Testimony of:

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May 24, 2016

Good afternoon Mr. Chairman, ranking member Blumenthal and to all of the esteemed members of this committee. I want to expressly thank Chairman Isakson for including S-2888 in this legislative hearing. My name is Jerry Ensminger. I am a retired U.S. Marine and I spent more than 11 of my 24 ½ years of service at Camp Lejeune, NC.

I would like to commend both Senators Burr and Tillis for writing and introducing this bill. This bill confirms to the hundreds of thousands of Marines, Sailors, their families, and the thousands of civilian employees who were negligently exposed to the highest levels of harmful contaminants ever recorded in a major drinking water system that the U.S. Senate delegation of NC has our backs. Not only is this legislation another step in rectifying the gross injustice committed against the Camp Lejeune victims, it also has the potential of saving the American taxpayers hundreds of thousands, if not millions of dollars in the future. This bill when passed, will require the Veterans Administration (VA) to utilize the Agency for Toxic Substances and Disease Registry (ATSDR) rather than exclusively contracting external government entities to perform evaluations and/or opinions on health effects related to the Camp Lejeune drinking water issue. ATSDR was created and mandated by Congress in 1980 to investigate, evaluate, and remediate human exposures to potentially harmful contaminants found at National Priority Listed (Super Fund) contamination sites such as Camp Lejeune. We all need to take a step back and ask ourselves why the VA refuses to utilize the preeminent governmental institutions

such as ATSDR, the National Center for Environmental Health (NCEH), or the National Institute for Environmental Health Sciences (NIEHS) for those evaluations and/or opinions relating to issues where veterans have been exposed to hazardous substances? Why does the VA automatically and exclusively resort to contracting external government entities for these evaluations and/or opinions? Here are some of the findings we have made concerning those questions. You can draw your own conclusions;

1) When the VA contracts an external entity to provide them with an evaluation and/or opinion, the VA writes a charge to the contractor. This is where the legitimacy of this practice comes into serious question. Every member of this committee is a politician and the best analogy I can use to describe the flaws in this process is political poll questions. A pollster with an agenda can write poll questions in a fashion which would provide them the response(s) they desire. There is no difference when writing a charge to a contractor. The person(s) writing the charge can fashion it in such a manner as to narrow the final evaluation and/or opinion.

2) None of the work performed by these external government entities falls under the Freedom of Information Act. We have no access to the procedures or what scientific materials the contractor used in creating their evaluations and/or opinions. Where is the transparency in this process? There is none!

3) Every time the VA contracts an external government entity for an evaluation and/or opinion, the American taxpayer is paying double. We are paying to maintain, equip, and staff our governmental agencies who are fully capable of performing these tasks. We are also paying the VA's contracted price for those external governmental entities to execute

this work.

Several years ago, I asked VA's Dr. Terry Walters why the VA constantly insists on using external government entities when seeking evaluations and/or opinions regarding potentially harmful exposures. She claimed that the VA uses external government contractors for such work because the veterans wouldn't trust the work product of a Governmental agency. Her response almost made me choke! Of course, most veterans don't know that the VA (an interested party) writes a charge to the external government entity (another interested party) to provide them with an evaluation and/or opinion. On the other hand, governmental agencies such as ATSDR, NCEH, and the NIEHS are uninterested parties who would give an evaluation / opinion based on available scientific evidence instead of a "charge" which could restrict the evaluation to the desires of the contractee. Furthermore, all of the procedures and scientific materials utilized by the aforementioned governmental agencies would be accessible under the Freedom of Information Act.

Mr. Chairman, if the VA truly had the best interests of Camp Lejeune veterans and their families at heart, they would never have created and utilized the training power point (Attachment A). This power point presentation was utilized to train VA clinicians who would be screening Camp Lejeune veterans and their family members pursuant to the passage and the President signing the "Honoring America's Veterans and Caring for Camp Lejeune Families Act" of 2012. This power point not only regurgitated outdated and disputed science (Attachment B), it reads like a "road map" for how to deny these Veterans and their families the care outlined in the law. Finally, the description of Dr.

