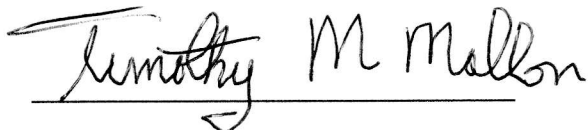


# Exhibit 402

# **Specific Causation Report of Timothy M. Mallon, M.D., M.P.H., MS. For Mr. David Downs**

**Prepared by:**

A handwritten signature in black ink that reads "Timothy M. Mallon". The signature is written in a cursive style with a horizontal line underneath the name.

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## **I. Summary of Opinions**

This report summarizes my medical expert opinion regarding the specific causation of Mr. David Downs' kidney cancer and the causal relationship between exposure to the chemicals in the water at the Camp Lejeune military base, including trichloroethylene (TCE), tetrachloroethylene (PCE) and vinyl chloride, and the development of Mr. Downs' kidney cancer. My opinions are based on my professional education, training and experience, knowledge of the pertinent scientific and medical literature reasonably relied upon by others in my profession and the documents cited in this report. I am qualified to evaluate the scientific literature and to render opinions about exposure to these substances causing kidney cancer. I hold all of my opinions in this report to a reasonable degree of medical and scientific certainty. I reserve the right to amend or supplement my report should new information become available.

Based on my general causation report on December 9, 2024, and the facts of this case, I conclude to a reasonable degree of medical and scientific certainty that Mr. David Downs' kidney cancer was more likely than not caused by the solvent exposure in the water at Camp Lejeune. This exceeds the "at least as likely as not" standard at issue in this litigation.

## **II. Expert Qualifications**

I am a Medical Doctor, board-certified in Preventive Medicine (Occupational Medicine). I hold a bachelor's degree in biology from Clarkson University. I earned a master's degree in public health from Johns Hopkins University School of Public Health in 1985; a master's degree in environmental health from CUNY Hunter College in 1986; and a Master of Science in Natural Resource Policy and Management from the University of Michigan, Graduate School of Natural Resources in 1987. I attended medical school at the Syracuse Upstate Health Science Center in Syracuse, New York in 1991.

Currently, I hold an adjunct Assistant Professor position in Preventive Medicine at Uniformed Services University in Bethesda, MD, and I consult for the Veteran's Evaluation Services and the Health and Human Services Federal Occupational Health Program. Prior to my retirement from military service in 2016, I was a full professor in Preventive Medicine at the Uniformed Services University from July 2004 to July 2016.

For over six years (January 2013 – August 2019), I led a team of investigators studying the association between certain diseases and exposures to burn pit smoke in Iraq and Afghanistan. This team included researchers from the University of Rochester, Clarkson University, Emory University, Uniformed Services University, and the Armed Forces Health Surveillance Agency. We completed a health assessment of 200 service members exposed to burn pit smoke in Iraq and Afghanistan which generated over 30 publications in the peer-reviewed literature and won several awards, including grants from NIEHS, and the Department of Defense's Defense Health Agency, and earned recognition by the American College of Occupational and Environmental Medicine.

I was awarded a Lifetime Achievement Award for Leadership in Academic Medicine and Research in 2019 and the Army Surgeon General's Academic Excellence Award "the A-

Designator” as the Residency Director in Occupational Medicine at the Uniformed Services University.

I served as the specialty editor for The Textbook of Military Medicine in Occupational and Environmental Medicine, the specialty editor of three supplements to the Journal of Occupational and Environmental Medicine in Workers Compensation Programs, and editor of two supplements on Burn Pit Exposures in Iraq and Afghanistan in 2016 and 2019.

I have authored or co-authored over 46 journal articles and written 23 book Chapters for the Textbook of Military Medicine and the Clinics of North America. I also served on the American Board of Preventive Medicine and the Accreditation Council for Graduate Medical Education Residency Review Committee in Preventive Medicine.

My training, expertise, and service have included work specific to environmental exposures and associated cancers. I trained specifically in toxicology, environmental health, environmental epidemiology, and cancer epidemiology as part of my coursework at Johns Hopkins University and CUNY. This included collaboration on epidemiologic studies of Agent Orange exposure, Non-Hodgkin’s Lymphoma, and soft tissue Sarcoma. I also served on the Advisory Board for several Residencies in Aerospace and Occupational and Environmental Medicine for the Air Force at Brook Air Force Base, Johns Hopkins Occupational and Environmental Medicine Residency Program in Baltimore Maryland, and the Navy School of Aerospace Medicine and Occupational Medicine in Pensacola, Florida.

I have taught over 200 residents in Occupational and Environmental Medicine as the Occupational and Environmental Medicine Residency Program Director at the Uniformed Services University in Bethesda, MD from 2005 to 2016. A copy of my curriculum vitae is attached as Exhibit 1.

### **III. Causation Standard**

I have reviewed the Camp Lejeune Justice Act of 2022 (CLJA),<sup>1</sup> which I understand to be the governing statute for the causation standard in this case. The CLJA requires that marines or family members bringing claims under the Act “show one or more relationships between the water at Camp Lejeune and the harm,” by “produc[ing] evidence showing that the relationship between exposure to the water at Camp Lejeune and the harm is – (A) sufficient to conclude that a causal relationship exists; or (B) sufficient to conclude that a causal relationship is at least as likely as not.”<sup>1</sup>

“As likely as not” is a standard that is less rigorous than a “more likely than not” standard. I am familiar with these terms and how the terms are applied in the sciences of environmental science, toxicology, epidemiology and other sciences dealing with these same issues.

I also reviewed the “ATSDR Assessment of the Evidence for the Drinking Water Contaminants at Camp Lejeune and Specific Cancers and Other Diseases” dated January 13, 2017.<sup>2</sup> The ATSDR Report used four categories to classify the strength of the evidence for a causal relationship between the chemicals in the water at Camp Lejeune and various harms. The

“Sufficient” and “Equipoise and Above” categories of this classification scheme employ the same language as the Camp Lejeune Justice Act: 1. Sufficient: “the evidence is sufficient to conclude that a causal relationship exists.” 2. Equipoise and Above: “the evidence is sufficient to conclude that a causal relationship is *at least as likely as not*, but not sufficient to conclude that a causal relationship exists.”<sup>2</sup> The authors of the ATSDR describe how, in their view, each of these categories can be met. For example, for “equipoise and above evidence for causation,” ATSDR states:

“Equipoise and above evidence for causation: The evidence is sufficient to conclude that a causal relationship is at least as likely as not, but not sufficient to conclude that a causal relationship exists. This category would be met, for example, if:

“1. The degree of evidence from human studies is less than sufficient but there is supplementary evidence from animal studies and/or mechanistic studies that supports causality, **or**

“2. A meta-analysis does not provide convincing evidence (e.g., the summary risk estimate is close to the null value of 1.0, i.e.,  $\leq 1.1$ ), or if the meta-analysis observes a non-monotonic exposure-response relationship) but there is at least one epidemiological study considered to be of high utility occurring after the meta-analysis has been conducted, in which an association between the exposure and increased risk of the disease of interest has been found and in which chance and biases can be ruled out with reasonable confidence.

“3. A meta-analysis has not been conducted, but there is at least one epidemiological study considered to be of high utility in which an association between the exposure and increased risk of the disease of interest has been found and in which chance and biases can be ruled out with reasonable confidence.”<sup>2</sup>

It is my opinion that these classifications are consistent with the sciences for which they apply (i.e., they are consistent with how the sciences of epidemiology, toxicology, and other related sciences apply these standards).

Based on my years of medical and epidemiological training and expertise, I am familiar with the term “equipoise,” and find ATSDR’s definition of “equipoise and above” or “at least as likely as not” to be appropriate in this case. The explanations by ATSDR for how each category of classification can be met are similarly appropriate for this case and based on sound scientific principles and methodology. Moreover, I have reached my opinion in this case to a reasonable degree of medical and scientific certainty under a “more likely than not standard,” which surpasses the “at least as likely as not” standard. I make clear throughout where each of my opinions are expressed under the “more likely than not” or “at least as likely as not” standard.

#### **IV. Methodology Employed**

The methodology I used to form my opinions in this case aligns with the standard practices that I and other experts utilize when conducting similar analyses. Specifically, my approach included

the following as stated in my general causation report, with additional methodology for these specific causation opinions:

- Conducting PubMed searches of peer-reviewed scientific literature examining associations between TCE, PCE, benzene, and/or vinyl chloride and kidney cancer.
- Searching the Cochrane database for systematic reviews and meta-analyses.
- Reviewing and analyzing reports from national and international agencies, such as the International Agency for Research on Cancer (IARC), the Agency for Toxic Substances and Disease Registry (ATSDR), the National Toxicology Program (NTP), and the United States Environmental Protection Agency (EPA). This included a thorough review and evaluation of the studies cited within these reports.

To contextualize my findings and to help with my analysis using a differential diagnosis approach for analyzing the risk factors involved in Mr. Downs' kidney cancer, I evaluated these studies and reports using the Bradford Hill<sup>3</sup> viewpoints, including strength of association, consistency, specificity, temporality, dose-response, plausibility, coherence, experiment, and analogy. While not every Bradford Hill viewpoint needs to be satisfied to establish causality, they serve as a valuable framework for causation determinations. In this report, I assess both the presence and strength of each Bradford Hill viewpoint and compare their relative significance to formulate my causation opinions. This assists in terms of what weight to give the causal association of the water at Camp Lejeune and Mr. Downs' kidney cancer.

