July 23, 2009

CAP position on the NRC Report:

We, the members of the Camp Lejeune Community Assistance Panel recommend that ATSDR not accept the major conclusions of the National Research Council report titled "Contaminated Water Supplies at Camp Lejeune – Assessing Potential Health Effects," dated June, 2009. Our reasons for this recommendation are as follows:

1. The NRC Committee, in Chapter 2 of their report, misunderstood critical information about the nature of the groundwater and drinking water contamination and misrepresented the analytic work done to date by scientists at ATSDR and Georgia Institute of Technology. These points were made verbally by Prof. Mustafa Aral at our CAP meeting on July 8, 2009 and in more detail in his June 30 Memorandum to Morris Maslia. We were persuaded by Prof. Aral that the NRC assessment of the water modeling work done by ATSDR to date and projected in the next phase of the work on Hadnot Point was fundamentally flawed and should be rejected by the Agency. A copy of Prof. Aral's Memorandum is attached to this statement.

   The reports of the Tarawa Terrace modeling effort have been reviewed by geohydrology and water modeling experts from outside the agency. The reliability of the monthly average estimates can be seen by comparing the model estimates with the actual measurements taken at the Tarawa Terrace Treatment Plant, as the water entered the distribution system. The modeled results were within a factor of two of the actual measurements (see Table A10 of Chapter A: Summary of Findings). This close agreement between estimated monthly averages and measurements taken at specific points in time demonstrates that the modeled estimates are of sufficient quality for use in epidemiological studies at the base. The NRC report failed to mention these findings.

   The specific conclusion, on p. 22 of the NRC report, that it would only be possible to "assign exposure categories of exposed and unexposed" in the current and future health studies should also be rejected by the Agency. The Camp Lejeune Water-Modeling Expert Panel meeting held in April 2009 agreed that the monthly average estimates for the Tarawa Terrace system were reliable and should be used in the epidemiological studies to assign exposures. This Panel also recommended that the water modeling effort at Hadnot Point produce similar monthly average estimates in the distribution system. The members of this panel are nationally recognized experts in the fields of geohydrology and exposure assessment, and they have extensive and broad expertise in all aspects of groundwater fate and transport modeling and water distribution system modeling. In addition, the panel included nationally recognized experts in the field of environmental epidemiology.

   Crudely categorizing people as exposed or unexposed in the Camp Lejeune studies would introduce a bias that could eliminate any chance of finding a health

effect from the drinking water exposures at Tarawa Terrace or Hadnot Point. The magnitude of the errors that would be introduced by the crude categorization, "exposed vs unexposed", can be seen by examining the monthly average estimates obtained from the Tarawa Terrace models (Appendix A2 of Chapter A: Summary of Findings). For example, over the study period covered by the adverse birth outcome study and the case-control study of specific birth defects and childhood cancers (i.e., from early 1967 when the first pregnancies began through the end of 1985), monthly average PCE levels ranged from <1 ppb to 183 ppb. Simply categorizing people as "exposed" would mix together those with very high exposures and those with exposures well below the current standard of 5 ppb. Furthermore, as one member of the April water modeling panel pointed out, if an "exposed/not exposed" categorization were used in the Cape Cod studies of PCE exposure through drinking water pipes, no effect would have been seen.

2. The NRC Committee, in Chapter 4 of their report, takes what appears to be a very conservative review of the toxicological literature regarding the hazards of exposure to TCE and PCE. The hazard evaluation of these two chemicals, beginning on p. 129, uses LOAEL values from animal studies and compares them to water contaminant levels measured in Camp Lejeune water at various points. They conclude that for health endpoints such as kidney cancer, kidney toxicity, immunosuppression and neurotoxicity the levels of contamination are not likely to cause these health problems in those exposed at Camp Lejeune. The report admits that exposure to other volatile organic compounds may have occurred at Camp Lejeune and that this may have added to the risk; they note that this additivity "is not formally incorporated into this appraisal." (p. 129)

   The NRC report also noted "the evaluation has not taken into account uncertainties and additional considerations (see Chapter 3) related to potentially sensitive subpopulations (such as fetuses and the elderly), possible interindividual variability in response related to sex and genetic background. . . and VOC interactions." (p. 132) These limitations render the toxicological conclusions of limited value in guiding what future health studies ATSDR should carry out.

   It is also worth noting the long footnote at the bottom of p. 132. We understand that, although the listed members of the NRC committee signed off on the content of the final report, there was considerable disagreement expressed at various points during the last few months prior to June, 2009. We urge ATSDR to examine the reasons for the disagreement expressed in the footnote and to contact the initial member of the committee who resigned and did not sign the final report.

