BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:	)	
	)	
WATER QUALITY STANDARDS AND	)	R08-9
EFFLUENT LIMITATIONS FOR THE	)	(Rulemaking - Water)
CHICAGO AREA WATERWAY SYSTEM	)	
AND THE LOWER DES PLAINES RIVER:	)	Subdocket B
PROPOSED AMENDMENTS TO 35 Ill.	)	
Adm. Code Parts 301, 302, 303 and 304	)	

NOTICE OF FILING

To: ALL COUNSEL OF RECORD
(Service List Attached)

PLEASE TAKE NOTICE that on the 14th day of June, 2010, I electronically filed with the Office of the Clerk of the Illinois Pollution Control Board, **Metropolitan Water Reclamation District of Greater Chicago's Motion for Leave to File and Set a Hearing on the UIC CHEERS Report**.

Dated: June 14, 2010.

METROPOLITAN WATER RECLAMATION DISTRICT OF GREATER CHICAGO

By: */s/ David T. Ballard*
One of Its Attorneys

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PROOF OF SERVICE

The undersigned attorney certifies, under penalties of perjury pursuant to 735 ILCS 5/1-109, that I caused a copy of the forgoing, **Notice of Filing** and **Metropolitan Water Reclamation District of Greater Chicago's Motion for Leave to File and Set A Hearing on the UIC CHEERS Report**, to be served via First Class Mail, postage prepaid, from One North Wacker Drive, Chicago, Illinois, on the 14th day of June, 2010, upon the attorneys of record on the attached Service List.

/s/ David T. Ballard
David T. Ballard

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BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:	)	
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WATER QUALITY STANDARDS AND	)	R08-9
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Adm. Code Parts 301, 302, 303 and 304	)	

METROPOLITAN WATER RECLAMATION DISTRICT OF GREATER CHICAGO'S MOTION FOR LEAVE TO FILE AND SET A HEARING ON THE UIC CHEERS REPORT

The Metropolitan Water Reclamation District of Greater Chicago ("the District"), by its attorneys Barnes & Thornburg LLP, hereby moves the Board for an Order granting the District leave to file the UIC CHEERS Report (the "CHEERS Report") by August 31, 2010, and scheduling a hearing on the CHEERS Report shortly thereafter. In conjunction with setting that hearing, the Board should also schedule deadlines for the submission of written, pre-filed testimony and questions related to the CHEERS Report. In support of its Motion, the District states as follows:

1. On June 12, 2008, the District filed a Motion to Stay IPCB R08-9, which was generally based on the premise that the District would be receiving numerous studies related to different aspects of this rulemaking, and that the rulemaking should not proceed until those studies were finalized and filed with the Board. The ongoing studies related to both IEPA's proposed recreational use designations and aquatic life use designations for the ("CAWS").

2. In the Motion to Stay, the District stated the following as to the CHEERS study:

> Currently, there is an ongoing epidemiological study of recreational contamination in the CAWS, which is intended to validate the results of the quantitative microbial risk assessment, to provide scientific data necessary to properly evaluate the actual risk of illness, and to provide scientific data on the risk of illness in correlation to indicator bacteria concentrations.

Mot. to Stay, at 10 (Jun. 12, 2008). The District also provided that the basis of its Motion to Stay was that "[t]he studies that are set forth above would be very helpful in filling those gaps, and in helping the Board to form an adequate scientific basis for its decisions." *Id.* at 14. The District also advised the Board that the CHEERS Report would take several years to complete. *Id.* at 10.

3. While the Board denied the District's request for a stay, it found that the District, as well as any party, should be allowed to fully present its studies and witnesses related to the studies. *See* Ex. A, Board Order, July 21, 2008, at 11 ("The hearing process and information gathering by the Board will continue at least until the Board has heard testimony from all participants who wish to testify on all aspects of the IEPA's proposal. Additional testimony will provide a more complete record and enable the Board to make the best possible decisions regarding the IEPA's proposed rules."). Based on the July 21, 2008 ruling, the District should be allowed to present the CHEERS Report, as well as testimony from witnesses involved with the Report.

4. As the rulemaking continued, the District updated the Board about the status of the CHEERS Report, and the District's witnesses testified to the critical value it will have on the Board's consideration of recreational use issues. Specifically, Dr. Samuel Dorevitch, who is "directing the epidemiologic study of CAWS recreation known as CHEERS, which stands for the Chicago Health, Environmental Exposure, and Recreation Study," explained in his testimony that "[b]ecause epidemiologic studies involve the direct measurement, rather than the statistical modeling of risk, they are of great importance in developing plans to protect the health of the public." Pre-Filed Testimony of Samuel Dorevitch, at 4, filed August 4, 2008, attached as Exhibit B.; *see also id.* at 6 ("Epidemiologic studies provide an opportunity to directly measure,

rather than model, risk. For this reason the U.S. EPA places considerable weight on epidemiologic studies when establishing environmental standards.").

5. Dr. Dorevitch then described the CHEERS Report for the CAWS and the analyses it will provide:

> This is the first epidemiologic study of the health risks of fishing, boating, rowing and paddling. This research uses the gold standard of observational epidemiologic studies, the prospective cohort design, and has been developed by a multi-disciplinary team of experienced researchers, with backgrounds in infectious disease medicine, environmental medicine, epidemiology, biostatistics, industrial hygiene and environmental science. A panel of recognized leaders in the fields of water microbiology and health from the U.S. Centers for Disease Control and Prevention, the U.S. Environmental Protection Agency, and other universities has reviewed and endorsed the design and protocols of the research, and continues to monitor the quality of data collected.

Id. at 4-5.

6. Dr. Dorevitch then provided details as to the data collection and analyses that are involved with the CHEERS Report. *Id.* at 5-6. Dr. Dorevitch concluded as to why the CHEERS Report is critical for determining risk and assessing recreational use issues:

> The results of those analyses will provide answers to the critical questions about risk, the determinants of risk, exposure, sources of microbes, and causes of illness. The final report will serve as the basis for establishing standards to protect limited contact uses.

Id. at 8.

7. Dr. Dorevitch also testified as to why the CHEERS Report is not yet finalized and needs to be completed to fully verify its conclusions:

> Preliminary analysis of the 2007 data identifies no difference in rates of gastrointestinal symptoms among recreators in the three study groups. Because that analysis involved less than 10% of the total number of participants who will have been enrolled at the completion of this research, firm conclusions are premature. However, consistent with the lack of reports by public health departments of outbreaks of disease linked to CAWS recreation,

> our preliminary observations suggest no danger to the health of the population of limited contact recreators on the CAWS.

Id. at 8; *see also id.* at 9 ("The UIC School of Public Health research team is well on the way to defining the risks that limited contact recreators face under current wastewater management practices. I believe that this research should be the basis for sound, science-based environmental policy.").

8. In response to Dr. Dorevitch's testimony, the Environmental Groups' experts consistently agreed that the CHEERS Report will be relevant to the Board's consideration of recreational issues. For example, Dr. Peter Orris, the Chief of Service for Occupational and Environmental Medicine at UIC Hospital, who is a witness for the Environmental Groups, testified repeatedly as to the relevance of the CHEERS Report and the high quality of the study being conducted by Dr. Dorevitch:

- "Certainly, epidemiological studies are helpful and these studies should help as one piece of evidence guiding your approach to understanding what risks and benefits there are from your decisions." April 15, 2009 Hearing Trans., at 8-9, attached as Exhibit C.

- "Otherwise, called how large is a false negative or whatever and by convention and with respect **to this quite excellent study that Dr. Dorevitch is projecting**, the standard that we set is based on our preconceived, at priority judgments that we hope that the power will be 80 percent." Ex. C, April 15, 2009 Hearing Trans., at 9-10 (emphasis added).

- "It doesn't mean it's a bad study. It's an excellent study. We support that study. We support this further review. It may demonstrate despite those problems, things we need to look at with respect to those waterways and what ought to be done about it, but it is only one piece of the overall puzzle." Ex. C, April 15, 2009 Hearing Trans., at 11-12.

- "MR. ANDES: And you're aware that in this record in addition to the epidemiological study which has been discussed in Dr. Dorevitch's testimony and will be available early next year there has been risk assessment information and other information provided to the Board all which I imagine

you think should be considered in considering the totality of the information?

MR. ORRIS: Certainly." Ex. C, April 15, 2009 Hearing Trans., at 15

- "MR. ANDES: In fact, the CHEER study is specifically looking at the exposures that people are undergoing on the CAWS system, correct?

  MR. ORRIS: Yes, absolutely." Ex. C, April 15, 2009 Hearing Trans., at 17.

- "MR. ANDES: Dr. Orris, is any one here suggesting or has said in writing that this should be the sole basis for the decision by the Board.

  MR. ORRIS: What I take to be the question I'm asked is should the Board rely on the CHEER study as the basis for making their regulatory decision within this situation and that is what I am specifically talking about. In fact, when I read my colleague, Dr. Dorevitch's excellent testimony about his – I want to say again, his excellent study. . . . reading his last line within his system and perhaps this was overstated unintentionally, but he does say this is the – that this should be the basis for consideration here. 'The' is the word I take issue with.

  MR. ANDES: Your --

  MR. ORRIS: **It should certainly be a basis.**" Ex. C, April 15, 2009 Hearing Trans., at 21-22 (emphasis added).

- "MR. ANDES: As to the CAWS itself, I gather we'll have a better sense through the questions in the CHEERS study as to what extent those precautions have affected people's habits, correct?

  MR. ORRIS: Again, this goes over what we previously talked about with respect to the study. **We may learn some very important things from that study about the water use, et cetera**." Ex. C, April 15, 2009 Hearing Trans., at 33 (emphasis added).

- "MR. ANDES: . . . Dr. Orris, when you reviewed the CHEER study as an excellent study, you're aware, are you not, that the research plan was evaluated by a panel of recognized leaders in the field and they determined the study, quote, has been designed to provide information that is valuable in the area of health risks associated with secondary contact recreation and addressed potential deficits in the current knowledge and health risks associated with limited contact water recreation and the measures acquired to

protect the public?

MR. ORRIS: Yes, I absolutely agree with that." Ex. C, April 15, 2009 Hearing Trans., at 48-49.

9. The Environmental Groups' expert Dr. Marilyn Yates, who is a Professor of Environmental Microbiology at the University of California, Riverside, also confirmed the relevance of the CHEERS Report to the Board's consideration of the recreational issues:

- "Q. And the epidemiological study being done as to the CAWS, which is the first one being done as to secondary contact, you would agree that that would as well be relevant in determining appropriate water quality standards for the CAWS?

  A. **I would say that the epidemiological study that's being conducted by Dr. Gorovich [sic] would certainly be one piece of information that would be relevant to consider when determining what happens with respect to the issues at hand here**." May 5, 2009 Hearing Trans., at 54, attached as Exhibit D (emphasis added).

- "MR. ANDES: The epidemiological study, the CHEERS study that's going on now will give us a better idea of that answer?

  DR. YATES: That's my understanding, yes.

  MR. ANDES: So that would also be information that the Board would want to consider in making a decision here?

  DR. YATES: **I would imagine that the Board would consider that information, yes**." Ex. D, May 5, 2009 Hearing Trans., at 143 (emphasis added).

- "Q. Question three asks, in your opinion, why is MWRDGC's epidemiological study not a sufficient tool to assess the needs for disinfection?

  A. First, let me say that I believe that the epidemiological study in general is being conducted in a very thorough way and **I have absolutely no reason to doubt that the information that comes out of that study will be extremely useful especially as it relates to the secondary recreational activities**." July 28, 2009 Hearing Trans., at 60, attached as Exhibit E.

10. The Environmental Groups' expert Dr. Marc Gorelick, a Professor of Pediatrics and Population Health and Chief of the Section on Emergency Medicine at the Medical College of Wisconsin, also confirmed the relevance of the Board's consideration of the CHEERS Report:

> "I think that's actually one of the nice strengths of the CHEER study is – that it is another study that is attempting to look at this in a way that identifies prospective diseases that may not occur in outbreaks. Like some of the other surveys that have already been done in other settings that have shown there is an increased risk. None out of this reported outbreaks. They were done through prospective surveillance. We need more of that kind of prospective surveillance to add to the existing body that shows that there are risks associated with that and to try to quantify it."

Ex. C, April 15, 2009 Hearing Trans., at 87.

11. On February 3, 2010, the Environmental Groups filed a Motion to Sever, Open Subdocket, and Proceed to Decision Concerning Recreational Use Issues (the "Motion to Sever"). In that Motion, among other things, the Environmental Groups argued that the Board did not need to wait to review the CHEERS Report, and should proceed immediately to decide recreational use issues. *See* Mot. to Sever, at 9-14.[1]

12. On March 8, 2010, the District filed its Response to the Motion to Sever. In that Response, the District requested that the Board enter an order allowing for a hearing on a CHEERS technical report that the District would file by May 5, 2010. *See* Resp. to Mot. to Sever, at 16-17. The District also stated that it would submit the CHEERS Report by September 15, 2010, and that the Board should also enter an order scheduling a hearing on that Report. *Id.* at 17.

[1] The District acknowledges that in their Motion to Sever, the Environmental Groups argued that to "the extent MWRD may suggest that [the] ongoing [CHEERS] studies justify yet more delay in the Board's decision regarding recreational use standards, it is clearly wrong. . . . IEPA has appropriately determined that these studies are not necessary to support its basic, and rather obvious, conclusion that disinfection is appropriate to reduce public exposure to sewage-related pathogens . . ." *See* Mot. to Sever, at 9. But the Environmental Groups' argument that the Board should not consider the CHEERS Report pre-judges the Report and improperly presumes that their expert witnesses are right without allowing the District to present testimony that the Report is relevant and critical to the Board's decision on recreational use and disinfection issues. As Dr. Dorevitch's above testimony shows, the District will present testimony to the Board that the CHEERS Report addresses primary questions in this rulemaking.