Numerous epidemiological studies relevant to the association between TCE, PCE, Vinyl Chloride, and Benzene and kidney cancer are available. This section identifies and examines meta-analyses, cohort studies, case-control studies, ecologic/water-contamination studies, reports from national and international agencies, and Camp Lejeune-specific studies related to contaminants and kidney cancer. It is standard practice among experts in my field to consider data from each of these categories when conducting a causality assessment.

I also assess any relevant toxicology and mechanistic data that provide additional relevant information to this causal analysis.

After concluding that the water at Camp Lejeune causes kidney cancer, including the four main toxins at issue, I then looked to the specifics of Mr. Downs' case and whether the toxins he was exposed to caused his kidney cancer. I reviewed the medical records and deposition testimony provided. I examined other case-specific material that was provided to me regarding Mr. Downs' history and exposure to the water at Camp Lejeune. I examined all of the potential personal and environmental risk factors for kidney cancer and analyzed whether those risk factors were relevant to Mr. Downs. I then utilized a differential diagnosis approach for evaluating which of the risk factors were most relevant for Mr. Downs' kidney cancer.



## **V. Discussion**

### **A. Mr. David Downs Medical History and Treating Physician Depositions**

1. Mr. David Downs lived at Tarawa Terrace and worked on Hadnot Point from February of 1960 until September of 1961. He was exposed to contaminated water at Camp Lejeune while he lived and worked on base. Mr. Downs developed kidney cancer that was caused by his extended exposure to contaminated drinking water at Camp Lejeune.

2. Dr. Craig Brown saw Mr. Downs from 3/17/2015 to 12/26/2017 at Adventist Health. Dr. Brown recorded on March 17, 2015, that Mr. Downs height was 5 feet 8 inches, and his weight was 182 pounds and had a BMI of 27.7. His blood pressure was 122/68. Dr. Brown noted Mr. Downs was a former smoker but did not list any detailed history. Mr. Downs was seen for bronchitis and was given Azithromycin and cough medication. Mr. Downs' active problem list noted Diabetes Type II controlled (which turned out to be inaccurate), Hyperlipidemia, BPH and prior TURP in 2002, osteoarthritis and right hip replacement, and varicose veins. Mr. Downs had laboratory work drawn on 4/7/2015 and he had a small amount of albumin in his urine. Mr. Downs was seen by Dr. Brown on 1/28/2016 for lower abdominal pain, suprapubic pain, and constipation. His blood pressure was 132/72 and his BMI was up slightly at 28.2 but there was a different height used so that could account for the difference going from 5 feet 8 inches to 5 feet 7.7 inches. He was given a stool softener and a urine culture and urinalysis were done. Dr. Brown saw Mr. Downs on 5/16/2016 for viral gastroenteritis with diarrhea for the last week and a half and now has constipation. He has been having lower abdominal cramping which resolves after a BM. His blood pressure was 112/68, his temperature was normal, his weight was 184 pounds. Mr. Downs physical exam noted some abdominal tenderness in the suprapubic area. Dr. Brown recommended increasing fluids and to call if not better in a couple days. Dr. Brown saw Mr. Downs on 6/6/2016 for gross hematuria or blood in the urine. Mr. Downs stated that he had a couple of episodes of blood in the urine in the last 3 months and another episode the day before the office visit. His blood pressure was 118/62, his BMI was 28. Review of systems was negative for fever and malaise/fatigue; gastrointestinal was negative for heartburn, nausea, vomiting, abdominal pain, diarrhea, and constipation; genitourinary was negative for dysuria, urgency, frequency and flank pain. Mr. Downs physical exam was unremarkable. The urinalysis showed trace blood, and leukocytes were negative. Dr. Brown ordered a complete blood count, complete metabolic panel, and urinalysis with culture. He also referred Mr. Downs for a CT Urogram.

The CT Urogram showed a right kidney mass and Mr. Downs was referred to Dr. Koppie, Urology for evaluation of the kidney mass. Dr. Brown saw Mr. Downs on 12/13/2016 and noted that he had a right kidney nephrectomy, his BMI was 29.3 and his blood pressure was 120/76. Dr. Brown did note that Mr. Downs hemoglobin A1C was 5.7 at the time and that Mr. Downs reported he did not have a diagnosis of diabetes. At his next visit, Dr. Brown noted Mr. Downs was no longer taking Metformin, used to control diabetes, under the advice of the VA.

3. Dr. Teresa Koppie informed Mr. Downs the renal mass was likely kidney cancer on 6/20/2016 and performed a right kidney nephrectomy on 7/26/2016. She indicated Mr. Downs was an 81-

year-old male with a recent history of gross hematuria who noted he was having constipation and was straining when he experienced some blood in his urine. Mr. Downs has a history of BPH and had a TURP in 2002. Mr. Downs had a CT scan to determine the cause of the blood in the urine and the scan showed a 3.8-centimeter mid-pole lateral mass concerning for renal cell carcinoma. The mass was well circumscribed, exophytic, and abutting the renal collecting system. Mr. Downs had labs drawn that showed a BUN of 26, Creatinine was 1.0 and the EGFR was over 60. His blood pressure at the time of admission was 122/69. Mr. Downs was noted to have arthritis, joint pain, and hematuria. At this time, he did not have a diagnosis of hypertension, nor did he have diabetes mellitus Type II. Dr. Koppie testified that kidney cancer is a genetically driven disease and people have an acquired genetic risk when they are exposed to carcinogenic chemicals that may lead to kidney cancer. She worked at Convergent Genomics in the past and worked to find a urine biomarker that detects cancer in the urine. She testified that there is weak data for smoking causing kidney cancer.

4. Dustin V Shackleton, MD, wrote a Surgical Pathology Report dated 7/29/2016 and indicated that Mr. Downs right kidney mass, after nephrectomy, was noted to be a clear cell renal cell carcinoma that was 4 centimeters in size with extensive fibrosis, patchy hemorrhage, inflammation and focal necrosis. The ureter, vascular, and radial margins were negative for tumor and the background (non-involved) kidney was free of significant glomerular, tubulointerstitial, or vascular abnormalities. So, there was no evidence of underlying kidney disease at the time of the examination. There was mild hydronephrosis present.

5. Anisa Moore, MD, Internal Medicine wrote a Veteran's Administration Medical Opinion Disability Benefits Questionnaire dated 10/5/2017 and indicated that Mr. Downs is an 83-year-old man who was stationed at Camp Lejeune. He was diagnosed with kidney cancer in June of 2016, approximately 55 years after the veteran's service at Camp Lejeune. Mr. Downs worked as a real estate salesman before retiring and has no known family history of kidney cancer. Dr. Moore opined that Mr. Downs' kidney cancer is less likely than not caused by or a result of veteran's exposure to CL solvents and was more likely due to his smoking. She wrote that Mr. Downs medical records reveal that he has a history of smoking, and smoking is the single best recognized risk factor for kidney cancer per Moore et. al. (2014).<sup>4</sup> The reference actually states, "smoking is one of four risk factors to include obesity, hypertension, and diabetes mellitus Type II that account for 50% of the risk of kidney cancer."<sup>4</sup> Dr. Moore goes on to say that compared with never smokers, the risk of kidney cancer increases by 50% in male smokers per Hunt et. al. (2005).<sup>5</sup> Similarly, in the Macleod et. al. (2013)<sup>6</sup> VITAL study, smokers with more than 22.5 pack-years of exposure had a greater than 50% increased risk of renal cell carcinoma compared with never smokers. Dr. Moore did not take into account the 50 or more years of smoking cessation on the risk of renal cell cancer when she wrote that Mr. Downs risk of kidney cancer associated with smoking exceeded the risk of kidney cancer associated with exposure to CL contaminated water. Dr. Moore also did not take into account the fairly limited smoking history Mr. Downs did have in terms of pack years smoking. Yuan et. al. (1998)<sup>7</sup> reported a 70% reduction in risk after 25 or more years of cessation. Also, Hunt et. al.(2005)<sup>5</sup> performed a meta-analysis of 5 cohort studies and 19 case-control studies reporting similar findings regarding smoking cessation and reduced RCC risk, particularly among men.

6. Ms. Emily Brodin noted Mr. Downs' chronic kidney disease on 3/27/2024. She noted labs were ordered for Mr. Downs. Mr. Downs went to the laboratory on 2/7/2024 and his hemoglobin A1C was 5.1, creatinine was 1.26 and his glomerular filtration rate was 55 so there was evidence of Stage III A chronic kidney disease. The EGFR was 55 milliliters per minute. Mr. Downs was not taking any medication for diabetes type II at the time.

7. Keith Grau wrote a Medical Encounter Note dated 4/21/2014 and noted that Mr. Downs blood pressure was 129/69 mmHg, and his laboratory results showed his hemoglobin A1C was 6.0 mg/dL on 04/18/2013; and was previously 5.8 mg/dL on 05/18/2012 and 5.9 mg/dL on 07/21/2011.

8. Dr. Mathew Becker, DO, saw Mr. Downs from July 2018, to September 2022, Dr. Becker saw Mr. Downs on many occasions over this time frame and noted that Mr. Downs presented with Stage 3A kidney disease. Dr. Becker never diagnosed Mr. Downs with diabetes mellitus nor hypertension. Dr. Becker did not discuss the Camp Lejeune chemical drinking contamination with Mr. Downs.

