



TALC LITIGATION CONFERENCE

The Midland Hotel, Chicago | May 20, 2025

Science and Genetics Update



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Updated IARC Monograph



2010

- Perineal use: Group 2B – **Possibly** Carcinogenic to Humans
- Inhalation: Group 3 – Not classifiable

2024

- Group 2A **Probably** Carcinogenic to Humans

Talc, Pleurodesis, and Cancer (Ghio, 2025)



- IARC Preamble changed in 2019
- “Exceptionally, a single study in one species and sex may be considered to provide sufficient evidence of carcinogenicity”
- Talc classification changed based on 1993 rat study
- Experts did not agree with reclassification
- Presents a “conundrum” for pulmonary medicine



FDA Expert Panel on Talc

Tuesday, May 20, 10 a.m. - noon

Dr. Sara Brenner, M.D., M.P.H.
Principal Deputy Commissioner



Dr. Martin Makary, M.D., M.P.H.
FDA Commissioner



- Publicly accessible independent panel of scientific experts to assess the safety and necessity of talc in food, drug, and cosmetic products
- Formed in response to rising public health concerns, including the EU's planned ban on cosmetic talc by 2027

[Click here to learn more about this event](#)

[Click here to virtually attend](#)

FDA Proposed Rule – Standardized Testing Methods



- Requires manufacturers of talc-containing cosmetic products to test each batch or lot for asbestos using PLM and TEM/EDS/SAED
- Any detection is considered “adulterated product”
- 90-day comment period already ended 3/27/25
- No FDA product testing has occurred since 2023



Talc and Cancer: Systematic Reviews



Epidemiology

(Boon et al., 2024)

- Evaluated 72 studies
- Evaluated cancers of respiratory system, female reproductive tract, gastrointestinal tract, urinary system, the lymphohematopoietic system, prostate, male genital organs, central nervous system, skin, eye, bone, connective tissue, peritoneal, and breast cancers.

“This systematic review indicates that epidemiology studies do not support a causal association between occupational, medicinal, or personal talc exposure and any cancer in humans.”

Animal + Mechanistic Studies

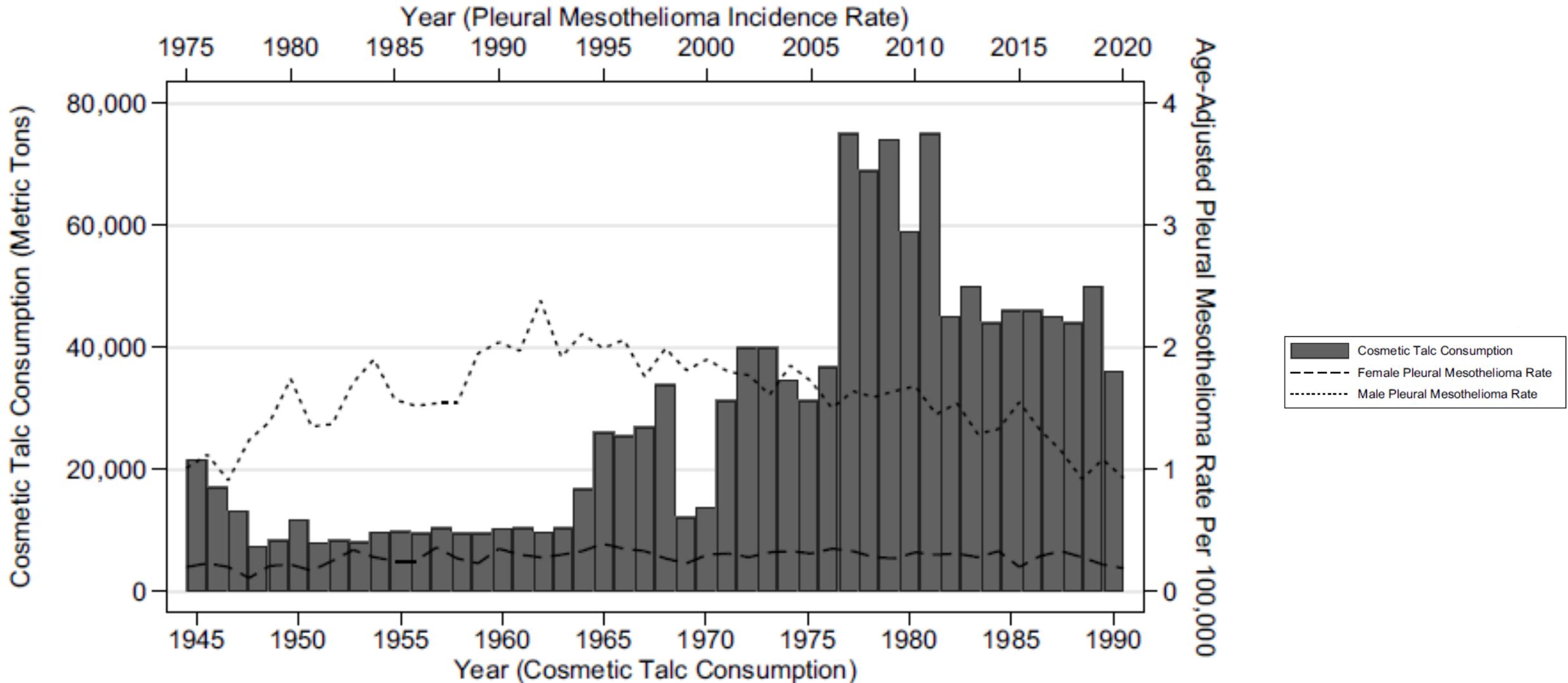
(Pruiett et al., 2024)

- Evaluated 7 animal and 11 mechanistic studies
- Studies cover multiple exposure routes, species, exposure durations.

