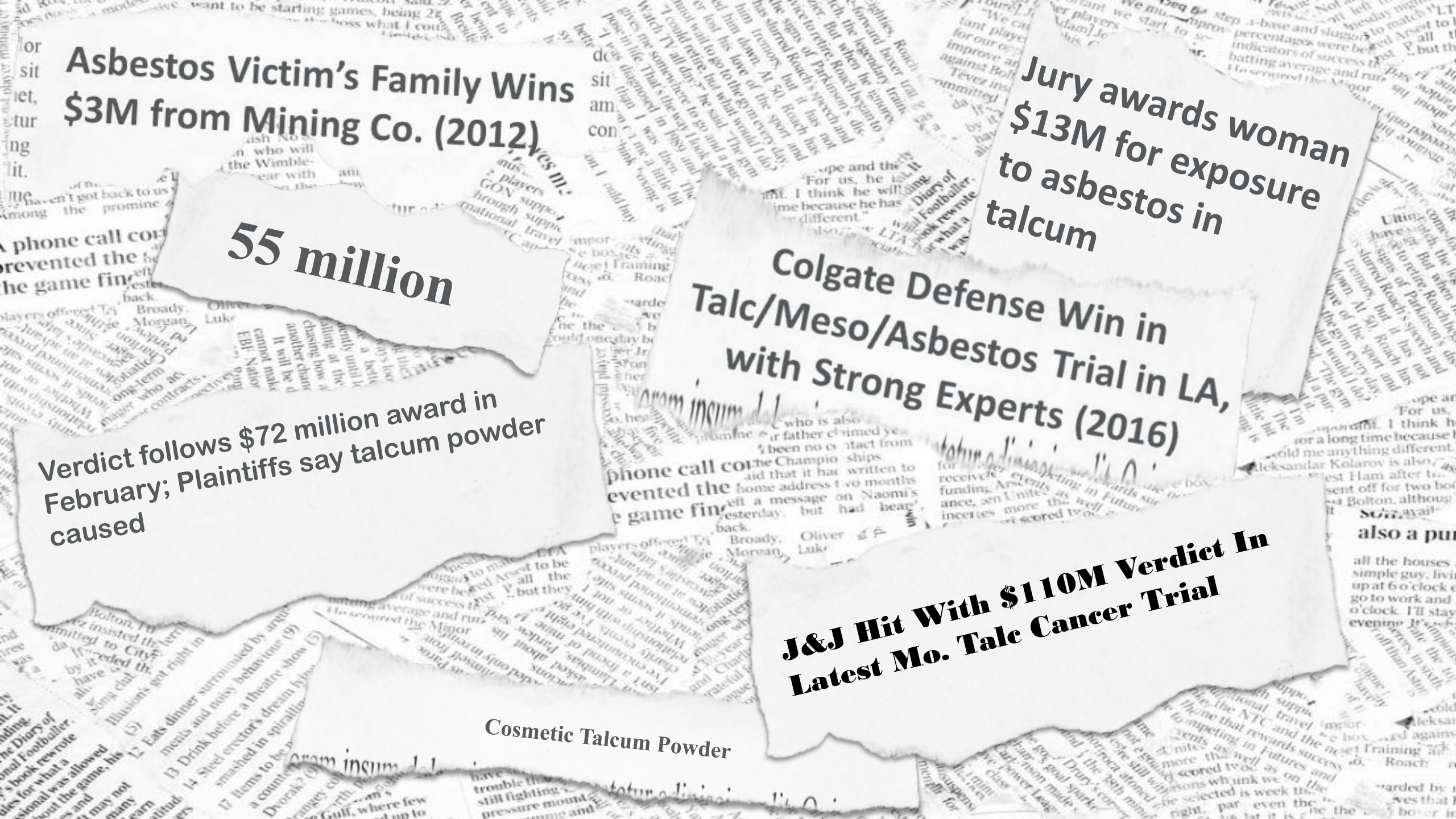
A Primer on Talc

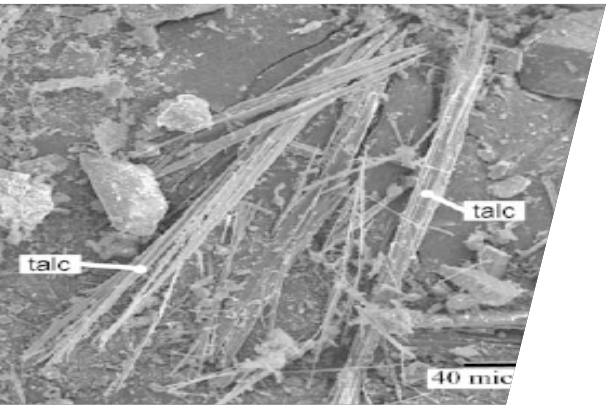
YPSW Annual Meeting
January 23, 2020
Eric W. Miller, MPH, CIH


Asbestos Victim's Family Wins $3M from Mining Co. (2012)
55 million
Verdict follows $72 million award in February; Plaintiffs say talcum powder caused
Jury awards woman $13M for exposure to asbestos in talcum
Colgate Defense Win in Talc/Meso/Asbestos Trial in LA, with Strong Experts (2016)
J&J Hit With $110M Verdict In Latest Mo. Talc Cancer Trial
Cosmetic Talcum Powder

Outline

- What is talc?
  - Deposits/accessory minerals
  - Industrial, cosmetic and pharmaceutical
- Product testing – past and present
- Analytical considerations
- Exposure studies
- Benchmarking potential exposures

What is Talc?