9. Dr. Shejut Guha saw Mr. Downs on 4/7/2022 and noted that Mr. Downs had chronic kidney disease stage 3A. Dr. Guha testified that there are several risk factors for kidney disease that included age, gender, obesity, medications to include NSAIDs, and chronic diseases including nephritis, diabetes mellitus Type II, and hypertension. Dr. Guha had laboratory findings in the chart that noted Mr. Downs' blood glucose was 98 mg/dL that was in the normal range and the hemoglobin A1C was 5.7 which was borderline high in the pre-diabetic range. Dr. Guha testified Mr. Downs blood pressure was in the normal range with a reading of 113/63 and Mr. Downs BMI was 27.3 to 28.

Regarding the major risk factors for kidney disease and kidney cancer, Mr. Downs had minimal increased risk from his distant smoking. There was minimal risk from his pre-diabetes and being mildly overweight. There was mention of NSAID use increasing the risk of chronic kidney disease, but he was not prescribed NSAIDs by his treating providers and he was specifically counseled about not using NSAIDs due to the increased risk of worsening kidney disease.

## **B. Chemicals in the Water at Camp Lejeune Associated with Kidney Cancer Causation**

1. Mr. Downs worked on Hadnot Point and lived on Tarawa Terrace, so he had two sources of exposure while he was stationed at Camp Lejeune.

2. The current U.S. EPA maximum contaminant levels (MCLs) for TCE and PCE are 5 ppb, established in 1989 for TCE and in 1992 for PCE.<sup>2</sup> The MCL for Vinyl Chloride is 2ppb.<sup>2</sup>

3. There was water modeling done related to the water at Camp Lejeune that showed TCE, PCE, and Vinyl chloride levels exceeding these limits in 1960-time frame.

4. Mr. Downs was exposed to solvents at Camp Lejeune including TCE, DCE, PCE, Vinyl Chloride, and total volatile organic compounds which were the sum of all four chemicals present at Camp Lejeune.

5. Mr. Downs stayed at Tarawa Terrace for 19 months and two weeks from February 16, 1960, to September 27, 1961. Masila (2007)<sup>8</sup> and Bove et. al. (2014a)<sup>9</sup> noted that Tarawa Terrace had 3 main chemicals present in the drinking water that included TCE, PCE, and Vinyl Chloride at the time.

6. Mr. Downs also worked at Hadnot Point delivering mail and would drink water while working at Hadnot Point and also periodically drink water on his mail route.

### **C. Non-Camp Lejeune Personal Risk Factor Analysis for Mr. Downs' Kidney Cancer**

1. Mr. Downs has few personal risk factors for developing kidney cancer. He was 82 years old when he developed kidney cancer, so he was at slight increased risk due to his age. However, age is not thought of as a significant risk factor for the causation of kidney cancer.

2. Obesity can be a cause of kidney tumors. Mr. Downs was slightly overweight when he was diagnosed with Kidney cancer and had a BMI of 28.1. A BMI of 28 is not significantly elevated and would come with a very little additional risk of kidney cancer.

4. Mr. Downs is a male, so he was slightly at increased risk due to his gender.

5. Mr. Downs was a prior smoker who stated that he smoked about a pack a day (sometimes slightly more) for approximately five years when he was in the military. There are medical records indicating Mr. Downs indeed smoked for approximately five years and there are medical records indicating he smoked for fifteen years. Mr. Downs says the medical records stating fifteen years are inaccurate. The point is ultimately moot, because whether Mr. Downs smoked for five years or fifteen years, the smoking occurred at a remote time and while it is considered a risk factor, its weight is much less because it is so distant. Mr. Downs stopped smoking, according to his testimony, approximately 50 years prior to his developing kidney cancer and renal failure. The medical literature does not support an increased risk of kidney cancer in former smokers who have over 25 years of smoking cessation. Cote et. al. (2012)<sup>10</sup> reported that the longer the period of smoking cessation, the greater the reduction in risk compared with current smokers (Ptrend = 0.008). Cote et. al. noted there was a 70% reduction in risk among those with 25+ years of smoking cessation (OR, 0.29; 95% CI, 0.13–0.65).<sup>10</sup>

6. Mr. Downs does not have hypertension now nor did he have hypertension when he was diagnosed with kidney cancer in 2016. The risk of kidney tumors is higher in people with high blood pressure. However, Mr. Downs does not have high blood pressure, nor does he take hypertensive medication, so he was not at increased risk of kidney cancer due to hypertension nor medication usage.

7. Mr. Downs likely does not have diabetes mellitus type II, even though there is a record stating it was a diagnosed condition. His blood sugars have fluctuated from normal into the pre-diabetic range and he has controlled his blood sugars by diet. He does not take Metformin for blood

glucose control. His most recent blood glucose was in the normal range and his hemoglobin A1C was 5.1 which was also in the normal range in July 2024. Therefore, he has virtually no increased risk from this potential risk factor.

8. People with a strong family history of kidney cancer have higher chance of developing kidney cancer. Usually this needs to occur with multiple people in different generations. Mr. Downs did not have such a family history and had virtually no increased risk of kidney cancer due to his family history.

9. Many studies have suggested that workplace exposure to toxic substances can increase the risk for kidney cancer. Some of these substances are cadmium, herbicides, organic solvents and lead. Mr. Downs did not have these exposures.

10. The medical literature on Crohn's disease indicates that individuals who have longstanding Crohn's disease are at increased risk of developing kidney cancer. Mr. Downs did not have a history of Crohn's disease, nor did he have a family history, so he was not at increased risk.

#### **D. Camp Lejeune Water Contamination Related Risks and the Levels that are Hazardous to Humans and Cause Kidney Cancer**

##### **1. Total Volatile Organic Compounds Exposure Risk and Kidney Cancer**

a. The chemicals in the water at Camp Lejeune, namely TCE, PCE, and VC, in combination, have been shown to be very dangerous to humans and create a significantly increased risk of kidney cancer.

b. Mr. Downs TVOC exposures at Camp Lejeune were estimated based on water modeling done by Masilla.<sup>8,11</sup> The total volatile organic compound (TVOCs) levels in the drinking water at Tarawa Terrace on Camp Lejeune when Mr. Downs was present ranged from 31.17 micrograms per liter (ug/L) to 64.40 ug/L for the Techflow model. Mr. Downs' total volatile organic compound (TVOC) exposure amounted to 1104 ug/L-month exposure to TVOCs during his 19 months at Tarawa Terrace. At Hadnot Point, Mr. Downs would have been exposed to concentrations in the water of 282 ug/L-month of TVOCs. Mr. Downs lived at Tarawa Terrace and worked at Hadnot Point. He would therefore have been exposed to the concentrations listed above from Tarawa Terrace when on that part of the base and the concentrations from Hadnot Point when he was at work.

c. Bove et. al 2014a<sup>9</sup> and 2014b<sup>12</sup> conducted cohort mortality studies of Marines/Navy personnel and civilian workers at Camp Lejeune. Bove et. al. (2014a)<sup>9</sup> reported that TVOC exposures between 1 and 4600 ug/L-months fall into the low exposure category for kidney cancer risk. Mr. Downs TVOC exposure would fall in the low exposure category and Bove reported this exposure category had a 1.42-fold increased risk of kidney cancer (95%CI: 0.58 to 3.47) due to TVOC exposure.<sup>9</sup>

d. Dr. Bove and ATSDR performed other studies that reflect a time on base quantification of exposure. These studies also help support the opinion that Mr. Downs kidney cancer was caused

by the water at Camp Lejeune.

## 2. Perchloroethylene Exposure and Kidney Cancer Risk

a. Mr. Downs exposure to PCE was approximately 939 ug/L-months during his time at Tarawa Terrace. This would place Mr. Downs in the high exposure category based on Bove et. al. (2014a)<sup>9</sup> Table 6.

b. Based on Bove et. al. (2014a)<sup>9</sup> Table 7, the high exposure category for cumulative PCE exposure was 1.59 (95% CI: 0.66 to 3.86) so Mr. Downs had a 1.59-fold elevated risk of kidney cancer due to his PCE exposure.

c. Aschengrau A, Ozonoff D, Paul C, et al.<sup>13</sup> noted an elevated kidney cancer risk with PCE in the range of 27-44 mg of PCE in the drinking water at Cape Cod. Mr. Downs' total cumulative PCE exposure exceeded these exposure numbers from Aschengrau to a reasonable degree of certainty.<sup>13</sup> As will be discussed below, the charts from Plaintiff's expert Kelly Reynolds show Mr. Downs ingested between 23,000 (23mg) and 59,000 ug (59mg) of PCE alone, depending on the assumptions used. This would exceed the Aschengrau numbers without factoring in inhalation and dermal exposure, which we know may be as high as the dose from the ingestion route.<sup>9</sup> For example, an internal dose via inhalation of volatile organic compounds during a 10-minute shower may be greater than internal dose via the ingestion of 2 liters of volatile organic compounds-contaminated drinking water.<sup>14</sup> It should also be noted that the 27-44mg numbers listed by Aschengrau were up to the 90<sup>th</sup> percentile.<sup>13</sup>

d. ATSDR (2018)<sup>15</sup> performed a morbidity study of Marines and Navy personnel who were assigned to Camp Lejeune and compared the results with personnel stationed at Camp Pendleton. The study found that there was an increased risk for cancers, including kidney cancer, as a result of exposure to water contaminated with perchloroethylene (PCE).<sup>15</sup> The morbidity study of Marines and Navy personnel stationed at Camp Lejeune, found an elevated Odds Ratio for kidney cancer of 1.31 (95% CI: 0.86, 1.99) compared to Camp Pendleton.<sup>15</sup> For high residential exposures ( $\geq$ 90th percentile) to PCE, the OR was even higher at 1.79 (95% CI: 1.02, 3.12). The Odds Ratio for high PCE exposure was 2.01 (95% CI: 1.29, 3.13) and a monotonic exposure-response relationship was observed.<sup>15</sup> These findings support Mr. Downs' contention that his solvent exposure at Camp Lejeune, particularly PCE, caused his kidney cancer.

