

<b>Matter of New York city Asbestos Litig.</b>
2013 NY Slip Op 33467(U)
November 26, 2013
Supreme Court, New York County
Docket Number: 107211/08
Judge: Martin Shulman
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SUPREME COURT OF THE STATE OF NEW YORK — NEW YORK COUNTY

PRESENT: SHULMAN  
Justice

PART 1

Index Number : 107211/2008  
BERNARD, SHELLY  
vs.  
BROOKFIELD PROPERTIES CORP.  
SEQUENCE NUMBER : 031  
PRECLUDE

INDEX NO. 107211/08  
MOTION DATE \_\_\_\_\_  
MOTION SEQ. NO. 031  
MOTION CAL. NO. \_\_\_\_\_

The following papers, numbered 1 to 4 were read on this motion to ~~file~~ preclude

Notice of Motion/ ~~Order to Show Cause~~ — Affidavits — Exhibits ...

Answering Affidavits — Exhibits \_\_\_\_\_

Replying Affidavits - Exhibits; Supplemental Hearing Aff. - Exhibits

PAPERS NUMBERED	
Notice of Motion/ <del>Order to Show Cause</del> — Affidavits — Exhibits ...	<u>1, 2</u>
Answering Affidavits — Exhibits	<u>3</u>
Replying Affidavits <u>- Exhibits; Supplemental Hearing Aff. - Exhibits</u>	<u>4, 5</u>

Cross-Motion:  Yes  No

Upon the foregoing papers, it is ordered that this motion is decided in accordance with the decision and order annexed hereto.

**FILED**

NOV 27 2013

NEW YORK  
COUNTY CLERK'S OFFICE

Dated: Nov. 26, 2013

MARTIN SHULMAN  
J.S.C.

Check one:  FINAL DISPOSITION  NON-FINAL DISPOSITION

Check if appropriate:  DO NOT POST  REFERENCE

SUBMIT ORDER/JUDG.

SETTLE ORDER /JUDG.

MOTION/CASE IS RESPECTFULLY REFERRED TO JUSTICE FOR THE FOLLOWING REASON(S):

SUPREME COURT OF THE STATE OF NEW YORK  
COUNTY OF NEW YORK: PART 1

-----X  
IN RE: NEW YORK CITY ASBESTOS LITIGATION  
-----X

LAWRENCE BERNARD AND MARILYN  
BERNARD, AS CO-EXECUTORS OF THE ESTATE  
OF SHELLEY BERNARD,

Index No: 107211/08

Plaintiff,

**ORDER**

-against-

BROOKFIELD PROPERTIES CORP., *et al.*,

Defendants.

-----X  
LORI KONOPKA-SAUER AND RICHARD  
KONOPKA, AS EXECUTORS OF THE ESTATE OF  
KAREN TEDRICK,

Index No: 190078/08

Plaintiff,

**FILED**

-against-

NOV 27 2013

COLGATE-PALMOLIVE COMPANY,

**NEW YORK  
COUNTY CLERK'S OFFICE**

Defendant.

-----X  
ARLENE FEINBERG AND JACOB FEINBERG,

Plaintiff,

Index No: 190070/11

-against-

COLGATE-PALMOLIVE CO., *et al.*,

Defendants.

-----X

WHEREAS, on or about November 18, 2011, Defendant Colgate-Palmolive Company ("Colgate") filed its motion *in limine* to preclude testimony of Plaintiffs' proffered testing experts, Dr. Ronald Gordon and Dr. James Millette, or in the

alternative, for a *Frye* hearing, in the *Bernard* and *Tedrick* actions (motion sequence 31); and

WHEREAS, on or about May 22, 2012 Colgate filed its motion *in limine* to preclude testimony of plaintiffs' proffered testing expert Dr. James Millette (motion sequence 5), or in the alternative, for a *Frye* hearing, in the *Feinberg* action; and

WHEREAS, on July 24, 2012 the court ordered a consolidated *Frye* hearing concerning the opinions of both Drs. Gordon and Millette in all three actions; and

WHEREAS, on June 25, 2013 plaintiffs withdrew Dr. Gordon as an expert in all three actions; and

WHEREAS, based upon the written submissions of the parties, the oral arguments and evidence adduced at the *Frye* hearing conducted on July 31, 2013, August 1, 2013 and November 7, 2013, the court granted defendant Colgate-Palmolive Company's motions at the conclusion of the hearing on November 7, 2013; it is hereby

ORDERED that Dr. James Millette is precluded from offering an expert opinion by affidavit or trial testimony in these actions.

