

Exhibit 394

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

Jacqueline Tukes

v.

**THE UNITED STATES,

Defendants.**

Case No. 7:23-cv-01553-BO-BM

SPECIFIC CAUSATION EXPERT WITNESS REPORT: JACQUELINE TUKES

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I. QUALIFICATIONS

I am a board-certified urologist, urologist oncologist, and robotic surgeon in full-time private practice in Los Angeles, California. I have been licensed to practice in California since 2001. I graduated *summa cum laude* from the University of California, Los Angeles (UCLA), earning a Bachelor of Science degree in Anthropology. I received my Doctor of Medicine degree from Albert Einstein College of Medicine in New York. I then completed a general surgery internship and Urology residency at the University of Southern California (USC). I completed fellowship in Genitourinary Oncology and Reconstructive Urology at USC and further fellowship training in Advanced Laparoscopic and Robotic Urologic Oncology from the City of Hope Comprehensive Cancer Center. Following my fellowship training, I served as the Program Director of the Urologic Oncology fellowship and the Surgical Director of the Kidney Cancer Program at City of Hope Comprehensive Cancer Center. While at City of Hope I also sat on the NCCN (national comprehensive cancer network) guideline committees for kidney and testis cancer to develop standards of care and core knowledge principles for these urologic diseases. I transitioned my practice to Cedars Sinai medical center in 2012 and was promoted to Professor in clinical urology in 2021. I now practice at Tower Urology at Cedars-Sinai Medical Center where I have been the Clinical Chief of Urology since January of 2020 and part of the Medical Executive Committee of Cedars Sinai. I served on the Board of City of Hope Medical Group until 2011. I currently serve on the Medical Executive Committee and part of the Board of Directors of the ASC Venture, a Cedars Sinai Affiliate. I am the Medical Director of the Precision Ambulatory Surgery Center and 90210 Surgery Medical Center. Lastly, I was previously the president of the Los Angeles Urologic Society. As part of my professional career, I have received numerous awards including the UCLA Alumni Associate Distinguished Scholar

Award, Housestaff Teaching Award from USC, the Pfizer Scholar in Urology Award, and the Golden Apple teaching award from the Housestaff at Cedars Sinai. I have been named in Consumer Research Council of America Guide to America's Top Surgeons, Castel Connolly Top Doctors, Los Angeles Magazine Super Docs and Newsweek's American Top Prostate Cancer Oncologist and Surgeons.

II. BASIS AND GROUNDS FOR OPINION

I base my opinions on my professional education, training and experience, and my knowledge of the pertinent scientific and medical literature reasonably relied upon by others in my profession.

III. FACTS AND DATA CONSIDERED

In forming my opinions as to this matter, I have considered: 1) all materials listed in Exhibit A and incorporated herein by reference; and 2) the medical and scientific literature listed in the Reference section below, and I will provide a list of any additional reliance materials prior to my deposition. I reserve the right to supplement this disclosure if new or additional information becomes available.

IV. SUBJECT MATTER OF TESTIMONY

I anticipate that I will offer testimony about the following subject matters: the fields of urology and oncology, including the anatomy and physiology of the urinary tract; the role of a urologic oncologist in the diagnosis, treatment, and prognosis of diseases of the urinary tract, specifically, but not limited to, the diagnosis and treatment of kidney cancer; the risk factors associated with diseases diagnosed and treated by urologists and oncologists, specifically, but not limited to, the risk factors associated with kidney cancer, including the chemicals found in the water at Camp Lejeune; and Ms. Tuke's clinical course, diagnoses, and treatment. I may also

comment on the opinions expressed by other witnesses, or any additional evidence developed before and during trial. My opinions are as follows:

a. Methodology

The development of my opinion provided in this report was based on a complete review of Ms. Tukes' medical records, the provided depositions, and other relevant documents. I also reviewed relevant literature by the following Pubmed search index:

((tetrachloroethylene) OR (PCE)) AND ((renal cell carcinoma) OR (rcc) OR (kidney cancer))

Furthermore, I have read the General Causation Expert Reports, which go through a very detailed summary of the toxicology of the various Camp Lejeune contaminants and their relationship with carcinogenicity, and additionally the expert report of Dr. Irving Allen with regard to his genetic analysis. I have used those reports and the data contained within those reports in my analysis regarding exposure and toxins. I subsequently synthesized Ms. Tukes' medical data and the relevant literature with my expertise in urologic oncology to consider the differential of each known etiology and risk factor for her kidney cancer, first determining whether the factor was at all relevant to Ms. Tukes, and if indeed relevant, then assigning weight as to the likelihood of its contribution.

b. "At Least as Likely as Not" Standard

The standard being evaluated in this case of possible harm from exposure to the water at Camp Lejeune is defined in the Camp Lejeune Justice Act is defined as follows:

“(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 a causal relationship exists; or

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

This standard affects the context of the opinions provided in this report as the burden of proof required to satisfy (B) is lower.

c. Kidney Cancer Generally

Kidney cancer is a disease in which malignant cancer cells arise from the various tissues of the kidney. The kidney is a solid organ which filters waste products and maintains water balance. The nephron is the functional unit of the kidney, and each kidney contains approximately 1 million nephrons. The most common form of Kidney cancer is referred to as renal cell carcinoma (RCC). There are numerous types of RCC including clear cell (ccRCC), chromophobe, papillary, and many others. In adults, ccRCC is the most common type of kidney cancer. The vast majority (>90%) of cases are non-hereditary and only a small minority are familial. Kidney cancer is primarily a disease of older adults, with the median age at diagnosis in the United States being 65 years. Medical risk factors for kidney cancer include high blood pressure, obesity, and chronic kidney disease.

Exposure to toxins, such as at Camp Lejeune, and smoking are the principal environmental risk factors for RCC. Studies generally cite increased risks for these exposures. This risk is directly linked to the degree of smoking history (quantified as pack-years, calculated by multiplying the number of packs-per-day smoked by the number of years smoked) and has been shown to exhibit a dose-dependent response. Smoking risks decline significantly with smoking cessation. Several hereditary types of RCC also exist but only account for 3% of all RCC cases, with von Hippel-Lindau (VHL) disease being the most common. Other hereditary syndromes that may predispose patients to RCC include *BAP1* tumor predisposition syndrome

(*BAP1*-TPDS), Birt-Hogg-Dubé syndrome (BHDS), HLRCC, hereditary papillary renal carcinoma (HPRC), hereditary paraganglioma/pheochromocytoma (PGL/PCC) syndrome, and tuberous sclerosis complex (TSC).

The diagnosis of kidney cancer is now usually made incidentally. As a result of the kidney's anatomic location there are often few symptoms until the disease has become significantly locally advanced or metastatic. Classic symptoms include flank pain and blood in the urine (hematuria).

There are four main options for the management of a localized (non-metastatic) RCC. Surgery, which can be either the removal of part of the kidney (partial nephrectomy) or the entirety of the kidney (radical nephrectomy), ablation, and active surveillance. Active surveillance is generally considered an option for renal masses are found at <2cm. Ablation is considered an alternate approach for the management of renal masses found at <3cm. Partial nephrectomy is a nephron-sparing approach where only the tumor and usually a margin of tissue around the tumor are removed, which reduces the impact on future loss of kidney function. This is particularly relevant for patients who are young, have bilateral tumors, have familial tumor syndromes, etc. Radical nephrectomy can be considered, however, when the tumor is considered highly complex, and the patient has normal renal function.