e. The Bove (2024)<sup>16</sup> cancer mortality study compared Marines and Navy personnel to Camp Pendleton personnel and noted an increased risk of death from kidney cancer with a SMR of 1.22 (95% CI: 1.03, 1.45) (Table S2). The civilian worker analysis noted an elevated SMR for kidney cancer death of 1.49 (95% CI: 0.76, 2.92).<sup>16</sup> The study also analyzed kidney cancer risk relative to exposure duration, measured by time spent on base. For personnel with low duration of exposure (1–2 quarters), the risk ratio was 1.33 (95% CI: 0.95-1.86) (Table S6).<sup>16</sup> For medium-term exposure (2–7 quarters), the risk ratio was 1.23 (95% CI: 0.88–1.72) (Table S.6).<sup>16</sup> These findings suggest that even the short exposure durations on base are linked to a higher risk of death due to kidney cancer.



f. The Bove et al. (2024)<sup>17</sup> conducted a cancer incidence study on Camp Lejeune personnel that noted Camp Lejeune Marines/Navy personnel had an elevated standardized incidence ratio (SIR) for renal cell carcinoma, NOS of 1.12 (95% CI: 0.94-1.34). These findings suggest that individuals exposed to contaminated water at Camp Lejeune were at above equipose elevated risk of developing kidney cancer. The study also analyzed kidney cancer risk relative to exposure duration, measured by time spent on base. The category for low duration was 1-6 quarters.<sup>17</sup> The medium duration of exposure was 7-10 quarters on base, and the high duration of exposure was over 10 quarters.<sup>17</sup> For personnel with low exposure levels, the risk ratio for RCC-NOS was 1.12 (95% CI: 0.91–1.38).<sup>17</sup>

g. As stated in my general causation report, PCE is a major cause of kidney cancer. In particular there is evidence from the studies of Camp Lejeune itself that show that individuals with high PCE exposure have a substantial risk of kidney cancer. I incorporate my general causation report statements as to the causal relationship between PCE and kidney cancer into this report. There were many studies cited in that report showing a causal association between PCE and kidney cancer, including at similar levels that existed for Mr. Downs.

h. In summary, the epidemiological evidence of an association between Mr. Downs' PCE exposure and kidney cancer exists and is supported by many different epidemiological studies, supported by animal data and mechanistic studies that support a causal association. In my opinion, the analysis of the currently assembled evidence, using the Bradford Hill framework, makes it more likely than not that Mr. Downs' PCE exposure is causally related to his kidney cancer (and therefore also exceeds the "standard of at least as likely as not" prescribed by the Camp Lejeune Justice Act.).

### **3. TCE Exposure and Kidney Cancer Risk**

a. Mr. Downs had TCE exposure at Tarawa Terrace that ranged from 1-3 ug/L-month and this totaled 43 ug/L-months over the 19 months at Tarawa Terrace. Mr. Downs also had 9 to 19 ug/L-months of TCE exposure at Hadnot Point which totaled 282 ug/L-months cumulative exposure while at Hadnot Point for 19 months.

b. Bove et al. (2014a)<sup>9</sup> noted that people with TCE cumulative exposure from 1 to 3100 ug/L-months were in the low exposure category and these individuals had a 1.54-fold increased risk of kidney cancer due to TCE exposure. Mr. Downs TCE exposure was in the lower end of the exposure range.

c. ATSDR (2018)<sup>15</sup> performed a morbidity study of Marines and Navy personnel who were assigned to Camp Lejeune and compared the results with Camp Pendleton. The study found that there was an increased risk for kidney cancer of 1.31 (95% CI: 0.86, 1.99). For high residential exposures ( $\geq 90$ th percentile) to TCE, the risk ratio was 1.55 (95% CI: 0.95, 2.54) and a monotonic exposure-response was observed.<sup>15</sup>

d. As stated in my general causation report, it is clear that TCE is a cause of kidney cancer. I incorporate my general causation report statements as to the causal relationship between TCE and kidney cancer into this report. There were many other studies cited in that report showing a

causal association between TCE and kidney cancer, including at similar levels that existed for Mr. Downs.

e. Mr. Downs' exposure to TCE is more likely than not causally related to his risk of kidney cancer.

#### **4. Vinyl Chloride Exposure and Kidney Cancer Risk**

a. Mr. Downs' monthly exposure to Vinyl Chloride ranged from 5 to 8 ug/L over the 19 months of exposure and the total cumulative Vinyl Chloride exposure was 122 ug/L-months.

b. Bove et. al. (2014a)<sup>9</sup> noted in table 6 that the total cumulative VC low exposure category ranged from 1-205 ug/L-months. Mr. Downs' exposure of 122 ug/L-months falls above the middle of the low exposure range. Bove et. al. (2014a)<sup>9</sup> found there was an elevated 1.66 fold increased risk of kidney cancer in the low exposure category for VC exposure, therefore Mr. Downs had a 1.66-fold increased risk of kidney cancer due to the VC exposure per Bove et. al. (2014a)<sup>9</sup>. Mundt et. al. (2017)<sup>18</sup> noted that kidney cancer deaths from VC exposure were elevated with an SMR=1.16, (95%CI 0.87 to 1.53). Hu J. et. al (2002)<sup>19</sup> found a 2-fold elevated risk of kidney cancer (95% CI: 1.2–3.3) in individuals exposed to vinyl chloride.

c. In summary, the epidemiological studies indicate a connection between Vinyl chloride and Kidney cancer per Hu 2002<sup>19</sup>, Bove 2014a<sup>9</sup>, and Mundt et. al. (2017)<sup>18</sup>. In my opinion, the analysis of the currently available medical evidence using the Bradford Hill framework makes it at least as likely as not that Vinyl Chloride is a cause of kidney cancer to a reasonable degree of medical certainty. Mr. Downs was at elevated risk due to his VC exposure and Mr. Downs met the threshold for several levels in the literature associated with kidney cancer.

#### **VI. Additive Effects of TCE, PCE and Vinyl Chloride on Kidney Cancer Risk**

When considering the carcinogenic potential of simultaneous exposure to two or more known carcinogens, one may reasonably and scientifically anticipate that the carcinogens increase risk of cancer in an additive fashion-which is typically the default assumption when regulators assess chemicals that act through a common mode of action. Adding the effects of TCE, PCE and Vinyl chloride in kidney cancer risk would be a reasonable approach to assess the total risk, since these chemicals have similar breakdown products and have similar mechanisms of action. The chemicals have been shown to be genotoxic by causing damage to DNA and to cause chromosomal malformations. As such, in my opinion, it is reasonable to apply an additive approach to carcinogens with a common mode of action and conclude that the combined risk is more likely than not to be at least additive.

#### **VII. Mr. Downs' Exposure at Camp Lejeune**

Mr. Downs lived at Tarawa Terrace and worked at Hadnot Point. Mr. Downs had exposure to the following concentrations in the water during his time at Camp Lejeune in his 589 days on base: 43 microgram/liter TCE, 939 microgram/liter PCE and 122 microgram/liter vinyl chloride at Tarawa Terrace. He was exposed to approximately 282 microgram/liter TCE at Hadnot Point.



The below chart summarizes Mr. Downs exposures at Tarawa Terrace:

Exposure Dates	TC E (ug/ l- M)	PCE (ug/l- M)(TechFlo wMP Model)	PCE (ug/l- M)(MT3D MS Model)	VC (ug/ l- M)	BZ (ug/ l- M)
2/16/1960-02/29/1960	1	31	44	5	0
3/1/1960-03/31/1960	2	33	46	5	0
4/1/1960-04/30/1960	2	34	48	5	0
5/1/1960-05/31/1960	2	36	50	5	0
6/1/1960-06/01/1960; 06/02/1960- 06/10/1960; 06/11/1960-06/30/1960	2	37	53	5	0
7/1/1960-7/31/1960	2	39	55	5	0
8/1/1960-8/31/1960	2	40	57	6	0
9/1/1960-9/30/1960	2	42	59	6	0
10/1/1960-10/31/1960	2	44	61	6	0
11/1/1960-11/30/1960	2	46	63	6	0
12/1/1960-12/31/1960	2	47	66	6	0
1/1/1961-1/31/1961	2	49	68	6	0
2/1/1961-2/4/1961; 2/5/1961-2/12/1961; 2/13/1961-2/28/1961	2	51	70	6	0
3/1/1961-3/30/1961	2	53	72	7	0
4/1/1961-4/30/1961	2	55	73	7	0
5/1/1961-5/8/1961; 5/9/1961-5/17/1961; 5/18/1961-5/31/1961	3	57	75	7	0
6/1/1961-6/22/1961; 6/23/1961-6/30/1961	3	59	77	7	0
7/1/1961-7/31/1961	3	60	79	7	0
8/1/1961-8/31/1961	3	62	81	7	0
9/1/1961-9/27/1961	3	64	83	8	0
	43	939	1281	122	0

