FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES AND PRODUCTS LITIGATION	:	MDL No. 2738 Civil Action No.: 16-2738(FLW) **OPINION**

WOLFSON, Chief Judge:

Individual consumer-plaintiffs ("Plaintiffs") brought product-liability actions in their respective states against defendants Johnson & Johnson ("J&J"), Johnson & Johnson Consumer Inc. f/k/a Johnson & Johnson Consumer Companies, Inc., Imerys Talc America, Inc. f/k/a Luzenac America, Inc. f/k/a Ro Tinto Minerals, Inc. ("Imerys"),[1] and Personal Care Products Council ("PCPC") (collectively, "Defendants"), alleging that the prolonged perineal use of talcum powder products manufactured by J&J has caused ovarian cancer. Those cases have been transferred to this Multidistrict Litigation ("MDL") by the MDL Panel for pretrial coordination purposes. Plaintiffs' theory of liability centers on their claim that talcum powder causes ovarian cancer, in substantial part, because it contains traces of cancer-causing asbestos and other heavy metals. After years of discovery, both parties have proffered their experts on various scientific issues related to, *inter alia*, causation and

[1] During the pendency of these matters, Imerys petitioned for bankruptcy in the United States Bankruptcy Court for the District of Delaware. As such, all cases against Imerys have been stayed as a result of the automatic stay, and no *Daubert* motions have been filed on behalf of Imerys.

testing of talcum powder for asbestos, and each side has moved to exclude the testimony of the other side's experts. Although each party has named numerous experts, a combined total of more than 35 experts, the Court held a *Daubert* hearing in which only five experts testified on behalf of Plaintiffs, and three experts testified on behalf of Defendants.[2] In this Opinion, the Court determines whether these eight experts are qualified to testify in this case and whether their proffered testimony is admissible under Rule 702 of the Federal Rules of Evidence. For the reasons set forth below, Defendants' motions are **GRANTED in part and DENIED in part**[3]**;** Plaintiffs' motions are **DENIED**. Importantly, the reasoning in this Court's Opinion, applies with equal force to the remainder of the pending *Daubert* motions; and, in that regard, the parties are directed to confer and raise any issues with respect to

---

[2] The *Daubert* hearing was held as a result of a number of motions filed by both parties to disqualify each other's experts. Rather than calling every expert challenged by the motions, the parties selected certain experts as representatives of each field of science involved in this case. The following experts testified on behalf of Plaintiffs: Dr. Ghassan Saed, Dr. William Longo, Dr. Arch Carson, Dr. Anne McTiernan, and Dr. Daniel Clarke-Pearson. The defense experts who testified are as follows: Dr. Benjamin Neel, Dr. Gregory Diette, and Dr. Cheryl Saenz.

[3] Defendants' motion to exclude the testimony of Dr. Saed is granted in part and denied in part; Dr. Saed will not be permitted to testify that his *in vitro* study demonstrated a causal relationship between talc and ovarian cancer. Defendants' motion to exclude the testimony of Dr. Longo is granted in part and denied in part; Dr. Longo will not be permitted to opine on the results of his PLM testing nor will he be permitted to opine as to whether talc users were exposed to asbestos. Defendants' motion to exclude Plaintiffs' general causation experts, Dr. McTiernan, Dr. Clarke-Pearson, and Dr. Carson, is granted in part and denied in part; the general causation experts will not be permitted to opine as to their theory that ovarian cancer may be caused by the inhalation of talcum powder that travels through the lymphatic system to the ovaries.

specific experts, *e.g.*, qualifications, that are not covered by this Opinion, within 45 days of the date of the accompanying Order.[4]

BACKGROUND

The following factual overview is derived from Plaintiffs' Amended Long Form Complaint. J&J manufactures certain Baby Powder and Shower to Shower products that contain talcum powder as their main ingredient. Imerys was in the business of mining and distributing talc for use in those J&J products during the relevant time period.[5] PCPC is a national trade association representing the personal care and cosmetics industry for the purposes of interacting with and influencing local, state and federal government agencies on issues related to the regulation and marketing of talc based body powders, including J&J talc products.

An inorganic mineral, talc is a magnesium trisilicate that is mined from the earth. While talc powder is used for many different purposes, J&J talc products use talcum powder to absorb moisture and to dry skin when applied on the human body. According to Plaintiffs, J&J advertised and marketed their talc products as safe for

---

[4] PCPC has joined J&J's *Daubert* motions to exclude Plaintiffs' experts. (*See* PCPC's Mot. to Join & Adopt J&J's *Daubert* Mots., ECF No. 9721.) In addition, Plaintiffs filed a motion to disqualify PCPC's epidemiologist, Jonathan Borak, who did not testify at the *Daubert* hearing. Although that motion is not addressed here, the reasoning, discussed in this Opinion, as to why Plaintiffs' motions to exclude Drs. Neel and Saenz are denied, apply with equal force to PCPC's expert. Nevertheless, if there are any remaining issues as to Dr. Borak, the parties may bring it to the Court's attention within 45 days of the date of the accompanying Order.

[5] Imerys is the successor or continuation of Luzenac America, Inc. and Rio Tinto Minerals, Inc. Imerys is legally responsible for the conduct of Luzenac America, Inc. and Rio Tinto Minerals, Inc.

use by women in the genital area in order to keep skin feeling dry and comfortable. Compl.,¶ 26. In that regard, Plaintiffs claim that J&J touted that its products are "clinically proven gentle and mild." *Id.* at ¶ 25.

The Complaint details various studies, conducted as early as 1971, that suggest an association between the perineal use of talc and ovarian cancer.[6] *See* Compl., ¶¶ 28-33. In fact, according to Plaintiffs, J&J knew the danger of talc as early as the 1970s. *Id.* ¶ 29; *see also* Compl., Ex. 8. In that regard, Plaintiffs maintain that Defendants knew of the adverse risks of using talc and talc-based body powders in the perineal area and developing ovarian cancer, and had a duty to warn about the potential hazards associated with use of those products. Compl., ¶ 50. Distilling Plaintiffs' claims to their essence, central to this case is whether the use of talcum powder increases the risk of ovarian cancer. In support of their claims, Plaintiffs, first, theorize that the presence of asbestos fibers, among other heavy metals, in talcum powder likely increases the risk of ovarian cancer. Moreover, Plaintiffs

[6] Because of talc's alleged carcinogenic properties, studies continue to be conducted by the scientific community. In fact, during the pendency of these motions, the parties have updated the Court with a number of studies that have been recently released on this topic. Those submissions, however, do not alter the Court's *Daubert* analyses in this Opinion, since the parties have not requested leave to supplement any expert reports based on newly published studies. Rather, because the experts who are the subject of these *Daubert* motions did not review the newly-released studies in forming their expert opinions challenged here, I will not consider those studies for the purpose of resolving the pending motions. However, this does not foreclose the possibility that the parties may seek leave from the Court to supplement an expert's report based on any new and relevant studies. And, indeed, if such supplemental reports impact my *Daubert* decisions made in this Opinion, I may amend my rulings at a later time.

submit that the vast majority of the epidemiological[7] studies prove a positive and strong correlation of talc use and ovarian cancer.

Plaintiffs seek to prove such a correlation through experts in the areas of epidemiology, biology/oxidative stress and ovarian cancer, and materials science. Drs. McTiernan, Carson, and Clarke-Pearson were proffered as experts in epidemiology. Dr. Saed was presented as an expert in oxidative stress and ovarian cancer. And, finally, Dr. Longo testified on behalf of Plaintiffs as an expert in materials science. Defendants seek to disprove such a correlation and presented Dr. Diette as an expert in epidemiology, Dr. Neel as an expert in molecular biology, and Dr. Saenz as an expert in gynecology and oncology.

DISCUSSION

I. LEGAL STANDARD

The admission of expert testimony is governed by Rule 702 of the Federal Rules of Evidence, which provides that

> 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

[7] Epidemiology is the study and analysis of the distribution (who, when, and where), patterns and determinants of health and disease conditions in defined populations. Michael D. Green, et al., *Reference Guide on Epidemiology,* in *Reference Manual on Scientific Evidence* 549, 551, 623 (Fed. Jud. Ctr., 3d Ed. 2011)

methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. It is well-established that "Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability, and fit." *Ruggiero v. Yamaha Motor Corp., U.S.A.*, 778 F. App'x 88, 93 (3d Cir. 2019) (quoting *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.2d 396, 404 (3d Cir. 2003)). In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court defined the operation and scope of Rule 702 with respect to expert testimony. The *Daubert* Court ruled that trial courts must perform a gatekeeping function to ensure the relevance and reliability of expert testimony. *Id.* at 589–95. In conducting this analysis, courts are to consider "all aspects of the expert's testing: the methodology, the facts underlying the expert's opinion, [and] the link between the facts and the conclusion." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 291–92 (3d Cir. 2012) (alteration in original) (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir. 1999)). Moreover, courts must ensure that expert testimony reflects accepted standards within the relevant scientific and business communities. *See In re Johnson & Johnson Derivative Litig.*, 900 F. Supp. 2d 467, 492 (D.N.J. 2012) ("[T]he Court's role under Rule 702 is to ensure that expert testimony reflects accepted standards within the relevant scientific and business communities—it is not to serve as an umpire between competing subsets of a given community.").

The first prong of admissibility considers whether an expert is qualified "to render an opinion when he or she 'possesses specialized expertise.'" *In re Human*

Tissue Prods. Liability Litig., 582 F. Supp. 2d 644, 655 (D.N.J. 2008) (quoting *Pineda v. Ford Motor Corp.*,520 F.3d 237, 244 (3d Cir. 2008)). This factor is applied liberally and "courts have been cautioned not to exclude expert testimony merely because the court feels that the expert is not the best qualified or that the expert does not possess the most appropriate specialization." *Id.*

The second prong of admissibility concerns the reliability of the expert's methodology. *See* Fed. R. Evid. 702(c). The Third Circuit has explained that "'an expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable." *Pineda*, 520 F.3d at 244 (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994)); *see also In re TMI Litig.*, 193 F.3d 613, 663–64 (3d Cir. 1999), *amended*, 199 F.3d 158 (3d Cir. 2000). This has been interpreted to mean that an "expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation.'" *In re Paoli*, 35 F.3d at 742 (quoting *Daubert*, 509 U.S. at 590); *see also Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 81 (3d Cir. 2017) ("'The test of admissibility is not whether a particular scientific opinion has the best foundation, or even whether the opinion is supported by the best methodology or unassailable research.' Instead, the court looks to whether the expert's testimony is supported by 'good grounds.'" (citation omitted) (quoting *In re TMI*, 193 F.3d at 665). In *Paoli*, the Third Circuit explained that even if the judge believes that "there are better grounds for some alternative conclusion," or that there are some flaws in the scientist's methods, the expert's testimony should be admitted so long as there are "good

grounds" for his or her conclusion. *Id.* at 744. In that connection, "an expert opinion is not inadmissible because it may contain flaws, nor is it excludable because it provides testimony regarding only one facet or aspect of an action but does not prove the whole case; such vulnerabilities affect the weight of the testimony, not its admissibility." *Feit v. Great-W. Life & Annuity Ins. Co.,* 460 F. Supp. 2d 632, 641 (D.N.J. 2006).

In evaluating whether an expert's particular methodology is reliable, a trial court may consider any of these several factors: (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. *See United States v. Downing*, 753 F.2d 1224, 1238–39 (3d Cir. 1985); *see also Pineda*, 520 F.3d at 247–48 & n.8; *Elcock v. Kmart Corp.,* 233 F.3d 734, 745–46 (3d Cir. 2000) (noting that "each factor need not be applied in every case"). While the court's reliability analysis is focused on the methodology employed by the expert, as opposed to his or her conclusions, the Supreme Court has acknowledged that "conclusions and methodology are not entirely distinct from one another." *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Thus, it is acceptable for the court to conduct "at least a limited review of the expert's conclusions 'in order to determine whether they could

reliably flow from the facts known to the expert and the methodology used.'" *In re Human Tissue*, 582 F. Supp. 2d at 656 (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 152 (3d Cir. 1999)).

The third prong of admissibility, fit, concerns whether the expert's testimony will be helpful to the trier of fact. *See* Fed. R. Evid. 702(a). The Third Circuit has explained that "admissibility depends in part on 'the proffered connection between the scientific research or test result to be presented and particular disputed factual issues in the case.'" *In re Paoli*, 35 F.3d at 743 (quoting *Downing*, 753 F.2d at 1237). Whether an expert's testimony meets the fit requirement "is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." *Id.* (quoting *Daubert*, 509 U.S. at 591).

II. PLAINTIFFS' EXPERTS

The Court will discuss each expert, and the relevant legal issues that pertain to each of them, separately.

A. DR. GHASSAN SAED

i. Qualifications

Plaintiffs proffer Dr. Saed as an expert in inflammation and oxidative stress. Dr. Saed is the Director of Ovarian Cancer Research and an Associate Professor at Wayne State University in Detroit, Michigan. (Saed *Daubert* Hr'g Tr., at 2.) He serves as a faculty member of the School of Medicine in the departments of Obstetrics & Gynecology, Cell Biology, and Anatomy & Physiology, and is also an Associate Professor in the Department of Oncology at Karmanos Cancer Institute in Detroit,

Michigan. (*Id.*) Before then, the doctor received a Ph.D. in Molecular Biology at the University of Essex in Colchester, England. (*Id.*) Dr. Saed's laboratory "studies the effect of oxidative stress, inflammation in the causation of diseases, especially cancer." (*Id.*) Indeed, he has purportedly published over 140 peer-reviewed articles in different specialty journals, over 50 of which are "specifically related to oxidative stress and ovarian cancer." (*Id.*)[8]

In August 2017, Plaintiffs contacted Dr. Saed to "discuss the possibility of acting as a witness expert in ovarian cancer[,] inflammation, and oxidative stress." (Saed Dep. Tr., Jan. 23, 2019, at 25.) Thereafter, Dr. Saed met with Plaintiffs' counsel and "agreed in principle to serve as a consultant for what [he is] an expert in, which is oxidative stress and ovarian cancer, and [he] promised to run data, do some work, because [he] wanted to find out if there is molecular evidence to support the effect of talcum powder on the . . . markers for risk of ovarian cancer." (*Id.* at 276.) Accordingly, in the fall of 2017, Dr. Saed and his laboratory began an *in vitro*[9] study

---

[8] Defendants do not specifically challenge Dr. Saed's qualifications to testify as an expert in his stated specialty of "inflammation and oxidative stress that is linked to ovarian cancer." (*See* Defs.' Br., in Supp. Mot. to Exclude Dr. Saed ("Defs.' Saed Br.,") at 5–6; Saed Dep Tr., Jan. 23, 2019, at 27.) Nevertheless, Defendants note in their briefing that Dr. Saed is not experienced in conducting studies with talc. (Defs.' Saed Br., at 5.) Notwithstanding this position, the Court is satisfied that Plaintiffs have met their threshold burden of demonstrating Dr. Saed's qualifications to testify as an expert in this matter. Simply because Dr. Saed had not previously conducted any studies involving talc does not disqualify him from testifying as an expert with respect to his *in vitro* study on talc, *see In re Human Tissue*, 582 F. Supp. 2d at 655, and Defendants do not suggest that Dr. Saed is unqualified to conduct *in vitro* studies related to oxidative stress.

[9] *In vitro* is defined as "[a] research or testing methodology that uses living cells in an artificial or test tube system, or that is otherwise performed outside of a living

to explore the role of talc in the carcinogenesis of ovarian cancer. (*See* Saed *Daubert* Hr'g Tr., at 116.) Upon completion of the study, Dr. Saed submitted a manuscript setting forth the results of his study for publication to *Gynecologic Oncology*, a peer-reviewed journal, which declined to publish the study. (*Id.* at 67.) Ultimately, Dr. Saed's manuscript was published in a journal, *Reproductive Sciences*, after undergoing peer review. (*Id.* at 18.)

ii. Dr. Saed's Experiment Design

In his expert report, Dr. Saed opined that talc, like asbestos, is a silicate mineral that has been linked to have potential carcinogenic effects. (Saed Expert Rep., at 10.) In order to determine whether there is a molecular basis for the association between the use of talcum powder and ovarian cancer, Dr. Saed designed a cellular experiment wherein he explored talc and its causal connection to the pathogenesis of ovarian cancer and the relationship between inflammation and other pathological conditions in ovarian cells. (*Id.* at 13.) A summary of his methodologies is set forth below.

First, Dr. Saed chose six different cells for his experiment: 1) three separate types of ovarian cancer cells (*i.e.*, SKOV-3, A2780 and TOV112D); 2) human macrophage cells; 3) human primary normal ovarian epithelial cells; 4) immortalized human fallopian tube secretory epithelial cells. The cells were grown pursuant to

---

organism." Bernard D. Goldstein & Mary Sue Henefin, *Reference Guide on Toxicology*, in *Reference Manual on Scientific Evidence* 633, 682 (Fed. Jud. Ctr., 3d ed. 2011).

each of their respective specifications. (*Id.*) Second, the cells were then seeded in 100mm cell culture dishes. After 24 hours, certain cell dishes were treated with a mixture consisting of talcum powder and a solvent, DMSO. The cells were treated with either 0, 5, 20 or 100 ug/ml of the mixture for 72 hours. (*Id.* at 14.) Thereafter, cell pellets were collected for RNA, DNA, and protein extraction. Cell culture was collected for CA-125 analysis, as well.

Once the cells were prepared, Dr. Saed performed the following tests:

1. Real Time-PCR ("RT-PCR") "to quantify RNA expression using redox gene specific primers." (Pls.' Saed Br., at 10.) In other words, the cells were subjected to reverse transcriptase, a method used in order to detect the presence of specific proteins in the cells. Dr. Saed explained that the presence of certain proteins or enzymes is an indicator that the cell is in a pro-oxidative state, or experiencing oxidative stress. (Saed Expert Rep., at 4.) According to Dr. Saed, those indicators include, *inter alia*, ß-actin, CAT, GSR, iNOS, MPO, GTX, and SOD3. (*Id.*) To opine on whether certain cells were experiencing oxidative stress, Dr. Saed measured the presence of these proteins or enzymes and recorded the data accordingly.

2. Commercially available ELISAs, which "measure redox protein levels and enzyme activities. (Pls.' Saed Br., at 9–10.) Dr. Saed explained that ELISAs are "a well-established technique" and were used to measure CA-125, a cancer antigen and "marker of inflammation," and the

enzymes CAT, SOD3, GSR, GPX1, and MPO. (*See* Saed *Daubert* Hr'g Tr., at 12, 54; Saed Expert Rep., at 15.)

3. MTT cell proliferation assay, "which is a very commonly used assay to measure cell divisions." (Saed *Daubert* Hr'g Tr., at 54; Pls.' Saed Br., at 10.) Cell proliferation "is cell division, but in cancer cell division which is uncontrolled." (Saed *Daubert* Hr'g Tr., at 56.)

4. Caspase 3 colorimetric assays "to measure apoptosis and programmed cell death." (Pls.' Saed Br., at 10; Saed *Daubert* Hr'g Tr., at 54.) Apoptosis is "a programmed cell death that occurs in the body that eliminates bad cells that develop very single minute in our body." (Saed *Daubert* Hr'g Tr., at 56.)

5. Taqman SNP Genotyping Assay, which "identif[ies] DNA point mutations induced by talcum powder treatment." (Pls.' Saed Br., at 10; Saed *Daubert* Hr'g Tr., at 54.)

Each of the tests was performed across all six cell lines and the samples, according to Dr. Saed, were assayed in triplicate. At the *Daubert* Hearing, the doctor explained the concept of testing in triplicate and how he conducted his study:

> Triplicate . . . in cell culture as we do it. We do it in one way to take one cell, one plate, and divide it into three different plates, and that's considered the triplicate.
>
> The other way which I like to do in cases like this is to, instead of getting one cell line, divid[ing] it into three, I got six different cell lines and I used them.
>
> So if you find the effect, the same that we found with talcum powder in six different cell lines, it will be way more

> powerful than finding this effect in one cell line split into three.

(Saed *Daubert* Hr'g Tr., at 50–51.) Further, Dr. Saed maintained laboratory notebooks of his research, where he, or an assistant, recorded the collected data for each assay or test. Dr. Saed explained that his laboratory's instruments are computerized, so all the data is collected from "the computer of the assay machine to a main computer" where the data is transferred to an Excel spreadsheet. (*Id.* at 19.) The spreadsheet of data for a certain assay is then printed and glued into the experiment's notebook. (*Id.* at 19–20.) The methodology being used for each assay is additionally set forth in the notebook adjacent to the relevant table of data. (*See id.*) Dr. Saed claims that these practices "are established methods in [his] laboratory and also very well known to the scientific research community." (*Id.* at 20.)

Based on the collective results of the various assays ran by Dr. Saed's laboratory, the relevant literature, and his experience in the field of oxidative stress, Dr. Saed makes several essential conclusions in his report:

> (1) Johnson's Baby Powder elicits an inflammatory response in normal ovarian and tubal cells and in ovarian cancer cells that can result in the development and the progression of ovarian cancer.
>
> (2) This pro-carcinogenic process involves oxidative stress, alteration of the redox environment by increasing oxidant enzymes and decreasing anti-oxidant enzymes, promotion of cell proliferation, inhibition of apoptosis, and induction of specific genetic mutations.
>
> (3) Johnson's Baby Powder exposure results in elevation of CA-125, a clinically relevant biomarker for ovarian cancer, in normal and ovarian cancer cells.

