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REPORT OF THE CAMP LEJEUNE SCIENTIFIC ADVISORY PANEL 17-18 FEBRUARY 2005
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Report of the Camp Lejeune Scientific Advisory Panel

**Convened February 17-18, 2005
Atlanta, Georgia**

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EXECUTIVE SUMMARY

In response to continuing public concern about health effects of exposure to contaminated drinking water at the U.S. Marine Corps Base at Camp Lejeune, North Carolina., the Office of Science, National Center for Environmental Health and the Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) convened a scientific advisory panel to explore opportunities for conducting additional human health studies of people previously exposed to contaminated drinking water at the Camp Lejeune. The panel was also to provide scientific input on the feasibility and usefulness of conducting these studies. The Camp Lejeune Scientific Advisory Panel met in Atlanta, Georgia on February 17 and 18, 2005. The panel consisted of 7 scientists with expertise in epidemiology and public health, biostatistics, drinking water contaminants, pesticides, toxicology, reproductive health, and environmental health.

The charge to the panel was to determine whether additional epidemiologic studies on health effects possibly associated with past exposure to drinking water contaminated with trichloroethylene (TCE) and tetrachloroethylene (PCE) should be conducted on the potentially exposed population (or specific sub-population) at Camp Lejeune.

There were several opportunities for public input into the Camp Lejeune Scientific Advisory Panel process. These included input into the composition of the panel, opportunities to provide written comments to the panel for their consideration prior to the meeting, public comment periods during the meeting, and ample time for questions and answers between panel members and the public participants. All panel deliberations occurred in public. The transcripts of the meeting and the final panel report are being distributed to all meeting participants and posted on the ATSDR website (<http://www.atsdr.cdc.gov/sites/lejeune/eventsarchive.html>).

The Camp Lejeune Scientific Advisory Panel made the following recommendations:

- Future studies should be conducted in full partnership with the exposed community.
- 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.
- Identify cohorts of individuals with potential exposure, including adults who lived on base; adults who resided off base, but worked on base; children who lived on base; and those who may have been exposed while *in utero*.
- 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.
- The 1997 ATSDR 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.
- All persons potentially affected by exposure to VOC in the drinking water at Camp Lejeune should be notified.
- 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.

INTRODUCTION

Panel Process

In response to continuing public concern about health effects of exposure to contaminated drinking water at the U.S. Marine Corps Base at Camp Lejeune, North Carolina, the Office of Science, National Center for Environmental Health and the Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) convened a scientific advisory panel to explore opportunities for conducting additional human health studies of people previously exposed to contaminated drinking water at Camp Lejeune. The panel was also to provide scientific input on the feasibility and usefulness of conducting these studies. The Camp Lejeune Scientific Advisory Panel met in Atlanta, Georgia on February 17 and 18, 2005. The meeting was open to the public. See Appendix 1 for a list of meeting participants.

Input on the nomination of scientific experts to serve on the panel was solicited from members of the Camp Lejeune community, interested Congressional staff, and the Division of Health Studies at ATSDR whose staff have worked on health investigations related to drinking water exposures at Camp Lejeune. The final selection of the panel members was made by the Office of Science. The goal of the Office of Science was to select a panel of 5-7 members who had well-established expertise in one or more areas of environmental or occupational epidemiology, cohort tracing, studies involving military populations, dose reconstruction, the health effects of trichloroethylene (TCE) and tetrachloroethylene (PCE), neurodevelopmental and other neurological disorders, and biostatistics. The Office of Science also sought to include on the panel scientists who had experience working in partnership with communities facing health problems potentially associated with environmental contamination. Invited scientists were asked to disclose any actual or perceived conflicts of interest. The final panel consisted of seven members who had expertise in epidemiology and public health, biostatistics, drinking water contaminants, pesticides, toxicology, reproductive health, and environmental health. The Camp Lejeune Scientific Advisory Panel members and their areas of expertise are described in Appendix 2.

In order to ensure that members of the public had ample opportunity to provide input to the Camp Lejeune Scientific Advisory Panel's deliberations, the public was invited to provide a brief written statement (no more than 3 single space pages) identifying their concerns or describing other key issues they wished the panel to consider. These comments were provided to the panel members in advance of the meeting.

In addition to the public comments, the panel members were provided with background material prepared by ATSDR staff. This included a summary of ATSDR's current understanding of the exposures that occurred at Camp Lejeune, a summary of ATSDR's activities at the site, and previous reports and articles released by ATSDR on the health impact of the water contamination at Camp Lejeune. The summary of the exposures and ATSDR activities is included in this report under the Background Section. Appendix 3 contains a list of materials provided to the panel members prior to the meeting.

In addition to opportunities for public input prior to the meeting, several public comment periods were scheduled during the two day meeting as well as time for questions and answers between the panel members and the public participants. The meeting agenda is included in Appendix 4. Many members of the public provided additional material to the panel during the meeting. A list of the material provided to the panel during the meeting is provided in Appendix 5.

Panel Charge

The following was the charge presented to the panel:

To determine whether additional epidemiologic studies on health effects possibly associated with past exposure to drinking water contaminated with trichloroethylene (TCE) and tetrachloroethylene (PCE) should be conducted on the potentially exposed population (or specific sub-population) at U.S. Marine Corps Base Camp Lejeune, North Carolina.