The concentrations Mr. Downs was exposed to at Hadnot Point were as follows:

Exposure Dates	Total Days	Exposure Location (Work)	TCE (ug/l-M)	PCE (ug/l-M)	VC (ug/l- M)	BZ (ug/l- M)
2/16/1960-02/29/1960	14	Hadnot Point	11	0	0	0
3/1/1960-03/31/1960	31	Hadnot Point	9	0	0	0

4/1/1960-04/30/1960	30	Hadnot Point	16	0	0	0
5/1/1960-05/31/1960	31	Hadnot Point	13	0	0	0
6/1/1960-06/01/1960; 06/11/1960-06/30/1960	21	Hadnot Point	12	0	0	0
7/1/1960-7/31/1960	31	Hadnot Point	12	0	0	0
8/1/1960-8/31/1960	31	Hadnot Point	15	0	0	0
9/1/1960-9/30/1960	30	Hadnot Point	14	0	0	0
10/1/1960-10/31/1960	31	Hadnot Point	13	0	0	0
11/1/1960-11/30/1960	30	Hadnot Point	18	0	0	0
12/1/1960-12/31/1960	31	Hadnot Point	14	0	0	0
1/1/1961-1/31/1961	31	Hadnot Point	16	0	0	0
2/1/1961-2/4/1961; 2/13/1961- 2/28/1961	20	Hadnot Point	12	0	0	0
3/1/1961-3/31/1961	31	Hadnot Point	10	0	0	0
4/1/1961-4/30/1961	30	Hadnot Point	18	0	0	0
5/1/1961-5/8/1961; 5/18/1961- 5/31/1961	22	Hadnot Point	15	0	0	0
6/1/1961-6/22/1961	22	Hadnot Point	14	0	0	0
7/1/1961-7/31/1961	31	Hadnot Point	14	0	0	0
8/1/1961-8/31/1961	31	Hadnot Point	19	0	0	0
9/1/1961-9/27/1961	27	Hadnot Point	17	0	0	0
	556		282	0	0	0

During the time Mr. Downs was present at Tarawa Terrace, he would have been exposed to the concentrations in the TT chart. During the time Mr. Downs was at work, he would have been exposed to the concentrations in the HP chart.

## VIII. Substantial Exposure

Mr. Downs had a substantial exposure while at Camp Lejeune. First, he was on base for 589 days. Mr. Downs testified that even during his annual leaves, he would stay on base at Tarawa Terrace. Thus, his body, and in particular his kidneys, never got a break from the assault of the chemicals at issue because of his exposure.

As evidence of his substantial exposure, Mr. Downs testified to the following at his deposition:

1. Mr. Downs often drank water at Camp Lejeune from the tap and from water fountains. Downs Dep. 109:18-21, 110:8-17, 110:21-112:6. There was a water cooler at his work that he would drink from several times a day. Downs 5-8-24 Dep. 22:4-7. With lunch he would often have a fountain coke or water. Downs 5-8-24 Dep. 22:21 – 23:6. With dinner, he testified he would have coffee or water. Downs 5-8-24 Dep. 22:3-10.
2. Mr. Downs showered once a day for 15 minutes. Downs Dep. 115:2 -116:15.
3. Mr. Downs worked in base headquarters at Hadnot Point and would drink from the tap. 01145\_DOWNS\_VBA\_0000000312; Downs Dep. 20:5-7.
4. Mr. Downs worked five days a week. He would work weekends as well on occasion. Downs Dep.97:8-13.
5. He lived with his wife at Tarawa Terrace and he would spend his time at Tarawa Terrace when he was not at work. Downs Dep. 97:14-98:1, 98:17-99:2; 01145\_DOWNS\_VBA\_0000001528; 01145\_DOWNS\_VBA\_0000001530; 01145\_DOWNS\_VBA\_0000001532.

Mr. Downs was exposed to TCE, PCE and Vinyl Chloride. Each of these chemicals is causally related to kidney cancer. Many different government agencies have classified these toxins as carcinogenic and mutagenic chemicals. Mr. Downs was drinking the toxic water, inhaling the toxic chemicals in the water and absorbed the toxic chemicals through his skin. Mr. Downs was frequently and consistently exposed to these toxins during his almost 600 days on base. When assessing whether an exposure is substantial or not, it is important to look at the duration of the exposure, the amount of the exposure, the frequency of the exposure and the intensity. In terms of duration, we know Mr. Downs was on base for approximately 589 days. In terms of the amount of exposure, we know Mr. Downs was exposed to very high levels of PCE, TCE and VC. These were discussed in the charts above, in the epidemiology cited above and in my general causation report. As listed above, Mr. Downs would be consistently drinking water at Camp Lejeune. He would drink with meals, at work and in between. He showered in the water, inhaling the steam on a daily basis. The intensity of the exposure is high. For example, Mr. Downs' PCE exposure would have been in the highest metrics of some of the Camp Lejeune studies themselves.

I formed my opinion that Mr. Downs had substantial exposure based upon the medical records, depositions and water modeling reports. I also had a chance to review the ingestion summary reports from Plaintiff's expert Kelly Reynolds. Dr. Reynolds calculated estimated doses of ingestion for Mr. Downs. These charts support my opinion that Mr. Downs sustained a substantial exposure that was causally related to his kidney cancer and are consistent with these opinions. For example, Dr. Reynolds' ingestion calculations indicate Mr. Downs ingested the following amounts of the following chemicals based on her different assumptions:

		Chart 1: 1L at each location	Chart 2: ATSDR RME with proportional work/residence exposures	Chart 3: ATSDR CTE with proportional work/residence exposures	Chart 4: Deposition Estimates with proportional work/residence exposures
	Cumulati ve ug/l- M	Cumulative consumption (total ug= days*concentra tion per L)	Cumulative consumption (total ug= days*concentra tion per ATSDR exposure assumptions)	Cumulative consumption (total ug= days*concentra tion per ATSDR exposure assumptions)	Cumulative consumption (total ug= days*concentra tion per deposition exposure assumptions)
<b>Hadnot Point</b>					
<b>TCE</b>	282	7,866	8,151	3,234	8,029
<b>PCE</b>	-	-	-	-	-
<b>VC</b>	-	-	-	-	-
<b>BZ</b>	-	-	-	-	-
<b>Tarawa Terrace</b>					
<b>TCE</b>	43	1,240	2,635	1,046	2,596
<b>PCE (ug/l- M)(TechFlow MP Model)</b>	939	27,838	59,157	23,475	58,278
<b>PCE (ug/l- M)(MT3DMS Model)</b>	1,281	37,980	80,689	32,020	79,491
<b>VC</b>	122	3,586	7,615	3,022	7,502
<b>BZ</b>	-	-	-	-	-
<b>Totals HP &amp; TT</b>					

<b>TCE</b>	325	9,106	10,786	4,280	10,626
<b>PCE (ug/l-M)(TechFlow MP Model)</b>	939	27,838	59,157	23,475	58,278
<b>PCE (ug/l-M)(MT3DMS Model)</b>	1,281	37,980	80,689	32,020	79,491
<b>VC</b>	122	3,586	7,615	3,022	7,502
<b>BZ</b>	-	-	-	-	-

Ingestion of thousands of ppb of TCE is a substantial exposure. This effect was amplified by the fact that according to Dr. Reynolds, Mr. Downs would have also ingested between 23,000 ppb and 59,000ppb of PCE. As described before, these are incredibly high levels for PCE exposure. It evidences the appropriateness of listing Mr. Downs as exceeding many of the metrics in the literature, both at Camp Lejeune and outside of Camp Lejeune, relating to a risk of kidney cancer. Importantly, this exposure is an underestimate of the cumulative ppb of chemicals that actually entered his body. That is because Dr. Reynolds' calculations only related to ingestion. Mr. Downs had additional exposure through inhalation of chemicals and dermal absorption of chemicals as well. The numbers in the chart would be larger and would be even more indicative of the substantial nature of the exposure for Mr. Downs.

#### **IX. Differential Diagnosis Methodology to Determine the Etiology of Mr. Downs' Kidney Cancer**

There were a number of sources used to develop a list of personal risk factors for kidney cancer. For example, the Mayo Clinic Fact Sheet on Kidney Cancer<sup>20</sup> was reviewed. Each of these personal risk factors was considered as potentially contributing to the cause of Mr. Downs kidney cancer. It is common practice in environmental medicine to conduct a differential diagnostic process where we proceed step by step in considering each potential risk factor to see if the plaintiff had one of the listed risk factors for kidney cancer. If the plaintiff does have the risk factor, an analysis of the relative contribution of this risk factor to the cause of the individual's kidney cancer is conducted. Then, once all the personal risk factors are considered, a weighing of all the personal risks is done by adding the individual risks together to come up with a summative personal risk estimate. Then, the individual's environmental risks are considered in a similar fashion to develop an environmental risk estimate. Finally, the personal risk factors are compared with the environmental risks. A weighing of the relative personal risks and environmental risks provides a good indicator of whether the kidney cancer was due to environmental risks or personal risks.

The personal risk factors for kidney cancer are well documented in the medical literature and are noted above in this report. Mr. Downs had few personal risk factors for the development of his kidney cancer other than his exposure to the toxins at Camp Lejeune. For purposes of the differential diagnosis, these risk factors will be briefly stated again below with an analysis of why they do not apply. Following this, an analysis of all of Mr. Downs environmental risks are

summarized from the sections. Finally, the personal risks are compared with the environmental risks to see if personal risks or environmental risks outweigh the other.

