Exhibit 410

Specific Causation Expert Report: David Downs

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I am writing in response to your request for an expert medical evaluation of Mr. David Downs, with respect to the potential relationship between his diagnosis of kidney cancer and his documented exposure to contaminated water at Camp Lejeune from February 16, 1960 to September 27, 1961. This evaluation will focus on assessing whether the patient's prolonged exposure to contaminants present in the water supply at Camp Lejeune, namely trichloroethylene (TCE), tetrachloroethylene (PCE) and Vinyl Chloride contributed to the development of his malignancy.

I. Introduction

United States Marine Corps (USMC) Base Camp Lejeune was known to have toxic and carcinogenic chemicals in the water at the base between the 1950s-1987. During this period of interest, researchers found high levels of chlorinated solvents in drinking water supplies at the main Hadnot Point and Tarawa Terrace water treatment plants. Researchers extensively investigated populations exposed to the chemicals of interest to determine potential carcinogenesis with regard to genitourinary (GU) cancers of the kidney, as well as other GU cancers. The science and literature has demonstrated that the chemicals in the drinking water at Camp Lejeune are known to cause kidney cancer. This is supported by epidemiologic studies, data from toxicology (animal) studies, mechanistic data and other forms of causal evidence.

It is my professional scientific and medical opinion that the toxic chemicals in the water at Camp Lejeune were at levels known to cause kidney cancer and were more likely than not the cause of Mr. David Downs kidney cancer. It is also my opinion that Mr. Downs was exposed to a substantial amount of the toxins in the water at Camp Lejeune and this substantial exposure was a substantial contributing factor in the development of his kidney cancer. This is based in part on the amount of chemicals Mr. Downs was exposed to, the duration of time he was exposed to the chemicals, the intensity of the exposure to the chemicals and the frequency with which he was exposed to the chemicals.

II. Qualifications

<u>My background</u>: As a Professor of Urology at the University of Texas Southwestern Medical Center, I have dedicated my career to the study and treatment of urologic cancers, with a particular focus on kidney cancers. As my Curriculum Vitae reflects, following my urology residency at the University of Texas Southwestern Medical Center, I further specialized through a fellowship in urologic oncology at the University of Texas MD Anderson Cancer Center, where I honed my expertise in managing urologic malignancies.

My research endeavors have centered on the molecular biology of kidney cancer, investigating genetic alterations that drive tumor progression and exploring potential therapeutic interventions. I have authored numerous publications in esteemed journals, including the *Journal of Clinical Oncology* and *Clinical Cancer Research*, contributing to the understanding of renal cell carcinoma pathogenesis and treatment.

Given my extensive background in the molecular mechanisms of kidney cancer and experience with environmental carcinogens, I am well-equipped to assess the potential impact of toxic

exposures, such as those at Camp Lejeune, on renal cancer development. My expertise enables me to provide a comprehensive evaluation of the etiological factors contributing to this patient's condition.

<u>This evaluation</u>: To perform this expert medical evaluation, I reviewed and relied upon the medical records and other documents in the attached materials reviewed list.

In preparing this evaluation, I have drawn upon the most rigorous and relevant peer-reviewed scientific literature. Throughout this report, I will cite specific studies to support my conclusions regarding Mr. Downs' diagnosis of kidney cancer.

After a thorough analysis of relevant literature, I conclude, with a reasonable degree of medical and scientific certainty, that David Downs' exposure to contaminated water at Camp Lejeune was the cause of the development of his renal cell carcinoma.

III. Methodology

I researched and reviewed peer reviewed scientific literature pertaining to kidney cancer and exposures to TCE, PCE, VC and benzene.

Further, I utilized a differential diagnoses methodology for determining the etiology of Mr. Down's renal cell carcinoma. In order to perform a differential diagnosis I needed to consider all possible risks for RCC and then rule each one in or out and give each the appropriate weight.

IV. Causation Standard

The statute at issue in this case states that there are two ways to meet the causation burden:

- "(2) Standards To meet the burden of proof described in paragraph (1) a party shall produce 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 a causal relationship is at least as likely as not."

These standards for causation are defined in science and medicine as either (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" that a causal relationship exists.⁴

The ATSDR (2017) offered different causality standards to assess the causal relationship between the toxins in the drinking water at Camp Lejeune and different diseases, including kidney cancer. Specifically, ATSDR outlined the following causality standards:

"<u>Sufficient evidence for causation</u>: the evidence is sufficient to conclude a causal relationship exists. This category would be met, for example, if:

- "1. There is sufficient evidence from human studies in which chance and biases (including confounding) can be ruled out with reasonable confidence, <u>or</u>
- "2. There is less than sufficient evidence from human studies but sufficient evidence in animal studies and strong evidence that the agent acts through a relevant mechanism in humans."

"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, <u>or</u>
- "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., ≤ 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 bias 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."

This is consistent with how I interpret these standards and this language in the applicable literature. It is how reasonable physicians in my field apply the same and similar standards.

V. Pollutants Detected and Known Harms of These Pollutants

Water samples were tested at Camp Lejeune on several occasions in the 1980s. Identified pollutants include trichloroethylene (TCE), tetrachloroethylene (PCE), Trans-1,2-dichloroethylene (DCE), vinyl chloride, and benzene.^{3, 4, 5} At HP, peak maximum detectable level of TCE reached 1400 μg/L while the maximum detectable level of PCE reached 100 μg/L.⁴ DCE, vinyl chloride and benzene were also detected.⁵ At TT, peak level of PCE reached 215 μg/L.⁴ From 1975-1985, median estimated average monthly levels of TCE, PCE, vinyl chloride, and benzene at HP were 366 ppb, 15 ppb, 22 ppb, and 5 ppb, respectively.⁴ At TT, corresponding levels of TCE, PCE, and vinyl chloride during the same period were 85 ppb, 4 ppb, and 6 ppb, respectively.⁴ Water modeling was done for the years 1953 through 1987.^{3,5} This is found in the ATSDR water modeling charts.^{3,5} For each month there is a corresponding value of the median level of the toxic chemical in the particular water disbursement facilities at Camp Lejeune. I have reviewed the ATSDR water modeling as well as the exhibits from Plaintiff's expert Morris Maslia which contain the same information. These documents provide evidence that Mr. Downs was exposed to a substantial amount of the toxins at issue in the water, that the exposure was

sufficiently intense to have caused Mr. Downs kidney cancer and that the toxins existed in the water for a sufficient duration of time to have caused a substantial exposure.

The International Agency for Research on Cancer (IARC) classified TCE, Vinyl Chloride and Benzene as Group 1 carcinogens and PCE as probably carcinogenic to humans (Group 2A), linking exposure to increased risk of cancer.^{6,7} The EPA concluded strong support for a relationship between TCE and kidney cancer.⁵ The 2015 National Toxicology Program (NTP) monographs on TCE concluded strong support for the relationship between TCE exposure and kidney cancer.⁸ The ATSDR reports from Camp Lejeune concur with the evaluations made by IARC, EPA and NTP.⁴

Just recently, the EPA publicly announced bans on TCE and PCE.⁹ The EPA made clear, for both TCE and PCE, that among the reasons for the ban was the connection between TCE and PCE to kidney cancer at low levels.

VI. Mode of Exposure and Mechanism of Action between Camp Lejeune Chemicals and Kidney Cancer

I have reviewed the general causation reports of Drs. Hatten and Bird and agree with their statements as to the mode of exposure and mechanism of actions for these chemicals as it pertains to kidney cancer.

Exposure to chlorinated compounds may be sustained through inhalation, ingestion, and dermal absorption. Onsidering the compounds of interest in this study, epidemiologic, occupational, and environmental studies have identified dry-cleaning solvents, degreasing fluids, and contaminated groundwater as key sources of occupational and environmental exposure of the toxins in the water. Metabolites of these chlorinated compounds are also preferentially excreted and concentrated in the urine potentially heightening the relative exposure experienced by the GU tract.

The literature demonstrates data regarding the mechanism of carcinogenesis with respect to TCE and PCE. Bacterial and animal studies have demonstrated the mutagenicity of each compound.⁶

Currently, the most is known about potential mechanisms of carcinogenesis with respect to TCE. DNA methylation and chromosomal aberration represent reasonable and medically valid etiologies for a genotoxic carcinogenic effect of TCE based on studies of human subjects.⁶ One epigenome-wide association study of humans demonstrated that TCE exposure increased methylation variation globally in white blood cells (p=0.00375), suggesting that TCE may contribute to epigenetic drift.¹¹

When it comes to kidney cancer specifically, several mechanisms have been researched. Many studies have focused on mutation of the *VHL* gene (a common mutation in renal cell carcinoma). Brauch et al. identified 44 patients with RCC who had been expose to TCE. 33 of 44 had VHL mutations and 14 of these had multiple. Moreover, only patients with high and medium exposure to trichloroethylene, but not low exposure, had VHL mutations, and there was a significant correlation between severity of exposure and presence of multiple mutations. A follow-up of the previous study compared the characteristics of VHL mutations in cases of renal

cell carcinoma in people exposed to trichloroethylene (n = 17) and cases in people not exposed to trichloroethylene (n = 21). Samples of tissues from tumor and non-tumor areas of the kidney were collected from the 38 cases, micro dissected, and amplification and sequencing of the individual VHL exons was conducted using polymerase chain reaction (PCR). Cases of renal cell carcinoma associated with occupational exposure to trichloroethylene were reported to be diagnosed at a younger age (median, 57.5 years) compared with cases with no exposure to trichloroethylene (median, 67 years). In addition, mutation characteristics of the VHL gene differed according to trichloroethylene-exposure status, as exposed cases had a higher frequency of somatic mutations (82% in exposed versus 10% in unexposed), multiple mutations (50% in exposed versus 0% in unexposed). and frequency of the nucleotide 454 C→T hot spot mutation previously identified (38% in exposed versus 0% in unexposed).

Additionally, it has been discussed in the literature as to whether TCE and PCE indirectly lead to mutagenesis through accumulation of a2u-globulin.⁶ Accumulation of this compound in renal proximal tubules has been thought to lead to local renal changes resulting in increased cellular proliferation.⁶ There is data to suggest PCE specifically may cause oxidative stress at the cellular level, which results in carcinogenesis directly.⁶

Further, studies indicate that several breakdown products have been thought to demonstrate mutagenic effects. Glutathione-dependent conjugation is a trichloroethylene - metabolism pathway that results in formation of several toxicologically relevant metabolites (1,2dichlorovinyl) glutathione (DCVG) and S-(1,2-dichlorovinyl) L-cysteine (DCVC) that can accumulate in the renal proximal tubules based on a genetic polymorphism in the proximal renal tubular organic anion transporter (OAT) protein. DCVG exhibited direct acting mutagenicity, with kidney mitochondria, cytosol, or microsomes enhancing the effects and AOAA diminishing, but not abolishing, the effects. 14 Importantly, the addition of liver subcellular fractions did not enhance the mutagenicity of DCVG, consistent with metabolism in situ (via GGT and dipeptidase) playing a significant role in the genotoxicity of the resulting cysteine conjugates in the kidney. 14 In the same study, DCVC exhibited direct-acting mutagenicity, with kidney mitochondria or cytosol enhancing the effects and AOAA diminishing, but not abolishing, the effects.¹⁴ Jaffe et al. (1985) further reported DNA strand breaks after administration of DCVC in vivo, in isolated perfused kidneys. 15 A study using porcine kidney tubular epithelial LLC-PK1 cells also reported increased expression of the proto-on cogene c-Fos in the DCVC-derived clones. 16 Overall, these studies support mutagenicity in the kidney of TCE-derived compounds. The following are charts that depict the likely carcinogenic effects of these chemicals:

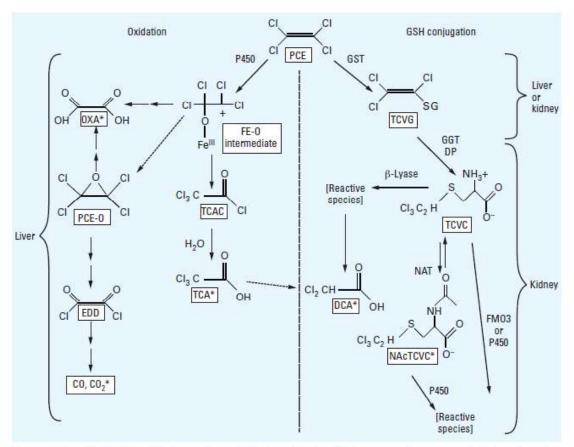
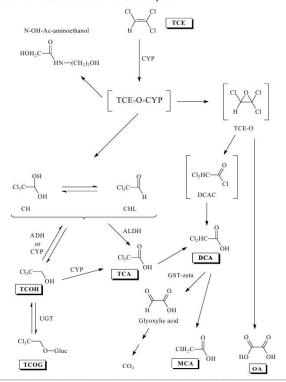


Figure 1. Simplified PCE metabolism scheme. PCE is metabolized in humans and experimental animal species by both oxidation (left) and GSH conjugation (right) metabolic pathways, yielding numerous toxicologically active compounds (Lash and Parker 2001). Tetrachlorethylene metabolism yields the oxidative metabolites TCAC, which hydrolyses to yield TCA, and the epoxide PCE-0, which decomposes in turn to EDD, CO, and CO₂. OXA is also a product of PCE oxidation. GSH conjugation products include TCVG, the cysteine conjugate TCVC, and the mercapturate NAcTCVC and its sulfoxidation products. DCA is likely produced via β-lyase-mediated bioactivation, although TCA dechlorination may be an additional minor source.
*Metabolites identified in blood, urine, or breath after in vivo PCE exposure (rodent or human).

