

### TALC LITIGATION CONFERENCE

The Midland Hotel, Chicago | May 20, 2025

### The Talc Litigation Overview



Moderator:
Patricia M. Henrich, Esq.
Reilly, McDevitt & Henrich P.C.
Cherry Hill, NJ



Leslie Lombardy, Esq.
O'Toole Scrivo
Cedar Grove, NJ



Danny R. Kraft, Jr., Esq. Meirowitz & Wasserberg New York, NY



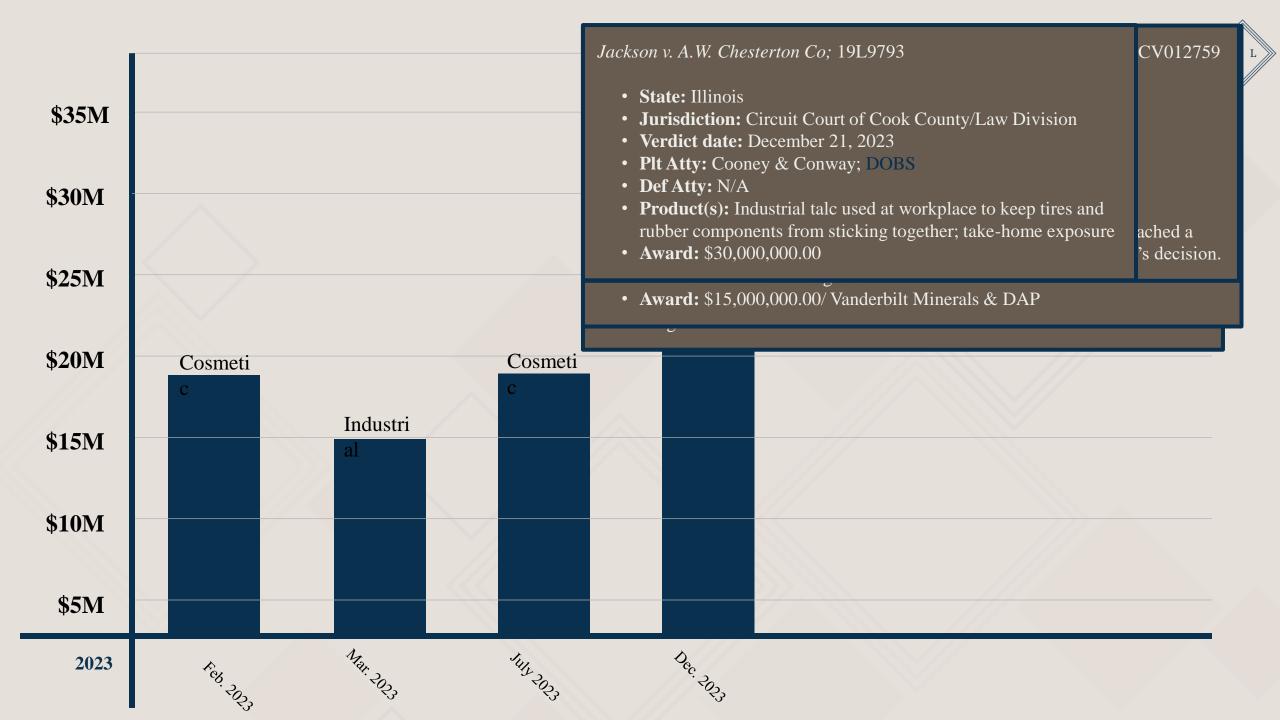
James Murdica, Esq.
Barnes & Thornburg LLP
New York, NY

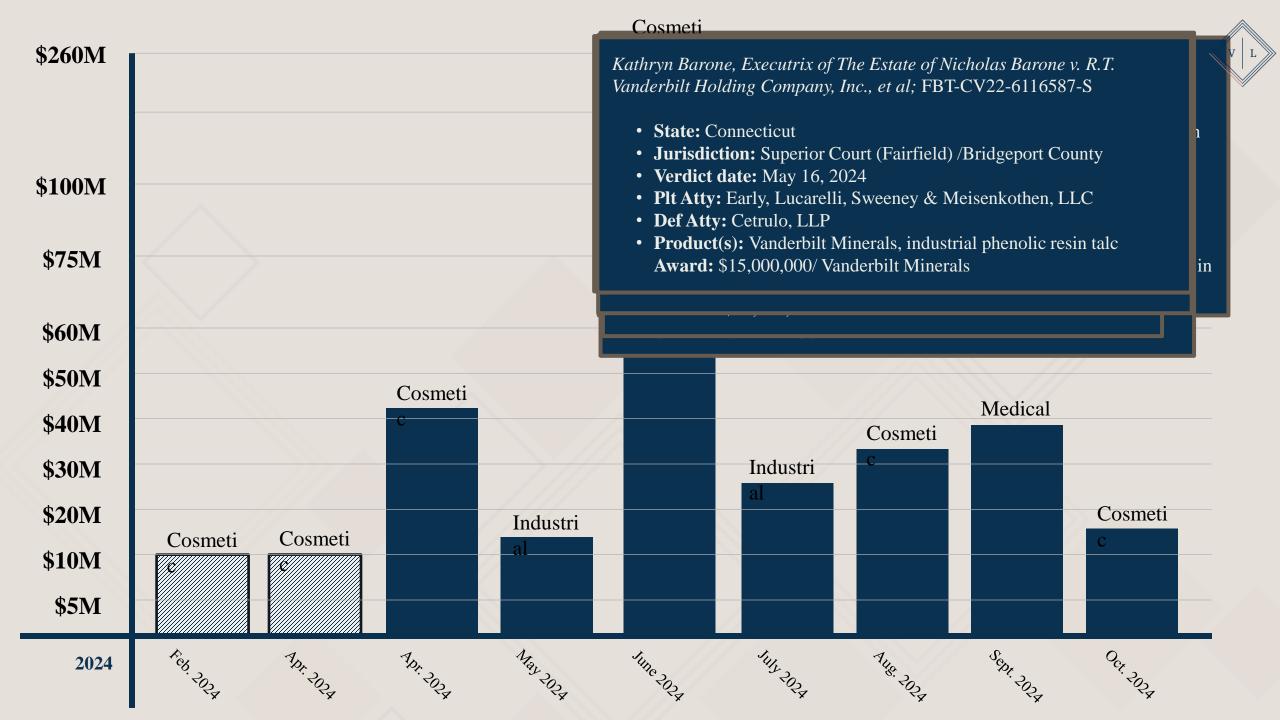


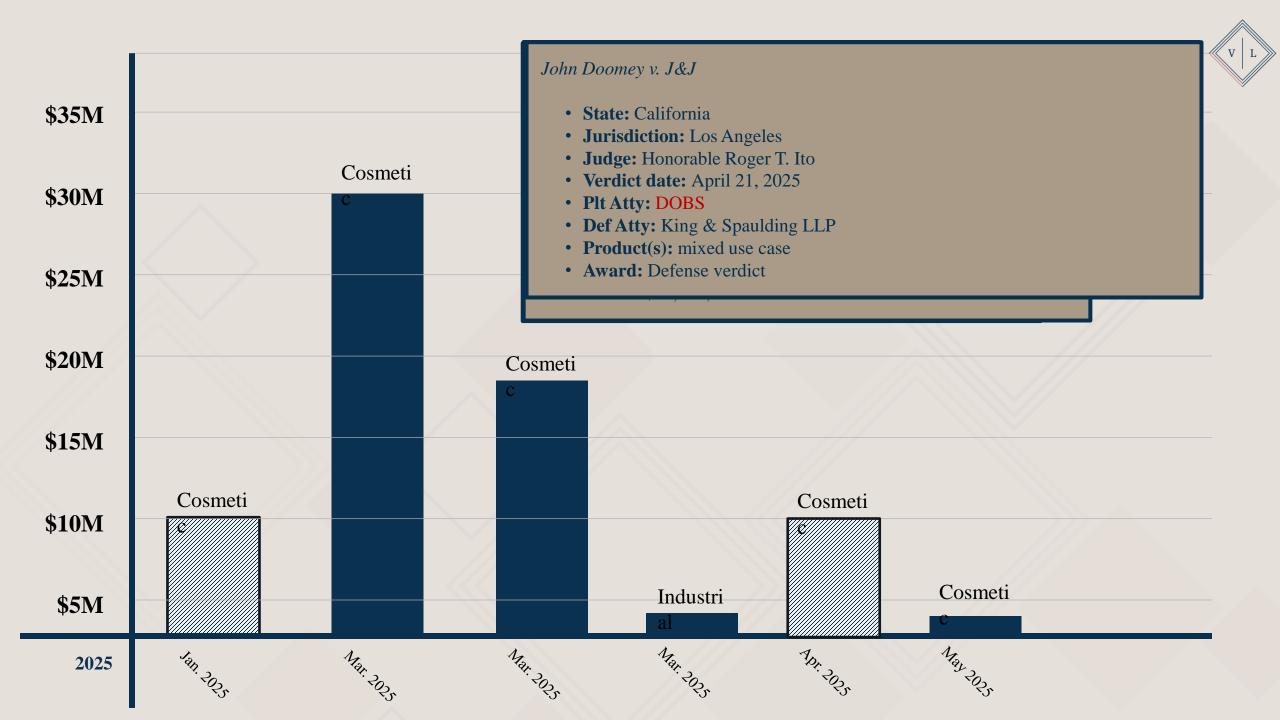
**David E. Rutkowski, Esq.**Goldberg Segalla
Newark, NJ



Nicholas J. Vogelzang, Esq. Vogelzang Law Chicago, IL







## Kyung H. Lee vs. Johnson & Johnson

B



**JUNE 3, 2024** 

- PLAINTIFFS' VERDICT \$260,000,000
  - Punitive Damages \$200,000,000
  - Noneconomic Damages \$60,000,000
- Oregon (Multnomah County)
- Honorable Katharine von Ter Stegge
- Kyung H. Lee (Liv) 50 y/o
- Plaintiffs' Counsel DOBS and Devin Robinson
- Defense Counsel Schwabe, Williamson & Wyatt
- Status Verdict Thrown Out; Plaintiff Appealed

## Kyung H. Lee vs. Johnson & Johnson

**JUNE 3, 2024** 



At least the <u>same</u> nine jurors must agree to your answer for <u>each and every</u> one of the following questions that you answer.

We the jury find as follows:

#### Negligence

Question 1: Was defendant negligent in one or more of the ways plaintiffs claim?

Johnson & Johnson

Yes / No

LLT Management LLC

Yes / No

If you answer Yes as to either defendant, go to Question 2 for that defendant. If you answer No as to both defendants, go to Question 3.

Question 2: Was defendant's negligence a cause of Kyung Lee's mesothelioma?

Johnson & Johnson

Yes\_ V No\_\_\_

LLT Management LLC

Yes\_ No\_\_\_

Go to Question 3.

#### Defective Product Liability

Question 3: Did the defendant sell a product in a condition that was defective and unreasonably dangerous to the ultimate consumer in one or more of the ways plaintiffs claim?

Johnson & Johnson

Yes / No\_\_\_

LLT Management LLC

Yes No

If you answer Yes as to either defendant, go to Question 4 for that defendant. If you answered No as to both defendants in Question 3, but Yes as to either defendant in Question 2, go to Question 5. Otherwise, sign the verdict form and answer no additional questions.

## Kyung H. Lee vs. Johnson & Johnson



**JUNE 3, 2024** 

Question 4: Was the product's defect a cause of Kyung Lee's mesothelioma?	
Johnson & Johnson Yes V No	Punitive Damages
LLT Management LLC Yes No  If you answered Yes as to either defendant for either Question 2 or Question 4, go to Question 5 for that defendant. Otherwise, sign the verdict form and answer no additional questions.	Only answer Question 8 if you have answered Yes to either Question 2 or Question 4 for Johnson & Johnson.  Otherwise, sign the verdict form and answer no additional questions.
Compensatory Damages  Question 5: What are Kyung Lee's non-economic damages?	Question 8: Did Plaintiff's prove with clear and convincing evidence that punitive damages should be assessed against Johnson & Johnson for the conduct that harmed plaintiff's?
\$s	Yes_/ No
Go to Question 6.  Question 6: What are Joe Lee's non-economic damages?	If you answer Yes to question 8, go to question 9. If you answer No to question 8, sign the verdict form and answer no additional questions.
S 12, 300, 000  Go to Question 7.	Question 9: What is the amount of punitive damages, if any, you assess against Johnson & Johnson?
Apportionment of Fault	s 200,000,000
Only answer Question 7 if you have found Johnson & Johnson at fault (answered Yes to either Question 2 or Question 4) <a href="mailto:and-have also found LLT Management LLC">and have also found LLT Management LLC</a> at fault (answered Yes to either Question 2 or Question 4). Otherwise, go to the instructions before Question 8.	Please have the Presiding Juror sign and date the form.
Question 7: What is the percentage of each party's fault? (The total must equal 100%)	Dated: 3 June 2024 PRESIDING JUROR
79.9% Johnson & Johnson  O. \ % LLT Management, LLC	After this verdict has been signed and dated, please notify the court clerk that you are ready to present your verdict in the courtroom.

## CIPRIANO RAMIERZ vs. AVON PRODUCTS

July 26, 2024





- Plaintiffs' Verdict \$24.4 Million
- Illinois (Circuit Court of Cook County)
- Judge Honorable Clare Elizabeth McWilliams
- Cipriano Ramirez (Living)
- Plaintiffs' Counsel Simmons Hanley Conroy
- Defense Counsel Foley Mansfield

## MICHAEL PERRY vs. JOHNSON & JOHNSON and A-I-I August 15, 2024





- Plaintiffs' Verdict \$63,000,000+
  - Economic Loss (past & future) \$3,800,000
  - Other Damages (past & future) \$19,237,500
  - Loss of Consortium (past & future) \$9,618,750
  - Punitive Damages J&J (\$30,000,000) and All (\$760,000)
- South Carolina (Richland County)
- Judge Honorable Jean Hoefer Total
- Michael Perry (Liv) 53 y/o
- Plaintiffs' Counsel DOBS and Kassell McVey
- Defense Counsel Fox Rothchild LLP & Nelson Mullins
- Status Defendants' Appeal Pending

## MICHAEL PERRY vs. JOHNSON & JOHNSON and A-I-I August 15, 2024



	VERDICT FORM	0, 5
	NEGLIGENCE	
We, the jury, find to negligence was a pro-	hat Defendant the Johnson & Johnson entities oximate cause of Plaintiff Michael Perry's injurie	were negligent, and its es:
No		
We, the jury, find the its negligence was a	at Defendant American International Industries ( proximate cause of Plaintiff Michael Perry's inju	AII), was negligent, and tries:
Yes		
No		
	STRICT LIABILITY	
We, the jury, find the defective products the	at Defendant the Johnson & Johnson entities are s at was a proximate cause of Plaintiff Michael Pe	strictly liable for selling rry's injuries:

l.	We, the jury, find that Defendant American International Industries (AII) is strictly liable for selling defective products that was a proximate cause of Plaintiff Michael Perry's injuries:
	Yes
	No
	FRAUDULENT MISREPRESENTATION
	We, the jury, find that Defendant the Johnson & Johnson entities engaged in fraudulent misrepresentation in selling its products and that fraudulent misrepresentation was a proximate cause of Plaintiff Michael Perry's injuries:
	Yes
	We, the jury, find that Defendant American International Industries (AII) engaged in fraudulent misrepresentation in selling its products and that fraudulent misrepresentation was a proximate cause of Plaintiff Michael Perry's injuries:
	Yes
	No
	DAMAGES
7.	If you answered "Yes" to any of Questions 1-6, please state the amount of actual damages that have been proven by the greater weight of the evidence:
licha	ael Perry's economic loss (past & future) \$ 3,800,000
licha	nel Perry's other damages (past & future) \$ 19,237,500
onni	e Long's loss of consortium damages (past & future) \$ 9, 618, 750

## MICHAEL PERRY vs. JOHNSON & JOHNSON and A-I-I August 15, 2024



#### WILLFUL, WANTON OR RECKLESS CONDUCT

 If you answered "Yes" to Questions 1, 2, 5, or 6, please answer this question as to any Defendant for which you answered "Yes." We, the jury, find by clear and convincing evidence that the conduct of the following Defendants was willful, wanton, or reckless:
 Johnson & Johnson

Yes

\_\_\_\_\_No

American International Industries (AII)

\_\_\_\_\_Yes

Foreperson

August 15, 2024

PUNITIVE DAMAGES VERDICT FORM	o
aintiff Michael Perry's claims against Defendant Johnson & Johnson entitles for damages, we, the jury, by unanimous consent, find:	or
 for Michael Perry in the amount of \$ 20,000 punitive damages (\$30 Million)	
aintiff Michael Perry's claims against Defendant American International Industrictive damages, we, the jury, by unanimous consent, find:  for Michael Perry in the amount of \$ \( \sum \bigcup	
Foreperson	
August 15, 2024	

### EVAN PLOTKIN vs. JOHNSON & JOHNSON

October 15, 2024





- Plaintiffs' Verdict \$15,000,000
- Connecticut (Fairfield at Bridgeport)
- **Judge** Honorable Barbara N. Bellis
- Evan Plotkin (Liv) 67 y/o
- Plaintiffs' Counsel DOBS and Early Lucarelli
- Defense Counsel Shook Hardy & Bacon

## EVAN PLOTKIN vs. JOHNSON & JOHNSON

B

#### October 15, 2024

We the jury find the issues for the plaintiff, EVAN PLOTKIN, as against the following

Defendants for which a checkmark is placed next to that Defendant's name:

,	_
$\checkmark$	Johnson & Johnson
/	4
✓_	Pecos River Talc, LLC
,	
	Johnson & Johnson Holdco (NA) Inc.
. /	
$\checkmark$	Kenvue, Inc.
_/	
$\checkmark$	LLT Management LLC

and award fair, just and reasonable compensatory damages in the amount as follows:

			,
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73 14	A . 1	l '	
713	/ W . I .	101	
	11/1		

SIGNED BY THE FOREPERSON

DATED

October 15, 2024

Verdict Ordered Accepted and Recorded October 15, 2024 3:35 pm Judge C. Reed

#### JURY INTERROGATORIES

#### SUCCESSOR LIABILITY

1. Do you find, by a fair preponderance of the evidence, that the following entities are the successors-in-interest to Johnson & Johnson and/or Johnson & Johnson Consumer Inc. (old JJCI) on the basis that they merely continued the business of Johnson & Johnson and/or Johnson & Johnson Consumer Inc. (old JJCI) as defined in the court's jury charge on the mere continuation/continuity of enterprise rule?

