

# Exhibit 344



# Toxicology Associates, Prof. LLC

*Dedicated to Patient Care, Research, and Teaching in Medical Toxicology*

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February 7, 2025

Re: Camp Lejeune (Dyer)

## CREDENTIALS, EXPERTISE, AND EXPERIENCE

By way of introduction, I am a medical toxicologist, emergency physician, and epidemiologist. I am currently an Associate Professor at the University of Colorado School of Medicine with a primary appointment in the Section of Medical Toxicology, Department of Emergency Medicine. In addition, I am an attending physician at the Rocky Mountain Poison and Drug Center as well as a member of Toxicology Associates, Prof. LLC, a hospital based, single specialty medical group dedicated solely to medical toxicology. I am board certified in both emergency medicine and medical toxicology, and I actively practice both emergency medicine and medical toxicology. Medical toxicology is an American Board of Medical Specialties recognized sub-specialty that deals specifically with human disease associated with any potentially toxic exposure. As a medical toxicologist, I specialize in the assessment, diagnosis, and treatment of adverse effects of pharmaceuticals, other chemicals, natural toxins, envenomations, and any other potential toxicants or toxicological conditions.

I received my M.D. at the University of Texas - Southwestern Medical Center in Dallas, Texas. After completion of this degree, I entered residency in emergency medicine at Denver Health Medical Center in Denver, Colorado. Following this, I worked as faculty in the emergency medicine residency program at Denver Health Medical Center and the University of Colorado School of Medicine for a single year. Subsequently, I entered medical toxicology fellowship training at Oregon Health and Science University in Portland, Oregon. During my fellowship, I simultaneously obtained a Masters in Public Health in epidemiology and biostatistics. Upon completion of my Fellowship and M.P.H. degree, I returned to Denver in 2013 and joined the faculty at the University of Colorado School of Medicine, the Rocky Mountain Poison and Drug Center, and Toxicology Associates.

In my role at the University of Colorado School of Medicine and the Rocky Mountain Poison and Drug Center, I provide case based teaching, didactic instruction, and supervision of clinical care provided by medical and pharmacy students, residents, and medical toxicology fellows-in-training. In addition, I am actively involved in research through the University of Colorado School of Medicine and the Rocky Mountain Poison and Drug Center. Furthermore, I have an active practice primarily caring for patients through Toxicology Associates. In all these capacities, I routinely evaluate and treat patients who present with both acute and chronic toxicologic issues. I have evaluated and treated thousands of patients with toxicologic conditions during my career.

## RATIONALE AND METHODS

I have previously provided reports discussing Camp Lejeune exposures as a cause of kidney and bladder cancers. Herein, I am supplementing the original report with an examination of the toxicologic significance of individual plaintiff specific exposure estimates with a focus on identifying those exposures that rise to a level “recognized to be hazardous to humans” as well as those that are “substantial” exposures. In performing this analysis, I am assuming that:

- modeling generated by the ATSDR are reasonable estimates of the monthly exposures in the Hadnot Point and Tarawa Terrace water systems at Camp Lejeune
- deposition testimony and available records accurately reflect times and locations on base for an individual patient
- estimates generated by expert Dr. Reynolds are sufficiently reliable for purposes of this analysis

For each plaintiff analyzed, I am providing a narrative discussion as well as a table of estimated cumulative exposures. If a plaintiff was only exposed via a single water system, I also performed a sensitivity analysis accounting for partial months of exposure. However, the primary analysis is consistent with the ATSDR’s approach in Dr. Bove’s series of published manuscripts with any time spent on base during a particular month considered a full month of exposure. In addition, if a plaintiff had exposures from both Hadnot Point and Tarawa Terrace, I either relied upon Dr Reynolds’ combined exposure table as realizing the apportionment of exposure between the systems or apportioned myself based on reported intake if not provided to me by Kelly Reynolds. In these cases, a sensitivity analysis accounting for partial months was not performed as such an exercise would include an excessive degree of uncertainty making the sensitivity analysis uninformative. For Ms. Dyer, I apportioned her exposures as 76% Tarawa Terrace and 24% Hadnot Point based on her testimony, assuming that 5 days a week she consumed ~1/3 of her water from Hadnot Point and ~2/3 of her water from Tarawa Terrace with the other 2 days exclusively from Tarawa Terrace.

