Exhibit 361

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MEDICINE

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April 8, 2025
United States Department of Justice
1100 L St. NW
Washington, DC 20005

Re: *Criswell v. United States, Case No: 7:23-cv-01482-BO*
Request for Urologic Oncology Expert Review

I, Max Kates, M.D., was retained by the United States Department of Justice to write an expert report and provide my expert opinions in this case. I am providing my expert opinions as a medical doctor and expert in Urologic Oncology to evaluate Jefferson Criswell's allegations about the cause of his bladder cancer and to respond to the expert report and opinions of his expert, Dr. Longo. Mr. Criswell alleges, and Dr. Longo opines, that Mr. Criswell's bladder cancer was as likely caused by exposure to water at United States Marine Corp Camp Lejeune in North Carolina as other risk factors. Based on my training, experience, and expertise, it is my opinion, to a reasonable degree of medical certainty, that Mr. Criswell's bladder cancer was most likely caused by a combination of his smoking history, obesity, and the idiopathic nature of bladder cancer and unlikely caused by exposure to water at Camp Lejeune.

I. Summary of My Qualifications

I am a board-certified urologist and a fellowship trained urologic oncologist, and one of the few clinicians in the United States whose clinical practice is more than 90% focused on diagnosing and treating bladder cancer. Currently, I am Associate Professor of Urology and Oncology, Director of the Bladder Cancer Program, and Director of the Urologic Oncology Division for the Brady Urology Institute at Johns Hopkins. The Brady Urologic Institute is the country's first urologic training program and one of the premier programs in the United States.

I received my BA from Wesleyan University in 2006 and my MD from Mount Sinai School of Medicine in 2012. During my medical training, I spent a year at Columbia University College of Physicians and Surgeons as a Doris Duke Clinical Research Fellow, where I focused on bladder cancer clinical trials and research. I then completed a six-year residency in Urology at the Brady Urologic Institute.

Following residency, I remained at the Brady Urologic Institute for a two-year Society of Urologic Oncology (SUO) fellowship, where I completed subspecialty training in Urologic Cancer Surgery and Care. In 2018, I received the prestigious American Cancer Society Clinician Scientist Development Grant, and I was one of the few urologists and bladder cancer experts to receive five years of funding in cancer research. In 2018, I was named an Assistant Professor of Urology and Oncology. In 2020, I was named Director of the Bladder Cancer Program, and in 2022, I was promoted to Associate Professor of Urology and Oncology. In 2023, I became Director of the Division of Urologic Oncology, where I oversee a busy group of clinicians that diagnose and treat the spectrum of genitourinary malignancies and oversee a group of researchers that aim to make important discoveries to improve the lives of patients suffering from those same cancers.

As a Urologist who specializes in bladder cancer and as Director of the Bladder Cancer Program at Johns Hopkins Hospital, I lead one of the busiest clinical bladder cancer groups in the United States. I personally see 6-8 new bladder cancer patients each week and manage the care of more than 1,000 bladder cancer survivors. In these visits, I use a differential etiology approach to evaluate risk factors for the patient developing bladder cancer, in order to assess whether mitigation of those risk factors can improve the patient's prognosis or prevent bladder cancer development in their family. Surgically, I perform 50-90 cystoscopies (procedure for examining the bladder), 25-30 transurethral resection of bladder tumors (TURBTs), and 4-10 radical cystectomies (bladder removal surgery) each month. I actively manage bladder cancer at all stages, sometimes alone, and often times on a multidisciplinary team. Thus, I am qualified to speak to any aspect of bladder cancer diagnosis etiology and clinical care.

In conjunction with my clinical duties, I maintain ongoing and active academic and clinical research in the field of bladder cancer. My research interests involve novel treatments for cancers of the urinary tract. I currently have a provisional patent for a novel intravesical chemotherapy developed with nano-engineer collaborators. Additionally, I have made scientific discoveries into the mechanism of action of intravesical BCG, the most common treatment for bladder cancer. I am the principal investigator on multiple clinical trials, and I am currently leading EA8212 BRIDGE, which is a randomized trial open in over 150 centers in the United States comparing BCG to GemDoce chemotherapy for early-stage bladder cancer.

I have authored more than 140 journal articles in the field of bladder cancer. I have coauthored the chapter entitled "Tumors of the Bladder" in Campbell-Walsh-Wein Urology, which is the most widely used and the only comprehensive urology textbook in my field. In that chapter, I review the epidemiology risk factors for the development of bladder cancer.

Additionally, I was a panelist on an American Urologic Association global webinar on bladder cancer, and I am currently giving the main lecture on muscle invasive bladder cancer for the American Urologic Association board review course. I thus am qualified to speak to ongoing scholarship and scientific literature in bladder cancer with a particular emphasis on bladder cancer risk, diagnosis, and staging. I have testified as an expert witness at trial or deposition in the past four years in one medical malpractice case: Otis F. Noboa v. Scott D. Boruchov, M.D. et al., Civ. No. 1:20-cv-6871 (S.D.N.Y).

My CV with my qualifications and a list of all my publications is attached. I am being compensated $600/hour for my time working on this case. A list of the materials that I considered in forming my opinions will be provided at a later date.

II. Summary of Bladder Cancer Risk Factors, Diagnosis, and Management[1]

A. General Epidemiology(1)

Bladder cancer is one of the most common cancers diagnosed each year in the United States, with an estimated 83,190 new cases and 16,680 deaths in 2024.(2) The lifetime risk of developing any cancer is 40% for men and 42% for women. In the United States, 1 in 27 men will develop bladder cancer over their lifetime, whereas 1 in 89 women will develop bladder cancer.(3) Additionally, because bladder cancer has fewer deaths relative to incident cases compared to several other common malignancies (for example, lung and colon cancers), it is one of the most prevalent cancers in the United States as well.(2) For example, it was estimated that in 2024, 83,190 patients would be diagnosed with bladder cancer, and 16,840 patients would die

[1] Section adapted from the chapter that I coauthored entitled "Tumors of the Bladder" in Campbell-Walsh-Wein Urology 12th Edition.

of their disease, providing a ratio of 0.20 deaths to diagnoses.(2) By comparison, it was estimated that 234,580 patients would be diagnosed with lung cancer in 2024, and 125,070 patients would die of their lung cancer (ratio 0.53). It was estimated that 152,810 patients would be diagnosed with colorectal cancer in 2024 with 53,010 deaths (ratio 0.35).(2)

Bladder cancer is typically a disease of aging, with age adjusted incidence rates increasing with each decade of life. The average age of diagnosis in the US is 73, with 90% of patients diagnosed after the age of 55. Men have a 3 times higher increased risk of developing bladder cancer compared to women. Several hypotheses have been proposed for increased bladder cancer rates among men. Smoking is more common in men in comparison to women, with age standardized prevalence of smoking declining in men from 41.2% in 1980 to 31.1% in 2012 in comparison from 10.6% to 6.2% among women.(1,4) However even when controlling for smoking, gender related incidence disparities persist.(5,6) It has been hypothesized that cellular metabolism of carcinogens may be different. In other words, there may be differences between genders in the body's ability and rate of breaking down and absorbing certain carcinogens. Glutathione-S-transferase M1 and 5′-diphosphoglucuronosyltransferase (UGT) are enzymes that aid the body in breaking down environmental toxins, certain drugs, and other carcinogens. Aromatic amines are a class of organic compounds comprising an aromatic ring and a nitrogen group and have been implicated as carcinogens—particularly in tobacco smoke. Enzymes such as GSTM1 and UGT that regulate how these amines are metabolized and absorbed have thus been themselves implicated in cancer development, and their increased expression in men thus is hypothesized to increase the metabolism and absorption of carcinogens leading to a higher incidence of bladder cancer in men.(7,8)

Although women have lower bladder cancer incidence, they are more likely to present with an advanced stage of disease, in part because hematuria (blood in urine) in women is often misattributed to urinary tract infections which delays the bladder cancer workup and diagnosis.(9) (10) Bladder cancer is most common among Caucasian Americans, with an incidence rate 1.5 times that of Black Americans and twice that of Hispanic Americans. However, similar to gender differences, Black patients are more likely to present with muscle invasive disease compared to White patients, and it remains unclear whether this increased risk is due to factors involving access to care or tumor biology. (9)

One of Plaintiff's experts, Dr. Longo, classified bladder cancer as "a disease of toxic exposure." (*See* Dr. Longo – Criswell Report; p. 2). I disagree with this assessment and view it as an oversimplification of the disease. Some bladder cancer is attributable to carcinogens such as in smoking. However, as will be discussed subsequently, there is a hereditary component to bladder cancer, as evidenced by the frequency of germline mutations identified in recent studies. (11,12) Bladder cancer risk is multifactorial, with multiple pathways and mechanisms for development in each individual. While some of these pathways are known, some are still unknown, which is why idiopathy continues to play a role in assessing the differential etiology for a particular patient.