Fig. 4.1 Scheme for oxidative metabolism of trichloroethylene



Trichloroethylene undergoes cytochrome P450 (CYP)-dependent oxidation to form either a trichloroethylene-CYP intermediate or an epoxide intermediate. Further processing through either non-enzymatic rearrangements or the actions of aldehyde dehydrogenase (ALDH), alcohol dehydrogenase (ADH), CYPs, or glutathione-5-transferase zeta (GSEZ) yield a variety of metabolites, including chloral (CHI) and chloral hydrate (CH), dichloroscetate (DCA), trichloroacetate (TCA), trichloroacetate (TCA), trichloroacetate (TCA), trichloroacetate (TCA), trichloroacetate (TCA), and oxalate (OA), Names of metabolites that are chorevered in urine are shown in boxes and those that are chemically unstable or reactive are shown in brackets. Other abbreviations: DCAC, dichloroacety ichnicale GSH, glattathione N-OH-Ac-aminoethanol, N-hydroxyacetyl aminoethanol; trichloroethylene-O, trichloroethylene epoxide; UGT, UDP-glucuronosyltransferase.

(IARC 2014)

Fig. 4.2 Scheme for glutathione-dependent metabolism of trichloroethylene

Trichloroethylene (trichloroethylene) undergoes conjugation with glutathione (GSH) to yield the GSH S-conjugate DCVG. After processing to yield the cysteine S-conjugate DCVG, three potential fates are detoxication to yield the mercapturate NAcDCVC or bioactivation by either the cysteine conjugate β-lyase to yield dichlorovinythiol, which rearranges to yield thioacylating species, or the flavin-containing monooxygenase to yield DCVC sulfoxide. The mercapturate can also be deacetylated to regenerate DCVC or it can undergo CYP3A-dependent sulfoxidation. Names of metabolites than are recovered in urine are shown in boxes and those that are chemical unstable or reactive are shown in brackets. Abbreviations CCBL, cysteine conjugate §-lyase; CYP3A, cyte-chrome P-459 36, CTAC, chlorothionoaccyti chlorionoisetene; DCVG, S-(1,2-dichlorovinyt)-L-cysteine; DCVG, S-(1,2-dichlorovinyt)-Lorovinythioi. PCCS, DCVC, sulfoxide; DCVT, 1,2-dichlorovinythioi; DCVG, S-(1,2-dichlorovinythioicy containing monooxygenase; GGT, glutamytransferase; GLy, glycine; GSH, glutathione; GST, GSH 5-transferase; L-Glu, L-glutamic acid; NAcDCVC, N-acetyl-S-(1,2-dichlorovinyth)-L-cysteine; NAcDCVCS, NAcDCVC sulfoxide; NAT, N-acetyltransferase; L-Glu, L-glutamic acid; NAcDCVC, N-acetyl-S-(1,2-dichlorovinyth)-L-cysteine; NAcDCVCS, NAcDCVC sulfoxide; NAT, N-acetyltransferase; CR, glutamytransferase; CR, glycine; GSH, glutathione; GST, GSH 5-transferase; CR, glycine; GSH, glutathione; CST, GSH 5-transferase; CR, gl

(IARC 2014)

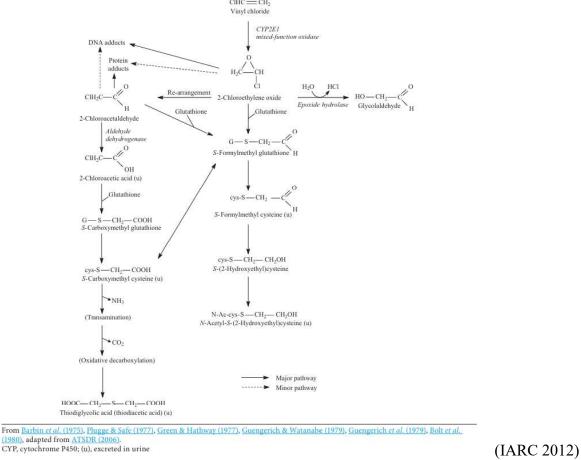


Fig. 4.1 Proposed metabolic pathways for vinyl chloride

(1980), adapted from ATSDR (2006) CYP, cytochrome P450; (u), excreted in urine

Vinyl chloride is a known carcinogen in humans according to the IARC, U.S. Department of Health and Human Services, and ATSDR. 7,4,17 "It is mutagenic, usually in the presence of metabolic activation, in various assays with bacteria, yeast or mammalian cells; it is also clastogenic in vivo and in vitro. Vinyl chloride induces unscheduled DNA synthesis, increases the frequency of sister chromatid exchange in rat and human cells, and increases the frequency of chromosomal aberrations and micronucleus formation in mice, rats, and hamsters in vivo."⁷

Kidney Cancer is Caused by TCE, PCE and Vinyl Chloride According to the VII. **Epidemiology and Other Literature**

I have reviewed the General Causation reports of Drs. Hatten and Bird who detailed a robust analysis of the epidemiology, toxicology and mechanism of action for the four main toxins at issue. These opinions and the data at issue in those reports support my opinions in this case.

a. TCE and Kidney Cancer

TCE is known to cause kidney cancer. 4,6,8,18,19,20,21,22 There are several particularly informative studies in this space. Zhao et al., a cohort study of aerospace workers, performed a rigorous estimation of exposure using a job exposure matrix (JEM). 18 To assess exposure-response, exposures were divided into low, medium, and high-dose groupings. 18 High exposure

significantly correlated with developing kidney cancer (95% CI 4.9, 1.23–19.6). Representing a strength of the study smoking was excluded as a potential confounder. A study by Charbotel et al., looked at TCE and kidney cancer. The OR found was 2.16 (95% CI, 1.02–4.60). More cancer relationship (p=0.04). Moore et al, a case control study of occupational exposure in central and eastern Europe, similarly rigorously defined dose-exposure and found significantly higher risk of kidney cancer in those with above median exposure (95% CI 2.41, 1.05-5.56). Each of these studies demonstrated sound study design and importantly demonstrated significant exposure-response relationships between exposure to TCE and kidney cancer.

I also reviewed several meta-analyses done with regard to TCE and kidney cancer. Scott et al. performed a systematic review on TCE and kidney cancer.²¹ The reported summary relative risk (RRm) was 1.27 (95% CI 1.13-1.43) for overall TCE exposure and kidney cancer risk. The RRm for the highest exposure group was 1.58 (95% CI: 1.28-1.96).²¹ Karami et al. is another metaanalysis that showed similar results and utilized mostly the same studies. ²² Subsequently, three additional studies published in 2013, Christensen et al., Hansen et al., and Vlaanderen et al., demonstrated no increase in kidney cancer among TCE-exposed individuals, but all are noted for having low incidence of high-exposure and/or less precise evaluation of dose-exposure, biasing results toward the null. ²³⁻²⁵ Accounting for some or all of these later studies, the 2014 International Agency for Research on Cancer (IARC) and the 2015 National Toxicology Program (NTP) monographs on TCE concluded strong support for a relationship between TCE exposure and kidney cancer. ^{6,8} The ATSDR reports from Camp Lejeune concur with the evaluations made by IARC, EPA and NTP. 4 Based on the overall consistent findings of increased risks of kidney cancer from exposures to TCE and the supporting mechanistic information, there is sufficient evidence for causation for TCE and kidney cancer. This will be used in this specific causation analysis.

b. PCE and Kidney Cancer

Several studies demonstrate a statistically significant positive relationship between PCE exposure and incidence of kidney cancer. ^{26,27,28,29,30,31} The case control study by Karami et al. supplies the strongest epidemiologic data in support of kidney carcinogenesis for PCE. ²⁷ The authors demonstrated a doubled risk of kidney cancer in dry-cleaning workers likely occupationally exposed to PCE. ²⁷ This heightened relative risk was 2.0 (95% CI: 0.9-4.4). ²⁷ Additionally, Mandel et al. conducted a wide-ranging study of various occupational exposures. Overall, 302/1732 cases with kidney cancer had been occupationally exposed to dry-cleaning solvents. ²⁸ The study found a significant relationship between employment in dry cleaning/laundering and kidney cancer in all men OR 1.4 (95% CI 1.1-1.7) and all women OR 1.6 (95% CI 1.0-2.7). ²⁸ There are several studies that deal with this topic that failed to demonstrate any significant relationship between PCE exposure and kidney cancer. ³² However, this does not negate the significant body of literature with positive findings of a causal relationship between PCE and kidney cancer. There are other kidney cancer studies and literature cited by general causation experts Drs. Hatten and Bird that support this proposition as well.

In a context similar to that of Camp Lejeune, Aschengrau et al. studied a population exposed to PCE-contaminated drinking water on Cape Cod, MA.²⁹ The study results showed that any PCE exposure (OR 1.23) and low PCE exposure (OR 1.36) demonstrated elevated measures of association with kidney cancer in an analysis not accounting for latency.²⁹

Some animal studies suggest a relationship between exposure to PCE and kidney cancer. Male mice were fed varying levels of PCE-laced corn oil ranging from dosages of 450-1100mg/kg over a 78 week period. Exposure to tetrachloroethylene caused toxic nephropathy (characterized in this study as degenerative changes in the proximal convoluted tubules at the junction of the cortex and medulla, with cloudy swelling, fatty degeneration, and necrosis of the tubular epithelium). One mouse developed renal cell carcinoma. A similar study of inhalation of PCE exposed rats to air containing tetrachloroethylene (purity, 99.9%) at concentrations of 0, 200, or 400 ppm (0, 1360, or 2720 mg/m3) for 6 hours per day on 5 days per week for up to 103 weeks. An increase in uncommonly occurring adenoma or carcinoma (combined) of the kidney tubule was observed in male rats (1/49, 3/49, 4/50); the historical incidence of these neoplasms in control male rats in inhalation studies conducted by the National Toxicology Program (NTP) at that time was 4 out of 1968 $(0.2 \pm 0.6\%)$.

c. Vinyl Chloride and Kidney Cancer

IARC has stated "There is *sufficient evidence* in humans for the carcinogenicity of vinyl chloride. Vinyl chloride causes angiosarcoma of the liver, and hepatocellular carcinoma. There is sufficient evidence in experimental animals for the carcinogenicity of vinyl chloride."⁷

The EPA has classified vinyl chloride as "Group A, "human carcinogen."³³ The NTP has also found that vinyl chloride "is known to be a human carcinogen based on sufficient evidence of carcinogenicity from studies in humans."³⁴

Hu 2002 studied kidney cancer with exposure to vinyl chloride. They reported an elevated risk with an OR of 2.0 (95% CI 1.2–3.3).³⁵ There was a monotonic response found for Vinyl Chloride and kidney cancer.

