Exhibit 365

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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: *Raymond v. United States, Case No: 7:23-cv-00546*
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 Edward Raymond's allegations about the cause of Mr. Raymond's bladder cancer and to respond to the expert report and opinions of his expert, Dr. Vincent M. Bivens. Mr. Raymond alleges, and Dr. Bivens opines, that Mr. Raymond'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. However, based on my training, experience, and expertise, it is my opinion, to a reasonable degree of medical certainty, that Mr. Raymond's bladder cancer was most likely caused by a combination of risk factors and unlikely caused by exposure to water at Camp Lejeune. Specifically, Mr. Raymond was a 75-

year-old man at the time of his bladder cancer diagnosis with a 50-year smoking history and a nearly 40-year occupational exposure history of working in a silicone factory.

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 resections 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

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

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 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." (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) 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.[3](15)

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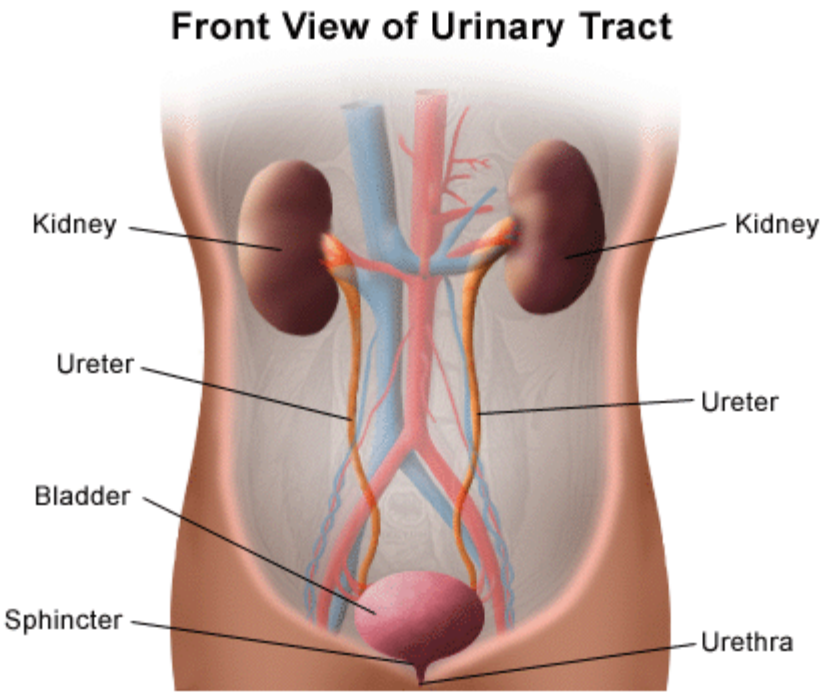
[2] U.S. Food & Drug Administration Orphan Drug Designations and Approvals (https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=445114).
[3] Illustration modified from Johns Hopkins Medicine (https://www.hopkinsmedicine.org/health/wellness-and-prevention/anatomy-of-the-urinary-system).



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 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

[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.

begin smoking between ages 18-20 compared to a 2 times increased risk among those who begin 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% diagnosed 30-39 years after quitting, 13% diagnosed 40-49 years after quitting, and 7% diagnosed 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.

iii. 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 five 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)

iv. 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, austosomal 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.

v. 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)." (*See* 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.

vi. 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.

vii. Idiopathy

Despite all that is known about bladder cancer risk factors, its estimated that approximately 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

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

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 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 Edward Raymond's Case

A. Diagnosis

Edward Raymond (DOB [redacted]1945) is a 79-year-old man that was diagnosed with non-muscle invasive bladder cancer based on a pathology report from a transurethral resection of a

bladder tumor (TURBT) performed on December 17, 2021. He was 75 years old at the time of diagnosis.

B. Camp Lejeune Exposure History

Mr. Raymond worked and resided at Camp Lejeune in the Hadnot area from approximately November 1963-December 1965. Mr. Raymond's bladder cancer was diagnosed in 2021, over 55 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. Raymond 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. Raymond'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. Raymond's exposures to TCE, PCE, benzene, vinyl chloride, and 1,2-tDCE from tap water during the approximately years that he was stationed at Camp Lejeune are causally associated with his bladder cancer.