   The dissenting committee member correctly pointed out that the use of LOAELs for non-cancer outcomes without incorporating uncertainty factors is inappropriate. Depending on the outcome and the quality of the toxicological or

epidemiological study being used, uncertainty factors of up to 3,000 are applied to the LOAEL. Applying a 3,000 uncertainty factor to the LOAELs used in the NRC report, those exposed to 1,400 ppb TCE in the drinking water at Hadnot Point could be at risk for immunosuppression and for renal disease (especially in children), and children exposed to PCE in the Tarawa Terrace drinking water supply could be at risk of neurotoxic effects.

For kidney cancer, the NRC report uses a LOAEL of 1,000 mg/kg per day. We are aware of other analyses that take into account human variability and other considerations (see Rhomberg, 2000) that indicate that the daily dose from an exposure to 1,400 ppb TCE at Hadnot Point would be unacceptably high. Other analyses indicate that the risk of non-Hodgkin lymphoma would also be a health concern from this exposure.

But a more fundamental point was raised at our July 8 meeting by ATSDR staff: LOAELs should not be used for cancers because it assumes a threshold dose when an appropriate measure is the cancer slope factor. Using reasonable assumptions about exposure of three years for children and adults, the cancer risks for TCE range from 3 per 100,000 to 3 per 1,000, and the cancer risks for PCE range from 2 per million to 2 per 10,000. Given that the cancer risk ranges for exposures to either PCE or TCE include values that exceed a 1 per 10,000 risk, this is evidence that these exposures have the potential to cause excess cancers in the Lejeune population. The NRC report describes these risks as "low,"when the measured levels of these chemicals were 40 to almost 300 times the current standard for drinking water. ATSDR should ignore the NRC characterization of Camp Lejeune exposures as low and health effects as "unlikely to have occurred."

For PCE, the NRC report uses a LOAEL of 50 mg/kg/day for neurotoxicity based on a rat study. However, studies of residents living near or above dry cleaning facilities have found neurological deficits at inhalation exposures much lower than this LOAEL. In these human studies, a LOAEL of about 1.1 mg/kg/day was observed. After adjusting this LOAEL by 100 to account for human variation and the use of a LOAEL, the adult dose that would occur from exposure to 200 ppb PCE at Tarawa Terrace would be just high enough to indicate a possible health concern. For children, their exposure would be more than enough to warrant a health concern.

Other contaminants such as benzene and vinyl chloride were not considered in the hazard evaluation in the NRC report. Depending on the levels of vinyl chloride in the drinking water at Hadnot Point (due to degradation of TCE and PCE in the groundwater) the cancer risks may be as high or higher than those calculated above for TCE. This is due to the high cancer potency for vinyl chloride (1.5 mg/kg/day lifetime exposure from birth).

The NRC Committee, in Chapters 5 and 6 of their report, reviewed the epidemiologic literature on the health effects of TCE and PCE in both exposed

workers and exposed communities. In Appendix D, they also provide brief reviews of the epidemiologic evidence regarding vinyl chloride, 1,1-dichloroethylene, 1,2-dichloroethylene, methylene chloride, benzene and toluene. In doing this, they used a series of categories that were developed by National Academy of Sciences Institute of Medicine (IOM) committees reviewing literature regarding exposures to veterans of the Vietnam and Persian Gulf Wars. The NRC committee concluded that none of the Camp Lejeune exposures reached the top two, e.g., Sufficient evidence of a Causal Relationship or Sufficient Evidence of an Association. This contradicts a previous IOM report in 2003, which concluded that studies of populations exposed to mixed solvents (including TCE and PCE) provided Sufficient Evidence of an Association with leukemia. Apparently, the Camp Lejeune committee reviewed the same and more recent literature and felt that this previous conclusion was too strong. On the contrary, we believe that the Camp Lejeune committee's conclusion is too weak.

Based on consistent positive findings across well-conducted occupational or drinking water studies, we believe that the following diseases, categorized in the NRC report as having "limited/suggestive evidence of an association," esophageal cancer and PCE, kidney cancer and TCE, lung cancer and PCE, liver cancer and TCE, cervical cancer and PCE, non-Hodgkin's lymphoma and TCE, miscarriage and PCE, scleroderma and solvent mixtures, and neurobehavioral effects and solvent mixtures (and specifically, PCE) should be placed in the higher category of "sufficient evidence of an association"

The NRC report categorized TCE and childhood leukemia as having "inadequate/insufficient evidence to determine whether an association exists." We believe that, based on the findings of the Woburn childhood leukemia studies, the Tom's River, NJ findings, and the findings in a study of 75 towns in northern NJ, and a valid animal model, childhood leukemia and TCE should be categorized as having "sufficient evidence of an association."