13. On March 18, 2010, the Board "directed the scheduling of a hearing by the end of June on the [District's] epidemiological study technical reports (Subdocket B)." *See* Board Order, dated March 18, 2010. Subsequently, on April 1, 2010, the Board set hearings on June 29 and 30, 2010 on the epidemiological study technical reports filed by the District. *See* Board Order, April 1, 2010.

14. While the Board's Orders set hearings on the CHEERS technical reports, the Board has not yet responded to the District's request in its Response to the Motion to Sever that the CHEERS Report be set for hearing.

15. On May 5, 2010, the District filed the "CHEERS Research Update – An Interim Technical Report Prepared for Submission to the Illinois Pollution Control Board" (the "CHEERS Technical Report"). To explain the CHEERS Technical Report, on May 28, 2010, the District filed the written testimony of Dr. Dorevitch. In that testimony, Dr. Dorevitch described the progress that had been made in developing the CHEERS Report since his first written testimony was filed in August 4, 2008, and then explained the purpose of the Technical Report:

> The Interim Technical Report provides a status update for the Board regarding the CHEERS research study. As the Interim Technical Report shows, participant recruitment and health follow-up have been completed and statistical analysis is ongoing. While final results of the research are not yet available, the Interim Technical Report provides interim summaries of key data elements. ***The report summarizes preliminary results of water quality and observation of recreational use of the CAWS during the last three recreation seasons.*** For the CAWS water exposure group, General Use water exposure group, and unexposed to water recreational group, the report further summarizes participant recruitment, the occurrence of gastrointestinal illness, and microbes isolated from stool samples of study participants who developed gastrointestinal symptoms following recreation. ***The summaries that comprise the Interim Technical Report, however, should not be viewed as answers to primary study questions.***

Ex. F, at 3 (emphasis added).

16. Dr. Dorevitch also provided a status update as to when the CHEERS Report would be ready for filing, and what analyses it would provide to the Board:

> The research team is continuing to work on analyses and preparation of its report. Based on the progress of the CHEERS research and analyses, a final CHEERS report will be completed and filed with the Board by August 31, 2010. That report will address, among other issues, occurrence of illness among study participants and rates of illness attributable to CAWS recreation adjusted for demographic differences among study participants, and microbes responsible for gastrointestinal symptoms among study participants. It will also contain information concerning development of a relationship between microbial water quality parameters and incidence of illness for recreational uses proposed for the CAWS, which will eventually be needed to develop scientifically-based bacterial water quality standards for the CAWS. A supplemental report reflecting completed analyses of the water quality-illness relationship will be submitted to the Board by the end of 2010.

Ex. F, at 4-5.[2]

17. In addition to Dr. Dorevitch's testimony, in response to the filing of the CHEERS Technical Report, the Natural Resources Defense Council filed the Testimony of Marc Gorelick, MD. In Dr. Gorelick's testimony, he stated that the raw data in the CHEERS Technical Report "are merely the first step in an epidemiological study, a collection of facts and numbers obtained from testing and study subject interviews." Ex. G, Testimony of Marc Gorelick, MD, at 1. Dr. Gorelick stated that it is important to recognize that "this raw data does *not* represent CHEERS study results – negative or otherwise – or anything approximating them." *Id.* (emphasis in original). Instead, Dr. Gorelick found that after collecting the data that was included in the CHEERS Technical Report, the "next critical step is evaluation of the data through statistical analysis and mathematical modeling in order to isolate the specific risk factors the study is

[2] The District notes that originally in its Response to the Environmental Groups' Motion to Sever, the District stated that it would file the CHEERS Report by September 15, 2010, or earlier if possible.

designed to evaluate. Without that step, the data, while intriguing, are essentially meaningless." *Id.*; *see also id.* at 3-4 ("The next step is critical, and in many ways at the heart of sound epidemiological research: evaluation of the data through statistical analysis and mathematical modeling in order to isolate the specific risk factors the study is designed to evaluate. In the absence of that step, the preliminary data has very limited meaning.")

18. The "critical step" that is "at the heart of sound epidemiological research," as described by Dr. Gorelick, is the set of analyses that will be included in the CHEERS Report that will be filed by August 31, 2010. As Dr. Dorevitch has stated, the results from the CHEERS Report "will provide answers to the critical questions about risk, the determinants of risk, exposure, sources of microbes, and causes of illness." Ex. B, at 8. Dr. Dorevitch has testified that while (as Dr. Gorelick stated) the CHEERS Technical Report only contains summaries of data, the CHEERS Report will address the final analyses of heath risks of incidental contact water recreational activities that are lacking in the Technical Report:

> Yet to be completed are analyses of health risks of incidental contact water recreational activities. Such analysis will take into account multiple factors that must be considered when describing relationships between key variables (such as water quality) and health outcomes (such as the development of gastrointestinal illness). For example, if users of the CAWS are different in important ways compared to users of General Use waters or to study participants that were not exposed to water – such as their age or presence of underlying health conditions – real differences in the health risk between the CAWS group and other groups may be distorted. The ongoing data analysis focuses on accounting for such difference in order to generate appropriate comparisons of risk across study groups.

Ex. F, at 3-4.

19. A hearing on the CHEERS Report is necessary in order for the Board to fully consider the final analyses of health risks that will be presented in the Report, so that the Board

can fully assess the validity of the Report and properly use it for its final decision on recreational use and disinfection issues.

WHEREFORE, the Metropolitan Water Reclamation District of Greater Chicago requests that the Board enter an Order granting the District leave to file the CHEERS Report by August 31, 2010, and scheduling a hearing shortly thereafter. Along with setting a hearing date, the District also requests that the Board set deadlines for the filing of pre-filed testimony and pre-filed questions prior to a hearing on the CHEERS Report.

Dated: June 14, 2010

METROPOLITAN WATER RECLAMATION DISTRICT OF GREATER CHICAGO

By: */s/ Fredric P. Andes*
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CHDS01 604673v1

Exhibit A

ILLINOIS POLLUTION CONTROL BOARD
July 21, 2008

IN THE MATTER OF:	)	
	)	
WATER QUALITY STANDARDS AND	)	R08-9
EFFLUENT LIMITATIONS FOR THE	)	(Rulemaking - Water)
CHICAGO AREA WATERWAY SYSTEM	)	
AND LOWER DES PLAINES RIVER	)	
PROPOSED AMENDMENTS TO 35 ILL.	)	
ADM. CODE 301, 302, 303, and 304	)	

ORDER OF THE BOARD (by G.T. Girard):

On June 12, 2008, the Metropolitan Water Reclamation District of Greater Chicago (District) filed a motion to stay the proceedings in this rulemaking (Motion). Between June 26 and June 30, 2008, the Board received seven responses to the Motion. Three of the responses supported the District, while four opposed the Motion. On July 11, 2008, the District filed a motion for leave to file a reply and a reply. The Board is cognizant of the concerns raised by the District and the other participants that support the motion. However, as discussed below, the Board is unconvinced that a stay of the proceeding is appropriate at this time. Therefore, the Board denies the Motion.

The discussion below will begin with a brief procedural history. Next the Board will summarize the motion and the filings that support the Motion. Then the Board will summarize the filings that oppose the motion. The Board will next summarize the reply. The Board will then explain the reasons for the decision.

PROCEDURAL HISTORY

On October 26, 2007, the Illinois Environmental Protection Agency (IEPA) filed a proposal under the general rulemaking provisions of Sections 27 and 28 of the Environmental Protection Act (Act) (415 ILCS 5/27, 28 (2006)). Generally, the proposal will amend the Board's rules for Secondary Contact and Indigenous Aquatic Life Uses to update the designated uses and criteria necessary to protect the existing uses of the Chicago Area Waterway System (CAWS) and the Lower Des Plaines River (LDPR). On November 1, 2007, the Board accepted the proposal for hearing. On November 1, 2007, the Board accepted the proposal for hearing.

Hearings were held in Chicago from January 28, 2008 through February 1, 2008 and on June 16, 2008. Hearings were then held in Joliet from March 10, 2008 through March 12, 2009. The Board also held hearings in Des Plaines on April 23, 2008 and April 24, 2008.
There have been 11 days of hearing and additional hearings are scheduled to begin September 8, 2008.

On June 12, 2008, the District filed a motion to stay the rulemaking proceeding. On June 26, 2008, Midwest Generation LLC (Midwest Generation) filed a memorandum in support of the

motion (MGmemo). On June 27, 2008, the Chemical Industry Council (CICI) filed a memorandum in support of the motion (CICImemo). On June 30, 2008, Stepan Company (Stepan) filed a concurrence with the motion (Smemo).

On June 25, 2008, the Environmental Law and Policy Center, Friends of the Chicago River, Sierra Club Illinois Chapter, Natural Resources Defense Council and Openlands (Environmental Groups) filed a response in opposition to the motion (EGResp.). On June 26, 2008, the Chicago Legal Clinic on behalf of the Southeast Environmental Task Force (SETF) filed a response in opposition to the motion (SETFResp.). On June 26, 2008, the Attorney General of the State of Illinois (People) filed a response in opposition to the motion (PResp.). On June 30, 2008, the IEPA filed a response in opposition to the motion (Resp.).

On June 30, 2008, the IEPA also filed numerous documents requested at the prior hearings along with a motion for leave to file a limited number of copies with the Board. That motion is granted.

On July 11, 2008, the District filed a motion for leave to file a reply along with a reply (Reply). The Board grants that motion and accepts the reply.

MOTION TO STAY

The Board will first summarize the District's arguments made in the motion to stay. Next, the Board will summarize each of the responses that support the motion to stay.

District's Motion to Stay

The District indicates that the obligation to protect public health and the environment is taken very seriously by the District and the District has spent "large amounts of money, time and resources" to improve the water quality of the CAWS. Mot. at 1. Further, the District participated in the rule development stakeholder process until the process ended and the rulemaking was proposed. *Id.* The District believes that the proposal has changed in significant ways and ignores "major studies, which could change the IEPA recommendations" and provide essential information in the rulemaking process. *Id.*

The District has participated in the rulemaking proceedings before the Board on the proposed rule. Mot. at 1. The District argues that the hearings have shown that the proposal has major problems scientifically, legally and from a policy perspective. *Id.* Because of these problems the District asks the Board to stay the proceedings until additional studies are completed and the results cans be considered. Mot. at 2.

Legal Standard for Motion to Stay Proceedings

The District claims that the Board has inherent authority to grant stays in Board proceedings and sole discretion to grant or deny motions to stay. Mot. at 4, citing Israel-Gerold's v. IEPA, PCB 91-108 (July 11, 1991) and People v. State Oil Co., PCB 97-103 (May 15, 2003). The District asserts that the Board has historically granted motions to stay:

inter alia, (1) to avoid wasting time, expenses, or resources (In the Matter of: Petition of Midwest Generation, LLC, Will County Generating Station for an Adjusted Standard from 35 Ill. Adm. Code 225.230, AS 07-04 (Mar. 15, 2007); (2) to avoid practical difficulties (*Id.*); (2) to avoid duplicative efforts by the Board and other review authorities addressing related issues (*Id.*); and (4) to assist the Board in making the appropriate determination (In the Matter of: Petition of Cabot Corporation for and Adjusted Standard from 35 Ill. Adm. Code Part 738, Subpart B, AS 07-06 (Aug. 9, 2007). Mot. at 4.

The District notes that a motion to stay must provide sufficient information detailing why a stay is needed and include a status report on the progress of the case. Mot. at 4, citing 35 Ill. Adm. Code 101.514.

Reasons For Stay

The District argues that during the hearing process the District and other parties have discovered "a number of substantial deficiencies" in the proposal by IEPA. Mot. at 5. Specifically, the District claims that the IEPA's responses to questions have indicated that the IEPA: 1) failed to clearly document the methodologies utilized to arrive at findings and recommendations; 2) did not have adequate data and information to assess aquatic life and water quality standards; 3) did not have adequate data to set water quality standards to protect recreational uses; and 4) did not have adequate information to assess the economic impact of the rulemaking. *Id.* The District delineates specific responses to questions on each of the four areas and asserts that those responses establish the inadequacies in the record. Mot. at 5-10.

The District argues that there are forthcoming studies that will assist the IEPA's analysis for the proposal and some studies have already been completed. Mot. at 10. The District has already performed a fecal coliform distribution study on CAWS waters and an expert panel study on secondary contact criteria feasibility in the CAWS. *Id.* In addition, a quantitative microbial risk assessment for the recreational uses proposed for the CAWS was recently completed and the report has been submitted to the IEPA. *Id.*

The District is also currently engaged in an ongoing epidemiological study of recreational contamination in the CAWS. Mot. at 10. The District states that the intent of the study is to: 1) validate the results of the quantitative microbial risk assessment, 2) provide scientific data necessary to properly evaluate the actual risk of illness, and 3) provide scientific data on the risk of illness in correlation to indicator bacteria concentrations. *Id.* The District indicates that the study has been approved through the peer review process and the study is scheduled for completion in 2010. *Id.*

The District points to another set of studies on recreational use development on the CAWS that focuses on the cost of complying with the proposed standards. Mot. at 11. Those studies include: 1) a "Blue Ribbon Panel" to evaluate and rank the suitability of all available disinfection technologies for the District's facilities; 2) preliminary design and cost estimate study for installing various disinfection units; 3) overall costs and environmental impacts

resulting from the proposed rule; 4) a comparison of several UV technologies; and 5) a study of end-of-pipe treatment of the combined sewer overflow (CSO) discharges on CAWS. *Id* The CSO study has been submitted to the IEPA. *Id.*

The District has a study program to generate more and better data to help develop appropriate aquatic life use designations for the CAWS including evaluation and improvement of habitat, sediment quality data, dissolved oxygen monitoring and ambient water quality monitoring. Mot. at 12. The District points to several ongoing or proposed engineering studies including development of an integrated water quality strategy for CAWS, field tests of aeration stations, and assessing control measures. Mot. at 12-13.

