

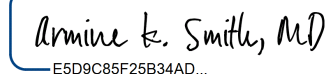
Exhibit 412

Specific Causation Expert Report for Frank Mousser

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1. Introduction

This report evaluates the causation of the upper tract urothelial carcinoma (UTUC) kidney cancer in Patient Frank Mousser and whether it is causally related to his exposure to the water at Camp Lejeune. The analysis integrates findings from epidemiology, toxicology, and mechanistic research, with emphasis on competing risk factors in his medical history.

2. Professional Background and Qualifications

I am a nationally recognized urologic oncologist with extensive expertise in the diagnosis, treatment, and research of genitourinary cancers, including upper tract urothelial carcinoma (UTUC) and kidney cancer. I graduated from the University of California, San Francisco (UCSF) School of Medicine, where I developed a strong foundation in patient care and clinical research. Following medical school, I completed my urology residency at the Cleveland Clinic, a program renowned for its leadership in urologic innovation and patient-centered care. I also completed a Society of Urology-accredited 3-year fellowship at the National Cancer Institute (NCI), where I conducted research on personalized risk factors and optimized treatment combinations for urothelial cancer. This work provided me with a deep understanding of the genetic and environmental factors driving urothelial cancer development and progression, as well as strategies for individualized patient care.

Currently, I serve as an Assistant Professor of Urology at Johns Hopkins University School of Medicine and Director of Urologic Oncology at Sibley Memorial Hospital. I have evaluated numerous cases involving potential links to environmental and occupational exposures, leveraging my expertise in interpreting epidemiological data, mechanistic studies, and clinical outcomes to assess causation and inform patient management. I also train urology residents and fellows, sharing my clinical expertise and mentoring the next generation of urologic oncologists.

My clinical focus includes the diagnosis and management of urothelial cancers, particularly complex and high-risk cases. I specialize in organ-preserving surgical approaches, minimally invasive techniques, and personalized treatment plans tailored to the individual risk factors of each patient. My research includes investigations into the pathophysiology of genitourinary cancers, exploring inflammatory and oncogenic pathways in urothelial carcinogenesis. I have published numerous peer-reviewed articles and book chapters on these topics, with an emphasis on understanding the role of environmental exposures in cancer development.

My combined clinical, research, and mentorship background uniquely positions me to assess and elucidate the role of environmental and occupational exposures in urothelial cancer. This expertise enables me to provide a comprehensive perspective on its prevention, early detection, and treatment, ultimately translating research findings into improved patient outcomes.

3. Methodology

I utilized the differential diagnosis methodology to systematically evaluate all potential factors contributing to the patient's cancer, prioritizing the identification and exclusion of less likely causes. This approach involved a comprehensive review of the patient's medical, family, and exposure histories, focusing on primary and competing risk factors. I analyzed the temporal

relationships between exposures and disease onset, including latency periods, and correlated mechanistic and pathophysiological evidence—such as genetic and molecular markers—with the known effects of suspected carcinogens. Additionally, I validated the patient's risk profile against established epidemiological research to ensure consistency. By integrating clinical, exposure, and mechanistic data, I assessed whether a specific exposure was more likely than not the primary cause of the cancer, providing a robust and evidence-based determination of causation.

4. Materials Reviewed

The materials I reviewed and relied upon in forming my opinions in this matter are found on the attached materials considered list.

5. Causation Standard

Under the statute at issue in this case, 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.”

The ATSDR, in their Assessment of the Evidence analyzing Camp Lejeune in 2017,¹ defined these classifications as follows:

“**Sufficient evidence for causation:** the evidence is sufficient to conclude that 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, **or**
- “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.”¹

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

- “1. The degree of evidence from human studies is less than sufficient but there is supplementary evidence from animal studies and/or mechanistic studies that supports causality, **or**
- “2. A meta-analysis does not provide convincing evidence (e.g., the summary risk estimate is close to the null value of 1.0, i.e., < 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.”¹

This is consistent with the science and medicine as I understand it and it informs this causation analysis.

6. Patient Background

Date of Birth: [REDACTED] 1963

Medical History:

- **Upper Tract Urothelial Carcinoma (UTUC):** Diagnosed in 2020 at age 57 (high-grade pTaN0 UTUC).
- Intermittent hematuria since 1983
- Chronic Kidney Disease (CKD) Stage 3a post-CABG (2016).
- Erectile dysfunction and overactive bladder.

Family History: No reported history of cancer.

Social History: Smoker during military service (pack a week or ten days) and occasional tobacco use thereafter. There is testimony from a co-worker Mr. Mousser smoked daily, of unknown quantities, for approximately a year in 2012. Mr. Mousser says in 2012 he would have smoked only 1-2 times a week and only a couple of cigarettes each time. Exposure to contaminated drinking water at Camp Lejeune from 1982-1986.

Occupation: Field artilleryman in the Marine Corps.

7. Exposure Assessment

Cumulative Contaminant Levels at Camp Lejeune (Days on Base 891):

- **TCE:** 10,373 µg/L
- **PCE:** 495 µg/L
- **Vinyl Chloride:** 864 µg/L
- **Benzene:** 227 µg/L

8. Factual History

Mr. Mousser enlisted in the Marine Corps in July of 1982, and he completed his basic training at Parris Island, South Carolina. 00667_Mousser_VBA_0000008254. Mr. Mousser joined for duty at Camp Lejeune on October 18, 1982. 00667_Mousser_VBA_0000008254. His military occupational specialty was field artillery man (0811). 00667_Mousser_VBA_0000008254. Mr. Mousser lived in the barracks in the French Creek area of Mainside, and he spent most of his time in that area. Mousser Dep. 66:12-16; 67:7-18.

On a typical day at Camp Lejeune, Mr. Mousser would wake up at 6:30am, get dressed, and eat breakfast at the Chow Hall directly behind his barracks. Mousser Dep. 65:20-22. At least three days a week, he would have physical training ("PT"). Mousser Dep. 65:2-3. He would then receive his orders for the day and begin work around 8:30 am. Mousser Dep. 65:24-66:2. He would have lunch between 11:30am and 1pm. Mousser Dep. 66:2-3. After lunch, he would usually be at the gun park performing maintenance on weapons until 4pm. Mousser Dep. 66:3-8.

Mr. Mousser would drink 2-3 cups of coffee at the Chow Hall in the morning. Mousser Dep. 268:18-19. In the afternoon, he would drink water or Kool-Aid. Mousser Dep. 268:21-24. They drank a "fair share" of water. Mousser Dep. 264:16. On days with PT, he would drink a canteen and a half of water, and about a half a canteen on days without PT. Mousser Dep. 264:15-19. On field days, they used water buffaloes to fill their canteens. Mousser Dep. 107:25-108:6. Mr. Mousser would shower at least once every day, and twice on days he had PT. Mousser Dep. 273:11-23. Each shower was approximately 10 minutes. Mousser Dep. 274:1-4.

During his time stationed at Camp Lejeune, Mr. Mousser spent periods away from the base, deployed elsewhere:

- 11/27/1982 – 12/19/1982: Camp Ripley
- 2/1/1983 – 4/18/1983: On board the ship Newport
- 5/31/1983 – 6/10/1983: Cuba
- 10/18/1983 – 2/10/1984: On board the Barnstable
- 9/6/1984 – 9/20/1984: Fort Bragg
- 12/3/1984 – 12/14/1984: Ph3b to the Atlantic
- 1/23/1985 – 8/8/1985: BLT 2/8 to the Mediterranean
- 9/20/1985 – 10/10/1985: Fort Bragg
- 1/13/1986 – 2/26/1986: 29 Palms in California

00667_Mousser_0000006042.

Mr. Mousser was transferred on September 7, 1986, after approximately four years at Camp Lejeune. 00667_Mousser_VBA_0000008254.

9. The Levels of the Toxins in the Water at Camp Lejeune

The levels of TCE, PCE, vinyl chloride, and benzene in the Camp Lejeune water supply far exceeded the EPA's maximum contaminant levels (MCLs). TCE levels, for example, were as high as 721 µg/L for Mr. Mousser, almost 150 times the current MCL of 5 µg/L. PCE levels reached up to 35 µg/L for Mr. Mousser, exceeding the MCL of 5 µg/L by nearly 7 times. Vinyl chloride levels peaked at 59 µg/L for Mr. Mousser, which is 29 times higher than the MCL of 2 µg/L. Benzene levels, recorded at 12 µg/L for Mr. Mousser, were significantly higher than the MCL of 5 µg/L.