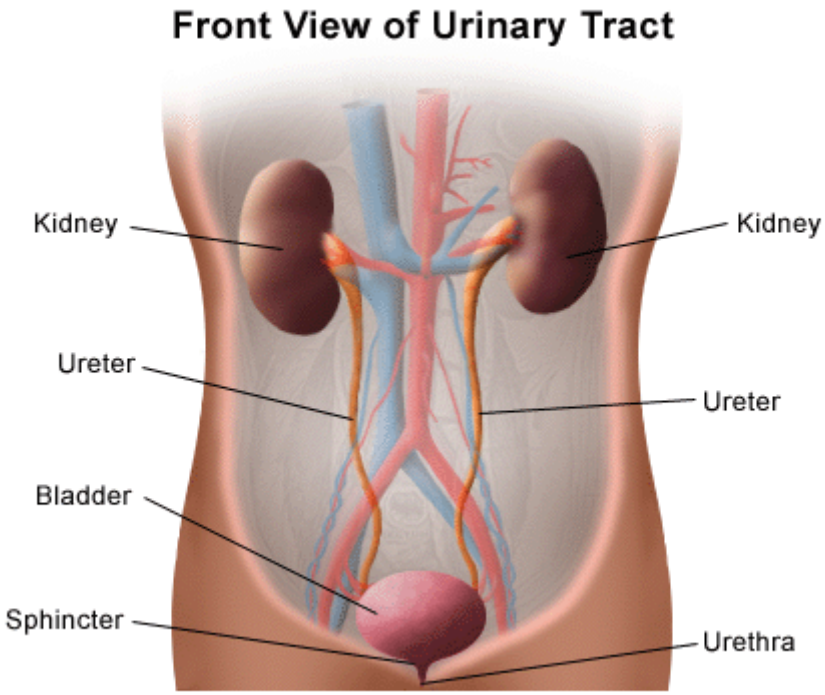
B. Bladder Cancer Subtypes and Upper Tract Urothelial Carcinoma

Urothelial cancer is the most common histology involved in bladder cancer, accounting for over 90% of cases. Urothelial carcinoma can further be subdivided by the 2004 WHO classification of low grade and high-grade urothelial carcinoma.(13) The grade of the cancer contributes to its pathologic stage as will be discussed in Section D. While urothelial carcinoma is most common, variant histologies, including micropapillary, sarcomatoid, plasmacytoid,

squamous differentiated, and glandular differentiated are often mixed with urothelial carcinoma and are treated similarly to it. Neuroendocrine bladder cancer, including small cell bladder cancer and large cell bladder cancer, are histologic variants which are treated differently, often with a chemotherapy as the first approach. Additionally, pure squamous cell carcinoma (i.e., not mixed with urothelial carcinoma) and pure adenocarcinoma of the bladder are also treated differently from conventional urothelial carcinoma, as these histologic subtypes are often treated primarily with surgery as they are resistant to other therapies.

Upper Tract Urothelial Carcinoma (UTUC) Upper Tract Urothelial Carcinoma (UTUC) is a related but biologically distinct entity from bladder cancer. Because of its rarity and distinctiveness, the FDA views UTUC as a disease that can be designated for orphan drug approvals.[2] UTUC involves cancer of the renal pelvis and ureter and only account for about 5-8% of all urothelial carcinomas.(14) UTUC has a few commonalities when compared to bladder cancer and some clear differences particular with regard to risk factors associated with each. There have been several studies comparing the molecular profile of upper tract urothelial carcinoma and bladder cancer, and these have demonstrated that there are distinct molecular differences between the two cancers, supporting the evidence that these are two separate diseases.(15) [3]

[2] U.S. Food & Drug Administration Orphan Drug Designations and Approvals (https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=445114).
[3] Illustration modified from Johns Hopkins Medicine (https://www.hopkinsmedicine.org/health/wellness-and-prevention/anatomy-of-the-urinary-system).



For example, FGFR3 mutations are widespread in the majority of UTUC cases, while they are present on a more limited scale among bladder cancers. With just 7,000 patients diagnosed with UTUC annually, there are limited clinical trials and evidence to support various management strategies, and because of this the management of UTUC is often similar to bladder cancer where there is more robust data. For example, neoadjuvant chemotherapy is widely recommended at my institution for high grade UTUC based on a randomized trial evaluating it for bladder cancer, and more limited retrospective data supporting its use in UTUC.

C. Bladder Cancer Risk Factors

There have been many risk factors proposed in the literature that may increase the risk of developing bladder cancer. The risk factors identified below have the most evidence in peer reviewed studies demonstrating risk.

i. Smoking

Tobacco use comprises the largest known risk factor for bladder cancer development, and accounts for 30-40% of all bladder cancer. I acknowledge Plaintiff's experts such as Dr. Sfakianos states that "approximately 50% of the patients who develop bladder cancer is due to their exposure to cigarettes" (Dr. Sfakianos – Cagiano Report; p. 15) and Dr. Longo states that smoking may account for 50% of all bladder cancer cases (Dr. Longo – Criswell Report; p. 17). Further, Dr. Culp cites to the 2014 Vlaanderen study which states that cigarette smoking accounts for "approximately 66% of new cases in men".[4] (Dr. Culp December 9, 2024, Report; p. 12). However, to be conservative in my approach regarding attributable risk, it is my opinion that the percentage of bladder cancer attributable to smoking cigarettes is slightly lower—on the order of 30-40%. Worldwide there are more than 1 billion current smokers, and smokers have a 2 to 3 times increased risk of bladder cancer.(16) Cigarette, pipe, and cigar smoking have all been linked to bladder cancer development.(17) Aromatic amines are the primary carcinogens contained in tobacco smoke that lead to bladder cancer development.(18) In general, the relative risk (RR) of developing bladder cancer increases with the intensity of cigarette smoking, with some studies showing up to a five times higher risk of bladder cancer with more than 15 cigarettes (3/4 pack) per day compared to a 2 times higher risk with less than 10 cigarettes (1/2 pack) per day.(19) Similarly, relative risk increases with the duration of smoking, from 1.2-1.9 times increased risk for those smoking less than 10 years to a 9.4 times increased risk for those smoking more than 40 years. (19) Additionally, the age of onset of smoking is highly associated with bladder cancer risk, with one study demonstrating a 4 times increased risk among those who begin smoking between ages 18-20 compared to a 2 times increased risk among those who begin

[4] Vlaanderen, Jelle *et al. (2014)* study "Tetrachloroethylene exposure and bladder cancer risk: a meta-analysis of dry-cleaning-worker studies." Environmental health perspectives vol. 122,7 (2014): 661-6.

after 31 years. Time since quitting also mitigates risk, with relative risk decreasing from 3-5 times among current or recent smokers to 1-2 times among those who quit more than 15 years prior.(19) Nevertheless, even individuals with a long latency period who smoked relatively few cigarettes are still at increased risk compared to the general population.(19) Unlike lung cancer, where one study estimates more than 80% of cases are diagnosed within 20 years of quitting cigarette smoking, bladder cancer has a longer lag time, with only 50% diagnosed in that first 20 year period.(20,21) In that study, approximately 15% were diagnosed 20-29 years after quitting, 15% 30-39 years after quitting, 13% 40-49 years, and 7% more than 50 years after quitting.(20)

I agree with United States expert, Dr. Peter Shields, that "tobacco smoking is among the best examples of a human carcinogen" and that "tobacco smoke contains more than 100 carcinogens and mutagens." (Dr. Shields – General Causation Report; pp. 76-81). I would also agree with Dr. Longo's assessment that "conventional wisdom would suggest that secondhand exposure to cigarette smoke may contribute to bladder cancer carcinogenesis." (Dr. Longo – Criswell Report; p. 17).

ii. <u>Occupational Exposures</u>:

Occupational exposures have been linked to 5-10% of all bladder cancers. Occupations that are considered high risk for developing bladder cancer include but are not limited to: analine dye, rubber, and tobacco workers, hairdressers, painters, leather workers, nurses, waiters, petroleum workers and seamen.(22) Workplace exposure to silica and asbestos in particular have also been linked to a 20% increased risk of bladder cancer. (23) More data exists linking occupational exposures to bladder cancer among petroleum workers, with one meta-analysis of eight studies demonstrating a 40% increased risk.(24–26) The typical latency period from workplace exposures to bladder cancer diagnosis is thought to be variable.(27) One study

evaluated factory workers from a dyestuff plant in Japan and found that the mean latency period was 29.5 years from initial work exposure to bladder cancer diagnosis and 20 years from the final exposure to tumor development. (28)

The chemicals at issue with respect to Camp Lejeune water (i.e., TCE, PCE, benzene, and vinyl chloride) are not ones that treating urologists typically consider as having a causal association with bladder cancer. In considering whether any relationship exists between bladder cancer and the exposure to water at Camp Lejeune, I am relying on the opinions of the United States' toxicology and epidemiology experts, Dr. Julie Goodman and Dr. Peter Shields. Dr. Goodman and Dr. Shields have concluded to a reasonable degree of scientific certainty that the currently available scientific evidence does not support a causal association between TCE, PCE, benzene, or vinyl chloride exposure and bladder cancer.