Dated: New York, New York  
November 26, 2013

ENTER:



**FILED** Martin Sullivan, J.S.C.

NOV 27 2013

**NEW YORK  
COUNTY CLERK'S OFFICE**

SUPREME COURT OF THE STATE OF NEW YORK  
COUNTY OF NEW YORK: PART 1

-----X  
IN RE: NEW YORK CITY ASBESTOS LITIGATION  
-----X

LAWRENCE BERNARD AND MARILYN  
BERNARD, AS CO-EXECUTORS OF THE ESTATE  
OF SHELLEY BERNARD,

Index No: 107211/08

Plaintiff,

-against-

Decision and Order

BROOKFIELD PROPERTIES CORP., *et al.*,

Defendants.

-----X  
LORI KONOPKA-SAUER AND RICHARD  
KONOPKA, AS EXECUTORS OF THE ESTATE OF  
KAREN TEDRICK,

Index No: 190078/08

Plaintiff,

-against-

**FILED**

NOV 27 2013

**NEW YORK  
COUNTY CLERK'S OFFICE**

COLGATE-PALMOLIVE COMPANY,

Defendant.

-----X  
ARLENE FEINBERG AND JACOB FEINBERG,

Plaintiff,

-against-

Index No: 190070/11

COLGATE-PALMOLIVE CO., *et al.*,

Defendants.

-----X  
Hon. Martin Shulman, JSC:

In these three product liability actions,<sup>1</sup> Plaintiffs claim they contracted mesothelioma from asbestos exposure through their historic use of Cashmere Bouquet dusting powder, a talc powder product Defendant, Colgate-Palmolive Company (“C-P” or “Defendant”) C-P manufactured and sold (“talc powder” or “product”). Unlike many products formulated with asbestos material for use in an occupational setting, this talc powder, sold for personal consumer use, was never formulated to be used as an asbestos-containing product.

On November 11, 2011, Defendant filed an *in limine* motion to preclude Plaintiffs’ proffered testing experts, Drs. James R. Millette (“Dr. Millette”) and Ronald Gordon from giving testimony based on bulk sampling studies they respectively conducted on certain product exemplars in which they purportedly detected asbestos contamination<sup>2</sup> or, alternatively, for a *Frye* hearing. C-P essentially contended that Dr. Millette’s 2009 bulk sampling studies did not comport with a generally accepted scientific methodology, thus, his proffered expert testimony would lack any scientific basis to satisfy a critical element in proving general/specific causation in each case.<sup>3</sup>

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<sup>1</sup> The NYCAL Coordinating Justice assigned these three cases to this court, which were then consolidated for a joint trial. See *Matter of New York City Asbestos Litig. (Bernard, et al.)*, 99 AD3d 410 (1<sup>st</sup> Dept 2012).

<sup>2</sup> By letter dated June 25, 2013, made a part of this record, Plaintiffs’ counsel withdrew Dr. Gordon as one of their CPLR §3101(d) testing experts at trial mooted the need for any discussion as to Defendant’s challenge to his bulk sampling studies.

<sup>3</sup> Defendant concomitantly filed motions to preclude Plaintiffs’ medical causation experts from testifying because these experts seemingly rely on testing expert opinions to support their anticipated testimony that these Plaintiffs contracted mesothelioma from using the allegedly asbestos-contaminated product. This court held these motions in abeyance pending the outcome of the testing expert preclusion motion.

In particular, Defendant pointed out that in Dr. Millette's seven reports, this expert claimed to have used the US Environmental Protection Agency's *Test Method: Method for the Determination of Asbestos in Bulk Building Materials* (July 1993) ("EPA method") and acknowledged finding no asbestos in any of the seven samples using polarized light microscopy ("PLM"). When Dr. Millette resorted to transmission electron microscopy ("TEM"), this expert reported trace numbers of alleged asbestiform fibers in four of the samples. In rendering these findings, C-P contended Millette ran afoul of certain established criteria to confirm the presence of asbestos in bulk materials including talc. Defendants further argued that these criteria adopted in the scientific community, as evidenced in peer-reviewed articles as well as pursuant to the EPA method, mandate both a minimum fiber population requirement (i.e., at least five fibers in the sample count) and a fiber size having a mean aspect ratio [the ratio of length to width of a particle] of 20:1 for fibers longer than 5 microns. More pointedly, Defendant charged Dr. Millette with ignoring the fiber population requirement endorsed in his own peer reviewed article, *A Standard TEM Procedure for Identification and Quantitation of Asbestiform Minerals in Talc*, *Microscope* (1990) 38 at p. 463 ("The detection of five or more asbestiform minerals of one variety in an analysis constitutes a quantifiable level of detection.") (*Frye* Exhibit 9). In opposition, Plaintiffs found flaws in the talc testing reports of Dr. Richard Lee, Defendant's expert and generally viewed the dueling expert