The specific concentrations of the water Mr. Mousser was exposed to are found in the below chart:

Exposure Dates	Total Days	TCE (ug/l-M)	PCE (ug/l-M)	VC (ug/l-M)	BZ (ug/l-M)
10/18/1982-10/31/1982	14	138	6	9	9
11/1/1982-11/26/1982	26	706	34	55	10
12/20/1982-12/31/1982	12	721	35	56	8
1/1/1983-1/31/1983	31	389	19	30	8
4/19/1983-4/30/1983	12	372	18	29	10
5/1/1983-5/30/1983	30	449	22	36	8
6/11/1983-6/30/1983	20	546	27	45	7
7/1/1983-7/31/1983	31	618	30	51	7
8/1/1983-8/31/1983	31	659	32	54	9
9/1/1983-9/30/1983	30	543	26	45	9
10/1/1983-10/17/1983	17	134	5	9	10
2/11/1984-2/29/1984	19	560	27	47	8
3/1/1984-3/31/1984	31	587	28	50	7
4/1/1984-4/30/1984	30	400	18	33	12
5/1/1984-5/31/1984	31	491	23	42	10
6/1/1984-6/30/1984	30	471	22	41	7
7/1/1984-7/31/1984	31	507	24	45	7
8/1/1984-8/31/1984	31	539	26	48	8
9/1/1984-9/5/1984; 9/21/1984-9/30/1984	15	443	21	39	8
10/1/1984-10/31/1984	31	94	3	6	8
11/1/1984-11/30/1984	30	639	31	59	8
12/1/1984-12/2/1984; 12/15/1984-12/31/1984	19	43	2	4	2
1/1/1985-1/22/1985	22	324	16	31	4
8/9/1985-8/31/1985	23	0	0	0	3
9/1/1985-9/19/1985	19	0	0	0	3
10/11/1985-10/31/1985	21	0	0	0	3

11/1/1985-11/30/1985	30	0	0	0	3
12/1/1985-12/31/1985	31	0	0	0	3
1/1/1986-1/12/1986	12	0	0	0	3
2/27/1986-2/28/1986	2	0	0	0	3
3/1/1986-3/31/1986	31	0	0	0	3
4/1/1986-4/30/1986	30	0	0	0	4
5/1/1986-5/31/1986	28	0	0	0	3
6/1/1986-6/30/1986	27	0	0	0	3
7/1/1986-7/31/1986	28	0	0	0	3
8/1/1986-8/31/1986	28	0	0	0	3
9/1/1986-9/7/1986	7	0	0	0	3
	891	10,373	495	864	227

As will be discussed below, there are scientific studies, including those by the ATSDR, that demonstrate these concentrations are sufficient to cause genotoxic effects and cause kidney cancer, including UTUC. Mr. Mousser's exposure levels meet or exceed the thresholds identified in epidemiological studies linking these contaminants to this cancer.

I have also reviewed the summary exposure charts from Plaintiff's expert Kelly Reynolds. Dr. Reynolds provides estimated doses of ingestion for Mr. Mousser based on the following assumptions for amounts of ingestion: 1L per day, ATSDR's assumptions of ingestion, Mr. Mousser's deposition statements and average ingestion from field training manuals put out by branches of the military.

The total ranges of exposures for Mr. Mousser, according to these charts, is listed below:

		Chart 1: 1L	Chart 2: ATSDR	Chart 3: Deposition	Chart 4 Deposition/FM
	Cumulative ug/l-M	Cumulative consumption (total ug= days*concentration per L)	Cumulative consumption (total ug= days*concentration per ATSDR exposure assumptions)	Cumulative consumption (total ug= days*concentration per deposition exposure assumptions)	Cumulative consumption (total ug= days*concentration per deposition/FM exposure assumptions)
TCE	10,373	267,296	1,160,828	788,229	1,771,027
PCE	495	12,752	55,380	37,604	84,491
VC	864	22,391	97,241	66,029	148,356
BZ	227	5,595	24,298	16,499	37,071

10. Causation Analysis

I have reviewed the general causation expert reports of Drs. Hatten and Bird. The analysis in those reports supports my opinions in this report and finds that the four chemicals in the water at Camp Lejeune are causally related to kidney cancer. I also researched and read the epidemiology, toxicology and mechanistic evidence that exists relating to the toxins at issue in this case and agree that the toxins as they existed in the water at Camp Lejeune are causally related to kidney cancer, including UTUC, under a more likely than not standard, which exceeds the “at least as likely as not” standard in this case.* A summary of some of the evidence is below and is used for purposes of weighing the potential harmful effects of the exposure Mr. Mousser had to the water at Camp Lejeune.

a. UTUC Grouped with RCC in Large Databases

UTUC is frequently grouped with renal cell carcinoma (RCC) in large epidemiological databases due to anatomical proximity and shared coding systems. The epidemiology literature for studies that include UTUC with RCC and the studies that do not include them together show similar increased risks for kidney cancer.^{2,3,4,5,6} Further, the epidemiology studies that look at UTUC separately and independently have similar increased risks as those studies that look at RCC alone.^{4,5}

For example, the Zhao et al. study classified UTUC with Kidney cancer. Kidney cancer incidence and mortality were elevated in this study at high exposures with RR of 4.90 (95% CI: 1.23, 19.6) and 2.03 (95% CI: 0.50, 8.32).²

Several studies specifically looked at UTUC separately from kidney cancer but the results showed a similar risk profile. Raaschou-Nielsen et al. assigned UTUC with kidney cancer and also performed a separate analyses of UTUC. The SIR for kidney cancer as a whole and UTUC were the same.⁴

Lynge et al. analyzed renal pelvis cancers individually with SIR of 2.0 (95% CI: 1.0-3.7). In the same study, the category of kidney cancer had an SIR of 1.3 (95% CI: 1.0-1.7). These both show elevated risks of similar magnitude.⁵

Therefore, it is appropriate to use kidney cancer literature and epidemiology studies to support the causal relationships at issue in this analysis. This is especially true given the similar mechanisms of injury for UTUC and RCC.

b. Urothelial Origin of UTUC

Shared Pathogenesis with Urothelial Bladder Cancer: Unlike RCC, UTUC originates from the urothelial lining of the renal pelvis and ureters, the same tissue type as urothelial bladder cancer. This shared origin highlights the relevance of bladder cancer risk factors, including environmental exposures such as TCE, PCE, benzene, and vinyl chloride. These carcinogens accumulate in the

*Any reference to my professional opinions that the toxins in the water at Camp Lejeune caused Mr. Mousser’s kidney cancer is meant to include UTUC.

urinary tract, inducing genotoxic effects and contributing to urothelial cell damage and carcinogenesis.

Environmental Exposure Relevance: The mechanisms underlying urothelial bladder cancer are directly applicable to UTUC, emphasizing the role of these carcinogens in increasing cancer risk in the upper urinary tract.

In addition to looking at kidney cancer literature and studies, I also reviewed literature specifically relating to upper tract urothelial carcinoma and found similar results showing increased risks relating to the chemicals at issue.

c. Trichloroethylene (TCE)

Trichloroethylene (TCE) is a widely used industrial solvent and volatile organic compound (VOC) that contaminates soil and groundwater, including at Camp Lejeune. It has been classified as a known human carcinogen by the International Agency for Research on Cancer (IARC) and the Environmental Protection Agency (EPA).⁷

i. Epidemiological Evidence

IARC concludes there is sufficient evidence in humans for TCE's carcinogenicity, particularly causing kidney cancer.⁷ The Agency for Toxic Substances and Disease Registry (ATSDR) also recognizes sufficient evidence of causation for kidney cancer associated with TCE.¹ A 2010 meta-analysis by Kelsh et al. demonstrated a statistically significant relative risk (RR) of 1.42 (95% CI 1.17-1.77) for occupational TCE exposure and kidney cancer.⁸ A 2011 EPA manuscript reported an overall RR of 1.27 (95% CI 1.13-1.43), with higher risks for groups exposed to elevated TCE levels (RR 1.58, 95% CI 1.28-1.96).⁹ A 2010 study by Kelsh et al. reviewed occupational TCE exposure and found a significant increase in relative risk (RR) for urinary tract cancers, including UTUC, particularly in populations with high cumulative exposures.⁸ Karami et al. (2012) reviewed 9 cohort studies and found an elevated RR of 1.26 (95% CI 1.02-1.56) for TCE exposure and renal cancer, with consistent results across cohort and case-control designs.¹⁰ The study noted that misclassification of exposure in earlier research likely underestimated the true risk.¹⁰

ii. Camp Lejeune Studies

Numerous investigations into the contaminated water at Camp Lejeune have demonstrated an increased risk of kidney cancer, including upper tract urothelial cancers associated with TCE exposure.^{11,12} Populations exposed to Camp Lejeune levels of TCE exhibited statistically significant increases in bladder and kidney cancers, both of which share a urothelial origin with UTUC.^{11,12,13,14,15}

iii. Mechanistic Plausibility

TCE is metabolized into toxic intermediates, such as S-(1,2-dichlorovinyl)-L-cysteine (DCVC), which bioactivate in renal and urothelial tissues. These intermediates cause genotoxic stress, DNA adduct formation, and inflammation, processes central to urothelial carcinogenesis. Additionally,

TCE-induced oxidative stress impairs DNA repair mechanisms and promotes abnormal cell proliferation, further contributing to the initiation and progression of urothelial cancers.

iv. Conclusion

In December 2024, the U.S. Environmental Protection Agency (EPA) implemented a ban on all uses of trichloroethylene (TCE) to safeguard public health from the associated risks, including kidney cancer, linked to TCE exposure.¹⁶

Mr. Mousser's levels of TCE are significantly higher than the levels in the literature that show a causal association between TCE and UTUC. According to Bove 2014a's cumulative exposure charts, Mr. Mousser would have been categorized as being in the "high" exposure group for TCE, which is the highest category of exposure that exists.¹³ This was associated with a 1.52 HR for kidney cancer.¹³

