

Talc Litigation- How and why did we get here and where are we going?

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**TALCUM POWDER USERS
TALC PRODUCTS LINKED TO OVARIAN CANCER**



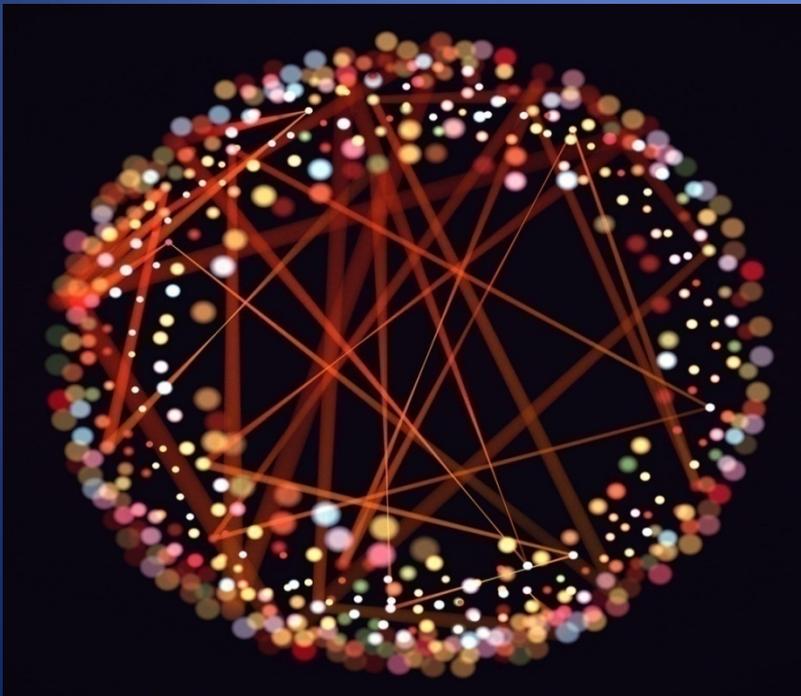
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Complex and Intertwined Issues

1. What's talc and "asbestos"?
2. Is asbestos in talc products?
3. Did some get harmed from use?
4. What kind and degree of harm?
5. Litigation "industry" explosion



What is the AGENT?

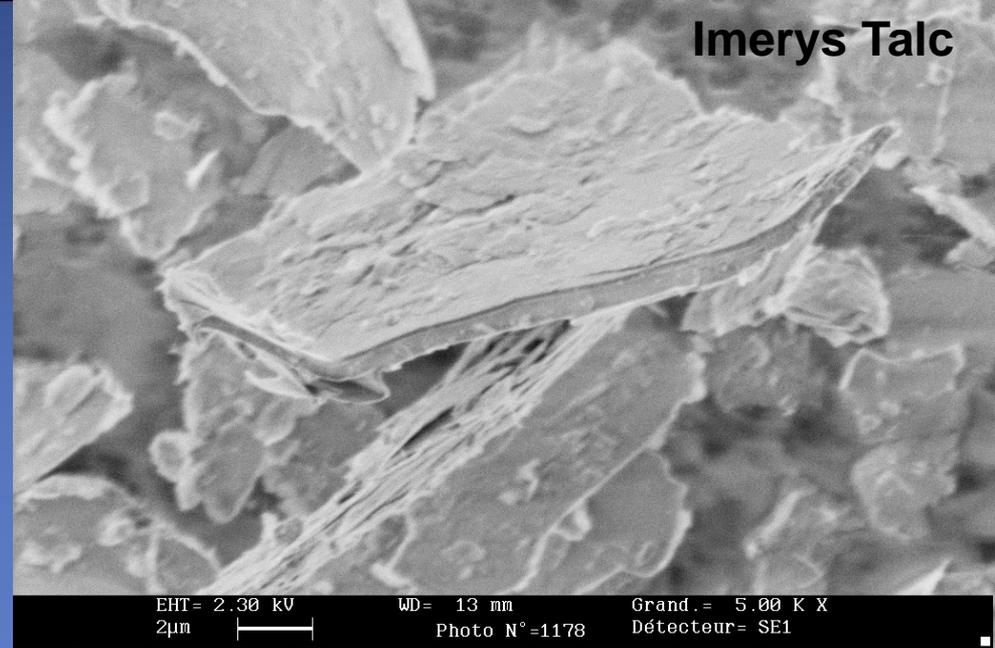
talc $Mg_3Si_4O_{10}(OH)_2$

or

talc with “asbestos”

(elongate ~~X~~ particulates,
esp. amphiboles)

Imerys Talc



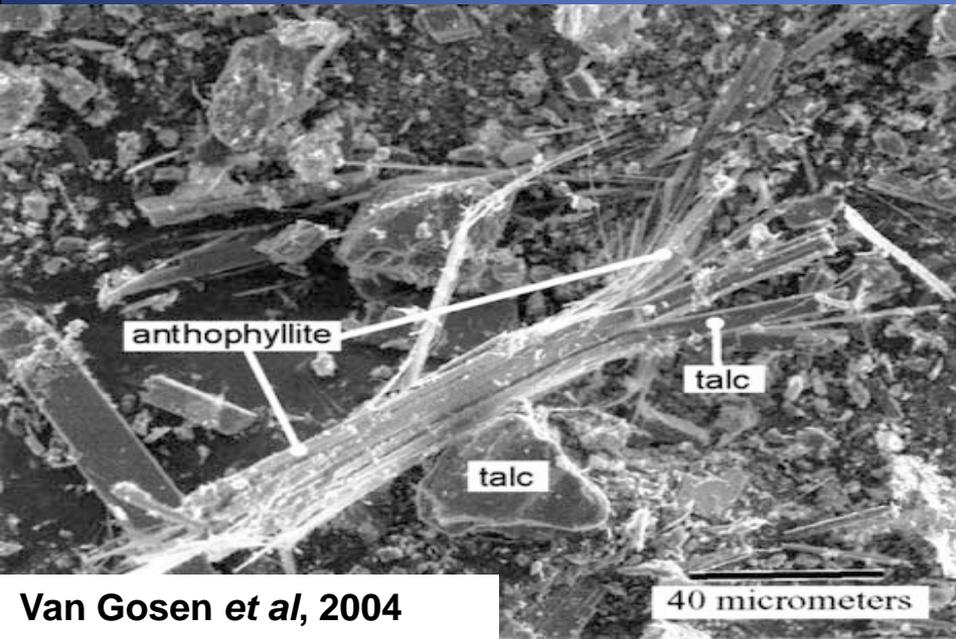
ORES/PRODUCTS

Past

Present

Future

How much is
too much?



Van Gosen et al, 2004

6% Talc production used in personal products



Do modern talc products
have the same characteristics as talc
ores and products from decades ago?



My opinion:
What went into products likely to have been
highly variable!