C. Social and Family History

Mr. Raymond's medical records reflect, and he testified, that he smoked one pack of cigarettes per day for 50 years before quitting in 2013 because he was diagnosed with chronic obstructive pulmonary disease (COPD). Mr. Raymond's wife also testified that she smoked one pack of cigarettes per day, that she and Mr. Raymond smoked together in their home, and that she quit smoking in 2013 after Mr. Raymond was diagnosed with chronic obstructive pulmonary disease. Mr. Raymond's cousin was also a former smoker and he was diagnosed with mouth

cancer, and Mr. Raymond's brother passed away from lung cancer after smoking for 60 years. Mr. Raymond's sister was diagnosed with and treated for pancreatic cancer.

In addition, Mr. Raymond worked as a control and chemical operator at a silicone plant in Waterford, New York for 38 years until he retired in 2006. In that role, Mr. Raymond testified that in that role, he worked with raw materials like silicon metal and silicone that were processed to make caulking material and silicone sealants. Mr. Raymond testified that he wore an N95 mask because "silicone dust itself is not good for you, so we would – you're required to wear masks or respirators." (Edward Raymond Deposition., pp. 153-154.) I am aware that the specific silicone plant that Mr. Raymond worked at appears to be the subject of litigation related to toxic exposure claims.

D. Bladder Cancer History

Prior to Mr. Raymond's bladder cancer diagnosis in 2021, Mr. Raymond had multiple significant and severe medical problems specifically related to his heart and lungs. Specifically, he had a diagnosis of COPD, diastolic congestive heart failure with preserved ejection fraction, pulmonary hypertension, and atrial fibrillation. On June 16, 2013, Mr. Raymond was treated for gastric and duaodenal ulcers with biopsy, thermal therapy, and proton pump inhibitors. It was recommended that he quit smoking at that time. On November 26, 2013, he had umbilical and inguinal hernias repaired surgically.

With respect to his bladder cancer, Mr. Raymond presented to the emergency room on October 28, 2021, with right lower quadrant abdominal pain and diarrhea for 3-4 weeks. He initially attributed his symptoms to bad food, but the pain persisted. Ultimately, these symptoms combined with feelings of a racing heart and palpitations prompted a visit to Saratoga Hospital ER. There he was found to be in atrial fibrillation and a subsequent workup with a CT of the

abdomen and pelvis with IV contrast on October 28, 2021, revealed a 2.3x1.4 cm mass in his bladder and a 10x7 cm mass in his cecum. A colonoscopy taken on November 1, 2021, identified an ulcerated area in the right colon; it was biopsied and found to be negative for malignancy. Given uncertainty whether this was a diverticular abscess versus a tumor, Mr. Raymond was started on IV antibiotics to cover for a diverticulitis flare. On November 2, 2021, he was scheduled to undergo a percutaneous biopsy of the abdominal mass under CT guidance, but this was unsuccessful because the mass was no longer seen on imaging; a follow up CT with IV contrast continued showing an ascending colon mass, and this was subsequently biopsied later in the day on November 2, 2021 and shown to not be cancer.

On November 15, 2021, Mr. Raymond underwent an outpatient cystoscopy by Dr. Zachary Passaretti, which revealed a large sessile appearing tumor on the left bladder wall, appearing more than 5cm. On December 17, 2021, Mr. Raymond underwent a transurethral resection of a >5cm bladder tumor by Dr Passaretti. During the procedure there was a bladder perforation secondary to an obdurator nerve response. Pathology was consistent with high grade bladder cancer invading the lamina propria (stage HGT1).

On March 4, 2022, Mr. Raymond underwent cystoscopy and random bladder biopsy as well as biopsy of prior resection site with fulguration. These biopsies demonstrated no evidence of malignancy. A subsequent cystoscopy on June 29, 2022, revealed several papillary recurrences, and another TURBT on July 26, 2022 was performed, with pathology demonstrating high grade noninvasive bladder cancer (stage HgTa). From September to October 2022, Mr. Raymond underwent an induction treatment course of intravesical BCG instillation weekly for 6 weeks. A cystoscopy on November 29, 2022, revealed possible erythema, but was otherwise without evidence of recurrence. A cystoscopy on March 7, 2023, continued to show this

erythema and it was fulgurated in the office at that time. During cystoscopies on November 22, 2023, and February 21, 2024, small papillary lesions were identified and fulgurated. Last available cystoscopy on May 22, 2024, demonstrated no evidence of recurrence but an area that Dr. Passaretti may plan to fulgurate at the time of next cystoscopy.