viewpoints as to the tested samples<sup>4</sup> to be a disputed issue of material fact for a jury to resolve.

On July 24, 2012, after hearing extensive argument on C-P's testing expert preclusion motion, this court granted Defendant's motion to the extent of directing a *Frye* hearing to determine the admissibility of Dr. Millette's product contamination opinion. Because this potential ruling could be outcome-determinative, this court stayed all further motion practice including C-P's then ready-to-be-filed motions for summary judgment.

Thereafter, Plaintiffs filed a motion to renew and for reconsideration of this court's July 24, 2012 order granting a *Frye* hearing. In its April 4, 2013 bench decision, this court denied Plaintiffs' motion and the *Frye* hearing was then held on July 31, August 1, and November 7, 2013.

During the direct and cross-examination of Dr. Millette over a two day period, here is what Defendant and this court learned from his sworn testimony:

- Dr. Millette utilized the criteria set forth in the EPA method when microscopically analyzing the samples using PLM and after applying the bundle morphology criteria, reported an inconclusive finding regarding a fiber in one sample (*Frye* Exhibit 17) which this court discounted (*Frye* Hearing Tr. 346:11-16), resulting in negative PLM findings for asbestiform fibers in the seven exemplars;
- When this expert witness microscopically analyzed these samples using TEM, he acknowledged for the very first time that he applied the criteria adopted by ASTM International<sup>5</sup> for air sampling tests designated D6281: Standard Test

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<sup>4</sup> Limited to these cases only, the parties' counsel entered into an on-the-record stipulation on April 4, 2013 not to challenge the authenticity of these product exemplars notwithstanding claimed chain of custody concerns.

<sup>5</sup> This international standards organization, formerly known as the American Society of Testing and Materials, "develops and publishes voluntary consensus technical standards. . ."



Method for Airborne Asbestos Concentration in Ambient and Indoor Atmospheres as Determined by Transmission Electron Microscopy Direct Transfer [TEM])<sup>6</sup> ("D6281" as *Frye* Exhibit H) but with certain modifications for bulk sample testing of talc;

- To date, there is no generally accepted method for confirming the presence of asbestos in talc through TEM testing (see *Frye* Hearing Tr. 19:21-22 and 184:19-25), and D6281 is not the generally accepted method for confirming the presence of asbestos contamination in talc;
- For counting asbestos fibers, D6281 presumes the existence of asbestos in the air samples being tested as did Dr. Millette in his modified application of same to his fiber count(s) of the talc samples (*Frye* Hearing Tr. 307:3-11);
- For purposes of identification, D6281 cannot differentiate between individual asbestos fibers and non-asbestiform cleavage fragments (see also, §1.1.2 in the **Scope** section of D6281, *supra*, and §1.1 in the **Scope** section of the ISO Method, *supra* ["The method cannot discriminate between individual fibres of the asbestos and non-asbestos analogues of the same amphibole material . . ."]), and there is no generally accepted method in the scientific community to differentiate an asbestos amphibole from a non-asbestos amphibole on the basis of a single fiber (*Frye* Hearing Tr. 175:13-24);
- In performing a TEM analysis on the talc samples to report alleged trace asbestos contamination in three out of the seven exemplars (i.e., one fiber in one sample, three fibers in a second one and a set of two different fiber types in a third sample), Dr. Millette adopted the D6281 use of probability fiber distribution table using the Poisson process (see Table A6.1 of *Frye* Exhibit H, at p. 29)<sup>7</sup> in

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(see <http://en.wikipedia.org/wiki/ASTM>).