iv. Radiation

Radiation to the pelvis is commonly performed to treat several malignancies, including prostate, cervical, vaginal, and rectal cancer. These patients are at a 2-4 fold increased risk of developing bladder cancer.(29) While tumors can develop within 5 years, the risk increases rapidly with longer latency. For example, among prostate cancer patients who received radiation therapy, the risk of secondary bladder cancer compared with the general population was 15% increased risk among all radiated patients to 55% among those diagnosed with bladder cancer more than 5 years after radiation and 75% among those diagnosed more than 10 years after radiation.(30)

v. Family History

First degree relatives of bladder cancer patients have a 2 times higher risk of developing bladder cancer. Sometimes this risk is part of a broader cancer syndrome such as Lynch

syndrome.(31) Lynch syndrome is a hereditary, autosomal dominant disorder that increases one's risk of many cancers. Patients with Lynch syndrome have a 22 times increased risk of developing UTUC. While Lynch syndrome is primarily associated with UTUC, patients with bladder cancer do have a modest increased risk, with a cumulative incidence of 2-5% over their lifetime. However, germline testing, which assesses hereditary risk, suggests that 13-24% of patients with urothelial carcinoma will harbor pathogenic germline variants, most commonly *MSH2* and *BRCA1/2*.(11) These germline mutations are passed down generations and are responsible for bladder cancer within families.

vi. Body Mass Index (BMI)

Increased body mass index (BMI) has been shown to be an independent risk factor for bladder cancer development. There is also a dose response relationship where it appears that the relative risk of developing bladder cancer increases as BMI increases.(32,33) While lifestyle-associated factors including high BMI, low physical activity, and related metabolic disorders are associated with bladder cancer, these relationships are most evident in never smokers because smoking dominates bladder cancer risk, obscuring the contributions of these other factors.(34)

I would agree with Dr. Shield's assessment that "[b]eing overweight and obese, and with metabolic syndrome, have been reported to increase the risk of bladder cancer, which may be more pronounced for never smokers. IARC considers there to be sufficient human evidence for obesity as a cause of bladder cancer. This includes in conjunction with diabetes for persons with metabolic syndrome (obesity, diabetes, hypertension and high cholesterol)." (Dr. Shields – General Causation Report; p. 209) (citations omitted). Data regarding UTUC and BMI is even more limited, as it is with all risk factors typically associated with bladder cancer.

vii. Chronic Inflammation or Infections

Certain medical conditions in which the bladder is in a chronically inflamed state increases one's risk of developing bladder cancer. Diseased states in which the bladder is exposed to repeated trauma, infection, or inflammation increase the risk of particular types of bladder cancer, most notably squamous cell carcinoma and adenocarcinoma of the bladder. This would include chronic infections such as Schistosomiasis or recurrent urinary tract infections (UTIs).(35,36) But it also includes conditions that cause a neurogenic bladder, requiring frequent catheterizations.(37,38) Patients with congenital anomalies such as bladder exstrophy and spina bifida that lead to bladder dysfunction and often require catheterizations also are at increased risk for bladder cancer development. Having a chronic catheter, whether due to a neurogenic cause such as a spinal cord injury or from a non-neurogenic cause such as benign prostate hyperplasis, primary bladder hypermotility, or urethral stricture disease has in it of itself been linked to a 4-8 fold increased risk of bladder cancer development.(39,40) The latency period from chronic catheter use to bladder cancer diagnosis is thought to be 20-30 years depending on the type of bladder drainage.

viii. <u>Idiopathy</u>

Despite all that is known about bladder cancer risk factors, its estimated that ~40% of bladder cancer cases cannot be attributed to a known risk factor.(41) These cases are termed idiopathic, as the underlying cause is either spontaneous or not yet known. Dr. Longo states in his report that it is his opinion that "bladder cancer is rarely idiopathic in the sense that it is likely to have a known cause." (Dr. Longo – Criswell Report; p. 14). He previously cites to the American Cancer Society website, which states that, in fact, "researchers don't know exactly what causes most bladder cancers. But they have found some risk factors and are starting to

understand how some of them might cause cells in the bladder to become cancer."[5] I would agree with this statement. Despite all that is known in the literature regarding risk factors, when I perform a differential etiology on my patients, I am often left with a lifetime non-smoker, without a family or occupational significant for bladder cancer development, and without any other contributing risk factors. This is a common occurrence in my bladder cancer focused practice and is termed idiopathy. It should also be noted that idiopathy is not a diagnosis sole of exclusion. When building a differential etiology, there are sometimes several weak potential risk factors, such as a very light smoking history or a single cousin with a bladder cancer history. In these cases, idiopathy may still be the most likely etiology even when there are other potential contributing risk factors.

D. Diagnosis and Management

i. Initial Presentation and Workup

Bladder cancer is typically discovered when a patient notices blood in their urine (termed gross hematuria) or when their doctor discovers microscopic blood in the urine (microscopic hematuria). Occasionally, a bladder mass is uncovered on imaging studies (i.e. a CT or ultrasound) performed for another reason. Typically, a patient with hematuria is referred to a urologist where a cystoscopy is performed. During a cystoscopy, a small flexible scope is placed through the urethra into the bladder where a tumor (benign or malignant) may be identified. The patient then undergoes a Transurethral Resection of a Bladder Tumor (TURBT), which is a surgery performed under anesthesia where the bladder mass is resected endoscopically. This is both therapeutic in that it removes the mass, and diagnostic in that if the mass is found to be

[5] American Cancer Society website at (https://www.cancer.org/content/dam/CRC/PDF/Public/8558.00.pdf).

malignant, the TURBT will stage the cancer. Bladder cancer stages are typically divided into 3 major subcategories: non-muscle invasive bladder cancer, comprising approximately 70% of all new bladder cancer cases, muscle invasive bladder cancer, comprising 25% of new cases, and metastatic cancer, comprising 5% of new cases. (1)

ii. Non-Muscle Invasive Bladder Cancer

Patients whose bladder cancer does not invade the muscularis propria (muscle layer) of the bladder are considered to have non-muscle invasive bladder cancer (NMIBC), which is Stage 1 bladder cancer. NMIBC can be further subdivided into low, intermediate, or high risk NMIBC. Low risk NMIBC is defined by a patient with a low grade, noninvasive tumor less than 3cm in size. Intermediate risk is defined by recurrent low grade noninvasive tumors, multiple low-grade tumors in the bladder, or a less than 3cm high grade noninvasive tumor. High risk NMIBC is defined by carcinoma in situ (CIS), high grade cancer invading the lamina propria (HGT1), or a greater than 3cm high grade noninvasive tumor.(42) Depending on the NMIBC risk category, these patients are treated with observation or bladder immunotherapy or chemotherapy washes (termed intravesical instillations). The most common such intravesical therapy is Bacillus Calmette-Guerin (BCG), which is the recommended treatment for high risk NMIBC. The typical course of treatment involves aqueous drug delivered through a urinary catheter, where it dwells within the bladder for 1-2 hours. BCG is given weekly for 6 weeks in the induction phase, and then if there is no evidence of recurrences, maintenance phase instillations would be given weekly for 3 weeks at 3, 6, 12, 18, 24, 30 and 36 months.

iii. Muscle Invasive Bladder Cancer

Patients whose bladder cancer invades their muscle wall but does not involve their lymph nodes or distant organs, have Stage 2, or muscle invasive bladder cancer (MIBC). These patients

typically undergo chemotherapy with radical cystectomy (bladder removal) and urinary diversion, or chemotherapy with radiation. The more common option involves 2-3 months of chemotherapy followed by a radical cystectomy, in which the bladder (and prostate in a man) is removed along with pelvic lymph nodes, and the urinary system is then reconstructed. After surgery patients may receive immunotherapy (nivolumab) for a year if they continue to have muscle invasive cancer on their pathology report, or if cancer is found in their lymph nodes. Patients typically choose one of three urinary diversions: 1) a ileal conduit, which is an incontinent diversion in which the urinary system is reconnected to a piece of intestine that functions as a tube, bringing urine to the skin where it drains through a stoma into an external appliance; 2) an ileal neobladder: in which a much larger piece of intestine is formed into a sphere within the body and attached on one end to the ureters and the other end to the urethra, functioning as an internal option in which patients learn to urinate by creating intraabdominal pressure to void; or 3) a continent cutaneous diversion, in which part of a patient's large and small intestine are used to formulate a reservoir internally, and patients eliminate urine by catheterizing themselves through a channel made of intestines connecting their umbilicus (belly button) to the reservoir.