A member of the CAP and four other scientists familiar with the Camp Lejeune exposure wrote a statement in which they expressed their disagreement with the review of the epidemiologic evidence in the NRC report. We urge ATSDR to consider the comments and reviews of the literature by these five scientists published in peer-reviewed scientific articles.

The NRC report stated: "on the basis of what is known about the contamination of water supplies at Camp Lejeune; the size, age, and residential mobility of the residents; and the availability of records, the committee concludes that it would be extremely difficult to conduct direct epidemiologic studies of sufficient quality and scope to make a substantial contribution to resolving the health concerns of former Camp Lejeune residents. We strongly disagree with this conclusion. A panel of epidemiologists, including one CAP member, convened by ATSDR in 2008 concluded that the mortality study and health survey study were feasible and could make an important contribution to the scientific literature on the health

effects of drinking water exposures at Camp Lejeune. The protocols for the mortality study and the health survey study have been reviewed by outside experts in occupational and environmental epidemiology. Both the mortality study and the health survey study will have more than sufficient statistical power (90%) to detect moderately elevated cancer risks among exposed Marines (e.g., for kidney cancer, ≥60% excess risk or a relative risk of ≥1.6). The CAP has discussed these studies at several meetings and we strongly endorse them.

For these reasons, we strongly urge ATSDR to reject the major conclusions and recommendations of the NRC report dated June, 2009. We support the plans to carry out the Camp Lejeune studies that ATSDR has already underway or planned, and which we have discussed at length in CAP meetings. We note that the NRC committee endorsed some of these, such as updating the birth outcomes study with new water information about who was exposed, and finishing the birth defects and childhood cancer studies. We urge ATSDR to complete these and other planned studies using the exposure information that will be provided by the water modeling work underway.

Finally, we would be remiss if we did not point out that ATSDR was created by Congress to protect the public from environmental contamination and conduct health studies in communities and populations where people were exposed. The ATSDR leadership has not yet taken a strong stand in support of the work done by their own staff regarding Camp Lejeune. The Investigations and Oversight Subcommittee of the House Science and Technology Committee addressed some of these leadership issues during testimony they received at a March 12, 2009 hearing; we have attached the Subcommittee's press release to this statement. It is imperative for ATSDR leadership to take a strong statement in opposition to the June NRC report and express public support for the on-going and planned health studies at Camp Lejeune.

Signed

Jerry Ensminger – community member
jmensminger@hotmail.com

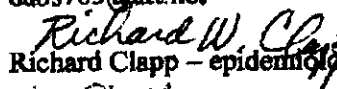
Jeff Byron – community member
Byron768@aol.com

Tom Townsend – community member
ttownsend@moscow.com

Sandra Bridges – community member
Sbridges31213056@aol.com

Mike Partain – community member
strashni@earthlink.net

Allen Menard – community member
dabs783@att.net



Richard Clapp – epidemiology advisor
rclapp@bu.edu

In remembrance of Denita McCall

CC: Office of Science & Technology Policy,
Secretary of Health and Human Services,
Administrator of the United States Environmental Protection Agency,
Director, Centers for Disease Control and Prevention,
Senator Daniel Akaka,
Senator Evan Bayh,
Senator Barbara Boxer,
Senator Richard Burr,
Senator Richard Durbin,
Senator Russell Feingold,
Senator Chuck Grassley,
Senator Kay Hagan,
Senator John F Kerry,
Senator Carl Levin,
Senator Edward M. Kennedy,
Senator Bill Nelson,
Senator Debbie Stabenow,
Senator Jim Webb,
Representative Allen Boyd,
Representative John Dingell,
Representative Bart Gordon,
Representative Brad Miller,
Representative Ike Skelton,
Representative Bart Stupak,
Representative Henry Waxman,
Senate Armed Services Committee,
Senate Committee on Commerce, Science and Transportation,
Senate Committee on Environment and Public Works,
Senate Committee on Veterans Affairs,
House Armed Services Committee,
House Committee on Energy and Commerce,
House Committee on Science and Technology,
House Committee on Veteran's Affairs,
Dr. Peter Preuss Environmental Protection Agency
Dr. James Reisa National Academy of Sciences,
Susan Martel National Academy of Sciences,
Rachel Libert Documentary Film Maker,

Amanda Greene Wilmington Star,
Dr. Devra Davis University of Pittsburgh Cancer Center,
Neil Fischbein TCE Blog,
Dr. Jennifer Sass NRDC,
Scott Bronstein CNN,
Bill Levesque St. Petersburg Times,
Martha Quillin Raleigh News and Observer,
Daniel Steinberger CBS,
Carrisa Etters WNCT,
Tim King, Salem News.com.
David Zuccihno Los Angeles Times.
Rita Beamish Associated Press