Collectively, epidemiological data, mechanistic studies, and meta-analyses provide robust evidence of the causal link between TCE exposure and kidney cancer, highlighting its significant public health implications. It is overwhelmingly probable that TCE causes kidney cancer/UTUC.

d. Perchloroethylene (PCE)

Perchloroethylene (PCE) is a VOC commonly used in dry-cleaning and as an industrial degreaser. It has been classified as a probable human carcinogen by IARC and the EPA,^{7,17} with increasing evidence of its relevance to urothelial cancer.

i. Epidemiological Evidence

Cape Cod Cohort: In Cape Cod, Massachusetts, PCE leaching into drinking water was linked to increased risks of bladder cancer.¹⁸ Given the shared urothelial lining, these findings are highly relevant to UTUC. It was also linked to increased incidences of kidney cancer.¹⁸

Dry-Cleaning Workers: A study by Ruder et al. (2001) evaluated over 1,700 dry-cleaning workers exposed to PCE.¹⁹ Although primarily associated with bladder cancer, the findings indicated elevated risks for upper tract cancers due to cumulative PCE exposure.¹⁹

Callahan et al. identified a dose-response relationship, with the highest exposure group showing a hazard ratio (HR) of 13.2 (95% CI 1.9-90.8) for kidney cancer mortality.²⁰

U.S. Kidney Cancer Study: Purdue et al conducted a case-control study and reported an odds ratio (OR) of 3.1 (95% CI 1.3-7.4) for high cumulative PCE exposure and kidney cancer, indicating a strong association.²¹

ii. Camp Lejeune Study

Bove et al. examined civilian workers at Camp Lejeune and found a standardized mortality ratio (SMR) of 1.30 (95% CI 0.52-2.67) for kidney cancer.¹⁴ In Bove 2014a, with particular respect to PCE, the relative risks of kidney cancer based on low, medium and high exposures were: 1.40 for

low exposure, 1.82 for medium exposure and 1.59 for high exposure.¹³ Mr. Mousser would have met the high exposure category.

iii. Mechanistic Plausibility

PCE undergoes metabolism into trichloroacetic acid (TCA) and dichloroacetic acid (DCA), which induce oxidative stress, DNA strand breaks, and urothelial cell damage. These metabolites also promote chronic inflammation and interfere with normal cell cycle regulation, fostering conditions that increase the risk of malignant transformation in urothelial tissues. These mechanisms mirror those implicated in bladder cancer and kidney cancer and are relevant to UTUC.

iv. Conclusion

In December 2024, the U.S. Environmental Protection Agency (EPA) implemented a ban on perchloroethylene (PCE) to protect public health from the associated risks, including its link to various cancers such as kidney and urothelial cancers.¹⁶

Mr. Mousser's levels of PCE are significantly higher than the levels in the literature that show a causal association between PCE and UTUC. According to Bove 2014a's cumulative exposure charts, Mr. Mousser would have been categorized as being in the "high" exposure group for PCE, which is the highest category of exposure that exists.¹³ This corresponded to a HR of 1.59 for kidney cancer.¹³

Epidemiological studies, particularly those involving occupational and environmental exposures, along with mechanistic data, support a causal association between PCE and kidney cancer. The findings underscore the carcinogenic potential of PCE, especially in high-exposure settings like Camp Lejeune and the dry-cleaning industry. It is more likely than not that PCE causes kidney cancer.

e. Benzene

Benzene is a carcinogenic compound historically used in industrial applications and present as a contaminant in fuel leaks, such as those at Camp Lejeune. It is recognized as a known human carcinogen by IARC and the EPA.²²

i. Epidemiological Evidence

Camp Lejeune: Benzene contamination at Camp Lejeune contributed to elevated kidney cancer risks in exposed populations, including urothelial cancers. Studies consistently reported higher incidences of bladder and kidney cancers in affected cohorts.^{11,12,13,14,15}

Case-Control Studies: Hu et al. (2002) found an increased odds ratio (OR) for renal cell carcinoma in individuals with occupational benzene exposure, particularly among those in industrial chemical settings.²³

Meta-Analyses: Seyyedsalehi et al. analyzed 29 studies and found a relative risk between Benzene and kidney cancer of 1.20.²⁴

Chemical Workers: Workers in industries involving benzene, such as manufacturing and petrochemicals, demonstrate elevated risks for urothelial cancers. Chronic exposure results in cumulative damage to urothelial cells due to benzene's genotoxic properties.

ii. Mechanistic Plausibility

Benzene is metabolized into reactive intermediates, such as hydroquinone and benzoquinone, which generate reactive oxygen species (ROS) and cause DNA adduct formation, strand breaks, and chromosomal aberrations in urothelial tissues. These genotoxic effects trigger chronic inflammation and disrupt cellular repair mechanisms, creating a microenvironment conducive to malignant transformation in the urothelium.

iii. Conclusion

Mr. Mousser's levels of Benzene are higher than the levels in the literature that show a causal association between Benzene and UTUC. According to Bove 2014a's cumulative exposure charts, Mr. Mousser would have been categorized as being in the "high" exposure group for Benzene, which is the highest category of exposure that exists.¹³ This corresponded with a HR of 1.36 for kidney cancer.¹³

There is evidence to support the causal relationship of benzene to kidney cancer/UTUC at least as likely as not and using an equipoise standard.

f. Vinyl Chloride and Urothelial Cancer

Vinyl chloride, predominantly used in the production of polyvinyl chloride (PVC), is another contaminant at Camp Lejeune. It is classified as a known human carcinogen by IARC and the EPA.²²

i. Epidemiological Evidence

Camp Lejeune Studies: Vinyl chloride, a significant contaminant in Camp Lejeune's water supply, was associated with increased risks of bladder, kidney and upper tract urothelial cancers in exposed populations.^{11,12,13,14,15}

Case Control Studies: The 2002 study by Hu et al. found significantly elevated risk of kidney cancer with exposure to vinyl chloride.²³ There was a monotonic dose response relationship found between VC and kidney cancer.²³

ii. Mechanistic Plausibility

Vinyl chloride forms DNA adducts, such as etheno-deoxyadenosine, and induces oxidative stress, disrupting cell cycle regulation and DNA repair mechanisms. These effects increase the likelihood of mutations conducive to malignant transformation in urothelial tissues.

iii. Conclusion

Mr. Mousser's levels of VC are significantly higher than the levels in the literature that show a causal association between VC and kidney cancer. According to Bove 2014a's cumulative exposure charts, Mr. Mousser would have been categorized as being in the "high" exposure group for VC, which is the highest category of exposure that exists.¹³ This corresponded with a HR of 1.51 for kidney cancer.¹³

There is evidence to support the causal relationship of vinyl chloride to kidney cancer and urothelial cancers at least as likely as not and using an equipoise standard.

g. Conclusion for All Chemicals

There was a monotonic response relationship for TVOCs at Camp Lejeune and kidney cancer.¹³ The HRs for this metric were 1.42 (low exposure), 1.44 (medium exposure) and 1.54 (high exposure).¹³

The epidemiological and occupational studies collectively underscore the link between TCE, PCE, benzene, and vinyl chloride exposures and kidney cancers, including UTUC. Findings from Camp Lejeune studies, occupational analyses, and dose-response models reinforce the carcinogenic roles of these chemicals, particularly in populations with high or prolonged exposures. Mr. Mousser's exposure meets the highest exposure groups from each of the four chemicals in the Bove 2014a study.¹³ For the TVOC analysis, Mr. Mousser was exposed to 11,959 ug/l-M and the threshold for the highest category was 12,250 ug/l-M.

Mr. Mousser's exposure was in the very highest category of exposures for all of the individuals who spent time at Camp Lejeune. The data from the Camp Lejeune studies of Bove and ATSDR provide compelling data that exposures of this kind are causally related to kidney cancer.^{11,12,13,14,15}

11. Patient-Specific Considerations

Age and Tumor Size: Mr. Mousser's diagnosis at age 57 and his tumor being high-grade pTaN0 UTUC are unusual circumstances for sporadic UTUC, which typically occurs in older individuals. These factors suggest a significant environmental contribution.

Latent Period: The 34-year latency between exposure (1982-1986) and diagnosis (2020) is consistent with TCE's long latency period for cancer development.

