IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

SALLY BRANDT **CHARLES BRANDT**	:	**DECEMBER TERM, 2015**
v.	:	**NO. 2987**
THE BON-TON STORES, INC. et al.	:	**CONTROL NO. 17034004, 17034007, 17034008**

MEMORANDUM OPINION

FACTUAL AND PROCEDURAL HISTORY:

This action arises from Plaintiff Sally Brandt's alleged exposure to asbestos from the use of Cashmere Bouquet brand cosmetic talc that was mined, milled, and sold by Defendants. Defendants filed three Motions to exclude the expert opinions of two of Plaintiff's experts, Mr. Sean Fitzgerald and Dr. Ronald Gordon, on the grounds they did not employ generally accepted scientific methodology in forming their scientific opinions. This Court reviewed the Motions, scheduled *Frye* hearings, and heard testimony over the course of four days from Mr. Fitzgerald, Dr. Gordon, and Defendants' expert Dr. Matthew Sanchez.

At issue are the methodologies used to establish whether Cashmere Bouquet[1] was capable of exposing Plaintiff to significant levels of asbestos, and whether that

[1] Defendants have moved to exclude the cosmetic talc samples at issue for unreliability and questionable sourcing, and have objected to identification of these samples as Cashmere Bouquet. This issue addressed separately. As a result, any reference to "Cashmere Bouquet" is made subject to this objection.

exposure was causally related to Plaintiff's mesothelioma. The three Motions challenge 1. Mr. Fitzgerald's "glovebox" testing methodology for establishing the presence of asbestos;[2] 2. Dr. Gordon's bulk testing methodology for establishing the presence of asbestos;[3] and 3. Dr. Gordon's methodology in ascribing causation of Plaintiff's mesothelioma.[4]

I. Sean Fitzgerald's Testing of Cashmere Bouquet for Asbestos

Mr. Sean Fitzgerald is a licensed professional geologist. 7/10/17 AM at 9. He has focused his career on the rocks and minerals which form asbestos, and the use of asbestos in building materials. *Id.* at 10. Mr. Fitzgerald's opinion, offered to a reasonable degree of scientific certainty, is that the cosmetic talc he tested contained significant numbers of asbestos fibers, particularly tremolite and anthophyllite, and that these fibers were released when the product, Cashmere Bouquet Talc, was used.

Mr. Fitzgerald initially discussed the definition of asbestos: Asbestos refers to the asbestiform varieties of one serpentine mineral and five amphibole minerals. *Id.* at 13. Serpentine is generally limited to chrysotile asbestos. Amphiboles, including tremolite and anthophyllite, are minerals which can form in both an asbestiform and non-asbestiform habit.[5] *Id.*

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[2] Control No. 17034007.
[3] Control No. 17034004.
[4] Control No. 17034008.
[5] It is uncontested that non-asbestiform variants of these minerals are not biologically harmful like their asbestiform variants.

Mr. Fitzgerald also discussed the various microscopic tools available in the identification of asbestos, including x-ray diffraction ("XRD"), light microscopy ("LM), and electron microscopy ("EM"). *Id.* at 24. XRD is a device that uses x-rays to determine by diffraction if the minerals present are consistent with standard minerals simply based on the geometry or the structure of the crystals present. 7/10/17 at 23. Light microscopy uses light waves to depict large crystals. *Id.* at 24. In the instant case, the only EM at issue is Transmission Electron Microscopy ("TEM"). Instead of using light waves, TEM uses an electron beam which allows for much higher resolutions of individual crystals on a very fine scale. *Id.*

Mr. Fitzgerald opined on the merits of LM, TEM, and XRD in terms of testing materials for the presence of asbestos. Mr. Fitzgerald, relying on a 1974 paper written by Rohl and Langer (Exhibit P-1), stated that TEM could be used to identify asbestos fibers in a substance which would be missed by XRD and LM on their own. *Id.* at 19-20. Mr. Fitzgerald testified that the superiority of TEM is due to the analytical sensitivity, noting the lesser ability of LM and XRD to detect smaller fibers and lower concentrations of asbestos fibers in a sample. *Id.* at 24.

