

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, 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: 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 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 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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**METROPOLITAN WATER RECLAMATION DISTRICT OF GREATER CHICAGO'S
TESTIMONY QUESTIONS FOR MARC H. GORELICK, M.D.**

1. How many of your 50 peer-reviewed original research papers in clinical epidemiology involved epidemiological studies related to illness or public health risk?
2. Did any of those studies result in a conclusion of positive results, *i.e.*, a positive correlation between a study factor and increased illness or public health risk? If so, how many of those studies yielded positive results?
3. Did any of those studies result in a conclusion of negative results, *i.e.*, a demonstrated lack of correlation between a study factor and increased illness or public health risk? If so, how many of those studies yielded negative results?
4. Do you believe that it is possible for an epidemiological study to support a conclusion that a certain factor does not or likely does not contribute to increased illness or public health risk?
5. Have you ever been involved in an epidemiological study that concluded that a certain factor did not or likely did not contribute to increased illness or public health risk? If so, did you agree with that conclusion?
6. Dr. Dorevitch testified that the CHEERS study used the prospective cohort design. Do you agree with this testimony?
7. Have you ever been involved in an epidemiological study that used the prospective cohort design? If so, what were the results of the study or studies?
8. Are you aware that the currently applicable microbial water quality criteria for recreational uses are based on the results of past prospective cohort epidemiological studies?
9. In your recent study published in Environmental Health Perspectives entitled "Association Between Rainfall and Pediatric Emergency Department Visits for Acute Gastrointestinal Illness," did you recommend that a cohort follow-up study be conducted to assess community-wide incidences of disease?

10. Dr. Dorevitch testified that the CHEERS study follows the study format used for the United States Environmental Protection Agency's (EPA's) National Epidemiological and Environmental Assessment of Recreational (NEEAR) Water Study. Do you agree with this testimony?
11. Have you ever been involved in an epidemiological study that used the study format used for the EPA's NEEAR Water Study? If so, what were the results of the study or studies?
12. Are you aware of other epidemiological studies that used the study format used for the EPA's NEEAR Water Study? If so, are you aware of the results of the study or studies? If so, what were the results? Did you agree or disagree with the results?
13. Are you aware that EPA has used and intends to continue using data from its NEEAR Water Study when developing national water quality standards?
14. Dr. Dorevitch testified that the design and protocols of the CHEERS study, as well as the quality of data collected and its analysis and interpretation, have been reviewed and endorsed by a panel of recognized leaders in the fields of water microbiology and health from the U.S. Centers for Disease Control and Prevention, the U.S. Environmental Protection Agency, and universities. Do you agree with that testimony?
15. Have you ever been involved in a study whose design, protocols, data quality, analysis, and interpretation were reviewed and endorsed by personnel from the CDC or EPA? If so, what were the subject and results of the study or studies?
16. Dr. Dorevitch testified that the Interim Technical Report provides interim summaries of key data elements, including preliminary results of water quality and observation of recreational use of the CAWS during the last three recreation seasons. Do you agree with that testimony?
17. Dr. Dorevitch testified that the Interim Technical Report summarizes participant recruitment, the occurrence of gastrointestinal illness, and microbes isolated from stool samples of study participants who developed gastrointestinal symptoms following recreation for the CAWS water exposure group, the General Use water exposure group, and the unexposed to recreational group. Do you agree with that testimony?
18. Have you ever been involved in an epidemiological study that analyzed differences among study subjects, which you call "confounding factors?" If so, how did the study or studies address those confounding factors? What were the subject and results of the study or studies? Did you agree that the results were valid?
19. Do you know whether the EPA NEEAR Water Study analyzed and addressed confounding factors?
20. Have you ever been involved in an epidemiological study that analyzed year of enrollment as a confounding factor? If so, how did the study or studies address that confounding factor? What were the subject and results of the study or studies? Did you agree that the results were valid?

21. Have you ever been involved in an epidemiological study that analyzed season as a confounding factor? If so, how did the study or studies address that confounding factor? What were the subject and results of the study or studies? Did you agree that the results were valid?
22. Have you ever been involved in an epidemiological study that analyzed gender as a confounding factor? If so, how did the study or studies address that confounding factor? What were the subject and results of the study or studies? Did you agree that the results were valid?
23. Have you ever been involved in an epidemiological study that analyzed age as a confounding factor? If so, how did the study or studies address that confounding factor? What were the subject and results of the study or studies? Did you agree that the results were valid?
24. Have you ever been involved in an epidemiological study that analyzed race or ethnicity as a confounding factor? If so, how did the study or studies address that confounding factor? What were the subject and results of the study or studies? Did you agree that the results were valid?
25. Have you ever been involved in an epidemiological study that analyzed water activity as a confounding factor? If so, how did the study or studies address that confounding factor? What were the subject and results of the study or studies? Did you agree that the results were valid?
26. Have you ever been involved in an epidemiological study that analyzed duration of activity as a confounding factor? If so, how did the study or studies address that confounding factor? What were the subject and results of the study or studies? Did you agree that the results were valid?
27. Have you ever been involved in an epidemiological study that analyzed post-activity behavior as a confounding factor? If so, how did the study or studies address that confounding factor? What were the subject and results of the study or studies? Did you agree that the results were valid?
28. Have you ever been involved in an epidemiological study that addressed confounding factors sufficiently to result in valid conclusions? If so, what were the subject and results of the study or studies?
29. Have you ever been involved in an epidemiological study that did not analyze or address confounding factors? Did you agree that the results were valid?
30. Did your recent study published in Environmental Health Perspectives entitled "Association Between Rainfall and Pediatric Emergency Department Visits for Acute Gastrointestinal Illness" consider disease etiology, clinical course, drinking water source, individual habits, recreational exposures, precipitation intensity, evidence of drinking water contamination, evidence of ineffective drinking water treatment, or evidence of breaches in distribution systems?