When kidney cancer is metastatic, the primary treatment is systemic medications. There have been rapid advancements in the systemic options for metastatic RCC over the past twenty years. Historically, the mainstay of systemic treatment was cytokine therapy, although these medications have now been supplanted by newer classes of medications. An additional consideration of the management of metastatic disease is whether to proceed with resecting the primary kidney containing the tumor, termed a cytoreductive nephrectomy. Although the role for

this surgery remains an area of active study in urology, the ideal patient is generally a patient with limited, resectable metastatic disease, a resectable kidney tumor, and good performance status.

d. Ms. Tukes' Clinical Course

Ms. Tukes was incidentally diagnosed with a renal mass at the age of 45 years in 2010. She was undergoing evaluation for hypertension, which included CT angiography of the abdomen and pelvis. She was incidentally found to have a 1.3cm R renal mass and elected to undergo partial nephrectomy which was done in 8/2010. The pathology from this surgery showed a T1a ccRCC. She was observed over the next several years with periodic imaging including ultrasounds and MRI. In 2012, MRI showed a very small (5mm) non-enhancing “focus” for which continued surveillance imaging was recommended. She additionally had what were described as bilateral simple renal cysts, which are benign and do not require surveillance. However, on MRI in 2015, she was now described as having bilateral *complex* renal cysts, and the left had slightly increased in size. Both were labeled as Bosniak II, which are usually benign and do not routinely require surveillance. She desired aggressive surgical management of these cysts and sought multiple opinions; however, her urologists were reasonably hesitant to perform extirpative surgery on what is generally a benign finding. However, on CT in 2018 her R kidney complex cyst now showed septations with questionable enhancement, and her L kidney had a solid enhancing mass (2mm) concerning for malignancy. She elected for aggressive surgical management and ultimately underwent L partial nephrectomy on 4/26/2018. During this surgery, she had three tumors which were removed, all of which were T1a clear cell papillary RCC. Surveillance imaging in 7/2018 and 8/2018 showed a new left renal lesion, distant from the resection bed, again concerning for malignancy. She underwent repeat L partial nephrectomy on

3/14/2019 showing T1a ccRCC. She continued to undergo routine surveillance imaging over the next several years. CT A/P in 4/2022 showed a 1.5cm R renal lesion, again separate from prior resection site, concerning for malignancy. She underwent R radical nephrectomy on 5/23/2022. Pathology showed multiple ccRCCs in the kidney. Her renal function began to deteriorate and she underwent AV fistula creation on 1/5/2023 in anticipation of need for dialysis. Surveillance imaging in 1/2023 also showed 1.3cm L renal lesions concerning for malignancy. She required hospitalization in 2/2024 for fluid overload in the setting of renal dysfunction. She underwent L radical nephrectomy in 6/12/2023. Pathology showed two papillary RCCs and one RCC of indeterminate subtype. Now anephric, she began dialysis. Her AV fistula did not function and she required permacath placement which was transitioned to peritoneal dialysis. She received a kidney transplant on 4/23/2024 and her permacath was subsequently removed.

At the time of original diagnosis in 2010, Ms. Tukes had a medical history of hypertension. Her BMI was between 29 and 30. She is a lifetime non-smoker. She worked as a CNA and had no occupational exposures to chemicals. Ms. Tukes was exposed to contaminated drinking water at Camp Lejeune from 6/1985 – 1/1987, primarily PCE.

Ms. Tukes has a possible family history of RCC but this was unknown. Specifically, while there is concern that her mother may have died from metastatic RCC, this has not been confirmed. For example, her nephrologist Dr. Brian Donnor writes “[w]ith regards to family history of CKD or ESRD, to the patients knowledge there has been; her mom in 2009 died, had cancer in her kidney presented with path hip [fracture] and was widely spread, but never had a biopsy—thus primary site is hearsay from patient at this time” (01553_TUKES_MEDRECS_0000000101). In her genetics evaluation, it was noted regarding her mother that she was “diagnosed with an unknown cancer which was metastatic at diagnosis. Ms.

Tukes remembers that her mother had a renal mass, but it is unclear if it truly was a renal primary cancer...” (01553_TUKES_0000000479). Ms. Tukes had negative VHL testing and then underwent further genetic testing with the “Invitae Renal/Urinary Tract Cancers Panel” (01553_TUKES_0000000480). Invitae states that this panel tests for the following disorders:

- BAP1 tumor predisposition syndrome
- Beckwith-Wiedemann syndrome
- Birt-Hogg-Dubé (BHD) syndrome
- Bloom syndrome
- CDC73-related conditions
- Constitutional mismatch repair deficiency (CMMR-D)
- DICER1-related pleuropulmonary blastoma familial tumor predisposition syndrome
- FH tumor predisposition syndrome
- Hereditary paraganglioma-pheochromocytoma syndrome
- Li-Fraumeni syndrome
- Lynch syndrome
- MET-related hereditary papillary renal cell carcinoma (HPRCC)
- Mosaic variegated aneuploidy syndrome
- Perlman syndrome
- PTEN hamartoma tumor syndrome (PHTS)
- Rhabdoid tumor predisposition syndrome
- Simpson-Golabi-Behmel syndrome (SGBS)
- Small cell carcinoma of the ovary, hypercalcemic type
- Tuberous sclerosis complex

Von Hippel-Lindau syndrome

Wilms tumor

WT1-related disorders

This panel covers the most common and many rare hereditary renal tumor syndromes. Ms. Tukes' panel resulted with two variants which were ultimately considered to be likely benign. Her geneticist summarized that "...it is very common to detect such variants and most do not cause disease. These variants are very likely unrelated to your history of renal cancer. With time, we suspect the lab will determine its significance, if any. Medical management should not be based on the presence of a VUS" (01553_TUKES_0000002401). Furthermore, in the expert report evaluation by Dr. Irving Allen it was determined that, based on the available medical data "it is more likely than not that the patient's RCC is not directly associated with an inherited or congenital mutation".

It is also notable, however, that the two genetic mutations noted in Ms. Tukes' evaluation were PMS2 and SMARCA4. PMS2 is occasionally known to urologic oncologists for its role in hereditary nonpolyposis colorectal cancer syndrome which, while *not* associated with RCC, is associated with other urologic malignancies. This gene is a DNA repair gene, which allows DNA to withstand damage without developing mutations, which can subsequently lead to malignancies. The expert report by Dr. Irving Allen reviews this mutation in greater depth, which he further concludes that Ms. Tukes' PMS2 mutation "...would be expected to result in increased cancer presentation following carcinogen exposure and greater sensitivity to carcinogens, specifically those that damage DNA." Dr. Allen reaches a similar conclusion for the SMARCA4 mutation.

e. Ms. Tukes' Exposure to the Toxins at Camp Lejeune was Substantial

To determine Ms. Tukes' overall carcinogenic exposure, including most substantially her PCE exposure, it is important to consider her daily activities while living at Camp LeJeune. Ms. Tukes lived in Tarawa Terrace with her husband and son. Tukes Dep. 37:3-9.

Ms. Tukes drank water with her meals. Tukes Dep. 51:12-22; 59:23-60:15. She would additionally have mixed orange juice from concentrate (Tukes Dep. 59:1-14); Kool-Aid (Tukes Dep. 52:8-15, 52:24-53:4) and lemonade four or five times a week (Tukes Dep. 53:7-18). She would occasionally meet her husband for lunch on base and would drink a cup of water. Tukes Dep. 50:3-7. When she was on base, she drank from the water fountain, including at the hospital and commissary. Tukes Dep. 49:14-19; Tukes Dep. 49:20-22; Tukes Dep. 55:23-57:8. She testified the Camp Lejeune water was the "nastiest tasting water." Tukes Dep. 65:24-66:9.

Ms. Tukes handwashed dishes and left water running the whole time. Tukes Dep. 61:13-15, 106:11-23. She did her laundry for the house at home, including washing her husband's military uniforms. Tukes Dep. 50:9-25. She also mopped her floors with hot water with a type of mop from which she had to wring out the water. Tukes Dep. 62:14-22.

The family all shared one bathroom and reported that they rarely used the vent but did if there was steam. Tukes Dep. 38:19-39:8, 55:16-21. Ms. Tukes reported she took hot showers two times a day and would usually spend about 15 to 20 minutes in the shower. Tukes Dep. 49:1-8, 54:2-17, 55:1-7. She also brushed her teeth up to six or seven times a day with lukewarm water. Tukes Dep. 107:4-13, 20-25.

The concentration of PCE in the water at Tarawa Terrace ranged from 3.58 – 8.28mcg/L. For reference, the EPA sets the maximum acceptable contaminant level for PCE at 5 mcg/L. The charts indicating Ms. Tukes exposures at Tarawa Terrace are below:

Exposure Dates	TCE (ug/l-M)	PCE (ug/l-M)(TechFlowMP Model)	PCE (ug/l-M)(MT3DMS Model)	VC (ug/l-M)	BZ (ug/l-M)
12/18/1985-12/31/1985	0.16	3.58	8.27	0.76	0.00
1/1/1986-1/31/1986	0.18	3.95	8.85	0.82	0.00
2/1/1986-2/28/1986	0.19	4.24	9.42	0.83	0.00
3/1/1986-3/31/1986	0.24	5.40	12.14	1.01	0.00
4/1/1986-4/30/1986	0.22	4.93	10.83	0.89	0.00
5/1/1986-5/31/1986	0.23	5.25	11.56	0.91	0.00
6/1/1986-6/30/1986	0.25	5.61	12.28	0.92	0.00
7/1/1986-7/31/1986	0.26	5.97	13.06	0.94	0.00
8/1/1986-8/31/1986	0.28	6.36	13.84	0.96	0.00
9/1/1986-9/30/1986	0.30	6.75	14.61	0.97	0.00
10/1/1986-10/31/1986	0.31	7.12	15.42	0.99	0.00
11/1/1986-11/30/1986	0.33	7.52	16.21	1.00	0.00
12/1/1986-12/31/1986	0.34	7.89	17.03	1.01	0.00
1/1/1987-1/8/1987	0.36	8.28	17.85	1.03	0.00
Totals	3.65	82.85	181.37	13.04	-

