if -- I don't think that the information in this table was tested for statistical significance.

MR. ETTINGER: Thank you.

MS. TIPSORD: And for the record, Albert?

MR. ETTINGER: I'm Albert Ettinger. I represent some environmental groups.

MS. ALEXANDER: I have one follow-up. What is the date of this document? When was it generated?

DR. DOREVITCH: I couldn't tell you the date. I could approximate that it was either late February or early March of 2010.

MS. ALEXANDER: Am I correct that there is no comparable table with this information in the technical report that was filed May 5th?

DR. DOREVITCH: Yes.

MS. ALEXANDER: Why was the decision

made not to include this table in the technical report?

DR. DOREVITCH: A couple of reasons. One is the -- this approach to analyzing data, number of cases per person day, relies on an assumption -- well, maybe I ought to back up and just explain what person days means.

There were over 10,000 people that were followed in the study. We contacted them by phone approximately two, five, and 21 days following recreation. Some of them remained in the study throughout that 21 day follow-up period, some dropped out, didn't respond to later phone calls. So they might have been in the study for two or ten days of follow-up.

So person days refers to the -- if you multiply the number of people times the average duration that each person remained in the study, you'd get the person days. An incidence per person day statistic assumes that the risk of getting sick is the same, whether you're looking at five people followed for 20 days, to get to 100 person days, or one person followed for 100 days to get 100 person days.

And in subsequent analysis of the data, we identified a specific time window immediately following recreation where people in the two water exposed group, the CAWS and the GUW group, have higher rates of illness than those in the unexposed group.

And given that observation, the assumption that the risk of getting sick is, sort of, evenly distributed across a follow-up period was proved to be untrue, and this type of analysis was not used in any subsequent analyses.

MR. HARLEY: Keith Harley, Chicago Legal Clinic on behalf of the Southeast Environmental Task Force. Good morning, Doctor.

DR. DOREVITCH: Good morning.

MR. HARLEY: Doctor, you just testified that of the 10,000 people you followed, some stayed throughout the 21-day period and some did not?

DR. DOREVITCH: Right.

MR. HARLEY: Can you give some greater clarity by what you mean by some stayed and some did not?

DR. DOREVITCH: I can. Hang on a

second.

MR. HARLEY: Madam Hearing Officer, if you want to defer the question until --

DR. DOREVITCH: Well, I can tell you that approximately 230 people did not participate -- approximately 230 people participated only in follow-up interview three, but not the prior two. But over all, 96 percent of the people who were in the study provided some telephone follow up information. The percent that --

MR. ANDES: You can use that. It shows the 96 percent.

DR. DOREVITCH: Yeah. Oh, this is it.

MR. ANDES: We have an exhibit.

DR. DOREVITCH: I apologize. Okay. The percent of people who participated in the first follow-up phone call was 77.69 percent. The percent that parted in the second telephone call was 87.71 percent. The percent that participated in the third follow-up phone call was 83.57 percent.

And the exhibit that's being distributed gets into a little bit more detail about how many were in only the first call, but not the second, or in the second and the third, in the first

and in the third, et cetera. But 96.28 percent participated in some telephone call, and about four percent participated in no telephone calls.

(Document tendered.)

MS. TIPSORD: And the exhibit that Dr. Dorevitch is referring to has been handed to me as, "CHEERS Recruitment and Attrition in the Field in Phone Follow-Up. If there's no objection, we'll mark that as Exhibit 385. Seeing none, it's Exhibit 385.

(Document marked as Exhibit No. 385 for identification.)

MR. HARLEY: Madam Hearing Officer, may I ask a follow-up, please?

MS. TIPSORD: Mm-hmm.

MR. HARLEY: You just cited numbers. I think they were based on the second page --

DR. DOREVITCH: Right.

MR. HARLEY: -- of the exhibit that have just been entered as Exhibits 385. At the bottom of the columns, on the same table we see phone call one, two, and three. Then we see significantly lower numbers, 64 percent, 65 percent, 61 percent. Can you describe what those numbers

signify?

DR. DOREVITCH: Those numbers signify the percent of people who participated in all three of the phone calls.

MR. HARLEY: Thank you.

DR. DOREVITCH: For the analyses of health outcomes that take place in the first days immediately following recreation, the relevant number is the ones who participated in phone one or two. And that number is in the 90 percent, but it's not in this table. But over 90 percent of the people participated in one of the two phone calls for the period of interest, the days zero, one, two, three, follow-up period.

MR. HARLEY: Thank you.

DR. DOREVITCH: There is an update. I don't know if there's a mechanism to update this exhibit, but I have a more complete table that does include this phone one or two category. So if there's a way, I can catch that up.

MR. ANDES: We can certainly file that.

MS. ALEXANDER: Ann Alexander. Just a quick follow-up. You referenced earlier a window, I

believe, in which most of the illnesses occurred following the recreation. Am I correct?

DR. DOREVITCH: Not quite. It's not that most of the illnesses occurred there, but that the difference between the water-exposed group and the unexposed -- water-exposed groups and the unexposed group was most apparent then.

MS. ALEXANDER: And what was that window?

DR. DOREVITCH: It was day zero, one, two, and three following enrolment in recreation.

MS. TIPSORD: Mr. Harley?

MR. HARLEY: Under, "CAWS," in the first column where it says, "Phone one only."

DR. DOREVITCH: Yes.

MR. HARLEY: And it has a number of 82?

DR. DOREVITCH: Right.

MR. HARLEY: And below that in parenthesis, "2.01 percent."

DR. DOREVITCH: Right.

MR. HARLEY: What does phone one mean?

DR. DOREVITCH: There are three rounds of telephone follow-up. Phone one takes place on

approximately day two, phone two takes place on approximately day five, and phone three takes place on approximately day 21. So phone one only means that there were 82 people in the CAWS group who we had telephone contact with and completed a follow-up interview for phone one, but none of the subsequent telephone follow-ups. So not two, not three.

MR. HARLEY: And phone two would be the same description?

DR. DOREVITCH: Correct, right. Those are a small percent. Most people participated in more than one round of follow-up.

MR. HARLEY: Thank you.

MS. TIPSORD: Back to the People.

MR. ARMSTRONG: Question 2E, the press release states that micro organisms associated with wastewater effluent are, quote, "Ever present in the environment, including Lake Michigan, all inland lakes, and rivers receiving disinfected effluent, and are not unique to the CAWS." And that quote is from the second paragraph on the second page of the press release.

Are the levels of bacteria and pathogens in the CAWS the same as other water bodies

included in the CHEERS study?

DR. DOREVITCH: That depends on which specific microbe we're talking about. For enterococci specifically, there are some of the inland lakes and rivers that were studied that have comparable levels to the CAWS. But for the other microbe study, generally the CAWS has higher levels.

MR. ARMSTRONG: Question three, the press release describes the CHEERS study is, quote, "The first research of its kind in the United States." What aspects of the CHEERS study are novel or unprecedented?

DR. DOREVITCH: Well, the focus of the study on limited contact recreation is novel and, in the United States, unprecedented. The degree to which we are trying to identify associations between pathogens and health outcomes is novel. The effort to identify pathogens responsible for illness in those stool samples of symptomatic study participants is relatively novel. It was tried once in England in an epidemiologic study in 1990, but studies since then have not done that. So that's relatively novel.

We're looking at a single body

of -- we're focusing on a very local question, the use of the CAWS, and we're sampling a relatively high percent of all CAWS users, unlike, say, an epidemiologic study of beach recreation where there are hundreds of millions of beach users and the percent that participate in epidemiologic studies of beach use is relatively small.

And generally, doing an epidemiologic study set in inland waters is relatively novel. It hasn't really been done in the United States, although it's been done in Europe.

MR. ARMSTRONG: Are you aware of any other studies that are sufficiently similar in design, focus, and scope that could be used to corroborate CHEERS findings?

DR. DOREVITCH: I'd say there is no study that's similar in design, focus, and scope to CHEERS. I think there are some ways of evaluating how comparable our results are to other studies. The USEPA is conducting a year study, and they provided us with their questionnaires, and we're trying to collect our data in a way that, to a degree possible, is similar to their study. They studied swimming and we're studying limited contact

recreation, but both studies have unexposed groups.

So rates of illness and patterns of illness among the unexposed would be one way to, kind of, evaluate the comparability of our findings to another study. I shouldn't say the "findings," but a way to evaluate the way our methods are being executed and the descriptive results would get about the unexposed to other studies.

MR. ARMSTRONG: Once completed -- question four, once completed, will the CHEERS study demonstrate whether a causal relationship exists between CAWS recreation and occurrence of gastrointestinal illness, respiratory skin, eye, and ear symptoms?

DR. DOREVITCH: I don't think any single epidemiologic study can prove a causal relationship. The process is a little bit more complicated than that. I think the focus of epidemiologic studies is first to identify associations.

So in your question, is CAWS recreation -- I would frame the question, "Is CAWS recreation associated with gastrointestinal illness, respiratory illness, et cetera," meaning is it not

just chance if the people in the CAWS group have higher rates of illness or lower rates of illness than another group, there's an association.

The next step would be to say is this association explained by something other than water recreation? Maybe the people in the CAWS group are different in some way in terms of their underlying health conditions or their exposures. So the next step would be to try to rule out other possibilities that explain that association.

And after going through a process of, sort of, testing alternative hypotheses, if all of those hypotheses are shot down, no, it isn't because the age distribution is different. No, it isn't because of the presence of underlying health conditions is different. The only explanation left standing is something about the exposure here, the water exposure leads to this association.

I don't think you can call that definitive proof, and I don't think other epidemiologic studies would use that kind of level of certainty about causality either.

MR. ARMSTRONG: I'd like to move to question six at this point. Your testimony

describes your previous advocacy efforts regarding a more stringent regulation of ozone, particulate matter, diesel and coal fired power flame emissions, and lead. Do you feel that these air quality issues represent public health risks?

DR. DOREVITCH: Yes, I do.

MR. ARMSTRONG: And what information lead you to conclude that these are public health risks that require a more stringent regulation?

DR. DOREVITCH: Well, there's a very large body of literature in medical and public health literature about air pollution and health outcomes, to the point that the USEPA publishes criteria documents every five or so years that compile hundreds and hundreds of studies that have been published within the five-year period.

And then the EPA internal scientists put together a summary of the science and the public health implications that goes to external review by external scientists, then the Cleaner Science Advisory Counsel, and they issue recommendations to the administrator of the EPA.

In the first half of, say, 2000 to 2008, there were a lot of -- there were several

cases where the EPA scientists and the outside scientists were arguing that the administrator should use the base of scientific knowledge and make more stringent health requirements. And it was to support that effort that I testified -- I shouldn't say "testified," but I offered public comment, and that was based on this extensive amount of research, including conclusions by EPA scientists.

MR. ARMSTRONG: So going back to question five then, is it your opinion that the CHEERS study that you testified as being unprecedented for the United States, is it your opinion that that study will be capable of concluding definitively whether or not biological contaminants in the CAWS pose a public health risk?

DR. DOREVITCH: I wouldn't say that we'd be able to conclusively determine that it's biological contaminants that are causing health risks. There are ways of evaluating the degree to which being in the CAWS group and having higher, lower, or different health risks may be due to water exposure and things in the water.

One way is to look at study participants who have more exposure than others.

Some people capsize, some people swallowed water, some people report just getting a few drops on their hands. And by looking at, sort of, a dose-response relationship, higher degrees of exposure being associated with higher rates of illness, that would suggest that it's something in the water. It may be a biological contaminant, or maybe something else, like a chemical contaminant.

