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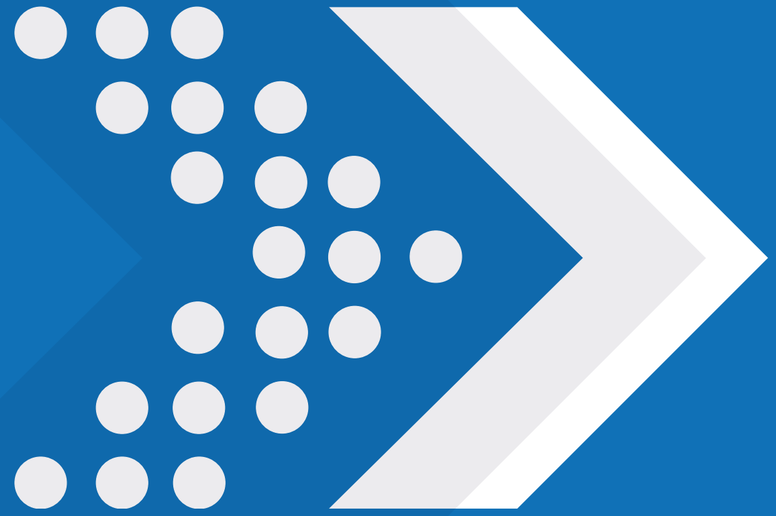
ROUNDTABLE DISCUSSION



Thursday, December 14th

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Today's Agenda:

- Applying studies on Track 1/Track 2 cases with regards to latency, onset and other confounders impacting each diagnosis
- How SimplyConvert is applying this information: Mass Torts 360™ Plaintiff Settlement Tracker

Two ways to ask a speak up / ask questions:

Raise Hand

Q&A

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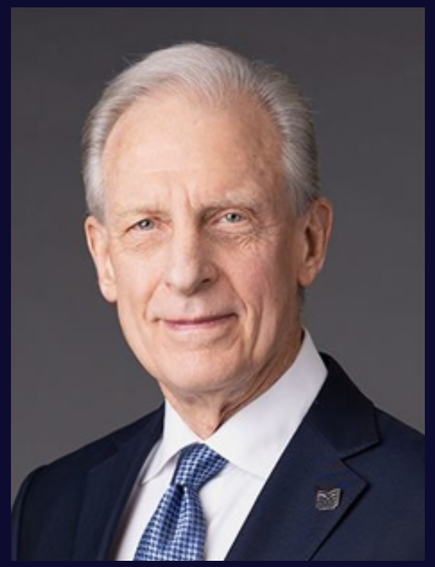
Today's Guest Speakers



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Equipoise Considerations

- "[A]pplying the Bradford Hill criteria to a set of data . . . the analysis requires a statistician to find a statistically significant association at step one before moving on to apply the factors at step two." (Lipitor at 642.)
  - Non-statistically significant results are accepted outside of a Bradford Hill analysis. (See id. at 641-42.)

- We can present a Bradford Hill analysis of epidemiological data that is statistically significant at the 90% confidence level.
  - We can also present evidence notwithstanding lack of statistical significance insofar as we bootstrap it through methods that are generally accepted in the field, e.g., dose-response, spatial analysis, differential diagnosis, temporality, and challenge-dechallenge data.

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Equipoise Considerations

- We first hypothesized that equipoise and preponderance can be distinguished in statistical terms insofar as equipoise translates to non-statistically significant elevations in risk at the 95% confidence level if preponderance is generally accepted as translating to statistically significant elevations in risk at the same confidence level.
- Nominally, we think the plain language interpretation of a non-statistically significant elevation in risk comports with the legal definition of equipoise, i.e., an elevation in risk that is as likely as not to be true.
- However, in Lipitor, the Fourth Circuit expressly disallows non-statistically significant evidence in the specific context of a Bradford Hill analysis.
- Accordingly, we modified our hypothesis with respect to equipoise insofar as non-statistically significant elevations in risk at the 95% confidence level can be statistically significant at the 90% confidence level.
- All else being equal, decreasing the confidence level narrows the confidence interval.
- The lower bound of the 90% confidence interval may rise above 1.0 (null value) if the corresponding lower bound of the 95% confidence interval is near 1.0 (borderline significant).
- In our opinion, this approach implies an analogy that is simple and sensical: if 95% confidence is required for preponderance of the evidence, then 90% confidence is sufficient for the attenuated equipoise standard.