In terms of methodology, Mr. Fitzgerald testified he makes use of fiber analysis by using TEM. One component of the analysis is consideration of a fiber's morphology (i.e. it's shape and size). *Id.* at 46. Mr. Fitzgerald also considers electron diffraction ("ED" or "SAED") patterns, which illustrate a fiber's crystalline structure. *Id.* at 49-50. Lastly, Mr. Fitzgerald makes use of an energy dispersive spectrometer ("EDS"), which produces a chart detailing the chemical composition of the object being scanned. *Id.* at

50. Mr. Fitzgerald testified that by combining analysis of visible morphology, ED patterns, and EDS results, he can accurately identify the mineral being examined. *Id.* at 51. Mr. Fitzgerald testified that this methodology has been used previously outside the litigation process. *Id.* at 72.

Mr. Fitzgerald conducted testing of Cashmere Bouquet cosmetic talc pursuant to a peer reviewed article he co-authored with Dr. Gordon and a Dr. Milette entitled "Asbestos in Commercial Cosmetic Talcum Powder as a Cause of Mesothelioma in Women." Exhibit P-4. Mr. Fitzgerald testified Cashmere Bouquet is not mentioned in the article, but it was the brand of cosmetic talc that was tested. *Id.* at 70. Mr. Fitzgerald's testing methodology involved "glovebox"[6] air sample testing, in which Mr. Fitzgerald released various amounts of cosmetic talc from samples provided to him. *Id.* at 88. Mr. Fitzgerald drew air out of the glovebox into air filter cassettes, which were then dissolved in a manner allowing Fitzgerald to collect the particulate so it can be placed on a grid and examined via TEM. *Id.* at 95. At times, if too much particulate was in a sample to allow for the use of different forms of microscopy, Mr. Fitzgerald created indirect samples by diluting the sample to spread the particulate out for analysis. *Id.* at 96-97. Mr. Fitzgerald testified this is a generally accepted practice. *Id.* at 99. Mr. Fitzgerald admits his glovebox sampling is more for use as a qualitative determination of whether asbestos can be released, not as a quantitative risk-assessment of that release.[7] 7/10/17 PM at 104-106.

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[6] A glovebox is a small plastic box with gloves built into the wall to manipulate the contents of the box.

[7] Notably, Mr. Fitzgerald's opinion in this case is not limited merely to the presence of asbestos, but suggests Mrs. Brandt was exposed to significant amounts of asbestos fibers from her use of Cashmere Bouquet talcum powder.

In terms of counting the number of asbestos fibers identified in his air testing analysis, Mr. Fitzgerald used the "AHERA" (Asbestos Hazard Emergency Response Act) criteria. AHERA counts asbestos fibers which are greater than 0.5 microns long with an aspect ratio of 5:1 or higher. Mr. Fitzgerald testified AHERA was designed to test for asbestos in the air of schools, and he selected the AHERA criteria because it was a generally accepted method for testing airborne particles. *Id.* at 13. Mr. Fitzgerald contrasted AHERA with "OSHA" and "NIOSH" protocol, which count as asbestos fibers greater than five microns long with an aspect ratio of 3:1 or greater. 7/10/17 PM at 11-12. Mr. Fitzgerald criticized OSHA and NIOSH as being more appropriate for field testing, using LM, rather than TEM. *Id.* at 16. Mr. Fitzgerald also identified another testing technique, "ISO 10312", which is a TEM method for determination of asbestos in the air, but did not identify why he declined to make use of it. *Id.* at 14. Lastly, Mr. Fitzgerald identified, and criticized, the "EPA R-93" method for testing because it was designed for "bulk building materials where the manufacturers had intentionally put in 2% or more asbestos into the actual product." *Id.* at 17.

Mr. Fitzgerald also testified regarding the "Yamate" protocol, which his methodology incorporated in part. *Id.* at 19. The Yamate protocol contains three levels of analysis. Yamate Level I involves the examination of a fiber's morphology and SAED patterns. *Id.* Level II involves examination of morphology and SAED patterns, along with an examination of the fiber's chemistry pursuant to EDS. *Id.* at 20. Mr. Fitzgerald testified that AHERA is based on the tenets of Yamate Levels I and II. *Id.* at 21. Yamate Level III requires "zone axis" ED analysis confirmation of 10-20% of the fibers

being tested. 7/11/17 AM at 64. Zone axis ED is analysis with the diffraction pattern taken multiple times at different angles. 7/10/17 PM at 48. This further confirms identification of a mineral beyond what is certain in level I and II analyses. *Id.* at 49. Mr. Fitzgerald admitted he performed some zone axis ED but did not adhere to Yamate Level III completely *Id.* at 53. Mr. Fitzgerald claims this is not ordinarily done or generally accepted. *Id.* at 50. He also claims he is able to confirm fiber type to a reasonable degree of scientific certainty without Level III zone axis. *Id.* at 54.