**TALC
ore
&
powder**



**Litigators travel the
“golden” road to seek out
in talc products
elongate minerals
whose chemistry
matches,
or is close to,
any of the six regulated
asbestos species!**

The Big Question



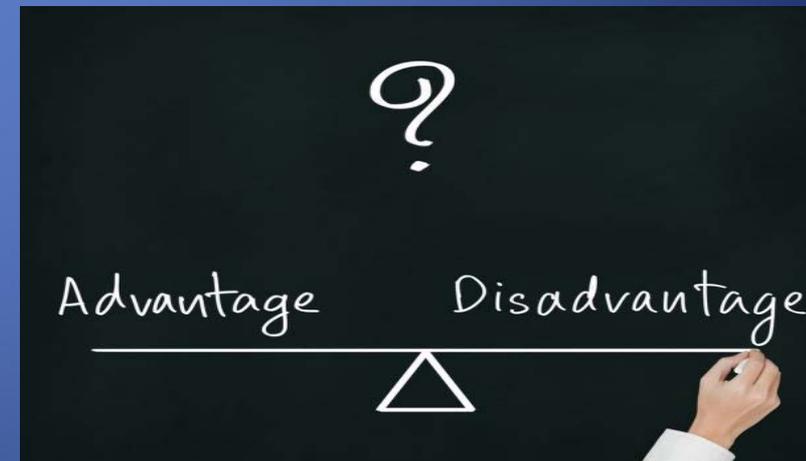
are “elongate” particles
of
talc? tremolite? anthophyllite?
(& some other minerals)
cleavage fragments?
asbestiform?
“dangerous”?
&
“regulatable”?



Analytical Procedures & Strategies

No one method is best for
ALL
situations
&
asbestos-amphibole
talc types!

PLM, PCM, XRD, SEM, TEM-
each has specific
INDIVIDUAL & COLLECTIVE
advantages
and
disadvantages.



Major Organizations Working on Upgrading/Modernizing Methods of Characterization of Materials of Concern in Talc Products

Personal Care Product Council-PCPC

[formerly Cosmetics, Toiletries, and Fragrance Association, CFTF]

U.S. Pharmacopeia (USP) (in cooperation w/FDA)

[see Modernization of Asbestos Testing in USP Talc]

American Society of Testing Materials (ASTM)

[note recent large number of new member applicants]



**“WHAT YOU SEE
DEPENDS ON
WHAT YOU'RE
LOOKING FOR.”**

quoteswave.com

- Unknown



IF YOU CHANGE
THE WAY YOU
LOOK AT THINGS,
**THE THINGS
YOU LOOK AT
CHANGE.**

WAYNE DYER

ZERODEAN.COM

**Talc,
Asbestos,
Amphiboles
&**

Numerous Minerals

**One can often find
“something” elongate
in almost all rocks!**

& talc comes from rocks!

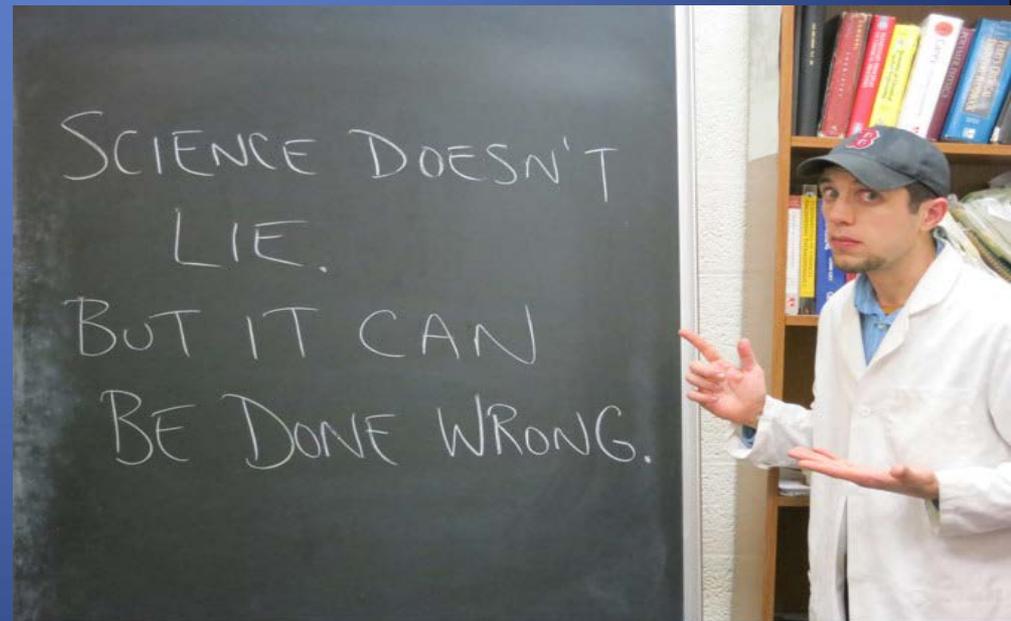


MY SUMMARY HYPOTHESES

much litigation based upon the word
ASBESTOS!

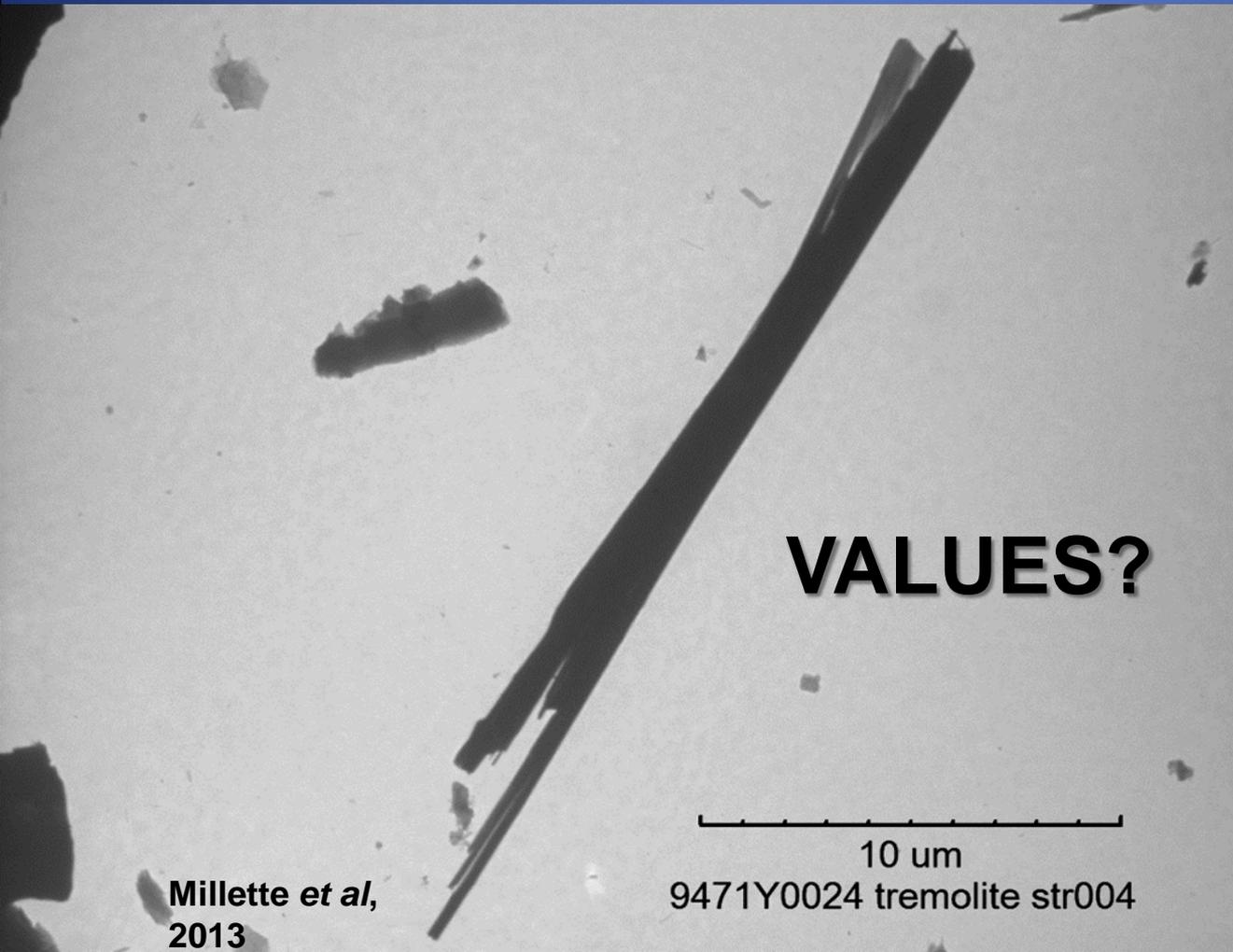
IT ISN'T SO MUCH THE "TALC"
as it is the possible "asbestos" content
(esp. tremolite and/or anthophyllite)

And also the
misidentification of
talc fibers and
cleavage fragments
as a regulated
asbestos species



TEM Limited Population Issues

Unequivocal ID from a single or very few “fibers” can be VERY misleading!



