Exhibit 354

Specific Causation Expert Report for Mark Cagiano
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John Sfakianos, MD

I. Background

I graduated from the State University of New York at Buffalo in 2007. I completed my residency in urology in 2012 and a fellowship in urologic oncology in 2014. I am board certified in urology. Currently, I am a professor in urology and the co-chair of the Investigator Initiated Clinical Trials Review Committee at the Icahn School of Medicine at Mount Sinai. As part of my practice, I regularly diagnose and treat patients with UTUC. UTUC is approximately 15% of my clinical practice including those who have suspected exposure to various chemicals. It is a rare disease with estimates of 2 new cases per 100,000person years. It accounts for approximately 5% of urothelial carcinomas.[1]

Similar to bladder cancer, UTUC is a cancer of the urothelium lining the urinary system. Furthermore, UTUC development in patients is due to carcinogen exposure with tobacco being the leading cause. There has been other more specific exposure that have been studied including Phenacetin and Aristochloic acid. In addition to my clinical practice, I oversee a lab that studies the effect of chemicals found in cigarettes on mice. My research has focused on mouse modeling of bladder cancer, which is a carcinogen induced model. N-Butyl-N-(4-hydroxybtyl) nitrosamine (OH-BBN) is an alkylating agent, which is placed in drinking water of mice leading to the production of invasive tumors within 20 weeks. In some instances the mice will also develop UTUC. OH-BBN is a carcinogen, which is derived from N-nitroso a compound found in cigarette smoke.[2]

For additional discussion of my qualifications, please refer to my curriculum vitae, which is included with this report. All my opinions in this case are stated to a reasonable degree of medical certainty. My opinions are based upon my review of the materials listed in my forthcoming reliance materials list, which include pertinent medical records and scientific papers. In addition, my opinions are based on my education, training and experience.

[1] Firas G Petros , Epidemiology, clinical presentation, and evaluation of upper-tract urothelial carcinoma Transl Androl Urol 2020 Aug;9(4):1794–1798. doi: 10.21037/tau.2019.11.22.
[2] (Slocum SL, Kensler TW: Nrf2: control of sensitivity to carcinogens. Arch Toxicol 85(4): 273-284, 2011).

II. Mandate

I was asked to provide my opinion on the causation of Mark Cagiano's diagnosis of upper tract transitional cell urothelial cancer (UTUC). In order to provide this opinion, I reviewed and relied on the following documents and materials:

Medical records for Mr. Cagiano from:
- Wellstar Urology, Douglas
- Douglas Neurology
- Arbor Place Family Medicine
- Piedmont Healthcare
- Atlanta VAMC
- City of Hope
- Carrollton CBOC
- Northwest Georgia Oncology
- Wellstar Cobb Hospital
- Emory University Hospital
- Additional medical records of Mark Cagiano

Litigation records for Mr. Cagiano:
- The short form complaint filed in this case
- The deposition transcript of Mark Cagiano
- The deposition transcript of Dr. Gaspar Msangi
- The deposition transcript of Dr. Victor Corrigan
- The deposition transcript of Dr. Thomas Garughese
- DOJ's Supplemental Responses to Interrogatories.
- Expert reports: General causation reports of Dr. Benjamin Hatten, Dr. Stephen Bird, Dr. Kathleen Gilbert, Dr. Laura Plunkett, and Dr. Stephen Culp.
- The exposure report of Kelly Reynolds, MSPH, PhD

Additional records:
- Scientific and medical literature referenced herein.
- Other documents listed on my materials considered list.
- Military records of Mr. Cagiano
- ATSDR
- EPA Ruling of December 17, 2024 (TCE)
- EPA Ruling of December 18, 2024 (PCE)

It is my understanding that the statute at issue in this case states that there are two ways to prove causation:

> (1) Standards – To meet the burden of proof described in paragraph (2) 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 a causal relationship exists; or

(B) sufficient to conclude a causal relationship is at least as likely as not.

This standard was considered in my approach to determining whether Mr. Cagiano's exposure to the water at Camp Lejeune was as least as likely as not the cause of his UTUC.

III. Methodology

In order to determine that a chemical exposure causes UTUC, or is at least as likely as not to cause UTUC as any other potential cause, I first look to determine if there is enough evidence to establish a causal relationship between the subject chemical(s) and UTUC. As a urologic oncologist and active scientific researcher, I am well-versed in the suspected causes of UTUC in humans and therefore rely on my knowledge, education, training and experience.

Specifically in this case, I have relied on accepted, reputable sources of information, such as the ATSDR, IARC Monographs, peer-reviewed medical and scientific articles and texts, and the recent EPA final ruling regarding the TCE and PCE ban. Finally, I also relied on the general causation reports issued in this case relating to UTUC, and related cancers.[3]

Once I am able to determine that there is enough evidence to establish a causal relationship, generally, I proceed to perform a differential etiology on the individual to determine if his or her particular exposure more likely than not caused the development of their UTUC.

"In a differential etiology, an expert first determines other known causes of the disease in question and then attempts to ascertain whether those competing causes can be 'ruled out' as a cause of plaintiff 's disease…" Reference Manual on Scientific Evidence, Third edition, p. 618. I regularly employ a differential etiology in my practice as part of my clinical work to help improve the treatment options and outcomes of my patients.

During an encounter of UTUC, a physician will often try to establish a differential etiology for the development of the patient's disease. (An important distinction, this is a differential etiology, not a diagnosis. The diagnosis is UTUC, the cause is the etiology.) A differential etiology involves a thorough, but not exhaustive line of questioning, because the cause of the disease is of less importance than the therapy plan for treating the disease. The most immediate goal of any patient visit for a treating physician is to develop the appropriate treatment plan for the patient. However, in a disease like UTUC, where the etiology is almost always from a toxic exposure, it is worthwhile to identify the exposure. This will make the patient aware, and permit them to avoid the exposure going forward, if possible. It may also afford an opportunity to warn others, particularly family

[3] I reviewed the reports of Dr. Benjamin Hatten, Dr. Stephen Bird, Dr. Kathleen Gilbert, Dr. Laura Plunkett, and Dr. Stephen Culp. I reviewed the reports, understood the opinions offered and verified that their opinions were supported.

and coworkers, with similar exposures. Gathering this data also reveals patterns that may be important to the health of society as a whole. In fact, the revelation of patterns of disease is what lead to the science of epidemiology.

It is not uncommon for UTUC to develop in a patient with more than one risk factor for the development of UTUC. Behavior based, environmental, and occupational exposures are well-established risk factors for the development of UTUC, and the American Cancer Society recognizes that multiple exposures – such as smoking and workplace exposures – "can act together to cause [UTUC]."[4] These risk factors can act in concert with one another and have additive effects. Whether individually or in combination with other risk factors, a differential etiology consists of creating a list of potential causes, and then excluding potential causes until you are left with one or more that cannot be excluded. By the process of elimination, you can arrive at the most likely cause or causes. In Mr. Cagiano's case, the only risk factor he had for developing UTUC was the contaminated water at Camp Lejeune, which I will later address in this report.

It is important to note that the quality of information matters when performing a differential etiology. The more uncertainty surrounding a particular risk factor, the more speculation is introduced into the differential etiology. If insufficient information exists concerning a risk factor or it requires a number of assumptions, then its value in considering it as a risk factor is substantially diminished or depleted altogether. Speculative or conjectural information is of little value in a differential etiology.

IV. Plaintiff's Factual Background

a. Exposure at Camp Lejeune

Mr. Cagiano was stationed at Marine Corps Base Camp Lejeune on two occasions. The first was from July 31, 1976 through May 26, 1980, and the second was from May 30, 1987 through December 31, 1987. In total Mr. Cagiano was stationed at Camp Lejeune for over 52 months, or 1,059 days, but he was deployed twice and had some training and annual leave that may have taken him off base for several days at a time. As will be addressed later in this report, I make no attempt to determine the actual number of days on base, or total amounts of water consumed while on Camp Lejeune. I have reviewed and relied on the expert report of Dr. Kelly Reynolds, and I rely upon her calculations for days on Camp Lejeune and exposure purposes.[5]

b. Family history

Mr. Cagiano has no family history of cancer. His father's medical history includes heart disease (with bypass surgery) and a benign brain tumor (removed); his mother's medical history includes glaucoma and arthritis.[6] Neither of Mr. Cagiano's parents smoked throughout his life with them; Mr. Cagiano testified that his mother may have

[4] https://www.cancer.org/content/dam/CRC/PDF/Public/8558.00.pdf
[5] Report of Kelly Reynolds, MSPH, PhD, February 7, 2025
[6] Cagiano Dep. 30:6 -32:16

smoked when he was very young, but that he has no recollection of her smoking.[7] Mr. Cagiano has two brothers, and neither of them have experienced cancer or kidney disease.[8] Similarly, Mr. Cagiano's children have never been diagnosed with cancer.[9]

c. Occupational history

Mr. Cagiano was commissioned into the Marine Corps as a Second Lieutenant.[10] Mr. Cagiano was first stationed at Camp Lejeune beginning July 31, 1976, and was assigned as a field artillery officer.[11] Mr. Cagiano had additional duties as the battery motor transportation officer.[12] These additional duties included responsibility for ensuring the battery vehicles were operational and maintained. Mr. Cagiano estimated that he was responsible for approximately 20 vehicles, and additional trailers including water buffalos, 500 gallon tank trailers that were used to carry water.[13] Mr. Cagiano recalls the water buffalos being filled in the 5th area, the same areas as the motor pool.[14] Mr. Cagiano stated that he would drink from the water buffalos when participating in field training, which could be from "one day a week, two weeks, ten days".[15]

On November 30,1976, Mr. Cagiano's job changed to liaison officer and he was assigned duties as the garrison property officer[16]. From April 21, 1977 to November 10, 1977, Mr. Cagiano was deployed on the USS Inchon in the Mediterranean Sea.[17] Mr. Cagiano returned to Camp Lejeune on November 14, 1977, and his primary duty was changed from liaison officer to fire director officer.[18] Mr. Cagiano explained that his duties as the fire director officer would be to receive calls for fire from forward observers in the field, and communicate their coordinates to the operators of howitzers to direct their fire.[19] On July 11, 1978, Mr. Cagiano's primary duty changed again to executive officer, or second in command of the battery.[20] On March 7, 1979, Mr. Cagiano and his battalion were transferred for temporary duty with the 34th Marine Amphibious Unit for deployment to the Mediterranean Sea.[21] Mr. Cagiano was deployed to the Mediterranean aboard the USS Guam from May 22, 1979 through November 14, 1979.[22] Upon his return from the second Mediterranean deployment Mr. Cagiano returned to his assignment at base