Kenvue, Inc.

Johnson & Johnson Holdco (NA), Inc.

YES NO
NO

2. Do you find, by a fair preponderance of the evidence, that the following entities are the successors-in-interest to Johnson & Johnson and/or Johnson & Johnson Consumer Inc. (old JJCI) on the basis of the product-line rule of successor liability in that they continued to manufacture the same line of talc products alleged to have caused injury to Plaintiff Evan Plotkin as defined in the court's jury charge on the product-line rule?

Kenvue, Inc.

Johnson & Johnson Holdco (NA), Inc.

YES

NO

NO

NO

## EVAN PLOTKIN vs. JOHNSON & JOHNSON

October 15, 2024

#### STRICT LIABILITY

3. Did the plaintiff prove, by a fair preponderance of the evidence, that the following defendants' products to which Mr. Plotkin was exposed were sold in a defective condition unreasonably dangerous to the consumer or user as defined in the court's jury charge on strict liability?

Johnson & Johnson	$_{\rm YES}$	NO
Pecos River Talc, LLC	YES 🗸	NO
Kenvue, Inc.	YES 🗸	NO
Johnson & Johnson Holdco (NA), Inc.	YES V	NO
LLT Management LLC (f/k/a LTL	YES	NO
Management, LLC)		

#### NEGLIGENCE

4. Did the plaintiff prove by a fair preponderance of the evidence that the following defendants were negligent in that they failed to use ordinary care in the sale of Johnson's Baby Powder as defined in the court's jury charge on negligence?

Johnson & Johnson	YES_\	NO
Pecos River Tale, LLC	YES	NO
Kenvue, Inc.	YES	NO
Johnson & Johnson Holdco (NA), Inc.	YES	NO
LLT Management LLC (f/k/a LTL	YES _	NO
Management, LLC)		

#### WARNINGS

5. Did the plaintiff prove by a fair preponderance of the evidence that the following defendants' products to which Mr. Plotkin was exposed were in a defective condition because the defendants failed to provide adequate warnings or instructions as defined in the court's jury charge on failure to warn?

	/	
Johnson & Johnson	YES 🗸	NO
Pecos River Talc, LLC	YES V	NO
Kenvue, Inc.	YES	NO
Johnson & Johnson Holdco (NA), Inc.	YES 🗸	NO
LLT Management LLC (f/k/a LTL	YES 🗸	NO
Management, LLC)		

If you answered "Yes" to any one of questions #3, #4, and #5, proceed to the next question. If you answered "No" to each of #3, #4, and #5, then you are directed to sign defendant's verdict form.

#### CAUSATION

6. Did the plaintiff prove by a fair preponderance of the evidence that a product defect or negligence by the following defendants was a proximate cause that led to the development of Mr. Plotkin's injury for which he seeks compensation as defined in the court's jury charge on proximate cause?

Johnson & Johnson	YES _	NO
Pecos River Talc, LLC	YES	NO
Kenvue, Inc.	YES	NO
Johnson & Johnson Holdco (NA), Inc.	YES/_	NO
LLT Management LLC (f/k/a LTL	YES	NO
Management, LLC)		

If you answered "Yes," proceed to the next questions. If you answered "No," then you are directed to sign defendant's verdict form.

#### COMPENSATORY DAMAGES

7. What damages, if any, has the plaintiff proven by a fair preponderance of evidence are fair, just and reasonable compensatory damages for the injuries sustained by Plaintiff Evan Plotkin as defined in the court's jury charge on damages?

#### FAILURE TO MITIGATE DAMAGES

8. What damages (if any, as set forth in your response to Question 7) have defendants proven by a fair preponderance of the evidence were the result of plaintiff's failure to mitigate damages as defined in the court's jury charge on duty to mitigate damages:



#### PUNITIVE DAMAGES

The jury finds as follows on whether the plaintiff has proven by a fair preponderance of the evidence that punitive damages, as defined in the court's jury charge on punitive damages, should be awarded against the following defendants:

Johnson & Johnson Pecos River Talc, LLC	YES YES	NO NO	_
Kenvue, Inc.  Johnson & Johnson Holdco (NA), Inc.	YES V	NO	
LLT Management LLC (f/k/a LTL Management, LLC)	YES	NO	



10/15/2024

PRINT:



## E/O MICHAELEEN LEE vs. JOHNSON & JOHNSON January 4, 2025





- **DEFENSE VERDICT –** Johnson & Johnson
- Pennsylvania (Allegheny County) 1/4/2025
- Judge Honorable Phillip J. Ignelzi
- Michaeleen Lee (Dec) 70 y/o
- Plaintiffs' Counsel DOBS
- **Defense Counsel –** Kelley Jasons McGowan

## E/O MICHAELEEN LEE vs. JOHNSON & JOHNSON January 4, 2025



## VERDICT SHEETS

VERDICT SLIP				
QUESTION 1				
Were any	of the following entities negligent?			
Avon:	YESNO			
Colgate Palmolive Company:	YESNO			
Estee Lauder Inc.:	YESV_NO			
Imi Fabi:	YESV_NO			
Johnson & Johnson:	YESNO			
Scholl's Wellness Co., LLC:	YESVNO			
If you have answered "YES" to any of the above please proceed to Question 2. If you have answered "NO" to all of the above please proceed to Question 4.				
If you have answered "N  Was the negligence of any entity	O" to all of the above please proceed to Question 4.			
If you have answered "N  Was the negligence of any entity	O" to all of the above please proceed to Question 4.  QUESTION 2  y below a factual cause of any harm to Michaeleen Lee?			
If you have answered "N  Was the negligence of any entity  Only answer for entities f	QUESTION 2  y below a factual cause of any harm to Michaeleen Lee? for which you have chosen "YES" in Question 1.			
Was the negligence of any entity Only answer for entities for	QUESTION 2  y below a factual cause of any harm to Michaeleen Lee?  for which you have chosen "YES" in Question 1. YESNO			
Was the negligence of any entity Only answer for entities for Avon: Colgate Palmolive Company:	QUESTION 2  y below a factual cause of any harm to Michaeleen Lee? for which you have chosen "YES" in Question 1. YES			

Scholl's Wellness Co., LLC:

#### **QUESTION 4**

Did Michaeleen Lee rely to her detriment on any statement of material fact that was made by Johnson & Johnson, to conceal or omit material information about the safety of the product at issue as proven by clear and convincing evidence?

\_\_\_\_\_ YES \_\_\_\_\_ NO

If you have answered "YES" to Question 4 please proceed to Question 5. If you have answered "NO" to Question 4 please proceed to Question 6.

#### **QUESTION 5**

Was Michaeleen Lee's detrimental reliance on any statement of material fact made to conceal or mit material information by Johnson & Johnson about the safety of the product at issue a factual cause of harm to Michaeleen Lee?

Please proceed to Question 6.

#### QUESTION 6

Did Michaeleen Lee rely to her detriment on any statement or conduct of material fact ntentionally or negligently made by Johnson & Johnson which misrepresented the safety of the product at issue as proven by clear and convincing evidence?

√ YES N

If you have answered "YES" to Question 6, please proceed to Question 7. If you have answered "NO" to Question 6, please proceed to Question 8.

## E/O MICHAELEEN LEE vs. JOHNSON & JOHNSON January 4, 2025



#### **QUESTION 7**

Was Michaeleen Lee's detrimental reliance on any statement or conduct of material fact intentionally or negligently made by Johnson & Johnson misrepresenting the safety of the product at issue a factual cause of harm to Michaeleen Lee?

\_\_\_\_YES \_\_\_\_\_NO

Only proceed to Question 8 if any of the following have occurred:

- a. If you have answered "YES" for any entity at Questions 1 & 2 and/or;
- b. If you answered "YES" for both Questions 4 & 5; and/or
- c. If you answered "YES" for both Questions 6 & 7.

#### **OUESTION 9**

Do you find Johnson & Johnson's conduct in this case warrants a finding of Punitive Damages?

If you have answered "NO" to Question 9 answer no further Questions. You have reached a verdict and the foreperson should sign and date the form. Please inform Court Staff you have reached a verdict.

If you have answered "YES" to Question 9, please proceed to Question 10

#### **QUESTION 10**

What amount of Punitive Damages, if any, do you award the Plaintiff's in this case?

s 22 million

FOREPERSON MUST SIGN AND DATE BELOW

1-4-25 DATE

SIGNATURE OF FOREPERSON

Please advise the Court Officer you have reached a verdict.

### JOHN DOOMEY VS. JOHNSON & JOHNSON

APRIL 21, 2025



- **DEFENSE VERDICT –** Johnson & Johnson
- California (Los Angeles County)
- Judge Honorable Roger T. Ito
- John Doomey (Living)
- Plaintiffs' Counsel DOBS
- Defense Counsel King & Spalding LLP

### JOHN DOOMEY VS. JOHNSON & JOHNSON

APRIL 21, 2025

## Verdict Sheets

	SECTION A: 1	NEGLIGEN	CE	
OUESTION 1: Was Defend				
Johnso	on & Johnson	YES	_ NO X	_
LLT	on & Johnson Management LLC	YES	NO_X	_
f you answered "YES" to Qi f you answered "NO" for ei inswered "NO" for both def	ther defendant, do n	iot answer Qu	estion 2 for tha	
QUESTION 2: Was Defend	ant's negligence a s	ubstantial fac	tor contributing	to John Doomey
isk of developing mesotheli	oma?			
Johnso	on & Johnson	YES	NO	
LLT	Management LLC	YES	NO	12
Proceed to Section B.				
SECTION B: STRICT	PRODUCTS LIA	BILITY - M	IANUFACTUR	ING DEFECT
QUESTION 3: Did the John	nson's Baby Powder	contain a ma	nufacturing def	ect when it left
Defendant's possession?			27	
Johnso	on & Johnson Management LLC	YES	_ NO X	
LLT	Management LLC	YES	_ NO_X	
				for that defenda

YES YES aby Powder's	reasonably foreseeable way? NO
aby Powder's	
aby Powder's	
aby Powder's	
	design outweigh the benefits?
VEC	NO X
VES	NO X
113	_ 110
Baby Powder	r a substantial factor contributir
YES	NO
YES	NO
LIABILITY	- FAILURE TO WARN
have potentia	al risks that were known or
nowledge that	was generally accepted in the
	950 🗱
YES	NO X
	J
	cither defendant AND 6 for eit NO" to Quest Baby Powder a? YESYES Thave potentian nowledge that



- Plaintiffs' Verdict \$3,000,000
- Louisiana (Parish of New Orleans)
- Judge Honorable Kern A. Reese
- Jeannine Henderson (Liv) 72 y/o
- Plaintiffs' Counsel DOBS
- Defense Counsel King & Spaulding LLP

#### JURY INTERROGATORIES

Do you find, by a preponderance of the evidence, that Jeannine Henderson had significant exposure to asbestos from products manufactured and/or sold by Johnson & Johnson and/or Pecos River Tale LLC, which was a substantial factor of Jeannine/Henderson's mesothelioma?

YES NO 1111

If you answered "No", then stop here, answer no further questions, have the jury foreperson sign and data this form, and return to the courtroom. Otherwise, proceed to Interrogatory No. 2.

2. Do you find, by a preponderance of the evidence, that any of the following entities were negligent and that their negligence was a substantial factor in the development of Jeannine Henderson's mesothelioma?

	YES	NO	_11ti
Johnson & Johnson	<b>/</b>		
Pecos River Talc LLC			THE !
Avon Products, Inc.			##
Bell South Telecommunications, Inc.		<b></b>	'
Colgate-Palmolive Company		V	HIIII
Johns-Manville	/		112111
Jefferson Transit/Transdev Services, Inc.		V	
WR Grace		/	IIII I

(Please proceed to the next question.)

Do you find, by a preponderance of the evidence, that any of the following entities' products were unreasonably dangerous per se, and that the unreasonably dangerous condition was a substantial factor in the development of Jeannine Henderson's mesothelioma?

•	YES	NO		116
Johnson & Johnson			111	31
Pecos River Talc LLC			110	11
Avon Products, Inc.	<b>√</b>		111	M
Colgate-Palmolive Company			拙知	
Johns-Manville	/		147	
WR Grace			1111	I

(Please proceed to the next question.)

4. Do you find, by a preponderance of the evidence, that any of the following entities' products were unreasonably dangerous in construction or composition, and that the unreasonably dangerous condition was a substantial factor in the development of Jeannine Henderson's mesothelioma?

		YES	NO	
Johnson & Johnson		/		1111
Pecos River Talc LLC		V		HIL
Avon Products, Inc.	1.	V		111
Colgate-Palmolive Company			<b>/</b>	
Johns-Manville		/		THI"
WR Grace			/	1411

(Please proceed to the next question.)

5. Do you find, by a preponderance of the evidence that any of the following entities' products were unreasonably dangerous due to a defective design, and that the defect was a substantial factor in the development of Jeannine Henderson's mesothelioma?

	YES	NO	
Johnson & Johnson			_111
Pecos River Talc LLC		<b>/</b>	HAT
Avon Products, Inc.		$\checkmark$	1121
Colgate-Palmolive Company		/	141
Johns-Manville		✓	tet!
WR Grace		/	_##1

(Please proceed to the next question.)

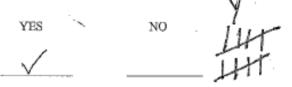
111

6. Do you find, by a preponderance of the evidence, that any of the following entities' products were unreasonably dangerous due to their failure to warn of the hazards associated with asbestos, and that their failure to warn was a substantial factor in the development of Jeannine Henderson's mesothelioma?

	YES	NO
Johnson & Johnson	· 🗸	11
Pecos River Talc LLC		4
Avon Products, Inc.	<b>√</b>	14
Colgate-Palmolive Company		V 4
Johns-Manville	V	H
WR Grace		/ 1

(If you answered "Yes" to Questions 2, 3, 4, 5, or 6, proceed to the next question. If you answered "No" to all of those questions, do not answer any of the other questions. Have the foreperson sign and date this form and advise the court personnel that a verdict has been reached.)