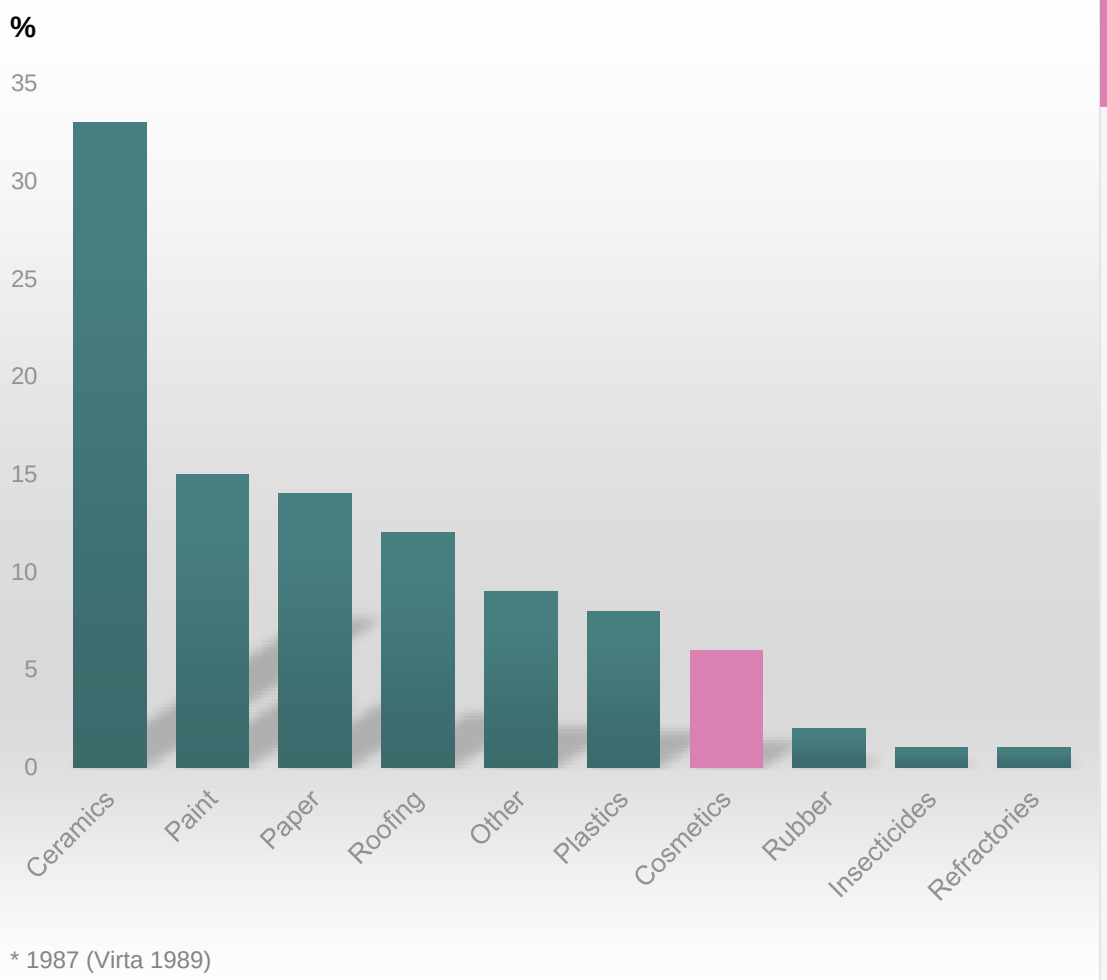


> Crystalline, hydrated silicate of magnesium
  - Typically platy (platiform); rarely found in fibrous form

> Composition varies depending on geological deposit
  - Industrial vs. cosmetic uses

> Talc deposits may contain additional minerals
  - Silicates (incl. chrysotile/tremolite*)

Cosmetic Uses of Talc



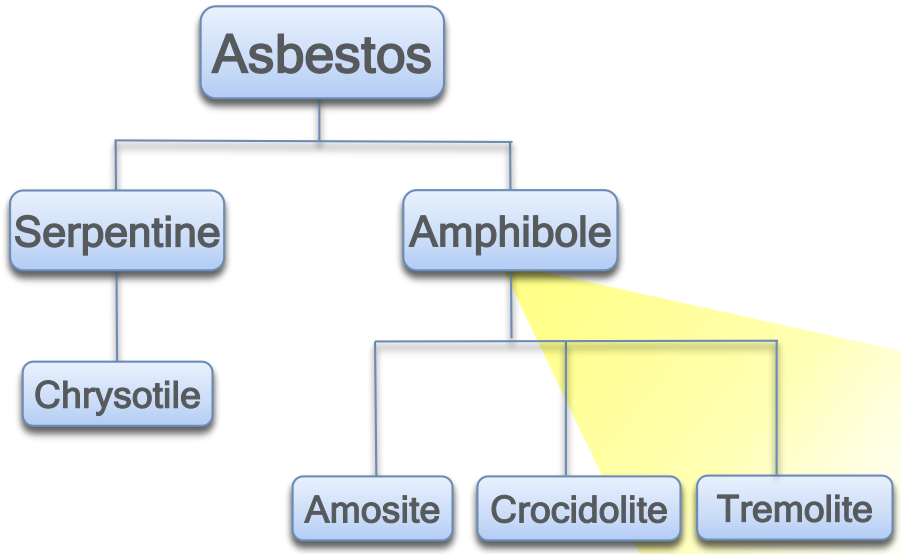
* 1987 (Virta 1989)

Select Cosmetic Uses:

- Baby products
- Eye Make-up
- Perfumes
- Fragrance
- Shampoo
- Conditioner
- Hair dye
- Face powder
- Foundation
- Lipstick
- Nail polish
- Oral hygiene products
- Deodorant
- Shaving products
- Foot-powder
- Sunblock
- Lotion

What is Tremolite?

- Naturally occurring, non-commercial amphibole
  - Not intentionally mined for any specific purpose
  - Occasionally found with substances (talc, chrysotile) used in commercial products

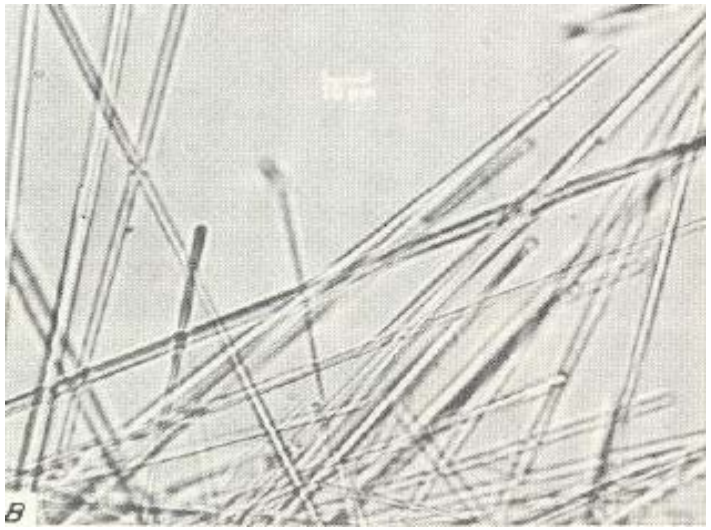


Asbestos (Asbestiform)	Non-Asbestiform
Crocidolite	Riebeckite
Amosite	Cummingtonite-Grunerite
Tremolite Asbestos	Tremolite
Anthophyllite Asbestos	Anthophyllite
Actinolite Asbestos	Actinolite