> (4) The molecular effects resulting from Johnson's Baby Powder exposure exhibit a clear dose-response pattern.
>
> (5) In [his] opinion, based on established molecular mechanisms for the pathogenesis of ovarian cancer (as evidenced in the peer-reviewed scientific literature and [his] previously published research) and [his] *in vitro* experiments, Johnson's Baby Powder exposure can cause ovarian cancer.
>
> (6) In [his] opinion, based on established molecular mechanisms for the pathogenesis of ovarian cancer (as evidenced in the peer-reviewed scientific literature and [his] previously published research) and [his] *in vitro* experiments, Johnson's Baby Powder exposure worsens the prognosis for patients with ovarian cancer.

(Saed Expert Rep., at 20–21.)

iii. Dr. Saed's Opinion on Talc Use and Ovarian Cancer

Defendants challenge the admissibility of Dr. Saed's opinions on multiple grounds. First, Defendants attack the reliability of certain methods employed by Dr. Saed and his laboratory in conducting his study. Defendants contend that Dr. Saed's study is unreliable pursuant to *Daubert* because (1) he failed to follow his own methods; (2) he failed to use a relevant dose of talc; (3) the results of the study were not replicated; and (4) his lab notebooks are rife with errors that undermine the study. (Defs.' Post-Hr'g Br. at 46–56.)[10] Second, Defendants argue that the results

[10] Defendants additionally challenge Dr. Saed's expert testimony based on his alleged failure to properly disclose to *Gynecologic Oncology* and *Reproductive Sciences* that he was retained by Plaintiffs' counsel to act as an expert in this matter and that Plaintiffs' counsel funded a portion of his study. (Defs.' Saed Br., at 75–79.) While this argument may undermine Dr. Saed's credibility as an expert, it does not render his study so unreliable as to warrant exclusion under *Daubert*. *See Venus v. Seville Food, LLC*, No. 14-2476, 2017 WL 2364192, at *17 (D.N.J. May 31, 2017) (declining to exclude expert testimony based on evidence of bias and instructing defendant that

of Dr. Saed's study do not support his ultimate opinions. (*Id.* at 56–64.) Specifically, Defendants maintain that Dr. Saed's study is one step removed from demonstrating causation because it is an *in vitro* study and the results have not been duplicated in either an *in vivo* or animal study. (*Id.* at 56–59.) Moreover, Defendants argue that Dr. Saed's study fails to establish any carcinogenic potential of talc at the *in vitro* level. (*Id.* at 60–64.)

Before discussing the reliability of Dr. Saed's study, the Court addresses Defendants' contention that the results of Dr. Saed's study do not support his opinion that the use of talc causes ovarian cancer. (*See* Defs.' Post-Hr'g Br. 56–64.) Defendants submit that "(1) [Dr. Saed] admitted that he needed to – but did not – conduct animal studies to confirm that his petri dish findings faithfully replicate what would happen *in vivo*; and (2) even his conclusions about what he found in his petri dishes are not supported by the data his experiment generated." (Defs.' Saed Br. at 56.)

In vitro studies, like the one conducted by Dr. Saed, must have good grounds to reach conclusions regarding human results. These particular studies "involve the examination of disease 'within an artificial environment, such as a test tube.'" *In re*

---

to the extent it sought to challenge the expert's bias, "it is permitted to do so on cross-examination"); *In re Welding Fume Prods. Liab. Litig.*, 534 F. Supp. 2d 761, 766 (N.D. Ohio 2008) ("[A]bsent a showing of bias so extreme that exclusion is appropriate under *Daubert*, the Court believes that disclosure of possible financial bias coupled with cross-examination by the parties is a more appropriate and fine-tuned mechanism for arriving at the truth."). Although relevant, possible bias alone is not a basis for exclusion here, but instead a proper avenue for cross-examination by Defendants.

Human Tissue, 582 F. Supp. 2d at 663 (quoting Michael D. Green, et al., *Reference Guide on Epidemiology, in Reference Manual on Scientific Evidence* 439, 444 (Fed. Jud. Ctr., 2d Ed. 2000)). In that connection, they "are not as helpful as either epidemiological or animal studies because they are conducted outside of a biological environment, and the conclusions of these studies will always remain one step removed from directly providing causation." *Id.*; *see also In re Accutane Prods. Liab.*, 511 F. Supp. 2d 1288, 1294–95 (M.D. Fl. 2007) ("The problem with [the *in vitro*] approach is also extrapolation—whether one can generalize the findings from the artificial setting of tissues in laboratories to whole human beings."). Nevertheless, such studies "can provide a reliable basis for medical and scientific opinions as long as their extrapolations are warranted." *In re Human Tissue*, 582 F. Supp. 2d at 663. In other words, there must be "good grounds" for the extrapolation. *See Paoli*, 35 F.3d at 742.

I do not find that Dr. Saed's opinion—that the use of talc causes ovarian cancer—is a supported extrapolation from his *in vitro* study. In his expert report, Dr. Saed explains that his study (and the related research) "demonstrates that talcum powder induces inflammation and alters the redox balance favoring a pro-oxidant state in normal and [epithelial ovarian cancer] cells." (Saed Expert Rep. at 186.) Dr. Saed then extrapolates from that finding that talcum powder can cause ovarian cancer. (*See id.* at 186–87.) However, Dr. Saed fails to support his conclusion that such an extrapolation is scientifically sound. In his deposition testimony, Dr. Saed candidly admitted that the study did not show any "transformation of normal ovarian

cells to cancerous cells" because he used immortalized cells which "do not transform." (Saed Dep. Tr., Feb. 14, 2019, at 464.) Significantly, Dr. Saed did not "test for actual cell transformation." (Saed *Daubert* Hr'g Tr., at 58.) Instead, Dr. Saed explained at the *Daubert* hearing that he relied upon apoptosis and proliferation[11] as "strong indicators of cells on their way to transformation." (Saed *Daubert* Hr'g Tr., at 57.) In that connection, however, Dr. Saed further conceded at his deposition that cell proliferation can occur "as a normal response of all normal cells to agents." (Saed Dep. Tr., Feb. 14, 2019, at 264.) And, he acknowledged that he was unable to determine through his study whether the cell proliferation was simply an acute response to talc, because "[i]n cell culture you cannot distinguish between acute

[11] Defendants argue that Dr. Saed's data on the proliferation analysis was erroneously recorded. Specifically, Defendants questioned Dr. Saed at the hearing regarding a ninth line of data that appeared in the tables, setting forth an analysis that was not identified in the table's key. (See Defs.' Post-Hr'g Br. at 49–52; Saed Daubert Hr'g Tr., at 209–21.) While Dr. Saed testified that the ninth line of data must have been the control, (Saed Daubert Hr'g Tr., at 210), that testimony conflicts with the laboratory notebooks, which appears to indicate that the seventh line of data was actually disregarded as the control. (*See* Defs.' Post-Hr'g Br. at 50–51.) Indeed, Dr. Saed did not provide a satisfactory explanation regarding the type of data recorded on the ninth line, and whether in fact, an error had occurred. In that regard, it appears that the reliability of the data on cell proliferation is called into question. However, even if the relevant data is accurate, Dr. Saed's experiment results with respect to cell proliferation are not admissible, because, as discussed *infra*, the doctor is not permitted to provide opinion testimony that talc use causes ovarian cancer. This is so, since Dr. Saed, himself, explained that "[p]roliferation is cell division, but in cancer cell division which is uncontrolled. So the cells keep dividing without control mechanism." (Saed *Daubert* Hr'g Tr., at 56.) But, as Dr. Saed admitted, the presence of cell proliferation only evidences a degree of cell transformation, not that a cell was fully transformed into a cancer cell. (*Id.* at 57 (testifying that he "found an increase in proliferation in uncontrolled cell division, which is a "strong indicator[] of cells on their way to transformation").) Accordingly, the Court need not resolve whether any error occurred when performing the cell proliferation assay, because Dr. Saed is not permitted to testify as to those results.

response versus chronic response." (*Id.*) Dr. Saed's testimony in this regard is damning to his own conclusion that talc use can ultimately lead to ovarian cancer.

The lack of support for Dr. Saed's extrapolation is consistent with, and bolstered by, comments Dr. Saed received from peer reviewers at *Gynecologic Oncology*, criticizing his manuscript. One reviewer specifically noted that "[t]he first bulleted highlight, 'Oxidative stress is a key mechanism to the initiation and progression of cancer' is not supported by this investigation and should be omitted." (Tersigni Cert., Ex. B-23, at 2.) The reviewer further recommended that an animal study be conducted to corroborate Dr. Saed's opinion on ovarian cancer, because "the cell lines studies alone and the increase in CA-125 while intriguing are not sufficiently convincing." (*Id.*) A second reviewer pointedly questioned the conclusions of the study because the "data do not show, despite the author's claim, any evidence that [the] cells are transformed." (*Id.* at 3.) Indeed, the second reviewer noted that the study did not document either "tumor initiation nor progression" and highlighted that "[w]hile changes in redox potentially play an important role in tumor biology in general, the present data are insufficient to back up the claim that talcum is central to the development of ovarian cancer." (*Id.*)

In addition to being unsupported by his study, Dr. Saed's opinions with respect to causation are similarly inadmissible because certain aspects of Dr. Saed's study render that portion of the opinion unreliable. Defendants argue in their opening brief that Dr. Saed relied on "irrelevant" cell lines in conducting his *in vitro* study.[12] (Defs.'

[12] Defendants do not re-raise this argument in their Post-Hearing briefing.

Saed Br. at 44–46.) Plaintiffs, however, maintain that the cell lines used by Dr. Saed are appropriate because the purpose of Dr. Saed's *in vitro* study was not to determine human causation but to "determine the effects of talcum powder on the expression of key redox enzymes, CA-125 levels, and cell proliferation and apoptosis in normal and [epithelial ovarian cancer] cells." (Pls.' Saed Br. at 39–40.) In his study, Dr. Saed used six different cell lines: three distinct ovarian cancer cells, human macrophage cells, human ovarian epithelial cells, and immortalized human fallopian tube secretory epithelial cells.[13] (Saed Expert Rep. at 13.)

A critical factor in determining the reliability of an *in vitro* study is "whether the test is predictive of *in vivo* outcomes related to the same cell or target organ system." Goldstein & Henefin, *supra* at 646. For example, in *In re Rezulin Products Liability Litigation*, the district court excluded expert testimony where the experts relied on studies that did not use normal human liver cells to opine that the drug in question caused silent liver injury in humans; rather, the expert used animal cells. *See* 369 F. Supp. 2d 398, 429 (S.D.N.Y. 2005). The *Rezulin* court determined that those studies were not a reliable basis for the expert's opinions. *Id.* at 430. Here, similarly, the Court finds that Dr. Saed's *in vitro* study is not a reliable basis for his opinion that the use of talc can cause ovarian cancer *in vivo* because, as Dr. Saed admitted, the cell lines he used did not, and could not, actually transform into cancer

---

[13] Dr. Saed explained at his deposition that immortalized cells "do not change unless you really beat them up." (Saed Dep., Feb. 14, 2019, at 464.)

cells.

Furthermore, Dr. Saed's failure to conduct a neoplastic transformation assay[14] demonstrates that his findings with respect to any "cause and effect" relationship between talc and ovarian cancer are unsupported. In a "Budget Proposal" created by Dr. Saed in planning his *in vitro* study, he expressed "Three Aims" for his study. (*See* Cert. of Tersigni, Ex. B-25.) The third aim of the Budget Proposal sets forth a goal of demonstrating that "[e]xposure to talc results in neoplastic transformation of normal ovarian surface epithelial cells." (*Id.* at 4.) To show such transformation, the Budget Proposal provides that a neoplastic transformation assay would be conducted as neoplastic transformation "is critical in establishing a cause and effect relationship" between talc and ovarian cancer. (*Id.*) Dr. Saed, however, did not perform such an assay because, as he explained:

> I proposed three specific aims [for his study], not one, three specific aims: Aim 1 to look at the redox balance change and look at genetic mutation. Aim 2, looking at inflammation; Aim 3, looking at neoplastic transformation. We started one by one. We got convincing evidence from Aim[s] 1 and 2; and when we did the proliferation and apoptosis, which are strong indicators of cell transformation, we were happy with that finding. We didn't need to do a new transformation assay.

(Saed *Daubert* Hr'g Tr., at 123.) As Dr. Saed's testimony reveals, the tests that he ran showed cell proliferation and apoptosis, which "indicated" cell transformation, but the tests did not show whether neoplastic transformation had occurred. As Dr.

---

[14] A neoplastic transformation assay is conducted to determine whether "normal ovarian cells chang[ed] into cancer cells." (*See* Saed *Daubert* Hr'g Tr., at 120–21.)

Saed never conducted the test he called "critical" to show transformation, the Court further finds that his study cannot support his opinion that talc can cause ovarian cancer.

Relatedly, Dr. Saed's study failed to show actual mutation of relevant single nucleotide polymorphisms ("SNPs"). Dr. Saed explains in his expert report that a SNP "occurs as a result of gene point mutations" and that common SNPs "are known to be strongly associated with an altered enzymatic activity in these enzymes and helps explain the enhanced redox state that has been linked to several malignancies, including ovarian cancer." (Saed Expert Rep., at 7.) Dr. Saed explained that his study "found that if you expose normal surface epithelial cells from the ovary to talcum powder 100 micrograms per mill for 72 hours, you get a switch in the genome in the DNA sequences that corresponds to these key enzymes that regulate the redox balance."[15] (Saed *Daubert* Hr'g Tr., at 57; *see also* Saed Expert Rep., at 19 (finding that "talc treatment induced gene point mutations that happen to correspond to SNPs in locations with functional effects, thus altering overall redox balance for the initiation and development of ovarian cancer"). Dr. Saed admits, however, that his treatment of talc showed only an *induction* of these mutations and no actual mutation or cell transformation occurred. (*See* Pls.' Saed Br., at 42; Saed *Daubert* Hr'g Tr., at 58 (noting the "gene mutation is before transformation" and that "[J&J] Baby Powder

[15] Plaintiffs and Defendants further dispute whether cell mutation can even occur in a 72-hour period. (*See* Defs.' Saed Br., at 48–49; Pls.' Saed Br., at 42.) The Court need not address this dispute because, as explained above, the fact remains that Dr. Saed only showed an induction of cell mutation and not actual mutation.

was able to *induce* mutations in key oxidant enzymes and antioxidant enzymes . . ."). But, induction does not equate mutation. While Dr. Saed states that treatment of talc induces certain mutations of relevant SNPs, his study fails to support the notion that those mutations actually occurred, or that any of the cells were transformed into cancer. Without evidence of mutation of relevant SNPs, the Court finds that this is yet another reason why Dr. Saed's opinion that talc can cause ovarian cancer is unreliable.

What is more, Dr. Saed's findings with respect to CA-125 further demonstrate that his opinion with respect to ovarian cancer causation is unreliable. Dr. Saed explains in his expert report that his study showed heightened levels of CA-125. (*See* Saed Expert Rep., at 19.) CA-125, as explained by Dr. Saed, is a cancer antigen marker that is used to "monitor patient response" to treatment for ovarian cancer. (Saed *Daubert* Hr'g Tr., at 59.) Defendants do not challenge Dr. Saed's finding of increased levels of CA-125 in the treated cells, but dispute whether CA-125 is a clinically relevant biomarker for showing increased risk of ovarian cancer. (*See* Defs.' Saed Br., at 73–74.) Indeed, Dr. Saed admitted as much at the *Daubert* hearing, testifying that that measurement of CA-125 levels is not used to diagnose ovarian cancer and conceding that he knew of no studies that showed an association between elevated CA-125 levels and increased risk of ovarian cancer. (Saed *Daubert* Hr'g Tr., at 144–45.) Ultimately, it is apparent that elevations of CA-125 are not a reliable measure of the risk of ovarian cancer resulting from talc use. This is one of many reasons why Dr. Saed's conclusion with respect to ovarian cancer causation is

unsupported by his study.[16]

For all these reasons, the Court finds that Dr. Saed's opinion that talc causes ovarian cancer is unsupported by the findings of his study—which can only arguably demonstrate that use of talcum powder causes inflammation in ovarian cells. Dr. Saed's extrapolation from inflammation to ovarian cancer is a step too far to constitute a reliable scientific opinion and, therefore, that opinion will be excluded from his testimony. Indeed, it is within my discretion to exclude unreliable portions of an expert's testimony "[w]hen faced with . . . testimony that contains both reliable and unreliable opinions." *In re Pfizer Inc. Securities Litig.*, 819 F.3d 642, 665 (2d Cir. 2016). The Court need not "'prune away all of the problematic' elements of an expert's proposed testimony 'to save the remaining portions, however small.'" *Id.* (quoting *Bricklayers & Trowel Trades Int'l Pension Fund v. Credit Suisse Sec. (USA) LLC*, 752 F.3d 82, 96 (1st Cir. 2014)). But, where "the unreliable portion of an opinion can be easily distinguished from testimony that could help the jury, it may be an abuse of discretion to throw out the good with the bad." *Id.* (citing *City of Tuscaloosa v. Hacros Chems., Inc.*, 158 F.3d 548, 564 (11th Cir. 1998)). The Court will thus excise only this, admittedly critical, portion of his proposed testimony because, as set forth below, the Court finds that other aspects of Dr. Saed's opinions meet the *Daubert* standard. In sum, Dr. Saed is not permitted to testify at any trial in this matter that his study

[16] While the Court will not permit Dr. Saed to testify that CA-125 evidences cell transformation into ovarian cancer cells, based on the Court's findings, *infra*, he will be permitted to testify as to his opinion that CA-125 is a marker of inflammation.

demonstrated a link between use of talcum powder and ovarian cancer.

ii. Dr. Saed's Conclusion Regarding Talc Use Causes Cellular Inflammation and Oxidative Stress

Having determined that Dr. Saed cannot opine on a causal link between talc use and ovarian cancer, the Court next determines whether Dr. Saed may opine on the association of the use of talc and cellular oxidative stress. In that regard, unlike his opinion on talc use and ovarian cancer, I find that Dr. Saed's study is sufficiently reliable under *Daubert* to show that the use of talc may cause inflammation and oxidative stress. Dr. Saed's opinion in this regard is based on "methods and procedures of science," as opposed to his own subjective beliefs. *See In re Paoli*, 35 F.3d at 742. Moreover, the Court finds that several of the factors that are to be considered with respect to reliability are satisfied by Dr. Saed's testimony: Dr. Saed's experiment used a methodology that consisted of a testable hypothesis; his work was subject to peer-review; and the methodology is generally accepted in the scientific community. *See id.* The Court addresses the arguments raised by Defendants as to why Dr. Saed's methods were unreliable, in turn, below. Ultimately, the Court finds that Defendants raise issues that go to the weight of Dr. Saed's testimony, the resolution of which is preserved for the factfinder, not for the Court in its capacity as a gatekeeper on a *Daubert* motion.

Defendants first argue that Dr. Saed's expert opinion is unreliable because he predetermined his conclusions before conducting the study and failed to follow his own methods. Defendants' argument is premised on the "Budget Proposal" drafted by Dr. Saed, which proposed three aims for his study. It appears that the Proposal

was drafted sometime after Dr. Saed's first meeting with Plaintiffs' counsel in or around August 2017. (*See* Saed Dep. Tr., Jan. 23, 2019, at 25, 276.) The Budget Proposal details Dr. Saed's aims and "expectations" for his research on the role of talcum powder exposure in ovarian cancer. (Saed *Daubert* Hr'g Tr., at 60–65; Pls.' Saed Opp. Ex. F.) At the *Daubert* Hearing, Dr. Saed explained that before his laboratory begins a new project, the laboratory "outline[s] the project in a hypothesis-driven research [budget]." (Saed *Daubert* Hr'g Tr., at 61.) The doctor further explained that this format is used by federal agencies and follows a "hypothesis rationale," which asks "what are your expected results, what do you expect to get; if you don't get what you expect to get, what is your alternative approach, and what is your future direction." (*Id.* at 61–62.) In this context, Dr. Saed clarified that "expectation doesn't mean this is what I want to get. It means based on the results would show positive, this is what we would get, and then we would have a[n] alternative approach if our approach doesn't work." (*Id.* 63–64.)

Based on the general purpose of the Budget Proposal, I cannot find that the Budget Proposal, in of itself, reveals that Dr. Saed drew his conclusions before conducting his study. Indeed, whatever flaws in Dr. Saed's study might be borne out at trial, the Budget Proposal is an internal document used by the laboratory to set forth the methodology of the study and its estimated costs. (*See* Saed *Daubert* Hr'g Tr., at 59–61.) Based on its plain language, the expectations proposed in the Budget Proposal neither support nor confirm that Dr. Saed reached any definitive conclusions regarding the relationship between talcum powder and ovarian cancer

before conducting his *in vitro* study, or that Dr. Saed somehow designed this study to reach certain results. The cases cited by Defendants in support of this argument do not lend significant support for their position. In those cases, the proffered experts were excluded because they signed affidavits setting forth their conclusions before reading the relevant literature, *see Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 502–03 (9th Cir. 1994); or there was clear evidence that the expert manipulated data to achieve a specific result, *see Snodgrass v. Ford Motor Co.*, No. 96-1814, 2002 WL 485688, at *12 (D.N.J. Mar. 28, 2002). Here, the mere use of the word "expect" in the Budget Proposal does not establish the necessary result-driven bias to exclude Dr. Saed's opinion under *Daubert*.