7. Do you find by a preponderance of the evidence, that at the time the product left Johnson & Johnson's control, they did not know and, in light of then-existing reasonably available scientific and technological knowledge, could not have known of the characteristic that caused the damage or the danger of such characteristic?



8. As to any of the entities listed below for which you answered "Yes" in Questions 2, 3, 4, 5, or 6, what percentage of fault do you assign to them?

	%	
Johnson & Johnson	45	1417 9011
Pecos River Talc LLC	2	11-1-1111
Avon Products, Inc.	8	##1
Bell South Telecommunications, Inc.	0	HT !'
Colgate-Palmolive Company	0	144-11
Johns-Manville	45	711
Jefferson Transit/Transdev Services, Inc.	0	HIII II
WR Grace	0	411-11
TOTAL	100%	1111

(Please proceed to the next question.)

9.	Please express in dollars, the total mor Plaintiffs for the damages, if any, Jeanni		
	Physical Pain and Suffering	s <u>85,000</u>	MIH

Mental Anguish S 85,000 HHIII

Loss of Enjoyment of Life S 85,000 HHIII

Medical Expenses \$ 2,570,206.09

TOTAL \$ 2,825,200.09

10. Please express in dollars, the total monetary compensation that will fairly compensate Plaintiffs for the damages, if any, they have sustained in the past or will sustain in the future as a result of Jeannine Henderson's death, including loss of the love, affection and companionship of the Decedent, and the grief and anguish of the beneficiary in question.

Joshua Henderson \$ 90,000 1HT IIII

Justin Henderson S 90,000 JH III

PLEASE SIGN AND DATE THIS JURY VERDICT FORM AND RETURN IT TO THE COURT.

FOREPERSON DATE

## O'TOOLE SCRIVO

ATTORNEYS AT LAW

## NEW JERSEY TALC LITIGATION: BACKGROUND AND DEVELOPMENTS

Leslie Lombardy, Esq., *Partner*O'Toole Scrivo, LLC
May 20, 2025





1) New Jersey Product Liability Act & Its Application to Cosmetic Talc Cases



2) Cosmetic Talc Cases vs. Traditional Asbestos Cases



3) What is a 104 Hearing?



4) Clark 104 Hearings and the Pending Motions



5) Judge Viscomi's Interesting Decisions: Design Defect Proofs at Summary Judgment



6) Judge Viscomi's Interesting Decisions: Application of Retailer Immunity



## NEW JERSEY PRODUCT LIABILITY ACT & ITS APPLICATION TO COSMETIC TALC CASES:

- N.J.S.A. 2A:58C-1 defines a product liability action as "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty."
- On June 30, 2015, Judge Ana C. Viscomi entered her decision in *Fishbain*, MID-L-5633-13AS, finding that the New Jersey Product Liability Act applied to actions involving personal use products allegedly containing asbestos.
- In *In re Accutane II*, 235 N.J. 229 (2018), the New Jersey Supreme Court explained that a choice of law analysis for each plaintiff in a consolidation case would eliminate judicial efficiency and applied the New Jersey Products Liability Act ("NJPLA") to 532 cases (including cases with plaintiffs from forty-four other jurisdictions).
- In 2019, at a hearing on motion to deconsolidate, Judge Viscomi relied on the NJ Supreme Court's decision in *In Re Accutane II* and announced her intent to apply the NJPLA to <u>all</u> cosmetic talc cases. Judge Viscomi indicated that a blanket application of the NJPLA to all cosmetic talc cases would eliminate the "arduous" task of determining whether the laws of another jurisdiction apply.
- Since 2019, Judge Viscomi has consistently applied the NJPLA to cosmetic talc cases.



## COSMETIC TALC CASES vs. TRADITIONAL ASBESTOS CASES



С	OSMETIC TALC CASES	TRADITIONAL ASBESTOS CASES
•	Concern harm caused by products intended for personal consumption or use (e.g. makeup and body powder)	<ul> <li>Concern harm caused by exposure to toxic chemicals or substances (e.g. industrial talc)</li> </ul>
•	NJPLA Applies- No Common Law Claims Permitted	Common Law Claims Permitted
•	Joint and Several Liability	Environmental Tort Exception

## WHAT IS A RULE 104 HEARING?

- Under N.J.R.E. 104(a), the court shall decide any preliminary question about whether a witness is qualified, a privilege exists, or evidence is admissible. In so deciding, the court is not bound by evidence rules, except those on privilege and Rule 403.
- Rule 104 hearings can be ordered by a *motion in limine* or can be ordered sua sponte.
- Historically, New Jersey trial courts have utilized the Landrigan standard to determine the admissibility of an expert's testimony. Presently, the courts also use the Daubert standard which was adopted in In Re Accutane Litigation, 234 N.J. 340 (2018) to determine the reliability and admissibility of expert testimony.





## CLARK 104 HEARINGS AND THE PENDING MOTIONS:

Judge Ana C. Viscomi held a series of Rule 104 hearings in *Clark*, MID-L-3809-18AS over the course of 2024 and heard closing arguments on the hearings on January 21, 2025.

There are eight pending 104 motions before Judge Viscomi:

- 1. Defendants' Motion to Exclude Dr. Longo's Tissue Digestion Testimony;
- 2. Defendants' Motion to Exclude Drs. Longo/Compton Amphibole Opinions;
- 3. Defendants' Motion to Exclude Dr. Bailey's Testimony Re: Geology;
- 4. Defendants' Motion to Exclude Dr. Madigan's Testimony;
- 5. Defendants' Motion to Exclude Dr. Brody's Testimony Re: Non-asbestiform Cleavage Fragments and Johnson's Baby Powder Lot 228P;
- 6. Defendants' Motion to Exclude Dr. Haber's Testimony Re: Non-asbestiform Cleavage Fragments;
- 7. Plaintiff's Motion Exclude Dr. Roggli's Testimony; and
- 8. Plaintiff's Motion to Exclude Dr. Sanchez.



## JUDGE VISCOMI'S INTERESTING DECISIONS: DESIGN DEFECT PROOFS AT SUMMARY JUDGEMENT

The trial court recently issued a tentative decision partially granting defendant's summary judgment motions as to plaintiffs' design defect claim because the plaintiffs did not offer competent expert opinion to support the claim. Specifically, plaintiffs' expert, Dr. Moline, was not competent to testify as to whether there were any feasible alternative designs for a powder product, and her opinion on that issue would be a net opinion.





## JUDGE VISCOMI'S INTERESTING DECISIONS: APPLICATION OF RETAILER IMMUNITY

- On May 23, 2024, Judge Viscomi denied Plaintiff's motion for reconsideration of the Court's April 28, 2023, Order granting Defendant retailer's summary judgment motion based on the N.J. PLA's retailer immunity provision (N.J.S.A. 2A:58C-9) in the Sanden, MID-L-7932-20AS matter.
- N.J.S.A. 2A:58:C-9(d)(2) provides that a product seller, shall be liable if: "[t]he product seller knew or should have known of the defect in the product which caused the injury, death or damage or the plaintiff can affirmatively demonstrate that the product seller was in possession of facts from which a reasonable person would conclude that the product seller had or should have had knowledge of the alleged defect in the product which caused the injury, death or damage."
- The Court found, based on the record, the Defendant retailer satisfied its burden demonstrating no genuine issue of material fact. The Court held that Plaintiff failed to "affirmatively" demonstrate that the Defendant retailer was in possession of facts from which a reasonable person could conclude it had or should have had knowledge of the alleged defects.







Bryce and Diane Zundel

## CIVBAR

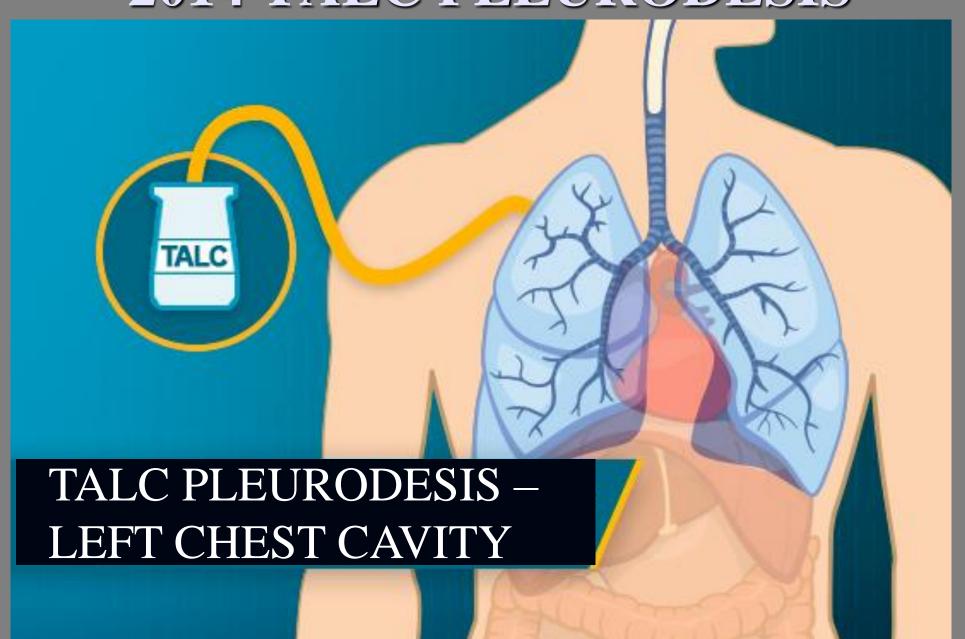
PERFORMANCE MINERALS





# THE PROCEDURE

# 2014 TALC PLEURODESIS



#### sterile talc 5 gram

Ordering Provide

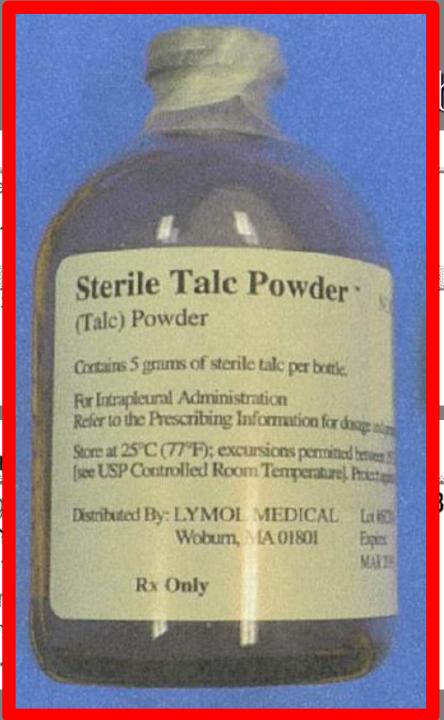
Ordered On: 06/

#### Timestamps

Performed 06/1: 0827 Documented: 06/13/14 0827

#### sterile talc 5 grai

Electronically sig Ordering user: In Frequency: 06/ Admin instruction Medication common Package: 63256



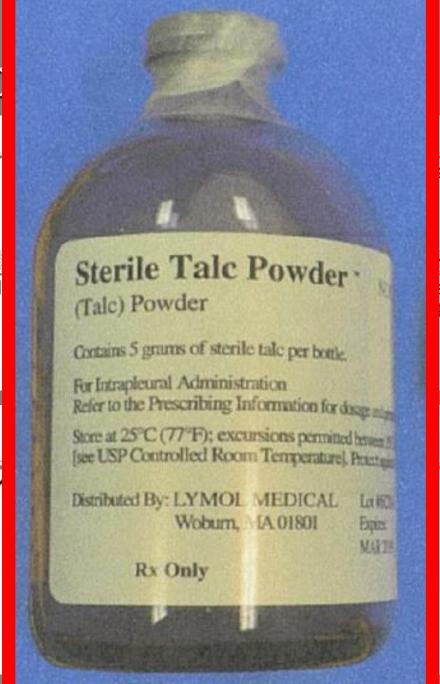


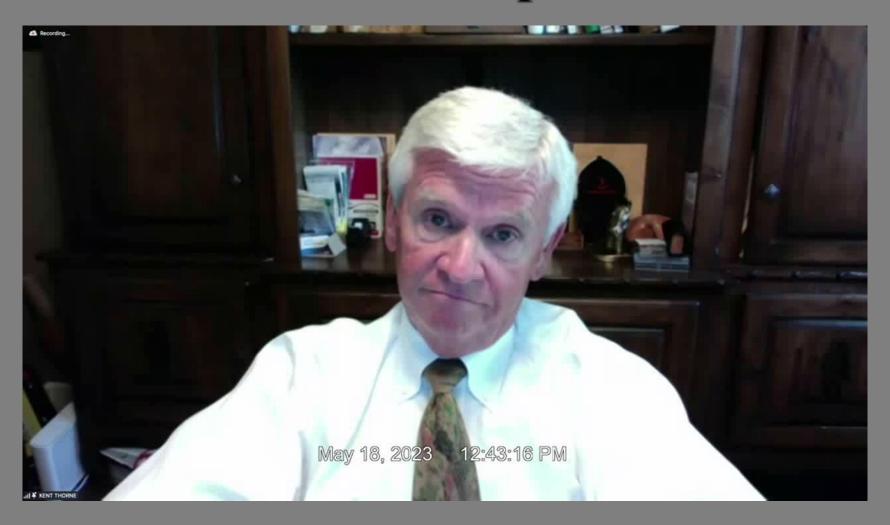
EXHIBIT 17

on: Patient

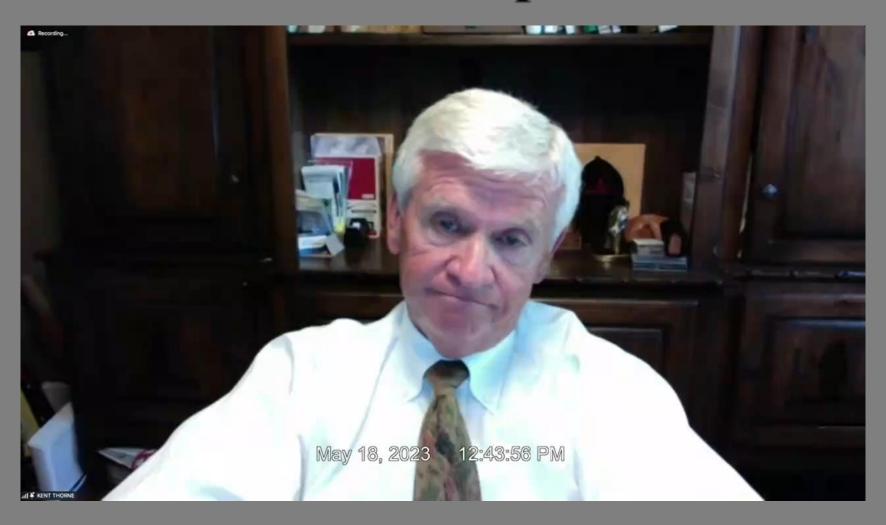
ent Thorne, MD laudia Swanson

Status: Active

# Dr. Thorne- talc pleurodesis



# Dr. Thorne- talc pleurodesis



# LEFT SIDE MALIGNANT PLEURAL MESOTHELIOMA



# LEFT SIDE MALIGNANT PLEURAL MESOTHELIOMA

#### SURGICAL PATHOLOGY REPORT

Specimen(s) Submitted As: A. Parietal pleura, B. Visceral pleura, C. Diaphragm, D. Parietal pleura

Pre-op Diagnosis:

Post-op Diagnosis:

Clinical History:

Special Exams Requested:

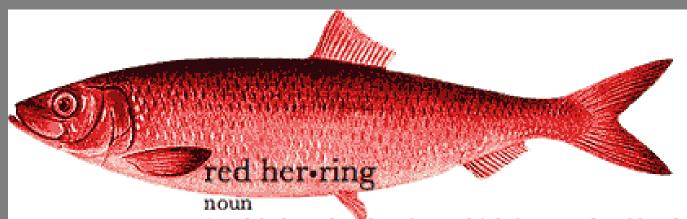
EXHIBIT 30

#### FINAL DIAGNOSIS:

- A-D. Pleura, parietal, visceral, diaphragmatic; biopsy/decortication:
  - Diffuse malignant mesothelioma, biphasic type (see comment).
  - Changes consistent with prior talc pleurodesis.