Mr. Fitzgerald acknowledged that one issue with TEM fiber analysis is distinguishing asbestiform and non-asbestiform amphiboles. Not all amphibole minerals are asbestos, and some are formed in a crystalline habit rather than an asbestiform habit. When these amphiboles break into smaller pieces, they are referred to as cleavage fragments. 7/10/17 AM at 110-111. In differentiating asbestos fibers from similar looking cleavage fragments, Mr. Fitzgerald noted that the aspect ratio is important. *Id.* at 112. ED and EDS are not very useful at differentiating asbestiform and non-asbestiform variants of a mineral as the results are very similar between the two; therefore, morphology is the most useful criteria for telling the two apart. *Id.* at 113-114. Mr. Fitzgerald suggested the typical morphological criteria for identifying asbestos fibers is an aspect ratio of 5:1. *Id.* at 116. Other methodologies suggest a ratio of 10:1 is a better criteria. *Id.* at 117-118. Mr. Fitzgerald admits when a product is milled, such as talc, non-asbestos amphiboles are likely to form fragments with an aspect ratio greater than 5:1. 7/10/17 PM at 65-66. However, Mr. Fitzgerald claims zone axis ED cannot differentiate between asbestos fibers and cleavage fragments. *Id.*

at 51. Mr. Fitzgerald does acknowledge that there are protocols which state confirmation of an amphibole can only be done with quantitative zone axis ED and quantitative EDS. 7/11/17 AM at 8-9.

In addition to the glovebox air testing described above, Mr. Fitzgerald also created wipe samples, where he wiped the inside of his glovebox to sample the accumulated particles that had fallen onto the box walls. 7/10/17 AM at 10. In doing so, Mr. Fitzgerald used the "ASTM" protocol, which is a standard test method for airborne asbestos concentration using TEM analysis. *Id.* at 103-104. The ASTM method calls for TEM in evaluating the wipe samples which are prepared indirectly. *Id.* at 106. Mr. Fitzgerald admitted that the ASTM protocol also requires zone axis ED. 7/11/17 AM at 9.

Mr. Fitzgerald testified that he did not initially do a bulk testing of the cosmetic talc samples he used because his client told him that the samples had been tested by a reputable lab and found to contain asbestos fibers. *Id.* at 24. On cross-examination, Mr. Fitzgerald admitted glovebox testing should be preceded by a bulk analysis to confirm the presence of asbestos in the sample itself. *Id.* at 67-68.

Mr. Fitzgerald claims he did some bulk testing analysis of two of the cosmetic talc samples, making use of the EPA R-93 testing protocol, after he had done the glovebox air testing. *Id.* at 70-73. The R-93 protocol defines countable asbestos as bodies with an aspect ratio of 20:1 - 100:1, or greater for fibers longer than five microns, usually with a width less than 0.5 microns. *Id.* at 79-80. The method also requires a population of fibers to determine if fibers are asbestiform or not. *Id.* at 79-

81. Mr. Fitzgerald did not report populations of fibers in his bulk testing, and he admitted it is impossible to differentiate an asbestos fiber from a cleavage fragment based on a single fiber. *Id.* at 116.

Mr. Fitzgerald notes the U.S. Pharmacopeia ("USP") has recognized potential gaps in the process for testing for asbestos in talc and is currently looking at possible changes to the accepted methodologies to address these gaps. 7/10/17 AM at 82-83. However, Mr. Fitzgerald admits the current USP monograph for talc ("the Monograph") is the current standard by which the FDA tests for asbestos in talc, and no changes to this process are yet generally accepted. 7/10/17 PM at 81-82. The Monograph mirrors the EPA R-93 criteria for identifying asbestos. *Id.* at 83-84. Mr. Fitzgerald admits it is likely he would not have identified asbestos in his testing if he had used the Monograph. *Id.* at 84-85.