Ms. Tukes' exposure at Hadnot Point was as follows:

Exposure Dates	visits to HP (2.5 days per week when living elsewhere)	TCE (ug/l- M)	PCE (ug/l- M)	VC (ug/l- M)	BZ (ug/l- M)
6/18/1985-6/30/1985	Hadnot Point	0	0	0	3
7/1/1985-7/18/1985	Hadnot Point	0	0	0	3
7/19/1985-7/31/1985	Hadnot Point	0	0	0	3
8/1/1985-8/31/1985	Hadnot Point	0	0	0	3
9/1/1985-9/30/1985	Hadnot Point	0	0	0	3
10/1/1985-10/31/1985	Hadnot Point	0	0	0	3
11/1/1985-11/30/1985	Hadnot Point	0	0	0	3
12/1/1985- 12/17/1985	Hadnot Point	0	0	0	3
12/18/1985- 12/31/1985	Hadnot Point	0	0	0	3
1/1/1986-1/31/1986	Hadnot Point	0	0	0	3
2/1/1986-2/28/1986	Hadnot Point	0	0	0	3
3/1/1986-3/31/1986	Hadnot Point	0	0	0	3
4/1/1986-4/30/1986	Hadnot Point	0	0	0	4
5/1/1986-5/31/1986	Hadnot Point	0	0	0	3
6/1/1986-6/30/1986	Hadnot Point	0	0	0	3
7/1/1986-7/31/1986	Hadnot Point	0	0	0	3
8/1/1986-8/31/1986	Hadnot Point	0	0	0	3
9/1/1986-9/30/1986	Hadnot Point	0	0	0	3
10/1/1986- 10/31/1986	Hadnot Point	0	0	0	3

11/1/1986-11/30/1986	Hadnot Point	0	0	0	3
12/1/1986-12/31/1986	Hadnot Point	0	0	0	3
1/1/1987-1/8/1987	Hadnot Point	0	0	0	2
		-	-	-	60

Based on the above daily activities of Ms. Tukes at Camp Lejeune and a reported exposure time of 570 days of exposure with 387 days at Tarawa Terrace, she would have been exposed to a substantial amount of PCE and other toxins, which would require the classification of her exposure as substantial.

I also reviewed the charts from Plaintiff's expert Kelly Reynolds that calculated ingested doses of the chemicals on base for Ms. Tukes. The summary charts show:

		Chart 1: 1L	Chart 2: ATSDR CTE	Chart 3: ATSDR RME	Chart 4: Deposition Estimates
	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 ATSDR exposure assumptions)	Cumulative consumption (total ug= days*concentration per deposition exposure assumptions)
TCE	3.65	100	107	271	259
PCE (ug/l-M)(TechFlowMP Model)	82.85	2,280	2,437	6,142	5,875
PCE (ug/l-M)(MT3DMS Model)	181.37	4,989	5,335	13,443	12,858
VC	13.04	361	386	974	931
BZ (only at HP)	60.00	678	373	939	898

The ingestion numbers shown in these charts indicate a substantial exposure for Ms. Tukes. This took place over an approximate year and a half time period, which means her kidneys were consistently working to combat carcinogenic chemicals. When you combine these cumulative ingestion amounts with the fact that Ms. Tukes was more susceptible to exposure to toxins such as these at lower levels, it makes these exposures more substantial.

f. Levels that are Known to Cause Kidney Cancer

I have read the general causation reports of Drs. Hatten and Bird. Those reports detail the levels at which the toxins at issue are hazardous to humans and are known to cause kidney cancer. Ms. Tukes has similar exposure to a number of those exposure metrics.

I utilized these general causation reports, and in particular the levels known to cause kidney cancer, in my analyses here.

For example, Ms. Tukes would have had similar exposure to the low exposure groups in Bove 2014a relating to PCE exposure.¹ The range of exposure for PCE was >1 – 155 mcg/L-months.¹ The HR for this low exposure group was 1.40 (.54, 3.58).¹ Ms. Tukes was above the middle number of the exposure group with a total mcg/L-month for PCE of 82.85.

Similarly, Ms. Tukes was exposed to Benzene through her time at Hadnot Point. If you calculate the total potential exposure in terms of concentration for Ms. Tukes relating to Benzene and the fact she was consistently at HP, the total mcg/L-months would be 60 mcg/L-months. This would put her in the medium exposure group.¹ It should be noted that she only lived there for one month and her other exposure to water at Hadnot Point was intermittent. However, even the low exposure group to Benzene (2-45 mcg/L-months) had a HR of 1.31.¹ The medium exposure group had a HR of 1.38.¹

There is other Camp Lejeune literature supportive of Ms. Tukes exposure, especially when taken in conjunction with Dr. Allen's report and the fact Ms. Tukes was more susceptible to these chemicals at low levels of exposure.

Finally, there are studies outside of Camp Lejeune that provide support for Ms. Tukes levels of exposure being related to kidney cancer. For example, the Aschengrau (1993) study found that persons exposed to PCE up through the 90th percentile of relative dose delivered between 27.1mg and 44.1mg had elevated kidney cancer risk with OR 1.36.² Ms. Tukes had similar levels of exposure, especially when inhalation and dermal are factored into her likely exposure.

Given that Ms. Tukes was genetically more susceptible to chemical exposures, such as her exposures at CL, she was exposed to levels that are known to have caused her kidney cancer.

g. Differential Diagnosis to Determine the Etiology of Ms. Tukes' Kidney Cancer

As described in the methodology, in performing this differential, I evaluated all possible risk factors and gave them weight based on Ms. Tukes' clinical history. There are a few principal risk factors for kidney cancer; namely, hypertension, obesity, genetic predisposition, and smoking / environmental factors. Ms. Tukes had a history of hypertension. She was considered overweight or slightly overweight by some standards. As previously stated, while there was initial concern for a hereditary component to her renal cancer, this was ultimately not found to be the case after extensive evaluation. The term "environmental exposures" refers to any number of different potentially carcinogenic chemicals or compounds which persons may be exposed to by occupation, local contamination, etc. Ms. Tukes has one primary known exposure: the toxins in the water at Camp Lejeune, primarily tetrachloroethylene (PCE).

In the available records, Ms. Tukes' required numerous surgeries, multiple hospitalizations, ultimately dialysis, and renal transplantation with subsequent life-long immunosuppression as a result of her kidney tumors. Since being rendered anephric, she has had no further evidence of disease and now would be considered in remission.

The principal question at hand is whether it is "at least as likely as not" that a causal relationship exists between Ms. Tukes' exposure to contaminated drinking water at Camp Lejeune and her numerous renal tumors. Ms. Tukes was primarily exposed to tetrachloroethylene (PCE) in her water supply for approximately thirteen months. The International Agency for Research on Cancer (IARC) published in *Lancet Oncology* a report about the carcinogenicity of TCE, PCE, and other chlorinated solvents.³ It found sufficient evidence that PCE is carcinogenic in mice and limited (but not inadequate) evidence for carcinogenicity in humans. The report states that "in rats, tetrachloroethylene [PCE] induces neoplasms of the haemopoietic system, testes, kidney, and brain... tetrachloroethylene was classified as probably carcinogenic to humans (Group 2A)",³ which is the second highest designation for risk of carcinogenicity. There have been no meta-analyses conducted for PCE and kidney cancer according to the Agency for Toxic Substances and Disease Registry (ATSDR).⁴ There are, however, multiple studies that have demonstrated an increased risk of kidney cancer in cohorts exposed to PCE.^{5,6}

Ms. Tukes' was diagnosed at a young age and ultimately developed numerous malignant renal tumors. While she did have some risk factors for the development of kidney cancer, her extreme disease burden clearly indicates that her development of kidney cancer is inconsistent with sporadic disease related to hypertension or obesity. This is especially true given her hypertension and weight went up and down, but she still continued to form multiple tumors in both kidneys, which is much more unique to a toxic exposure. For example, her hypertension

was well controlled and within normal ranges for a large part of the 2010 – 2023 time frame of Ms. Tukes’ diagnosis of kidney tumors, yet she still developed so many of them.