Defendants further argue that Dr. Saed's failure to conduct a neoplastic transformation assay, as written in the Budget Proposal, evidences that he failed to adhere to his own methodology, such that it substantiates the unreliability of Dr. Saed's whole study. I disagree. As I discussed above, the lack of neoplastic transformation is fatal to Dr. Saed's opinion that talc use causes ovarian cancer. However, this type of assay has no bearing on the doctor's opinion on inflammation and oxidative stress. As already noted, Dr. Saed's experiment had three separate aims; while Dr. Saed failed to conduct the neoplastic transformation, which would satisfy aim three of his experiment, it does not render other parts of his study, *i.e.*, conclusions as to the first and second aims, unreliable. Rather, because the transformation assay would tend to prove or disprove that talcum powder causes ovarian cancer, a conclusion that the Court has not permitted Dr. Saed to testify, the

failure to conduct the assay does not impact Dr. Saed's other opinions regarding cell oxidative stress or inflammation for the purposes of *Daubert*. Indeed, unlike the cases cited by Defendants in support of their argument, Dr. Saed did not fundamentally alter the way his studies were conducted on an *ad hoc* basis to achieve some desired result. *See, e.g.*, *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268–69 (2d Cir. 2002) (excluding expert testimony where expert failed to include in his calculations available data regarding variables that he stated should be included in any such assessment); *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 561 (W.D. Pa. 2003) (excluding expert testimony where experts inconsistently applied their stated methodology); *Wade-Greux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1460 (D. V.I. 1994) (excluding expert testimony where expert failed to conduct certain tests required to support his conclusion).[17]

Defendants next argue that Dr. Saed's testimony should be excluded because Dr. Saed did not "attempt" to use a relevant dose when exposing the cell lines to talcum powder. As part of the *in vitro* study, Dr. Saed testified that his laboratory

[17] In their Post-Hearing Brief, Defendants additionally take issue with the fact that Dr. Saed did not perform "all the tests for redox balance in his proposal" or "single nucleotide polymorphism ('SNP') testing for BRCA mutations." (Defs.' Post-Hr'g Br., at 47.) While Defendants highlight that Dr. Saed did not perform these particular tests, they do not explain how that failure impacts the reliability of Dr. Saed's study, except to suggest that he departed from his "own specified methods." (*See id.*) Indeed, it is unclear to the Court what impact these tests would have had on Dr. Saed's experiments. Rather, Defendants are free to explore this issue on cross-examination; at this stage, the Court finds it inappropriate to exclude Dr. Saed's testimony, particularly in light of the fact that this testing method, which was suggested by Dr. Saed, himself, has not been shown here to be indispensable or required by the scientific community.

used doses of talc of "zero, five, 20, and 100-micrograms per milliliter."[18] (Saed *Daubert* Hr'g Tr., at 50.) According to Dr. Saed, these doses were chosen because they are "similar" to doses used in published studies that discuss "testing talcum powder and determining whether the powder has a biological effect in cells." (*Id.* at 50.) Indeed, the published studies are as follows: Shukla, et al., *Alterations in Gene Expression in Human Mesothelial Cells Correlate with Mineral Pathogenicity*, 41 Am. J. Respir. Cell Mol. Biol. 114–123 (2009); Buz'Zard, et al., *Pycnogenol reduces Talc-induced Neoplastic Transformation in Human Ovarian Cell Cultures*, 21 Phytother. Res. 579–586 (2007); Akhtar, et al., *The Primary role of iron-mediated lipid peroxidation in the differential cytotoxicity cause by two varieties of talc nanoparticles on A549 cells and lipid peroxidation inhibitory effect exerted by ascorbic acid*, 24 Toxicology, 1139–1147 (2010); Akhtar, et al., *Cytotoxicity and Apoptosis Induction by Nanoscale Talc Particles from Two Different Geographical Regions in Human Lung Epithelial Cells*, Environ. Tech. (2012). (*See* Pls.' Saed Br., at 32.) Dr. Saed explained that relying on these studies was helpful in ensuring that he was "right in the range of doses and not using an excessive dose that may kill the cell." Saed *Daubert* Hr'g Tr., at 50.)

Nevertheless, on cross-examination during the *Daubert* hearing, the doctor was pressed as to whether those doses he used "are similar to or the same level of

---

[18] Dr. Saed testified that he determined the doses by first treating the cells with high levels of talc—starting with 1000 micrograms, then 500 micrograms, and then 200 micrograms. (*Id.* at 148.) Dr. Saed then chose the relevant doses used for the study. (*Id.*)

exposure in women who use talc." (*Id.* at 146.) In response, Dr. Saed conceded that he was not aware of the doses of talc that women use in real life. (*Id.*) Based on that concession, Defendants contend that Dr. Saed's testimony should not be admitted because he did not use a dose similar to that used by women in real life. (*See* Defs.' Post-Hr'g Br. at 46–47.) Plaintiffs counter that a determination of the relevant dose was not necessary since Dr. Saed's study was never intended to mimic the dose used in humans. (Pls.' Saed Br. at 31–32.)

The Court does not find Defendants' argument persuasive. First, Defendants do not suggest what specific doses would have been appropriate for the purpose of Dr. Saed's testing. Indeed, Defendants do not dispute that the doses used by Dr. Saed were appropriate in conducting his *in vitro* study on cellular inflammation or oxidative stress. On this issue, Defendants' own expert, Dr. Brooke Mossman, a toxicologist, testified that the doses used by Dr. Saed are "appropriate concentration levels to determine pathogenicity of asbestos and talc." (Mossman Dep., at 355–358.) Rather, Defendants take issue with Dr. Saed's failure to use a dose that would mimic the amount of talc that a woman uses. But, that apparent failure does not render the doctor's opinion on inflammation or oxidative stress unreliable. As discussed above, portions of Dr. Saed's testimony that pertain to human causation, *i.e.*, that the use of talc can cause ovarian cancer, are excluded as unsupported. Absent that conclusion, the question of dose is less critical. Courts have generally determined that "*in vitro* tests provide useful information about metabolic processes at a cellular level, and may supplement existing animal and human data." *See, e.g.*, *Bourne ex rel. Bourne*

v. E.I. Dupont de Nemours & Co., Inc., 189 F. Supp. 2d 482, 496 (S.D. W. Va. 2002) (citing *Allen v. Pa. Engineering*, 102 F.3d 194, 198 (5th Cir. 1996)). Only where experts extrapolated human causation from the results of *in vitro* studies do questions of relevant dose arise with respect to the reliability of the expert's methods. *See id.* at 498 (excluding expert testimony where they relied on animal and *in vitro* studies that involved high dosage of the relevant chemicals and long exposure periods). Here, because Dr. Saed's study can only be admitted to show that the use of talc may cause inflammation in cells, his failure to use a relevant dosage that mimics actual human use in an *in vitro* study does not render the study regarding inflammation unreliable. *See Feit,* 460 F. Supp. 2d at 641.

Defendants next argue that Dr. Saed's methodology was unreliable because he failed to properly replicate his experiment. (*See* Defs.' Post-Hr'g Br. at 48–49.) Dr. Saed stated in his manuscript that all assays were performed in triplicate. (*See* Tersigni Cert., Ex. A38, at 5–7, 9.) As discussed above, Dr. Saed explained that he performed each part of the study in triplicate by dividing each cell into three different plates and, further, by performing each test on six separate cell lines. (*See* Saed *Daubert* Hr'g Tr., at 50–51; *see also* Saed Dep. Tr., Jan. 23, 2019, at 123–26.) Defendants, nonetheless, insist that Dr. Saed's purported failure to conduct his experiment in triplicate, and in a manner consistent with how their own experts would conduct the experiment, renders his study unreliable and impossible to reproduce. Plaintiffs respond that Dr. Saed did conduct his experiments in triplicate and that his study can be reproduced. (Pls.' Saed Br. at 37–39.) While there can be

no doubt that replication is an important part of the scientific process, the Court is satisfied that Dr. Saed's methods, in this regard, are reliable under *Daubert*.

Dr. Saed's testimony demonstrated that the specific triplicate methodology he used was based on known scientific methods and was regularly conducted by his laboratory. (*See* Saed *Daubert* Hr'g Tr., at 51–52.) Indeed, Dr. Saed testified that he had published peer-reviewed studies that employed the same triplicate methodology. (*See id.* at 52.) Most critically, the Court reiterates that the article, written by Dr. Saed and published in *Reproductive Sciences*, that discusses the *in vitro* study at issue was peer reviewed, and the methodology was not a concern of those who reviewed the article.[19] The fact that a study has been subject to peer review "does not equate with reliability," but it does suggest that good science was used by the authors. *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145 (3d Cir. 2000) (quoting *Daubert*, 509 U.S. at 593); *see also Daubert*, 509 U.S. at 593 ("[S]ubmission to the scrutiny of the scientific community is a component of 'good science,' in part because it increases the likelihood that substantive flaws in methodology will be detected."). I find that the fact that Dr. Saed's study was peer reviewed, suggests that the triplicate methodology is based on "good science."

Defendants, nonetheless, argue that Dr. Saed's triplicate procedure was wrong. Defendants do not, however, cite to any scientific support for this assertion. Rather, Defendants refer to the Court a single statement from one of their experts,

---

[19] As discussed *supra*, the reviewers at *Gynecologic Oncology* criticized certain aspects of Dr. Saed's *in vitro* study. However, those criticisms did not involve the triplicate methodology used by Dr. Saed.

Dr. Mossman, who, without citation or elaboration, provides in her expert report that Dr. Saed failed to perform his experiment in triplicate. (*See* Defs.' Saed Br., at 43 & n.120 (quoting Mossman Expert Rep., at 33).) Moreover, although Dr. Neel, a rebuttal expert to Dr. Saed, heavily criticizes Dr. Saed's *in vitro* study, Dr. Neel's report does not provide any explanation as to the purported flaws of the triplicate methodology. Indeed, Dr. Neel's testimony at the *Daubert* hearing on this issue is similarly limited; he testified as to his understanding of how to conduct an experiment in triplicate, but he did not comment upon, or explain why, the methodology used by Dr. Saed was flawed. (*See* Neel *Daubert* Hr'g Tr., at 308–09.) Without any evidence that Dr. Saed's triplicate methods are somehow contrary to those used in the scientific community, the Court has no basis to find that those methods were unreliable. To the extent Defendants' experts may disagree with Dr. Saed's triplicate methodology, the Court is faced with a classic battle of the experts scenario. *See United States v. W.R. Grace*, 455 F. Supp. 2d 1196, 1199 (D. Mont. 2006) ("It is not the Court's role to settle scientific disputes."); *see also Dzielak v. Whirlpool Corp.*, No. 12-0089, 2017 WL 1034197, at *26 (D.N.J. Mar. 17, 2017). [20]

[20] In addition to the arguments set forth, *supra,* Defendants additionally assert that Dr. Saed's study is unreliable because he "failed to use valid controls." (Defs.' Saed Br., at 37.) Although this argument is raised in their moving brief, Defendants did little to cross-examine Dr. Saed on this issue at the *Daubert* hearing and do not focus on it in their post-hearing brief. (*See* Saed *Daubert* Hr'g Tr., at 148–51.) In their view, Dr. Saed improperly treated certain cells with dimethyl sulfoxide ("DMSO") without "rul[ing] out the possibility that DMSO and talc interacted in a way that skewed the results" (*id.* at 36–38), and for allegedly failing to incorporate other "negative controls such as glass beads, cornstarch, or other inert substances to verify that the alleged changes in protein levels and DNA are caused by exposure to talc specifically, rather than exposure to foreign particulate matter generally." (*Id.* at

Finally, Defendants argue that errors and inconsistencies in Dr. Saed's laboratory notebooks further indicate the unreliable nature of his *in vitro* study, because these errors make it "impossible to replicate his work." (Defs.' Post-Hr'g Br. at 49–56.) For example, Defendants identify the following issues with Dr. Saed's laboratory notebooks: (1) use of white-out throughout the notebooks; (2) errors in certain calculations; and (3) missing pages. (*Id.* at 49–55.) Dr. Saed testified at length regarding his laboratory notebooks during both his deposition and the *Daubert* hearing.[21]

39–41.) However, as Plaintiffs point out, and which Defendants do not dispute, DMSO is a "universal solvent" typically used in the scientific community as a control in *in vitro* studies. In fact, Defendants' own expert admitted this fact. (*See* Boyd Dep., at 36.) Dr. Saed explained that if there were any unusual interactions with DMSO and talc, he would have been able to observe such interactions by the design of his experiments, and the doctor testified that no such interactions occurred. (*See* Saed Dep., Jan. 23, 2019, at 272-73.) In addition, Dr. Saed claims that for the purposes of his experiment, he did not include any negative control such as cornstarch or glass beads. (*Id.*) Essentially, the points raised by Defendants with respect to Dr. Saed's choice of controls go not to the reliability of his methodology but to the weight of his testimony, because they reflect mere *disagreements* over the controls used by Dr. Saed. *See W.R. Grace*, 455 F. Supp. 2d at 1199.

[21] Defendants additionally contend that Dr. Saed altered his methodology after receiving comments from a peer reviewer at *Gynecologic Oncology*. (Defs.' Post-Hr'g Br., at 55.) Defendants explain that Dr. Saed's manuscript and initial reports stated that he treated cells with talc for 48 hours. (*Id.*; *see also* Tersigni Cert., Ex. A38, at 1.) Dr. Saed's expert report and final published manuscript, however, state that the cells were treated for 72 hours. (Defs.' Post-Hr'g Br., at 55.) Dr. Saed explained that this was "an error in the actual manuscript" and that no such error appeared in his laboratory notebooks." (Saed *Daubert* Hr'g Tr., at 38.) Dr. Saed testified that "trainees[,] like clinical residents and fellows" draft the manuscript and he later reviews and corrects any errors that do not match what is in the laboratory notebooks." (*Id.* at 38–39.) The Court has reviewed Dr. Saed's laboratory notebooks and finds that the data in the notebooks confirms that the cell lines were treated for 72 hours. (*See* Tersigni Cert., Ex. B13 at 26 (setting forth methodology and stating that "after *72 hours treatment*, collect cells and medium for ELISA").)

Defendants point out the improper use of whiteout in Dr. Saed's laboratory notebooks. While admitting that using whiteout in laboratory notebooks is not "proper laboratory practice," (Saed *Daubert* Hr'g Tr., at 177), Dr. Saed testified that whiteout was used only where the methodology was written out, and he emphasized that there was "no white-out in any of the original data." (*Id.* at 178.) Indeed, on cross-examination, defense counsel reviewed several instances in which whiteout was used with Dr. Saed. (*See id.* at 177–82.) These instances included (1) an entry where "Johnson & Johnson" was written over whiteout; (2) an entry where a reference to the sterilization method used was written over whiteout; (3) an entry where the name of a cell line used was whited-out and rewritten below the whiteout; and (4) several entries where part of the date entry was whited-out. (*Id.*)

Defendants also note computation errors that appear in Dr. Saed's laboratory notebooks. (*See id.* at 183–85.) For example, at the *Daubert* hearing, defense counsel highlighted an erroneous average calculation in a table measuring glutathione reductase ("GPX") levels of the cell lines. (*See* Saed *Daubert* Hr'g Tr., at 184; Tersigni Cert., Ex. B-13 at 122.) For a particular cell line, the average of 2.17, 2.46, and 2.39 was listed as 2.47. (*See* Saed *Daubert* Hr'g Tr., at 184; Tersigni Cert., Ex. B-13 at 122.) Dr. Saed explained that these computations are conducted by a computer program that determines what outliers should be excluded. (Saed Daubert Hr'g Tr., at 184–87.)

Finally, with respect to missing pages in his laboratory notebooks, Dr. Saed explained at the hearing that certain pages had been removed from the notebooks by

a new research assistant who "was not familiar with the . . . normal practice of lab notebooks." (*Id.* at 33.) Dr. Saed explained that

> She wanted to keep everything related to talcum powder in one notebook. So she started a different project in those two pages. So she decided to take them out. I instructed her not to do it. This is very bad laboratory conduct.

(*Id.*) Dr. Saed explained that this was not his ordinary practice of maintaining laboratory notes, but that the missing pages had no substantive effect on his study because they "are completely for a different project." (*Id.* at 33–34.) Moreover, to the extent that handwritten methodologies were replaced with the computer-generated data, Dr. Saed explained that such data is glued into the notebooks once the calculations are completed. (*Id.*)

Certainly, each of these issues calls into question the credibility of Dr. Saed's testimony as to his explanations of these errors, but they do not fundamentally undermine the methodologies Dr. Saed utilized when conducting the cell line testing, itself. While these errors, taken together, may well impact whether Dr. Saed exercised good practices and his credibility, especially since certain mistakes were admitted by Dr. Saed to be improper laboratory conduct, the laboratory notebooks clearly disclosed the methods and procedures used in conducting the experiment. *Cf. 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 (11th Cir. 2013) (excluding expert testimony where expert "failed to document and disclose the procedures he used to

conduct tests").[22] While Defendants point out these errors, what this Court lacks is how these errors impacted the reliability of the conducted studies such that I must exclude Dr. Saed's opinion wholesale. Indeed, having reviewed the multiple entries of the notebooks, I find that careless mistakes and shoddy record keeping occurred. They do not indicate, however, that the actual data collected from the cell lines were unreliable or somehow altered in bad faith. As such, these issues go to the weight of Dr. Saed's opinion and the credibility of his testimony. *Crowley v. Chait*, 322 F. Supp. 2d 530, 540 (D.N.J. 2004) ("*Daubert* does not require that an expert's testimony be excluded simply because he admitted . . . his own mistakes or retracted his false statements."); *see also Oddi*, 234 F.3d at 145-46 (the test of admissibility is not whether a particular scientific opinion has the best foundation or whether it is demonstrably correct); *Mahli, LLC v. Admiral Ins. Co.*, No. 14- 175, 2015 WL 4915701, at *7 (S.D. Miss. Aug. 18, 2015) (holding that any miscalculations or inaccuracies go to the weight of the expert's opinions, not its admissibility); *Aetna Inc. v. Express Scripts, Inc.*, 261 F.R.D. 72, 81 (E.D. Pa. 2009) ("'[F]laws' in an expert's investigative process do not render the opinion excludable. An expert's opinion is suspect when it is based on a 'subjective belief' or 'unsupported speculation' but remains admissible so long as the process used by the expert is reliable."); *Southwire Co. v. J.P. Morgan Chase & Co.*, 528 F. Supp. 2d 908, 935 (W.D. Wis. 2007) (finding that "alleged errors and inconsistencies are grounds for impeaching the credibility of

[22] *See also Hanson v. Colgate-Palmolive Co.*, 353 F. Supp. 3d 1273, 1284–85 (S.D. Ga. 2018) (excluding expert's testimony where he failed to record the location of fibers alleged to be asbestos found in talc).

the experts . . . however, mistakes and miscalculations are not grounds for excluding evidence"); *Phillips v. Raymond Corp.*, 364 F. Supp. 2d 730, 743 (N.D. Ill. 2005) (noting that miscalculations and inaccuracies in an expert's testimony go to weight); *Astra Aktiebolag v. Andrx Pharms., Inc.*, 222 F. Supp. 2d 423, 493–94 (S.D.N.Y. 2002) (finding that the fact that expert's test results had very high standard deviation went to weight, not admissibility); *In re TMI Litigation Cases Consolidated II*, 911 F. Supp. 775, 813 (M.D. Pa. 1996) (the potential rate of error of expert's study goes to weight to be accorded the testimony). Indeed, serious questions have been raised by Defendants which a jury will have to weigh.

In conclusion, the Court will admit the testimony of Dr. Saed, but subject to the limitations outlined above. While Dr. Saed's opinion may not be "supported by the best methodology or available research," *Karlo*, 849 F.3d at 81, or without flaws, I ultimately conclude that in light of my limited role as gatekeeper on a *Daubert* motion, the flaws in Dr. Saed's testing and record keeping do not so undermine the reliability of the doctor's opinion as to warrant exclusion. Defendants have not presented sufficient grounds on which the Court can find that Dr. Saed's opinions, other than his cursory conclusion that the use of talc can cause ovarian cancer, are not "good science" or otherwise "inadmissible junk science." The potential flaws in Dr. Saed's lab practices and the study may well negatively impact the weight that a factfinder gives to Dr. Saed's opinions, but those flaws may be tested by cross-examination, and do not warrant exclusion of Dr. Saed's testimony.

B. Dr. William Longo

Plaintiffs present Dr. Longo as an expert in materials science, who will testify as to the presence of asbestos in Defendants' talc products. Dr. Longo received a Bachelor of Science in microbiology, with a minor in chemistry; a Master of Science in materials science and engineering; and Ph.D. in materials science and engineering from the University of Florida. (Longo *Daubert* Hr'g Tr., at 441.) Dr. Longo explained that materials science "is literally the study of materials[,] both to characterize them, to understand them, and to develop new materials." (*Id.*) Dr. Longo is currently the president of Materials Analytical Services ("MAS"), a company that tests materials for asbestos, among other substances. (*Id.* at 441, 447.)[23] In the late 1980s and early 1990s, Dr. Longo served on the Environmental Protection Agency ("EPA") peer review group for the EPA's asbestos engineering program. (*Id.* at 449.) In that capacity, Dr. Longo collaborated on the creation of the American Society for Testing of Materials ("ASTM") protocol for testing asbestos materials with a transmission electron microscope (ASTM-5755). (*Id.* at 452.) There is no dispute that Dr. Longo is qualified to testify as an expert on the issue of whether the subject talc products contain asbestos. I will note at the outset that while Defendants repeatedly reference Dr. Longo's status as a "professional expert," the fact that he testifies on behalf of plaintiffs regularly raises questions of his credibility, rather than his expertise, which are reserved for the factfinder. *See In re Paoli*, 35 F.3d at 753–54.

In this proceeding, Dr. Longo and MAS tested 72 historical talc samples from

---

[23] Plaintiffs have also designated Dr. Longo's former-assistant, Mark Rigler, as a potential expert in this matter as the coauthor of Dr. Longo's expert report. (*See* Longo *Daubert* Hr'g Tr., at 597–98.)