Defendants offered the testimony of Dr. Sanchez to rebut the testimony of Mr. Fitzgerald, particularly in terms of Mr. Fitzgerald's treatment of cleavage fragments and his failure to perform zone axis ED. Dr. Sanchez has a Ph.D. in geology with an emphasis in mineralogy, and he is currently employed as a principal investigator by the RJ Lee Group. 7/13/17 AM at 5-6. Dr. Sanchez emphasized the need for populations of fibers when making the determination between asbestiform or non-asbestiform minerals, specifically when distinguishing cleavage fragments. He stated that without a population of fibers, morphology alone is not sufficient to make a scientifically reliable determination. *Id.* at 24-26, 35-36. Moreover, Dr. Sanchez explained that zone axis ED is the only definitive way to differentiate morphologically similar minerals. *Id.* at 63.

These zone axis ED patterns must be analyzed in comparison to standard parameters for identification. *Id.* at 66-67.

Dr. Sanchez criticized Mr. Fitzgerald's choices in terms of testing criteria. Specifically, Dr. Sanchez confirmed there are potential changes to the USP method that might require TEM methods, but they are not yet agreed upon nor generally accepted. *Id.* at 40-41. Dr. Sanchez also criticized Mr. Fitzgerald's use of airborne testing pursuant to AHERA without performing R-93 bulk testing first. He testified that AHERA is meant as a "clearance" method, to be used in determining whether an area known to contain asbestos has been cleared of that asbestos. *Id.* at 45. He claimed that Mr. Fitzgerald's glove box testing would not be able to determine if the cosmetic talc at issue contained asbestos, and that Mr. Fitzgerald would have had to do bulk testing with a protocol like R-93 or the Monograph prior to doing an air releasability study. *Id.* at 47.

Dr. Sanchez suggested there is a difference between the definition of asbestos and the counting criteria which are meant to allow different labs to reliably quantify asbestos in a sample known to contain asbestos. *Id.* at 47-48. These methods are for counting asbestos fibers, not differentiating them from non-asbestos fragments. *Id.* at 51. As a result, Dr. Sanchez testified that Mr. Fitzgerald deviated from accepted standards and did not do enough to differentiate asbestos from non-asbestos. *Id.* at 75.

II. Dr. Ronald Gordon's Testing of Cashmere Bouquet for Asbestos

Ronald Gordon, Ph.D. is an experimental pathologist working at Mt. Sinai hospital. 7/11/17 AM at 83-84. Dr. Gordon is a full professor and director of the

electron microscopy facility, and he has been working with electron microscopes since the 1970s. *Id.* at 85. Dr. Gordon testified that he primarily examines human tissue, but over the years he has tested approximately ten to fifteen products for the presence of asbestos. *Id.* at 105. As noted above, Dr. Gordon co-authored the article with Mr. Fitzgerald on the presence of asbestos in Cashmere Bouquet cosmetic talc. *Id.* at 97.

Dr. Gordon analyzed "bulk" samples of Cashmere Bouquet looking for the presence of asbestos. Like Mr. Fitzgerald, Dr. Gordon's methodology involved fiber analysis using TEM to examine morphology (size and shape), crystalline structure (ED), and chemistry (EDS). 7/11/17 PM at 11-13. In order to perform his bulk testing, Dr. Gordon took samples of the Cashmere Bouquet provided to him by Plaintiff's attorney, diluted them, and placed them on coated "grids" to be examined by TEM. *Id.* at 17-21. A grid has one hundred openings which can be examined differently, depending on the analyst's preferred analytical sensitivity. *Id.* at 24. Here, Dr. Gordon examined a minimum of five hundred grid openings (one hundred openings over five grids). *Id.* at 25. Dr. Gordon testified that labs generally examine ten to twenty grid openings, but he stated that this increases the risk of false negative results due to the decreased analytical sensitivity. *Id.* at 26-27. Dr. Gordon testified that increasing the number of grid openings to examine is an accepted method for increasing analytical sensitivity. *Id.* at 27-28. Gordon later admitted to looking at a variable number of grid openings until he found asbestos in a sample, even though he admits he should set the number of grid openings to be reviewed at the beginning of the test. 7/12/17 PM at 54-56.