<sup>6</sup> As further gleaned from Dr. Millette's testimony, except for minor variations, D6281 was adapted from a test method adopted by the International Standard Organization denominated ISO 10312: "Air quality - Determination of asbestos fibres - Direct transfer transmission electron microscopy method" ("ISO method") (*Frye* Exhibit H at p 1, footnote 2 and *Frye* Exhibit G), and in 1998 was formally adopted by consensus of thousands of members of the ASTM International.

<sup>7</sup> This statistical table was adopted from the ISO method, *supra*, which allows for lower and upper limits of fiber(s) detection to achieve a 95% confidence level of analytical certainty. Notably, in dealing with the lower limits of detection, the ISO method apprised analysts that "[f]or total structure [i.e., fiber] counts less than 4, the lower 95% confidence limit corresponds to less than 1 structure [i.e., zero]. Therefore, it is not meaningful to quote lower confidence interval points for structure counts if less than 4 . . ." (bracketed matter added)(*Frye* Exhibit G at p. 44).

lieu of the historic, albeit statistically significant five-fiber population criterion; and in this vein, never found 5 or even 4 alleged asbestiform fibers of the same amphibole mineral in any of the talc powder samples (*Frye* Hearing Tr. 286:19-26);

- Dr. Millette also chose not to apply the EPA method's asbestos fiber identification criteria (i.e., a dimensional aspect ratio of 20:1 to positively identify an asbestiform fiber as opposed to a non-asbestiform cleavage fragment), and conceded not performing a more in-depth SAED (selected area electron diffraction) study to accurately classify any trace fiber as an amphibole mineral particle as opposed to a talc particle (*Frye* Hearing Tr. 285:21-25 through 286:1-18; see also, Table A4.2 in the D6281 at p. 24); and
- Illustratively, as noted in *Frye* Exhibit 13, in Sample No. UO654, where Dr. Millette found one presumed asbestiform fiber, this expert witness extrapolated this finding to calculate a total concentration of 286 million asbestos fibers in an ounce of talc powder (*Frye* Hearing Tr. 307:3-14).

At the close of Plaintiffs' case, this court preliminarily concluded that Plaintiffs made a prima facie showing that their testing expert's opinion purports to comply with the analytical methodology accepted in the scientific community for bulk sample testing but reserved its decision on C-P's *Frye* motion to preclude to await the testimony of Dr. Richard Lee, Defendant's testing expert ("Dr. Lee").

On November 7, 2013, after a full day of questioning by the parties' attorneys, this court gleaned the following from Dr. Lee's testimony:

- ◆ Outside of Dr. Millette's testimony during the *Frye* hearing, there is no peer-reviewed publication by any other member of the scientific community that supports the notion that Plaintiffs' testing expert's modified application of D6281 for bulk sample testing can reliably detect asbestiform fiber contaminants in talc, nor is there a generally accepted method for confirming the presence of asbestos in talc through TEM testing (*Frye* Hearing Tr. 388:4-8 and 19-23);
- ◆ In the late 1960's, the CFTA (Cosmetic, Toiletry and Fragrance Association) developed a scientifically accepted/FDA approved protocol, USP-32<sup>8</sup> with PLM,

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<sup>8</sup> USP is an acronym for the United State Pharmacopeia which "establishes written (documentary) and physical (reference) standards for medicines, food ingredients, dietary

for testing pharmaceutical grade talc for asbestos contamination which utilizes the same bundle morphology/fiber dimension criteria as the EPA method (*Frye* Hearing Tr. 390:3 through 394:5);

- ◆ Dr. Lee opines that the fiber dimension criterion in the EPA method for bulk sample testing expressly noted in Dr. Millette's scholarly, peer-reviewed article(s), book chapter, etc. (i.e., to recognize an asbestiform fiber population in the tested sample, the fibers longer than 5 microns should generally have a mean aspect ratio of 20:1 to 100:1 or higher) and, contrary to Plaintiffs' testing expert's opinion, the scientific community has not jettisoned this significant asbestos identification "marker" with any of the varied tools used in microscopy studies (*Frye* Hearing Tr. 395:1 through 396:25);
- ◆ Illustratively, before a testing analyst starts counting fibers in a talc sample, it is not only necessary to scientifically establish via SAED whether the fiber is a true amphibole, among other factors, because the platy structure of talc particles can lead to false positives even with TEM high resolution<sup>9</sup> (*Frye* Hearing Tr. 410:4 through 415:18), but it is also equally necessary to correctly classify the amphibole as a true asbestiform fiber via D6281's requisite quantitative zone axis electron diffraction study (see Table A4.2 in the D6281 at p. 24);
- ◆ Dr. Millette intentionally eliminated this rigorous scientific method when Plaintiffs' testing expert used D6281, as modified, for bulk sample testing of the product (*Frye* Hearing Tr. 416:14 through 423:3) because he erroneously presumed the existence of asbestiform fiber(s) in the three product samples (*Frye* Hearing Tr. 429:10 through 432:14); and
- ◆ By eliminating what is currently a scientifically reliable and statistically significant fiber population criterion (a criterion Plaintiffs' testing expert wholly endorsed in his scholarly writings published prior to his testimony at the *Frye* hearing) and adopting a claimed consensus standard (a new testing analysis based on the