The many studies looking particularly at Camp Lejeune show a causal relationship between vinyl chloride and kidney cancer.

VIII. The Levels of The Chemicals at Camp Lejeune Are Known to Cause Kidney Cancer

Current U.S. maximum contamination levels in drinking water are 5 μ g/L for TCE, PCE and benzene, and 2 μ g/L for vinyl chloride. Levels of TCE, PCE, and VC were significantly higher than those deemed acceptable by government agencies. As discussed by Bove et al, exposure through drinking water represented a significant exposure, but inhalation exposure through solubilized chemicals in water vapor sustained during showering and bathing also accounts for additional exposure.^{1,2}

As outlined above, increased exposure to TCE demonstrates strong evidence for causing kidney cancer. This is supported by reviews from credible government agencies. PCE's contribution to

kidney cancer is supported by epidemiologic studies showing such a causal relationship and this relationship is supported by some animal studies.

Evidence for a causal relationship between Vinyl Chloride and kidney cancer has support in the epidemiologic literature, including the studies specifically examining Camp Lejeune. There is, however, less literature outside of Camp Lejeune on this topic.

I have read Plaintiff's general causation expert reports of Drs. Hatten and Bird. Both reports examine the levels at which the toxins at issue are known to cause kidney cancer. I agree with the methodology and reasoning in these expert reports and agree with the levels known to cause kidney cancer in those reports. For example, the literature cited in these general causation reports has stated the following levels show a causal relationship with kidney cancer and therefore will be used to compare the exposure experienced by Mr. Down's at Camp Lejeune:

- 1. Cumulative exposure to 27.1-44.1 mg of PCE;²⁹
- 2. Exposure to a TCE concentration of > 76 ppb;²⁰
- 3. Cumulative exposure of > 1,580 ppb-years;²⁰
- 4. Sustained exposure to 0-25.3 ppb of TCE;³⁶
- 5. Exposure to a TCE concentration of 267.4 ppb;³⁷
- 6. Exposure to a PCE concentration of 20.8 ppb;³⁷
- 7. Cumulative exposure of 1 3,100 μg/L-month of TCE;¹
- 8. Cumulative exposure of 1 155 μ g/L-month of PCE;¹
- 9. Cumulative exposure of $1-4,600 \mu g/L$ -month of exposure to all compounds at Camp Lejeune;¹
- 10. Cumulative exposure of $3{,}100 7{,}700 \mu g/L$ -month of TCE;¹
- 11. Cumulative exposure of 155 380 µg/L-month of PCE;¹
- 12. Cumulative exposure of $4,600 12,250 \,\mu\text{g/L-month}$ of exposure to all compounds at Camp Lejeune;¹
- 13. Cumulative exposure greater than 7,700 μg/L-month of TCE;¹
- 14. Cumulative exposure greater than 380 µg/L-month of PCE;1
- 15. Cumulative exposure greater than 12,250 μg/L-month of exposure to all compounds at Camp Lejeune;¹
- 16. 18 months of residence on base from 1975 to 1985;¹
- 17. Employment on base for 2.5 years;²
- 18. Cumulative exposure to 110 11,030 ppb-months of TCE;³⁸

- 19. Cumulative exposure to 36 711 ppb-months of PCE;³⁸
- 20. Cumulative exposure greater than 11,030 ppb-months of TCE;³⁸
- 21. Cumulative exposure greater than 711 ppb-months of PCE;³⁸
- 22. 1-6 quarters stationed on base as a service member from 1975 to 1985;³⁹
- 23. More than 21 quarters spent on base as a civilian worker from 1975 to 1985.³⁹

These levels will be used as part of the causation analysis in this case and inform a differential diagnosis as to the etiology of Mr. Downs kidney cancer.

IX. David Downs: Medical Assessments, Relevant Diagnosis, Family History

<u>Primary Diagnosis</u>: Clear cell renal cell carcinoma (pathologic grade T1a) status-post laparoscopic right hand assisted radical nephrectomy on 07/26/2016. Metastasis of this cancer was found in 2024.

Secondary Diagnoses: Chronic kidney disease (Stage 3a) following radical nephrectomy

Medical History: Benign prostatic hyperplasia (diagnosed 2000), depression (diagnosed 2001; treated with fluoxetine), osteoarthritis (diagnosed 2008), eczema (2011; non-chronic), pulmonary nodules (noted 2011-2021; remained stable/statistically benign); chronic venous insufficiency (diagnosed 2012), diabetes mellitus with neuropathy (diagnosed 2014 – although it appears that there were not elevated A1C or glucose levels above the threshold for this diagnosis), dysphagia (diagnosed 2014), chronic rhinitis (diagnosed 2016), chronic headaches (diagnosed 2018), chronic pansinusitis (diagnosed 2020), microscopic hematuria (diagnosed 2021), ischemic colitis with acute ischemia of the large intestine (diagnosed 2021), colon polyps (diagnosed 2023), hyperlipidemia (unknown date of diagnosis), and gastroesophageal reflux disease (unknown date of diagnosis).

<u>Surgical History:</u> Hernia repair x2 (1966, 1999; unspecified), hiatal hernia repair (1974), tonsillectomy (during childhood), right hip replacement (2008) complicated by chronic pain requiring surgical revision (2009), cataract extraction x2 (2018, 2018), varicose vein surgery (date unspecified), nasal sinus surgery (date unspecified).

<u>Family History</u>: Two brothers with brain cancer, one brother with prostate cancer and diabetes, one sister with lung and skin cancers.

Genetic Testing: None

International Travel: Military service in Korea and Vietnam (1953-1973).

Smoking History: Smoked approximately a pack per day for 5 years while he was in the marines. There are medical records showing that he smoked for up to 15 years, but Mr. Downs disputes this and says it was only 5 years.

Occupational History: Served in the Marines (1953-1973), reaching the rank of captain, followed by work in real estate until retirement in the 1980s.

<u>Environmental History</u>: Potentially exposed to Agent Orange in Vietnam and Camp Lejeune-contaminated water during military service.

X. David Downs: Camp Lejeune Exposure Assessment

Hadnot Point was primarily contaminated with TCE while Tarawa Terrace was primarily contaminated with PCE.^{3,4} Exposure to TCE and PCE at these sites for Mr. Downs' from February 1960 to September 1961 can be reasonably estimated from ATSDR summary finding documents on analyses of groundwater flow and distribution of drinking water at Tarawa Terrace (Figure Appendix A2) and Hadnot Point (Figure Appendix A7).^{3,4} I have also looked at these same reports in the exhibits to Plaintiff's expert Morris Maslia that contain the same data.

From February 1960 to September 1961, the time-weighted average concentrations of TCE at Hadnot Point and PCE at Tarawa Terrace exceed the EPA's 5 μ g/L threshold.^{3,4} This is also true for vinyl chloride at Tarawa Terrace for which the EPA threshold is 2 μ g/L.³

Importantly, as discussed by Bove et al., exposure to TCE and PCE through drinking water may underestimate true exposure to these toxins. ^{1,2} Drinking water exposure to these contaminants is integrally related to that from inhalation and transdermal. ^{1,2} In fact, exposure from these other routes may meet that incurred from direct consumption. ^{1,2} For example, inhalation during a 10-minute warm shower may be equivalent to consumption of 2 liters of TCE-contaminated water. ^{1,2}

Mr. Downs worked at the headquarters in Hadnot Point. He also worked for some period of time in the Holcomb Boulevard area. Downs Dep. 20: 5-7. Mr. Downs worked in mail service and his job took him around the base. 01145_DOWNS_VBA_0000000312; Downs Dep. 20: 8-10, 68:13-19.

In addition to being on duty five days a week, Mr. Downs also worked at least once a month on weekends. Downs Dep.97:8-13. Mr. Downs lived at Tarawa Terrace. Downs Dep. 97:14-98:1, 98:17-99:2; 01145_DOWNS_VBA_0000001528; 01145_DOWNS_VBA_0000001530; 01145_DOWNS_VBA_0000001532.

Mr. Downs drank significant amounts of water from the tap on base. For example, Mr. Downs used the faucet at home and at work would use the water fountains at headquarters or at the stops along his mail route. Downs Dep. 109:18-21, 110:8-17, 110:21-112:6. He testified that he would sometimes also drink coffee and tea from water that came from the tap at his house. Downs Dep. 112:12-14.

Mr. Downs showered approximately one time a day for approximately fifteen minutes.

Below are the relevant charts from ATSDR and Morris Maslia relating to the time period for Mr. Down's exposure at Hadnot Point and Tarawa Terrace:

Appendix A7. Reconstructed (simulated) monthly mean concentrations in finished water for tetrachloroethylene (PCE), trichloroethylene (TCE), trans-1,2-dichloroethylene (1,2-tDCE), and vinyl chloride (VC) at the Hadnot Point water treatment plant, Hadnot Point-Holcomb Boulevard study area, U.S. Marine Corps Base Camp Lejeune, North Carolina, January 1942–June 2008.—Continued

[Concentrations in finished water computed using mixing-model approach; —, water treatment plant not operating; *, model simulations not conducted]

			Concentrations in	inished water, in mic	rograms per liter	
Stress period	Month and year	Tetrachloroethylene (PCE)	Trichloroethylene (TCE)	Trans-1,2- dichloroethylene (1,2,-tDCE)	Vinyl chloride (VC)	Benzene
218	Feb. 1960	0	11	0	0	0
219	Mar. 1960	0	9	0	0	0
220	Apr. 1960	0	16	0	0	0
221	May 1960	0	13	0	0	0
222	June 1960	0	12	0	0	0
223	July 1960	0	12	0	0	0
224	Aug. 1960	0	15	0	0	0
225	Sept. 1960	0	14	0	0	0
226	Oct. 1960	0	13	0	0	0
227	Nov. 1960	0	18	0	0	0
228	Dec. 1960	0	14	0	0	0
229	Jan. 1961	0	16	0	0	0
230	Feb. 1961	0	12	0	0	0
231	Mar. 1961	0	10	0	0	0
232	Apr. 1961	0	18	0	0	0
233	May 1961	0	15	0	0	0
234	June 1961	0	14	0	0	0
235	July 1961	0	14	0	0	0
236	Aug. 1961	0	19	0	0	0
237	Sept. 1961	0	17	0	0	0

Appendix A2. Simulated tetrachloroethylene and its degradation by-products in finished water, Tarawa Terrace water treatment plant, January 1951—March 1987!.—Continued

[PCE, tetrachloroethylene; µg/L, microgram per liter; 1,2-tDCE, trans-1,2-dichloroethylene; TCE, trichloroethylene; VC, vinyl chloride; WTP, water treatment plant]

Stress period	Month and year	Single specie using MT3DMS model ²	M	ultispecies, multiphase ı	using TechFlowMP m	odel ³
,		⁴ PCE, in μg/L	⁵ PCE, in μg/L	51,2-tDCE, in µg/L	⁵TCE, in μg/L	⁵VC, in µg/l
110	Feb 1960	43.85	31.17	7.12	1.46	4.86
111	Mar 1960	46.03	32.58	7.33	1.52	4.97
112	Apr 1960	48.15	34.16	7.57	1.59	5.10
113	May 1960	50.37	35.67	7.79	1.66	5.21
114	June 1960	52.51	37.24	8.03	1.73	5.33
115	July 1960	54.74	38.79	8.26	1.80	5.45
116	Aug 1960	56.96	40.45	8.51	1.87	5.59
117	Sept 1960	59.09	42.13	8.76	1.94	5.73
118	Oct 1960	61.30	43.80	9.02	2.02	5.86
119	Nov 1960	63.42	45.57	9.28	2.09	6.01
120	Dec 1960	65.61	47.31	9.54	2.17	6.15
121	Jan 1961	67.69	49.15	9.82	2.25	6.30
122	Feb 1961	69.54	51.03	10.10	2.33	6.46
123	Mar 1961	71.56	52.73	10.35	2.41	6.61
124	Apr 1961	73.49	54.69	10.64	2.49	6.77
125	May 1961	75.49	56.57	10.92	2.58	6.92
126	June 1961	77.39	58.53	11.20	2.66	7.07
127	July 1961	79.36	60.43	11.46	2.75	7.22
128	Aug 1961	81.32	62.42	11.74	2.83	7.36
129	Sept 1961	83.19	64.40	12.01	2.92	7.51

These charts reflect concentrations per month/cumulative at the time Mr. Downs would have resided at Tarawa Terrace. As previously stated, Mr. Downs worked at Hadnot Point. Thus, when he was at his house and at Tarawa Terrace he would have been exposed to the concentrations above from TT. When he was working he would have been exposed to the concentrations above from Hadnot Point.

