BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

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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 III. Adm. Code Parts 301, 302, 303 and 304

R08-9 (Rulemaking - Water) Subdocket B

NOTICE OF FILING

To: ALL COUNSEL OF RECORD (Service List Attached)

PLEASE TAKE NOTICE that on the 4th day of October, 2010, I, on behalf of the

Metropolitan Water Reclamation District of Greater Chicago (the "District"), electronically filed

with the Office of the Clerk of the Illinois Pollution Control Board, the District's Testimony

Questions for Marc H. Gorelick, M.D.

Dated: October 4, 2010

METROPOLITAN WATER RECLAMATION DISTRICT OF GREATER CHICAGO

By: <u>/s/ Fredric P. Andes</u> One of Its Attorneys

Fredric P. Andes David T. Ballard **BARNES & THORNBURG LLP** One North Wacker Drive Suite 4400 Chicago, Illinois 60606 (312) 357-1313

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 Testimony Questions for Marc H. Gorelick, M.D.**, to be served via First Class Mail, postage prepaid, from One North Wacker Drive, Chicago, Illinois, on the 4th day of October, 2010, upon the attorneys of record on the attached Service List.

/s/ Fredric P. Andes

Fredric P. Andes

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BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:)	
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WATER QUALITY STANDARDS AND) R08-9	
EFFLUENT LIMITATIONS FOR THE) (Rulemaking - Water)
CHICAGO AREA WATERWAY SYSTEM)	
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METROPOLITAN WATER RECLAMATION DISTRICT OF GREATER CHICAGO'S TESTIMONY QUESTIONS FOR MARC H. GORELICK, M.D.

- 1. Your testimony identifies "heterogeneity bias" as "perhaps the most serious potential bias" in the CHEERS study. Can you identify a scientific definition for "heterogeneity bias" in a cohort study from a recognized scientific publication?
- 2. Your testimony complains that "the analysis treats the entire CAWS as one group." Do canoers and kayakers stay in one location throughout their time in the water, or do they paddle from place to place?
- 3. Are you aware that the CHEERS analysis adjusted for type of recreational activity, which varies depending on the particular segment of the CAWS at issue?
- 4. Your testimony raises concerns about non-validated survey questions. Are you aware that the CHEERS survey questionnaire items regarding water ingestion have been validated?
- 5. Are you aware that the questionnaire used by EPA in its current studies to develop water quality criteria for swimming waters has not undergone validation of water ingestion assessments?
- 6. Have you validated every questionnaire used in studies that you have conducted?
- 7. Were the same questions asked of the CAWS recreators and the recreators on General Use Waters (GUW)?
- 8. Your testimony raises as a possible source of "selection bias" that the study leaders did "recruiting among organized recreational groups such as rowing clubs." Would you recommend that they not ask questions of any rowing club members, who are among the most frequent users of the CAWS?
- 9. Your testimony points out that motor boaters have the highest risk for GI illness, and appears to complain that the CHEERS study did not enroll enough people from this group relative to other groups. Would you agree that motor boaters have less risk of water

ingestion than canoers and kayakers? Would you recommend that the study have surveyed less canoers and kayakers and more motor boaters? How would this assist in assessing the relationship between water ingestion and GI illness?

- 10. Given that motor boaters do have the highest risk of GI illness among the surveyed groups, and that group does not have significant risk of water ingestion, doesn't that indicate that the risk of GI illness is not strongly related to ingestion of water while recreating, and that other factors are likely more important in determining whether people suffer GI illness?
- 11. Your testimony raises a concern that the CHEERS study surveyed too many people recreating in the CAWS-North relative to other areas. The basis for this concern is that this area had the "lowest risk of disease." Are you aware that this area had the highest levels of bacterial indicators of any area in the CAWS? Doesn't it make sense to survey heavily in the area with the highest bacteria levels? Does the fact that the area with the highest bacteria levels has the lowest risk of disease indicate that there is not a strong relationship between bacteria levels in the CAWS and risk of GI illness?
- 12. Do the stool sample results suggest any relation between water recreation or CAWS use and risk of GI illness?
- 13. You raise concerns about possible self-reporting bias. Weren't the same questions asked of CAWS recreators and GUW recreators? Is there any reason to believe that one of those groups would have different self-reporting bias than the other?
- 14. Your testimony states that this study "lacks the statistical power to fully evaluate the risk to potentially more vulnerable CAWS subgroups." Is there a test to determine how much statistical power is needed in order to say that a study has the power needed to "fully evaluate" a risk? Please provide the scientific publications that discuss that test.
- 15. Among the "potentially more vulnerable CAWS subgroups" that you discuss are anglers and power boaters. Do those groups ingest significant amounts of water while recreating? Why do you believe that they are "more vulnerable"? Aren't they actually less vulnerable than canoers and kayakers? Don't the canoers and kayakers have lower rates of GI illness in this study than anglers and power boaters? What does that tell you about the relationship between water ingestion and risk of GI illness?
- 16. It appears that among the subgroups that you refer to as potentially more vulnerable are young people and old people. How do you define those groups? What is your basis for asserting that these groups are more vulnerable to contracting GI illness from ingestion of water while recreating on the CAWS? Are you aware that EPA, in developing recreational criteria for swimming waters, bases their criteria on protecting the general population, not these or other subgroups?
- 17. Your testimony states that the proper way to determine if a subgroup is at higher risk of to conduct "interaction analysis." Are you aware that the CHEERS researchers actually