The District argues that the IEPA's proposal has substantial deficiencies and that there are studies currently underway that would be helpful in filing those gaps. Mot. at 14. The District asserts that a stay would allow the IEPA to analyze the scheduled studies, collect other information and submit a complete rulemaking proposal to the Board. Mot. 14. Therefore, the District asks that the Board stay these proceedings, including the schedule set for submittal of testimony, until after ruling on the stay.

Midwest Generation's Response

Midwest Generation states that during the years the IEPA held stakeholder meetings, Midwest Generation actively participated in the process. MGmemo at 1. Midwest Generation has also been actively participating in the hearings on the proposed rules. *Id.* Midwest Generation shares the District's concerns that the IEPA proposal is fundamentally flawed and cannot be supported based on the factual gaps and faulty assumptions in the record. *Id.* Midwest Generation claims that the IEPA's testimony establishes that development of the proposed rules was harmed by fundamental problems, including IEPA's failure to consider the stakeholders' meaningful input. *Id.*

In addition to specific deficiencies listed in the response (*see* MGmemo at 4-7), Midwest Generation argues that the IEPA failed to consider the need to obtain and review relevant data relating to constraints limiting the attainable uses of the waterways. MGmemo at 2. Midwest Generation further argues that the IEPA failed to consider the technical feasibility or economic costs of the proposed rules. *Id.* Midwest Generation asserts that the IEPA also failed to consider any alternative approaches to the proposed thermal water quality standards. *Id.*

Midwest Generation notes that the IEPA admitted that a 2007 submission by Midwest Generation regarding alternative thermal standards methodology and proposed numerical standards for Upper Dresden Island Pool[1] was not reviewed by the IEPA. MGmemo at 2. Midwest Generation further notes that the IEPA failed to consider 20 years of fish survey data for the Upper Dresden Island Pool that the IEPA had when preparing this rulemaking. *Id.* Midwest Generation asserts that the testimony revealed a complete absence of review of key data or analysis regarding environmental stressors. *Id.*

[1] The Upper Dresden Island Pool is part of the LDPR.

Midwest Generation maintains that moving ahead with this rulemaking when the IEPA's supporting record "suffers from so many key deficiencies" is not beneficial to the Board, the IEPA, or interested members of the public. MGmemo at 2. Midwest Generation concedes that the burden and expense of presenting Midwest Generation's view in this rulemaking is Midwest Generation's burden. *Id.* However, Midwest Generation asserts that the burden has become unreasonable given the many omissions in the IEPA's record. *Id.* Midwest Generation argues that a pause in the proceedings would result in a more streamlined, cost-effective, and less time consuming rulemaking process before the Board. MGmemo at 3.

Midwest Generation asserts that only at hearing was the IEPA's "selective consideration of limited data related" to Upper Dresden Island Pool evident and Midwest Generation is trying to address the gaps. MGmemo at 3. Midwest Generation is attempting to: 1) gather, review, and analyze data the IEPA ignored; 2) address gaps in the more recently collected data presented by IEPA in this rulemaking; 3) prepare and present a more complete data set and analysis to the Board. *Id.* Some of the data Midwest Generation is collecting cannot be collected until July and that data could have a direct bearing on the IEPA's use designations. *Id.*

Midwest Generation argues that a stay would allow the necessary time to collect and review current data as opposed to the current prefiling deadline for Midwest Generation testimony. MGmemo at 3. Midwest Generation further argues that a stay would allow the data to be presented first to the IEPA and other stakeholders outside the formal constraints of the rulemaking process. *Id.* Such a process could serve to narrow or resolve the many disputed issues currently in this proceeding. *Id.* For all these reasons, Midwest Generation agrees with the District that a stay is appropriate in this proceeding. *Id.*

CICI'S Response

CICI joins the District and Midwest Generation in requesting a stay of these proceedings. CICImemo at 1. CICI notes that, as pointed out by both the District and Midwest Generation, the record developed by IEPA "suffers obvious problems" that should be resolved before proceeding. *Id.* CICI asserts that the record reveals a significant lack of data including information and analysis on economic and social impacts of the proposal. *Id.* CICI claims that there is a deficiency in the collection and analysis of environmental data and given these shortcomings a stay should be granted. CICImemo at 2.

Stepan's Response

Stepan agrees with the District's motion to stay and agrees that a stay would allow IEPA to consider additional information. Smemo at 1. Stepan notes that in addition to those matters that IEPA failed to consider, as determined by the District, IEPA failed to consider potential particulate matter emissions from cooling towers, the cost of retrofitting existing sources, and the thermal quality of industrial dischargers. Smemo at 1-2. Stepan requests that a stay be granted.

RESPONSES IN OPPOSITION TO MOTION TO STAY

The Board received four responses in opposition to the motion to stay. The Board will first summarize the response from the IEPA and then the response from the People. Next the Board will summarize the Environmental Groups response and the response by SETF.

IEPA's Response

The IEPA agrees with the District that a stay may be granted; however, the IEPA emphasizes that the District does not cite to a single case where the Board granted a motion to stay in a regulatory proceeding without the support of the IEPA. Resp. at 2. The IEPA notes that the District states there are four situations where the Board typically grants a stay; but that four-part test is not found in the cases cited in the District's motion. *Id.* The IEPA argues that a stay would not save time, expenses or resources and would cause practical difficulties. *Id.* Further, the IEPA asserts that there are not ongoing proceedings that would duplicate the work of the parties in this proceeding, and a multi-year span between the IEPA's testimony and the regulated community would not assist the Board in a final determination. *Id.*

IEPA states that the IEPA has worked on this proposal since 2000 and the District has been a participant since the beginning. Resp. at 2. The IEPA met all the filing requirements under the Act and the Board's rules. *Id.* In addition, the IEPA has answered questions in hearings over 10 days and filed additional information with respect to the proposal in March and April of 2008. Resp. at 3. Further, the proposal submitted is a very detailed rulemaking package and the IEPA asserts that the submission of the proposal and the answering of questions meet the IEPA's burden. *Id.*

The IEPA argues that instead of delaying these proceedings for two years in the "hopes that more relevant information will be produced" now is the time for the District or any other party who disagrees with the proposal to come forward and present counter arguments. Resp. at 3. The IEPA disagrees that the requested delay would add to the record or produce needed changes to the IEPA's proposal. *Id.* The IEPA also does not feel a delay is necessary for studies currently being undertaken. *Id.* The IEPA states that no delay is needed for review of the studies as the IEPA is prepared to review the studies as the rulemaking moves forward. *Id.*

The IEPA notes that the District "makes much of the need for additional information" regarding bacteria. Resp. at 3. The IEPA points out that the IEPA's Statement of Reasons recognized that the states are waiting on USEPA to update national criteria for bacteria. *Id.*, citing Statement of Reasons at 42-46. The IEPA maintains that this issue was addressed in the proposal by the technology based effluent requirement in 35 Ill. Adm. Code 304 and proposing appropriate designated recreational uses for both the CAWS and the LDPR. Resp. at 3-4.

The IEPA argues that granting a stay at this juncture would cause a delay in the rulemaking that could be detrimental to the waterway that needs improvement now. Resp. at 4. The IEPA maintains that the IEPA and participants have already dedicated a lot of time and resources to this rulemaking and a return to the stakeholder process would not be appropriate. *Id.* As to the District's arguments regarding economic reasonableness, the IEPA states that the IEPA has stated on the record that the proposal is economically reasonable and technically feasible. *Id.*

People's Response

The People oppose the motion to stay arguing that staying the rulemaking "would be injurious to the public interest, harmful to the environment, and would result in an extraordinary waste of the resources" of the Board. PResp. at 1. The People argue that when considering a motion to stay, the Board "carefully weighs" the extent to which a stay would burden the Board or otherwise waste time and resources. *Id.*, citing Vernon and Elaine Zohfeld v. Bob Drake *et. al.*, PCB 05-193 (Feb. 2, 2006). Further, the Board denies stays when the effect of the stay could harm the environment or be injurious to public interest. *Id.*, citing People v. ESG Watts, PCB 96-107 (Mar. 19, 1998).

The People argue that the motion to stay is premised on:

> (1) a one-sided (mis)characterization of the record offered by counsel for the District; (2) alleged deficiencies in the record [footnote omitted] that counsel for the District claims to have identified; and (3) unsupported and self-serving assertions regarding the nature and the expected findings of certain studies that the District might perform during the pendency of a stay. PResp. at 2.

The People assert that these premises are not a factual basis for a stay and no affidavits or verified filings were included. *Id.* The People maintain that "counsel's unsupported and unverified assertions" are insufficient for the Board to base a decision to stay the proceeding. *Id.*

The People argue that the granting of the stay would interfere with the Board's ability to manage the Board's docket and would waste time and resources. PResp. at 2. The People claim that the IEPA has spent nearly a decade "conducting detailed analyses" in preparation for this rulemaking. *Id.* Further IEPA has actively involved stakeholders in the process since at least 2002 and IEPA's efforts culminated in the proposal. PResp. at 3. Also, with the deadline for prefiling of testimony for the next hearings scheduled for August 4, many parties including the People, have retained witnesses and are working to finish testimony for the deadline. *Id.*

The People argue that all stakeholders have had "ample time to conduct studies and prepare testimony" for the rulemaking. PResp. at 3. The People maintain that the District's decision to file a motion to stay rather than testimony is "surprising" and if the District needs more time the problem is of the District's own making. *Id.*

The People note that under the Clean Water Act (33 U.S.C. §1251), the State is required to conduct a triennial review and to review and revise, as necessary, effluent limitations at least every five years. PResp. at 5, citing 33 U.S.C. §1311(c)(1), 40 C.F.R. 131.20. The People argue that the Board is on course to make a determination on attainable uses in CAWS and the LDPR and the water quality standards and effluent limitations necessary to attain those uses. PResp. at 6. The People assert that failure to make this determination would not only be harmful to the environment and the public interest but would also violate clear deadlines established by federal law. *Id.*

The People argue that the granting of the stay is contrary to Board precedent and the District does not cite any previous Board orders in which the Board granted a motion to stay by a participant. PResp. at 6. The People note that a search of the Board's records indicates that the Board has never been presented with such a motion. *Id.* The People argue that the cases cited by the District are easily distinguishable and that in those cases the Board primarily granted the motion because of a related concurrent proceeding. PResp. at 7.

Environmental Group's Response

The Environmental Groups oppose the District's motion for stay because the need to upgrade the standards protecting recreation and aquatic life in the CAWS is urgent and supported by the evidence. EGResp. at 2. The Environmental Groups argue that the proposed rules are not rushed and may be arguably decades overdue. *Id.* The Environmental Groups note that the IEPA is required to evaluate uses for water-bodies every three years; however most of the CAWS has not been formally reviewed since 1972. *Id.* The Environmental Groups note that IEPA began the review process for CAWS in 2002 and the District cooperated in the studies and other portions of the use attainability analysis (UAA). EGResp. at 3. The Environmental Groups state that IEPA circulated a draft set of rules in January, 2007 and USEPA indicated that the rules did not offer sufficient protection. *Id.* Additional meetings were then held on the draft proposal before the final proposal was made to the Board. *Id.*

In response to the "laundry list of deficiencies" cited by the District, the Environmental Groups argue that the burden is on opponents of the rulemaking to demonstrate that the CAWS cannot sustain uses proposed by the IEPA. EGResp. at 4. The Environmental Groups state that the law is clear that there is a rebuttable presumption that every water body should support fishable and swimmable uses. *Id.*, citing Kansas Natural Resource Council v. Whitman, 255 F.Supp. 2d 1208. 1209 (D. Kan. 2003); Idaho Mining Ass'n v. Browner, 90 F. Supp. 2d 1078, 197-98 (D. Idaho 2000). The Environmental Groups further state that unless the state demonstrates using the UAA factors that a use cannot be attained in a particular water body, fishable and swimmable uses are assumed. EGResp. at 4-5.

The Environmental Groups maintain that the UAA regulations provide six ways to rebut the presumption of a fishable/swimmable water and five of those reason deal with physical limitations and one allows for consideration of economic factors. EGResp. at 5, citing 40 C.F.R. § 131.10(g). The Environmental Groups argue that without putting on any evidence, the District alludes to the possibility that the proposed standards should not apply because of economic hardship. *Id.* The Environmental Groups assert that the Board's evaluation of technical feasibility and economic reasonableness must be done in conjunction with the federal requirements. EGResp. at 5-6. The Environmental Groups claim that an argument that disinfection is infeasible or economically unreasonable is "preposterous" as disinfection is required almost everywhere across the State. EGResp. at 6, citing 35 Ill. Adm. Code 302.209.

The Environmental Groups maintain that the alleged deficiencies in the record cited by the District are based on a distortion of the record and the Environmental Groups offer responses to many of the listed deficiencies. EGResp. at 8-13. The Environmental Groups argue that the studies cited by the District are not indispensable to this proceeding and that no explanation on

why the studies were not undertaken earlier. EGResp. at 13-14. The Environmental Groups point particularly to the epidemiological study and assert that a colleague of the leading researcher on that study does not believe the study is a reason for delay. EGResp. at 14. As to the other studies, the Environmental Groups claim that the District will need to complete some of those studies regardless of this rulemaking. EGResp. at 16.

SETF's Response

SETF opposes the motion to stay arguing that the motion is premature and incorrect. SETFResp. at 6. The motion is premature because a "major, legally required component of this rulemaking" is not complete and that component is the opportunity of participants other than IEPA to present testimony and comment. *Id.* SETF argues that if a stay is granted the evidence gathering necessary for the Board to evaluate the arguments of the District or any other participant would be prematurely terminated. *Id.* SETF plans to present testimony concerning the recreational uses of the Calumet River system and the parks and recreational areas through which the Calumet River flows. SETFResp. at 6-7. SETF states that this testimony and subsequent comments by SETF will help the Board in evaluating the IEPA's use designations and the disinfection requirements. SETFResp. at 7.

