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ATSDR Response to the Report of the Camp Lejeune Scientific Advisory Panel Held February 17-18, 2005

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Introduction

On February 17 and 18, 2005, the Office of Science, National Center for Environmental Health and the Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) convened a scientific panel to deliberate the feasibility and usefulness of conducting additional human health studies of populations potentially exposed to drinking water contaminated with volatile organic compounds (VOCs) at the U.S. Marine Corps Base at Camp Lejeune, North Carolina. The panel meeting was open to the public and ample time was set aside for public participation. The final report of the panel was completed on June 24, 2005. Transcripts of the proceedings and the final report of the panel were posted on the ATSDR Web site for ATSDR's Camp Lejeune health-related activities.

The final report contained several recommendations for the agency's consideration. The panel addressed the charge given to it (recommendations #3 and #4). However, they also went beyond their charge and recommended additional actions related to ATSDR's interactions with the affected community (recommendations #1, #2, #6), revision of a previous public health assessment of Camp Lejeune (recommendation #5), and funding of future Camp Lejeune-related activities conducted by ATSDR (recommendation #7). The panel's recommendations were summarized in the Executive Summary of the report as follows:

- 1. Future studies should be conducted in full partnership with the exposed community. Agency Response
- 2. An advisory panel, with long-term stability, should be established to oversee health studies of persons with potential exposure to volatile organic compounds (VOCs) at Camp Lejeune. Agency Response
- 3. Identify cohorts of individuals with potential exposure, including adults who lived on base; adults who resided off base, but worked on base (civilian and military); children who lived on base; and those who may have been exposed while in utero. Agency Response
- 4. Initiation of recommended research activities need not await completion of current ATSDR activities to better characterize past exposure, but should be conducted in parallel with the current work. Agency Response
- 5. The 1997 ATSDR Public Health Assessment of Camp Lejeune should be amended with a recognition that adult exposures to VOCs may result in adverse health outcomes, and also include updated information on potential exposures and estimates of the risk they pose. Agency Response
- 6. All persons potentially affected by exposure to VOC in the drinking water at Camp Lejeune should be notified. Agency Response
- 7. Future funding for Camp Lejeune health studies should come through direct Congressional action, not DOD, to avoid even the appearance of a conflict of interest. Agency Response

ATSDR has carefully considered the panel's recommendations and has prepared the following responses to each of these recommendations.

Panel Recommendation #1. Future studies should be conducted in full partnership with the exposed community.

Agency Response:



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persons with potential exposure to volatile organic compounds (VUCs) at Camp Lejeune.

Agency Response:

ATSDR enthusiastically agrees that representatives of the affected community should participate in the decisions concerning future epidemiological studies at Camp Lejeune. In the past, the mechanism used by ATSDR for community participation at National Priority List (NPL) sites has been the community assistance panel (CAP). CAPs are panels established by ATSDR as set forth in a Federal Register notice (see Vol. 57. No. 120, June 22, 1992, p. 27779).

A CAP consists of representatives of the community affected by an NPL site. A CAP may also include representatives from other interested stakeholders in the affected community, such as the local government or local businesses. A CAP meets regularly and makes recommendations to ATSDR. A CAP does not oversee ATSDR's activities, but its recommendations are carefully considered by the agency and made available to the public.

ATSDR proposes that a CAP be established for the Camp Lejeune site and that the CAP hold its first meeting in early 2006. One agenda item for the CAP will be to discuss the recommendations of the Scientific Panel and ATSDR's response. The CAP will likely review any assessment of the feasibility of conducting additional epidemiological studies of the affected community and make recommendations on methods to identify individuals who lived or worked at the base. If the agency decides to conduct an epidemiological study, then the CAP will be asked to provide input on protocol development, study implementation, and information dissemination.

The CAP should consist of five or more representatives from the affected community. Since additional epidemiological studies will likely be on the agenda of the CAP, it is important that the CAP also have access to, or include, 1-2 scientists with appropriate expertise who are trusted by the community representatives and who have experience in environmental and/or occupational epidemiological research. If necessary, ATSDR will reimburse the travel expenses of the CAP's members. The CAP also would involve *ex officio* members, including representatives of the Navy. ATSDR will seek recommendations from the CAP about meeting location and frequency. ATSDR will be responsible for the creation, administration, and dissolution of the CAP.

Panel Recommendation #3. Identify cohorts of individuals with potential exposure, including adults who lived on base; adults who resided off base, but worked on base (civilian and military); children who lived on base; and those who may have been exposed while in utero.

Agency Response:

ATSDR agrees that efforts should be undertaken to evaluate the feasibility of identifying potential databases to enumerate adults who lived or worked on the base and children who lived on the base. ATSDR believes that the cohort exposed while *in utero* has already been identified as completely as possible for the years 1968-1985. ATSDR collected data from birth certificates during the Camp Lejeune study of adverse birth outcomes and from the survey conducted as part of the current case-control study of specific birth defects and childhood cancers. ATSDR will not go further back in time for the *in utero* cohort because birth certificates were not computerized before 1968.

