Exhibit 363

JOHNS HOPKINS
MEDICINE

Brady Urological Institute
600 North Wolfe Street | Marburg 401C
Baltimore, Maryland 21287-2101
Office: 410-614-0009
Fax: 410-614-3695
Email: mkates@jhmi.edu

Max Kates, M.D.
R. Christian B. Evensen Professor of Urology and Oncology
Director, Division of Urologic Oncology
Associate Professor of Urology and Oncology

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

Re: *Robert J. Fiolek v. United States, Case No: 7:23-cv-00062-D-BM*
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 Robert J. Fiolek's allegations about the cause of Mr. Fiolek's bladder cancer and to respond to the expert report and opinions of Mr. Fiolek's expert witness, Dr. Damian Laber. Mr. Fiolek alleges and Dr. Laber suggests that Mr. Fiolek's bladder cancer and upper tract urothelial carcinoma (UTUC) were secondary to or caused by his treatment for chronic lymphocytic leukemia (CLL). However, based on my training, experience, and expertise, it is my opinion, to a reasonable degree of medical certainty, that Mr. Fiolek's bladder cancer and UTUC were most likely caused by a combination of risk factors. Specifically, Mr. Fiolek was an 84-year-old man at the time of his bladder cancer and UTUC diagnosis, and he was a former smoker with a history of bladder cancer in his immediate family.

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 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

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

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)

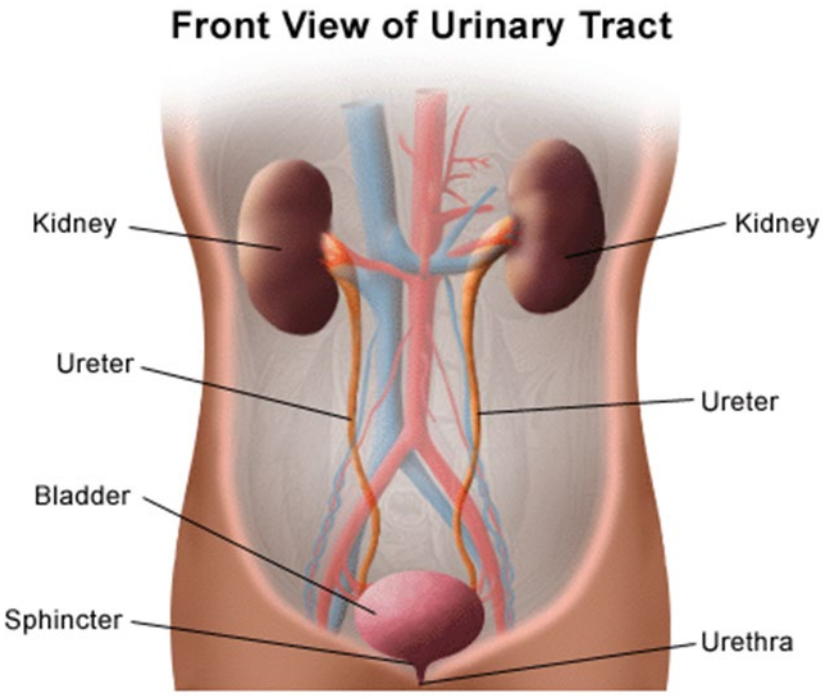
Bladder cancer is typically a disease of aging, with age adjusted incidence rates increasing with each decade of life. The average age of diagnosis in the US is 73, with 90% of patients diagnosed after the age of 55. Men have a three times higher increased risk of developing bladder cancer compared to 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 Caucasian patients, and it remains unclear whether this increased risk is due to factors involving access to care or tumor biology. (9)

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. (10) 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. (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, who 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, who 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%.

[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.

Worldwide there are more than 1 billion current smokers, and smokers have a 2 to 3 times increased risk of bladder cancer. (13) Cigarette, pipe, and cigar smoking have all been linked to bladder cancer development. (14) Aromatic amines are the primary carcinogens contained in tobacco smoke that lead to bladder cancer development. (15) 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 two times higher risk with less than 10 cigarettes (1/2 pack) per day. (16) 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. (16) Additionally, the age of onset of smoking is highly associated with bladder cancer risk, with one study demonstrating a four times increased risk among those who begin smoking between ages 18-20 compared to a two 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. (16) Nevertheless, even individuals with a long latency period who smoked relatively few cigarettes are still at increased risk compared to the general population. (16) 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. (17,18) 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. (17)

I agree with the 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. Occupational Exposures:

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. (19) Workplace exposure to silica and asbestos in particular have also been linked to a 20% increased risk of bladder cancer. (20) More data exists linking occupational exposures to bladder cancer among petroleum workers, with one meta-analysis of eight studies demonstrating a 40% increased risk. (21–23) The typical latency period from workplace exposures to bladder cancer diagnosis is thought to be variable. (24) 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. (25)