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supplement products and ingredients. These standards are used by regulatory agencies and manufacturers to help to ensure that these products are of the appropriate identity, as well as strength, quality, purity, and consistency . . ." ([http://en.wikipedia.org/wiki/United States Pharmacopeia](http://en.wikipedia.org/wiki/United_States_Pharmacopeia)).

<sup>9</sup> In a US Bureau of Mines publication, Campbell, R.L., *Selected Silicate Minerals and Their Asbestiform Varieties: Mineral Definitions and Identification-Characterization*, IC 8751, Washington, D.C., (1977), there is a brief description of how a platy talc particle could create a false positive for a fibrous amphibole: "Talc is of interest here because some talc deposits have associated asbestiform and nonasbestiform minerals. Platy talc, when seen in thin sections or as fragments in oil, may occur in various orientations. Plates, lying flat look like plates, but, if standing on edge [viz., rolled over on its side], could appear fibrous." (bracketed matter added)(*Frye* Exhibit 15 at p. 27).

Poisson distribution table) purportedly allowing for one fiber in a tested sample to be deemed statistically significant to show asbestos contamination, Plaintiffs' testing expert wrongly deviated from the quantitation analysis deemed reliable in the scientific community (in other words, it is the consensus of the scientific community that a reported 4 or less fiber count in a tested sample is below the detection limit<sup>10</sup> and must be deemed insignificant statistically)(*Frye* Hearing Tr. 446:17 through 454:6).

### This Court's Ruling

At the close of Dr. Lee's testimony the parties' attorneys respectively made closing statements in support of, and in opposition to, C-P's *Frye* motion to preclude Plaintiffs' testing expert's opinion, and this court reconsidered its preliminary bench decision issued on August 1, 2013 and orally granted C-P's motion on the record. A review of this court's questions to witnesses and counsel as well as extensive colloquy on the *Frye* hearing record allows for inferred factual findings supporting the bench decision granting C-P's motion. Nonetheless, as a matter of caution to ensure a proper record for purposes of a potential appeal, this court issues this written decision setting forth the essential findings of fact as the basis for its ruling as required by CPLR 4213 (b). See also, *For the People Theatres of N.Y. Inc. v City of New York*, 84 AD3d 48, 60 (1<sup>st</sup> Dept 2011).

In state and federal courts as well as here in New York, asbestos litigation is a mature litigation, and in this context, it is essentially unquestioned that asbestos exposure causes mesothelioma. Moreover, when an injured plaintiff's exposure to an asbestos-containing product is undisputed, if there are disputed issues of material fact

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<sup>10</sup> The *Frye* hearing record includes references to a fiber count consensus protocol ASTM International adopted in 2006 (reapproved in 2010) designated D6620: Standard Practice for Asbestos Detection Limit Based on Counts.

as to the friable nature of the asbestos materials, components or parts and/or the level and extent of exposure, a resolution of those disputed issues will never warrant a *Frye* hearing. This is so because there is typically “no novel scientific technique or application of science . . . at issue . . .” *Matter of New York City Asbestos Litig. (Weigman v A.C.&S, Inc.)*, 24 AD3d 375 (1<sup>st</sup> Dept 2005); see also *Berger v Amchem Prods.*, 13 Misc3d 335, 344-347 (Sup Ct NY Co, 2006, Freedman, J)(not novel science for an expert to proffer medical causation testimony linking plaintiff’s product exposure to his/her mesothelioma).