XI. Mr. Downs' Exposure to the Toxins in the Water at Camp Lejeune was Substantial and Exceeded Levels Known to Cause Kidney Cancer

As referenced above, Mr. Downs was exposed to a substantial amount of the toxins in the water at Camp Lejeune. For instance, Mr. Downs was exposed to the chemicals at issue for approximately 589 days during the time he was at Camp Lejeune. The totals of the microgram/L-months of each chemical Mr. Downs was exposed to, for example, were approximately 282 microgram/L-months of TCE at HP and 939 microgram/L-months of PCE, 43 microgram/L-months of TCE and 122 microgram/L-months of Vinyl Chloride at TT. The reason these concentrations are important is that this is the exposure metric chosen to be used by Bove and ATSDR in all of the studies of the Camp Lejeune water contamination and also by other relevant epidemiology studies of the toxins at issue.

As described above, Mr. Downs was exposed to these toxins multiple times per day in amounts that were very significant and substantial. Mr. Downs' exposure, as described above, was through all three routes of exposure (ingestion, inhalation and dermal) and was consistent throughout the day.

For example, as mentioned above, the following levels have been shown in the epidemiology and other sciences to be causally related to kidney cancer:

- 1. Cumulative exposure to 27.1-44.1 mg of PCE;²⁹
- 2. Sustained exposure to 0-25.3 ppb of TCE;³⁶
- 3. Exposure to a PCE concentration of 20.8 ppb;³⁷
- 4. Cumulative exposure of 1 3,100 μg/L-month of TCE;¹
- 5. Cumulative exposure of 1 155 μg/L-month of PCE;¹
- 6. Cumulative exposure of $1-4,600~\mu g/L$ -month of exposure to all compounds at Camp Lejeune; 1
- 7. Cumulative exposure of 155 380 μg/L-month of PCE;¹
- 8. Cumulative exposure greater than 380 μg/L-month of PCE;¹
- 9. Cumulative exposure to 110 11,030 ppb-months of TCE;³⁸
- 10. Cumulative exposure to 36 711 ppb-months of PCE;³⁸
- 11. Cumulative exposure greater than 711 ppb-months of PCE;³⁸

12. 1-6 quarters stationed on base as a service member from 1975 to 1985;³⁹

Mr. Downs' exposure at Camp Lejeune was at similar levels to many of these citations. There are other examples of levels found to be causally related to kidney cancer that are sufficiently similar to Mr. Downs exposure to support that Mr. Downs' kidney cancer was caused by the water at Camp Lejeune.

In addition to the above, which provides a sufficient basis with which to say that Mr. Downs' exposure at Camp Lejeune was substantial, I have also reviewed the cumulative ingestion summary charts for Plaintiff's expert Kelly Reynolds. Dr. Reynolds put together ingestion doses for Mr. Downs relating to different assumptions made as to Mr. Downs' ingestion at Camp Lejeune. The charts show the following summary:

Chart 4:

		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)
Hadnot Point					
TCE	282	7,866	8,151	3,234	8,029
PCE	-	-	-	-	-
VC	-	-	-	-	-
BZ	-	-	-	-	-
Terawa Terrace					
TCE	43	1,240	2,635	1,046	2,596
PCE (ug/l- M)(TechFlow MP Model)	939	27,838	59,157	23,475	58,278
PCE (ug/l- M)(MT3DMS					
Model)	1,281	37,980	80,689	32,020	79,491
VC	122	3,586	7,615	3,022	7,502
BZ	-	-	-	-	-

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

As can be seen in these charts, Mr. Downs had substantial ingestion of PCE, TCE and VC. It is worth stating that this only accounts for one of the routes of exposure, namely, ingestion. This dose analyses does not take into account inhalation or dermal exposure, which would increase the dosage numbers in these charts significantly. In summary, ingestion of between 23,000 ppb and 59,000 ppb of PCE is substantial and is a level that is known to cause kidney cancer. Ingestion of TCE at levels ranging from 4,000 ppb to 10,000 ppb is substantial and is causally associated with kidney cancer. When all of these chemicals are combined, including the VC that Mr. Downs was exposed to, it is clear that just based on these ingestions numbers alone Mr. Downs had a substantial exposure that was at levels known to cause kidney cancer.

XII. Analysis of Potential Risk Factors Other Than Camp Lejeune Water

a. Mr. Down's Smoking History was Not Likely the Cause of His Kidney Cancer

Mr. Downs smoked cigarettes in the marines for a short time period. As stated above, he smoked approximately a pack a day for approximately 5 years while in the service. This limited and dated smoking history was not likely the cause of his renal cell carcinoma.

There was a C&P Examination (Rocky Mountain Regional VAMC -10/05/2017) letter that concluded: "Veteran's kidney cancer is less likely than not caused by or a result of the veteran's exposure to CLCW." It was further enumerated that "Veteran's kidney cancer is less likely than not caused by or a result of veteran's exposure to CLCW because it is more likely due to smoking. Medical records reveal that veteran has a history of smoking, and tobacco smoking is the single best recognized risk factor for kidney cancer."

Notwithstanding the fact that smoking is an established risk factor for kidney cancer, the above statement fails to reflect the fact that smoking cessation is an independent protective factor against the development of kidney cancer. Further, among prior smokers, duration of tobacco abstinence appears highly relevant in determining kidney cancer risk. To this end, a prior meta-analysis on cigarette smoking and kidney cancer risk published by Hunt et al. reported a significant reduction in the relative risk for kidney cancer among those who had quit smoking

more than a decade prior as compared to those who had quit smoking between 1 and 10 years prior. ⁴⁰ More recently, a meta-analysis from Liu et al., which pooled data from 56 original research studies, likewise reported a linear decrease in kidney cancer risk with time since quitting. ⁴¹ The nuanced – and highly time-dependent – relationship between cigarette use and risk for kidney cancer is noteworthy in view of the fact that Mr. Downs' last tobacco used occurred almost 50 years prior to his diagnosis of kidney cancer. The same is true if one assumes Mr. Downs smoked for 15 years and quit approximately 40 years prior to his diagnosis.

Also significantly relevant is the statute at issue and the "at least as likely as not" standard applicable to this case. It would be misleading and inaccurate to claim that a five-year limited smoking history, 50 years prior to the diagnosis of kidney cancer, was more likely than the known toxins in the water at Camp Lejeune to have caused his kidney cancer. In this case it is more likely than not that Mr. Downs' kidney cancer was caused by his exposure to the toxins in the water at Camp Lejeune, however, it is unquestionably at least as likely as not the cause.

b. Mr. Down's Family History was Not Likely the Cause of His Kidney Cancer

Family history is a recognized risk factor for kidney cancer, with approximately 3% of kidney cancer cases linked to hereditary syndromes such as von Hippel-Lindau (VHL) disease, hereditary leiomyomatosis, and renal cell cancer (HLRCC). 42 However, there is no indication that Mr. Downs has a personal or family history of these syndromes, nor is there evidence of genetic mutations such as VHL, MET, or FH, which are commonly implicated in hereditary RCC. While he has a family history of cancer, including brain and prostate cancer, these are not directly associated with hereditary RCC syndromes. The absence of such familial genetic markers significantly weakens the slight possibility that family history played a role in Mr. Downs' kidney cancer. Moreover, the presence of a family history of cancers unrelated to RCC does not come close to the strong causal link between the environmental exposure to carcinogens Mr. Downs had a Camp Lejeune and kidney cancer. Taken together, in Mr. Downs' case, the timeline and circumstances of his exposure to Camp Lejeune's contaminated water provide a far more compelling explanation for the development of his kidney cancer than any speculative contribution from his family history.

XIII. Kidney Cancer Survivorship: Multifaceted Implications

Unfortunately, Mr. Downs was recently noted to have recurrence of his kidney cancer. Recurrent kidney cancer is associated with poor prognostic outcomes, often marked by limited treatment success and significantly reduced survival rates. Studies show that patients experiencing a recurrence of renal cell carcinoma (RCC) after initial treatment face a median progression-free survival of approximately 11–23 months, depending on the timing and extent of the recurrence. Tumors that recur often exhibit more aggressive behavior, including higher metastatic potential, resistance to systemic therapies, and poor response to second-line treatments such as immunotherapy or targeted agents. The recurrence of kidney cancer in Mr. Downs' case is particularly concerning given his history of exposure to TCE and PCE from Camp Lejeune's contaminated water. In and of themselves, these compounds have been linked to aggressive tumor phenotypes due to their DNA-damaging properties and promotion of chronic

inflammation in renal tissues. 45, 12

More than half of all patients with a history of prior abdominal surgery such as radical nephrectomy will develop bands of scar tissue known as adhesions, ⁴⁶ which can complicate subsequent surgeries by making it more challenging to access and visualize the surgical area, potentially increasing the risk of injury to surrounding organs and tissue. Additionally, the presence of adhesions may prolong the duration of the surgery and elevate the likelihood of postoperative complications, such as infections or hernia recurrence. Accordingly, a history of prior major abdominal surgery including radical nephrectomy is well known amongst surgeons to be a major risk factor for complications following subsequent abdominal surgeries. ⁴⁶ Mr. Downs has undergone multiple operations for hernia repair in his lifetime, and should he require subsequent interventions in the future, his post-nephrectomy status would almost certainly confer higher risk for both acute and long-term complications with abdominal hernia surgery.

In view of Mr. Downs' normal renal function prior to radical nephrectomy, his development of chronic kidney disease was almost certainly a direct result of the surgery required to address his kidney cancer. Chronic kidney disease can progress to end-stage renal disease, necessitating dialysis or kidney transplantation. However, even before end-stage renal disease, chronic kidney disease in and of itself is associated with increased mortality⁴⁷, mediated by a host of chronic kidney disease-related complications including hypertension, cardiovascular disease, anemia, mineral bone disorders, physiologic body fluid volume dysregulation, and electrolyte disorders.⁴⁸

To a reasonable degree of medical certainty, Mr. Downs metastasis was causally related to his original kidney cancer diagnosed in 2016 and was caused by the water at Camp Lejeune.

XIV. Defendant's Supplemental Interrogatory Responses

Defendant's supplemental responses to interrogatories state: "There may be alternative causes or contributing factors for the Plaintiff's alleged illnesses and conditions." Specifically, the Defendant lists the following as to why Defendant believes that the Camp Lejeune water might not be the cause of Mr. Down's kidney cancer:

Interrogatory Answer: "Plaintiff was first diagnosed with kidney cancer just before his 82nd birthday and was also of advanced age when he was diagnosed with chronic kidney disease."

While these facts are true, it does not negate the fact that the drinking water was the cause of Mr. Down's kidney cancer because advanced age is not a cause of kidney cancer. Rather it is a contextual factor in the timing of its diagnosis. Moreover, multiple peer-reviewed studies and government acknowledgments, including from the Department of Veterans Affairs, have linked Camp Lejeune's contaminated water to kidney cancer irrespective of age at time of diagnosis. In other words, the causal relationship between exposure to TCE and PCE with kidney cancer has been established independent of the timing of diagnosis.²⁰

Interrogatory Answer: "A personal history of smoking cigarettes, being overweight or obese, diabetes or prediabetes, and exposure to secondhand smoke."

These facts do not alter my analysis of the cause of Mr. Down's kidney cancer because his smoking cessation occurred approximately five decades before his diagnosis—a period during which kidney cancer risk due to smoking significantly diminishes. 40,41 Further, while obesity and diabetes have been associated with kidney cancer, evidence of a direct cause-and-effect relationship between these factors and kidney cancer is lacking. Mr. Downs' BMI around the time of diagnosis was at or around 28. This is a BMI that is of the very lowest values considered to be overweight. This is such a relatively insignificant factor in this analysis that it should be given very little weight, if any at all. Further, it does not appear that Mr. Downs met the criteria for diabetes based on his lab values and the other facts of his case.