Another approach is to look at the relationship between things we measure in the water and health outcomes, so E. Coli and other microbes. If people who are using the water when the implications where the E. Coli level is high, if they, all things being equal, have higher rates of illness than people using the water where numbers of E. Coli are low, that would suggest that something that goes along with E. Coli or E. Coli is responsible for that association.

So I wouldn't say, you know, quite so strongly, like you asked about, will it -- you know, concluding definitively whether or not it's biological contaminants, but it is generating information that would be part of a more definitive answer to that question.

MR. ARMSTRONG: Well, on the other parts of that, speaking more generally about the public health concerns posed by the bacteria specific to sewage effluent, are you familiar with a publication entitled, "Toxicology Secrets?"

DR. DOREVITCH: I am.

MR. ARMSTRONG: And I do have a couple of copies of this.

MR. ANDES: It's not secret.

MR. ARMSTRONG: It's been declassified.

(Document tendered.)

MS. TIPSORD: I've been handed, "Toxicology Secrets. Questions You Will Be Asked: On Rounds, in the ED, on bedside oral exams," by Louis J Ling, M.D.; Richard F. Clark, M.D.; Timothy B. Erickson, M.D.; John H. Trestrail III, RPh. If there's no objection, we will admit this as Exhibit 386.

MR. ARMSTRONG: I do have --

MS. TIPSORD: Seeing no objection, we'll admit this as Exhibit 386.

(Document marked as Exhibit No. 386 for identification.)

MR. ARMSTRONG: I should note that this book is apparently out of print, and it's only available on Google Books as far as I can tell in truncated fashion, insofar as Pages 240 and 242 are missing. But the section I wanted to reference is fully included in this copy of the chapter.

DR. DOREVITCH: I may have the only copy ever purchased. And if you need it, let me know.

MR. ARMSTRONG: Nine people are selling it for $45 on Amazon right now, so there's still an audience.

Obviously, Dr. Dorevitch, you are familiar with this publication?

DR. DOREVITCH: Yes. It's been a while.

MR. ARMSTRONG: And I've excerpted Chapter 56, "Air and Water Pollution," here. And would it be safe to say that you helped prepare this chapter?

DR. DOREVITCH: Correct.

MS. TIPSORD: Specifically, I'd like to go to Page 241, Paragraph 15, and the section is entitled -- actually, I should ask first, what type

of book is Toxicology Secrets?

DR. DOREVITCH: This is a book for residents in emergency medicine training.

MR. ARMSTRONG: So is this trying to distill, I guess, basic medical knowledge into one text for the student to consult?

DR. DOREVITCH: I wouldn't say that, but it's useful information for people who are training in emergency medicine, and specifically toxicology.

MR. ARMSTRONG: Well, on Paragraph 15, "What Water Pollutants are Hazardous to Human Health," the book states, "Multiple biological hazards exist in water in the form of infectious disease." It goes on to list bacterial pathogens such as such as salmonella, shigella, two others I don't know how to pronounce, viral pathogens, protozoa pathogens. It also notes, "Human and animal feces are significant contaminants of water, with sewage being the largest public health concern."

Do you agree with the general statement that sewage is a large public health concern?

MR. ANDES: Excuse me. "Sewage being the largest public health concern," is the statement, right?

MR. ARMSTRONG: That's what it does say in the --

MR. ANDES: You're asking him whether it was a large concern?

MR. ARMSTRONG: Yes. Well, generally speaking, is it a large concern, or is it the largest public health concern in water?

DR. DOREVITCH: Well, I'm not even sure it's saying -- I don't think it's the largest health public concern in water, but I think that they're saying sewage -- I shouldn't say they're saying -- I was saying that sewage is the largest public health concern regarding fecal pollution of water, meaning human and animal. Sewage would be the greatest concern among -- you know, within that category.

MR. ARMSTRONG: And then do you do -- do you agree with the statement that bacterial pathogens, viral pathogens, and protozoa pathogens are biological hazards, when in water, that are hazardous to human health, generally speaking?

DR. DOREVITCH: Well, I think the sentence says, "Cross contamination of drinking water by sewage was common in the U.S. until the mid-19th century, and is still a significant problem in third world countries."

So I don't want to -- I think the -- this doesn't specifically say "recreational water." I think it's really describing more drinking water as the focus, and that, in the developing world, sewage contamination of drinking water is a major public health problem. In the U.S., cross contamination can occur.

But again, from the perspective of drinking water, sure, it would be a very significant public health problem if drinking water were contaminated with bacteria and viral protozoa pathogens.

MR. ARMSTRONG: Generally speaking, what research is there that exists that demonstrates that bacteria pathogens and viral pathogens and protozoa pathogens are hazardous to human health?

DR. DOREVITCH: Well, in the context of drinking water, there was an outbreak of cryptosporidiosis in Milwaukee in 1993, and about

half a million people got sick -- 400,000 people got sick and 50 died. So that's pretty convincing evidence.

MR. ARMSTRONG: And concerns of drinking water would obviously be the ingestion of the water?

DR. DOREVITCH: Correct.

MR. ARMSTRONG: Moving on to the --

MS. TIPSORD: Mr. Harley has a follow-up.

MR. HARLEY: Just a follow-up, yes. Dr. Dorevitch, were there people in the CAWS group who reported while being surveyed that they swallowed water?

DR. DOREVITCH: Yes.

MR. HARLEY: Were there people in the CAWS group who were surveyed who reported getting water on their hands?

DR. DOREVITCH: Yes.

MR. HARLEY: Were there people who reported that water on their hands -- that they had water on their hands and they engaged in hand-to-mouth contact?

DR. DOREVITCH: Well, we don't

specifically ask about hand-to-mouth contact, but we ask about eating, drinking, and smoking as examples of hand-to-mouth contact. So yes, people did get their hands wet and engage in eating, drinking, or smoking.

MR. HARLEY: And would that be regarded as a pathway of exposure?

DR. DOREVITCH: Yes.

MR. HARLEY: Thank you, Doctor.

MR. ARMSTRONG: Moving on to question seven, will the results of the CHEERS study be capable of characterizing risks through sensitive subgroups, such as children, the elderly, or those that have a health condition that makes them susceptible to infection?

DR. DOREVITCH: The CHEERS study does enroll children, the elderly, and people with underlying health conditions that may make them susceptible to infection. The degree to which the CHEERS study will be capable of characterizing those risks depends on how many such people are in the study and how great the risk. If a risk is subtle, detecting a five percent increase of risk is much more difficult than detecting a doubling of risk.

So the more subtle the risk, the more people you need. If we have very few, say, children under the age of four in this study, they could only be identified as having an elevated risk compared to others if their elevated risk were very high. So there isn't a straightforward answer to yes, we can or no, we can't. It does depend both on the degree of excess risk and the number of such people that are enrolled in the study.

What I can tell you is that we have been evaluating all of those -- evaluating looking for sensitive subgroups in our statistical analysis, and that information will be in the final report.

MR. ARMSTRONG: Question eight, if CHEERS study participants develop asymptomatic confessions from waterborne pathogens that are passed to other family members, will these secondary illnesses be captured in the study?

DR. DOREVITCH: The CHEERS study was designed using the EPA NEAR study as a template. That study doesn't try to determine secondary spread of infection from the study participants to others or from others outside of the study to study

participants, and the same is true with our study.

MR. ARMSTRONG: Does the CHEERS study account for the possibility that individuals with more frequent exposure to CAWS water may be at greater risk of experiencing gastrointestinal or other illnesses?

DR. DOREVITCH: The CHEERS study has evaluated whether people with more frequent -- with frequent exposure have the same risks or different risks, possibly higher, possibly lower than others. So yes, that is definitely something that we're interested in.

MR. ARMSTRONG: What portion of the cohort was studied following only a single recreational event?

DR. DOREVITCH: I wasn't quite sure what you meant. Do you mean people who enrolled only once, or do you mean a big single recreational event like the Flat Water Classic, as opposed to kayak rental facilities once in awhile?

MR. ARMSTRONG: The first of your interpretations, people who only enrolled once.

DR. DOREVITCH: Yes. I don't have that answer. That is -- that will be in the final

report. But it isn't as simple as it sounds to identify repeat participants, just in that somebody might enroll with the name William the first time and Bill the second. A last name might be spelled a little differently or a phone number changes. And it's actually a pretty intensive process to identify repeat participants, taking into account the fact that the data each time could be entered slightly differently. So I will have that information, but I don't now.

MR. ARMSTRONG: Following up to your answer to the previous question, how will the study account for the frequency of exposure to individual study participants?

DR. DOREVITCH: By looking at -- we've looked at it in a few ways. One way is just looking at whether each additional time -- there's a question in the -- all parts are asked about how many times have they used the CAWS, or if they're at Lake Michigan in the past 12 months.

So if somebody's a first time user of the waterway, that particular waterway, their answer would be zero. If it's their second then they previously used it once. There are kids on

rowing teams who say that they've used the water 200 times.

So we have that information, and we're looking at whether the number of uses is related to health risks and we're also looking at, sort of, categories, maybe days zero to -- if you've used it a few times, your risk might be different if you've used it a dozen times, and that might be different than if you used it 50 times. So those data analyses have taken place.

MR. ARMSTRONG: Sub question D, the technical report indicates that study participants were asked about additional water contact during the follow-up telephone calls. If a participant indicated that they had additional water contact during the 21 day follow-up period, how was that information used?

DR. DOREVITCH: Right. You know, one of the benefits of having, as I mentioned earlier, restricted the analysis to that day zero to three time window for GI illness is that repeat use within that narrow window is relatively -- you know, it isn't as common as it would be if we were looking at a full 21 day period. But within that window, we

can look at whether people who did or did not reuse the water since we spoke to them last have a different health risk than others.

MR. ARMSTRONG: Question 11 -- and I'm assuming that the updated tables that were filed fairly recently address this question. Your testimony indicates that some of the water quality samples measuring E. Coli enterococcus are, quote, "Low and therefore will be excluded from the study." Subpart A, "How many samples does this infect?"

MS. TIPSORD: And let me interject just for a second. The tables you're talking about are the tables filed and listed as public comment 300 A in the docket. Is that correct?

MR. ARMSTRONG: That is what I was referring to.

DR. DOREVITCH: I have a table that summarizes that.

MR. ANDES: We'll submit this as an exhibit.

DR. DOREVITCH: The revisions in the data set --

MS. TIPSORD: Dr. Dorevitch, let's admit it as an exhibit so you have it when you start

talking about it.

DR. DOREVITCH: Sure.

(Document tendered.)

MS. TIPSORD: I have a table with, "Original Database, Revised Database," at the top, and on the left, "First number of days of indicator bacteria sampling." We'll admit that as Exhibit 387 if there's no objection. Seeing no objection, it is Exhibit 387.

(Document marked as Exhibit No. 387 for identification.)

DR. DOREVITCH: So in the original data set, there were 146 days where there were E. Coli samples collected. In the revised data set, there were 109 days, and the table goes through how many days of enterococci measurements were collected in the original and the revised data set. Within a day, there are multiple locations where water was sampled.

So the next couple of rows show the change in enterococci and E. Coli observations in terms of location days. And then within a given location on a given day, water was sampled multiple times, and can be organized as the water quality

measure at a given day on a given location during a given hour. So the number of day location hours has decreased, and total number of samples for which E. Coli and enterococci bacteria are useable has decreased as well.

MR. ARMSTRONG: 11 B, to what do you attribute the implausibly low results?

DR. DOREVITCH: Well, it was more than just an issue of implausibly low. It was a problem of inconsistent recovery, and I can back up and just explain what the recovery issue is.

It's a way of evaluating the accuracy of a laboratory report. So if we have two cups of CAWS water, you dunk them in the water, they fill up with water, and let's say one of them has 100 E. Coli, and then we'll add 100 E. Coli to the second one. So we would -- that's called spiking.