More specifically, the General Causation report of Dr. Steven Bird states that “PCE is metabolized in the liver to trichloroacetic acid (TCA) and other metabolites, which can be further processed in the kidney. These metabolites can form DNA adducts, leading to mutations and initiating carcinogenesis. This is supported by studies showing DNA damage in the liver and kidney of exposed animals.” Although Ms. Tukes did not have an extraordinarily high level of exposure, it is likely that, as supported in the expert report by Dr. Irving Allen, a patient with a known DNA repair mutation would be significantly more susceptible than average to damage from any environmental exposures. Moreover, Dr. Nagesh Jayaram indicated in Ms. Tukes’ medical records and testified that Ms. Tukes’ kidney cancer was caused by her exposure to contaminants in the water at Camp Lejeune. Consequently, it is my opinion that more likely than not, her exposure to carcinogens at Camp Lejeune known to cause kidney cancer, primarily PCE, amplified by her genetic susceptibility, caused her kidney cancers. Her exposure to TCE, VC and Benzene during these exposures likely added to or worked synergistically to cause her kidney cancer.

I hold all of my opinions to reasonable degree of medical probability

REFERENCES

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3. Guha, N., Loomis, D., Grosse, Y., et al. Carcinogenicity of trichloroethylene, tetrachloroethylene, some other chlorinated solvents, and their metabolites. *Lancet Oncol*. 2012;13:1192–1193.
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5. Purdue, M P, Stewart, PA, et al. Occupational exposure to chlorinated solvents and kidney cancer: a case-control study. *Occup. Environ. Med.* 2017;74(4):268–274. doi:10.1136/oemed-2016-103849.
6. Callahan, CL, Stewart, PA, et al. Extended mortality follow-up in a cohort of dry cleaners. *Epidemiol.* 2019;30(2):285–290. doi:10.1097/EDE.0000000000000951.

EXHIBITS

I anticipate using some or all of Ms. Tukes' available medical records as exhibits. I may also use diagrams, illustrations, and models of the structures of the urinary tract as demonstrative exhibits to illustrate my testimony.

I hold all of my opinions to reasonable degree of medical probability.

PREVIOUS TESTIMONY

I generally spend less than 5% of my time on medical legal work. I have testified either by deposition or at trial in the following cases within the last four years:

Case	Attorney		Date
Grey Vs Kaiser	Darren McBratten	Plaintiff	April 2024, Deposition and Arbitration
Gallagher Jr. vs. RJ Reynolds Tobacco Company	Morgan Pensinger	Defense	November 2023, Deposition and Trial
Dodd vs Li	Bob Reback	Defense	August 2023, Deposition/Arbitration
Roman Vs Kassabian	Ray Blessey	Defense	Trial May 2022
Hayden Barry vs RJR		Defense	Deposition June 2022
Vahanyan vs Lift		Plaintiff	Deposition June 2022
Perkins Vs RJR		Defense	Deposition, September 2022
Rossi vs UCI	Margaret Holm	Defense	June 2022, Deposition
Guerra vs Chapardal	Bob Reback	Defense	May 2023, Deposition
Zober vs Kim	Tina Lee	Defense	Feb 2023, dropped
Munduni vs Kaiser	Lisa McClain	Defense	June 2022 settled
Morris vs Lee	Ray Blessey	Defense	October 2022, trial

FEES

My fee schedule is \$800.00 per hour for review of records and consultation as well as deposition and trial testimony. Deposition testimony is billed at \$950 per hour with a two hour minimum. Trial Testimony is billed at \$9500 per half day and \$17,000 for full day of trial testimony. Out of town travel requiring flights to another city and missing office hours are billed at \$20,000 per day for trial testimony. I spend approximately 60% of my time testifying on behalf of the defense and approximately 40% of my time testifying on behalf of Plaintiffs.

DEPOSITION

I am available for deposition upon request in Los Angeles, California.

**DAVID JOSEPHSON'S
EXHIBIT A: MATERIALS
REVIEWED**

Exhibit A: Materials Reviewed – Tukes

Name	Bates
Medical Records	000000 01553 TUKES 0000000010
Medical Records	000000 01553 TUKES 0000000732
Medical Records	000000 01553 TUKES AU 0000000001
Medical Records	000000 01553 TUKES MEDRECS 0000000001
Medical Records	000000 01553 TUKES MEDRECS 0000000137
Medical Records	000000 01553 TUKES NH 0000000001
Medical Records	000000 01553 TUKES SMO 0000000001
Medical Records	000001 01553 TUKES 0000000797
Medical Records	000001 01553 TUKES 0000007559
Medical Records	000001 01553 TUKES NH 0000000591
Medical Records	000002 01553 TUKES 0000007865
Medical Records	000003 01553 TUKES 0000000248
Medical Records	000004 01553 TUKES 0000000259
Medical Records	000005 01553 TUKES 0000000330
Medical Records	000005 01553 TUKES 0000002394
Medical Records	000006 01553 TUKES 0000000339
Medical Records	000006 01553 TUKES DVKC 0000000877
Medical Records	000008 01553 TUKES 0000000432
Medical Records	000008 01553 TUKES DVKC 0000000978
Medical Records	000009 01553 TUKES 0000002410
Deposition of Jacqueline Tukes	
Deposition of Dr. K.V. George Thomas	
Deposition of Dr. Nagesh Jayaram	
Deposition of Dr. Roc McCarthy	
J. Tukes Profile Form	
J. Tukes Short form Complaint	
Kidney Cancer Cumulative Exposure Spreadsheet	
Tukes, Jacqueline Exposure Spreadsheet	

DAVID JOSEPHSON'S CV

DAVID Y JOSEPHSON MD, FACS

CURRICULUM VITAE

PERSONAL INFORMATION

Name: David Y Josephson
Work Address: Tower Urology at Cedars Sinai Medical Office Towers,
8635 West Third Street, Suite 1W, Los Angeles, CA 90048
Work Phone: 310-854-9898
FAX: 310-854-0267
E-mail: josephsond@towerurology.com or josephson.david@gmail.com
Citizenship: United States of America
Marital Status: Married
Languages Spoken: English, Spanish, Farsi

ACADEMIC APPOINTMENTS

Cedars-Sinai Medical Center

Department of Urology
Attending Surgeon, 2011-present
Clinical Department Chief, 2020-present

Precision Ambulatory Medical Center (Cedars-Sinai Affiliate)

Medical Director, 2011-present

90210 Surgery Medical Center (Cedars-Sinai Affiliate)

Medical Director, 2011-present

City of Hope Comprehensive Cancer Center

Department of Surgery/Division of Urology
Assistant Professor, 2007-2011
Fellowship Director, Robotic and Urologic Oncology, 2008-2011
Co-Director, Kidney Cancer Program, 2009-2011

University of Southern California

Keck School of Medicine
Department of Urology/Urologic Oncology
Clinical Instructor, 2005-2006

SURGICAL TRAINING

City of Hope Comprehensive Cancer Center

Department of Urology/Urologic Oncology
Fellow in Advanced Laparoscopic and Robotic Urologic Oncology, 2006-2007

University of Southern California

Keck School of Medicine
Department of Urology/Norris Comprehensive Cancer Center
Fellow in Genitourinary Oncology and Reconstructive Urology, 2005-2006

University of Southern California

Keck School of Medicine
Department of Urology
Resident Physician, July 2001-June 2004
Chief Resident Physician, July 2004-June 2005

University of Southern California

Keck School of Medicine
Department of General Surgery
Resident Physician, June 2000 – June 2001

University of Southern California

Keck School of Medicine
Department of General Surgery
Internship, June 1999 – June 2000

EDUCATION

Albert Einstein College of Medicine

Yeshiva University, Bronx, New York
Doctor of Medicine degree, June 1995- June 1999

University of California at Los Angeles

Bachelors of Science in Anthropology, September 1991 - June 1995
Departmental Honors & *summa cum laude*

HONORS/AWARDS

- Phi Beta Kappa, 1994
- UCLA Alumni Association Distinguished Scholar Award, 1995
- Departmental Scholar in Anthropology, UCLA, 1995
- Golden Key National Honors Society, 1991- 1995
- Student Teaching Award, Department of Urology, 2002
- House Staff Teaching Award, USC Keck School of Medicine, 2002
- Cleveland Clinic National Urology Resident Preceptorship in Laparoscopic Surgery, 2004
- Pfizer Scholar in Urology Award, 2004
- David A. Cofrin Fellowship, Urologic Oncology, Department of Urology, University of Southern California, 2005-2006
- “Guide to America’s Top Surgeons” – Consumers’ Research Council of America, 2007-2010
- Cambridge Who’s Who – Healthcare edition, 2008
- Best Doctor’s – Pasadena Magazine, 2008-2012
- City of Hope Academic Achievement Award - 2010
- Los Angeles Magazine/Southern California Super Docs – 2010-24
- Golden Apple Award/Excellence in Teaching – Cedars Sinai, Urology 2018