ATSDR agrees that the first steps to assess feasibility for these additional cohorts are to determine the proportion of each cohort that can be identified through available data sources and how far back in time the data are available. In addition, ATSDR will continue its efforts to identify available data on health outcomes that are biologically plausible (i.e., are known or are suspected based on scientific evidence to be associated with exposure to VOC-contaminated drinking water) and that can be linked to the cohort data.

ATSDR agrees that mortality and cancer incidence should receive the highest priority and are the outcomes most feasible to study.



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varied sufficiently during this time period. In addition, extending a study beyond 1985 may introduce biases because of changes over time (e.g., the availability during the most recent years of more complete and accurate health outcome data and more accurate water consumption information). The period after 1985 would not be comparable to the earlier years. Moreover, to achieve a sufficient sample size to compare the years during and after the exposure period would likely require expanding the study period for at least 10 years beyond 1985. However, this issue can be discussed further with the CAP.

As part of its effort to determine what health outcomes are biologically plausible and feasible to study, ATSDR will continue its ongoing review of the health effects literature on the drinking water contaminants found at the base and present this information to the CAP. ATSDR will also present to the CAP its assessment of the biological plausibility and feasibility of conducting an epidemiological study of each health outcome mentioned in the Scientific Panel's report.

Panel Recommendation #4. Initiation of recommended research activities need not await completion of current ATSDR activities to better characterize past exposure, but should be conducted in parallel with the current work.

Agency Response:

ATSDR will continue to press forward to complete its ongoing case-control study as quickly as possible, while addressing the recommendations made by the panel. ATSDR's highest priority considering existing staff resources is to complete the current case-control study before the end of 2007. ATSDR recognizes that additional efforts to create a CAP and to explore the feasibility of additional studies likely will require additional staffing and resources. ATSDR will identify additional resources that are required and communicate these needs to DOD.

Panel Recommendation #5. The 1997 ATDSR Public Health Assessment of Camp Lejeune should be amended with a recognition that adult exposures to VOC may result in adverse health outcomes, and also include updated information on potential exposures and estimates of the risk they pose.

Agency Response:

The 1997 PHA acknowledges the current, inconclusive state-of-the-science regarding TCE exposure at the levels found at Camp Lejeune in this statement, "not enough scientific information on humans is available to rule out the possibility of cancerous health effects from low-dose exposure to VOCs." ATSDR agrees that the information provided to the public must be based on up-to-date scientific information, and is continuing to increase its understanding of the health risks at Camp Lejeune by monitoring the developments of the ongoing U.S. Environmental Protection Agency's (EPA) trichloroethylene (TCE) risk assessment and other new research. At this time, however, ATSDR does not believe the 1997 PHA should be amended. Unrelated to the panel recommendation, ATSDR revised the PHA on the agency's Camp Lejeune Web site in November 2004. This new material clarifies information presented in Table 3, page 26 of the 1997 PHA and reiterates the uncertainty of the science.

The purpose of a PHA is to identify potentially exposed populations, make recommendations to stop, prevent, or reduce exposure, and to make recommendations for follow-up public health actions. In the 1997 PHA, ATSDR made recommendations for health studies to address the need for more scientific information regarding non-occupational exposures to VOCs in drinking water. One study was published in 1998 and another study is currently being carried out with the possibility for additional studies in the future. Should new information result in a change of the agency's conclusions or recommendations, ATSDR may revise the 1997 document.

Panel Recommendation #6. All persons potentially affected by exposure to VOC in the drinking water at Camp Lejeune should be notified.

Agency Response:



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Panel Recommendation #7. Future funding for Camp Lejeune health studies should come through direct Congressional action, not DOD, to avoid even the appearance of a conflict of interest.

Agency Response:

ATSDR recognizes that the affected community has a level of distrust of ATSDR and DOD. To address issues of trust and transparency, ATSDR proposes the establishment of a CAP. By working closely and respectfully with representatives of the affected community, ATSDR will be able to conduct the best science possible and at the same time carefully consider the views of the community, regardless of the funding sources used by the agency. ATSDR's past and future work is conducted independently of the funding source, and DOD has no say in final decision making about study design, analysis, or reporting.

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) funds, commonly known as Superfund, are not currently available to conduct additional studies at Camp Lejeune, and funds from CERCLA are not anticipated. Therefore, it is likely that additional funds from DOD will be necessary to conduct new health-related activities at the base. The appearance of conflict of interest can be avoided if the agency is seen by the community to be transparent in its decision-making and to be making a serious attempt to be attentive and to seek input from the community.

Related Links Camp Lejeune Expert Panel to Meet (News Release) Report of the Camp Lejeune Scientific Advisory Panel

Last Reviewed: January 16, 2014 (archived document)

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