However, C-P steadfastly maintains that this personal consumer product was manufactured and distributed as a safe asbestos-free product and takes strong exception to Plaintiffs’ claim that its talc powder was the competent producing cause of their terminal cancer. For Plaintiffs’ medical causation experts to have the factual foundation to support their anticipated opinions linking the product to Plaintiffs’ mesothelioma, Plaintiffs must establish with scientific certainty that the talc powder these Plaintiffs used decades ago was sufficiently contaminated with hazardous asbestiform fibers. Thus, Plaintiffs’ testing expert became a critical player to successfully advance their product liability claims.

The reliability of a novel scientific testing methodology can never be solely grounded on the stellar reputation of Dr. Millette no matter how impressively credentialed he is as a material scientist. That he is the chair of an ATSM International subcommittee that develops internationally accepted, consensus testing methodologies, while impressive, is similarly of no moment in this *Frye* review of his modification of the D6281 methodology for the bulk sample testing of talc. This court

must keep in mind that “[w]hile foundation concerns itself with the adequacy of the specific procedures used to generate the particular evidence to be admitted, the test pursuant to *Frye v United States* (293 F 1013) poses the more elemental question of whether the accepted techniques, when properly performed, generate results accepted as reliable within the scientific community generally.” *People v Wesley*, 83 NY2d 417, 422 (1994). Of singular importance, the acceptability and reliability of a testing methodology emphasizes counting scientists’ votes, rather than on verifying the soundness of a scientific conclusion. *Parker v Mobil Oil Corp.*, 7 NY3d 434, 447 (2006) (quotation marks and citation omitted).

Here is what we now know. When Dr. Millette completed his bulk sample testing of the product exemplars in 2009, his CPLR 3101(d) reports and subsequent deposition testimony expressly reference only the EPA method limiting its bundle morphology criteria to PLM analysis and eliminating the five-fiber population criterion in his TEM analysis of the talc powder sample, without more.<sup>11</sup> What is most unusual is that until Dr. Millette testified at the *Frye* hearing in July-August 2013, no one (viz., not even Defendant, its counsel, Dr. Lee, C-P’s testing expert, this court or, for that matter, any member of the relevant scientific community) had any meaningful clue that Dr. Millette actually used the 1998 D6281, as he unilaterally modified in 2009 for TEM analysis of

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<sup>11</sup> When Dr. Millette was asked why he never expressly discussed his novel fiber analysis methodology in his 2009 CPLR 3101(d) reports, he answered that his clients would find such scientific information either boring or too difficult to comprehend (*Frye* Hearing Tr. 234:10-20). But, with this expert witness’s extensive experience in product liability litigation, he had to have known his scientific reports prepared for litigation would presumably be scrutinized by others fully capable of understanding his adaptation of D6281 for bulk sample testing. Thus, the Plaintiffs’ testing expert’s rationale for this glaring omission simply makes no sense.

bulk samples, to scientifically conclude the product samples allegedly contained trace asbestos contaminants.<sup>12</sup>

Except for his testimony in this litigation, Dr. Millette has never published any literature, peer reviewed or otherwise, distancing himself from the very scientifically reliable criteria he historically ascribed to in the quantitation of hazardous asbestos fibers using the varied testing modalities.<sup>13</sup> As to asbestos identification, Dr. Millette presumed the existence of asbestiform fibers in the samples he tested under TEM without applying the EPA method's bundle morphology criteria. Yet, a mere two years before his *Frye* hearing testimony, Plaintiffs' testing expert continues to publicly acknowledge the continued relevance and importance of using these criteria to identify

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<sup>12</sup> Plaintiffs' counsel makes much of the fact that on Plaintiffs' testing expert's Air Sample Analysis Sheet (*Frye* Exhibit F) for Sample No. UO654, his staff analyst marked an "x" on the line next to "Method ISO 10312". This should have been a sufficient clue, Plaintiffs' counsel argues, for C-P's attorneys to pose appropriate questions of this expert witness at his deposition to learn about his fiber analysis methodology much earlier than Defendant did. This court finds this contention somewhat reaching. When asked to explain why his reports and affidavit omitted the fiber population and bundle morphology criteria, Dr. Millette could easily have attested that since ASTM International's adoption of D6281 for TEM analysis, these criteria are no longer applicable. He chose to say nothing until his compelled testimony at the *Frye* hearing.