“This systematic review of the experimental animal carcinogenicity and mechanistic evidence for talc indicates that an association between talc exposure and cancer is not expected in humans.”

Talc Consumption and Meso

(Roberts et al. 2024)



Mesothelioma Long-Term Trends in SEER Age-Adjusted Incidence Rates, 1975-2019

Observed SEER Incidence Rate By Sex, All Races, All Ages

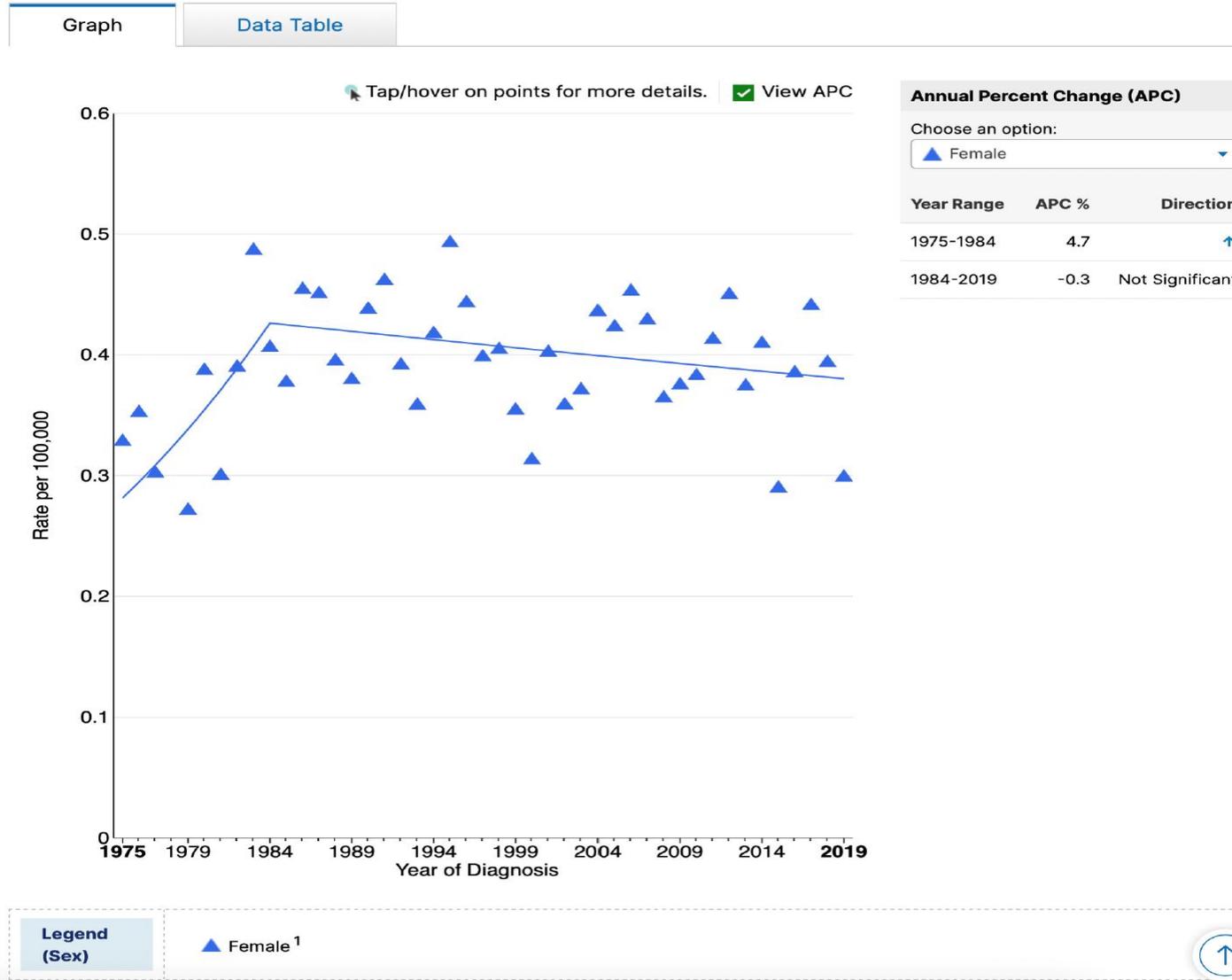


Figure 5. SEER 8 female Mesothelioma incidence rates, 1975-2019, joinpoint fit

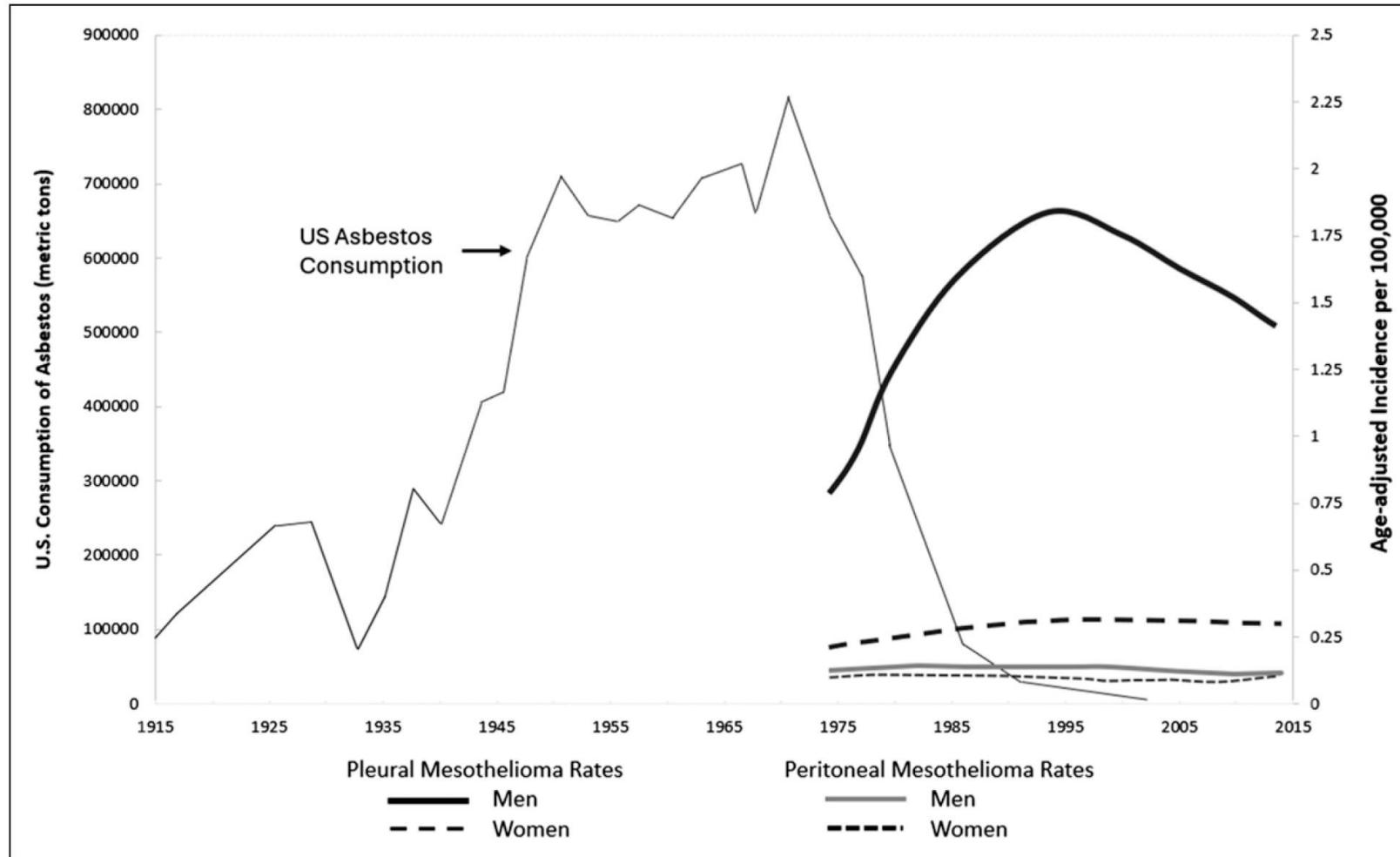


Figure 1. Observed and expected SEER data regarding age-adjusted incidence of pleural and peritoneal mesothelioma from 1915 to 1995 as well as the relevant exposures from 1973 to 2012 (recreated from Mezei et al., 2017). When considering a 30–40-year latency period, there is a strong association between asbestos use and pleural mesothelioma amongst men. Commercial asbestos use in the U.S. did not have a significant effect on peritoneal mesotheliomas for either men or women as the age-adjusted peritoneal mesothelioma rates are generally flat.

Trends in Meso Among Women (Stevens et al. 2024)



From MMWR (CDC) 2022:

What is added by this report?

The annual number of deaths with mesothelioma among women significantly increased, from 489 (age-adjusted death rate = 4.8 per 1 million women) in 1999 to 614 (4.2) in 2020. The largest number of deaths in 2020 was associated with the health care and social assistance industry (89; 15.7%) and homemaker occupation (129; 22.8%).

What are the implications for public health practice?

Efforts to limit exposure to asbestos fibers, including among women, need to be maintained.

Genetic Susceptibility and Meso (Congedo et al. 2024)