Interrogatory Answer: "The Plaintiff's exposure to water at Camp Lejeune may not have been significant enough to cause the alleged illness or injury, and the length of time (latency period) between any exposure to the water at Camp Lejeune and the onset of the Plaintiff's illness or injury may indicate an alternative cause or that the cause of the Plaintiff's illness or injury is idiopathic."

As previously mentioned in this report, Mr. Downs was exposed to a substantial amount of toxic chemicals in the water, which are all known to be causally related to the development of kidney cancer. Similarly, the latency period between exposure to carcinogens like TCE and the development of kidney cancer is well documented to span several decades. ^{49,50} In fact, this latency precisely aligns with the timeline of Mr. Downs' exposure during military service, actually reinforcing the causal relationship.

XV. Differential Diagnosis to Determine Etiology and Causation Analysis for Mr. Downs

The methodology used in a differential diagnosis is a medically sound, valid and peer-reviewed approach. In this case, the objective is not to try to identify a diagnosis because a diagnosis of kidney cancer already exists. However, the methodology employed in attempting to determine a diagnosis is a useful and necessary methodology in determining the likely etiology of a persons cancer. The same methodology and principles exist in this context and this type of methodology is commonly used by physicians such as myself in determining a patient's etiology.

The differential diagnosis methodology requires first making a list of potential risk factors for the condition at issue, in this case kidney cancer. The risk factors for kidney cancer that have a valid basis for consideration are: (1) environmental exposures, such as the toxins in the water at Camp Lejeune, (2) obesity, (3) smoking history, (4) sex of the person and (5) familial history.

In this case it is much more likely than not that Mr. Down's kidney cancer was caused by the toxins in the water at Camp Lejeune. As described above, there is significant science and literature to support the connection of the toxins in the water at Camp Lejeune and kidney cancer. This is true generally and at the levels that Mr. Downs was exposed to, as described above.

Obesity is a risk factor for kidney cancer but not a strong one. Further, Mr. Downs was not significantly overweight at the time of his diagnosis. His BMI at or around the time of diagnosis was 28.1 and in 2018 was 24.7 at 5'9" and 166lbs. His BMI ranged from 24-28 over the several years preceding his nephrectomy and following his nephrectomy.

Mr. Down's did have a very distant smoking history of approximately a pack a day for 5 years, but this history pales in comparison to the exposure he had from Camp Lejeune. There is literature that suggests smoking cessation is a highly determinative factor in cancer causation. Further, the literature as to smoking and kidney cancer shows that kidney cancer is not as likely to occur with smoking as, for example, lung cancer. Some of Mr. Down's medical records say that he smoked for 15 years. Mr. Downs testified this was inaccurate. However, even if that was true, it wouldn't make a difference. If Mr. Downs smoked for 15 years on and off, he would have ceased smoking in the 1970s. That would have still been approximately 40 years before his kidney cancer diagnosis. Medical literature shows that smoking one pack a day for 15 years, having ceased smoking 35 years prior, does not put you at an increased risk of kidney cancer.

Being of the male sex is a slight increased risk profile than being female. However, again, it does not equate in any manner to the marked increased risk from the toxins in the water at Camp Lejeune.

Mr. Downs was sent oversees to Korea and Vietnam and this in theory would create a risk of exposure to agent orange. There is no actual evidence Mr. Downs was exposed to agent orange and certainly no evidence of the levels to which he would have been exposed. To Mr. Downs' knowledge, he was not aware of any exposure. However, even if Mr. Downs was exposed to agent orange, it would not change this analysis. Agent Orange is not known to be nearly as nephrotoxic as the chemicals in the water at Camp Lejeune. Further, given the lack of evidence as to any potential exposure, it cannot be said that this was more likely than the very significant exposure at Camp Lejeune to have caused Mr. Downs' kidney cancer.

Finally, family history can be an increased risk factor but only when there are multiple very close family members who have developed kidney cancer. None of Mr. Downs immediate family members have kidney cancer and therefore he was not at increased risk on this basis.

The only risk factor Mr. Downs had that was of significance was his exposure to the toxins in the water at Camp Lejeune. When performing this type of analysis, this risk factor stands alone as the likely cause of Mr. Downs kidney cancer. Therefore, I conclude this differential diagnosis methodology with the fact that more likely than not Mr. Down's kidney cancer was caused by the toxins in the water at Camp Lejeune.

As part of my medical opinions in this case there was no further information or documentation that I needed in order to perform my differential diagnosis, and I hold these opinions to a reasonable degree of medical certainty.

XVI. Mr. Downs' Damages

Mr. Downs has suffered damages due to his kidney cancer, including metastasis of the cancer he was diagnosed with in 2016. To a reasonable degree of medical certainty, the metastasis Mr. Downs developed was causally related to his original diagnosis of RCC in 2016 and 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 and metastasis, the surgery to remove his kidney and the follow up treatment related to his kidney cancer was reasonable and medically necessary.

XVII. Conclusion

In conclusion, I hold the opinion that more likely than not Mr. Downs kidney cancer was caused by the water at Camp Lejeune and specifically the toxins in the water at Camp Lejeune. I hold to this opinion to a reasonable degree of medical certainty.

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VITALY MARGULIS'S CV



Curriculum vitae

Date Prepared: January 2025

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Dallas, TX 75390-9164

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(214) 648-8786 Work Fax:

Place of Birth: Ukraine

Education

Year	Degree (Honors)	Field of Study (Thesis advisor for PhDs)	Institution
1993 – 1997	Bachelor of Science	Biology, Biochemistry	University of Texas
1997 – 2001	Doctor of Medicine		University of Texas Southwestern Medical School

Postdoctoral Training

Year(s)	Titles	Specialty/Discipline (Lab PI for postdoc research)	Institution
2001 – 2006	Residency	Urology	University of Texas Southwestern Medical Center
2006 – 2008	Fellowship	Urologic Oncology	University of Texas MD Anderson Cancer Center

Faculty Academic Appointments

Year(s)	Academic Title	Department	Academic Institution
2008 – 2009	Clinical Specialist	Urologic Oncology	University of Texas M.D. Anderson Cancer Center Houston, Texas
2009 – 2014	Assistant Professor	Urology	University of Texas Southwestern Medical Center Dallas, Texas

2014 – 2019	Associate Professor	Urology	University of Texas Southwestern Medical Center Dallas, Texas
2019 – Present	Professor	Urology	University of Texas Southwestern Medical Center Dallas, Texas
2020 – 2021	Paul C. Peters, M.D., Chair in Urology	Urology	University of Texas Southwestern Medical Center Dallas, Texas

Current Licensure and Certification

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2002 – Present	Texas Board of Medical Examiners
2002 – Present	Texas Department of Public Safety
2002 - Present	DEA Controlled Substances
2010 – Present	National Provider Identification

Board and Other Certification

2007

American Board of Urology
MdxHealth Bladder Cancer Scientific Advisory Board 2015

TUS Board Executive Committee 2018

2018-2019 UT Southwestern Robotic Executive Committee

Honors and Awards

Year	Name of Honor/Award	Awarding Organization	
1993 – 1997	Presidential Full Tuition Merit Scholarship	University of Texas	
1997	Summa Cum Laude	University of Texas	
2001	Alpha Omega Alpha	University of Texas Southwestern Medical Center	
2004	Travel Grant	American Geriatric Society Meeting	
2004 – 2005	Excellence in Urologic Pathology Award	University of Texas Southwestern Medical Center	
2005	Travel Grant	Cleveland Clinic Foundation Endourologic Workshop	
2005	Travel Grant	Northwestern University Visiting Resident	
2006 – 2008	American Urologic Association Foundation Research Scholar Award, (AFUD)	American Urological Association	
2006 – 2007	Ruth L. Kirschstein National Research Service Award	University of Texas M.D. Anderson Cancer Center	

2007	Travel Grant	Best of American Society of Clinical Oncology	
2007 – 2011	NIH Clinical Research Staff LRP Award	National Institute of Health	
2008, 2013	Merit Award	American Society of Clinical Oncology	
2009	Best Poster Award	Society of Urologic Oncology	
2010, 2013	Faculty Teaching Award	University of Texas Southwestern Medical Center	
2009 – 2011	NIH Clinical Research Scientist LRP Award	National Institute of Health	
2012	American Urological Association / Japanese Urologic Association Academic Exchange Scholar	American Urological Association	
2012	Texas Rising Stars	Super Doctors	
2012	Best Reviewer	The Journal of Urology	
2014	Castle Connolly Top Doctor – Urology	Castle Connolly Medical LTD.	
2014, 2022	Best Doctors in Dallas	D Magazine – Urology category	
2014 – 2015,2017- 2018, 2021- 2024	Texas Super Doctors	Texas Monthly	
2015 – 2017	Urology Care Foundation Public Education Council	Urology Care Foundation	
2016 – 2024	Best Doctors in Dallas	D Magazine – Urology category	
2017	Top Urologist	International Association of Healthcare Professionals (IAHCP)	
2017-2019	Best Doctors in America	Best Doctors Poling and Research (Peer Selected)	
2019 – 2020	Detection of invasive renal cell carcinoma with targerted. SPA0003043	American Urological Association	

Appointments at Hospitals/Affiliated Institutions

Past			
Year(s)	Position Title	Department/Division	Institution
2008 -2009	Clinical Specialist	Urologic Oncology	University of Texas M.D. Anderson Cancer Center

Current			
Year(s)	Position Title	Department/Division	Institution
2009 – Present	Assistant Professor	Urology	University of Texas Southwestern Medical Center
2006 – Present	Active Attending	Urology	VA North Texas
2006 – Present	Chief of Urology	Urology	Parkland Memorial Hospital
2006 – Present	Active Attending	Urology	Zale-Lipshy University Hospital
2006 – Present	Active Attending	Urology	Children's Medical Center
05/2017- Present	Active Attending	Urology	John Peter Smith Hospital
12/2019 – Present	Active Attending	Urology	Texas Health Hospital Frisco

Major Administrative/Leadership Positions

Year(s)	Position Title	Institution
2013 – Present	Fellowship Director	Society of Urologic Oncology
2013 – 2017	Chief of Urology	Parkland Memorial Hospital

Committee Service

Year(s)	Name of Committee	Institution/Organization
2016-2017	South Central Representative of the Young Urologist Committee	American Urological Association
2020	IKCS – Kidney Cancer Symposium Scientific Program Committee	International Kidney Cancer Association
2021	NCCN – Bladder/Penile Cancers Guidelines Institutional Review	National Comprehensive Cancer Network
<u>UTSW</u>		
2009 – Present	Annual Paul C. Peters Urologic Symposium Organizing Committee	University of Texas Southwestern Medical Center and Affiliated Hospitals
2010 – Present	Applicant Interviewer Medical School Admissions	University of Texas Southwestern Medical Center and Affiliated Hospitals
2011 – Present	Surgical Services Executive Committee	University of Texas Southwestern Medical Center and Affiliated Hospitals

2012– Present	Applicant Interviewer Medical School Admissions	University of Texas Southwestern Medical Center and Affiliated Hospitals
2012 – Present	STARS Summer Research Program Mentor	University of Texas Southwestern Medical Center and Affiliated Hospitals
2015 – 2017	Bylaws Committee (SCSREP)	AUA (American Urological Association)
2015 – 2017	UCF – Public Education Council (LEAD)	AUA (American Urological Association)
2015 – 2017	Young Urologists Committee (SCSREP)	AUA (American Urological Association)
2015-2017	Urology Care Foundation's Kidney and Adrenal Health Committee	Urology Care Foundation
2016	Residents Program Committee	SCS (South Central Section)
2018	Program Abstract Reviewer	SCS (South Central Section
<u>Hospital</u>		
2011 – Present	Operation Room Committee	Parkland Health and Hospital System
2012 – Present	Surgical Chiefs Committee	Parkland Health and Hospital System
National/Interna	ational	
2011 – Present	Annual Congress Content Reviewer	American Urological Association
2013	Co-Director American Urologic Association Course on Locally Advanced Renal Cell Cancer	American Urological Association