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90% Confidence is Already Accepted

- In multiple studies linking VOCs to preterm birth, SGA, LBW, and MBW, both the ATSDR and independent academics reported 90% CIs, not 95% CIs.

- Examples abound of 90% confidence being accepted in the statistical literature:
  - Simundic AM. Confidence interval. Biochemia Medica. 2008 Apr;18(2):154-61.
  - Hazra A. Using the confidence interval confidently. J Thorac Dis. 2017 Oct;9(10):4125-30.
  - Section 15.3.1 of the current Cochrane Handbook for Systematic Reviews of Interventions
  - Finch S, Cumming G. Putting research in context: understanding confidence intervals from one or more studies. J Pediatr Psychol. 2009 Oct;34(9):903-16.
  - Kamper SJ. Confidence Intervals: Linking Evidence to Practice. J Orthop Sports Phys Ther. 2019 Oct;49(10):763-764.
  - Textbooks such as Biostatistical Analysis by Zar JH and A Modern Introduction to Probability and Statistics by Dekking FM et al.

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Other Considerations

- For injuries that lack sufficient support in the epi we can turn to mechanistic evidence to support general causation per the Westberry factors in the Fourth Circuit.

- Certain VOCs such as TCE don’t cause cancer through a traditional mutagenic mechanism.

- Other pathways exist, e.g., TCE and its metabolites cause oxidative stress which induces apoptosis (cell death) and genotoxicity (binding to DNA).
  - See, e.g., Rusyn I, Chiu WA, Lash LH, Kromhout H, Hansen J, Guyton KZ. Trichloroethylene: Mechanistic, epidemiologic and other supporting evidence of carcinogenic hazard. Pharmacol Ther. 2014 Jan;141(1):55-68.

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Cancer Latency Study

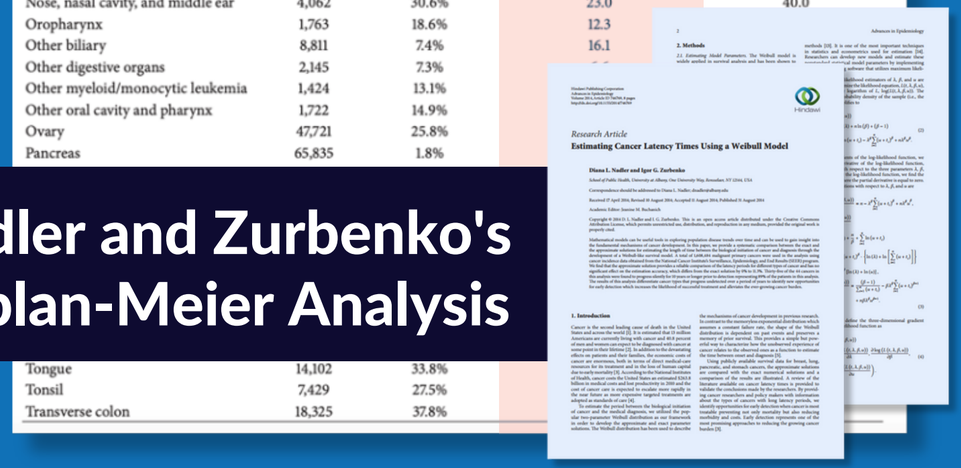
- “Years from onset to diagnosis” column contains the back-end latency for each cancer site

- When looking at a potential Track 1 case, we are looking the back end latency to determine the strength/weakness of the latency period for the specific client and if it their onset beyond the years listed on the table.