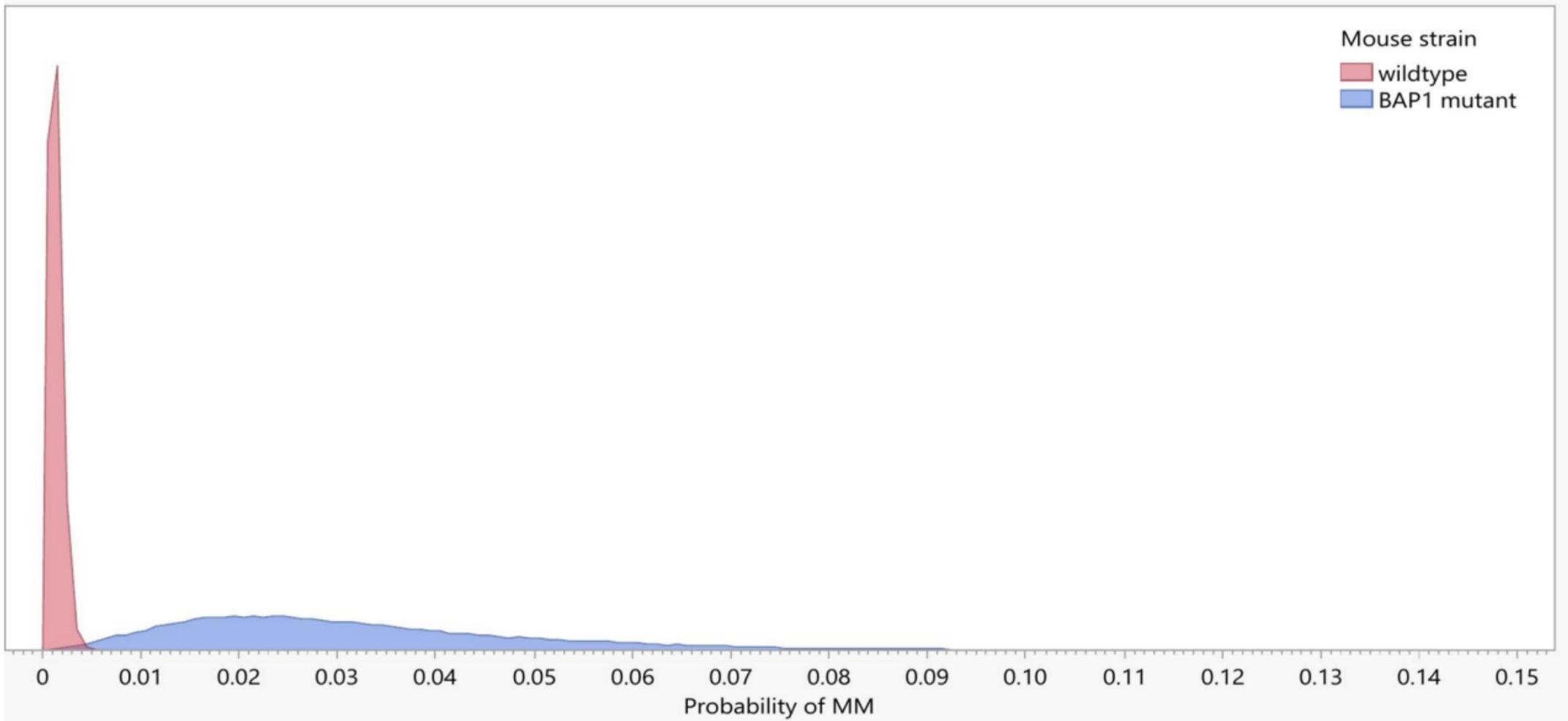
Table 3 Epidemiological and clinical differences between AR-MPM and GR-MPM

Epidemiological and clinical differences	AR-MPM	GR-MPM
Association with asbestos exposure	Strong	Not strong
Age of presentation (years), (mean)	72.3	56.3
Gender ratio (M:F)	5:1	1:1
Symptoms frequency	+++	+/-
Presence of pleural effusion	+++	+/-
Stage at presentation	Usually advanced	Usually initial

+++ , common; +/- , rare. AR, asbestos-related; MPM, malignant pleural mesothelioma; GR, gene-related; M, male; F, female.

“Several candidate genes have been associated with a predisposition to MPM and most of them play a role in DNA repair mechanisms: overall, **approximately 20%** of MPM cases may be related to genetic predisposition. ”

Genetic Susceptibility and Meso (Nielsen et al. 2025)



Meso in a talc mucker (Dodson et al. 2024)



- Case report of a single case
- Male, age 77
- Worked as a mucker at an industrial talc mine for 9 years (48 years prior to death)
- Lung tissue analysis: 706 ferruginous bodies/g (wet weight) including tremolite
- General population: 20 FB/g (wet)
- Tremolite was found in the bulk talc from the mine and also in the lung