J&J and Imerys from the 1960's, 1970's, 1980's, 1990's, and the early 2000's for asbestos using two methods: transmission electron microscope ("TEM") and polarized light microscope ("PLM"). (Longo 2d Supp. Rep., Feb. 1, 2019, at 2, 5; *see also* Longo *Daubert* Hr'g Tr., at 473–75.) In short, after performing these tests, Dr. Longo found that "[t]here was a total of 50 positive containers ([TEM] and PLM combined) out of the 72 tested that gave an overall 69 % positive result for the historical [Johnson's Baby Powder/Shower to Shower] containers and Imerys' railroad car samples that were tested for [Dr. Longo's] report." (Longo 2d Supp. Rep., at 32.) Based on this testimony, Dr. Longo opines that "individuals that used Johnson & Johnson talcum powder products (Johnson's Baby Powder and Shower to Shower) in the past, would have, more likely than not, been exposed to significant airborne levels of both regulated amphibole asbestos and fibrous (asbestiform) talc." (*Id.*)

Having considered the parties' arguments and Dr. Longo's *Daubert* hearing testimony, I find that Plaintiffs' have met their burden of demonstrating that the doctor's testimony regarding the results of his TEM analysis is reliable for the purposes of admission under *Daubert*. *See Crowley*, 322 F. Supp. 2d at 537 ("The proponent bears the burden of establishing admissibility by a preponderance of the evidence.") Indeed, the Court finds that Defendants' arguments in support of excluding Dr. Longo's testimony, as to his testing, more appropriately go to the application of his methodologies, rather than their reliability. However, with two critical exceptions as detailed *infra*, the Court excludes Dr. Longo's testimony to the extent he bases his opinions on his PLM analysis or opines on the exposure of talc

users to asbestos.

The Court first addresses the reliability of Dr. Longo's TEM methodology. Dr. Longo testified that he followed the three-step TEM method, a scientifically accepted method when analyzing a material to determine whether it contains asbestos. (*Id.* at 487.) The first step—morphology—involves measurement of "the dimensions of the fiber or bundle of asbestos." (*Id.* at 488.) The second step is "called energy dispersive X-ray analysis [("EDXA") which] determine[s] the chemistry of that particular asbestos structure." (*Id.*) Finally, the third step is "what's called selected area electron diffraction or SAED, which gives you information on the crystalline structure of that asbestos structure." (*Id.*) Defendants do not challenge the reliability of the three-step TEM methodology. That methodology is a generally accepted method in the scientific community and is recommended by the EPA Asbestos Hazard Emergency Response Act ("AHERA"), (*see* Asbestos-Containing Materials in Schools ("AHERA Regs."), 52 Fed. Reg. 41826 (Oct. 30, 1987) (to be codified at 40 C.F.R. pt. 763)); ISO Methods 22262-1 and -2, (*see* Cert. of Tersigni, Ex. A74 (ISO 22262-1); *id.*, Ex. A75 (ISO 22262-2)); and the American Society for Testing Materials ("ASTM") Standard 5755. Notably, Defendants have employed the same three-step TEM analysis for testing their own talc products for asbestos. (*See* Johnson & Johnson, Analysis of Powdered Talc for Asbestiform Minerals by Transmission Electron Microscopy, Mar. 8, 1989, Pls.' Hr'g Binder, Tab 6.)

Instead, Defendants take issue with Dr. Longo's application of the three-step TEM method. First, Defendants maintain that "Dr. Longo's hearing testimony made

clear that his TEM methodology failed to distinguish asbestos particles or asbestiform (an alleged cause of ovarian cancer) from cleavage fragments (which no scientific literature has linked to ovarian cancer)." (Defs.' Post-Hr'g Br., at 33.) Defendants' argument in this regard is based on their disagreement with the "counting rules" used by Dr. Longo in the morphology step of the TEM method. (*See id.* at 33–34.)

The EPA AHERA regulations identify as asbestos any of the designated asbestos minerals (*i.e.*, tremolite, actinolite, or anthophyllite) that are fibrous; the regulations specify that a mineral is fibrous if it has 1) parallel sides; 2) is at least .5 microns in length; 3) and has an aspect ratio of 5-to-1 or greater. (*See* Longo *Daubert* Hr'g Tr., at 467–69.) Defendants argue that Dr. Longo should not have relied upon these regulations, because they were "not designed to distinguish between asbestos and cleavage fragments,"[24] and were instead intended "for asbestos remediation in school buildings, where there is no question that the building previously contained asbestos." (Defs.' Post-Hr'g Br., at 34.) Defendants posit that because these regulations are not "designed" to distinguish cleavage fragments from asbestiform, Dr. Longo's use of the regulations regarding "counting" is unreliable.

At the outset, the Court finds that Dr. Longo's reliance on the AHERA regulations does not render his opinion unreliable. While Defendants contend that the AHERA regulations should not be followed in a situation, such as this, where it is not known whether asbestos is present in the test subject, Defendants do not

[24] A cleavage fragment is a crushed-up piece of non-asbestiform rock. (Longo *Daubert* Hr'g Tr., at 569.) Dr. Longo testified that "a true cleavage fragment is not asbestos," but cleavage fragments may meet the AHERA counting rules. (*Id.* at 569.)

identify different "counting rules" that should be used, or point to any other specific rules used by the scientific community under these circumstances; this is fatal to their argument. *See In re Air Cargo Shipping Servs. Antitrust Litig.*, MDL No. 1775, 2014 WL 7882100, at *17 (E.D.N.Y. Oct. 15, 2014) (finding that the mere fact a party disagrees with an expert's methodology is not a basis for exclusion under *Daubert*), *report and recommendation adopted*, 2015 WL 5093503 (E.D.N.Y. July 10, 2015); *In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d 712, 733-34 (N.D. Ohio 2011) (holding that "[t]he fact that different studies [have] obtained different results does not render [the expert's] opinions 'junk science[,]'" so long as the results are the product of reliable methods).

I stress that, as the Supreme Court has advised, "[t]here are no certainties in science," *Daubert*, 509 U.S. at 590, and establishing reliability does not require Plaintiffs to prove that the assessments of their experts are correct. *See id.* Perceived weaknesses in Dr. Longo's methods, such as those identified here by Defendants, go to weight rather than to admissibility, particularly since Dr. Longo has published numerous peer-reviewed studies in which he applied the AHERA "counting rules" in situations where the substances were not previously confirmed to contain talc. (*See* Longo *Daubert* Hr'g Tr., at 489–96). The Court finds that Dr. Longo's reliance upon the AHERA regulations to designate asbestos minerals does not render his opinions unreliable.

Next, Defendants dispute Dr. Longo's utilization of the AHERA "counting rules" because, they argue, the regulations do not appropriately distinguish between

asbestiform and cleavage fragments, which permits Dr. Longo to include in his findings of what is "asbestos," minerals that do not meet the "universal" definition of asbestos, *i.e.*, the "asbestiform version of six regulated minerals"—chrysotile, crocidolite, amosite, tremolite, anthophyllite, and actinolite. (Defs.' Asbestos Br., at 6, 26.) Defendants further argue that while Dr. Longo accepts the universal definition of asbestos, the AHERA "counting" rules he applies in his study "sweep[] in minerals that cannot be asbestos," including cleavage fragments. (*Id.* at 29.) Plaintiffs counter that Dr. Longo's method was not overinclusive because he "eliminated non-asbestos fibers that did not meet the requisite morphological criteria" and subsequently "subjected the fibers to further analysis by SAED and EDXA to confirm they are asbestos." (Pls.' Post-Hr'g Br., at 62.)

Fundamentally, the dispute between the parties is their disagreement over what fibers should be identified as "asbestos." Defendants take the view that the "counting rules" of the AHERA regulations are, when applied in this instance, overly broad, such that cleavage fragments are counted as asbestos when they are not. On this issue, Dr. Longo explained that during the first step of the TEM testing, the purpose is to count the number of asbestos fibers contained in the talc sample by utilizing the AHERA counting rules. Because certain cleavage fragments do in fact resemble asbestos fiber, Dr. Longo agrees that—at the first step—certain cleavage fragments could be counted as asbestos in accordance with the rules. (*See* Longo *Daubert* Hr'g Tr., at 577–78.) However, Dr. Longo goes on to explain that steps two and three of the TEM eliminate most of those fragments based on their chemistry

and electron diffraction pattern. (*See also id.* at 502 (explaining that an analyst would not identify a fiber until all three TEM steps have been completed); *id.* at 517 (stating that a fragment would not be identified as asbestos if "[i]t doesn't meet one of [the] criteria, the morphology, the EDXA, the chemistry, or the electron diffraction pattern"); *see also id.* at 578.) Defendants' position on this issue does not take into account that steps 2 and 3 of the TEM seek to eliminate certain fibers, which are counted in step 1, that are not asbestos. But, more importantly, Defendants do not challenge whether Dr. Longo performed his counting in accordance with the AHERA counting rules. Indeed, those rules do not eliminate the possibility that cleavage fragments could be included in step 1. Again, Defendants make no suggestion that there are other scientific methods which should have been used in counting asbestos fibers in this instance. Instead, Defendants take issue with the rules themselves. In other words, Defendants contend the AHERA counting rules are not accurate, but yet, they do not identify to which set of rules Dr. Longo should have adhered. What this boils down to is that Defendants raise a scientific disagreement that is not for the Court to decide in its capacity as a gatekeeper under *Daubert*. *See, e.g.*, *W.R. Grace*, 455 F. Supp. 2d at 1199 ("It appears that there is some scientific disagreement as to the dangerousness of cleavage fragments and as to how these fragments should be treated when performing asbestos sampling. It is not the Court's role to settle scientific disputes."); *see also Broe v. Manns*, No. 15-985, 2016 WL 7048988, at *4 (M.D. Pa. Dec. 5, 2016) ("Any disagreement plaintiffs have with the expert can be dealt with through cross-examination, presentation of contrary evidence and proper

jury instructions."); *In re Gabapentin Patent Litig.*, MDL Dkt. No. 1384, 2011 WL 12516763, at *10 (D.N.J. Apr. 8, 2011) (concluding that disagreement between experts regarding application of a methodology presents "a battle of the experts" to be resolved by the trier of fact); *In re Asbestos Prods. Liab. Litig.*, 714 F. Supp. 2d 535, 544 (E.D. Pa. 2010); *In re Diet Drugs Prods. Liab. Litig.*, MDL No. 1203, 2000 WL 962545, at *13 (E.D. Pa. June 28, 2000) (finding that disagreement with the methods used by an expert is a question that "goes more to the weight of the evidence than to reliability for *Daubert* purposes").

In short, I find that the three-step TEM method applied by Dr. Longo, and his reliance on the AHERA counting rules, were reliable; thus, any disagreement with those rules is a question for the jury. *See Walker v. Gordon*, 46 F. App'x 691, 695–96 (3d Cir. 2002). Indeed, the role of this Court on a *Daubert* motion is "simply to evaluate whether the *methodology* used by the expert is reliable, *i.e.*, whether, when correctly employed, that methodology leads to testimony helpful to the trier of fact." *Id.* at 695. Accordingly, the Court declines to exclude Dr. Longo's testimony on the grounds that he improperly counted cleavage fragments as asbestos at step 1 of the TEM method.

Related to their argument regarding inadequacies in the AHERA counting rules, Defendants also argue that the prevalence of "bundles" of asbestos fibers in Dr. Longo's step 1 analysis underscores the unreliability of his methods. (*See* Defs.' Post-Hr'g Br., at 35–36.) A bundle is defined by the EPA as "[a] structure composed of three or more fibers in a parallel arrangement with each fiber closer than one fiber

diameter." AHERA Regs., 52 Fed. Reg. at 41858. The AHERA counting rules provide that asbestos structures may be designated as "fibers, bundles, clusters, or matrices." *Id.* at 41867; *see also* Longo *Daubert* Hr'g Tr., at 524 ("One is not more asbestos than the other. It is all regulated asbestos if it is a fiber bundle or what have you."). Of the asbestos fibers found in the historical talc samples examined by Dr. Longo, 93 % of identified asbestiform are designated as bundles. (Longo *Daubert* Hr'g Tr., at 592.) Defendants' challenge to Dr. Longo's finding of bundles is twofold: (1) the increased prevalence of bundles in Dr. Longo's supplemental expert report constitutes a sudden reversal of opinion that undermines the reliability of his testimony,[25] and (2) that the analysts who conducted the testing had "no objective way of determining whether a particle is a single fiber or bundle." (Defs.' Post-Hr'g Br., at 36.)

The Court again finds that these issues go to the weight of Dr. Longo's opinions,

---

[25] Notably, in a report from March 2018, referenced by Defendants, with respect to testing conducted on Defendants' products, Dr. Longo states that 53% of the identified asbestos were counted as bundles. (*See* Tersigni Cert., Ex. E14; *see also* Tersigni Cert., Ex. E26, at 153.) In that report, Dr. Longo tested 30 talc samples that had been provided to him by various law firms. (*See* Tersigni Cert., Ex. E14, at 4.) Then, in Dr. Longo's expert reports in this MDL proceeding, he classified 96% of the counted asbestos as bundles. (*See* Longo 2d Supp. Rep., Feb. 1, 2019, at 25.) Importantly, in preparation for the MDL reports, Dr. Longo tested different historical samples that were provided by Defendants. (*See id.* at 2 ("The J&J and Imerys' containers and samples analyzed for this report were all supplied by both J&J and Imerys from their historical inventory.").) In that respect, Defendants' position does not take into account that each of these rounds of testing were conducted on *different* talc samples. Accordingly, the Court does not find that the fact Dr. Longo reported different numbers of bundles from different talc samples constitutes a change in opinion. I note that during the *Daubert* hearing, Dr. Longo attempted to address this very issue, however, counsel did not provide the doctor the opportunity to explain this purported discrepancy. (*See* Longo *Daubert* Hr'g Tr., at 592–94.) Hence, in resolving this question, the Court painstakingly reviewed all of Dr. Longo's past reports submitted by the parties, including the ones prepared for the MDL.

rather than reliability. The genesis of Defendants' argument in this context is that Dr. Longo's counting method is inaccurate when it comes to differentiating between bundles and fibers of asbestos. They illustrate the inconsistencies by comparing different images of asbestos structures from Dr. Longo's expert reports and argue that one report classifies certain structures as a fiber, and in the supplemental report, those similar structures are identified as bundles. Putting aside the inconsistencies, the AHERA counting rules, as iterated above, group bundles and fibers alike as asbestos. Simply stated, the rules call for the counting of both structures as asbestos. Indeed, Dr. Longo's explanation in this regard is consistent with the purpose of the rules; he testified that distinguishing between a fiber and a bundle is one of the more difficult aspects of the TEM analysis. But, whether a particular asbestiform is a fiber or bundle does not make any qualitative difference since they are both asbestos. (*See* Longo *Daubert* Hr'g Tr., at 528 (stating that it does not "make a difference whether it is a fiber or bundle in terms of whether it is asbestos").) Significantly, Defendants do not express any views on how the purported inconsistency between the differentiation of bundles and fibers impacts Dr. Longo's overall test results about the quantity of asbestos found in any given historic sample of talc. In fact, Defendants do not dispute that bundles and fibers are both asbestiform that must be counted under AHERA regulations. In short, because bundles and fibers are both qualitatively asbestos, to challenge the reliability of Dr. Longo's testing results, Defendants must explain how the inconsistency impacts the overall study. Simply pointing out that certain asbestiform should be counted as bundles rather than fibers

and *vice versa*, does not somehow impugn Dr. Longo's analysis under step 1 of the TEM.

Moreover, regarding the identification of bundles and fibers, Defendants argue that Dr. Longo and his analysts do not have an objective method to ensure that their counting of bundles and fibers can be replicated. Dr. Longo testified that the AHERA rules, on this issue, are inherently subjective; that is, depending on the analyst and the manner in which he or she conducts the analysis, different analysts may come to differing counting results. To account for this subjectivity, Dr. Longo and his laboratory conducted a quality control study—which is not required under the AHERA regulations—"to measure the error rate of the four TEM analysts counting and looking at the same grid openings and determining how many asbestos structures that they are seeing and identifying compared to the next analyst." (*Id.* at 524–25.) That control study determined the percentage of agreement among the analysts as to whether an asbestos was a fiber or a bundle was 72 % with respect to tremolite, and 83.7 % with respect to anthophyllite. (*Id.* at 526.) Because Dr. Longo, in his view, considered that to be a low percentage of error rate, he was satisfied that his lab was accurately differentiating between bundles and fibers, and more importantly, that the lab was counting these structures as asbestos.[26] (*See id.* at 524–28, 575.) In any event, any errors in differentiating between fibers and bundles, *at step 1 of the TEM*, does not ultimately demonstrate that Dr. Longo's testing is

[26] Putting aside that this control study was not necessary under the AHERA regulations, Defendants do not suggest that these percentages were statistically significant or do not demonstrate a low error rate.

unreliable, because steps 2 and 3 further confirm whether the counted fibers or bundles—at step 1—are asbestos or cleavage fragments.

Accordingly, pursuant to *Daubert*, the Court cannot find that Dr. Longo's counting method in this regard was unreliable. On a threshold level, Dr. Longo's test results as to step 1 of the TEM rest on "good grounds" and are based on reliable scientific methods under the AHERA rules. *See United States v. Mitchell*, 365 F.3d 215, 244 (3d Cir. 2004). To the extent Defendants seek to attack Dr. Longo's opinion in this context, they may do so before a jury, as any purported inaccuracies in his method of counting go more appropriately to the weight of his opinion rather than reliability.

Defendants next challenge the reliability of step 3 of Dr. Longo's TEM methodology—the SAED analysis. A SAED analysis "gives you information on the crystalline structure of [the particular] asbestos structure being examined." (Longo *Daubert* Hr'g Tr., at 489.) According to the AHERA regulations, to which Dr. Longo adhered, SAED is intended to "verify the identification of the pattern by measurement or comparison of the pattern with patterns collected from standards under the same conditions." AHERA Regs., 52 Fed. Reg. at 41870; (Longo *Daubert* Hr'g Tr., at 508). Dr. Longo explained that this final step of the TEM is critical "to distinguish between the fibrous talc and anthophyllite asbestos." (*Id.* at 508.) Defendants disagree with Dr. Longo's approach and contend that his SAED methodology is unreliable because he did not take multiple diffraction patterns at different zone-axis orientations. Defendants further contend that "[i]n order to

uniquely identify a mineral by SAED, the analyst must obtain diffraction patterns from 'near-exact zone axis orientations.'"[27] (Defs.' Asbestos Br., at 52.) In support of their argument, Defendants primarily rely on a TEM protocol authored by Dr. George Yamate in the early 1980s. (*See id.*) I disagree with Defendants' position on this issue.

The SAED methodology that Dr. Longo applied is derived from the AHERA regulations and the more recent ISO standards. These standards have not been challenged by Defendants as unreliable, and indeed, there is no dispute that these standards are generally accepted by the scientific community. Moreover, Dr. Longo testified that ISO Standard 22262-1 specifically provides that "laboratory samples in general seldom require zone axis measurements." (Longo *Daubert* Hr'g Tr., at 512.) That is because, Dr. Longo explained, "the types of asbestos [they were] looking at, beside the anthophyllite, which you should tilt for the two diffraction patterns, either the tremolite series or the anthophyllite series, is fairly straightforward and you are not dealing in unknowns." (*Id.* at 513.) To the extent Defendants disagree with Dr. Longo's methodology and advance that the Yamate protocol is superior—that is an issue for cross-examination.[28] Indeed, this is a classic "battle of the experts" scenario.

---

[27] At the *Daubert* hearing, Dr. Longo testified that "[i]n some cases, some of the analysts did perform zone axis. Our mineralogists will tend to do it from time to time, but it is not required. It is not a required step in the EPA AHERA method other than a typical what we'll call a d-spacing diffraction pattern that allows you to say this is an amphibole." (Longo *Daubert* Hearing Tr., at 507.)

[28] Defendants rely on *Hanson v. Colgate-Palmolive Co.*, 353 F. Supp. 3d 1273, 1285–86 (S.D. Ga. 2018), to support their argument that a zone-axis analysis is required. In that case, the court excluded expert testimony where an expert followed

See In re Gabapentin Patent Litig., 2011 WL 12516763, at *10.

Defendants' final argument with respect to the doctor's TEM analysis relates to the second step of TEM—EDXA. Defendants maintain that Dr. Longo's opinions should be excluded because his EDXA analysis was unreliable and "deliberately designed to be unverifiable." (Defs.' Asbestos Br. at 62.) Specifically, Defendants fault Dr. Longo for omitting certain numerical data from his EDXA graphs. (Defs.' Asbestos Br., at 66.) The EDXA analysis, which is required by the AHERA regulations, involves "compar[ing] spectrum profiles[29] with profiles obtained from asbestos standards. The closest match identifies and categorizes the structure." AHERA Regs., 52 Fed. Reg. at 41887; (Longo *Daubert* Hr'g Tr., at 503). Dr. Longo testified that the AHERA method does not require inclusion of any numerical values of each element because this step "is [solely] a visual comparison [of the profiles] to the asbestos standards." (Longo *Daubert* Hr'g Tr., at 504.) He then went on to explain that the numerical values are similarly not required by the ASTM and ISO methods. (*Id.* at 506.) Defendants do not contest Dr. Longo's visual comparisons of the profiles from the talc samples and the standard asbestos profiles. Instead, they insist that

---

an unreliable "modified Yamate method" that did not involve using step 3 of SAED. Here, Dr. Longo does not rely on the Yamate method and, further, his methodology complies with other generally accepted scientific methodologies for TEM analysis—namely, the EPA's AHERA regulations and ISO Standard 22262-1. Accordingly, I find that the *Hanson* decision does not alter my analysis of this issue.