Given Mr. Raymond's severe lung disease, his urologist decided that the risk benefit of fulgurations is favored over TURBTs in the operating room under general anesthesia, which carries risk for someone with Mr. Raymond's pulmonary disease. In September of 2024, Mr. Raymond was admitted to the hospital with shortness of breath and found to have lung and mediastinal lesions on CT Scan. A full body PET scan was subsequently performed and demonstrated widespread metastatic disease involving the bladder, prostate, seminal vesicles, iliac lymph nodes, mediastinum lungs, and his T12 vertebral body. In October 2024, he met with Dr. Mahmood, a medical oncologist, with plans to begin systemic therapy with enfortumab vedotin and pembrolizumab (EV-Pembro).

E. Post Bladder Cancer Medical History

In the time following his bladder cancer diagnosis, Mr. Raymond has continued to be challenged by worsening lung function. On May 13, 2022, he was admitted to the hospital for pneumonia and acute respiratory failure, and more recently from February 27, 2024, to March 4, 2024, he was hospitalized for a COPD exacerbation and severe emphysema, where worsening lung function was noted. He is currently dependent on oxygen both at home and out of the house. Regarding his metastatic lung cancer on EV-pembro, Mr. Raymond's condition and clinical management is evolving, and this report may be supplemented as more records are available.

In addition to his bladder cancer, Mr. Raymond suffers from erectile dysfunction (ED), which has been treated with sildenafil (Viagra) with a good response. Mr. Raymond partially attributes his ED to his bladder cancer treatments, but as discussed below ED is not a typical side effect of treatments for localized bladder cancer. Furthermore, when discussing the ED in his deposition Mr. Raymond primarily "blames it on age" and I would agree that most men in their late 70s, especially with cardiac issues, will have some degree of ED.

IV. Opinions

My opinions regarding potential causes of Mr. Raymond 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 upper tract urothelial 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. Raymond was diagnosed with bladder cancer in 2021 at the age of 75. This was over 55 years after his last day at Camp Lejeune.

Smoking: Mr. Raymond's urologist, Dr. Passaretti, and I agree that the primary known risk factors for developing urothelial cancer is cigarette smoking. Mr. Raymond smoked 1-2 packs per day for 50 years, beginning in boot camp in 1963 and quitting in 2013 due to a diagnosis of COPD. His gastroenterologist on June 16, 2013, noted that he had a 50-pack-year smoking history, while his cardiologist Dr. Mikhail Mavashev noted on June 20, 2023, that Mr. Raymond

had an “extensive” smoking history, smoking 1-2 packs per day for fifty years. Kimberly O’Meara Zimmer NP on February 17, 2022, states that he had a 100-pack year smoking history. If each cigarette is smoked for 5-6 minutes, 1.5 packs (30 cigarettes) translates to 180 minutes of daily smoke inhalation for 50 years. As previously discussed, while smoking to any degree increases one’s risk of bladder cancer, long term, intensive smoking beginning at a young age puts one in the highest risk category. Mr. Raymond began smoking in 1963, at age 18. 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. Additionally, the dose response relationship in smoking has been established and reproduced in many different studies and in multiple different cancers, including bladder cancer. Those that smoke more than 40 pack years as Mr. Raymond did are at highest risk—with one study estimating a 9.4 fold increased risk of bladder cancer. (19) While Dr. Bivin notes that one’s risk of bladder cancer is reduced by 30% after 1-4 years of quitting, the most important factors in bladder cancer risk are duration and intensity of smoking behavior.(44) In a recent study evaluating risk of bladder recurrence, duration of smoking cessation was not found to be a factor in bladder cancer recurrence at all, while total pack years were the primary driver of carcinogenesis. Regardless, such an extensive smoking history likely caused, contributed to, or worsened several other of Mr. Raymond’s medical problems, including gastric and duodenal ulcer disease, COPD, pulmonary hypertension, and diastolic congestive heart failure. Taken together, cigarette smoking is the strongest risk factor for Mr. Raymond developing bladder cancer.