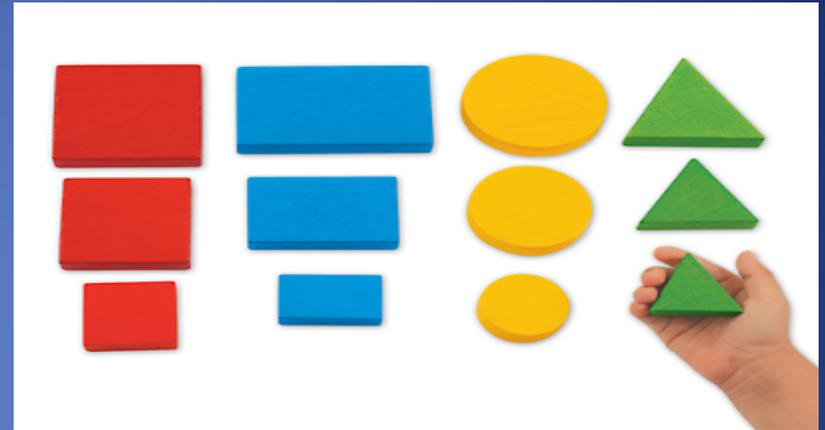
It's “likely” to be asbestos on basis of:

Aspect ratio
Parallel sides
Terminations
Unit cell
Chemistry
“Population”
Nomenclature

Litigation

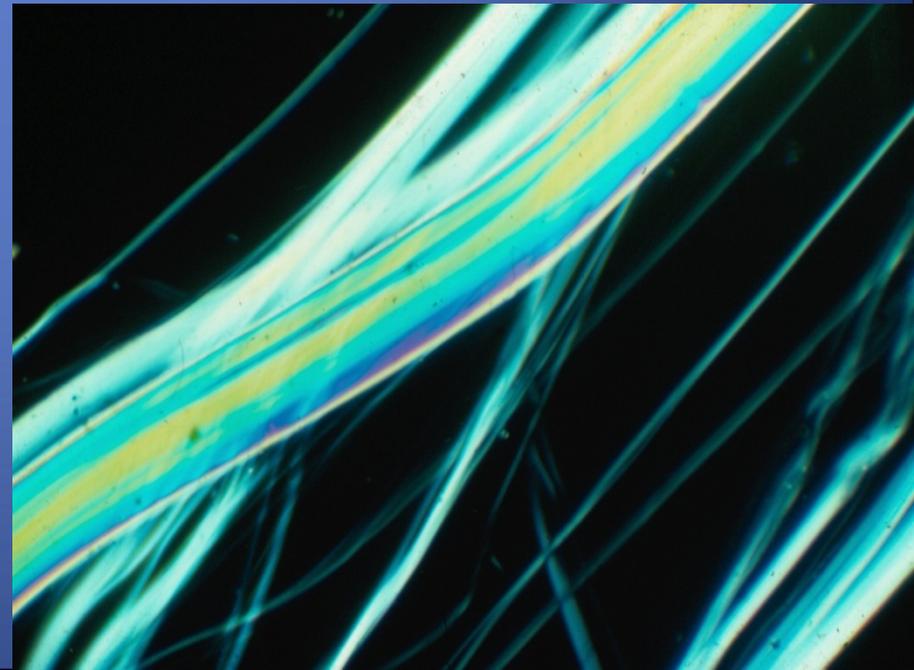
SHAPE (“morphology” & aspect ratio)

The “easier” stuff, especially ACBM

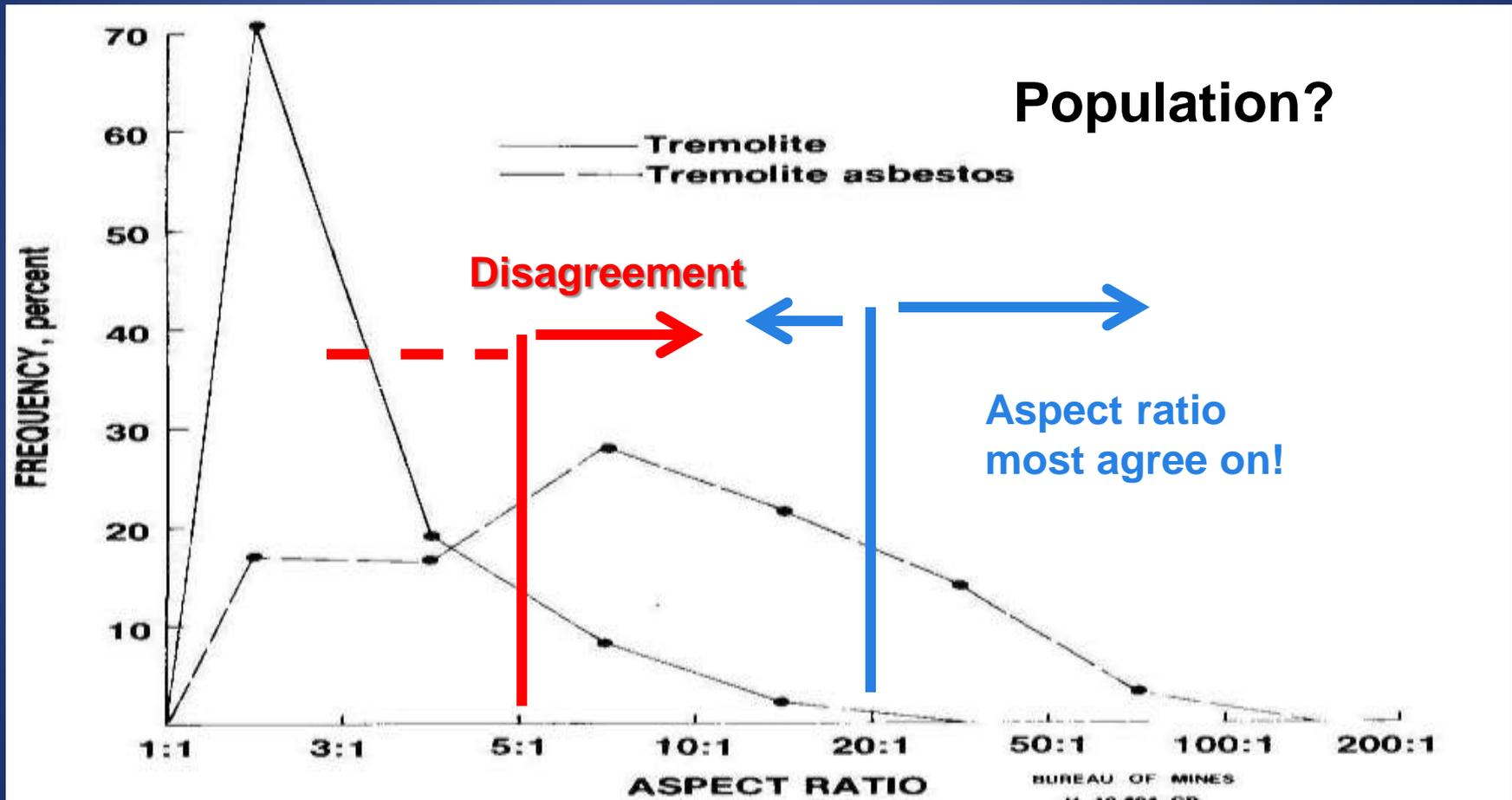


© asbestorama

chrysotile



ASPECT RATIO & "Federal Fiber"