## EXPOSURES

### *Time on Base*

Terry Dyer experienced exposures at Camp Lejeune that are recognized to be hazardous to human health when considering bladder cancer as an outcome. Military personnel have demonstrated elevated measures of association with bladder cancer diagnosis when stationed for at least 7 quarters at Camp Lejeune from 1975-1985 (Bove 2024a). Ms. Dyer spent 54.7 quarters on base between August 1958 and January 1973. Although this is not the same period studied, the estimated exposure for each toxin falls within the range of exposures estimated between 1975 and 1985. Ms. Dyer’s cumulative exposure estimates for TCE, vinyl chloride and benzene most aligned with exposures for 7-10 quarters during the study period while PCE estimates were more consistent with >10 quarters of exposure during the study period. Given that a monotonically elevated measure of association with at least 7 quarters is present (7-10 quarters=aHR 1.18; >10 quarters=aHR 1.20) for development of bladder cancer, either are reasonable risk estimates that are relevant for Ms. Dyer’s reported exposure. A minimum exposure of 1-21 quarters on base for civilian personnel at Camp Lejeune between October 1972 and December 1985 has also been associated with bladder cancer diagnosis (Bove 2024a). Ms. Dyer spent 54.7 quarters on base

between August 1958 and January 1973. Although this is not the same exposure period studied, the estimated exposure for each toxin falls within the range of exposures estimated between October 1972 and December 1985. Thus, it is reasonable to conclude that Ms. Dyer's exposure is similar enough to civilian exposures from October 1972 to December 1985 such that the elevated measure of association (1-21 quarters=aHR 1.18) for development of bladder cancer in this population is applicable to her exposure. Of note, the population in this study is limited to civilian personnel who may have less intense exposures than military personnel.

#### *TVOC*

At least "medium" exposures to TVOC (>4600 ug/L\*month) in Camp Lejeune water systems demonstrated a nonmonotonic association with bladder cancer (Bove 2014a). The estimated TVOC modeled in the Hadnot Point water system while Ms. Dyer was on base was 7327 ug/L\*month ("medium" exposure [ $>4600-12250$  ug/L\*month]=HR 3.33). Of note, the modeled TVOC exposure for Ms. Dyer is an underestimate as it excludes DCE while Dr. Bove included DCE in his TVOC exposure estimates.

#### *PCE*

At least "low" exposures to PCE (>0 ug/L\*month) in Camp Lejeune water systems demonstrated a nonmonotonic association with bladder cancer diagnosis (ATSDR 2018). The estimated PCE modeled in the Hadnot Point water system while Ms. Dyer was on base was 5714 ug/L\*month ("high" exposure [ $\geq 711$  ug/L\*month]=OR 2.07 when compared to Camp Pendleton and OR=1.54 in an internal Camp Lejeune analysis). Additionally, at least "medium" exposures to PCE (>155 ug/L\*month) in Camp Lejeune water systems demonstrated a nonmonotonic association with bladder cancer mortality (Bove 2014a). The estimated PCE modeled in the Hadnot Point water system while Ms. Dyer was on base was 5714 ug/L\*month ("high" exposure [ $>380$  to 8585 ug/L\*month]=HR 1.24). PCE exposures have also been studied with bladder cancer as an outcome in populations outside of Camp Lejeune. Massachusetts water system contamination demonstrated monotonic elevated measures of association (OR 1.16 and OR 6.04 without latency) in those exposed to "low" and "high" doses (Ashchengrau 1993). Although not explicitly defined for cases, the "low" dose category in controls ranges from any exposure (at least 0.01mg) up to the 90<sup>th</sup> percentile of relative dose delivered (27.1mg with latency and 44.1mg without latency). Given exposure expert Dr. Reynolds' calculations that the dose of PCE delivered to Ms. Dyer while at Camp Lejeune ranged from 95.3mg to 630.5mg, this range of exposure corresponds to the "high" exposure group with an elevated measure of association (OR 6.04) in a water system contamination study of a non-Camp Lejeune population.