- Example:
  - Kidney cancer: avg. years from onset to diagnosis = 48.2 years.
  - Hypothetical client is within that latency period — 40 years
  - Falls beyond the 35 year period that the EO/DOJ has established for latency
  - However, based on this study, we would still be in the acceptable range of latency

Table 2: Approximate latency times from cancer initiation to diagnosis by cancer site.

Cancer site	Sample size	5-year survival rate	Years from onset to diagnosis	Median age at cancer onset
Acute lymphocytic leukemia	3,701	21.5%	35.7	8.3
Acute monocytic leukemia	1,118	8.8%	15.7	47.3
Acute myeloid leukemia	17,733	12.3%	25.7	39.3
Aleukemic, subleukemic, and NOS	1,785	15.5%	19.3	52.7
Ascending colon	30,038	46.2%	56.8	16.2
Brain	36,828	9.9%	21.9	36.1
Breast	378,477	54.3%	16.3	43.7
Cecum	46,552	36.7%	52.4	20.6
Chronic lymphocytic leukemia	24,466	15.9%	2.2	67.8
Chronic myeloid leukemia	10,498	9.6%	5.1	58.9
Descending colon	13,634	42.4%	52.4	16.6
Esophagus	26,504	6.0%	9.4	56.6
Floor of mouth	5,260	31.5%	21.9	40.1
Gallbladder	8,105	9.6%	25.2	46.8
Gum and other mouth	9,834	37.5%	28.7	34.3
Hypopharynx	5,241	4.8%	9.6	53.4
Kidney and renal pelvis	56,093	33.2%	48.2	14.8
Large intestine, NOS	9,225	19.0%	37.9	36.1
Larynx	22,545	43.1%	35.4	27.6
Liver	22,316	6.0%	10.8	53.2
Lung and bronchus	358,750	6.4%	13.6	53.4
Myeloma	33,252	3.8%	3.6	65.4
NHL-nodal	70,558	27.5%	26.5	37.5
Nasopharynx	4,435	32.4%	25.2	29.8
Nose, nasal cavity, and middle ear	4,062	30.6%	23.0	40.0
Oropharynx	1,763	18.6%	12.3	
Other biliary	8,811	7.4%	16.1	
Other digestive organs	2,145	7.3%		
Other myeloid/monocytic leukemia	1,424	13.1%		
Other oral cavity and pharynx	1,722	14.9%		
Ovary	47,721	25.8%		
Pancreas	65,835	1.8%		
Tongue	14,102	33.8%		
Tonsil	7,429	27.5%		
Transverse colon	18,325	37.8%		



Nadler and Zurbenko's Kaplan-Meier Analysis

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Camp Lejeune — Track 1 EDNC Filing Case Considerations

GENERAL CONSIDERATIONS:

- Client's age and latency period
- Is client/representative in relatively good health (for trial demands?)
- Any felonies or criminal history?
- Loss of income?

PREPARED BY KERSHAW TALLEY BARLOW
LAST UPDATED: 10.13.23

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BLADDER CANCER

RISK FACTORS / CONFOUNDERS	EXPOSURE / LOCATION TIMEFRAME	OTHER EXPOSURE CONSIDERATIONS	MISCELLANEOUS
Smoking — smokers are 3x as likely to get bladder cancer. Smoking causes about half of all bladder cancers **Workplace exposures** — certain industries ie: dye industry, makers of rubber, leather, textiles, paint products. Those working as painters, machinists, printers, hairdressers, truck drivers **Medication** — Actos (diabetes); dietary supplements including aristolochic acid	**Associated contaminant:** PCE **Hadnot Point:** 1953-1987 **Tarawa Terrance:** 1953-1987 **Holcomb Blvd:** 1972-1975	**Age** — 9 out of 10 people with bladder cancer are older than 55 **Ethnicity** — white people twice as likely to develop bladder cancer	**Genetics** — People who have family history of bladder cancer have a higher risk of getting it themselves