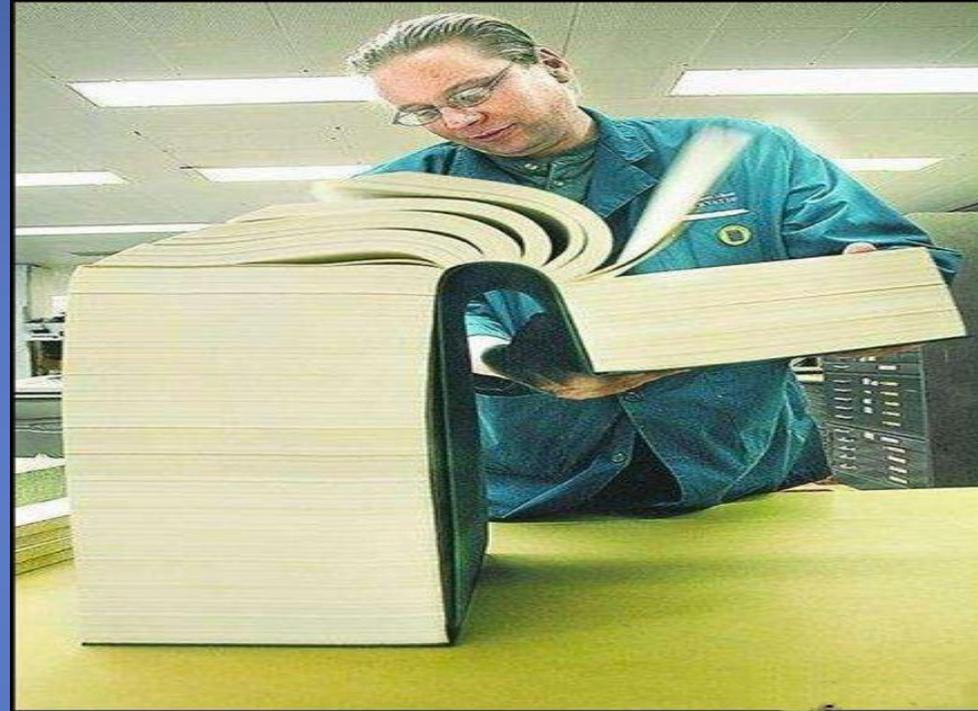
Modified from US Bureau of Mines Report No. IC 8751, "Selected Silicate Minerals and their Asbestiform Varieties". Campbell, 1977

“Asbestos” and Mineral Nomenclature

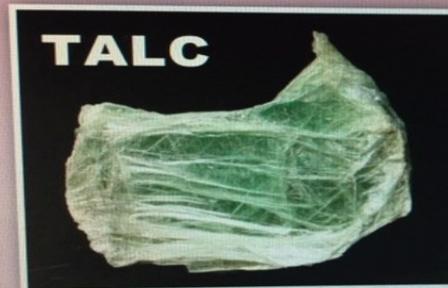
Many different
definitions
of
asbestos,
asbestiform,
fiber...



Word meanings can
change with time!



Talc & Asbestos are relatives & look alike!



Definitional Conundrums

Conflicting definitions:
mineralogical, industrial, regulatory & legal



Need for protocols
to discriminate
asbestos
from
non-asbestos,
especially in
consumer products



Core issues in the Pharmaceutical Producers' talc litigation cases are:

- 1) Is there asbestos, a generally-accepted deadly material, in the talc used in personal care products;**
- 2) Whatever mineral(s) and shape(s) are present, do talcum powder personal care products cause human disease, especially ovarian cancer and mesothelioma;**
- 3) Were the Defendants responsible because they knowingly and deliberately produced and sold a hazardous product?**

Medical & Mineral Issues

Diseases-

Ovarian cancer

1971- particles of talc deeply embedded in 10 of 13 ovarian tumors.

Mesothelioma

lab found asbestos as well as *'a lot of talc, both fibrous and platy, in her lungs and lymph nodes.'*

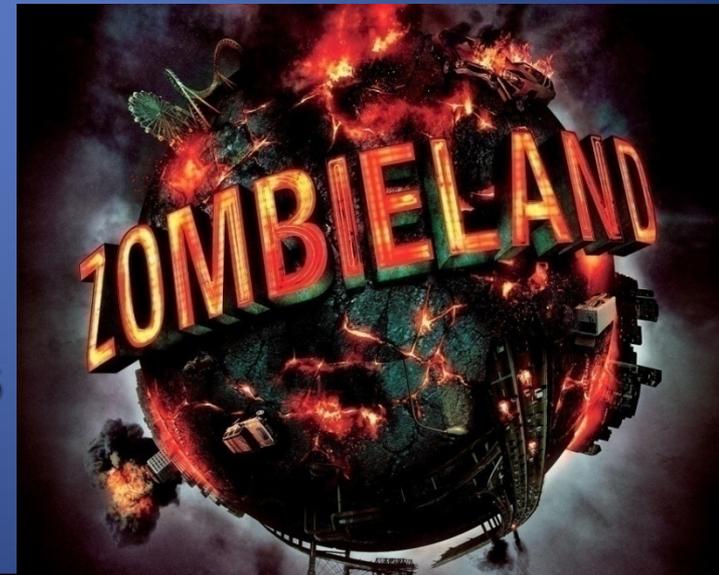
Agent

Talc

Talc with asbestos

Talc with elongate amphiboles

“Federal Fiber”

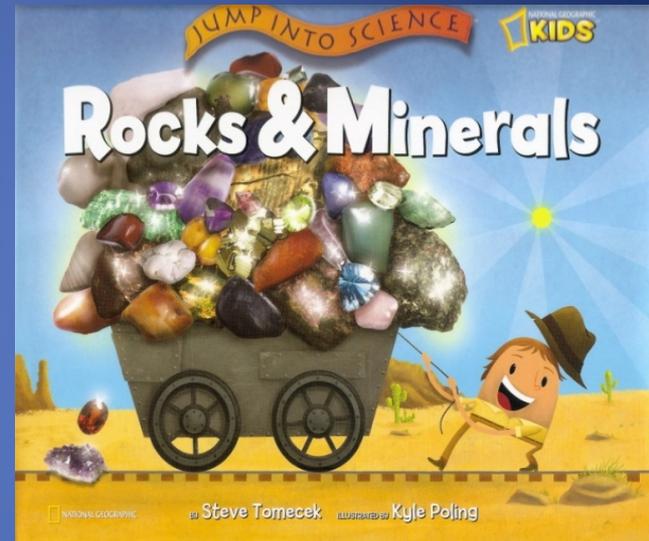


Talc Sources- 3 different rock sources

1. Higher temperature metamorphosed calc-silicate rocks (“sandy” limestones)
2. Moderate temperature ultrabasic rocks (Fe-Mg silicates)
3. Lower temperature heated water alteration of calcium carbonate rocks (Mg-limestones)