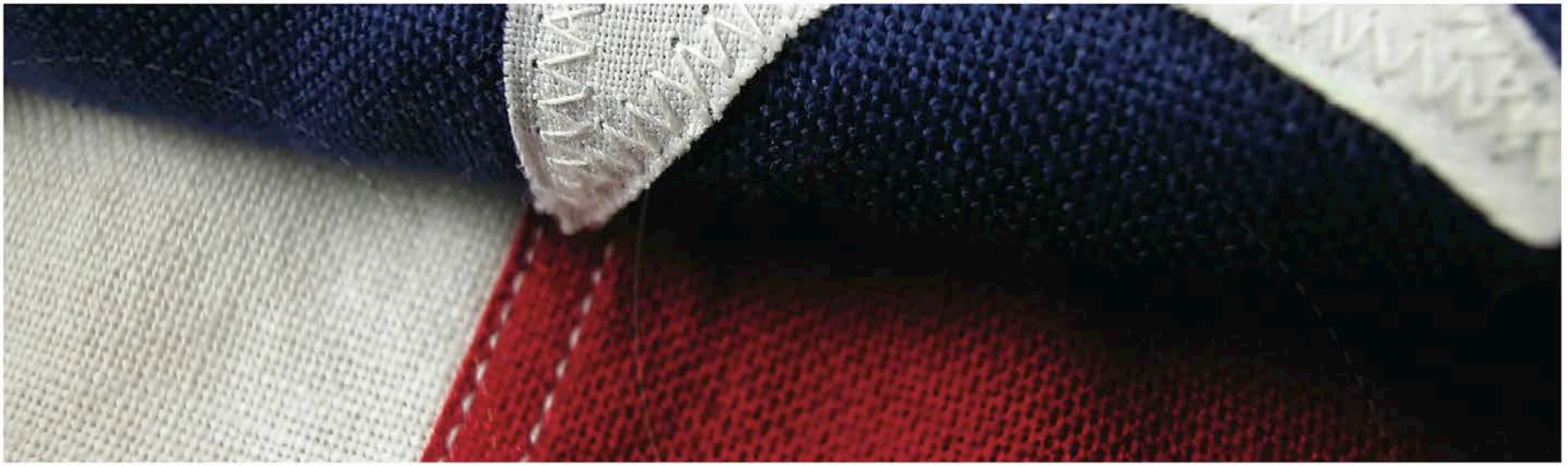
Walters' vision of a Camp Lejeune veteran's wife (slides #10 & #12 of Attachment A) went beyond the pale. It was demeaning and outright despicable. What makes this even worse is the fact that when Dr. Walters was asked if this depiction was a real individual, she replied, "No, I took several actual individual cases and lumped them together to create that one example." Does anyone need to wonder why we don't trust the VA?

Lastly, the VA created a Camp Lejeune task force in 2012 to map out a direction forward supposedly to meet the requirements of the new law. It wasn't until last month that we were finally made aware of the make-up of that VA task force (Attachment C/D) and oddly enough, we discovered that Dr. Kelly Brix, Division Director, Research Development, Department of Defense, Defense Health Headquarters, and a Mr. Scott Williams, DoD liaison, were members of this Camp Lejeune task force. It is our belief that this task force was directly responsible for the creation and eventual implementation of the now infamous so-called VA Camp Lejeune SME Program. We can't confirm our suspicions on this subject because the VA has refused to honor our FOIA requests.

I challenge every member of this committee to research how much money the VA has expended since FY-2012 on external governmental contracts for evaluations and/or opinions. I would venture a guess that between Camp Lejeune and the C-123 aircraft Agent Orange issues alone, hundreds of thousands of taxpayers dollars were spent. A lot of money that could have been spent caring for our veterans rather than devising methods in attempts to cheat them out of the benefits they deserve. Thank you and I look forward to answering any questions you may have.

Attachments:

Attachment A - VA Training Power Point dated August 2013
Attachment B - Director ATSDR letter dated October 22, 2010
Attachment C - VA Camp Lejeune Task Force Roster (1)
Attachment D - VA Camp Lejeune Task Force Roster (2)



Domestic Environmental Exposures

Terry Walters MD MPH
Deputy Chief Consultant Post-Deployment Health

August 2013

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

Agenda

- Historical water contamination at Camp Lejeune
- Potential Case History
- Implementation of the Section 102 of the "Honoring America's Veterans and Caring for Camp Lejeune Families Act of 2012"
- Implications
- Other U.S. installations with possible contamination issues
- Residual Agent Orange contamination issues

VA Implementation of Section 102 of the "Honoring America's Veterans and Caring for Camp Lejeune Families Act of 2012"

Camp Lejeune Historical Water Contamination

- 1950s – mid 1980s drinking water at Camp Lejeune contaminated with volatile organic compounds (VOCs)
  - Dry cleaning chemical – perchloroethylene (PCE), trichloroethylene (TCE)
  - Leaking Underground Storage Tanks (yes LUST!) - Benzene

- Over 1 million individuals may have been exposed
- 2009 National Research Council (NRC) report:
  - Identified 14 adverse health outcomes with limited/suggestive evidence of an association with exposure to TCE or PCE.
  - "The available scientific information does not provide a sufficient basis for determining whether the population of Camp Lejeune has, in fact, suffered adverse health effects as a result of exposure to contaminants in the water supply."
- Agency for Toxic Substances and Disease Registries (ATSDR) studies ongoing
- Section 102 of H.R. 1742 signed August 6, 2012
- VA Implementation Task Force

Information known at present

- Water supplies at Camp Lejeune were contaminated from approximately 1953 to 1985
- Long term benzene exposure strongly associated with increased risk of leukemia (AML)
  - Supported by occupational and epidemiological studies
  - Classified as a “known human carcinogen”
- TCE associated with possible increased risk of kidney cancer
  - Increased risk shown in rats exposed to high levels of TCE
  - The National Toxicology Program (NTP) determined that TCE is "reasonably anticipated to be a human carcinogen."
  - The International Agency for Research on Cancer (IARC) has determined that trichloroethylene is "probably carcinogenic to humans."