Source: American Cancer Society https://www.cancer.org/cancer/types/bladder-cancer/causes-risks-prevention/risk-factors.html

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KIDNEY CANCER

RISK FACTORS / CONFOUNDERS	EXPOSURE / LOCATION TIMEFRAME	OTHER EXPOSURE CONSIDERATIONS	MISCELLANEOUS
Smoking — smoking increases risk of renal cell carcinoma. Increased risk seems to be related to how much you smoke. Risk drops if you stop smoking, but it takes many years to get to the risk level of someone who never smoked. **Obesity** — people who are very overweight have a higher risk **Medication** — risk of kidney cancer higher in people with high blood pressure. Risk does not seem to be lowered even if someone is taking medicines to treat for high blood pressure	**Associated contaminant:** TCE **Hadnot Point:** 1953-1987 **Tarawa Terrance:** NOT PRESENT **Holcomb Blvd:** 1972-1975	**Certain medications—** some studies have suggested that acetaminophen may be linked to an increase in the risk of RCC	**Genetics and hereditary risks—** certain hereditary conditions can result in a much higher risk for getting kidney cancer: von Hippel-Lindau disease; papillary renal cell carcimnoma; familial renal cancer; cowden syndrome.

Source: American Cancer Society https://www.cancer.org/cancer/types/kidney-cancer/causes-risks-prevention/risk-factors.html

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LEUKEMIA

RISK FACTORS / CONFOUNDERS	EXPOSURE / LOCATION TIMEFRAME	OTHER EXPOSURE CONSIDERATIONS	MISCELLANEOUS
Smoking—the only proven lifestyle related risk for Acute Myeloid Leukemia as smoking **Workplace exposures—**those who work in the rubber industry, oil refinery, chemical plant, shoe manufacturing, and gasoline related industry (since these involve solvents which have benzene). Also is found in cigarette smoke, gasoline and motor exhaust, some glues, cleaning products, detergents and paints.	**Associated contaminant:** TCE and Benzene **Hadnot Point:** 1953-1987 **Tarawa Terrance:** NOT PRESENT **Holcomb Blvd:** 1972-1975	**Possible risk factors—**none have been conclusively linked but still good to note if client has been exposed to diesel, gasoline and any herbicides or pesticides	**Chemotheraphy—**certain chemo drugs are more likely to develop AML in the years following treatment: alkylating agents **Genetic syndromes—**more on list but this includes Fanconi anemia, bloom syndrome

Source: American Cancer Society https://www.cancer.org/cancer/types/acute-myeloid-leukemia/causes-risks-prevention/risk-factors.html

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NON-HODGKINS LYMPHOMA

RISK FACTORS / CONFOUNDERS	EXPOSURE / LOCATION TIMEFRAME	OTHER EXPOSURE CONSIDERATIONS	MISCELLANEOUS
Age-- most cases occurring in people in their 60s or older **Immune system disorders**—HIV/AIDS risk factor for developing certain types of NHL such as CNS lymphoma, Burkitt lymphoma and diffuse large B-cell lymphoma	**Associated contaminant:** TCE, PCE and Benzene **Hadnot Point:** 1953-1987 **Tarawa Terrance:** 1953-1987 **Holcomb Blvd:** 1972-1975	**Herbicides and insecticides**—specifically weed and insect killing substances	**Family history**—having a first degree relative with NHL increases risk

- American Cancer Society https://www.cancer.org/cancer/types/non-hodgkin-lymphoma/causes-risks-prevention/risk-factors.html

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PARKINSON'S DISEASE

RISK FACTORS / CONFOUNDERS	EXPOSURE / LOCATION TIMEFRAME	OTHER EXPOSURE CONSIDERATIONS	MISCELLANEOUS
Age—biggest risk factor for developing Parkinson's is advancing age- average age of onset is 60 **Genetics**—Individuals with a parent or sibling who is affected have approximately two times the chance of developing Parkinson's	**Associated contaminant:** TCE **Hadnot Point:** 1953-1987 **Tarawa Terrance:** NOT PRESENT **Holcomb Blvd:** 1972-1975	**Chemicals**—exposure to farming chemicals, like pesticides and herbicides; Vietnam-era exposure to Agent Orange; and working with heavy metals, detergents and solvents have all been implicated and studied for a clearer link.	