[29] A spectrum profile is a graph generated by the EDXA that shows "the ratios and levels of different elements that are shown in the mineral." (Longo *Daubert* Hr'g Tr., at 503.)

Dr. Longo should have included certain numeric data that Defendants, themselves, have not disputed are not required under the relevant standards. These numeric data, Defendants posit, are essential to verify Dr. Longo's results. However, because Defendants' challenge does not go to the reliability of the methodologies employed by Dr. Longo, this is, again, an issue for cross-examination. Defendants may present evidence and argue to the jury as to why this numeric data is important, even though generally accepted scientific methods do not require it. Hence, the Court will not exclude Dr. Longo's testimony on this ground.

However, the same does not hold true as to Dr. Longo's testing using the PLM methodology. Because I find Dr. Longo's testing in this context unreliable, I exclude any portions of his proposed testimony related to the results derived from the PLM testing. I note that while Dr. Longo was not required by any of the relevant scientific methods to use the PLM methodology, he nevertheless conducted the PLM analyses to further support his results under the TEM. In his report, Dr. Longo explains that "[t]he PLM method is primarily used today for the analysis of asbestos-added products where the asbestos-content of these products are typically over 1% by weight." (Longo 2d Supp. Rep. at 5.) Dr. Longo states:

> The strengths of the method are that it can positively identify the different regulated asbestos mineral types and provide a qualitative estimate of the weight percent of asbestos. The primary weaknesses of the method are 1) analytical sensitivity issues for samples that may contain less than 0.1 wt. % of asbestos such as cosmetic talcs and 2) because asbestos fiber and bundle structure resolution in the PLM method is dependent on the wave length of light, asbestos particles must be at least 0.5 um in the smallest dimension to be visible. . . . For [this] analysis the

ISO 22262-1 PLM method was used.

(*Id.* at 5.) In addition to the ISO 22262-1 PLM methodology, Dr. Longo conducted a heavy liquid separation before conducting the PLM analysis because it "increase[es] the analytical sensitivity of the PLM analysis for cosmetic grade talc." (*Id.* at 5.)

Defendants argue that Dr. Longo should have followed the PLM methodology set forth in ISO 22262-2, as opposed to ISO 22262-1.[30] Defendants assert that ISO 22262-1 states that "when the asbestos concentration found is between 0% and 5% and 'it is necessary to make critical decisions on the basis of the results' (including a result of 'non-detected') then ISO 22262-2 should be used." (Defs.' Asbestos Br., at 74.) Indeed, Defendants correctly point out that under the more powerful TEM microscope, Dr. Longo claimed to have detected asbestos at concentrations ranging from .0092% on the high end to .0000033% on the low end. With this ultra-trace amount of asbestos, there is no conceivable reason why Dr. Longo determined that the ISO 22262-1 standard was appropriate for testing cosmetic talc. Tellingly, nowhere in Dr. Longo's expert report, his testimony, or even Plaintiffs' opposition papers, is there an explanation as to why Dr. Longo used ISO 22262-1. To quote Dr. Longo, the "primary weakness" of this method is "the analytical sensitivity issues for samples that may contain less than 0.1 wt. % of asbestos, such as cosmetic talcs."

[30] The Court's analysis of whether ISO 22262-1 should have been utilized in the context of PLM method does not impact Dr. Longo's usage of ISO 22262-1 in conducting his TEM analysis. Both ISO 22262-1 and ISO 22262-2 set forth separate standards for testing asbestos in materials using TEM and PLM. *See* Cert. of Tersigni, Ex. A74 (ISO 22262-1); *id.*, Ex. A75 (ISO 22262-2). Importantly, while Defendants challenge Dr. Longo's use of ISO 22262-1 with respect to his PLM analysis, they do not do so as to his use of the ISO standards in the TEM testing.

(Longo 2d Supp. Rep. at 5.) Even having so admitted, Dr. Longo, nevertheless, used this standard to perform his PLM analyses.

Significantly, this very decision is contrary to Dr. Longo's view prior to this litigation, as demonstrated by the following *Daubert* hearing testimony:

> Q. Prior to issuing your MDL report, you had not used PLM in your initial report. Correct?
>
> A. That is correct.
>
> Q. And in fact you were of the opinion back then in 2017 and 2018 that PLM basically wasn't going to work. Correct?
>
> A. Using the standard method, yes ma'am.
>
> Q. You were of the opinion that PLM was not appropriate for this kind of cosmetic talc analysis. Correct?
>
> A. That is correct.

(Longo *Daubert* Hr'g Tr., at 606–07.) The fact that Dr. Longo changed his view regarding the use of PLM to test cosmetic talc for asbestos solely for the purposes of this litigation, and combined with the lack of an appropriate explanation as to why ISO 22262-1 was used, I cannot find, on these bases, that Dr. Longo's PLM testing is reliable under *Daubert*.

What is more, as Defendants further point out, Dr. Longo's PLM methodology is unreliable because it was replete with subjectivity and reproducibility problems. Dr. Longo explained at the *Daubert* hearing that pursuant to the PLM methodology, for positive asbestos samples, the quantity of asbestos in the samples was determined by visual examination "based on past standards, based on petrographic that show

what the various percentages are." (Longo *Daubert* Hr'g Tr., at 611–13.) These standards (weight percentages) were generated by MAS and were not produced to Defendants. (*Id.* at 614.) Defendants argue that because Dr. Longo did not disclose this information in connection with his expert report, replication of Dr. Longo's testing is difficult. I agree. Dr. Longo was questioned on the stand during the *Daubert* hearing as to why he did not disclose the weight percentages. (*Id.* at 611–615.) He did not have an adequate explanation. This is troubling, because the weight percentages are central to the asbestos analysis under the PLM; indeed, these percentages were used by individual lab analysts to determine the amount of asbestos in a given sample. Without that information, which is internally created by MAS, reproducing Dr. Longo's test under the PLM would not be possible, and hence, the testing is unreliable.

This reproducibility issue was made plain by Dr. Longo's decision to have a third-party laboratory replicate his findings. Dr. Longo requested Dr. Lee Poye of J-3 Laboratory ("J-3") to perform a PLM analysis using the same ISO 22262-1 method on 22 of the historical talc samples. (*See* Longo *Daubert* Hr'g Tr., at 618.) However, J-3's PLM analysis was negative for asbestos for each sample. (Longo 2d Supp. Rep. at 20.) While Dr. Longo attempted to explain away why this discrepancy occurred, he nevertheless conceded that "[t]hese differing results between the two labs will require further investigation to understand the reason for these differences." (Longo 2d Supp. Rep. at 5.) Again, Dr. Longo had no explanation. This underscores the very real reliability and reproducibility issues plaguing Dr. Longo's PLM testing. As such,

Dr. Longo is not permitted to testified as to his testing results under the PLM.

Finally, Defendants argue that Dr. Longo's testimony should be excluded as it is irrelevant to the issue of general causation because he failed to conduct any sort of exposure analysis. (Defs.' Post-Hr'g Br., at 40.) This argument specifically challenges Dr. Longo's opinion "that individuals who used Johnson & Johnson talcum powder products (Johnson's Baby Powder and Shower to Shower) in the past would have, more likely than not, been exposed to significant airborne levels of both regulated amphibole asbestos and fibrous (asbestiform) talc." (Longo 2d Supp. Expert Rep., at 32.) Dr. Longo opines as such, despite the fact that he has described the amount of talc in Defendants' products as "ultra-trace." (*See* Longo *Daubert* Hr'g Tr., at 559–61.) Indeed, Dr. Longo and the MAS analysts have found asbestos levels of less than one percent in the asbestos products tested. (*See id.* at 559.) Defendants cross-examined Dr. Longo on this issue at the *Daubert* hearing:

> Q. And what you state in your report, Doctor, is that you were of the opinion that individuals who used Johnson & Johnson talcum powder products in the past would have more likely that not been exposed to significant airborne levels of both regulated amphibole asbestos and fibrous asbestiform talc. Right?
>
> A. That's correct.
>
> Q. So it is your opinion that individuals who used this product have a significant exposure. Correct?
>
> A. Yes.
>
> Q. But you haven't done in this MDL an exposure analysis. Correct?
>
> A. Not with these samples, no.

Q. Meaning you have not calculated, Dr. Longo, whether or not it is even possible for those ultra, ultra trace levels that we just looked at to make it out of a bottle and into a human being who is using that product as a consumer. Correct?

A. We haven't done that study. If it is in the bottle, and even though those, quote, ultra, trace concentrations are still very significant, it is going to get out of the bottle, will get it up in the air, and be in the breathing zone.

THE COURT: How do you use the term "significance"?

THE WITNESS: I term it as, can we measure it? So it is 10 to 20 times above background. In this case, there is very little to no background involving tremolite and anthophyllite. It is not on a health basis. It is, is there an exposure?

. . .

Q. You just said 10 to 20 times above background. The fact of the matter here, as it relates to the MDL samples, you haven't measured or calculated anything at all?

A. Not with the MDL samples.

Q. And it is not that your facility at MAS doesn't know how to do an exposure simulation, Right?

A. Right. We have done those, not with the MDL samples.

THE COURT: What was your opinion based on; it was significant in the MDL?

THE WITNESS: That it is significant in that they would have had an exposure that more than half of the samples that we measured were positive for asbestos. We have done exposure calculations in the past with Johnson & Johnson in which we have calculated these exposures with Johnson & Johnson products and made a measurement.

THE COURT: How about these samples that you were given?

THE WITNESS: No, ma'am.

(Longo *Daubert* Hr'g Tr., at 560–62.)

The Court agrees that Dr. Longo has not presented "good grounds" for this opinion. Dr. Longo fails to offer any scientific support for his opinion that the use of Defendants' talc products causes exposure, let alone significant exposure, to asbestos. It is well-established that "nothing in either *Daubert* or the Federal Rules of evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). In that connection, "[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Id.* By failing to conduct an exposure analysis, Dr. Longo's opinion on the likelihood that talc users were exposed to "significant" amounts of asbestos, and indeed, any exposure, is too attenuated from his findings of trace levels of asbestos in talc. Accordingly, Dr. Longo is not permitted to testify as to this opinion at any trial in this matter.

Nevertheless, the Court finds that Dr. Longo's remaining opinion on the presence of "ultra-trace" asbestos in Defendants' talc products is still admissible as useful to the trier of fact. Indeed, the issue of whether there is asbestos, and the amount of asbestos, in Defendants' talc products are key issues in this litigation. For example, Plaintiffs' epidemiology experts rely upon Dr. Longo's report for the assumption that Defendants' talc products contain asbestos to support their opinions that talc use is associated with ovarian cancer. (*See* McTiernan Expert Rep., at 57; Carson Expert Rep., at 5; Clarke-Pearson Expert Rep., at 6.) Hence, the Court, in its discretion, only excludes Dr. Longo's opinion on exposure. *See In re Pfizer*, 819 F.3d

at 665 ("When faced with expert testimony that contains both reliable and unreliable opinions, district courts often exclude only the unreliable testimony."). In that connection, to the extent that other Plaintiffs' experts in this litigation rely upon Dr. Longo's findings, their reliance will be limited solely to his finding that Defendants' talc products contain asbestos, and they cannot rely on his opinion that talc users were exposed to asbestos.

C. Plaintiffs' General Causation Experts

The following three experts testified on behalf of Plaintiffs on the issue of general causation, *i.e.*, whether use of talc products can cause ovarian cancer: Dr. Anne McTiernan, an epidemiologist; Dr. Daniel Clarke-Pearson, a gynecologic-oncologist; and Dr. Arch Carson, a toxicologist (the "general causation experts"). A plaintiff in a products liability action must prove both general and specific causation. *In re Zoloft (Sertralinehydrochloride) Products Liab. Litig.*, 176 F. Supp. 3d 483, 491 (E.D. Pa. 2016). Specifically, "[g]eneral causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual's injury." *Id.* Generally speaking, "epidemiology is the best evidence of general causation in a toxic tort case." *Id.* (quoting *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005)).

Because the parties address the admissibility of these experts collectively, the Court, first, sets forth the experts' qualifications and opinions, and then determines the admissibility of those opinions under *Daubert*.

i. The Experts

a. Dr. Anne McTiernan, Ph.D., M.D.

Dr. McTiernan is proffered as an expert in epidemiology. She completed a Ph.D. program in epidemiology at the University of Washington Seattle in 1982. (McTiernan *Daubert* Hr'g Tr., at 715.) She obtained her medical degree at New York Medical College in 1989, and thereafter, did a residency in internal medicine at the University of Washington in 1992. (*Id.*) Dr. McTiernan currently serves as a member of the Fred Hutchison Cancer Research Center in Seattle, Washington, where she conducts epidemiologic research, identifies risk factors for women with respect to breast and ovarian cancer, and studies "prevention methods to reduce population and other markers of cancer risk." (*Id.* at 716.) The doctor is also a research professor in the epidemiology and gerontology and geriatric medicine departments at University of Washington Schools of Medicine and Public Health. (*Id.*) The Court finds that Dr. McTiernan is qualified to act as an expert in epidemiology.[31]

Dr. McTiernan opines that use of talcum powder products in the female genital perineal area can increase the risk of, or indeed cause, ovarian cancer. (*Id.* at 720.)

---

[31] Defendants attempt to present Dr. McTiernan's opinions as unreliable and "made for litigation" based on the fact that Dr. McTiernan met with Plaintiffs' counsel before testifying before Congress regarding the alleged connection between talc and ovarian cancer. (*See* Defs.' Post-Hr'g Br., at 78.) The Court is unconvinced that this undermines the reliability of Dr. McTiernan's testimony. As set forth below, the Court finds that Dr. McTiernan reliably applied the Bradford Hill factors and considered the body of epidemiologic evidence. To the extent Defendants wish to explore any possible biases of Dr. McTiernan's opinions and/or testimony, that is an issue for cross-examination. *See Venus*, 2017 WL 2364192, at *17; *see also infra*, note 32.

Dr. McTiernan explained her methodology, which included formulating a question to answer, *i.e.*, (1) "What is the association between talcum powder products and ovarian cancer," and (2) "can the use of talcum powder products cause ovarian cancer." (*Id.* at 726.) Dr. McTiernan then conducted a systematic review of the available evidence – "in this case, epidemiologic evidence, and [she did] a careful [search] through a database and through relevant journal articles to make sure [she had] the totality." (*Id.* at 726–27.) She then reviewed the data and in doing so

> considered the statistical data, the strength and weaknesses of study type, the effect of possible bias, chance, confounding and differences in exposure measures. [She] considered dose-response . . . . [She] also considered data from non-epidemiologic lines of evidence, such as animal, cell, clinical and pathological studies. [She] considered non-talc components of talcum powder products and impact on carcinogenicity such as asbestos, fibrous talc, heavy metals, and fragrances.

(*Id.* at 727–28.) Dr. McTiernan explained that her opinion was based "on the statistically significant elevated risk seen with the epidemiology data when they are combined, the pathological evidence, the consistency of results across geographic areas, and in different race and ethnic groups, evidence of a positive dose-response effect and the plausible biological mechanism." (*Id.*) Dr. McTiernan further extracted certain information from the studies, including

> the study characteristics that would be most important to know about the breadth and depth of the individual studies, particularly to be able to know how large the study was, where it was conducted, when it was conducted, how many cases were included, how many people without cancer were included, if it was a cohort, [and] how long it had been followed. [She] looked at dose-response. The key metric is relative risk. Relative risk is clearly the

> important element. And [she] also looked at the statistical testing on cancer subtype.

(*Id.* at 728–29.) Based on that information, Dr. McTiernan conducted a Bradford Hill analysis[32] "to assess for causality" and based on her independent judgment and weight of the relevant evidence, she reached her conclusion "that use of talcum powder products, including Johnson & Johnson Baby Powder and Shower to Shower, in the genital perineal area can cause ovarian cancer." (*Id.* at 720.)

b. Dr. Daniel Clarke-Pearson

Dr. Clarke-Pearson has been presented as an expert in gynecologic oncology. (Clarke-Pearson *Daubert* Hr'g Tr., at 1519.) Dr. Clarke-Pearson received a Bachelor of Science in biology from Harvard University and an M.D. at Case Western University. (*Id.*) He completed both a residency in obstetrics/gynecology and a fellowship in oncology at Duke University Medical Center. (*Id.*) Following his fellowship, for 18 years, the doctor was part of the faculty at Duke University. (*Id.*) During his career in academic medicine, Dr. Clarke-Pearson has published approximately 250 peer-reviewed publications, most of which "are in the field of gynecologic oncology, and some have dealt with ovarian cancer, in particular, clinical trials describing advances in the treatment of ovarian cancer." (*Id.* at 1523.) Dr. Clarke-Pearson is qualified to act as an expert in this matter.

Dr. Clarke-Pearson followed a similar methodology as Dr. McTiernan. He first

---

[32] A Bradford Hill analysis involves consideration of the Bradford Hill criteria, "which are nine factors widely used in the scientific community to assess general causation." *Gannon v. United States*, 292 F. App'x 170, 172–73 (3d Cir. 2008).

conducted a literature search and reviewed the epidemiological studies, including "case-control studies, cohort studies, pooled studies, and meta-analyses." (*Id.* at 1531.) Dr. Clarke-Pearson explained that based on his "extensive research," he "believes that genital application of talcum powder, such as Johnson & Johnson's Baby Powder and Shower to Shower, increases the risk of epithelial ovarian cancer in all women and can cause epithelial ovarian cancer in some women." (*Id.* at 1530.) The doctor also applied a Bradford Hill causation analysis to reach his conclusion, which is "similar to what I do in medicine with an evidence-based medicine decision analysis to come to the conclusion what's best to treat a patient." (*Id.*)

c. Dr. Arch Carson

Dr. Carson is offered as an expert in toxicology. Dr. Carson is an associate professor at the University of Texas School of Public Health and "a physician scientist who specializes in medical toxicology." (Carson *Daubert* Hr'g Tr., at 1258.) He received an M.D. from Ohio State University and a Ph.D. in toxicology from the Kettering Laboratory at the University of Cincinnati. (Carson Expert Rep., at 1.) The doctor is currently an Associate Professor at the University of Texas School of Public Health and the Program Director of the Occupational and Environmental Medicine Residency training program at the University of Texas Health Center in Houston, Texas. (*Id.*) Dr. Carson's professional activities "have included patient care, basic and applied research, teaching of medical students, graduate students and post-graduate medical trainees, and professional consulting." (*Id.*) Dr. Carson has also been the Program Director of the National Institute for Occupational Safety and

Health-funded Education and Research Center at the University of Texas for 19 of the past 21 years. (*Id.*) Based on his professional background, I find that Dr. Carson is qualified to testify as an expert. [33]

In this proceeding, Dr. Carson opines that

> Johnson's Baby Powder and Shower to Shower pose a significant health hazard. The epidemiological studies show me that there is a consistent positive relationship between the genital use of talcum powders and about a 30 percent increase in ovarian cancer. Talcum powder clearly migrates through the female reproductive tract when it's applied to the perineum and exposes the ovaries.
>
> Inhalation of dust during those applications is a potential secondary route. Talcum powder produces chronic inflammation in the tissues in which it contacts and is sequestered.
>
> Johnson's Baby Powder and Shower to Shower contain mineral fibers including asbestos and fibrous talc that intensifies this exposure, and the inflammatory responses including cell growth and proliferation.
>
> Johnson's Baby Powder and Shower to Shower are

[33] Despite the Third Circuit's liberal approach to Rule 702's qualification requirement, *see Pineda*, 520 F.3d at 244, Defendants raise certain challenges to Drs. McTiernan's and Carson's qualifications. Specifically, Defendants argue that Drs. McTiernan and Carson are not qualified to opine on certain issues that go outside their areas of stated expertise, epidemiology and toxicology, respectively. (*See* Defs.' Qualifications Br., at 3–5, 17–19.) For example, Defendants claim that Dr. McTiernan is not an oncologist or gynecologist such that she can opine on issues related to biological plausibility, and that Dr. Carson cannot opine on epidemiology. I disagree and decline to exclude these experts on that basis. As Defendants candidly conceded in their brief, it is well-accepted that an expert should not be excluded "merely because the court feels that the expert is not the best qualified or that the expert does not possess the most appropriate specialization." *In re Human Tissue*, 582 F. Supp. 2d at 655. As set forth in detail *supra*, Plaintiffs have sufficiently demonstrated that Drs. McTiernan and Carson are qualified to conduct a Bradford Hill analysis utilizing various epidemiological data.

> carcinogenic, and I believe the regular genital use of Johnson's Baby Powder and Shower to Shower can cause epithelial ovarian cancer.