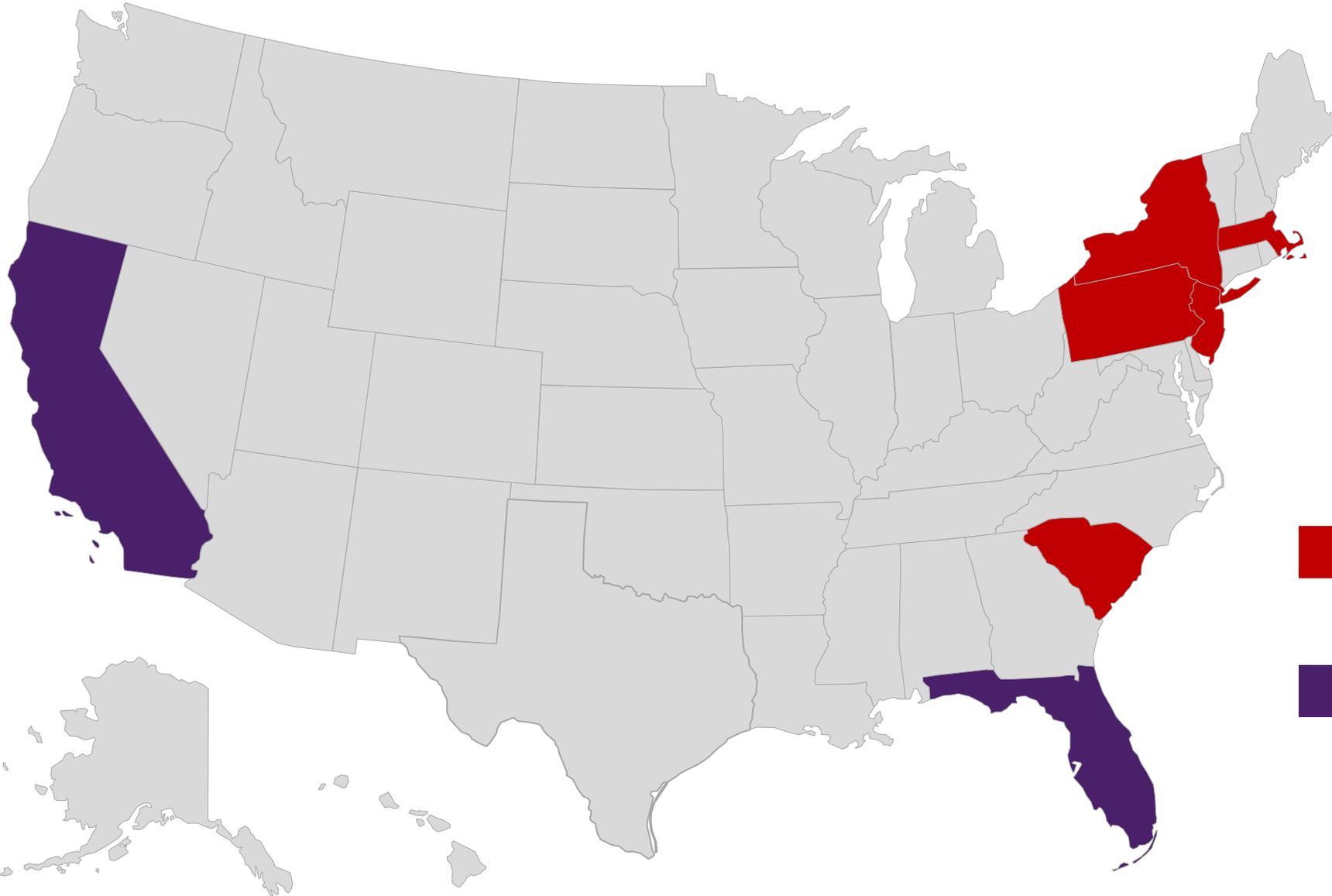
“It is our conclusion, that the individual in the study developed the rare cancer- mesothelioma as a result of his exposure to elongated mineral particles. Both the bulk sample of the talcum product and the tissue burden analysis confirmed the presence of **asbestiform tremolite**.”

Reference List



1. Boon, D., Goodman, J. E., Colonna, K. J., Espira, L. M., & Prueitt, R. L. (2024). A systematic review of the epidemiology evidence on talc and cancer. *Critical Reviews in Toxicology*, 54(6), 394-417.
2. Congedo, M. T., West, E. C., Evangelista, J., Mattingly, A. A., Calabrese, G., Sassorossi, C., ... & Lococo, F. (2024). The genetic susceptibility in the development of malignant pleural mesothelioma: somatic and germline variants, clinicopathological features and implication in practical medical/surgical care: a narrative review. *Journal of Thoracic Disease*, 16(1), 671.
3. Dodson, R. F., Moline, J., Salinas, C. D., & Poye, L. W. (2024). Elongated particulate burden in an individual who died of mesothelioma and had an occupational history as a talc “mucker”. *Inhalation Toxicology*, 36(3), 205-216.
4. Food and Drug Administration. Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products 21 CFR Part 730. December 27, 2024.
5. Ghio, A. J. (2025). Talc, Pleurodesis, and Cancer. *American Journal of Respiratory and Critical Care Medicine*, (ja).
6. Nielsen, D. M., Hsu, M., Zapata III, M., Ciavarra, G., & van Zyl, L. (2025). Bayesian analysis of the rate of spontaneous malignant mesothelioma among BAP1 mutant mice in the absence of asbestos exposure. *Scientific Reports*, 15(1), 169.
7. Prueitt, R. L., Drury, N. L., Shore, R. A., Boon, D. N., & Goodman, J. E. (2024). Talc and human cancer: a systematic review of the experimental animal and mechanistic evidence. *Critical Reviews in Toxicology*, 54(6), 359-393.
8. Roberts, B., Lewis, R., Smith, S., Miller, E., & Pierce, J. (2025). Historical cosmetic talc consumption and incidence of mesothelioma in the United States. *International Journal of Environmental Health Research*, 35(4), 972-980.
9. Stayner, L. T., Carreón-Valencia, T., Demers, P. A., Fritz, J. M., Sim, M. R., Stewart, P., ... & Schubauer-Berigan, M. K. (2024). Carcinogenicity of talc and acrylonitrile. *The Lancet Oncology*, 25(8), 962-963.
10. Stevens, M. E., Tuttle, B. P., Brew, D. W., & Paustenbach, D. J. (2025). An evaluation of trends for mesothelioma mortality in American women: Addressing the content of a recent Morbidity and Mortality Weekly Report (MMWR). *Toxicology and Industrial Health*, 41(1), 40-60.