So the unspiked sample, we would expect the results to be 100, and for the spiked sample, we would expect it to be the baseline 100 plus the 100 that were added. If we got 200 on the spiked sample, that would be called a recovery of 100 percent. If we got 150 back, that would be a 50 percent recovery, 50 percent of the 100 that were

recovered.

So it wasn't strictly a problem of low values. It was a problem of inconsistency at the laboratory that resulted in some implausibly low values. We were aware of that in 2008 and worked to try to troubleshoot the problem. And by the spring of 2009, I brought to the peer review the suggestion that we should change laboratories, which we did, and the data quality, the predictability of recovery improved.

Now, throughout the period of variable recovery, the average recovery remained acceptable. So strictly speaking, we could have made the argument for just using all of the data that was collected during that time. But again, I brought to our peer review this past May the idea that although, strictly speaking, our average recovery is okay, there's a period in which we have concerns about data quality.

I presented a range of options about how to deal with that, one of them being to disregard the data that was collected during the problematic time, and, you know, to be conservative and to not use suspect -- not suspect meaning

tampered with, but just not meeting the highest quality standards.

The peer review agreed that it's best to consider that data missing and to not use it, and that is what resulted in the change from the original to the revised data set.

MR. ARMSTRONG: Sub question C, is it possible that the laboratory issues you just described could have affected the results of other water samples for other organisms as well?

DR. DOREVITCH: That particular laboratory only analyzed E. Coli enterococci. But I did go back -- there's a project quality manager and there's a project -- there's somebody who's in charge of the whole water sampling and analysis, and they and I have reviewed the performance data for the coliphages and giardia and cryptosporidium, as has the peer review, and we're staffed with data quality there.

MR. ARMSTRONG: Question number 12, water sampling methods and the specific pathogens analyzed as reported in the interim technical report vary by study year. Sub question A, is this common in a study like CHEERS?

DR. DOREVITCH: It's not unusual, sure. The EPA NEAR study began by looking at bacteroides by QPCR. And because of quality concerns, they ended up not using the information in their analysis. They described that in the publication, and they instead used another microbe that they were measuring by QPCR enterococci, so that isn't usual.

We began with a standard basic package of things that we were going to measure in the water all the time, and that would be E. Coli and enterococci. And after getting input from the USEPA office of water, we also incorporated coliphages in that basic package.

Then there were other things that we tried the first year, such as salmonella, shigella, giardia cryptosporidium. Of those, giardia cryptosporidium met quality requirements and we continued using them for the duration of the study. The other ones did not. And after reviewing the quality data with the peer review, we were in agreement not to continue collecting that type of information.

By 2009, the study was functioning

-- you know, we made a big change going from 2007 to 2008. We were at multiple locations at multiple times of day. It was a much larger scale study. But by 2009, this whole scaled up version of this study was something that the staff in the field were very experienced with. And at that point, it was possible to add on additional analysis, like QBCR measures of enterococci.

So it's not unusual to change. There are reasons for the additions and the deletions, but the basic core package of microbes has remained constant throughout the few years.

MR. ARMSTRONG: Question 14 -- and based on Exhibit 385, which was the summary of telephone follow-up efforts of the -- it looks like my numbers may be off. But question 14, the interim technical report refers to a study sample size of 11,297, which includes those who participated in at least one phone call. However, only 7,478 -- and I'm looking at Exhibit 385, Page 2 and it looks like that number might actually be 7,464.

DR. DOREVITCH: That's right.

MR. ARMSTRONG: Only 7,464 participated in all three phone calls. Is it

possible that symptoms in the remaining participants could have been over looked?

DR. DOREVITCH: Yeah. Again, this goes back to -- you know, if we're interested in the time window from day zero to three and we have missing data from day 15, that would impact the day zero to three analysis. So it isn't accurate that there were -- you know, it wouldn't be correct to think that we only have useable data from those 7,464. It's over 10,000.

MR. ARMSTRONG: The interim technical report -- question 15, the interim technical report indicates that only 745 of 2,433, or 31 percent, of participants with any gastrointestinal symptoms provided a stool sample. Is this an adequate sample size from which you draw conclusions about detection of pathogens?

DR. DOREVITCH: I'll tell you, it's not really a sample size issue. I think it's more of a bias issue. If the 745 who did provide stool samples were different in an important way of those who did not, then we may be getting misleading information. We may be arriving at false conclusions.

And this is something that we're on top of, whether those who provide samples are different, whether they used -- they were more likely to have been in one study group than another or participated in a certain recreational activity, or began the study with a different perceived risk of using the CAWS. So that has all been summarized and will be in the August 31st report.

MR. ANDES: And to follow up, isn't it -- and maybe this is just in the lamest sense, but isn't 31 percent of the group a fairly high percentage of the group that are willing to provide a stool sample?

DR. DOREVITCH: It is actually very high. The centers for disease control is interest in foodborne outbreaks, and they aren't able to get this kind of response rate, as high as 31 percent.

MR. ARMSTRONG: Question 16, the interim technical report provides a specific definition for acute gastrointestinal illness. Regardless, stool samples were collected from individuals with any new gastrointestinal symptoms. Is it possible that some of the stool samples were taken from people without illness?

DR. DOREVITCH: It's more than possible. Definitely there were people who had symptoms but didn't needn't meet criteria for acute gastrointestinal and who provided stool samples.

MR. ANDES: And is part of the -- is part of the analysis to look at the samples from those people, versus the people who had the acute symptoms?

DR. DOREVITCH: Yes.

MR. ARMSTRONG: Question 17, the interim technical report indicates that the timing of follow-up with participants was based on the latency period between exposure and acute gastrointestinal illness. Subpart A, is this same follow-up schedule used for other illnesses, for example, respiratory symptoms?

DR. DOREVITCH: No. The same follow-up -- the same, sort of, time window is the subject of the analysis for skin symptoms. For respiratory symptoms it's day zero to seven, and for ear symptoms we're looking at the full 21-day period.

MR. ARMSTRONG: I guess that goes to supplying the answer to sub question B, which is:

Do these other illnesses, for example, the skin, respiratory, and ears, have similar latencies?

DR. DOREVITCH: Right. It's working with, sort of, what's available in the literature and looking at our own time course to illness data, specifically looking for time windows where the people in the water exposed groups may have different rates of illness than the unexposed group. Those were the two pieces of information that were used to find those timings for us.

MR. ARMSTRONG: Question 18, have you received any written comments from the peer review panel as of yet?

DR. DOREVITCH: I have.

MR. ARMSTRONG: Will you be able to -- would you please file them with the Board?

DR. DOREVITCH: I don't have a problem with that. I think the peer reviewers and the organization that's organizing the peer review, the Water Environment Research Foundation, need to weigh in on that. I'm not sure that the reviewers were writing with the expectation that everything they've said up until now would be made public.

I'm all for transparency, and I

think the final comments that will come back on the final results are structured in a way that each member of the peer review will provide information about strengths, limitations, do they agree with the conclusions of the study. And I would have no objection to making all that information available, as long as the reviewers themselves know that that's what's going to happen.

Up until now, I think it's been -- you know, one of the real benefits of the peer review is people's ability to speak frankly and to not hesitate to raise suggestions or criticisms. And I'm not sure everybody would have said everything that they said or the way they said it had they known that it would become a public document.

MR. ANDES: If I can add to that, the District's understanding from the Water Environment Research Foundation, which is the sponsor of this study, is that the final report issued by WERF will include, in an appendix, comments by the peer reviewers and the responses.

MR. ARMSTRONG: Excellent. Has the USEPA provided any comments on the CHEERS study yet?

DR. DOREVITCH: No, it has not. There are individuals on the peer review from USEPA, but the Agency hasn't issued any statement about CHEERS.

MR. ARMSTRONG: Do you intend to seek USEPA's review of the CHEERS study results?

DR. DOREVITCH: I believe that the District has been -- has received comments from USEPA regarding the risk assessment. I don't know myself what the plan is to have USEPA review it. I'd be all -- you know, I have no objection at all to that.

MR. ARMSTRONG: Would you be able to file with the Board the monthly updates that you've sent to the District regarding the CHEERS study?

DR. DOREVITCH: Again, those are not really prepared for public consumption. If we had a personnel issue or details of what goes into these summaries, I'm not sure that it's appropriate to make all of that available.

But, I mean, generally these took the form of recruitment summaries during the course of the study week by week how many people were recruited in each group at each location, and I have no objection to making that available.

MR. ARMSTRONG: Would it be possible to file with the Board the full draft of the interim technical report for which we received the first chapter today?

MR. ANDES: I think that --

DR. DOREVITCH: Oh, no. That wasn't a full technical report, Chapter 1. That was actually being prepared for the internal review document that I mentioned earlier. There wasn't a multi-chapter technical report.

MR. ARMSTRONG: So it was more of an overview?

DR. DOREVITCH: It was preparing a multi-chapter report for the internal reviewers, which came before this technical report, and then taking sections of it and compiling a summary, which became the technical report.

MR. ARMSTRONG: That's all we have. Thank you very much.

DR. DOREVITCH: You're welcome.

MS. TIPSORD: Thank you, Mr. Armstrong. Ms. Wallace, do you have any follow-up?

MS. WALLACE: No.

MR. ARMSTRONG: All right. Let's take a ten-minute break then.

(Whereupon, a break was taken, after which the following proceedings were had.)

MS. TIPSORD: Dr. Dorevitch, you had something else to add?

DR. DOREVITCH: Yeah. Mr. Harley had asked about -- I was trying to give Mr. Harley the number of people -- the percent of people who participated in phone one or two. I have a more updated version of the table than what was distributed as exhibit, and that exhibit will be updated. But the information is that there were 11,032 people who participated in phone one or two, and that's 94.03 percent of the total.

MR. ANDES: And we'll file that.

MS. TIPSORD: Thank you. With that, I think we're ready to start with Ms. Alexander.

MS. ALEXANDER: Good morning, Dr. Dorevitch. I'm Ann Alexander from the National Resource Defense Counsel. I'll be asking you questions on behalf of the environmental group, and I would like to turn in my pre-filed questions to

number 3. I'm going to go to -- this is referring to the paragraph at the bottom of Page 3 over to Page 4 in your pre-filed testimony. And since it's short, I'll just read it into the record for reference.

"Yet to be completed are analyses of health risks of incidental contact water recreational activities. Such analysis will take into account multiple factors that must be considered when describing relationships between key variables, such as water quality, and health outcomes, such as the development of gastrointestinal illness."

"For example, if users of the CAWS are different in important ways, compared to users of general use waters or to study participants that were not exposed to water, such as their age or presence of underlying health conditions, real differences in the health risks between the CAWS group and other groups may be distorted. The ongoing data analysis focuses on accounting for such differences in order to generate appropriate comparisons of risks across study groups."

My first question is: Can you

please describe the analyses of health risks and incidental contact water recreational activities that remain yet to be completed in the CHEERS study, just generally?

DR. DOREVITCH: Sure. Do you want me to talk about specifically since the time that the interim technical report was written, or from this time forward?

MS. ALEXANDER: That's correct. You can identify what's already been done, as opposed to what will be done in the future, but please describe everything since the technical report.

DR. DOREVITCH: Okay. Since the technical report analysis of the risk of developing skin conditions following recreation, skin rashes, it has been completed what's called a multi-varied analysis that takes into account all of these potential differences in groups that could distort the results or confounding.

That is ongoing and nearing completion. It's been done for multi-varied analysis for GI illness, respiratory illness, ear symptoms, and for -- and it's ongoing for skin symptoms. Analyses that will translate the analysis

of association into excess cases per thousand uses is ongoing.