In addition, the Camp Lejeune Scientific Advisory Panel was asked to address the following specific questions:

1. What additional human health effects studies are warranted of people exposed to TCE and PCE in drinking water at levels found at Camp Lejeune? In discussing this question the panel should consider:

- the population's (or specific sub-population's) average length and levels of exposure to the contaminants*
- the biological plausibility that such exposures can cause the particular health outcome(s) of interest.*

2. What additional human health effects studies would be feasible to conduct on people who were at Camp Lejeune? In discussing this question the panel should consider:

- the characteristics of the population or specific sub-population under consideration (e.g., size and percent exposed, age, mobility, length of time exposed, length of time from first exposure, length of time since exposure ended, possible confounding military service and occupational exposures, etc.)*
- complete case ascertainment and verification of the particular health outcome(s) of interest given the time period of interest*

As this panel was not a federal advisory committee, panel members were asked to provide their individual opinions. Consensus was not sought and votes were not conducted. The Office of Science asked the Camp Lejeune Scientific Advisory Panel to develop a written report of their recommendations. This report along with transcripts from the meeting will be provided to all meeting participants, other interested parties, and will be posted on the ATSDR website at <http://www.atsdr.cdc.gov/sites/lejeune/eventsarchive.html>.

BACKGROUND

(Information prepared by ATSDR staff and provided to the panel members prior to the meeting)

Site Information

The United States Marine Corps (USMC) Base at Camp Lejeune, North Carolina began operations during the 1940s. Currently, the base is home to an active duty, dependent, retiree, and civilian employee population of nearly 150,000 people. About 43,000 are active military personnel and their dependents total about 53,500. About 42,000 are retired and about 4,900 are civilian employees. The base has a relatively young population with almost two-thirds of the active military personnel and their dependents under the age of 25. There has been considerable in- and out-migration from the base. For example, ATSDR was told by staff of the Camp Lejeune Naval Hospital that an estimated one-third of mothers receiving prenatal care at the hospital during the 1970s and 1980s were transferred from Camp Lejeune before delivery.

Base housing for enlisted personnel, officers, and their families are located in 15 different areas on the base. During the 1970s and 1980s, the base's drinking water was extracted from over 100 wells, treated at eight treatment plants, and distributed to its residents through a network of distribution pipes. Three water distribution systems provided water for Camp Lejeune's base housing areas: the Tarawa Terrace, Holcomb Boulevard, and Hadnot Point systems. The Hadnot Point system was constructed in the 1940s, the Tarawa Terrace system was constructed in 1954, and the Holcomb Boulevard system was constructed in 1972.

During the 1940s and 1950s, underground storage tanks were installed at Hadnot Point and used to store waste degreasing solvents. In 1954, ABC One-Hour Cleaners, a dry cleaning firm, began operation near the base. In 1958, a supply well for the Tarawa Terrace family housing units was installed near the septic tank system of the dry-cleaning operation. During the period 1980-1985, a sampling program of the supply wells and water distribution systems at the base found that some of the wells in the Hadnot Point and Tarawa Terrace systems were contaminated with volatile organic compounds (VOCs). However, the contamination of these wells likely began many years before contamination was detected. An important feature of the contamination of these two drinking water systems at Camp Lejeune was its intermittent nature. Each system had many more wells than were necessary to supply water on any given day. Wells were rotated in and out of service and contamination levels in the drinking water distribution system varied depending on the wells being used at a particular time. In each system, water from all the wells in use was mixed before treatment and distribution.

The base began sampling the Hadnot Point system in October 1980 for trihalomethanes (THMs), a chlorination disinfectant byproduct. The analysis of the sample at Hadnot Point indicated the presence of VOCs other than THMs. Samples taken in 1981 also indicated the presence of VOCs other than THMs in the Hadnot Point system. In April 1982, the base began using a different laboratory for the analyses of drinking water samples. This laboratory noted difficulty in measuring THMs in the Hadnot Point system

and the Tarawa Terrace system because of interference by unidentified VOCs. Reanalysis of the samples from Hadnot Point and Tarawa Terrace were conducted in May 1982. At Hadnot Point, trichloroethylene (TCE) was detected at 1,400 ppb and tetrachloroethylene (PCE) was detected at 15 ppb, slightly above its detection limit of 10 ppb. At Tarawa Terrace, PCE was detected at 80 ppb. No action was taken at the time because water quality standards had not been established for these VOCs in 1982.

The possible sources of contamination of the Hadnot Point system were leaking underground storage tanks, spills, and other waste disposal practices. It is unknown when the contamination of the Hadnot Point system wells began, but the contamination could have started back in the 1950s. In July 1982, TCE was detected at levels around 20 ppb, much lower than the level detected in the sample taken a few months before. THM samples taken at Hadnot Point in November 1982 and in 1983 were found to be contaminated with TCE and PCE. In November 1984, the base received results of samples taken in July 1984. In one well at Hadnot Point, both TCE and benzene were detected. Among the contaminated wells at Hadnot Point and finished water at one building served by the Hadnot Point system, TCE levels ranged from 5 ppb to 1,600 ppb. In December 1984, some of the Hadnot Point wells were shut down or placed offline.