did conduct interaction analysis, and found no statistically significant difference between user groups?

- 18. Your testimony points out a comment from one peer reviewer that told the researchers to "Keep in mind" that certain tests have low statistical power. You claim that this comment means that "investigators have set the bar too high for including these interactions and establishing separate risks for different subgroups." Did the reviewer actually say that? Did that reviewer eventually approve issuance of the CHEERS Report?
- 19. In assessing risks to subgroups, isn't there a pitfall involving multiple comparisons, which can lead to finding associations by chance that do not really exist?
- 20. Your testimony states that the CHEERS study did not address several possible confounders, including socioeconomic status, hand washing behavior, and duration of activity. Did the peer reviewers recommend that any of these factors be addressed?
- 21. Are you aware that the study did ask questions concerning amount of water swallowed? Isn't that a more direct measure of water ingestion than a person's socioeconomic status? Among kayakers on the CAWS, is there any reason to believe that kayakers that have different socioeconomic status will ingest different amounts of water if they fall in?
- 22. As to the effort to identify pathogens responsible for GI illness symptoms, which was conducted through analysis of stool samples, your testimony notes that this information "might be of less direct relevance...to assessing CAWS risk." Is there anything in the stool sample results that shows a connection between pathogens in the CAWS and GI illness symptoms? Is there any evidence that CAWS recreators have different pathogens in their stool than GUW recreators?
- 23. Your testimony states that "[m]any of the peer review comments were highly critical" of the stool sample analysis. Are you aware that the comments were directed toward a draft version of the report, and that the issues raised were addressed in the final version? Did the peer reviewers accept the final report?
- 24. As to asymptomatic illness, your testimony expresses a concern that the survey does not capture information about non-surveyed people who might have come into contact with recreators and gotten sick as a result. Isn't it true that the study included some recreators who suffered GI illness from other sources than recreation, and attributed those illnesses to recreation? Wouldn't that balance off the people who might have contracted illnesses but were not counted?
- 25. Do the EPA studies that are being done to develop criteria for swimming waters consider non-surveyed people who may have contracted GI illness through contact with recreators?

- 26. Does the non-inclusion of people who became ill through person-to-person spread apply any differently in the CHEERS study for CAWS recreation versus GUW recreation?
- 27. Your testimony indicates that the CHEERS study "incompletely" addresses the issue of varying water conditions. Do you have any evidence that bacteria levels downstream of the District's treatment plants, or downstream of treatment plants on GUW waters, vary substantially over time? Is there any reason to believe that this factor would apply differently in the CAWS as opposed to GUW waters?
- 28. Are you aware of any other recreational illness study that collected as much water quality information regarding pathogens as the CHEERS study?
- 29. The CHEERS report does not present water quality levels as indicators of illness. Instead, it assesses illness rates directly, and compares those rates among user groups. So why are possible variations in water quality conditions even relevant to assessing the results of the CHEERS study and their relevance to IEPA's disinfection requirement?
- 30. Your testimony states that the CHEERS results must be interpreted in the context of other studies that assess risk of illness when recreating in sewage-impacted waters. Isn't the CHEERS study, conducted to directly assess the risks to recreators that use the CAWS system, more relevant to determining that risk than a study conducted on a whitewater slalom course in England? Isn't the CHEERS study, which focused on the types of secondary contact that occur in the CAWS, such as kayaking, canoeing, fishing and motor boating, more relevant to determining risk to CAWS recreators than studies on the risks of swimming at beaches?

Dated: October 4, 2010

Respectfully submitted,

METROPOLITAN WATER RECLAMATION DISTRICT OF GREATER CHICAGO

By: <u>/s/ Fredric P. Andes</u>

One of Its Attorneys

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