

ILLINOIS POLLUTION CONTROL BOARD

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

R08-09
 (Rulemaking-
 Water)

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REPORT OF PROCEEDINGS **STATE OF ILLINOIS**
 Pollution Control Board

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

A P P E A R A N C E S

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

1 HEARING OFFICER TIPSORD: Let's go on
2 the record. I am going to be repetitious
3 today, just so you all know. Be warned.
4 Good afternoon. My name is Marie Tipsord and
5 I've been appointed by the board to serve as
6 a hearing officer in this proceeding entitled
7 the Water Quality Standards and Effluent
8 Limitations for the Chicago Area Waterway
9 System and Lower Des Plaines River. Proposed
10 amendments to 35 Ill. Admin. Code 301, 302,
11 303, and 304. This is Docket No. 08-9 and
12 this is Subdocket B. With me today to my
13 immediate left is acting chairman G. Tanner
14 Girard, the presiding board member, to his
15 left board member Carrie Zalewski, to her
16 left board member Andrea Moore. To my far
17 right is board member Thomas Johnson and to
18 my immediate right is Alisa Liu from our
19 technical staff.

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

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

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

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

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

17 With that, Dr. Girard.

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

21 HEARING OFFICER TIPSORD: Forty-one.

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

1 HEARING OFFICER TIPSORD: Anybody have
2 anything before we begin?

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

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

1 right.

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

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

8 MR. ANDES: Thank you.

9 E X A M I N A T I O N

10 BY MR. ANDES:

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

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

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

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

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

12 A. Yes.

13 Q. Okay.

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

17 Q. What year was that?

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

23 Q. I think that's six so far.

24 A. Emergency Department of Management of

1 sexual transmitted infections in U.S. adolescents.

2 That's 2004 as well.

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

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

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

16 A. That's correct.

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

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

22 Q. Is that the 1992?

23 A. That was 2003.

24 Q. Okay.

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

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

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

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

1 A. Correct.

2 Q. And you agreed with those conclusions?

3 A. Correct.

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

7 DR. GORELICK: Yes.

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

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

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

1 DR. GORELICK: About 42,000.

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

4 DR. GORELICK: Oh, yes.

5 MS. ALEXANDER: How many about.

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

10 MS. ALEXANDER: And did -- ultimately
11 did these studies support a conclusion, this
12 42,000 person study, together with these
13 eight or ten other studies, then support a
14 conclusion essentially that a particular risk
15 did not exist and the CAT scan procedure was
16 not necessary?

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

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

16 MS. ALEXANDER: Okay. Thank you.

17 BY MR. ANDES:

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

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

1 appropriate?

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

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

7 BY MR. ANDES:

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

10 A. Yes.

11 Q. Can you tell me which studies?

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

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

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

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

1 MS. WILLIAMS: Illinois EPA?

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

3 MS. WILLIAMS: Can you give a date?

4 MR. ANDES: 1986, I believe.

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

1 for this type of epidemiological study.

2 BY MR. ANDES:

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

9 A. Yes.

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

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

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

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

24 Q. Well, I guess first question is are

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 Q. Can we get copies of that?

22 MS. ALEXANDER: That's the --

23 DR. GORELICK: This is one of the

24 NEEAR -- you asked for publications from the

1 NEEAR study.

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

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

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

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

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

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

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

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

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

15 MS. ALEXANDER: We will absolutely
16 make sure.

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

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

24 HEARING OFFICER TIPSORD: I'm just

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

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

6 MS. ALEXANDER: Sure.

7 HEARING OFFICER TIPSORD: The second
8 article is High Sensitivity of Children to
9 Swimming Associated Gastrointestinal
10 Illnesses - Results Using a Rapid Assay of
11 Recreational Water Quality, same authors;
12 looks like Timothy J. Wade, Rebecca Caldron.
13 This is May 3 -- May 2008, copyright
14 Lippenpot, Williams, and Wilkes. If there is
15 no objection, we'll reserve Exhibit No. 392
16 for this article. Seeing none, we'll reserve
17 292.

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

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

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

24 MS. ALEXANDER: I didn't know those

1 would be presented today. My apologies.

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

13 BY MR. ANDES:

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

18 HEARING OFFICER TIPSORD: 388.

19 BY MR. ANDES:

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

1 studies?

2 A. Yes. Many of them are the same.

3 Q. Thank you.

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

9 DR. GORELICK: Yes.

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

14 DR. GORELICK: We've done it several
15 ways. But the best way to do it is to
16 actually find out what their household income
17 is. Sometimes people use, for example, zip
18 code and you can look at the median income
19 for that zip code. So if I live in zip code
20 53213, I know what the average household
21 income is. But, of course, not everybody in
22 that zip code has the same -- people live on
23 one side of the town versus the other, people
24 who have different incomes. So that tends to

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

8 BY MR. ANDES:

9 Q. Were you asking them in a private
10 setting?

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

13 Q. Not at a public beach?

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

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

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

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

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

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

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

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

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

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

1 down based on consideration of various factors?

2 Say, including, let me suggest, biological
3 plausibility would be one thing you would consider
4 in determining whether something is likely to be
5 confounding factor or not?

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

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

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

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

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

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

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

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

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

10 A. Correct.

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

15 A. Yes.

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

19 A. That's right.

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

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

1 two or three. Sometimes it's seven or eight. When
2 we did our study of CAT scans -- because we had --
3 the number of confounders you look at is somewhat
4 depends on the sample size. So we looked at about
5 35 factors in that study in a model because we had
6 42,000 patients. So we were able to do that.