Amphiboles tend to form in
Types 1 and 2,
but not usually in Type 3

Types 1 & 2 were use for industrial purposes
Type 3 was used in personal care products

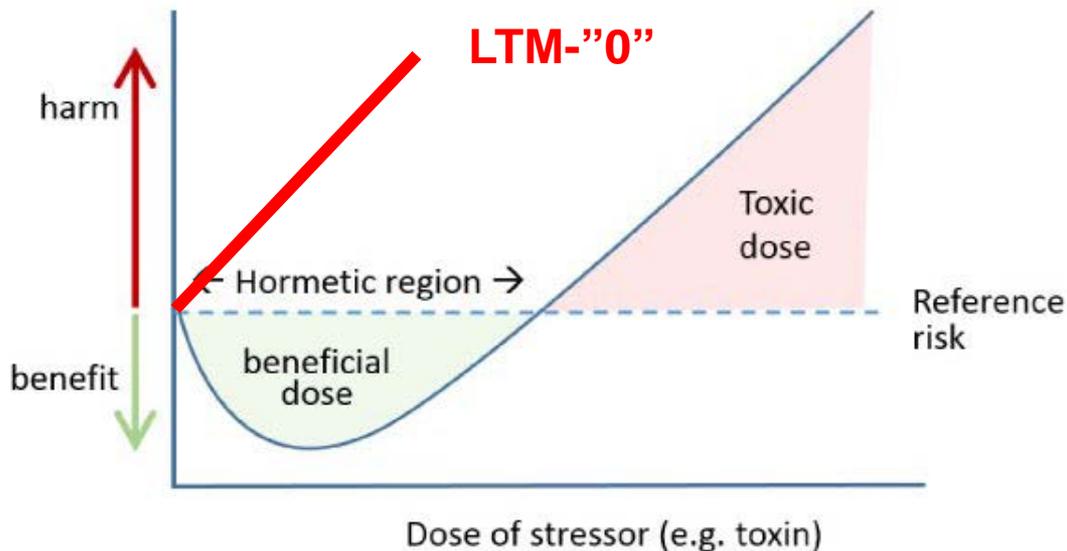


DOSE ISSUES

Exposure Level
mere presence

linear threshold model vs. “hormesis”

more Zombie concepts?
any level is dangerous
&
one fiber kills



Modified from Mangan, 2017-
see Calabrese, various)

Jurisdictional Variations

St Louis- \$4.7 billion jury verdict- upheld 12/2019

Philadelphia 1/2019- summary judgment for Defense

NYCAL- New York “asbestos” court

Stage 1- December 18, 2018- J&J settled \$1.5 million

Stage 2 – on-going; new standards

4 cases now going trial



Fact Witness



Expert Witness

The Expert Witness

An individual who has expertise
in a certain area
due to
education, experience
or
a combination of both



Medical
Geologist
Analyst
Hygienist

Litigation “Rules” for Experts

Frye Standard (1923): science experts can testify if their methods are “generally accepted” in scientific community.

Daubert standard: scientific principles “sufficiently established to have general acceptance in the field to which it belongs.”

Do it according to “accepted” practices or you are out!



“New” Legal Doctrine for Talc Cases

Juni- “Demonstrable” Hazardous level

Plaintiffs must prove a product is dangerous by itself, and NOT merely because it contains an ingredient that has been found to be capable of causing disease.

IMPACT- will be harder to prove exposure to any “tiny” amounts of asbestos that could possibly be in talc and be the cause of cancer, (esp. MESOTHELIOMA).

January 31, 2019- NYCAL Judge Mendez in *Mantovi v. American Bilrite* ruled that defendants successfully showed that the fibers embedded in its floor tiles couldn't cause mesothelioma.



Ovarian Cancer Legal “History”

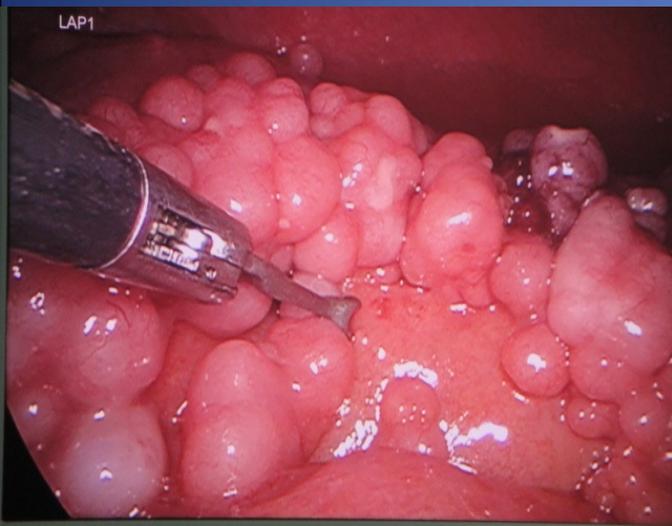


Multi-million dollar jury awards

Search for “asbestos” in any and all personal care products

**Business Insider- Reuters-
December 14, 2018**

<https://www.businessinsider.com/johnson-and-johnson-knew-for-decades-baby-powder-contained-asbestos-2018-12>



The Reuters report sourced from Plaintiff lawyers:

What and when did Johnson & Johnson know about iconic product and why fail to warn consumers.

J & J claims talc products asbestos-free since 1970's. Internal company memos, reports and other documents show that the company's raw talc and powders intermittently tested positive for trace amounts of asbestos from 1971 through 2003.

In spite of positive tests, J&J persuaded federal regulators not to limit asbestos in cosmetic talc products and heavily influenced scientific research on the safety of talc.

J&J Responses after Initial Plaintiff “wins”:

Johnson & Johnson called the Reuters report “one-sided, false and inflammatory,” and dismissed it as a “conspiracy theory.”

J&J took out ads in major newspapers, including The Wall Street Journal and The New York Times.

The J&J ad headlined “Science, Not Sensationalism.”

J&J asserted:

“If we had any reasons to believe our talc was unsafe, it would be off our shelves.”



February 20, 2019 J&J Subpoenaed by DOJ & SEC

J&J now facing >13,000 lawsuits

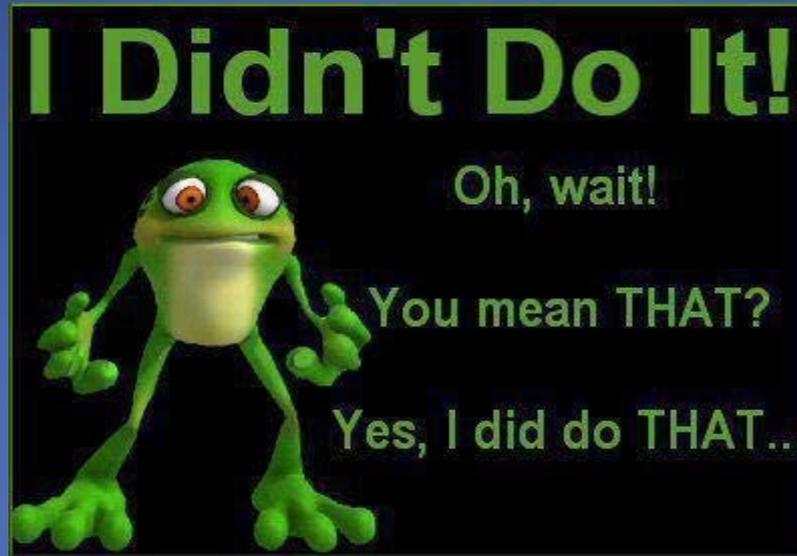


Major Legal Questions

1. Is TALC, per se, a health hazard and if so, how and why, and at what dose?
2. Are commercial personal care talc products “contaminated” with regulatory asbestos and/or elongate mineral particulates that some identify as regulated asbestos?
3. Are elongate mineral particulates present in some talcs inherently dangerous to humans?