[7] Cagiano Dep. 30:24- 32:3
[8] Cagiano Dep. 28:25-30:5
[9] Cagiano Dep. 28:12-20
[10] Cagiano Dep. 34:25-35:2
[11] Cagiano Dep.37:11-38:3
[12] Cagiano Dep.39:6-25
[13] Cagiano Dep.40:24-42:21
[14] Cagiano Dep. 42:9-21
[15] Cagiano Dep.83:24-84:10
[16] Cagiano Dep.38:24-39:5; 45:21-46:14
[17] Cagiano Dep. 52:3-20
[18] Cagiano Dep.55:3-14.
[19] Cagiano Dep.55:23-56:4
[20] Cagiano Dep.58:21-59:7
[21] Cagiano Dep.60:2-10
[22] Cagiano Dep.60:11-25

Headquarters, Battery 2nd Battalion 10th Marines on Camp Lejeune.[23] On November 29, 1979, Mr. Cagiano became commanding officer of the 5th Battalion of the 10th Marine; in this position he was responsible for the entire battery.[24] From January 13 – 26, 1980, Mr. Cagiano was on sick leave and admitted to the base hospital for a kidney stone.[25] On May 26, 1980, Mr. Cagiano was transferred to become the officer selection office in Nashville, Tennessee, and ended his first assignment to Camp Lejeune.[26]

Mr. Cagiano remained in Nashville for thirty-five months, and was then transferred to Fort Sill, Oklahoma to attend an artillery officer's advanced course.[27] After eight months at Fort Sill, Mr. Cagiano was transferred to Marine Corps Headquarters in Washington, D.C., where he remained for thirty-seven months.[28] On April 25, 1987, Mr. Cagiano transferred back to Camp Lejuene, and remained stationed at Camp Lejeune until December. 31, 1987. Throughout Mr. Cagiano's time at Camp Lejeune he lived mostly on base, although there is some reference to brief time living off base. During his second time stationed at Camp Lejeune, in 1987, Mr. Cagiano lived off base.[29] There were also discussions during his deposition regarding annual leave. Mr. Cagiano's testimony was that for some annual leave he and his wife would leave Camp Lejeune, and other times they did not.[30] I have made no judgment as to which annual leave days were taken on or off base; I have reviewed the exposure report for Mr. Cagiano prepared by Dr. Kelly Reynolds, and rely upon her calculations of time on base, and for exposure purposes.

Mr. Cagiano did confirm that he drank the water at Camp Lejeune throughout his time stationed there, but could not quantify a daily amount.[31] Mr. Cagiano stated that he drank from water buffalos.[32] He also testified that he filled his canteen more than once a day[33].He stated that he would drink water from the sink, water fountains in buildings and from water buffalos when doing field training.[34] His average shower lasted fifteen minutes, and it was a hot shower.[35] At times when Mr. Cagiano lived off base he would shower on base, in the barracks, after physical training.[36] Mr. Cagiano stated that her rarely ate lunch and often ran during his lunch hour and showered in the barracks.[37] Mr. Cagiano described similar water consumption for both of his times stationed on Camp Lejeune.

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[23] Cagiano Dep. 61:12-63:7
[24] Cagiano Dep. 63:8-13
[25] Cagiano Dep. 64:2-11
[26] Cagiano Dep. 64:12-21
[27] Cagiano Dep.65:1-12
[28] Cagiano Dep.65:16-20
[29] Cagiano Dep.77:10-17
[30] Cagiano Dep.50:23-51:17
[31] Cagiano Dep.81:25-88:4; 86:2-7; 87:25-88:4
[32] Cagiano Dep.87:25-88:4
[33] Cagiano Dep.82:5-11.
[34] Cagiano Dep.87:20-24
[35] Cagiano Dep.80:23-25
[36] Cagiano Dep.81:5-16
[37] Cagiano Dep.81:5-16

After an honorable discharge from the Marines, Mr. Cagiano had four different jobs, none of which exposed him to toxic chemicals. Mr. Cagiano first worked for Federal car rental company for two years as director of rental operations.[38] His duties were administrative. He then worked for Xerox as a customer account manager, managing other employees working with customers.[39] Mr. Cagiano worked for CMD Services, a marketing and distribution firm as a senior customer account manager.[40] Mr. Cagiano then became the pastor of sports and recreation ministries for First Baptist Church of Douglasville.[41] Based on the description of the post-Camp Lejeune jobs Mr. Cagiano worked after his honorable discharge from the Marines, there does not appear to be any exposure to toxins related to UTUC, and no employment related exposures. There is no evidence in the records reviewed that Mr. Cagiano was exposed to toxins in a work environment after leaving Camp Lejeune.

d. Medical history

Prior to joining the United States Marine Corps, we have very little in the way of past medical history for Mr. Cagiano. We do know that Mr. Cagiano attended the University of South Carolina on an ROTC scholarship.[42] During his deposition Mr. Cagiano was questioned about a 1974 visit to the infirmary at the University of South Carolina.[43] On June 24, 1974, Mr. Cagiano gave a history of having a bladder infection earlier that year.[44] This was the only episode of a bladder infection noted in his past medical history. Additionally, Mr. Cagiano had two prior episodes of kidney stones, requiring lost time from work in 1978 and 1980, both of which presented with hematuria (blood in the urine).[45] He was treated for both kidney stones at Camp Lejeune. Mr. Cagiano was noted to have no other complicating medical history.[46] Mr. Cagiano's medical records do not reveal any further history of kidney stones or hematuria until his presentation with UTUC.

In June 2009 Mr. Cagiano underwent a cystourethroscopy and transurethral resection of his prostate and bladder (TURP and TURBT) at Emory University Hospital that demonstrated benign prostatic hypertrophy, histology showed unremarkable urothelial mucosa.[47] At the time of his TURP/TURBT surgery Mr. Cagiano gave a past medical history of "1970's surgery for kidney stones," 2003 and 2008 cardiac stent placement, and rotator cuff surgery in 2005, revised in 2006.[48]

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[38] Cagiano Dep.92:8-93:5
[39] Cagiano Dep.93:12-22
[40] Cagiano Dep.94:2-7
[41] Cagiano Dep.94:24-95:3; 166:9-11
[42] Cagiano Dep. 24:20-25
[43] Cagiano Dep.103:10-10:8
[44] 00569_Cagiano_0000001059
[45] Cagiano Dep.106:18-108:23
[46] 00569_Cagiano_0000001070
[47] 00569_Cagiano_EUH_000000250-253, 00569_Cagiano__EUH_0000000333-334
[48] 00569_Cagiano_EUH_0000000052

Mr. Cagiano was treated for a melanoma lesion on his right forehead on December 27, 2013.[49] He underwent a shave biopsy that revealed melanoma in situ with wide margins; the melanoma was stage 0, in situ, and he was advised to continue his skin exams.[50]

On December 31, 2013, Mr. Cagiano saw Dr. Myfratt with Wellstar Urology after noticing light brown urine with right back pain, and providing a history of kidney stones.[51] Mr. Cagiano had a KUB/abdominal xray of his kidneys, ureters and bladder, that did show non-significant findings – a possible CT scan was suggested if warranted.[52] On April 16, 2014 Mr. Cagiano was seen by Dr. Varughese for abdominal pain, frequent urination and pain in his lower back.[53] Mr. Cagiano presented with a BMI of 36.52. His routine urinalysis did not demonstrate gross hematuria, and urine was yellow and clear. Dr. Varughese ordered a CT scan with contrast.

Mr. Cagiano saw Dr. Mygatt, Wellstar Urology, on October 20, 2014 and reviewed his CT scan; Dr. Mygatt notes all prior histories noted above.[54] No direct diagnosis was made at that time, but a renal scan was ordered and performed at Wellstar Douglas Hospital that showed 46% of renal activity in the right kidney and 54% in the left, relatively equal activity between the kidneys.[55]

Mr. Cagiano continued his regular follow-up visits with his various physicians without demonstrating any signs or symptoms of impending bladder, kidney or upper urinary tract cancer, until January 2, 2018. Mr. Cagiano presented with a several day history of discomfort in the pelvic area and an urge to void all the time. He did not report dysuria or hematuria, but on urinalysis he had trace amounts of blood.[56] Dr. Mygatt ordered a CT of the abdomen and cytology of the urine that were performed the same day. Mr. Cagiano underwent an MRU of the abdomen and pelvis on January 30, 2018, that was read as strongly concerning for urothelial malignancy/transitional cell carcinoma.[57]

On February 2, 2018, Mr. Cagiano sees Dr. Msangi in follow-up after his MRU; he was not experiencing hematuria or back pain at that time.[58] Mr. Cagiano had a cystourethroscopy and left ureteroscopy, and renal mass biopsy confirmed a urothelial carcinoma.[59] On February 12, 2018, in consultation with Dr. Msangi, Mr. Cagiano

[49] 00569_Cagiano_0000000747-748
[50] 00569_Cagiano_0000000747-748, 744
[51] 00569_Cagiano_0000001353-1356
[52] 00569_Cagiano_0000001359
[53] 00569_Cagiano_APFM_0000000057-60
[54] 00569_Cagiano_0000001346-
[55] 00569_Cagiano_WSU_0000000751
[56] 00569_Cagiano_0000001393-1394; 00569_Cagiano_0000001389-1407(full note)
[57] 00569_Cagiano_VBA_0000001194-1195
[58] 00569_Cagiano_0000001407-1435
[59] 00569_Cagiano_VBA_0000001191-1192

decided to undergo a left nephroureterectomy.[60] Surgery was performed on March 13, 2018, at Wellstar Cobb Hospital.[61] Mr. Cagiano was discharged from Wellstar Cobb Hospital on March 16, 2018.[62]

Because UTUC/transitional cell carcinoma is unique and can occur in the bladder, in the kidney, or anywhere along tract of the ureothelium, it is necessary to monitor and treat the bladder in follow-up. In Mr. Cagiano's case this included routine cystoscopies. Because Mr. Cagiano had a bad experience with a cystoscopy in the past, he requested that his future cystoscopies be done under anethesia.[63] Mr. Cagiano began surveillance cystoscopies following the removal of his kidney, on September 14, 2018.[64] Eventually Mr. Cogiano was transitioned to surveillance cystoscopies on a yearly basis.[65] Dr. Msangi noted on December 9, 2019, that cytologies have been negative thus far for malignancies, but that his doctor resected some benign tissue on the latest cystoscopy.[66]

Following repeated unremarkable cystoscopies for recurrence of his UTUC in the bladder, Mr. Cagiano was diagnosed with prostatic adenocarcinoma, grade 2(Gleason score 3=4=7).[67] At present, Mr. Cagiano elected to forego surgery for his prostate cancer, and instead keep active surveillance on the progress of the disease.[68] During a May 18, 2023 appointment at Cancer Treatment Centers of America, Mr. Cagiano's prostate cancer was noted as "IIB prostatic adenocarcinoma, found incidentally while undergoing TURP".[69]

V. Exposure Assessment

Concerning Mr. Cagiano's exposure to volatile organic compounds at Marine Base Camp Lejeune, I have reviewed the report and exposure modeling compiled by Plaintiff's expert, Kelly Reynolds, MSPH, PhD. Dr. Reynolds' modeled levels of exposure support my opinion that Mr. Cagiano had substantial exposure to toxins on Camp Lejeune. Her cumulative exposure charts set out reasonable estimates, based on objectively derived data, and the best available evidence to predict exposure levels. And the levels compiled by Dr. Reynolds demonstrate that Mr. Cagiano had substantial exposure to TCE and PCE primarily.