#### *TCE*

TCE in Camp Lejeune water systems demonstrated a nonmonotonic association with bladder cancer diagnosis at "low" and "medium" cumulative exposures (ATSDR 2018). The estimated TCE modeled in the Hadnot Point water system while Ms. Dyer was on base was 1107 ug/L\*month ("medium" exposure [ $\geq 110-11030$  ug/L\*month]=OR 1.68 when compared to Camp Pendleton and OR=1.34 in an internal Camp Lejeune analysis). Additionally, "medium" exposures to TCE (>3100-7700 ug/L\*month) in Camp Lejeune water systems demonstrated a nonmonotonic association with bladder cancer mortality (Bove 2014a). The estimated TCE modeled in the Hadnot Point water system while Ms. Dyer was on base was 1107 ug/L\*month

("low" exposure=>1-3100 ug/L\*month). The limited number of cases meant that the measure of association could not be calculated for this subgroup.

#### *Vinyl Chloride*

"Medium" cumulative exposures to vinyl chloride (>205-500 ug/L\*month) in Camp Lejeune water systems demonstrated an association with bladder cancer mortality (Bove 2014a). Estimated vinyl chloride modeled in the Hadnot Point water system while Ms. Dyer was on base was 468 ug/L\* ("medium" exposure (>205-500 ug/L\*month]=HR 2.59).

#### *Benzene*

At least "medium" exposures to benzene (>45 ug/L\*month) in Camp Lejeune water systems demonstrated a nonmonotonic association with bladder cancer mortality (Bove 2014a). The estimated benzene exposure modeled in the Hadnot Point water system while Ms. Dyer was on base was 39 ug/L\*month ("low" exposure=2-45 ug/L\*month). The limited number of cases meant that the measure of association could not be calculated for this subgroup.

#### *Inhalational studies*

In three additional studies with nonmonotonic exposure response relationships, exposures were predominantly inhalational. Given that Ms. Dyer's exposures represent a combination of ingestion, dermal, and inhalational routes, it is unclear whether risk estimates from these studies are directly informative. A Nordic study of largely inhalational exposures in various occupations revealed an elevated measure of association only in the highest tertiles of TCE exposure (>129.50 ppm\*year=HR 1.23) and benzene exposure (>15.04 ppm\*year =HR 1.16) as well as only in the middle tertile (13.60-87.55 ppm\*year=HR 1.12) of PCE exposure (Hadkhale 2017). In another Nordic study, dry cleaning workers occupationally exposed to PCE demonstrated a nonmonotonic association (RR 0.91-2.39 depending on duration of exposure) with bladder cancer where a mean measurement of "at least 60-minute exposures to PCE" was 164mg/m<sup>3</sup> (Lynge 2006). Finally, an Italian air pollution study of exclusively inhalational exposures indicated an association only in the medium tertile of geographically segmented estimates (1.1-1.8 ug/m<sup>3</sup>=HR 1.16) of benzene air pollution (Hadkhale 2017).

#### LEVELS RECOGNIZED TO BE HAZARDOUS TO HUMAN HEALTH

Ms. Dyer experienced exposures at levels recognized to be hazardous to humans and consistently demonstrate elevated measures of association with bladder cancer. This includes exposure metrics evident in the Camp Lejeune population from 1972-1985 such as time on base at Camp Lejeune (Bove 2024a), the combination of individual compounds expressed as TVOC (Bove 2014a), PCE (Bove 2014a, ATSDR 2018), TCE (ATSDR 2018), and vinyl chloride (Bove 2014a). Furthermore, the exposure experienced by Ms. Dyer is similar to a water system exposure outside of the Camp Lejeune population that demonstrated an elevated measures of association with bladder cancer for PCE (Aschengrau 1993).

#### SUBSTANTIAL EXPOSURES

As a practicing medical toxicologist, I conclude that the delivered dose estimates generated by exposure expert Dr Reynolds represent "substantial" rather than "de minimis" exposures to PCE, TCE, and vinyl chloride when considering an outcome of bladder cancer. This is evident in the quantified exposures recognized to be hazardous to human health examined above. Additionally,

I would consider exposures of this magnitude in a differential diagnosis for a patient presenting to my practice with suspected bladder cancer.