While clinical outcomes related to radical cystectomy have improved over the last several decades, the surgery continues to be associated with an approximately 20% rate of hospital readmission and an approximately 40% rate of complications of varying severities. Some patients are candidates for bladder preservation based on the location, stage and histology of the bladder cancer. Termed trimodality therapy (TMT), the cancer is treated with 4-6 weeks of daily radiation with concurrent weekly chemotherapy. Approximately 5-10% of patients with MIBC in

the United States are treated with this modality. This is always coupled with routine imaging (i.e. CT scan or MRI) as well as cystoscopies to assess for local and systemic cancer recurrences.

iv. Locally Advanced and Metastatic Bladder Cancer

Patients with Stage 3-4 bladder cancer have locally advanced or metastatic disease and these patients receive systemic therapy (either chemotherapy, immunotherapy, targeted therapies, or combination therapy) with a more limited role for surgery or radiation. In recent years there have been dramatic changes in therapies approved for advanced bladder cancer. While historically chemotherapy was the only option, more recent immunotherapies in the form of immune checkpoint inhibitors (i.e. pembrolizumab) have been approved, and in 2024 combination therapies (i.e. Enfortumab Vedotin/pembrolizumab or cisplatin/gemcitabine/nivolumab) have now largely replaced traditional chemotherapy as a new standard of care for these patients.

v. Prognosis

Stage is a crucial indicator of prognosis, with estimated 5-year cancer specific survival (CSS) for patients with High-Risk Non-muscle invasive bladder cancer (Stage 1) being 90%, while patients with locally advanced bladder cancer (Stage 2) have a 5-year CSS of 48% and patients with metastatic disease (Stage 3-4) have a 5 year CSS of 8%.(43)

III. Summary of Pertinent Facts in Mr. Criswell's Case

A. Diagnosis

Jefferson Criswell (DOB [redacted]1955) was diagnosed with muscle invasive bladder on October 20, 1997, based on a surgical pathology report obtained from a transurethral resection of a bladder tumor (TURBT). Many years later, in February of 2014, Mr. Criswell was diagnosed

with low-grade noninvasive bladder cancer. He was then disease free for several years on cystocscopic surveillance, and ultimately had a small recurrence of a low-grade noninvasive bladder tumor in August of 2016.

B. Camp Lejeune Exposure History

Mr. Criswell is a 69-year-old male who was stationed at Camp Lejeune from January 1975 to April 1977, comprising a total of about 2.25 years. Based on his service records and testimony, he initially lived off-base for approximately six (6) months, before obtaining housing in Tarawa Terrace, where he remained for the rest of his time at Camp Lejeune. Mr. Criswell testified to working daily in Hadnot Point, or Mainside, during the entirety of his time at Camp Lejeune, except for when he would be off base for training or working as a cross-country chaser for the military police. Mr. Criswell's bladder cancer was diagnosed approximately 20 years after his last day at Camp Lejeune.

I am relying on the opinions of the United States' risk assessment experts, Dr. Judy LaKind and Dr. Lisa Bailey. In her report, Dr. LaKind describes the daily exposure doses for oral and dermal exposures and daily exposure concentrations for inhalation exposures calculated for Mr. Criswell for the volatile organic compounds at issue with respect to Camp Lejeune water. Using Dr. LaKind's exposure estimates, Dr. Bailey performed a risk assessment to assess Mr. Criswell's cancer risk with respect to his estimated chemical exposures. Based on conservative regulatory risk calculations, it is Dr. Bailey's opinion to a reasonable degree of scientific certainty that there is insufficient evidence to conclude that Mr. Criswell's exposures to TCE, PCE, benzene, vinyl chloride, and 1,2-tDCE from tap water during the 2.25 years that he was stationed at Camp Lejeune are causally associated with his bladder cancer.

C. Social and Family History

Mr. Criswell is a former cigarette smoker. He testified at his deposition that he started smoking as a young teenager around the age of 13 or 14, which would be around 1968. He also testified to considerable secondhand smoke exposure, as both of his parents smoked. His memory around his smoking history was limited and he could not provide an estimate of how many years he smoked or how much he smoked during this time. However, his medical records indicate that he reported quitting smoking in 1974 (close to when he joined the Marine Corps), restarted smoking in 1977 (when he left the Marine Corps), and quitting again in 1978. Mr. Criswell denied in his deposition ever smoking after he left the Marine Corps and testified that he didn't know why that was in his records. His medical records also note that at one point Mr. Criswell reported smoking 2-3 cigarettes per day while he was a smoker.

Dr. Longo characterizes Mr. Criswell as a "non-smoker for medical purposes," based on the Centers for Disease Control's definition of a non-smoker as "an adult who has never smoked, or who has smoked less than 100 cigarettes in his or her lifetime." (Dr. Longo – Criswell Report; p. 18). Despite the varying reports of Mr. Criswell's smoking history in the medical records and in his deposition testimony, Dr. Longo assumes low exposure: "Mr. Criswell reports that he smoked socially on a handful of occasions as a teenager due to peer pressure in approximately 1973-1974." (Dr. Longo – Criswell Report; p. 17). Dr. Longo cites to a portion of Mr. Criswell's deposition testimony that does not support this statement.[6] Even if we assume that Mr. Criswell's smoked only one cigarette per day for one year (a generous assumption given the conflicting medical records), this would still place Mr. Criswell far above the threshold of 100 cigarettes in his lifetime. Therefore, by Dr. Longo's own assessment of what constitutes a non-smoker for

[6] See Criswell Deposition at 171:11-172:3.

medical purposes, Mr. Criswell cannot be labeled a non-smoker even assuming a much more limited smoking history than supported by the records.

Mr. Criswell has no known family history of bladder cancer but has a maternal aunt who died of lung cancer and a sister who died of pancreatic cancer.

D. Bladder Cancer History

On October 15, 1997, Mr. Criswell was referred to urologist Dr. Leihugh Moseley with several weeks of left lower quadrant pain and gross hematuria. An intravenous pyelogram (IVP) demonstrated a 2 cm calcified bladder mass in the posterior wall. A bladder mass was confirmed on cystoscopy on October 17, 1997, and a Transurethral Resection of the Bladder Tumor (TURBT) was performed on October 20, 1997, with pathology consistent with muscle invasive bladder cancer. On October 24, 1997, Dr. Moseley had a discussion with Mr. Criswell and his wife regarding options for muscle invasive bladder cancer with a subsequent discussion on November 10, 1997. He was offered a radical cystectomy and urinary diversion as the preferred options or intravesical BCG as another option, albeit with risk of subclinical persistent cancer and increased risk of progression. Mr. Criswell chose to undergo a 6-week course intravesical BCG instead of the radical cystectomy. After another TURBT on December 29, 1997, which demonstrated no residual cancer in the bladder, Mr. Criswell proceeded with the 6-week induction course of intravesical BCG, followed by one 3-week course of maintenance BCG therapy.

The 3-week maintenance course was complicated by intractable BCG cystitis, ultimately managed with a course of INH therapy—a highly unusual treatment in managing BCG cystitis in this context. Typically, I would withhold further BCG and treat symptoms with anti-spasmatics and not initiate INH—a drug that has a number of serious side effects.

On April 6, 1997, he underwent cystoscopy with bladder biopsies which demonstrated no cancer present but BCG granulomatous disease, which is a benign inflammatory condition of the bladder that is often associated with BCG cystitis leading to urinary frequency and urgency. Due to this toxicity, further BCG was withheld, and he was managed with cystoscopic surveillance alone. Dr. Longo characterizes Mr. Criswell's symptoms from his BCG treatment as severe and refers to a record from Dr. Moseley that characterizes Criswell as a "urological cripple." (Dr. Longo – Criswell Report; p. 6). Unfortunately, many patients experience local side effects from BCG and BCG intolerance rates are globally very high. In fact, more than half of patients on BCG are unable to complete a full induction and 3-year maintenance course due to symptoms. However, in the vast majority of patients, these symptoms improve with time and avoidance of further BCG. I would not characterize Mr. Criswell as a "urological cripple." Firstly, that is not language I routinely use to describe bladder symptomatology. Secondly, this implies a permanently non-functional bladder of which there is no evidence to support. His urgency and frequency symptoms may persist and can typically be managed with medications. Currently, more than twenty-five years post-diagnosis, he still has his bladder in place, and doesn't appear to have had further procedures (i.e., botox, interstim, etc.) to manage severe urgency frequency symptoms. Thus, I don't see any obvious signs of severe, permanent bladder damage, though I would agree many patients have mild to moderate symptoms managed with medications that persist after BCG.

On November 19, 1999, Mr. Criswell was referred to Dr. Scott Shelfo at Georgia Urology, P.A. Dr. Shelfo assumed primary care for Mr. Criswell's bladder cancer from that point forward. On October 17, 2002, another cystoscopy was unremarkable and reflected Mr. Criswell was five years with no evidence of disease. While the standard of care was to continue to

monitor with regular cystoscopies, Mr. Criswell did not return to Dr. Shelfo's office or receive any care for bladder cancer for approximately the next 12 years between 2002 and 2014.