Exposure: Mr. Mousser's TCE exposure (10,373 µg/L) far exceeds safe thresholds of levels implicated in kidney cancer cases. The reports of Drs. Hatten and Bird detail the levels at which the chemicals at issue have been known to be causally associated with kidney cancer/UTUC. I

have read the reports and agree with the findings in those reports as to the levels that are known to cause kidney cancer. For example, some of the levels known to cause kidney cancer, relating to these toxins, are as follows:

- **Cumulative exposure to 27.1-44.1 mg of PCE¹⁸**
- **Sustained exposure to 0-25.3 ppb of TCE²⁵**
- **Exposure to a TCE concentration of 267.4 ppb²⁶**
- **Cumulative exposure of 1 - 3,100 µg/L-month of TCE¹³**
- **Cumulative exposure of 1 - 155 µg/L-month of PCE¹³**
- **Cumulative exposure of 1 – 4,600 µg/L-month of exposure to all compounds at Camp Lejeune¹³**
- **Cumulative exposure of 3,100 – 7,700 µg/L-month of TCE¹³**
- **Cumulative exposure of 155 - 380 µg/L-month of PCE¹³**
- **Cumulative exposure of 4,600 – 12,250 µg/L-month of exposure to all compounds at Camp Lejeune¹³**
- **Cumulative exposure greater than 7,700 µg/L-month of TCE¹³**
- **Cumulative exposure greater than 380 µg/L-month of PCE¹³**
- **Cumulative exposure greater than 12,250 µg/L-month of exposure to all compounds at Camp Lejeune¹³**
- **Approximately 18 months of residence on base from 1975 to 1985¹³**
- **Employment on base for 2.5 years¹⁴**
- **Cumulative exposure to 110 – 11,030 ppb-months of TCE¹⁵**
- **Cumulative exposure to 36 - 711 ppb-months of PCE¹⁵**
- **Cumulative exposure greater than 11,030 ppb-months of TCE¹⁵**
- **Cumulative exposure greater than 711 ppb-months of PCE¹⁵**

Mr. Mousser's exposure meets and exceeds many of the levels that are known to be hazardous to humans and that cause kidney cancer, including UTUC. This data is important in the differential diagnosis analysis conducted below.

12. Substantial Exposure

As shown above through the deposition testimony of Mr. Mousser, his exposure to these chemicals at these concentrations was substantial. Mr. Mousser was, on a daily basis, frequently and consistently exposed to these chemicals through all three known routes of exposure. Mr. Mousser was drinking the water at each meal and when he was training, he was showering and inhaling the toxic chemicals at least daily and often multiple times a day (other than when he was in the field training) and he was exposed to the chemicals on his skin daily. This shows a substantial exposure that is more likely than not causally related to the UTUC kidney cancer he developed. I was able to draw my conclusions as to the substantial nature of his exposure from the records reviewed in this case, Mr. Mousser's deposition testimony and the concentrations in the water at the times Mr. Mousser was exposed.

Additionally, the charts from Plaintiff's expert Kelly Reynolds indicate a substantial exposure. For example, Dr. Reynolds calculated that Mr. Mousser would have ingested 1,160,828 ppb of TCE

using the ingestion assumptions from the ATSDR studies. Dr. Reynolds calculated an ingestion amount of 788,229 ppb of TCE if one were to assume the facts from Mr. Mousser's deposition testimony. Dr. Reynold's charts detail that, assuming ingestion numbers used from field manuals published by the United States military, Mr. Mousser's ingestion of TCE would reach 1,771,027 ppb of TCE.

These numbers are demonstrative of the substantial exposure for Mr. Mousser and an exposure that is clearly causally related to the development of his kidney cancer. These numbers are strengthened by the fact these charts take into account one exposure route: ingestion. Mr. Mousser would have been exposed via inhalation and also dermal exposure. When factoring in those routes of exposure, Mr. Mousser's actual exposure would be greater.

Dr. Kelly Reynolds charts provide additional support for my opinions and are consistent with my opinions.

13. Differential Diagnosis to Determine Etiology and Competing Risk Factors

a. Tobacco Use

Tobacco use is a well-established risk factor for urothelial carcinomas, including UTUC. Studies show that smoking increases the relative risk of UTUC, with a clear dose-response relationship between smoking intensity and cancer risk.

In Mr. Mousser's case, his smoking history of 0.5 pack-years to 1 pack-years was limited to his military service period and very limited social smoking after that time. This significantly reduces his cumulative exposure compared to long-term smokers. Mr. Mousser testified that he smoked either a pack a week or a pack every ten days during only a limited time in his Marine Corps service. He testified that he quit after his Marine Corps service. An exposure of 0.5 pack-years to 1 pack-years is considered minimal and is unlikely to significantly increase the risk of urothelial cancer. In addition, research indicates that smoking's impact on urothelial cancer risk diminishes substantially with cessation.^{27,28} Former smokers have lower risks compared to current smokers, with risk declining further over time after quitting. There is testimony from a co-worker, Mr. Mercer, that Mr. Mousser smoked daily while working at a car dealership for approximately a year in 2012. Mr. Mercer was not able to quantify how much Mr. Mousser smoked during this time. Mr. Mousser says that he only smoked 1-2 days a week and only a couple of cigarettes each time during the 2012 year. This is a very limited amount of smoking. Even if one were to assume the testimony of Mr. Mercer was correct, which is not a first-hand account and one that Mr. Mousser says is not accurate, Mr. Mousser's smoking history would not be nearly as likely as the very significant amounts of exposure Mr. Mousser had to the four different toxins at Camp Lejeune. This is because a limited and relatively isolated smoking history for a year or less is simply not correlated with the same risk profile as compared to the incredibly high exposures Mr. Mousser had at Camp Lejeune.

Overall, while smoking is recognized as a potential co-factor in urothelial cancer risk, its role in Mr. Mousser's case is clearly secondary to the well-documented carcinogenic effects of TCE, PCE, and other contaminants. This is due in large part to the very limited amount of smoking that took place, and the large amount of exposure Mr. Mousser had at Camp Lejeune.

b. Chronic Kidney Disease (CKD)

CKD Stage 3a, diagnosed post-CABG, results in reduced renal function but is not directly linked to increased UTUC risk. CKD-related inflammation may exacerbate carcinogenic processes if a predisposing factor is already present.

In Mr. Mousser's case, his CKD was caused by his original diagnosis of UTUC. Mr. Mousser did not have CKD until after his nephroureterectomy for the original UTUC diagnosis.

c. Recurrent Infections and Hematuria

Intermittent hematuria and episodes of cystitis are not a cause of Mr. Mousser's UTUC. While chronic inflammation and infections are recognized as risk factors for urothelial cancer, it is not likely that the limited and intermittent bleeding Mr. Mousser experienced starting in 1983 was due to an existing cancer. The heavy bleeding in his urine he had in 2020, however, was directly related to his cancer, given the timing and severity of the symptoms.

d. Family History

Mr. Mousser has no reported familial cancer history, minimizing the likelihood of hereditary predisposition. Genetic studies indicate that environmental exposures overwhelmingly contribute to sporadic urothelial cancers in patients without a family history of malignancy.

e. Occupational Exposures Beyond Camp Lejeune

Patient Mousser's post-military employment history does not indicate significant exposure to industrial solvents or carcinogenic chemicals, further isolating Camp Lejeune contaminants as the primary environmental risk factor.

I have considered all of the risk factors that are medically relevant for Mr. Mousser. There are several risk factors that are not applicable to Mr. Mousser that are generally associated with UTUC. Those are a potential family history, such as Lynch syndrome, other occupational exposures, a history of bladder cancer and Balkan endemic neuropathy. Because Mr. Mousser did not have any of these risk factors they were not discussed above.

Finally, I have considered the Defendants contentions as stated in their supplemental answers to interrogatories as to other potential causes of Mr. Mousser's kidney cancer in the below section.

f. Conclusion

Mr. Mousser's UTUC kidney cancer is more likely than not caused by the water at Camp Lejeune, which was contaminated with TCE, PCE, benzene and vinyl chloride. This is supported by robust epidemiological and mechanistic evidence.

14. Reponses to the Defendant's Supplemental Answers to Interrogatories

In response to Interrogatories sent by the Plaintiff, Defendant has stated the following may have been contributory to his kidney cancer, to the exclusion of Mr. Mousser's exposure to the water at Camp Lejeune:

a. Plaintiff's Exposure Levels and Latency

Defendant states "Initially, the Plaintiff's exposure to water at Camp Lejeune may not have been significant enough to cause the alleged illness or injury. Additionally, 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 – he was diagnosed with kidney cancer in August 2020, which is over 34 years after he left Camp Lejeune – may indicate an alternative cause or that the cause of the Plaintiff's illness or injury is idiopathic."

This is not likely the case for Mr. Mousser because the levels of TCE, PCE, benzene, and vinyl chloride in the water at Camp Lejeune far exceeded the levels in the literature associated with kidney cancer causality. Exposure to these carcinogens is supported by epidemiological, toxicological, and mechanistic evidence linking them to kidney cancer, including clear associations with cumulative and high-dose exposure seen in cohorts like Camp Lejeune residents.