Major Pharmaceutical Defense Arguments



<1% NOT a hazard to babies

Talc can't "migrate" to ovaries

Analytical methods flawed

"Blending" reduced hazards

BUT, internal documents show concerns!

OVARIAN CANCER-MAINSTREAM SCIENCE/MEDICAL CONCLUSIONS-2016

Risks for epithelial ovarian cancer
from genital talc use vary by

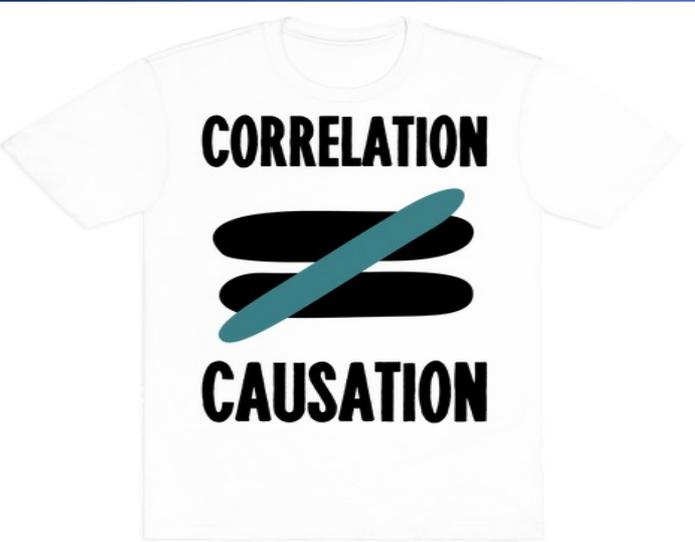
cancer type

menopausal status

hormone therapy use

smoking

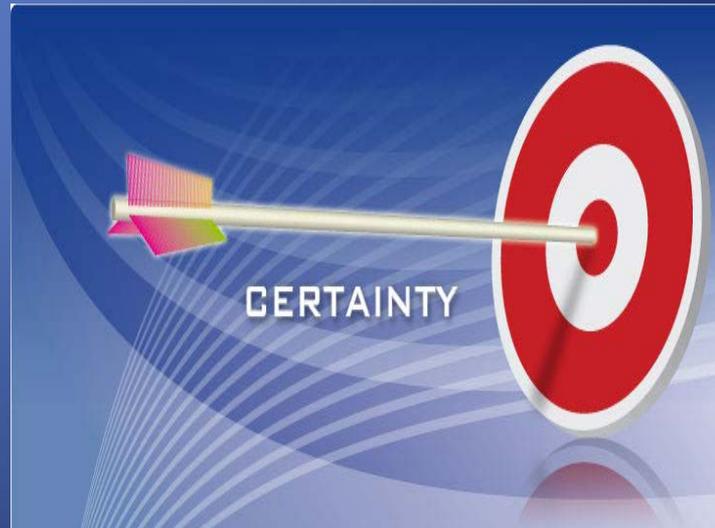
weight



CORRELATION



CAUSATION



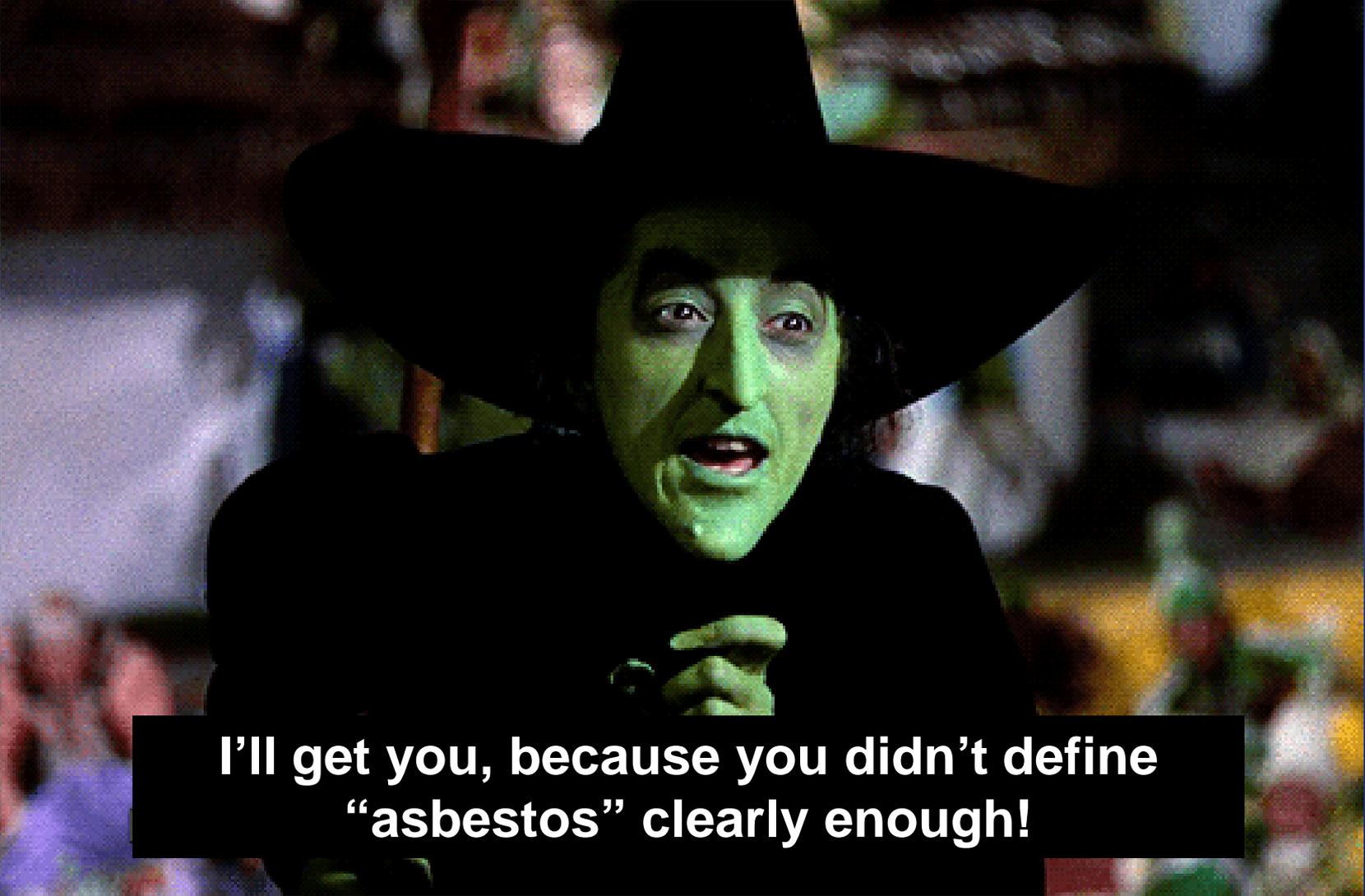
CERTAINTY



Juggernaut of lawsuits-
thousands of individual and
class actions filed as lawyers
seek redress and also to get
on the gravy train



As we seek the “perfect method” and
chase after “analytical zero’s” ...