In terms of fiber burden methodology, Dr. Gordon testified that he applied the Yamate II criteria, because CFA and USP protocols "were not sensitive enough to pick up asbestos in the material." 7/11/17 PM at 60. Dr. Gordon admitted that he did not follow the Yamate II protocol completely. 7/12/17 AM at 9. Specifically, he did not keep track of which grid contained countable fibers and he did not record the SAED results in his initial tests. *Id.* at 72. When asked why he did not follow the Yamate Level III protocol, which requires zone axis ED, Dr. Gordon stated that zone axis ED is "unnecessary" because "the only thing you get from doing that on a fiber is you would get a potentially lower count without doing it." 7/11/17 PM at 61. Dr. Gordon admitted that if he had followed the Yamate Level III protocol he would not have reported asbestos in any of the talcum powder samples he tested. 7/12/17 AM at 30.

Dr. Gordon ultimately found that about 80% of the tested samples contained anthophyllite fibers, which he testified is not found in background air. 7/11/17 PM at 51. However, in 83% of those, Dr. Gordon reported only a single asbestos fiber. 7/12/17 AM at 90. As a result, Dr. Gordon admitted that he did not have a population of fibers to consider. 7/12/17 AM at 91. Dr. Gordon concedes that in a crushed specimen like talc it is impossible to differentiate between an asbestos fiber and a cleavage fragment without a population of particles. *Id.* at 91. Gordon also admitted he did not know all of the possible interference minerals (minerals which could be confused for various types of asbestos) in talc. *Id.* at 98-102.

Much of Dr. Sanchez's criticisms of Mr. Fitzgerald's methodology applied to Dr. Gordon's methodology as well. Specifically, Dr. Sanchez stated without a population of

fibers, morphology alone is not sufficient to make a scientifically reliable determination between asbestos fibers and cleavage fragments. *Id.* at 24-26, 35-36. Dr. Sanchez also noted that Dr. Gordon's failure to make use of zone axis ED was a critical failure, as the omission of zone axis ED makes it is impossible to distinguish, with scientific certainty, asbestiform from non-asbestiform minerals. *Id.* at 76.

III. Dr. Ronald Gordon's Causation Opinion

In addition to testifying about his bulk testing of Cashmere Bouquet, Dr. Gordon also testified as to how he ascribed causation of Plaintiff's mesothelioma. Dr. Gordon is not a medical doctor, but he is employed at the Icahn School of Medicine at Mt. Sinai in New York City. 7/11/17 AM at 84. Dr. Gordon engages in clinical pathology in conjunction with a pulmonary pathologist. *Id.* at 85. Generally, Dr. Gordon reviews tissue specimens by light microscope, then smaller sections by electron microscope, and then turns over the photographs he takes to the signing pathologist. *Id.* at 86. Dr. Gordon has tested thousands of human tissue samples over his career, and the majority of his work at Mount Sinai has been looking at human tissue. *Id.* at 104.

Dr. Gordon stated that he is unqualified to offer any opinions with a reasonable degree of medical certainty, and his opinions in this case are instead based on a reasonable degree of scientific certainty. 7/12/17 AM at 11. However, Dr. Gordon acknowledged that none of the opinions he offered in this case were formed using the scientific method. 7/12/17 at 12.

Dr. Gordon utilized the same TEM fiber analysis used in his testing of cosmetic talc to conduct a fiber analysis of Plaintiff's lung tissue and lymph tissue. Dr. Gordon

testified that the only difference between products and human tissue, in terms of detecting asbestos, is how the sample is prepared. 7/11/17 AM at 108. The organic component of human tissue has to be removed to test for any minerals or metals, so the tissue is treated with a substance that digests the tissue away and then washed. *Id.*

In order to conduct his fiber analysis, Dr. Gordon prepared 1/600th of a gram of Plaintiff's lung tissue and 1/600th of a gram of Plaintiff's lymph tissue. 7/11/17 PM at 77. Dr. Gordon admitted that this was less than the optimal amounts of two grams for lung tissue and one gram for lymph tissue. *Id.* Ultimately, Dr. Gordon identified two anthophyllite asbestos fibers in Plaintiff's lung tissue, and one anthophyllite asbestos fiber in Plaintiff's lymph tissue.[8] 7/11/17 PM at 78-82.