MEMBERSHIPS

- National Comprehensive Cancer Network (NCCN) – Kidney Cancer Panel (past)
- NCCN – Testicular Cancer Panel (past)
- Society of Urologic Oncology
- American Urological Association
- American Society of Clinical Oncology (89519)
- Western Section, American Urological Association (ACTIVE)
- American College of Surgeons (Fellow-03101678)
- Los Angeles Urologic Society – Past President
- Endourological Society
- Los Angeles County Medical Association
- Phi Beta Kappa Honor Society
- Journal of Robotic Surgery – Reviewer (past)
- Cancer.net – Advisory Editorial Board (past)

LICENSURE

California Medical License 2001 (Certificate A-75701)
 DEA BY7355375
 Fluoroscopy x-ray supervisor – RHC 147927
 Holmium Laser Certification
 American Board of Urology (ABU# 15994)

MEDICAL STAFF PRIVELEDGES

LAC-USC Medical Center, 2005-2006
 USC University Hospital, 2005-2006
 City of Hope, 2006-2014
 Huntington Memorial, 2007-2011
 Garfield Medical Center, 2007-2013
 Cedars Sinai Medical Center, 2011-present
 Providence Tarzana Medical Center, 2014-present

RESEARCH TRIALS

Janssen (J&J Pharma): A Randomized, Double-blind, Placebo-controlled Phase 3 Study of JNJ-56021927 in Subjects with High-risk, Localized or Locally Advanced Prostate Cancer Treated with Primary Radiation Therapy (Co-I)

Astellas 9785-CL-0335: A multinational, phase 3, randomized, double-blind, placebo-controlled efficacy and safety of Enzalutamide plus Androgen Deprivation Therapy (ADT) versus placebo plus ADT in patients with metastatic hormone sensitive prostate cancer (mHSPC) (Co-I)

Churchill Pharma: A Randomized, Open-Label, Active-Controlled, Multi-Center Study to Evaluate Serum Testosterone Levels in Patients with Metastatic Castration-Resistant Prostate Cancer on SoluMatrix™ Abiraterone Acetate 500 mg (4 x 125 mg qd) with Methylprednisolone (4 mg bid) as Compared to Zytiga® 1,000 mg (4 x 250 mg qd) with Prednisone (5 mg bid) PI

ENACT (Astellas Pharma): A multicenter, randomized, open-label exploratory study of evaluating the efficacy and safety of Enzalutamide for extension of time to prostate cancer progression (pathological or therapeutic) in patients with

clinically localized, histologically proven prostatic cancer who are considered low risk or intermediate risk and undergoing active surveillance (Co-I)

Blue Earth: The impact of 18F-fluciclovine (FACBC) PET/CT on management of patients with rising PSA after initial prostate cancer treatment PI

Orion Pharma: ORION-3104007: A MULTINATIONAL, RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE III EFFICACY AND SAFETY STUDY OF ODM-201 IN MEN WITH HIGH-RISK NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (Co-I)

Astellas: TRUMPET-ONC-MA-1004: A Prospective Observational Cohort Study of Patients with Castration Resistant Prostate Cancer (CPRC) in the United States PI

Spectrum: A Multicenter, Multi-Arm, Randomized, Multi-Dose, Placebo-Controlled, Double-Blind, Phase 3 Study of Intravesical Apaziquone (EOquin®) as a Surgical Adjuvant in the Immediate Postoperative Period in Patients Undergoing Transurethral Resection for Non-Muscle Invasive Bladder Cancer PI

Viventia: An Open-Label, Multicenter, Phase 3 Study to Evaluate the Efficacy and Tolerability of Intravesical Vicinium™ in Subjects with Non Muscle-Invasive Carcinoma in Situ (CIS) and/or High-Grade Papillary Disease of the Bladder Previously Treated with Bacillus Calmette-Guérin (BCG) PI

Allena Pharma 713: A phase 2 multicenter, randomized, placebo-controlled, double-blind study to evaluate the efficacy and safety of study drug treatment over 28 days in patients with secondary hyperoxaluria and kidney stones (Co-I)

Claurus Therapeutics: A phase 3, randomized, active-controlled, open-label study of the safety and efficacy of oral Testosterone Undecanoate (TU) in hypogonadal men PI

Allergan: LINKA 1-201025-001: A Multicenter, Randomized, Double-blind, Placebo-controlled Study, Evaluating Safety and Efficacy of LiRIS 400 mg in Females with Interstitial Cystitis with Hunner's Lesion (Co-I)

Allergan: LINKA 2-201025-002: A Multicenter, Randomized, Double-blind, Placebo-controlled Study, Evaluating Safety and Efficacy of LiRIS 400 mg in Females with Interstitial Cystitis/Bladder Pain Syndrome (Co-I)

Astellas: A phase 4, double-blind, randomized, placebo-controlled, multi-center study to evaluate the efficacy, safety and tolerability of Mirabegron in men with Overactive Bladder (OAB) symptoms while taking the Alpha blocker Tamsulosin Hydrochloride for lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) (Co-I)

Intra-operative Optical Imaging utilizing anti-PSMA (Prostate Specific Membrane Antigen) Fluorescence Antibody during Robotic Assisted Laparoscopic Prostatectomy (PI)

A Prospective Investigation of the Use of Fluorescence Imaging on the da Vinci Surgical System for Intraoperative Near Infrared Imaging of Renal Cortical Tumors (PI)

Development of a Blood Test of Anti-IMP3 Autoantibody for the Detection of Renal Cell Carcinoma with Metastasis and Metastatic Potential (Co-PI)

CALGB 90203: A Randomized Phase III Study of Neo-Adjuvant Docetaxel and Androgen Deprivation Prior to Radical Prostatectomy Versus Immediate Radical Prostatectomy in Patients with High-Risk, Clinically Localized Prostate CA (Co-I)

Pre-Surgical EPS Biomarkers as Predictors of Recurrence (Co-I)

Erectile Dysfunction Recovery in Men age ≤ 65 Treated with Bilateral Nerve Sparing Robotic Assisted Prostatectomy (BNS-RAP) for Prostate Cancer (Co-I)

Outcomes of Robotic-Assisted Laparoscopic Management of Upper Tract Urothelial Carcinoma: Nephroureterectomy and Distal Ureterectomy with Ureteral Reimplantation (PI)

A randomized, phase II crossover study comparing bevacizumab and pazopanib monotherapy in treatment-naïve patients with metastatic renal cell carcinoma (mRCC) (Co-PI)

A Randomized, Phase II assessing Axitinib as pre-surgical therapy in patients with high-risk prostate cancer. (CO-I)

A Double-blind, Randomized, Placebo-Controlled Study of the Effects on Spermatogenesis with BOTOX® (Botulinum Toxin Type A) Purified Neurotoxin Complex to Treat the Signs and Symptoms of Benign Prostatic Hyperplasia 191622-091 (PI)

Study of Botulinum Toxin Type A for the Treatment of Patients With Idiopathic Overactive Bladder With Urinary Incontinence Allergan iOAB 191622-095 (PI)

Long Term Follow-up Study of Safety and Efficacy of Botulinum Toxin Type A for the Treatment of Patients With Idiopathic Overactive Bladder With Urinary Incontinence Allergan iOAB 191622-096 (PI)

Determination of the Reliability of Expressed Prostatic Secretion and Post Massage Urine Biomarkers in the Detection of Prostate Cancer in Men Undergoing Biopsy for Prostate Cancer (CO-I)

Assessment of change in peripheral pStat3 levels, circulating tumor cells, and MDSC quantity in high risk prostate cancer pre- and post-prostatectomy (PI)

A Phase 3, Multicenter, Open-Label Study to Assess the Diagnostic Performance and Clinical Impact of 18F-DCFPyL PET/CT Imaging Results in Men with Suspected Recurrence of Prostate Cancer (CONDOR). PI

A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Talazoparib with Enzalutamide in Metastatic Castration-Resistant Prostate Cancer. (Co-I)

Ferring Pharma: A Multicenter, Randomized, Assessor-Blind, Controlled Trial Comparing the Occurrence of Major Adverse Cardiovascular Events (MACEs) in Patients with Prostate Cancer and Cardiovascular Disease Receiving Degarelix (GnRH antagonist) or Leuprolide (LHRH agonist) Adenocarcinoma of Prostate with Cardiovascular Disease will start Leuprolide (Lupron) or Degarelix (Firmagon). Co-I