Definitions

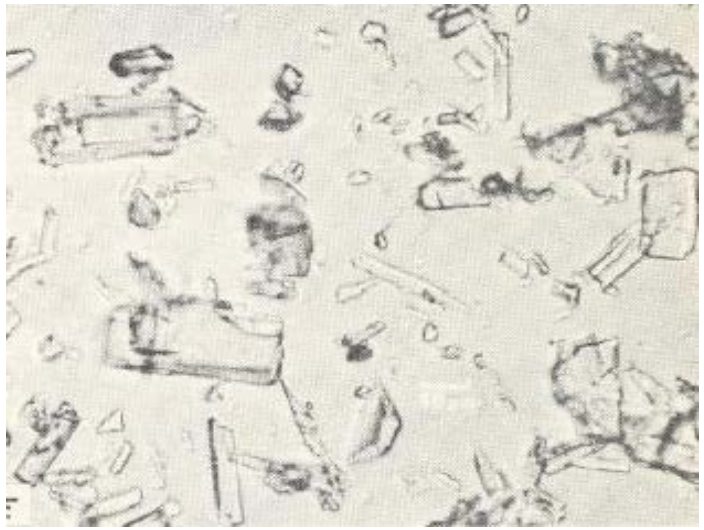
Asbestiform

- Rare
- High length-to-width aspect ratio
- Long, thin, flexible fibers



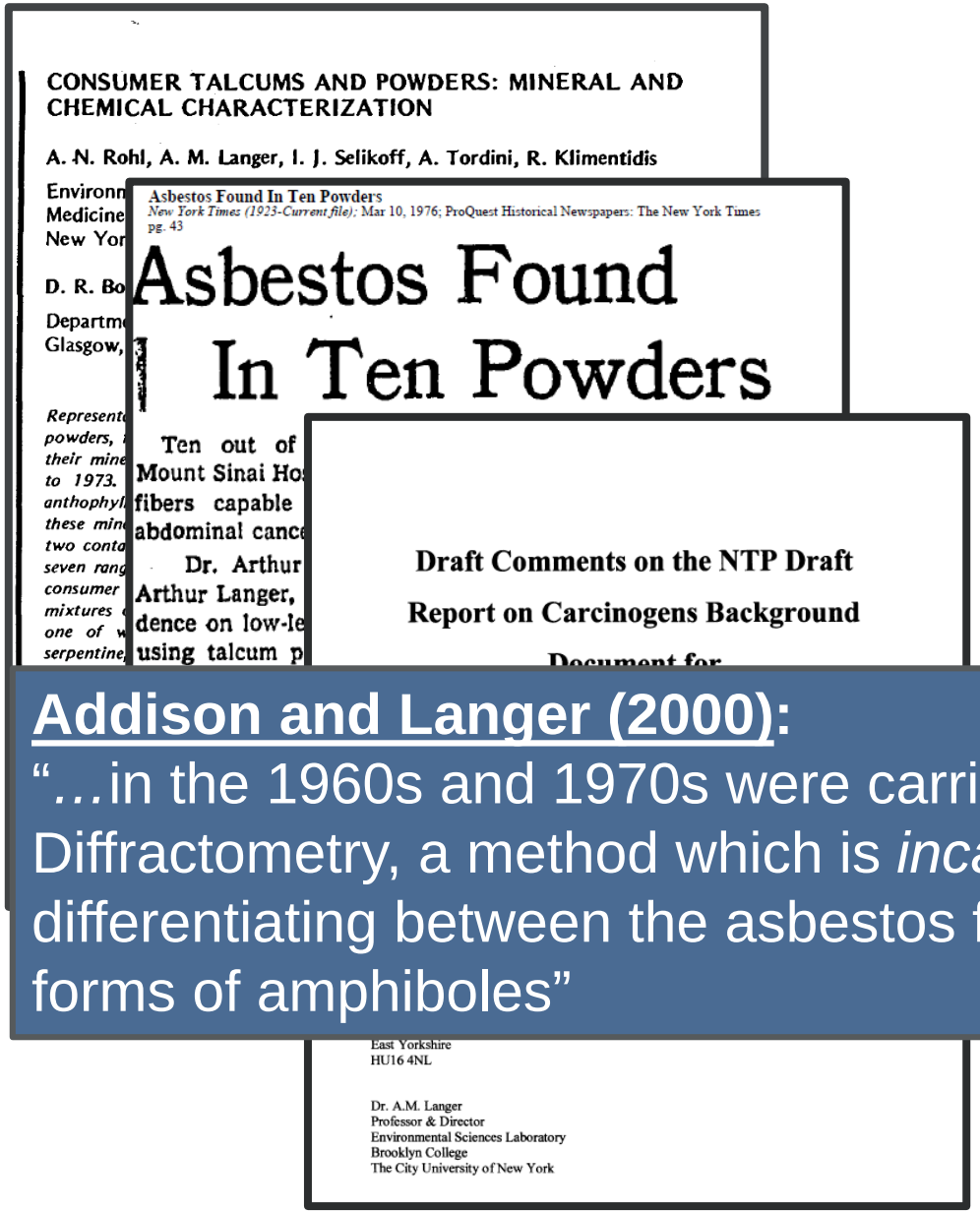
Non-Asbestiform

- Common
- Low length-to-width aspect ratio
- Short, thick, brittle fibers
- *Cleavage fragments*



Composition of Cosmetic Talc

- Initial concerns raised in the late-1960s/early-1970s
- A handful of historical studies and newspapers reported asbestos in cosmetic talc powders
  - Did not distinguish between asbestiform and non-asbestiform


CONSUMER TALCUMS AND POWDERS: MINERAL AND CHEMICAL CHARACTERIZATION

A. N. Rohl, A. M. Langer, I. J. Selikoff, A. Tordini, R. Klimentidis

Asbestos Found In Ten Powders

New York Times (1923-Current file); Mar 10, 1976; ProQuest Historical Newspapers: The New York Times pg. 43

Asbestos Found In Ten Powders

Ten out of Mount Sinai Ho fibers capable abdominal cance Dr. Arthur Arthur Langer, dence on low-le using talcum p

Draft Comments on the NTP Draft Report on Carcinogens Background Document for

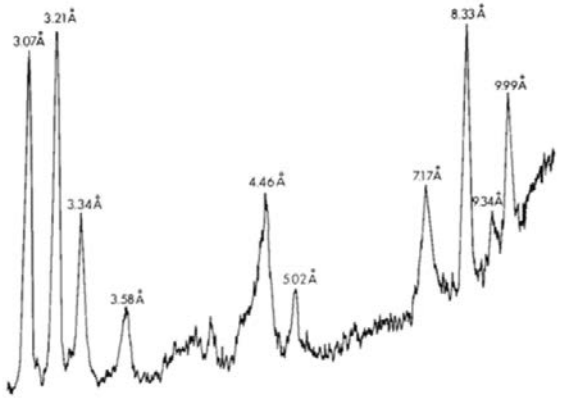
East Yorkshire
HU16 4NL

Dr. A.M. Langer
Professor & Director
Environmental Sciences Laboratory
Brooklyn College
The City University of New York

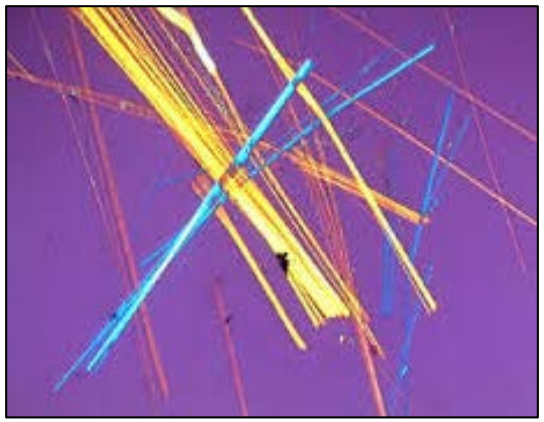
Addison and Langer (2000):
"…in the 1960s and 1970s were carried out using X-Ray Diffractometry, a method which is *incapable* of differentiating between the asbestos form and the normal forms of amphiboles"

Analytical Methods Required?