Information that is Unknown

- Is there any difference in the prevalence of disease in the Camp Lejeune population as compared with a similar population?
  - Studies by ATSDR pending
- At what level and for how long were Camp Lejeune residents exposed to contaminated water?
  - Pending further studies by ATSDR
- Was benzene a significant contamination?
  - Water modeling by ATSDR suggests that benzene was not a significant contaminant in the aquifer
  - National Research Council opines that this will not produce useful information

Review of Epidemiologic Studies

- Occupationally exposed workers
  - Limited/Suggestive evidence of an association (TCE, PCE)
    - Esophageal, Lung, Breast, Bladder, Kidney cancers
    - Miscarriage
  - Cohort studies of benzene exposed workers & those environmentally exposed → ↑risk of AML & other leukemias
- Exposure through contaminated water supplies
  - The epidemiological studies of solvent contaminated water supplies and adverse health effects are of limited quality.
  - All studies are limited by ability to determine exposure levels.
- Epidemiological studies on the Camp Lejeune population
  - Pregnancy outcome study – possible association between PCE exposure & low birth weight. (study later withdrawn due to new information that invalidated some of the study assumptions; study presently being redone)
  - All other epidemiological studies are pending

Exposure Levels

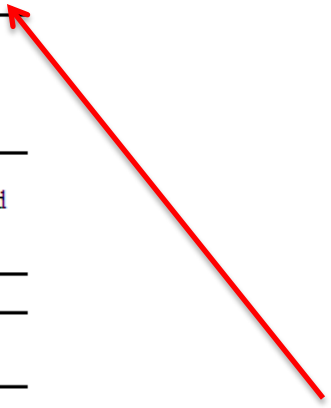
- Maximum measured concentrations (1982-1985)
  - TCE = 1,400 µg/L
  - Benzene 2,500 µg/L (one time spike, most levels non detectable)
- The estimated human adult dose of TCE at Camp Lejeune is 12,500 times lower that twice the highest measured concentration of TCE found to be associated with rats developing kidney cancer after TCE exposure

TABLE 4-3 LOAELs from Animal Studies Used for Comparison with Estimated Daily Human Doses to TCE Related to Water-Supply Measured Concentrations

Range of Doses	End Point	LOAEL, mg/kg per day
High	Kidney cancer, rats	1,000
Medium	Kidney toxicity, rats	250
Low	Immunosuppression, mice (sensitive strain)	22

TABLE 4-4 From Animal Studies Used for Comparison with Estimated Daily Human Doses to PCE Related to Water-Supply Measured Concentrations

Range of Doses	End Point	LOAEL, mg/kg per day
High	Kidney toxicity, rats	600
Low	Neurotoxicity, rats	50



1,400 µg/L (higest TCE level) x 4 L/day (amt of water per day) = 80µg/Kg per day = **0.08 mg/Kg per day**
70 kg (body wt)

Useful References

- VHA Office of Public Health
  - http://www.publichealth.va.gov/exposures/camp-lejeune/index.asp
- National Research Council report “Contaminated Water Supplies at Camp Lejeune” (2009)
  - http://www.nap.edu/catalog.php?record_id=12618
- Agency for Toxic Substances and Disease Registries
  - http://www.atsdr.cdc.gov/sites/lejeune/
- United States Marine Corps website on the Historic Drinking Water issue
  - https://clnr.hqi.usmc.mil/clwater/index.aspx

Potential Case History

- Former Marine Sgt. C (now a Veteran) comes to see his provider because he has heard that there is a new law covering Camp Lejeune. He wants a registry exam so he can file a claim. What do you tell him?
  - There is a new law that allows him to enroll in the VA.
  - There is no Camp Lejeune Registry.
  - He can file a claim but the new law only covers health care.
  - Registry exams are not the same as compensation exams. You direct him to the office where he can file a claim.
  - You direct him to the local office that enrolls Veterans into the VA.
- Because you have helped him he returns to your office after enrolling and asks "Is my health and my family's health at risk?" What do you tell him?
  - Take an exposure history
  - Provide information sources
  - Provide risk assessment
- He then goes on to tell you about his wife …….

Potential Case History

- Mrs. Joan C is a 63 year old female who claims to have lived at Camp Lejeune with her Marine husband from 1975 to 1979. She now lives in Boone, NC.
  - Diagnosed with breast cancer in the right breast and currently having chemotherapy. Only available oncologist located 100 miles away. Does not have a car and finds it very difficult to travel.
  - Previously diagnosed with breast cancer in the left breast about 6 years ago. Very strong family history of breast cancer (mother and all of her sisters have breast cancer).
  - Other medical problems include a 20 year history of poorly controlled diabetes, 30 year history of smoking, obesity, and hypertension.
  - Presently unemployed & bankrupt due to medical bills, relies on Medicaid for her health care. House being foreclosed.
  - Her daughter, who was born August 1987 at CL, married last year and has had a miscarriage. She is now having trouble getting pregnant.
- What do you say to Veteran C?