Aragon Pharmaceuticals, Inc.: SPARTAN-ARN-509-003: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of ARN-509 in Men with Non-Metastatic (M0) Castration-Resistant Prostate Cancer. Co_I

A Phase 3, Randomized, Efficacy and Safety Study of Enzalutamide Plus Leuprolide, Enzalutamide Monotherapy, and Placebo Plus Leuprolide in Men with High-Risk Non-Metastatic Prostate Cancer Progressing After Definitive Therapy. Co-I

HIFU: FSI 003 STAR Trial: A Multicenter Clinical Study of the Sonoblate 500 for the Treatment of Locally Recurrent Prostate Cancer with HIFU. Co-PI

GTx: Phase 2 Open-Label Study of the Effect of GTx-758 as Secondary Hormonal Therapy on Serum PSA and Serum-Free Testosterone Levels in Men with Metastatic Castration-Resistant Prostate Cancer Maintained on ADT. (Co-I)

STRIVE: A Multicenter, Phase 2, Randomized, Double-Blind, Efficacy and Safety Study of Enzalutamide vs. Bicalutamide in Men with Prostate Cancer who have Failed Primary Androgen Deprivation Therapy. . (Co-I)

AbbVie: Testosterone Replacement Therapy for Assessment of Long-Term Vascular Events and Efficacy Response in Hypogonadal Men (TRAVERSE) Study. (Co-I)

TesoRx: A Phase 1/2a Pilot Study of Intravesical TSD-001 for Treatment of Low-Grade, Stage Ta, Non-Muscle Invasive Bladder Cancer. PI

UroGen: A Phase 2b, Single-Arm Multicenter Trial to Evaluate the Efficacy and Safety of UGN-102 as Primary Chemoablative Therapy in Patients with Low-Grade (LG) Non-Muscle Invasive Bladder Cancer (NMIBC) at Intermediate Risk of Recurrence. (Co-I)

A Multicenter, Single-Arm Study Evaluating the Efficacy of Synergo® Radiofrequency-Induced Thermochemotherapy Effect (RITE) with Mitomycin C (Synergo® RITE + MMC) in CIS Non-Muscle Invasive Bladder Cancer (NMIBC) Bacillus Calmette- Guérin (BCG) Unresponsive Patients with or without Papillary NMIBC. (Co-I)

Prevail: A Prospective, Non-Interventional Study to Assess the Prevalence of PD-L1 Expression in the First-Line Setting of Locally Advanced/Unresectable or Metastatic Urothelial Carcinoma. (Co-I)

Randomized, Double-Blind, Placebo-Controlled, Dose-Finding Phase 2 Study Comparing Oral Daily Dosing of VERU-944 after a Week of Loading (daily dosing) with Placebo to Ameliorate the Vasomotor Symptoms Resulting from Androgen Deprivation Therapy in Men with Advanced Prostate Cancer PI

Marrero: A Phase 2b Multicenter, Double-Blind, Dose-Ranging, Randomized, Placebo-Controlled Study Evaluating Safety and Efficacy of BGS649 in Male

Subjects with Hypogonadotropic Hypogonadism. PI

Allergan Lobot: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate an Alternative Injection Paradigm for OnabotulinumtoxinA (BOTOX®) in the Treatment of Overactive Bladder in Patients with Urinary Incontinence: >18 years old and weighs >88 lbs., symptoms of OAB for at least 6 months, not adequately managed with an anticholinergic. (Co-I)

A Study Evaluating the Efficacy and Safety of BOTOX® Intravesical Instillation in Patients with Overactive Bladder and Urinary Incontinence. (Co-I)

Aquinox: A 12-Week, Randomized, Multicenter, Double-Blind, Placebo-Controlled, 3-Arm, Parallel-Group Phase 3 Trial to Evaluate the Efficacy and Safety of 2 Doses of AQX-1125 Targeting the SHIP1 Pathway in Subjects with Interstitial Cystitis/Bladder Pain Syndrome Followed by a 2-Arm, 14 or 40-Week Open-Label Extension: 6 months duration, daily average pain score 5 to 9.5, and micturition frequency of 8 episodes. (Co-I)

Aquinox: A 12-Week, Randomized, Multicenter, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 2 Trial to Evaluate the Efficacy and Safety of AQX-1125 (200 mg) in Male Subjects with Chronic Prostatitis/Chronic Pelvic Pain Syndrome. (Co-I)

BOND 2: An Open-Label, Single-Arm, Phase 2, Multicenter Study of the Safety and Efficacy of CG0070 Oncolytic Vector Regimen in Patients with Non-Muscle Invasive Bladder Carcinoma Who Have Failed BCG Therapy and Refused Cystectomy. (Co-I)

Allergan 191622-095: A Multicenter, Long-Term Follow-Up Study of the Safety and Efficacy of BOTOX® in Patients with Idiopathic Overactive Bladder with Urinary Incontinence. (Co-I)

PUBLICATIONS/ABSTRACTS/VIDEOS

Daniels JP, Patel DN, Galvan GC, Friedrich NA, Das S, Akhavein A, Daskivich T, **Josephson D**, Desai P, De Nunzio C, Freedland SJ. Investigating trends in interest for benign prostatic hyperplasia surgery options using Google Trends. Prostate Cancer Prostatic Dis. 2024 Mar;27(1):150-152.

Surasi DS, Eiber M, Maurer T, Preston MA, Helfand BT, Josephson D, Tewari AK, Somford DM, Rais-Bahrami S, Koontz BF, Bostrom PJ, Chau A, Davis P, Schuster DM, Chapin BF; LIGHTHOUSE Study Group. Diagnostic Performance and Safety of Positron Emission Tomography with ¹⁸F-rhPSMA-7.3 in Patients with Newly Diagnosed Unfavourable Intermediate- to Very-high-risk Prostate Cancer: Results from a Phase 3, Prospective, Multicentre Study (LIGHTHOUSE). Eur Urol. 2023 Oct;84(4):361-370.

Jani AB, Ravizzini GC, Gartrell BA, Siegel BA, Twardowski P, Saltzstein D, Fleming MT, Chau A, Davis P, Chapin BF, Schuster DM; SPOTLIGHT Study Group. Diagnostic Performance and Safety of ¹⁸F-rhPSMA-7.3 Positron Emission Tomography in Men With Suspected Prostate Cancer Recurrence:

Results From a Phase 3, Prospective, Multicenter Study (SPOTLIGHT). J Urol. 2023 Aug;210(2):299-311.

Morris MJ, Rowe SP, Gorin MA, Saperstein L, Pouliot F, **Josephson D**, Wong JYC, Pantel AR, Cho SY, Gage KL, Piert M, Iagaru A, Pollard JH, Wong V, Jensen J, Lin T, Stambler N, Carroll PR, Siegel BA; CONDOR Study Group. Diagnostic Performance of ¹⁸F-DCFPyL-PET/CT in Men with Biochemically Recurrent Prostate Cancer: Results from the CONDOR Phase III, Multicenter Study. Clin Cancer Res. 2021 Jul 1;27(13):3674-3682.

Solanki AA, Savir-Baruch B, Liauw SL, Michalski J, Tward JD, Vapiwala N, Teoh EJ; LOCATE study group. ¹⁸F-Fluciclovine Positron Emission Tomography in Men With Biochemical Recurrence of Prostate Cancer After Radical Prostatectomy and Planning to Undergo Salvage Radiation Therapy: Results from LOCATE. Pract Radiat Oncol. 2020 Sep-Oct;10(5):354-362.

Andriole GL, Kostakoglu L, Chau A, Duan F, Mahmood U, Mankoff DA, Schuster DM, Siegel BA; LOCATE Study Group. The Impact of Positron Emission Tomography with ¹⁸F-Fluciclovine on the Treatment of Biochemical Recurrence of Prostate Cancer: Results from the LOCATE Trial. J Urol. 2019 Feb;201(2):322-331.

Chapin, B, et al Diagnostic performance and safety of ¹⁸f-rhpsma-7.3 pet in patients with newly diagnosed prostate cancer: results from a phase 3, prospective, multicenter study (lighthouse) SUO 2022

Josephson DY, The diagnostic performance of piflufolastat f ¹⁸-pet/ct in high-risk and recurrent prostate cancer: osprey and condor study results, Plenary talk, Proceedings of the Western Section AUA 2021.

Caroll P et al. Diagnostic performance of piflufolastat f ¹⁸-pet/ct in men with biochemical recurrence of prostate cancer after definitive treatment: a condor study subanalysis, Proceedings of the SUO meeting 2021.