Mr. Downs was slightly overweight when he was diagnosed with Kidney cancer, so he was only at a minimally increased risk due to his weight.

Mr. Downs was a short-term smoker who smoked about a pack a day for 5 years based on various reports in his medical record and deposition. There are medical records indicating that Mr. Downs may have smoked for 15 years, but Mr. Downs disputes the accuracy of those records. Mr. Downs quit smoking approximately 50 years before his kidney cancer diagnosis if his deposition testimony is accurate. Thus, the length of smoking cessation largely eliminated his risk of kidney cancer. This would be true even with an assumption he smoked for 15 years and quit 40 years before his kidney cancer diagnosis.

Mr. Downs age was 82 years old when he was first diagnosed with kidney cancer in 2016, so he was at a slightly increased risk of developing kidney cancer due to his age.

Kidney cancer is more common in men, so Mr. Downs was at a slightly increased risk due to his gender. Mr. Downs is Caucasian, so he was not at an increased kidney cancer risk due to ethnicity. Mr. Downs did not have high blood pressure prior to the time he was diagnosed with kidney cancer. Mr. Downs has a family history of other cancers in his family, but no one that was diagnosed with kidney cancer. His brother was diagnosed with prostate cancer according to his deposition testimony. This does not meet the criteria for having a family history of kidney cancer which requires kidney cancer in family members across multiple generations.

Mr. Downs' TVOC exposures at Camp Lejeune were estimated based on water modeling performed by Masilla.<sup>8,11</sup> Mr. Downs' total volatile organic compound (TVOC) exposure amounted to approximately 1104 ug/L-month at Tarawa Terrace during his 19 months at Camp Lejeune and 282 ug/L-month at Hadnot Point for work. Bove et. al. (2014a)<sup>9</sup> reported that TVOC exposures between 1 and 4600 ug/L-months fall into the low exposure category for kidney cancer risk. Using Bove et. al. (2014a)<sup>9</sup> risk determination for low TVOC levels in the Camp Lejeune Cohort, Mr. Downs TVOC exposure increased his risk of kidney cancer by 1.42-fold.

Mr. Downs exposure to PCE for 19 months at Camp Lejeune was 939 ug/L-months at Tarawa Terrace. Based on the assessment discussed above, Mr. Downs exposure to PCE was in the high-risk category determined by Bove et. al (2014a).<sup>9</sup> So, this increased Mr. Downs' kidney cancer risk by 1.59-fold.<sup>9</sup> Mr. Downs cumulative PCE exposures levels were as high or higher than the levels noted by Aschengrau to cause cancer.<sup>13</sup> The ATSDR (2018)<sup>15</sup> study found an increased risk for kidney cancer due to high exposure to PCE with an elevated risk ratio of 2.01 (95% CI: 1.29, 3.13). These findings, especially the Camp Lejeune specific studies, give support to the fact that Mr. Downs PCE exposure was more likely than not causally related to the development of kidney cancer.

Mr. Downs had TCE exposure at Hadnot Point and Tarawa Terrace. The total amounts were 43 ug/L-month at TT and 282 ug/L-month at HP. Bove et al. (2014a)<sup>9</sup> noted that people with TCE

cumulative exposure from 1 to 3100 ug/L-months were in the low exposure category and these individuals had a 1.54-fold increased risk of kidney cancer due to TCE exposure. ATSDR (2018)<sup>15</sup> performed a morbidity study of Marines and Navy personnel assigned to Camp Lejeune and found that there was an increased risk for kidney cancer due to medium exposure to TCE of 1.33-fold (95% CI: 0.84, 2.13). Mr. Downs TCE exposure totaled between the two locations was 324 ug/L which was in the lower of the exposure ranges for the low exposure to TCE in Bove 2014a.<sup>9</sup> More likely than not Mr. Downs TCE exposure was causally related to his kidney cancer.

Mr. Downs' monthly exposure to Vinyl Chloride ranged from approximately 5 to 8 ug/L over the 19 months of exposure and the total cumulative Vinyl Chloride exposure was 122 ug/L-months. Bove et. al (2014a)<sup>9</sup> noted in table 6 that the total cumulative VC low exposure category ranged from 1-205 ug/L-months. Mr. Downs' exposure of 122 ug/L-months falls above the middle of the low exposure range. Bove et. al. (2014a)<sup>9</sup> found there was an elevated 1.66-fold increased risk of kidney cancer in the low exposure category for VC exposure.

In this report and in my general causation report I cite several levels at which the epidemiology literature indicates that the toxins in the water at Camp Lejeune were known to cause kidney cancer. Mr. Downs met or exceeded many of these well-studied levels for TVOCs, PCE, TCE, and Vinyl Chloride. The risk related to these toxins levels was significantly elevated and far exceeded at least as likely as not standard. Therefore, the risk of kidney cancer due to his exposure to these toxins, at the levels he was exposed to, was high.

In sum, Mr. Downs' exposure to the water at Camp Lejeune was more likely than not the cause of his kidney cancer. The other risk factors noted above may have contributed to his kidney cancer, but they all are relatively small compared to the very significant risk of the toxic water at Camp Lejeune.

## **X. Response to Defendants Supplemental Answers to Interrogatories**

The defendant notes that alternative explanations may exist for the cause of the plaintiff's kidney cancer to include that he was first diagnosed with kidney cancer just after his 82<sup>nd</sup> birthday. Defendants claim Mr. Downs was overweight, had prediabetes, and had a smoking history and second-hand smoke exposure. In regard to his age, Mr. Downs was over 60 so he was at some slight increased risk of kidney cancer due to his age. Mr. Downs had a minimal increased kidney cancer risk due to his being overweight. There is limited to no risk of kidney cancer related to being pre-diabetic. Further, Mr. Downs had a personal history of smoking one pack a day for five years. As discussed above, Mr. Downs' smoking cessation for over 50 years eliminated his increased kidney cancer risk due to smoking. This is true even if Mr. Downs smoked for 15 years and he had stopped smoking for 40 years prior to his diagnosis.

The Defendant stated that the Plaintiff's exposure to water at Camp Lejeune may not have been significant enough to cause the alleged illness or injury. As discussed above, Mr. Downs had significantly elevated risk of kidney cancer according to the literature based on his substantial exposure and according to my education, training and experience with these chemicals. Evidence from the medical literature supports that the dose from inhalation and

dermal absorption may be almost as high as the ingestion dose. This would make the actual dose much higher than just the amount of ingestion.<sup>14</sup>

There is medical literature on latency periods relating to solvent exposure and kidney cancer noting that latency periods generally exceed 20 years.<sup>21</sup> So, Mr. Downs kidney cancer development is a little longer than the average latency period but within a normal expected time period for this type of cancer.

## **XI. Summary Medical Opinion for TCE, PCE, and VC Exposure and Kidney Cancer Risk**

There is epidemiologic, toxicologic and mechanistic evidence in the literature that proves to a reasonable degree of medical and scientific certainty that TVOCs, TCE and PCE more likely than not cause kidney cancer. Further, there is epidemiologic, mechanistic and other scientific and medical evidence that vinyl chloride at least as likely as not causes kidney cancer.

Given that there are very few risk factors for Mr. Downs, and none with close to the level of significance of the water at Camp Lejeune, it is my opinion that to a reasonable degree of medical certainty, the kidney cancers Mr. Downs developed were more likely than not caused by his exposure to the contaminated drinking water at Camp Lejeune. This exceeds the “at least as likely as not” standard required in this case.

## **XII. Damages**

Mr. Downs suffered significant personal hardships and emotional damages caused by contaminated drinking water at Camp Lejeune. Mr. Downs subsequently developed metastatic cancer. To a reasonable degree of medical certainty, Mr. Downs’ metastatic cancer was causally related to his original kidney cancer diagnosed in 2016 and therefore also causally related to the water at Camp Lejeune. Additionally:

1. The harms and injuries and damages suffered by Mr. Downs that are described in this report are permanent.
2. The treatment and care Mr. Downs has received and is now receiving is reasonable and medically necessary.
3. The Plaintiff is expected to live a normal life expectancy.
4. The medical billing relating to Mr. Downs’ kidney cancer diagnosis, the surgery to remove his kidney and the follow up treatment related to his kidney cancer was fair, reasonable, and medically necessary.