Professional Societies

Dates	Fellowships
2013	Society of Urological Oncology, Member
	American Association for Cancer Research, Member
	American College of Surgeons, Member
	Endourologic Society, Member
	American Urological Association, Member
	American Medical Association, Member
	Texas Medical Association, Member
	Dallas County Medical Society, Member
	Harris County Medical Society, Member

Editorial Activities

2014	Minerva Urologic e Nefrolica, Editorial Board
2018 - 2021	Journal of Urology Editorial Board (Four year term) South Central Section

2018	Urology – Clinics in Medicine Editorial Board
2018 - 2020	Translational Andrology and Urology (TAU)
2018	Current Opinion in Urology, Editorial Board
2022	Operative Standards for Cancer Surgery – American College of Surgeons and the Alliance for Clinical Trials of Oncology, Volume 3, Editorial Board
Editor/Associate	e Editor
2014	BMC Urology, BioMed Central, Associate Editor
2015	International Archives of Translational Medicine, Research
2020 - 2021	Frontiers in Oncology
2022	JU Open Plus
Ad Hoc Review	<u>rer</u>
	Urologic Oncology
	Clinical Cancer Research
	Journal of Clinical Oncology
	European Journal of Cancer
	Expert Reviews in Oncology
	Oncogene
	Cancer Epidemiology Biomarkers and Prevention
	Urology
	International Journal of Cancer
	International Journal of Urology
	Expert Reviews in Anticancer Therapy
	Molecular Cancer Therapeutics
	Brazilian Journal of Urology
	Indian Journal of Urology
	The Prostate
	World Journal of Urology
	Journal of Urology
	British Journal of Urology
	European Urology

Grant Support

<u>Present</u>	
1	Title of Project: Using deep machine learning to identify aggressive tumor characteristics in renal cell carcinoma
	Role (Principal Investigator, Co-Investigator): Mentor
Total amount of award (if multi-year) and dates (direct costs only): \$75,000	
	Annual amount and date (direct costs only): \$25,000 2/1/2020 – 8/1/2021
	Grantor: KCCURE - Kidney Cancer Research Alliance

2	Title of Project: The University of Texas Southwestern Medical Center SPORE in Kidney Cancer	
	Role (Principal Investigator, Co-Investigator): Co-Investigator	
	Total amount of award (if multi-year) and dates (direct costs only): \$1,350,895	
	Annual amount and date (direct costs only): \$6,783.255 7/1/2016-7/31/2021	
	Grantor: NIH – National Cancer Institute	

<u>Past</u>	Detection of invasive renal cell carcinoma with targeted molecular imaging
	Mentor
	\$40,000 7/1/2019 - 12/1/2020
	AUA – American Urological Association
	Title of Project: Advancing CT and fluorescence imaging of kidney cancers with gluthathione-mediated contrast enhancement
	Role (Principal Investigator, Co-Investigator): Other significant Contributor
	Total amount of award (if multi-year) and dates (direct costs only): \$191,207 3/1/2020-2/28/2021
	Annual amount and date (direct costs only): \$63,373
	Grantor: UT Dallas

Clinical Trials Activities

Present	Grantor: None
12/21/10	Title of Project: Registry for Determining Clinical Outcomes in Patients with Kidney Cancer and Testis Cancer
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Grantor: None
4/15/11	Title of Project: Establishment of Urologic Tissue and Serum Respository
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Grantor: Southwest Oncology Group
9/14/11	Title of Project: A Phase III Surgical Trial to Evaluate the Benefit of a Standard Versus an Extended Pelvic Lymphadenectomy Performed at Time of Radical Cystectomy for Muscle Invasive Urothelial Cancer
	Role (Principal Investigator, Co-Investigator): : Co-Investigator
	Grantor: Baylor College of Medicine

6/1/12	Title of Project: A multi-center prospective assessment of practice patterns following non-invasive bladder cancer patients
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Grantor: Astellas Pharma US, Inc
12/13/13	Title of Project: Phase II study of enzalutamide (MDV3100) and gonadotropin-releasing hormone (GnRH) agonist before, during and after radiation therapy in treatment of patients with high-risk localized prostate cancer
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Grantor: None
12/27/13	Title of Project: Randomized Trial of Adjuvant Curcumin after Radical Prostatectomy
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Grantor: None
7/24/14	Title of Project: Success of active surveillance in patients with untreated small renal masses with the option of delayed treatment
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Grantor: None
7/29/14	Title of Project: Deciphering Androgen receptor signaling in primary prostate cancer
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Grantor: None
2/27/15	Title of Project: Tissue MicroArrays for Evaluation of Molecular Alterations in Urologic Malignancies
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Grantor: ECOG-ACRIN Cancer Research Group
6/11/15	Title of Project: EA8141: A prospective Phase II Trial of Neoadjuvant systemic Chemotherapy Followed by Extirpative Surgery for Patients with High Grade Upper Tract Urothelial Carcinoma
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Grantor: None
9/15/15	Title of Project: A Multi-Institutional Development of a Preoperative Clinical Risk Stratification Tool for Upper Urinary Tract Tumors
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Grantor: None

11/22/16	Title of Project: Molecular characterization of patients with germ cell tumors
	Role (Principal Investigator, Co-Investigator):
	Grantor: None
2/28/17	Title of Project: Prospective molecular characterization of patients with penile carcinoma
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Grantor: Children's Oncology Group Operations Center
5/17/17	Title of Project: AGCT1531 A Phase 3 Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Grantor: None
6/26/17	Title of Project: Retrospective review of upper tract urothelial carcinoma
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Grantor: Photocure ASA
9/11/17	Title of Project: Blue Light Cystoscopy with Cysview Registry
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Grantor: None
9/13/17	Title of Project: Anti-1-amino-3-18F-flurocycobutane-1-carboxylic acid (Axumin) Positron Emission Tomography Prior to Retroperitoneal Lymph Node Dissection for Testicular Cancer
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Grantor: USC Norris Comprehensive Cancer Center
10/23/17	Title of Project: Surgery in Early Metastatic Seminoma (SEMS): Phase II Trial of Retroperitoneal Lymph Node Dissection and First Line Treatment for Testicular Seminoma with Isolated Retroperitoneal Disease (1-3cm)
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Grantor: Karl Storz Endoscopy America
3/16/18	Title of Project: Cystoscopy with IMAGE1 S CHROMA for Detection of Bladder Lesion
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Grantor: Dana Farber Cancer Institute
1/9/19	Title of Project: Genetic Counseling Processes and Outcomes Among Males with Prostat Cancer (ProGen)

	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Grantor: NIH – National Institute of DDK Diseases
7/19/19	Title of Project: Effects of cellular Anatomy on Therapeutic outcomes in BPH
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Grantor: ECOG-ACRIN Cancer Research Group
5/14/20	Title of Project: EA8134: Impact – International Penile Advanced Cancer Trial (International Race Cancers Iniative Study): Impact – neoadjuvant and Impact Pelvis
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Grantor: None
6/24/20	Title of Project: Safe and Timely management of hemorrhage after upper urinary tract procedures
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Grantor: None
8/24/20	Title of Project: Robotic Post-chemo RPLND
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Grantor: Merck Sharpe and Dohme
9/16/20	Title of Project: A Phase 3, Randomized, Comparator-Controlled Clinical Trial to Study the Efficacy and Safety of Pembrolizumab (MK-3475) in Combination with Bacillus Calmette-Guerin (BCG) in Participants with High-Risk Non-Muscle Invasive Bladder Cancer (HR-NMIBC) that is persistent or Recurring Following BCG Induction (KEYNOTE-676)
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Grantor: None
9/18/20	Title of Project: Outcomes of radical or partial nephrectomy after immune checkpoint inhibitor therapy
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Grantor: None
11/19/20	Title of Project: Outcomes of patients with clinically node-positive bladder cancer
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Grantor: None
In Process	Title of Project: A Prospective Observational Cohort study to Assess miRNA 371 for outcome prediction in patients with newly diagnosed germ cell tumors

	Role (Principal Investigator, Co-Investigator): Co-Investigator	
	Grantor: None	
In Process	Title of Project: PROSPER: Phase III Randomized Study Comparing PERioperative Nivolumab versus Observation in Patients with Renal Cell Carcinoma (RCC) Undergoing Nephrectomy (ECOG-ACRIN EA8143)	
	Role (Principal Investigator, Co-Investigator): Co-Investigator	

Past	Grantor:
None	Title of Project:
	Role (Principal Investigator, Co-Investigator):

Invited Lectures

Year(s)	Title	Location	
International	[nternational		
2010	Genetic basis in renal cell cancer	Society of Translational and Clinical Oncology, Chiclayo, Peru.	
2011	Minimally invasive options for management of localized kidney cancer	Jikey University Grand Rounds, Tokyo, Japan	
2012	Integration of surgery and systemic therapy for management of advanced renal cell cancer	Spanish Oncology Genitourinary Group, Madrid, Spain	
2017	Modern concepts and techniques in management of penile cancer	ONCO 2017 Conference, (Ukranian Association of Oncourilogist), April 27-30, 2017, Kiev, Ukraine	
2017	Upper tract urothelial cancer updates on diagnosis and management	ONCO 2017 Conference, (Ukranian Association of Oncourilogist), April 27-30, 2017, Kiev, Ukraine	
2017	Neo and adjuvant strategies in RCC	ONCO 2017 Conference, (Ukranian Association of Oncourilogist), April 27-30, 2017, Kiev, Ukraine	
2018	Operator – Robotic Assisted Partial Nephrectomy	International Urology Meeting, Sechenov University, International Urology Meeting, Sechenov University, March 30 – April 3, 2018. Moscow Russia	
2018	Moderator – Laparoscopic and Robotic Surgery	International Urology Meeting, Sechenov University, International Urology Meeting, Sechenov University, March 30 – April 3, 2018. Moscow Russia	
2018	Speaker – Cava Thrombectomy, Radical Nephrectomy, Neo-adjuvant chemotherapy	Bench-to-Bedside (B2B) Symposium on Bladder and Kidney Cancer, May 23-28, 2018, Vienna, Austria	

2018	Invited Speaker – Cytoreductive nephrectomy what is the new standard?	4 th (MJM) Michael J. Marberger Annual Meeting, December 13-14, 2018, Vienna, Austria
2023	Presentation – Tips and tricks for nephrectomy with caval tumor thrombus.	Rabin Medical Center (Israel), March 16, 2023
<u>National</u>		
2008	Locally advanced renal cell cancer: resecting the unresectable	Seventh International Kidney Cancer Symposium, University of Chicago, Chicago Illinois
2010	Targeted systemic therapy in management of advanced renal cell cancer	American Urologic Association Annual Meeting, San Francisco, California.
2012	Management of small renal mass in the modern era	Society of Urologic Nurses and Associates, Washington, D.C.
2013	Management of lymph nodes in renal cell carcinoma	Kidney Cancer Association, Chicago, IL
2013	Locally advanced renal cell cancer course	American Urologic Association Annual Meeting, San Diego, CA
2014		American Urologic Association Annual Meeting, Orlando, FL
2015	Mentor and Participants – Increased Violent Acts against Urologist	AUA Leadership Program-Joint Advocacy Conference, Washington, DC, March 8-10, 2015
2015	Upper Tract Disease Working Group. Upper tract urothelial carcinoma (UTUC) is an uncommon disease with little evidence-based data to guide clinical decision-making.	BCAN 2015 Think Tank, August 6-8, 2015, Charlotte, NC
2015	Locally-Advanced RCC. Debate: Optimal Treatment for cT1b Renal Mass in Patient with Normal GFR – Partial Nephrectomy	14 th International Kidney Cancer Symposium, November 6-7, 2015, Miami, FL
2015	Controveries in Upper Tract Urothelial Carcinoma	SUI 2015 35 th Congress of the Societe Internationale d'Urologie, October 15-18, 2015, Melbourne, Australia
2016	Lecture – Follow up for Active Surveillance for Localized RCC: Nonsense	SUI 2016 36 th Congress of the Societe Internationale d'Urologie, October 20-23, 2016, Buenos Aires, Argentina
2017	Speaker – Session: Testicular Cancer Update	UAPA 6 th Annual Meeting, March 31-April 2, 2017, Las Vegas, NV
2017	Panelist – Session: Prostate Cancer	UAPA 6 th Annual Meeting, March 31-April 2, 2017, Las Vegas, NV