In other words, the analyses that are generally done in epidemiologic studies will say something like the risk in group A is 20 percent higher than group B or something like that. But that's not the same thing as saying there are 20 extra cases per thousand, if at all. To go to that kind of number for every thousand people who use the CAWS, approximately how many would develop illness attributable to CAWS recreation, meaning taking into account what happens in the undisclosed group, differences across groups, that is ongoing.

Analysis of water quality as a predictor of health outcomes is yet to be completed. It's ongoing. It's somewhat involved in that there are multiple health endpoints, and there are multiple things we measure in the water. So a lot of permutations of looking at different measures of water quality in relation to different health outcomes. And those are the primary analyses that are ongoing now.

MS. ALEXANDER: Can you please describe what potential differences between CAWS

users and GUW users you seek to identify, besides the two examples that you provide in your testimony? And those are age and underlying health conditions.

DR. DOREVITCH: Right. Just a second.

(Witness peruses document.)

DR. DOREVITCH: I've listed those, and it's an exhibit that I'm going to distribute.

MS. ALEXANDER: Okay.

MR. ANDES: We actually have -- this is two-sided. Sorry for the confusion. We are using the page that says CAWS/GUW comparison.

(Document tendered.)

MS. TIPSORD: I've received a two-sided document, side one with the numbers appearing at the left, I'm calling side one, "Potential Confounders Included in Analyses of Developing GI Illness CAWS/GUW Comparison." On the flip side, "Potential Confounders Included in Analyses of Developing GI Illness, Three Group Comparison." I'll mark this as Exhibit 388 if there's no objection. Seeing none, it's Exhibit 388.

(Document marked as Exhibit No. 388 for identification.)

DR. DOREVITCH: So the answer to your question, the confounders being included in the final model, this is -- are age category, gender, race, ethnicity, frequency of using the water, contact with a person who has symptoms of GI illness, perceived risk of illness -- or perceived risk of CAWS use, baseline average number of bowel movements per day, recent exposure to other animals, recent injection of raw, runny, or undercooked eggs, recent injection of rare, raw, or undercooked meat, recent injection of hamburger, recent injection of fresh produce, recent injection of a prepackaged sandwich, preexisting diabetes, a preexisting GI condition, having a condition that makes an individual prone to infection, recent antibiotic use, antacid use, specific recreational activity, meaning boating, canoeing, kayaking, fishing, and rowing, and water exposure.

MS. ALEXANDER: So by number 20, do you mean the type of recreational activity as a confounder?

DR. DOREVITCH: Right. So boating, canoeing, kayaking, fishing, rowing.

MS. ALEXANDER: And can you please

explain why Items 20 and 21 were not included in the three-group comparison?

DR. DOREVITCH: Because people in the unexposed group don't canoe, kayak, fish, or boat. They are jogging, bicycling, et cetera. So that analysis couldn't be performed. Likewise, water exposure couldn't be analyzed in the three group comparison because one of the groups doesn't have water exposure.

MR. ANDES: So just to clarify, listed on the other side of the page, we can also admit that is the factors that were looked at for all three groups when they were compared, including the unexposed group.

MS. TIPSORD: Isn't that correct, Dr. Dorevitch?

DR. DOREVITCH: That is correct.

MS. ALEXANDER: And can you please briefly describe the statistical power calculation reflected at the bottom of the three group comparison?

DR. DOREVITCH: Sure. Maybe just to start by saying what statistical power is. It's the probability of failing to identify a difference

that's really there, meaning the two groups really are different, or there is a difference among groups. But not enough people were enrolled to identify that difference. The higher the power, the more unlikely it becomes for there to be a difference and for that difference to not reach statistical significance.

MR. ANDES: So in other words, if we turn that around the other way, the higher the power, the more likely a difference is relevant?

DR. DOREVITCH: The higher the probability a difference will be detected.

MR. ANDES: Thank you.

DR. DOREVITCH: The power calculation was done taking into account two issues that influence power; one is missing data, and one is the number of confounders in the model. So in the model, this three group comparison, there are 19 items in that model. There are actually more because some of them have multiple levels on each level, like the three different age categories becomes three things in the model.

But there are these 19 different issues, potential confounders, that are included in

the model, and there is the amount of data that's missing. If data is missing on any one of these, then that person's -- none of the person's data can be used. So after taking into account the number of variables in the model and the amount of missing data, there's a statistical procedure done on the program, and using the Shay O'Brien (phonetic) approximation, this power calculation was done. And it's not based on, sort of, theoretical numbers, it's based on the actual observed percent of people who developed illness in the study.

The power for detecting a difference between CAWS and unexposed is .91, meaning there's a nine percent chance that the groups are different and we would fail to identify that difference. And for GUW, the general use waters, versus unexposed, the power is .93, or a seven percent chance that a real difference would go undetected.

MS. ALEXANDER: Would I be correct in understanding that this statistical power is for all study participants collectively, as opposed to any particular subgroup?

DR. DOREVITCH: It's for making

specific comparisons out of the larger data set, yes.

MS. ALEXANDER: So in other words, the statistical power might be different for a subgroup within that data set?

DR. DOREVITCH: Well, the model does already take into account age categories, preexisting diabetes, et cetera. So sure, if we said let's only look at one group, that would mean very little power. But there would be no basis for comparison anymore -- if we only looked at the people with diabetes, there would be no comparison. So it's the total sample.

MS. ALEXANDER: And would your conclusion be the same for, say, children under four?

DR. DOREVITCH: The conclusion is that that is being evaluated in the overall model. But that isn't the same thing as saying -- you know, this is talking about an overall risk if we want to compare CAWS users to unexposed users or something like that. So after taking into account the distribution of diabetes, children under four, whatever, after taking into account all of that, we

can identify differences across groups. But if you're saying is the risk different for a small subgroup, no, that would not -- that would have a lower power.

MS. ALEXANDER: Okay. That's my question. A moment ago you said that if you were just comparing users with diabetes, you would have have little statistical power. Is that correct?

DR. DOREVITCH: If you wanted to know whether the health risk to people with diabetes is different to the health risk of all people, you would have much less statistical power because there are not many people with -- you know, a relatively small number of people with diabetes in this study.

MS. ALEXANDER: Would the same be true if you are comparing users with diabetes on the CAWS or the GUW, is there diabetes that would have less statistical power?

DR. DOREVITCH: I wouldn't necessarily try to analyze that. I mean, I think it would be -- I mean, yes, if you wanted to find out people with diabetes on the CAWS, do they have a different health risk than people on the GUW, sure. That's doable. That would take a much larger number of

people with diabetes on the CAWS and a much larger number with diabetes on the GUW. There aren't that many, so this study couldn't tell you with a high level of certainty that a true difference isn't there.

MS. ALEXANDER: Would that also be true for, say, children under four, that this study couldn't really tell you, given the lack of statistical power, the difference between risk to GUW user children as opposed to CAWS user children under four?

DR. DOREVITCH: That is correct.

MR. ANDES: If I can follow up, do we know how many children under four were found to be recreating in either the CAWS or the GUW waters?

DR. DOREVITCH: In the interim technical report, on Page 26, there were 33 children under the age of four in the CAWS group and 37 in the GUW group.

MR. ANDES: And how many were in the unexposed group?

DR. DOREVITCH: There were 62. Over all, the percent of people in the study under the age of five, meaning zero to four, was 1.2 percent.

MR. ANDES: Thank you.

MS. ALEXANDER: Would your statement be the same that you -- there is insufficient statistical power in this study to determine the risk to children five to nine years old, comparing GUW user children versus CAWS user children?

DR. DOREVITCH: In general, yeah. If the risks were dramatically different, then it would be more likely to be detected. But if we're talking about a subtle risk, a ten percent increase in risk, that couldn't be detected.

MS. ALEXANDER: Same conclusion regarding kayakers on the GUW versus kayakers on the CAWS?

DR. DOREVITCH: I don't know the answer. I mean, sure there's less power than for the overall study, but there are -- 26 percent of the CAWS users were kayakers, and 378 percent of the GUW -- I'm sorry. 34 percent of the CAWS users were kayakers, and 31 percent of the GUW users were kayakers. So that's in the ballpark of having -- potentially having statistical significance. I couldn't do that calculation. That takes a computer. But that kind of difference could be

detected if it's very large.

MR. ANDES: Let me follow up on that. So Dr. Dorevitch, is part of what you're saying is the difference in risk -- I think you talked about it being slight. When we're talking about smaller risks, it's hard to tell the difference between groups. Is that true?

DR. DOREVITCH: Yes.

MR. ANDES: In this case, are you talking about small risks relative?

DR. DOREVITCH: Well, in the case of GI illness, we're starting out with a risk of about four percent of people developing GI illness in day zero to three. So a ten percent increase in risk would be a 4.4 percent developing GI illness. That's pretty small. That would take a lot of people to detect a difference that small.

MR. ANDES: And if the risk instead were, say, 50 percent --

DR. DOREVITCH: So we're talking about four percent to a six percent difference. That might be detectable in the kayaker versus kayaker comparison, but not in the children under the age of four or five to nine.

MS. ALEXANDER: Would it be fair to say that the statistical power for the kayaker-to-kayaker comparison we're discussing would be less than the .91 statistical power reflected in your calculation for the overall study?

DR. DOREVITCH: That's, sort of, by definition, you know, the fewer people involved in a comparison, the fewer the observations in a comparison, the less power.

MS. ALEXANDER: Would I be correct in understanding from this list that you are not considering the year of enrolment as a confounding factor?

DR. DOREVITCH: No. This is the list of variables that made it to the final model. Year of enrolment, season -- there are -- I don't know if you participated in the study, but there are lots of questions that people are asked, and we've looked at many others as potential confounders. But most of them did not -- most of them were not related to either a study group or outcome, or didn't have any sort of biological plausibility in terms of leading potential of a GI illness or other illness.

MS. ALEXANDER: So do I understand

correctly that you contemplated evaluating year of enrolment as one of your final confounder data points but decided against that?

DR. DOREVITCH: Right.

MS. ALEXANDER: And what was the basis for that decision specifically with respect to year of enrolment?

DR. DOREVITCH: That it didn't -- whether you include it or didn't include it in the model, it didn't change the results.

MS. ALEXANDER: And what analysis -- what did you do to figure that out?

DR. DOREVITCH: We did a logistic regression model that had a study year, and a model that did not have study year.

MS. ALEXANDER: Did you collect data on people's socioeconomic status as opposed to race and ethnicity?

DR. DOREVITCH: The closest we got would be zip code.

MS. ALEXANDER: Did you make any effort to evaluate socioeconomic status as a possible confounding factor?

DR. DOREVITCH: We evaluated using

spacial mapping techniques where participants in the three groups live. We didn't identify differences in the distribution of participants by zip code.

MS. ALEXANDER: When you say you attempted to identify differences between zip code, did you evaluate socioeconomic data concerning different zip codes?

DR. DOREVITCH: Well, if -- yes, we have median household income by zip code. But if the distribution among zip codes is the same, then the distribution of median household income is the same. So it was a map of where all study participants lived divided by group.

MS. ALEXANDER: Other than what you have just described, did you do any other analysis concerning socioeconomic factors and their possible impact on the study?

DR. DOREVITCH: No.

MR. ANDES: Can I ask, are the reasons why someone might answer more honestly with respect to zip code than with respect to socioeconomic status?

DR. DOREVITCH: Well, socioeconomic status isn't the easiest thing to measure. You

know, it can be measured as the highest level of educational attainment or household income. The study is conducted in a fairly public setting, at a tent at a water access point, maybe with a lot of people around. So we didn't want to ask sensitive information. The zip code is a pretty good piece of information we need anyway to mail people a thank-you check for being in the in the study. So we had that, and it wasn't intrusive to obtain that.