The latency involved for Mr. Mousser falls squarely within the range of time expected for a cancer to arise following an environmental exposure such as Mr. Mousser experienced. Moreover, the timing of his diagnosis is entirely consistent with established scientific understanding of latency periods for environmentally induced kidney cancers.

b. Plaintiff's Smoking History

As described above, Mr. Mousser's smoking history during his military service was limited, both in duration and intensity amounting to an estimated 0.5 pack-years to 1 pack-years. Research demonstrates that former smokers have substantially reduced cancer risks compared to current smokers, with risk declining over time after cessation. Any potential smoking that took place in the 1980s was minimal, and his occasional smoking in 2012—limited to only a couple of cigarettes at a time—adds negligible cumulative exposure. This is true even assuming the statements made by Mr. Mercer, who testified that Mr. Mousser smoked daily for a period in 2012, though he provided no quantifiable details about the amount. Given that this exposure represents an extremely low cumulative exposure, it is unlikely to have meaningfully contributed to Mr. Mousser's cancer risk. While smoking may have been a minor co-factor, the magnitude of chemical exposure to TCE, PCE, benzene, and vinyl chloride at Camp Lejeune likely outweighed any contribution of smoking to his cancer development.

c. Plaintiff's Potential Exposure to Burn Pits While in the Military

This is not likely related because Mr. Mousser's exposure to burn pits occurred very minimally. Mr. Mousser testified he almost never was around a burn pit and if he had to guess, it was less than

30 minutes of total time for his entire military career. He also stated he was not around the smoke in the limited time he saw a burn pit. Further, the specific carcinogenic risks associated with burn pits are not nearly as strongly linked to kidney or urothelial cancers as the contaminants in Camp Lejeune water. Furthermore, the dose-response relationship and direct urinary tract exposure from Camp Lejeune chemicals make this a far more plausible primary cause.

d. VA Examiners Have Found Plaintiff's Conditions Are Not Related to His Water Exposure at Camp Lejeune

Defendant states "Further, various VA examiners have found that many of Mr. Mousser's conditions are not related to his water exposure at Camp Lejeune or resulting injuries." Specifically, VA opinions relating to sleep apnea, diabetes, erectile dysfunction and hypertension not being related to the Camp Lejeune water.

This is irrelevant to this analysis because the cited conditions (e.g., sleep apnea, diabetes) are unrelated to kidney or urothelial cancer causation. The focus of this analysis is on the scientific and medical evidence linking Mr. Mousser's exposure to Camp Lejeune water and his kidney cancer.

e. At Various Times Mr. Mousser's BMI Indicated He Was "Overweight"

This is not likely related to his kidney cancer because obesity is not a recognized risk factor for UTUC kidney cancer. Further, Mr. Mousser's BMI prior to his kidney cancer diagnosis was not significantly elevated. The specific exposures to TCE, PCE, benzene, and vinyl chloride at Camp Lejeune are more directly implicated in his cancer, as evidenced by the significant dose-response relationships observed in studies of these chemicals.

f. A Witness Testified That Mr. Mousser Smoked Cigarettes Daily in 2012

A witness, Mr. Richard Mercer, testified that Mr. Mousser smoked cigarettes daily for at least the first year they worked together at National Car Sales in May 2012. This is likely not related to Mr. Mousser's kidney cancer, even if it were true, because occasional smoking later in life has a minimal impact on cancer risk compared to long-term, heavy smoking. By 2012, the cumulative damage caused by Mr. Mousser's prior exposure to Camp Lejeune water, including TCE and PCE, would already have been the predominant factor in the pathogenesis of his kidney cancer.

15. Mr. Mousser's Damages

I will discuss Mr. Mousser's harms suffered as a result of the Camp Lejeune water and Mr. Mousser's kidney cancer. This includes the medical treatment related to his kidney cancer, the surgery required to remove his kidney, his CKD and the typical medical course for individuals like Mr. Mousser. Additionally:

1. The harms and injuries and damages suffered by Mr. Mousser that are described in this report are permanent.

2. The treatment and care Mr. Mousser has received and is now receiving is reasonable and medically necessary.
3. The medical billing for Mr. Mousser's treatment and care related to his kidney cancer is fair and reasonable and this treatment was medically necessary.

16. Conclusion

Considering Patient Mousser's significant exposure to Camp Lejeune contaminants, the prolonged latency period, and the consistent epidemiological and mechanistic evidence linking these chemicals to UTUC, it is more likely than not that his cancer was caused by the toxic exposures at Camp Lejeune. While competing risk factors such as limited smoking history may have contributed minimally, they are insufficient to independently explain the diagnosis.

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ARMINE SMITH'S CV

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2/4/2025

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Current Appointments

University

2013-present	Assistant Clinical Professor of Urology, George Washington School of Medicine
2014-present	Assistant Professor of Urology, Department of Urology, Johns Hopkins University School of Medicine Hospital
2013-present	Urologist, George Washington Hospital
2014-present	Urologist, Johns Hopkins Hospital
2014-present	Urologist and Director of Johns Hopkins Urologic Oncology, Sibley Memorial Hospital
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Education and Training

Undergraduate

2001 B.S., Biology, University of Southern California, Los Angeles, CA

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2005 M.D., University of California in San Francisco, San Francisco, CA

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2011 Resident, Urology, Cleveland Clinic, Cleveland, OH

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Professional Experience

2015-2017 Participant, MBA program in Healthcare Management, Johns Hopkins University Carey Business School, Baltimore, MD

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4. **Smith AK**, Jarrett TW. Atlas of Laparoscopic Surgery, 3rd ed. Chapter 18/Nephroureterectomy. Elsevier 2015.
5. **Smith AK**, Matin SF, Jarrett TW. Wein: Campbell-Walsh Urology, 12th ed. Chapter. 99/Surgical Management of Upper Urinary Tract Urothelial Tumors. Elsevier 2020.
6. Coleman JA, Singla N, Jarret TW, Matin SF, **Smith AK**. Dmochowski, Roger R.: Kavoussi/Campbell Walsh Wein Urology, 13th ed. Chapter 139/Surgical Management of Upper Urinary Tract Urothelial Tumors. Elsevier 2025.

Other Publications:

Opinions, Perspectives, Political Commentary, Advocacy, Essays [OP]

1. **Smith A**. Technological innovations driving cancer treatment. MedTech Outlook. Nov 2021.
2. **Smith A**. Quality of Life in the Phase 2/3 Trial of N-803 Plus Bacillus Calmette-Guérin in Bacillus Calmette-Guérin–Unresponsive Nonmuscle-Invasive Bladder Cancer. Urol Pract. 2024 Mar;11(2):375.
3. McConkey DJ, Barb JJ, **Smith AK**, Sears CL. Microbiome-based Therapeutics: Cutting-edge Innovation or Perpetual Promise? Eur Urol Focus. 2024 Dec 7:S2405-4569(24)00248-7.

Media Releases or *Invited Interviews [MR] 1

1. <https://www.youtube.com/watch?v=9mSlhcXZhJQ> Jun 2014
2. https://www.youtube.com/watch?v=EwsLHnF_a6w Jul 2016
3. <https://clinicalconnection.hopkinsmedicine.org/videos/treating-bladder-cancer-qanda> August 2016
4. <https://www.bizjournals.com/washington/news/2016/09/29/some-d-c-doctors-are-tackling-cancer-cures-in-a.html> Sept 2016
5. <https://greaterwashingtonmd.hopkinsmedicine.org/videos/physician-profile-armine-smith-md> April 2018
6. <https://archive.storycorps.org/interviews/ddb002360/> May 2018*
7. <https://hopkinskimmel.libsyn.com/cancer-matters-with-dr-bill-nelson-bladder-cancer-in-women> Nov 2018
8. <https://clinicalconnection.hopkinsmedicine.org/videos/surgical-advances-for-prostate-cancer> June 2021
9. https://ysmu.am/en/content/ysmu_visiting_professor_medicine_demands_to_be_ready_for_challenges/#sthash.0tR5F6Ej.dpbs August 2021*
10. [Sex After Bladder Cancer - HealthyWomen](#) May 2022*
11. [Why Sex and Race Matter in Bladder Cancer Treatment - HealthyWomen](#) May 2022*
12. https://www.youtube.com/watch?v=D_HdctamXRI Nov 2022
13. [Ask the Expert: Urothelial Bladder Cancer - HealthyWomen](#) Oct 2023*
14. [Los sobrevivientes de cáncer de vejiga y los segundos cánceres primarios - HealthyWomen](#) March 2024*
15. [Bladder Cancer Survivors and Second Cancers - HealthyWomen](#) March 2024*
16. [The Biggest Risk Factor for Bladder Cancer Has Nothing to Do With Pee, Diet, or Genes \(verywellhealth.com\)](#) June 2024*
17. UroToday: Optimizing Care for Women with Bladder Cancer with Armine Smith & Ashish Kamat <https://www.urotoday.com/video-lectures/bladder-cancer/video/4159-advancing-female-bladder-cancer-care-insights-from-aua-s-first-specialized-course-armine-smith.html> June 2024*
18. Oncology News Central: Oncologists Concerned Over FDA's Bladder Cancer Guidance, with David McConkey <https://www.oncologynewscentral.com/article/oncologists-concerned-over-fdas-bladder-cancer-guidance> July 2024*

Other Media [OM]

1. Blog: <https://www.beckershospitalreview.com/ehrs/what-clinicians-patients-think-of-charging-for-mychart-messages.html>, November 2022
2. Blog: <https://twitter.com/urogenpharma> Nov 2022
3. Blog: <https://www.benefitspro.com/2023/12/20/health-systems-have-begun-charging-for-patient-portal-interactions/?slreturn=20230002112633>, December 2022

4. LinkedIn <https://www.linkedin.com/in/armine-smith-md-5b7b7042>
5. Twitter @akfsurgeon

FUNDING

EXTRAMURAL Funding – Previous (2008)