I'll get you, because you didn't define
“asbestos” clearly enough!

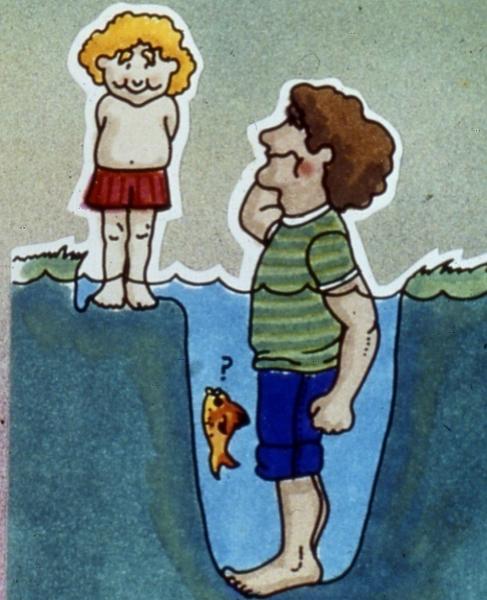


Questions & Issues

Is it possible to establish a current standard for the definition of asbestos that “ALL” agree on?

What are relevant physical and chemical criteria for the definition of asbestos?- and by which analytical method and magnitude of magnification?

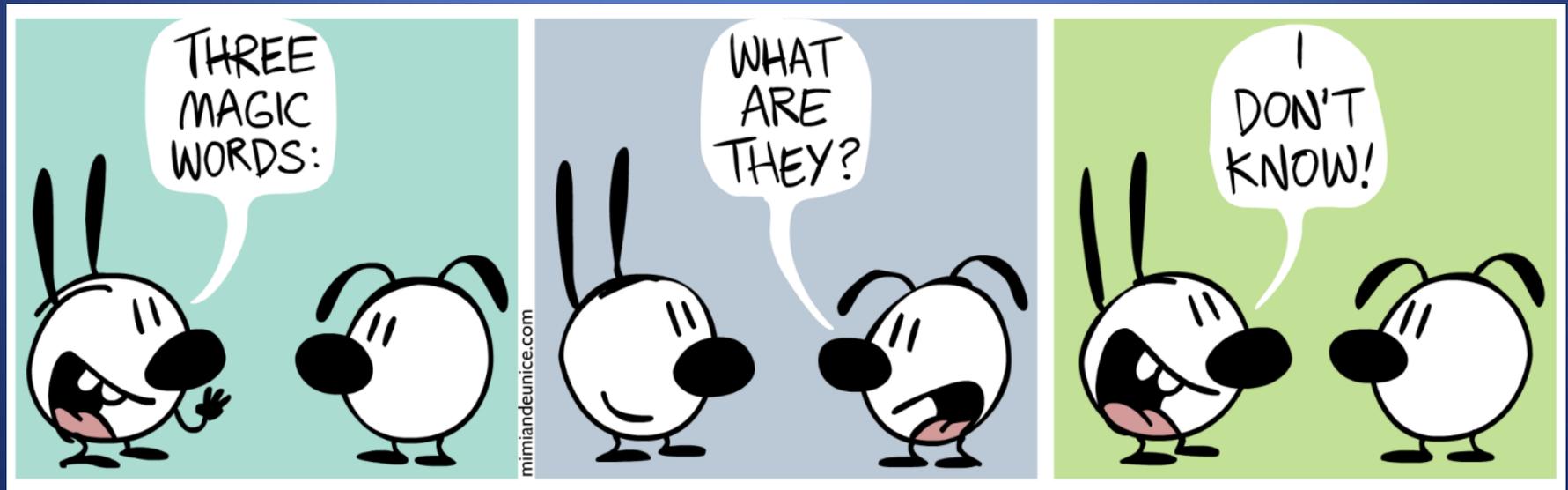
You can't tell
how deep a
puddle is
until you
step in it.



Questions & Issues

Should elongate mineral particulates be considered as human biohazards?

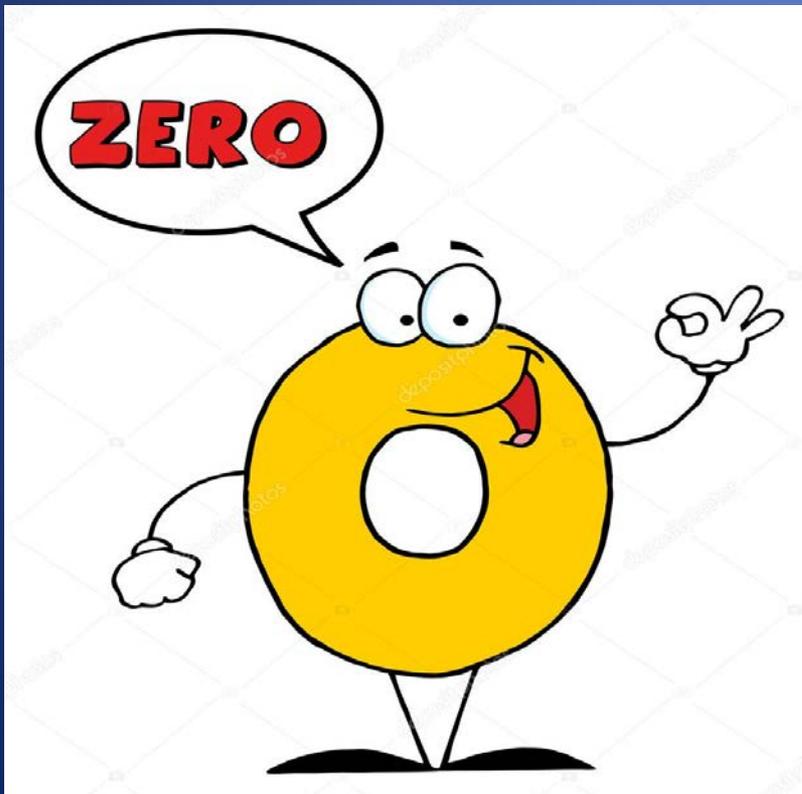
Can we endorse and accept TEM results of *ambiguous* and *indeterminate* as valid analytical/legal conclusions?



Questions & Issues

Does a personal care talc product have to meet a ZERO concentration of "asbestos" (as defined) or is "some" OK?

And if some OK, how much is "some"?



**How Much Is
Too Much?**



NOW, DO YOU HAVE ANY
QUESTIONS FOR ME?



Where are we going with asbestos industry regulations? The good, the bad and the ugly!

Martin. S. Rutstein (PhD) and Marc E. Rutstein, NYC Certified Asbestos Investigator

No one enjoys getting a regulatory agency violation. Unfortunately, there are those in the industry who do not perform properly, either knowingly, sloppily or through ignorance, and we firmly and strongly endorse that they should go to the gallows. However, what about "less serious" violations? Are they to be considered as personal, professional flaws or a cost of doing business in New York?

In our opinion, NYS DOL has long been "relatively open" to discussing rules and violation issues and being "fair". We do not believe that is necessarily the case with NYC DEP.

We have nearly five decades of asbestos industry experience. In those years, we have performed scores of site investigations and overseen countless abatement actions. Over this past year, we company received violations that really got us thinking about what was going on. We felt that we were "good guys" in the industry and were now getting hit with so-called "Mickey Mouse" violations and fines.