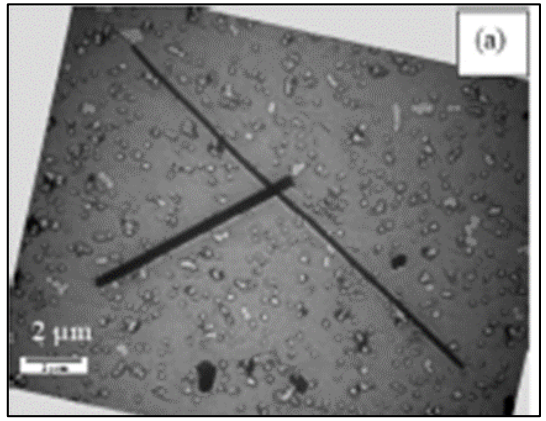
XRD (X-ray Diffraction)



PLM (Polarized Light Microscopy)



TEM (Transmission Electron Microscopy, w/ SAED)



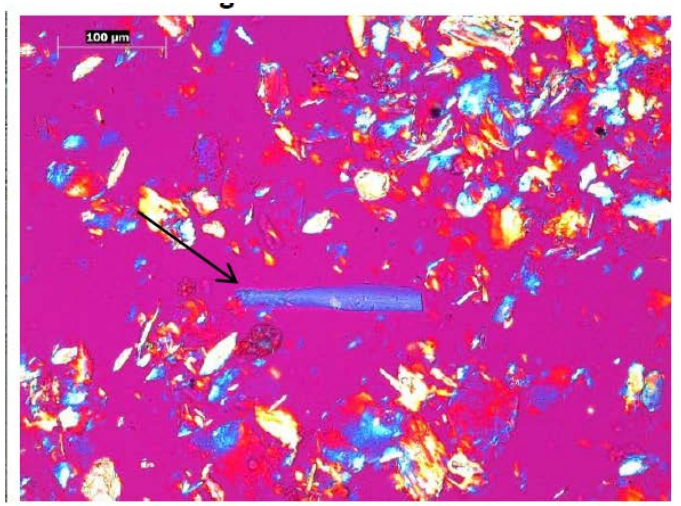
Cosmetic, Toiletry and Fragrance Association (CTFA, n/k/a Personal Care Products Council) (1976)

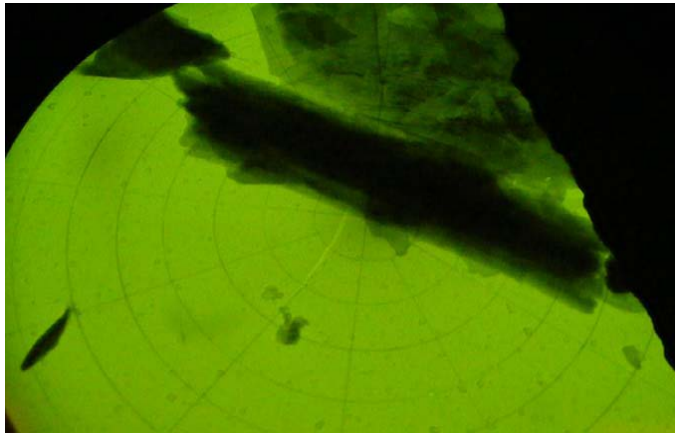
- Detection limit of 0.5%
- Recommends using XRD, PLM, and TEM

Recent Research

Results of Bulk Analyses of Cosmetic Talcum Products

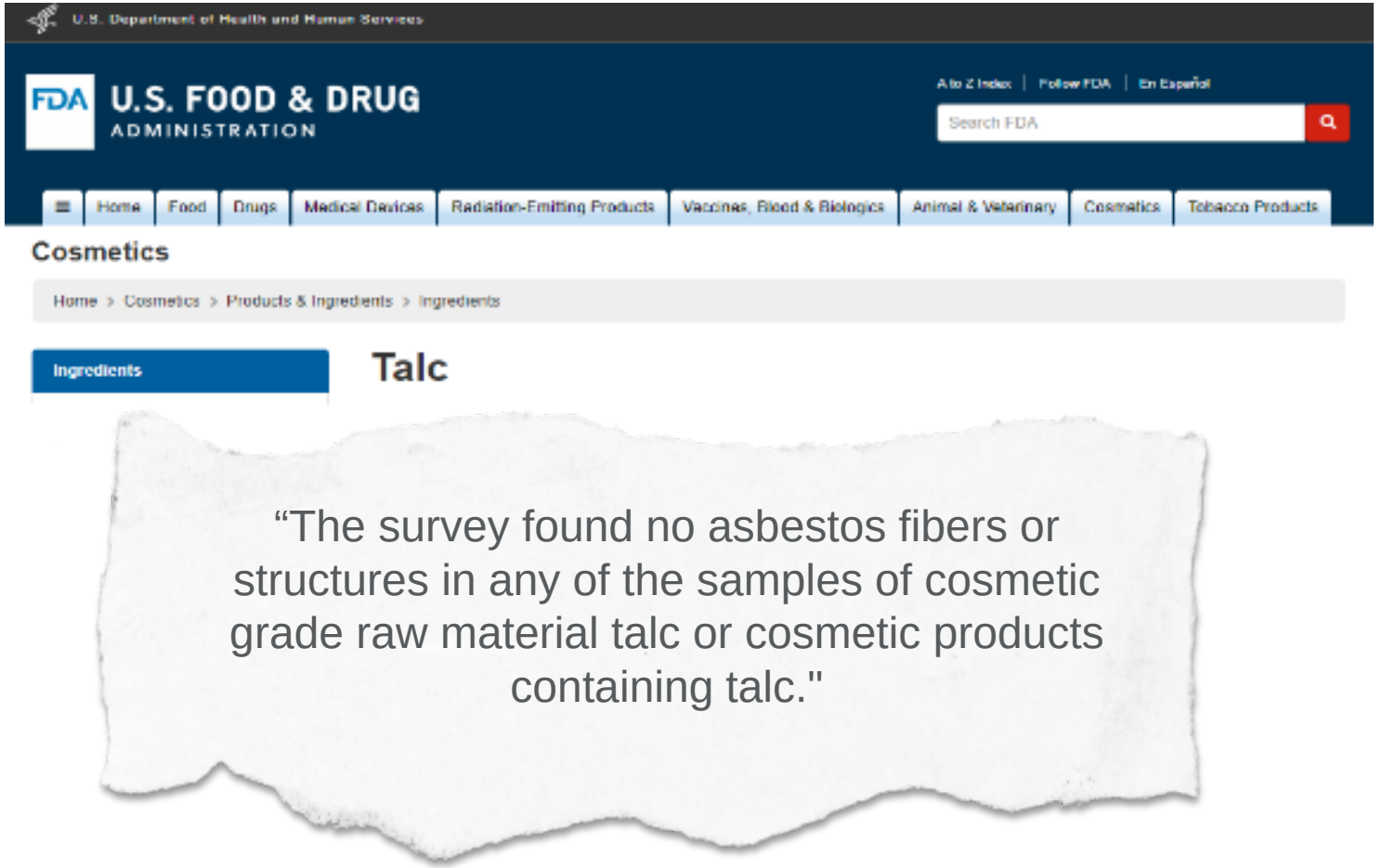
Product	Product Type	Years of Manufacture	Laboratory A		Laboratory B	
			XRD	PLM	PLM	TEM
A	Baby Powder	1961	Peaks of Monoclinic Amphibole	Tremolite cleavage fragments	Tremolite cleavage fragments	ND
B	Beauty Dust	1969-1970	Peaks of Monoclinic Amphibole	Tremolite cleavage fragments	Tremolite cleavage fragments	ND
C	Facial Powder	1940-1941	ND	ND	ND	ND
D	Body Powder	1970s	ND	ND	Tremolite cleavage fragments	ND
E		1962-1963	ND	ND	ND	ND
F		1973-1977	ND	ND	ND	ND





Food and Drug Administration's 2009-2010 Market Survey

- FDA conducted survey in 2009-2010
- Major talc suppliers (n=4)
- Cosmetic products (n=34)
- PLM and TEM
  - Very low detection limits



FDA's Recent Testing (Claire's/Justice Products & Beauty Plus)

> Ongoing testing and reporting since 2017

> FDA issued a consumer warning and requested a recall of specific Claire's and Justice products
  - Make-ups

> Source mines are unclear

J&J Response

Press Contacts:

Ernie Knewitz
(732) 524-6623
(917) 697-2318 (M)

Investor Contacts:

Christopher DelOrefice
(732) 524-2955

Matthew Stuckley
(732) 524-2617

JOHNSON & JOHNSON CONSUMER INC. TO VOLUNTARILY RECALL A SINGLE LOT OF JOHNSON'S BABY POWDER IN THE UNITED STATES

Reca

NEW B
Johnso

Press Contacts:

Ernie Knewitz
(732) 524-1090
media-relations@its.jnj.com

Jake Sargent
(202) 569-5086
JSargen3@ITS.JNJ.com

Investor Contacts:

Christopher DelOrefice
(732) 524-2955

Lisa Romanko

15 New Tests from the S Previously

Over 60 New Tests of the Labora

NEW BRUNSWICK, NJ, (OCTO Inc. (the Company) today annou Johnson's Baby Powder previous Administration (FDA) found no as samples from the single lot of Jo voluntarily recalled on October 1

Press Contacts:
Ernie Knewitz
(732) 524-1090
media-relations@its.jnj.com

Company Investigation Confirms No Asbestos in Johnson's Baby Powder

More Than 150 Tests Show No Asbestos

NEW BRUNSWICK, NJ, (December 3, 2019) – Johnson & Johnson Consumer Inc.

Current Analytical Considerations

> What analytical methods should be used?

> What limit of detection is acceptable? Feasible?

> What counting criteria should be followed?

> What is the significance of the particles observed?

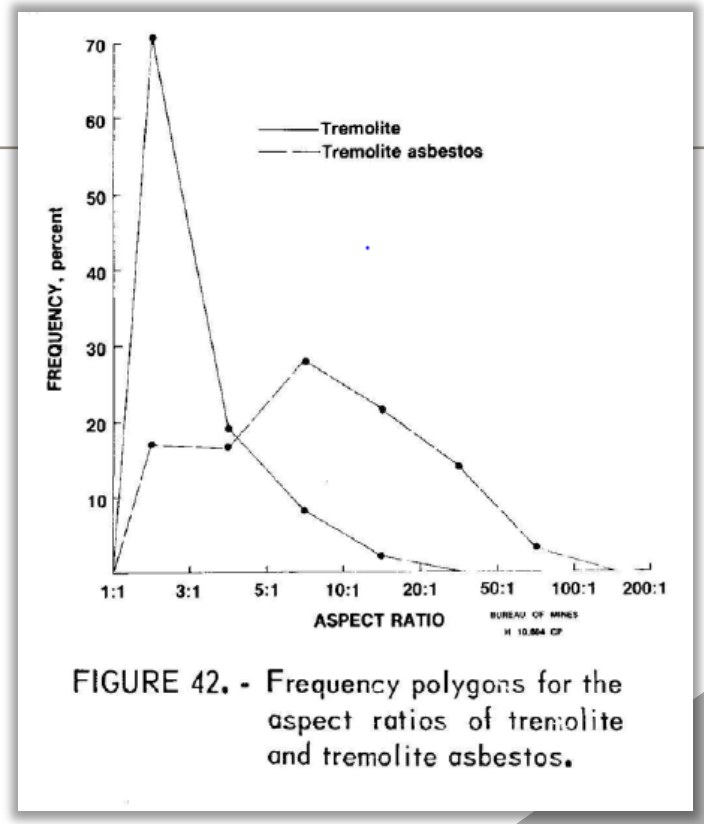
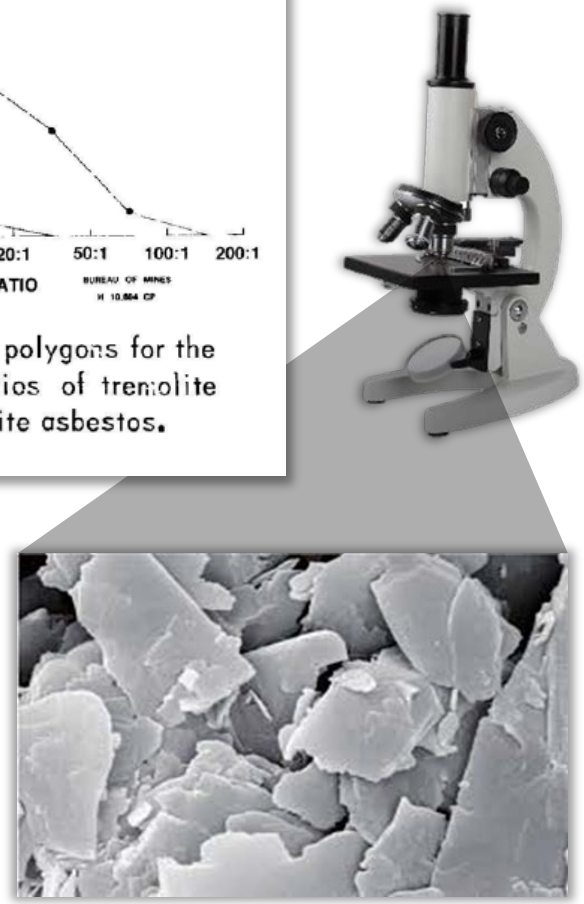


FIGURE 42. - Frequency polygons for the aspect ratios of tremolite and tremolite asbestos.



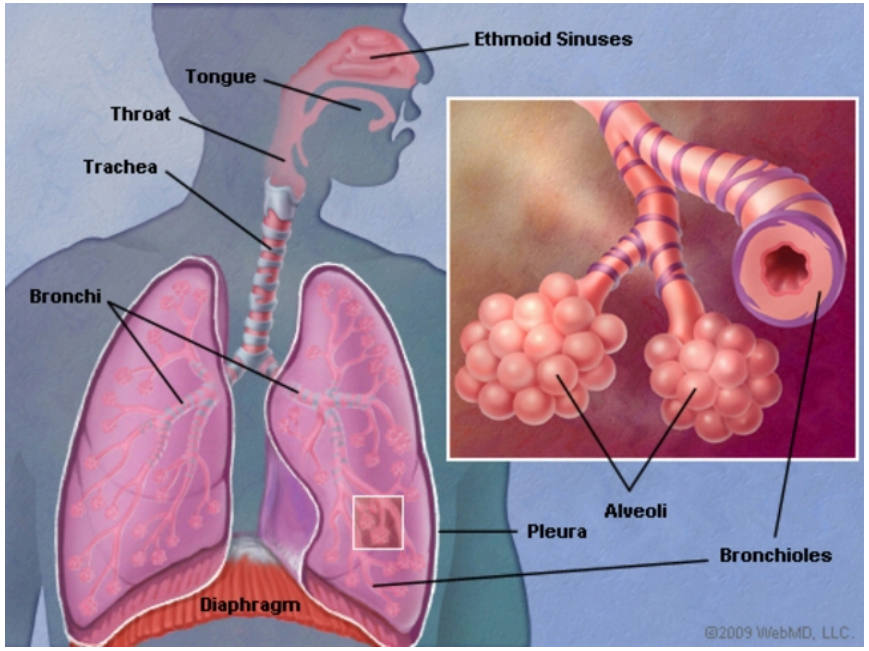
Toxicological Considerations

> Cosmetic talc exposure does not cause mesothelioma

- Miner and miller epidemiology (Italy, Vermont, North Carolina)
- Animal studies

> Cleavage fragments

- Vast majority not respirable (>1µm diameter)
- Biopersistence
- Animal studies



Airborne Exposures From Consumer Use of Cosmetic Talc

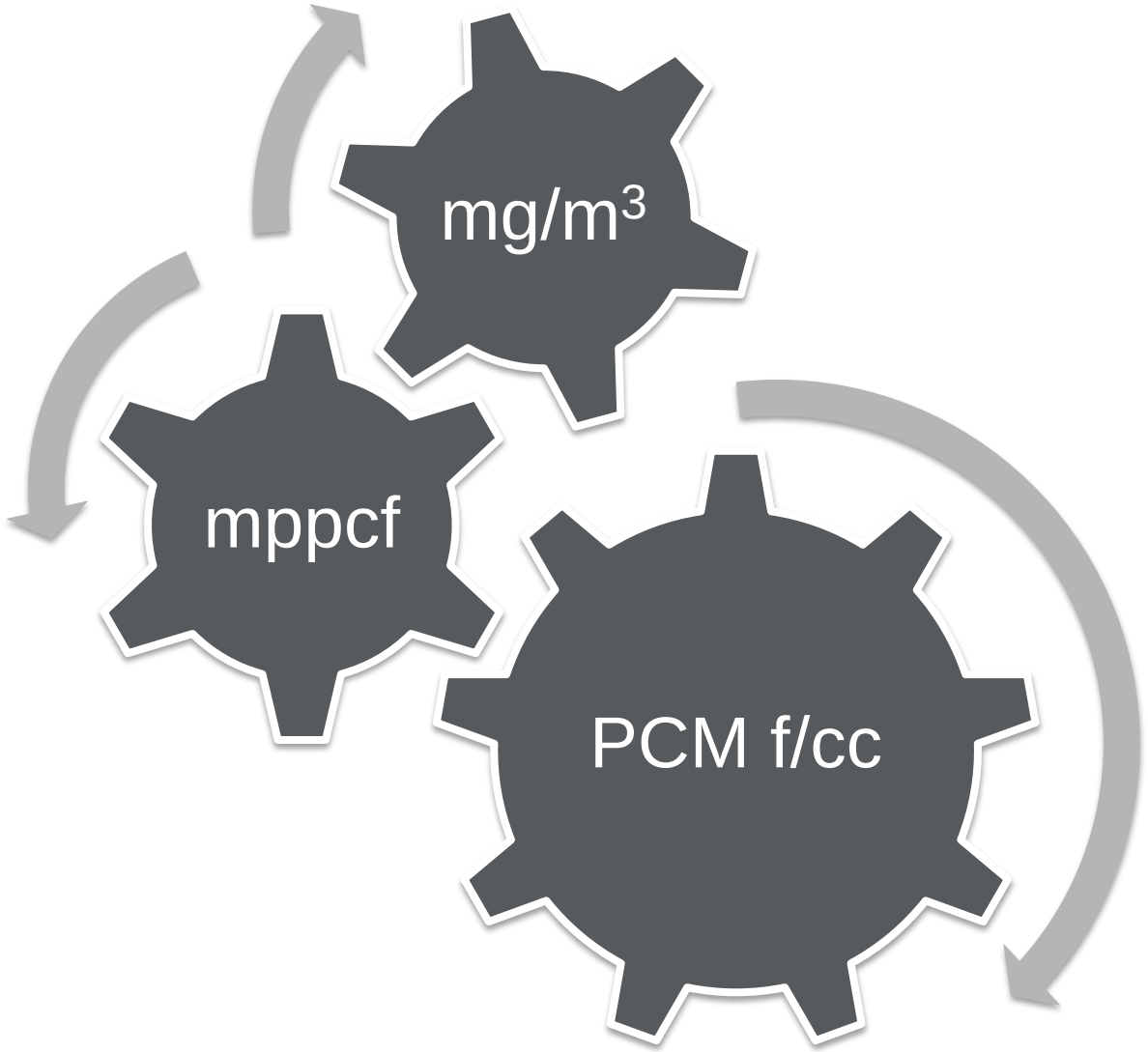
> Several studies have evaluated airborne concentrations associated with consumer use of talcum powder (n=7)

> Typical use scenarios evaluated:

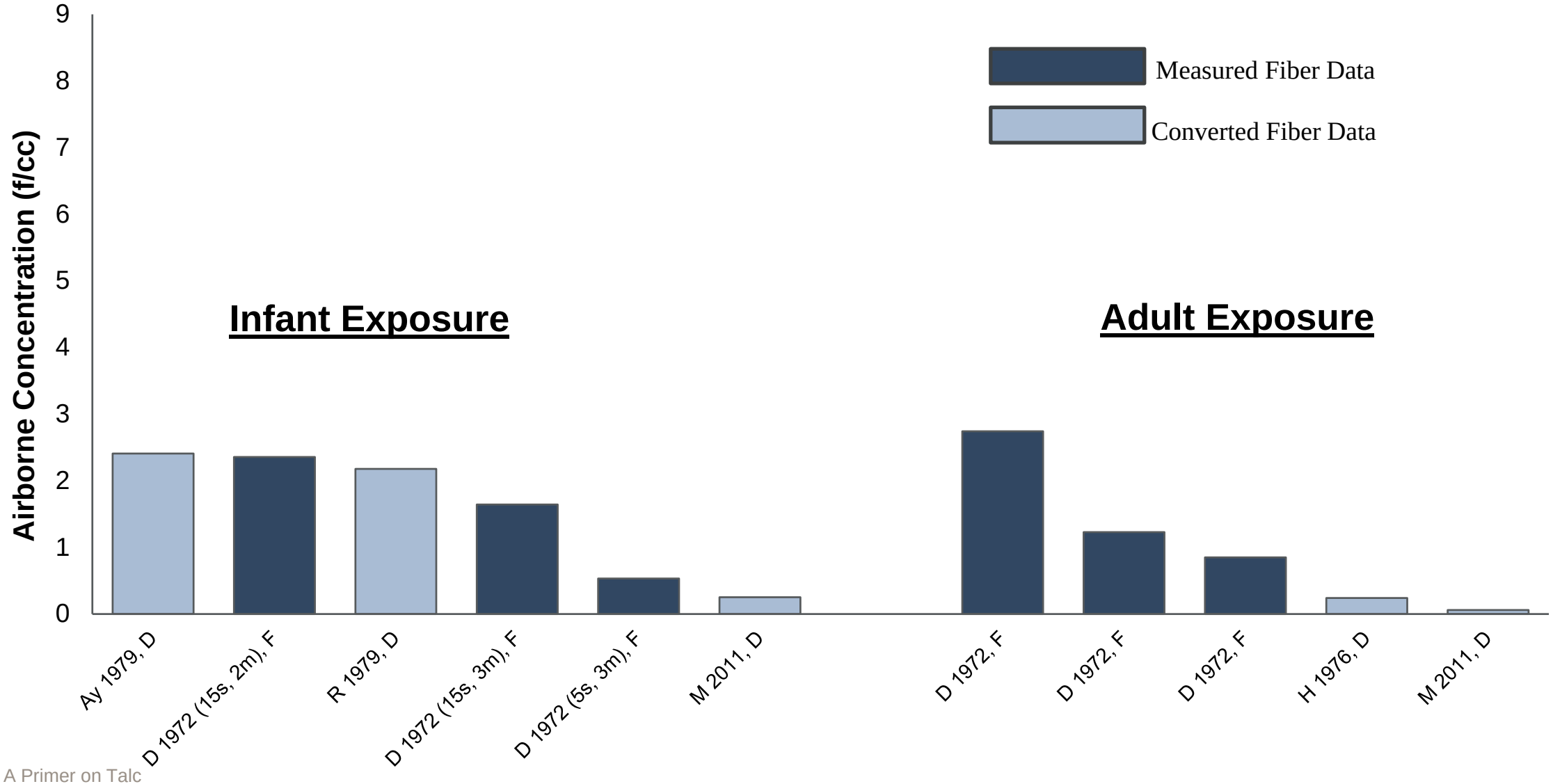
- Diapering
  - Infant exposure
  - Adult exposure
- Face powdering
  - Adult exposure
- Body powdering
  - Adult exposure

Evaluation of Airborne Exposure Data

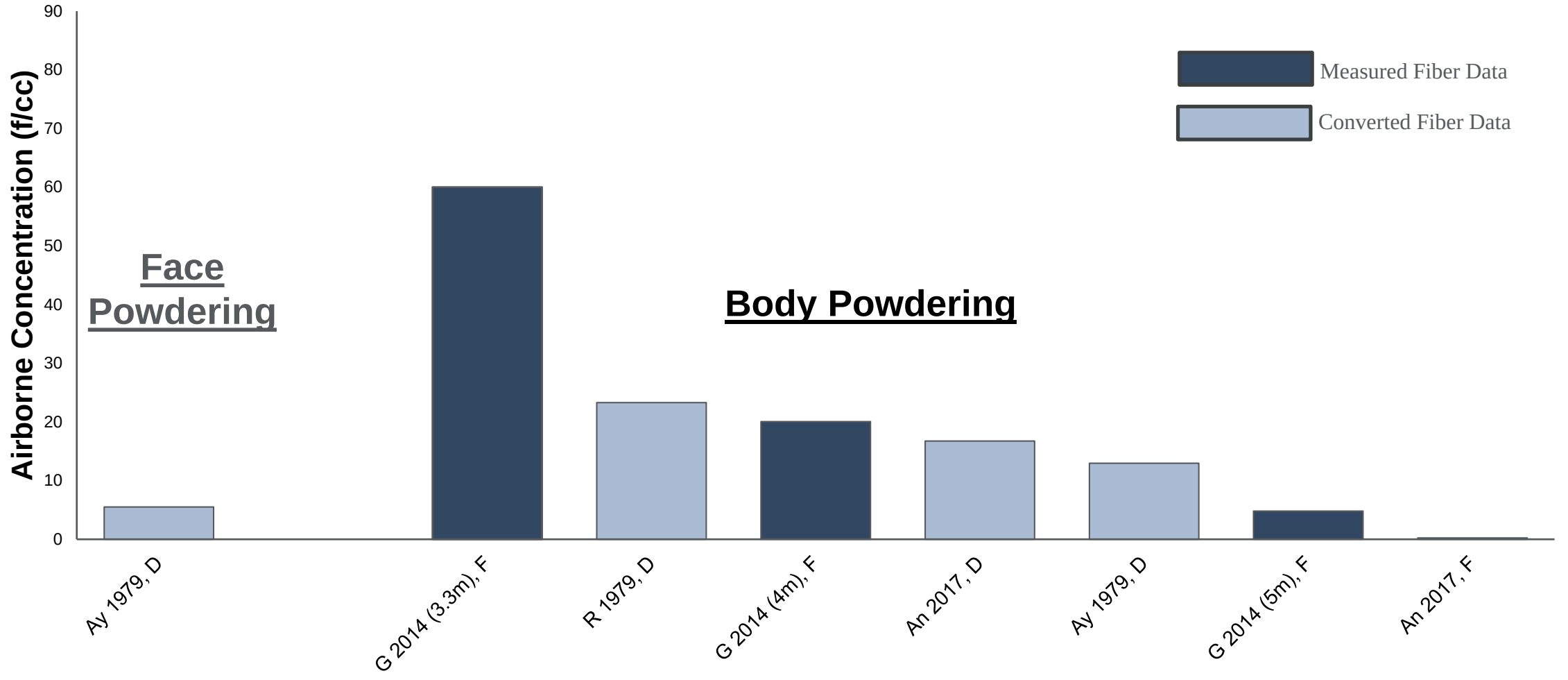
- Conversion factors are used to describe the relationship between different units of measure
  - Identified historical data relating measured airborne talc dust to talc fiber concentrations
- Allows for inclusion of all available exposure data in standard units of PCM (f/cc)



Diapering Scenarios

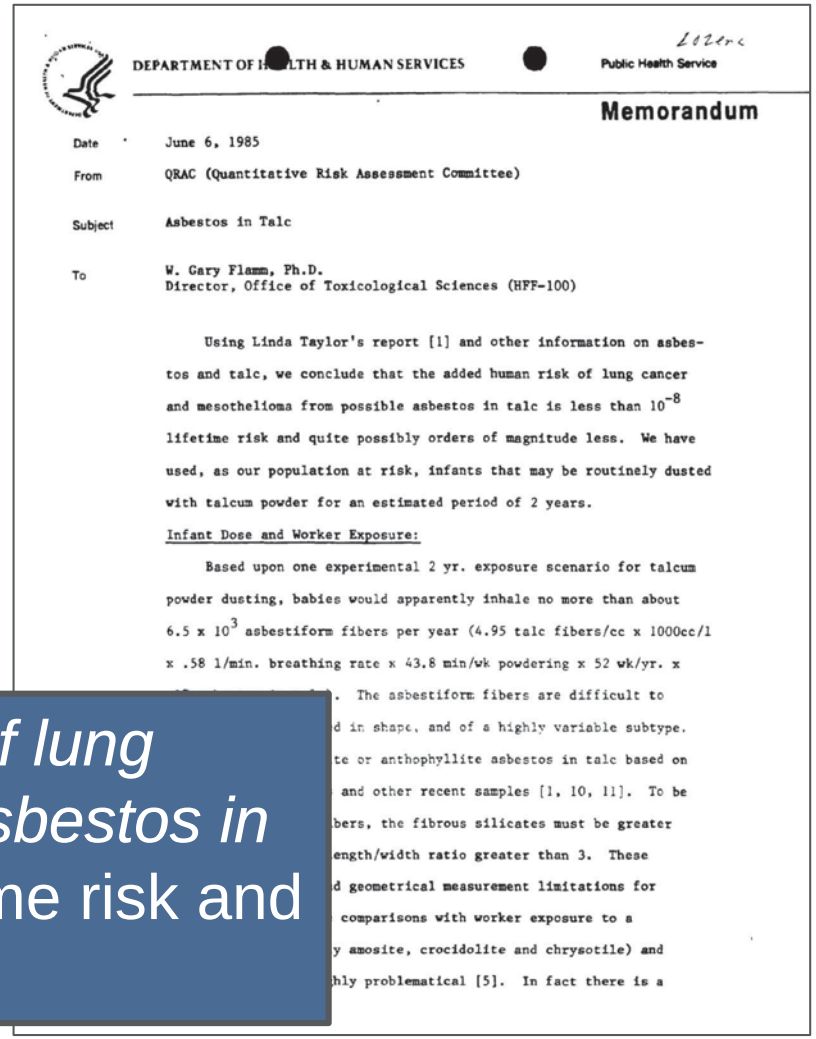


Adult Use Scenarios



FDA (1985) – *Risk Assessment*

- Evaluated potential infant exposure to asbestos in talcum powder
  - Assumed that 0.1% of fibers found in talc were asbestos
- Cumulative exposure: 0.0001 f/cc-years
  - Assumes 43.8 min exposure/week, for 2 years



DEPARTMENT OF H[illegible]LTH & HUMAN SERVICES — Public Health Service

Memorandum

Date June 6, 1985

From QRAC (Quantitative Risk Assessment Committee)

Subject Asbestos in Talc

To W. Gary Flamm, Ph.D.
Director, Office of Toxicological Sciences (HFF-100)

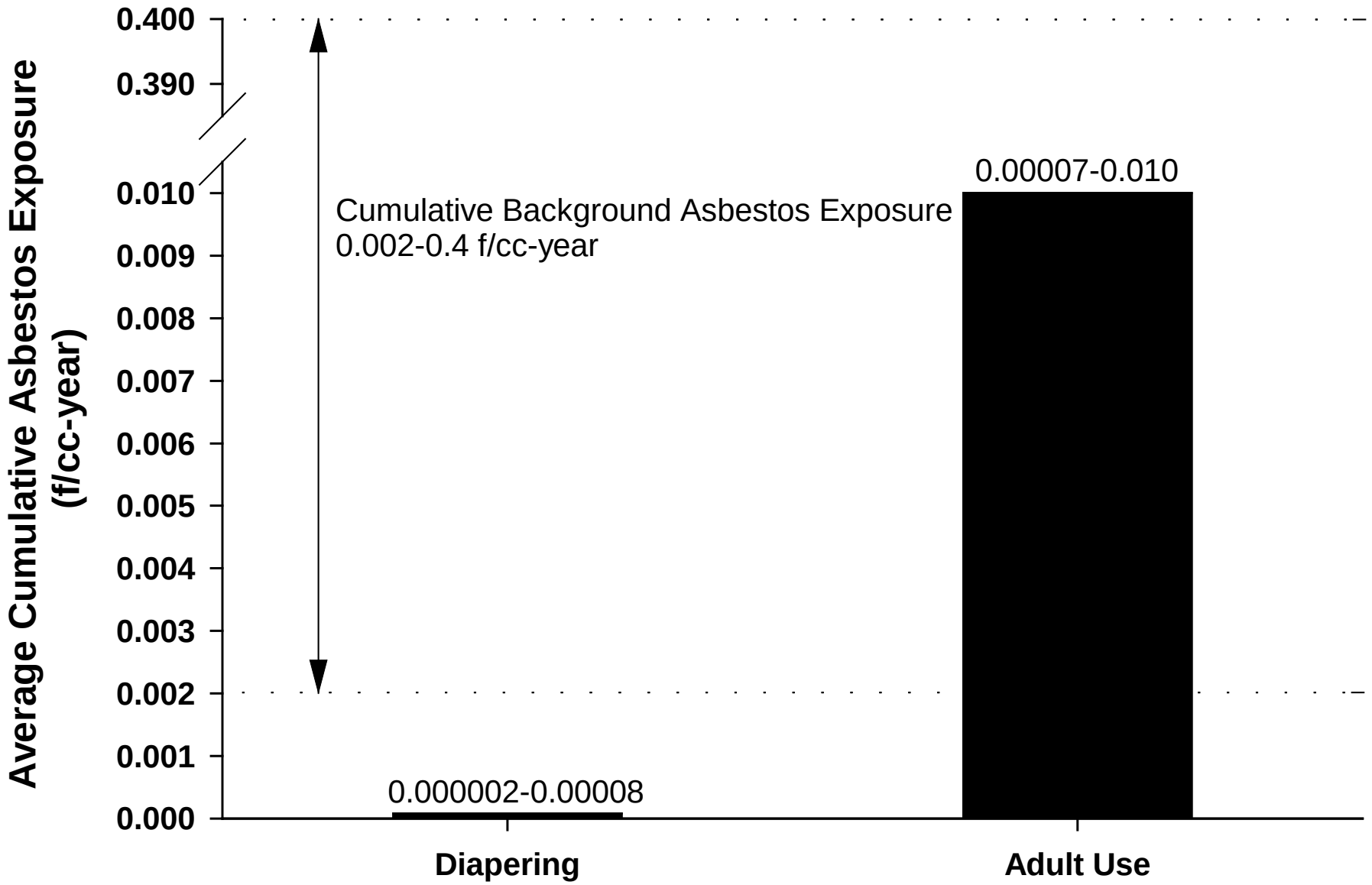
Using Linda Taylor's report [1] and other information on asbestos and talc, we conclude that the added human risk of lung cancer and mesothelioma from possible asbestos in talc is less than 10^{-8} lifetime risk and quite possibly orders of magnitude less. We have used, as our population at risk, infants that may be routinely dusted with talcum powder for an estimated period of 2 years.

Infant Dose and Worker Exposure:

Based upon one experimental 2 yr. exposure scenario for talcum powder dusting, babies would apparently inhale no more than about 6.5×10^{3} asbestiform fibers per year (4.95 talc fibers/cc x 1000cc/l x .58 l/min. breathing rate x 43.8 min/wk powdering x 52 wk/yr. x [illegible]. The asbestiform fibers are difficult to [illegible]d in shape, and of a highly variable subtype. [illegible]te or anthophyllite asbestos in talc based on [illegible] and other recent samples [1, 10, 11]. To be [illegible]bers, the fibrous silicates must be greater [illegible]ength/width ratio greater than 3. These [illegible]d geometrical measurement limitations for [illegible] comparisons with worker exposure to a [illegible]y amosite, crocidolite and chrysotile) and [illegible]hly problematical [5]. In fact there is a

"We conclude that the *added human risk of lung cancer and mesothelioma from possible asbestos in talc is less than 10^{-8} [1 in 100 million]* lifetime risk and *quite possibly orders of magnitude less*."

Consumer Exposure Potential from Cosmetic Talc Use



Final Thoughts

> Findings of historical and current testing should be interpreted carefully

> New product testing methods should differentiate mineral habit

> Risk assessment practices can be used to understand significance of potential exposures

Thank you

Eric Miller, MPH
eric.miller@cardno.com
(415) 618-3479