Identification number RPC ID#2008-1012

Sponsor Cleveland Clinic Research Program Committee Funding

Total direct cost \$60,000

Role: PI, 25% FTE

EXTRAMURAL Funding – Previous (2008)

Identification number FAMRI ID#072099CIA

Sponsor Flight Attendant Medical Research Institute Grant

Total direct cost \$250,000

Role: co-PI, 10% FTE

PI: Warren Heston, PhD

INTRAMURAL Funding – Previous (2015)

Identification number JHGBCI ID#80035923

Sponsor Greenberg Bladder Cancer Institute Grant

Total direct cost \$50,000

Role: PI, 10% FTE

INTRAMURAL Funding – Previous (2018)

Identification number: Evaluation of PSMA-based PET as an imaging biomarker of androgen receptor signaling in high-risk localized and locally advanced prostate cancer

Sponsor The Robert L. Sloan Fund for Cancer Research

Total direct cost \$70,000, 2-year renewable

Role: co-PI, 1% FTE

PI: Curtiland Deville, MD

INTRAMURAL Funding – Previous (2020)

Identification number: Exploration of the Microbiome in Patients with Newly Diagnosed Bladder Cancer

Sponsor The Robert L. Sloan Fund for Cancer Research

Total direct cost \$70,000, 2-year renewable

Role: co-PI, 1% FTE

PI: Jean Hoffman-Censits, MD

INTRAMURAL Funding – Current (2024)

Identification number: Association of microbiome composition and its modulation with response to first line therapy in patients with bladder cancer.

Sponsor The Robert L. Sloan Fund for Cancer Research

Total direct cost \$70,000, 2-year renewable

Role: PI, 2% FTE

INTRAMURAL Funding – Current (2024)

Identification number: Mary and Armeane Choksi Scholar

Sponsor Mary and Armeane Choksi

Total direct cost \$500,000 5-year

Role: PI

Description: This endowed scholar award was granted directly to me in recognition of my contributions to urologic oncology research and education, supporting my ongoing efforts to advance innovative treatments and multidisciplinary collaboration at Sibley Memorial Hospital.

INTRAMURAL Funding – Current (2024)

Identification number: Kovler fund for translational research

Sponsor Kovler family

Total direct cost \$200,000

Role: PI and fund manager

Description: Dedicated to advancing translational research at Sibley Memorial Hospital, with a focus on fostering innovative approaches in urologic oncology.

EXTRAMURAL Funding - Pending

Identification number FAMRI ID# 213133

Sponsor Flight Attendant Medical Research Institute Grant

Total direct cost \$300,000

Role: PI, 5% FTE

CLINICAL ACTIVITIES

Clinical Focus

My clinical focus is urologic oncology and program building in the National Capital Region (NCR). In July 2014 I assumed my current position at Johns Hopkins University, being the only faculty member of the Brady Urological Institute in the DMV area. Under my regional leadership as a director of urologic oncology, the department was able to build a successful program at the Sibley Memorial Hospital with reputation of stable clinical excellence, which now has a stable referral stream and four additional full-time urologists and plans to add at least two more full-time urologists over the course of the next 2 years. The program's success can be seen from my personal work RVUs, which increased from 44 in the academic year 2014 to 2,578 in 2015 and 9,132 in 2022, reaching 152% of RVU targets. In collaboration with the Sidney Kimmel Comprehensive Cancer Center and Radiation Oncology Department, I have created the bi-weekly regional Multidisciplinary Prostate Cancer Program. Working with the Greenberg Bladder Cancer Institute, I have established a one-of-a-kind Women's Bladder Cancer Program, which provides gender-specific multidisciplinary care and clinical trials for patients, has ongoing educational series drawing patients from all over the US, and monthly support programs. This model for care for women with bladder cancer is now being replicated on the national level via Bladder Cancer Advocacy Network. Personally, I have a regional and nationwide reputation for complex reconstructive surgeries, and I am recognized in the field as an expert in bladder cancer in women.

Certification

2011-present Advanced Cardiac Life Support license, American Heart Association

2011-present Basic Life Support license, American Heart Association

Medical, other state/government licensure

2011-present Physician and Surgeon, Maryland Board of Physicians, # D73382

2011-present Controlled Dangerous Substances License, Maryland, #M76529

2011-present Controlled Substance Registration (DEA), #FS2759237

2014-present Physician and Surgeon, District of Columbia Board of Medicine #MD042441

2014-present Controlled Dangerous Substances License, District of Columbia, #CS1400387

Boards, other specialty certification

2017-present The American Board of Urology Diplomate, No 18052

Clinical (Service) Responsibilities

2011-2014 Urology attending, National Cancer Institute

2013-current Urology attending, George Washington Hospital

2014-2016 Urology attending, Suburban Hospital

2014-2018 Consultant, National Cancer Institute

2014-current Co-director of Prostate Cancer Multidisciplinary Clinic, Sibley Memorial Hospital

2014-current Urology attending, Sibley Memorial Hospital

2014-current Urology attending, Johns Hopkins Hospital

2018-current Co-director of Women's Bladder Cancer Program, Greenberg Bladder Cancer Institute

Clinical Productivity

FY 2014 Work RVUs 33

FY 2015 Work RVUs 2578

FY 2016 Work RVUs 4866

FY 2017 Work RVUs 6036

FY 2018 Work RVUs 5285

FY 2019 Work RVUs 5782

FY 2020 Work RVUs 9132

FY 2021	Work RVUs 7701
FY 2022	Work RVUs 9132
FY 2023	Work RVUs 8943
FY 2023	Work RVUs 8861

Clinical Draw from outside local/regional area

A minority of the patients that I see come from the centralized JH scheduling pool; these referrals are both from the National Capital Region (NCR) and nationwide. About 70% of the patients are direct referrals to me for bladder cancer treatment and nephron-sparing kidney surgery; these referrals come from the local primary care physicians, gynecologists and urologists, Bladder Cancer Advocacy Network, and other patients. Outside of NCR, in the past 5 years I have seen international patients from Middle East, South America and Armenia. From the nationwide pool, I have had patients from Arkansas, California, Delaware, Florida, Indiana Nevada, New Jersey, New Mexico, New York, Ohio, Pennsylvania, and West Virginia.

Clinical Program Building / Leadership

2014-present	Staff Urologist and Director of Urologic Oncology at Sibley Memorial Hospital Established and developed Johns Hopkins Urology practice in the NCR
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Clinical Demonstration Activities to external audience, on or off campus

2015	Laparoscopic surgery/hands-on animal lab, George Washington School of Medicine
2016	Laparoscopic surgery/hands-on animal lab, George Washington School of Medicine

EDUCATIONAL ACTIVITIES

Educational Focus

I am a passionate educator dedicated to advancing urologic surgery and oncology training. As a faculty member at both Johns Hopkins University and George Washington University, I provide mentorship, hands-on instruction, and structured training for urology residents and urologic oncology fellows. In 2024, I became the Site Fellowship Director for the National Cancer Institute, overseeing the entire Johns Hopkins National Capital Region. This role has established a regular rotation for NCI fellows across our sites, further integrating advanced oncologic training throughout the region. Additionally, I have hosted several international residents as observers, elevating the reputation of Johns Hopkins Urology at Sibley to an international level. We also welcome a steady stream of observers from various Johns Hopkins engineering programs, fostering interdisciplinary collaboration that is poised to result in multiple innovative projects. Beyond clinical education, I have co-authored chapters in multiple editions of *Campbell-Walsh-Wein Urology*, focusing on the pathogenesis and surgical management of urologic cancers—contributions that serve as foundational resources for urologic training programs worldwide.

Teaching

Clinical instruction

JHMI/Regional

2014-present	Supervising attending for GW and JH urology residents
2023-present	Supervising attending for urologic oncology branch fellows

Classroom instruction

2019	Content developer and speaker, Tips and tricks for successful cystectomy George Washington School of Medicine
2023	Content developer and speaker, Partial nephrectomy in the modern era JHU School of Medicine
2024	Content developer and speaker, Variant histologies in bladder cancer JHU School of Medicine

CME instruction

JHMI/Regional

11/2020	Content developer and speaker Audience: JHCP providers Advances in the treatment of benign prostatic hyperplasia. CME series
12/2020	Content developer and speaker Audience: JHCP providers

Invited National

10/2018 Member faculty
ASCO Advantage Prostate Cancer course, American Association for Cancer Research

12/2019 Member faculty
ASCO Advantage Renal Cell Carcinoma course, American Association for Cancer Research

1/2020 Member faculty
ASCO Advantage Prostate Cancer course, American Association for Cancer Research

4/2020 Member faculty
ASCO Advantage Renal Cell Carcinoma course, American Association for Cancer Research

9/2020 Member faculty
ASCO Advantage Renal Cell Carcinoma course, American Association for Cancer Research

1/2021 Member faculty
ASCO Advantage Prostate Cancer course, American Association for Cancer Research

10/2021 Member faculty
ASCO Advantage Renal Cell Carcinoma course, American Association for Cancer Research

4/2024 Member faculty
ASCO Advantage Renal Cell Carcinoma course, American Association for Cancer Research