I'd say that -- you know, I don't think other epidemiologic studies have gone beyond race, ethnicity, age, gender, as a demographic consideration in evaluating the relationship between water quality and health.

MS. ALEXANDER: What about skill or experience level? Did you evaluate that as a potential confounding factor?

DR. DOREVITCH: Indirectly we did. People who use the water more frequently are assumed to have higher skill.

MS. ALEXANDER: So are you saying you ran analysis on frequent versus less frequent use as a potential confounding factor?

DR. DOREVITCH: Yes.

MR. ANDES: That's number four on the list.

MS. ALEXANDER: But no specific analysis concerning skill level in your questions or analysis. Is that correct?

DR. DOREVITCH: I'm not familiar with any sort of question that could be asked to rank each person's skill level.

MS. ALEXANDER: Do you have an opinion one way or the other as to whether skill level could influence risk outcomes?

DR. DOREVITCH: I think it could. I think that it's, sort of, incomplete though. I think the frequency of use is probably a better indicator of that.

MS. ALEXANDER: Why do you say that?

DR. DOREVITCH: Well, I think it combines two potential issues. One is level of skill, and the other one has to do with level of prior exposure to the water, potentially the development of immunity to microbes in the water.

MS. ALEXANDER: What about the question of years for which data was available? It's my understanding that it was -- there were some

years for which certain data was not available. Did you consider that as a confounding factor?

DR. DOREVITCH: Well, all of the data on this list of -- in this exhibit was available.

MS. ALEXANDER: One second. I'm going to come back to this question after a break so as not to waste time.

What about the season in which the activity took place, spring versus summer versus fall? Did you consider that as a confounding factor?

DR. DOREVITCH: Yes.

MS. ALEXANDER: And what analysis did you do underlying your decision not to include it on the list we were just provided?

DR. DOREVITCH: Analysis of a model that included season compared to a model that did not include season.

MR. ANDES: Is that a logistic regression analysis?

DR. DOREVITCH: Right.

MR. ANDES: And did that show no significant difference between the two groups?

DR. DOREVITCH: Right.

MR. ANDES: Thank you.

DR. DOREVITCH: I should be a little more precise. It showed no difference in the health risks, whether you include season in the model or not.

MS. ALEXANDER: Is the logistic regression analysis of these confounding factors now included in the final analysis going to be included the final report that is provided?

DR. DOREVITCH: Definitely.

MS. ALEXANDER: Based on the data that you have evaluated, have you identified any differences between CAWS and GUW users that appear to impact the health risk?

DR. DOREVITCH: In the technical report, there were some differences between CAWS and GUW users that were noted. The composition of the study groups in terms of gender and race, ethnicity, was different, and in the comparison of CAWS and GUW participants, the recreational activity and degree of water exposure were different.

MS. ALEXANDER: In the technical report, I would call to your attention the fact that it appears that only 30 percent of the CAWS users

were enrolled in 2009, compared with 40 percent of the GUW users in that year. Does that sound correct to you?

DR. DOREVITCH: Yes.

MS. ALEXANDER: Does water quality vary by year?

DR. DOREVITCH: It can.

MS. ALEXANDER: So is it possible that that difference in enrolment could impact your final results?

DR. DOREVITCH: In theory, it could. But that's something that's been evaluated, and it doesn't.

MS. ALEXANDER: So if an item is on this list that we have been provided, has a preliminary determination been made that, in fact, that confounding factor does affect the risk calculation?

DR. DOREVITCH: Not necessarily, no.

MS. ALEXANDER: What is the positive finding that resulted in a factor being included on this list?

DR. DOREVITCH: It wasn't that simple. We were using a conceptual model of things that

relate -- things that caused symptom recording. In other words, somebody could have GI illness because they got sick on the water because there was a microbe that they ingested. So ingesting water would be on that causal pathway.

There are confounders, things off of the causal pathway. So somebody might have preexisting intestinal conditions that puts them at risk for having GI symptoms, independently of water exposure or the age category. Children are more likely to have diarrheal disease than adults.

So things that could potentially cause symptoms, but not through the causal pathway of ingesting water, they go on the model. And then what are called effect modifiers, variables that have different associations between group and outcome depending on the level. In other words, people with diabetes may have a different risk than people who don't have diabetes. That would be not a confounder, but a potential affect modifier.

Based on each conceptual -- the conceptual model for each outcome, variables were, sort of, a priority to determine what makes sense here. If we're looking at developing GI symptoms,

previous symptoms have shown that eating a hamburger is associated with a higher rate of illness. So that goes in that particular model, and it remains there whether or not we find it to be statistically significant or not.

On the other hand, eating a hamburger should have nothing to do with getting swimmer's ear. And even if they were statistically significant, it wouldn't go in that model because there's no biologic plausibility that I can think of that would explain that connection.

So that was the general approach, to develop a causal pathway and a conceptual model, and to include variables in that model that makes sense that have biological plausibility. And to some degree, it's been entered, and we have looked at some variables that show no relation and really don't have any biological plausibility.

For example, season has biological plausibility, and year doesn't. The relationship between water quality and health should be about the same. The relationship between a certain E. Coli level and health should be about the same, no matter what year we did that, whereas with season, I

wouldn't say that's true. There are seasonal illnesses, and there are patterns in finding microbes in wastewater. So I'd say season is different than year.

So some additional variables were evaluated that way. And these are the analysis of -- in the analysis of water quality as a predictor, the list is a little different.

MS. ALEXANDER: Can you explain specifically the basis for including gender on this list?

DR. DOREVITCH: It's really -- previous studies have shown higher rates of reporting GI symptoms among women compared to men, including previous studies of water recreation. So I don't think it has biological plausibility. I think it may have to do with perceiving and reporting symptoms. But because that has been previously identified, including other studies of water recreation, that's concluded in the model.

MS. ALEXANDER: Does your logistic regression analysis account for clustering?

DR. DOREVITCH: Are you referring to Dr. Gorelick's comment about clustering?

MS. ALEXANDER: Yeah, the general idea of clustering, meaning a family sharing a boat or a rowing team, and that effect on statistical data.

DR. DOREVITCH: Not to that level. But participants in large events versus others, yes. Let's say there's an outbreak of a disease that is or isn't related to water quality but it's happening in a certain point in time. If there was a large event, let's say the Flat Water Classic or the Des Plaines River Marathon, it's conceivable that participants in that event would have a higher rate of illness than had they done the same thing when this unrelated outbreak was taking place.

So yes, I've analyzed clustering in terms of participants who are in large events versus others. We do ask questions though about households and contact with other people with GI illness in determining whether it's a family member or another contact. So we do have information about illness among contacts, and that hasn't -- I haven't analyzed that, but that could be done.

MS. ALEXANDER: What types of clustering did you evaluate besides that? You mentioned the Flat Water Classic. Is there any

other type of clustering that you concluded in your analysis?

DR. DOREVITCH: Well, like I said, it's not restricted to the Flat Water Classic, it's large evens where the occurrence of a cluster could distort the overall results. So the Flat Water Classic in 2007 and 2008, the Des Plaines River Marathon, the Fox River dragon boat races, the Ping Tom Park dragon boat races -- and there's probably another one that I'm forgetting -- but we looked for large clusters -- places where clusters might be observable.

If there's a family of four and two of them got sick, that wouldn't be something that could be detected as a cluster. It would be differentiated from chance -- even knowing whether other family members have symptoms it wouldn't be possible to say that this is a cluster. It's too small.

MS. ALEXANDER: What about a rowing team? Did you look at that?

DR. DOREVITCH: No. We don't actually record membership in rowing teams. We do have information about who was recruited where and when,

and it's pretty obvious in terms of who are the Lincoln Park rowers and who are the Skokie Rowing Center rowers. But it's not to the point that we can say this is the Northwestern rower, and that's a New Trier rower, other than looking at their age.

MS. ALEXANDER: What about clustering of people not sharing a household but sharing a boat?

DR. DOREVITCH: No, that was not analyzed. I would say that none of the statisticians or epidemiologists would have advised cluster analysis.

MS. ALEXANDER: Have you scrutinized your data for sources of bias and systematic error?

DR. DOREVITCH: Yes.

MS. ALEXANDER: And what sources of those bias and error have you scrutinized?

DR. DOREVITCH: Well, I'd say that the design that we're using, the perspective cohort study, was selected because it's not subject to a lot of the biases that other study designs are, such as case control study. A potential bias within a cohort study could result if there's differential loss to follow-up. So if the people who get sick

remain in the study and the people who stay healthy drop out, or the reverse, that would be a type of systematic error that can cause a bias.

You know, a number of measures are in place to prevent recall bias. If we ask people at the time that they got sick that they report illness on the phone, "How wet did you get," or, "Did you swallow water," or, "How risky do you think it is to use the Chicago River," their answer to that might be influenced by their development of symptoms. So those questions are all asked up front at the time and place of recreation.

So a lot of the types of information bias and selection bias that could occur in other study designs are something that we're able to avoid. I think if the -- you know, one potential selection bias would be if people who enroll -- let's say there are people on the CAWS who do risky recreational activities, risky meaning a high limit of developing GI illness and people who do activities that are low risk, and only the people in the low risk category enroll in CHEERS, or only the people with the high risk enroll in the study, that would be a type of selection buys.

And to evaluate that, I looked at the new survey results that are presented in the technical report. And if anything, the study under-represents boaters and over-represents kayakers. So if anything, the kayakers, I would suspect, have a higher degree of water exposure, and that has been borne out in our analysis. If anything, there is a higher percent of them in the study than the boaters.

So the argument could be made that it's biased high, but I think that really the people who participate in the study are pretty representative of the people who use the CAWS.

MS. ALEXANDER: Would it be your view that, notwithstanding your efforts to address recall bias, that the study may still have some recall bias issues?

DR. DOREVITCH: If they were -- I think it's possible peoples memory may be clouded in some way when we speak to them later. But when they immediately get out of the water and nobody has developed an illness yet, I don't really see that. I think the strength of the study though is that we have CAWS users and GUW users and unexposed users.

So if there's something funny about the way people remember things, it should be distributed across groups.

When people are reporting illness on the phone two days later, that's all three groups. I don't have any reason to think that there would be some differential across groups regarding the way people respond on the follow-up.

MS. ALEXANDER: But it would be fair to say that recall will inherently be imperfect in the sense, for example, that parents might have trouble remembering whether their child had loose stools several days previously, that sort of thing?

DR. DOREVITCH: Right. And again, I think parents of children in the unexposed group would have the same difficulty as the parents in the CAWS group.

MS. ALEXANDER: Will your final report address all sources of bias and systematic error that you believe are potentially significant?

DR. DOREVITCH: Well, I think the standard approach to writing results includes a discussion of strengths and limitations. So that would, sort of, fall into the limitation discussion.

I mean, it would be unusual to say, "Here are the systematic areas that we identified." Because if you've identified them, you have a way of dealing with them. But the limitations of the study would be addressed definitely.

MS. ALEXANDER: When you say that you would deal with the bias and systematic errors, do you mean that you would factor it into your power calculation?

DR. DOREVITCH: No. I would think about doing analyses that could evaluate what is happening. For example, we have parents who provide information regarding their children. We know whether -- if we receive information about whether a child has a GI illness, we also ask the question about whether this is a proxy interview, that it was a parent providing information about their child and the child provided that information, and we could look at overall are there differences in the rates of illness within the same age category, whether it's a proxy interview or an individual interview.

So it wouldn't really go back to the power calculation. It would go to trying to analyze the data in a different way that takes into

account a potential bias, like you mentioned.

MS. ALEXANDER: Have you considered at all whether a concern among some with losing access to the river might be a source of bias? For instance, a high school rower who is worried that reporting illness might result in not being able to row on the CAWS and, hence, get a scholarship, that kind of thing. Have you considered that at all?