Dr. Gordon extrapolated his findings using a formula based on the weight of the tissue used and the average number of fibers per grid opening. 7/11/17 PM at 80. Dr. Gordon's results indicated 15,333 anthophylite fibers per gram in Plaintiff's lung tissue and 11,500[9] fibers per gram in Plaintiff's lymph tissue. *Id.*

Dr. Gordon used the figures he extrapolated from Plaintiff's lung and lymph fiber analysis to attribute asbestos as the cause of Plaintiff's mesothelioma. In doing so, Dr. Gordon claims he relied on the Helsinki criteria (admitted as Exhibit D-13). 7/12/17 PM at 29. The specific section that Dr. Gordon relied on reads: "Lung fiber count exceeding the background range for the laboratory in question or the presence of radiographic or

[8] Dr. Gordon initially identified two asbestos fibers in Plaintiff's lymph tissue, but he admitted on cross that his identification of a tremolite asbestos fiber was in error. 7/11/17 PM at 106; 7/12/17 AM at 81.
[9] Dr. Gordon initially calculated a per gram figure of 23,000, but due to the above correction the figure was reduced in half.

pathologic evidence of asbestos-related tissue injury or histopathologic evidence should be sufficient to relate a case of pleural mesothelioma to asbestos exposure on a probability basis." Exhibit D-13, p. 313; see also 7/12/17 AM at 74.

Dr. Gordon attributed his fiber count findings as being in excess of "background range for the laboratory in question" based upon comparison to a control group used by his laboratory at Mt. Sinai. This control group consisted of thirty five individuals that "could not be identified as having an exposure to any asbestos or asbestos product." 7/11/17 PM at 87. Mt. Sinai had a previous control group, consisting of roughly 200 individuals, which Dr. Gordon no longer uses. *Id.* Dr. Gordon stated that he updated the control group because of both changes in background levels over time, and because much of the original control group file (except summary sheets) has been lost. *Id* at 87-91. Ultimately, Dr. Gordon testified that there were no anthophyllite fibers present among the thirty five individuals in the Mt. Sinai control group. 7/11/17 PM at 89.

In comparing the number of anthophyllite fibers found in Plaintiff's tissue to the number of anthophyllite fibers found in the control group, Dr. Gordon based his extrapolation on the "limit of detection". 7/12/17 AM at 78. Pursuant to the Yamate protocol, the minimum detectable difference between a blank sample and a study sample (i.e. the number of fibers necessary to be 95% certain that the true value is greater than zero) is five fibers. *Id.* at 79. Dr. Gordon admitted that here, the difference between the number of fibers found in Plaintiff's lung and lymph tissue (three) and the control (zero) was less than that minimum detectible difference. *Id.*

Dr. Gordon also admitted that his extrapolation was not based on any statistical analysis, and that neither lung tissue nor lymph tissue is homogenous. *Id.* at 78-83.

As with Dr. Gordon's testing of cosmetic talc, there was concern about whether Dr. Gordon had ruled out cleavage fragments in his analysis. Again, Dr. Gordon relied upon identification of asbestos fibers by an aspect ratio of 5:1 and a fiber length greater than five microns. *Id.* at 92. Dr. Gordon admitted that in one of the articles he relied upon (by Dr. Dodson), anthophyllite fibers longer than five microns were found in a control group, however Dr. Gordon alleged without further proof that these results were problematic because they "came from East Texas and they lived in vicinities near factories that produced products containing asbestos." *Id.* at 108.

In addition to concerns about the reliability of the Mt. Sinai control group, Defendants questioned Dr. Gordon's lack of adherence to the Helsinki criteria's requirements for ruling out Plaintiff's exposure to asbestos. The Helsinki criteria advises using structured questionnaires and checklists so that trained interviewers can identify persons who have work histories compatible with asbestos exposure. 7/12/17 AM at 53. Dr. Gordon admitted that he did not use a structured questionnaire or checklist to personally interview Plaintiff. *Id.* Dr. Gordon further admitted he has never spoken to Plaintiff or any of her family members, and he has never reviewed Plaintiff's medical records to determine whether any of her treating physicians had any information to obtain an exposure history. *Id.* at 54.

Lastly, Defendants criticized Dr. Gordon's methodology because there is no reference to lymph node tissue (only "lung tissue") in in the Helsinki criteria, yet Dr.