Accounting for days away from Camp Lejeune for deployments, training, or annual leave, Dr. Reynolds has calculated Mr. Cagiano's total days of exposure to the contaminated water on base at 1,056 days of exposure. And on a monthly basis Dr.

[60] 00569_Cagiano_0000001440-1443
[61] 00569_Cagiano_VBA_0000001188-1192
[62] 00569_Cagiano_VBA_0000001182
[63] 00569_Cagiano_0000001502-1503; 00569_Cagiano_0000001499-151(full note)
[64] 00569_Cagiano_0000001485; 00569_Cagiano_0000001509
[65] Cagiano depo125:14-18
[66] 00569_Cagiano_0000001681-1695
[67] 00569_Cagiano_0000000406-0408
[68] Cagiano depo126:20-127:11
[69] 00569_Cagiano_0000000034-37

Reynolds calculated the total exposure, or cumulative consumption, of the VOCs, and totaled these up for a cumulative exposure for each of the toxins.

		Chart 1: 1L	Chart 2: ATSDR	Chart 3: 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/FM exposure assumptions)**
TCE	12,365	115,100	1,319,000	2,012,342
PCE	510	5,187	54,399	45,738
VC	701	7,219	74,593	113,803
BZ	168	2,237	18,340	27,980

Using the ATSDR's estimated consumption of water, and utilizing Dr. Reynolds' calculated days on Camp Lejeune, Mr. Cagiano was exposed to 1,319,000μg of TCE, or 1,319mg. He was exposed to 54,399 µg of PCE, 54,399mg.[70] These amounts are well beyond exposures demonstrated to be causative of UTUC, bladder and kidney cancer. Dr. Reynolds' modeling done using data from Mr. Cagiano's deposition and the Marine Field Manual increases his cumulative exposure to TCE while decreasing exposure to PCE, but still well above the levels demonstrated to be toxic.[71]

In concluding that Mr. Cagiano had substantial exposure to TCE and PCE primarily, it is important to note that there are three recognized routes of exposure to these toxins: ingestion, inhalation, and dermal. Dr. Reynolds' model only addresses ingestion. Focusing on only one avenue of exposure can result in an underestimation of the true risk. Specifically, "for typical activities of drinking and showering, each exposure route contributes similar internal doses, and the total
internal dose for a 10-minute shower or a 30-bath is greater than that from ingesting over 2L of water."[72] Accounting for exposures via inhalation and dermal routes would dramatically increase the exposure numbers in the below chart compiled by Dr. Reynolds.

I have also reviewed the report of Dr. Bird. Dr. Bird's recent report sets out various study sources that have identified levels of exposure that demonstrate toxic levels of TCE,

[70] Report of Kelly Reynolds, MSPH, PhD, February 7, 2025
[71] Report of Kelly Reynolds, MSPH, PhD, February 7, 2025
[72] Weisel, C. and Wan-Kuen, J., Ingestion, Inhalation, and Dermal Exposure to Chloroform and Trichloroethylene from Tap Water, Environmental Health Perspectives, Vol. 104, Number 1, 48-51, Jan. 1996.

PCE, vinyl chloride and Benzene. I have compared Mr. Cagiano's cumulative level of exposure to these toxins and note that his exposure was well above the amounts noted as toxic.

Viewing Dr. Reynolds' exposure numbers against these demonstrated toxic levels clearly establishes that Mr. Cagiano's exposure was significant and substantial. Mr. Cagiano exceeds each of the demonstrated levels identified by Dr. Bird. And he was stationed for well over the six quarters addressed in *Bove,* 2024.

VI. General Causation

Before advancing to the application of a differential etiology for Mr. Cagiano, it is important to first recognize whether there is enough evidence to establish whether the chemicals in the water at Camp Lejeune are capable of causing UTUC as a general matter. As addressed in my footnote regarding the studies above, because of a shared pathogenesis, I set out my overview of the bladder cancer science, which is a cancer of the urothelium, below and draw distinctions to and highlight the UTUC science specifically here and in my differential etiology below. Again, this is due to the common pathogenesis of these two cancers.

Numerous regulatory and scientific bodies have recognized that these four chemicals are toxic and capable of causing cancer. IARC recognizes TCE, VC, and benzene as having sufficient evidence for carcinogenicity in humans, and that that PCE is probably carcinogenic to humans.[73],[74] EPA concluded that "TCE is carcinogenic to humans by all routes of exposure," that is, by ingestion, inhalation, and dermal exposure.[75] Further, EPA PCE is "likely to be carcinogenic in humans by all routes of exposure" by EPA (2012). Similarly, the National Toxicology Program has recognized TCE as "a known human carcinogen" (2015) and PCE as "reasonably anticipated to be a human carcinogen." (2021a). ATSDR's 2017 Assessment of the Evidence for the Drinking Water Contaminants at Camp Lejeune and Specific Cancers and Other Diseases found sufficient evidence exists for PCE causing bladder cancer, stating that "the epidemiological studies provide sufficient evidence for causation and are consistent with the mechanistic information that certain genetic polymorphism may enhance the production of genotoxic PCE metabolites in the bladder via the GSH conjugate pathway."[76] While ATSDR 2017 did not find sufficient evidence for TCE and bladder cancer, later studies have strengthened the association as noted by Dr. Hatten. As

[73] International Agency for Research on Cancer. Trichloroethylene, Tetrachloroethylene, and Some Other Chlorinated Agents. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. 2014;106:1-514.
[74] Environmental Protection Agency. Toxicological Review of Tetrachloroethylene (CAS No. 127-18-4). 2012
[75] EPA 2011
[76] Agency for Toxic Substances and Disease Registry. ATSDR Assessment of the Evidence for the Drinking Water Contaminants at Camp Lejeune and Specific Cancers and Other Diseases. 2017:1-150.

reported by Dr. Hatten and Dr. Plunkett, epidemiological studies have identified elevated bladder cancer diagnoses associated with benzene and vinyl chloride.

As reported by Dr. Hatten, Dr. Plunkett, Dr. Gilbert, and Dr. Bird, both TCE and PCE share similar metabolic pathways: toxic metabolites are eventually excreted from the kidneys into urine where it sits in the bladder until voided. Dr. Plunkett identifies the same endpoint for benzene and vinyl chloride metabolites as well. This means that the toxic metabolites can spend hours in contact with urothelial cells inside the bladder and have contact with urothelial cells throughout the tract. Below is a figure from Dr. Gilbert explaining the metabolic pathways and outcome for TCE and PCE-induced bladder cancer, and I would extend this to include UTUC.

Dr. Gilbert reports that inhalation and dermal exposure from TCE-contaminated water at least doubles ingestion consumption figures (and with similar evidence for PCE). Dr. Gilbert further explains that a mixture of TCE, PCE, and benzene can produce additive effects that can cause bladder cancer in that both TCE and PCE share a similar metabolic pathway and all three chemicals promote chronic inflammation and immunosuppression. This is the shared pathogenesis.

Over time, the scientific consensus has progressed to greater certainty, and action, regarding the toxicity of the chemicals at Camp Lejeune. In December 2024 EPA finalized a rule banning on TCE and most commercial uses of PCE under the Toxic Substances Control Act, describing TCE as "extremely toxic" and PCE as "cancer-causing."[77] As noted by Dr. Bird in his supplemental report, "the EPA determined that any lesser restrictions on the use of TCE or PCE would fail to adequately protect public health." Dr. Bird further explained that EPA's safety measures were based on the wastewater concentrations, not consumption, meaning that the risk for those at Camp Lejeune (whose ingested concentrations alone are than the concentrations identified in the EPA rule) is even greater.

Accordingly, there is a sufficient basis to conclude that the chemicals in the water at Camp Lejeune are capable of causing bladder cancer. Again, I will point out more UTUC-specific support in my differential etiology below.

VII. Differential Etiology

UTUC arises from the cells lining the urinary system including the bladder, ureter, renal pelvis and prostatic urethra, most commonly in the transitional epithelium (also

[77] Environmental Protection Agency. Biden-Harris Administration Announces Latest Actions under Nation's Chemical Safety Law to Protect People from Cancer-Causing Chemicals Trichloroethylene and Perchloroethylene. December 9, 20214. https://www.epa.gov/newsreleases/ biden-harris-administration-announces-latest-actions-under-nations-chemical-safety-law.

known as urothelium). It can present as non-invasive bladder cancer in the organ proper or throughout the renal pelvis, where it is characterized as UTUC.

The primary risk factors for UTUC, much like bladder cancer, include smoking, exposure to environmental and occupational carcinogens, and certain hereditary conditions. In addition, other risk factors for UTUC include phenacetin (an analgesic medicine), aristolochic acid (found in some herbal remedies) and chronic kidney stones and bladder infections. While UTUC is treatable when detected early, late-stage diagnosis significantly reduces survival rates.

UTUC can arise from the presence of a single risk factor or a combination of risk factors. UTUC risk factors often interact in a way that magnifies an individual's overall risk, a phenomenon known as synergistic or cumulative risk. For instance, smoking is the most prominent risk factor for UTUC, with smokers being three to four times more likely to develop UTUC compared to non-smokers. However, when combined with environmental carcinogen exposure, such as that from industrial chemicals like benzene, trichloroethylene (TCE), or perchloroethylene (PCE), commonly found in workplaces or contaminated water supplies, the risk can be significantly higher. Studies show that individuals exposed to both smoking and toxic chemicals, such as those at Camp Lejeune, experience a greater risk of UTUC than the sum of the risks posed by each factor alone. The interaction between these factors may increase the concentration of carcinogens in the bladder, elevate the frequency of genetic mutations, or impair the body's ability to repair cellular damage, thus accelerating the cancerous process. Additionally, genetic predispositions, such as mutations related to Lynch syndrome, can further exacerbate this risk, making it crucial for individuals with multiple risk factors to be monitored closely for early signs of UTUC. With UTUC, the combination of lifestyle choices, environmental exposures, and genetic factors can work together to create an increased risk for developing UTUC, as well as bladder cancer.[78]

My previous research has focused on understanding the genetic alterations in UTUC and how the compare to bladder cancer. My work and others have shown that UTUC and bladder cancer share several genetic and molecular similarities in their development. Both cancers primarily arise from mutations in the urothelial cells, which line the urinary tract from the renal pelvis down to the prostatic urethra including the ureter and bladder. The most common genetic alterations in both UTUC and bladder cancer involve mutations in tumor suppressor genes such as TP53 and oncogenes such as FGFR3. The development of both cancers involves a multi-step process that includes the accumulation of genetic mutations, leading to the transformation of normal urothelial cells into malignant ones. Carcinogen filtration from the parenchyma of the kidney leads to excretion into the urine, which then is in contact with the urothelial throughout the urinary system. The urothelial is exposed to the same carcinogens throughout the urinary system leading similar cancer formation. Despite differences in the anatomical sites of

[78] Dickman K.G., e.a., Epidemiology and Risk Factors for Upper Urinary Urothelial Cancers. , in Upper Tract Urothelial Carcinoma. , X.E.e. In: Shariat S., Editor. 2015, Springer: New York, NY, USA

origin, the genetic pathways leading to tumorigenesis in UTUC and bladder cancer are strikingly similar.[79]

UTUC, like bladder cancer, typically exhibits a significant lag time between exposure to carcinogenic risk factors and the onset of diagnosis, often taking decades for the disease to develop. This delay is primarily due to the slow accumulation of genetic mutations and cellular damage that occurs over time, as carcinogens gradually affect the bladder lining. Chronic exposure to risk factors such as smoking, occupational chemicals, or infections can lead to repeated DNA damage, inflammation, and the gradual formation of abnormal cells that eventually become cancerous. Because urothelial cells line the bladder, kidney, and ureters that transports urine from the kidneys to the bladder, they are continuously exposed to these carcinogens in the natural processes in the renal pelvis. This means that the latency period for UTUC is typically long, with diagnoses often occurring 20 to 40 years after initial exposure.