(*Id.* at 1259–60.) Dr. Carson reached this conclusion by performing a "step-by-step risk assessment process that is similar to the one that is used by the National Institute for Occupational Safety and Health." (*Id.* at 1261.) That process involved "identification of the hazard followed by assessment of whether or not there is potential for exposure, then assessment of response to what is known of regarding response to that exposure, and then characterization of the risk." (*Id.*) Dr. Carson also performed a Bradford Hill analysis, through which he determined that "genital application of talcum powder over time raises the risk of ovarian cancer in everyone exposed and causes ovarian cancer in some of the people who are exposed." (*Id.* at 1310.)

ii. The Experts' Bradford Hill Analyses

Plaintiffs' experts formed their general causation opinions using the Bradford Hill criteria, "which are nine factors widely used in the scientific community to assess general causation." *Gannon*, 292 F. App'x at 172–73. Those nine factors are (1) temporal relationship; (2) strength of association; (3) dose-response relationship; (4) replication; (5) biological plausibility; (6) consideration of alternative explanations; (7) cessation of exposure; (8) specificity of the association; and (9) consistency with other knowledge. Michael D. Green, et al., *Reference Guide on Epidemiology,* in *Reference Manual on Scientific Evidence* 549, 600 (Fed. Jud. Ctr., 3d Ed. 2011).[34]

[34] The Court relies on the *Reference Guide on Epidemiology* for guidance on how

In weighing the Bradford Hill factors, the general causation experts conducted a review of the available epidemiologic studies, which included 28 case control studies, 3 cohort studies, 3 meta-analyses, and 1 pooled analysis. Both case control and cohort studies are observational studies. *See id.* at 556–57. The difference between case-control and cohort studies is "that cohort studies measure and compare the incidence of disease in the exposed and unexposed ('control') groups, while case-control studies measure and compare the frequency of exposure in the group with the disease (the 'cases') and the group without the disease (the 'controls')." *Id.* at 557. A meta-analysis aggregates information from published studies and "collects this number called relative risk from different studies and they combine those relative risks so that they could have one relative risk. It gives you a very big summary of what the literature looks like overall." (McTiernan *Daubert* Hr'g Tr., at 733.) A pooled analysis "is where individual level data are obtained from the individuals in the study" and the "data then are analyzed as if it is one large study," creating a

---

a Bradford Hill analysis is conducted in the scientific community. This guide is a part of a series of guides included in the *Reference Manual on Scientific Evidence*, promulgated by the Federal Judicial Center. The Manual's purpose is "to provide the tools for judges to manage cases involving complex scientific and technical evidence." Fed. Judicial Ctr., *Reference Manual on Scientific Evidence*, at xv (3d ed. 2011). Indeed, the *Reference Guide on Epidemiology* has been relied upon by many courts in this Circuit in assessing the admissibility of an experts' Bradford Hill analysis. *See, e.g.*, *Rowland v. Novartis Pharms. Corp.*, 9 F. Supp. 3d 553, 562 n.21 (W.D. Pa. 2014); *Pritchard v. Dow Agro Sciences*, 705 F. Supp. 2d 471, 484 (W.D. Pa. 2010); *In re Human Tissue*, 582 F. Supp. 2d at 663; *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 590 (D.N.J. 2002). Various Courts of Appeals have also cited to the Guide in assessing the reliability of an expert's general causation analysis. *See, e.g.*, *Goodpaster v. City of Indianapolis*, 736 F.3d 1060, 1068 n.1 (7th Cir. 2013); *McClain v. Metabolife Inter., Inc.*, 401 F.3d 1233, 1239 (11th Cir. 2005); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005).

summary of the statistics. (*Id.* at 734.)

As a general matter, "consideration of the Bradford Hill factors is a reliable method for determining causation." *In re Roundup Prods. Liab. Litig.*, 390 F. Supp. 3d 1102, 1130 (N.D. Cal. 2018); *see also In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 795 (3d Cir. 2017) (acknowledging that the Bradford Hill analysis is "generally reliable"); *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1235 n.4 (9th Cir. 2017) ("The Bradford Hill methodology refers to a set of criteria that are well accepted in the medical field for making causal judgments."). Nevertheless, the Third Circuit has cautioned that "despite the fact that the methodology is generally reliable, each application is distinct and should be analyzed for reliability." *Zoloft*, 858 F.3d at 795. Accordingly, the *Zoloft* court held that "the specific techniques by which the weight of the evidence/Bradford Hill methodology is conducted must themselves be reliable according to the principles articulated in *Daubert*." *Id.* at 796. In other words, "the 'techniques' used to implement the [Bradford Hill] analysis must be 1) reliable and 2) reliably applied." *Id.*[35]

Defendants argue that the Bradford Hill analyses conducted by Plaintiff's general causation experts are "unreliable and conclusion driven." (*See* Defs.' General Causation Br., at 31.) In response, Plaintiffs maintain that the experts' analyses are

[35] In assessing the experts' analyses of the Bradford Hill factors, the Court refers to case law outside of the Third Circuit. While a number of district courts in this circuit have examined these factors, they do not discuss each factor with the type of detailed analysis that this Court is called upon to conduct here. Moreover, there is a dearth of case law in the Third Circuit on these issues. Accordingly, where appropriate, the Court seeks guidance from out-of-circuit cases.

reliable under *Daubert* and that Defendants' arguments go only to the weight of their testimony. (Pls. General Causation Br., at 75–76.) Below, the Court addresses the reliability of the experts' applications of each Bradford Hill factor.

a. Strength of Association

The strength of association factor asks "[h]ow strong is the association between the exposure and disease." Green, *supra*, at 602. Strength of an association may be measured in terms of "relative risk," which is the approach taken by Plaintiffs' experts. *See id.* at 566. Relative risk "is defined as the ratio of the incidence rate . . . of disease in exposed individuals to the incidence rate in unexposed individuals." *Id.*

Plaintiffs' general causation experts placed significant weight on the strength of association factor, finding a 1.2 to 1.6 relative risk. Dr. McTiernan explains in her expert report:

> The meta-analyses and pooled analysis showed that risk of ovarian cancer among users of talcum powder products is 22-31% higher than in women who never used these products. A total of 28 case-control studies, 3 prospective cohort studies, 2 meta-analyses, and one pooled analysis were reviewed in depth. The meta-analyses found a statistically significant 24-25% increased risk of developing serous ovarian cancer—representing 52% of epithelial ovarian cancer cases—in women who had ever used talcum powder products compared with never users. The pooled analysis, which included data from 5 previously published and 3 unpublished case-control studies, found similar statistically significant increased risks for overall epithelial ovarian cancer and serous ovarian cancer (24% and 20%, respectively). Thus, when combining these studies through meta-analyses, the totality of the evidence shows a statistically significant increased risk of ovarian cancer with use of perineal talcum powder products. Viewed in the context of the high consistency of the study results across time, diverse study populations, and strong

> study designs, bias and chance as explanation for the increased risk are unlikely. Further, my confidence in the reliability of the data on magnitude of the risk is enhanced. Therefore, my analysis of these studies strongly supports a causal association and, given the high prevalence of the use of talcum powder products in this population, these levels of risk present a clinically significant public health concern. [I] placed high weight on this aspect of determination of causality.

(McTiernan Expert Rep., at 63–64 (footnote omitted).) Drs. Clarke-Pearson and Carson, for similar reasons, afford this factor significant weight in their Bradford Hill analyses. (*See* Clarke-Pearson Expert Rep., at 8; Carson Expert Rep., at 8–9.)

Defendants argue that these experts' opinions with respect to this Bradford Hill factor are unreliable because "they mischaracterize the objective magnitude of the association reported in the studies and rest on inapposite comparisons to causal relationships." (Defs.' Post-Hr'g Br., at 18.) They further argue that while the experts opine that the association between use of talc products and ovarian cancer is strong, it is in fact, objectively weak. (*Id.* at 15–16.) In that connection, Defendants maintain that at least one court has recognized the 1.2 to 1.6 relative risk identified by the experts as "a weak, not strong, association by any objective measure." (Defs.' General Causation Br., at 32 (citing *Carl v. Johnson & Johnson*, Nos. ATL-L-6546-14, ATL-L-6540-14, 2016 WL 4580145, at *18 (N.J. Super. Ct. Law Div. Sept. 2, 2016).)[36]

[36] *Carl* is a parallel New Jersey mass tort litigation involving perineal talc use and ovarian cancer. The court in *Carl* issued its decision in 2016, excluding the epidemiological experts presented by the plaintiffs in that matter, prior to a significant number of additional studies and testing having been conducted, and more data having been published, on the possible link between talc use and ovarian cancer. Importantly, the epidemiological experts presented in *Carl* are different than those presented by Plaintiffs in the instant matter. Indeed, the experts in this case, at

Defendants further fault Plaintiffs' causation experts for relying primarily on case-control studies, as opposed to cohort studies, which Defendants maintain provide more reliable results. (*See* Defs.' General Causation Br., at 34–41.)

I find that the opinions of the general causation experts with respect to this factor are admissible. The experts, both at the *Daubert* hearing and in their expert reports, provided good grounds for their decisions to place significant weight on the strength of association factor. Defendants have not presented any compelling grounds for the Court to find otherwise. First, Defendants' argument with respect to whether the association is "weak" or "strong" is one that goes to the weight of the experts' testimony, not the reliability.

Relative risk is the foundation of the strength of association factor and "[d]etermining the relative risk is important in understanding the results of a study because virtually every disease associated with a risk factor also occurs, at some rate, in the general population not exposed to the risk factor." *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 591 (D.N.J. 2002). The *Reference*

---

arriving their conclusions, relied upon epidemiological studies that have been released since *Carl*. *See*, *e.g.*, Taher, et al., *Critical Review of the Association Between Perineal Use of Talc Powder and Risk of Ovarian Cancer*, 90 Reproducers. Toxicol. 88 (2019); Penninkilampi, et al., *Perineal Talc Use and Ovarian Cancer: A Systematic Review and Meta-Analysis*, 29(1) Epidemiology 41 (2018); Berge, et al., *Genital Use of Talc and Risk of Ovarian Cancer: A Meta-Analysis*, 27(3) Eur. J. Cancer Prev. 248 (2018); Schildkraut, et al., *Association Between Body Powder Use and Ovarian Cancer: The African American Cancer Epidemiology Study*, 25(10) Cancer Epidemiol. Biomarkers Prev. (2016). But, more importantly, one crucial difference between the proofs of causation in *Carl* and in this MDL, is the theory of asbestos and the biological testing conducted in light of the alleged presence of asbestos in talc products, which was not done in *Carl*.

Guide on Epidemiology explains that relative risk can be interpreted as follows:

> If the relative risk equals 1.0, the risk in exposed individuals is the same as the risk in unexposed individuals. There is no association between the exposure to the agent and disease.
>
> If the relative risk is greater than 1.0, the risk in exposed individuals is greater than the risk in unexposed individuals. There is a positive association between exposure to the agent and the disease, which could be causal.
>
> If the relative risk is less than 1.0, the risk in exposed individuals is less than the risk in unexposed individuals. There is a negative association, which could reflect a protective or curative effect of the agent on risk of disease.

Green, *supra* at 567 (footnotes omitted). A relative risk of 2.0 means the risk has doubled, "indicating that the risk is twice as high among the exposed group as compared to the non-exposed group." *Magistrini*, 180 F. Supp. 2d at 591. In epidemiology, there is, however, no threshold, or a magical number, of a relative risk that must be found in order to place significant weight on the strength of association factor. Indeed, "[a] relative risk of 2.0 is not so much a password to a finding of causation as one piece of the evidence, among others for the court to consider in determining whether an expert has employed a sound methodology in reaching his or her conclusion." *Magistrini*, 180 F. Supp. 2d at 606 (quoting *Landrigan v. Celotex Corp.*, 127 N.J. 404, 419 (1992)).[37] Courts may also "consider whether the authors of

[37] I note that in the context of relative risk, courts have endorsed "a flexible *Daubert* inquiry rather than bright-line rules." *Pritchard*, 705 F. Supp. 2d at 486 (concluding that "a relative risk of 2.0 is not dispositive of the reliability of an expert's opinion relying on an epidemiology study, but it is a factor, among others, which the Court is to consider in its evaluation"). Accordingly, in the context of relative risk on

the study found the association to be statistically significant and, where the authors found an association to not be statistically significant, an opinion may be unreliable." *Pritchard*, 705 F. Supp. 2d at 486.

The question of whether the relative risk found by Plaintiffs' experts can be categorized as "strong" or "weak" is best left to the jury. As to reliability, the Court's inquiry, here, must focus on whether the experts used a sound methodology in reaching their conclusion that the relative risk range of 1.2 to 1.6 demonstrates a risk association between talc powder use and ovarian cancer. Defendants do not challenge the experts' basis for this conclusion, and in fact, do not suggest that the experts' calculation of relative risk, based on the aggregate studies, was not reliably reached. Instead, they focus solely on whether the relative risk can be characterized as objectively "weak" or "strong." In Defendants' view, a range of 1.2 to 1.6 is a weak indicator of associational risk. But, the resolution of that dispute is a question that goes to the weight of the evidence. As previously explained, the Court is satisfied that Plaintiffs' general causation experts employed a sound methodology in deciding to place a significant weight on the "strength of association" factor. The experts

---

a *Daubert* motion, the Court's role is to determine whether the expert has reliably arrived at, based on sound scientific methods, a relative risk that in his or her view could be clinically significant. *See, e.g., Pick v. Am. Med. Sys., Inc.*, 958 F. Supp. 1151, 1160 (E.D. La. 1997) ("A relative risk above 1.0 is statistically significant, even if not sufficient, by itself, to establish causation by a preponderance of the evidence."); *Miller v. Pfizer Inc.*, 196 F. Supp. 2d 1062, 1079 (D. Kan. 2002) (declining to find, as a matter of law, that a relative risk must be above a certain number to be clinically significant). Of course, the greater the relative risk, the stronger an association would be, and indeed, if the relative risk is 2.0, the "agent was more likely than not the cause of an individual's disease." *Magistrini*, 180 F. Supp. 2d at 591.

examined, as they must, the totality of the available epidemiological evidence on talc use and ovarian cancer, and drew conclusions based on sound scientific reasoning. Even if the range of relative risk given by Plaintiffs' causation experts is found not to be objectively "strong," it is not for the Court to decide whether they reached the correct conclusion on strength of association or to otherwise disagree with their opinions. *See Daubert*, 509 U.S. at 595 (noting that the court's focus "must be solely on principles and methodology, not on the conclusions that they generate"). In fact, to do so would unnecessarily broaden the scope of this Court's role as a gatekeeper. *See In re Viagra Prods. Liab. Litig.*, 572 F. Supp. 2d 1071, 1081 (D. Minn. 2008) ("[O]n a *Daubert* motion involving general-causation evidence in an MDL matter, lack of statistical significance under some circumstances 'does not detract from the reliability of the study.'" (quoting *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.,* MDL No. 1407, 289 F. Supp. 2d 1230, 1241 (W.D. Wash. 2003))).

Moreover, contrary to Defendants' position, the Court finds that the experts' reliance on the case-control studies does not render their opinions unreliable under *Daubert*. Defendants submit that there is a hierarchy of observational epidemiologic studies, "which include[s] in descending order of reliability – cohort studies, case-control studies and cross-sectional studies." (Defs.' General Causation Br., at 10.) Based on that hierarchy, Defendants posit that "it is especially unreliable for plaintiffs' experts to characterize the objectively 'weak' 1.2-.6 figure as indicative of a strong association because that figure is artificially inflated by the fact that it is based primarily on case-control studies." (*Id.* at 34.) What is more, Defendants contend

that Plaintiffs' experts fail to consider the weaknesses of the case-control studies, *i.e.*, recall bias and confounding. (*Id.* at 35–41.) Plaintiffs counter that "even the most basic epidemiology textbooks teach that there is not a rigid hierarchy [of evidence]," and maintain that their general causation experts properly considered the strengths and weaknesses of all relevant talc studies. (Pls.' General Causation Br., at 114–131.)

The Court finds that Plaintiffs' experts reliably considered all the relevant studies. Dr. McTiernan explained at the *Daubert* hearing, which I found credible, that there are "benefits and drawbacks" to both the case-control and cohort studies. (McTiernan *Daubert* Hr'g Tr., at 737.) Dr. McTiernan expressed her belief that the case-control studies are better suited for assessing the relationship between talc usage and ovarian cancer, and explained that

> when you are looking at what a woman has used, and you want to know her lifetime exposure, and you want details, you are going to see that best described in a case-control study that can be focused. The cohort studies have their strengths, and we'll go over those in a bit also. I found both types of studies provided useful information, and I summarized that in my deliberations.

(*Id.*) Dr. McTiernan also explained her opinion with respect to the weaknesses in the cohort studies, more in depth, in her report, noting that

> three cohort studies have reported on talcum powder use and ovarian cancer risk. The Women's Health Initiative recruited from the general population of postmenopausal women from 40 clinical centers around the U.S. The rate of response was only around 1-2%, however, and therefore the cohort is unlikely to represent the population of American postmenopausal women. The Nurses' Health Study recruited nurses from around the U.S. Their rate of

> response was higher than for the Women's Health Initiative, but they are all nurses, and therefore have different health knowledge, income, and socioeconomic status compared with the general U.S. population. The Sisters' Study recruited from the general population, targeting women who had at least one sister with breast cancer. The responding participants therefore represent only women with a family history of breast cancer, and given their self-selection, likely differ from the general population in vulnerability to cancer and other characteristics.

(McTiernan Expert Rep., at 16.)

Dr. Clarke-Pearson testified that he did not find the cohort studies "useful in terms of going to the totality, and that what we're trying to talk about." (Clarke-Pearson *Daubert* Hr'g Tr., at 1678.) Instead,

> [w]hat [he] did was to look at the case-control studies, the cohort studies, and the pooled studies, and then the meta-analysis. So looking at the totality, the meta-analyses, were much more helpful and stronger evidence to identify the real outcome of use of talc in the perineal area which increases the risk of ovarian cancer in every one of those meta-analyses.

(*Id.* at 1678.) Dr. Clarke-Pearson further elaborated on his decision not to cite to the cohort studies in his report, explaining that "the cohort studies were included in the meta-analysis, so I was considering them in that setting, but just not isolated as cohort studies." (*Id.* at 1679.) Dr. Clarke-Pearson went on:

> [The cohort studies] contributed to the meta-analysis; and even though they were not very strong studies in many ways, and were not statistically significant, they did show an increased relative risk. They were included in the meta-analysis, and they didn't bring down the fact the meta-analysis showed a statistically significant increased risk of developing ovarian cancer with perineal talc use. If I excluded them, the results in the meta-analysis would have

> been even more negative in the use of talc in the perineal area.

(*Id.*)

Finally, Dr. Carson testified that he reviewed the cohort studies in connection with his review of the meta-analyses, and that "when [the meta-analyses] looked at the cohort studies alone, they showed that there was a significant and positive relative risk associated with serous epithelial ovarian cancer, which is the most common and most deadly form of the disease." (Carson *Daubert* Hr'g Tr., at 1277.) Dr. Carson explained further that he did not cite to the cohort studies in his expert report, because he was not of the view that the "three cohort studies contributed to the opinions that [he] expressed," and noted that he "did cite to the meta-analyses that included them and looked at those data. So they are included within those meta-analyses, and that was much more fundamental to [his] opinions." (*Id.* at 1418.) Moreover, Dr. Carson stated that "those cohort studies likely suffered from an underpowered condition, and when they reanalyzed them as a group with a larger sample size [in the meta-analyses], they were able to increase the power and were able to detect an effect." (*Id.* at 1422.)

Based on this testimony, the Court is satisfied that the general causation experts have demonstrated that their decisions to rely on the case-control studies, as opposed to the three cohort studies, is supported by good grounds and does not constitute a "rigid" dismissal of the cohort studies. *See Carl*, 2016 WL 4580145, at *19. Indeed, this is not a situation where the experts purposefully ignored the cohort studies entirely because they were inconsistent with their opinions.

The Northern District of California addressed a similar dispute over the relevant weight of observational epidemiology studies in *In re Roundup Products Liability Litigation*, 390 F. Supp. 3d 1102 (N.D. Cal. 2018). In *Roundup*, as here, the plaintiffs' experts relied heavily on the case-control studies and meta-analyses, whereas defendants maintained that a cohort study was more reliable and not properly considered by plaintiffs' experts. *Id.* at 1116–26. The court reviewed the relevant studies and the plaintiffs' experts' reasons for relying on the case-control studies versus the cohort study; the court ultimately found that the studies were "open to different interpretations, and the potential flaws in the data from the case-control studies and meta-analyses are not overwhelmingly greater than the potential flaws in the data from the [cohort] study." *Id.* at 1126. Accordingly, the *Roundup* court concluded that "an expert who places more weight on the case-control studies than the [cohort] study cannot be excluded as categorically unreliable for doing so." *Id.*

The same holds true here. The Court cannot deem Plaintiffs' experts' opinions unreliable simply because they determined that the case-control studies were entitled to greater weight than the cohort studies, particularly since the experts' explanations of their methods were supported by scientific reasons. In the end, Defendants may disagree with the experts' interpretations of those studies and their usefulness, but such issues go to the weight of the experts' testimony, and not their reliability. Defendants may cross-examine the experts on questions of interpretation. *See, e.g.*, *Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414–15 (3d Cir. 2002) ("A party

confronted with an adverse expert witness who has sufficient, though perhaps not overwhelming, facts and assumptions as the basis for his opinion can highlight those weaknesses through effective cross-examination."); *Gutierrez v. Johnson & Johnson*, No. 01-5302, 2006 WL 3246605, at *8 (D.N.J. Nov. 6, 2006) ("[D]isagreements about the conclusions to be drawn from a particular test affect the weight of a[n expert] report, not its admissibility."); *see also Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000) ("The soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusion based on that analysis are factual matters to be determined by the trier of fact, or, where appropriate, on summary judgment.").

Finally, I do not agree with Defendants that Plaintiffs' general causation experts failed to consider issues of confounding and recall bias in relying on the case-control studies. Defendants maintain that the experts specifically failed to consider the issue as to whether media attention to the relationship between talc and ovarian cancer skewed results in certain of the case-control studies and, further, whether certain results are skewed by "confounders," such as douching. (*See* Defs.' General Causation Br., at 35–41.) However, a review of the experts' reports and testimony reveals that they in fact accounted for these external circumstances and factors. For example, Dr. McTiernan's expert report details her findings with respect to the possible sources of bias in the epidemiological studies she reviewed. As to recall bias and media attention, Dr. McTiernan explained that

> [f]or the case-control studies, media reports of associations between talc and ovarian cancer could have influenced

> cases such that they recalled use of talcum powder products to a greater degree than controls. However, the studies for which data collection pre-dated news reports of this association showed similar effects to those for which data were collected afterward. Thus, "recall bias" is unlikely to be an issue. As mentioned above, recall bias is a theoretical bias; studies that have investigated other sources of data on exposures have failed to confirm the presence of differential recall between cases and controls.

(McTiernan Expert Rep., at 26.)

Nevertheless, Defendants contend that Dr. McTiernan's opinion on this point is supported only by her own *ipse dixit*, and assert that "major U.S. newspapers" have written on the relationship between talc and ovarian cancer. (Defs.' General Causation Br., at 36–37.) However, at least one study relied upon by Dr. McTiernan came to the same conclusion. As explored at the *Daubert* hearing, the authors of one meta-analysis determined that "[w]hile the results of case control studies are prone to recall bias especially with intense media attention following commencement of litigation in 2014, the confirmation of an association in cohort studies between perineal talc use and serious invasive ovarian cancer is suggestive of a causal association." (*See* McTiernan *Daubert* Hr'g Tr., at 944 (quoting Penninkilampi, et al., *Perineal Talc and Ovarian cancer: A Systematic Review and Meta-Analysis*, 29 Epidemiology 41 (2018)).) In the end, Defendants and their experts may disagree with Plaintiffs' general causation experts' assessment of recall bias in the case-control studies, but that does not render their opinions unreliable under *Daubert*. *See Walker*, 46 F. App'x at 694.

The same is true for Plaintiffs' general causation experts' assessment of

potential confounders in the epidemiologic literature. Defendants argue that these experts "fail to meaningfully address" certain possible confounders. (*See* Defs.' General Causation Br., at 38–42.) "Confounding occurs when another causal factor (the confounder) confuses the relationship between the agent of interest and the outcome of interest." Green, *supra* at 591. Dr. McTiernan explained her methodology as to confounding factors at the *Daubert* hearing:

> In all but one of the case-control studies presented the information on confounders. The problem with confounding, you can't assume from reading the paper that these are all the potential confounding variables because the studies will present the confounding variables and they will present them for their data for their own study; and you can't assume something should be a confounder, if it wasn't in that study. It's always study specific, the confounding.
>
> I did go through the exercise of looking at those individual studies that had reported on when they took the confounders into account and when they didn't, when they had a relative risk that was just a plain old relative risk and then had one that adjusted for these confounders and then presented both of those types of data, and the relative risk were almost identical in all but one, and that one only changed, that relative risk changed a small amount. That tells me if the relative risks don't change with adjusting for confounding, then it really wasn't a problem in their study. If the relative risk looks the same after the adjustment, then it didn't affect the relative risk.

(McTiernan *Daubert* Hr'g Tr., at 759–60.) Again, Defendants' argument reveals their disagreement with the conclusions of the experts—not the methodology employed in consideration of the studies. To the extent Defendants contend that the general causation experts' consideration of confounding elements is insubstantial or weak, they may explore those inquiries on cross-examination. *See Daubert*, 509 U.S. at 596

("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

b. Consistency

The consistency factor considers whether the results of the relied upon studies have been replicated. *See* Green, *supra* at 604. As explained in the *Reference Guide*:

> In epidemiology, research findings often are replicated in different populations. Consistency in these findings is an important factor in making a judgment about causation. Different studies that examine the same exposure-disease relationship generally should yield similar results. Although inconsistent results do not necessarily rule out a causal nexus, any inconsistencies signal a need to explore whether different results can be reconciled with causality.

Id. With respect to this Bradford Hill factor, Plaintiffs' general causation experts found that both the case-control and cohort studies are "remarkably consistent" in "indicating increased risk of ovarian cancer in women who used talcum powder products compared to women who do not use them." (McTiernan *Daubert* Hr'g Tr., at 752; *see also* Carson *Daubert* Hr'g Tr., at 1311 ("If you consider the forest plot of the various studies looking at the connection from an epidemiological point of view over time, there is little doubt there is consistency among those studies almost all showing a positive odds ratio or relative risk, and the majority of those being statistically significant studies."); Clarke-Pearson *Daubert* Hr'g Tr., at 1530 ("Looking particularly at the epidemiologic studies in their totality, there are many studies – and it's only fair to look at them in their totality – the data shows really consistent statistically significant increase risks of developing epithelial ovarian

cancer after application of talcum powder to the perineum.").)

More to the point, Dr. McTiernan provides a detailed consistency analysis in her expert report, explaining that 24 of the 28 case-control studies show relative risks greater than 1.1 "for women who had any perineal exposure to talcum powder products, compared with never users." (McTiernan Expert Rep., at 64.) Of those 24 studies, Dr. McTiernan notes that 16 were statistically significant. (*Id.*) The doctor observes that 7 of the 8 studies that were not statistically significant "had a sample size lower than that estimated to be needed to have power to detect a statistically significant result." (*Id.*) With respect to the cohort studies, the doctor opines that they "on average showed more attenuated relative risks of ovarian cancer in relation to use of talcum powder products," likely because the "studies were not well designed to determine true risk for ovarian cancer and perineal talc use." (*Id.*) Thus, Dr. McTiernan finds that the cohort studies' "results as a group do not negate the significant case-control study findings and the significant results of the meta-analyses and the pooled analysis." (*Id.*) Nevertheless, Dr. McTiernan opines that the cohort studies, similar to case control studies, also tend to show a positive association between talc use and ovarian cancer, albeit the connection is weaker. Overall, as explained by Dr. McTiernan, because both cohort and case control studies demonstrate a positive association, they are consistent. (*See* McTiernan *Daubert* Hr'g Tr., at 752.)

Defendants raise two main arguments in challenging these experts' opinions on consistency. First, Defendants contend that the epidemiological studies are not,

in fact, consistent, in that the cohort and case-control studies have reached different results. (*See* Defs.' Post-Hr'g Br., at 19.) In other words, Defendants argue that because no cohort study concluded there was a statistically significant association between talc use and ovarian cancer, the two types of studies cannot be consistent. (*See id.*; *see also* Defs.' General Causation Reply Br., at 26.) Moreover, Defendants argue that the experts unreliably "attack the long-established concept of statistical significance" in opining on this Bradford Hill factor. (*See* Defs.' General Causation Br., at 61–66.) Specifically, Defendants maintain that the causation experts found consistency of the association simply because a majority of the studies show a relative risk greater than 1.0. *(See id.* at 63.) By so opining, Defendants reason that the experts "ignore the statistically insignificant nature of purportedly positive results" from cohort studies that may not even support an association. (Defs.' General Causation Reply Br., at 35.)

Defendants' challenge to Plaintiffs' general causation experts' opinions on consistency is, fundamentally, a dispute over the role that statistical significance plays in determining the consistency of epidemiological studies. In assessing whether epidemiology studies are statistically significant, it is important that an expert determine whether a positive association (a relative risk greater than 1.0) "represents a true association or is the result of random error." Green, *supra* at 575. The *Reference Guide on Epidemiology* identifies two methods for assessing random error: (1) by calculating a *p*-value, or (2) by using confidence intervals.[38] *See id.* at 576–77.

[38] A *p*-value "represents the probability that an observed positive association

The Third Circuit addressed the role of statistical significance in proving causality in *In re Zoloft*. There, the court declined to adopt a bright-line rule and instead stated certain guiding principles:

> A causal connection may exist despite the lack of significant findings, due to issues such as random misclassification or insufficient power. Conversely, a causal connection may not exist despite the presence of significant findings. If a causal connection does not actually exist, significant findings can still occur due to, *inter alia*, inability to control for a confounding effect or detection bias. A standard based on replication of statistically significant findings obscures the essential issue: a causal connection. This is not to suggest, however, that statistical significance is irrelevant. Despite the problems with treating statistical significance as a magic criterion, it remains an important metric to distinguish between results supporting a true association and those resulting from mere chance.

Zoloft, 858 F.3d at 793 (footnote omitted).

Despite Defendants' arguments to the contrary, the causation experts considered statistical significance with respect to both cohort and case control studies, and did so in a reliable fashion. For example, at the *Daubert* hearing, Dr. McTiernan

---

could result from random error even if no association were in fact present." Green, *supra*, at 576. Thus, "[t]o minimize false positives, epidemiologists use a convention that the *p*-value must fall below some selected level known as alpha or significance level for the results of the study to be statistically significant." *Id.* Calculating a confidence interval, the *Reference Guide* explains, "permits a more refined assessment of appropriate inferences about the association found in an epidemiologic study." *Id.* at 579 "A confidence interval is a range of possible values calculated from the results of a study. If a 95% confidence interval is specified, the range encompasses the results [one] would expect 95% of the time if samples for new studies were repeatedly drawn from the same population. Thus, the width of the interval reflects random error. The narrower the confidence interval, the more statistically stable the results of the study." *Id.* at 579–80.

testified that, in reviewing each study, she considered the type of statistical significance analysis performed—whether *p*-value or confidence interval. (McTiernan *Daubert* Hr'g Tr., at 830.) In addition, Dr. McTiernan explained that she also gave weight to positive, non-significant results where such weight was warranted:

> Q. Would it be appropriate as a scientist to dismiss studies due to their p-Value?
>
> A. I believe it would be especially when you are looking in the totality of evidence than to say one study is statistically significant and one is not, and, therefore, to dismiss the one where the p-Value is greater than something doesn't give you the full picture. You really need the full picture.
>
> Q. Would it be inappropriate methodology to dismiss as a finding a result that is not statistically significant?
>
> A. To dismiss a study that is not significant, not statistically significant? It would be inappropriate to dismiss that, yes.
>
> Q. It would be inappropriate?
>
> A. Inappropriate.
>
> Q. Dr. McTiernan, looking at this forest plot of both case-control and cohort studies, what does the data from this forest plot of the epidemiological studies that you reviewed both case-control and cohort tell us about the consistency of the data from your review?
>
> A. It tells me it is remarkably consistent because you could see that almost all of those relative risk data points are to the right of the line. They are all indicating increased risk in ovarian cancer in women who used talcum powder products compared to women who do not use them.
>
> Q. That's regardless of study design. Is that correct?
>
> A. Yes.

(McTiernan *Daubert* Hr'g Tr., at 751–52.)

The doctor's view in this regard is based on a recent expert opinion by Dr.

Kenneth Rothman, a leading epidemiologist, in *Modern Epidemiology*. Dr. Rothman opined that "[i]t is sometimes claimed that a literature or set of results is inconsistent simply because some of the results are statistically significant and some are not. This sort of evaluation is completely fallacious even if one accepts the use of significance testing methods." (*Id.* at 934–35.) In other words, according to the experts, in the epidemiology context, inconsistent statistical significance from one study to the next does not, in of itself, show inconsistency under Bradford Hill.

While Defendants may disagree with the general causation expert's approach to statistical significance, the Court does not find that their methodology is unreliable and unsupported by science. Rather, at this stage, I find that they have provided detailed reasons for their findings and their approach to considering statistical significance within the studies in determining consistency. What Defendants have ultimately presented on statistical significance is a battle of the experts. *See In re Gabapentin Patent Litig.*, 2011 WL 12516763, at *10. For instance, Defendants' epidemiology expert, Dr. Diette, as discussed *infra*, follows the exact method of assessing consistency that Defendants promote to be the correct methodology. Defendants may well believe this is the better approach, but that is not a question for this Court to decide when Plaintiffs' experts have provided good grounds for their approach.

Defendants additionally argue that the general causation experts "mostly ignore the inconsistency between cohort and case-control studies or brush the cohort studies aside as flawed and irrelevant." (Defs.' General Causation Br., at 48 (footnote

omitted).) Stated differently, Defendants argue that the experts fail to meaningfully address the cohort studies, which show a weaker connection between perineal talc use and the increased risk of ovarian cancer. (Defs.' General Causation Reply. Br., at 50.) As the Court discussed *supra*, I do not find that the experts dismissed the cohort studies outright without considering them in conducting their Bradford Hill analyses. Indeed, while the experts explained why the results of cohort studies may have yielded a non-statistically significant casual connection, they nevertheless concluded that these cohort studies, like the case control studies, are consistent because they show a positive association (greater than 1.0 relative risk). In arguing that the experts' opinions should be excluded in this context, Defendants challenge the causation experts' conclusion that cohort studies, which show a weaker association between talc use and ovarian cancer, are designed with flaws. Specifically, Defendants take issue with the experts' position on the cohort studies' lack of statistical power, for employing an insufficient follow-up period in light of the long latency period of ovarian cancer, and for failing to ascertain the exposure of each participant to talc. (Defs.' General Causation Br., at 50–58.) What is evident, however, from Defendants' arguments is that they dispute the experts' conclusions and interpretations of the different studies, not the experts' methodologies. Stated differently, Defendants may very well disagree with Plaintiffs' criticisms of the cohort studies, but a dispute over whether the experts are correct in discounting the causative results of the cohort studies relate to the weight of their testimony, not their reliability. *See Stecyk*, 295 F.3d at 414–15.

c. Biological Plausibility

The next Bradford Hill factor weighed by the general causation experts is biological plausibility, *i.e.*, whether the purported association biologically plausible and consistent with existing scientific knowledge. *See* Green, *supra* at 604. Commenters have observed that biological plausibility is a difficult criterion because it "depends upon existing knowledge about the mechanisms by which the disease develops." *Id.* Indeed, "observations have been made in epidemiologic studies that were not biologically plausible at the time but subsequently were shown to be correct. When an observation is inconsistent with current biological knowledge, it should not be discarded, but the observation should be confirmed before significance is attached to it." *Id.* at 604–05.

Plaintiffs' general causation experts present two theories of biological plausibility, both of which are premised on their understanding that talc contains asbestos and other heavy metals.[39] Drs. McTiernan, Carson, and Clarke-Pearson

[39] The Court finds that the causation experts can reasonably rely on the assumption that talc contains asbestos. Indeed, as I have already determined, Dr. Longo, on whose report these experts rely, will be permitted to testify as to his opinion that J&J talc contains asbestos. Apart from asbestos, Defendants argue that Dr. Carson's testimony—that the heavy metals contained in talc, *i.e.*, cobalt, chromium, and nickel, may also cause ovarian cancer—is unreliable, because these metals have not been proven to be specifically carcinogenic to the ovary. (*See* Defs.' Post-Hr'g Br., at 43–45.) At the outset, for the purposes these *Daubert* motions, Defendants do not dispute that talc powder may contain these heavy metals. (*See id.*) Dr. Carson explained that while there are no studies linking these specific metals to ovarian cancer, they have been identified by the International Agency for Research on Cancer ("IARC") as carcinogens, and these metals have been linked to specific types of cancer. (*See* Carson *Daubert* Hr'g Tr., at 1308.) However, importantly, the IARC, in its 2012 Monograph explains that while it may identify certain carcinogens as having specific target organs or tissues where an increased risk of cancer has been shown, it further

present two different theories as to how the purported carcinogens in talc reach the ovaries and fallopian tubes: (1) talc migrates up and through the female reproductive system when applied to the perineum, or (2) inhaled talc particles travel through the lymphatic system to the ovaries and fallopian tubes. Then, once talc is present in the ovaries, the carcinogens contained in talc cause chronic inflammation which can lead to carcinogenesis and ovarian cancer.

Defendants argue that the theory of the experts that talc "migrates up" the female reproductive system to the ovaries must be excluded as unsupported by medical evidence. (*See* Defs.' Post-Hr'g Br., at 67.) In support of this theory, Dr. Carson testified that

> [t]here are a number of studies that have been done over the years looking at various kinds of particulate substance and their ability to migrate through the female reproductive system. . . .
>
> The earliest [study] being Egli and Newton in 1961 where they looked at the transport of carbon particles through the female reproductive system and noted that transport occurred.
>
> In 1979, Venter and Iturralde, they studied the migration

---

states that "identification of a specific target organ or tissue *does not preclude* the possibility that the agent may cause cancer at other sites." Int'l Agency for Research on Cancer, 100C *Monographs on the Evaluation of Carcinogenic Risks to Humans: Arsenic, Metals, Fibres, and* Dusts, at 29 (2012) (emphasis added). As such, in conducting this analysis, Dr. Carson relied, *inter alia*, on the IARC's conclusions and, consistent with that conclusion, opined that similar to asbestos, the carcinogenic heavy metals found in talc may plausibly cause other types of cancer, such as ovarian cancer. In that regard, because Dr. Carson's opinion is based on biological plausibility, the Court will permit him to testify that it is *plausible* that, as carcinogens, these heavy metals may cause ovarian cancer with respect to his Bradford Hill analysis only. To the extent Defendants take issue with that opinion, they may cross-examine Dr. Carson on that basis.

of technetium-labeled particles through the reproductive system from the vagina to the peritoneal cavity and ovaries and showed that occurred as well.

There have been other studies since notably studies on retrograde menstruation and Halme and colleagues in 1984, that showed that retrograde menstruation occurs frequently in many women.

The Kunz article in 1997 studied the uterine peristaltic pump, which is produced by muscular activity in the uterus and fallopian tubes, and showed that sperm traveled much faster through the reproductive system than would be expected based on their motility, and in fact non-motile sperm traveled at about the same rate all the way through the reproductive system.

There was a study by Heller in 1996 that showed perineal cosmetic talc usage and the relationship of talc being found in ovarian specimens.

. . .

[T]here were animal studies that were done mostly in rodent species, and it was determined by the authors that rodents really are not a good model of the human reproductive system. As a matter of fact, there is not really a good nonprimate model of the female reproductive system for this purpose. And so I pretty much discounted animal research trying to look at this issue.

There was one study in monkeys that was done by an investigator named Wehner and colleagues that looked at migration in monkeys. They did not find that migration occurred in these monkeys, but the authors still were of the opinion that this was a viable transport mechanism and listed reasons why their study may not have been able to show that.

. . .

[T]he Food & Drug Administration has reached the opinion that while there exists no direct proof of talc and ovarian carcinogenesis, the potential for particulates to migrate

> from the perineum and the vagina to the peritoneal cavity is indisputable. And then the Health Canada report, . . . stated:
>
> "This evidence of retrograde transport supports the biological plausibility of the association between perineal talc application and ovarian exposure."

(Carson *Daubert* Hr'g Tr., at 1279–81.)[40] Dr. Clarke-Pearson, an expert in gynecologic-oncology, explained

> These are all human experiments where the first one, carbon particles, were put in the vagina, radioactive particles were put in the vagina, glove powder just on the pelvic examination came off the gloves. It was not intentionally put in the vagina. It was just glove powder.
>
> In those three papers, migration from the vagina to the fallopian tube and ovary occurred within 24 hours. Then you could say: Well, wait a minute. This is a particle. It doesn't have any motility to it. It's just a carbon particle or radioactive microsphere. How did it get here?
>
> So this paper on uterine peristaltic pump, it's been well demonstrated with ultrasound that the uterus actually has – the uterus is contracting in labor to push the baby out. But the uterus during the menstrual cycle contracts and has a retrograde so it pumps upward, if you will, and that pumping mechanism increases in the early part of the menstrual cycle until the mid-cycle, right before the follicle comes out, before the egg comes out of the follicle. That gets the maximum pumping mechanism in a retrograde fashion which pumps things up and works toward getting that egg into the fallopian tube.
>
> It can also pump sperm, and that's intense. I think biologically, the pump is pulling sperm. If we just put sperm in the cervix and believe it is going to get to the tubes

[40] Dr. McTiernan testified similarly on the issue, stating that "several clinical studies in humans show that application of particles of similar size to talc when applied to the genital tract can move up to the Fallopian tubes and ovaries." (McTiernan *Daubert* Hr'g Tr., at 780–82.)

> in a very short period of time, the sperm is motile, but it doesn't move fast. The experiments with this peristaltic pump show that sperm moves much faster than what would be expected up into the fallopian tube to hopefully achieve pregnancy because of this peristaltic pump.
>
> So there is this pump that's going backward, and it is a demonstration of putting microspheres on the cervix at different points in the menstrual cycle. In mid-cycle, when you want to biologically optimize pregnancy, that pump is bringing sperm up into the uterus and fallopian tubes.
>
> So whether it's the pump bringing up sperm or bringing up talcum powder or other things, it pumps or pulls that up. It's not just a passive flow, because there's been arguments I've read where: Well, there is a flow out of the uterus, menstrual period, and that sort of thing, and that's true. But this peristaltic pump in mid-cycle when there is not a menstrual period, is actually going the other direction, pulling things up into the fallopian tubes.

(Clarke-Pearson *Daubert* Hr'g Tr., at 1560–62.)

As Defendants point out, the studies cited by Drs. Clarke-Pearson and Carson do not directly support their theory that *externally applied* talc can migrate up the vagina to the ovaries. (Defs.' Post-Hr'g Br. at 66.) However, biological plausibility does not require certainty or even proof for the biological mechanism in question—the relevant question is "whether the hypothesized causal link is credible in light of what is known from science and medicine about the human body and the potentially offending agent." *Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 25 (1st Cir. 2011). The fact that there remains debate in the scientific community as to the mechanism which permits talc to migrate up to the ovaries does not preclude admission of the experts' theory. *See In re Fosamax Products Liability Litigation*, 645 F. Supp. 2d 164, 183 (S.D.N.Y. 2009) ("That the mechanism remains unknown

does not mean that the one proposed by the [plaintiffs'] experts is not widely accepted as *plausible*." (emphasis added)); *see also In re PPA*, 289 F. Supp. 2d at 1247 ("The fact that the mechanism remains unclear does not call the reliability of the opinion into question . . . ."). Indeed, "biological plausibility is not the same as biological certainty." *In re Abilify Products Liab. Litigation*, 299 F. Supp. 3d 1291, 1308 (N.D. Fl. 2018); *see also Milward*, 639 F.3d at 22 ("Lack of certainty is not, for a qualified expert, the same thing as guesswork." (quoting *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010))). Thus, Bradford Hill and *Daubert* do not require that an expert *prove* the proposed mechanism—they need only provide reliable support that demonstrates that the mechanism is *plausible*. The Court is satisfied that these experts, based on the various studies and their past scientific experience and knowledge, have done so under *Daubert*; I will permit them to testify as to this theory of biological plausibility. Of course, Defendants may vigorously cross-examine the experts on this theory before a jury.