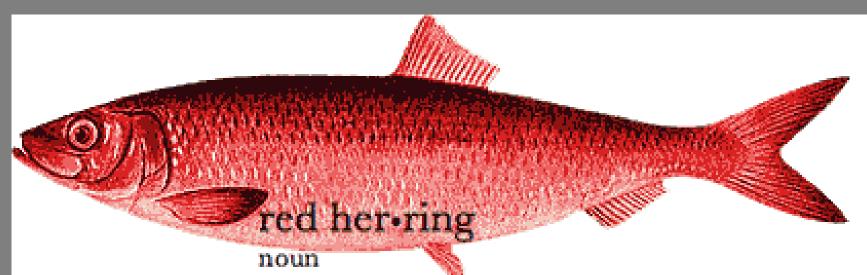
# Changes consistent with prior talc pleurodesis.

# LATENCY-inhalation



- 1 a dried smoked herring, which is turned red by the smoke.
- 2 something, esp. a clue, that is or is intended to be misleading or distracting: the book is fast-paced, exciting, and full of red herrings. [ORIGIN: so named from the practice of using the scent of red herring in training hounds.]

## **Zundel is First Case**



- 1 a dried smoked herring, which is turned red by the smoke.
- 2 something, esp. a clue, that is or is intended to be misleading or distracting: the book is fast-paced, exciting, and full of red herrings. [ORIGIN: so named from the practice of using the scent of red herring in training hounds.]

# MEDICAL CAUSATION- SUBSTANTIAL CONTRIBUTING FACTOR AND LATENCY

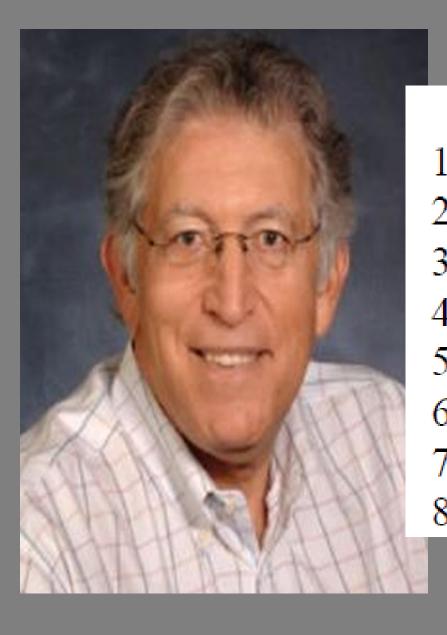


Page 2760

Q. We've asked you to come in and discuss
the concept of latency as it relates to
inhalation versus direct application of
asbestos fibers to the pleura.

Are you prepared to talk to the jury
about that today?

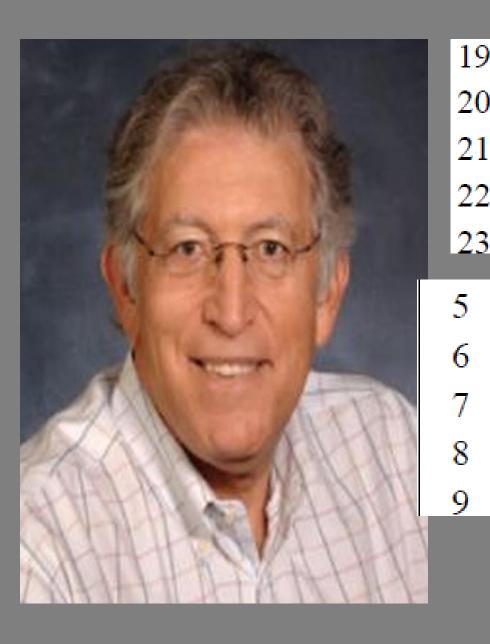
A. Yes.



A. That's right.

Q. You indicated that, based upon your research and your review of the scientific literature, an average latency period may take on the order of a decade to many decades before asbestos that's inhaled can cause mesothelioma, correct?

A. Correct.



Q. To a reasonable degree of scientific certainty, what, if any, opinion do you hold regarding whether the sterile talc containing EliteTalc from Cimbar was or was not a cause of Mr. Zundel's mesothelioma?

A. Right. Well, the way it was applied and the timing involved and the developments of the mesothelioma, with knowledge that there's asbestos that was in the treatment, my opinion is it caused the disease.



1	Q. Is there a difference, Doctor, in
2	terms of latency period from interaction with
3	asbestos as it relates to inhalation exposures
4	and direct application or instillation of
5	asbestos on the plural surface?
6	A. Yes, no question.
7	Q. Can you explain that to the jury?
8	A. Yes. So these are both in vitro when
9	you're using cells, just cells. And then
10	there are what are called injection studies.
11	I haven't done this, but a number of
12	scientists have taken asbestos and injected it
13	directly into the peritoneal cavity or into
14	the pleural cavity. So then the fibers go
15	directly onto the mesothelial cells, and there
16	the latencies are much shorter.



Q. And what's the significance of that in terms of when animals develop mesothelioma from inhalation versus injection studies to our discussion here today in the Zundel case?

A. Well, of course, I mean, in this case, you're talking about application of the material directly to the mesothelial surface. So you'll have a -- you should expect a faster transformation period, a faster latency.

# Dr. Thorne



# Dr. Thorne



# Dr. Patel



# Dr. Patel



#### BY MR. KRAFT:

O. All right. If it's found that t	there
------------------------------------	-------

9 A. So if there was asbestos present, then my recommendation would be not to put that in 10 the pleural cavity. 11 12 BY MR. KRAFT: Q. Why? 13 A. Because asbestos is a carcinogen. 14 And asbestos, as a carcinogen, has 15 16 been linked to mesothelioma, correct? A. Yes, it has --17

# TALC WITH ASBESTOS IS CARCINOGENIC AND CAUSES MESOTHELIOMA

# IARC 1987 IARC 2012

# CIMBAR

## NOT EVEN A SPECK



- Q. No amount of asbestos would have been acceptable in Cimbar's talc, correct?
  - A. Correct statement.
  - Q. Even a speck of asbestos was too much, according to Cimbar, correct?
    - A. That's correct.

9

10

11

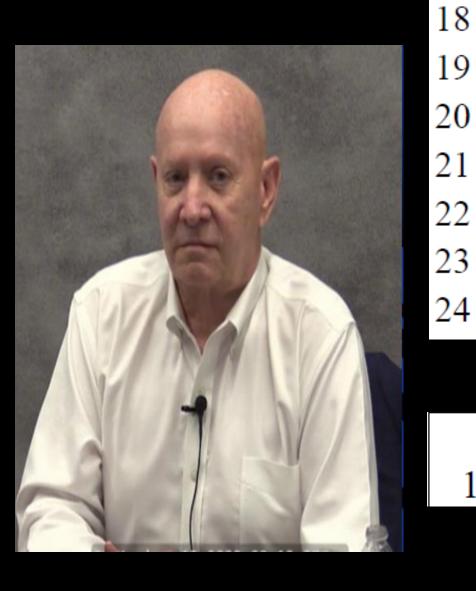
12

13

15

16

- Q. You saw Dr. Patel testify to this jury that it would be improper to use a talc containing asbestos for a talc pleurodesis procedure. Does Cimbar agree with that?
- A. Again, Cimbar is not an expert, not a doctor, but I heard -- I did hear his statements, yes.



	Q. The reason that Cimbar would not
ac	cept even a speck of asbestos in its talc is
be	cause Cimbar knew even before purchasing
this tale plant that asbestos was a known,	
co	nfirmed human carcinogen capable of causing
a c	disease like mesothelioma, the very disease
tha	at Mr. Zundel has, correct?

Page 2316

A. That's a fair statement, yes.

### **Mount Vernon Indiana Facility**

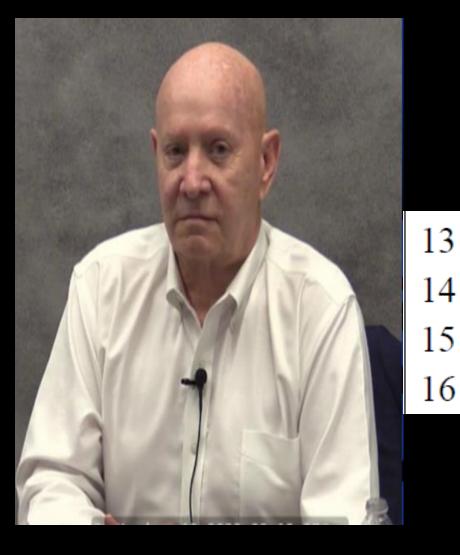


### **Houston Talc Facility**



#### **Houston Talc Facility**





Q. So that's anywhere from 800,000 to a million pounds of processed talc within that Houston talc facility silo?

A. That's correct.

## **Houston Talc Facility Lab**





Q. Not a single speck of talc -- not a single speck was ever tested for the presence of asbestos at this Cimbar talc facility laboratory location, correct?

A. That is correct.

# USP PHARMACEUTICAL GRADE TALC

WHAT METHOD DID CIMBAR AND THE TALC INDUSTRY CHOOSE?

"CTFA J4-1"

CTFA J4-1 IS NEITHER "ACCURATE" OR "RELIABLE"

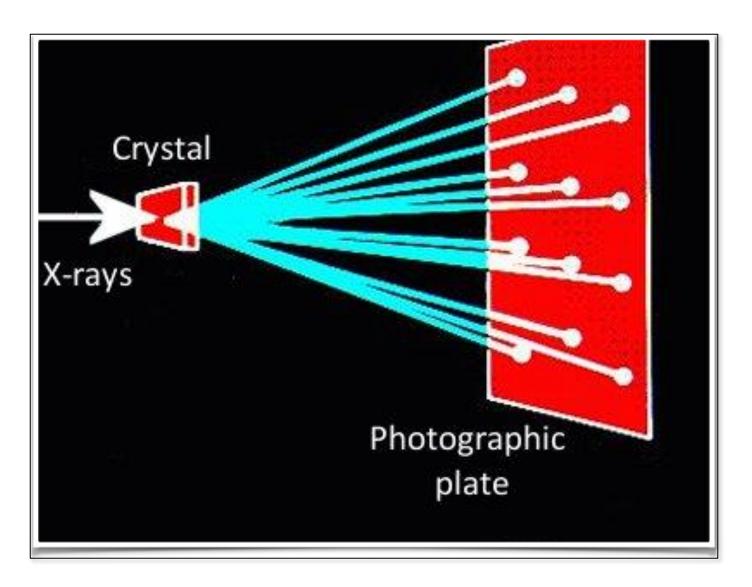
WHAT METHOD DID CIMBAR AND THE TALC INDUSTRY CHOOSE?

## "JULIE PIER EMAIL

# USP IS WORSE- NOT "ACCURATE" OR "RELIABLE"

# Testing Methods and Limit of Detecting

## X-Ray Diffraction

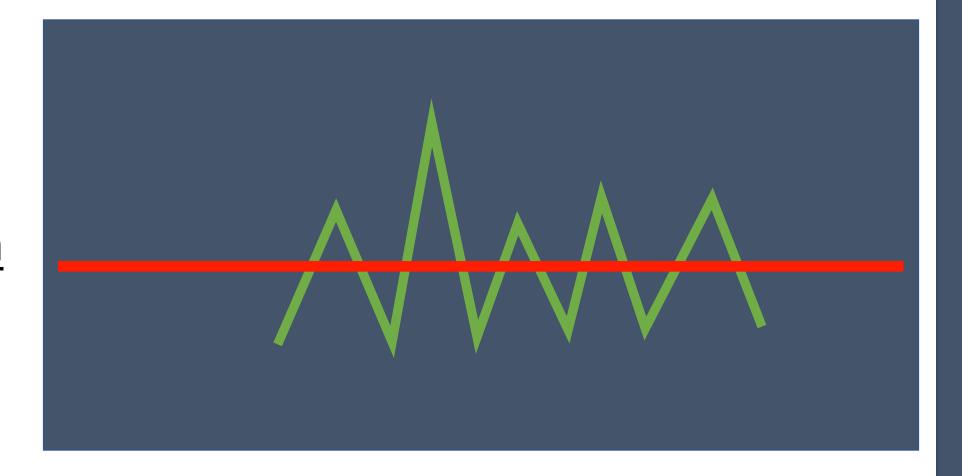


Sensitivity 0.5%

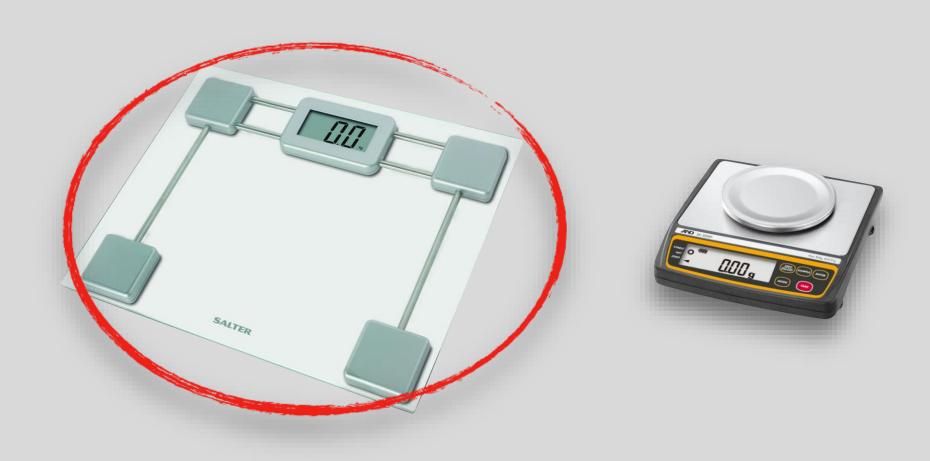
## Infrared Spectroscopy

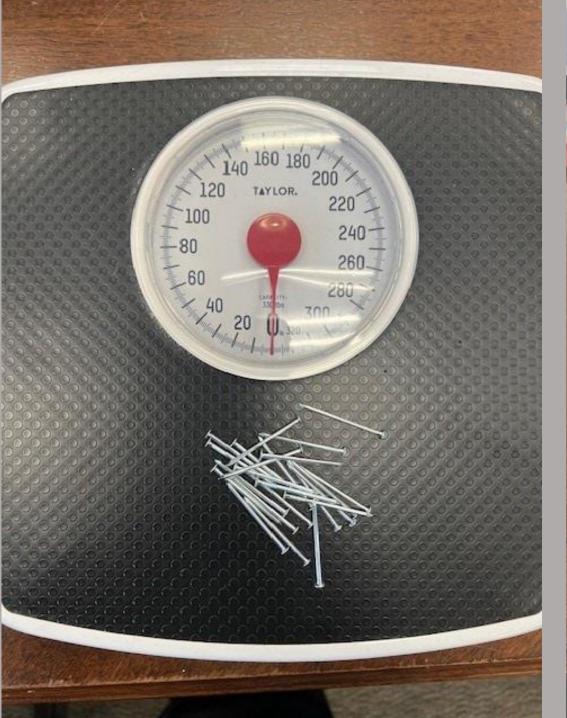


# Limit of Detection



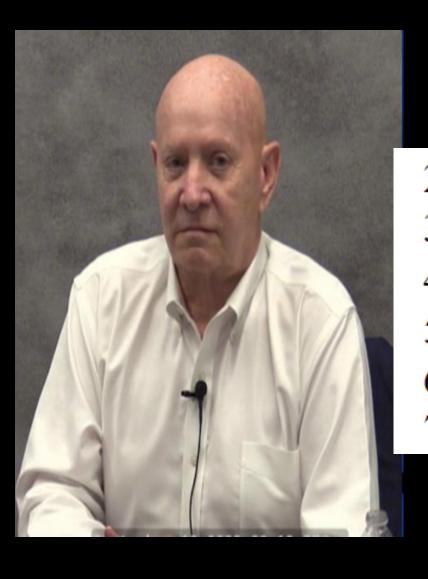
# Cimbar relied on tests designed so the talc couldn't fail.











Q. And your testimony was, out of all these millions of pounds of tale and out of all the grams in those millions of pounds of tale, SGS tests about a thimbleful of tale, right?