Section 102 of the "Honoring America's Veterans and Caring for Camp Lejeune Families Act of 2012"

- Provides health care for 15 conditions to Veterans and Family Members who were stationed or resided at Camp Lejeune (CL) for ≥ 30 days between 1957 to 1987:
  - Veterans on active-duty status assigned to Camp Lejeune
  - Family Members who were residents on Camp Lejeune or in-utero
- Care provisions:
  - Cannot provide care for conditions found to have another cause
  - Family Member care requires Congressional appropriation (March 2013)
  - VA is the last payer for family member care

Esophageal cancer	Non-Hodgkin's lymphoma	Breast cancer	Bladder cancer
Kidney cancer	Myelodysplastic syndromes	Multiple myeloma	Leukemia
Renal toxicity	Hepatic steatosis	Female infertility	Miscarriage
Scleroderma	Neurobehavioral effects	Lung cancer	

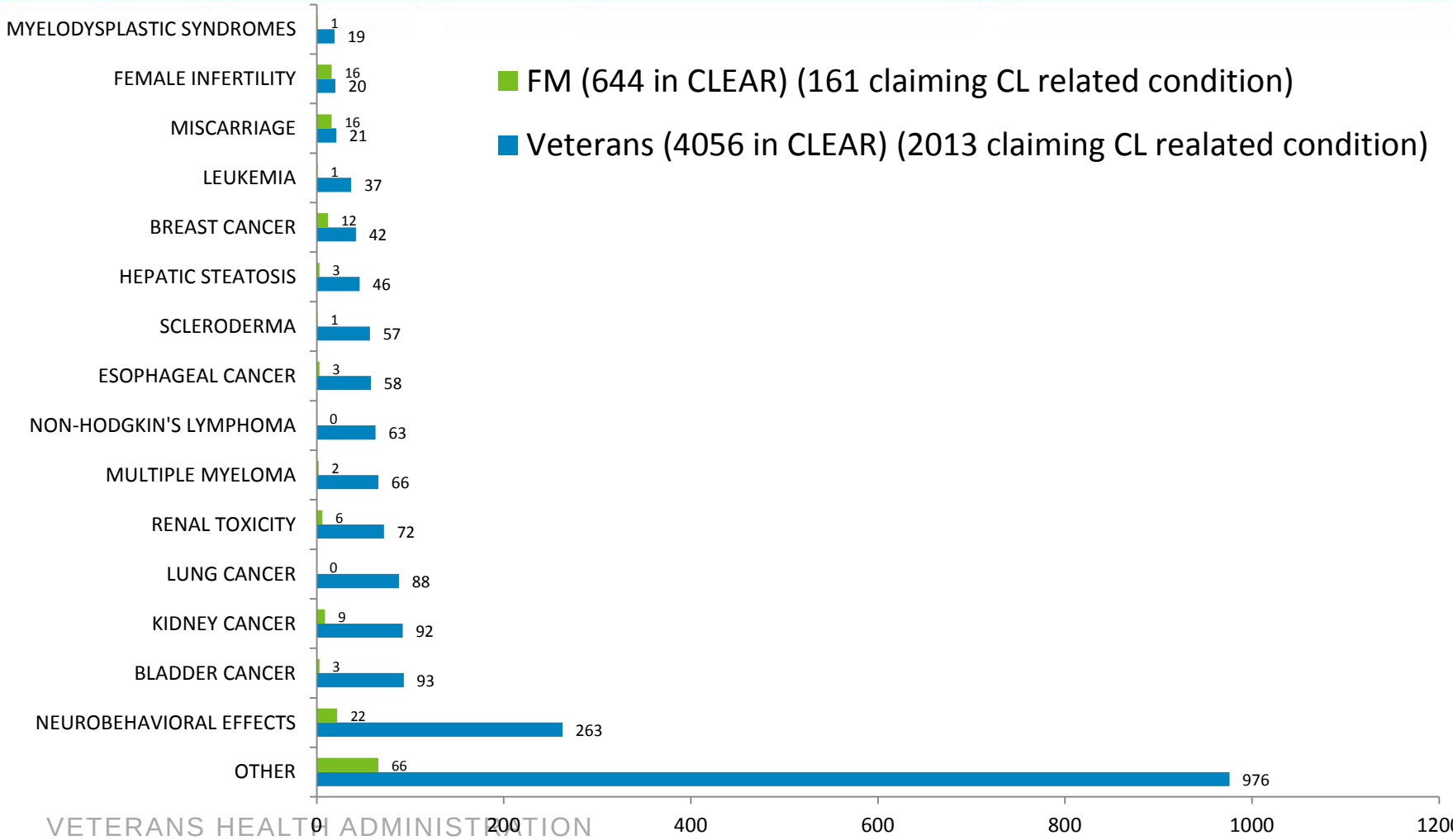
Need to implement a system to answer the following:

- What does VA do with the following requests?
- Mrs. C wants:
  - Reimbursement for all medical bills.
  - Wants her daughter tested and treated for her pregnancy and fertility issues
  - She wants a wig and reconstructive surgery
  - Since her chemotherapy she has noted that her teeth are getting worse. Is VA going to pay her dental bills?
  - She wants to be paid for travel expenses to get health care.
  - She wants compensation.
- What does VA do when her claim to have lived at Camp Lejeune cannot be verified?

Implementation Steps

- VA began implementing the law for the Veterans on August 6, 2012 - Priority 6
- Implementation Task Force was organized to engage and coordinate subject matter experts from across multiple work centers within VA (VHA, VBA, OGC, OCLA).
- VA created mechanism to track requests for care from CL Veterans and Family Members (Camp Lejeune Environmental Action Report (CLEAR).
- Developed outreach campaign.
- Social workers and eligibility clerks at all VA medical centers alerted to ensure that Family Members seeking care are sent to social work for assistance with identifying alternate care until congressional appropriation is provided.
- Worked with DoD to create system to verify administrative eligibility.
- Identified method to provide care to family members. They will receive care from their usual civilian providers and VA will pay out of pocket costs → VA Financial Services to enter (FSC) to pay bills.
- Identified IT issues and started implementing solutions.
- Created Clinical guidelines.
- Drafted Regulations.

CLEAR Data - Current CL Contact Data



Outreach

- VA public health web page updated

- Banner on all VA medical center web pages

- Updates for health care providers and other VA staff began in August; announced as they occur
- Briefings provided to congressional staff, VSOs, and Veterans on how VA is implementing the law
- Used USMC mailing to send a Fact Sheet for Veterans/Family Members
- Briefed the ATSDR Camp Lejeune (CL) Community Assistance Panel (CAP) members

Verifying Eligibility

Service Member Eligibility Process

Step 1 – Request OMPF files from NPRC

Step 2 – Search Digitized Muster Rolls**

Step 3 – Search Digitized Housing Card Info

Step 4 – Evaluate Applicant Supplied Info (training certs, schools)

Step 5 – Eligibility Unclear - Sign Affidavit***

or

Step 6 - Formal Finding of Unavailability of service records (memo)***

Dependent Eligibility Process

Step 1 - Search CLEAR

Step 1 – Request OMPF files from NPRC

Step 2 – Search Digitized Muster Roll**

Step 3 – Search Digitized Housing Card Info

Step 4 – Search DEERS and other VA sources for Dependent Info

Step 5 – Evaluate Applicant Supplied Info (marriage cert, birth cert)

Step 6 – Eligibility Unclear - Sign Affidavit***

or

Step 7 - Formal Finding of Unavailability of service records and other necessary documentation (memo)***

**Honoring America's Veterans and Caring for Camp Lejeune Families Act of 2012*

***To be completed for field use by 31DEC13*

**** Under review and consideration by VA*

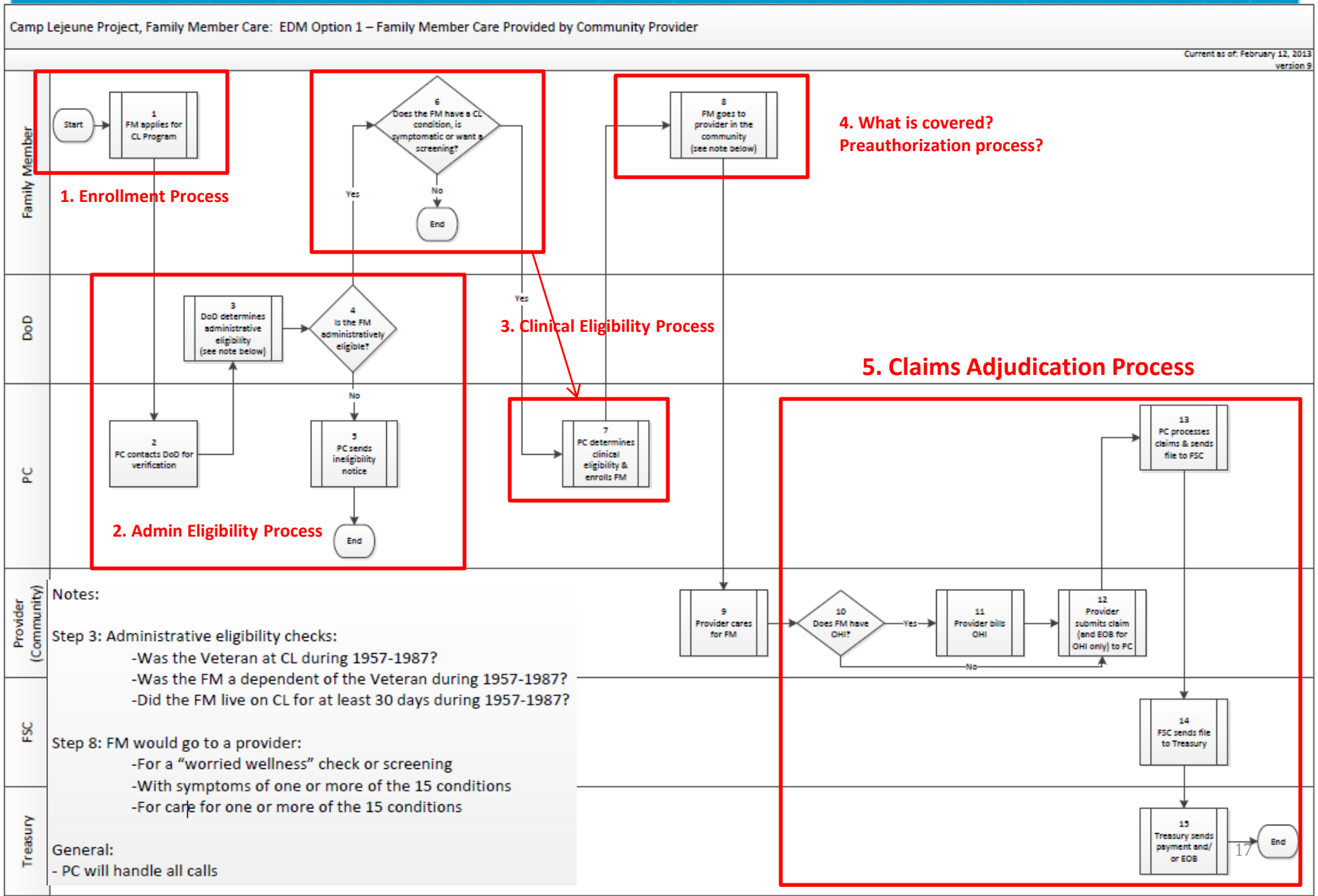
OMPF – Official Military Personnel Files

NPRC – National Personnel Records Center

DEERS - Defense Enrollment Eligibility Reporting System

High level flow diagram for FM care

Who, What, When, How, Resources, Time

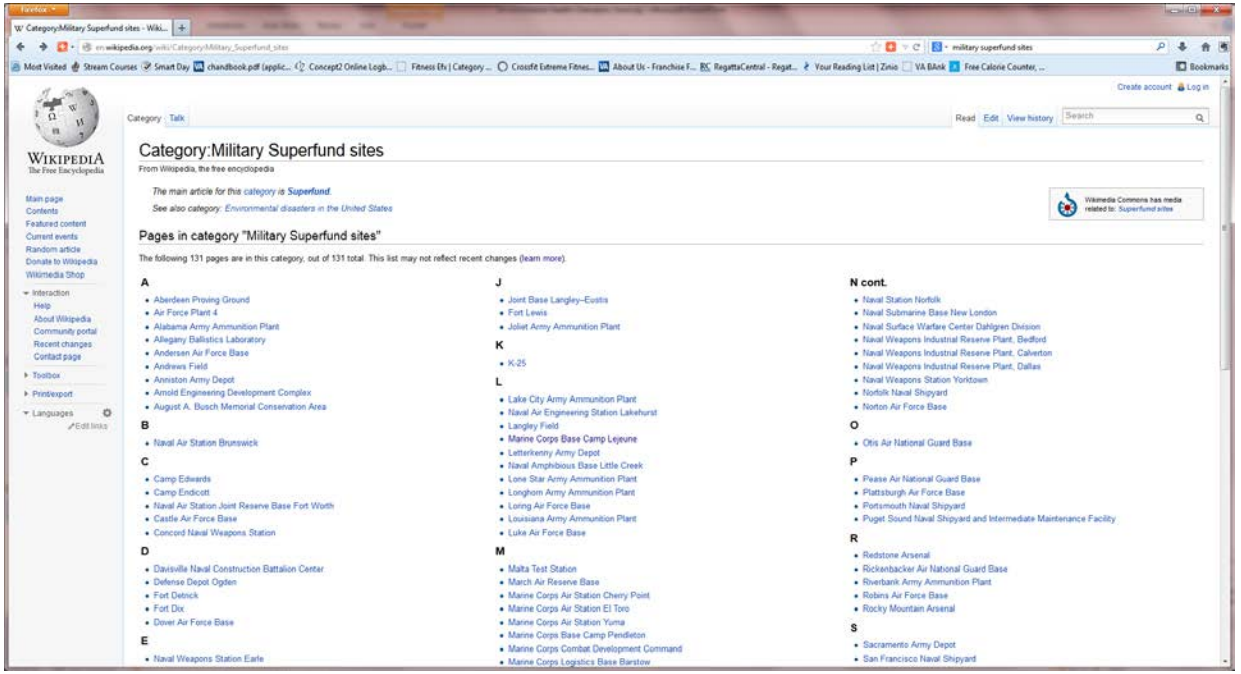


Camp Lejeune Clinical Guidelines

- Guidance for clinicians to determine if a qualified Camp Lejeune Veteran or FM has a medical condition or illness that is covered under the law
- 12 of the 15 medical conditions specified in the law have clear relatively unambiguous diagnostic criteria (example kidney or bladder cancer).
- 3 conditions specified in the law have less well established diagnostic criteria or many potential causes. In these cases determining if a CL Veteran or FM is covered will require medical judgment which integrates the clinical guidelines and the unique history of the individual Veteran or FM.
  - Hepatic steatosis has many common causes (alcohol abuse , obesity, medication side effects) not related to exposure to contaminated water at Camp Lejeune.
  - Neurobehavioral effects – many non-specific common symptoms such as headache and fatigue. Time course of symptoms is important.
  - Kidney toxicity – not a specific clinical diagnosis, many common causes such as long term diabetes
- If a clinician comes to the conclusion that it is more likely than not that the patient's medical condition is due to causes other than exposure to contaminated water at Camp Lejeune, then VA should not waive copayments for Veterans or reimburse care for FM.

Implications & Complications

- Law provides health care to family members - this requires new systems.
- Separates compensation health care benefits
- How does VA pay for partial health care?
- Does this set a precedent for other military camps, posts, & stations that are potentially contaminated?



Fort McClelland

- Proposed legislation: Fort McClellan Health Registry Act
- Alleged contaminants:
  - Barracks asbestos exposure
  - Chemical Corps and Edgewood Test Veterans
  - Leeching PCB's on the north end of the base from an improperly capped WW II landfill
  - The Pelham Range Radiological Contamination
  - TCE contamination of the Anniston water supply by the Army Depot
  - Monsanto air pollution

Residual Agent Orange Contamination – Gagetown, Canada

- Agent Orange, Agent Purple, and other herbicides were tested at CFB Gagetown for 3 days in June 1966 (June 14-16) and four days in June 1967 (June 21-24).
- The Canadian government has paid one-time, lump sum payments of $20,000 to those who worked on or lived within five km of the base between 1966 and 1967, and have illnesses associated with Agent Orange exposure.
- Maine National Guard Veterans were present at CFB Gagetown years later but are concerned that they were exposed to Agent Orange.
- Epidemiological studies of communities surrounding CFB Gagetown have shown a **lower** incidence of illness compared to the province of New Brunswick.
- Veterans who believe they were exposed to Agent Orange outside of Vietnam and have illnesses related to Agent Orange may apply for compensation. These cases are adjudicated on a case-by-case basis by the Veterans Benefit Administration.

Residual Agent Orange Contamination (AO) – C-123 Planes

- Small number of these C-123s (approximately 30) were rotated through Vietnam and used for the aerial spraying of tactical herbicides, such as AO.
- All C-123s in Southeast Asia were sent back to the United States where they were used by Air National Guard or Reserve units for the remainder of their useful life.
- Stateside C-123 crewmembers claim AO exposure based on a hexane wipe test sample of residual TCDD found in only one C-123 named “Patches”.
- Analysis of surface wipe samples taken from four mothballed Operation Ranch Hand C-123 aircrafts between 1996 and 2009 showed no evidence of TCDD in two of the aircraft and only trace amounts of TCDD in the other two.
- Air samples from all four planes showed no TCDD.
- The % of TCDD in a wipe sample obtained with a solvent does not translate into a high dose that would be absorbed by the human body.
  - The skin ia strong barrier against absorption.
  - Extremely high temperatures would be required to vaporize TCDD and make it available for absorption through the lungs.

Residual Agent Orange Contamination (AO) – C-123 Planes

- The 20-year longitudinal *Air Force Health Study*, initiated in 1982, followed and studied 1,261 Vietnam Veterans who were actual pilots and crew members of Operation Ranch Hand C-123s.
- As such, they were exposed to tactical herbicides on a daily basis and testing showed the presence of TCDD in their bodies.
- Current health data (obtained as late as 2012) fail to show a general increased risk of adverse long-term health effects when compared to other populations.
- Given that the evidence from actual participants in Operation Ranch Hand does not show a health risk from direct exposure to TCDD, it is difficult to ascertain a basis upon which to find a health risk among crew members of post-Vietnam Operation Ranch Hand C-123s.
- Veterans who believe they were exposed to Agent Orange outside of Vietnam and have illnesses related to Agent Orange may apply for compensation. These cases are adjudicated on a case-by-case basis by the Veterans Benefit Administration.

Summary

- All VA health care providers need to be aware of environmental exposure issues as they continue to be of significant concern to Veterans and their family members.
- It is essential but very challenging to provide good risk communication about the absolute and relative risks of environmental exposures.

QUESTIONS?

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta, GA 30341-3724

October 22, 2010

Mr. Donald R. Schregardus
Deputy Assistant Secretary of the Navy
Environment
1000 Nay Pentagon
Washington, D.C. 20350-1000

Lt. General Frank A. Panter
Deputy Commandant, Installations and Logistics
3000 Marine Corps, Pentagon, Room 4E516
Washington, D.C. 20350-3000

Dear Mr. Schregardus and Lt. General Panter:

I recently met with Senator Kay Hagan (D-NC) regarding our work on the potential for health effects from exposure to contaminated drinking water at Marine Corp Base Camp Lejeune (Camp Lejeune). During our conversation, it became evident that there was still some confusion regarding the position of the ATSDR regarding the 2009 National Research Council (NRC) report, *Contaminated Water Supplies at Camp Lejeune – Assessing* Potential Health Effects. Because of our collaboration and joint concern regarding exposures to military personnel, their families and others at Camp Lejeune, I wanted to be certain you understood our position regarding this report. This letter is intended to clarify our position and to provide a brief explanation on how we reached this position.

There is one constraint and five conclusions in the NRC report that are essential to the issue of whether harm may be expected in populations exposed to Camp Lejeune contaminated drinking water. These relate to:

1. the contaminants and health outcomes considered by the NRC;
2. the dose-response assessment used by the NRC;
3. the water modeling for Tarawa Terrace published by the ATSDR;
4. the use of alternative modeling strategies;
5. the need for detailed statistical analysis plans;
6. the utility of the epidemiological studies proposed by the ATSDR.

I will address each of these issues in sequence.