DR. DOREVITCH: I didn't consider that. I imagine that there are biases that have gone two directions. There are people who might say, "This water body needs to be cleaned up, and I want to let them know how sick I got." It's, sort of, impossible to get into the heads of individuals and say are they really reporting because they think the risk is high, or because they think it's low, or because they don't want to lose their scholarship? And it's certainly conceivable that such a thing exists.

There is a wide range of water quality in locations that we study. I'm not sure that people would know the water quality here is good or bad today, therefore, I'll bias my results up or down. In the analysis of water quality as a

predictor of health, I think that's free of that, kind of, individuals trying to skew the results one way or another, whereas specifically in the CAWS group, people may have all kinds of agendas for wanting to paint the picture more bleak than it is or more rosy than it is.

But there isn't a way in survey research in general, not specifically our study, to differentiate the true response from the true response that's been doctored in some way.

MS. ALEXANDER: Would it be fair to say that what I've just referenced is a potential source of bias in the sense that it's possible that it's simply not possible to account for in your research? Is that what you're saying?

DR. DOREVITCH: I would say that there's sort of an equal and opposite potential bias the other way that can't be accounted for either. I wouldn't overstate the importance of the potential that somebody might have a bias in a particular direction, because there are reasons that it potentially could be in the reverse direction. There are biases that can be identified and biases that are purely hypothetical. I wouldn't know. I'm

not aware of any way of evaluating whether the net bias is towards overstating one's symptoms or understating one's symptoms.

MS. ALEXANDER: So would it -- I'm sorry. I didn't mean to interrupt.

MR. ANDES: To the extent biases exist, they could also exist in the GUW users, correct?

DR. DOREVITCH: Correct.

MR. ANDES: The users of other water bodies?

DR. DOREVITCH: Correct.

MS. ALEXANDER: Would it be fair to say, or would I be understanding correctly, that it's not your intention to specifically address the potential bias I'm referencing in your final report?

DR. DOREVITCH: If you tell me how to address that bias, I'm all over it. But I don't -- you know, it's so hypothetical that it could make an infinite list of hypothetical biases that can't be identified, and therefore, not accounted for. So you show me how to account for that bias, and I'll run the analysis.

I mean, I don't mean to take

lightly your comment, but I do think that the question -- we do ask the question of study participants, on a zero to ten scale, how much of a health risk do you think it is to use the CAWS for recreation. And I think that is related to your idea that people might skew their results based -- skew their reporting of symptoms based on their perceived risk. And that is something that's -- we're well aware of and have accounted for in the analysis.

MS. ALEXANDER: Now, am I correct in understanding, referencing averaging as a potential bias, that your microbe counts are an average of -- daily averages at a given sampling site?

DR. DOREVITCH: For the summary table, yes. But for the analysis, no. If John Doe enrolls in a study and he's at North Avenue launch on a given day, we wouldn't use the yearly average value of E. Coli to estimate his health risk. We would use a measure of E. Coli at North Avenue on that day at that hour. So the averaging was just for the purposes of summarizing the whole data.

MS. ALEXANDER: Now, do I understand correctly that it's possible that this user was not

on the River at the same time that you took the sample? Is that correct?

DR. DOREVITCH: That is correct.

MS. ALEXANDER: And is it possible that the microbe count at the time the users were on the river is different than the microbe count when you took the sample?

DR. DOREVITCH: Not only that, but it's possible that we took a sample at that time that he was on the water, but when he got splashed 15 minutes later at a different spot, the water quality was different there.

MS. ALEXANDER: Will that issue be addressed in your analysis?

DR. DOREVITCH: That isn't something that is directly -- that you can directly account for. But what that says is that there's a possibility of misclassification, that people could be misclassified to having been on the water at a low E. Coli time, but they were actually there on a high E. Coli time or vice versa.

In practice, the variability within locations on a given day at the CAWS is actually fairly small. There's substantial

variability across locations. But within a given location for the same weather conditions, there's not a whole lot of variability, so there probably is some misclassification. We measured E. Coli at 500, before they got splashed it was 475 or it was 525. But I don't think there's any direction to that misclassification.

In other words, people are being falsely assigned lower or higher values systematically. So that comes out in the wash. It adds to a little bit of imprecision in the estimates of the relationship between water quality and health.

MS. ALEXANDER: You also, if I understand correctly, referenced the issue that the user may have moved from the spot at which the sample was taken in a space of, say, 15 minutes.

DR. DOREVITCH: Sure.

MS. ALEXANDER: Is that issue being addressed in your analysis?

DR. DOREVITCH: Well, we collect information about where people start and where people end and what time they start and what time they end. So some people -- most of the people on

the CAWS actually start and end at the same place, except for the big events like the Flat Water Classic.

On the other hand, there are big GUW events which account for a reasonable percentage of GUW participants where people begin up north on the Des Plaines River and finish up down the south -- they remain in the Upper Des Plaines River, but they get farther down. And we collect water at multiple locations on the river, so we know each person's start and end point.

We can come up with a consolidated average number of water quality at the start location and at their end location, and we sample water every two hours. If it's a long event, like the Des Plaines River Marathon, there could be a measure of water quality in between that they passed on their way to the finish line.

MS. ALEXANDER: And I guess my question is: Assuming you can account for that in between difference, will that fact that you can account for it be referenced in the final report?

DR. DOREVITCH: It's a limitation of exposure assessment. I think it's actually less

problematic in our study than these studies of beaches where there's a very high minute-to-minute variability in water quality at Chicago beaches or marine beaches. The CAWS is a pretty constant system outside of precipitation effects, and I don't think it would have much of an effect on the CAWS at all.

MS. ALEXANDER: I guess my question is: In your final report, will there be a section that references data limitations such as this one?

DR. DOREVITCH: Yeah, that exposure is an estimate. It's not a direct measure. When a person gets splashed, we don't collect a sample of what's splashed right on them. So yes, it's a limitation. I haven't written that section yet, but it's on the list of things that need to be described.

MR. ETTINGER: Can I just follow up on this variability issue? You said that in the lake, basically, there can be high variability in the pathogen levels over the course of the day?

DR. DOREVITCH: The indicator levels.

MR. ETTINGER: The indicator levels. And how does that happen?

DR. DOREVITCH: Tides and waves. That sediment is resuspended with wave action, and that's really not a phenomenon in the CAWS.

MR. ETTINGER: And in the CAWS then, did you -- you said you didn't look at precipitation events, or did you?

DR. DOREVITCH: I didn't say anything about looking for it.

MR. ETTINGER: Well, then let me state my question. Is there variability based on precipitation events to your knowledge?

DR. DOREVITCH: Yes.

MR. ETTINGER: Did your study look at that specifically as to how pathogen levels vary as based on precipitation events?

DR. DOREVITCH: Yes.

MR. ETTINGER: Did you look at any relationship between usership of the water and precipitation events?

DR. DOREVITCH: No.

MR. ETTINGER: Do we know whether people are using the CAWS more or less in relation to -- do we have any data on how people are using the CAWS in relationship to precipitation events?

DR. DOREVITCH: I have that data. I haven't analyzed it in that way.

MR. ETTINGER: Is that data going to be part of the final report?

DR. DOREVITCH: Honestly, I hadn't thought about looking at precipitation in relation to rates of recruitment or anything like that. I think that the water -- the precipitation, or the CFO effects, translate into changes in water quality.

And since we're looking directly at water quality as a predictor, that's obviously getting more subtle to say, "Well, is the risk of illness higher or lower when the E. Coli is influenced by precipitation or storm runoff." And that will be in the analysis of water quality as a predictor. But in the group comparison analysis, no, I haven't included whether it was a rainy day or not when the participant enrolled.

MR. ETTINGER: Okay.

MS. WILLIAMS: Good morning, Dr. Dorevitch. I'm Deborah Williams from Illinois EPA. I just have a quick follow-up on this issue of water quality. Is it correct to say that your study

concluded that generally E. Coli densities are higher downstream of the MWRD plants than upstream?

DR. DOREVITCH: Yes.

MS. WILLIAMS: Thanks. That's all I have.

MS. TIPSORD: Ms. Alexander?

MS. ALEXANDER: Going to question six, have you completed your assessment of the amount of missing data in participant responses?

DR. DOREVITCH: Yes.

MS. ALEXANDER: Beyond what we've talked about in terms of the participation in the phone calls one, two, and three, can you summarize any additional missing data conclusions at this stage?

DR. DOREVITCH: Yes. There were 14 people who didn't state what their race or ethnicity is, so that can't be -- those people can't be analyzed in this multi-varied analysis with race and ethnicity as a confounder. There were 340 people who had missing data of how frequently they use the water, and there were 90 people who were missing a smattering of the other 19 items on that model. So there was a total -- and then there were people who

had baseline symptoms.

So if somebody at the time of enrolment had GI symptoms, they could not be considered to be at risk for getting the GI symptoms because they have them already. They can be considered at risk for getting respiratory symptoms. But for each health outcome, people with baseline symptoms were excluded.

So there were 550 people who had baseline symptoms, and the total number of people with complete data for the multi-varied analysis of GI illness under age zero to there was 10,303. And that's the number that was used in the power calculation.

MS. ALEXANDER: Question seven, I believe the initial question has been responded to, but just to ask a couple of follow-ups, do you have data on how many pregnant women participated in this study?

DR. DOREVITCH: No.

MS. ALEXANDER: Did you ask that question, whether people were pregnant?

DR. DOREVITCH: Not exactly. If people developed -- we didn't ask that question at

the time of enrolment. If somebody developed certain symptoms, they were asked if they think the symptoms are related to menstrual cramps or pregnancy. But we didn't ask all women of childbearing age whether they were pregnant.

MS. ALEXANDER: Would I be correct in understanding that pregnant women are a sensitive population in the sense of a higher risk from exposure to pathogens?

DR. DOREVITCH: That's not something I said.

MS. ALEXANDER: No, it's something I'm asking. Would I be correct in understanding that pregnant women are at a higher risk of infection?

DR. DOREVITCH: That hasn't been studied.

MS. ALEXANDER: By you or by anybody?

DR. DOREVITCH: I'm not aware of any study of water recreation and pregnancy.

MS. ALEXANDER: Okay. But my question is not that. It's whether, as a general matter, is it your understanding that pregnant women are at higher risk of infection than non-pregnant women?

DR. DOREVITCH: Well, I don't think it

makes sense to talk about infection broadly. If you want to talk about a urinary tract infection, yes. If you're saying there's a systemic loss of immunity in pregnancy, you know, I'm not an obstetrician. But I'm not aware of a higher susceptibility of infection in general for a pregnancy. But that's, sort of, beyond my area of expertise. But specifically about water recreation, no.

MS. ALEXANDER: Did you ask whether people were on chemotherapy?

DR. DOREVITCH: We did not ask that question. We asked the question, "Do you have any health condition that makes you at risk for infection or prone to getting infection." We didn't want to ask in this relatively public arena, "Do you have aids? Are you HIV positive? Are you on high does steroids? Have you received an organ transplant? Are you on chemotherapy?" So we asked, sort of, more blanket question about health conditions that make you prone to infection.

MS. ALEXANDER: Do you recall exactly or approximately how many people answered yes to that question?

DR. DOREVITCH: No, I don't recall. I

might have it with me, but it would take a little time to open up my files and track it down. So I have looked at that. I don't know the number. It wasn't a very high percent of participants.

MS. ALEXANDER: Okay. So would it be fair to say, following up on the earlier questions, that a comparison of persons with medically compromised immunity on the CAWS, versus persons of medically compromised immunity on the GUW, that you would not have much statistical power to make that comparison in this study?