On January 27, 1985, a fuel pump broke at the Holcomb Boulevard system and water from Hadnot Point was supplied to the Holcomb Boulevard service area while repairs were made. On January 31, 1985, buildings in the Holcomb Boulevard service area that were temporarily receiving water from Hadnot Point were sampled and high contamination was found at the Berkeley Manor Elementary School (1,148 ppb TCE and 407 ppb 1,1-Dichloroethene [DCE]), an Officers club (890 ppb TCE and 332 ppb DCE), the Married Officers Quarters (1,041 TCE), and two Berkeley Manor Housing Units (905 ppb and 981 ppb TCE, 335 ppb and 369 ppb DCE). All contaminated wells in the Hadnot Point system were closed in early February 1985.

The likely source of the Tarawa Terrace system wells contamination was the dry cleaning operation. Since a supply well for Tarawa Terrace was drilled in close proximity to the dry cleaner's septic tank and the soil at the base was highly permeable, it is likely that the well was contaminated soon after it was installed in 1958. In July 1982, PCE levels at Tarawa Terrace ranged from 76 ppb to 104 ppb. THM samples taken at Tarawa Terrace in November 1982 and in 1983 were found to be contaminated with PCE. In early February 1985, a tap water sample detected 215 ppb PCE, 8 ppb TCE, and 12 ppb DCE. The contaminated wells were shut down on February 8, 1985. Both Camp Lejeune and ABC One-Hour Cleaners were listed as United States Environmental Protection Agency (US EPA) National Priority List (NPL) "Superfund" sites in 1989.

1997 ATSDR Public Health Assessment (PHA)

The Agency for Toxic Substances and Disease Registry (ATSDR) is required by law to conduct a public health assessment (PHA) at each NPL site. The aim of each assessment is to determine whether the population residing around a particular site might have been exposed to any toxic substance and also to assess whether there might have been any adverse health effects resulting from this exposure. Known health effects are documented

in these assessments and public health recommendations are made accordingly. Potential health effects are also identified and referred to ATSDR scientists for additional investigation.

In 1997, ATSDR completed a PHA for Camp Lejeune (ATSDR, 1997). The assessment determined that the estimated drinking water VOC exposures at Camp Lejeune were several thousand times lower than levels of concern in animal studies. They were also hundreds of times lower than levels linked to adverse health effects found in workplace studies. ATSDR concluded that both cancer and non-cancer health effects were unlikely in adults exposed to VOC-contaminated drinking water at Camp Lejeune based on worst-case estimates. However, because of the limited information available in the scientific literature on how these chemicals might affect a fetus or child, it was suggested that an epidemiologic study be performed at Camp Lejeune to evaluate whether mothers exposed during pregnancy to chlorinated solvents (e.g., PCE and TCE) in drinking water had a higher risk of giving birth to a child with a birth defect or a childhood cancer.

1998 ATSDR Study of Adverse Birth Outcomes

As a first step in following up the PHA recommendation to conduct an epidemiologic study, ATSDR utilized available databases to evaluate whether associations existed between potential maternal exposure to the drinking water contaminants at the base and preterm birth (<37 weeks gestational age), small for gestational age (SGA), and mean birth weight deficit (ATSDR, 1998; Sonnenfeld et al., 2001). SGA was determined as <10th percentile weight by gestational week using published sex-specific growth curves for whites in the state of California. The study was completed and published as an ATSDR report in August 1998.

The study obtained electronic birth certificate information for 12,493 live births born during the period January 1, 1968 through December 31, 1985 to women who resided in base family housing at time of delivery. After exclusions for poor data quality, 11,970 live births were included in the analyses. The year 1968 was chosen as the starting point of the study because that was the year that North Carolina began computerizing its birth records. Information from the birth certificate was used to determine birth weight and gestational age.

Birth certificates were linked to the base's family housing records on mother's address at delivery and, in most cases, father's name. The housing records contained dates of occupancy and military pay grade for the family member assigned to the unit (i.e., the active duty person). This information was used to estimate the dates during pregnancy when the mother resided in the base housing unit. The study estimated that the mothers of 6,117 births resided at Tarawa Terrace for at least one week before birth occurred. These births were considered exposed to PCE. Mothers of 31 births that resided at Hospital Point (served by the Hadnot Point system) for at least one week before birth occurred were considered having "long-term" exposure to TCE. Mothers of 141 births that resided in housing units supplied briefly in 1985 by the Hadnot Point system when the Holcomb Boulevard system was down (due to a fuel pump failure) for at least one week before birth occurred were considered having "short-term" exposure to TCE. Mothers of 5,681 births (nearly half of the total number of births on base during the study period) resided in housing units that were not served by either the Hadnot Point or Tarawa Terrace systems and were therefore considered unexposed to VOCs in drinking water.

The study showed that “long-term” TCE exposure from Hadnot Point water was associated with an elevated risk for SGA (OR=3.9, 90% CI: 1.1, 11.9) only among male infants (ATSDR, 1998). Exposure to PCE from Tarawa Terrace water was associated with elevated risk for SGA among infants born to mothers aged >35 years (adjusted OR=2.1, 90% CI: 0.9, 4.9) and among mothers with two or more prior fetal losses (adjusted OR=2.5, 90% CI: 1.5, 4.3) (Sonnenfeld et al., 2001). The following potential confounders and effect modifiers were included: sex of infant, maternal and paternal ages, maternal race, maternal and paternal education, military pay grade, maternal parity, adequacy of prenatal care, marital status, and year of birth.