Court Orders & Case Reports



-  Fiber Burden Analysis (FBA)
-  Both FBA & Genetic Testing

California – Genetic Testing

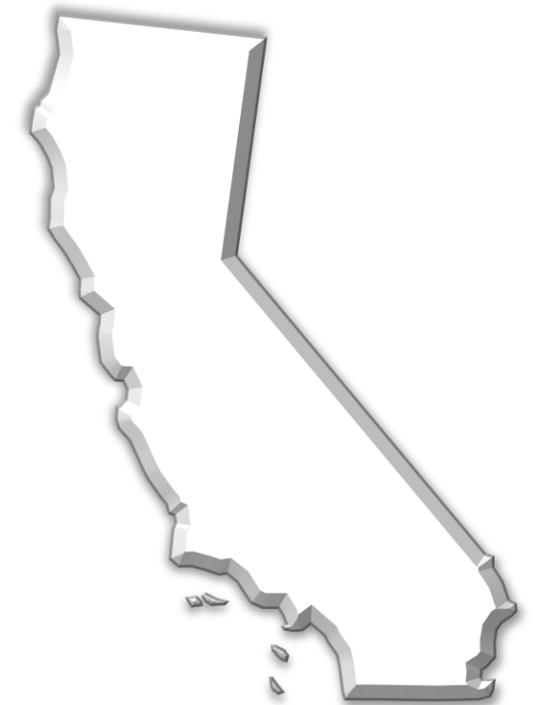


■ *Alvarino DaSilva, et al. vs. Arvinmeritor, Inc., et al.*

- **Venue:** Alameda County
- **Date:** September 4, 2024
- **Judge:** Hon. McKinney
- **Pltf:** 61-year-old mesothelioma alleges exposure through automotive work and talc powder
- **Firm:** Maune Raichle Hartley French & Mudd LLC
- **Order:** 2024 Motion for genetic testing

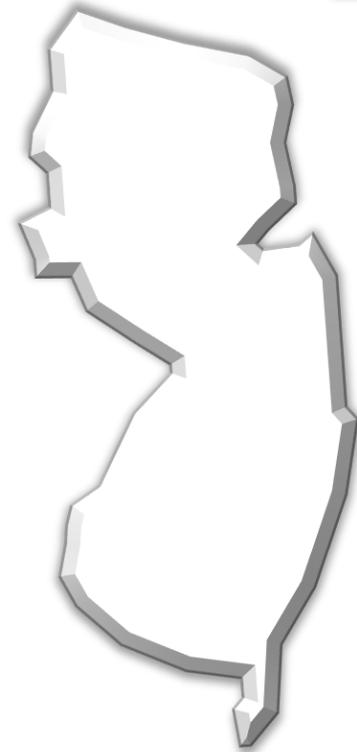
■ *Jeanette Combs, et al. vs. ABB Inc., et al*

- **Venue:** Alameda County
- **Date:** February 10, 2025
- **Judge:** Hon. McKinney
- **Pltf:** 38-year-old mesothelioma alleges secondary exposure through her father
- **Firm:** Simmons Hanly Conroy LLP
- **Order:** 2025 Order granting motion to compel genetic testing





- ***Barbara Mizer, et al. vs. Aisin U.S.A. MFG., Inc., et al.***
 - **Venue:** Middlesex County
 - **Date:** September 27, 2024
 - **Judge:** Hon. Viscomi
 - **Pltf:** 73-year-old mesothelioma alleging exposure from use of cosmetic talc products and take-home exposure from husband's auto mechanic work
 - **Firm:** Maune Raichle Hartley French & Mudd, LLC
 - **Order:** 2024 Stipulation & Protective Order granting blood DNA extraction and whole genome sequencing (through Breakthrough Genomics)





- ***Patricia Sadler, et al. vs. Banner Supply Co., et al.***
 - **Venue: Miami-Dade County**
 - **Date: November 11, 2024**
 - **Judge: Hon. Rodriguez**
 - **Pltf: 70-year-old mesothelioma alleged secondary exposure from her brother (prior asbestos-related lawsuit)**
 - **Firm: Bauta & Associates**
 - **Order: 2024 Agreement for genetic testing**



California – Fiber Burden Analysis



- ***Joy Moore, et al. vs. Avon Products, et al.***

- Venue: Los Angeles County
- Date: February 10, 2022
- Judge: Hon. Rice
- Pltf: 88-year-old (dec) mesothelioma alleged exposure to talc from make-up products
- Firm: Dean Omar Branham Shirley, LLP
- Order: 2022 Order for division of tissue material

- ***Jessica Rose vs. Basco Drywall, et al.***

- Venue: Alameda County
- Date: January 10, 2023
- Judge: Hon. Seabolt
- Pltf: 39-year-old mesothelioma secondary exposure alleged through her father's work around AC pipe
- Firm: Simmons, Hanly & Conroy
- Order: 2023 Order denying motion for digestion analysis



California – Fiber Burden Analysis



■ *Judy Golby, et al. vs. Amcord, Inc., et al.*

- Venue: Los Angeles County
- Date: February 7, 2024
- Judge: Hon. Seigle
- Pltf: 74-year-old (dec) mesothelioma alleges secondary exposure through her husband's work as a lumberyard laborer and floor tiler
- Firm: Simmons Hanly Conroy
- Order: 2024 *Tentative* order granting motion for digestion
(party settled prior to entering of the order)