DR. DOREVITCH: That there are so few people with compromised immunity on the water, right. It is impossible to study them.

MR. ANDES: Can I ask a follow-up? Dr. Dorevitch, as a medical doctor, would you -- what advice would you give to people with compromised immune systems in terms of recreating on the CAWS, or for that matter, in the general use waters?

DR. DOREVITCH: Well, if their immunity is severely compromised, I would say avoid exposure to pathogens, which would include recreating on these recreational waters. I think

probably a swimming pool wouldn't be a whole lot better, in that there are outbreaks of pretty severe illness that occur in pools. I'm sure an oncologist would have an answer to this question, because I'm sure it comes up from their patients on chemotherapy, "Can I go swimming?"

I don't know that answer, but I would say avoid surface water recreation if you have a compromised immunity, such as low white blood cell counts following chemotherapy.

MS. ALEXANDER: Would you offer the same advice to other sensitive populations, such as children?

DR. DOREVITCH: Well, I think that's something that we actually have some data on. I mean, we do have hundreds of children in the study. And although the study was not powered to identify that difference, I think it's reasonable to see what we're finding.

MS. ALEXANDER: Let me ask the question a little differently. Would you agree that children are a sensitive population in the sense that they are more susceptible to illness than members of the general population, young children I

mean?

DR. DOREVITCH: It's a little broad.

MS. ALEXANDER: Children under four.

DR. DOREVITCH: If you mean children in relation to water recreation getting GI illness, I don't think it's so straightforward. There was a study paper that was published out of the NEAR study whose title is something like, "Children are at high risk of gastrointestinal illness following swimming." But I'm not convinced that that's actually the case. I think that paper, if anything, suggests that people over the age of 55 may be at greater risk than others.

But I don't see -- I haven't seen the evidence that says children are higher risk. In swimming pools, it's a whole other story, or in small lakes where kids are leaving stool samples in the water, that's a setting where it's been documented many times that other children get sick.

But I don't -- you know, I think the jury is out on -- if you want to get that specific, children under the age of five are they at higher risk than others in terms of limited water contact recreation, I don't know that.

MS. ALEXANDER: Would it be your advice to people over 55 that they not recreate on the water?

DR. DOREVITCH: No.

MS. ALEXANDER: Why?

DR. DOREVITCH: Well, there's a difference between saying there's an increase in risk and saying it's dangerous. If you're talking about a fairly mild outcome and the risk goes from five in 100 to six in 100, I wouldn't say you better not do that. There are health benefits to physical activity. People enjoy water recreation. I wouldn't say no excess risk is tolerable. It depends on how great the risk is and how severe the outcome is.

MS. ALEXANDER: But you would tell people with other types of immunocompromise not to recreate?

DR. DOREVITCH: Well, specifically somebody who had recently had cancer chemotherapy, sure, they could be killed by exposure to a pathogen. But somebody who's 56 years old instead of 55, that doesn't mean that they're at risk of dying in the way somebody who recently received

chemotherapy or recently received an organ transplant and is immunocompromised suppressed. Those are folks that -- I don't need to see data. I would say with death as a potential outcome they shouldn't do it.

MS. ALEXANDER: Do you have an understanding generally as to approximately what percentage of the population is considered a sensitive population, medically speaking, in the sense that they are at greater risk of infection?

DR. DOREVITCH: I don't think there's a definition of sensitive population.

MS. ALEXANDER: If I were to define it in a way that I just did, categories of people who are inherently at greater risk of infection, could you answer the question?

DR. DOREVITCH: Well, you got to say what the category is. I couldn't answer the question. I mean, I don't -- I couldn't rattle off the statistics that ten percent of the population is under the age of ten or whatever. But I don't think that there's this widely accepted medical definition of people at risk. I think it's specific to a particular outcome.

MS. ALEXANDER: Have you heard an estimate anywhere from anyone of that sensitive category being approximately 20 percent of the population?

MR. ANDES: Are we introducing evidence here on a number? Is this documented somewhere? It's very hypothetical.

MS. ALEXANDER: I can make it non-hypothetical when I get the right documents off my computer. But I'm asking the question generally now. Have you heard that number?

DR. DOREVITCH: I believe it's come up in a prior round of testimony more than a year ago.

MS. ALEXANDER: Do you recall that Dr. Gerba (phonetic), the District's witness, specifically presented that number?

DR. DOREVITCH: That sounds right. I don't -- I wasn't here for all of his testimony. But if that's what he said, that's what he said.

MS. ALEXANDER: Do you disagree with his conclusion in any way?

DR. DOREVITCH: I don't know what it means. I don't know what "sensitive" means. I think if you want to say -- I'm sure you can

calculate the percent of the population in different age categories, the percent of the population receiving cancer chemotherapy, the percent of the population with diabetes. That might add up to 20 percent. But I couldn't comment one way or another whether it does or doesn't.

MS. ALEXANDER: Would you -- you referenced children swimming in lakes being at higher -- or a potentially higher risk. Would you recommend that children not swim in lakes, as a medical doctor?

DR. DOREVITCH: No. I was speaking specifically about outbreaks that have occurred in small lakes. And I wouldn't recommend not swimming either. What I think is important to the public health message that the CDC is trying to get out, is that if you are sick, or if you recently were sick with intestinal symptoms, don't go in the water because you're going to spread it to other people. I think that's the real message, not that children shouldn't use lakes.

MS. ALEXANDER: What about people with diabetes? Would you recommend that they stay off the water?

DR. DOREVITCH: I think the final report will have some information about the risk for diabetes, for people with diabetes.

MS. MEYERS-ELEN: I have a follow-up. Does everyone who has diabetes, for the sake of argument, pregnancy, immunocompromised in some way, that they may be pregnant or have other issues with their health so that they're immunocompromised, do all of those people know probably that they are, in fact, immunocompromised for the sake of this study?

DR. DOREVITCH: Well, I'd say if somebody received an organ transplant or gets cancer chemotherapy, they know.

MS. MEYERS-ELEN: How about diabetes or pregnancy? Is there a possibility that someone can have one of these conditions or that there are a decent percentage of the population that actually does have diabetes or could be pregnant at the time that they're out in the water and not know it?

DR. DOREVITCH: We ask people if they have diabetes specifically. So are there people who have subclinical diabetes, absolutely. That's a big public health problem in this country. But a sizeable percent of the study participants noted

that they do have diabetes. And sure, there could have been people who have diabetes -- prediabetes and don't know it. Pregnancy, of course it's possible that somebody is pregnant but doesn't know it yet. But that doesn't mean that they're at an increased risk for infection. But sure, they may be pregnant and not know it.

MS. MEYERS-ELEN: Thank you.

MS. ALEXANDER: I'm going to move on now to question nine in the pre-filed testimony, which references the article cited on Page 2 of your pre-filed testimony in the June 2010 issue of environmental health perspectives. And I would like to have this marked as -- 388 are we up to?

MS. TIPSORD: No, it would be 389.

MS. ALEXANDER: 389.

(Document tendered.)

THE COURT: I've been handed, "Meeting Report: Knowledge and Gaps in Developing Microbial Criteria for Inland Recreational Waters," by Samuel Dorevitch, Nicholas Ashbolt, et al. If there's no objection -- this is from Environmental Health Perspectives, Volume 188, June 2010. If there's no objection, we will mark this as Exhibit 389. Seeing

none, it's Exhibit 389.

(Document marked as Exhibit No. 389 for identification.)

MS. ALEXANDER: Dr. Dorevitch, is this the article that is referenced on Page 2 of your testimony?

DR. DOREVITCH: Yes.

MS. ALEXANDER: I'd like to call your attention to Page 875 of the document. You'll see that in column one there's your reference to long-term research. Specifically concerning the first long-term goal identified, modeling water quality in real time, is it fair to say that this research goal that you're identifying here is to gain an understanding of the impact of the environmental factors you're citing, which are solar radiation, rainfall, biotic, and hydrological factors on risk?

DR. DOREVITCH: Well that's two steps away. It's about predicting water quality, not about predicting health risks. So that if you -- just like meteorologists can look at barometric pressure and wind and clouds and they can predict, with some accuracy, the weather, this is

like saying if the Chicago Park District wants to know today whether the beaches should have a swim ban or swim advisory that there should be enough information out there that if you look at things like the solar -- you know, how sunny it is outside and other factors, you can predict water quality, not specifically predict health.

MS. ALEXANDER: So in other words, do I understand correctly that these are factors that are potentially constantly influxed, and goal would be to understand at any given moment, if you look at those factors, what their impact on water quality is?

DR. DOREVITCH: Generally, yes.

MS. ALEXANDER: And they could be influxed potentially within the course of one day, correct?

DR. DOREVITCH: Definitely.

MS. ALEXANDER: Would I also be correct in understanding that the CHEERS study is not performing this analysis of the impacting factors on water quality that you identify as a long-term research goal?

DR. DOREVITCH: The CHEERS study is

collecting some data that could be used in future analyses like that. But our data is -- our health projections are based on something better than modeled water quality. It's measured water quality.

This is a way around measuring water quality and around waiting for test results to come back. We actually did the test and have the results, so we don't need to know to what degree solar radiation changes the E. Coli level. We know what the E. Coli level is.

MS. ALEXANDER: You know it for a particular time of day, correct?

DR. DOREVITCH: Correct.

MS. ALEXANDER: So you would not necessarily know, for instance, how the difference in solar radiation might have impacted the level of E. Coli at a different point in the day, correct?

DR. DOREVITCH: Just like all epidemiologic studies like this, right. We collect water more frequently than is done in the NEAR study. So any study is potentially subject to this question of misclassification, that the water quality changed or couldn't have been accurately estimated, given the volume of water tested.

So that's, sort of, a generic issue about measuring water quality as a way of estimating exposure of individuals. But I think between measuring and modeling, measuring is the gold standard, not -- one day maybe ten years from now there will be models that are good enough to approximate measurements, but that's pretty far off.

MS. ALEXANDER: I want to call your attention now to Page 873. In column three, over to the right in that first continued paragraph -- this is now sub question B and question nine. Can you discuss in further detail what's meant by the contrast or drawing between epidemiologic studies that have described rates of GI illness generally thought to be mild and self limited, versus outbreaks and inland waters that have included rare but potentially life threatening infections?

DR. DOREVITCH: Sure. What I think happens is that every time people are using any beach, a small percent gets sick due to beach recreation. Maybe five percent, maybe ten percent, maybe two percent. Those folks tend to have fairly mild symptoms, meaning they get better on their own without going to a hospital, maybe losing a day from

work or school, and then there are outbreaks which are unpredictable and rare, and those would be things like children in the lake. If one of them is getting over a serious intestinal infection sheds bacteria from their stool into the water, it's a small lake, so there's a limited capacity for dilution, and other people on the beach nearby come down with a potentially serious infection. And that's been described in a couple of studies, one by Keen and one by Bruce, in the specific northwest.

So that's, I think, different than the sporadic illness, where maybe a few percent of the -- five percent of the people, ten percent of the people, get some mild disease. These are rare events of very serious disease that is caused by -- where this source of the fecal matter is the bathers themselves.

MS. ALEXANDER: Are these different types of infections that are occurring in these inland water settings that you referenced?

DR. DOREVITCH: I think so. You know, I mean, E. Coli O157:H7, the bad hemorrhagic E. Coli that causes meat recalls, has been described in these inland water outbreaks. Over the course of

epidemiologic studies of coastal waters, outbreaks of E. Coli O157:H7 have not been described.

MS. ALEXANDER: Just calling your attention now on Page 875, again to appendix one, critical questions for inland water criteria development, do I understand correctly that these are all questions that have not been fully researched and you're stating need to be researched in the future?