A. That's correct.



6 million pounds

2,721,554,220 grams

Thimble = 1 gram

.000000005

15	Q. If we did the math, one gram divided
16	by 2 billion grams, what percentage of the
17	total talc that's being shipped over to the
18	United States do you think is being tested?
19	It's, like, infinitesimally small,
20	right?
21	A. That would be a fair statement.



## Longo and Segrave







- Q. You recognize that Dr. Longo is well
- 6 respected in his field, right?
- A. Sure.
  - Q. And, in fact, you've testified in the
- 9 past that he's an authority in his field,
- 10 right?
- 11 A. Yes.

#### ATLANTA

Corporate Headquarters 3945 Lakefield Court Suwanee, GA 30024 (770) 866-3200 FAX (770) 866-3259



#### MAS Project M71604 Talcum Powder Analysis Bryce Zundel- Sterile Talc Powder Bottle



Prepared for: Lanier Law Firm

Prepared By: William E. Longo, Ph.D., CEO

Materials Analytical Services, LLC

05/12/2023

#### **EXHIBIT**

Table 1 provides a sample description summary of the Sterile Talc Powder that was analyzed for asbestos.

Table 1
Sterile Talc Powder Sample Container Descriptions

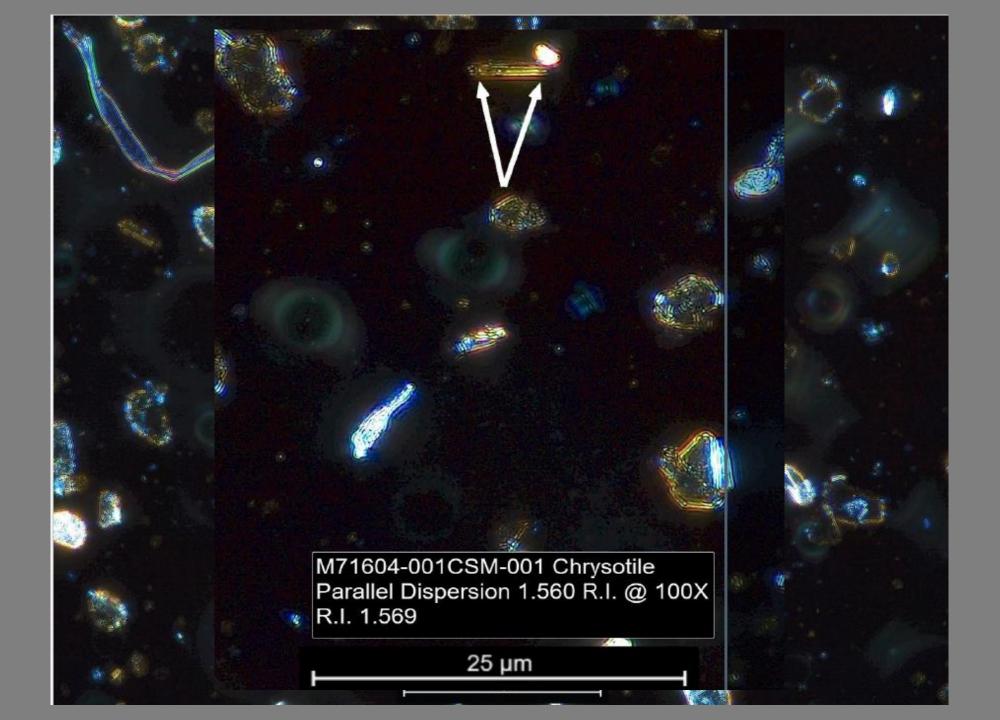
MAS Sample No.	Product	Container size	Container Code	Condition of Container Received	Source of Sample
	Sterile Talc Powder Lot # 6C004				
	Manufactured:				
	2/26/2016			Onanad	Distributed by
M71604-001	Expires: 3/2019	5 grams	NDC 63256-200-05	Opened	Lymol Medical

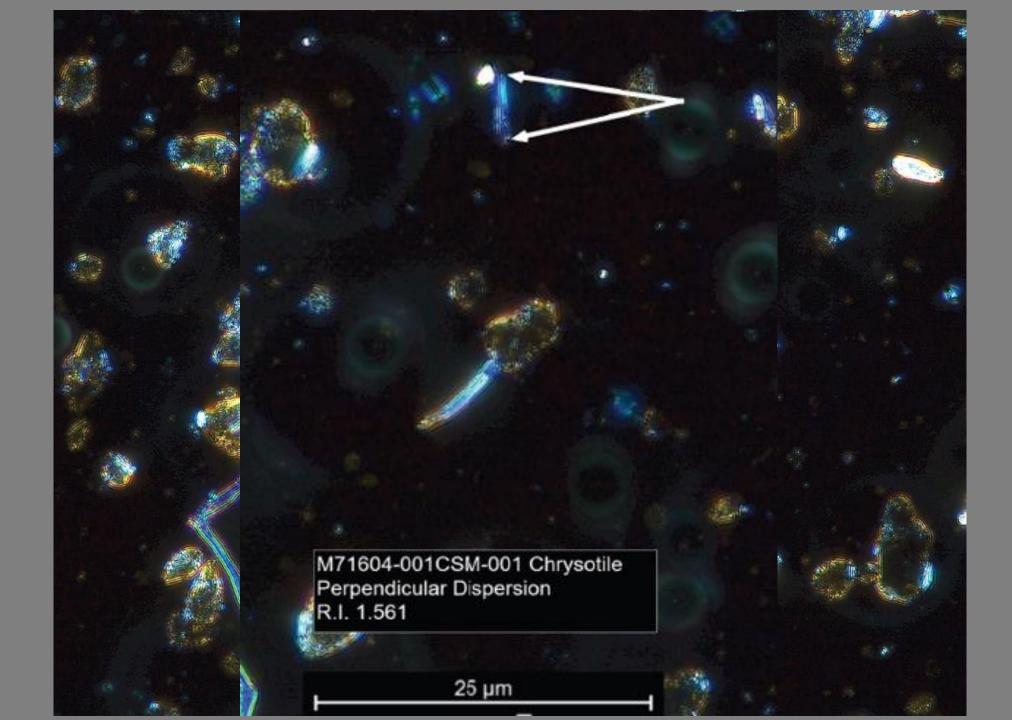
#### Amount of Asbestos in Tested Bottle Sterile Talc Powder

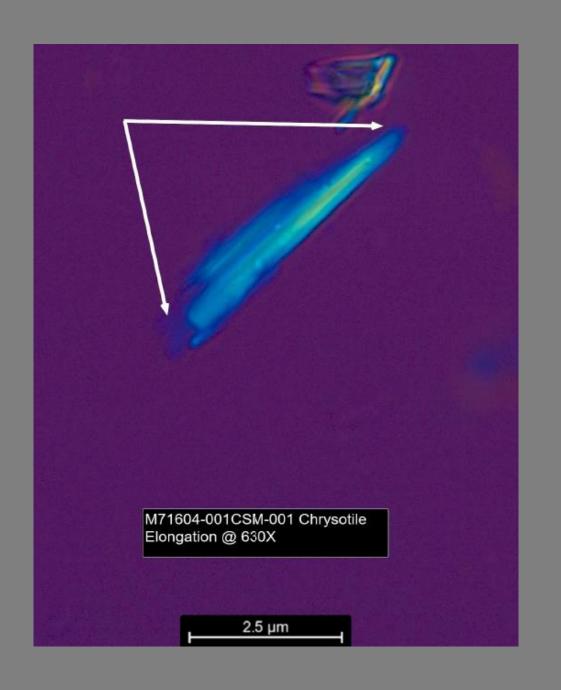
The chrysotile bundle results for PLM analysis shows that one gram of 0.18 oz. (5 g) Sterile Talc Powder contained an average of 37,000 chrysotile bundles per gram of talcum powder.

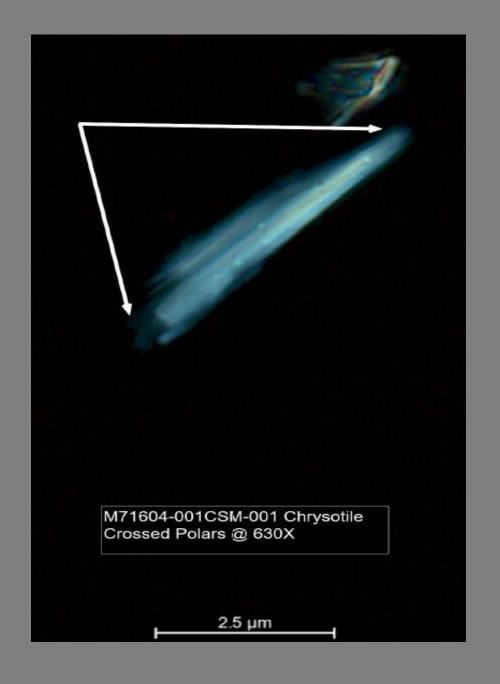
In addition, sample M71604-001 had detectable amounts of tremolite asbestos at 104,000 fibers/bundles per gram. Using the combined average of chrysotile bundles and the addition of tremolite structures would equal approximately 141,000 chrysotile/tremolite bundles per gram of powder.

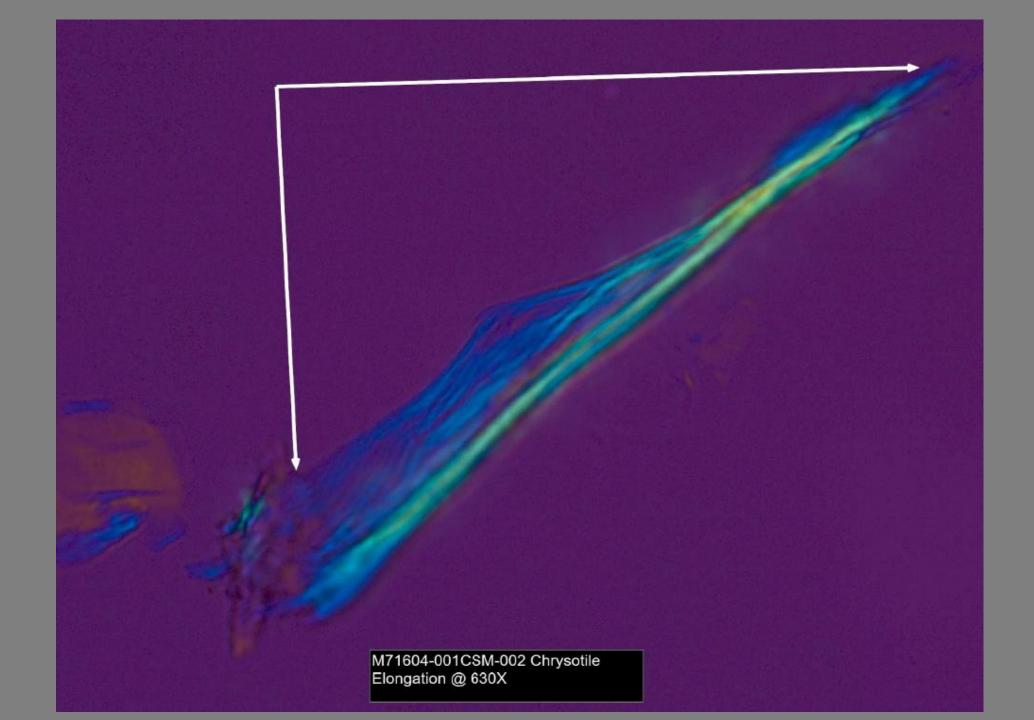
Multiplying 141,000 chrysotile/tremolite bundles by 5 grams would equal approximately 705,000 chrysotile/tremolite fibers/bundles, on average, in the one (5 g) Sterile Talc Powder bottle. For the Sterile Talc Powder Bottle sample MAS analyzed was from lot #6C004, and according to Sciarra Laboratories, 20,000 bottles were produced (SCIARRA 000516). It would be my opinion that every one of these 20,000 bottles would have amphibole asbestos and or chrysotile asbestos in with the talc. Furthermore, it is my opinion that all of the talcum powder products used in this country that was sourced from Chinese Guangxi talc mine, will also contain amphibole asbestos and or chrysotile asbestos, it just a matter of detection limit.