■ *Cara Grimes vs. AAON, Inc., et al.*

- Venue: Alameda County
- Date: May 5, 2025
- Judge: Hon. McKinney
- Pltf: 75-year-old mesothelioma alleges secondary exposure from her brother and father's work in HVAC repair
- Firm: Maune Raichle Hartley French & Mudd, LLC
- Order: 2025 Pending Motion to compel production of tissue blocks for testing





- ***Fred Watford, et al. vs. Akebono Brake Corporation, et al.***

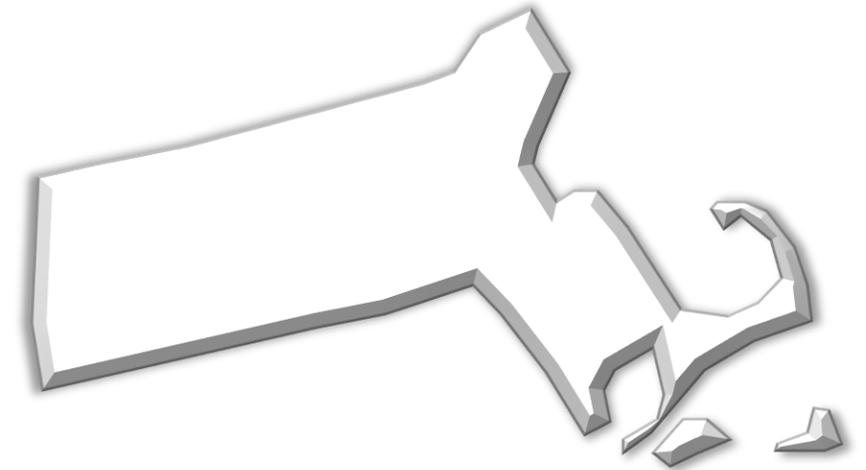
- **Venue: Broward County**
- **Date: November 5, 2023**
- **Judge: Hon. Bidwill**
- **Pltf: 86-year-old mesothelioma alleging exposure from automotive work and home remodeling/construction**
- **Firm: Maune Raichle Hartley French & Mudd, LLC**
- **Order: 2023 Order permitting limited autopsy**



Massachusetts – Fiber Burden Analysis



- ***Bryce Zundel vs. Boston Medical Products, et al.***
 - **Venue: Middlesex County**
 - **Date: February 28, 2024**
 - **Judge: Hon. Fishman (Special Master)**
 - **Pltf: 63-year-old mesothelioma alleging exposure to asbestos containing talc during the talc pleurodesis**
 - **Firm: Lanier Law Firm & Duffy Law LLC**
 - **Order: 2024 Order to compel plaintiffs to produce tissue blocks and digestion reports from experts**



Zundel (MA) – ERI Report March 25, 2024



Date: March 15, 2024

File No: ERI AS # 240333

Case Name-Bryce Alan Zundel

Specimen: A package with
in paraffin (C21-21748 A
of 3; CLN21-3295 A1 2 of
3, A4 2 of 3; CLS21-649
of 3, D1 2 of 3, D2 2 of 3
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by 0.4727 gm. tissue pool

Tissue was sent by: See a

Date received: March 5,

Date analyzed: March 11,
Bodies (R
March 14

Morphology of Specimen
original embedded mater

A.S. # 240333A. As much paraffin as possible was cut from the edge adjacent to the tissue after
which the respective sample of tissue underwent deparaffinization. The procedure for



ERI ANALYTICAL

Date: March 15, 2024

File No: ERI AS # 240333 A

Case Name-Bryce Alan Zundel

P. O. Box 2024, Tyler, Texas 75710
2026 Republic Drive, Suite A, Tyler, Texas 75701
Ph: (903) 534-5001 Fax: (903) 534-8701
www.ericonsulting.com

Zundel (MA) – ERI Report April 17, 2024



Date: April 17, 2024

File No: ERI AS # 240333

Case Name-Bryce Alan Zundel

Specimen: A package with
in paraffin (C21-21748 A
of 3; CLN21-3295 A1 2 of
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This sample was designat
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Tissue was sent by: See al

Date received: March 5, 2

Date analyzed: April 4, 20
Bottles: (R
April 16, 2

Morphology of Specimen

original embedded materi
as ERI A.S. # 240333D. As much paraffin as possible was cut from the edge adjacent to the tissue
after which the respective sample of tissue underwent deparaffinization. The procedure for