SETF disagrees with the characterization by the District of the law on stays. SETFResp. at 7. SERF argues that the Board is authorized to: 1) control only one source category, 2) control discharges despite collateral environmental impacts, 3) control discharges because of potential threats without finding actual harm, 4) control discharges from sources even if contributions to overall pollution is small, and 5) implement requirements even if regulated entities will bear costs. SETFResp. at 7-8, citing In the Matter of: Proposed New 35 Ill. Adm. Code 225 Control of Emissions from Large Combustion Sources (Mercury), R06-25.

Further SETF claims that the legal requirements behind this proceeding are very different than the District asserts. SETFResp. at 8. SETF argues that under the Clean Water Act the IEPA is under a non-discretionary duty to assess Illinois waters to ensure that the waters are safe for the people and wildlife using them, "now and in the future, until the waters are fully fishable and swimmable." *Id.*, citing 33 U.S.C. § 1313(c)(1), 40 CFR 131.10(j)(1). SETF states that to fulfill this duty, IEPA engaged in a process, over several years, involving multiple stakeholders to assess the present attainable uses of the CAWS, and IEPA determined that some decades old classifications should be changed. SETFResp. at 8. SETF notes that new recreational uses trigger Clean Water Act mandates to ensure that the CAWS is safe for these uses. *Id.* SETF points out that the District's wastewater treatment plants are sources of pathogens into waters which are now classified for recreational uses and disinfection is almost uniformly employed by POTWs in Illinois and throughout the United States to control these kinds of pathogens. *Id.* SETF opines that affording "any value" to the District's broad claims that disinfection is technically infeasible and will result in substantial and widespread economic and social impact, is difficult. *Id.*

SETF states that from their perspective, the IEPA proposal designates uses for which CAWS should be maintained and protected, prescribes water quality standards necessary to sustain the designated uses, and establishes effluent standards to limit contaminant discharges to

CAWS. SETFResp. at 8-9. SETF argues that the IEPA's proposal is within IEPA's legal mandate under both federal and state law. SETFResp. at 9, citing 35 Ill. Adm. Code 301.102 and 33 U.S.C. § 1370.

SETF argues that granting the stay would be fundamentally unfair to the participants in this rulemaking as the Board has received over 70 comments on the rule and 44 individuals testified at a June 16, 2008 hearing regarding the proposal. SETFResp. at 9. Further, for the first time in the September hearings environmental organizations will be given an opportunity to present testimony and evidence concerning the proposed rule. *Id.* SETF claims that the stay could be viewed as an attempt to allow the testimony already given to go stale and this is against the public interest. *Id.*

SETF asserts that granting the stay would allow the District to subvert the rulemaking process that dozens of participants have engaged in good faith. SETFResp. at 10. SETF maintains that many of the internal District activities cited in the motion have been underway for years and will take many more years to complete. *Id.* Further, SETF asserts that a stay would "damage the public trust and confidence in the Board" because the rulemaking is generating public interest and participation from numerous entities. SETFResp. at 11. SETF maintains that the stay will be ascribed to the Board and the Board will be regarded as responsible for allowing additional years of human contact with pathogens. SETFResp. at 11-12.

DISTRICT'S REPLY

The District notes that the participants seem to recognize that a stay would be appropriate to avoid wasting time, expenses and resources, and that is the purpose of the District's motion. Reply at 2. The District claims the motion to stay was filed to avoid the needless expense of pushing forward with rulemaking proceedings that may ultimately need to be repeated. *Id.* The District indicates that in the coming months the District will present over 20 witnesses and other participants also intend to present witnesses. *Id.* The District asserts that based on the substantial number of witnesses that will need to be questioned, proceeding with this rulemaking when much of the support needed will be provided in the reports outlined by the District does not make much sense. *Id.* The District also notes that many of the reports, identified in the motion, were specifically requested by IEPA or that current studies are being conducted to address issues raised by the reports requested. *Id.*

The District notes that the responses in opposition to the motion offer several specific challenges to the motion to stay, but the common themes are that the UAA process has been ongoing for six years and the IEPA has adequately supported the proposal or need not support certain aspects. Reply at 3. The District agrees that the IEPA has answered numerous questions and that the rulemaking has been ongoing for six years. Reply at 3-4. The District argues that a great volume of data is not a substitute for complete analysis and much of the IEPA's testimony shows that the IEPA has failed to perform the necessary legal and technical analysis. Reply at 4.

The District disagrees that the burden to justify the changed use designations is not on the IEPA. Reply at 4. The District agrees that if the CAWS designation was fishable/swimmable, then the IEPA would not need to justify the standard, but the streamlined process does not apply

when designating other than fishable/swimmable. *Id.* The District also takes issue with the claim that Illinois specifically requires disinfection for vast stretches of water and that the requirements are simple proximity to parks or residential areas to require disinfection. Reply at 6.

The District argues that discussions about proposed water quality standards have been on going so the push for an urgent resolution is disingenuous. Reply at 22. The hearings that have already taken place will not go to waste unless the rulemaking continues and the significant holes are not resolved and the rule proposal fails to withstand the Board's scrutiny. Reply at 21. The District is not using the motion as a tactical ploy to delay the rulemaking as many of the studies being undertaken are done so at the request of the IEPA. Reply at 23. The IEPA did not wait for the District to complete the studies but proceeded to propose changes and the District argues that the District can hardly be blamed for timing issues associated with particular studies. Reply at 23-24. The District undertook additional studies as soon as the District became aware that IEPA would be proposing new standards without much of the information needed to justify them. Reply at 24.

The District maintains that the District was not obligated to undertake these studies. Reply at 24. The IEPA is attempting to change the designated uses and IEPA has the responsibility to justify UAAs with information supporting the decision. Reply at 24, citing 40 C.F.R. § 131.10(g), (j). The District's desire to supplement the rulemaking with studies to fill gaps is not an obligation to conduct the studies. Reply at 24. Furthermore, the District could not know the full extent of the informational gaps in the IEPA's proposal until the IEPA proposed the rulemaking and the District could not fully appreciate the gaps until the IEPA completed the testimony in April. Reply at 25. Thus, the District timely moved for a stay and Midwest Generation, Stepan, and CICI support that motion. Reply at 26.

DISCUSSION

The Board has reviewed the arguments by the participants concerning the requests to stay the proceedings. The Board notes that there have already been 11 days of hearing beginning in January 2008, including one evening hearing between the April hearings and the hearings scheduled for September. Since the September hearings are devoted to testimony by participants other than the IEPA on use designations only, there will be future hearings on the proposal so participants have the opportunity to testify on the water quality standards proposed by the IEPA. The hearing officer will schedule additional hearings on the water quality standards after conclusion of testimony on the use designations. Finally, the Board has already given participants several months to prepare testimony for the scheduled September hearing.

The Board is not convinced that an additional delay is warranted at this time. The hearing process and information gathering by the Board will continue at least until the Board has heard testimony from all participants who wish to testify on all aspects of the IEPA's proposal. Additional testimony will provide a more complete record and enable the Board to make the best possible decisions regarding the IEPA's proposed rules. The Board finds that this process is proceeding in an appropriate manner and a stay is not necessary at this time. The Board denies

the motion to stay and will not disturb the hearing officer's order on the prefiling of testimony and questions for the September hearings.

CONCLUSION

The Board finds that a stay is not warranted at this time and therefore denies the motion for stay. The hearing schedule, including all prefiling deadlines for the hearings starting September 8, 2008, is unchanged from the hearing officer's May 19, 2008 order. Thus, prefiled testimony is due August 4, 2008, and the mailbox rule does not apply.

IT IS SO ORDERED.

I, John T. Therriault, Assistant Clerk of the Illinois Pollution Control Board, certify that the Board adopted the above order on July 21, 2008, by a vote of 4-0.

John T. Therriault, Assistant Clerk
Illinois Pollution Control Board

Exhibit B

BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:	)	
	)	
WATER QUALITY STANDARDS AND	)	
EFFLUENT LIMITATIONS FOR THE	)	R08-9
CHICAGO AREA WATERWAY SYSTEM	)	(Rulemaking - Water)
AND THE LOWER DES PLAINES RIVER:	)	
PROPOSED AMENDMENTS TO 35 Ill.	)	
Adm. Code Parts 301, 302, 303 and 304	)	

PRE-FILED TESTIMONY OF SAMUEL DOREVITCH

My name is Samuel Dorevitch and I am an environmental health researcher at the University of Illinois at Chicago School of Public Health. I am a medical doctor, with training and board certification in Emergency Medicine and also in Preventive Medicine, with specialization in Occupational Medicine. Over the last six years, I've conducted research on local environmental health issues, such as the effects of public housing demolition and the reconstruction of the Dan Ryan expressway on air quality. In addition to being a scientist, I have been an advocate for reducing pollution and improving the environment. Over the years, I have testified at U.S. EPA hearings in favor of setting more stringent regulatory standards for ozone, particulate matter air pollution, and off-road diesel emissions. I have also spoken out in the media about the impact of coal-fired power plants on local air quality. I have added my name to the National Resources Defense Council's list of those opposed to the U.S. EPA's recent effort to stop regulating lead as an air pollutant.

I have advocated for tighter regulations in the above contexts because there is an overwhelming body of public health research that demonstrates negative consequences of air pollution. For ozone, particulate matter, lead and other air pollutants, a solid scientific foundation exists for setting a regulatory standard. Just as I support improvements in air quality as a means of promoting public health, I recognize the critical role that improvements in drinking

water quality have played in promoting the health of the public. The scientific basis for improving air quality and drinking water quality are well-established, strong, and based on thousands of scientific studies. However, in the case of water recreation, and limited contact recreation in particular, we are just beginning to develop the scientific data that will help define what regulatory measures are appropriate for protecting the health of public.

In contrast with the thousands of scientific papers that have addressed the health effects of air pollution, less than 20 observational epidemiologic studies of primary contact recreation in the US have been published. For limited contact recreation, no studies have been done in the US, less than 5 have been done in Europe, and those looked primarily at whitewater canoeing, an activity that does not take place on the Chicago Area Waterway System, or CAWS. No research has ever characterized the health risks of activities observed on the CAWS, namely boating, paddling, rowing and fishing. We do not know if people who engage in limited contact recreational activities develop illnesses, such as gastroenteritis or eye infections or skin infections or respiratory problems at higher risk than the general population.

Because the scientific literature does not provide guidance for establishing health-based regulations for CAWS recreation, one would want to know the following in developing efforts to improve water quality on the CAWS:

- Are rates of illness higher among CAWS recreators compared to recreators doing the same activities on waters that do not receive treated wastewater?
- If so, how frequently do such cases of illnesses occur above background rates?
- Are the pathogens responsible for illness bacteria, viruses or parasites, which may require different water quality treatment strategies?

- Are people who engage in specific recreational activities at increased risk while those who engage in other activities are not?
- Are there differences in risk on different CAWS reaches?
- How does the contribution of water reclamation plants to microbial measures of water quality compare to the contributions of runoff and sewer overflows?
- If the Pollution Control Board were to establish a disinfection requirement rather than a microbial water quality standard, how would risk to the public be determined along various CAWS reaches?
- Following rainfall and other events that are unrelated to wastewater treatment, what microbes should be measured in the water to evaluate and communicate risk to the public?
- If the Pollution Control Board were to establish a water quality standard, rather than a disinfection requirement, is there a microbial water quality level above which risk is unacceptable and below which risk is acceptable?

If there were known outbreaks of disease linked to CAWS recreation, I would suggest public health action now, rather than research. However, I am not aware of epidemics attributed to CAWS recreation. Since 1978, the U.S. Centers for Disease Control and Prevention has monitored disease outbreaks linked to water recreation. Using "WBDOSS," the Waterborne Disease Outbreak Surveillance System, the CDC compiles information about outbreaks due to treated and untreated recreational waters. Hundreds of outbreaks and thousands of cases of illness have been identified, described, and in varying degrees, investigated over the years. Outbreaks from Illinois – including a recent outbreak of *Cryptosporidiosis* in Tazewell County – have been reported. To the best of my knowledge, local health departments, the Illinois

Department of Public Health, and the CDC have not identified outbreaks of disease attributed to CAWS recreation.

This does not mean that people haven't gotten sick after using the CAWS. It is possible that such cases fly beneath the radar of the public health monitoring system. That is why it is important to identify such cases, to determine the microbes responsible for illness, to evaluate the locations where water contact took place, to characterize the water quality at that location, and to estimate the frequency with which such illness occurs. The fact that outbreaks linked to CAWS recreation have not been identified does suggest that we have the opportunity to define the scope and specifics of the problem before developing a potential solution. This lack of known outbreaks of disease is consistent with the finding of the recent quantitative microbial risk assessment. That study used hundreds of measurements of water quality on the CAWS and estimated that rates of illness among limited contact recreators are about 1-2 cases per 1,000 uses.

Although risk assessment can be very useful in comparing various risk scenarios, such analyses do not involve direct measurement of risk in populations. That type of research – the study of the distribution and determinants of states of health and disease in population – is epidemiology. Because epidemiologic studies involve the direct measurement, rather than the statistical modeling of risk, they are of great importance in developing plans to protect the health of the public. I am directing the epidemiologic study of CAWS recreation known as CHEERS, which stands for the Chicago Health, Environmental Exposure, and Recreation Study. This is the first epidemiologic study of the health risks of fishing, boating, rowing and paddling. This research uses the gold standard of observational epidemiologic studies, the prospective cohort design, and has been developed by a multi-disciplinary team of experienced researchers, with

backgrounds in infectious disease medicine, environmental medicine, epidemiology, biostatistics, industrial hygiene and environmental science. A panel of recognized leaders in the fields of water microbiology and health from the U.S. Centers for Disease Control and Prevention, the U.S. Environmental Protection Agency, and other universities has reviewed and endorsed the design and protocols of the research, and continues to monitor the quality of data collected. A copy of the review panel's endorsement has been submitted by Mr. Daniel Woltering of the Water Environment Research Foundation and is Public Comment Number 63 in the docket for this rulemaking.