Gordon attributed Plaintiff's mesothelioma, in part, to fibers found in Plaintiff's lymph tissue. *Id.* at 74. Dr. Gordon argued that the lymph nodes can be part of the lung, but could not identify where Plaintiff's lymph tissue had come from. Id. at 77.

DISCUSSION

Due to the influential nature of expert testimony, it falls to the courts to act as a gatekeeper to ensure the scientific experts presented have based their opinions on sound scientific principles and methodologies; this vetting of expert witnesses is done during a *Frye* hearing. Pa.R.C.P. 207.1. A *Frye* hearing is limited to the question of the acceptability of the methodologies of the scientific experts being offered to the court. The court's role is not to weigh in on the findings of these experts, but to ensure the methodologies they have employed are generally accepted and reliable. *Trach v. Fellin*, 817 A.2d 1102, 1112 (Pa.Super. 2003)

"[A] *Frye* hearing is warranted when a trial judge has articulable grounds to believe that an expert witness has not applied accepted scientific methodology in a conventional fashion in reaching his or her conclusions." *Betz v. Pneumo Abex LLC*, 615 PA. 504, 545 (2012). The burden in a *Frye* hearing rests on the party presenting the challenged expert testimony. *Grady v. Frito-Lay, Inc.*, 576 Pa. 546, 558 (2003). This party must prove that the methodologies employed by its experts are "generally accepted" by the scientific community in the relevant field. *Id.* at 558. The challenged expert need not prove his conclusions are generally accepted as well, merely the methods used to reach those conclusions. *Id.* at 558.

This Court finds that although some individual components of Mr. Fitzgerald's methodology are generally accepted, others components, and the methodology used to analyze his findings, are not. That's the problem. Mr. Fitzgerald first assumes the samples he received had been bulk tested. He acknowledges that the accepted methodology requires this first step of bulk testing. He does not perform bulk testing because he assumes, or accepts his client's assurance, that bulk testing was performed. He produced no documentation to confirm bulk testing. In fact as will be discussed later, Dr. Gordon performs bulk testing later "because he'd heard complaints that it hadn't been done."

Mr. Fitzgerald begins with "glovebox" testing, which he contends is generally accepted methodology. Again he begins with a presumption that the products he's using have been bulk tested and found to contain asbestos. Therefore, he starts with a premise that he should find asbestos fibers. However, the testing, how he structures the testing, and how he measures and analyzes the results, are in fact self-designed variations of scientifically accepted methodologies; a mishmash of scientifically accepted methodologies. The standards he uses to measure acceptable levels of asbestos exposure, i.e. the background, change not in accordance with the item and the environment being measured but in a manner that would appear arbitrary at times. This Court finds that Mr. Fitzgerald modified, varied and therefore deviated from generally accepted methodology.

Mr. Fitzgerald also admits that if he conducted his testing pursuant to the talc testing methodology currently accepted by the FDA, the USP Monograph protocol, he

most likely would not have identified asbestos in his testing. Instead he chose an alternative method, which he claims to be generally accepted because it was discussed in a published peer reviewed article he co-authored with Drs. Gordon and Milette. Yet, even in his selection of alternative methodology, he deviated and neglected to adhere to its requirements.

Additionally, Mr. Fitzgerald offered his opinion within a reasonable degree of scientific certainty despite analyzing individual fibers without a population upon which to compare. Dr. Sanchez testified, and Mr. Fitzgerald admitted, that without a population there is no scientific basis for differentiating harmful asbestos fibers from mere non-asbestiform cleavage fragments.

The Court finds that Dr. Gordon also deviated from generally accepted methodology in his limited bulk testing of the Cashmere Bouquet samples he had available. Specifically, the Court finds Dr. Gordon's admission to the use of a variable numbers of grid openings until asbestos was found to be inherently unscientific.