31. Were any confounding factors considered in your recent study published in Environmental Health Perspectives entitled “Association Between Rainfall and Pediatric Emergency Department Visits for Acute Gastrointestinal Illness?” If so, how many confounding factors were analyzed, what were those confounding factors, and how were they addressed in the study?
32. Did your recent study published in Environmental Health Perspectives entitled “Association Between Rainfall and Pediatric Emergency Department Visits for Acute Gastrointestinal Illness” conclude that there is a significant association between rainfall and pediatric emergency visits for acute gastrointestinal illness? Did you agree that the results were valid?
33. Have you ever been involved in an epidemiological study that addressed six or more confounding factors? If so, were the actions used to address those factors sufficient to result in valid conclusions? If so, what were the subject and results of the study or studies? Did you agree that the results were valid?
34. What is the maximum number of confounding factors successfully addressed by an epidemiological study in which you were involved? What were those factors, and what were the subject and results of that study? Did you agree that the results were valid?
35. Dr. Dorevitch testified that the analyses of health risks of incidental contact water recreational activities, including consideration of the multiple factors that must be considered when describing relationships between key variables, would be conducted in the future. Do you agree with that testimony?
36. Dr. Dorevitch testified that the ongoing data analysis focuses on accounting for differences—such as age or presence of underlying health conditions—in order to generate appropriate comparisons of risk across study groups. Do you agree with that testimony?
37. Do you have any basis to believe that the analysis stage of the CHEERS study will not identify and consider any confounding factors?
38. Have you ever been involved in an epidemiological study that addressed information bias? If so, how was that bias addressed? What were the subject and results of the study or studies? Did you agree that the results were valid?
39. Have you ever been involved in an epidemiological study that addressed recall bias? If so, how was that bias addressed? What were the subject and results of the study or studies? Did you agree that the results were valid?
40. Have you ever been involved in an epidemiological study that addressed perceived risk? If so, how was that issue addressed? What were the subject and results of the study or studies? Did you agree that the results were valid?
41. Do you have any basis to believe that recall bias or perceived risk issues will not be adequately identified and considered in the CHEERS study?

42. Are you aware that the CHEERS team is conducting a study on Measuring Water Ingestion During Water Recreation to validate the findings of the study?
43. Have you ever been involved in an epidemiological study that utilized data averages, such as daily averages? If so, how was the issue of averages addressed? What were the subject and results of the study or studies? Did you agree that the results were valid?
44. You indicated in your testimony that the question of sample size is largely determinative of the statistical power of a study. How large must the sample size be to yield a statistically valid study?
45. Are you aware of data or published reports that clearly state the optimum sample size requirement for a valid epidemiological study? What are those data or reports?
46. What was the sample size considered in your recent study published in Environmental Health Perspectives entitled "Association Between Rainfall and Pediatric Emergency Department Visits for Acute Gastrointestinal Illness?"
47. What is the smallest sample size relied upon in an epidemiological study in which you were involved? How did the study address the issue of sample size? What were the subject and results of the study? Did you agree that the results were valid?
48. Do you know the sample size of the CHEERS study? What is it?
49. Do you know the sample size of the various sub-populations of CAWS users included in the CHEERS study? What are they?
50. Have you ever been involved in an epidemiological study that involved a margin of error of plus or minus 3.3% or greater? If so, what was that margin of error and how was it addressed? What were the subject and results of the study or studies? Did you agree that the results were valid?
51. What is the largest margin of error resulting from an epidemiological study in which you were involved? How was the margin of error addressed? What were the subject and results of the study or studies? Did you agree that the results were valid?
52. Have you ever been involved in an epidemiological study that addressed clustering? If so, how was that issue addressed? What were the subject and results of the study or studies? Did you agree that the results were valid?
53. Have you ever been involved in an epidemiological study that addressed missing data? If so, how was that issue addressed? What were the subject and results of the study or studies? Did you agree that the results were valid?
54. Dr. Dorevitch testified that the summaries that comprise the Interim Technical Report should not be viewed as answers to primary study questions. Do you agree with that testimony?

55. Do you believe that the Illinois Pollution Control Board should wait to review the statistical analysis and final report of the CHEERS study before determining whether valid conclusions can be drawn concerning health risks associated with the CAWS?

Dated: June 14, 2010

Respectfully submitted,

**METROPOLITAN WATER RECLAMATION
DISTRICT OF GREATER CHICAGO**

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