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. (26) 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. (27)

iv. Family History

First degree relatives of bladder cancer patients have a two times higher risk of developing bladder cancer. Sometimes this risk is part of a broader cancer syndrome such as Lynch syndrome. (28) 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*. (29) 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. (30,31) 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. (32)

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). 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). (33,34) But it also includes conditions that cause a neurogenic bladder, requiring frequent catheterizations. (35,36) 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 hyperplasia, primary bladder hypermotility, or urethral stricture disease has itself been linked to a 4-8 fold increased risk of bladder cancer development. (37,38) 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, it is estimated approximately 40% of bladder cancer cases cannot be attributed to a known risk factor. (39) These cases are termed idiopathic, as the underlying cause is either spontaneous or not yet known.

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 malignant, the TURBT will stage the cancer. Bladder cancer stages are typically divided into three 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 <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 more than 3cm high grade noninvasive tumor. (40) Depending on the NMIBC risk category, these patients are treated with observation or bladder immunotherapy or chemotherapy washes (termed intravesical instillations). The most common 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 or 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%. (41)

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

A. Diagnosis

Robert Fiolek (DOB [redacted]/1940) was diagnosed with non-muscle invasive bladder cancer and non-invasive upper tract urothelial cancer of the distal left ureter based on a transurethral resection of a bladder tumor (TURBT) on April 19, 2024. He was 84 years old at the time of diagnosis.

B. Bladder Cancer History

I have reviewed the thorough summary of Mr. Fiolek's medical history in the Expert Report of Dr. Harry P. Erba, M.D., Ph.D, who offered opinions from his expertise as a leukemia specialist

and doctor. I also have reviewed the transcript and exhibits from the deposition of the urologist and treating physician for Mr. Fiolek's bladder cancer and UTUC, Dr. Jeffrey Goodwin.

To briefly recap the medical history relevant to Mr. Fiolek's bladder cancer, on February 13, 2024, Mr. Fiolek was seen in clinic for gross hematuria, and a subsequent CT of the abdomen and pelvis on March 5, 2025, demonstrated no urologic abnormalities. He was referred to Dr. Goodwin, who obtained a urine cytology on March 8, 2024, which came back with atypia—an inconclusive diagnosis that that is seen with any benign or malignant inflammation of urothelial cells. A subsequent CT urogram on April 2, 2024, showed concern for a left ureteral filling defect on delayed phase. On April 19, 2024, Mr. Fiolek underwent a cystoscopy and a TURBT of a bladder tumor involving the left ureteral orifice. Because a tumor was seen tracking up into the left ureteral orifice, a ureteral stent was placed. He was given perioperative chemotherapy (gemcitabine) at that time. Pathology came back as high grade noninvasive urothelial cancer (HgTa). He obtained a second opinion at UNC with Dr. Marc Bjurlin and the genitourinary tumor board, which recommended a left ureteral stent in place or surgery with a robotic left distal urethrectomy.

From April 28, 2024, to June 11, 2024, he underwent an induction course of intravesical BCG, and then a second induction course with a stent in place from August 13, 2024, to October 1, 2024. A subsequent cystoscopy and ureteroscopy on November 15, 2024, demonstrated residual papillary disease in the left distal ureter, which were biopsied and returned as high grade invasive urothelial carcinoma. A surgical referral was made to University of North Carolina Hospitals and he was seen in clinic by Dr. Marc Bjurlin on February 3, 2025, where a plan was made for him to 1) undergo repeat ureteroscopy to determine the exact location and length of tumor involvement of the ureter; 2) perform a surgical resection of the diseased part of the ureter with a reimplantation

of the left ureter into the bladder; and 3) delivery of intravesical combination gemcitabine and docetaxel for the recurrence of urothelial cancer after BCG. It appears that this evaluation and plan is currently ongoing and this report may be supplemented as more records are available.

IV. Opinions

In terms of evaluating Mr. Fiolek's risk of urothelial cancer development, he has a few risk factors that are well known causes of urothelial cancer. My opinions regarding potential causes of Mr. Fiolek developing urothelial 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 urothelial cancer, in order to provide an opinion on the factors most likely responsible for causing their urothelial cancer.

A. Differential Etiology/Diagnosis

Smoking: The primary known risk factor for developing urothelial cancer is cigarette smoking. Mr. Fiolek smoked 1-1.5 packs/day for approximately 15 or more years (approximately 1956 to the early 1970s), and began smoking at approximately age 16. As discussed, there is data suggesting that age of onset is crucial in urothelial cancer risk development, with one study demonstrating a four times higher increased risk among those who begin smoking between ages 18-20 compared to a two times higher risk among those that begin after age 31. (16) Additionally, the dose response relationship in smoking has been established and reproduced in many different studies and in multiple different cancers, including urothelial cancer.