In February 2014, Mr. Criswell saw Dr. Scott Shelfo and was diagnosed with a low-grade noninvasive bladder cancer. This recurrence was managed with a TURBT and a single instillation of intravesical chemotherapy (mitomycin C), which is a local bladder wash that is the standard of care for that type of tumor recurrence. He was then disease free for the following two years on cystoscopic surveillance, and ultimately had a small recurrence of a low-grade noninvasive tumor in August 2016. He appears to have been disease free since and is due to follow up for another cystoscopy in early 2025.

Dr. Longo opines that Mr. Criswell's lapse of several years in surveillance "did not impact his recurrence or the ultimate outcome". (Dr. Longo – Criswell Report; p. 9). I disagree that the lapse in time period did not impact the time to recurrence. There very well may have been a recurrence for years prior to 2014 when he was ultimately diagnosed with bladder cancer. However, I do agree that it did not impact his outcome, as low-grade non-invasive bladder cancer has virtually no risk of cancer progression, and thus a recurrence in 2014 versus 2011, for example, would not have impacted his bladder cancer outcomes because either way his prognosis is excellent.

E. Post Bladder Cancer Medical History

Currently, Mr. Criswell experiences urge urinary incontinence and has had erectile dysfunction since 2015. Urinary incontinence is a common side effect of bladder cancer treatment, as frequent cystoscopies, TURBTs, and intravesical bladder therapies can ultimately lead to urinary frequency and urgency, and both stress and urge urinary incontinence. Erectile

dysfunction is likely unrelated to his bladder cancer and is a common co-existing issue for many bladder cancer patients that occurs as men age for reasons unrelated to their cancer diagnosis.

Mr. Criswell also claims to have experienced vision loss as a result of the INH therapy he received in 1998. However, his medical records to date have not demonstrated any vision loss associated with his bladder cancer treatment and his urology expert, Dr. Longo, did not provide an opinion on this issue. Mr. Criswell applied for VA disability benefits for vision loss in 2013, claiming it was due to his bladder cancer treatment in 1998. The VA conducted an eye examination and determined that apart from a corneal astigmatism in his left eye, Mr. Criswell's visual acuity was normal, and he had no visual field defect. The VA further found that there was no evidence of damage from INH exposure. This is aside from the point made earlier that there was no indication to treat Mr. Criswell with INH therapy at that time period for cystitis related to BCG.

Additionally, in his report Dr. Longo discusses Mr. Criswell's history of depression that he alleges was caused by his bladder cancer. Neither I or Dr. Longo, I presume, have any qualifications or experience in the field of psychiatry to opine on this claim. As a general note, in my clinical practice it is uncommon for bladder cancer patients to develop clinical depression as a result of their bladder cancer or treatment.

IV. Opinions

My opinions regarding potential causes of Mr. Criswell developing bladder cancer have been formed by building a differential diagnosis of competing risks. This differential diagnosis is something that I do on a daily basis as a clinician, where I observe signs and symptoms in a patient to formulate potential diagnoses that could be the cause of the aforementioned signs and symptoms. In a similar manner when assessing risk factors for developing bladder cancer, I

incorporate the patient's known risk factors, weighted by their relative risk associated with bladder cancer, in order to provide an opinion on the factors most likely responsible for causing their bladder cancer.

A. Differential Etiology/Diagnosis

Mr. Criswell was diagnosed with muscle invasive bladder cancer in his early 40s. This was approximately 20 years after his residency at Camp Lejeune, and approximately 20 years after his last exposure to cigarette smoking.

Smoking: The primary known risk factor for developing bladder cancer in this patient is cigarette smoking. Based on Mr. Criswell's medical records, he smoked less than ½ a pack per day of cigarettes for a few years as a teenager. His medical records at one point say, "smoked less than ½ ppd; 2 years as teenager" and at another say, "quit in 1974, restarted in 1977, and quit in 1978; smoked 2-3 cigs per day when he did smoke." He also denied ever smoking in multiple medical records.

Even if Mr. Criswell only smoked 2-3 cigarettes per day for 2 years, even a short interval of daily inhalation of cigarette smoke increases one's lifetime bladder cancer risk with an odds ratio >1. (19) As discussed, there is data suggesting that age of onset is crucial in bladder cancer risk development, with one study demonstrating a 4 times higher increased risk among those who begin smoking between ages 18-20 compared to a 2 times higher risk among those that begin after age 31. That Mr. Criswell smoked primarily as a teenager at age 13 and 14 increases his risk compared with smoking later in life.(19) Thus, I conclude that Mr. Criswell's smoking history, although minimal, is a risk factor for his bladder cancer.

Occupation History: As previously discussed, I am relying on the United States' general causation experts, Dr. Goodman and Dr. Shields, and the United States' risk assessment experts,

Dr. LaKind and Dr. Bailey. There is insufficient evidence to conclude that Mr. Criswell's potential exposures to TCE, PCE, benzene, vinyl chloride, and 1,2-tDCE from tap water during the 2.25 years that he was stationed at the Camp Lejeune are causally associated with his bladder cancer. Thus, I am able to rule out exposure to Camp Lejeune water as a risk factor for Mr. Criswell's bladder cancer.

After Mr. Criswell left the Marines, he worked as a police officer, a physical education teacher, and a business owner (Firehouse subs). Therefore, I am able to rule out occupational history as a risk factor.

Family History: He has no family history of bladder cancer, but he has a maternal aunt who died of lung cancer and a sister who was diagnosed with pancreatic cancer. Mr. Criswell has a history of cancer in his family, but no clear history of bladder cancer or bladder cancer associated malignancies. Thus, I am able to rule out family history as a risk factor.

Inflammation: Mr. Criswell does not have any inflammatory conditions placing him at increased risk of bladder cancer exposure. Therefore, I am able to rule out inflammation as a risk factor.

Body Mass Index: On June 2, 2015, Mr. Criswell was seen at Cancer Treatment Centers of America by Dr. Shelfo and was documented as having a BMI of 38.2, which is considered obese. When reviewing all of the medical records, Mr. Criswell's BMI was consistently elevated between 2008 (BMI of 34.97) and the time of his last bladder cancer recurrence in 2016 (BMI 36.49). A normal healthy weight is considered a BMI of 18.5-24.9 and any BMI above 25 is considered overweight, with a BMI above 30 obese. As previously discussed, it appears that there is a dose response relationship where the relative risk of developing bladder cancer

increases as BMI increases.(32,33) Thus, I conclude that Mr. Criswell's history of elevated BMI is a risk factor for his bladder cancer.

Idiopathy: Despite multiple potential risk factors for development of bladder cancer, idiopathy remains the strongest associated cause. Dr Longo argues that idiopathy is not a cause of Mr. Criswell's bladder cancer due to him being diagnosed at age 42. However, there is no data to suggest that patients diagnosed younger are more likely to have known risk factors than patients diagnosed older. In fact, it is far more likely that an older patient will have more identifiable risk factors than a younger patient, and therefore not be considered an idiopathic case of bladder cancer. In my bladder cancer clinical practice, the vast majority of patients who are young (i.e., more than 50 years old) are non-smokers, with no known occupational exposures, and no known family history. My research group at Johns Hopkins is actively investigating this group of individuals, but as a generally rule they fall into the idiopathic category when understanding their bladder cancer risk.

Conclusions regarding differential etiology: Given what is known about these competing risk factors, my opinion to a reasonable degree of medical certainty is that idiopathy, his cigarette smoking history, and obesity are the strongest and most likely risk factors for him developing bladder cancer.

B. Prognosis

Mr. Criswell was offered a radical cystectomy for his muscle invasive bladder cancer in 1997, which at the time was the standard of care approach to treating that stage of bladder cancer. However, he chose instead to undergo an induction course of intravesical BCG, something that was unconventional treatment of muscle invasive bladder cancer then and now. Unfortunately, this was complicated by severe BCG cystitis, which is known to have long

standing toxicity with persistent and severe urinary urgency and frequency. Ultimately, Mr. Criswell was cancer free for a prolonged period of time, from 1998 to 2014. In 2014 and 2016 he had small low grade noninvasive recurrences and appears to now be disease free. If he had undergone a radical cystectomy and urinary diversion in 1997 as recommended, he would not have had bladder cancer recurrences later on, although he may have had other short and long term complications of surgery. Regardless, his prognosis moving forward from a cancer standpoint is excellent. Even the fact that he was lost to follow up for 12 years between 2002-2014 likely did not impact his prognosis. If he had continued cystoscopic surveillance during that time period, the tumor may have been discovered earlier but it wouldn't have mattered because these low-grade noninvasive tumors are so unlikely to spread or progress. Specifically, the low-grade noninvasive bladder cancer that was diagnosed in 2014 and 2016 are highly unlikely to progress to invasive cancer. Therefore, when we consider his bladder cancer prognosis, the most relevant diagnosis is the muscle invasive (Stage 2) bladder cancer from 1997, of which he is now about 28 years out. I can, therefore, conclude to a reasonable degree of medical certainty that Mr. Criswell is unlikely to have any risk of metastatic cancer or cancer death.