Occupation: A key secondary risk factor is occupation. Mr. Raymond had several different occupations that increased his risk of bladder cancer. Prior to enlisting in the military, Mr. Raymond grew up on a farm, working the fields, bailing hey. Mr. Raymond described fertilizer use in the fields at that time, though he was not involved in the fertilization of the crops. While long term agricultural work with longstanding pesticide and fertilizer exposure may be associated with bladder cancer development, this occupational risk is likely minor compared with Mr. Raymond's later nearly 40-year exposure working in a silicone production plant.(45)

On March 13, 1963, Mr. Raymond enlisted in the Marine Corp in Albany, New York after graduating from high school. He was in Parris Island, South Carolina in July 1963, where he was in basic training with the Third Rifle Battalion Infantry. From November 5, 1963, to December 1965, he served at Camp Lejeune maintaining equipment and training. As discussed above, 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. Raymond's potential exposures to TCE, PCE, benzene, vinyl chloride, and 1,2-tDCE from tap water during the 2 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. Raymond's bladder cancer.

After Camp Lejeune, Mr. Raymond went to Camp Pendelton in January 1966, and then Okinawa Japan in February 1966. He then served in Vietnam, in the Chu Lai area from March - November 1966 and then the Don Ha area from November 1966 to February 1967. His main job in Vietnam was serving in "coms support". Although he did check a box stating he was exposed to Agent Orange, this was a generalized statement given his service in Vietnam. Thus, there are no clear occupational risk factors related to Mr. Raymond military occupation.

In June 1967, Mr. Raymond was honorably discharged. He moved back home and "helped on the farm for a while". In September 1967, Mr. Raymond joined a General Electric silicone production plant where he was a control operator at GE for 38 years (eight years as a chemical operator actually injecting zinc catalyst with the silica dust and 30 years as control operator overseeing the equipment). He officially retired in 2006. In his role at GE, he would monitor the silicone reactor, stating, "we would take raw material, silica, and mix it with some heated gas. That was part of your job, is control the proper stuff going into the reactor mixing with the silicone powder to get the best quality." Mr. Raymond stated that hearing protection was used in addition to safety glasses, a helmet and a respiratory mask because "the silicone dust itself is not good for you." I disagree with the plaintiff expert Dr. Bivins's claim that Mr. Raymond's work in a chemical plant using silica dust does not constitute an occupational risk factor for bladder cancer. There is strong evidence to suggest that working in a manufacturing environment with silica dust and with organic solvents increases ones risk of bladder cancer.(46,47) For example, rubber workers have one of the strongest associations with bladder cancer.(22) Mr. Raymond worked in a factory for more than 38 years with silica dust, and thus his occupation plays a risk in his bladder cancer development. Thus, I conclude that Mr. Raymond's nearly 40-year exposure working in a silicone production plant is a risk factor for his bladder cancer.

Family History: Another risk factor for bladder cancer that likely is not a factor in this particular case is familial risk. Mr. Raymond has no known family history of bladder cancer. His brother died of lung cancer, which Mr. Raymond attributed to 60 years of smoking. His sister is currently being treated for pancreatic cancer. His father is deceased at age 82 from congestive

heart failure. His mother passed at age 94 of cardiopulmonary disease. He has a brother with cardiovascular disease. I would thus rule out family history as a risk factor.

Inflammation: Mr. Raymond has no known history of chronic catheterizations or other inflammatory conditions that might increase his risk of developing bladder cancer. I am able to rule out inflammation as a risk factor.

Body Mass Index: Mr. Raymond was documented as having a BMI of 25.09 kg/m^2 on May 22, 2024. A normal healthy BMI is considered a BMI of 18.5-24.9 and any BMI above 25 is considered overweight, with a BMI above 30 obese. Mr. Raymond's BMI likely is not a risk factor to his bladder cancer development and can be ruled out.

Idiopathy: Given the strong competing risks of smoking and occupational exposures, idiopathy is less likely the primary contributing cause of his bladder cancer, but it can never be ruled out completely even though in this case there are 2 other primary strong risk factors in his cigarette smoking and occupational histories.