Morris MG et al. Diagnostic performance of ¹⁸f-dcfpyl-pet/ct in men with biochemically recurrent prostate cancer: results from the condor phase 3, multicenter study, Clin Cancer Res, 2021 jul 1: 27 (13):3674-3682.

Andriole gl et al. Locate study group. The impact of positron emission tomography with ¹⁸f-fluciclovine on the treatment Of biochemical recurrence of prostate cancer: results from the locate trial. J urol. 2019 feb;201(2):322-331

Dru CJ, **Josephson DY**. Bochdalek-type Diaphragmatic Hernia Leading to High-grade Kidney Obstruction. Urology. 2016 Nov;97:e17-e18. doi:10.1016/j.urology.2016.08.025. Epub 2016 Aug 24.

Shao C, Liao CP, Hu P, Chu CY, Zhang L, Bui MH, Ng CS, **Josephson DY**, Knudsen B, Tighiouart M, Kim HL, Zhau HE, Chung LW, Wang R, Posadas EM. Detection of live circulating tumor cells by a class of near-infrared heptamethine carbocyanine dyes in patients with localized and metastatic prostate cancer. PLoS One. 2014 Feb 14;9(2):e88967.

Carmichael C, Lau C, **Josephson DY**, Pal SK. Comprehensive overview of axitinib development in solid malignancies: focus on metastatic renal cell carcinoma. Clin Adv Hematol Oncol. 2012 May;10(5):307-14. Review.

B Yuh, S Muldrew, A Menchaca, W Yip, C Lau, T Wilson, **D Josephson**. Integrating robotic partial nephrectomy to an existing robotic surgery program. Can J Urol. 2012 Apr;19(2):6193-200.

Torrey RR, Chan KG, Yip W, **Josephson DY**, Lau CS, Ruel NH, Wilson TG. Functional outcomes and complications in patients with bladder cancer undergoing robotic-assisted radical cystectomy with extracorporeal Indiana pouch continent cutaneous urinary diversion. Urology. 2012 May;79(5):1073-8.

J Linehan, R Torrey, **D Josephson**, T Wilson, C Lau. Selective Arterial Clamping in Robotic Partial Nephrectomy Using Near Infrared Fluorescence Imaging. Proceedings of the WSAUA, Hawaii, 2012.

D Josephson, R Torrey, C Lau, B Yuh, J Linehan, J Yamzon, C Whelan, M Kawachi, T Wilson. The Use of Near-Infrared Fluorescence Imaging During Robotic-Assisted Laparoscopic Partial Nephrectomy: Initial Clinical Applications and Experience at City of Hope Cancer Center. Submitted, European Urology.

SK Pal, S Williams, **D Josephson**, C Carmichael, N Vogelzang, D Quinn. Novel therapies for metastatic renal cell carcinoma: efforts to expand beyond the VEGF/mTOR signaling paradigm. Mol Cancer Ther, online Feb 17, 2012.

C Talug, **D Josephson**, N Ruel, C Lau, M Kawachi, T Wilson. Controlling the dorsal venous complex during robotic prostatectomy. Can J Urol, 2012 Feb; 19(1): 6147-54.

C Lau, J Talug, S Williams, **D Josephson**, N Ruel, K Chan, T Wilson. Robotic-assisted laparoscopic radical cystectomy in the octogenarian. Int J Med Robot, 2012, Jan 4.

R Torrey, P Spiess, SK Pal, **D Josephson**. Role of surgery for locally advanced and metastatic renal cell carcinoma. J Natl Compr Canc Netw. 2011 Sep 1;9(9):985-93.

D Vasani, **D Josephson**, C Carmichael, O Sartor, SK Pal. Recent advances in the therapy of castration-resistant prostate cancer: the price of progress. Maturitas, 2011, 194-6.

Motzer RJ, Agarwal N, Beard C, Bhayani S, Bolger GB, Carducci MA, Chang SS, Choueiri TK, Hancock SL, Hudes GR, Jonasch E, **Josephson D**, Kuzel TM, Levine EG, Lin DW, Margolin KA, Michaelson MD, Olencki T, Pili R, Ratliff TW, Redman BG, Robertson CN, Ryan CJ, Sheinfeld J, Spiess PE, Wang J, Wilder RB; NCCN Kidney Cancer. Kidney Cancer. J Natl Compr Canc Netw. 2011 Sep 1;9(9):960-77.

S Williams, A Lay, C Lau, **D Josephson**, T Wilson, T Choueiri, S Pal. New therapies for castrate-resistant prostate cancer. Expert Opin Pharmacother. 2011 Sep;12(13):2069-74. Epub 2011 Jun 11.

S Williams, CS Lau, **D Josephson**. Initial series of robot-assisted laparoscopic retroperitoneal lymph node dissection for clinical stage I nonseminomatous germ cell testicular cancer. Eur Urol. 2011 Dec;60(6):1299-302.

J Linehan, R Torrey, **D Josephson**, T Wilson, C Lau. Renal suspension during robotic assisted laparoscopic partial nephrectomy. Proceedings of the WSAUA, Vancouver, 2011

D Josephson, R Torrey, B Yuh, J Linehan, C Whelan, J Yamzom, C Lau, M Kawachi, T Wilson. Robotic assisted laparoscopic partial nephrectomy with near infrared fluorescence imaging. Proceedings of the WSAUA, Vancouver, 2011

B Yuh, H Nikzad, **D Josephson**, T Wilson. Anatomical Extended Pelvic Lymph Node Dissection at robot assisted laparoscopic radical prostatectomy. Proceedings of the WSAUA, Vancouver, 2011

B Yuh, T Wilson, **D Josephson**. Use of T3 MRI for surgical planning of prostate cancer prior to robot assisted radical prostatectomy. Proceedings of the WSAUA, Vancouver, 2011

R Torrey, J Linehan, C Lau, **D Josephson**, T Wilson, K Chan. Management of ureteral strictures following Indiana pouch reconstruction at the time of robot assisted laparoscopic radical cystectomy. Proceedings of the WSAUA, Vancouver, 2011

R Torrey, J Linehan, B Yuh, **D Josephson**, K Chan, M Kawachi, C Lau, T Wilson. Outcomes of robotic assisted salvage radical cystectomy: single institution case series. Proceedings of the WSAUA, Vancouver, 2011

R Torrey, J Linehan, N Ruel, B Yuh, J yamzon, C Lau, **D Josephson**, T Wilson, K Chan. Clinical factors involved with postoperative ileus following robotic assisted laparoscopic radical cystectomy. Proceedings of the WSAUA, Vancouver, 2011

D Vasani, **D Josephson**, C Carmichael, O Sartor, S Pal. Recent advances in the therapy of castration-resistant prostate cancer. The price of progress. Maturitas, 2011

S Williams, C Lau, **D Josephson**, Initial Series of Robotic Assisted Laparoscopic Retroperitoneal Lymph Node Dissection for Clinical Stage I Non-Seminomatous Germ Cell Testicular Cancer. Epub, European Journal of Urology, 2011.

Williams SB, Lay AH, Lau CS, **Josephson DY**, Wilson TG, Choueiri TK, Pal SK: New therapies for castrate-resistant prostate cancer. Expert Opin Pharmacother 2011 Jun 11. Epub ahead of print

M Hayn ,A Stegemann, N. Hellenthal, P Agarwal, D Balbay, **D Josephson**, A. Kibel, K Nepple, J. Pattaras, J Peabody, J Redorta, K Rha, L Richstone, M Saar, D. Scherr, S Siemer, M Stoeckle, P Wiklund, T Wilson, M Woods, B Yuh, K.

Guru. Complications after Robot-Assisted Radical Cystectomy Using Standardized Reporting Methodology: Results from the International Robotic Cystectomy Consortium. Proceedings of the AUA, Washington DC, 2011.

M Hayn ,A Stegemann, N. Hellenthal, P Agarwal, D Balbay, **D Josephson**, A. Kibel, K Nepple, J. Pattaras, J Peabody, J Redorta, K Rha, L Richstone, M Saar, D. Scherr, S Siemer, M Stoeckle, P Wiklund, T Wilson, M Woods, B Yuh, K. Guru. Lymph Node Yield and Predictors of Extended Lymphadenectomy at the time of Robot-Assisted Radical Cystectomy: Results from the International Robotic Cystectomy Consortium. Proceedings of the AUA, Washington DC, 2011.

M Hayn ,A Stegemann, N. Hellenthal, P Agarwal, D Balbay, **D Josephson**, A. Kibel, K Nepple, J. Pattaras, J Peabody, J Redorta, K Rha, L Richstone, M Saar, D. Scherr, S Siemer, M Stoeckle, P Wiklund, T Wilson, M Woods, B Yuh, K. Guru. Pathologic and early oncologic outcomes after robot-assisted radical cystectomy: Results from the International Robotic Cystectomy Consortium. Proceedings of the AUA, Washington DC, 2011.