Specifically, his risk of having another low grade recurrence, now that he is about 9 years from his most recent cancer diagnosis is less than 5% and his risk of having a high risk recurrence (progressing to a high grade tumor) is less than 3%.(44) He is also unlikely to die from bladder cancer, now that he is almost 30 years out from his muscle invasive diagnosis.

V. Conclusion

In conclusion, it is my opinion that 1) Mr. Criswell did have a pathologically confirmed diagnosis of muscle invasive bladder cancer in 1997, with recurrences of low-grade non-invasive bladder cancer in 2014 and 2016. 2) His bladder cancer was more likely caused by a combination

of his smoking history, his elevated BMI, and the idiopathic nature of bladder cancer and unlikely caused by exposure to water at Camp Lejeune. 3) It is unlikely, and there is no evidence I have seen to support, that Mr. Criswell experienced vision loss as a result of receiving INH therapy. 4) Mr. Criswell's erectile dysfunction was unlikely to have resulted from his bladder cancer.

These are my opinions as of the day of this report. These opinions are based upon my training and experience and my review of the case-specific records or materials, depositions, and expert reports, as well as my review of the medical literature. As further information is acquired, I reserve the right to amend, alter, or supplement my opinions as appropriate. All my opinions are made to a reasonable degree of medical certainty.

Sincerely,

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2018-present R. Christian B. Evensen Professor of Urology
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Education and Training

Undergraduate

2006 B.A. Wesleyan University, Middletown, CT; graduated High Distinction

Doctoral/graduate

2012 M.D, Mount Sinai School of Medicine, New York, NY

Postdoctoral

2010-2011 Doris Duke Clinical Research Fellow, Columbia University College of Physicians and Surgeons, New York, NY (Mentor: James McKiernan_
2012-2013 Intern, General Surgery, Johns Hopkins Hospital, Baltimore, MD
2013-2018 Resident, Urologic Surgery, Johns Hopkins Hospital, Baltimore, MD
2018-2020 Society of Urologic Oncology Fellow, Johns Hopkins Hospital, Baltimore, MD

Professional Experience

2006 – 2007 Research Assistant, Harvard Medical School, Department of Health Policy
2018-2022 Assistant Professor, Urology, Johns Hopkins University School of Medicine
2022-present Associate Professor, Urology, Johns Hopkins University School of Medicine
2023-present Director, Division of Urologic Oncology, Brady Urologic Institute

RECOGNITION

Awards, Honors

2002	National Association of Secondary School Principals Leader Award
2004	Mount Sinai School of Medicine Humanities and Medicine Scholar
2005	Finalist, Truman Scholar
2006	Team Captain, Wood Memorial Award, Wesleyan University Tennis Team
2011	Oral Presentation Award, Mount Sinai Medical Student Research Day
2011	Gold Humanism Honor Society, Mount Sinai School of Medicine
2011	Alpha Omega Alpha (AΩA) Honor Medical Society, Mount Sinai School of Medicine
2012	Harold Lamport Biomedical Research Award
2012	Distinction in Research, Mount Sinai School of Medicine
2014	Johns Hopkins Walter and Lucille Rubin Research Award
2015	Bladder Cancer Advocacy Network (BCAN) John Quale Travel Fellow
2015	Johns Hopkins Septembeard Research Scholar Award
2015	AUA Urology Care Foundation Russell W Scott Resident Scholar
2016	Society of Urologic Oncology Annual Meeting 1st prize Poster Award
2016	Mid-Atlantic AUA Resident Essay Prize
2016, 2017	Best Reviewer Urologic Oncology: Seminars and Original Investigations
2018	American Urological Association Annual Meeting 1st prize Poster Award
2021	Reviewer of the Month, European Urology

PUBLICATIONS
Peer Reviewed Original Research (Published)

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14. Joice GA, Bivalacqua TJ, **Kates M**. Optimizing pharmacokinetics of intravesical chemotherapy for bladder cancer. *Nat Rev Urol*. 2019;16(10):599–612.
15. Patel SH, Metcalf M, Bivalacqua TJ, **Kates M.** Plastic exposure and urological malignancies - an emerging field. Nat Rev Urol. 2020 Dec;17(12):653-654
16. Bo S, Sedaghat F, Pavuluri K, Rowe SP, Cohen A, **Kates M**, McMahon MT. Dynamic Contrast Enhanced MRCEST Urography: An Emerging Tool in the Diagnosis and Management of Upper Urinary Tract Obstruction. *Tomography* 2021. Mar2;7(1) 80-94
17. **Kates M**, Chu X, Hahn N, Pietzak E, Smith A, Shevrin DH, Crispen P, Williams SB, Daneshmand S, Packiam VT, Porten S, Westerman ME, Wagner LI, Carducci M. Background and Update for ECOG-ACRIN EA8212: A Randomized Phase 3 Trial of Intravesical Bacillus Calmette-Guérin (BCG) Versus Intravesical Docetaxel and Gemcitabine Treatment in BCG-naïve High-grade Non-muscle-invasive Bladder Cancer (BRIDGE). Eur Urol Focus. 2023 Jul;9(4):561-563
18. Sepehri S, Rezaee ME, Su ZT, **Kates M**. Strategies to Improve Clinical Outcomes and Patient Experience Undergoing Transurethral Resection of Bladder Tumor. Curr Urol Rep. 2024 Oct 11;26(1):13. doi: 10.1007/s11934-024-01243-3. PMID: 39390270

Book Chapters

1. Badalato GM, **Kates M.** Sadeghi N, and McKiernan JM. Renal Cortical Neoplasms and Associated Renal Functional Outcomes, *Diseases of Renal Parenchyma*. 2012. Prof. Manisha Sahay (Ed.), ISBN: 978-953-51-0245-8, InTech.
2. **Kates M**, Carter H.B., Macura, K. MRI and Active Surveillance, *MRI of the Prostate*. 2016, Thieme Publishers
3. **Kates M**, Bivalacqua TB. Tumors of the Urinary Bladder, *Campbell-Walsh-Wein Urology, 2020*
4. Gabrielson A, Christopher VandenBussche, **Kates M.** Urine Cytology in the Clinical Management of Bladder Cancer. *Comprehensive Diagnostic Approach to Bladder Cancer, 2021, Straive Publishers*

Invited Editorials:

1. **Kates MR**, Wisnivesky JP. Author reply to a letter. *American Journal of Respiratory and Critical Care Medicine.* 2009. 180: 794-5
2. **Kates M,** McKiernan J. Reply to editorial. 2012 *Urology.78:*560

3. **Kates M**, Bivalacqua TB. Editorial. 2018. J Urol. 2018 Nov;200(5):1011-1012
4. **Kates M**. Editorial Comment. J Urol. 2019 Jul 9
5. Chappidi MR, Stimson CJ, **Kates M**, Odisho AY, Bivalacqua TJ. Reply by Authors. J Urol. 2020 Mar;203(3):552-553. Epub 2019 Nov 26. PubMed PMID: 31769720.
6. Patel SH, **Kates M.** Open Versus Robot-assisted Radical Cystectomy: Is Standardization Without Randomization Possible? Eur Urol. 2021 Jan 20:S0302-2838(21)00009-9.
7. Rodriguez K, **Kates M**. Novel intravesical gemcitabine delivery system (TAR-200) for neoadjuvant treatment of MIBC: context is everything. Nat Rev Urol. 2022 Oct;19(10):579-580..
8. Solanki AA, **Kates MR**, Tran PT. Paving the Road to the Future of Chemoradiotherapy in Muscle-invasive Bladder Cancer: 10-year Follow-up of BC2001. Eur Urol. 2022 Sep;82(3):280-282.
9. **Kates M**. Doing Less with More: Towards a New Paradigm of Non-muscle-invasive Bladder Cancer Care. Eur Urol Focus. 2023 Jul;9(4):555-556.