In this section I explore the known risk factors for UTUC and provide references to support the analysis. Next, I consider whether the known risk factors for UTUC are applicable to Mr. Cagiano. Finally, I consider whether Mr. Cagiano's exposure to the water at Camp Lejeune was at least as likely as not the cause of Mr. Cagiano's UTUC.

Before addressing the risk factors for UTUC individually, it is important to address whether UTUC is idiopathic. Idiopathic means that a disease has no known cause. I understand and use this term in my medical practice when an individual presents with a condition for which I cannot identify a known cause. While we cannot have complete certainty on the precise cause of many cancers, UTUC has well-defined risk factors that explain the vast majority of diagnoses.[80]

Whenever I perform a differential etiology in my practice, I first consider the relevant risk factors for that disease and if (and only if) I cannot reasonably identify a potential risk factor to cause an individual's disease do I conclude that the cause is idiopathic. As I discuss further in this report, Mr. Cagiano was exposed to chemicals at Camp Lejeune that have a known association with the very disease of which he was diagnosed. While I still consider other alternative causes for Mr. Cagiano's UTUC diagnosis, I do not consider his diagnosis to be idiopathic.

[79] Sfakianos, J. et al, Genomic Characterization of Upper Tract Urothelial Carcinoma Comparative Study Eur Urol 2015 Dec;68(6):970-7; Sfakianos, J. et al, Genetic Differences Between Bladder and Upper Urinary Tract Carcinoma: Implications for Therapy Eur Urol Oncol 2021 Apr;4(2):170-179

[80] Colin, P., et al. Environmental factors involved in carcinogenesis of urothelial cell carcinomas of the upper urinary tract. BJU Int, 2009. 104: 1436; Dickman, et al., 2015. Dickman K.G., e.a., Epidemiology and Risk Factors for Upper Urinary Urothelial Cancers. , in Upper Tract Urothelial Carcinoma. , X.E.e. In: Shariat S., Editor. 2015, Springer: New York, NY, USA.

1. Potential Relevant Risk Factors: Smoking

Smoking is a significant and well-established risk factor for UTUC. According to the American Cancer Society, smoking contributes to approximately 50% of all UTUC (and bladder cancer) cases in the United States (American Cancer Society, 2023). This does not mean that 50% of smokers will get bladder cancer or UTUC. But of the people that are diagnosed with bladder cancer, approximately 50% are current or prior long-term smokers. While the mechanism of how smoking causes bladder cancer/UTUC is not fully developed, it is generally understood that the carcinogens from tobacco are absorbed into the bloodstream and filtered by the kidneys, where they are excreted into the bladder. Tobacco smoke contains a wide range of carcinogens, including polycyclic aromatic hydrocarbons (PAHs), nitrosamines, benzene, and arsenic, all of which are harmful to the urothelial cells in the kidneys, bladder, and ureters. When inhaled, these toxic substances are absorbed into the bloodstream and filtered by the kidneys, where they accumulate in the upper urinary tract. The carcinogens in cigarette smoke cause direct DNA damage to the urothelial cells, leading to mutations that can trigger cancerous growth. These toxic substances also cause chronic inflammation, oxidative stress, and cell turnover, further increasing the likelihood of genetic mutations and malignant transformation. Long-term exposure to these carcinogens through smoking significantly increases the risk of UTUC, and the more a person smokes, the higher their risk becomes. The risk of UTUC is not only higher in current smokers but also in former smokers, as the effects of tobacco-related carcinogens persist in the body for years after cessation. Studies consistently show that smokers are more likely to develop UTUC at a younger age and often present with more advanced stages of the disease. The mechanism of tobacco-induced UTUC involves both direct genotoxicity and the promotion of chronic cellular damage that eventually leads to cancer. Smoking remains the most significant preventable cause of UTUC, and cessation is critical to reducing risk. [81] [82]

There is no need to focus on smoking as a risk factor in this case, as Mr. Cagiano was not a smoker. His testimony was that he smoked "occasionally as a teenager, but I stopped about the time I turned 18."[83] When asked to quantify his level of smoking Mr. Cagiano stated "very occasionally. Maybe once a week," one cigarette a week for less than two years.[84] According to the Center for Disease Control, a person who smokes less than 100 cigarettes in a lifetime is considered a "never smoker."[85]

[81] Dickman K.G., e.a., Epidemiology and Risk Factors for Upper Urinary Urothelial Cancers. , in Upper Tract Urothelial Carcinoma. , X.E.e. In: Shariat S., Editor. 2015, Springer: New York, NY, USA.
[82] McLaughlin, J.K., et al. Cigarette smoking and cancers of the renal pelvis and ureter. Cancer Res, 1992. 52: 254.
[83] Cagiano depo. 99:12-22.
[84] Cagiano depo. 99:18-100:4
[85] CDC, Adult Tobacco Use, Glossary, https://www.cdc.gov/nchs/nhis/

Mr. Cagiano is a non-smoker/"never-smoker," and smoking is not a risk factor that needs to be included in my differential etiology for the cause of his UTUC.

2. Environmental and Occupational Exposure to Carcinogens

Environmental exposure to carcinogens is another key risk factor for UTUC. These carcinogens include volatile organic compounds (VOCs), aromatic amines, and certain industrial chemicals, which can be found in workplaces and contaminated water supplies.

Exposure to Chemicals at Work: Occupational exposure is a significant risk factor for UTUC, especially for individuals working in industries that involve carcinogenic chemicals. Workers in the manufacturing of dyes, rubber products, and textiles are at an increased risk due to their exposure to aromatic amines, a class of carcinogens strongly linked to UTUC (Smith et al., 2018). Additionally, individuals working with solvents such as benzene, trichloroethylene (TCE), and perchloroethylene (PCE) are also at heightened risk, as these chemicals can be absorbed into the body and concentrate in the bladder.[86] Long-term exposure to these substances, particularly in poorly ventilated environments, can lead to chronic bladder irritation and genetic mutations that increase the likelihood of cancer. Furthermore, workers in the metal industry, hairdressers, and those exposed to certain pesticides and industrial waste also face increased risks due to prolonged contact with carcinogenic agents[87]

Water Contamination: Water contamination, particularly in military or industrial settings, also presents a significant risk. For example, the contamination of drinking water at Camp Lejeune in North Carolina with toxic substances such as trichloroethylene (TCE) and perchloroethylene (PCE) has been associated with an increased incidence of UTUC among those who lived or worked there. TCE, a degreasing agent, and PCE, a solvent used in dry cleaning, are both classified as human carcinogens or suspected human carcinogens by the International Agency for Research on Cancer (IARC). US EPA has also banned both TCE and significantly limited the industrial use of PCE because they are cancer-causing agents, and used Camp Lejeune as a key example for why banning these chemicals was necessary.

Mr. Cagiano has as very clean presentation when it comes to potential risk factors for bladder cancer/UTUC. He is not a smoker, and as addressed earlier in this report he was not exposed to second-hand smoke while growing up in his parents' home. His mother was a prior smoker, but Mr. Cagiano had no memory of his mother smoking, only that here were ashtrays in the house.[88] Smoking is not a credible potential cause for Mr. Cagiano's UTUC and can be excluded from the list of possible causes in my differential etiology.

[86] Morris, et al. 2017
[87] Bertazzoni, et al. 2020
[88] Cagiano depo. 32:1-3

3. Occupational exposures

Occupational exposure to certain chemicals and toxins is a well-established risk factor for developing upper tract urothelial carcinoma (UTUC). Workers in industries like dye manufacturing, rubber production, and chemical processing are particularly at risk due to exposure to carcinogenic substances, such as aromatic amines. One of the most notable carcinogens in this category is 2-naphthylamine, which has been linked to both bladder and UTUC. Benzidine, another aromatic amine, is also a significant risk factor and has been implicated in the development of urothelial carcinoma. In addition to aromatic amines, workers exposed to asbestos and benzene in certain manufacturing and construction industries may face an increased risk of UTUC due to the carcinogenic nature of these substances. Asbestos fibers can cause chronic irritation and inflammation in the urinary tract, increasing the likelihood of cancerous mutations. Prolonged exposure to these chemicals leads to cumulative DNA damage, which can result in malignancy in the renal pelvis and ureter. The risk is further amplified by the duration and intensity of exposure, with long-term workers being at a higher risk of developing UTUC. Even protective measures in the workplace may not fully mitigate the risks if the exposure is substantial or prolonged. Studies have consistently found elevated rates of UTUC among workers in these high-risk industries, underscoring the importance of monitoring and regulating exposure to harmful substances. See. Dickman, et al., 2015.

Following his honorable discharge from the Marine Corps, Mr. Cagiano worked four different jobs. He worked for a rental car company, with administrative duties; he worked for Xerox, again with primarily administrative duties; he worked as a customer sales representative for a marketing and distribution company; and he was an associate pastor of sports and recreation for a church. There has been no evidence of exposures to any toxins in Mr. Cagiano's post-Marines employment history. In order to include a potential cause on the list of "possibles" in a differential etiology there must be some evidence that an exposure occurred. Here there simply is no evidence of post-Camp Lejeune employment-related exposures. Mr. Cagiano does not have any significant environmental exposure history, other than the significant exposure at Camp Lejeune addressed in this report and thus I do not find this to be a risk factor for his development of UTUC.

4. Chronic Use of Analgesics (Phenacetin)

Phenacetin, a pain-relieving drug widely used in the past, that has been linked to the development of upper tract urothelial carcinoma (UTUC). Initially used in analgesic formulations, phenacetin was found to have carcinogenic effects on the urinary tract after prolonged use. When metabolized in the body, phenacetin is converted into harmful metabolites, including hydroxyphenacetin and phenacetin catechol, which can cause DNA damage in the urothelial cells of the kidneys and ureters. The toxic metabolites from

phenacetin are thought to induce mutations and promote cellular changes that lead to cancer. Chronic use of phenacetin, particularly in high doses, has been shown to increase the risk of both bladder cancer and UTUC, as the kidneys filter these harmful substances, concentrating them in the upper urinary tract. The mechanism by which phenacetin contributes to UTUC is believed to involve oxidative stress, chronic inflammation, and direct DNA damage. Overall, the use of phenacetin has a clear association with UTUC, emphasizing the importance of limiting exposure to known carcinogens in pharmaceutical products.[89],[90],[91]

There is no evidence that Mr. Cagiano was ever exposed to Phenacetin at any time, so this is not a risk factor for causing his UTUC.