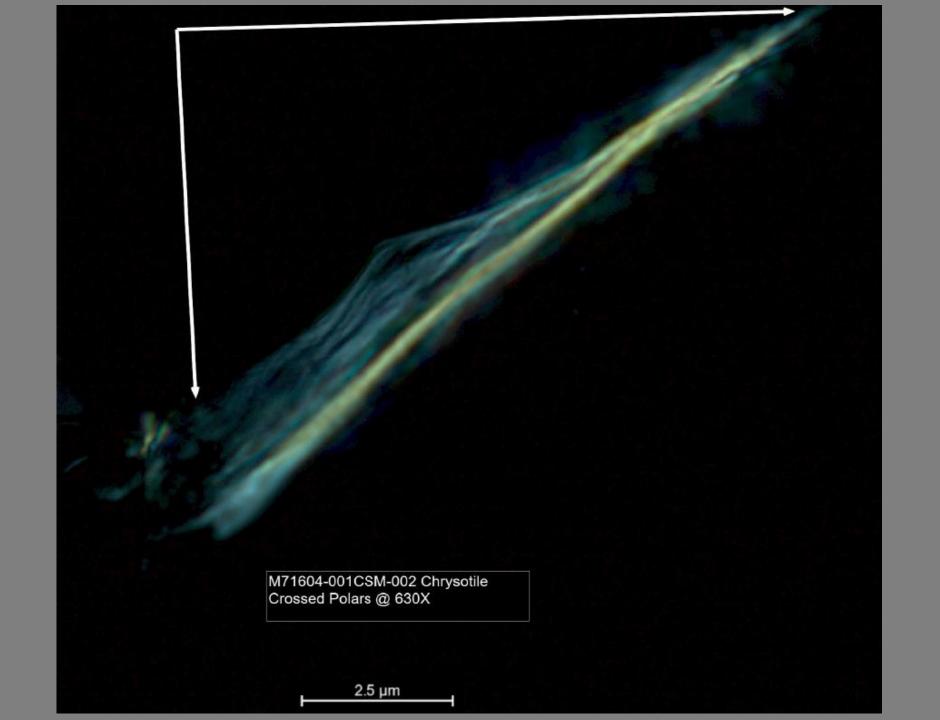


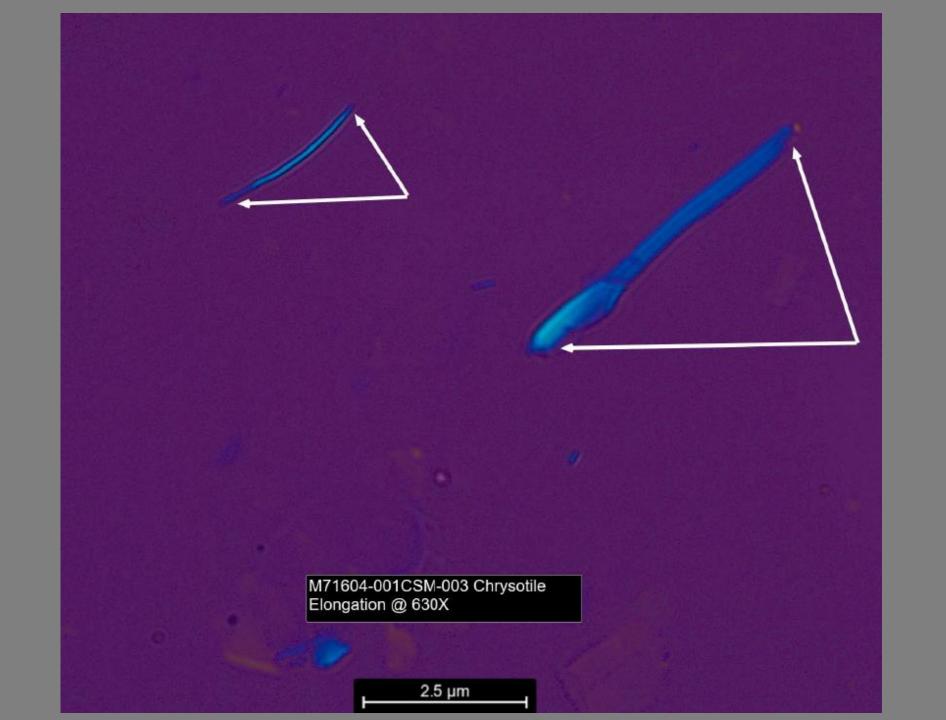


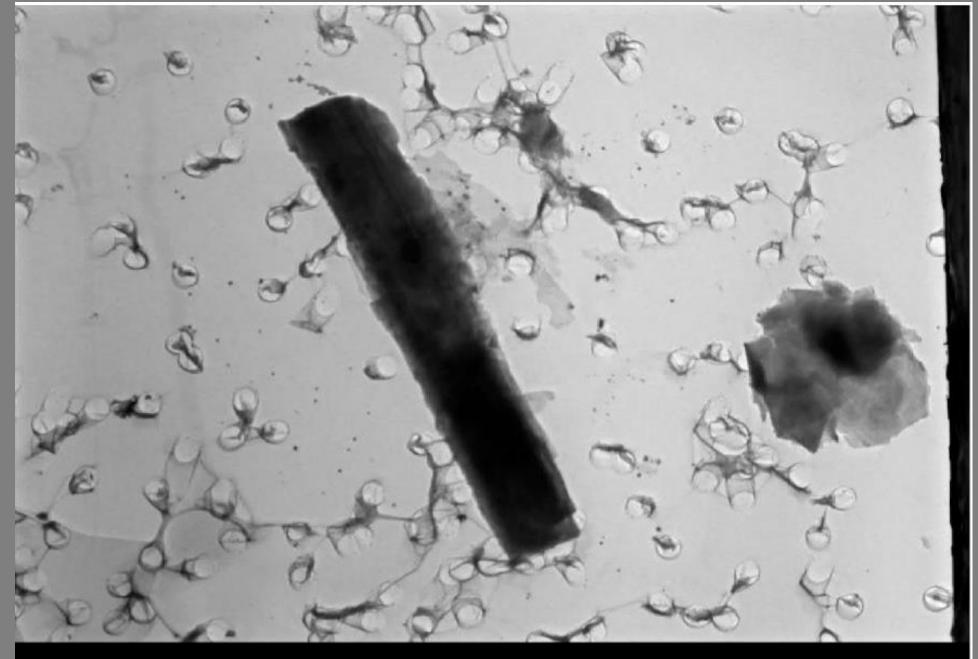


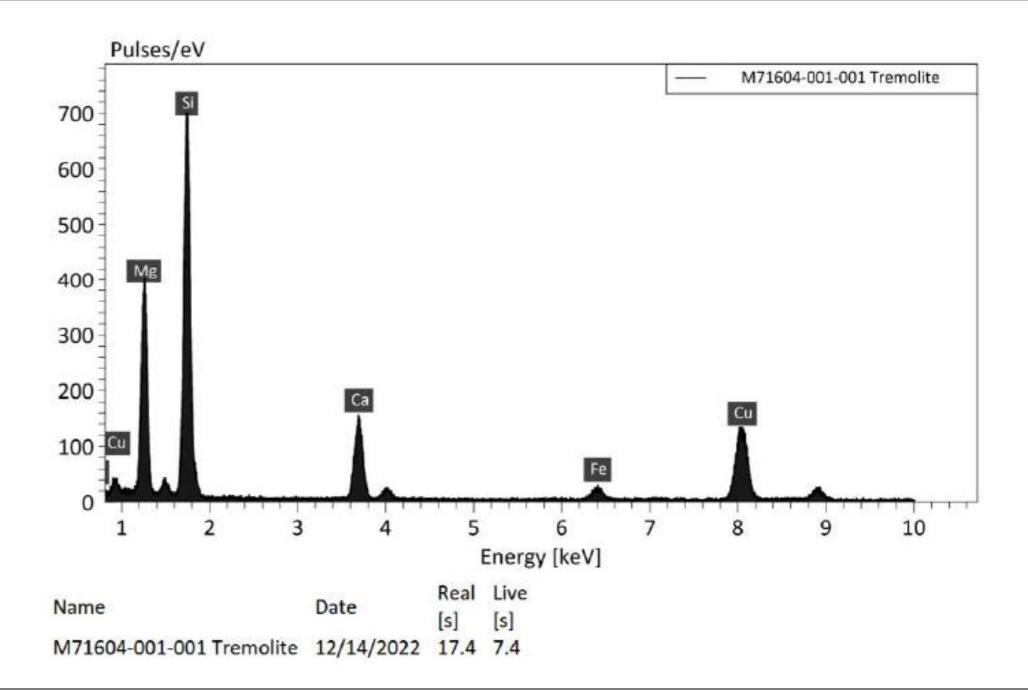




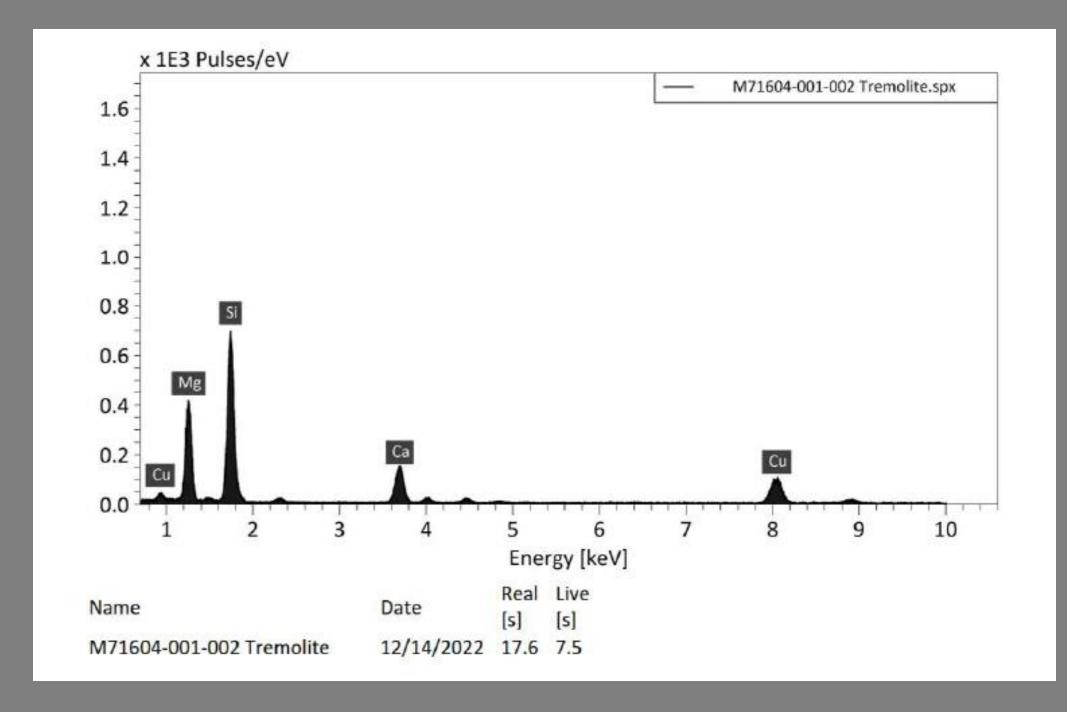












#### COMBINED ALL U.S. CHINESE ORE SUMMARY

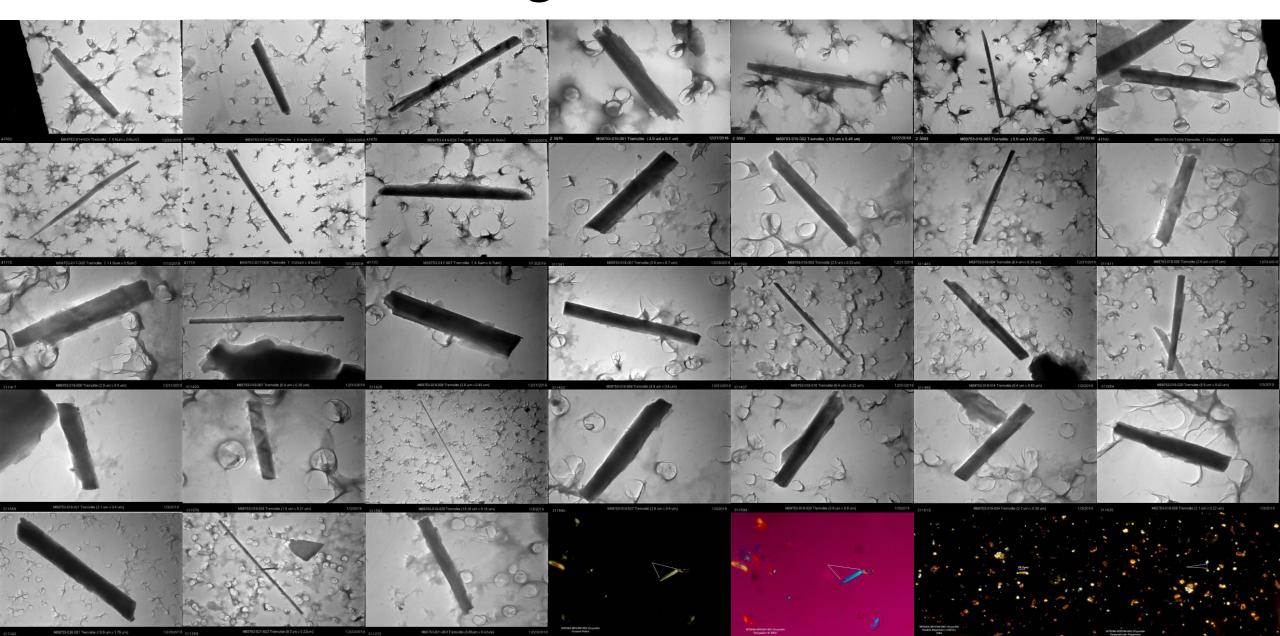
Guang Xi/Supra H Ores	All Chinese Ore Total
29/29 = 100%	77/81 = 95%

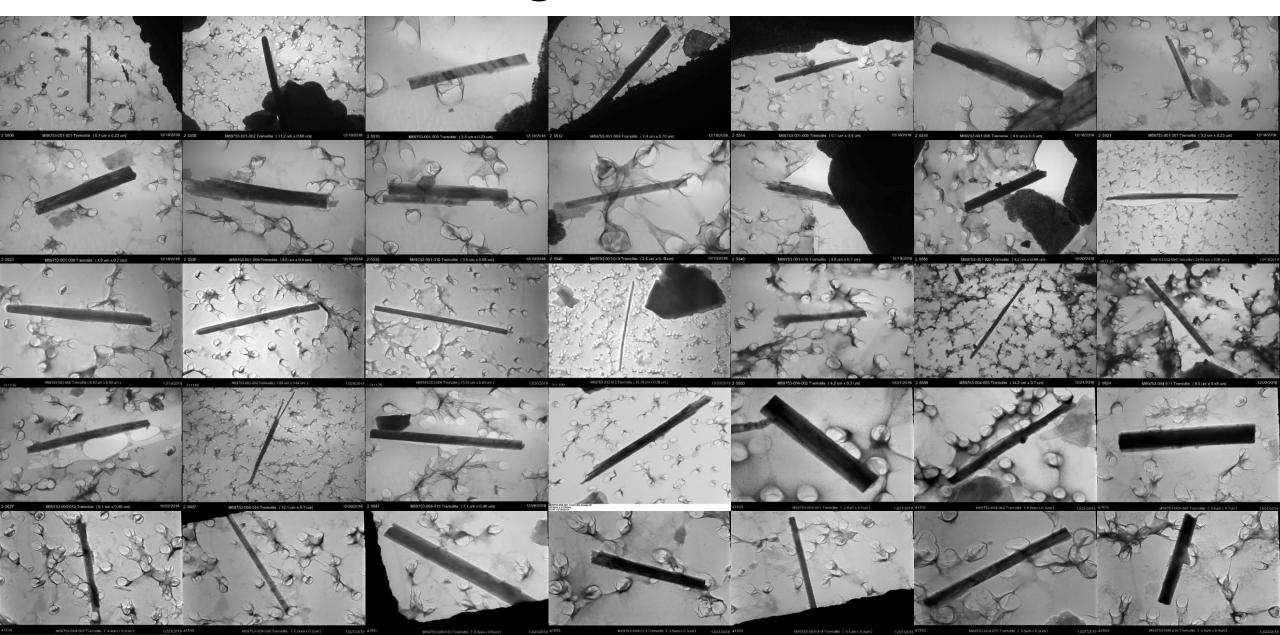
TABLE III – CHANE

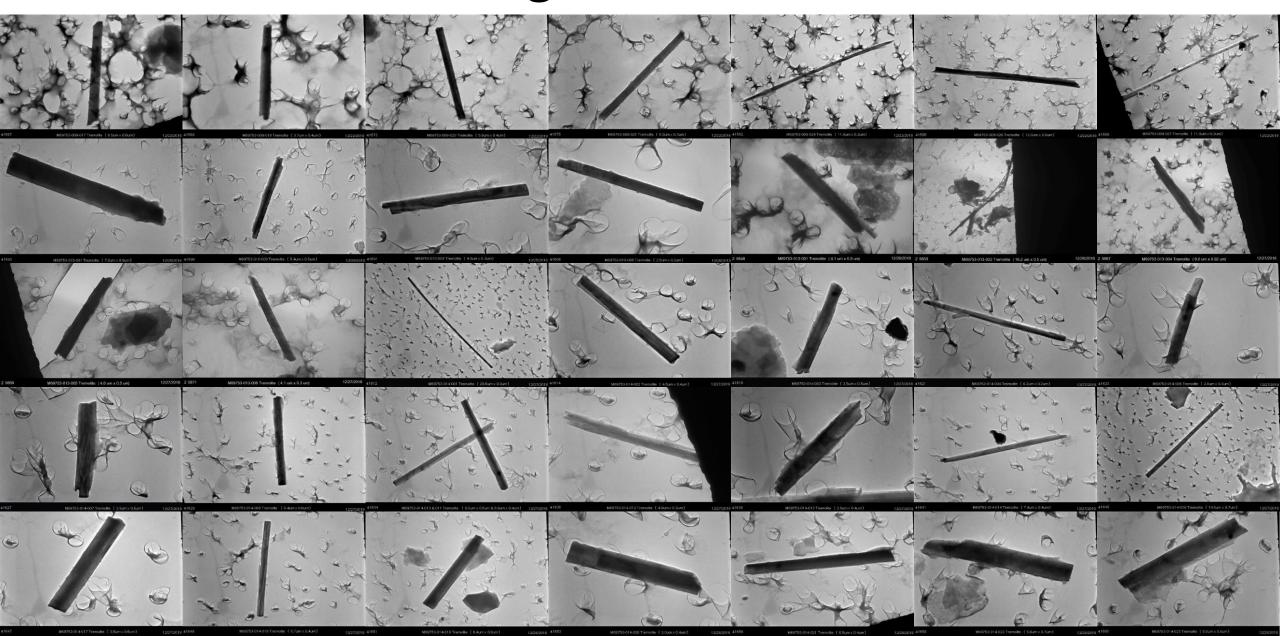
Results	Italian or Italian/Australian
MAS	23/24 = 95.8%