## References Consulted

- <sup>1</sup> Camp Lejeune Justice Act of 2022, <https://www.congress.gov/117/plaws/publ168/PLAW-117publ168.pdf>.
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- <sup>4</sup> Moore LE, Stewart PA et al. Kidney Cancer in *Occupational Cancers*. London: Springer-Verlag; 2014:439-459.
- <sup>5</sup> Hunt JD, Van der Hel OL, et al. Renal cell carcinoma in relation to cigarette smoking: Meta-analysis of 24 studies. *Int. J. Cancer*. 2005;114:101-108.
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- <sup>7</sup> Yuan JM, Castelao JE, et al. Tobacco use in relation to renal cell carcinoma. *Cancer Epidemiol. Biomarkers Prev*. 1998;7(5):429-433.
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# **TIMOTHY MALLON'S CV EXHIBIT 1**

## **CURRICULUM VITAE**

### **I. PERSONAL DATA**

Name: Timothy M Mallon, MD, MPH, FACOEM  
Address: 6508 Folded Leaf Square, Columbia, MD 21044  
E-Mail/Tel#:mallonti03@gmail.com/ 443-370-9267

### **II. EDUCATION**

<u>Year</u>	<u>Degree</u>	<u>Type of Degree / Institution</u>
1977	BPS	Bachelor Professional Studies Clarkson University Potsdam, NY
1986	MS	Resource Policy and Management School of Natural Resources University of Michigan
1987	MS	Environmental Health Hunter College City University of New York

### **III. POST GRADUATE EDUCATION**

<u>Year</u>	<u>Position</u>	<u>Type of Degree / Institution</u>
1991	Medical Student	Doctor of Medicine Upstate Medical University Syracuse, NY
1992	Resident Year 1	Internship in Internal Medicine Tripler Army Medical Center, Honolulu, HI
1995	Resident Year 2	Master of Public Health School of Hygiene & Public Health Johns Hopkins, Baltimore, MD
1996	Resident Year 3	Occ. & Env. Medicine Residency US Army Public Health Center Edgewood Area-APG, Gunpowder, MD

### **IV. ACADEMIC APPOINTMENTS**

<u>Year</u>	<u>Position</u>	<u>Institution</u>
2016	Professor/Adjunct Professor	Uniformed Services University
2012	Associate Professor	Uniformed Services University
2004	Assistant Professor	Uniformed Services University
1996	GPM Residency Faculty	Madigan Army Medical Center
1995	Teaching Fellow	Johns Hopkins University School of Medicine

### **V. CURRENT POSITIONS**

**Veterans Evaluation Services      Occupational Medicine      Oct 2017 to Present**  
**Contract Consultant**

Duties/Accomplishments      Hours per work- 30  
-Review Camp Lejeune & Agent Orange cases for service members and Veterans  
-Review Gulf War Injury Claims, PACT Act TERA Claims and write medical opinion for VBA  
-Address causal connection between exposure and related health outcomes

**Montgomery County Retirement      Occupational Medicine      Oct 2017 to Present**

Duties/Accomplishments      Hours per work- 5  
-Review disability cases for Montgomery County employees  
-Apply standards of medical fitness for police, firefighters, other employees who are injured  
-Advise management regarding whether medical documentation supports ongoing disability

**Federal Occupational Health      Occupational Medicine      Oct 2016 to Present**  
**Bethesda, MD      Contract Consultant**

Duties/Accomplishments      Hours per work- 10  
- Review ADA and FMLA cases for medical employability determinations  
- Review preventive medicine informational booklets for technical accuracy  
- Review respirator questionnaires and make recommendations for respirator wear

**Department of Prev. Med.      Adjunct Professor      July 2016 to Present**  
**and Biostatistics, USU**

Duties/Accomplishments:      Hours per week 10  
- Serve as mentor to colleagues in PMB on current research projects  
- Serve as Specialty Editor for the Textbook of Military Medicine

## **VI. PRIOR POSITIONS HELD**

**Health Research Sys Admin.      Occupational Medicine      April 2022 to May 2023**  
**Comp. Injury Countermeasures      Consultant**

Duties/Accomplishments      Hours per work- 10  
-Review claims for injuries related to COVID-19 vaccinations  
-Make determination of whether injury exists and causation  
-Prepare recommendations for program director & legal review

**Brown and Brown      Occupational Medicine      April 2017 to Oct 2021**  
**Physician Disability Associates      Consultant**

Duties/Accomplishments      Hours per work- 5  
-Review disability cases for multiple insurance companies  
-Apply standards of medical fitness for workability for injured/ill employees  
-Advise management regarding whether medical documentation supports ongoing disability

<u>Prior Jobs (Cont)</u>	<u>Duty Title</u>	<u>Dates</u>
<b>Department of Prev. Med. and Biostatistics, USU</b>	<b>Professor and OEM Residency Director</b>	<b>July 2012 to June 2016</b>
Duties/Accomplishments:                      Hours per week 80 <ul style="list-style-type: none"> <li>- Serve as Residency Director of the OEM Residency Program at USU,</li> <li>- Selected, trained, and mentored OEM physicians for the Department of Defense.</li> <li>- Revised training and assessment of residents to document ACGME competencies.</li> <li>- Oversaw the training of 25 military OEM physicians from the US and Canada.</li> <li>- Led efforts nationally among residency directors to implement ACGME Milestones, developed Milestones Translation Tools and shared best practices.</li> <li>- Led ACOEM President's Task Force on Recruiting physicians to OEM</li> <li>- Prepared the residency for an accreditation site visit, received maximal accreditation.</li> <li>- Preceptor for Occupational medicine residents and medical students. Served as course director for four occupational medicine courses.</li> <li>- Authored 8 book chapters and 45 peer reviewed journal articles</li> <li>- Invited to speak at national meetings including the AOHC, APHA, and ACPM conferences and presented multiple poster and oral presentations.</li> <li>- Chaired Residency Advisory Committees for OEM Residencies at Madigan and Pensacola and served on Committees for Dayton, Johns Hopkins, Walter Reed &amp; USUSU Prev. Medicine</li> </ul>		
<b>Dept of Preventive Med. and Biostatistics USU</b>	<b>Vice Chair for Prev Med.</b>	<b>July 2010 to June 2012</b>
Duties/Accomplishments:                      Hours per week: 40 <ul style="list-style-type: none"> <li>- Led efforts to support for Medical School Curriculum Reform, enlarged role of Public Health.</li> <li>- Led the PMB leadership committee, providing policy guidance to the Chair</li> <li>- Served on the Medical School Student Promotions Committee for the University.</li> <li>- Served as Chair of the Preventive Medicine Leadership Committee.</li> <li>- Participated on the Medical School Curriculum Committee representing the Department.</li> </ul>		
<b>US Army Surgeon General's Office</b>	<b>Consultant in OEM</b>	<b>July 2008 to June 2012</b>
Duties/Accomplishments:                      Hours per week 30 <ul style="list-style-type: none"> <li>- Served as subject matter expert &amp; consultant to Army Surgeon General.</li> <li>- Provided OEH consults to 130 OH clinics worldwide.</li> <li>- Recommended to Human Resources Command assignments/deployments of OEM physicians.</li> <li>- Developed OH Improvements that focused on Staffing, Training, Credentialing &amp; performance.</li> <li>- Validated workload, staffing requirements successfully obtained \$54.5 million for OH Program.</li> <li>- Developed Army web-based OHP checklist to track OH clinic performance.</li> <li>- Updated DoD OEM physician credentialing requirements for OH providers.</li> <li>- Served as Chair of DoD OEM Working Group: Updated OH Surveillance Manual (DoD 6055.05M) that provides guidance on meeting federal law and regulations from OSHA.</li> <li>- Led efforts to develop a DoD Biomarker Policy; developed DoD process/outcome performance measures for OH Program execution.</li> <li>- Led VA and DoD efforts to revise the DoD Post Deployment Health Assessment DD FORM 2796 to better capture soldier deployment OEH health exposure concerns.</li> </ul>		

- Linked deployment exposures in Defense Medical Surveillance System with health outcomes.

**Dept of Preventive Med.  
and Biostatistics**

**OEM Residency Director**

**July 2004 to June 2010**

**Duties/Accomplishments:**

Hours per week: 40

- Serve as Residency Director of the OEM Residency Program at USU,
- Selected, trained, and mentored OEM physicians for the Department of Defense.
- Revised training and assessment of residents to document ACGME competencies.
- Obtained additional training starts and successfully recruited best DoD physicians to the field.
- Doubled the size of the residency from eight to sixteen residents a year each year.
- Oversaw the training of sixty military OEM physicians from the US and Canada.
- Led residency programs nationally in implementing the Milestones and was commended by the National Capital Consortium and ACGME for these efforts
- Prepared the residency for two ACGME site visits and received the maximal accreditation.
- Preceptor for Occupational medicine residents and medical students. Served as course director for four Occupational medicine courses.
- Authored a book chapter and 13 peer reviewed journal articles and was invited to speak at national civilian medical meetings including the American OH Conference and Federal Occupational Health Conference and presented multiple poster and oral presentations.

**Army Center for Public Health,  
Aberdeen Proving Grounds,  
Gunpowder, MD**

**Director, OEM**

**August 2000 to July 2004**

**Duties/Accomplishments:**

- Served as Director of the OEM Directorate at the US Army Public Health Command.
- Provided oversight of Army OEH worldwide technical consultations.
- Supervised staff of 32 and managed a budget of over \$3.9 million
- Developed policy and programs to reduce injuries, illnesses; lower FECA costs; obtained \$1 million for pilot project demonstrated medical case managers effective and achieved a 4:1 ROI.
- Developed policy and advised commanders on FHP measures related to CRBN threats.
- Primary author of "Occupational Health" for the 2005 revision of DA Pamphlet 40-11.
- Assessed the quality of Army worker's compensation, OH, and NBC surety programs.
- Developed OH templates for the electronic medical record, AHLTA.
- Standardized OH business practices world-wide as proponent for the MEDCOM commander.
- Coordinated OH support for Pentagon and World Trade Center response: developed exposure guidelines for contaminants to support consequence management and building re-entry
- Oversaw health assessments of 8000 soldiers who deployed to the WTC, Pentagon.