5. Exposure to Aristolochic Acid (AA)

Aristolochic acid (AA) is a potent carcinogen that has been linked to the development of upper tract urothelial carcinoma (UTUC), particularly in individuals who have been exposed to it through the use of traditional herbal remedies.[92] Aristolochic acid is found in plants of the Aristolochia genus, which has been used in some cultures for medicinal purposes. When consumed, AA is absorbed into the bloodstream and filtered by the kidneys, where it concentrates in the renal pelvis and ureters, the primary sites affected by UTUC. AA is known to cause DNA damage by forming adducts with the DNA, leading to mutations, chromosomal aberrations, and ultimately cancer. The key mechanism by which AA induces cancer is through its ability to form highly mutagenic aristolactam DNA adducts, which can lead to the activation of oncogenes and the inactivation of tumor suppressor genes, such as Tp53. Chronic exposure to aristolochic acid results in persistent DNA damage and the accumulation of mutations in the urothelial cells of the upper urinary tract. Research has demonstrated that the risk of developing UTUC is significantly higher in individuals who have ingested AA-containing herbal products, particularly when used over extended periods. The carcinogenic effects of AA are so severe that it has been classified as **a** Group 1 carcinogen by the International Agency for Research on Cancer (IARC). As a result, exposure to aristolochic acid is a major cause of UTUC, particularly in regions where the use of these herbal remedies is prevalent. Because there is no evidence that Mr. Cagiano was ever exposed to aristolochic acid, this is not a risk factor for causing his UTUC.

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[89] McCredie M, Coates MS, Ford JM, Disney AP, Auld JJ, Stewart JH. Geographical distribution of cancers of the kidney and urinary tract and analgesic nephropathy in Australia and New Zealand. Aust NZ J Med. 1990;20(5):684–8

[90] McCredie M, Stewart JH, Mathew TH, Disney AP, Ford JM. The effect of withdrawal of phenacetin-containing analgesics on the incidence of kidney and urothelial cancer and renal failure. Clin Nephrol. 1989;31(1):35–9.

[91] IARC. Phenacetin. IARC Monogr Eval Carcinog Risk Chem Hum. 2012;100A:377–98.)

[92] Jelakovic, B., et al. Aristolactam-DNA adducts are a biomarker of environmental exposure to aristolochic acid. Kidney Int, 2012. 81: 559., Cosyns, J.P. Aristolochic acid and 'Chinese herbs nephropathy': a review of the evidence to date. Drug Saf, 2003. 26: 33.; Dickman, et al, 2015.

6. Genetic and Familial Factors

Lynch syndrome, also known as hereditary non-polyposis colorectal cancer (HNPCC), is an inherited genetic condition that significantly increases the risk of various cancers, including upper tract urothelial carcinoma (UTUC). It is caused by inherited mutations in the mismatch repair (MMR) genes, specifically MLH1, MSH2, MSH6, and PMS2, which are responsible for correcting errors in DNA replication.[93] When these genes are mutated, the body's ability to repair DNA mismatches is impaired, leading to the accumulation of mutations in critical genes, including those involved in regulating cell growth. These accumulated mutations increase the risk of developing cancers in various organs, including the kidneys, ureters, bladder and renal pelvis. In Lynch syndrome, UTUC is one of the cancers that can arise due to the genetic instability caused by defective MMR. The loss of DNA repair function allows cells in the upper urinary tract to accumulate harmful mutations over time, which may result in malignant transformation. Studies have shown that individuals with Lynch syndrome are at an elevated risk for UTUC compared to the general population, particularly when there is a family history of the condition. The mechanism behind this increased risk is the defective DNA repair pathway, which promotes both the initiation and progression of UTUC. Patients with Lynch syndrome who develop UTUC tend to have a more aggressive form of cancer and may experience it at a younger age than those without the syndrome. Early diagnosis and genetic screening for Lynch syndrome are crucial in identifying at-risk individuals, enabling early surveillance and intervention for UTUC.[94]

Mr. Cagiano has no family history of cancer, and there is no evidence that he has any inherited genetic condition, such as Lynch syndrome. Because Mr. Cagiano's family history does not include any first-degree relatives with cancer, and no history of Lynch syndrome, I can remove genetic or family history as a possible cause of Mr. Cagiano's UTUC.

7. Chronic Kidney Stones and Chronic inflammation

Chronic kidney stones, or nephrolithiasis, are a risk factor for developing upper tract urothelial carcinoma (UTUC), particularly when they cause chronic irritation or obstruction in the renal pelvis and ureters. The formation of stones in the kidneys leads to mechanical damage to the urothelial lining, which can result in chronic inflammation and irritation over time. This persistent irritation stimulates cell turnover, creating an environment conducive to genetic mutations that can lead to cancer. The stones themselves can cause localized tissue damage, which can disrupt the normal cellular repair process, increasing the likelihood of abnormal cell division and malignancy. Additionally, kidney stones can lead to the formation of urinary tract infections (UTIs), which contribute to further inflammation

[93] Koornstra, J.J., et al. Management of extracolonic tumours in patients with Lynch syndrome. Lancet Oncol, 2009. 10: 400.

[94] Roupret, M., et al. Upper urinary tract urothelial cell carcinomas and other urological malignancies involved in the hereditary nonpolyposis colorectal cancer (lynch syndrome) tumor spectrum. Eur Urol, 2008. 54: 1226.)

and potential carcinogenic changes in the urothelial cells. The chronic inflammatory environment caused by recurrent stones or infections can promote oxidative stress, which increases DNA damage and mutations in the urothelial lining. People with long-term kidney stones are at higher risk for developing UTUC, especially when stones cause persistent obstruction or create conditions that favor bacterial growth. Furthermore, certain types of kidney stones, such as those made from uric acid or cystine, may exacerbate this risk by contributing to crystal formation that further damages the urothelial cells. Over time, the repeated cycles of stone formation, inflammation, and cellular repair increase the likelihood of malignant transformation in the upper urinary tract. Although not all kidney stone patients develop UTUC, the risk is notably higher for individuals with recurrent or long-standing stones in the kidneys or ureters.

Further, I co-authored an article directly relevant to this issue. When a patient's chronic UTIs and/or kidney stones are considered as contributing to bladder cancer/UTUH, the resulting cancer has different histology than UTUC, particularly squamous cell carcinoma, which is more associated with chronic infection.[95] I was a co-author on the Mihalopoulos paper investigating the link between kidney stones and UTUC. Mr. Cagiano's UTUC was transitional cell carcinoma.

Moreover, the critical characteristic of this risk factor is the word "chronic." As was addressed earlier in this report, Mr. Cagiano had a single bladder infection in 1974, a kidney stone in 1978, and another kidney stone in 1980. I understand that the DOJ has raised Mr. Cagiano's "kidney and bladder issues, including blood in his urine and a bladder infection" as an alternative cause for his UTUC. The distant and sporadic kidney stone events, and a single bladder infection are not the type of events that would cause an increased risk for UTUC. I can rule this out as a potential cause of Mr. Cagiano's UTUC.

Related Medical Conditions

As a result of Mr. Cagiano's nephroureterectomy he is left with one kidney, meaning he has permanently lost approximately one-half of his toxin filtering capacity. His kidney scan in 2014 demonstrated that his right kidney provided approximately 46% of his renal activity.[96] Kidneys are made up of a system of nephrons; nephrons are the toxin filtering agents in the kidney. The loss of his kidney resulted in a roughly 50% loss of toxin filtering capacity.

Following the removal of his kidney Mr. Cagiano has experienced chronic renal insufficiency demonstrated by his continued elevated creatinine levels, and a lowered glomerular filtration rate (GFR), a blood test that measures how well your kidneys (or kidney in Mr. Cagiano's case) is filtering waste and toxins out of your blood. Proper renal function is critical to good health. Mr. Cagiano's chronic elevated creatinine levels coupled with a chronically low GFR is evidence of diminished function or chronic kidney

[95] Mihalopoulos, M., et al., Understanding the link between kidney stones and cancers of the upper urinary tract and bladder Am J Clin Exp Uro 2022 Oct 15;10(5):277-298.
[96] 00569_Cagiano_WSU_0000000751

disease. There is no predicting if or when Mr. Cagiano's renal function will deteriorate further, but the possibility of further deterioration could ultimately lead to Mr. Cagiano needing dialysis.

VIII. Opinions

Mr. Cagiano's exposure to the water at Camp Lejeune was at least as likely as not a cause of Mr. Cagiano's UTUC.

The absence of any other identifiable risk factor, as addressed above, is telling. Mr. Cagiano's only credible and realistic risk factor for his UTUC is his time spent on Camp Lejeune, and his exposure to the contaminated water there. As a result, based upon my education, training and experience, my review of the materials addressed herein, including the expert reports relied upon, it is my opinion to a reasonable degree of medical and scientific certainty that it is at least as likely as not that the contaminated water at Camp Lejeune was a cause of Mr. Cagiano's UTUC, diagnosed in March 2018.

It is my opinion that Mr. Cagiano had only one risk factor for the development of UTUC - exposure to contaminated water while stationed at Camp Lejeune. It is further my opinion that Mr. Cagiano had significant and substantial exposure to both PCE and TCE via the contaminated water at Camp Lejeune.

Mr. Cagiano developed UTUC at the age of 65, which is 8 years earlier than the median age of development in the United States. He furthermore developed UTUC over 30 years after exposure to the contaminated water at Camp Lejeune, which is an expected latency period.

Given the nature of Mr. Cagiano's bladder cancer/UTUC he will continue to undergo repeated, annual, cystoscopies as standard surveillance for his cancer recurring. He remains at risk for possible bladder removal with urinary diversion.

Finally, it is my opinion that Mr. Cagiano's ongoing compromised kidney function is the natural consequence of having UTUH, and having a kidney removed, and although it is not possible to predict if or when Mr. Cagiano's kidney function will further deteriorate, it may and it may to the point that future dialysis will be necessary.

I am being compensated for my time devoted to this consulting work at an hourly rate of $550.