I would like to give you a broad brushstroke view of the CHEERS research. A copy of the epidemiologic study protocol has been submitted as an attachment to my written testimony for anyone who wishes to see the details of this research. We recruit people into one of three study groups. The CAWS Group is composed of people who row, paddle, fish or go boating on the CAWS. The General Use Waters Group consists of people who do these same activities on a number of area lakes, rivers and lagoons not including the CAWS. The Unexposed Group includes people who do outdoor activities that do not involve water (such as jogging or biking) at about the same time and about the same place as the recruitment of participants into the other two groups. Individuals in all three groups undergo interviews on the day of recreation, and then are contacted for three telephone interviews over the following three weeks. All interviews are conducted using computer assisted methods, which ensure that participants are asked the same questions in a neutral fashion. Field interviews address current health, and for those who engage in water recreation, the extent of their contact with the water. Telephone interviews address changes in health status and additional water exposure since recruitment. While the participants are on the water, samples of water are collected and sent for analyses of bacteria,

viruses and parasites. If a participant develops illness, clinical specimens are collected so that the pathogen responsible for illness may be identified. The study uses state-of-the-art methods, which in several respects, surpass the U.S. EPA's ongoing research about primary contact recreation known as the National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) study.

Additionally, a module of CHEERS known as the exposure study seeks to answer important questions regarding water contact among recreators. Rowers, paddlers, boaters and fishers may be exposed to water microbes via several routes: ingestion, inhalation, and skin contact. Ingestion may result from getting water on ones hands and then touching ones mouth, it could result from a splash to the mouth, or it could occur in the unlikely event of capsizing or falling into the water. The exposure study will allow us to describe for the first time how much water exposure occurs by each route for specific recreational activities. These results may be useful in establishing whether some activities pose lower levels of risk (due to lower exposure) than others. We will also have the opportunity to evaluate the assumptions of risk assessments regarding exposure, dose, and risk. Preliminary analyses of 2007 data show that assumptions regarding the duration of various recreational activities were quite accurate. The conduct of an epidemiologic and a risk assessment in tandem is unusual and this opportunity to evaluate the strengths and limitations of risk assessment methods is one reason that there is considerable national interest in applying the final results of this research to the development of water quality regulation.

Epidemiologic studies provide an opportunity to directly measure, rather than model, risk. For this reason the U.S. EPA places considerable weight on epidemiologic studies when establishing environmental standards. A well-designed epidemiologic study seeks to minimize

the possibility that the research will fail to identify a real risk that may exist (a "false negative result") and to minimize the possibility that a risk will be identified when none exists (a "false positive result"). Early in the development of CHEERS, the research team evaluated numerous approaches for minimizing the possibility of a false positive or a false negative result. In calculating our necessary number of study participants, we used typical values of a 1 in 20 chance of a false positive result and a 1 in 5 chance of a false negative result. We made numerous conservative assumptions in that sample size calculation, and it is becoming apparent that we will have more statistical power than originally anticipated because the rate of drop out by study participants is less than a third of the 15% we had projected. Thus, the chances of failing to identify a real risk are likely less than one in five.

We calculated that a total of 9,330 people should be enrolled in the three recreational categories (i.e. approximately 3,110 people per recreational category as described above). Last summer and fall – the first year of the study – over the first 800 participants signed up for the study. CHEERS has been scaled up substantially this summer, and for the months of May, June and July, an average of more than 1,000 participants were enrolled per month. A breakdown of recruitment by group, by month is included as an appendix to this testimony. By the date of this hearing, we project that 5,500 participants will have been enrolled in CHEERS. We collected data about use of the CAWS, for specific activities at specific locations. A summary of the findings of CAWS recreational use survey in 2007 has been submitted as an appendix to this testimony. Highlights of that summary include the observation that the dominant uses on the North Branch and North Shore Channel are rowing and paddling while the dominant use on the Cal-Sag Channel is motor boating. Fishing from shore is relatively uncommon, and jet skiing is rarer still. Swimming and water skiing were never observed. Data obtained from field

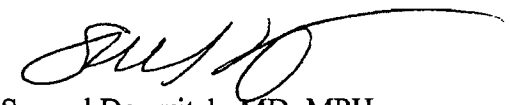
interviews of study participants demonstrates that several dozen individuals on rowing team each use the CAWS more 100 times per year. Similarly, some boaters at the Worth and Alsip launches use the Cal-Sag Channel dozens of times per season. Thus, a small number of users account for a large proportion of uses. These observations add detail to the picture sketched out by the assessment of current uses reported in the UAA. Inconsistencies between our observations and those of the UAA regarding the frequency of specific recreational activities and the distinction between uses and users are likely due to difference in methodologies.

Over 5,000 water samples have been analyzed and more than 150 stool samples have been obtained for analysis by the UIC laboratory and the Illinois Department of Public Health. We are well on our way to completing data collection and moving on to data analyses. The results of those analyses will provide answers to the critical questions about risk, the determinants of risk, exposure, sources of microbes, and causes of illness. The final report will serve as the basis for establishing standards to protect limited contact uses. Preliminary analysis of the 2007 data identifies no difference in rates of gastrointestinal symptoms among recreators in the three study groups. Because that analysis involved less than 10% of the total number of participants who will have been enrolled at the completion of this research, firm conclusions are premature. However, consistent with the lack of reports by public health departments of outbreaks of disease linked to CAWS recreation, our preliminary observations suggest no danger to the health of the population of limited contact recreators on the CAWS.

I favor strong, science-based environmental regulation as a means of protecting public health. Reducing the potential risks of limited contact recreation on the CAWS is an important and complex public health goal. From a policy perspective, one would want to know what the benefits and risks are of current wastewater management and recreation practices, and what the

benefits and risks are of various alternative approaches. The UIC School of Public Health research team is well on the way to defining the risks that limited contact recreators face under current wastewater management practices. I believe that this research should be the basis for sound, science-based environmental policy.

Respectfully submitted,



By: Samuel Dorevitch, MD, MPH
University of Illinois at Chicago
School of Public Health

Exhibit C

ORIGINAL

ILLINOIS POLLUTION CONTROL BOARD

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

REPORT OF THE PROCEEDINGS held in the above entitled cause before Hearing Officer Marie Tipsord, called by the Illinois Pollution Control Board, taken by Steven Brickey, CSR, for the State of Illinois, 100 West Randolph, Chicago, Illinois, on the 15th day of April, 2009, commencing at the hour of 9:00 a.m.

A P P E A R A N C E S

MS. MARIE TIPSORD, Hearing Officer
MS. ALISA LIU, Environmental Scientist
MR. ANAND RAO, Senior Environmental Scientist
MR. TANNER GIRARD, Acting Chairman
MR. THOMAS JOHNSON
MR. NICHOLAS MELAS

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REPORTED BY:

Steven J. Brickey, CSR
CSR License No. 084-004675

study, no matter how well designed and executed, no matter what the ultimate result, is sufficient basis to refuse to address water borne pathogens in the CAWS." Would you recommend that regulators make the decision without the benefit of epidemiologic studies?

MR. ORRIS: Certainly not.

MR. ANDES: So what do they need in order to make a decision?

MR. ORRIS: Well, first of all, thank you very much for inviting me today. I appreciate this opportunity and thank you for your service on this Board. These are very important issues that you are coping with and often outside of the public limelight so I appreciate that. For those of us in the academic field in environmental health, we are very happy that those of you are serving in this way and making these decisions.

Having said that, what do I think you need to take into account when you are arriving at regulatory decisions in this specific matter? Certainly, epidemiologic studies are helpful and these studies should help as one piece of evidence guiding your approach to understanding

what risks and benefits there are from your decisions. The problem with epidemiologic studies as you know, as with any science, is they try to approximate the world around us and try to educate us as to what are the risks and benefits in the world around us, but they are limited because they are based on people and they are looking at the world around us. We are not able to look epidemiologically at controlled studies in which people are placed in certain environments and one can control those environments entirely.

Having said that, even the best epidemiologic studies have -- always have problems in their ability to identify actual events and actual relationships that are really there. And that's characterized, in general, by an assessment of the power of that study. The power of the study means how likely is it when we look at a study and when this study looks at a problem and looks for a relationship how likely it is given the design of the study and the size of the study that we will actually see a relationship if it is there. Otherwise, called how large is a false negative or whatever and by convention and with

respect to this quite excellent study that Dr. Dorevitch is projecting, the standard that we set is based on our preconceived, at priority judgments that we hope that the power will be 80 percent.

In other words, if there's a real relationship, we will see it 80 percent of the time and we will miss it 20 percent of the time. By definition, this is not as stringent as we place on the reverse side and that is in the study if there's a relationship how likely is it that we are going to see it erroneously? We'll see the relationship, but, in fact, it will be due to something else. That's the sensitivity of that study and we set that standard higher on the basis that we understand that epidemiologic studies help us identify relationships and help us less in ruling out relationships that may well exist.

So, for one, epidemiologic studies in and of themselves are limited by the science of that and this study, while excellent, is limited by those same things. In addition, this study, and epidemiologic studies in general, look at rather large homogeneous populations so

that if you have subpopulations at particular risk in this study design, you will lose their risk within the overall grouping here and this study talks about adults. It talks about population in general. It does not discuss the subsections of small children, young children, who may be using these waterways in more depth or more --

MR. ANDES: Are you aware of any way in which they're excluding those people?

MR. ORRIS: No, they are included but the problem is when you put them in with the 9,000 you're looking at you lose that particular aspect when you don't look particularly at that group. And the problem with looking at that group, as you know, is you get smaller and smaller populations and, therefore, your power to see a real relationship in a smaller population is much more difficult. So that's the second aspect of this particular study that is problematic. It doesn't mean it's a bad study. It's an excellent study. We support that study. We support this further review. It may demonstrate despite those problems, things we need to look at with respect to those waterways and what ought to be done about

it, but it is only one piece of the overall puzzle.

And, unfortunately, you have quite a high threshold here. You have one of the oldest known associations between the environment and disease and that is the ingestion of pathogens from water. We have known since antiquity that the injection of pathogens from water causes disease. We have known for many years that one of the most important public health initiatives, one of the most important public health preventive measures taken in the last 100, 200 years is the disinfection of water when it comes into contact with human beings in a variety of ways.

Having said that, then we also have a standard adopted throughout the country and much of the world that says that these waterways ought to be disinfected and that recreational waterways of this sort ought to be disinfected. And, finally, we have what looked to me to be a very balanced recommendation from the IEPA on it also.

So to overturn all of that weight, if you will, you need to have considerable

MR. ANDES: Okay. You're aware -- are you aware that NRDC has signed a settlement agreement with EPA concerning the Beach Act criteria which specifically requires EPA to conduct epidemiological studies to be used in developing water quality criteria?

MR. ORRIS: Of course. Having read it, and I'm not an expert in all these aspects of water control here. It looks quite complete to me. It has epidemiologic studies. It looks at subpopulations. It does monitoring. It does a whole wrath of -- or they commit themselves to a whole wrath of investigations that are most appropriate for this problem.

MR. ANDES: And you're aware that in this record in addition to the epidemiologic study which has been discussed in Dr. Dorevitch's testimony and will be available early next year there has been risk assessment information and other information provided to the Board all which I imagine you think should be considered in considering the totality of the information?

MR. ORRIS: Certainly.

MR. ANDES: Okay. As to this

do not include wind surfing?

MR. ORRIS: Well, you had that strange word in there "some". Obviously, some could be different. If you're saying all, if you're saying are there activities that may be frequently done in the waterways that may parallel the amount of exposure as wind surfing or as the rowing, kayaking and other studies, I would say absolutely there will be activities on these waterways that will parallel some of these other studies that should inform us or rather these other studies should be part of our consideration or part of the Board's consideration when they look at this.

MR. ANDES: In fact, the CHEER study is specifically looking at the exposures that people are undergoing on the CAWS system, correct?

MR. ORRIS: Yes, absolutely.

MR. GORELICK: If I might add. There are -- I'm aware of no studies that have looked at the amount of water that's ingested during secondary contact recreation such as boating. There are studies that have looked at how much water is swallowed during swimming, some

lights, which corners shouldn't. That's way beyond my expertise and I suspect not terribly relevant to this.

That was an example of the problem before a board such as yours and other regulatory board's and that's what you have to weigh. I'm here to help with an understanding of the question as to whether or not a single epidemiologic study can be used as the basis, especially a single negative epidemiologic study, can be used as the basis for a regulatory decision to overturn current approaches and policies that are well established.

MR. ANDES: Dr. Orris, is any one here suggesting or has said in writing that this should be the sole basis for the decision by the Board?

MR. ORRIS: What I take to be the question I'm asked is should the Board rely on the CHEER study as the basis for making their regulatory decision within this situation and that is what I am specifically talking about. In fact, when I read my colleague, Dr. Dorevitch's excellent testimony about his -- I want to say

again, his excellent study. And we appreciate the fact that you came to the U of I to secure such an excellent study.

MR. ANDES: As the brother of an alumnus, I appreciate that as well.

MR. ORRIS: Good. Having said that, reading his last line within his system and perhaps this was overstated unintentionally, but he does say that this is the -- that this should be the basis for consideration here. "The" is the word I take issue with.

MR. ANDES: Your --

MR. ORRIS: It should certainly be a basis.

MR. ANDES: So your quarrel is with that one word in Dr. Dorevitch's testimony?

MR. ORRIS: I'm sorry?

MR. ANDES: Your quarrel is with that one word in Dr. Dorevitch's testimony.

MR. ORRIS: Yes. The rest I thought I have some differences with, but he has high quality testimony.