Source: https://www.hopkinsmedicine.org/health/conditions-and-diseases/parkinsons-disease/parkinsons-disease-risk-factors-and-causes

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Life at Lejeune Specific Causation Questionnaire

	Bladder Cancer	Kidney Cancer	Leukemia	Non-Hodgkins Lymphoma	Parkinson's Disease
Associated Contaminant(s)	PCE	TCE	TCE, Benzene	TCE, PCE, Benzene	TCE
Hadnot Point	1953-1987	1953-1987	1953-1987	1953-1987	1953-1987
Tarawa Terrace	1953-1987	Not present	Not present	1953-1987	Not present
Holcomb Blvd	1972-1975	1972-1975	1972-1975	1972-1975	1972-1975
Age	9 out of 10 people with Bladder Cancer are over 55			most cases occurring in people in their 60s or older	biggest risk factor for developing Parkinson's is advancing age- average age of onset is 60
Ethnicity	White people 2x as likely to develop bladder cancer				
Genetics / Family History	Yes (People who have family history of bladder cancer have a higher risk of getting it themselves)	certain hereditary conditions can result in a much higher risk for getting kidney cancer: von Hippel-Lindau disease; papillary renal cell carcimnoma; familial renal cancer; cowden syndrome	Genetic syndromes—more on list but this includes Fanconi anemia, bloom syndrome	Family history—having a first degree relative with NHL increases risk	Individuals with a parent or sibling who is affected have approximately two times the chance of developing Parkinson's
Smoking	smokers are 3x as likely to get bladder cancer. Smoking causes about half of all bladder cancers	smoking increases risk of renal cell carcinoma. Increased risk seems to be related to how much you smoke. Risk drops if you stop smoking, but it takes many years to get to the risk level of someone who never smoked	the only proven lifestyle related risk for Acute Myeloid Leukemia as smoking		
Obesity		people who are very overweight have a higher risk			
High Blood Pressure		risk of kidney cancer higher in people with high blood pressure. Risk does not seem to be lowered even if someone is taking medicines to treat for high blood pressure			
Other Risk Factors / Confounders			Chemotheraphy—certain chemo drugs are more likely to develop AML in the years following treatment: alkylating agents	Immune system disorders—HIV/AIDS risk factor for developing certain types of NHL such as CNS lymphoma, Burkitt lymphoma and diffuse large B-cell lymphoma	
Workplace Exposures	Manufacturing company [Dye, Rubber, Leather, Textiles, Paint]		Workplace exposures—those who work in the rubber industry, oil refinery, chemical plant, shoe manufacturing, and gasoline related industry (since these involve solvents which have benzene). Also is found in cigarette smoke, gasoline and motor exhaust, some glues, cleaning products, detergents and paints.		Chemicals—exposure to farming chemicals, like pesticides and herbicides.
Occupation	[Painter, Machinist, Printer, Hairdresser, Truck Driver]				
Other Exposure Considerations			Possible risk factors—none have been conclusively linked but still good to note if client has been exposed to diesel, gasoline and any herbicides or pesticides	Herbicides and insecticides—specifically weed and insect killing substances	Vietnam-era exposure to Agent Orange; and working with heavy metals, detergents and solvents have all been implicated and studied for a clearer link.
Medication	[Actos (Diabetes), Dietary supplements including aristolohic acid	Certain medications—some studies have suggested that acetaminophen may be linked to an increase in the risk of RCC			
Source	https://www.cancer.org/cancer/types/bladder-cancer/causes-risks-prevention/risk-factors.html	https://www.cancer.org/cancer/types/kidney-cancer/causes-risks-prevention/risk-factors.html	https://www.cancer.org/cancer/types/acute-myeloid-leukemia/causes-risks-prevention/risk-factors.html	https://www.cancer.org/cancer/types/non-hodgkin-lymphoma/causes-risks-prevention/risk-factors.html	https://www.hopkinsmedicine.org/health/conditions-and-diseases/parkinsons-disease/parkinsons-disease-risk-factors-and-causes

https://docs.google.com/spreadsheets/d/1jOTi8RG7zRMoU1sQ8YyrlosGGeBiD9y1MOqsJFeK5Oc/edit?usp=sharing