An attempt was made to evaluate fetal deaths that occurred on base during the study period, but was abandoned for several reasons. First, the total number of fetal deaths identified through the computerized state database was small (N=83). Second, the cause of death was missing for most of the fetal deaths. Finally, the number of fetal deaths in the computerized database likely constituted an under ascertainment of the true occurrence of fetal death on base because the race-specific rates of fetal deaths were considerably lower than expected based on US rates.

Current ATSDR Epidemiologic Study of Specific Birth Defects and Childhood Leukemia

Because the adverse birth outcome study relied on birth certificate information, it could not evaluate birth defects or childhood cancers. In order to evaluate these adverse childhood outcomes in an epidemiologic study, ATSDR initiated a multi-step process. First, a review of the scientific literature was conducted to narrow the focus of potential adverse outcomes to study. Second, a telephone survey was conducted to identify potential cases of the selected adverse childhood outcomes among the births occurring during the period 1968-1985 to mothers residing at the base anytime during their pregnancy.

The next step was to verify the diagnoses of the cases ascertained by the survey. This work is ongoing and a progress report was issued in July 2003. In July 2003, work began to develop a study protocol. The protocol received approval from the CDC Institutional Review Board and the US Office of Management and Budget in 2004. Work is now proceeding on the epidemiologic study. The expected completion date of the study is 2007.

In order to narrow the focus of the epidemiologic study to adverse childhood outcomes that might be related to the drinking water exposures on base, ATSDR reviewed the toxicological and epidemiologic literature. Based primarily on the evidence from the epidemiologic studies of VOC-contaminated drinking water, the following adverse childhood outcomes were selected for further evaluation: neural tube defects (NTDs), oral cleft defects, conotruncal heart defects (i.e., tetralogy of Fallot, D-transposition of the great arteries, truncus arteriosus, pulmonary valve atresia with ventricular septal defect, and double outlet right ventricle), choanal atresia, childhood leukemia and childhood non-Hodgkin's lymphoma. In some of these studies, the drinking water was contaminated by a mixture of VOCs that included TCE and/or PCE.

The studies that evaluated birth defects were recently reviewed (Bove et al., 2002). Neural tube defects and oral cleft defects were found to be associated with TCE in a NJ drinking

water study (Bove et al., 1995). Major heart defects were associated with exposure to TCE-contaminated drinking water in a study conducted in Tucson (Goldberg et al., 1990). A decision was made to focus on conotruncal heart defects because these defects are pathogenetically similar and they were associated with maternal residential proximity to toxic waste sites in a California study (Croen et al., 1997). A cluster of choanal atresia was associated with drinking water primarily contaminated with TCE in the Woburn Environmental and Birth study (Bove et al., 2002). A drinking water study at Woburn also found an association with childhood leukemia (Costas et al., 2002). A New Jersey study found an association between childhood leukemia in females and TCE-contaminated drinking water (Cohn et al., 1994). A study of drinking water contaminated with TCE, PCE, and a styrene-acrylamide trimer in Dover Township, NJ found an association with childhood leukemia among females (New Jersey Department of Health and Senior Services, 2003). Associations between non-Hodgkin's lymphoma and drinking water contaminated with TCE and with PCE were found in the NJ study, but the finding was not limited to children (Cohn et al., 1994). Nevertheless, it was decided to include childhood non-Hodgkin's lymphoma in the list of selected adverse outcomes for further evaluation.

An important objective of the survey was to determine whether an epidemiologic study of these adverse outcomes was feasible. In particular, several questions needed to be answered: Could a high percentage of the population be identified and contacted? Could most of the cases of these adverse outcomes in the population be reliably ascertained and verified? Would there be sufficient numbers of cases to study? The telephone survey began in September 1999 and was completed in January 2002.

The survey sought information on all children who were born to mothers who were pregnant while living in base housing during the period 1968-1985. This included births at the base and births that occurred after the mother was transferred off the base. If the survey was successful in obtaining information on a high percentage of these children, and if a sufficient number of cases of each of the adverse childhood outcomes could be ascertained and verified, then an epidemiologic study could proceed. The survey was necessary because: (1) data from NC cancer and birth defect surveillance systems were not available before 1985, and (2) a number of mothers who were pregnant while residing at Camp Lejeune were transferred off the base prior to delivery and gave birth outside NC.

ATSDR attempted to locate and contact the parents of each eligible child to elicit information on the child's health as well as to confirm that the mother was a resident at the base at some point during the pregnancy. Eligible children were identified in two ways. First, the survey used the birth certificate information from the previous Camp Lejeune study of SGA (ATSDR, 1998). A total of 12,493 birth certificates were obtained for children born from 1968 through 1985 to mothers who lived in base housing at the time of delivery.

Second, children born from 1968 through 1985 to mothers whose pregnancies occurred while they lived in base housing but who lived off the base at the time of delivery were identified primarily by word-of-mouth (e.g., parent groups), by referrals from other parents during their interviews, or by parents prompted by media information about the

survey to contact ATSDR or the USMC. The number of births occurring off the base is unknown. However, staff of the Camp Lejeune Naval Hospital estimated that about one third of mothers receiving prenatal care at the hospital were transferred from Camp Lejeune before delivery. Based on this information, ATSDR estimated that between 3,500 and 4,500 mothers were transferred from Camp Lejeune before delivery. Therefore, an estimated total of 16,000 to 17,000 births occurred among women who were pregnant while living at Camp Lejeune during the study period (ATSDR, 2003).