DR. DOREVITCH: Yes.

MS. ALEXANDER: And would it be fair to say that none of these questions are specifically the questions of the CHEERS research?

DR. DOREVITCH: I would say that some of these are subjects of the CHEERS research, but I wouldn't say that the CHEERS research study results apply nationally. I think that this study was tailored to meet a local regulatory question. And what we may find about sources of pollution are microbes that cause illness or relationships between modeled risk and measured risk would be very relevant to local issues. But I wouldn't say that CHEERS is going to answer these questions for all sites around the country.

MS. ALEXANDER: I want to reference on Page 871, in the footnote concerning authorship, you state that you're currently receiving research support from MWRD and that the remaining authors declare they have no actual or competing financial interests. Why did you reference MWRD as a competing financial interest in this study?

DR. DOREVITCH: I didn't say it's a competing financial interest. I said I received research support.

MS. ALEXANDER: Why did you reference that research support?

DR. DOREVITCH: Because the guidelines of the journal are to include things like sources of research funding.

MS. ALEXANDER: Do you receive research funding from sources other than WERF and the District?

DR. DOREVITCH: I do.

MS. ALEXANDER: Why weren't those listed here?

DR. DOREVITCH: Well, because they were -- I mean, they weren't relevant. I mean, I received funding from the American Lung Association

-- or the Respiratory Health Association of Metropolitan Chicago, and I received research funding from the the U.S. Department of Housing and Urban Development. Since the time that this was accepted for publication, I will be receiving additional research funding from the USEPA. But that was just at the stage of a proposal under review at that time.

I mean, I'm not sure -- the other authors are saying that they -- I think one of the other authors listed his affiliation with his consulting company. So it's not that no authors accepting have anything listed. You know, I did try to clarify with the journal whether employment by EPA or the U.S. Geological Survey needed to be declared. But it's already stated as the author's affiliation for those folks.

So in a theoretical way, those are not conflicting and they're not necessarily conflicts, but information that the journal requests.

MS. ALEXANDER: Okay. I have no further questions for Dr. Dorevitch at this time.

MS. TIPSORD: Does anyone else have

any questions for Dr. Dorevitch?

MS. WILLIAMS: I have one really quick follow-up. Dr. Dorevitch, in your study you break it into three categories, CAWS users, unexposed, and general use. Is it correct that under the general use recreators you're including Lake Michigan?

DR. DOREVITCH: Yes.

MS. WILLIAMS: Are you aware that Lake Michigan is not classified as a general use water?

DR. DOREVITCH: Yes. It's just shortened. I mean, it would be just as accurate to say non-CAWS sites.

MS. WILLIAMS: Is there a reason that you didn't break out Lake Michigan in the general use waters?

DR. DOREVITCH: Well, we certainly did look at Lake Michigan being different. We have, sort of, three groups of what we call general use locations, rivers, inland lakes, and Lake Michigan. And then within Lake Michigan, there are harbors and beaches. And in our analysis, we're looking at those differently.

So I don't mean to suggest that that is the regulatory categorization, but it's a

short way of saying these are the places that aren't the CAWS that are general.

MS. WILLIAMS: I just wanted to make sure the record was clear on that point. Thank you.

DR. DOREVITCH: I mean, full contact recreation is permitted in all of the locations that the study refers to as general use.

MS. TIPSORD: Mr. Harley?

MR. HARLEY: Dr. Dorevitch, perhaps I missed this. You have given us a list of the potential confounders as they relate to GI lists. Are there similar lists for respiratory infection and for ear infection?

DR. DOREVITCH: And for skin infection as well, yes.

MR. HARLEY: And how would they compare in terms of the confounders?

DR. DOREVITCH: I'd say they're a little shorter, in that dietary exposures are not concerns for these. They're all a little different. I think for GI exposure -- for GI illness it's ingesting water that is considered to be on the causal pathway to illness, whereas for skin illness it may be contact with water at the body region

where symptoms develop. Or for swimmer's ear, otitis externa, it may be head immersion in the water rather than injection of water.

So they're, kind of, tailored to the outcome of interests, but some of the general ones of age category, gender, race, ethnicity, frequency of using the water, perceived risk, those are common to the different models.

MR. HARLEY: Now, to then accurately track those other potential health outcomes over much longer latency periods, you would have to get that information throughout the three calls, for example, for ear an infection?

DR. DOREVITCH: Correct.

MR. HARLEY: How many total questions would you ask someone at the point at which they were initially interviewed as a CAWS user?

DR. DOREVITCH: It's hard for me to answer that, just because they're not listed, one, two, three, four. It's, sort of, sequentially three B one, three B two. I would guess that when they're enrolled they probably answer about ten questions pre-recreation, and about, depending on their responses, 50 or 75 questions after.

There's a logic to the -- the internal logic to these computer-assisted questions, so that if you say, "No, I did not get wet," you're not going to get questions about did your face get wet, did your hands get wet. So it varies by individual. But a ballpark, something like 50 or 75 per person.

MR. HARLEY: Right as they were emerging from the water?

DR. DOREVITCH: Yeah.

MR. HARLEY: And then how many questions would they be asked during that first phone survey?

DR. DOREVITCH: Again, it depends on their responses. "Do you have any of the following symptoms?" "No." There isn't any need to get into, "When did it start? Did you miss work or school? Did you see a physician? Did you go to a hospital? Did you need prescription drugs? Did you take over-the-counter drugs?" So it's highly variable.

MR. HARLEY: What would be the range, Doctor?

DR. DOREVITCH: I think it's easier to give you a range of the amount of time it takes than

the number of questions. I would say between two and 15 minutes.

MR. HARLEY: And what about the second call?

DR. DOREVITCH: Same.

MR. HARLEY: And the third call?

DR. DOREVITCH: Same. No, the third call is a little shorter. There are some questions that are asked a little differently on the third call. If people say they have experienced water recreation since we spoke to them last, not as much detail is asked.

MR. HARLEY: And so in order to get a complete view of any individual user's potential health outcomes, including for an ear infection with a long latency period, you would need complete answers to questions from before use, after use, and through three phone calls?

DR. DOREVITCH: Not necessarily. I mean, to get technical, if somebody developed an ear infection after the first phone call, we don't need the third phone call to answer that question anymore. But in general, yes.

MR. HARLEY: So to see the entire

round of questioning from before you use, after you use, and one, two, three, phone calls, how many questions would someone have to answer in total?

DR. DOREVITCH: Well, again, using the how many minutes does it take, you know, including what happens in the field and on the phone, 30 minutes, maybe 15, maybe 45. It all depends on people's responses to -- you know, that drive the survey logic.

MR. HARLEY: You seem to be looking at the degree of specificity of some of these questions. They seem to be testing people's memories, not testing whether or not they might have been made sick by exposure to pathogens in the CAWS.

MR. ANDES: Do you have specific questions in mind?

MR. HARLEY: Ingestion of runny or undercooked eggs.

DR. DOREVITCH: Well, that is a question that, on the first phone call, we're asking about in the last two days since recreation, meaning they were asked it on day zero in the field and they're being asked it on day two over the phone.

On day five, the question is

again, "Since we spoke to you last," meaning now it's day five, "since day two, have you had runny eggs, et cetera?" For phone three, it is a longer time period. I don't think of it as testing their memory, but it is certainly a longer time window that we're asking about.

MS. TIPSORD: Excuse me, if I may? Dr. Dorevitch, you wouldn't ask them about runny eggs unless they indicated they had a GI disturbance, correct?

DR. DOREVITCH: No, that's asked --

MS TIPSORD: That's standard?

DR. DOREVITCH: Yeah, that's pretty standard. That's not driven by the survey logic.

MR. HARLEY: You would have to establish --

MR. ANDES: You ask that of all three user groups?

DR. DOREVITCH: Correct.

MR. ANDES: So to the extent there are memory issues, you have no reason to expect it would differ between the CAWS users and any of the other rivers?

DR. DOREVITCH: Right. And I think

specifically, about the 21-day follow-up period, that's something that at this stage we're just looking at in relation to ear symptoms. So runny ear -- runny egg is not used in the analysis of, you know, what, besides water quality, could have given this person ear pain.

So I don't think that if somebody had an ear infection between day five and 21 that they would necessarily forget that. And I certainly don't think that there's any particular direction to this, where the CAWS people would remember it and the unexposed would forget it, and the GUW, including Lake Michigan, would remember it differently than the others.

MR. HARLEY: Thank you, Dr. Dorevitch.

MS. TIPSORD: Ms. Wallace?

MS. WALLACE: Earlier in one of your responses, you used the term "risky behavior" in relation to activities on the river. So what would you characterize as risky behavior and why?

DR. DOREVITCH: Well, I was just speaking in general terms, trying to -- I think the question was about bias and systematic area in the study. And what I was saying is that if the people

who enrolled in the study were doing something that put them at higher risk for infection, you know, for illness, and that were different than the actual distribution of that activity among the overall population of users, our results would not accurately reflect the rate of illness among other users, as opposed to those who enrolled in the study.

I didn't have a specific risky behavior in mind, but I think generally, in the context of acquiring recreational or waterborne illness, the issue is exposure. So the more heavily exposed somebody is, a priori I would expect that would be associated with a higher risk of illness and the final report will suggest that as well.

MS. WALLACE: So what you're thinking is that any activity on the river that would give you a higher exposure to the water would put you at more risk for illness?

DR. DOREVITCH: In very general terms, yes. In the case of GI illness, if you swallow more water, I would think that that would lead to more illness. That puts an individual at a higher risk than somebody who doesn't swallow water, whereas for

a skin illness it may be somebody who gets splashed or submerged, rather than whether they swallowed water or did not swallow water.

MR. LONG: Thank you.

MS. TIPSORD: Any further questions for Dr. Dorevitch? Thank you. Oh, go ahead. Please identify yourself for the record.

MS. STITH: Dr. Dorevitch, my name is Cynthia Stith and I'm with the MWRG. I had just a question I was curious as to how the times between the days were chosen, the two to the five, and then the span from five to 21.

DR. DOREVITCH: Good question. I suppose I could have listed this when I was asked earlier about what is unique about the design of our study. But the ongoing epidemiologic study in the U.S. just looks at the day 10 to 12 time period and tries to contact participants then. We wanted to be more -- better able to identify the time point that illness occurs to be able to collect a stool sample from ill participants, so we wanted to have multiple time points.

The day two call was based on the expectation that there would be illnesses caused by

microbes with short incubation periods, and that would include viruses like neurovirus or roto virus, and that there would be illnesses potentially caused by bacteria, which could have a longer incubation period, and there could be illnesses caused by protozoan pathogens, like giardia cryptosporidium, which would have a longer incubation period still, and that the 21-day time point would be an opportunity to, with relative confidence, identify people who have these late presentations of cryptosporidiosis.

MS. TIPSORD: Anything further? Thank you very much, Dr. Dorevitch. We will reconvene here at 1:00 o'clock tomorrow afternoon. We will start promptly at 1:00 o'clock. Please try to be here. There are over 54 questions for Dr. Gorelick, so we're hopefully going to get through those tomorrow afternoon.

STATE OF ILLINOIS)
) SS
COUNTY OF COOK)

REBECCA A. GRAZIANO, being first duly sworn on oath, says that she is a court reporter doing business in the City of Chicago, that she reported in shorthand the proceedings given at the taking of said hearing, and that the foregoing is a true and correct transcript of her shorthand notes so taken as aforesaid, and contains all the proceedings given at said hearing.

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SUBSCRIBED AND SWORN TO
before me this 16th day
of July, A.D., 2010.

Kimberly A Meeks
Notary Public

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KIMBERLY A. MEEKS
MY COMMISSION EXPIRES
NOVEMBER 30, 2011

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