National/International

5/2024 Course director and faculty
Audience: American Urologic Association, 2024 Annual Meeting
Optimizing Care for Women with Bladder Cancer: Female Cystectomy and Preservation of Sexual Function

Workshops /seminars

JHMI/Regional

2/2021 Content developer and speaker
Teamwork in Women's Bladder Cancer: The Advantage of the Multidisciplinary Approach, Greenberg Bladder Cancer Institute
https://www.hopkinsmedicine.org/greenberg-bladder-cancer-institute/about-bladder-cancer/virtual_grand_rounds.html

3/2021 Content developer and speaker
Newly Diagnosed with Bladder Cancer: Questions I Wish I Had Known to Ask, Greenberg Bladder Cancer Institute

6/2021 Content developer and speaker
Non-Muscle Invasive Bladder Cancer in Women, Greenberg Bladder Cancer Institute

9/2021 Content developer and speaker
Surgery and Bladder Cancer in Women, Greenberg Bladder Cancer Institute

12/2021 Content developer and speaker
Life with and after Bladder Cancer for Women, Greenberg Bladder Cancer Institute

3/2022 Content developer and moderator
Integrative Health and Cancer: Six Considerations, Greenberg Bladder Cancer Institute

6/2022 Content developer and moderator
Interpreting Population Science for Cancer Survivors, Greenberg Bladder Cancer Institute

9/2022 Content developer and moderator
The Complexities of Being Female with Bladder Cancer, Greenberg Bladder Cancer Institute

10/2022 Content developer and moderator
Living in the Now: Using Mindfulness as a Tool to Cope with Cancer, Greenberg Bladder Cancer Institute

12/2022 Content developer and moderator
Now What? Managing Health after Bladder Cancer, Greenberg Bladder Cancer Institute

Invited National/international

3/2017 Content developer and speaker
Women and Bladder Cancer Series, Bladder Cancer Advocacy Network
<https://www.facebook.com/watch/244123254014/1879686475652215/>

8/2022 Content developer and speaker
The importance of Patient Education When Selecting Treatments for Low-graded UIC, Urology Times

<https://www.urologytimes.com/view/ep-4a-the-importance-of-patient-education-when-selecting-treatments-for-low-grade-utuc>

7/2023

Content developer and speaker

Urinary diversions: which one is right for me? Bladder Cancer Advocacy Network

<https://bcan.org/selecting-your-best-urinary-diversion-for-women/>

Mentoring

Pre-doctoral Advisees /Mentees

- 2014-2017 Raju Chelluri, medical research scholar at National Institutes of Health, currently urologist at National Cancer Institute
Role: research and career mentorship
- 2014-2018 Lernik Ohanian, postdoctoral research fellow at National Institutes of Health, currently medical director at H3 Biomedicine, MA
Role: career mentorship
- 2015-2017 Mehrsa Jalalizadeh, postdoctoral research fellow at Johns Hopkins University, formerly MD in Iran, currently PhD student at Universidad Estadual de Campinas, Brazil
Role: research mentorship
Shared publications: RA2
- 2021-2023 Meghan McNamara, MPH, research assistant at Johns Hopkins University
Role: research and career mentorship

Post-doctoral Advisees /Mentees

- 2014-2015 Paulina Gorney Wilson, MD, chief resident at George Washington University, currently urologist at Inova Fairfax Hospital, VA
Role: career mentorship
- 2014-2018 Alice Semerjian, MD, chief resident at George Washington University and urologic oncology fellow at Johns Hopkins University, currently director of urologic oncology at Trinity Health Ann Arbor Hospital, MI
Role: career mentorship

Educational Program Building / Leadership

- 2020-present CME question writer, Urology for Doximity
- 2021-present Organizer, lecturer and moderator, Women's Bladder Cancer Series, Johns Hopkins/Greenberg Bladder Cancer Institute

RESEARCH ACTIVITIES

Research Focus

Bladder cancer has been the focus of my research. During my research year in residency at Cleveland Clinic and fellowship at the National Cancer Institute, I was involved in translational research in combination treatments with novel drugs and novel drug delivery systems in the cell and animal model of bladder cancer. Building on the foundation acquired during my fellowship, I have continued collaborative discoveries in the basic science and clinical research in bladder cancer. I serve as a reviewer for multiple urologic journals, scientific committee reviewer for Bladder Cancer Advocacy Network and Women in Urologic Oncology Society. During my tenure with Johns Hopkins University, I have served as a regional PI for multiple clinical trials, and since 2021 I have launched four primary IRB-approved clinical trials at Sibley Memorial Hospital, three of which are multi-center trials. Additionally, working with the leadership of the National Capital Region, Brady Urological Institute and Greenberg Bladder Cancer Center, I am currently developing a regional specimen processing center and translational laboratory at Sibley Memorial Center.

Research Program Building / Leadership

- 2014-2019 Member, GUMDROP
- Participated in multi-institutional initiative to integrate research across the DMV area
- 2015-present Special volunteer, National Institutes of Health, Bethesda, MD
- Collaborated with the Urologic Oncology Branch to promote multi-site research projects on bladder cancer

SYSTEM INNOVATION AND QUALITY IMPROVEMENT ACTIVITIES

- 2017 Sibley Hospital Robot Committee: establish cross-discipline requirements for new and ongoing users, set benchmarks to assess quality for users, monitor costs and monitor appropriate utilization of robotic equipment.
- Developed robotic credentialing metrics for surgeons practicing at Sibley Hospital
- 2021 Johns Hopkins Health System Perioperative Playbook Committee: create standardize definitions, key performance indicators, and calculations for perioperative activities at a system level for items like first case starts, turnover time, ERAS, periprocedural optimization, block utilization, block management, inpatient bed management throughput and patient safety and quality issues. Development of the following policies to date:
- JHM Perioperative Clinical and Administrative Policy Development Process standards
 - Turn Over Time (TOT) policy
 - Periprocedural/Perioperative Code Status and Limitations of Life Sustaining Treatment Policy
 - Perioperative/Procedural Fire Prevention and Management Policy
 - External Subcutaneous Devices for Management of Diabetes Mellitus (Includes Insulin Pumps and Continuous Glucose Monitors)
 - Block Utilization & Management
- 2022 Sibley Hospital Clinical Resource Management Committee: quality improvement of collective use of hospital resources.
- Improved length of stay and provider use of patient complexity indicators
- 2023 Sibley Hospital Operating Room Committee: quality improvement of operating room

ORGANIZATIONAL ACTIVITIES

Journal peer review activities

ORCID 0000-0002-3846-0235

- 2012 BMC Urology
 2016 American Family Physician
 2018 World Journal of Urology
 2018 Urologic Oncology
 2018 Urology

Invited Advisory Committees, Review Groups/Study Sections

- 2019 Scientific committee member for John Quale Travel Fellowship Program, Bladder Cancer Advocacy Network
 2020 Scientific committee member for John Quale Travel Fellowship Program, Bladder Cancer Advocacy Network
 2021 Scientific committee member for Young Investigator Awards, Bladder Cancer Advocacy Network
 2020 Scientific committee member for John Quale Travel Fellowship Program, Bladder Cancer Advocacy Network
 2022 Scientific committee member for Young Investigator Awards, Bladder Cancer Advocacy Network
 2022 Scientific committee member for Women in Urologic Oncology
 2023 Scientific committee member for Young Investigator Awards, Bladder Cancer Advocacy Network
 2023 Scientific committee member for John Quale Travel Fellowship Program, Bladder Cancer Advocacy Network
 2024 Scientific committee member for Young Investigator Awards, Bladder Cancer Advocacy Network
 2024 Steering committee member for Bladder Cancer Advocacy Network Think Tank
 2024 Steering committee member for Mid-Atlantic AUA sectional meeting

Professional Societies

- 2011-present Member, American Urologic Association (AUA)
 2014-present Member, American Association for Cancer Research (AACR)
 2014-present Member, Society of Urologic Oncology (SUO)
 2019-present Founding member of Women in Urologic Oncology (WUO), a section of SUO, the objective of which is to advance the recruitment, retention, and promotion of women in Urologic Oncology, with the goal of fostering diversity, equity, and inclusion for the SUO overall.
 2023-present Member, Mid-Atlantic AUA health policy committee

Conference Organizer

- 5/2022 AUA-GBCI bladder cancer symposium

Consultantships

- 2015 Case 7:23-cv-00897-RJ Document 493-3 Filed 08/26/25 Page 35 of 43

2015-present Photocure
2022-present Urogen
2023-present CG Oncology

RECOGNITION

Awards, Honors

2020	Northern Virginia Magazine Top Doctor, peer-nominated award based on internal evaluations, patient reviews, and overall quality of care.
2021	Northern Virginia Magazine Top Doctor, peer-nominated award based on internal evaluations, patient reviews, and overall quality of care.
2021	Washingtonian Top Doctor, peer-nominated award for excellence in patient care.
2023	Northern Virginia Magazine Top Doctor, peer-nominated award based on internal evaluations, patient reviews, and overall quality of care.
2023	Washingtonian Top Doctor, peer-nominated award for excellence in patient care.
2023	Women's Achiever Award, presented to women who exemplify excellence and exhibit Johns Hopkins Medicine core values by making outstanding contributions to the field of healthcare and/or surrounding communities.
2023	Outstanding Clinical Instruction Award, for recognition of teaching excellence to urology residents at George Washington University
2024	Northern Virginia Magazine Top Doctor, peer-nominated award based on internal evaluations, patient reviews, and overall quality of care.
2024	JHM Physician of the year nominee, for recognition of high standards in practicing medicine, excellent clinical skills, leadership, and collaborative and innovative spirit.
2024	Washingtonian Top Doctor, peer-nominated award for excellence in patient care.
2024	<i>Mary and Armeane Choksi Scholar</i> , awarded in recognition of contributions to urologic care and research
2025	Northern Virginia Magazine Top Doctor, peer-nominated award based on internal evaluations, patient reviews, and overall quality of care.
2025	Washingtonian Top Doctor, peer-nominated award for excellence in patient care.