It is true that Mr. Fiolek appears to have stopped smoking in the early 1970s, decades before his bladder cancer and UTUC diagnosis. However, as noted above, while his relative risk of bladder cancer decreased over time following his cessation of smoking, it remains significantly elevated compared to a never-smoker. Thus, Mr. Fiolek's smoking history, especially given that he began smoking at a young age and accrued approximately 15-20 pack-years, is a strong risk factor for his bladder cancer.

Family History: Another risk factor for urothelial cancer is familial risk. Mr. Fiolek's mother, Ms. Genevieve Potter, died from urothelial cancer at a young age. As previously stated, first degree relatives with urothelial cancer lead to a two-fold increased risk of urothelial cancer in their progeny. Similarly, an estimated 13-24% of patients with urothelial carcinoma will harbor pathogenic germline variants, suggesting there is a portion of patients who pass down germline mutations to their family. Mr. Fiolek's family history of lethal urothelial cancer thus comprises a strong risk factor for his own urothelial cancer development.

Body Mass Index: Mr. Fiolek was documented as having a BMI of 36.77 kg/m^2 in August 2014. 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. As previously discussed, there may be a dose response relationship where the relative risk of developing urothelial cancer increases as BMI increases. Therefore, I cannot rule out BMI as a risk factor in this case.

Occupation: After his military service, Mr. Fiolek worked as a detective. He does not appear to have any occupational risk factors for developing urothelial carcinoma. Therefore, I am able to rule out occupational history as a risk factor in this case.

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

Idiopathy: Given the strong competing risks of smoking and familial history (and possibly obesity), idiopathy is less likely the primary cause of his urothelial cancer.

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. Fiolek's CLL or its treatment played no role in him developing urothelial cancer. Mr. Fiolek likely developed urothelial cancer due to his extensive smoking history and strong family history, with his elevated BMI playing a potential role.

B. Prognosis

Mr. Fiolek is currently 85 years old, and thus far he has stage 1 bladder cancer/UTUC of the distal ureter that has been resistant to intravesical BCG. In this type of patient, set to undergo a distal urethrectomy, the risk of cancer metastasizing is approximately 10%, which is about the same as the risk of cancer death. His treatment is ongoing and I may change my view of the patient's prognosis and ongoing needs as more information regarding his treatments is reported.

C. Response to the Opinions of Dr. Laber

Dr. Laber opines that "[s]urvivors of leukemia and lymphoma treatment have an increased risk for developing a second cancer like bladder cancer compared with the general population." (Dr. Laber – Fiolek Report; p. 9). This is incorrect with regard to urothelial cancer.

Urothelial cancer is not thought to be a secondary malignancy after chemotherapy or any anti-cancer systemic therapy. There is no data to support the concept that a CLL diagnosis and subsequent treatment is a risk factor for urothelial cancer development, and the paper cited by Dr.

Laber is from the SEER database—a source only designed to identify cross sectional associations. Further, urothelial cancer is not discussed in that paper.[5]

The only chemotherapy that has been found to increase one's risk of urothelial cancer is cyclophosphamide and Mr. Fiolek never was exposed to that therapy. The CLL medications that he received (i.e., obinutuzumab, ibrutinib, and venetoclax) have not been found to increase the risk of urothelial cancer. Similarly, pelvic radiation for certain malignancies (i.e., rectal, prostate, cervical cancer) is a known risk factor for urothelial cancer. However, there is also no evidence to suggest Mr. Fiolek underwent pelvic radiation. Thus, Dr. Laber's opinion that it is "well known that prior chemotherapy and CLL both predispose patents to secondary malignancies" is not true when it comes to urothelial cancer. It is not agreed upon or even postulated in the urothelial cancer literature or research community that CLL increases one's risk for urothelial cancer, and thus there is no evidence to suggest that Mr. Fiolek was at increased risk for developing urothelial cancer due to his diagnosis or treatment of CLL.

Dr. Laber also opines that: "it is very likely that the intravesical BCG and the intravesical chemotherapy gemcitabine were not effective for Mr. Fiolek due to the presence of immune dysregulation of his CLL and the increased resistance to therapy in secondary malignancies as compared to primary ones." (Dr. Laber – Fiolek Report; p. 17). Again, I disagree with this opinion.

I have spent over a decade in my own research evaluating mechanisms of resistance to intravesical BCG and intravesical chemotherapy. Nowhere in the published literature is there evidence to suggest that a prior diagnosis of CLL, or any proposed immune dysregulation from

[5] Solomon BM, Rabe KG, Slager SL, Brewer JD, Cerhan JR, Shanafelt TD. Overall and Cancer-Specific Survival of Patients With Breast, Colon, Kidney, and Lung Cancers With and Without Chronic Lymphocytic Leukemia: A SEER Population-Based Study. J Clin Oncol. 2013;31(7):930-937. doi:10.1200/JCO.2012.43.4449.) (cited on p. 9 of Dr. Laber's report).