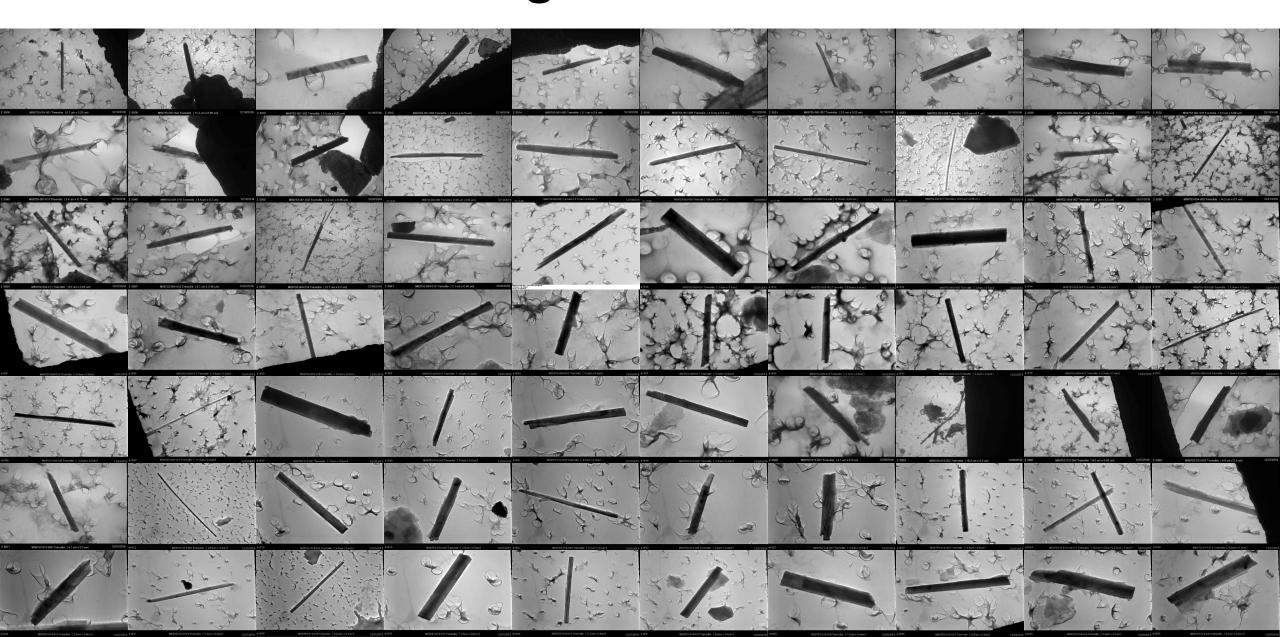
#### Chinese

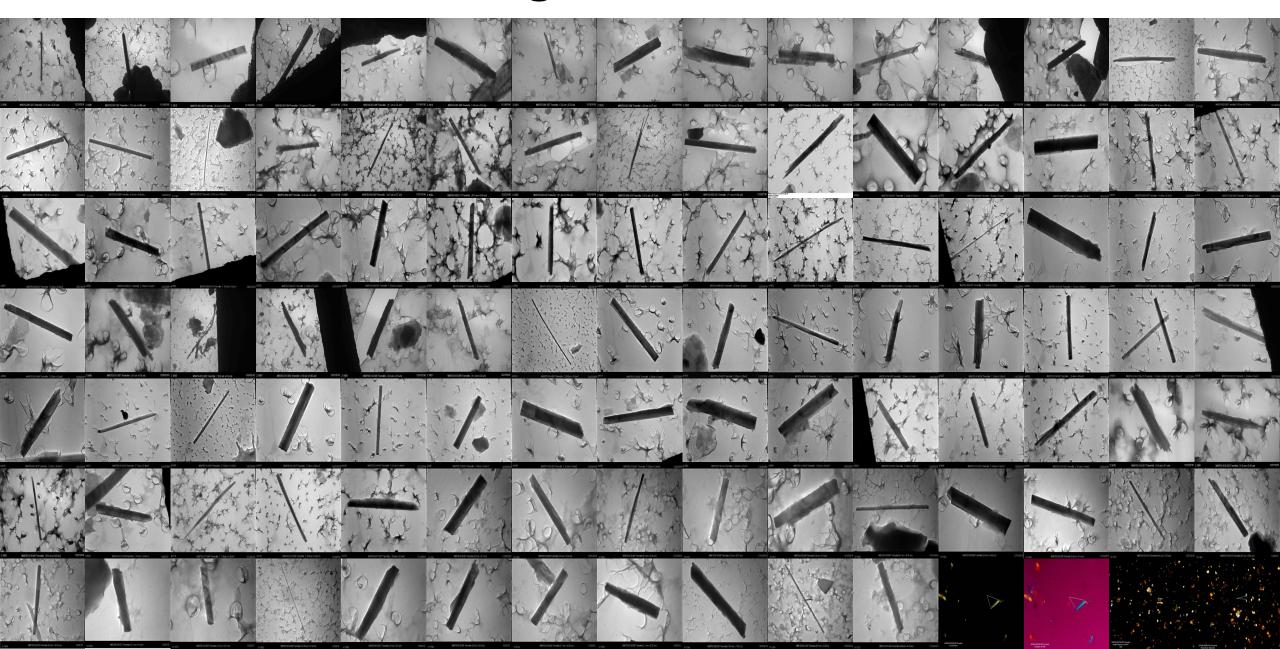
22/22 = 100%

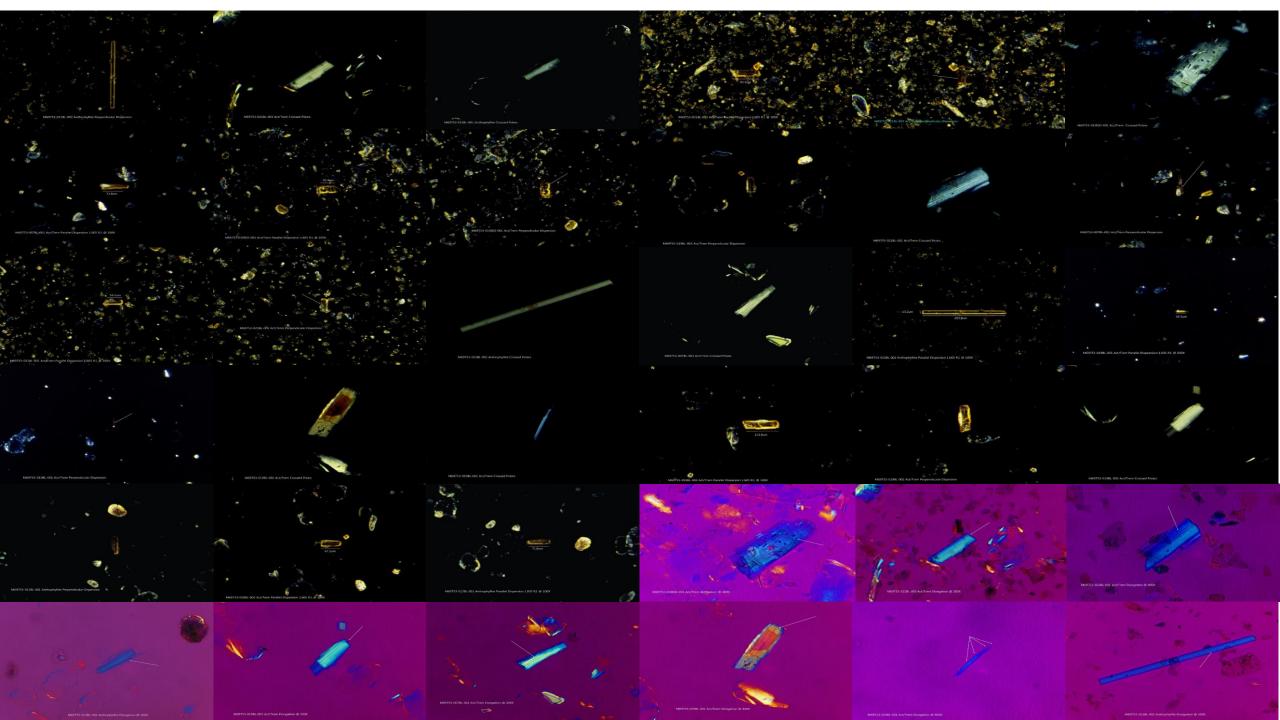




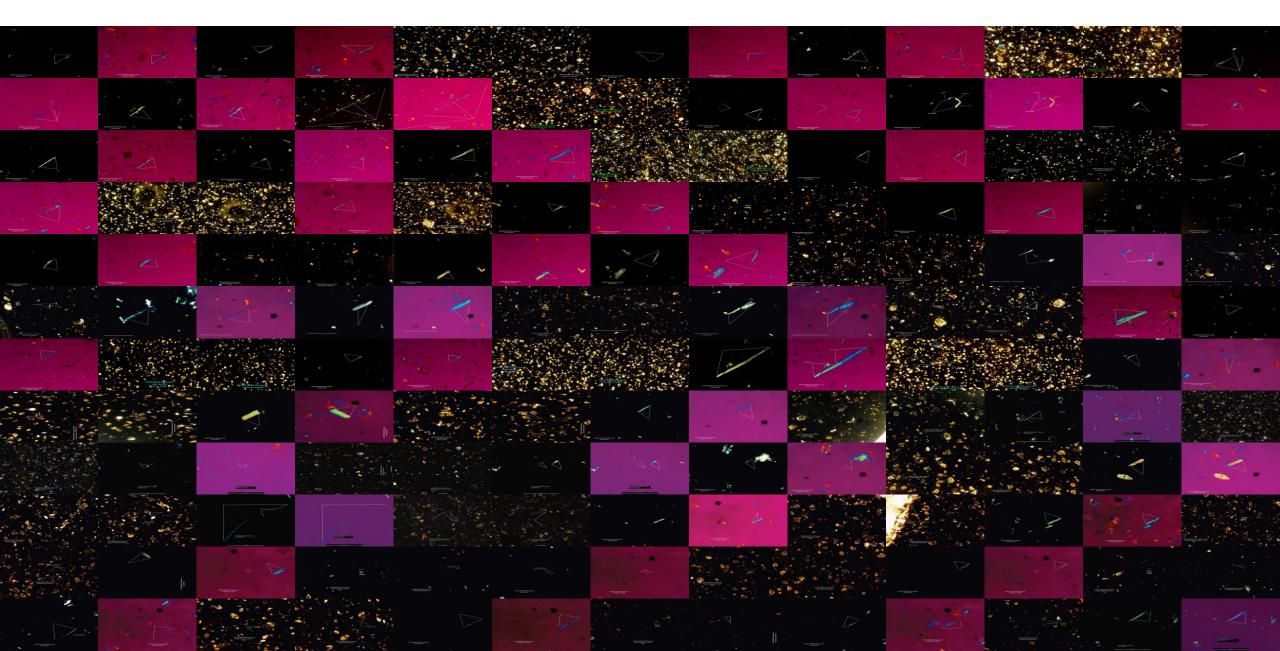




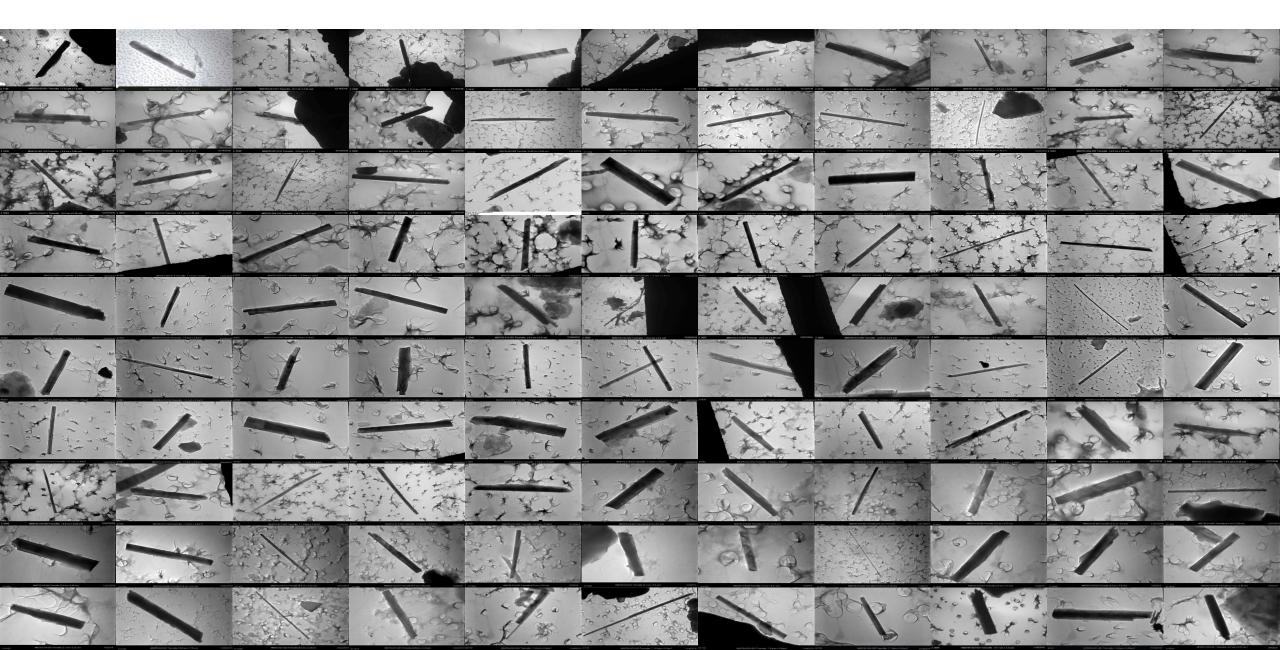




#### PLM of Chinese Talc



#### Tremolite In Chinese Talc

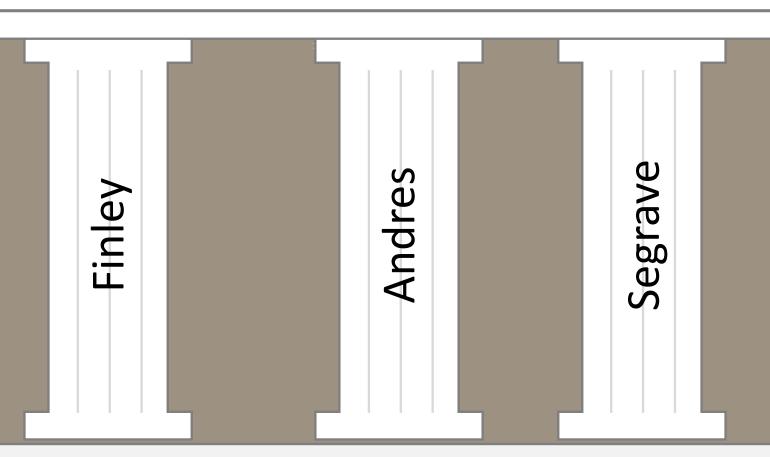


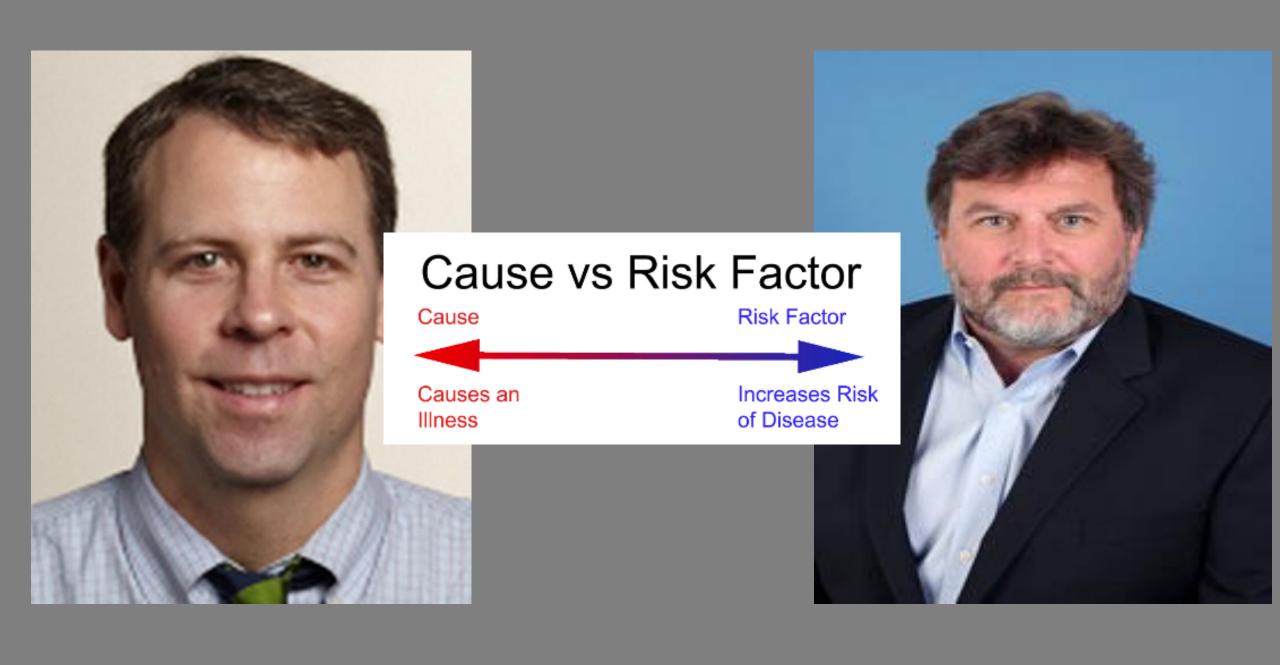
## Segrave – can't say its asbestos

- 1. Found asbestos once and claims its from laboratory contamination with no basis
- 2. FDA/Saldivar (JnJ testing expert) tested JnJ talc from Guangxi, China and found chrysotile. JnJ recalled the lot. Segrave tests same lot and didn't find asbestos.
- 3. Segrave tests 11 sample. Finds asbestos in 1 of 11 first time. Tests again and finds asbestos in 3 of 11. SOMETHING IS WRONG
- 4. Segrave tests talc sample spiked with asbestos --- finds NO ASBESTOS in sample spiked with asbestos

#### THE DEFENSE









### 1.SPONTANEOUS

# 2. PHANTOM AMPHIBOLE EXPOSURE



OUTSIDE THE COURTROOM NO ONE CARES WHAT HIS OPINIONS ON CAUSATION MAY BE



NO METHODOLOGY

NO PUBLICATIONS

NO EXPERIENCE

NO RATIONAL BASIS

# ENDRES ISLAND



### DOUBT IS HIS PURPOSE

NO BACKGROUND

NO SUPPORT

NO METHODOLOGY

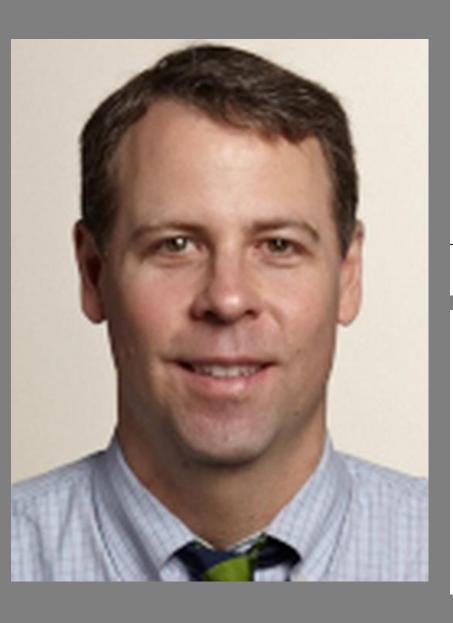


### Page 3301



Q. In the 220-odd cases that you've reviewed, in over 90 percent of the reports that you've issued, you have -- you have reached the opinion that the asbestos disease in that person was either spontaneous or caused by some unknown amphibole exposure, correct?