2017	Ukrainian Association of Oncourilogist	VII Annual International Scientific and Practical Conference, April 27- 29, 2017, Kiev, Ukraine
2017	Upper Tract Disease Working Group. Upper tract urothelial carcinoma (UTUC) is an uncommon disease with little evidence-based data to guide clinical decision-making.	BCAN 2017 Think Tank, August 3-5, 2017, Charlotte, NC
2017	FY17 KCRP Stakeholders Meeting	CDMRP Kidney Cancer Research Program, Herndon, VA
2018	ECOG-ACRIN 2018 Meeting	Chicago, IL, May 3-5, 2018
2018	Moderator – Session: Kidney and Ureter Surgery – Benign/Malignant Podium Session	97 th Annual Meeting of the South Central Section of the AUA, Nashville, TN, September 26- 29,2018
2018	Neoadjuvant Therapy for Locally Advanced Renal Cell Carcinoma: Status in 2018	KCA – Kidney Cancer Association National Patient and Caregiver Conference, September 22, 2018, Chicago, IL
2018	Moderator- Kidney and Ureter Surgery – Benign/Malignant Podium Session	SCS-South Central Section of the AUA Annual Meeting, September 26-29, 2018, Nashville, TN
2018	Invited Speaker – Small Renal Masses	SUNA 2018 – Society of Nurses and Associates Urologic Conference, October 25-28, 2019, San Diego, CA
2019	Speaker – Urothelial and Variant Cases: Urologic Oncology Perspective	ASCO 2019 Annual Meeting, May 31-June 4, 2019, Chicago, IL
2020	Invited Presenter – Session 7	International Kidney Cancer Symposium 2020 – Virtual
2021	Panelist – Debate: Recurrent high grade ta/t1 bladder cancer	TUS 2021 – Texas Urological Society, June 10-12, 2021, Chicago, IL
2021	Panelist – Debate: Management of NIMBC with BCG Shortage	TUS 2021 – Texas Urological Society, June 10-12, 2021, Chicago, IL
2021	Gu Tumor Board Panel	TUS 2021 – Texas Urological Society, June 10-12, 2021, Chicago, IL
Regional/Loc	cal cal	
2007	Surveillance after surgical management of renal cell carcinoma and observation of small renal masses	Kidney Cancer Association Patient Advocacy Meeting. University of Texas M.D. Anderson Cancer Center, Houston, Texas

2009	Surveillance for recurrent disease: how often should I be seen and what tests should be ordered	Kidney Cancer Association Patient Advocacy Meeting. University of Texas M.D. Anderson Cancer Center, Houston, Texas
2009	PSA and prostate puzzle	University of Texas Southwestern Medical Center Continued Education, Dallas
2009	Advances in prostate cancer management	Presbyterian Hospital Group Grand Rounds
2010	Chemoradiation in management of bladder cancer	Annual Paul C. Peters Urologic Symposium, Dallas
2010	Active surveillance for small renal masses	Annual Paul C. Peters Urologic Symposium, Dallas
2010	Penile cancer in 2010	Texas Urologic Society, San Antonio
2010	Renal cell cancer	Texas Academy of Physician Assistants, Fort Worth
2011	Multimodality management of upper urinary tract cancer	Annual Paul C. Peters Urologic Symposium, Dallas
2011	Perioperative systemic therapy for advanced renal cancer	Annual Paul C. Peters Urologic Symposium, Dallas
2011	Current state of adjuvant therapy in prostate cancer	Annual Paul C. Peters Urologic Symposium, Dallas
2011	Partial nephrectomy: current status	Texas Urologic Society, San Antonio
2011	Epithelial to mesenchymal transition in renal cancer	Renal Cell Carcinoma Task Force, M.D. Anderson Cancer Center
2013	Risk assessment and integration of systemic therapy in upper tract urothelial cancer	The 50 th Annual Harry M. Spence Visiting Professor Conference, Dallas
2013	Upper tract urothelial cancer updates	Annual Paul C. Peters Urologic Symposium, Dallas
2014	Clinical cases in Urologic Oncology	Urology Update 2013, Dallas
2015	Robotic-Assisted Laparoscopic Prostatectomy	21 st Annual Paul C. Peters Urology Symposium, Dallas, TX, Jan 23-25, 2015
2015	Case Discussion: Urothelial Carcinoma	21 st Annual Paul C. Peters Urology Symposium, Dallas, TX, Jan 23-25, 2015
2015	Case Discussions: Genomics Testing in Prostate Cancer	21 st Annual Paul C. Peters Urology Symposium, Dallas, TX, Jan 23-25, 2015
2016	Speaker – AUA Young Leadership Update	South Central Section of the AUA, Inc. 94 rd Annual Meeting, September 28–October 1, 2016, Scottsdale, AZ

2016	Speaker – Presentation	LA Urological Society, February 10, 2016, Los Angeles, CA
2017	Speaker and Panelist – General Session6: Orphan Cancers With Oppoartunities for Improved Treatment (ARS) – Urologist	2017 Genitourinary Cancers Symposium, February 16-18, 2017, Orlando, FL
2017	Chair – Title: Oral Absract Session C: Renal Cell Cancer	2017 Genitourinary Cancers Symposium, February 16-18, 2017, Orlando, FL
2017	Kidney Cancer Research Program	FY17 Stakeholders Meeting, August 23, 2017, Herndon, VA
2017	Kidney Marker Research Meeting	September 27 –Octboer 1, 2017, Nijmegen, Netherlands
2017	Moderator – Renal Mass/Localized Reanl Cancer Panel Discussions: Difficult Cases	2017 South Central Section of the AUA, November 26-29, 2017, Naples, FL.
2018	Speaker –Bladder Cancer	UAPA 7 th Annual Meeting, April 6-8,2018, Scottsdale, AZ
2018	Panelist – Oncology Panel Discussion	UAPA 7 th Annual Meeting, April 6-8,2018, Scottsdale, AZ
2018	Moderator – 2018 AUA Annual Meeting	2018 AUA Annual Meeting, May 18-22, 2018, San Francisco, CA
2018	Moderator – BCAN (Bladder Cancer Advocacy Network) Think Tank	2018 BCAN Meeting, August 2-4, 2018, Denver, CO
2018	Moderator: Kidney and Ureter Surgery – Benign/Malignant Podium Session	97 th Annual Meeting of the South Central Section of the AUA, September 26-29, 2018. Nashville, TN.
2018	Speaker – Topic of small renal masses	2018 SUNA Conference, October 25-28, 2018, San Diego, CA
2018	Moderator – Kidney Cancer Session I	SUO 2018 Annual Meeting, November 28-30, 2018, Phoenix, AZ
2019	Cytoreduction Nephrectomy: What is the Treatment Paradigm and is it Time to Change it?	25 th Annual Paul C. Peters Symposium, Irving, TX
2019	Difficult Renal Cancer Cases	25 th Annual Paul C. Peters Symposium, Irving, TX
2019	Moderator: Poster Session: Title MP18: Prostate Cancer: Detection & Screening II	AUA 2019 Annual Meeting, May 3-6, 2019, Chicago, IL
2019	Moderator – BCAN (Bladder Cancer Advocacy Network) Think Tank	2019 BCAN Meeting, August 8-10, 201, Washington, DC
2019	Moderator – Kidney and Ureter Podium Session	2019 Annual Meeting of the South Central Section of the AUA, September 25-28, 2019, Colorado Springs, CO

2020	Presenter – Session 7 – Lunch by the Woodfire	2020 International Kidney Cancer Symposium, Virtual, November 6-7, 2020.
2021	Speaker – Kidney Cancer Update: Advances in imaging, staging and selection for surgery, ablation or observation.	2021 South Central Section of the AUA, September 29-October 2, 2021, Scottsdale, AZ.
2021	Speaker – Session 5:Translational Cancer Insights: Metabolomics in RCC	2021 – International Kidney Cancer Symposium, November 5-6, 2021, Austin, TX
2021	Speaker – Kidney Cancer II – Panel discussion: Treatment of Metastatic RCC	2021 SUO 22 nd Annual Meeting, December 1-3, 2021, Orlando, FL
2022	Speaker How to talk to patients about 5ARIs and Prostate Cancer	SoBPD 2022 Annual Meeting, August 19-20, 2022, Dallas, TX
2024	Co-Moderator: Session V Organ Specific Break Out Session (Focus on Collaboration) Rare Cancers.	2024 Christopher G. Wood Symposium, April 12-14, 2024, Austin, TX

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Peer-Reviewed Publications

Original Research Articles

1.	Margulis V, Lemack GE, Molberg K, Saboorian MH. Bladder "Müllerianosis" in a
	woman with lower urinary tract symptoms and hematuria. J Urol 2001 Jun; 165(6 Pt 1):
	1996-7. PMID: 11371906.
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	of enterocele recurrence by high midline levator myorraphy: physical examination and
	questionnaire-based follow-up. Eur Urol 2001 Dec; 40(6): 648-51. PMID: 11805411.
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4.	Margulis V, Defreitas G, Zimmern PE. Urinary retention after tension-free vaginal tape
	procedure: from incision to excisionto complete urethrolysis. Urology 2004 Sep; 64(3):
	590. PMID: 15351609.
5.	Margulis V, Matsumoto ED, Lindberg G, Tunc L, Taylor G, Sagalowsky AI, Cadeddu JA.
	Acute histologic effects of temperature-based radiofrequency ablation on renal tumor
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	JA. Short-term efficacy of temperature-based radiofrequency ablation of small renal
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10.	Malaeb BS, Gardner TA, Margulis V , Yang L, Gillenwater JY, Chung LW, Macik G, Koeneman KS. Elevated activated partial thromboplastin time during administration of first-generation adenoviral vectors for gene therapy for prostate cancer: identification of lupus anticoagulants. Urology 2005 Oct; 66(4): 830-4. PMID: 16230147.
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13.	Abdel-Aziz KF, Anderson JK, Svatek R, Margulis V , Sagalowsky AI, Cadeddu JA. Laparoscopic and open retroperitoneal lymph-node dissection for clinical stage I nonseminomatous germ-cell testis tumors. J Endourol 2006 Sep; 20(9): 627-31. PMID: 16999613.
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- 127. Hutchinson R, Feldkoren B, Rapoport Y, Mahajan A, Margulis V. Integrin Signaling Potentiates Tranforming Growth Factor-Beta 1 (TGF-?1) Dependent Down-Regulation of E-Cadherin Expression Important Implications for Epithelial to mesenchymal Transistion (EMT) in Renal Carcinoma. (Poster# NM10) South Central Section of the AUA, Inc. 94rd Annual Meeting, September 28 October 1, 2016, Scottsdale, AZ.
- 128. Podium Session: Oncology Kidney, Testes, Moderators: Vitaly Margulis, MD, Dallas, TX and Ronald Rodrguez, MD, San Antonio, TX, South Central Section of the AUA, Inc. 94rd Annual Meeting, September 28 October 1, 2016, Scottsdale, AZ.
- 129. Singla N, Hutchinson R, Haddad AQ, Sagalowsky AI, Lotan Y, Margulis V. Preoperative Hydronephrosis is Associated with Less Decline in Renal Function After Radical Nephroureterectomy for Upper Tract Urothelial Carcinoma. (#10) South Central Section of the AUA, Inc. 94rd Annual Meeting, September 28 October 1, 2016, Scottsdale, AZ.
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- 131. Sundaram V, Singla N, Roehrborn C, Margulis V, Gahan J. Peripoperative Outcomes of Robotic Assisted Simple Prostatectomy for Benign Prostatic Hyperplasia. (Poster M8) South Central Section of the AUA, Inc. 94rd Annual Meeting, September 28 – October 1, 2016, Scottsdale, AZ.
- Minimally Invasive Surgery for Kidney Cancer: Partial nephrectomy, Nephroureterctomy, 132. Pediatric Tumors: Moderator – Vitaly Margulis, MD. South Central Section of the AUA, Inc. 94rd Annual Meeting, September 28 – October 1, 2016, Scottsdale, AZ.
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- 134. Damodaran S, Karam J, Masterson T, Master V, Margulis V, Lorentz A, Bauman T, Blute M, Wood C, Abel J, Aldousaari S, Bloom E. Comparing predictive accuracy for four prognostic models of recurrence following surgery in non-metastatic renal cell carcinoma with thrombus. (Poster#192) Society of Urologic Oncology 2016 Annual Meeting, San Antonio, TX.
- 135. Panel on surgical management for advanced kidney cancer: Controversies in case management. Society of Urologic Oncology 2016 Annual Meeting, San Antonio, TX.
- 136. Krabbe LM, Heitplatz B, Hutchinson R, Woldu S, Presusscand S, Bogemann M, Wood C, Karam J, Weizer A, Raman J, Remzi M, Rioux-Leclercq N, Haitel A, Roscigno M, bolenz C, Bensalah K, Sagalowsky A, Shariat S, Lotan Y, Xylinas E, Margulis V. Prognostic value of PD-1 and PD-L1 expression in patients with high-grade urothelial carcinoma of the upper urinary tract. (Poster #9) Society of Urologic Oncology 2016 Annual Meeting, San Antonio, TX
- 137. Updated clinical outcomes and analysis of lymphadenectomy (LND) and perioperative chemotherapy (CT) interplay in patients (pts) with clinically non metastic upper tract urothelial carcinoma (UTUC): a multicenter study. (Abstract Temp ID#178948) 2017 Genitourinary Cancers Symposium (February 16-18, 2017), Orlando, FL.
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- 139. Aydin A, Woldu S, Lowrey T, Hutchinson R, Krabbe LM, Singla N, Sagalowsky AI, Margulis A. Neutrophil-To-Lymphocyte – A simple biomarker in testicular cancer. V, Bagrodia Abstract: MP80-16, AUA 2017, Boston, MA.
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- 141. Woldu S, Hutchinson R, Singla N, Biers B, Krabbe LM, Sagalowsky AI, Lotan Y, Bagrodia, Margulis V. Factors associated with stage at presentation and survival in penile cancer. Abstract: MP92-14, AUA 2017, Boston, MA.
- 142. Woldu S, Hutchinson R, Singla N, Viers B, Krabbe LM, Sagalowsky AI, Lotan Y, Bagrodia A, Margulis V. Adherence to guidelines: Surgical staging of inguinal lymph nodes in high-risk clinically localized penile cancer and survival implications. Abstract: PD49-03, AUA 2017, Boston, MA.
- 143. Damodaran S, Spiess PE, Karam J, Margulis V, Master VA, Raman JD, Sexton WJ, Patil D, Borregales L. Survival following neoadjuvant targeted therapy and cytoreductive nephrectomy in mRCC patients with tumor thrombus: a contemporary multi-institutional series. Abstract: PD04-03, AUA 2017, Boston, MA.