Invited Talks

National

- 2017 Variant histology in bladder cancer. Urotrack, Philadelphia PA
- 2021 Gender considerations in muscle invasive bladder cancer: Considering QOL with definitive therapies. Society of Urologic Oncology, Orlando FL
- 2022 Gender considerations in muscle invasive bladder cancer. AUA Bladder Health Alliance, Linthicum MD

International

- 2015 Radical prostatectomy. Keynote Address. Annual Congress of Armenian Association of Urology, Yerevan Armenia
- 2021 Muscle-invasive bladder cancer: the current state of organ preservation. West African Surgical Training Initiative, Web-based
- 2024 Management of renal cell carcinoma. American Urological Association, Bogota, Colombia

Visiting Professorships

- 2018 Yerevan State Medical University, Armenia
- 2021 Yerevan State Medical University, Armenia
- 2024 Yerevan State Medical University, Armenia

OTHER PROFESSIONAL ACCOMPLISHMENTS

Posters

1. Brian H Irwin, Andre Berger, Ricardo Brandina, David Canes, **Armine K Smith**, Sebastien Crouzet, Georges-Pascal Haber, Kazumi Kamoi, Robert J Stein, Mihir M Desai. Experience with complex percutaneous resections for upper tract urothelial carcinoma. 2009 American Urologic Association Annual Meeting, Chicago, IL
2. Brian R Lane, **Armine K Smith**, Benjamin T Larson, Michael C Gong, Inderbir S Gill, Steven C Campbell, Andrew J Stephenson. Development of chronic kidney disease after nephroureterectomy for upper tract urothelial carcinoma and implications for the administration of cisplatin-based chemotherapy. 2009 American Urologic Association Annual Meeting, Chicago, IL
3. Eddie S y Chan, William A. Larchian, **Armine K. Smith**, John B. Klein, Anil A. Thomas, Warren D. Heston, Amit R. Patel. Targeted contrast ultrasound detection and quantification of vascular endothelial growth factor receptors in bladder cancer. 2009 American Urologic Association Annual Meeting, Chicago, IL
4. Amit R Patel, William A. Larchian, **Armine K Smith**, John B. Klein, Anil A. Thomas, Eddie S y Chan. Quantification of sunitinib's antitumor effects in a localized orthotopic bladder cancer model. 2009 American Urologic Association Annual Meeting, Chicago, IL
5. Eddie S.Y. Chan, Amit R. Patel, **Armine K. Smith**, John B. Klein, Anil A. Thomas, Warren D. Heston, William A. Larchian. Optimizing Orthotopic Bladder Tumor Implantation in a Syngeneic Mouse Model. 2009 American Urologic Association Annual Meeting, Chicago, IL
6. Mary Samplaski, **Armine Smith**, William Larchian, Vinod Labhasetwar, Warren Heston. Successful intravesical therapy for bladder cancer utilizing paclitaxel containing nanoparticles. 2010 American Urologic Association Annual Meeting, San Francisco, CA
7. Nitin Yerram, Dmitry Volkin, Faisal Ahmed, Jeffery Nix, An Hoang, Gopal Gupta, **Armine Smith**, W. Marston Linehan, Adam Metwalli, Peter A. Pinto. Long term outcomes of simultaneous bilateral partial adrenalectomy for pheochromocytomas. 2012 American Urologic Association Annual Meeting, Atlanta, GA
8. Mehresa Jalalizadeh, MD; Leonardo O. Reis, MD, PhD; Hiroki Ide, MD; Hiroshi Miyamoto, MD, PhD; **Armine K. Smith, MD**. Dysregulation of erβ pathway as a mechanism of bcg resistance in urothelial bladder cancer. 2015 Society of Urologic Oncology Annual Meeting, Washington, DC
9. Raju Chelluri, Piyush K. Agarwal, Leonard M. Neckers, **Armine K. Smith**. Synergistic effect of targeted combination therapy in bladder cancer model using hsp90 inhibitors. 2015 American Urologic Association Annual Meeting, New Orleans, LA
10. Mehresa Jalalizadeh, Leonardo O. Reis, John L. Silberstein, Hiroshi Miyamoto, **Armine K. Smith**. Tumor necrosis factor-related apoptosis-inducing ligand (trail) potentiates the effect of bacillus calmette-guérin (bcg) in urothelial carcinoma model. 2016 American Urologic Association Annual Meeting, San Diego, CA

1. **Armine K Smith**, Kenneth W Angermeier. Second stage urethroplasty augmented by oral mucosa: an alternative to revision of the first stage. 2008 American Urologic Association Annual Meeting, Orlando, FL
2. **Armine K Smith**, Benjamin T Larson, Andre Berger, Brian R Lane, Donna E Hansel, Andrew J Stephenson, J Stephen Jones. Is there a role for cytology in the diagnosis of upper tract urothelial cancer? 2009 American Urologic Association Annual Meeting, Chicago, IL
3. **Armine K Smith**, Brian R Lane, Benjamin T Larson, Andre Berger, Donna E Hansel, Michael C Gong, Steven C Campbell, Inderbir S Gill, Andrew J Stephenson. Does the choice of technique for management of the bladder cuff affect oncologic outcomes of nephroureterectomy for upper tract urothelial cancer? 2009 American Urologic Association Annual Meeting, Chicago, IL
4. **Armine K Smith**, William A Larchian, Amit R Patel, Shihua Jin, Eddie S y Chan, Anil A Thomas, John B Klein, Warren D Heston, Vinod Labhasetwar. Nanotechnology-mediated delivery of chemotherapy in the treatment of urothelial carcinoma. 2009 American Urologic Association Annual Meeting, Chicago, IL
5. **Armine Smith**, Bethany Kerr, Eric Klein, Warren Heston, Tatiana Byzova. Role of circulating neoplastic progenitor cells in detection and staging of prostate cancer. 2010 American Urologic Association Annual Meeting, San Francisco, CA
6. **Armine K. Smith**, Martha Ninos, James Peterson, Rabindra Gautam, Maria Merino, Berton Zbar, Laura Schmidt, Gennady Bratslavsky, Inger Rosner, An Hoang, Adam Metwalli, Peter A. Pinto, Ramaprasad Srinivasan, W. Marston Linehan. Hereditary papillary renal cell carcinoma: a 20-year experience in management of a unique hereditary cancer syndrome. 2012 American Urologic Association Annual Meeting, Atlanta, GA

Philanthropic Activities

2014-present	Sibley Memorial Hospital Foundation
2014-present	The James Buchanan Brady Urological Institute Foundation

ARMINE SMITH'S STATEMENT OF COMPENSATION

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

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

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

ARMINE KARAPETIAN SMITH, MD'S STATEMENT OF COMPENSATION

Pursuant to Fed. R. Civ. P. 26(a)(2)(B)(vi), Plaintiffs provide the following statement of compensation: In the present action, Armine Karapetian Smith, MD charges \$650 per hour for review, \$750 per hour for deposition testimony, and \$8000 per day for trial. Dr. Smith required a \$3,250 retainer.

ARMINE SMITH'S TESTIMONY HISTORY

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

IN RE:)	
)	
CAMP LEJEUNE WATER LITIGATION)	
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ALLAN WAYNE HOWARD)	7:23-CV-00490-BO
)	
FRANK W. MOUSSER)	7:23-CV-00667-BO-RN
)	
JACQUELINE JORDAN TUKES)	7:23-CV-01553-BO-BM

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

ARMINE KARAPETIAN SMITH, MD'S LIST OF TESTIMONY

Pursuant to Fed. R. Civ. P. 26(a)(2)(B)(v), Plaintiffs provide the following list of testimony:

To the best of her recollection, Armine Karapetian Smith, MD has testified as an expert at trial or by deposition in the following actions during the previous 4 years:

1. Quaranta v. Smolev et al., Maryland;
2. Estate of Mehmet Aras vs. Northwest United Urology, LLC, Illinois, docket number 17 L 010800;
3. Tyron Tann v. Jefferson Health System, Pennsylvania; and
4. Edward Lancaster v. LAMMICO Insurance Company et al, Louisiana, 24th JDC, docket number 809-045 Div L; and

5. Estate of Steven Agnew v. Primary Care Solutions, New Mexico, 1st JDC, docket number D-101-CV-2022-00285.