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

10 A. That's right.

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

14 A. That's correct.

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

17 A. Yes.

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

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

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

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

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

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

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

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

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

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

4 A. Again, that would be a helpful step.

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

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

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

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

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

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

1 This was a review of the --

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

4 HEARING OFFICER TIPSORD: I've been
5 handed Review of Epidemiological Studies on
6 Health Effects From Exposure to Recreational
7 Water, International Journal of Epidemiology,
8 1998. And I'm having a hard time finding
9 authors. Annette Pruss (ph.). If there is
10 no objection, we will mark this as
11 Exhibit 393.

12 Seeing none, it's Exhibit 393.

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

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

6 BY MR. ANDES:

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

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

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

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

24 BY MR. ANDES:

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

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

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

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

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

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

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

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

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

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

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

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

9 BY MR. ANDES:

10 Q. And recognizing the final report?

11 A. Correct.

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

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

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

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

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

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

6 Q. Okay.

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

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

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

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

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

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

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

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

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

24 MR. HARLEY: Yes. Thank you. In

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

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

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

1 illness than adults?

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

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

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

1 MR. HARLEY: And what are the --

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

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

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

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

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

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

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

19 DR. GORELICK: There is a higher risk
20 in children from recreation. One of the
21 NEEAR studies that we entered, I think it was
22 392, it's called High Sensitivity of Children
23 to Swimming Associated Gastrointestinal
24 Illness, was one of the studies that showed

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

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

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

1 MR. HARLEY: As opposed to less
2 precise.

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

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

7 MR. HARLEY: Thank you, Doctor.

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

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

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

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

22 DR. GORELICK: Yes.

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

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

3 DR. GORELICK: Yes, I have.

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

7 DR. GORELICK: Yes.

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

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

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

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

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

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

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

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

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

17 DR. GORELICK: Increase.

18 BY MR. ANDES:

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

23 A. High risk subpopulations are 20
24 percent.

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

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

13 Q. That didn't really answer my question.

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

16 MS. ALEXANDER: Which water are you
17 referring to?

18 DR. GORELICK: The water in the river.

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

21 DR. GORELICK: Correct.

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

24 HEARING OFFICER TIPSORD: I actually

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

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

14 HEARING OFFICER TIPSORD: Thank you.

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

20 DR. GORELICK: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 additional three minutes of questioning.

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

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

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

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

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

8 DR. GORELICK: Yes.

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

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

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

18 Seeing none, it's Exhibit 396.

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

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

1 Those with various immuno suppression,
2 pregnancy, and age.

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

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

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

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

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

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

6 DR. GORELICK: That they swallow more
7 water.

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

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

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

20 HEARING OFFICER TIPSORD: I think
21 you're correct.

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

24 HEARING OFFICER TIPSORD: I think

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

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

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

21 MS. ALEXANDER: Thank you.

22

23 BY MR. ANDES:

24 Q. So these studies are all about

1 swimming activities?

2 A. This particular one is about swimming,
3 yes.

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

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

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

11 A. Correct.

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

14 A. Right.

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

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

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

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

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

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

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

9 A. Correct.

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

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

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

22 A. There's a combination of those.

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

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

3 A. You couldn't lump them all together.

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

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

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

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

21 Q. Okay.

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

1 (Short break taken.)

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

5 BY MR. ANDES:

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

12 A. I have not seen that.

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

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

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

9 MS. ALEXANDER: Is that a question?

10 BY MR. ANDES:

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

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

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

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

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

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

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

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

20 HEARING OFFICER TIPSORD: Go ahead.

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

23 DR. DOREVITCH: Sure.

24 HEARING OFFICER TIPSORD: And I note

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

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

7 The study, I don't remember
8 the exhibit number, but one of the papers
9 that Dr. Gorelick just talked about Dufor
10 2006, the swimming pool study; people, adults
11 and children, were in a swimming pool.
12 Cyanuric acid a tracer of swimming pool
13 exposure was measured in the pool water and
14 in the urine samples of children and adults
15 who used the pool and they were able to
16 calculate how much water people swallowed
17 while swimming. And like Dr. Gorelick said,
18 children swallow about twice as much as
19 adults in a swimming pool while swimming.
20 The university conducted a similar study
21 where, in fact, people in canoes and kayaks
22 were in park district pools with cyanuric
23 acid in them which is the standard. That's
24 in all outdoor swimming pools. And some

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

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

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

19 DR. DOREVITCH: It was -- there were
20 685 people in the study across all
21 recreational activities. And, yes, it was
22 children and adults.

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

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

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

7 DR. DOREVITCH: They were wearing life
8 jackets.

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

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

23 BY MR. ANDES:

24 Q. Let's go back to the seven

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

3 A. Yes.

4 Q. And how did they do that?

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

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

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

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

14 A. That could be accounted for.

15 Q. Okay.

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

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

1 A. Exactly.

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

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

1 people who did answer the question. So if you just
2 don't include them you have a biased idea of what's
3 going on. And the second is you thought you had
4 10,000 subjects and really you have 9,500. It's not
5 a huge difference, but all these things add up. So
6 first you account for your clustering and you do
7 logistic regression with 20 co-variants and you have
8 500 people with missing data. Each of those eats
9 away a little bit at your power and bit by bit
10 increases the margin of error in the study. So you
11 get bias and you get reduction of power.

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

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

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

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

16 A. It's hard to assess.

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

19 A. Right.

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

23 A. Right.

24 Q. Other similarities, those -- some

1 aspects that could help you --

2 A. That's right.

3 Q. -- get a beat on it?

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

24 So those are a couple of ways that

1 people deal with missing data.

2 Q. Okay.

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

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

11 With that, I think I have no more
12 questions.

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


22 (Which were all the
23 proceedings had.)

24 * * * * *

1 STATE OF ILLINOIS)
) SS.
2 COUNTY OF COOK)

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



LAURA MUKAHIRN, CSR
CSR NO. 084-003592

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