Appendix 1

CURRICULUM VITAE

John P. Sfakianos, MD

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Tel (Office): (212) 241-4812
Tel (Mobile): [redacted]
Mailing Address (Office): 1425 Madison Avenue, 6th Floor, Room L6-58, New York, NY 10029
Mailing Address (Home): [redacted]

APPOINTMENTS/EMPLOYMENT

Icahn School of Medicine at Mount Sinai, New York, NY	Professor Urology (10/2024-present)
Icahn School of Medicine at Mount Sinai, New York, NY.	Associate Professor Urology (04/2022–10/2024)
Department of Urology Mount Sinai, New York NY	Medical Director (07/2015-06/2018)
Icahn School of Medicine at Mount Sinai, New York, NY	Assistant Professor Urology (07/2014–03/2022)
Memorial Sloan Kettering Cancer Center, New York, NY	Clinical Instructor Surgery/Urology (07/2012-06/2014)

Gaps in Employment
Not applicable

EDUCATION

Leadership Emerging in Academic Departments (LEAD)	Student (2023-present)
Memorial Sloan Kettering Cancer Center (Urologic Oncology)	Fellowship (06/2014)
SUNY Downstate Medical Center (Urology)	Residency (06/2012)
SUNY Downstate Medical Center (Surgery)	Internship (6/2008)
SUNY Buffalo School of Medicine and Biosciences	Doctoral of Medicine (09/2007)
Hunter College CUNY (Biochemistry)	Bachelors of Science (06/2002)

Certification

ISMSS Mindfulness Course	(2023)
American Board of Urology	(2016)

Licensure
New York Medical: 265049
DEA: FS3492674
NPI: 1295904084

HONORS/AWARDS

Bladder Cancer Advocacy Network (BCAN) 2023 Translational Clinical Trial Award	(2022)
Bladder Cancer Advocacy Network (BCAN) 2022 Innovation Award	(2022)
Tisch Cancer Institute Development Funds Award	(2022)
Faculty Council Award Junior Faculty, Icahn School of Medicine	(2021)
Faculty inductee Alpha Omega Alpha	(2020)
Teacher of the Year, Icahn School of Medicine Department of Urology	(2018, 2019)
Sharing and Caring Physician Recognition Award	(2017)

Patents
N/A

Other entrepreneurial opportunities

N/A

OTHER PROFESSIONAL ROLES

Journal Editor
Bladder Cancer- Editorial Board 1/2020-present Urologic Oncology-Consulting editor 1/2020-present
Journal Assignments
Reviewer, European Urology
Reviewer, European Urology Oncology
Reviewer, Journal of Urology
Reviewer, Nature Communication
Reviewer, Seminars in Urologic Oncology

Research Profile

My translational research focuses on human Natural Killer (NK) cells and CD8 T cells and their functional roles in bladder cancer. I collaborate extensively with Drs. Amir Horowitz, Nina Bhardwaj, and Matthew Galsky and the human immune monitoring center (HIMC) to profile human NK cells, T cells and innate lymphoid cells in human bladder cancer. We have established an effective pipeline for profiling NK cells and ILCs as well as for studying their crosstalk with other immune cells (myeloid cells, T cells, neutrophils, and B cells), stroma, and tumors. The Main focus of my research is focused on BCG unresponsive non-muscle invasive bladder cancer. The focus is to understand the underlying immune resistance mechanism and to identify novel therapeutic options. To achieve this goal, we use an array of cutting-edge technologies, including mass cytometry (CyTOF), imaging mass cytometry (IMC), Olink proteomics, and single-cell and Spatial RNA sequencing along with genomic data on HLA class I genes to profile NK and CD8 T cells with ultra-resolution. Our work has identified a novel therapeutic target in the NKG2A:HLA-E pathway.

Clinical Profile

My clinical focus has been on identifying novel methods in helping patients with bladder cancer. My translational research has focused on non-muscle invasive bladder cancer in which our work has led to the funding of a novel Phase 2 clinical trial for BCG unresponsive tumors. Furthermore, my clinical research focus has been centered on patients undergoing radical cystectomy. Our group has been focused on improving the Enhanced Recovery After Surgery (ERAS) pathway for patients undergoing radical cystectomy. Our clinical work has improved outcomes on many aspects of surgery. We have published several patients on improving infection rates by using an antibiogram specific antibiotic regimen and intracorporeal robotic surgery, safety of using oral anticoagulation for VTE prophylaxis and safely performing surgery without drains. Most importantly using regional blocks and intracorporeal robotic surgery we can safely perform surgery without using opioids (Non-opioid protocol (NOP)).

MENTORING PROFILE

I have mentored multiple medical students, residents, and a postdoctoral fellow. Additionally, through collaborations with Drs. Amir Horowitz (Immunology, ISMMS) we have emphasized a co-mentorship dual-training approach focused on both clinical and basic science/translational research. One notable example to highlight focused on three medical students: Drs. Daniel Ranti (ISMMS), Y. Alice Wang

(ISMMS), and Christine Bieber (St. Georges University) whose time with me ranged from one to 2.5 years. These three trainees partnered together to develop an understanding of resistance to M. bovis BCG treatment of non-muscle-invasive bladder cancer (NMIBC), which has resulted in federal NIH/NCI R21 and R01 awards and a funded Phase 2 clinical trial in BCGunresponsive NMIBC. We have submitted a co-first authorship manuscript for peer review, and they have each co-authored numerous clinical and translational research and review articles. All three of them have now matched for top Urology residency programs (Columbia, Johns Hopkins, SUNY Albany). Finally, Daniel Ranti was awarded Mount Sinai's Dr. Harold Lamport Biomedical Research Prize as well as the PORTAL thesis award in clinical research upon his graduation

Diversity and Inclusion Impact

Working with medical students I have been volunteering my time as a Urology faculty member covering the East Harlem Health Outreach Partnership (EHHOP) Urology clinic. The focus of the clinic is to help a diverse underserved patient population at the same time work with medical students to help them understand the field of Urology and help those interested in developing into Urologist.

Overall Impact

Over the last 30 years BCG has been and still is the only FDA approved treatment for non-muscle invasive bladder cancer. There has been little understanding of its mechanism of action in cancer therapy and furthermore little understanding in the biology of resistance to this therapy. My work over the last 10 years has been vital in understanding the immune microenvironment in BCG unresponsive bladder cancer. We have identified a critical role of NK cells and their interactions with other immune cells in the tumor microenvironment as pivotal for resistance. With this knowledge I have been successful in securing numerous funding sources for continued work in this area including a DOD team translational award (co-PI), an R01 (Co-PI) and R21 (PI) and several private grants including the BCAN innovation award (PI). Most importantly our findings have led to an investigator initiated clinical trial targeting NK and T cells in BCG unresponsive bladder cancer. This clinical trial has been funded by BCAN and will initiate enrollment of patient in 2024.

Clinically I have successfully modified an Enhanced Recovery after Surgery (ERAS) protocol for patients undergoing radical cystectomy to allow for the elimination of narcotics after surgery and decreased the risk of infections. I have implemented several protocols that are published in peer reviewed journals using nerve blocks prior to surgery along with anti-inflammatory medications leading to ~90% of patients post radical cystectomy not needing opioids. Furthermore, we developed a Mount Sinai Hospital specific antibiogram for patients undergoing radical cystectomy and modified our antibiotic prophylaxis regimen leading to the reduction of post-operative infections by almost 50%. The changes have allowed patients to be discharged sooner with lower readmissions. The successful implementation of this modified ERAS program for patients undergoing radical cystectomy has been well accepted by collogues nationally and internationally leading to invitations for presentations at several conferences and guideline implementation.

Grants, Contracts and Foundation Support

Past Grants

List Funding Source, Project Title and Number	Role in Project	Dates	Direct Costs	Supplemental info
DOD (PD/PI: Sfakianos.)	**PI;** to characterize the dysfunctional NK cell	7/15/2019 - 7/14/2023	$1,584,753	N/A

Project #: W81XWH1910269 **Project title**: Dissection of suppressive axes underlying Natural Killer cell dysfunction in human bladder cancer	phenotype in the TME and blood of individuals with bladder cancer, identify mechanisms underlying NK cell dysfunction in nonmuscle-invasive and muscle-invasive tumors and to design rational, preclinical interventions to enhance NK function and reverse NK dysfunction. **% effort:** 1.2 CM			
NINR/NIH (PD/PI: Mohamed.) **Project #:** 5R21NR016518 **Project title:** Novel Approach to Enhance Ostomy Care in Patients with Bladder and Colorectal Cancer	**Co-PI;** Study results will guide further refinement of the ostomy-education program for a larger experimental trial. **% effort:** 0.36 CM	05/01/2017 – 04/30/2019	$126,777	N/A
NINR/NIH (PD/PI: Mohamed.) **Project #:** 5 R21 **Project title**: The personal patient profile decision support for patients with bladder cancer	**Co-I;** The personal patient profile decision support for patients with bladder cancer **% effort:** 0.24 CM	07/01/2020-06/30/2022	$225,000	N/A

Current Grants

List Funding Source, Project Title and Number	Role in Project	Dates	Direct Costs	Supplemental info
DISRUPT (SU2C) (PD/PI: Horowitz.) **Project #:** N/A **Project Title:** Understanding the immunogenetic drivers of health disparities in Afro-Caribbean men with prostate cancer	**Co-I;** to define a cohort of Black Afro-Caribbean and EuropeanCaucasian prostate cancer patients receiving care across distinct areas of New York City and perform WES and RNA-seq on germline and tumor tissue to generate HLA-I genotypes and quantify abundance of RNAtranscripts associated with NKcell phenotypes and antitumor functions. **% effort: 0.1 CM**	02/1/2023 - 01/31/2027	$50,000	N/A
NIH/NCI (PD/PI: Horowitz, Sfakianos.) **Project #:** 1 R01 CA269954-01 **Project title:** HLA-E and NKG2A define a novel	**MPI;** to (1) analyze intratumoral NK cells and T cells and their interactions with tumors in response to BCG therapy, (2) longitudinally assess blood and tumor phenotypes in response	02/1/2023 - 01/31/2027	$3,359,953	N/A

immune checkpoint axis in non-muscle-invasive bladder cancer.	to BCG therapy, and (3) determine the effects of combination PD-L1 and NKG2A blockade on anti-tumor immunity **% effort:** 4.2 CM			
NIH/NCI (PD/PI: Sfakianos.) **Project #:** 1 R21 CA274148 **Project title:** Identifying novel resistance mechanisms in non-muscle-invasive bladder cancer treated with Bacillus Calmette-Guerin (BCG)	**PI;** using two distinct cohorts of tumors, both BCG alone and BCG and PD1-combination resistant tumors, to investigate the spatial and immunologic heterogeneity underlying resistance to these standard of care therapies. **% effort:** 0.852 CM	8/1/2022 - 7/31/2024	$150,000	N/A
NIH/NCI (PD/PI: Bhardwaj, N.) **Project #:** CA249175 **Project title**: Dissecting Myeloid-Cell Mediated Resistance to Immune Checkpoint Blockade in Bladder Cancer	**Co-I;** to (1) dissect gene modules associated with response resistance to CPI using high resolution maps of the cellular and molecular landscape of muscle-invasive bladder cancer (MIBC), (2) determine the role of stromal module genes in controlling the immunophenotyped and function of monocyte-macrophages, and (3) refine and validate a monocyte-macrophage-related gene signature as a biomarker of CPI resistance in clinical trial cohorts. **% effort:** 1.0 CM	4/20/2020 - 3/31/2025	$3,502,929	N/A
Bladder Cancer Advocacy Network Clinical Trials Award (PD/PI: Horowitz, Sfakianos, Galsky.) **Project #:** N/A **Project title**: Targeting HLA-E/NKG2A for overcoming BCG resistance in non-muscle-invasive bladder cancer	**MPI**; we will conduct a Phase 2 clinical trial of combination PD-L1/NKG2A blockade (durvalumab/monalizumab) in patients with BCG-unresponsive NMIBC. We will determine whether measuring the proteins HLA-E and NKG2A in pretreatment tumors might be used in the future to identify patients who are most likely to respond to this novel treatment regimen. **% effort:** 1.2 CM	5/1/2023 - 4/30/2026	$2,237,527.89	N/A

NIH/NCI (PD/PI: Mullholand.) **Project #:** R21 CA286309 **Project title:** Targeting the Androgen Receptor to Sensitize Bladder Cancer to Immune Check Point Blockade	**Co-I;** The goal of this project it so better understand the role of the Androgen Receptor in bladder cancer and to assess if inhibition of immune point blockade can be enhanced with co-blockade. **%effor**t: 0.36 CM	1/1/2024-13/31/2025	$434,542	N/A
Bladder Cancer Advocacy Network Clinical Trials Award (PD/PI: Sfakianos) **Project #:** N/A **Project title:** High Resolution Molecular Imaging to Elucidate the Contextual Mechanisms of BCG Resistance in Non-muscle Invasive Recurrent Bladder Cancer	**PI**; This project seeks to understand novel immune mechanisms of NMIBC through the careful dissection of tumor, stromal and immune cells and secondarily from the combinatorial interactions between them. **% effort:** 0.9 CM	08/1/2022-07/31/2024	$300,000	N/A
DOD (PD/PI: Mullholand.) **Project #:** HT94252310186 **Project title:** Determining the contribution of lineage intermediate tumor cells during progression to t-SCNC	**Co-I;** The goal of this project is to understand the impact of AR signaling and targeting agents to preclude the progression of prostate cancer lineage intermediate tumor cells to small cell neuroendocrine cells. **% effort: 1.2 CM**	08/1/2023-07/31/2026	$1,521,002	N/A

Pending Grants

List Funding Source, Project Title and Number	**Role in Project**	**Dates**	**Direct Costs**	**Supplemental info**

Clinical Trial Participation

Project	**Role in Project**	**Dates**	**Award**	**Other Info**
Urogen Pharma A Phase 3, Single-Arm, Multicenter Study to Evaluate the Efficacy and Safety of UGN-102 as Primary Chemoablative Therapy in Patients with Low Grade (LG) Non-Muscle Invasive Bladder	PI	12/18/2022-12/17/2024	$101, 370	Phase III

Cancer (NMIBC) at Intermediate Risk (IR) of Recurrence				
Jiangsu Yalong Meditech Co A Phase I/II Open-Label Multicenter Study to Evaluate the Safety and Efficacy of Oral APL-1202 in Combination with Tislelizumab Compared to Tislelizumab Alone as Neoadjuvant Therapy in Patients with Muscle Invasive Bladder Cancer	PI	5/15/2022-08/10/2024	$67, 314	Phase II/III
Irrimax Corporation Chlorhexidine antiseptic irrigation of the bowel segment during radical cystectomy and urinary diversion	PI	05/1/2023-04/30/2025	$99, 525	Investigator initiated trial
Janssen Research & Development A Phase 2, Open-Label, Multi-Center, Randomized Study of TAR-200 in Combination with Cetrelimab and Cetrelimab Alone in Participants with Muscle-Invasive Urothelial Carcinoma of the Bladder who are Scheduled for Radical Cystectomy and are Ineligible for or Refusing Platinum-based Neoadjuvant Chemotherapy	PI	07/15/2023-07/14/2025	$80, 353	Phase II

Trainees

Name	**Level of Trainee**	**Role & dates of training**	**Training Venue**	**Trainee's current status/employment**
Iyinyeoluwa Okulate	Research Associate	Mentor; 1/2023 - Present	Icahn School of Medicine at Mount Sinai	**Research Associate**, Icahn School of Medicine at Mount Sinai
Jordan Rich	Research Associate	Mentor; 7/2022-08/2023	Icahn School of Medicine at Mount Sinai	**Urology resident**, New York University
Daniel Ranti	Medical student	Mentor; 5/2020 – 1/2023	Icahn School of Medicine at Mount Sinai	**Urology resident**, Columbia University School of Medicine
Y. Alice Wang, PhD	Medical student	Mentor; 5/2020 – 6/2022	Icahn School of Medicine at Mount Sinai	**Urology resident**, Johns Hopkins University School of Medicine

Christine Bieber	Medical student	Mentor; 5/2021 – 6/2022	Icahn School of Medicine at Mount Sinai	**Urology resident,** SUNY Albany School of Medicine
Bérengère Salomé, PhD	Postdoctoral fellow	Mentor; 1/2018 – 8/2022	Icahn School of Medicine at Mount Sinai	**Principal Research Scientist,** Genentech (gRED), Cancer Immunology
Andrew Charap	Medical student	Mentor; 1/2017 – 6/2019	Icahn School of Medicine at Mount Sinai	**ENT resident**, Washington University School of Medicine
Jorge Daza, MD	Medical doctor (Colombia)	Mentor; 6/2017 – 6/2020	Icahn School of Medicine at Mount Sinai	**Urology faculty**, private practice Buffalo NY
Joy Park	Research Associate	Mentor; 6/2017 – 12/2018	Icahn School of Medicine at Mount Sinai	**Graduate student,** SUNY Upstate
Harry Anastos MD	Research Associate	Mentor; 9/2016 – 6/2018	Icahn School of Medicine at Mount Sinai	**Urology Fellow, endourology** Columbia University School of Medicine
Andrew Katims MD	Urology Resident	Mentor; 9/2016- 6/2021	Icahn School of Medicine at Mount Sinai	**Urology Oncology Fellow,** Memorial Sloan Kettering Cancer Center
Zynep Gul MD	Urology Resident	Mentor, 7/2014- 6/2018	Icahn School of Medicine at Mount Sinai	**Assistant Professor,** University of Washington at St. Louis
Kyrollis Atalla MD	Urology Resident	Mentor, 7/2014- 6/2018	Icahn School of Medicine at Mount Sinai	**Assistant Professor**, Icahn School of Medicine at Mount Sinai

Teaching Activities

Teaching Activity/Topic	Level	Role	Level of Learners	Number of hours week/month/yr	Evaluation Summary	Years Taught
2nd Year Urology course	Medical School Course	Lecturer	Medical Students (~100)	2 hours per year		2018-present
Systems Biomedicine course	Masters students	Lecturer	Masters Students (~20)	2 hours per year		2016-present
Urology Residency Education Rounds	Urology Residents	Organizer/Proctor	Urology Residents (24)	10 hour per week		2015-present

ADMINISTRATIVE LEADERSHIP APPOINTMENTS

Intramural Service

East Harlem Health Outreach Partnership (EHHOP) (faculty), Mount Sinah Hospital (01/2024-present)
Clinical Competency Committee (Chair), Department of Urology ISMMS (7/2022-present)

Investigator Initiated Clinical Trials Review Committee (Co-Chair), Tisch Cancer Institute ISMMS (05/2021 – present)
Clinical Research Steering Committee (Member), Tisch Cancer Institute ISMMS (1/2018 – 2024)
Protocol Review and Monitoring Committee (PRMC) (Voting Member), Tisch Cancer Institute (0/12018-12/2022)
Tumor Board, Department of Urology, ISMSS (Coordinator) (07/2014-present)
Disease Focus Group, Urology, ISMSS (07/2014-present)

Extramural Service
NCI/NIH Reviewer, Therapeutic Immune Regulation (TIR) study section (2023-Present)
Urology Care Foundation research grand review panel (2023)
NIH/CSR Reviewer, Kidney, Urology and Digestive Disease study section (2022)
CUASF Bladder Cancer Canada study section (2020 – Present)
Swiss National Science Foundation grant reviewer (2022-Present)

PUBLICATIONS

Peer Reviewed Original Contributions (H-Index = 34, Date last checked: 06/24/2024)

1. Rich JM, Geduldig J, Cumarasamy S, Ranti D, Mehrazin R, Wiklund P, Sfakianos JP, Attalla K. Eliminating the routine use of postoperative drain placement in patients undergoing robotic-assisted radical cystectomy with intracorporeal urinary diversion. Urol Oncol. 2023 Oct 19.

2. Rich JM, Garden EB, Arroyave JS, Elkun Y, Ranti D, Pfail JL, Klahr R, Omidele OO, Adams-Sommer V, Patel G, Schaefer SH, Brown C, Badani K, Lavallee E, Mehrazin R, Attalla K, Waingankar N, Wiklund P, Sfakianos JP. Infections After Adoption of Antibiogram-directed Prophylaxis and Intracorporeal Urinary Diversion for Robotassisted Radical Cystectomy. Eur Urol Focus. 2023 Oct 12.

3. Galsky MD, Daneshmand S, Izadmehr S, Gonzalez-Kozlova E, Chan KG, Lewis S, Achkar BE, Dorff TB, Cetnar JP, Neil BO, D'Souza A, Mamtani R, Kyriakopoulos C, Jun T, Gogerly-Moragoda M, Brody R, Xie H, Nie K, Kelly G, Horwitz A, Kinoshita Y, Ellis E, Nose Y, Ioannou G, Cabal R, Haines GK, Wang L, Mouw KW, Samstein RM, Mehrazin R, Bhardwaj N, Yu M, Zhao Q, Kim-Schulze S, Sebra R, Zhu J, Gnjatic S, Sfakianos J, Pal SK. Gemcitabine and cisplatin plus nivolumab as organ-sparing treatment for muscle-invasive bladder cancer: a phase 2 trial. Nat Med. 2023 Oct 2.

4. Yuk FJ, Carr MT, Schupper AJ, Lin J, Tadros R, Wiklund P, Sfakianos J, Steinberger J. Da Vinci Meets Globus Excelsius GPS: A Totally Robotic Minimally Invasive Anterior and Posterior Lumbar Fusion. World Neurosurg. 2023 Sep 13;180:29-35.

5. Rich J, Tillu N, Grauer R, Busby D, Auer R, Breda A, Buse S, D'Hondt F, Falagario UG, Hosseini A, Mehrazin R, Minervini A, Mottrie A, Sfakianos J, Palou Redorta J, Wijburg C, Wiklund NP, John H. Robotic-Assisted Repair of Ureteroenteric Strictures after Cystectomy with Urinary Diversion: Technique Description and Outcomes from the ERUS Scientific Working Group. J Endourol. 2023 Sep 11.

6. Wong JL, Smith P, Angulo-Lozano J, Ranti D, Bochner BH, Sfakianos JP, Horowitz A, Ravetch JV, Knorr DA. IL-15 synergizes with CD40 agonist antibodies to induce durable immunity against bladder cancer. Proc Natl Acad Sci U S A.2023 Aug 29;120(35).