As noted by the EPA in banning both TCE and PCE in final rules published in December 2024 (EPA 2024), each toxin represents an “unreasonable threat to health”. There is no safe level of exposure identified for either. The EPA’s rationale specifically recognized TCE as a cause of kidney cancer, and TCE is presumed to act via a similar mechanism as a cause of bladder cancer. Compared to oral exposures, the EPA estimated that for an equivalent delivered dose of TCE, inhalational exposures were approximately twice as potent in causing kidney cancer (EPA 2011). The ban for PCE was justified, at least in part, by the associations between PCE exposures and cancers (including bladder cancer). In light of the robust evidence for TCE and PCE exposure as a cause of bladder cancer, the potency of exposure in inhalational data, and the unquantified but at minimum additive impact of combined exposure to multiple toxins by various routes, even a less robust exposure to toxins that may not reach a level recognized to be hazardous to human health still represents contributory exposure for Ms. Dyer. Additionally, Ms. Dyer was exposed as a child, a uniquely susceptible window for cancer causation (EPA 2011). Consequently, I conclude that Ms. Dyer experienced “substantial” exposures to TCE, PCE, vinyl chloride, and benzene at Camp Lejeune.

The opinions expressed above are to a reasonable degree of medical and scientific certainty.

Respectfully

A handwritten signature in black ink, appearing to be 'Benjamin Hatten', written in a cursive style.

Benjamin Hatten MD MPH

## **APPENDIX A: Analysis Tables**

Summed variable totals

	Chart 1: 1L	Chart 2: ATSDR RME	Chart 3: ATSDR CTE	Chart 4: ATSDR RME; deposition ingestion age 6+	
	Cumulative ug/L-M	Cumulative consumption (total ug= days*concentration per L)	Cumulative consumption (total ug= days*concentration per ATSDR exposure assumptions)	Cumulative consumption (total ug= days*concentration per deposition/FM exposure assumptions)	Cumulative consumption (total ug= days*concentration per deposition/FM exposure assumptions)
<b>Hadnot Point</b>					
TCE	3,608	26,042	40,097	13,871	93,536
PCE	-	-	14,049	4,772	35,403
VC	10	66	-	-	-
BZ	161	1,157	40,097	13,871	93,536
<b>Terawa Terrace</b>					
TCE	317	7,258	3,783	3,783	24,544
PCE (TechFlowMP Model)	7,518	172,268	90,529	90,529	595,062
PCE (MT3DMS Model)	9,236	211,660	110,277	110,277	715,375
VC	612	14,050	6,948	6,948	41,177
BZ	-	-	-	-	-
<b>Totals HP &amp; TT</b>					
TCE	1,107	33,300	50,956	17,655	118,080
PCE (TechFlowMP Model)	5,714	172,268	274,503	95,301	630,465
PCE (MT3DMS Model)		211,660	330,565	115,049	750,778
VC	468	14,116	19,632	6,948	41,177
BZ	39	1,157	40,097	13,871	93,536
<b>TVOC</b>	<b>7,327</b>				

Y/N (exposure with elevated measure of association)
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Levels harmful to human health

	Duration	TCE	PCE	VC	Benzene	TVOC	
<u>Monotonic</u> Bove 2024a (>= 7 quarters)	54.7 quarters aHR 1.18-1.20						Y
Ashcengrau 1993 (>0 ug PCE dose delivered)			OR 6.04				Y
<u>Nonmonotonic</u> Bove 2024a (1-21 quarters)	aHR 1.18						Y
Bove 2014a (>3100-7700ug/L*month TCE; >155-380ug/L*month PCE; >205 to 500ug/L*mor)			HR 1.24	HR 2.59		HR 3.33	Y
ATSDR 2018 (110-<11030ug/L*month TCE; >=36-<711ug/L)		OR 1.68/OR 1.34	OR 2.07/OR 1.54				Y