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Resolution Priority Score

Fact Data by Condition				Plaintiff Data							
3rd party data	3rd party data	SC Data		Case Data	Case Data	Calculation	Calculation	Calculation			
Average Age at Diag	5-year survival rat	Average Ag		Plaintiff Dx date	Plaintiff Ag	Plaintiff years from dx da	Plaintiff years beyond national dx age	Plaintiff Years beyond average passing of peers	EO Tier	EO Settlement Offer	SC Exposure Score
48.2	33%	66		1/1/2007	89	16	40.8	23	1	$150,000	90
48.2	33%	66		1/1/2017	89	6	40.8	23			90
48.2	33%	66		1/1/2014	86	9	37.8	20			90
48.2	33%	66		1/1/2020	86	3	37.8	20			90
48.2	33%	66		1/1/1979	85	44	36.8	19	1	$450,000	90
48.2	33%	66		1/1/2010	84	13	35.8	18			90
48.2	33%	66		1/1/1995	82	28	33.8	16	1	$300,000	90
48.2	33%	66		1/1/2014	82	9	33.8	16			90
48.2	33%	66		1/1/2017	82	6	33.8	16			90
48.2	33%	66		1/1/2021	81	2	32.8	15			90
48.2	33%	66		1/1/2019	80	4	31.8	14			90
48.2	33%	66		1/1/2017	79	6	30.8	13			90
48.2	33%	66		1/1/2022	79	1	30.8	13			90
48.2	33%	66		1/1/1993	78	30	29.8	12	1	$300,000	90
48.2	33%	66		1/1/2003	78	20	29.8	12	1	$300,000	90
48.2	33%	66		1/1/2022	77	1	28.8	11			90
48.2	33%	66		1/1/2016	76	7	27.8	10			90
48.2	33%	66		1/1/2021	76	2	27.8	10			90
48.2	33%	66		1/1/2002	75	21	26.8	9	1	$300,000	90
48.2	33%	66		1/1/1987	74	36	25.8	8	1	$300,000	90
48.2	33%	66		1/1/2007	74	16	25.8	8	1	$150,000	90
48.2	33%	66		1/1/2013	74	10	25.8	8			90
48.2	33%	66		1/1/1990	73	32	24.8	7	1	$300,000	90
48.2	33%	66		1/1/2015	73	8	24.8	7			90
48.2	33%	66		1/1/2017	73	6	24.8	7			90
48.2	33%	66		1/1/2017	73	6	24.8	7			90
48.2	33%	66		1/1/2022	73	1	24.8	7			90
48.2	33%	66		1/1/2022	73	1	24.8	7			90
48.2	33%	66		1/1/1971	71	52	22.8	5	1	$450,000	100
48.2	33%	66		1/1/2010	71	13	22.8	5			90
48.2	33%	66		1/1/2013	71	10	22.8	5			90

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Proposed Track 2 Injuries

Plaintiff Track 2	Gov't Track 2
Liver Cancer	Prostate Cancer
Sclerosis / scleroderma	Breast Cancer
Multiple Myeloma	Lung Cancer
Kidney Disease	Pancreatic Cancer
Aplastic Anemia	Esophageal Cancer

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ROUNDTABLE DISCUSSION

- Holiday Break:
  - Dec 21st - Jan 4th
- Jan 11 - Roundtable Returns in New Location: SC Community
  - *Look for email with details after the holidays!*