MR. ANDES: Now, when you talk about balancing, it sounds like there are other factors

the assessment of the small studies that are done of this kind of use of contaminated water. In fact, lower levels than these contaminations have been identified and the fact that that's incorporated into people and has produced symptomatic disease. So we know that this type of use of this type of contaminated water is a problem and it needs effective preventive measures. And, again, a sign that says "Keep your mouth shut. Don't swallow anything," to a kayaker or wind surfer is not effective public health. It may be the only thing we have available now, but long term, we have to come up with better approaches.

MR. ANDES: As to the CAWS itself, I gather we'll have a better sense through the questions in the CHEERS study as to what extent those precautions have affected people's habits, correct?

MR. ORRIS: Again, this goes over what we previously talked about with respect to the study. We may learn some very important things from that study about the water use, et cetera. If we do not see a relationship that we

the bacteria or inactivates all the bacteria and some are better than others.

MS. TIPSORD: And, for the record, I would note that Dr. Blatchley's testimony was Exhibit 93.

MR. GORELICK: If I could add because this question, again, came up in pre-filed questions to me. I've also looked at Dr. Blatchley's testimony as well as his article and my understanding is that disinfection does not, in fact, remove all pathogens, however the disinfection method studies shows that when you disinfect levels of indicator bacteria do drop. That in some cases they come back, that some methods are more beneficial than others, but I don't think the conclusion was that disinfection is useless.

MR. ANDES: I don't think anyone suggested that. As to the -- and to some extent we may have addressed this, Dr. Orris, when you reviewed to the CHEER study as an excellent study, you're aware, are you not, that the research plan was evaluated by a panel of recognized leaders in the field and they determined the study, quote,

has been designed to provide information that is valuable in the area of health risks associated with secondary contact recreation and addressed potential deficits in the current knowledge and health risks associated with limited contact water recreation and the measures acquired to protect the public?

MR. ORRIS: Yes, I absolutely agree with that.

MR. ANDES: Okay. Thank you.

MS. TIPSORD: Excuse me, Mr. Harley has a question.

MR. HARLEY: Hi. My name is Keith Harley. I'm an attorney for the Southeast Environmental Task Force. There was a pre-filed question I believe you skipped over that I believe might be helpful in terms of creating the record. The pre-filed question was seven and it was subpart A. It was: What do you consider to be high levels of indicator bacteria? You eluded to the effect in an answer to another question that you believe the levels of indicator bacteria found in the CAWS were high. Could you please explain for the Board on what basis you came to that

think the same is true when you're looking at recreational exposure.

Try to identify outbreaks of diseases is very challenging for a lot of reasons about which Peter talked about. Many of these things don't get reported. When the diseases come to medical attention, they don't necessarily get attributed to the exposure at hand unless all of a sudden you get 400,000 people showing up in the emergency room like you did in Milwaukee.

I think that's actually one of the nice strengths of the CHEER study is -- that it is another study that is attempting to look at this in a way that identifies prospective diseases that may not occur in outbreaks. Like some of the other surveys that have already been done in other settings that have shown there is an increased risk. None out of those reported outbreaks. They were done through prospective surveillance. We need more of that kind of prospective surveillance to add to the existing body that shows that there are risks associated with that and to try to quantify it.

MS. TIPSORD: Excuse me,

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

I, Steven Brickey, Certified Shorthand Reporter, do hereby certify that I reported in shorthand the proceedings had at the trial aforesaid, and that the foregoing is a true, complete and correct transcript of the proceedings of said trial as appears from my stenographic notes so taken and transcribed under my personal direction.

Witness my official signature in and for Cook County, Illinois, on this 27th day of April, A.D., 2009.

Steven Brickey

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Phone: (312) 419-9292
CSR No. 084-004675

Exhibit D

ORIGINAL

ILLINOIS POLLUTION CONTROL BOARD

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

REPORT OF PROCEEDINGS held in the above-entitled cause before Hearing Officer Marie Tipsord, called by the Illinois Pollution Control Board, taken before Laura Mukahirn, CSR, a notary public within and for the County of Cook and State of Illinois, at the Thompson Center, Chicago, Illinois, on the 5th day of May, 2009, commencing at the hour of 10:00 a.m.

A P P E A R A N C E S

MS. MARIE TIPSORD, Hearing Officer
MR. THOMAS JOHNSON, Member
MR. ANAND RAO, Member
MS. ALISA LIU, Member
DR. SHUNDAR LIN, Member
appearing on behalf of the Illinois Pollution Control Board

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(312)357-1313
BY: MR. FREDRIC P. ANDES
Appearing on behalf of the Metropolitan Water Reclamation District

****

A. I certainly hope so.

Q. Okay. Whatever the results, they will be relevant, correct?

A. They will be one part of the considerations that EPA evaluates and members of the scientific community evaluate as they develop those criteria. They're not just doing risk assessment studies. That's one component of the process.

Q. And the epidemiological study being done as to the CAWS, which is the first one being done as to secondary contact, you would agree that that would as well be relevant in determining appropriate water quality standards for the CAWS?

A. I would say that the epidemiological study that's being conducted by Dr. Gorovich would certainly be one piece of information that would be relevant to consider when determining what happens with respect to the issues at hand here.

MS. WILLIAMS: I'd like to follow up on this question four real quick.

Can you explain the statement that Mr. Andes has flagged here from your testimony regarding efforts to reevaluate pathogen indicator criteria have no bearing

STATE OF ILLINOIS)
) SS.
COUNTY OF COOK)

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

Laura Mukahirn

LAURA MUKAHIRN, CSR

CSR NO. 084-003592

ORIGINAL

BEFORE THE 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:	)	No. R08-9
PROPOSED AMENDMENTS TO	)	
35 Ill. Adm. Code Parts	)	
301, 302, 303 and 304	)	

REPORT OF PROCEEDINGS had before the ILLINOIS POLLUTION CONTROL BOARD held on May 5, 2009, at 1:15 o'clock p.m. at the Thompson Center, Room-9-40, Chicago, Illinois.

A P P E A R A N C E S:

ILLINOIS POLLUTION CONTROL BOARD:
MS. MARIE TIPSORD, Hearing Officer
MR. THOMAS E. JOHNSON, Member
MR. ANAD RAO, Senior Environmental Scientist
LIN SHUNDAR
ALISA LIU
ILLINOIS ENVIRONMENTAL PROTECTION AGENCY:
Ms. Stefanie Diers
Ms. Deborah Williams

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BY: MR. ALBERT ETTINGER and JESSICA DEXTER
Appeared on behalf of ELPC, Prairie Rivers Network and Sierra Club;

APPEARANCE CONTINUED:

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BY: MR. FREDERIC P. ANDES

Appeared on behalf of the MWRDGC.

MR. ANDES: The epidemiological study, the CHEERS study that's going on now will give us a better idea of that answer?

DR. YATES: That's my understanding, yes.

MR. ANDES: So that would also be information that the Board would want to consider in making a decision here?

DR. YATES: I would imagine that the Board would consider that information, yes.

MR. ANDES: The next question was what is the actual micro exposure dose exposed by paddlers, boaters and fishers in the CAWS?

DR. YATES: Well, I guess the actual number of microorganisms they would consume would depend on the amount of water they ingest, as well as the concentration of microorganisms that were present in that water.

MR. ANDES: So one would look at the Risk Assessment and the epidemiological study together to get some perspective on that since you can't measure directly the

STATE OF ILLINOIS)
) SS.
COUNTY OF C O O K)

I, DENISE A. ANDRAS, being a Certified Shorthand Reporter doing business in the City of Des Plaines, 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.

Denise Andras

DENISE A. ANDRAS, CSR
CSR NO. 084-0003437

Exhibit E

ORIGINAL

IN THE MATTER OF:	)	
	)	
WATER QUALITY STANDARDS AND	)	
EFFLUENT LIMITATIONS FOR THE	)	No. R08-9
CHICAGO AREA WATERWAY SYSTEM	)	
AND THE LOWER DES PLAINES RIVER:	)	
PROPOSED AMENDMENTS TO 35 ILL.	)	
ADM. CODE PARTS 301, 302, 303	)	
AND 304.	)	

TRANSCRIPT OF PROCEEDINGS held in the above-entitled cause before Hearing Officer Marie Tipsord, taken before Tamara Manganiello, RPR, at 160 North LaSalle Street, Room N-502, Chicago, Illinois, on the 28th day of July, A.D., 2009, commencing at 9:06 a.m.

APPEARANCES

ILLINOIS POLLUTION CONTROL BOARD
Ms. Marie Tipsord, Hearing Officer
Mr. G. Tanner Girard, Acting Chairman
Ms. Andrea S. Moore, Board Member
Mr. Thomas E. Johnson, Board Member
Mr. Shundar Lin, Board Member
Mr. Gary L. Blankenship, Board Member
Ms. Alisa Liu, Environmental Scientist

ILLINOIS ENVIRONMENTAL PROTECTION AGENCY
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BY: MR. FREDERIC P. ANDES,

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

of the exposure from noroviruses. And the other big issue with respect to the analytical methods was the ignoring of the potential enterovirus positive samples.

So in all, I believe that the biggest flaw in the analytical portion of the sample analysis portion of the risk assessment was that there would be an underestimate of the magnitude of the exposure to human pathogens in the water and therefore the risks would be biased low.

Q. Question three asks, in your opinion, why is MWRDGC's epidemiological study not a sufficient tool to assess the needs for disinfection?

A. First, let me say that I believe that the epidemiological study in general is being conducted in a very thorough way and I have absolutely no reason to doubt that the information that comes out of that study will be extremely useful especially as it relates to the secondary recreational activities.

I do believe, though, that there are some things that are not going to be determined through that study, one of them is the risk of

STATE OF ILLINOIS)
) SS.
COUNTY OF WILL)

I, Tamara Manganiello, CSR, RPR, do hereby certify that I reported in shorthand the proceedings held in the foregoing cause, and that the foregoing is a true, complete and correct transcript of the proceedings as appears from my stenographic notes so taken and transcribed under my personal direction.

Tamara Manganiello

TAMARA MANGANIELLO, CSR, RPR
License No. 084-004560

SUBSCRIBED AND SWORN TO
before me this 7th day
of August, A.D., 2009.

Notary Public

NOTARY PUBLIC OFFICIAL SEAL STATE OF ILLINOIS
DIANA CANNA
MY COMMISSION EXPIRES
JULY 8, 2013

Exhibit F

BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:	)	
	)	
WATER QUALITY STANDARDS AND	)	
EFFLUENT LIMITATIONS FOR THE	)	R08-9
CHICAGO AREA WATERWAY SYSTEM	)	(Rulemaking - Water)
AND THE LOWER DES PLAINES RIVER:	)	
PROPOSED AMENDMENTS TO 35 Ill.	)	
Adm. Code Parts 301, 302, 303 and 304	)	

PRE-FILED TESTIMONY OF SAMUEL DOREVITCH REGARDING CHEERS RESEARCH UPDATE: AN INTERIM TECHNICAL REPORT PREPARED FOR SUBMISSION TO THE ILLINOIS POLLUTION CONTROL BOARD

My name is Samuel Dorevitch and I am an environmental health researcher at the University of Illinois at Chicago School of Public Health. I am a medical doctor, with training and board certification in Emergency Medicine and also in Preventive Medicine, with specialization in Occupational Medicine. Over the last eight years, I've conducted research on local environmental health issues, such as the effects of public housing demolition and the reconstruction of the Dan Ryan expressway on air quality. In addition to being a scientist, I have been an advocate for reducing pollution and improving the environment. Over the years, I have testified at U.S. EPA hearings in favor of setting more stringent regulatory standards for ozone, particulate matter air pollution, and off-road diesel emissions. I have also spoken out in the media about the impact of coal-fired power plants on local air quality. I have added my name to the National Resources Defense Council's list of those opposed to the U.S. EPA's effort to stop regulating lead as an air pollutant.

In February, 2009, I participated in a conference held by the Water Environment Research Foundation entitled "Expert Scientific Workshop on Critical Research and Science Needs for the Development of Recreational Water Criteria for Inland Waters." Thirty-one national and international experts participated in the meeting, which was supported in part by the

US EPA's Office of Water. I served on the planning committee, led the working group on "Health Risks: Epidemiology and Risk Assessment," and participated in the writing of the final report. With the other group leaders I summarized the state of the science in an article entitled "Knowledge and gaps in developing microbial criteria for inland recreational waters," to be published in the June, 2010 issue of Environmental Health Perspectives.

I am directing the epidemiologic study of recreation in the Chicago Area Waterway System ("CAWS") known as CHEERS, which stands for the Chicago Health, Environmental Exposure, and Recreation Study. This is the first epidemiologic study of the health risks of fishing, boating, rowing and paddling. This research uses the gold standard of observational epidemiologic studies, the prospective cohort design, and follows the study format used for the United States Environmental Protection Agency's National Epidemiological and Environmental Assessment of Recreational (NEEAR) Water Study. which will generate national microbial water quality criteria for primary contact water. The CHEERS study design has been developed by a multi-disciplinary team of experienced researchers, with backgrounds in infectious disease medicine, environmental medicine, epidemiology, biostatistics, industrial hygiene and environmental science. A panel of recognized leaders in the fields of water microbiology and health from the U.S. Centers for Disease Control and Prevention, the U.S. Environmental Protection Agency, and other universities has reviewed and endorsed the design and protocols of the research, and continues to monitor the quality of data collected as well as its analysis and interpretation. A copy of the review panel's endorsement has been submitted by Mr. Daniel Woltering of the Water Environment Research Foundation and is Public Comment Number 63 in the docket for this rulemaking.