The NRC report only focused on tetrachloroethylene (PCE) and trichloroethylene (TCE), without considering other drinking water contaminants at Camp Lejeune such as benzene, vinyl chloride and mixtures of volatile organic compounds (VOCs). As noted in the very recent International Agency for Research on Cancer (IARC) Monograph Volume 100, benzene causes acute myologenous leukemia and is associated with other leukemias. The National Toxicology Program (NTP) Report on Carcinogens (ROC) reaches the same conclusion. Both reports reach a similar conclusion for vinyl chloride with regard to liver tumors. Both the IARC and the NTP label benzene and vinyl chloride as "known human carcinogens". The failure of the NRC Committee to consider these contaminants may lead one to conclude that the NRC findings of "*limited/suggestive evidence of an association*" pertains to all contaminants in the drinking water at Camp Lejeune. This conclusion would be incorrect based upon the evidence of the occurrence of these other exposures in Camp Lejeune drinking water. Thus, the review of cancer risks by the NRC was incomplete and only partially addressed concerns at Camp Lejeune. Finally, the NRC conclusions for PCE and TCE differ from the NTP and IARC which classify these chemicals as "probable human carcinogens" (IARC) or "reasonably anticipated to be a human carcinogen" (NTP) with various cancers including most notably kidney tumors.

Thus, let me be perfectly clear; there was undoubtedly a hazard associated with drinking the contaminated water at Camp Lejeune. The epidemiological studies and the associated exposure modeling will hopefully help us to decide on the level of risk associated with this hazard.

Although the availability of definitive reviews on other health endpoints besides cancer is limited, another shortcoming of the NRC review pertains to other health outcomes including adverse birth outcomes and immunotoxicity. In deciding what needed to be done to evaluate the potential health effects at Camp Lejeune, the ATSDR has taken all contaminants and all health outcomes into account and is acting accordingly.

ATSDR has studied the NRC report regarding the remaining issues. The use of the "lowest observed adverse effect level" (LOAEL) from animal studies without consideration of the uncertainties inherent in the LOAEL and the appropriateness of the use of this metric for assessing genotoxic cancer risks is a major shortcoming of the NRC report. Most regulatory agencies would either address the uncertainty in the LOAEL through the use of multiplicative factors to reduce the acceptable exposure or use an entirely different metric, such as the slope of the dose-response curve or a confidence bound around this curve, to arrive at values for comparison against environmental exposures. By doing neither, the NRC report suggests a much wider difference between exposure and effect

than would normally be derived. In determining potential risks in order to develop power calculations for our epidemiological investigations, the ATSDR used the slope of the dose-response curve.

ATSDR disagrees with the NRC Committee's conclusion that the results of the water modeling for Tarawa Terrace were not sufficiently reliable to do dose characterization in the epidemiological studies. Modeling of the movement of contaminants through sub-surface water is a well established area of science and has been used on multiple occasions to address exposures in communities throughout the United States [reference: Anderson, MP. 1979. Using models to simulate the movement of contaminants through ground water flow systems. Critical Reviews in Environmental Control, 9(2): 97–156.] The state-of-the-art modeling being conducted by ATSDR shows sufficient concordance between the modeled PCE results and the actual measurements of PCE in the finished water at Tarawa Terrace to conclude that one could characterize exposure into several different groups. This conclusion is critical to the future epidemiological studies since it allows ATSDR to separate highly exposed individuals from individuals exposed to moderate and/or low exposures from the drinking water thus limiting exposure misclassification and the resulting bias in the direction of no effect on the study populations. Without these different classifications, ATSDR would need to rely on a simple grouping of exposed versus unexposed, severely limiting the utility of the epidemiological evaluations.

ATSDR agrees with the NRC report that, due to the complexity of the situation at Hadnot Point, alternative modeling strategies should be considered. We have addressed this issue in the current modeling activities and are moving forward with a strategy that will yield sufficiently reliable estimates for this complex exposure scenario.

ATSDR also agrees with the NRC recommendation that detailed plans for the statistical analyses should be and have been developed by ATSDR for the re-analysis of the adverse pregnancy outcome study and the birth defect/childhood cancer case-control study. ATSDR disagrees with the NRC that these studies should be completed as soon as possible; data analysis will not proceed until the drinking water modeling has been completed and is available for both Hadnot Point and Tarawa Terrace.

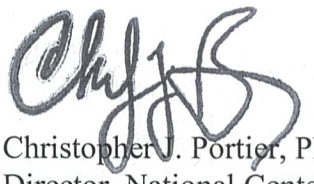
ATSDR disagrees with the NRC report's conclusion that the mortality study and the health survey/morbidity study lack sufficient statistical power and would be so limited by biases that they would not produce useful scientific information or be definitive. In the June 2008 ATSDR report Assessment of the Feasibility of Conducting Future Epidemiologic Studies at USMC Base Camp Lejeune, statistical power calculations were presented showing that the studies would have sufficient power for the cancers of interest, in particular, cancers associated with benzene, vinyl chloride, TCE or PCE exposure such as kidney cancer, non-

Hodgkin's lymphoma, leukemias, liver cancer, and esophageal cancer. Moreover, ATSDR emphasized that the studies would use standard research methodologies to minimize biases.

ATSDR is proceeding with the USMC Camp Lejeune Mortality Study and the Health Survey. ATSDR will establish a panel of experts to recommend adequate participation rates and consider potential biases in using the health survey for the follow-up morbidity study. We appreciate your financial support for these studies and your cooperation in the Data Discovery Technical Working Group. We are currently working on a request for additional FY 2011 funding requirements which should be completed soon.

Thank you again for your support.

Sincerely,



Christopher J. Portier, Ph.D.
Director, National Center for
Environmental Health, and
Agency for Toxic Substances and
Disease Registry