ATSDR surveyed the parents of 12,598 eligible children, representing an overall participation rate of between 74% and 80% depending on the estimate used for births that occurred off base. Of the 12,493 births that occurred on base, the survey was able to obtain information on 80.4%. Of the children born after the mother transferred off the base, information was obtained from 2,558. Assuming a total number of off-base births ranging from 3,500 to 4,500, this represented a participation rate of 64% to 73%. The survey demonstrated that an epidemiologic study of this population could have high participation rates. Parents were asked if the child had had a birth defect or had developed a childhood cancer. Sufficient numbers of cases of NTDs, oral clefts, and childhood leukemias were ascertained to move forward with a study of these adverse outcomes.

Verification of the NTD, oral cleft, and childhood leukemia cases is ongoing. All verified cases and a random sample of non-cases will be selected for inclusion in the epidemiologic study. Detailed interviews are currently ongoing with parents in order to obtain data on maternal water consumption habits, residential history, and maternal and paternal risk factors. In order to provide a quantitative estimate of exposure, an historical exposure reconstruction approach will be taken, consisting of the modeling of the water distribution system at Camp Lejeune and the ground water contamination plumes. The method of historically reconstructing the water distribution system at Camp Lejeune will be similar to the approach taken in the Dover Twp, NJ study (Maslia et al., 2001; New Jersey Department of Health and Senior Services, 2003). Using water-distribution system modeling, it is possible to estimate quite accurately the proportional contribution of water from a water source to any location serviced by the water-distribution system. This technique can also provide the relative concentrations of specific contaminants in the water delivered to study subject residences. Work has begun on the modeling of the ground water contamination plumes and the water distribution system.

SUMMARY OF PUBLIC COMMENTS

During the two day meeting, members of the public were provided opportunities to present their concerns to the Camp Lejeune Scientific Advisory Panel. Most of the public testimony centered around a discussion of the health problems, and in some instances premature death, of children who lived at Camp Lejeune. There was also significant concern expressed about the possible health impact of contaminated drinking water among people exposed as adults.

Numerous health problems were reported among children. These included:

- Failure to thrive, low weight gain
- Birth defects (neural tube defects, oral cleft defects)
- Childhood cancers (Childhood leukemia, non-Hodgkins lymphoma)
- Heart defects
- Aplastic anemia
- Spinal meningitis
- Unexplained high fevers
- Ear infections
- Urinary tract infections
- Respiratory infections
- Rashes
- Gastrointestinal problems
- Crohn's Disease
- Kidney and liver problems
- Convulsions
- Chronic pain
- Learning and developmental disabilities
- Speech and hearing impairments

Health outcomes reported among people exposed as adults included:

- Non-Hodgkin's lymphoma
- Numerous types of cancers and tumors
- Infertility, miscarriage, premature labor, and other reproductive health outcomes
- Graves Disease
- Migraines
- Ulcers
- Fatigue
- Depression
- Fibromyalgia

Other points made during public testimony focused on the following concerns:

- Concern about the amount of time it took the Department of Defense to take action to close the contaminated wells and to notify residents of the potential exposure.

- Concern that there has not been complete notification of potential exposure to contaminated drinking water for all Camp Lejeune residents and people working on the base.
- Concern that ATSDR's studies have been limited in focus (i.e., limited to children exposed *in utero*). Numerous public participants recommended that the studies be expanded to include all children and adults living on the base and civilian employees who worked on the base.
- Concern about other methodological issues with the ATSDR studies (e.g., use of incorrect data on exposure, lack of access to all the data needed to appropriately conduct the studies, exclusion of children born to families who moved from the base prior to delivery)
- Concern about the amount of time it has taken for ATSDR to complete its studies.

A more detailed description of the public comments made during the meeting can be found at <http://www.atsdr.cdc.gov/sites/lejeune/eventsarchive.html> (see meeting transcripts).

PANEL RECOMMENDATIONS

Partnership with the Community

Several panel members recommended that all future studies should be conducted with full participation of the community. One panel member suggested a formal collaborative arrangement with paid staff. Many persons who lived at Camp Lejeune as children or adults and who had likely exposure to TCE have been very active in placing their health concerns before the public. These individuals were instrumental in having ATSDR convene this meeting of a scientific panel, in which a substantial part of the agenda was devoted to personal testimony by many of these individuals. The effectiveness of this group, the experience of several panel members in working with other exposed communities with past exposure to environmental contaminants, and the personal testimony of community members led panel members to this recommendation.

Community involvement must take place with full recognition of the uniqueness of the community of exposed individuals who had lived at Camp Lejeune. In contrast with many other places where toxic contamination of the environment has been a concern, the population at Camp Lejeune is relatively transient. Relatively few potentially exposed persons lived on the base for more than two or three years. In addition, many individuals lived off base and had potential exposures while working on base for various lengths of time. Therefore, health studies involving persons who were at Camp Lejeune (either as residents or workers or both) and may have been exposed to contaminated water poses special challenges in identifying and locating individuals. Most of the population of potentially exposed individuals from Camp Lejeune is now widely spread throughout the United States and in some instances, around the world. This creates challenges in tracking individuals, in contacting and interviewing them where necessary, in gaining permission for access to their medical records (if necessary), and in communicating study findings to them. In all of these areas, the panel felt that community members, with a personal involvement and concern about health effects associated with their past exposures, must be fully involved in any future research effort. These individuals can work closely with researchers and serve a liaison function with members of the more broadly exposed population(s) from Camp Lejeune.