ERI ANALYTICAL

Date: April 17, 2024

File No: ERI AS # 240333 D

Case Name-Bryce Alan Zundel

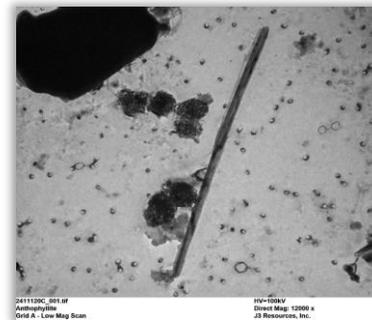
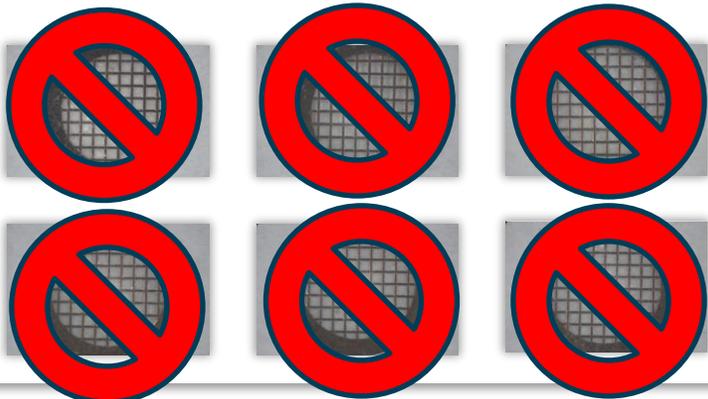
P. O. Box 2024, Tyler, Texas 75710
2026 Republic Drive, Suite A, Tyler, Texas 75701
Ph: (903) 534-5001 Fax: (903) 534-8701
www.ericonsulting.com

Pennsylvania – Fiber Burden Analysis



■ *Heather Carson vs. Mack Trucks, et al.*

- Venue: Philadelphia
- Date: December 3, 2024
- Judge: Hon. Levin
- Pltf: 54-year-old mesothelioma alleges secondary exposure through her father's (lab engineer) alleged bystander exposure to gasket and clutch work
 - Possible exposure on 9/11/2001 (NYC), and from cosmetic talc
- Firm: Locks Law Firm & Thornton Law Firm
- Order: 2024 agreement to divide tissue for digestion



1 anthophyllite asbestos fiber identified – lymph tissue only

New York – Fiber Burden Analysis



- ***Michael Wagner vs. AERCO International, Inc., et al.***

- Venue: New York
- Date: August 9, 2024
- Judge: Hon. Frank
- Pltf: 76-year-old mesothelioma alleging exposure through work as a soldier, flooring installer and auto mechanic
- Firm: Weitz & Luxenberg
- Order: 2024 Order granting request for tissue digestion



- ***Janet Perosi (Richard Edelson) vs. Amchem Products, Inc., et al.***

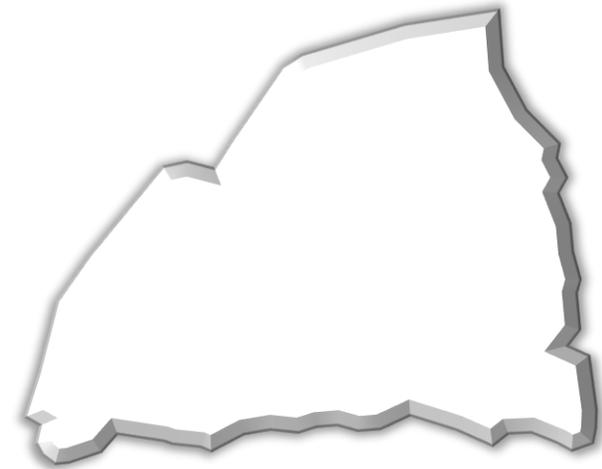
- Venue: New York
- Date: December 24, 2024
- Judge: Hon. Adams
- Pltf: 93-year-old (dec) mesothelioma alleging exposures from work with floor tiles
- Firm: Weitz & Luxenberg
- Order: 2024 Order permitting tissue digestive study



South Carolina – Fiber Burden Analysis



- ***Curtis Bolton, et al. vs. 3M Company, et al.***
 - **Venue: Spartanburg**
 - **Date: August 26, 2022**
 - **Judge: Hon. Toal**
 - **Pltf: 73-year-old (dec) mesothelioma alleged exposure through work as a welder and personal talc use**
 - **Firm: Simon Greenstone Panatier**
 - **Order: 2022 Consent Order allowing additional pathology testing**



Dr. Moline 2020 Paper – 33 “medico legal” subjects



- **September 2022:** *Bell v. Am. Int’l Indus.* (M.D.N.C. 2022). Motion practice resulted in disclosure that Betty Bell was a subject
 - Bell had previously claimed occupational exposure to asbestos at Hoechst Celanese Corporation and Pillowtex Corporation
- **May 2023:** Dr. Moline issued an erratum acknowledging that one subject had additional exposure through crocidolite cigarette filters
 - Dr. Moline’s own expert report in the *Kohr* case attributed causation to Kent cigarettes

Dr. Moline 2020 Paper – 33 “medico legal” subjects



- Additional individuals with alternative exposure:
 - **Danielle Polakow**: claimed bystander exposure to asbestos-containing roofing cement
 - **Doris Jackson**: Claimed exposure to degrading pipe insulation as a public school teacher
 - **Valerie Jo Dalis**: Submitted claim to bankruptcy trust
 - **Stephen Lanzo**: home contained exposed asbestos insulation, and Dr. Moline agreed at trial his schools likely had ACM
 - **Ann Zoas**: substantial family history of cancers, and extensive prior ionizing radiation for throat cancer



- Some qualifications acknowledging that some individuals had other exposures, **BUT**:
 - **Beverley Alleyne**: appears to be the 1st entry in the table indicating NO other exposures
 - Alleyne submitted sworn documents in the UK claiming workplace exposure and exposure in school buildings
 - **Leann Hurley**: appears to be final entry in the table, again NO alternative exposures
 - Had prior radiation therapy for endometrial carcinoma (Defense verdict 2022)
- **Additional subjects still being identified ...**

THANK YOU!