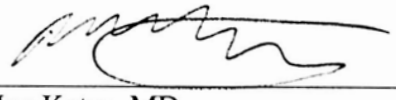
prior cancer, mitigates response to these intravesical therapies. Furthermore, the reason intravesical BCG was ineffective in managing Mr. Fiolek's urothelial cancer is that BCG often is ineffective for urothelial cancer. When intravesical therapies are delivered they are designed to treat the bladder. Even with a ureteral stent in place, very little drug can get refluxed into the ureter and thus intravesical therapies for urothelial cancers are more often than not a "Hail Mary"—highly unlikely to fully treat the disease and designed to try and avoid surgery in patients who are not good surgical candidates. With Mr. Fiolek being in his 80s, a former smoker with pulmonary and cardiac disease, general anesthesia and major surgery comes with significant risk and even though BCG was likely to be ineffective, it was attempted first given Mr. Fiolek's surgical risk. Thus, I would have expected the BCG to be ineffective for his urothelial cancer.

V. Conclusion

In conclusion, it is my opinion that 1) Mr. Fiolek did have a pathologically confirmed Bladder Cancer and Upper Tract Urothelial Cancer; and 2) his urothelial cancer was most likely caused by a combination of his extensive smoking history and his family history of bladder cancer and not caused by his prior diagnosis of CLL or its treatment.

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,



Max Kates, MD
Associate Professor of Urology and Oncology

Director, Division of Urologic Oncology
Director, Bladder Cancer Program
James Buchanan Brady Urological Institute
The Johns Hopkins Medical Institutions
600 N. Wolfe Street / Marburg 401c
Baltimore, Maryland 21287

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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

Urological Surgery
James Buchanan Brady Urological Institute
The Johns Hopkins Medical Institutions
600 N. Wolfe Street / Marburg 401c
Baltimore, Maryland 21287
Office: (410) 614-0009
Fax: (410) 502-7711
Mkates@jhmi.edu

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

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RE, Kutikov A, Guo G, Masterson TA, Adra N, Kaimakliotis HZ. A Phase 1 Trial of Durvalumab in Combination with Bacillus Calmette-Guerin (BCG) or External Beam Radiation Therapy in Patients with BCG-unresponsive Non-muscle-Invasive Bladder Cancer: The Hoosier Cancer Research Network GU16-243 ADAPT-BLADDER Study. Eur Urol. 2023 Jun;83(6):486-494.

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Other Publications
Review Articles

1. Sadeghi N, Badalato GM, **Kates M**, McKiernan JM. Management of residual non-retroperitoneal disease following chemotherapy for germ cell tumor. Urol Oncol. 2011 Nov-Dec;29(6):837-41.
2. **Kates M**, Badalato GM, McKiernan JM. Renal functional outcomes after surgery for renal cortical tumors. Curr Opin Urol. 2011 Sep;21(5):351-5.
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4. **Kates M**, Singh A, Matsui H, Steinberg GD, Smith ND, Schoenberg MP, Bivalacqua TJ. Tissue Engineered Urinary Conduits. Current Urology Reports. 2015; 16 (3):480-485.
5. Sopko NA, **Kates M**, Bivalacqua TJ. Use of regenerative tissue for urinary diversion. Curr.Opin.Urol. 2015;25 578-85.
6. **Kates M**, Sopko NA, Matsui H, Drake CG, Hahn NM, Bivalacqua TJ. Immune checkpoint inhibitors: a new frontier in bladder cancer. World J.Urol. 2015.
7. **Kates M,** Drake C. Immunotherapy for Prostate Cancer: Why Now. Urology Practice. *In Press*

8. Patel HD, **Kates M**, Allaf ME. Adjuvant Therapy for Urothelial and Renal Cell Carcinoma. Eur Urol Focus. 2020 Jan 15;6(1):3-6. doi: 10.1016/j.euf.2019.04.007. Epub 2019 Apr 26. PubMed PMID: 31031041.
9. Becker R, **Kates MR**, Bivalacqua TJ. Identification of Candidates for Salvage Therapy: The Past, Present, and Future of Defining Bacillus Calmette-Guérin Failure. *Urol Clin North Am*. 2020;47(1):15–21.
10. for bladder cancer. Nat Rev Urol. 2019 Oct;16(10):599-612. doi:10.1038/s41585-019-0220-4. Epub 2019 Aug 21. Review. PubMed PMID: 31434998.
11. Joice GA, Bivalacqua TJ, **Kates M**. Optimizing pharmacokinetics of intravesical chemotherapy
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.