Advisory Panel

Panel members recommended that an advisory panel, with long-term stability, be established. The advisory panel would consist of persons with scientific expertise as well as representatives of the community. The advisory group would have several roles involving oversight of Camp Lejeune study activities: providing advice on methods to identify various groups of individuals who had lived or worked on the Base; suggesting health end-points for studies and study approaches; reviewing study protocols; and serving as liaison between scientific investigators, the military, and the community. The advisory panel would pull on the expertise of community members with knowledge of military and civilian databases that may be of value. Members of the panel from the community would also have knowledge of how to notify persons who lived at Camp Lejeune during the exposure period.

Establish Cohorts

A wide range of health endpoints of interest were suggested by panel members (as described below). As a starting point for studies to investigate any of these outcomes, the panel agreed that the initial approach should be establishment of a registry to consist of several cohorts, including both exposed and unexposed individuals who had lived and/or worked at Camp Lejeune, that would serve as the population base for further study. There was discussion among panel members as to whether a “Registry” or “Cohorts” should be established; however, the difference between these may be more semantic than substantive, and there was agreement that persons who had lived and/or worked at Camp Lejeune during a defined period should be included. The panel identified four groups of potentially exposed individuals: adults who lived on base during the period of interest; adults who lived off base, but worked on base (both military and civilian); children who lived on base; and those who were *in utero* during the time period of interest, whether or not they later lived on base. As expressed by one panel member, the commonality among these groups is that they spent time at Camp Lejeune and were potentially exposed to contaminated drinking water. There is clearly overlap between some groups – for example, those who lived at Camp Lejeune during the exposure period and were also there earlier, *in utero*. These individuals could be considered to be in both groups, or if there are adequate numbers for study, they should be split off into a study cohort consisting of individuals with both *in utero* and childhood experience (and possible exposure) at Camp Lejeune.

In constructing rosters of each of the cohorts, researchers would need to rely heavily on members of the community to help identify (and possibly to access) databases and data repositories, such as military rosters, housing data, school records, etc. As part of this effort, researchers would identify and record networks of people who regularly communicate via phone, email, USPS, personal visits and any other medium or activity. Using these record systems, lists of persons who belonged to each of the groups described could be developed, including postal addresses and electronic addresses. Such lists should also include personal identifiers that would permit linkage with health and mortality record systems, as well as current contact information, when available.

The panel discussed time periods of eligibility for the cohorts, with several points of view expressed regarding the best approach. Since exposure ended in late 1984 or early 1985, it was suggested that the end of the time period for eligibility be extended for a few years beyond those dates. This would allow one to look at the temporal relation with disease by including persons during and after the relevant exposure period. The beginning of the exposure period is not as clear, and may have been as early as 1950 in some instances. Establishing cohorts with exposure potential from this early in the time period may not be possible and would have to be determined by feasibility work. The current modeling effort at ATSDR is expected to provide estimates of exposure in the early- and mid 1960's forward, and inclusion of this period should be considered. The panel recommended that a decision as to which years of residence/work at Camp Lejeune to include for eligibility in future cohorts should be made by researchers and the oversight panel in the future, after completion of ongoing exposure assessment studies and future feasibility studies.

Conduct Feasibility Studies

Before embarking on full-scale studies of the impact on health of exposures at Camp Lejeune, many issues must be addressed, requiring one or more feasibility or pilot studies. For example, for a successful study to be conducted on any of the cohorts noted above, it would be necessary to first identify a large proportion of the members of the cohort, and then to link them with medical or mortality records. A first step would be to determine the proportion of each population that could be identified, using school, employment, military, housing, and other relevant record systems, and the types of personal identifiers that are available to qualified researchers. One panel member suggested that a few years during the exposure period could be selected for feasibility purposes to test whether a subset of the larger exposed group of people could be identified. Other members proposed that all years be considered, but that a random sample of a fraction of records be selected for all possible years. Regardless of the exact procedure, the general principal was that feasibility work be conducted on a limited subset of the overall eligible population, so that feasibility tasks would be manageable. Details on how this would be accomplished is best be left in the hands of the research team that will be directly involved, in consultation with the proposed oversight group. In addition to evaluating feasibility of identifying and tracking individuals, other issues need to be addressed before large-scale studies could be performed. The types of past medical records available would need evaluation, including their location, completeness, and the types of information they contain. Below, we list several types of health outcomes that may be of interest. The feasibility of which health outcomes to study would have to be evaluated on a case by case basis.

Health Outcomes for Study

The panel discussed a large range of possible adverse health impacts that could be related to short- and long-term exposure to TCE and other VOCs in the drinking water of Camp Lejeune. Several of these would be extremely challenging to study, and may not be feasible subjects for investigation, such as studies of effects that could involve medical evaluation of hundreds of individuals now living in widely scattered locations. There was agreement, however, that a study of mortality outcomes would be feasible (assuming the availability of adequate personal identifiers) and that a study of incident cancer might be feasible. For mortality studies, the National Death Index, a roster of all deaths in the United States since 1979, is available for epidemiologic research. The roster can be queried with lists of individuals (including full name and either date of birth or social security number), and deaths identified. In several states, newly incident cancer cases are recorded in state cancer registries, and a similar approach could be used in selected locations to identify cancer cases among cohort members living in these areas.