In my pre-filed testimony that was filed with the Illinois Pollution Control Board (the "Board") on August 4, 2008, I provided a broad brushstroke view of the CHEERS research and its methodologies, and outlined the issues that the final analysis would address. Since that time, I have continued to direct the CHEERS research described in my testimony. As a result of the continuing research, on May 5, 2010, the Metropolitan Water Reclamation District of Greater Chicago (the "District") filed a copy of "CHEERS Research Update: An Interim Technical Report Prepared for Submission to the Illinois Pollution Control," (the "Interim Technical Report") with the Board. The Interim Technical Report provides a status update for the Board regarding the CHEERS research study. As the Interim Technical Report shows, participant recruitment and health follow-up have been completed and statistical analysis is ongoing. While final results of the research are not yet available, the Interim Technical Report provides interim summaries of key data elements. The report summarizes preliminary results of water quality and observation of recreational use of the CAWS during the last three recreation seasons. For the CAWS water exposure group, General Use water exposure group, and unexposed to water recreational group, the report further summarizes participant recruitment, the occurrence of gastrointestinal illness, and microbes isolated from stool samples of study participants who developed gastrointestinal symptoms following recreation. The summaries that comprise the Interim Technical Report, however, should not be viewed as answers to primary study questions.

Yet to be completed are analyses of health risks of incidental contact water recreational activities. Such analysis will take into account multiple factors that must be considered when describing relationships between key variables (such as water quality) and health outcomes (such as the development of gastrointestinal illness). For example, if users of the CAWS are different in important ways compared to users of General Use waters or to study participants that were not

exposed to water – such as their age or presence of underlying health conditions – real differences in the health risk between the CAWS group and other groups may be distorted. The ongoing data analysis focuses on accounting for such difference in order to generate appropriate comparisons of risk across study groups.

Recently, we convened a meeting of the peer review group for CHEERS. The meeting provided an opportunity for the CHEERS research team to present specific questions about data quality and methods of analysis to the review team. Although Section 2.02 (a) of the Interim Technical Report notes that data are of sufficient quality to meet study objectives, the peer review group and the research team agreed that a subset of water quality data did not meet CHEERS project quality criteria, and should be excluded from analysis, even though they were generated by a certified lab that reported that its internal QC was acceptable during the generation of these data. Specifically, in the dataset for E. coli and enterococcus that formulates the basis for data presented in Table II-6 and Figure II-1 (a-b) of the Interim Technical Report, there are implausibly low values of indicator bacteria, collected at sites on the CAWS and other waters. The effect of excluding these data will likely increase the mean values of these indicators somewhat for the 2008 season, though the impact on median values would be minimal. I will be revising Tables II-6 and Figure II-1 (a-b) to address this issue in the next ten (10) days, after which the District will file the revised Tables with the Board.

The research team is continuing to work on analyses and preparation of its report. Based on the progress of the CHEERS research and analyses, a final CHEERS report will be completed and filed with the Board by August 31, 2010. That report will address, among other issues, occurrence of illness among study participants and rates of illness attributable to CAWS recreation adjusted for demographic differences among study participants, and microbes

responsible for gastrointestinal symptoms among study participants. It will also contain information concerning development of a relationship between microbial water quality parameters and incidence of illness for recreational uses proposed for the CAWS, which will eventually be needed to develop scientifically-based bacterial water quality standards for the CAWS. A supplemental report reflecting completed analyses of the water quality-illness relationship will be submitted to the Board by the end of 2010.

Respectfully submitted,

By: Samuel Dorevitch
University of Illinois at Chicago
School of Public Health

Exhibit G

BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:	)	
	)	
WATER QUALITY STANDARDS AND	)	
EFFLUENT LIMITATIONS FOR THE	)	R08-9
CHICAGO AREA WATERWAY SYSTEM	)	(Rulemaking – Water)
AND THE LOWER DES PLAINES RIVER:	)	
PROPOSED AMENDMENTS TO 35 ILL.	)	Subdocket B
ADM. CODE PARTS 301, 302, 303, AND 304	)	

TESTIMONY OF MARC GORELICK, MD

I. Introduction

My name is Marc H. Gorelick, M.D. I am a Professor of Pediatrics and Population Health and Chief of the Section on Emergency Medicine at the Medical College of Wisconsin, and Jon E. Vice Chair in Pediatric Emergency Medicine at Children's Hospital of Wisconsin. I have extensive expertise in clinical epidemiology, and have published more than 50 peer-reviewed original research papers in that field.

I am testifying today, for the second time in this proceeding, on behalf of Natural Resources Defense Council, Environmental Law and Policy Center, Sierra Club – Illinois Chapter, Friends of the Chicago River, and Openlands in support of the regulation proposed by the Illinois Environmental Protection Agency ("IEPA") that would require the Metropolitan Water Reclamation District ("MWRD" or the "District") to disinfect the effluent from its three wastewater treatment plants ("WWTPs") that discharge into the Chicago Area Waterway System ("CAWS").

In my previous testimony in April, 2009, I explained the severe limitations of epidemiological research, which I have conducted extensively myself, as a means of assessing a public health risk. I further explained the limited significance of negative epidemiological study results, *i.e.* a failure to find elevated risk, particularly in a study such as this one with many diverse variables and confounding factors (age, health, type of activity, *etc.*).

My testimony today concerns the preliminary technical reports submitted by MWRD describing raw data collected by researchers in the epidemiological study commissioned by the District, the Chicago Health, Environmental Exposure, and Recreation Study ("CHEERS"). My review of the CHEERS preliminary data indicates that the concerns I expressed in my 2009 testimony, concerning the scope of the study and inherent ambiguity of any negative result, are materializing. Equally important to recognize, however, is that this raw data does *not* represent CHEERS study results – negative or otherwise – or anything approximating them. They are merely the first step in an epidemiological study, a collection of facts and numbers obtained from testing and study subject interviews. The next critical step is evaluation of the data through statistical analysis and mathematical modeling in order to isolate the specific risk factors the study is designed to evaluate. Without that step, the data, while intriguing, are essentially meaningless. I strongly urge the Board not to consider the technical reports as a basis for its decisionmaking in this matter.

II. Qualifications

I am an expert in epidemiology and public health. A copy of my curriculum vitae is attached as Exhibit 1. A biographical sketch summarizing my work and expertise in epidemiology is attached as Exhibit 2.

My current professional positions include the following:

- Professor, Departments of Pediatrics and Public Health, Medical College of Wisconsin (2004-present).
- Chief, Section of Pediatric Emergency Medicine, Department of Pediatrics, Children's Hospital of Wisconsin (2000-present).
- Jon E. Vice Chair in Pediatric Emergency Medicine, Children's Hospital of Wisconsin.
- Associate Director, Children's Research Institute, 2007-present.

I have had numerous faculty appointments in the field of epidemiology, including the following:

- Assistant Professor, Departments of Pediatrics and Epidemiology, University of Pennsylvania School of Medicine (1994-1998).
- Senior Scholar, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania School of Medicine (1994-98).
- Adjunct Assistant Professor, Department of Epidemiology, University of Pennsylvania School of Medicine (1998-2000).
- Associate Professor, Departments of Pediatrics and Epidemiology, Medical College of Wisconsin (2000-2004).

I have conducted extensive published research in the area of epidemiology. I have co-authored more than 50 peer-reviewed original research papers publications in different areas of clinical epidemiology, including case-control and cohort studies, controlled clinical trials, and meta-analyses. Some representative publications include:

Gorelick MH, Shaw KN, Murphy KO. Validity and reliability of clinical signs in the diagnosis of dehydration in children. *Pediatrics* 1997;99(5):e6.

Gorelick MH, Shaw KN. Clinical decision rule to identify young febrile children at risk for UTI. *Archives of Pediatrics and Adolescent Medicine* 2000;154:386-390.

Gorelick MH, Brousseau DC, Stevens MW. Validity and responsiveness of a brief asthma-specific quality of life instrument in children with acute asthma. *Ann Asthma Allerg Immunol* 2004; 92:47-51.

Gorelick MH, Meurer J, Walsh-Kelly C, Brousseau DC, Cohn J, Kuhn E, Grabowski L, Kelly K. Controlled trial of two emergency department-based follow-up interventions to improve asthma outcomes in children. *Pediatrics* 2006;117:S127-S134.

Gorelick MH. Bias arising from missing data in predictive models. *J Clin Epidemiol* 2006;59:1115-23

Gorelick MH, Yen K. The kappa statistic was representative of empirically-observed inter-rater agreement for physical findings. *J Clin Epidemiol* 2006;59:859-861.

Gorelick MH, Alessandrini EA, Cronan K, Shults J. Revised Pediatric Emergency Assessment Tool [RePEAT]: a severity index for pediatric emergency care. *Acad Emerg Med* 2007;14;316-323.

Redman R, Nenn C, Eastwood D, **Gorelick MH**. ED visits for diarrheal illness increased after release of undertreated sewage. *Pediatrics* 2007;120:e1472-1475.

Gorelick MH, Wagner D, McLellan S. Validation of a questionnaire to evaluate water exposures in children. *Ambul Pediatr* 2008;8:388-91.

Freedman SB, Eltorky M, **Gorelick MH**, and the PERC Gastroenteritis Study Group. Evaluation of a gastroenteritis severity score for use in an outpatient setting. *Pediatrics* 2010;125: doi:10.1542/peds.2009-3270

Gorelick MH, McLellan SL, Wagner D, Klein J. Water use and acute diarrhoeal illness in children in a United States metropolitan area. *Epidemiol Infect* 2010 [accepted for publication]

Drayna P, McLellan SL, Simpson P, Li S-H, **Gorelick MH**. Association between rainfall and pediatric emergency department visits for acute gastrointestinal illness. *Env Health Persp* 2010 [accepted for publication]

I have extensive teaching experience in the area of epidemiology. Course I have taught in that area include the following:

- University of Pennsylvania: Course developer and director, Advanced Topics in Clinical Epidemiology (elective course for Master of Science in Clinical Epidemiology Program); taught in Critical Appraisal workshop for MSCE students.
- Jefferson Medical College: developed and taught course in Evidence-Based Medicine for senior pediatric residents.
- Medical College of Wisconsin: Annual Introduction to Research Design seminar for pediatric fellows; taught in Protocol Development course for MCW fellows and junior faculty; preceptor for K30 Clinical Research Scholars Program

III. Nature and Significance of the CHEERS Technical Report

I have reviewed the document entitled "CHEERS Research Update, an Interim Technical Report Prepared for Submission to the Illinois Pollution Control Board, and Appendices" ("Technical Report"). The Technical Report is a preliminary description of data gathered in the CHEERS epidemiologic study, which has been conducted by a team led by Dr. Samuel Dorevitch of the University of Illinois-Chicago School of Public Health for the MWRD, which provided the funding for this study.

This compilation of information represents completion of the initial step in conducting an epidemiological study: a population survey and gathering of related information. This initial step, reflected in the Technical Reports, is essentially a compilation and description of raw data. The next step is critical, and in many ways at the heart of sound epidemiologic research: evaluation of the data through statistical analysis and mathematical modeling in order to isolate the specific risk factors the

study is designed to evaluate. In the absence of that step, the preliminary data has very limited meaning.

As discussed in my 2009 testimony, even after this second analytical step – the "number crunching" step as it were – has been completed, there are still likely to be many factors unrelated to the risk being assessed that confuse efforts to isolate and quantify that risk. These are referred to as "confounding factors," which I address in more detail in the next section. However, without the critical step of statistical analysis to attempt to strip away some of the impact of these confounding factors, the preliminary data has little meaning at all. Indeed, knowing that there are very large differences in numerous risk factors between the groups under study, it is inappropriate and misleading to draw any conclusions about those groups without properly accounting for these other factors. Moreover, it is essential to understand that the process of disaggregating the confounding factors will in most instances reduce the statistical power of the study, and hence the significance and reliability of its results. This problem is also addressed in more detail in the section below.

As discussed in my 2009 testimony, confounding factors abound in the CHEERS study. The study's design is extraordinarily broad. Rather than zeroing in on a particular population of recreators – for example, kayakers, or canoeists, or children, or healthy adults – the study casts its net widely, gathering data on *all* CAWS recreators (and many others) participating in a broad array of activities, regardless of age or health. All of these differences among study participants, among many other factors, constitute confounding factors that must be accounted for in further analysis – and which will reduce the statistical power of the study.

Thus, there is no sound scientific basis for drawing conclusions from the Technical Report regarding risks associated with CAWS recreation, and it would be a serious error to attempt to do so. Indeed, the authors of the Technical Report acknowledge this on page 33 of the report, where they state, "It must be emphasized that these comparisons do not account for differences in the demographic and other characteristics of the three groups highlighted in Chapter 4.... Thus, firm conclusions can not be drawn from these data regarding differences in AGI across groups or recreational water exposure as a cause of AGI." For this reason, I was surprised and dismayed to see that the District has claimed publicly that the Technical Reports represent a finding that "there are no increased health risks for recreational users in the inland Chicago Area Waterways System (CAWS) compared to swimmers in Lake Michigan."[1] There is absolutely no basis in the preliminary Technical Report data to reach that conclusion. Moreover, as described in the next section, it appears that the confounding factors I identified in my 2009 testimony – plus a number of additional factors and potential statistical biases that have emerged – will preclude a sweeping conclusion of that nature even when the study analysis is complete.

[1] *See* http://www.mwrd.org/irj/go/km/docs/documents/MWRD/internet/News&Media/Newsroom/Media/Press%20Releases/May/2010/CHEERS_study_filing.pdf (last accessed May 24, 2010).

IV. Confounding Factors Reflected in the Technical Report Raw Data

The CHEERS study represents an admirably ambitious attempt to conduct a broad survey of health impacts of all CAWS recreational uses and all categories of users. While these study results may ultimately yield an interesting first look at the health of CAWS recreators, as I explained in my 2009 testimony, the study is inherently not capable of providing a statistically meaningful assessment of health risk to the many sub-populations subsumed in the study.

A review of the preliminary Technical Report data indicates that many of the issues I identified in 2009 regarding the scope of the study and its statistical significance are materializing. Specifically, the data reflects numerous very significant confounding factors that have not yet been addressed through statistical analysis, which when sorted out will significantly reduce the statistical power of the study – to the extent they can be sorted out at all, which is not always the case. In addition, I have identified potential statistical biases that have not been accounted for, and that will weaken the reliability of the study results.