Conclusions regarding differential etiology: Given what is known about these competing risk factors, my opinion to a reasonable degree of medical certainty is that Mr. Raymond's 50-100 pack year smoking history combined with his occupational exposures working daily with silica dust in a silicone chemical plant are the strongest and most likely risk factors for him developing bladder cancer. My opinion is consistent with the testimony of Mr. Raymond's urologist, Dr. Passaretti. When asked whether he had an opinion about the cause of Mr. Raymond's bladder cancer, Dr. Passaretti testified that "I don't, other than he was a smoker…" and that Mr. Raymond "worked as a chemical engineer as well, and who knows what -- what exposures can occur." (Zachary Passaretti Deposition., pp.89-90).

B. Prognosis

Currently, Mr. Raymond has metastatic bladder cancer on EV-pembro. At the time of his last clinical note (February 18, 2025) that I have been able to review, Mr. Raymond's pembrolizumab was being held due to pneumonitis, and he was being treated with EV monotherapy. His stage would thus be T4N3M1b, according to TNM staging, due to locally advanced bladder cancer into the prostate (T4), nodal disease up the common iliac chain (N3), and more than 1 site of distant disease spread (T12 vertebra and lungs—M1b). The median overall survival of patients with metastatic bladder cancer on EV-pembro is 31.5 months; however, given the extent of Mr. Raymond's disease and his other pulmonary and cardiac problems, his prognosis is likely worse than this, and he is more likely to die of bladder cancer than any other cause. The intent of his current treatment has been stated in the records as palliative. While some patients experience long term durable complete responses with EV-pembro, unfortunately Mr. Raymond has thus far not demonstrated this after more than 6 cycles. Additionally, he continues to be on EV monotherapy alone due to pulmonary toxicity from the pembrolizumab. Treatment associated with EV-Pembro, while effective, does come with toxicity. Up to 55% of patients will have some type of toxicity that leads to a hospital admission (Grade 3). As his cancer progresses, he is likely to experience increasing pain due to cancer spread to other areas of the body, and his urinary symptoms may worsen.

Mr. Raymond alleges that he is experiencing erectile dysfunction secondary to his bladder cancer. Mr. Raymond complained of erectile dysfunction and diminished libido at a clinic visit on June 13, 2023. Dr. Passaretti notes this would not be unusual at age 77 and that it is amazing he had not needed medications up to that point. I would concur given the patient's

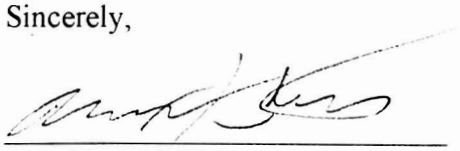
cardiac disease and age that some degree of ED is expected. Therefore, his ED is unrelated to his bladder cancer diagnosis or treatment.

V. Conclusion

In conclusion, it is my opinion that 1) Mr. Raymond did have a pathologically confirmed Bladder Cancer. 2) His bladder cancer was most likely caused by a combination of risk factors and unlikely caused by exposure to water at Camp Lejeune. Specifically, Mr. Raymond was a 75-year-old man at the time of his bladder cancer diagnosis with a 50-year smoking history and a 40-year occupational exposure history of working in a silicone factory.

These are my opinions as of the day of this report. These opinions are based upon my training and experience, my review of the case-specific records or materials, and 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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CURRICULUM VITAE
The Johns Hopkins University School of Medicine

Max Kates Date of this version: April 8, 2025

DEMOGRAPHIC AND PERSONAL INFORMATION

Current Appointments

University

2018-present	R. Christian B. Evensen Professor of Urology Associate Professor, Urology and Oncology Director, Bladder Cancer Program Director, Division of Urologic Oncology Johns Hopkins Hospital Baltimore, MD

Hospital

2018-present	Attending Physician, Johns Hopkins Hospital

Personal Data

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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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12. Yoshida T, **Kates M**, Fujita K, Bivalacqua TJ, McConkey DJ. Predictive biomarkers for drug response in bladder cancer. Int J Urol. 2019 Nov;26(11):1044-1053. doi: 10.1111/iju.14082. Epub 2019 Aug 1. Review. PubMed PMID: 31370109.
13. Gupta M, **Kates M,** Bivalacqua TJ. Immunotherapy in nonmuscle invasive bladder cancer: current and emerging treatments. Curr Opin Oncol. 2019 May;31(3):183-187.doi: 10.1097/CCO.0000000000000533. PubMed PMID: 30893148
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.