7. Rich JM, Elkun Y, Geduldig J, Lavallee E, Mehrazin R, Attalla K, Wiklund P, Sfakianos JP. Outcomes from a prospectively implemented protocol using apixaban after robot-assisted radical cystectomy. BJU Int. 2023 Oct;132(4).

8. Daza J, Grauer R, Chen S, Lavallèe E, Razdan S, Dey L, Steineck G, Renström-Koskela L, Li Q, Hussein AA, Mehrazin R, Waingankar N, Guru K, Wiklund P, Sfakianos JP. Development of a predictive model for recurrencefree survival in pTa low-grade bladder cancer. Urol Oncol. 2023 May;41(5).

9. Grossmann NC, Soria F, Juvet T, Potretzke AM, Djaladat H, Ghoreifi A, Kikuchi E, Mari A, Khene ZE, Fujita K, Raman JD, Breda A, Fontana M, Sfakianos JP, Pfail JL, Laukhtina E, Rajwa P, Pallauf M, Poyet C, Cacciamani GE, van Doeveren T, Boormans JL, Antonelli A, Jamil M, Abdollah F, Ploussard G, Heidenreich A, Storz E, Daneshmand S, Boorjian SA, Rouprêt M, Rink M, Shariat SF, Pradere B. Comparing Oncological and Perioperative Outcomes of Open versus Laparoscopic versus Robotic Radical Nephroureterectomy for the Treatment of Upper Tract Urothelial Carcinoma: A Multicenter, Multinational, Propensity Score-Matched Analysis. Cancers (Basel). 2023 Feb 23;15(5):1409.

10. Daza J, Salomé B, Okhawere K, Bane O, Meilika KN, Korn TG, Qi J, Xe H, Patel M, Brody R, Kim-Schulze S, Sfakianos JP, Lewis S, Rich JM, Zuluaga L, Badani KK, Horowitz A. Urine supernatant reveals a signature that predicts survival in clear-cell renal cell carcinoma. BJU Int. 2023 Jul;132(1):75-83.

11. Wong JL, Smith P, Angulo-Lozano J, Ranti D, Bochner BH, Sfakianos JP, Horowitz A, Ravetch JV, Knorr DA. IL-15 synergizes with CD40 agonist antibodies to induce durable immunity against bladder cancer. bioRxiv [Preprint]. 2023 Feb 1:2023.01.30.526266. doi: 10.1101/2023.01.30.526266. Update in: Proc Natl Acad Sci U S A. 2023 Aug 29;120(35).

12. Rosenzweig SJ, Ranti D, Mehrazin R, Sfakianos JP, Wiklund PN, Waingankar N. Characteristics Contributing to Survival Differences Between Black and White Patients Following Cystectomy. Urol Oncol. 2023 Apr;41(4).

13. Antonelli L, Sebro K, Lahmar A, Black PC, Ghodoussipour S, Hamilton-Reeves JM, Shah J, Bente Thoft J, Lerner SP, Llorente C, Lucca I, Preston MA, Psutka SP, Sfakianos JP, Vahr Lauridsen S, Williams SB, Catto J, Djaladat H, Kassouf W, Loftus K, Daneshmand S, Fankhauser CD; Enhanced Recovery After Surgery ERAS Cystectomy Committee. Association Between Antibiotic Prophylaxis Before Cystectomy or Stent Removal and Infection Complications: A Systematic Review. Eur Urol Focus. 2023 Jul;9(4):631-636.

14. Pallauf M, D'Andrea D, König F, Laukhtina E, Yanagisawa T, Rouprêt M, Daneshmand S, Djaladat H, Ghoreifi A, Soria F, Fujita K, Boorjian SA, Potretzke AM, Mari A, Roumiguié M, Antonelli A, Bianchi A, Khene ZE, Sfakianos JP, Jamil M, Boormans JL, Raman JD, Grossmann NC, Breda A, Heidenreich A, Del Giudice F, Singla N, Shariat SF, Pradere B. Diagnostic Accuracy of Clinical Lymph Node Staging for Upper Tract Urothelial Cancer Patients: A Multicenter, Retrospective, Observational Study. J Urol. 2023 Mar;209(3):515-524.

15. Katayama S, Pradere B, Grossman NC, Potretzke AM, Boorjian SA, Ghoreifi A, Daneshmand S, Djaladat H, Sfakianos JP, Mari A, Khene ZE, D'Andrea D, Hayakawa N, Breda A, Fontana M, Fujita K, Antonelli A, van Doeveren T, Steinbach C, Mori K, Laukhtina E, Rouprêt M, Margulis V, Karakiewicz PI, Araki M, Compérat E, Nasu Y, Shariat SF. Biological and prognostic implications of biopsy upgrading for high-grade upper tract urothelial carcinoma at nephroureterectomy. Int J Urol. 2023 Jan;30(1):63-69.

16. Mihalopoulos M, Yaghoubian A, Razdan S, Khusid JA, Mehrazin R, Badani KK, Sfakianos JP, Atallah WM, Tewari AK, Wiklund P, Gupta M, Kyprianou N. Understanding the link between kidney stones and cancers of the upper urinary tract and bladder. Am J Clin Exp Urol. 2022 Oct 15;10(5):277-298. 1

17. Bieber C, Katims A, Ranti D, Sfakianos JP, Amend G. Isolated corpora cavernosa germ cell tumor metastasis requiring complex excision and reconstruction. Urol Case Rep. 2022 Sep 23;45.

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worse renal function decline after robotic assisted radical cystectomy: Implications for postoperative management. Urol Oncol. 2022 Jun;40(6):275.e11-275.e18. doi: 10.1016/j.urolonc.2022.02.011. Epub 2022 Apr 23. PMID: 35473916.

26. König F, Grossmann NC, Soria F, D'Andrea D, Juvet T, Potretzke A, Djaladat H, Ghoreifi A, Kikuchi E, Hayakawa N, Mari A, Khene ZE, Fujita K, Raman JD, Breda A, Fontana M, Sfakianos JP, Pfail JL, Laukhtina E, Rajwa P, Pallauf M, Cacciamani GE, van Doeveren T, Boormans JL, Antonelli A, Jamil M, Abdollah F, Budzyn J, Ploussard G, Heidenreich A, Daneshmand S, Boorjian SA, Rouprêt M, Rink M, Shariat SF, Pradere B. Pentafecta for Radical Nephroureterectomy in Patients with High-Risk Upper Tract Urothelial Carcinoma: A Proposal for Standardization of Quality Care Metrics. Cancers (Basel). 2022 Mar 31;14(7):1781.

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28. Dovey Z, Pfail J, Martini A, Steineck G, Dey L, Renström L, Hosseini A, Sfakianos JP, Wiklund P. Bladder Cancer (NMIBC) in a population-based cohort from Stockholm County with long-term follow-up; A comparative analysis of prediction models for recurrence and progression, including external validation of the updated 2021 E.A.U. model. Urol Oncol. 2022 Mar;40(3).

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35. Martini A, Shah QN, Waingankar N, Sfakianos JP, Tsao CK, Necchi A, Montorsi F, Gallagher EJ, Galsky MD. The obesity paradox in metastatic castration- resistant prostate cancer. Prostate Cancer Prostatic Dis. 2022 Sep;25(3):472-478.

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Books and Book Chapters

Eilender B, Katims A, Pfail J, Sfakianos JP. Evelving Treatment in Non-Muscle invasive bladder cancer. Springer 2022.

Bhardwaj N, Farkas A, Gul Z and Sfakianos JP. Harnessing natural killer cell function for genitourinary Cancers. Elsevier 2020

Sfakianos JP, Ficara V. Key leaders' opinion on novel progress in diagnosis and treatment of bladder cancer. AME 2019

Sfakianos JP, Anderson C, Musser J. Upper urinary tract Urothelial Carcinoma. Springer 2015

Administrative Leadership Appointments

Internal
Not Applicable

External
Not Applicable

Publications

Invited Lectures/Presentation (2014- Present) *Presentations at scientific meetings

2023 Immunobiology of BCG unresponsive non-muscle invasive bladder cancer
Venue: AUA designee to the Congress of the SIU Istanbul, Turkey*

2023 BCG and non-muscle invasive bladder cancer: so many unanswered questions
Venue: Paul Lange Visiting Professor University of Washington, Seattle, WA

2023 BCG: Mechanisms of Action Venue: Canada Bladder Cancer Forum Kingston, ON*

2023 Dually targeting NK cells and CD8 T cells for the treatment of bladder cancer Venue: Visiting Professor Centre de Recherche des Cordeliers (CRC) Paris, France

2023 Robotic Assisted Laparoscopic Retroperitoneal Lymph node Dissection: Change of Tides?
Venue: Challenges in Laparoscopic and Robotics (CLIR) Stockholm, Sweden*

2022 Neoadjuvant program-Surgeon's Perspective Venue: SITC Boston, MA*

2022 BCG: past, present, future Venue: Congress of the SIU Montreal, CA*

2022 Immune landscape of T1 urothelial carcinoma what does it mean for future therapeutic targets?
Venue: 8th Annual symposium of the Albert Institute for Bladder Cancer and Research, Houston, TX*

2022 MIS and Pain Control in Urologic Surgery Venue: 8th ERAS world Congress Madrid, Spain*

2022 Open vs Robotic Radical cystectomy are we at a turning point? Venue: 25th Panhellenic Congress of urology Athens, Greece*

2022 Retroperitoneal Lymphadenopathy tips and tricks to avoid vascular injury. Venue: North American Robotic Urologic Symposium Las Vegas, NV*

2022 Retroperitoneal Lymphadenopathy tips and tricks to avoid vascular injury Venue: North American Robotic Urologic Symposium Las Vegas, NV*

2021 Urothelial Carcinoma: Past, Present and Future Venue: Visiting Professor Lenox Hill Hospital New York, NY

2020 Endoscopic Management of Upper Tract Urothelial carcinoma Venue: 22nd Panhellenic Congress of urology Kalamata, Greece*

2019 Unraveling the role of natural killer cells in urothelial carcinoma of the bladder. Venue: Englander Institute for Precision Medicine at Weill Cornell seminar series New York, NY *

2019 DVT prophylaxis and pain control in urologic surgery Venue: ERAS world Congress Liverpool, UK*

2018 Upper Tract Urothelial Carcinoma can “-omics” drive Care? Venue: Bladder cancer advocacy network (BCAN) think tank Denver, CO*

Media Resource Educational Materials

2021 UroToday Interview with Ashish Kamat (MD Anderson), John Sfakianos (ISMMS) and Amir Horowitz.
Novel immune checkpoint axis to understand BCG resistance and improve treatment in non-muscle-invasive bladder cancer

2018 Medscape Education
Clinical Pearls of the Management of Immune-Mediated AEs

Appendix 2

List of Expert Testimony in Last 4 Years
John Sfakianos, MD

Trial:
9/16/2024 – Rosado vs Peters (New Jersey)

Deposition:

01/22/2025 – Leonard vs Kim Jr (New Jersey)

08/21/2024 – Dery vs. Quest (Florida)

11/10/2021 – Jensen vs. Mykulak (New Jersey)

10/28/2021 – Rosado vs Peters (New Jersey)