- 144. Damodarn S, Karam JA, Masterson TA, Master VA, Margulis V, Patil D, Bauman T, Blute M, Bloom E. Comparing predictive accuracy for four prognostic models of recurrence following surgery in non-mestatic renal cell carcinoma with thrombus using contemporary date from six institutions. Abstract: MP55-13, AUA 2017, Boston, MA.
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- 152. Woldu S, Hutchinson R, Krabbe LM, Rao A, Clinton T, Singla N, Passoni N, Lotan Y, Sagalowsky A, Bagrodia A, Margulis V. Impact of Socioeconomic Factors on Management of Testicular Germ Cell Tumors in Areas of Controversy. (Abstract Session #18, South Central Section of the AUA, Inc., 96th Annual Meeting, November 26-29, 2017, Naples, FL.
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268.	Bhanvadia R, Taylor J, Bagrodia A, Gaston K, Woldu S, Tachibana I, Lotan Y, Margulis V. Overcoming medical vulnerability: Cancer center partnership associated with improved outcomes for bladder cancer. PD08-09. 2024 AUA Annual Meeting, May 2, 2024, San Antonio, TX.
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- 275. Yu A, Hensley P, Huelster H, Martin A, Pham J, Pallauf M, Katims A, Potrezke A, Raman J, Singla N, Margulis V, Coleman J, Matin S, Spiess P. Response to neoadjuvant chemotherapy is associated with improved survival in upper tract improved survival in upper tract urothelial carcinoma-an upper tract collaborative network (UCAN) study. PD20-08. 2024 AUA Annual Meeting, May 2, 2024, San Antonio, TX.
- 276. Coleman J, Shore N, Marcq G, Colombel M, Psutka S, Raman J, Margulis V, Singla N, Djaladat H, Aigner R, Busquets C, Amato G, Cohen Y, Mroz A, Koudinova N, Krasnopolskaya I. Efficacy and safety of padeliporfin vascular targeted phohdynamic therapy (VTP) for treatment of low-grade upper tract urothelial cancer (LG UTUC): Phase 3 preliminary results. PD20-02. 2024 AUA Annual Meeting, May 2, 2024, San Antonio, TX.
- 277. Saitta C, Meagher M, Autorino R, Afari J, Nguyen M, Hakimi K, Cerrato C, Buffi N, Porpiglia F, Lughezzani G, Casale P, Simone G, Tuderti G, Sundaram C, Margulis V. Development and validation of a novel nomogram to predict lymph node invasion in upper tract urothelial carcinoma.MP36-19. 2024 AUA Annual Meeting, May 2, 2024, San Antonio, TX.
- 278. Meagher M, Wu Z, Franco A, Wang L, Margulis V, Bhanvadia R, Abdollah F, Antonelli A, Finati M, Ditonno F, Singla N, Broenimann S, Simone G, Projetti F. Comparative analysis of neoadjuvant versus adjuvant therapy for upper tract urothelial carcinoma in the setting of clinical node positive disease: Analysis of the robust registry. PD20-06. 2024 AUA Annual Meeting, May 2, 2024, San Antonio, TX.
- Tuderti G, Projetti F, Wu Z, Franco A, Wang L, Margulis V, Bhanvadia R, Abdollah F, Finati M, Antonelli A, Ditonno F, Singla N, Broenimann S, Derweesh I, Puri D, Rais-Bahrami S. Real-world data: Call for paradigm shift towards neoadjuvant chemotherapy in patients with upper tract urothelial carcinoma treated with nephrourectomy-analysis of the robust registry. PD20-05. 2024 AUA Annual Meeting, May 2, 2024, San Antonio, TX.
- 280. Moghaddam F, Ghoreifi A, Wu Z, Abdollah F, Antonelli A, Eun D, Guo S, Hung A, Ma L, Margulis V, Matin S, Mehrazin R, Porter J, Potretze A, Pradere B, Roupret M, Seisen T. Structured training curriculum for robotic radical nephroureterectomy for upper tract urothelial carcinoma: A Delphi consensus study. MP39-09. 2024 AUA Annual Meeting, May 2, 2024, San Antonio, TX.
- 281. Ditonno F, Franco A, Manfredi C, Wu Z, Wang L, Abdollah F, Finati M, Simone G, Tuderti G, Helstrom E, Correa A, De Cobelli O, Ferro M, Porpiglia F, Amparore D, Tuffano A. Robotic distal ureterectomy for high-risk distal ureteral urothelial carcinoma: A retrospective multicenter comparative analysis (Robuust collaborative analysis). PD20-04. 2024 AUA Annual Meeting, May 2, 2024, San Antonio, TX.
- 282. Tuderti G, Projetti F, Wu Z, Franco A, Wang L, Margulis V, Bhanvadia R, Abdollah F, Finati M, Antonelli A, Ditonno F, Singla N, Broenimann S, Derweesh I, Puri D, Rais-Bahrami S. Real-world management of high-risk upper tract urothelial carcinoma level of adherence to EAU-AUA guidelines-Analysis of the robust registry. MP38-17. 2024 AUA Annual Meeting, May 2, 2024, San Antonio, TX.
- 283. Moghaddam F, Ghoreifi A, Wood E, Franco A, Wu Z, Wang L, Antonelli A, Ditonno F, Abdollah F, Finati M, Simone G, Tuderti G, Helstrom E, Correa A, De Cobelli O, Ferro M. Predictors and outcome of lymph node involvemnt following neoadjuvant chemotherapy and radical nephroureterectomy for primary upper tract urothelial carcinoma (robust collaborative group). MP38-03. 2024 AUA Annual Meeting, May 2, 2024, San Antonio, TX.
- Popokh B, Bhanvidia R, Taylor J, Franco A, Wu Z, Wang L, Antonelli A, Ditonno F, Abdollah F, Finati M, Simone G, Tuderti G, Helstrom E, Correa A, De Cobelli O, Ferro M. Pathologic down staging with neoadjuvant chemotherapy as a predictor of oncological

	outcomes for upper tract urothelial carcinoma treated with nephroureterectomy: A robust registry analysis. PD33-09. 2024 AUA Annual Meeting, May 2, 2024, San Antonio, TX.
285.	Popokh B, Bhanvadia R, Taylor J, Franco A, Wu Z, Wang L, Antonelli A, Ditonno F,
	Abdollah F, Finati M, Simone G, Tuderti G. Pathologic down staging with neoadjuvant
	chemotherapy as a predictor of oncological outcomes for upper tract urothelial carcinoma
	treated with nephroureterectomy: A Robuust registry analysis. PD33-09. 2024 AUA Annual
	Meeting, May 2, 2024, San Antonio, TX.

VITALY MARGULIS'S TESTIMONY HISTORY

Depositions – Vitaly Margulis

Perechocky, DDS, Joseph, et al vs. State of Connecticut, et al -1/2024

Chad Corley case review and deposition 12/2023

Perechocky vs. State of Connecticut 3/2024

Harold Price vs Kidney Care Specialist - Montgomery County, Dayton, Ohio 8/2023

Jennifer Hancock v. Sunil Purohit, MD. 11/2023 - Covington, Louisiana

Craig Snowden v. KEVIN SNYDER ART, M.D., SAINT JOSEPH UROLOGY ASSOCIATES and KENTUCKYONE HEALTH MEDICAL GROUP, INC. - COMMONWEALTH OF KENTUCKY FAYETTE CIRCUIT COURT 2023

Zantac Medical Literature – Expert Witness – Princeton, NJ 9/2023

DEBRA MARTIN, as Personal Representative of the Estate of DOROTHY FREDERICK, deceased, Plaintiff, vs. ISLAND LAKE CENTER, LLC d/b/a ,ISLAND LAKE CENTER; OPIS ,MANAGEMENT RESOURCES, LLC; GABRIEL LIVING CENTERS, LLC; and SAGE ENTERPRISES III, LLC, 10/2023

JEROME LEWIS, Plaintiff, v. CHRISTIANA CARE HEALTH SERVICES, INC., Defendant - State of Delaware 2022

Walter Wayne Singleton vs. Dr. Avi Trimbak Deshmukh, M.D. Parker County, Texas 12/2020

TESSIE LACAROL SMITH AND UERGA MUSETTE SMITH V. SUJEET ACHARYA, M.D., TEXAS ONCOLOGY, P.A. AND TEXAS UROLOGY SPECIALISTS Deposition cancelled 10/2022

VITALY MARGULIS'S FEE **SCHEDULE**



DEPARTMENT OF UROLOGY LEGAL FEES REVISED 1/1/2022

Fees for depositions, trial testimony and/or other legal discussions for the Department of Urology should be charged as listed below:

Review of legal documents and medical records (1 hour minimum)	\$800/hour
Telephone conference calls (1 hour minimum)	\$800/hour
Depositions (1 hour minimum)	\$1,000/hour
Witness stand time (1 hour minimum)	\$1,500/hour
Time away from office (minimum)	\$4,500/day
Retainer Fee	\$4,000

Notes:

- 1. Fees charged are in one-half hour increments after the first hour. One hour is the minimum charge for any service unless indicated otherwise.
- 2. Approval by the Chairman is required <u>before</u> faculty agree to provide testimony for a plaintiff.
- 3. Cancellation or postponement of a trial with scheduled faculty testimony with less than 48 hours' notice will be charged \$5,000.
- 4. Approval is not required to review records and provide an opinion to an attorney concerning the merits of a case.
- 5. Time away from the office begins when the faculty member leaves his/her office and ends upon return (during regular business hours).