A. I would say that's correct, being that I'm able to select the cases that I accept.



20	Q. There is not a single published
21	article in the medical literature where
22	somebody reports being exposed to asbestos and
23	the author says, A mesothelioma in that
24	context is spontaneous, correct?

Page 3425

Q. -- someone develops mesothelioma and the authors conclude that mesothelioma was spontaneous.

Can you cite any article?

10 A. No.





For someone who has asbestos or an asbestos-contaminated product, including asbestos-contaminated talc, instilled or injected into someone's pleural cavity, on the pleural surface, would it ever be appropriate to refer to someone who developed mesothelioma after that, that that mesothelioma would be considered spontaneous?

A. No.

#### Page 2484



Q. For someone who was exposed to asbestos or has a known instillation of asbestos into their chest cavity or has some external contact with asbestos and then develops mesothelioma, in your professional opinion, to a reasonable degree of medical certainty, is it appropriate to call that mesothelioma a spontaneous mesothelioma? No.



### Page 3420



- Q. What facts can you offer this jury
- about Mr. Zundel being exposed to an amphibole
- 19 form of asbestos?
- A. Well, I just said I was not provided
- with any of that information.
- Q. And therefore --
- A. Or facts, if that's the word you're
- looking for.

### Dodson TESTING – LIBBY Amphibole

OFFERS NO EXPLANATION FOR WHAT INCREASED MR. ZUNDEL'S RISK OF MESOTHELIOMA

LUCKIEST EXPERT EVER --- THE ASBESTOS CLIENT'S THAT HIRE HIM .... THEIR ASBESTOS NEVER INCREASES ANYONE'S RISK OF MESOTHELIOMA



Page 4430

Q. Have you looked at or have you found a single study that says talc contaminated with asbestos, injected into the pleural space of somebody, does not increase the risk of disease?

A. That statement, no.

Animal inhalation of talc does not cause mesothelioma Human inhalation of talc does not cause mesothelioma Animal pleural injection with talc does not cause mesothelioma Human pleurodesis with talc does not cause mesothelioma

# Animal <u>inhalation</u> studies of cosmetic talc have found no evidence of an increased risk of mesothelioma

Wagner et al. (1977) Wehner et al. (1977) National Toxicology Program Studies (1993)

# Animal <u>talc injection</u> studies have found no evidence of mesothelioma

Pott et al. (1974)

Wagner et al. (1977)

Endo-Capron et al. (1990)

There were no mesotheliomas following intrapleural or intraperitoneal injection of talc in rats.



Talc Pleurodesis Literature Review

### **Pro/Con Editorials**

**Talc Should Be Used for Pleurodesis** 

### Talc Should Not Be Used for Pleurodesis

Andrew J. Ghio and Victor Roggli "TALC SHOULD NOT BE USED FOR PLEURODESIS IN PATIENTS WITH NONMALIGNANT PLEURAL EFFUSIONS", American Journal of Respiratory and Critical Care Medicine, Vol. 164, No. 9 (2001), pp. 1741.

doi: 10.1164/ajrccm.164.9.correspondence\_c

# TALC SHOULD NOT BE USED FOR PLEURODESIS IN PATIENTS WITH NONMALIGNANT PLEURAL EFFUSIONS

PLAINTIFFS' EXHIBIT

654

Andrew J. Ghio, Victor Roggli, and + Author Affiliations

Sections:

### Roggli/Ghio- 2001

in the treatment of patients with malignant recurrent effusions. However, there should continue to be concern regarding the use of talc for pleurodesis in individuals with nonmalignant pleural effusions and spontaneous pneumothorax. This dilemma results from a possible increased risk of malignant mesothelioma in those patients treated with talc. Consequently, an alternative agent should be employed in any individual without malignancy requiring pleurodesis.

pleurodesis. The paucity of evidence of malignant mesothelioma occurring after the use of talc for pleurodesis may reflect either an inadequate latency period or an insufficient number in the investigations conducted. Assuming a risk of the same magnitude as that seen in the cohort of asbestos-exposed insulation workers (3), less than one case of mesothelioma would have been expected in the two investigations of patients exposed to talc used in pleurodesis (4, 5). However, case reports of malignant mesothelioma after

The assertion that contemporary purified preparations of talc do not contain asbestos, therefore eliminating a risk of mesothelioma, should be closely examined prior to its acceptance for clinical application. The methodology used to confirm the lack of asbestiform minerals in a finished product (i.e., X-ray diffraction, optical microscopy, and electron microscopy techniques) and its sensitivity must be provided. Even if the

doi:10.1510/icvts.2006.147546

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### Best evidence topic - Thoracic general

# Is talc pleurodesis safe for young patients following primary spontaneous pneumothorax?

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PLAINTIFF'S EXHIBIT TTP-16









I don't know.

I don't know.

I don't know.

## David Madigan, PhD

















### <u>r. David Madigan</u>

- Education: PhD in Statistics from Trinity College, Dublin (1990)
- <u>Current Employment</u>: Provost and Professor of Statistics Northeastern University, MA
- Prior Appointments:
  - Executive VP and Dean of Faculty of Arts and Sciences Columbia University (2013-2018)
  - Chair of Dept. of Statistics Columbia University (2007-2013)
  - Professor of Statistics and Biostatistics Rutgers University (2001-2007)
  - Director of Institute of Biostatistics Rutgers University (2003-2004)
  - Professor of Statistics U of Wash, Fred Hutchison Cancer Research Center (1995-1999)

#### Elected Honors:

- Member of International Statistics Institute
- Elected Fellow of American Association for the Advancement of Science
- <u>Publications & Participation in Peer Review Process</u>
  - Over 180 Peer Reviewed/Refereed Publications
  - Over 40 Epidemiological Publications
  - Associate Editor Harvard Data Science Review
  - Editor in Chief, Statistical Science (2008-2010)
  - Editor in Chief, Statistical Analysis and Data Mining (2013-2015)
  - Member of FDA Advisory Committee on Drug Safety and Risk Management (2011-2014)



- Publications & Participation in Peer Review Process
  - Over 180 Peer Reviewed/Refereed Publications
  - Over 40 Epidemiological Publications
  - Associate Editor Harvard Data Science Review
  - Editor in Chief, Statistical Science (2008-2010)
  - Editor in Chief, Statistical Analysis and Data Mining (2013-2015)
  - Member of FDA Advisory Committee on Drug Safety and Risk Management (2011-2014)







# Question I was asked to address:

• I was asked to address the following question: What is the statistical power of the extant long-term studies concerning the potential association between talc pleurodesis and mesothelioma?

### "POWER"

Power refers to the ability of a study to detect an effect when one is truly present.

Power is a function of both the size of the effect one seeks to detect, the number of patients enrolled in the study, and the length of follow-up.

### My Methodology

My methodology in this case followed established, unassailable epidemiological and biostatistical principles.

### My Methodology

Standard statistical formulas exists to perform these calculations

The formulas use the binomial and hypergeometric distributions and can be found in many textbooks

### Patients that underwent talc pleurodesis

# HOW I SEARCHED FOR RELEVANT STUDIES THAT I CONSIDERED

#### Patients that underwent talc pleurodesis

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Özcan, C., McGahren, E. D., & Rodgers, B. M. (2003). Thoracoscopic treatment of spontaneous pneumothorax in children. *Journal of Pediatric Surgery*, 38(10), 1459-1464.

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#### Patients that underwent talc pleurodesis

# I EXCLUDED MALIGNANT PLEURAL EFFUSION PATIENTS

### Patients that underwent talc pleurodesis

### WHY?

As noted by Lumachi et al., "Malignant pleural effusion (MPE) is common in most patients with *advanced cancer*, especially in those with lung cancer, metastatic breast carcinoma and lymphoma." In fact, Lumachi et al. noted that the overall survival of these patients with advanced cancer was 11.2 ± 8.9 months and that "the prognosis for patients' with MPE is usually poor, ranging between 3 and 12 months..." Therefore, like MPE patients with malignant mesothelioma,

MPE patients with other advanced cancers have very short life expectancies and, therefore, were properly excluded from my analysis.

The talc pleurodesis studies individually and collectively <u>lack</u> <u>statistical power</u>. Statistical power is the probability of finding a statistically significant difference between exposed and control subjects when one truly exists.

Collectively, these studies include 1577 talc pleurodesis patients with approximately 15,000 patient years of follow-up (see Appendix 2).

#### Appendix 2

Study	n	PYR
Committee	210	4420
Lange	80	2800
Viksum	99	2150
Gyorik	63	619.5
Cardillo	861	3767
de Campos	157	785
Milanez	18	54
Ozcan	28	112
Tschopp	61	305
	1577	15012

#### Appendix 1: R code

```
power.smr.test <- function(n = NULL, smr, r, sig.level = 0.05, power = NULL,
               alternative = c("two.sided", "one.sided"),
               tol = .Machine$double.eps^0.25){
 if (sum(sapply(list(n, power), is.null)) !=
   1)
  stop("exactly one of 'n' and 'power' must be NULL")
 if (!is.null(sig.level) && !is.numeric(sig.level) | |
   any(0 > sig.level | sig.level > 1))
  stop("sig.level' must be numeric in [0, 1]")
 alternative <- match.arg(alternative)
 tside <- switch(alternative, one.sided = 1, two.sided = 2)
 p.body <- quote({
  pnorm(sqrt(r * n * 4 * (sqrt(smr) - 1)^2) - qnorm(sig.level/tside, lower.tail = FALSE))
 })
 if (is.null(power))
  power <- eval(p.body)
 else if (is.null(n))
  n <- uniroot(function(n) eval(p.body) - power, c(1, 1e+07),
         tol = tol, extendint = "upX")$root
 NOTE <- "n is amount of person-time needed for the study;\n Ea is the expected number of deaths needed for
the study"
 METHOD <- "Standardized Mortality Ratio (SMR) Test power calculation"
 structure(list(n = n, smr = smr, r = r,
         Ea = (qnorm(sig.level/tside, lower.tail = FALSE) + qnorm(power))^2 /(4 * (sqrt(smr) - 1)^2),
         sig.level = sig.level,
         power = power, alternative = alternative, note = NOTE,
         method = METHOD), class = "power.htest")
```

Several authors have estimated a background rate of 1-2 cases per 1,000,000 person years. 1 Teta et al. utilized SEER data through 2002 to estimate a background rate. I extended their analysis through 2016 producing an estimated "hypothetical background" rate of 2.1 per 1,000,000. Using this rate, these studies have a statistical power of 7% to detect a doubling and 10% to detect a quadrupling.

Even using a more conservative background rate of 2 per 100,000 (the overall SEER rate including exposed and unexposed individuals), these studies have a statistical power of 12% to detect a doubling and 29% to detect a quadrupling.

#### WHAT IF YOU INCLUDED MPE PATIENTS?

Background Rate	2/100,000	2/100,000	2.1/1,000,000	2.1/1,000,000
Increased Risk	Doubling	Quadrupling	Doubling	Quadrupling
Original	11.7%	29.1%	6.7%	9.9%
studies	·	·	-	
Include MPE studies	12.4%	32.2%	6.9%	10.4%
Add 10,000 "MPE patients"	14.5%	40.9%	7.3%	11.8%

Even if one were to consider a hypothetical scenario that includes studies with four times as many (10,000) patients, there is only a slight impact on power.

In no instance does the power approach the **80% level** that is commonly used when designing studies

Thus, the talc pleurodesis studies would almost certainly not be able to find a substantial difference in mesothelioma rates between "exposed" and "unexposed" subjects, if one existed.

These studies provide <u>no meaningful scientific</u> evidence with regards to mesothelioma.



- Q. With only approximately 300 individuals
- 2 that were studied, is it your opinion that there
- 3 was sufficient statistical power in these
- 4 studies?
- 5 A. No. I mean, again, I would say this
- 6 doesn't prove that pleurodesis can't cause
- 7 mesothelioma. It's just a piece of evidence one
- 8 needs to look at. I mean, you can't ignore this.
- Does it on its own prove that pleurodesis
- 10 doesn't increase the risk of mesothelioma? No.
- 11 But it's just, you know, another pile of negative
- 12 evidence, just like the other studies I've talked
- 13 about.

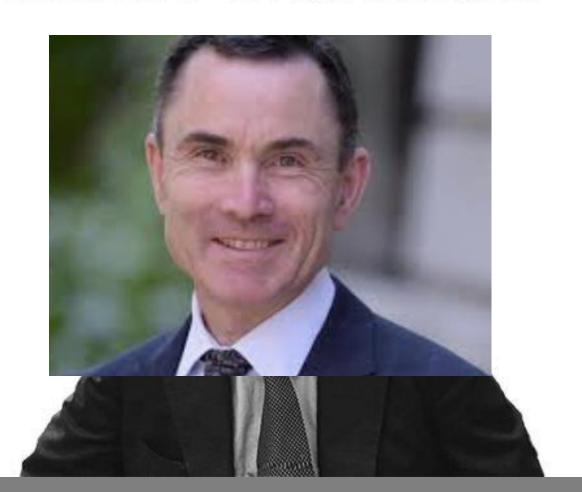


19	BY MR. KRAFT:
20	Q. Dr. Finley testified that looking at
21	these studies neither proves nor disproves that
22	pleurodesis can cause meso. Do you agree with
23	that?

A. I agree. That's exactly the point. Like my example with the alcohol and pancreatic cancer with 1,000 patients, you are none the wiser. You just don't know one way or another.

So the point is, if you do a study like that, you run the study and there are no pancreatic cancer cases, you're kind of none the wiser. You know, it's an absence of evidence. You really haven't learned anything. You can't make any conclusions one way or the other, does alcohol cause pancreatic cancer, does it not cause pancreatic cancer. It's -- you just don't know.

# "Absence of evidence is not evidence of absence."









#### TALC LINGATION CONFERENCE

The Midland Hotel, Chicago | May 20, 2025

#### The Talc Litigation Overview



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