In addition to evaluating mortality and cancer risk within exposed and unexposed segments of the Camp Lejeune population, the panel discussed other health outcomes of interest that might be studied. It was recognized that feasibility issues loom large with each of the outcomes, and preliminary work would be needed to see which of them would be possible to study, and which not. Some conditions that should be considered for study are: autoimmune diseases or decrements in immune function; spontaneous abortion; neurological effects; organ failure; adult heart disease related to electrical failure;

reproductive outcomes of male and female children born (eg. *in utero*) at Camp Lejeune (i.e., second generation effects); birth defects beyond those considered by ATSDR; ocular problems; and others. Without data from preliminary investigation and a thorough review of the literature, it was not possible for panel members to assign clear research priorities to these outcomes. Given available information, however, panel members did state that it would be possible to conduct a mortality study, and possibly a cancer incidence study, if the respective cohorts could be established.

Timing of Future Research Activities

Panel members agreed that initiation of further research on the health effects of contamination at Camp Lejeune should not await completion of the current study underway at ATSDR of childhood leukemia, non-Hodgkins lymphoma, and several adverse reproductive outcomes, which could take two years before findings are available. The panel recognized that a crucial part of any study of health effects of TCE or other chemicals in drinking water is an accurate assessment of past exposures. In particular, it is crucial to understand how these exposures were distributed in space and time at Camp Lejeune, and what the levels were. One panel member expressed this notion by stating that "exposure assessment is the Achilles heel of environmental epidemiology". By this, he meant that the reliability of study findings are dependent on having accurate information on the exposure histories of each study subject. An important part of the current ATSDR study of reproductive outcomes is the work in progress to better define the spatial extent, the timing, and the levels of exposure to TCE at Camp Lejeune. In order to proceed with further work, it is not necessary to await results of this improved and more accurate exposure assessment, since the information developed from these exposure assessment activities can be used in any future health effects study.

1997 Public Health Assessment

In 1997, ATSDR issued a Public Health Assessment of potential risks to health at Camp Lejeune. The Public Health Assessment covered three major areas: lead in drinking water; volatile organic compounds in drinking water; and pesticide levels in surface soil that could expose children in a former day-care center as well as office and lawn-care workers. In describing "Past Public Health Hazards" related to exposure from volatile organic compounds, the report states: "Even though adverse health effects are not expected in adults, concern was raised about potential toxic effects on developing fetuses." A panel member expressed his surprise and strong disagreement with the Assessment's statement about potential adult health effects. Several panel members agreed that ATSDR should amend the public health assessment to include the possibility that adult cancers and other adverse health outcomes may be related to VOC exposures. In the period since release of the original Public Health Assessment of Health Hazards at Camp Lejeune, much additional information on these exposures at the Camp and the potential risk posed have been developed. This additional material should also be incorporated into an amended document.

Notification

Several panel members felt strongly that the military has an ethical responsibility to notify all potentially exposed and affected persons from Camp Lejeune, and the nature of

the exposure. A few suggestions were made regarding how the media could be used to this end; however, the best routes and methods for systematic notification are best left to the Marine Corp. Community members could be brought in to advise and assist in notification activities.

Funding Recommendations

The panel recognizes that the types of studies that are required to investigate health effects of the Camp Lejeune VOC exposures carry with them a substantial cost, possibly ranging to the tens of millions of dollars. More precise estimates of cost must await completion of pilot and feasibility studies that would guide the direction and scope of future research. Several panel members stated that direct funding by DOD of studies conducted by ATSDR carries with it at least an apparent conflict of interest that could compromise scientific independence and study validity and therefore public acceptance of whatever findings may be forthcoming. Thus the panel members recommended that funding for future Camp Lejeune health studies should not come through DOD, but rather through direct Congressional action. Recognizing how tightly current budgets are stretched within CDC and ATSDR to conduct mandated activities, panel members further recommended that Camp Lejeune studies should not be supported by reprogrammed funds within the agency, but rather from newly appropriated monies.

SUMMARY

In summary, members of the Camp Lejeune Scientific Advisory Panel recommended the following:

- Future studies should be conducted in full partnership with the exposed community.
- An advisory panel, with long-term stability, should be established to oversee health studies of persons with potential exposure to VOCs at Camp Lejeune.
- 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*.
- Initiation of recommended research activities should not await completion of current ATSDR activities to better characterize past exposure, but can be conducted in parallel with the current work.
- The 1997 ATSDR Public Health Assessment of Camp Lejeune should be amended with a recognition that adult exposures may result in adverse health outcomes, and also include updated information on potential exposures and estimates of the risk they pose.
- All persons potentially affected by exposure to VOC in the drinking water at Camp Lejeune should be notified.
- 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.

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APPENDIX 2: Camp Lejeune Scientific Advisory Panel Members

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J. Wanzer Drane, P.E., Ph.D. received his Ph.D. in biometry from Emory University in Atlanta, Georgia; mechanical engineering studies at the Louisiana Polytechnic Institute; and nuclear engineering studies at the Oak Ridge School of Reactor Technology. Dr. Drane is currently professor of biostatistics at The Arnold School of Public Health at the University of South Carolina. In addition to biostatistics, Dr. Drane holds expertise in the areas of biometric modeling, disease clusters, community trials, GIS (geographic information systems), imputations of multi-prompt sample surveys, and improving biostatistics in developing countries.