Likewise, as with Mr. Fitzgerald, Dr. Gordon's failure to adhere to and complete Yamate Level III protocol shows a deliberate deviation from accepted standard scientific methodology. He admits he varies the protocol because if he didn't he wouldn't find asbestos. Yet in doing so he deviates from accepted scientific methodology. As a result, the Court agrees with Dr. Sanchez' assertion that Dr. Gordon did not make a scientifically reliable determination of asbestos fibers in the cosmetic talc he tested. Again, Dr. Gordon acknowledged that he did bulk testing after he "had heard complaints." He acknowledges that he varied from the standard method by increasing

the number of grids from the accepted standard number of ten to twenty, to five hundred grids (one hundred openings over five grids). He claimed this was an accepted method to increase analytical sensitivity but then acknowledged that he looked at a variable number of grid openings until he found asbestos. He did not use a base number of grids and then conduct a comparison and admitted such in his testimony. He did not keep track of which grids contained countable fibers. He also acknowledged using "a modified Yamate" methodology. He varied from acceptable scientific methodology to reach his results. Finally he admits that he lacked a population to which his findings could be compared. This would have allowed him to differentiate between an asbestos fiber and a cleavage fiber. Dr. Gordon varied from accepted scientific methodology by not comparing his findings with a population, by failing to use a Zone Axis ED, by varying the Yamate protocols and the resultant inability to distinguish between asbestos fiber and cleavage fiber. Dr. Gordon modified accepted analytical methodology for bulk testing.

Finally, the Court finds Dr. Gordon's methodology in ascribing causation of Plaintiff's mesothelioma was not established through generally accepted scientific methodology. Dr. Gordon used substantially less than the standard amounts for his testing of both lung and lymph tissue samples. Similar to Mr. Fitzgerald, he used some generally accepted testing methods in combination with methodologies not generally accepted; he varied and/or modified accepted methodology. When asked why he varied the methodology, his response was "to find asbestos."

As to Dr. Gordon's findings as to the fiber burden/correlation in the analysis of Mrs. Brandt's lung and lymph tissue samples, which results in his causation opinion, Plaintiff again fails to establish that Dr. Gordon's methods and analysis are generally accepted. To begin, Dr. Gordon acknowledges the tissue sample is smaller than optimal. Dr. Gordon's finding of asbestos fibers in Plaintiff's lung tissue had to be measured, extrapolated and then compared to the laboratory control group to determine if it is excess of background. He admits his extrapolation was not based on any statistical analysis. He claims to find asbestos in the samples and then extrapolates. As Dr. Gordon and Mr. Fitzgerald acknowledge, asbestos is all around us. Dr. Gordon's analysis requires he compare his findings with the control group for his lab at Mt. Sinai. Comparing findings to the lab specific control group is generally accepted. However, Dr. Gordon admits the original lab control group was 200. It now consists of 35. The reasons or basis for elimination of the 165 is unclear. The control is small and has limited records, calling into question its reliability as a standard for comparison thus deviating from the generally accepted scientific methodology. Further, Dr. Gordon acknowledges the Helsinki criteria to be generally accepted when analyzing for background both for the control group and Mrs. Brandt. Yet he acknowledges his own failure to adhere to this criteria.

Plaintiff contends that these issues are for the jury and that the methodologies used by both Mr. Fitzgerald and Dr. Gordon were generally accepted. This Court disagrees. Rule 702 (c) of the Pennsylvania Rules of Evidence requires that "the expert's methodology is generally accepted in the relevant field." As noted in *Trach v.*

Fellin, supra. , the *Frye* test as adopted in *Commonwealth v. Topa,* 369 A.2d 1277, applies only when a party seeks to introduce novel science. This Court finds that the methodologies employed by both Mr. Fitzgerald and Dr. Gordon are not generally accepted in the relevant scientific community. Although each employed some generally accepted methodologies, each modified, varied or deviated from those generally accepted methodologies.

In *Trach* the Superior Court stated

> The scientific method is a method of research in which a problem identified, relevant data is gathered, a hypothesis is formulated from these data, and the hypothesis is empirically tested. Within the meaning of the definition of the scientific method, empirical means provable or verifiable by experience or experiment. Key aspects of the scientific method include the ability to test or verify a scientific experiment by parallel experiment or other standard of comparison (control) and to replicate the experiment to expose or reduce error.
>
> *Id.* At 1113

Although Plaintiff contends this is a question of weight as to the opinions of dueling experts, this Court finds it to be a question of admissibility involving scientific opinion and generally accepted methodologies. Under Pennsylvania law, this Court finds that Mr. Fitzgerald and Dr. Gordon employed methodologies not generally accepted in the relevant scientific community.

Although some methodologies employed by each may have been generally accepted, each in deciding to modify and/or vary from accepted methodologies, requires this Court to grant the Motions filed by Defendants to preclude their testimony.

BY THE COURT: