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October 29, 2020

VIA OVERNIGHT DELIVERY/FILING
AND COURT-PASS FILING

Re: *Nemeth v. Brenntag North America,*
APL-2020-00122

John P. Asiello
Chief Clerk and Legal Counsel to the Court
Clerk's Office
20 Eagle Street
Albany, New York 12207-1095

Dear Mr. Asiello:

Amici the Chamber of Commerce of the United States of America and Coalition for Litigation Justice, Inc. hereby submit this letter brief in support of Defendant-Appellant Whittaker, Clark & Daniels, Inc. ("WCD") pursuant to Section 500.23(a)(2). *Amici* urge the Court to reverse the Appellate Division's opinion and adopt in its place the opinion of the dissent, which accurately reflects the law under *Parker v. Mobil Oil* and its progeny.[1]

Statement of Interest

The Chamber of Commerce of the United States of America (the "Chamber") is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. An

[1] *Parker v. Mobil Oil Corp.*, 7 N.Y.3d 434 (2006); *Cornell v. 360 W. 51st St. Realty, LLC*, 22 N.Y.3d 762, 784 (2014); *Sean R. v BMW of North America*, 26 N.Y.3d 801, 810-11 (2016); *In re NYC Asbestos Litig.* (*Juni v. A.O. Smith Water Prods.*), 148 A.D.3d 233 (1st Dep't 2017), *aff'd*, 32 N.Y.3d 1116 (2018).

important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases that raise issues of national concern to the business community.

The Coalition for Litigation Justice, Inc. is a nonprofit association formed by insurers in 2000 to address the asbestos litigation environment.[2] The Coalition files *amicus* briefs in cases that may have a significant impact on the asbestos litigation environment and on similar product-exposure and causation dockets. The Coalition has filed over 150 *amicus* briefs and filed such briefs before this Court in the appeals of *Parker v. Mobil Oil Co.,* and *Juni*.

This case presents questions about the appropriate standard for admitting expert testimony in a novel litigation contending that cosmetic talc products cause mesothelioma. Amici have a strong interest in seeing that courts insist on reliable science before allowing juries to reach verdicts upending years of established science.

Disclosure Pursuant to Rule 500.1(f)

Pursuant to Rule 500.1(f) of the Court's Rules of Practice, there are no corporate parents, subsidiaries or affiliates for either of the proposed *amici* herein, The Chamber of Commerce of the United States of America nor the Coalition for Litigation Justice, Inc.

Introduction

This appeal represents an opportunity for the Court of Appeals to reinforce and reapply the principles articulated in the *Parker* opinion, this time to a case involving a widely used and

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[2] The Coalition includes Century Indemnity Company; Allianz Reinsurance America, Inc.; Great American Insurance Company; Nationwide Indemnity Company; Resolute Management, Inc., a third-party administrator for numerous insurers; and TIG Insurance Company.

safe product that plaintiff claims contains asbestos. The *Parker* Court rejected vaguely stated exposure testimony in lieu of a scientific assessment of the actual dose necessary to cause disease. The Court must now restate and apply *Parker* to the facts and ruling in *Nemeth*[3] – asserting a highly novel claim of cosmetic talc-induced mesothelioma – to uphold the dose assessment requirement of *Parker* and to prevent the expansion of a scientifically unwarranted new brand of lawsuits.

Since the *Parker* opinion issued in 2006, New York's lower courts have attempted to apply *Parker's* 'competent dose assessment" requirement in toxic tort and product litigation. Uncertainty surrounding those rules required this Court to issue two further opinions, *Cornell* and *Sean R.* to lock down the dose element in mold and gasoline litigation.[4]

In the meantime, in the asbestos world the Appellate Division has issued widely divergent opinions, some of which misapplied *Parker* to permit experts to speculate about dose and causation. A number of these opinions issued even after the Court provided its *Cornell* and *Sean R.* guidance. The failure to apply *Parker* in asbestos (and now talc/asbestos) litigation is widespread and must be addressed. This Court's affirmation of the First Department's *Juni* opinion, affirmed by the Court of Appeals, should have solidified the dose obligation in asbestos cases as well, but the Appellate Divisions continue to issue opinions contradicting *Parker* and *Juni*. Those opinions are often accompanied by strained attempts to reconcile the now obsolete

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[3] *Nemeth v. Brenntag North America,* 183 A.D.3d 211 (1st Dep't 2020).

[4] In *Cornell,* the Court rejected the notion that a "differential diagnosis" was a substitute for a quantifiable dose assessment. *Cornell,* 22 N.Y.3d at 785. *Sean R.* similarly rejected the "smell of gasoline" as a sufficient basis for identifying the causative dose. *Sean R.,* 26 N.Y.3d at 809-811.

Lustenring approach[5] with that in *Juni*. The *Nemeth* opinion represents the latest round in this back-and-forth.

The struggle to apply a scientific dose requirement correctly is not unique to New York. As discussed below, other federal and state courts also have struggled to ensure that lower appellate and trial courts properly apply and enforce the gatekeeping rules articulated by their supreme courts. In several instances, the state's highest court has had to issue multiple opinions to enforce the necessity of dose and scientific reliability in causation opinions, and it appears that approach may be necessary in New York as well to confirm that the *Parker, Cornell, Sean R.,* and *Juni* causation analysis applies to asbestos and talc litigation.

Amici submit this letter brief to urge the Court to reject the approach of the majority in the Appellate Division and instead adopt the sound reasoning and correct application of *Parker* in the dissenting opinion by Justice Friedman. We first offer a brief overview of the direction of asbestos litigation and how the new and unscientific world of talc litigation fits into the attempt to extend and expand asbestos litigation indefinitely and without scientific basis. This brief then discusses some of the key scientific principles that should apply under *Parker* to long latency causation cases such as this one, but which the Appellate Division did not follow.

I. The Cosmetic Talc Litigation Relies on Speculative Exposure Opinions to Extend Suspect Low-Dose Asbestos Litigation.

The novel cosmetic talc litigation at issue in this appeal is part of an attempt to create a beachhead for speculative "cosmetic talc" litigation in the state courts around the country. This new litigation is driven by the alleged presence of asbestos in talc, and thus this case can be

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[5] *Lustenring v. AC & S, Inc.,* 13 A.D.3d 69 (1st Dep't 2004), *lv. denied* (2005).

viewed as an effort to extend asbestos litigation beyond what science would permit. To achieve this goal, Plaintiffs must undermine this Court's rulings in *Parker, Cornell, Sean R.,* and *Juni*. Otherwise, those rulings would foreclose the cosmetic talc litigation by exposing the unreliability of the plaintiff experts' testimony.

To help put *Nemeth* in perspective, we first provide some background on the course of asbestos and talc litigation. Asbestos litigation has morphed over the years from the early "old" asbestos cases, typically involving workers in the asbestos industry who were heavily exposed in shipyards and factories, to a docket dominated by minor and even trivial exposures never proven to cause disease. Most of the early defendants, such as insulation companies, have long since gone bankrupt.[6] Lacking targets in that industry, the plaintiffs' bar shifted to attacks on bonded products that produce little asbestos exposure, primarily brakes and gaskets. These cases generated hard-fought causation arguments, largely because the epidemiology related to automotive mechanics does not support the causation claims.[7] Because brake and gasket cases involve only limited exposures, plaintiffs' attorneys sometimes have withheld exposure evidence of much more impactful amphibole exposures in order to avoid undercutting their brake/gasket

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[6] *See* Deborah Hensler *et al*., *Asbestos Litigation in the U.S.: A New Look at an Old Issue*, RAND Corp., 14-15 (2001), *available at http://www.rand.org/pubs/documented_briefings/2005/DB362.0.pdf* (last visited Oct. 22, 2020).

[7] *See Juni*, 148 A.D.3d at 237 (faulting plaintiff expert for ignoring that 21 out of 22 epidemiology studies of brake workers and mechanics did *not* find any association with mesothelioma); *Yates v. Ford Motor Co.*, 113 F. Supp. 3d 841, 859 (E.D. N.C. 2015) (referencing 30 epidemiology studies "which find no association between brake work and mesothelioma"). The most recent meta-analysis and summary is reported in David H. Garabrant et al., *Mesothelioma Among Motor Vehicle Mechanics: An Updated Review and Meta-Analysis*, 60 ANN. OCCUP. HYG. 8 (2016).

causation claims and to ratchet up settlement values.[8] The effort to spread the "old" asbestos litigation to bonded products and much smaller exposures resulted in thousands of such cases pending today, even though the exposures demonstrated in studies to cause mesothelioma largely ended in the early 1970s and the epidemiology of mechanics to this day has not found any association with mesothelioma.

More critically for this case, the expansion of asbestos litigation to low exposures also involved unscientific causation testimony generated and propagated by a handful of plaintiffs' testifying experts. These experts, including Dr. Moline (one of the experts in this case), routinely testify that "every exposure" to asbestos, no matter how small, is a contributing or causal factor in mesothelioma. Dr. Moline was in fact one of the expert witnesses excluded in the *Juni* case by the same First Department (and affirmed by this Court on appeal) that decided *Nemeth.* In *Juni*, she testified that Juni's "cumulative exposures to asbestos caused his mesothelioma," referring to "the sum total of [his] exposure to asbestos ... over [his] lifetime."[9] This is the "cumulative exposure" version of the "every exposure" theory – as many courts have

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[8] *In re Garlock Sealing Tech.,* 504 B.R. 71 (W.D.N.C. 2014). "It is clear that Garlock's products resulted in a relatively low exposure to asbestos to a limited population and that its legal responsibility for causing mesothelioma is relatively de minimis." *Id.* at 73. The Garlock opinion contains a succinct review of the early litigation and bankruptcies that ensued, exposing entities such as Garlock with minimal exposure profiles to the bulk of the litigation and deceptive litigation practices. *Id.* at 82-84. Furthermore, the Court excoriated plaintiffs and their lawyers for "withholding of exposure evidence" that inflated recoveries against Garlock. *Id*. at 86.

[9] *Juni,* 148 A.D.3d at 235.

recognized, these two formulations are basically the same testimony.[10] These experts' "every exposure" theory began to unravel in 2005, when the courts first excluded such testimony as unscientific.[11] Since then, dozens of federal and state courts, including this Court in *Juni,* have rejected plaintiff experts' reliance on a dose-less approach to causation that merely points to dust, or to "cumulative", "above background" or "significant" exposure to a product, as the cause.[12]

The opinions rejecting "every exposure" causation testimony are on all fours with the *Parker* opinion. *Parker* issued in the early stages of the efforts of courts nationwide to analyze, and ultimately reject, the "every exposure" approach. By the time of *Parker,* some of these asbestos experts were already trying to export their dose-ignoring approach to other litigation, including benzene litigation. The *Parker* case represented such an effort – rather than identifying a causative dose for the plaintiff gas station worker, the *Parker* experts opined only

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[10] *Juni v. A.O. Smith Water Prods.*, 148 A.D.3d at 235 (rejecting cumulative exposure theory as irreconcilable with required quantification of exposure); *Yates v. Ford Motor Co.*, 113 F. Supp. 3d 841 (E.D.N.C. 2015), *reconsideration denied*, 143 F. Supp. 3d 386 (E.D.N.C. 2015); *Haskins,* 2017 WL 3118017, at *6-*8 (D.S.C. July 21, 2017) (cumulative exposure testimony violates the substantial factor causation standard); "[The district judge] readily and correctly concluded that the cumulative exposure theory was no different from the 'each and every exposure' theory…." *Krik v. Exxon Mobil Corp.,* 870 F.3d 669, 676 (7th Cir. 2017) ("[Expert's] cumulative exposure theory was no different from the 'each and every exposure' theory in all relevant ways.").

[11] *See, e.g., Bartel v. John Crane, Inc.,* 316 F. Supp. 2d 603 (N.D. Ohio 2004), *aff'd sub nom. Lindstrom v. A-C Prod. Liab. Trust,* 424 F.3d 488 (6th Cir. 2005); *In re Toxic Substances Cases,* 2006 WL 2404008 (Pa. Com. Pl. Allegheny Cnty. Aug. 17, 2006), *aff'd sub nom. Betz v. Pneumo Abex, LLC,* 44 A.3d 27 (Pa. 2012).

[12] *See generally* William Anderson & Kieran Tuckley, *How Much Is Enough? A Judicial Roadmap to Low Dose Causation Testimony in Asbestos and Tort Litigation,* 42 AMER. J. TRIAL ADVOC. 39, 56 *et seq*. (2018).

that the exposures were "excessive" or "extensive" or "frequent."[13] This is classic "every exposure" testimony – the substitution of vague descriptors in lieu of characterizing the actual exposures compared to proven causative levels. The *Parker* court recognized the flaw in this approach in the benzene/gasoline context and rightly rejected the causation evidence and testimony.

In New York, the battle over *Parker's* impact on asbestos litigation continues. Some trial courts of the NYCAL docket, often supported by Appellate Division opinions, have not applied *Parker's* principles and have instead resorted to the old *Lustenring* "dust" approach.[14] *Lustenring* was an "old asbestos" case that allowed plaintiffs to meet their burden of exposure proof merely by showing a large exposure to asbestos-containing dust. Whatever the value of *Lustenring* for the litigation as it existed two decades ago, *Parker* rejected *Lustenring* as the appropriate and scientifically supportable approach to admitting expert causation testimony. As discussed further in Section III below, the Court should make clear that in the wake of *Parker*

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[13] *Parker,* 7 N.Y.3d at 449.

[14] Several Appellate Division opinions have applied *Parker* on its terms and rejected causation testimony lacking a quantified or scientific expression of dose, as Dr. Moline uses here. *See Juni; see also Corazza v. Amchem Products, Inc.,* 170 A.D. 3d 610, 611 (1st Dep't 2019); *DiScala v. Charles B. Crystal Co.,* 173 A.D.3d 573 (1st Dep't 2019) (short ruling upholding exclusion of experts in talc case because experts opined only that exposures were "detectable" or "significant," citing *Juni* and *Parker*).

Most of the Appellate Division opinions, however, permit such testimony by relying heavily on *Lustenring* and on the "exceptions" language of *Parker. See, e.g., Battistoni v. AERCO Intl.,* 2016 N.Y. Misc. LEXIS 4775; 2016 NY Slip Op. 32552(U) (Sup. Ct. N.Y. Cnty. Dec. 21, 2016) (. Moulton, J.) (following *Lustenring* and "visible asbestos dust" and distinguishing *Parker*); *Miller v. BMW of North America,* 154 A.D.3d 441 (1st Dep't 2017) (short opinion affirming verdict based on "asbestos-laden dust" created by brake grinder, citing to *Sean R.* and *Juni* but without analysis); *Robaey v. Air & Liquid Systems Corp.,* 186 A.D.3d 401 (1st Dep't 2020) (relying heavily on *Lustenring* to distinguish *Parker* and *Juni*), *appeal pending.*

and its progeny, *Lustenring* is no longer good law, and the courts cannot rely upon or utilize *Lustenring* to avoid *Parker's* dose requirement in the new world of trivial and low-dose asbestos cases. Because *Parker* controls today, the New York courts should reject asbestos causation testimony based on any form of assumed or non-quantified exposure that was admitted in reliance on *Lustenring*. The Appellate Division got this right in the *Juni* appeal, as did the dissent in *Nemeth* – and both opinions represent an appropriate and meaningful application of *Parker's* dose requirement.

Notwithstanding *Parker's* and *Juni's* clear guidance, the message in New York's asbestos appeals is still mixed, requiring another reversal from this Court. The New York courts are not alone in this regard. The United States Supreme Court, for instance, found it necessary to issue a string of three successive opinions to apply fully and solidify the import of the federal *Daubert* standard requiring a scientific and reliable methodology to support expert testimony.[15] Other states have experienced this same lower court failure to enforce expert gatekeeping,[16] and New York apparently will need to follow a similar course.[17]

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[15] *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993); *General Elec. Co. v. Joiner,* 522 U.S. 136 (1997); *Kumho Tire Co. v. Carmichael,* 526 U.S. 137 (1999).

[16] The Texas Supreme Court in *Borg-Warner Corp. v. Flores,* 232 S.W.3d 765 (Tex. 2007), rejected the "every exposure" theory of causation and instructed courts to require a competent dose quantification to support causation. But it took several more intermediate court opinions and another Supreme Court opinion to fully apply those lessons to Texas asbestos litigation. *See, e.g., Smith v. Kelly-Moore Paint Co.*, 307 S.W.3d 829 (Tex. App. 2010); *Georgia-Pac. Corp. v. Stephens,* 239 S.W.3d 304 (Tex. App. 2007); *Bostic v. Georgia-Pacific Corp.*, 439 S.W.3d 332 (Tex. 2014). Similarly, the New Jersey Supreme Court is in the process of addressing how its game-changing *In re Accutane* opinion will affect other litigation, including talc litigation alleging ovarian cancer. *See In re Accutane Litig.*, 191 A.3d 560 (N.J. 2018); *Carl v. Johnson & Johnson,* __ A.3d ___, 2020 WL

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This history now brings us to cosmetic talc litigation. The cosmetic talc docket did not exist even a few years ago, despite the fact that the composition of talc and its widespread usage has not materially changed in many years. In part, the lack of any litigation was because no health agency or epidemiology studies had ever identified cosmetic talc as a cause of mesothelioma – and still have not done so to this day.[18] Yet talc-mesothelioma lawsuits are now pending all over the country. The engine driving this novel docket is the same one that drove low-dose asbestos litigation for many years until courts began to address the problem – the "every exposure" approach to causation that eschews any dose quantification. As demonstrated by Dr. Moline's refusal to identify an actual causative dose, the talc experts follow the "every exposure" approach which requires no dose quantification or even meaningful estimate. "Dust" is all Dr. Moline needs for her opinion, in direct contradiction to *Parker* and *Juni.*

The cosmetic talc/asbestos litigation is thus best understood as yet another strained attempt to keep asbestos litigation going. That litigation is reaching the bottom of the barrel in terms of trying to find some asbestos exposure, *any* asbestos exposure, to support lawsuits against companies that have not already been bankrupted by asbestos litigation. The same experts in this and other talc cases (such as Mr. Fitzgerald in *Nemeth*) who claim that talc even

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4497263 at *27 (N.J. Super. Ct. App. Div., Aug. 5, 2020), *appeal pending*, Docket Nos. A-0387-16T1, A-0978-16T1 (N.J.).

[17] The Court will have another opportunity to apply *Parker* in asbestos litigation in the upcoming appeal of the *Robaey* case.

[18] *Nemeth,* 183 A.D.3d at 238-40 (finding no epidemiological support in the "Welch article," "Helsinki article," "Andrion article," or in the record generally, for whether there exists a level of asbestos exposure for cosmetic talc use sufficient to cause peritoneal mesothelioma).

contains asbestos at all have themselves been excluded in other cases because their method of identifying asbestos is unscientific and led to an unreliable "finding" of asbestos in talc.[19] That issue is not before this Court on appeal, but it adds to the speculative nature of this new attempted wave of litigation.

The Court should address this case in the same manner as it did in *Parker* and in the manner the Appellate Division did in *Juni*. The *Nemeth* experts refused to identify any causative dose, instead asserting only that the exposures were levels above background.[20] These experts fully subscribed to the approach repudiated in *Parker* to render a causation opinion. The reasons for rejecting the *Nemeth* testimony are well-articulated in the dissent and in the WCD letter. *Amici* urge the Court to hold that the *Juni* Appellate Division opinion (and the dissent here) reflect a proper gatekeeping inquiry in New York, and that cosmetic talc/asbestos opinions are not exempt from such an inquiry.

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[19] As these other courts have found, the experts who claim to find large amounts of asbestos in talc are engaged in an unscientific "fiber hunt" through which they manipulate and misuse the testing methodologies. The experts are not finding asbestos "fibers" but are instead counting broken rock fragments that fit the aspect ratio of 3:1 for fiber counting. *See Brandt v. The Bon-Ton Stores*, No. 2987, Memorandum Opinion (Ct. Common Pleas, Phila. Cty., Sept. 25, 2017) (attached as Exhibit A), *aff'd on other grounds,* 2020 WL 865276 (Pa. Super. Ct. 2020); *Hanson v. Colgate-Palmolive*, CV 216-034, Order (U.S.D.C. Ga., Sept 25, 2018) (attached as Exhibit B). *See also Chapp. v. Colgate-Palmolive Co.,* 388 Wis.2d 622, 935 N.W.2d 553 (Ct. App. 2019) (excluding Dr. Moline in talc case and discussing difference between "cleavage fragments" and asbestiform fibers in context of Fitzgerald testing). The invalidity of Fitzgerald's testing methodology is not before this Court. But these opinions help to confirm that men and women who used cosmetic talc for many years were not exposing themselves to asbestos in doing so.

[20] To contend that plaintiff's home use of talc created exposures that were "above background," the experts improperly relied on the mere presence of dust and on the irrelevant "glove box" testing of Mr. Fitzgerald – a highly artificial simulation intended to document asbestos exposure in a small, fully sealed box rather than in the actual exposure environment.

II. The Court Should Reaffirm Key Scientific Principles Applicable to All Exposure-Causation Cases.

In its opinion in this matter, the Court should reiterate certain key propositions to which the New York trial and appellate courts have not yet fully subscribed. With the mish-mash of opinions coming out of the First Department, trial courts currently have no clear guidance on how to proceed with cases like *Nemeth*. An opinion from this Court reiterating these principles and their application to asbestos and talc litigation would contribute meaningfully to a more orderly and principled adjudication of New York cases.

The Essential Element of Dose: To begin with, the Appellate Division in *Nemeth* rejected or at least minimized the importance of proving a quantified and causative dose. Scientific publications are clear that without a competent and proven dose sufficient to cause disease, the disease cannot be attributed to the exposure. For toxicologists, "[d]ose is the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect."[21] This dose principle holds true for carcinogens like asbestos just as much as it does for any other toxin:

> Most chemicals that have been identified to have "cancer-causing" potential (carcinogens) do so only following long-term, repeated exposure for many years. Single exposures or even repeated exposures for relatively short periods of time (*e.g.*, weeks or months) generally have little effect on the risk of cancer, unless the exposure was remarkably high and associated with other toxic effects.[22]

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[21] David L. Eaton, *Scientific Judgment and Toxic Torts—A Primer In Toxicology For Judges And Lawyers*, 12 J.L. & POL'Y 5, 11 (2003).

[22] *Id.* at 13.

In the face of this reality and *Parker's* acknowledgement of it, the Appellate Division in *Nemeth* made an erroneous statement about the *Parker* case that must be forcefully corrected. The *Nemeth* majority stated:

> *Parker* is significant because it recognizes that mathematically precise quantification of exposure to a toxic substance, years after a plaintiff's exposure to such substance, may be impossible and, consequently, alternative means of proof should be available for an injured plaintiff to pursue what may otherwise be a valid claim. This recognition is particularly apt in asbestos exposure cases where the latency period between exposure and the onset of disease can be 20, 40 or 50 years.[23]

This statement is the exact opposite of *Parker's* actual holding. *Parker* is "significant" because it requires a clear and scientifically defensible dose articulation, not because it acknowledged there might be a possible scientifically-defensible exception. The Appellate Division's contrary statement distorts *Parker* until it is unrecognizable. The scientific principle articulated in *Parker* – that experts must identify a causative dose – is not the exception. It is the *rule*.

The Appellate Division's opinion would reverse the proof requirement. As the Appellate Division recognized, these experts are not genuinely using an alternative such as a mathematical model – they are simply reverting to the *Lustenring* "visible dust" approach that *Parker* rejected. The Court should instruct the state's lower courts that exceptions to the "dose" requirement are few and far between and that the exceptions must themselves articulate some kind of measurable or identifiable dose, not merely refer to "significant" or "above background."

The Primacy of Epidemiological Evidence: The Appellate Division allowed Dr. Moline to testify that talc is a cause of mesothelioma even though she could not cite a single epidemiology study of talc-exposed individuals as support. That is clear scientific error, and also

legal error under the *Parker* line of cases. Epidemiology is the "gold standard" of latent disease causation, and without it plaintiffs are left with inferior evidence. Their burden of proof should be *higher,* not lower.

Identifying the right substance: In addition, these experts should not be allowed to substitute studies involving asbestos product exposures at high levels, such as insulation and factory workers, to contend that *talc* causes mesothelioma. In *Parker,* Plaintiffs' experts tried to rely on studies of benzene exposure in factory workers, but the plaintiff was exposed to gasoline, not benzene itself. The gasoline studies in turn showed no association with Parker's disease. *Parker* made it clear that the substance at issue in that case was *gasoline*, not pure benzene, even though gasoline had some small amounts of benzene in it.

The logic of the gasoline/benzene distinction in *Parker* applies with equal force to *Nemeth* – if talc does in fact contain small amounts of asbestos, and if talc exposure causes mesothelioma, studies should document the link between *cosmetic talc* (not asbestos) and mesothelioma. Studies of talc mine and factory workers do exist, and those studies show no such association.[24] Indeed, Dr. Moline admitted the lack of any studies of talc supporting her opinion, but tried to generalize to studies of asbestos products to justify her opinion:

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[23] *Nemeth,* 183 A.D.3d at 222-23.

[24] The studies addressing the much heavier talc miner and factory worker studies have never identified any risk of mesothelioma in these workers. The lack of talc-related disease in these studies exposes the fallacy in Dr. Moline's approach, which claims to find excessive and extensive mesothelioma in the much lower exposed group of individuals using cosmetic talc. *See* Brent Finley, *et al., Cosmetic Talc as a Risk Factor for Pleural Mesothelioma: A Weight of Evidence Evaluation of the Epidemiology*, 29 INHAL. TOXICOL. 179 (2017); Gary Marsh, *et al., Occupational Exposures to Cosmetic Talc and Risk of Mesothelioma: An*

(continued…)

> Dr. Moline explained that although there were no specific epidemiological studies regarding asbestos contaminated cosmetic talc and peritoneal mesothelioma, she was able to draw her conclusion by analogy from other relevant epidemiological studies, because it is the asbestos and not the talc per se that causes the disease.[25]

Her effort to substitute asbestos for talc studies is just as unavailing as the attempt in *Parker* to substitute benzene for gasoline. The Court should restate the rule in *Parker* and instruct the courts to apply that rule in talc and asbestos litigation.

The "above ambient" fallacy: Plaintiff based her causation case on the assertion of Mr. Fitzgerald, the expert who performed the artificial glove box test, that her use of talc in the bathroom would have produced exposures "several orders of magnitude" above ambient or background level exposures. *Nemeth,* 183 A.D.3d at 217-18. This is fallacious scientific reasoning for the fundamental reason that no one has established "above ambient" as the benchmark for causation. Without such proof, a measure of exposure "above ambient" has no meaning. Exposures could be a hundred orders of magnitude above ambient and still cause no harm. This "above ambient" statement is a sleight of hand that plaintiffs' experts used to avoid estimating and identifying an actual causative dose of talc, which Dr. Moline refused to do. Dr. Moline's testimony, in fact, goes even further to declare that "even brief or low-level exposure to asbestos, including asbestos contaminated talcum powder, causes all types of mesothelioma (including both pleural and peritoneal mesothelioma)…." *Nemeth,* 183 A.D.3d at 218. The

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Updated Pooled Cohort and Statistical Power Analysis with Consideration of Latency Period, 31 INHAL. TOXICOL. 213 (2019); G. Rubino, *et al., Mortality Study of Talc Miners and Millers*, 18 J. OCCUP. MED. 186 (1976); M. Coggolia, *et al, An Update of a Mortality Study of Talc Miners and Millers in Italy*, 44 AM J. INDUST. MED. 63 (2003); E. Pira, *et al.,* 59 OCCUP. & ENVIRON. MED. 659 (2017).

[25] *Nemeth,* 183 A.D.3d at 219.

Court should reject any attempt to rely on "above background" or "above ambient" estimates as a true dose assessment because this approach does not include any articulation of what the causative dose actually is. The reliance on "above ambient" is no better than the testimony relying on "excessive" exposures that *Parker* rejected.

III. The Court Should Eliminate the Use of *Lustenring* in Today's Asbestos and Talc Litigation.

Finally, *Amici* request the Court to reject outright the use of *Lustering* as a vehicle to avoid the dose quantification and proof required by the *Parker* line of cases. One of the primary causes of the confused and competing decisions applying *Parker* to talc and asbestos litigation is the continuing influence of *Lustenring* in asbestos cases and its use by lower courts to allow testimony from experts who fail the *Parker* test. In *Juni* the majority followed *Parker* while the dissent relied heavily on *Lustenring.* Now we have the reverse – the *Nemeth* majority has followed *Lustenring,* while the dissent has appropriately applied *Parker.* The Court should make clear that *Lustenring* does not offer an end run around the dose requirement and scientific principles established in *Parker* and later in the *Juni* Appellate Division majority opinion. Otherwise, the lower courts will be torn between *Lustenring* and *Parker*, with no consistent rule of law in the asbestos, talc, and similar dockets.

Conclusion

For the reasons stated above, and in the brief of Petitioner WCD, *Amici* request that the Court reverse the Appellate Division with instruction that the dissenting opinion is the correct statement of the law under *Parker.*

Respectfully submitted,

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AFFIRMATION OF COMPLIANCE

Pursuant to the Rules of Practice of the New York Court of Appeals, 22 NYCRR § 500.11m, Gary A. Stahl, an attorney at Crowell & Moring LLP admitted to practice before the Courts of the State of New York, hereby affirms that according to the word count feature of Microsoft Word, the word processing system utilized to prepare this letter-brief, the letter-brief contains 5,089 words, which complies with the limitations set forth in Section 500.11(m).

Gary A. Stahl

EXHIBIT A

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

DOCKETED
COMPLEX LIT CENTER:
SEP 25 2017
J. STEWART

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

MEMORANDUM OPINION

Brandt Etal Vs The Bon-Ton Stores, Inc Etal-OPFLD
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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.

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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:

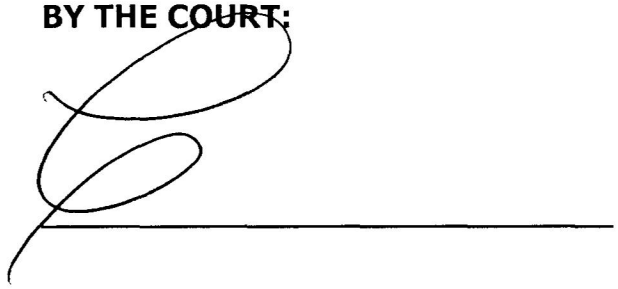


EXHIBIT B

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF GEORGIA

BRUNSWICK DIVISION

DOUGLAS B. HANSON, individually as the surviving spouse of Sharon M. Hanson, deceased, and in his capacity as the duly appointed Executor of the Estate of Sharon M. Hanson,	)	
Plaintiff,	)	
v.	)	CV 216-034
COLGATE-PALMOLIVE COMPANY,	)	
Defendant.	)	

O R D E R

Sharon Hanson suffered from pleural mesothelioma and ovarian cancer allegedly caused by exposure to asbestos in Defendant's Cashmere Bouquet Body Talc ("CB talc"). Before the Court is a series of motions to exclude testimony by scientific and medical experts. (Doc. nos. 51, 52, 56, 60, 67, 118, 120, 132, 133, 172.) After careful consideration of the briefs, evidence, and oral argument, the Court

(1) **DENIES AS MOOT** Plaintiff's motion to exclude evidence of Dr. Ronald Gordon's felonious past;

(2) **EXCLUDES** Plaintiff's expert Dr. Gordon's opinions CB talc is contaminated with asbestos and caused Mrs. Hanson's pleural mesothelioma;

(3) **EXCLUDES** the causation opinions of Plaintiff's experts Drs. Richard Kradin and Jacqueline Moline because of their reliance on Dr. Gordon's now excluded opinion CB talc is contaminated with asbestos;

(4) **EXCLUDES** Plaintiff's expert Dr. James Webber's opinions regarding alleged Cosmetic, Toiletry, and Fragrance Association ("CTFA") misconduct during its collaboration with EPA in development of the J4-1 test method;

(5) **DENIES** Defendant's motion to preclude admission into evidence of vintage CB talc containers;

(6) **ALLOWS** defense expert Dr. Matthew Sanchez's opinions regarding the absence of asbestos in CB talc and biological benignity of cleavage fragments;

(7) **ALLOWS** defense expert Dr. Brooke Mossman's opinions regarding threshold levels of asbestos exposure and biological benignity of cleavage fragments;

(8) **DENIES** Plaintiff's motion to exclude reference to six articles Dr. Mossman cited for the first time during her deposition and **DENIES AS MOOT** Plaintiff's motion to exclude statements by Dr. Mossman that are critical of Plaintiff's expert Dr. Arnold Brody; and

(9) **ALLOWS** defense expert Dr. Suresh Moolgavkar's opinion age was Mrs. Hanson's biggest risk factor for mesothelioma and CB talc was not a risk factor.

I. FACTUAL AND PROCEDURAL BACKGROUND

A. Amended Complaint Allegations

Seeking compensatory and punitive damages, the Amended Complaint asserts claims under Georgia law against Defendant Colgate-Palmolive Company, as manufacturer of CB talc, for negligence, product liability, breach of warranty, loss of consortium, and wrongful death. (Doc. no. 200, pp. 6-17.) The Amended Complaint alleges Mrs. Hanson's exposure to asbestos occurred through her and her mother's use of CB talc during the period of 1952 through 1974. (Id. at 4, 6-7.) Mrs. Hanson's mother used CB talc daily, and Mrs. Hanson's exposure occurred through contact with her mother, inhalation of suspended particles during application, and contact with surfaces upon which CB talc settled. (Id. at 7.)

Mrs. Hanson personally used CB talc daily from 1962 through 1970, and her exposure occurred through direct contact with her skin and inhalation of talc particles

suspended in the air during application. (Id.) Mrs. Hanson and her mother did not know CB talc contained asbestos and would not have used CB talc had they known. (Id. at 8-9.) Mrs. Hanson was diagnosed with ovarian cancer in the Fall of 2009 and with pleural mesothelioma in the Fall of 2014, which led to the realization in the Summer of 2015 that CB talc could cause ovarian cancer and pleural mesothelioma. (Id. at 5.) Mrs. Hanson died on April 21, 2018, at the age of sixty-six. (Doc. no. 148-55, pp. 7:25-8:1; doc. no. 195.)

B. Key Mineralogy Concepts

The Food and Drug Administration ("FDA") regulates talc powder as a cosmetic, defined as an "articl[e] intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance . . . ." 21 U.S.C. § 321(i); 21 C.F.R. § 73.1550. The Federal Food, Drug, and Cosmetic Act prohibits (1) adulteration of cosmetics in interstate commerce; (2) introduction, delivery, and receipt of adulterated cosmetics in interstate commerce; and (3) manufacture of adulterated cosmetics. 21 U.S.C. § 331.

Federal regulations promulgated by the Occupational Safety and Health Administration ("OSHA") and the Environmental Protection Agency ("EPA") define asbestos as the asbestiform variety of the following six naturally occurring minerals: chrysotile, amosite, crocidolite, anthophyllite, tremolite, and actinolite. 29 C.F.R. § 1910.1001; 40 C.F.R. § 763.163; Occupational Exposure to Asbestos, Tremolite, Anthophyllite, and Actinolite, 57 Fed. Reg. 24310-01, 24316 (June 8, 1992); James R. Millette, Asbestos Analysis Methods, in Asbestos: Risk Assessment, Epidemiology, and Health Effects, 42 (Ronald F. Dodson, et al., eds., 2d ed. 2011) [hereinafter "Millette 2011"].

Chrysotile belongs to the serpentine family of minerals, and the remaining five belong to the amphibole family of minerals. Occupational Exposure to Asbestos, Tremolite, Anthophyllite, and Actinolite, 57 Fed. Reg. at 24316; Millette 2011 at 42.

The shape or form a crystal takes during crystallization as determined by environmental and geological conditions is described as its "habit." Occupational Exposure to Asbestos, Tremolite, Anthophyllite, and Actinolite, 57 Fed. Reg. at 24316. The asbestiform crystallization habit is unusual because it requires unique temperature and pressure conditions inducing unidirectional and rapid crystal growth and formation of long thread-like fibers with aspect ratios of 20:1 to 100:1 and higher. Id.; Millette 2011 at 42. Asbestiform fibers bend like a wire under pressure, and they are polyfilamentous, meaning they grow in bundles. Occupational Exposure to Asbestos, Tremolite, Anthophyllite, and Actinolite, 57 Fed. Reg. at 24316. Asbestiform fibers have many commercial applications because of their stability in acids and alkalies, thermal and electrical insulating properties, and high tensile strength. Id. Asbestiform and nonasbestiform amphibole minerals have the same chemical composition and crystal structure, and the sole difference is caused by unique crystallization of the asbestiform habit. Id.; (Gordon Dep. 5/1/2017, doc. no. 147-23, pp. 42:18-43:8). Nonasbestiform prismatic crystals are the common crystal habits of amphiboles. Occupational Exposure to Asbestos, Tremolite, Anthophyllite, and Actinolite, 57 Fed. Reg. at 24316.

A mineral particle formed by breakage is called a cleavage fragment. Id.; (WHO IARC Monograph, doc. no. 63-1, p. 13; EPA Region IX Response, doc. no. 147-18, p. 14). While asbestiform fibers typically separate from their populations when crushed or milled, non-asbestiform minerals break into fragments along their plane of growth. Occupational

Exposure to Asbestos, Tremolite, Anthophyllite, and Actinolite, 57 Fed. Reg. at 24316. Some commentators contend non-asbestiform cleavage fragments occur in similar dimensions as asbestiform cleavage fragments. Id. at 24317-19. Others contend this is not true except for infrequent occasions when a non-asbestiform cleavage fragment has an abnormally high aspect ratio or an asbestiform fibril has an abnormally low aspect ratio. Id. Plaintiff argues, citing EPA Region IX's Response to the November 2005 National Stone, Sand & Gravel Association Report, the distinction between asbestos fibers and cleavage fragments is artificial and meaningless for the purpose of evaluating health hazards. (Doc. no. 147, p. 7 (citing EPA Region IX Response, p. 14).)

C. Asbestos Detection Standards

The United States Pharmacopeia ("USP") method is FDA's standard test for detecting the presence of asbestos in talc. See 21 C.F.R. § 73.1550(b) ("Talc shall meet the specifications for talc in the United States Pharmacopeia XX (1980) . . . ."). To distinguish a fiber as asbestos rather than a cleavage fragment, talc, or an accessory mineral, an analyst uses optical microscopy to identify asbestos fibers with the following three characteristics:

1) a range of length to width ratios of 20:1 to 100:1, or higher, for fibers longer than 5 μm;
2) capable of splitting into very thin fibrils; and
3) two or more of the following characteristics:
   (i) parallel fibers occurring in bundles;
   (ii) fiber bundles displaying frayed ends;
   (iii) fibers in the form of thin needles; or
   (iv) matted masses of individual fibers and/or fibers showing curvature.

(USP Monograph, doc. no. 145-1, p. 6.)

The FDA Monograph Modernization Task Group is considering revisions to the USP Monograph to ensure "the tests for asbestos have adequate specificity" to detect the presence of asbestos in talc. (Doc. no. 72-2, p. 2.) The task is still underway, and the USP Monograph remains the industry standard for detection of asbestos in talc. (Doc. no. 185, p. 80.)

EPA applies a similar standard to analyze bulk building materials for asbestos in EPA R-93, entitled *Method for the Determination of Asbestos in Bulk Building Materials*, which defines an asbestos fiber as follows:

> 1) Mean aspect ratios ranging from 20:1 to 100:1 or higher for fibers longer than 5 µm. Aspect ratios should be determined for fibers, not bundles.
> 2) Very thin fibrils, usually less than 0.5 micrometers in width, and
> 3) Two or more of the following:
> (i) Parallel fibers occurring in bundles,
> (ii) Fiber bundles displaying splayed ends,
> (iii) Matted masses of individual fibers, and/or
> (iv) Fibers showing curvature.

(EPA R-93, doc. no. 143-4, p. 71.) EPA R-93 explains, "It is not unusual to observe occasional particles having aspect ratios of 10:1 or less, but it is unlikely that the asbestos component(s) would be dominated by particles (individual fibers) having aspect ratios of <20:l for fibers longer than 5µm." (Id.)

Other organizations and agencies have different length and aspect ratio standards, examples of which are as follows:

> **OHSA**: A countable fiber is equal to or longer than 5µ (microns) and has an aspect ratio (length-to-width ratio) of equal to or greater than 3:1;
>
> **MSHA (Mine Safety and Health Administration)**: A countable fiber is equal to or longer than 5µ (microns) and has an aspect ratio (length-to-width ratio) of equal to or greater than 3:1;

> **EPA/AHERA (Asbestos Hazard Emergency Response Act)**: A structure greater than or equal to .5μ in length with an aspect ratio of 5:1 or greater and having substantially parallel sides.

(Doc. no. 60, p. 6.)

D. Plaintiff's Criticisms of Asbestos Detection Standards

At the core of Plaintiff's case is the contention traditional methods for defining and detecting asbestos are too lenient and allow harmful asbestos to be ignored and unreported in talc powder. Plaintiff challenges the USP method because it allegedly (1) lacks analytical sensitivity to detect the presence of asbestos; (2) ignores fibers with aspect ratios less than 20:1; and (3) requires a fiber to be found in a larger population of fibers exhibiting at least two characteristics of asbestos, i.e. parallel fibers occurring in bundles, fiber bundles displaying splayed ends, matted masses of individual fibers, and fibers showing curvature. (Id. at 9-12.) Plaintiff alleges these requirements are inappropriate for talc powder because the milling of talc shortens the aspect ratios and removes fibers from bundles. (Id. at 12-13.)

Consistent with Plaintiff's theory, Dr. Ronald Gordon, Plaintiff's expert electron microscopist, argues the USP method is "totally inadequate to assess . . . talcum powders." (Gordon Dep. 5/1/2017, p. 80:1-5.) Accordingly, Dr. Gordon eschews the USP method and analyzed CB talc for asbestos utilizing a modified version of the Yamate method developed for the purpose of identifying and measuring the concentration of airborne asbestos fibers through electron miscroscopy. (Gordon, et al., 2014 Article, doc. no. 147-30, p. 3; Yamate Method, doc. no. 63-8, pp. 1-2, 6, 13-15.)

E. The Yamate Method for Detecting Asbestos

The Yamate method consists of three levels, and the analyst determines the number of levels to perform based on the information sought and level of effort deemed acceptable. (Yamate Method, pp. 6, 15.) Levels I, II, and III require approximately 200, 400, and 1,200 minutes per analysis, respectively. (Id. at 18.) Before beginning Level I, the analyst prepares a sample and places it on an electron microscope grid containing 100 grid openings. (Id. at 21-28, 38-45, 58.) The grid is three millimeters per side, approximately the size of a pencil eraser. (Id. at 27; Hearing Trans. 10/24/2017, doc. no. 185, p. 6.) For this initial work, Dr. Gordon removed CB talc from the containers, suspended the fibers in distilled water and ethanol, and dripped the solution over the grid to distribute fibers randomly over the 100 grid openings. (Gordon, et al., 2014 Article, p. 3.)

1. Yamate Level I

Level I analyzes each sample by morphology and selected area electron diffraction ("SAED") pattern recognition and is appropriate to screen many samples for asbestos because it is a "relatively rapid procedure." (Yamate Method, pp. 6, 15, 17.) First, because asbestiform and non-asbestiform amphiboles may have similar elemental and crystalline characteristics, an analyst must distinguish them on the basis of morphology. (Id. at 60.) To perform a morphology analysis, the analyst views a grid opening with an electron microscope and determines if an asbestos fiber, bundle, cluster, or matrix is located within the opening. (Id. at 29.) An asbestos fiber is "a particle with an aspect ratio of 3:1 or greater, with substantially parallel sides." (Id.) An asbestos bundle is a "particulate composed of fibers in a parallel arrangement, with each fiber closer than the diameter of one fiber." (Id.) An asbestos cluster is "a particulate with fibers in a random arrangement such that all fibers

are intermixed and no single fiber is isolated from the group." (Id.) An asbestos matrix is "a fiber or fibers with one end free and the other end embedded or hidden by a particulate." (Id. at 30.)

Second, the analyst performs SAED analysis, which determines the crystal structure of a particle by viewing the diffraction pattern created when the electron beam in the microscope passes through the particle. (Id. at 31-32.) Comparing the diffraction pattern of the fiber with an SAED pattern obtained from an asbestos standard sample, the analyst classifies the particle as chrysotile, amphibole group, ambiguous, or "no identification." (Id.)

2. Yamate Level II

Level II consists of an elemental analysis of the particles by energy dispersive spectrometer ("EDS"), and the author states Level II is sufficient for regulatory action but not anticipated litigation. (Id. at 6, 15, 17, 49.) EDS obtains a spectrum of the x-rays generated by the particle that reveals elements present in the structure. (Id. at 49.) The spectrum profile is compared with profiles of known particles to determine whether it corresponds to a form of asbestos. (Id.) EDS is "semiquantitative at best" because "asbestos has a varying elemental composition" and other variables can affect the results. (Id. at 51.)

3. Yamate Level III

Level III requires "a quantitative SAED analysis from two different near-exact zone-axis orientations on a selected number of fibers . . . ." (Id. at 6, 15, 56.) Because of its rigor, Level III is appropriate for "confirmatory analysis of controversial samples" and required if "legal proceedings are anticipated." (Id. at 6, 15, 17.) Unlike the SAED analysis required at Level I, the Level III SAED analysis requires "tilting of the specimen to align major crystallographic directions with the electron beam." (Id. at 62-63.) Such an alignment is

called a "zone axis" and is a "line parallel to a set of intersecting crystal planes and nearly parallel to the electron beam." (Id. at 63.) The SAED pattern created at the zone axis "gives regular repeat distances and even intensities of spots throughout the pattern," thus better enabling the analyst to quantify the SAED pattern. (Id.)

Zone axis SAED is important because identification of a particle "may not be absolute" based on the single zone-axis orientation at Level I. (Id. at 56.) Furthermore, unlike the visual comparison at Level I, the analyst must measure the location of the spots on the resulting diffraction pattern at the zone-axis orientation to obtain the d-spacings—distances between the crystal planes measured in angstroms—and the corresponding interplanar angles. (Id. at 67-70.) The analyst compares the d-spacings and angles to measurements from known minerals. (Id. at 59.) Because of the rigorous requirements of a quantitative SAED analysis, "Level III analysis should always be conducted by or under the close supervision of a professional electron microscopist knowledgeable in crystallography, SAED analysis, mineralogy, plus Level I and Level II asbestos analyses." (Id. at 57.)

4. Other Yamate Specifications

The Yamate method states the minimum counting rule is a "minimum 100 fibrous structures per known area (complete grid opening) or 10 grid openings, whichever is first." (Id. at 17 (quotation omitted).) However, the method recommends counting ten grid openings from two grids, a total of twenty grid openings, for "very low asbestos presence, or for asbestos contamination studies." (Id.) Additionally, the Yamate method states data should be recorded "in a systematic form" on data sheets to promote ease in data reduction and subsequent reporting of results. (Id. at 33, 50.) The exemplar data sheets indicate the

first piece of data to be reported is the grid opening where the fiber structure was found by simply noting the number of the grid opening on the data sheet. (See id. at 94, 98.)

5. Dr. Gordon's Yamate Modifications

Dr. Gordon modified the Yamate method in at least four important ways. First, he did not record the grid openings of fibers he determined to be asbestos. Second, rather than reviewing ten grid openings per grid, Dr. Gordon reviewed all 100 grid openings in every grid of CB talc he tested. Third, Dr. Gordon did not observe the minimum detection limit, which requires an analyst to locate at least five fibers in a sample of ten grid openings per grid before he or she can report a positive finding of asbestos, reasoning that if he checked every one of the 100 grid openings he could make a positive finding after locating even one fiber. Fourth, Dr. Gordon did not perform Level III analysis on any of the CB talc samples, but instead stopped at Level II.

II. STANDARD FOR ADMISSIBILITY OF EXPERT TESTIMONY

Admissibility of expert testimony is governed by Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), and its progeny. Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. The three broad requirements of Rule 702 are qualifications, reliability, and helpfulness. United States v. Frazier, 387 F.3d 1244, 1260 (11th Cir. 2004) (*en banc*).

When evaluating the reliability of scientific expert testimony, the trial court must assess "whether the reasoning or methodology underlying the testimony is scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue." Daubert, 509 U.S. at 592–93. In assessing reliability, a trial court has "considerable leeway" in deciding which tests or factors to use. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999). In Daubert, the Supreme Court suggested a trial court consider "(1) whether the expert's theory can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error of the particular scientific technique; and (4) whether the technique is generally accepted in the scientific community." Daubert, 509 U.S. at 593–95. Trial courts must remain mindful "Daubert does not require certainty; it requires only reliability." Hendrix ex rel. G.P. v. Evenflo Co., 609 F.3d 1183, 1198 n.10 (11th Cir. 2010). The focus of reliability "must be solely on principles and methodology, not on the conclusions that they generate." Daubert, 509 U.S. at 595.

Expert testimony must also help the trier of fact to understand the facts in evidence or to determine a fact in issue. This consideration "goes primarily to relevance." Id. at 591. Expert testimony is helpful "if it concerns matters that are beyond the understanding of the average lay person." Frazier, 387 F.3d at 1262 (citing United States v. Rouco, 765 F.2d 983, 995 (11th Cir. 1985)). Expert testimony also does not help the trier of fact when "a large analytical leap must be made between the facts and the opinion." McDowell v. Brown, 392 F.3d 1283, 1299 (11th Cir. 2004).

The Daubert analysis "is not intended to supplant the adversary system or the role of the jury." Allison v. McGhan, 184 F.3d 1300, 1311 (11th Cir. 1999). Where the basis of expert testimony satisfies Rule 702, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking [debatable] but admissible evidence." Daubert, 509 U.S. at 596.

III. CHALLENGES TO PLAINTIFF'S EXPERTS AND EVIDENCE

A. The Court Excludes the Product Contamination and Specific Causation Opinions of Dr. Ronald Gordon

Having a Ph.D. in experimental biology and pathology, Dr. Gordon is a Research Professor and Director of Electron Microscopy within the Department of Pathology at Mount Sinai's Icahn School of Medicine. (Gordon Dep. 3/20/2015, doc. no. 147-1, p. 172:11-14; Gordon Expert Rep., doc. no. 65, pp. 3, 21.) Dr. Gordon teaches college courses in electron microscopy, pathology, and biology, has authored or co-authored more than 150 publications, serves as reviewer for several peer review journals, and reviews grant applications for seven institutions including the National Institutes of Health and National Science Foundation. (Gordon Expert Rep., pp. 3, 23-24, 32-47, 50-52.)

1. The Court Denies As Moot Plaintiff's Motion Regarding Admissibility of Dr. Gordon's Felonious Past and Denials of Same Under Oath

Arrested in September 1992 for conspiracy to commit money laundering and bank fraud, Dr. Gordon agreed to cooperate with the government and entered the witness protection program. (Gordon Reyes Testimony I 7/8/1993, doc. no. 64-8, pp. 175:3-6; Gordon Reyes Testimony II 7/8/1993, pp. 275:1-4, 277:12-19, 278:14-19.) At trial of his coconspirators, Dr. Gordon admitted he engaged in "criminal activity regarding drugs and

drug laundering money" by arranging for issuance and cashing of falsified checks. (Gordon Reyes Testimony I 7/8/1993, pp. 180:4-7.) In an April 2012 civil deposition, however, Dr. Gordon testified he had never been arrested. (Gordon Dep. 4/23/2012, doc. no. 186-1, pp. 181:23-182:19.) One year later, Dr. Gordon denied in a deposition having ever falsified documents or testified in any capacity other than an expert witness. (Gordon Dep. 4/18/2013, doc. no. 61-5, pp. 19:5-11, 84:11-12.)

By motion in limine, Plaintiff argues these unfortunate events are improper impeachment material because they occurred a long time ago, there was no conviction, and there is a high risk of prejudice, citing decisions excluding this evidence. (Doc. no. 172, pp. 2-6.) Because the Court excludes the heart of Dr. Gordon's testimony below for unrelated reasons, the present motion is **DENIED** as **MOOT**. Should the case proceed to trial, Plaintiff may renew the motion by the deadline for filing motions in limine.

2. The Court Excludes Dr. Gordon's Opinion CB Talc Is Contaminated with Asbestos

Dr. Gordon's contamination opinion originates in his 2014 study and article entitled "Asbestos in Commercial Cosmetic Talcum Powder as a Cause of Mesothelioma in Women." (Gordon Expert Rep., p. 5.) Utilizing the modified Yamate method described in § I.E. *supra*, Dr. Gordon tested more than fifty containers of alleged CB talc and reported asbestos in all, specifically anthophyllite, tremolite, and chrysotile. (Id.) Dr. Gordon also analyzed tissue samples of women who developed mesothelioma without any known exposure to asbestos except CB talc and found asbestos correlating with the types he found in CB talc. (Id.) Based on a fiber burden analysis of Mrs. Hanson's ovaries and lungs, Dr. Gordon opines "all the containers of Cashmere Bouquet talcum powder . . . contained

asbestos fibers of the same type found in Mrs. Hanson's lungs and gynecologic tissues." (Id. at 13.)

Defendant argues Dr. Gordon's talc contamination opinion is unreliable because (1) testing talc for asbestos is outside his expertise of diagnosing disease by examining human tissue; (2) the modified Yamate method deviates from the industry standard USP Monograph for Talc; (3) he failed to address the risk of false positives by foregoing Yamate Level III; (4) he did not record the location of fibers found to be asbestos; (5) he ignored the method's detection limit of five fibers per sample; and (6) he improperly extrapolated his findings to all CB talc ever manufactured. (Doc. no. 56, pp. 16-24.) The Court excludes Dr. Gordon's opinion because of items three and four and finds the remainder more appropriate for cross examination.

a. Dr. Gordon's Failure to Record the Location of Alleged Asbestos Fibers Renders His Opinion Unreliable

Defendant argues its experts cannot replicate and test Dr. Gordon's findings because he did not record the grid location of each fiber he determined to be asbestos, in violation of Yamate reporting protocols. (Doc. no. 56, p. 22; see also Gordon Dep. 3/20/2015, doc. no. 64-1, pp. 166:17-23, 131:4-7.) Instead of analyzing ten or twenty grid openings per sample as Yamate recommends, Dr. Gordon analyzed between 500 and 3,000 grid openings for each of approximately 138 samples taken from approximately fifty CB talc containers, resulting in a range of 69,000 to 414,000 grid openings analyzed. (See Gordon Dep. 3/20/2015, p. 163:12-18; doc. nos. 151-6 through 151-13.) The Yamate method requires the analyst to systematically record data for all detected fibers, even providing a suggested form to record the grid opening information. (Yamate Method, pp. 33, 50, 94, 98.)

Dr. Gordon admits he did not bother to record the location of the reported fibers and concedes another expert reviewing his work would have no way of knowing which grid openings he determined to contain asbestos fibers. (Gordon Dep. 3/20/2015, p. 165:3-10.) At best, as Dr. Gordon admits, another analyst could only reconstruct the entire project by inspecting each of the thousands of grid openings and guessing whether a particular grid opening was one Dr. Gordon identified as containing an asbestos fiber. (Id. at 165:3-10, 131:8-18.) While Dr. Gordon did take visual images of each alleged asbestos fiber, another expert would have no idea which grid opening correlates with each image. (Id.) Dr. Gordon admits "chances are" another analyst would not be able to locate the grid opening containing the fiber he identified and his decision to not record the locations would make a defense expert's task more difficult. (Id.; Gordon Dep. I 4/18/2013, doc. no. 147-11, p. 220:8-17.)

By failing to record location, Dr. Gordon ensured no other analyst could replicate his work and test his findings, as he understands having explained testing talc powder for asbestos is "like looking for a needle in a haystack." (Gordon Jackson Testimony, 2/13/2017, doc. no. 61-7, pp. 121:20-122:3.) Without location information, Dr. Gordon's findings are supported merely by his personal assurance he found asbestos fibers somewhere in the thousands of grid openings. This is exactly the sort of chicanery and *ipse dixit* the Court must exclude. See Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997) (finding expert opinion inadmissible if connected to data only by *ipse dixit* of expert); Rembrandt Vision Techs., L.P. v. Johnson & Johnson Vision Care, Inc., 282 F.R.D. 655, 667 (M.D. Fla. 2012) *aff'd*, 725 F.3d 1377 (Fed. Cir. 2013) (finding expert's failure to document testing procedures strongly weighed against reliability); United States v. Hebshie, 754 F. Supp. 2d

89, 125 (D. Mass. 2010) ("Documentation is necessary to test a hypothesis; in fact, reproducibility is the *sine qua non* of 'science.'").

Plaintiff argues defense experts are not prejudiced because Dr. Gordon tested all 100 grid openings per grid, produced all grids, and produced fiber analysis worksheets containing an image and EDS spectrum for each reported asbestos fiber. (Doc. no. 147, p. 13; see Gordon Expert Rep., pp. 72-87.) The argument ignores the scant effort required of Dr. Gordon to record the grid coordinates and the costly guessing game he foisted on defense experts when he produced thousands of grid openings with no indication of which correlate with his worksheets, images, and EDS spectra. Plaintiff also points to the acknowledged risk of damage to grids that may render replication difficult or impossible even when an analyst records location. (Doc. no. 147, pp. 13-14.) They never offer an example of where this occurred in the case *sub judice*. (Id.; doc. no. 189, p. 9.) Even if they could, the immense and needless difficulty caused by Dr. Gordon's methodical failure to record grid opening locations is not ameliorated by other inherent replication difficulties.

Plaintiff argues defense experts would never agree the reported fibers are asbestos even if located because (1) Dr. Gordon applies a broad definition of a particle 5µ or longer with an aspect ratio of at least 3:1 or 5:1; and (2) defense experts apply a narrower definition requiring a population of fibers longer than 5µ with an aspect ratio of at least 20:1. But for Dr. Gordon's omission of location information, Defendant could have analyzed the fibers identified as asbestos, referenced Dr. Gordon's images and EDS spectra for that fiber, and formed an opinion concerning the soundness of Dr. Gordon's findings under all arguably applicable definitions and standards. The debate could have occurred on a level playing field with all material facts available to everyone as contemplated by Daubert and its progeny.

Because such a debate cannot be had, omission of the location information is sufficient by itself to exclude Dr. Gordon's contamination opinion.

b. Because Dr. Gordon Skipped Yamate Level III, He Did Not Distinguish Talc from Asbestos Reliably

Defendant also argues Dr. Gordon's modified Yamate method is unreliable because he failed to perform Yamate Level III, and this final step is necessary to distinguish talc from asbestos reliably. (Doc. no. 56, pp. 10-12.) By stopping at Level II, Defendant argues, Dr. Gordon may have identified fibers as asbestos that may have been revealed as harmless talc particles at Level III. (Id.) Defendant is correct. Talc is a widely known interference in asbestos testing that can generate false positives according to many sources including American Society for Testing and Materials ("ASTM") International, World Health Organization ("WHO"), and EPA. (ASTM Draft Protocol, doc. no. 61-13, p. 5; Kremer, et al., 1990 Article, doc. no. 63, p. 4; WHO IARC Monograph, p. 13; Krause 1978 Article, doc. no. 63-3, pp. 13-14; EPA R-93, pp. 44-46.) As WHO explains, "[t]alc platelets on end and talc intergrown with amphibole in fibrous talc have complex electron diffraction patterns that may resemble other silicates, including amphiboles . . . unless carefully indexed." (WHO IARC Monograph, p. 13.) Accordingly, a zone-axis SAED analysis is necessary to distinguish amphiboles from talc and prevent false positives. (Id.)

Yamate Level III is the only level that employs a zone-axis SAED analysis. (Yamate Method, p. 44.) Yamate Levels I and II test for morphology and elemental chemistry, but Dr. Gordon admits talc and anthophyllite can be similar morphologically and have a similar if not identical chemical structure. (Gordon Dep. 2/12/2015, doc. no. 63-10, p. 344:16-19; Gordon Dep. II 7/9/2013, doc. no. 64, pp. 334:19-335:12.) Furthermore, Dr. Gordon even

concedes talc can produce an SAED pattern similar to amphiboles at certain orientations. (Gordon Dep. II 7/9/2013, pp. 335:13-336:13)

While Dr. Gordon opines the pattern will not be similar if the electron beam hits the fiber perpendicular to the flat side, he concedes one must still perform a dual-zone access analysis to ensure the analyst is not looking at the wrong orientation. (Id.) Yet, Dr. Gordon chose not to perform the Yamate Level III zone-axis SAED analysis for his product testing. (Gordon, et al., 2014 Article, p. 3.) Nor is he qualified to do so because Yamate Level III requires expertise in crystallography, and Dr. Gordon has no such expertise. (Gordon Dep. 4/18/2013, p. 47:21-23; Yamate Method, p. 57.) Compounding the problem created by Dr. Gordon's omission of Yamate Level III is his decision to not record the grid opening locations of fibers he identified as asbestos, which renders it impossible for any defense expert to find those fibers and conduct Yamate Level III to rule out false positives.

Plaintiff advances three arguments in support of his contention Dr. Gordon's opinion is reliable despite his decision to forego Yamate Level III. None are convincing. First, Plaintiff argues the Yamate method does not require a Level III analysis when legal proceedings are anticipated. (Doc. no. 147, p. 13.) In direct contradiction, the Yamate method states "If a legal proceeding is anticipated, Level III analysis will be required . . . ." (Yamate Method, p. 17.) Even if the Yamate method stated otherwise, it would not change this Court's finding Dr. Gordon's failure to perform Yamate Level III renders his opinion unreliable under Daubert and its progeny.

Second, Plaintiff argues former defense experts Messrs. Van Orden and Saldivar did not perform Yamate Level III in past cases. (Doc. no. 147, pp. 10, 12.) Regarding the prior case cited by Plaintiff, Mr. Van Orden testified he obtained "SAED patterns with zone axis

diffraction patterns" and used them as the "primary criterion for identification" of the particles. (Van Orden Dep. 9/22/2016, doc. no. 147-26, pp. 20:25-21:13; Van Orden Expert Rep., doc. no. 150-6, pp. 2-3.) Mr. Saldivar has never used the Yamate method when testing for asbestos in talc. (Saldivar Dep. 3/13/2015, doc. no. 147-31, pp. 49:2-50:14, 11:12-25, 25:23-26:8.) Furthermore, Mr. Saldivar testified he "tilt[ed] the sample" any time he obtained a hexagonal diffraction pattern in order to rule out anthophyllite and ensure the accuracy of his finding. (Id. at 125:19-126:2.)

Third, Plaintiff argues Dr. Gordon's skipping of Yamate Level III only benefits Defendant because Level III would only change the outcome if a fiber appears to be talc at Level II but is actually anthophyllite at Level III. (Doc. no. 185, pp. 83-86.) This is because (1) tilting what appears to be anthophyllite at Level III to obtain the zone axis diffraction pattern may reveal that it is actually talc; and (2) talc, in contrast, will produce the same diffraction pattern regardless of the tilt. (Id.) Both during the hearing and in his post-hearing brief, Plaintiff pointed unequivocally to Dr. Millette's 2015 article entitled "Procedure for the Analysis of Talc for Asbestos," to support its contention Level III can only eliminate false negatives and cannot eliminate false positives. (Id. at 83; doc. no. 189, p. 5; Millette 2015 Article, doc. no. 189-3, p. 7.) Plaintiff misreads the article.

The critical excerpt from Dr. Millette's article provides as follows:

> Table 4 in the draft Yamate document (23) lists [–1 4 2] as a reference zone axis for anthophyllite. With d_1 and d_2 both at 4.56 angstroms and an angle of 60°, this pattern is very close to the zone axis measured on a typical pseudo-hexagonal pattern obtained from a talc plate. Therefore, a fiber cannot be considered to be anthophyllite on the basis of a zone axis index match of the [–1 4 2] alone. Fortunately, a talc fiber can be differentiated from an anthophyllite fiber because the talc pattern remains evident as the talc particle is tilted, but the pattern changes when an anthophyllite fiber is tilted.

(Millette 2015 Article, p. 7.) The second sentence explains anthophyllite can display a diffraction pattern, with d-spacings and a corresponding interplanar angle, "very close" to talc when analyzed at the reference zone axis of [-1 4 2]. This means the analyst could at first believe a fiber to be anthophyllite when it is talc or believe it to be talc when it is anthophyllite. Accordingly, as the third sentence explains, one cannot determine a fiber to be anthophyllite based on a match at the reference zone axis alone. As the final sentence explains, one must tilt the fiber to reveal its true identity because the diffraction pattern will remain the same if the fiber is talc but the diffraction pattern will change if it is anthophyllite.

Quite obviously, therefore, an initial finding of talc will change to anthophyllite if the pattern changes, and an initial finding of anthophyllite will change to talc if the pattern does not change. Dr. Millette's observations are entirely consistent with the Yamate method, which requires analysis of two zone-axis orientations because identification of a particle "may not be absolute" based on SAED patterns from a single zone-axis orientation. (Yamate Method, p. 56.) They are also consistent with Dr. Millette's acknowledgement in an earlier article talc is an interference that "must be distinguished from positively identifiable asbestos" when testing using an electron microscope. (Kremer, et al., 1990 Article, p. 4.) Also worthy of a second mention is the WHO IARC Monograph, which states talc may resemble amphibole asbestos unless carefully indexed. (WHO IARC Monograph, p. 13.)

The Court thus excludes Dr. Gordon's product contamination opinion for the second and independent reason he failed to distinguish talc from anthophyllite reliably by skipping Yamate Level III. Notably, Defendant filed a secondary motion to exclude Dr. Gordon's contamination opinion that is, from the Court's perspective, largely redundant of the primary

motion and irrelevant in light of the conclusions reached above. The Court thus **DENIES** the secondary motion as **MOOT**. (Doc. no. 52.)

3. Dr. Gordon's Specific Causation Opinion Is Unreliable

Dr. Gordon's causation opinion is as follows: "Based on my review of Mrs. Hanson's pathology material including lung and gynecological tissue provided to me, and my findings, I state to a reasonable degree of scientific certainty that Mrs. Hanson's exposures to asbestos fibers, including anthophyllite asbestos, was a substantial contributing factor in the development of her malignant mesothelioma and ovarian cancer." (Gordon Expert Rep., p. 2.) Plaintiff later stipulated Dr. Gordon will not opine regarding ovarian cancer. (Gordon Dep. 5/1/2017, p. 80:1-5.)

General causation considers "whether an agent increases the incidence of disease in a group" and is not a point of serious debate when the toxin is generally recognized as causing the alleged injury. McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1242-43 (11th Cir. 2005). A general causation inquiry is unnecessary here because Plaintiff makes the widely accepted claim asbestos causes mesothelioma rather than claiming talc powder itself causes mesothelioma. (Gordon Expert Rep., p. 13; Gordon Dep. 5/1/2017, p. 82:12-21.) Specific causation is the battleground, and it considers whether (1) the plaintiff was exposed to enough of the toxin to cause the alleged injury; (2) the chronological relationship between exposure and effect is biologically plausible; and (3) the likelihood the chemical caused the injury in the context of other known causes. Chapman v. Procter & Gamble Distrib., LLC, 766 F.3d 1296 1306 (11th Cir. 2014); McClain, 401 F.3d at 1242-43.

With respect to specific causation, i.e. Plaintiff's burden of proving Mrs. Hanson's mesothelioma was in fact caused by her exposure to asbestos in talc power, the International

Expert Meeting on Asbestos, Asbestosis, and Cancer published an article in 1997 entitled "Asbestos, asbestosis, and cancer: the Helsinki Criteria for diagnosis and attribution." (Helsinki Criteria Article, doc. no. 70.) The purpose of the group was "to discuss disorders of the lung and pleura in association with asbestos and to agree upon state-of-the-art criteria for their diagnosis and attribution with respect to asbestos." (Id. at 2.) Regarding attribution of mesothelioma to asbestos exposure, the Helsinki Criteria provides:

> A lung fiber count exceeding the background range for the laboratory in question *or* the presence of radiographic or pathological evidence of asbestos-related tissue injury (eg, asbestosis or pleural plaques) *or* histopathologic evidence of abnormal asbestos content (eg, asbestos bodies in histologic sections of lung) should be sufficient to relate a case of pleural mesothelioma to asbestos exposure on a probability basis.

(Id. at 4.) "In the absence of such markers, a history of significant occupational, domestic, or environmental exposure to asbestos will suffice for attribution." (Id.)

Because Dr. Gordon concedes there was never a diagnosis of asbestosis or pleural plaques and he did not observe asbestos bodies, the Helsinki Criteria require a finding Mrs. Hanson had (1) a lung fiber count exceeding the background range established by a valid control group; or (2) significant domestic exposure to asbestos by use of CB talc. (Gordon Dep. 5/1/2017, pp. 16:10-15, 59:25-60:18.) Concerning the first prong, Dr. Gordon reported a total of three anthophyllite asbestos fibers in Mrs. Hanson's lung tissue samples. (Id. at 71:16-19.) From these three fibers, he extrapolated the level of anthophyllite in Mrs. Hanson's lungs to be 3,450 fibers per gram wet weight. (Id. at 72:9-12; Gordon Expert Rep., p. 13.) Comparing this fiber burden with the background range established by his control group, Dr. Gordon opines Mrs. Hanson's level of asbestos "significantly exceed[s] background levels." (Gordon Expert Rep., p. 13.) With regard to the second prong, Dr.

Gordon relied on his finding CB talc contains asbestos and tests he conducted to determine the level of exposure caused by consumer use of CB talc.

The Court agrees with Defendant that Dr. Gordon's specific causation opinion is unreliable for four reasons. First, Dr. Gordon failed to record the grid opening where he found the three anthophyllite fibers in Mrs. Hanson's tissue, just as he failed to do when finding anthophyllite in CB talc. (Gordon Dep. 5/1/2017, p. 73:14-17.) This glaring omission renders unreliable his entire fiber burden analysis. Second, Dr. Gordon's finding of anthophyllite in Mrs. Hanson's lungs, and by extension his fiber burden calculation, relies on the same flawed Yamate method that skips Level III and fails to eliminate the risk of falsely identifying talc as anthophyllite. (Id. at 52:6-9.). Third, Dr. Gordon's opinion of Mrs. Hanson's significant domestic exposure to asbestos through use of CB talc, relevant to the second Helsinki criterion, runs headlong into the Court's exclusion in § III.A.2. *supra*, of his opinion CB talc contains anthophyllite, leaving no basis for finding any asbestos exposure.

Fourth, with respect to the first Helsinki criterion, Dr. Gordon's finding of above-background asbestos levels in Mrs. Hanson's lungs relies on a control group of his own creation for which there are too many unanswered questions and hallmarks of impropriety. Dr. Gordon's current control group consists of thirty-five patients who have been "documented" not to have any evidence of asbestos exposure based on "histories taken by trained individuals, trained MDs . . . ." (Id. at 128:9-16.) But Dr. Gordon does not have any documentation of their medical or exposure histories. (Id. at 139:2-11.) Documentation is limited to age range, gender, a list of "means and ranges," and fiber analysis worksheets. (Id. at 139:9-11; 140:23-141:16.) Dr. Gordon has never submitted his control group to the scientific community or had the group peer reviewed. (Id. at 136:25-138:1.)

While it is true a valid control group must consist of persons without lung disease who have no history of exposure to asbestos, Dr. Gordon's entire control group is pristine with respect to asbestos, meaning no one returned a tissue sample with any countable asbestos fibers. (Gordon Brandt Testimony 7/12/2017, doc. no. 67-3, p. 28:2-4.) Dr. Gordon admits there is no control group in the world other than his where the members have no countable asbestos fibers. (Id. at 27:4-15.) Dr. Gordon explains "no other laboratory depends on results that are even current" and "if they did it the way I did it, they probably would" have no countable asbestos fibers in their control group. (Id.)

Dr. Gordon's control group previously exceeded 200 people and had members with countable asbestos fibers. (Id. at 16:23-25.) Dr. Gordon admits "some" of the decrease from 200 to thirty-five occurred when he discovered members had countable asbestos fibers, and he further admits none of those removed suffered an asbestos-related disease necessitating their removal from the control group. (Id. at 18:5-8.) Dr. Gordon explains the reduction from 200 to thirty-five patients was warranted because he never found anybody with countable asbestos fibers caused by background sources since the 1980s. (Id. at 17:5-10.) Nevertheless, Dr. Gordon has co-authored studies where countable asbestos fibers were detected in tissue of the background group. (Id. at 18:9-12.)

Dr. Gordon admits the amount of background asbestos can vary depending on where a person lives. (Gordon Dep. 5/1/2017, p. 135:3-6.) Nevertheless, even though asbestos would be part of the ambient air for a person living near a factory using or producing asbestos products, according to Dr. Gordon, the person could not represent "true background." (Id. at 130:14-20.) Thus, Dr. Gordon testified only people who have "never had any contact with asbestos of any kind" can create "true background levels." (Id. at

131:6-8.) As a result, a finding of a single countable asbestos fiber exceeds the background established by Dr. Gordon's current control group. (Id. at 127:14-16.)

Dr. Gordon's control group appears from the circumstances to be a creation of his own making designed to generate a pristine environment where a single countable asbestos fiber exceeds background levels. The control group has not been peer reviewed, and Dr. Gordon's penchant for little to no documentation of his work makes it impossible for defense experts to conduct a meaningful review of the selection process for the original group of 200 or the winnowing to the current group of thirty-five. The Court has no reasonable assurance the control group accurately reflects background levels in the general population.

For all of these reasons, the Court excludes Dr. Gordon's specific causation opinion. (Doc. no. 67.)

4. Other Courts Have Excluded Dr. Gordon's Contamination and Specific Causation Opinions

This is not the first occasion courts have excluded Dr. Gordon's asbestos contamination and specific causation opinions. See Brandt v. The Bon-Ton Stores, Inc., No. 2987, 2017 WL 4271039 (Pa. Com. Pl. Sept. 25, 2017) (excluding Dr. Gordon's talc contamination opinion because of failure to conduct Yamate Level III, and excluding causation opinion because control group is small, insufficiently documented, and unreliable); Green v. Acans, Inc., No. 24x15000563, slip. op. at 1 (Md. Cir. Ct. May 16, 2017) (excluding Dr. Gordon's opinions regarding CB talc contamination and specific causation); Cade v. Union Pacific R.R. Co., No. CI 12-393, slip. op. at 7 (Neb. Dist. Ct. Feb. 18, 2015) (excluding Dr. Gordon's specific causation opinion based on control group of thirty-five due

to lack of transparency, absence of peer review, and absence of general acceptance within scientific community).

B. The Court Excludes the Causation Opinions of Drs. Kradin and Moline Because of Their Reliance on Dr. Gordon's Product Contamination Opinion and Prior Scientific Findings of Asbestos in Talc

Dr. Kradin, board certified in internal medicine, anatomic pathology, and pulmonary medicine, is a professor of pathology and medicine at Harvard Medical School and an adjunct faculty member at Pacifica University. (Kradin CV, doc. no. 154-1, pp. 2-3.) Dr. Kradin serves on the editorial board of five journals and has authored or coauthored more than 120 medical publications. (Id. at 4, 8-18.) Dr. Moline, board certified in occupational and environmental medicine, is a Professor of Occupational Medicine, Epidemiology & Prevention, and Internal Medicine at Hofstra Northwell School of Medicine and an adjunct professor at Mount Sinai School of Medicine. (Moline CV, doc. no. 154-2, p. 3.) She is Director of the World Trade Center Clinical Center of Excellence and has authored or coauthored more than sixty medical publications. (Id. at 4, 21-25.)

Dr. Kradin' opinions are as follows:

> It is . . . my opinion that both [Mrs. Hanson's] ovarian carcinoma and her malignant mesothelioma were caused by her cumulative exposures to asbestos and that these exposures were caused by the contamination of Cashmere bouquet [sic] cosmetic talc by amphibole asbestos (anthophyllite), as noted in the digestion study performed by Dr. Gordon and the section on cosmetic talc in this report.
>
> Although her tumor cells show a mutation in the BRCA2 gene, this does not negate the fact that she was repeatedly exposed to asbestos, which can independently cause ovarian cancer.

(Kradin Expert Rep., doc. no. 119-5, p. 33.) Dr. Moline's opinions are as follows:

> M[r]s. Hanson also developed ovarian cancer, which is associated with exposure to asbestos. While she does have a genetic predisposition to the

> development of ovarian cancer (BRCA2 mutation), this does not negate the fact that she was repeatedly exposed to asbestos, which can independently cause ovarian cancer.

(Moline Expert Rep., p. 25.) Dr. Kradin will testify regarding general and specific causation while Dr. Moline limits her opinions to general causation. (Doc. no. 185, pp. 310-11.)

Defendant first contends there are no scientific studies linking ovarian cancer to asbestos exposure. (Doc. nos. 118, 167.) On the contrary, Drs. Kradin and Moline cite many scientific articles linking asbestos exposure to ovarian cancer. (Kradin Expert Rep., pp. 22-23; Moline Expert Rep., pp. 31-32; see also doc. no. 154, pp. 8-11.)

Defendant next contends Dr. Kradin failed to conduct a proper analysis to exclude other potential causes of Mrs. Hanson's mesothelioma, including most importantly her BRCA2 gene mutation. (Doc. no. 118, pp. 12-15.) A differential diagnosis considers all potential causes of an injury systematically eliminates them. Chapman, 766 F.3d at 1308 (citing McClain, 401 F.3d at 1252). "Although a reliable differential diagnosis need not rule out all possible alternative causes, it must at least consider other factors that could have been the sole cause of the plaintiff's injury." Guinn, 602 F.3d at 1253. The following deposition excerpts confirm Dr. Kradin properly considered Mrs. Hanson's gene mutation and determined asbestos still played a significant role in her mesothelioma:

> I think, as I just mentioned, the etiology of cancer is -- is complex, and certainly there are individuals who have pre -- genetic predispositions to developing cancer. So I would say the BRCA gene mutation that runs in her germline is certainly a factor that would predispose her, but in the absence of other mutative agents I'm not certain that she would definitely have developed cancer. So there are environmental factors and age related factors as well as the genetic factors. That's -- That's the state of the art with respect to neoplasia . . . .
>
> I would say [Mrs. Hanson's BRCA2 gene mutation is] a predisposing element that would increase her risk of developing an ovarian cancer, but I certainly

> cannot exclude an environmental contribution, in this case her exposure to asbestos . . . .
>
> All I can say is that having the BRCA gene certainly predisposed her. I don't think the BRCA gene by itself would be sufficient; that the fact that -- the fact that asbestos has been shown now, I think, by a consensus of medical opinion to be a cause of ovarian cancer would implicate asbestos as at least a contributory factor to the development of her ovarian malignancy as well . . . .
>
> I think what -- what research cancer biologists would suggest -- And I brought this article by Doctor Vogelstein to support it – is that the general pathways for the development of cancer require at least -- at least three mutations, the BRCA mutation being one in -- in -- in this case, the other two being questionable, but with asbestos being a recognized cause of this -- of ovarian cancer it would have to be implicated. So the BRCA gene by itself probably does not produce cancer. There need to be additional mutative events in order for the cancer to develop . . . .
>
> It's my opinion that these [asbestos] exposures [from her use of CB talc] are the cause of her mesothelioma and contributory cause of her ovarian cancer.

(Kradin Dep., doc. no. 148-59, pp. 63:24-64:24, 101:5-13, 103:19-104:6, 132:18-20.) Dr. Kradin opines BRCA2 and asbestos exposure were both significant in the development of mesothelioma. Defendant's criticisms are more appropriate for cross examination.

Finally, the Court must consider the impact on Drs. Kradin and Moline of excluding Dr. Gordon's product contamination opinion. Both physicians rely on Dr. Gordon's now excluded opinion CB talc contains asbestos. Without it, they have no basis for opining Mrs. Hanson's use of CB talc caused her cancer. Because the Court has excluded Dr. Gordon's opinion, these physicians obviously cannot rely on it. See § III.A, *supra*.; see also Rink v. Cheminova, Inc., 400 F.3d 1286, 1294 (11th Cir. 2005) (affirming exclusion of toxicology experts who "relied on [another expert]'s findings, which we have found to be unreliable"); Jones v. Novartis Pharm. Corp., 235 F. Supp. 3d 1244, 1295 (N.D. Ala. 2017), aff'd in part

sub nom. Jones v. Novartis Pharm. Co., 720 F. App'x 1006 (11th Cir. 2018) (excluding specific causation opinion relying on stricken general causation opinions).

Drs. Kradin and Moline also rely on findings talc products from the source mines for CB talc were contaminated with asbestos fibers, as stated in a 1976 article by Drs. Rohl and Langer and a 2014 article by Dr. Gordon. (Kradin Expert Rep., pp. 18-20; Moline Expert Rep., pp. 29-31.) Defendant moves to strike their reliance on these articles. They cannot rely on the 2014 article by Dr. Gordon because it reports the same product contamination opinion excluded *supra*. Drs. Kradin and Moline cannot offer a meaningful opinion concerning the soundness of the methodologies and conclusions stated in the 1976 article, and they are not qualified to offer opinions concerning the presence of asbestos in CB talc or the extent of Plaintiff's exposure. Even a cursory review of their depositions confirms these topics are completely outside their specialized expertise of medical causation. (Kradin Dep. 9/10/2017, doc. no. 52-8, pp. 35:25-38:3, 45:10-46:24, 47:13-48:18, 52:22-53:10, 53:11-18, 54:12-25; 59:14-19, 75:20-76:17, 77:10-12; Moline Dep. 5/2/2017, doc. no. 52-6, pp. 17:14-17, 29:6-15, 32:10-20 102:6-15, 122:8-123:4; Moline Dep. 6/6/2017, pp. 180:4-9, 190:18-22.).

Allowing them to parrot findings concerning these topics from the 1976 article would improperly relieve Plaintiff of his burden to prove the presence of asbestos in CB talc and Plaintiff's exposure to the same, which are the most hotly contested issues in the case. "An expert 'may not simply repeat or adopt the findings of another expert without attempting to assess the validity of the opinions relied upon.'" Hernandez v. Crown Equip. Corp., 92 F. Supp. 3d 1325, 1352 (M.D. Ga. 2015) (quoting In re Polypropylene Carpet Antitrust Litigation, 93 F. Supp. 2d 1348, 1357 (N.D. Ga. 2000)). "Particularly when parties do not

have the opportunity to examine the information relied upon, courts must ensure that an expert witness is sufficiently familiar with the reasoning or methodology behind the information to permit cross-examination." In re Polypropylene Carpet Antitrust Litigation, 93 F. Supp. 2d at 1357 (citing TK-7 Corp. v. Estate of Barbouti, 993 F.2d 722-732-33 (10th Cir. 1993)). Applying this rule, the court in Carpet Antitrust excluded an expert's opinion to the extent it relied on conclusions of another expert because the testifying expert failed to demonstrate a valid basis for concluding the report was reliable and showed no familiarity with the methods and reasons underlying the hearsay report.

C. The Court Disallows Dr. Webber's Testimony Regarding Alleged CTFA Misconduct in its Dealings with FDA

Dr. Webber is an environmental health scientist with training, education, and experience in toxicology, epidemiology, and environmental health hazards. (Webber Expert Rep., doc. no. 51-1, pp. 2-4; Webber CV, doc. no. 51-4.) During his illustrious career, Dr. Webber started an asbestos analysis laboratory, developed asbestos laboratory accreditation programs for New York state, and authored or critically reviewed many publications regarding airborne asbestos control and screening. (Webber Expert Rep., pp. 2-4; Webber CV, pp. 2-10.) From 2008 to 2014, Dr. Webber chaired the ASTM International Committee D22, *Air Quality*, which writes standards for sampling and analysis of air. (Webber CV, pp. 2-10.) In 2011, Dr. Webber began his tenure on the U.S. Pharmacopeia Talc Expert Panel, the panel that is evaluating analytical methods best suited for detection of asbestos in talc. (Id.)

Based on his review of historical FDA documents from the 1970s, Dr. Webber opines CTFA (1) proposed to collaborate with FDA to develop a reliable method for detection of

asbestos in talc; (2) failed to share with FDA the results of a test series in which six out of seven laboratories, utilizing CTFA's J4-1 test method, failed to detect tremolite asbestos known to be in the samples; and (3) failed to remedy the problem. (Webber Expert Rep., pp. 10-13.) The CTFA J4-1 method became the cosmetic talc industry's method for assuring asbestos-free talc for four decades. (Id.) Dr. Webber opines FDA was unaware of the J4-1 method's analytical shortcomings based on documents such as a 1986 letter in which FDA cited "its cooperation with the talc industry such that an 'analytical methodology was sufficiently developed' to assure that 'talc be free of fibrous amphibole . . . .'" (Id.)

Dr. Webber is qualified to testify concerning analytical methods to determine the presence of hazards to human health such as asbestos in talc powder. However, there is an unbridgeable gap between (1) Dr. Webber's expertise and experience; and (2) his opinions regarding CTFA's historical collaboration with FDA and effectiveness of FDA's oversight of the talc industry. Dr. Webber has never had any job responsibilities related to policymaking or regulatory functions, has never worked for CTFA, FDA, or any company in the cosmetics industry, and has no firsthand knowledge of CTFA or FDA. (Webber Trial Test. 11/14/2016, doc. no. 51-5, p. 92:7-25; Webber CV.) Dr. Webber did not take part in any CTFA discussions in the 1970s concerning the testing of cosmetic talc for asbestos. (Webber Trial Test. 11/14/2016, p. 92:18-21.)

Dr. Webber does not know whether FDA has regulatory authority concerning cosmetics and cosmetic talc and "imagine[d] it is zero." (Webber Dep. 5/31/17, pp. 240:21-241:1.) Dr. Webber also does not know "offhand" what FDA is, nor did he know the regulatory authority FDA holds over cosmetic talc now or exercised when it collaborated with CTFA in the 1970s. (Id. at 241:7-242:1.) When asked what professional expertise he

brought to interpretation of the minutes from the CTFA talc subcommittee reports, Dr. Webber replied, "I'm just using the words right there that to me in common English say that we are going to do it when the time is right for us." (Id. at 84:4-85:15.)

Because Dr. Webber's expertise and experience do not inform his opinion, the Court excludes his testimony. See Lopez v. Allstate Fire & Cas. Ins. Co., No. 14-20654-CIVCOOKTORRES, 2015 WL 5584898, at *6 (S.D. Fla. Sept. 23, 2015) (finding expert must explain how his experience leads to opinion, why experience is sufficient basis for opinion, and how experience is reliably applied to case facts); Kaufman v. Pfizer Pharm. Inc., No. 1:02-cv-22692, 2011 WL 7659333, at *7 (S.D. Fla. Aug. 4, 2011) (explaining expert's experiences and expertise must inform her opinions).

Even if Dr. Webber had expertise regarding FDA regulatory oversight of the talc industry, there would be no benefit to the jury for him to summarize correspondence and explain conclusions he draws solely from that correspondence. Jurors can review the documents and draw their own conclusions. See Frazier, 387 F.3d at 1263 (explaining expert testimony must offer something beyond understanding of average citizen.); Omar v. Babcock, 177 F. App'x 59, 63 (11th Cir. 2006) (explaining testimony unnecessary if expert merely recounts facts and offers conclusion jury should reach); see also Dugas v. 3M Co., No. 3:14-CV-1096-J-39JBT, 2016 WL 7327666, at *3 (M.D. Fla. Mar. 30, 2016) (explaining expert testimony unnecessary where jury can read documents and reach own conclusions).

Nor for similar reasons may Dr. Webber testify regarding the fact or frequency of asbestos contamination in the source talc mines for CB talc, or the extent of asbestos contamination in CB talc. Based on his review of twelve historical documents dating from 1942 through 1977 reporting asbestos in consumer talc products and talc ores, and Dr.

Gordon's product testing, Dr. Webber opines "tremolite, anthophyllite, and chrysotile asbestos had been detected . . . in several talc ores and talc products." (Webber Expert Rep., p. 10.) Dr. Webber concedes, however, he is not a geologist and is not qualified to offer an expert opinion on the mining or milling of talc. (Webber Dep. 5/31/2017, pp. 31:3-6, 64:20.) Dr. Webber "couldn't give . . . a detailed description" of the mining and milling processes for talc. (Id. at 24:10-12.) Dr. Webber is merely pulling information from historical documents and borrowing Dr. Gordon's findings rather than applying any of his considerable expertise or experience. Indeed, he has no expertise or experience regarding the extent or degree of asbestos contamination in CB talc or its source mines. (See generally Webber Expert Rep.) Accordingly, Dr. Webber's testimony on these subjects is inadmissible.

D. The Court Overrules Defendant's Objection to Admission of CB Talc Containers Because Federal Rule of Evidence 901 Does Not Apply

Invoking Federal Rule of Evidence 901, Defendant objects to admission of vintage CB talc containers from which Dr. Gordon obtained his samples because they "cannot be authenticated as genuine Cashmere Bouquet in its original condition." (Doc. no. 120, pp. 2, 9–11.) Plaintiff contends Rule 703 applies rather than Rule 901 because, rather than seeking admission of the containers, they "seek to introduce expert opinion testimony based on the results of testing those materials . . . ." (Id.)

Rule 901 applies to authentication of "an item of evidence." Fed. R. Evid. 901. Rule 703 applies where, as here, a party presents expert analysis of the item but does not enter the item into evidence. See United States v. Woods, 684 F.3d 1045, 1062 (11th Cir. 2012) (holding no authentication needed where expert opined regarding pictures but did not seek to admit them); see also 29 Victor James Gold, Federal Practice and Procedure Evidence

§ 6273 (2d ed. 2017) ("[R]ule 703 determines what is a proper basis for expert opinion."); Broussard v. Maples, 535 Fed. App'x 825, 828–829 (11th Cir. 2013) (comparing Rule 702 and 703). Because Defendant objected under Rule 901 only, and there is a paucity of argument concerning Rule 703, the Court **DENIES** the motion. (Doc. no. 120.)

IV. CHALLENGES TO DEFENSE EXPERTS

A. The Court Allows Dr. Sanchez's Opinions Regarding the Absence of Asbestos in CB Talc and Biological Benignity of Cleavage Fragments

Dr. Sanchez holds a Ph.D. in geology and specializes in characterization of asbestos in raw materials and building products, and development of asbestos analytical methods. (Sanchez Expert Rep., doc. no. 60-3, p. 2.) In addition to having tested thousands of talc samples for asbestos, Dr. Sanchez performs human tissue digestion and fiber burden studies by light and electron microscopy for the presence of asbestos. (Sanchez Trial Test. 7/19/16, doc. no. 143-2, p. 85:21-26; Sanchez Expert Rep., p. 2.) Dr. Sanchez serves on the USP Talc Expert Panel, which in collaboration with ASTM is currently drafting asbestos testing methods for cosmetic and pharmaceutical grade talcs. (Sanchez Expert Rep., p. 2-3.)

Applying the USP Monograph's requirements regarding fiber populations rather than individual fibers, Dr. Sanchez and his colleagues found no asbestos in more than seventy containers of CB talc. (Id. at 18.) Dr. Sanchez also used the Yamate method to examine CB talc, except he completed Level III rather than stopping at Level II, and found no asbestos. (Id.) Plaintiff argues (1) Dr. Sanchez's narrow definition of asbestos is not used by health and regulatory bodies to make health assessments; and (2) he has no scientific foundation to conclude the fibers he identified as non-asbestos or cleavage fragments lack biological potency. (Doc. no. 60, p. 2.)

The Court rejects Plaintiff's arguments because Dr. Sanchez's determination of what constitutes countable asbestos complies with the USP Monograph for Talc, his primary test method that is generally accepted and adopted by FDA to test talc for the presence of asbestos. (Webber Dep. 3/14/17, doc. no. 145-2, p. 87:7-11; Webber Dep. 7/18/16, doc. no. 145-3, p. 67:4-16; Webber Jackson Test. 2/13/2017, doc. no. 145-4, p. 100:5-9); see also 21 C.F.R. § 73.1550(b). Because Plaintiff's criticisms of USP and Dr. Sanchez are best reserved for cross examination, the Court **DENIES** the motion to exclude his testimony.

B. The Court Allows Dr. Mossman's Opinions Regarding Threshold Levels of Asbestos Exposure and Biological Benignity of Cleavage Fragments

Dr. Mossman has a Ph.D. in Cell Biology from the University of Vermont and is a Professor of Pathology at the University of Vermont. (Mossman Expert Rep., p. 5.) She has studied the role of asbestos in the induction of lung cancers, asbestosis, and mesotheliomas for more than forty years. (Id.) Dr. Mossman opines "[p]eer reviewed research . . . and dose-response studies, including my own, support the existence of a threshold level of exposure to asbestos necessary for disease causation." (Id. at 3.) In support, Dr. Mossman cites (1) experimental studies demonstrating no observed adverse effects from exposure to certain levels of asbestos; and (2) a 2011 monograph discussion of demonstrations in research "that asbestos fibers at high concentrations act epigenetically rather than as mutagens." (Id. (citation omitted).)

Dr. Mossman opines "there is a threshold for exposure that must be met for different types of asbestos" but the limit cannot be easily quantified because it depends on a host of variables. (Mossman Dep. 9/26/16, doc. no. 132-2, pp. 45:23-47:20.) Because asbestos exposure is dose-dependent, scientists determine risk by utilizing a number of variables

including the source, fiber length, dissolution of material, asbestiform structures, surface properties, valence, and iron availability. (Id. at 46:2-47:5.) Therefore, "there is no magic number" that can be assigned to the threshold limit value. (Id. at 49:2-16.)

Plaintiff contends Dr. Mossman's opinion should be excluded because her inability to specify a numerical value of exposure below which mesothelioma will not occur renders her testimony "manifestly unhelpful" to a jury. (Doc. no. 132, pp. 6-7.) That Dr. Mossman cannot define a precise numerical threshold does not render her opinion unhelpful. To meet his burden of proof, Plaintiff must demonstrate Mrs. Hanson was exposed to asbestos from a product made or sold by Defendant at a dose sufficient to cause her disease. Dr. Mossman's testimony, based on peer-reviewed research and dose-response studies, will aid the jury in evaluating Plaintiff's causation evidence. Indeed, Plaintiff has his own expert, Dr. Jacqueline Moline, who will testify "there . . . is no threshold that has been determined below which you can say a specific quantity" of asbestos is safe. (Moline Dep. 7/8/2011, doc. no. 140-3, p. 29:9-23; Moline Expert Rep. doc. no. 119-6, p. 22.) It is the province of the jury to determine the credibility of these competing experts.

Plaintiff also contends Dr. Mossman failed to recognize exposure to asbestos below the level of detection is nonetheless harmful, pointing to her statement she used "[t]alc, including talc with amphibole cleavage fragments and fibrous talc" in her laboratory as a "negative control particle for research concerning the biological potency of asbestos minerals." (Doc. no. 132, pp. 7-10; Mossman Expert Rep., p. 4.) However, Dr. Mossman's report explains "*[i]n vitro* and animal studies demonstrate that cleavage fragments show no adverse biologic effects" because "[l]ong, thin, fibrous geometry is important in critical steps leading to cancer development whereas cleavage fragments are inactive." (Mossman Expert

Rep., pp. 3-4.) She further explains "[e]xperiments have consistently revealed that non-asbestiform cleavage fragments of amphiboles or serpentine are inactive, regardless of endpoints examined, including cell proliferation and cell death (cytotoxicity) (reviewed in Mossman, 2008)." (Id. at 4.) In her opinion, "[r]esearch supports the opinion that cleavage fragments, even those chemically similar to pathogenic asbestos minerals, do not cause mesotheliomas." (Id.)

Dr. Mossman cites multiple studies in support of her conclusion non-asbestiform cleavage fragments are not harmful. (Id. at 3-4.) Plaintiff disagrees, citing studies finding exposure to asbestos in doses below the detection limit may be harmful. (Doc. no. 132, pp. 7-10.) It is best for the jury to declare a victor in the expert battle concerning whether cleavage fragments traditionally not defined as asbestos cause cancer given their chemical likeness but morphological dissimilarity to asbestos. For these reasons, Dr. Mossman's testimony regarding threshold exposure and non-asbestiform cleavage fragments are sufficiently reliable for admission at trial.

Plaintiff raises two related issues concerning Dr. Mossman. First, Plaintiff moves to exclude Dr. Mossman's discussion of six articles she did not list in her expert report but identified to Plaintiff's counsel as additional reliance materials at her July 10, 2017 deposition. (Id. at 4-6.) Because the articles merely provide additional support for opinions timely disclosed by Dr. Mossman, there is no prejudice suffered as a result of the late disclosure. However, Plaintiff may seek leave of court to conduct a second deposition limited to these articles fourteen days prior to any pre-trial conference. Second, Plaintiff seeks to exclude any statements by Dr. Mossman that are personally critical of Dr. Arnold

Brody. (Id. at 10-12.) Defendant does not intend to offer such testimony, and Plaintiff's motion as to this issue is moot.

C. The Court Allows Dr. Moolgavkar's Opinions Age Was Mrs. Hanson's Biggest Risk Factor for Mesothelioma and Talc Was Not a Risk Factor

Dr. Moolgavkar has a Ph.D. in Mathematics with postdoctoral training in Pharmacology, Biophysics, Epidemiology, and Biostatistics. (Moolgavkar Expert Rep., doc. no. 139-1, pp. 2-3.) In addition to a Ph.D., Dr. Moolgavkar holds an M.B. B.S., the British system equivalent to M.D. (Id.) Dr. Moolgavkar currently serves as a Senior Fellow and Principal Scientist at Exponent, Inc., an international consulting company. (Id.) Prior to joining Exponent, Dr. Moolgavkar was a Professor of Epidemiology and Adjunct Professor of Biostatistics at the University of Washington. (Id.)

Dr. Moolgavkar was instrumental in developing a biologically-based mathematical model for quantitative estimation and prediction of cancer risk, known formally as the two-stage clonal expansion ("TSCE") model and informally as the Moolgavkar-Venzon-Knudson ("MVK") model. (Id. at 3.) Cancer researches worldwide utilize the MVK model to study the impact of age and environmental factors on the risk of cancer. (Id. at 3, 14-15.) Dr. Moolgavkar has published more than 170 papers, including papers discussing carcinogenesis following exposure to fibers such as asbestos. (Id. at 3-4.)

Dr. Moolgavkar summarizes his opinions as follows:

1. Most cases of pleural mesothelioma among women in the U.S. are not attributable to asbestos exposure.

2. Ms. Hanson's risk of developing spontaneous mesothelioma in her mid-to-late-fifties was approximately 25- to 30-fold the risk at age 30.

3. Alleged exposure to asbestos from cosmetic talc made no contribution to the development of Ms. Hanson's mesothelioma.

> 4. From the material provided to me, Ms. Hanson's mesothelioma arose spontaneously as a consequence of naturally occurring biological processes; age was the strongest risk factor contributing to the development of Ms. Hanson's pleural mesothelioma.

(Id. at 31.) Plaintiff challenges items two through four and also argue Dr. Moolgavkar is not qualified to testify regarding the spontaneity of mesothelioma. (Doc. no. 133.)

1. Dr. Moolgavkar Is Qualified

Plaintiff asserts Dr. Moolgavkar "has no relevant qualifications or expertise to offer the opinion that Mrs. Hanson's mesothelioma was 'spontaneous'" because he is an epidemiologist and biostatician rather than a medical doctor or molecular/cellular biologist. (Id. at 7-8.) "Epidemiology, a field that concerns itself with finding the causal nexus between external factors and disease, is generally considered to be the best evidence of causation in toxic tort actions." Kilpatrick v. Breg, Inc., 613 F.3d 1329, 1337 n.8 (11th Cir. 2010) (internal quotation marks and citation omitted). As an accomplished epidemiologist and cancer researcher, Dr. Moolgavkar is qualified.

2. Dr. Moolgavkar's Opinion Regarding Mrs. Hanson's Age As Her Primary Risk Factor for Cancer Should Not Be Excluded

Plaintiff argues, "Dr. Moolgavkar has no scientifically reliable evidence with which to support his opinion that Mrs. Hanson's age was the cause of her mesothelioma." (Doc. no. 133, p. 4.) Dr. Moolgavkar opines mesothelioma can occur spontaneously without exposure to asbestos and cites numerous supporting epidemiological studies. (Moolgavkar Expert Rep., pp. 11-14.) Plaintiff does not disagree. Dr. Moolgavkar further explains age is a significant risk factor for cancer and references a large body of epidemiological studies

finding age a significant risk factor overall for cancer because the number of cell mutations increase as cell DNA is replicated over a lifespan. (Id. at 7, 14.) Plaintiff does not disagree.

Dr. Moolgavkar also opines age is a significant risk factor for mesothelioma. Plaintiff contends this opinion is misleading because the research cited does not show age itself to be a factor, but instead shows mesothelioma typically occurs later in life because of the long latency period between asbestos exposure and onset of mesothelioma. (Doc. no. 133, pp. 4-7.) Dr. Moolgavkar and his colleagues developed the MVK model to study the impact of age and environmental factors on mesothelioma and other types of cancer. (Moolgavkar Expert Rep., pp. 3, 14-15 (listing citations).) In 2009, they published a study analyzing Surveillance, Epidemiology, and End Results ("SEER") data and finding "every doubling of age increases the risk of spontaneous pleural mesothelioma about 30-fold and that of spontaneous peritoneal mesothelioma approximately eight fold." (Id. at 15; Moolgavkar, *Pleural and Peritoneal Mesotheliomas in SEER: Age Effects and Temporal Trends, 1973-2005*, 2009, doc. no. 133-5.)

Dr. Moolgavkar's peer-reviewed study applying his MVK model is sufficient by itself to support his opinion regarding age and mesothelioma. However, he also cites other studies demonstrating strong age effects on the incidence of pleural mesothelioma in Canada and Europe. (Moolgavkar Rep., pp. 14-15; see also Cree, *Explaining Alberta's Rising Mesothelioma Rates*, 2009, doc. no. 133-6; La Vecchia, *An Age, Period and Cohort Analysis of Pleural Cancer Mortality in Europe*, 2000, doc. no. 133-7; Schonfeld, *Regional Variations in German Mesothelioma Mortality Rates: 2000-2010*, 2014, doc. no. 133-8.) While none of these studies specifically disentangle age as an independent factor from asbestos exposure, all show an increase in mesothelioma based on birth cohort years, indicating asbestos

exposure and age have independent effects on mesothelioma rates. Plaintiff's criticisms of these studies and Dr. Moolgavkar's opinion are more appropriate for cross examination.

3. The Court Allows Dr. Moolgavkar's Opinions Regarding Mrs. Hanson's Relative Risk from Use of Cosmetic Talc

Plaintiff argues Dr. Moolgavkar's opinion Mrs. Hanson's use of CB talc did not increase her risk of mesothelioma should be excluded because "[t]he only basis he gives for this opinion is his review of, and extrapolations from, epidemiological evidence." (Doc. no. 133, p. 8.) Plaintiff contends Dr. Moolgavkar bases his opinions on SEER data containing no information regarding use of cosmetic talc and studies involving industrial hygiene techniques for air sampling talc for asbestos, an area outside of his expertise. (Id. at 8-9.)

Dr. Moolgavkar bases his opinion primarily on multiple epidemiological studies of talc miners and millers finding no association between extensive occupational exposure to talc, including talc contaminated with anthophyllite, and mesothelioma. (Moolgavkar Expert Rep., pp. 9-10, 30-31.) Dr. Moolgavkar cites epidemiological studies conducted in Italy, France, Austria, and Norway that failed to report a single case of mesothelioma among talc miners and millers. (Id. at 9-10.) In addition, Dr. Moolgavkar cites epidemiological studies of Vermont and New York talc workers where talc was possibly contaminated with small quantities of chrysotile, anthophyllite, and tremolite. (Id. at 10.) These studies also showed no evidence of an increase in risk of mesothelioma. (Id.) Epidemiological studies are "the best evidence of causation in toxic tort actions." Kilpatrick, 613 F.3d at 1337 n.8 (quotation omitted). Thus, Dr. Moolgavkar's opinion is reliable and should not be excluded.

Notably, Plaintiff claims Dr. Moolgavkar intends to testify he has never seen asbestos in CB talc. (Doc. no. 133, p. 9.) Defendant has no intention of offering this testimony.

V. CONCLUSION

Accordingly, for the reasons stated above, the Court

(1) **GRANTS** Defendant's motion to exclude Dr. Webber's testimony, (doc. no. 51);

(2) **GRANTS** Defendant's motion to exclude testimony of alleged exposure to asbestos, as to Drs. Kradin, Molin, and Webber, and **DENIES AS MOOT** Defendant's motion as to Dr. Gordon, (doc. no. 52);

(3) **GRANTS** Defendant's motion to preclude Dr. Gordon's product contamination opinions, (doc. no. 56);

(4) **DENIES** Plaintiff's motion to exclude Dr. Sanchez's testimony, (doc. no. 60);

(5) **GRANTS** Defendant's motion to preclude Dr. Gordon's specific causation opinions, (doc. no. 67);

(6) **GRANTS** Defendant's motion to preclude Drs. Kradin and Moline's causation opinions, (doc. no. 118);

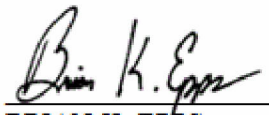
(7) **DENIES** Defendant's motion to preclude admission into evidence of vintage CB talc containers, (doc. no. 120);

(8) **GRANTS IN PART** and **DENIES IN PART** Plaintiff's motion to limit the testimony of Dr. Mossman, subject to the option to conduct a follow-up deposition, as described above, (doc. no. 132);

(9) **DENIES** Plaintiff's motion to exclude Dr. Moolgavkar's risk factor opinions, (doc. no. 133); and

(10) **DENIES AS MOOT** Plaintiff's motion to exclude evidence of Dr. Gordon's felonious past, (doc. no. 172).

SO ORDERED this 24th day of September, 2018, at Augusta, Georgia.



BRIAN K. EPPS
UNITED STATES MAGISTRATE JUDGE
SOUTHERN DISTRICT OF GEORGIA