**Madigan Army Med. Ctr,  
Fort Lewis WA**

**Chief & Region Consultant  
Occ. & Env. Med. Service**

**July 1996 to August 2000**

**Duties/Accomplishments:**

Hours per week: 50

- Served as Western Region Medical Cmd. OEM Consultant, oversaw delivery of care in eleven OH clinics in six states from Alaska to Southern California, supported 60,000 personnel.
- Significantly improved patient care, customer satisfaction, and OH clinic utilization.
- Standardized region respiratory protection, blood borne pathogens, latex allergy programs.
- Served as Chief of OEM at Madigan Army Medical Center, provided OM services for 10,000 employees and 40,000 active, guard and reserve soldiers.

- Supervised staff of 39 providers, His, OHNs and support staff.
- Updated Blood Borne Pathogen, Latex & Infection Control Programs, commended by Joint Commission for model infection control and disaster response programs.
- Chaired the Infection Control, member Hospital Executive, QA/QI and Safety Committees.
- Overhauled tuberculosis (TB) surveillance program to meet JC and OSHA requirements.
- Enhanced chemical response capability through training and exercises.
- Developed and implemented a region wide heat injury prevention plan.

**Patterson Army Cmty  
Hospital, Fort Monmouth, NJ**

**Chief of Prev. Medicine**

**July 1992 to June 1994**

Duties/Accomplishments:

Hours per week: 45

- Oversaw delivery of PM services for five installations in NY and NJ;
- Supervised 4 MDs, 4 Industrial Hygienists, 7 nurses, 7 medics, 6 staff.
- Served on PACH Executive Committee, Chair of Infect Control Cmtte, hospital QA/QI.
- Upgraded OH services in region by organizing, updating SOPs and QI programs for PM that resulted in accessible, high quality care and commended by Joint Commission.
- Provided oversight of disease, injury prevention programs at two OH clinics, acute care clinic.
- Ensured workplace IH monitoring conducted that guided worker medical surveillance programs, obtained \$250K for IH regional support.
- Provided Installation Commanders advice on community health, safety, lead poisoning and TB prevention and control plans, Travel Medicine, Post Deployment Surveillance for soldiers.

## VII. CERTIFICATION AND LICENSURE

Date

American Board of Preventive Medicine

Board Certification in Occupational Medicine

16 Jan 1997

License: Maryland

## VIII. MEMBERSHIP IN SCIENTIFIC SOCIETIES\PROFESSIONAL ORGANIZATIONS.

Association of Military Surgeons of the United States

American College of Occupational and Environmental Medicine (ACOEM)

American College of Preventive Medicine (ACPM)

## IX. FUNDED GRANTS

<u>Title</u>	<u>Role</u>	<u>Funded (amount)</u>	<u>Grant Period</u>
Exposure biomarkers & health outcomes in Iraq and Afghanistan, funded by DoD/NIEHS	PI	\$4,650,000	9/8/2013 to 7/31/2019

## X. PRIOR TEACHING ACTIVITIES

PMO 973	OEM Journal Club- Co-course Director
PMO 542	Clinical Occupational / Environmental Medicine- Co-course Director
PMO 655	Safety and Injury Prevention- Course Director
PMO 642	Clinical PM Services and Selected Topics in OEM- Co-course Director
PMO 558	Intro to Preventive / Occ. Medicine Residencies- Co-course Director
PMO 549	Toxicology - Course lecturer



## **XII. OTHER PROFESSIONAL ACTIVITIES**

Specialty Editor, Textbook of Military Medicine in Occupational Medicine 2019  
Special Editor J. Occupational and Environmental Medicine Supplement December 2019  
- Deployment Environmental Exposures, Metabolomics, Inflammatory and microRNA  
- Biomarkers and Health Outcomes Related to Burn Pits in Iraq and Afghanistan. 2016  
- Federal Workers Compensation Programs, Published March 2015.  
Editor, Mil. Med. Supplement July 2011, Hazardous Exposures in Military Populations.  
Reviewer, Military Medicine on Preventive and Occupational Medicine topics, 2007 to present.

## **XIII. CLINICAL ACTIVITIES**

Staff occupational medicine physician, Federal Occupational Health, Bethesda, MD.  
Staff Occupational Medicine Physician Walter Reed Army Medical Center 2004 to 2016

## **XIV. COMMITTEES (national advisory, professional societies, hospitals)**

Member, Residency Review Committee for Preventive Medicine, Accreditation Council for Graduate Medical Education- 7/2016 to 7/2019  
Member, American Board of Preventive Medicine- 7/2016 to 7/2019

## **XV. HONORS AND AWARDS**

ACOEM Award for Leadership in Academic Medicine and Research, April 2016  
Delta Omega Public Health Honor Society as USU Faculty 2015  
Defense Superior Service Medal 2016  
US Army Surgeon General's "A-Designator" Award for Academic Excellence  
Recipient, Military Order of Medical Merit  
Fellow, American College of Occupational and Environmental Medicine.

## **XVI. BIBLIOGRAPHY**

### **Publications (Peer Reviewed)**

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Commentary "Hazardous Non-combat Exposures in the Department of Defense". December  
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Krahl, Pamela L.; Benchoff, Edward; Mallon, Timothy. Advances in Comprehensive Exposure Assessment: Opportunities for the US Military. Journal of Occupational and Environmental Medicine. 61:S5-S14, December 2019.

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Go, Young-Mi; Smith, Matthew R.; Walker, Douglas I.; Uppal, Karan; Rohrbeck, Patricia; Krahl, Pamela L.; Hopke, Philip K.; Utell, Mark J.; Mallon, Timothy M.; Jones, Dean P. "Metabolome-Wide Association Study of Deployment to Balad, Iraq or Bagram, Afghanistan". Journal of Occupational and Environmental Medicine. 61:S25-S34, December 2019.

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Thatcher, Thomas H.; Woeller, Collynn F.; Thakar, Juilee; Khan, Atif; Hopke, Philip K.; Smith, Matthew Ryan; Uppal, Karan; Walker, Douglas I.; Go, Young-Mi; Jones, Dean P.; Krahl, Pamela L.; Mallon, Timothy M.; Sime, Patricia J.; Phipps, Richard P.; Utell, Mark J. "Analysis of Post deployment Serum Samples Identifies Potential Biomarkers of Exposure to Burn Pits and Other Environmental Hazards of Exposure to Burn Pits and Other Environmental Hazards". Journal of Occupational and Environmental Medicine. 61:S45-S54, December 2019.

Khan, Atif; Thatcher, Thomas H.; Woeller, Collynn F.; Sime, Patricia J.; Phipps, Richard P.; Hopke, Philip K.; Utell, Mark J.; Krahl, Pamela L.; Mallon, Timothy M.; Thakar, Juilee. "Machine Learning Approach for Predicting Past Environmental Exposures From Molecular Profiling of Post-Exposure Human Serum Samples". Journal of Occupational and Environmental Medicine. 61:S55-S64, December 2019.

Thakar, Juilee; Thatcher, Thomas H.; Smith, Matthew Ryan; Woeller, Collynn F.; Walker, Douglas I.; Utell, Mark J.; Hopke, Philip K.; Mallon, Timothy M.; Krahl, Pamela L.; Rohrbeck, Patricia; Go, Young-Mi; Jones, Dean P.; Uppal, Karan. "Integrative Network Analysis Linking Clinical Outcomes With Environmental Exposures and Molecular Variations in Service Personnel Deployed to Balad and Bagram". Journal of Occupational and Environmental Medicine. 61:S65-S72, December 2019.

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“Benzo[a]pyrene Perturbs Mitochondrial and Amino Acid Metabolism in Lung Epithelial Cells and Has Similar Correlations With Metabolic Changes in Human Serum”. *Journal of Occupational and Environmental Medicine*. 61:S73-S81, December 2019.

Woeller, Collynn F.; Thatcher, Thomas H.; Thakar, Juilee; Cornwell, Adam; Smith, Matthew R.; Jones, Dean P.; Hopke, Philip K.; Sime, Patricia J.; Krahl, Pamela; Mallon, Timothy M.; Phipps, Richard P.; Utell, Mark J. “Exposure to Heptachlorodibenzo-p-dioxin (HpCDD) Regulates microRNA Expression in Human Lung Fibroblasts”. *Journal of Occupational and Environmental Medicine*. 61:S82-S89, December 2019.

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**TIMOTHY MALLON'S  
STATEMENT OF  
COMPENSATION**

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
SOUTHERN DIVISION

IN RE:	)	
	)	
CAMP LEJEUNE WATER LITIGATION	)	
	)	
This Document Relates to:	)	Case Nos.:
	)	
ALL CASES	)	7:23-CV-897
	)	
DAVID DOWNS	)	7:23-CV-01145-BO
	)	
DAVID WILLIAM FANCHER	)	7:23-CV-00275-BO-BM
	)	
ALLAN WAYNE HOWARD	)	7:23-CV-00490-BO
	)	
FRANK W. MOUSSER	)	7:23-CV-00667-BO-RN
	)	
JACQUELINE JORDAN TUKES	)	7:23-CV-01553-BO-BM

**PLAINTIFFS' DESIGNATION AND DISCLOSURE OF PHASE III EXPERT  
WITNESSES WITH RESPECT TO KIDNEY CANCER**

**TIMOTHY M. MALLON'S STATEMENT OF COMPENSATION**

Pursuant to Fed. R. Civ. P. 26(a)(2)(B)(vi), Plaintiffs provide the following statement of compensation: Timothy M. Mallon charges \$650 per hour for work on the present matter.