<sup>13</sup> In addition to Dr. Millette's 1990 peer-reviewed article (*Frye* Exhibit 9) requiring the five fiber population criterion for TEM analysis of asbestos in talc, the *Frye* hearing record includes a 1979 report this expert authored with others at the US Environmental Protection Agency titled, *Exposure to Asbestos from Drinking Water in the United States* (*Frye* Exhibit D). In this report, there is a section captioned "Statistical Significance" which states, in relevant part:

When a total fiber count is less than 5 fibers, the statistics are particularly poor. . . . The lower limit therefore includes the zero (0) concentration. Because the high statistical variation associated with fiber counts under 5 fibers, concentration values determined on the basis of less than 5 fibers counted are listed in the computerized data base preceded with an "N". These values, while evidence that asbestos was present in the sample, are considered not statistically significant. *They were not given much weight in the assessment of exposure to the U.S. population from drinking water.* (Emphasis added)

asbestiform fibers with scientific certainty. In this expert witness-authored Chapter 2 of Dodson, R, *Asbestos: Risk Assessment, Epidemiology and Health Effects*, Boca Raton, 2<sup>nd</sup> Ed, (2011) § 2.16 **Cleavage Fragments** at p.41 (see text excerpt as *Frye Exhibit I*), the following authoritative identification criteria for asbestiform fibers was noted without limiting it to a particular type of microscopic analysis:

The distinction of how to tell an asbestos fiber from a cleavage fragment is currently being debated in the scientific community. A population of fibers as observed in a bulk sample having the asbestiform habit is generally recognized by several characteristics. These include mean A[spect]R[atios] in the range from 20:1-100:1 or higher for fibers longer than 5 µm. Asbestos is characterized by very thin febrils, usually less than 0.5 µm in width and two or more of the following:

- Parallel fibers occurring in bundles
- Fiber bundles displaying splayed ends
- Matter masses of individual fibers
- Fibers showing curvature

It is more difficult to classify individual fibers as to asbestiform or cleavage fragments because individual fibers do not exhibit all the characteristics of a population . . . (bracketed matter added).

Based on Dr. Millette's non-existent fiber identification analysis, it cannot be opined with scientific certainty that the four fibers he collectively counted among the three product exemplars are true amphibole asbestiform fibers.

Query: Where are the scientists' votes for Dr. Millette's modification of D6281 for bulk sample testing and its resultant analytical methodology, without the need for a statistically significant fiber population criterion, without the need for the application of the bundle morphology criteria to accurately distinguish between an asbestiform fiber and a non-asbestiform cleavage fragment and without the need for the more exacting SAED - zone axis diffraction study the D6281 otherwise requires for proper classification of an asbestiform amphibole? Where are the scientists' votes for a



modified analytical methodology that presumes the existence of asbestiform contaminants in a talc powder sold for personal consumer use that was never formulated as an asbestos containing product? And where are the scientists' votes to demonstrate that Dr. Millette's modified analytical methodology for bulk sample testing if done in any accredited laboratory will achieve the same uniform results accepted as scientifically reliable?

After a thorough *Frye* review of Plaintiffs' testing expert's informed opinion grounded on his novel modification of D6281 (a consensus testing protocol adopted by thousands of members of ASTM International as an otherwise scientifically acceptable methodology for air sample testing with admitted limitations for asbestiform fiber identification),<sup>14</sup> and his fiber analysis as to identification and quantitation reflecting his intentional disregard of criteria otherwise accepted as reliable in this expert witness's own scholarly writings as well as in the scientific community, this court respectfully concludes there is only the vote of Dr. Millette or, as Defendant's counsel noted in his closing arguments at the conclusion of the *Frye* hearing, a sample testing opinion grounded on a consensus of one.

This is not, as Plaintiffs insist, a question of weight as to the opinions of dueling expert witnesses to be resolved by a jury, but rather a question of admissibility involving a scientific opinion this court is constrained to conclude does not pass muster under *Frye*. Accordingly, C-P's motion is granted to preclude Dr. Millette from offering any

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<sup>14</sup> As stated earlier, in these consensus protocols accepted in the scientific community, both D6281(Scope §1.1.2) and the ISO (Scope §1.1) expressly acknowledge at the onset that these test methods are not capable of distinguishing between asbestiform and non-asbestiform variants of the same amphibole mineral.

opinion in these product liability cases that any talc powder sample he tested contains any hazardous asbestiform contaminant. An order will be signed and entered consistent with this ruling.

This constitutes this court's Decision and Order. Courtesy copies of same have been provided to counsel for the parties.

DATED: New York, New York  
November 26, 2013

  
HON. MARTIN SHULMAN, J.S.C.