FUNDING

EXTRAMURAL Funding

Current

2021-2026 Title: A study of intravesical enfortumab vedotin for treatment of patients with non-muscle invasive bladder cancer (NMIBC) [EV-10]
PN22032704
Seagen
$1,124,883.00
Role: PI (2% effort)

2022-2027 Phase 3, Single-Arm, Multicenter Study of UGN-102 as Primary Chemoablative Therapy in Patients with Low grade Non-Muscle-Invasive Bladder Cancer at intermediate Risk of Recurrence
Urogen
$300,000
Role: PI (1% effort)

Previous

2015-2016 "Nanoparticle Approaches to Improving the Immunologic Response to Intravesical Chemotherapy for Non-Muscle Invasive Bladder Cancer"
Russell Scott, Jr. MD Urology Research Fund
Urology Care Foundation and American Urological Association Office of Research
$40,000
PI (50% effort)

2015-2016 "T-cell receptor sequencing in urine as a biomarker for bladder cancer"

Adaptive Biotechnology
$50,000
PI (0% effort)

2018-2022 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 (TC-BC-12)
TC-BC-12
Urogen
$142,749
Role: PI (4% effort)

2019-2024 "Intravesical Cisplatin Chemotherapy and Mechanisms of Resistance for NMIBC"
CSDG-19-001-01
Clinician Scientist Development Grant
American Cancer Society
$729,000
Principal Investigator (50% effort)

2019-2024 Phase 1/2 Trial Evaluating the Safety and Tolerability of NanoDoce® Injection and Intravesical Instillation in Subjects with Urothelial Carcinoma
J18180
US Biotest
$427,458
Role: PI (10% effort)

2022-2024 " Phase 1/2 Study of Modern Immunotherapy in BCG-Relapsing Urothelial Carcinoma of the Bladder- (ADAPT-BLADDER)"
R01 CA235681
Noah Hahn (PI)
$628,148
Role: Co-investigator (5% effort)

INTRAMURAL Funding

Previous

2015-2016 "Establishment of a Multi-Institutional Active Surveillance Research Network"
Johns Hopkins Septembeard Fund
Brady Urological Institute
$25,000
Role: PI (0% effort)

2015-2017 "Nanomedicine Approaches for Improving Intravesical Delivery of Chemotherapeutic Agents."

Greenberg Bladder Cancer Institute Research Fund
Johns Hopkins Greenberg Bladder Cancer Institute
$100,000
Role: co-PI (0% effort)

2014-2015 "Development of a novel intravesical agent that prevents radiation hemorrhagic cystitis"
Walter and Lucille Rubin Award
Brady Urological Institute
$20,000
Role: PI (0% effort)

2020-2022 "A Phase II trial for the use of Intravesical Gemcitabine and Docetaxel (GEMDOCE) in the treatment of BCG naïve Non-muscle invasive Urothelial Carcinoma of the Bladder."
Chad Holiday Pilot Project Fund
Brady Urological Institute
$22,500
Role: PI (0% effort)

CLINICAL ACTIVITIES

Clinical Focus:
I have expertise in all areas of urologic oncology, with a particular emphasis on bladder and prostate cancer surgery. With training in both open and minimally invasive approaches, my surgical philosophy is to assess the unique needs of each patient and develop the right treatment plan for their malignancy. As clinical director of the bladder cancer multidisciplinary clinic, I work with the team at the Johns Hopkins Greenberg Bladder Cancer Institute to deliver a personalized approach to bladder cancer.

Certification

Medical, other state/government licensure
NPI: 1487910600
Maryland License: D0079254 Expiration: 9/30/2024
DEA: FK5267706 Expiration 12/31/2026
Maryland Controlled Dangerous Substance License: M83609 Expiration 4/30/2026

Boards, other specialty certification
2/22 American Board of Urology (Board Certified) #21094 Expiration 2/28/2032

Clinical (Service) Responsibilities
Associate Professor, Attending Surgeon (50% clinical)

Clinical Productivity
FY 23: 12,135 wRVU, 329 outpatient surgeries, 106 inpatient surgeries, >500 procedures

Clinical Draw from outside Local/Regional Area
28% of my patients come from outside the state of Maryland

Clinical Program Building / Leadership

2018 Co-Director, Bladder Cancer Precision Medicine Center of Excellence
This program constitutes one of the first programs of its kind for bladder cancer in the United States, and involves a multidisciplinary clinical team working seamlessly with a translational science team to tailor bladder cancer patient management based on cancer genomics and predictive biomarkers.
2020 Director, Bladder Cancer Program
In this current role I lead the clinical and research aspects of the bladder cancer program in the urology department. Under my leadership from 2020 to 2023, surgical case volumes increased 28%, medical oncology visits increased 56% and we underwent a coordinated expansion of our enterprise into the Washington DC area and Southern Pennsylvania. Our research program also grew between 2020 and 2023, with a 28% increase in patients accrued to clinical trials, and multiple PIs with multi-year extramural funding.
2023 Director, Division of Urologic Oncology
In this current role I oversee a team of 14, including 5 urologic oncology faculty members as well as 2 advanced practice providers, 2 nurses, and 5 administrative assistants. Highlights of my tenure thusfar have included the recruitment of 3 faculty members and the successful fundraising of a $300K urologic oncology innovation fund, which provides early stage "seed" funding for junior faculty and trainees.

Clinical Demonstration Activities to external audience, on or off campus

9/7/19 Resident Preceptorship in Robotic Surgery to national group of urology residents, JHU Blalock building
11/18/19 Presented techniques regarding robotic cystectomy to visiting Chinese delegation, JHU Viragh building

Development of nationally/internationally recognized standard of care
Currently serving as Study Chair on EA8212 BRIDGE, which is a potentially practice changing trial that is randomizing newly diagnosed non-muscle invasive bladder cancer patients to standard of care BCG or Gemcitabine/Docetaxel chemotherapy.

EDUCATIONAL ACTIVITIES

Educational Focus
I am a dedicated educator to the medical students, residents, and fellows I interact with on a daily basis. My educational goals are to train technically sound and emotionally caring physicians and surgeons, and I do that through formal didactics and informal apprentice style teaching in the operating room.

Classroom Instruction

JHMI/Regional
2014-2015 Small Group Instructor, genitourinary pathophysiology for 1st year medical students, Johns Hopkins School of Medicine
2020 Lecturer, "Genes to Society" course for second year medical students
2020-2023 Lecturer, "Approach to hematuria", Bayview internal medicine didactics (3 separate lecturers)
National
NA

International
2023 & 2024 Course Director, "Contemporary Techniques in TURBT" American Urologic Association Annual Meeting, instructional course.

Leading a team of 4 faculty, we present case based didactic discussion regarding best practices in transurethral resection for bladder tumors.

Clinical Instruction

JHMI/Regional

2018-2024 As an Attending Surgeon at Johns Hopkins Hospital, I participate daily in surgical education of the resident and medical students

Mentoring

I spend many hours each week mentoring medical student, resident, and fellows in both clinical urology as well as on their research skills and careers. The following is a brief list of trainees that have spent a dedicated research year or summer with me.

Pre-doctoral Advisees /Mentees

2015-2018 Meera Chappidi (mchappi1@jhmi.edu): [Medical Student] currently urology resident UCSF. I mentored Meera during her dedicated research year. Working on clinical bladder cancer projects, she presented at several national meetings and had multiple first author publications. Co-authored article OR40 OR43 OR49 OR50 OR52 OR54 OR58

2015-2017 Aaron Brant (abrant@jhmi.edu): [Medical Student] Currently urology resident NYUI mentored Aaron in his Persky summer research fellowship between 1st and 2nd year of medical school. His project focused on the role of TURBT in accounting for the complete responses seen after neoadjuvant therapy for bladder cancer. He was able to present his work at several national meetings including the AUA and GU-ASCO, and published his work in *Urologic Oncology* article OR 80

2016-2018 Niv Milbar (nmilbar1@jhmi.edu) : [Medical Student]. Currently plastic surgery resident, NYU. Also Mentored Niv during Persky research fellowship on a project assessing our institutional experience with intravesical gemcitabine/docetaxel. Co-authored article OR59

2018-2019 Marcus Daniels (mdaniel56@jhmi.edu): [Medical Student] Currently radiology resident NYU. Spent a dedicated research year with me to advance his knowledge in clinical and translational research in bladder cancer. Co-authored articles OR81 OR84

2022-present Pranjal Agrawal (pagrawa9@jhmi.edu): [Medical Student] Currently an incoming urology resident at Johns Hopkins. Spent a dedicated Persky summer evaluating opportunistic salpingectomy to prevent ovarian cancer at the time of radical cystectomy.

Post-doctoral Advisees /Mentees

2020-present Sunil Patel [urologic oncology fellow]. Co-authored articles OR93 RA15
2022-present Katherine Mahon [urology resident]
2022-present Tony Su [urology resident]
2023-present Michael Rezzae [urologic oncology fellow]

RESEARCH ACTIVITIES

Research Focus

My research seeks to improve care for patients with urologic disorders by 1) Predicting response to current treatments including intravesical BCG for bladder cancer 2) Developing novel therapies and diagnostic modalities to aid in treating and characterizing disease and 3) Assessing outcomes of failure including surgical complications and staging. As a surgeon with one eye towards the laboratory bench and another towards the patient experience, I hope to be well-adapted to generate important questions and tangible solutions for my patients.