In NYC, violations come at a steep price, and fines of up to \$4,800 per issue are assessed to the asbestos contractor, as well as the owner. The purpose of the double "hit" was ostensibly to constrain property owners from hiring shoddy contractors!

Over the years, beginning in the early 1980's when many of the initial regulations were promulgated, important changes have occurred within New York City with the hiring of many new inspectors and a dramatic increase in enforcement and violations. The above was certainly in response to the seventeen Certified Asbestos Investigators (CAI) arrested for falsifying asbestos investigations. In addition, there was the indictment and resultant plea bargain adjudication of a high-level regulatory agency agent who was charged with corruption and receiving bribes from a contractor to not enforce regulations and to inform them of pending site investigations.

Ultimately, the city generates an enormous revenue stream as most violations stipulate and settle. In any case, it seems clear to us that there have been three major stages in the evolution and development of regulations in NYC, NYS and in most other jurisdictions, and that the number of violations for minor infractions is rapidly outpacing those for serious malfeasance (dry removal, unlicensed workers, improper disposal, etc...).

The modern era of asbestos regulation largely began in the late 1970's and culminated in the implementation of the AHERA regulations. The few of us who are still around had to wage the battle that damaged and friable asbestos-containing materials were even a problem! When those battles were won, a set of initial measures were designed and implemented to identify and remediate ACBM. A second developmental stage began in the 1990's when the initial regulations were found to be inadequate and experienced "asbestologists" modified and largely improved the initial procedures. Over the next few decades, as experienced asbestos consultants and regulators left the industry, a new crop of regulators came along. Many looked at the regulations and thought that they could be improved- and did so without regard to function. After all, "improvements" had to be good, right?

So, having a superlative record for prior regulatory violations from DOL and DEP, what were our DEP violations in this modern era of enforcement?

1. "failed to conduct air sampling during abatement as required". Seemingly, this is certainly a very serious failure to comply. However, the DEP Inspector in his written summary and detailed description of his site inspection wrote "air monitoring being performed in accordance/compliance as required" and did not make any mention to the site hygienist that pumps or samples were in violation. During his site inspection, the inspector photographed a portion of the roof and apparently upon reviewing his pictures back in the office (possibly even with his supervisors), re-evaluated and determined that there were not the required number of pumps (4) and issued a violation. We challenged the violation and produced our Job Logbook, filled out chain of custody forms (showing the required number of samples) along with the analytical laboratory PCM analyses, also supporting that the required number of samples had been collected. The DEP countered with their photograph of the partial roof abatement area (the roof was an L-shaped roof with a stairwell bulkhead so the other side was obscured) which they said was all-inclusive of the work area and despite the inspector have type-written in his report that air monitoring WAS being performed as required, the Administrative Law Judge ruled that his written statements

were not binding and that despite all our evidence including the preceding and post-inspection documentation showing the same required documentation, the DEP photograph was "proof enough" that an insufficient number of pumps were on the roof and he ruled against us. Under EXTREME objection, we paid the stipulated penalty to avoid having to hire a lawyer and go through a trial.

2. "failed to create/maintain air sampling log". Wow! It is well accepted that a logbook is to be maintained on an asbestos job. Most commonly, this has been via the so-called black and white "marbled" school composition book. Well, a few years ago, we opted to use a professionally bound VeloBind^(TM) binding system logbook. Over the past five years, numerous DEP inspectors praised the quality of our site records. Then, along comes an inspector who didn't like our log book and he issued a violation because the log book was not, in his opinion, "permanently bound".

We were not the only company to receive such a violation. While we are appealing it, we learned that other companies were judged to be guilty and assessed a fine. We have learned that "bound" now means what the DEP says it means. Remember what Lewis Carroll wrote in Alice in Wonderland-

“When I use a word,” Humpty Dumpty said in rather a scornful tone, ‘it means just what I choose it to mean — neither more nor less.’

‘The question is,’ said Alice, ‘whether you can make words mean so many different things.’

‘The question is,’ said Humpty Dumpty, ‘which is to be master — that’s all.’”

We also cite a situation that involves a Catch 22 situation that is seemingly to impossible to satisfy "honestly" without setting up a possible criminal charge.

In NYC, only a Certified Asbestos Inspector is authorized to file the inspection paperwork (not the report) on a computer-accessible form known as the ACP 5. A CAI was recently arrested and charged with improperly submitting the correct information.

On the form, there are five possible answers ranging from no asbestos to limited asbestos to asbestos will not be disturbed. In this case, the CAI signed off that the Scope of Work did not contain any ACM, assumed, presumed or suspect. However, the DEP interpreted the phrase "the premises or the portion(s) of the premises....determined that there was no asbestos-containing materials (ACM) present" to mean premises (the entire building at the address) and since the exterior roofing of the premises' building was ACM, he was charged with a criminal action.

Wait, it gets worse!

Given input from a cadre of CAI's, the form was changed. However, most recently, the internet form became changed from a first set of descriptions that a CAI would fill out to a default form that accompanied the filing fee payment. So, it would seem that a CAI's correct assessment would undergo default change whereby the CAI could be charged. What a brave new world!

So what comes next? Do the regulators regulate the kind of pen or pencil or the perhaps the penmanship of the logbook entries? Or will they grade the quality and accuracy of the hand-drawn site map? Will the placement of the air sampling pump in an "unobstructed" location be determined by measuring the distance to a wall or using a smoke tube to evaluate air currents?

And the one we really "love"- the filing has a check-off that the ACM was "properly abated". Since asbestos remediation should be about doing the work correctly and completely, one might assume that the answer means that "the work was done correctly". But no- DEP says it means only that the asbestos is "gone"!

And it is not only investigators who get such violations. We have heard literally scores of complaints from abatement contractors. Here is a sampling of some of the most recent.

The contractor was cited for having equipment that was not being used without HEPA attachments hooked up. In fact, the HEPA filter was being stored alongside of the equipment and the contractor told us that he was going to use the HEPA attachments when he used the equipment. However, the Inspector's judgment was that because it was not connected, there would have been usage of improper equipment and a violation was issued.

A worker was on site with an expired license. When he went to the DEP office to get a new license, he was told not to worry about it. However, the contractor was issued a violation for having unlicensed workers on the site

And when it comes to "adequately wetting ACM debris", here is one for the books. A contractor was inspected based upon a complaint of excessive dust during the removal of an air handling unit. Upon the field inspection, the DEP observed no dust, but gave the contractor a violation for using too much water.

Some contractors may believe that they are being singled out in a revenue-generating plan. Some then pose the question of "to file the job or not to file", hoping that without notifications, they can stay under the radar. Alternatively, most do file the job and many budget monies for fines as a cost of doing business.

Where does it all go? Are the changes done merely to add "form over function" instead of meaningful and workable changes? Aren't the goals to increase the quality and effectiveness of the works and thereby protect the public and the environment in a cost-efficient manner (recall the obligations of a Management Planner under AHERA)?

So what is the future? Will the intense and perhaps zealous over-reach spread to other enforcement agencies?

We urge that consultants and contractors become ever more rigorous in anticipating not only the "as written rules", but also the nuances, and insuring adherence to what is written. For ambiguous rules, efforts should be made to engage with regulators. Often such efforts lead to a constructive dialogue where rules can be modified and improved; and, at a minimum, make professionals more aware of the pitfalls of not adhering to the rules and regulations..

So, while we believe that there is hope, we fear that it will be over the bodies of the good folks who really try to do it right!