Those confounding factors, biases, and impacts on the statistical power of the CHEERS study (and on the significance of the raw Technical Report data) are discussed in the sections below.

A. Many Confounding Factors Are Reflected in the Technical Report Data

All observational epidemiologic studies, where subjects do what they would normally do rather than being assigned to those activities, are subject to confounding factors. This refers to the fact that individuals who differ with respect to the factor of interest (in this case, CAWS exposure) may also systematically differ with respect to other factors. It may appear that the factor of interest is associated with the outcome (in this case, GI illness), when in fact it is the other factors that are really the cause. For example, cigarette smoking is known to cause lung cancer. If one compares drinkers with non-drinkers, one might find a higher rate of lung cancer in those who drink, and conclude that drinking also causes lung cancer. However, if people who drink are also more likely to smoke, then it might *appear* that drinking causes cancer when in fact it is the smoking that does so. We say that the association between drinking and cancer is confounded by smoking.

Confounding can thus occur any time there are differences in factors other than the one under study, and those factors can themselves be associated with the risk of the outcome of interest. Confounding may also work to obscure an association. For example, if adults who use the CAWS are generally younger and hence statistically healthier than those who use Lake Michigan, then a simple comparison of those who use the CAWS would reveal that illness is less likely – not because the water is safer, but because those who go on it are less prone to get sick. One could falsely conclude that the risk from the CAWS is lower than it actually is unless you account for the difference in age as it relates to overall health.

In the CHEERS study, the researchers hope to compare people who recreate on the CAWS, those who recreate on General Use Waterways (GUW), and those who recreate but not on water, to draw conclusions about the relative risk of illness from CAWS and GUW compared with no water exposure. However, the characteristics of the study participants on pages 24-30 show that there are large and important differences in many other factors that are very likely to affect the risk of acute illness. These include:

Year of enrollment. For example, only 30% of the CAWS users were enrolled in 2009, compared with 40% of the GUW users. Water quality varies by year, and risk of illness is therefore likely to vary by year as well.
Season. For example, only 14.5% of CAWS users were enrolled in spring (March-May), compared with 30% of GUW users and almost 45% of unexposed recreators. Water quality varies by season, and risk of illness is therefore likely to vary by season as well. Additionally, other causes of illness are more prevalent in the community at certain times of year. For example, rotavirus, the most common cause of gastroenteritis, is usually present at high frequency in the community in the spring. If more GUW and unexposed recreators are enrolled in spring, their risk of illness will be overstated, diminishing the apparent relative risk to CAWS users.
Gender. 50% of CAWS users were male, compared with almost 60% of GUW users. It is well known among epidemiologists that gender may affect not only risk of illness but reporting of illness.
Age. As shown in Table IV-4, the age distribution differs significantly among the three groups. Age is known to be associated with risk of illness. People 18-44 are on average least susceptible to infectious diseases, but they are overrepresented in the CAWS group. This could serve to underestimate the association between CAWS use and illness in an unadjusted analysis.
Race/ethnicity. As shown in Table IV-5, the racial and ethnic characteristics of the three groups are different. Race and ethnicity are often associated with economic status, which may in turn affect the risk of GI illness.
Water activity. The types of activities performed by CAWS and GUW users differ significantly, and these also vary by year. Type of activity affects the likelihood of water exposure, and would therefore affect the risk of waterborne illness.

These are merely examples. Other confounders that must be addressed include the duration of activity (*i.e.* people on the water for a longer time will have greater exposure), and post-activity behavior (*i.e.*, people who eat or drink immediately after recreation will have greater exposure, and people who wash up immediately after recreation will have less exposure).

Given the large number of actual and potential confounders, and the very large differences between the exposure groups with regard to these factors, the simple, unadjusted analysis presented in this preliminary report, which in no way accounts for this confounding, is essentially meaningless. Even when the adjustments are made to the extent they can be, as discussed below, these adjustments will negatively impact the statistical power of the study.

B. Numerous Potential Sources of Bias

In addition to the problem of confounding, epidemiologic studies generally – and the CHEERS study is no exception -- are prone to various sources of bias, or systematic error. An important source of bias is called information bias, which arises when the accuracy of information is compromised. If the accuracy of information differs between groups, then a researcher may falsely conclude there is a difference between groups when in truth there is none, or to falsely conclude that the two groups are similar when in fact they are different. For example, if CAWS users perceive

their exposure to be riskier, they may be more likely to report symptoms they believe to be related to the water than unexposed participants. This would tend to inflate the apparent risk of illness from the CAWS. Alternatively, if CAWS users are concerned about losing access to the waterway if they report illness to the research team, they may hold back on reporting, thereby making the CAWS seem safer than it truly is. Similarly, if CAWS users are more concerned about potential illness from contact with water, they may be more aware of such contact and hence more likely to report it. Such bias, known as recall bias, is a well-known problem in epidemiologic studies. The fact that CAWS users reported much higher rates of exposure to water suggests that CAWS users may be reporting differently than GUW users.

Additionally, in any study such as the CHEERS study that is based on after-the-fact participant self-reporting, the quality of information may suffer. For example, the longer the period of time that passes between an illness and being questioned about it, the less accurate the information is likely to be. Some people may have had diarrhea but forgotten about it, or may not be able to recall the exact day they became sick when asked 3 weeks later. When parents are asked about illness in their children, they may not know whether the child had loose stools or not. When this happens – some people over-report while others under-report - then groups of people will seem more similar to each other than they really are (the extreme example would be if everyone just flipped a coin when answering), and this always produces a bias such that any association between the exposure and the outcome will be underestimated. Another important example of potential bias in this study is the averaging of microbe counts. Even at the lowest level of aggregation, what is presented is an average of daily averages at a given sampling site. This would tend to obscure important peaks (for example, if microbe counts are highest when people are actually on the river), leading to an underestimate of the association between microbe count and illness.

Another important source of bias that may need to be recognized in the CHEERS study is selection bias, when the participants are selected in a way that makes the groups non-comparable, or when the participants are not truly representative of all the people in the population of interest. For example, by recruiting among organized groups such as rowing clubs, the study may obtain results that do not apply to the general population that might use the CAWS. Unlike confounding, it is difficult to know how much recall or selection bias there may be in a study, and virtually impossible to account for it in the analysis. It simply needs to be recognized in the study analysis as a potential limiting factor.

To the extent that potential biases exist, they call into question the strength of the CHEERS study's conclusions and generalizability of its results. For this reason, it is important in the research context to identify all such biases in evaluating data, so that its strength and significance can be better understood. Certainly, the statistical data in the Technical Report should not form the basis for any conclusions whatsoever until the potential epidemiologic biases are identified and discussed in a final study report.

C. Diminished Statistical Power

Critical to the predictive value of an epidemiological study is the size of the study sample. This is because epidemiology is, by its essence, a statistical endeavor. Much like a political poll, one surveys a large group of people to determine whether any patterns emerge that may be predictive for the larger population. And like a political poll, since one is reviewing only a sample and not the whole population, it is necessary to interpret the results with a "margin of error." That is, if one finds that out of 1,000 people surveyed that 50 of them will get sick, one cannot then make a straightforward extrapolation that in a population of 1,000,000, 50,000 people will get sick. The proper way to understand the result is that 50,000 people plus or minus X percent (the margin for error) will get sick.

The margin for error – X – is inversely correlated with the size of the sample. That is, the more people involved in the study, the more precise your results will be, and the smaller X will be. But if you do not have enough people in your study, your results will have a much larger margin of error. Thus, if you survey only 100 people and find that 5 of them got sick, this five percent positive finding is less reliable, and needs to be understood as a broad range of possible illness rates, ranging far above and far below 5 percent. X, the percentage margin for error, is necessarily very large. If you survey only 10 people, your results are essentially meaningless.

For this same reason, very little can reliably be concluded from negative results based on a small sample. There may be a small but significant percentage of the population that is becoming ill from the risk being screened for, but too small a sample may well miss all such people merely by chance. In other words, if approximately 50 out of every 1,000 people are getting sick, but you survey only 100 of those 1,000 people, there is a substantial possibility that you will not find among those random 100 even one of the 50 in 1,000 who is actually getting sick.

The question of sample size is largely determinative of the "statistical power" of a study. Statistical power refers to the probability that a study would conclude that there is a difference between groups if such a difference truly exists. Statistical power is most strongly related to sample size: the more subjects included in a study, the smaller the margin of error in the estimate for each group, and the easier it is to identify even a relatively small but important difference between groups.

The CHEERS study is a very large, ambitious epidemiologic study, and the investigators are to be congratulated for their successful enrollment and follow-up over several years. However, the ambitious size and scope of the study is not reflective of meaningful statistical power. In my 2009 testimony, I set forth my preliminary concern that the study as designed, despite its large overall sample size, lacks sufficient statistical power to identify clinically important differences in risk, in particular risk to the various sub-populations of CAWS users. That concern is borne out by the Technical Report data. That data reflects both an inherent inability of the study to assess health impacts to CAWS subgroups, as well as the prospect of reduced statistical power when the confounding factors are accounted for through statistical analysis. The Technical Report data also reflects two other limitations on the statistical power of the study: clustering and missing data.

1. Small Sample Size of Important Subgroups

As noted in my 2009 testimony, it is likely that subgroups of users have different risks, and may be of particular interest. For example, children may be at higher risk of illness due to differences in how much water they are exposed to, and underlying differences in immunity to infectious agents; those engaged in certain activities such as kayaking may be at particular risk as opposed to those who are fishing. While the margin of error for estimating illness among all the participants in the study may be adequately narrow to draw meaningful conclusions, that margin of error will be far greater for these important subgroups. To give a single example: if the risk of illness among all CAWS users is 4.3% (Table V-2), then the margin of error for this estimate is +/- 0.7%. However, for the group of CAWS users under 10 years of age, the margin of error is +/- 3.3% - five times higher. Because of these greater margins of error, this study will be unable to identify risks to important subgroups of people even if those subgroups are truly at higher risk.

2. *Effect of Adjustment for Confounding.*

I have already discussed the problem of confounding. It is possible to adjust for confounding when analyzing the data, but this comes at the cost of decreasing the power. Confounding has traditionally been accounted for by doing a type of analysis, called a stratified analysis, which divides the total study population into subgroups based on the factors of interest and the possible confounders. This is perhaps best understood using the drinking and smoking example I alluded to above. We know that drinkers are more likely to smoke, and we think that the association between drinking and cancer could be explained by the smoking, rather than the drinking. To know whether drinking itself truly causes cancer, we could look at people who smoke and those who do not smoke separately. We would then compare the rate of cancer among smokers who drink and smokers who do not drink. If, when we look at the smokers in isolation, we see a higher rate of cancer in those who drink, we would conclude that drinking has an independent effect on cancer. On the other hand, if drinking is *not* a cause of cancer, than the rates of cancer would be similar in both the drinking smokers and the non-drinking smokers; the same would be true if we look at the isolated subgroup of non-smokers and compare drinkers and non-drinkers.

In a stratified analysis, instead of comparing 2 groups (drinkers and non-drinkers), one compares 4 groups (drinking smokers, non-drinking smokers, drinking non-smokers, and non-drinking non-smokers). Now say there is also the possibility that people who drink are also less likely to get enough cancer-preventing vitamins; we might also have to account for diet as a confounder. Then we would have at least 8 groups to compare, based on drinking, smoking, and diet. (This assumes adequate diet is a yes/no question. If it is, say, low, medium, and high levels of vitamins, then there would be 16 groups.) With each additional confounder, the size of the subgroups gets smaller, and the margin of error for those subgroups gets wider – and the power to find a difference goes down.

Modern techniques to adjust for confounding use mathematical models called logistic regression models, rather than stratified analysis. With modeling, the same effect of adjusting for confounding is achieved at less loss of power, but the margin of error (also known as the confidence

interval) does get wider and there is a loss of power; the greater the number of confounders, the greater the loss of power.

3. Effect of Clustering.

The type of analysis noted above – logistic regression – is based on the idea that each participant in a study is completely independent of all the other participants. Whenever participants are somehow clustered, or linked in a way that makes them more similar than would be expected if participants were sampled completely at random, this must be accounted for. This is a technical statistical issue, but the end effect is that the margin of error (confidence interval) is wider than would be expected based solely on sample size, leading to further loss of power. In this study, participants were recruited at least in part in clusters. For example, a family of four sharing a boat would be counted as four individual participants. A more important example would be recruitment at an organized event, or from group activities (*e.g.*, a high school rowing team) where many individuals who may share important unmeasured characteristics (such as skill level, which may impact exposure and other factors) are considered independent when they are not. Assuming the investigators account for such clustering in the analysis, there would be some loss of study power.

4. Effect of Missing Data on Statistical Power

It is almost inevitable in an epidemiologic study that some participants will be missing some information. For example, someone may forget to check the box for male/female, or may fail to return a stool specimen. Although the investigators have done a thorough job in data collection, the magnitude of missing data is unclear from this report, and will need to be addressed in the next phase of the analysis. While the amount of data missing for any given variable may be very small, they can add up when many variables must be accounted for, since only those subjects with complete information for all of the variables in the analysis can be included in that analysis. For example, if there are 8 confounding variables to be considered in the model, and data are missing for only 1% for each variable, then the cumulative effect would be to drop 8% of the subjects from the analysis, with a corresponding loss of power.

Conclusion

I again congratulate the CHEERS study team on their successful completion of this ambitious study, which is a good overview and first step toward better understanding of risks associated with water exposure in the Chicago region. However, it is clear that the Technical Report can in no way serve as a sufficient basis for any conclusions whatsoever regarding health risks associated with the CAWS. Additionally, the Technical Report data bears out my initial concern with the lack of statistical power of the study to provide a meaningful evaluation of risk to CAWS recreators, and suggests additional study limitations as well.

I therefore urge the Board to draw no conclusions from the Technical Reports; and to be extraordinarily cautious and skeptical of any ultimate claims regarding the significance of the final CHEERS study once it is available.

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