Courtney Denning-Johnson Lynch, Ph.D., M.P.H. received her Ph.D. in reproductive and perinatal epidemiology from Johns Hopkins Bloomberg School of Public Health in Baltimore, Maryland, and her M.P.H. from the Ohio State College of Medicine and Public Health. Dr. Lynch is a Staff Scientist, with the Epidemiology Branch, Division of Epidemiology, Statistics, and Prevention Research at the National Institute of Child Health and Human Development, National Institutes of Health. Dr. Lynch has expertise in the areas of reproductive epidemiology, reproductive environmental health, epidemiologic methods, statistics, and exposures & conception.

Richard Maas, Ph.D., M.S.P.H. received his Ph.D. and his M.S.P.H. in environmental chemistry from the University of North Carolina at Chapel Hill. Dr. Maas is the Director and Professor at the Environmental Studies Department at the University of North Carolina, Asheville. Dr. Maas has expertise in the areas of chemistry, environmental science, water, lead, air, arsenic, pesticides, and health effects & pediatrics.

David Ozonoff, M.D., M.P.H. received his M.D. from the Cornell University Medical College and his M.P.H. from Johns Hopkins University School of Hygiene and Public Health. Dr. Ozonoff is a Professor at Boston University School of Public Health in the Environmental Health Department. Dr. Ozonoff is the Director of the Superfund Basic Research Program and the Co-Editor-in-Chief of the online journal Environmental Health. Dr. Ozonoff holds expertise in the areas of medicine, environmental health, epidemiology, community health, mathematical models, cancer, hazardous waste, TCE, and PCE.

Ornella Selmin, Ph.D. received her Ph.D. from the University of Padova, Italy in molecular and cellular biology. Dr. Selmin currently serves as an Assistant Professor at the University of Arizona in the Department of Veterinary Science and Microbiology. Dr. Selmin's research focuses on the molecular mechanisms of congenital heart defects,

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Paul Visintainer, Ph.D. received his Ph.D. in epidemiology from the University of Pittsburgh. Dr. Visintainer is a Professor and the Program Director for Quantitative Sciences in the Graduate School of Health Sciences of New York Medical College. Dr. Visintainer has expertise in the areas of epidemiologic methods, perinatal epidemiology, biostatistics, and behavioral science.

APPENDIX 3: List of Material Provided to the Panel Prior to the Meeting

1. The panel's charge and questions.
2. A summary of ATSDR's actions at Camp Lejeune (prepared by the Division of Health Studies)
3. Published Reports/Articles:
 - Agency for Toxic Substances and Disease Registry. *Public Health Assessment: U.S. Marine Corps Camp Lejeune, Onslow County, North Carolina*. Atlanta: US Department of Health and Human Services, 1997.
 - Agency for Toxic Substances and Disease Registry. *Volatile Organic Compounds in Drinking Water and Adverse Pregnancy Outcomes: U.S. Marine Corps Camp Lejeune, Onslow County, North Carolina*. Atlanta: US Department of Health and Human Services, 1998.
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4. CDC announcement regarding the meeting of the Camp Lejeune Scientific Advisory Panel.
5. Letters from the public.

APPENDIX 4: Camp Lejeune Scientific Advisory Panel Meeting Agenda

Thursday, February 17, 2005

9:00 am	Call to Order Introductions and Opening Remarks
9:30 am	Public Comment
10:30 am	Break
10:45 am	ATSDR Staff Presentation and Discussion with Panel Members
12:00 pm	Lunch Break
1:30 pm	Expert Panel Deliberation
3:45 pm	Break
4:00 pm	Public Comment
5:00 pm	Open Discussion for Panel and Public
5:30 pm	Adjourn

Friday, February 18, 2005

9:00 am	Call to Order
9:10 am	Expert Panel Deliberation
12:00 pm	Lunch Break
1:30 pm	Public Comment
2:30 pm	Break
2:45 pm	Expert Panel Deliberation Wrap-up
4:30 pm	Summary and Closing Remarks
5:00 pm	Adjourn

**Agenda may change as priorities dictate*

APPENDIX 5: List of Material Provided to the Panel During the Meeting*

1. Copy of PowerPoint presentation used by ATSDR staff to provide background on Camp Lejeune related activities conducted by ATSDR staff.
2. Questionnaire used for the 1999 to 2002 Childhood Cancers and Birth Defects survey.
3. Article from the May 17, 2001 issue of *Stars and Stripes* entitled, "Family links tainted water to kids' illnesses."
4. Article from the August/September 2004 issue of *The VVA Veteran* entitled, "Troubled water: The toxic legacy of Camp Lejeune's contaminated water supply".
5. Page from www.denix.osd.mil/denix/Public/News/Mariens/ECP/mcecp.html on Marine Corps Environmental Campaign Plan, 1997.
6. The STAND Victims Register from www.watersurvivors.com/victims.asp.
7. Information distributed by Ms. Lita Hyland regarding her daughter's medical history.
8. Information distributed by Ms. Terry Dyer regarding her family's medical history.
9. Photos distributed by Ms. Paula Orellana's depicting her mother's medical condition.
10. Photos of a residence at Camp Lejeune indicating contamination due to asbestos.
11. Copies of correspondence distributed Mr. Jerome Ensminger regarding data pertaining to contamination of drinking water data at Camp Lejeune.

*Items 1 and 2 were distributed by ATSDR staff; all other items distributed by members of the public in attendance at the meeting.