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A. Shpall, J. DeOrio, **D. Josephson**, S. Daneshmand. Lord of the Rings: The Story of a Paduang Penis. Proceedings of the Annual AUA Western Section Meeting, Las Vegas, 2003.

S. Daneshmand, **D. Josephson**, E. Skinner. Review of Techniques to Remove a Foley Catheter When the Balloon Does Not Deflate. *Urology*, 2002; 59(1): p. 127-129.

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INVITED EDITORIAL COMMENT

D. Josephson, and Stein J.P.: *J. Urology*, 171:2159, 2004.

SELECTED PRESENTATIONS

Prostate Cancer: advances in localized disease. Cedars Sinai Housestaff Grand Rounds, November 19, 2013, Los Angeles, CA.

Renal Cell Carcinoma. Cedars Sinai Housestaff Grand Rounds, November 26, 2013, Los Angeles, CA.

Urologic Emergencies. ER Grand Rounds, Cedars-Sinai Medical Center. Oct 25, 2012.

Advances in Robotic Urologic Surgery and the Use of Fluorescence Imaging Technology. Medical Grand Rounds, Hollywood Presbyterian Medical Center, October 5, 2012.

Advances in Minimally Invasive Surgery: Have The Robots Taken Over? Assil Eye Institute Continuing Education, September 19, 2012, Beverly Hills, CA.

The Prostate: everything you needed to know. First Friday Forum Meeting, September 14, 2012, Beverly Hills, CA.

Advances in Robotic Urologic Surgery and the Use of Fluorescence Imaging Technology. Medical Grand Rounds, Cedars-Sinai Medical Center, February 24, 2012.

Prostate Cancer: advances in localized and metastatic disease. Intuitive Surgical Physician Education Seminar, Santa Monica, Aug 19, 2011.

Kidney Cancer: Update on Management and Impact of Fluorescence. Intuitive Surgical Worldwide Sales Meeting, Boca Raton, FL, July 12, 2011

Evolution of Robotic assisted surgery for prostate and kidney cancer. Intuitive Surgical Physician Education Seminar, Los Angeles, CA, June 22, 2011

Treatment and Surveillance of Non-Muscle Invasive Bladder Cancer. Bladder Cancer Advocacy Network (BCAN) Expert Lecture Series, Los Angeles, CA, March 12, 2011.

Use of Robotic Technology in Urologic Oncology: 2010 Update. Visiting Professorship, Universita Campus Bio-medica, Rome, December 21-22, 2010.

Surgical Issues in patient with Renal Cell Carcinoma: Kidney Cancer Support Group lecture, COH, October 4, 2010.

Management of Renal Cell Carcinoma, Medicine Grand Rounds, Torrance Memorial Medical Center, Torrance, CA August 18th, 2010.

Improving Outcomes in Patients with Renal Cell Cancer, City of Hope CME lecture series, Duarte, CA , June 10, 2010.

Biology of Prostate Cancer. Biology and Cancer Awareness Lecture Series, California State Polytechnic University, May 17, 2010.

Controversies and Update on Screening and Surgical Treatment of Prostate Cancer. Medical Staff Grand Rounds, Ventura County Medical Center Grand Rounds, Ventura, CA, May 13, 2010.

Update on Management of T1 Renal Masses, Surgical Grand Rounds, Kern Medical Center, Bakersfield, Oct 21, 2009.

Management Small Renal Masses, New Technologies and Innovative Treatment Strategies for Genitourinary Malignancies Meeting, Coronado, San Diego, Oct 3, 2009.

Robotic Surgery for Prostate Cancer (Moderator). New Technologies and Innovative Treatment Strategies for Genitourinary Malignancies Meeting, Coronado, San Diego, Oct 3, 2009.

Prostate Cancer, Outline of symptoms and treatment. City of Hope Spirit of Life Reception, Chicago, Sep 24, 2009.

Controversies and Update on Screening, Prevention and Treatment of Prostate Cancer. Medical Staff Grand Rounds, St. Vincent's Medical Center, Los Angeles, July 23, 2009.

Update on Prostatic Diseases and Management. Men's Health Conference, Iranian Jewish Federation, Los Angeles, July 26, 2009.

Surgical Approaches in Advanced Bladder Cancer, City of Hope CME lecture series, Duarte, CA , May 7, 2009.

Biology and Overview of Prostate Cancer. Biology and Cancer Awareness Lecture Series, California State Polytechnic University, May 6, 2009

Intraoperative Optical Imaging: Use of Fluorescent Antibodies in Robotic Surgery. City of Hope Developmental Cancer Therapeutics/Phase 1 Retreat, April 4, 2009.

Management of Muscle Invasive Bladder Cancer: Is robotic Surgery an Appropriate Option?, Alexander and King Visiting Professorship in Urology and Joseph D. Mitchell MD Symposium, Dallas, TX, March 20, 2009

Comparison of Robotic and Open Prostatectomy, Alexander and King Visiting Professorship in Urology and Joseph D. Mitchell MD Symposium, Dallas, TX, March 20, 2009

Surgical Considerations in Renal Cell Carcinoma: Kidney Cancer Support Group lecture, COH, March 2, 2009.

Minimally Invasive Surgical Options for Prostate Cancer, Patient Education Seminar, Sun City, AZ , February 5, 2009.

Surgical Management of Renal Cell Carcinoma. City of Hope Hematology, Oncology and Pathology lecture series, January 29, 2009.

Minimally Invasive Surgical Options in Renal and Bladder Cancer. Medical Grand Rounds, Northridge Hospital, December 12, 2008.

Prostate Cancer: Controversies and Update on Screening and Surgical Options. Medical Staff Grand Rounds, Alvarado Hospital, San Diego, November 13, 2008.

Evolution of Robotic Surgery in Urology: Academy of American Pediatric Physicians, Santa Barbara, Oct 12, 2008.

Minimally Invasive Surgery for Renal Cell Carcinoma, New Technologies and Innovative Treatment Strategies for Genitourinary Malignancies Meeting, Coronado, San Diego, Sep 26, 2008.

Robotic Surgery for Prostate Cancer (Moderator). New Technologies and Innovative Treatment Strategies for Genitourinary Malignancies Meeting, Coronado, San Diego, Sep 26, 2008.

Prostate Cancer: Controversies and Update on Screening and Surgical Options. Medical Staff Lecture, Henry Mayo Newhall Memorial Hospital, June 19, 2008.

Biology of Prostate Cancer. Biology and Cancer Awareness Lecture Series, California State Polytechnic University, May 14, 2008.

Minimally Invasive Surgical Options for Prostate Cancer, Intuitive Surgery Patient Education Seminar, Whittier, CA , March 26, 2008.

Minimally Invasive Surgical Options for Urologic and Colorectal Cancer. Intuitive Surgery Patient Education Seminar, Woodland Hills, CA , February 27, 2008.

Robotic Cystoprostatectomy and Salvage Prostatectomy In the Management of Urological Malignancies. City of Hope, Division of Surgery CME lecture, Duarte, June 20, 2007.

da Vinci Laparoscopic Robotic Radical Prostatectomy: City of Hope Technique. Intuitive Surgical Moderator, AUA Annual Meeting, Anaheim, May 22, 2007.

Prostate Cancer: Controversies and Update on Management with Robotic Surgery. Medical Staff Lecture, Encino-Tarzana Regional Medical Center, April 30, 2007.

Radical Retropubic Prostatectomy: Treatment of Localized Prostate Cancer. Universita Campus Biomedico Roma, Italy, November 22, 2005.

Urinary Diversion: Principles and Practice – Monthly lecture for medical students on Urology Clerkship, USC Keck School of Medicine, 2005-2006.

MEDIA/OTHER

The Urologist's Perspective of the Role of Immunotherapy in Metastatic Castrate resistant Prostate Cancer Advisory Board, Las Vegas, NV, March 2, 2012

KTLA Health: 5 days that could save your life: Prostate Cancer. February 17, 2011.

Cancer Awareness Auto Show in OC: Role of PSA testing. Interview with Denise Drador, KABC TV Sep 24, 2010.

OC Car Show for detection of prostate cancer. Interview with David Kunz, KABC TV, Sep 25, 2009

Role of Circumcision and Sexual Health, interview with Penny Griego, KFWB 980 AM radio. May 29, 2008.

Minimally Invasive Surgical Treatment of Prostate Cancer, AirTalk with Larry Mantle, KPCC 89.3 FM. Los Angeles, CA, Feb 20, 2008.