Inventions, Patents, Copyrights

4/22/2020 Co-author [Ensign, L, Hanes J, Date A, Bivalacqua T, Kates M].Method to achieve enhanced delivery to the bladder C1402, pending

ORGANIZATIONAL ACTIVITIES

Institutional Administrative Appointments
NSQIP Collaborative Committee
Robotic Steering Committee
Surgical Instrument Committee
SOM Research Council
ERAS Steering Committee
Wellspan Expansion Committee
Surgical Instrument Committee
Clinical Competency Committee

Editorial Board Appointments

2021-present Consulting Editor, *Urologic Oncology: Seminars and Original Investigations*

Journal peer review activities

2015-present *European Urology*
2015-present *Scientific Reports*
2012-present *Journal of Urology*
2013-present *Urologic Oncology: Seminars and Original Investigations*
2012-present *Urology*
2013-present *BJUI*
2017-present *Clinical Genitourinary Cancer*
2018-present *Bladder Cancer*
2018-present *Journal of Clinical Oncology*
2024-present *New England Journal of Medicine*
2024-present *Journal of Controlled Release*
2024-present *Clinical Cancer Research*

Advisory Committees, Review Groups/Study Sections

2016 Grant Reviewer, Medical Research Council (MRC), United Kingdom 2016
2020 Grant Reviewer, Bladder Cancer Advocacy Network John Quale Fellow, 2020
2021 Grant Reviewer, Swiss National Science Foundation, Switzerland, 2021
2022,2023 Grant Reviewer, Bladder Cancer Advocacy Network Career Development Award

Professional Societies

2012-current Gold Humanism Society

2012-current	Alpha Omega Alpha Honor Society
2012-present	American Urological Association
2018-present	Society of Urologic Oncology
2018-current	International Bladder Cancer Network
2020-present	Mid-Atlantic Section of American Urologic Association, Young Urologist Committee Member
2021-present	Bladder Cancer Advocacy Network, BCAN Think Tank Steering Committee (3yr term 9/2021-8/2024)
2023-present	Committee Chair, BCAN John Quale Travel Fellowship Committee

Invited Talks

JHMI/Regional

5/17 Speaker, "Bladder Cancer" ; Bladder Cancer Awareness Month Lunch n' Learn, Johns Hopkins, Baltimore, MD

5/18 Speaker, "Bladder Cancer"; Bladder Cancer Awareness Month Lunch n' Learn, Johns Hopkins, Baltimore, MD

9/19 Guest Faculty/Moderator, National Resident Preceptorship in Robotic Surgery (JHH Campus) , Baltimore, MD

9/19 Speaker, Adaptive Immune Resistance to Intravesical BCG in Non-Muscle Invasive Bladder Cancer: Implications for Prospective BCG Unresponsive Trials, *Amtrak Alliance Meeting,* Philadelphia, PA

12/20 Speaker, "Muscle Invasive Bladder Cancer: A Guidelines Based Approach" Mid-Atlantic AUA UroBrief Webinar Series.\, virtual

1/21 Speaker, "Bladder Cancer—Management with updates on Chemo/Immunotherapeutic Agents", Mid-Atlantic AUA APP Annual Meeting, virtual

3/23 Speaker- Mid-Atlantic Mondays. "BCG Unresponsive", virtual

9/23 Keynote Speaker, "Updates in NMIBC Trials." Advances in the Management of Prostate, Kidney, and Bladder Cancers 2023, Washington DC

National

10/17 Speaker, AUA Bladder Health Alliance Roundtable, National Bladder Cancer Representative, Linthecum, MD

6/18 Speaker, Biology of Bladder Cancer Workshop, National Cancer Institute, Bethesda, MD

4/20 Speaker, "Updates in Muscle Invasive Bladder Cancer", Empire Urology Series, New York, NY (This talk was given via zoom videoconference)

5/20 Moderator, Bladder Cancer & Urinary Diversion Video Session, American Urological Association Annual Meeting (*This conference was cancelled secondary to the COVID-19 Pandemic)*

8/20 Plenary Speaker: "BCG Unresponsive Bladder Cancer: Time to Recalibrate". Bladder Cancer Advocacy Network Think Tank Virtual Session (2 hr virtual session in lieu of meeting)

10/20 Panelist: New Developments and Therapies. Bladder Cancer Summit for Patients and Families (*This conference was made a virtual event secondary to the COVID-19 Pandemic)*

12/20 Plenary Speaker: "Next Generation Clinical Trial Design for BCG Unresponsive NMIBC, Society of Urologic Oncology Annual Meeting (*This conference was made a virtual event secondary to the COVID-19 Pandemic)*

1/21 *Speaker: What They See in my Pee: Uncovering the Mysteries of Urine Cytology.* Bladder Cancer Advocacy Network Patient Webinar (*This conference was made a virtual event secondary to the COVID-19 Pandemic)*

3/21 Speaker: "Predicting response to BCG". FDA/AUA/GBCI Joint Symposium: Drug Development in NMIBC from Scientific, Regulatory, Clinician, and Patient Perspectives. (*This conference was made a virtual event secondary to the COVID-19 Pandemic)*

5/21 Plenary Speaker: American Urologic Association Annual Meeting, Virtual Kickoff Weekend. Bladder Cancer: Management with Updates on Chemo/Immunotherapeutic Agents

8/21 Plenary speaker: BCG and the Tumor Microenvironment. Bladder Cancer Advocacy Network Think Tank (*This conference was cancelled secondary to the COVID-19 Pandemic)*

10/21 Speaker: *Beyond BCG to exploit immunomodulation for bladder cancer therapy* 7th Leo & Anne Albert Institute Bladder Cancer Symposium, Kansas City, MO.

5/22 Speaker, Montefiore Urology Grand Rounds (virtual)

5/22 Plenary Speaker: "Rescue Therapy and BCG Alternatives in Non-Muscle Invasive Bladder Cancer". American Urologic Association Annual Meeting, Society of Urologic Oncology section, New Orleans, LA.

8/22 Speaker, UPenn Urology Grand Rounds (virtual)

10/22 Speaker: "Biomarkers of GEMDOCE response", Urologic Research Society (URS), Charlottsville, VA

12/22 Plenary Speaker: "The future of BCG Naïve Therapy is intravesical", Society of Urologic Oncology (SUO) Annual Meeting, San Diego, CA

2/23 Plenary Speaker "Next generation therapies in NMIBC", ASCO-GU Annual Meeting, San Francisco, CA

4/23 Plenary Speaker "Optimal Management of cN+ MIBC: PRO local consolidation", SUO at the AUA Annual Meeting, Chicago, IL.

9/23 Speaker, "The Rationale for Chemoablation in IR-NMIBC", Albert Institute Annual Meeting. Denver, CO.

2/24 Plenary Speaker "A New Era in the Perioperative Management of Muscle invasive Bladder Cancer", ASCO-GU Annual Meeting, San Francisco, CA

International

8/18 Speaker, XV Paulista Congress of Urology (Sao Paolo, Brazil). Guest Faculty
Case Discussions
- Prostate Cancer Challenging Clinical Case Discussion - International Panel
- Kidney Cancer Challenging Clinical Case Discussion - International Panel
- Bladder Cancer Challenging Clinical Case Discussion - International Panel
- Complications of cystectomy and bladder cancer recurrence after cystectomy (plenary)

Lectures
- "BCG shortage, BCG failure and emerging intravesical drugs"
- Flourescent light guided cystoscopy – new gold standard? (plenary)
- Cystectomy in the elderly over 75 years - contemporary evaluation (plenary)
- Urothelial bladder carcinoma (pT1) - multiple recurrences after intravesical therapy

6/19 Speaker, Pearl River Urology Hi-Tec Forum (Guangzhou, China). Guest Faculty
- Flourescent Blue Light Guided Cystoscopy—The New Gold Standard?

9/19 Speaker, Uro Onco Litoral (Santos, Brazil). Guest Faculty
Case Discussions
- Bladder Cancer Challenging Clinical Case Discussion - International Panel

Lectures

- "BCG Unresponsive Bladder Cancer: When and How to Avoid Cystectomy"
- Muscle Invasive Bladder Cancer Preservation, who, what, and how?
- Bladder Cancer Lymph Node Dissection in 2019

7/20 Speaker, Association of Urologists of Central American and the Caribbean (Meeting cancelled due to COVID-19 and converted to online format). Guest Faculty. "Trimodal therapy for bladder cancer"

6/21 Speaker, European Association of Urology (EAU) Section of Urological Research (ESUR) Monthly Webinar Series. Speaker, "Understanding the tumor micro-environment in urological cancers to improve immuno-therapy"

10/23 Speaker, Updates on a Phase 2 trial of GemDoce for BCG Naïve NMIBC, and Explorations into Mechanisms of Response. Urologic Research Society, Heidelberg, Germany

10/23 Keynote Speaker and Guest Faculty, 15th Hong Kong Urology Symposium, Hong Kong

- "Sequential intravesical gemcitabine and docetaxel for high risk NMIBC"
- "How to Optimize kidney sparing surgery for UTUC"

Background and Interests

Married - Rena Stern Kates, Esq
Children- Eli (9), Amira (7), Henry (4)
Academic – Student Body President, Alamo Heights High School, San Antonio, Tx
Hobbies – Tennis (former Texas team tennis state champion, former college team captain and #1 player), Gardening, skiing, hiking, travel.