For the same reasons, the Court will permit Plaintiffs' general causation experts to testify that it is biologically plausible that talc can lead to chronic inflammation, which in turn increases the risk of ovarian cancer. First, with respect to whether talc can cause chronic inflammation in the ovaries, Defendants fault the experts for failing to cite any studies that have found that talc causes chronic inflammation in the fallopian tubes or ovaries. Again, the question of biological plausibility does not require proof of the mechanism. *Abilify*, 299 F. Supp. 3d at 1335–36. And, indeed, Plaintiffs' experts provided a solid basis for their theory. Dr.

Clarke-Pearson explained at the *Daubert* hearing that *in vitro* studies in which ovarian cells are treated with talc have "demonstrated an inflammatory response." (Clarke-Pearson *Daubert* Hr'g Tr., at 1544.) Dr. Clarke-Pearson further explained that research on this issue is limited because *in vivo* studies cannot be performed due to ethical issues. (*Id.*) Thus, the *in vitro* studies provide the best evidence—as of now—for the theory that talc exposure causes a "chronic inflammatory response to the ovary . . . which then leads to oxidative stress, production of cytokines and then gene mutations, and those mutations result in cancer." (*Id.* at 1552–53.) Furthermore, as opined by Dr. Saed in this case, when ovarian cells are treated with talcum powder, inflammation and oxidative stress may occur. I have allowed that testimony to be introduced at trial. Accordingly, in the context of demonstrating biological plausibility, the Court is satisfied that the hypothesis that talcum powder can cause chronic inflammation, which may ultimately lead to cancer, is reliable under *Daubert*. The hypothesis is based on scientific research and reasoning. Contrary to Defendants' position, the fact that the mechanism has not been *proven* does not negate the reliability of the experts' opinion on this issue. Moreover, Defendants have not introduced any evidence that this theory has been disproven as a matter of science, and therefore, I have no basis to find that such a hypothesis is implausible so as to warrant exclusion under a *Daubert* inquiry. *See Berg v. Johnson & Johnson*, 940 F. Supp. 2d 983, 993 (D. S. Dakota 2013). To the extent Defendants seek to challenge the basis for Plaintiffs' theory further, they may do so before a jury and that jury will determine what weight to ascribe to this scientific hypothesis. *See*

In re Neurontin Mktg., 612 F. Supp. 2d 116, 159 (D. Mass. 2009) ("[D]isputes over [the expert's] theory of biological plausibility 'should be tested by the adversary process - competing expert testimony and active cross-examination—rather than excluded from a jury's scrutiny." (quoting *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998))); *In re PPA*, 289 F. Supp. 2d at 1248 (finding that an expert's opinion on biological plausibility is reliable when that opinion is founded on "reports, textbooks and treatises, and the clinical experience of several experts and other scientists"); *see also Berg*, 983 F. Supp. 2d at 1161; *see also Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1124–25 (9th Cir. 1994); *Glaser v. Thompson Med. Co.*, 32 F.3d 969, 972–75 (6th Cir. 1994).

The Court, however, excludes the inhalation theory presented by Plaintiffs' general causation experts. In addition to positing that talc can migrate up the female reproductive system to the ovaries—which the Court finds plausible—the experts additionally opine that talc particles can reach the ovaries through inhalation. Dr. Carson explained, albeit not convincingly:

> A portion of talcum powder that is aerosolized as dust during hygienic applications can be inhaled into the respiratory system. A very small portion of that may enter the bloodstream and be able to circulate to other tissues including the ovaries. I think the potential for that to be a significant exposure is very insignificant, and it is although a secondary route of exposure to perineal application of talc I think it is an extremely minor one.

(Carson *Daubert* Hr'g Tr. at 1282–83.) Dr. Clarke-Pearson's testimony on this theory was similarly scant:

> Q. Let's transition from migration and talk just briefly

> about inhalation. Did you consider inhalation as another route of exposure to the ovary?
>
> A. Yes. I think it's possible.
>
> THE COURT: Possible or probable?
>
> A. I think its plausible. It's less likely than the ascension through the vagina and the genital application. I think it's much stronger.

(Clarke-Pearson *Daubert* Hr'g Tr., at1563–64.)

Dr. McTiernan similarly provided very little support for the inhalation theory, explaining in her expert report that:

> Data also plausibly indicates that inhalation of talcum powder products can result in exposure leading to cancer, including mesothelioma. Studies also show that talcum powder products can be absorbed and transported via the lymphatic system or blood stream. Therefore, inhalation of talcum powder products could result in similar ovarian exposure. Published scientific data shows that talc reaches the ovary and becomes imbedded in the ovarian tissue.

(McTiernan Expert Rep., at 66.) The "studies" referred to by Dr. McTiernan in this testimony presumably refer to the study cited for this proposition in her expert report: the 2007 Cramer study.[41] (*See* McTiernan Expert Rep., at 59.) However, that study,

[41] The 2007 Cramer study was a case study that examined the pelvic lymph nodes of a 68-year old woman with stage III serous ovarian cancer and "used talc daily for 30 years as a body powder on the perineum and also applied it to underwear and sanitary napkins." Daniel W. Cramer, et al., *Presence of Talc in Pelvic Lymph Nodes of a Woman with Ovarian Cancer and Long-Term Genital Exposure to Cosmetic Talc*, 110(2) Obstetrics & Gynecology 498, 498 (2007). The Cramer study concluded that its finding of "talc in pelvic lymph nodes of a long-term talc user with ovarian cancer may begin to reshape understanding about the relationship between talc and ovarian cancer and shed new light on whether talc used externally in the genital area is capable of migrating into the pelvis." *Id.* at 501.

which revealed the presence of talc in a patient's *pelvic* lymph nodes, makes no findings as to how the talc ended up in the pelvic lymph node, let alone suggest that the talc entered the lymphatic system through inhalation. *See* Cramer, *supra*, at 498–501.

Aside from these experts claiming that the inhalation theory may be plausible, they fail to otherwise provide any scientific basis for the theory that talc somehow moves through the lymphatic system to the ovaries. More particularly, the experts fail to give any scientific support that findings of talc in the pelvic lymph nodes lends credence to their opinion that talc, once inhaled, moves through the lymphatic system to the reproductive tract and ultimately to the ovaries. While, as the Court discussed above, biological plausibility does not require proof of the biological mechanism, any such opinion must be "derived from and supported by reliable scientific knowledge and reasoning." *Abilify*, 299 F. Supp. 3d at 1308. This Court need not "admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 563 (W.D. Pa. 2003) (citing *Joiner*, 533 U.S. at 146). That is precisely what Plaintiffs' experts have done in connection with their theory that inhalation of talc can cause ovarian cancer. For these reasons, I will exclude Plaintiffs' general causation experts' opinion on their secondary theory of biological plausibility, *i.e.*, inhalation.

d. Dose-Response

Under Bradford Hill, the dose-response factor considers whether there is a "dose-response relationship," meaning "that the greater the exposure, the greater the

risk of disease." Green, *supra* at 603. The *Reference Guide on Epidemiology* states that

> [g]enerally, higher exposures should increase the incidence (or severity) of disease. However, some causal agents do not exhibit a dose-response relationship when, for example, there is a threshold phenomenon . . . . Thus, a dose-response relationship is strong, but not essential, evidence that the relationship between an agent and disease is causal.

Id. Plaintiffs' general causation experts generally found this factor to support causation. Dr. Carson explains in his expert report that "[a]lthough some studies have failed to find evidence of a dose-response relationship, several more recent reports have shown a clear dose-response when the number of subjects rose to a level producing sufficient statistical power to allow the analysis after subdivision of subjects into pertinent categorical groups, and frequency and duration were measured." (Carson Expert Rep., at 9.) Dr. Clarke-Pearson noted that there has been difficulty in assessing dose-response because it is dependent on the recollection of the user, and studies have attempted to determine the frequency of use and/or duration. (Clarke-Pearson Expert Rep., at 9.) Nevertheless, Dr. Clarke-Pearson notes that "a number of studies have demonstrated an association between 'dose' and the occurrence of [epithelial ovarian cancer]" and the doctor expresses that he expects more data on this factor "as more *in vitro* studies are performed with talcum powder." (*Id.*) Dr. McTiernan similarly placed significant weight on this factor, noting that more recent studies contained information that relate to dose-response. (McTiernan Expert Rep, at 65–66.) She specifically relied on the meta-analyses, which "found

evidence of relationships between increasing amount of exposure to talcum powder products in the perineal/genital area . . . and increased risk of developing epithelial ovarian cancer." (*Id.*)

At the *Daubert* hearing, Dr. McTiernan described her methodology for finding a dose-response relationship, explaining that the relevant question she asked when looking at the studies was "[d]oes increasing use of talcum powder products increase risk of ovarian cancer." (*See* McTiernan *Daubert* Hr'g Tr., at 791–98.) For example, Dr. McTiernan explained how the Terry pooled analysis[42] assessed dose-response. (*Id.* at 791.) Dr. McTiernan explained that in that study participants were divided "into four categories by level of use of talcum powder products, and compared to never users" based on their relative risk of ovarian cancer. (*Id.*)[43] The study showed an increasing relative risk based on level of use—the relative risk for never users was

---

[42] The Terry pooled analysis "estimated the association between self reported genital powder use and epithelial ovarian cancer risk in eight population based case control studies." Kathryn L. Terry, et al., *Genital Powder Use and Risk of Ovarian Cancer: A Pooled Analysis of 8,525 Cases and 9,859 Controls*, 6 Cancer Prevention Research 811 (2013). The Terry study concluded that "genital powder use is a modifiable exposure associated with small to moderate increases in risk of most histologic subtypes of epithelial ovarian cancer." *Id.*

[43] The four categories of use were based on an estimate of lifetime number of application of talc "by multiplying total months of use by frequency of use per month, for all direct and indirect genital powder applications." Terry, *supra* at 815. More specifically, "[n]ever regular users of genital powders and women who only reported nongenital use were coded as having zero lifetime genital powder applications." *Id.* The four categories of talc users "were determined on the basis of the specific quartile cutoff points in controls (25th, 50th, and 75th percentile cutoff points are 612, 1,875, and 5,400 for participants <40 years old; 612, 2,160, and 7,200 for 41 [to] 50 years; 720, 3,600, and 10,800 for 51 [to] 60 years; 1,440, 5,760, and 14,440 for 61 [to] 70; 840, 7,200, and 18,800 for > 70 years)." *Id.*

1.0; for the first category of users the relative risk was 1.14; "for the second, 1.23; the third, 1.22; and the fourth, 1.32." (*Id.* at 792.) According to Dr. McTiernan, "[t]he authors' calculated confidence intervals for each of those levels of relative risk, and they all show significance or near significance." (*Id.*) Moreover, Dr. McTiernan referred to the Penninkilampi[44] meta-analysis's finding on dose-response, explaining

> they were able to find most studies that had some information either on duration of use or total lifetime applications. When they looked at the 12 studies who had duration of use, they looked at for those women who used for more than 10 years compared to less use, the relative risk was 1.25. So that tells us long-term use has an effect. Five of those studies they included [in] the meta-analysis had total lifetime applications. So its frequency times duration. And they divided those into two categories corresponding to daily use for 10 years. So 3600 total applications more or less, and you did see an increase. You see a relative risk of 1.32 for the lower group users and 1.42 for the higher, and this is compared to non-users. The confidence intervals did not include one, so they are statistically significant.

(*Id.* at 796.) Finally, Dr. McTiernan explained that while a few studies did not look at dose-response in this fashion, or at all, or, if the study did look at dose-response, it did not find any effect, she nevertheless found, based on the totality of available evidence, there is a dose-response relationship between talc use and ovarian cancer. (*See id.* at 796–97.)

---

[44] The Penninkilampi meta-analysis examined the results of observational studies, both case-control and cohort, that involved at least 50 cases of ovarian cancer. Ross Penninkilampi, et al., *Perineal Talc Use and Ovarian Cancer: A systematic Review and Meta-Analysis*, 29(1) Epidemiology 41, 41 (2018). The authors of the Penninkilampi study conclude that although there is "[s]ome variation in the magnitude of effect . . . when considering study design[,]" "[i]n general, there is a consistent association between perineal talc use and ovarian cancer." *Id.*

Defendants submit that "evidence of dose-response is integral to an assessment of whether talc use causes ovarian cancer" and that the causation experts' testimony demonstrate that "dose-response data are absent in many studies, and the data that do exist are inconsistent." (Defs.' Post-Hr'g Br., at 26.) Defendants further argue that the studies relied on by the experts do not, in fact, support their conclusions. (*Id.* at 28.) Plaintiffs, however, contend that Defendants' argument ignores the Bradford Hill definition of dose-response and rests on the false requirement that evidence of dose-response "be clear and seen consistently 'through the body of data.'" (Pls.' General Causation Br., at 155–56.) Plaintiffs, instead, maintain that in the context of a Bradford Hill analysis, the relevant question is whether there is any evidence that would support a dose-response relationship. (*Id.* at 159–60.) Plaintiffs disagree with Defendants' position that the studies, upon which the causation experts rely, do not support the experts' opinions. (*See id.* at 161–62.)

Essentially, the parties' dispute with respect to dose-response raises two issues: (1) the weight dose-response is given in a Bradford Hill analysis, and correspondingly, what type of data is required for finding of a dose-response; and (2) whether Plaintiffs' general causation experts' finding of a dose-response is adequately supported by the studies on which they rely. On the first issue, as a threshold question, the parties dispute how to weigh dose-response in the greater Bradford Hill inquiry. Defendants, on one hand, assert that dose-response "is integral to an assessment of whether talc use causes ovarian cancer," whereas Plaintiffs maintain that, in the context of a Bradford Hill analysis specifically, a strong dose-response

relationship is not necessarily essential.

Generally, "while precise information concerning the exposure necessary to cause specific harm to humans and exact details pertaining to the plaintiff's exposure are beneficial, such evidence is not always available, or necessary, to demonstrate that a substance is toxic to humans given substantial exposure and need not invariably provide the basis for an expert's opinion on causation." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 264 (4th Cir. 1999) (admitting expert testimony that exposure to talc caused sinus problems despite inability to determine threshold level of exposure necessary to cause plaintiff's injuries). Here, the Court acknowledges, as correctly pointed out by Defendants, that strong evidence of dose-response would tend to show a stronger causative relationship between talc use and ovarian cancer. However, based on epidemiological principles, a strong dose-response is not necessarily required for an expert to find a casual nexus. *See, e.g., Ferguson v. Riverside Sch. Dist. No. 416*, No. 00-0097, 2002 WL 34355958, at *6 (E.D. Wash. Feb. 5, 2002) ("The Court determines that the lack of a model for determining causation based on a 'dose-response' relationship does not undermine the reliability of [the expert's] testimony."). Even so, the causation experts have pinpointed studies that demonstrate evidence of dose-response, *i.e.*, meta-analyses, and adequately explained why the studies, themselves, are reliable. *See* Green, *supra* at 603.

Next, Defendants argue that, contrary to the causation experts' opinions, only a limited number of studies show a dose-response relationship between talc use and ovarian cancer, and even in those studies that do show a dose-response, the

relationship tends to be weak. Thus, Defendants submit that the Court must find that the causation experts' opinions are unreliable. I disagree for two reasons. First, as I already explained, the dose-response factor need not be significant in order for an expert to, nevertheless, find a causative relationship, so long as there is reliable epidemiological evidence of a dose-response. *See* Green, *supra* at 603 (observing that "a dose-response relationship is strong, but not essential, evidence that the relationship between an agent and disease is causal").

Second, as indicated above, Plaintiffs' experts relied upon certain meta-analysis and pooled studies, which they interpreted as having demonstrated a dose-response relationship. While Defendants disagree with Plaintiffs' general causation experts' interpretation of those studies, the experts provided "good grounds" for their interpretations. For example, Defendants argue that, in their view, the Terry study "concluded that there was no trend in risk with increasing talc use," and does not actually support a dose-response, contrary to Dr. McTiernan's interpretation. (*See id.*) In support of their argument, Defendants point to the Terry study's conclusion that "[a]lthough a significant increase in risk with an increasing number of genital powder applications was found for nonmucinous epithelial ovarian cancer when non-users were included in the analysis, no trend in cumulative dose was evident in analyses restricted to ever users of genital powder." (*See* McTiernan *Daubert* Hr'g Tr., at 888.) On that point, however, Dr. McTiernan explained that she interpreted the study to show a dose-response relationship based on the comparison of never-users and users of talc." (*Id.* at 888–91.) Dr. McTiernan further testified that it is

"appropriate to include non-users when you are looking at a dose-response effect, unless there is some other reason non-users are so different they should be excluded. I liken it to if you are testing a dose for effectiveness in a randomized trial, you would compare it to a placebo." (*Id.* at 890–91.) In fact, the Terry study also concluded, "[t]aken together, these observations suggest that the significant trend test largely reflects the comparison of ever regular use with never use." Terry, *supra* at 817.

Based on the parties' arguments, I find that both sides offer different interpretations of the Terry study, which did not wholly rule out a dose-response relationship, but instead found the data inconsistent. *See* Terry, *supra* at 819. Admittedly, while the body of evidence with respect to dose-response is inconclusive, the experts' conclusions drawn from such evidence do not constitute an "unsupported scientific leap," as the experts have explained the bases for their findings. *See Roundup*, 390 F. Supp. 3d at 1134. Distilled to its essence, the dispute between the parties as to whether the studies support the experts' opinions appears to be based on competing interpretations of the studies' results and whether those results support a dose-response relationship. But, it is not the Court's position as gatekeeper to determine whose interpretation of the studies is correct, as long as the competing interpretations are each rooted in some sound ground. *See Stecyk*, 295 F.3d at 414–15 ("A party confronted with an adverse expert witness who has sufficient, though perhaps not overwhelming, facts and assumptions as the basis for his opinion can highlight those weaknesses through effective cross-examination."). That is an issue for cross-examination.

e. Specificity

The next Bradford Hill factor, specificity, provides that "[a]n association exhibits specificity if the exposure is associated only with a single disease or type of disease." Green, *supra* at 605. While "evidence of specificity may strengthen the case of causation, lack of specificity does not necessarily undermine it where there is a good biological explanation for its absence." *Id.* Each of Plaintiffs' experts found this factor to weigh in support of causation, but did not place significant weight on the factor. Dr. Clarke-Pearson explained that "the epidemiologic studies appear[] that this is specific for ovarian cancer, not other cancers, vaginal cancer, uterine cancer." (Clarke-Pearson Daubert Hr'g Tr., at 1542.) Dr. Carson similarly opined that

> [s]pecificity is a little less easy to define, but essentially it means that this exposure causes a specific disease and not other diseases, and that there is not a lot of confounding. We know that ovarian cancer occurs at a particular rate in women. What we have shown through research is that it occurs more often in women who use talcum powder for hygienic purposes on a regular basis. So based on that information, I believe the specificity consideration is satisfied.

(Carson Daubert Hr'g Tr., at 1311–12.) Defendants argue that the experts' findings "ignore[] the undisputed fact that ovarian cancer is not a single disease, but instead a number of different diseases, all with different genetic origins, risk factors, and treatments." (Defs.' Post-Hr'g Br., at 29.) Plaintiffs, however, maintain that Defendants' position ignores the body of scientific evidence that demonstrates specificity with epithelial ovarian cancer, and more specifically, serous ovarian cancer. (Pls.' General Causation Br., at 179–81.)

The testimony of Plaintiffs' experts demonstrates that their opinions rest on good grounds and considered scientific evidence to conclude that the association is specific to ovarian cancer. The experts do not opine as to any link between talc use and any other genital cancer. Their findings are limited to epithelial ovarian cancer. While epithelial ovarian cancer may have various subtypes, Defendants have not sufficiently demonstrated that Plaintiffs' findings are unreliable. Defendants may disagree with the experts' conclusions as to specificity, but that is fodder for cross-examination and not exclusion under *Daubert*.

f. Temporality

The Court next considers the parties' arguments with respect to temporality. It is well-established that "[a] temporal, or chronological, relationship must exist for causation to exist," *i.e.,* the exposure must have occurred before the disease develops. Green, *supra* at 601. Plaintiffs' general causation experts weighed this factor highly because "it's been shown that talcum powder exposure [occurs] before the onset of ovarian cancer." (*See* Clarke-Pearson *Daubert* Hr'g Tr., at 1542; Carson *Daubert* Hr'g Tr., at 1312; McTiernan *Daubert* Hr'g Tr., at 799.) Defendants, however, maintain that "the notion that talc use precedes the onset of ovarian cancer is unremarkable given that ovarian cancer typically develops late in life, whereas most women begin using talc by their mid-20s." (Defs.' General Causation Br., at 93–94.) Both positions are true. Talc use precedes an ovarian cancer diagnosis, and that fact is "unremarkable." The weight to be given this factor is an issue for the fact-finder. Defendants' argument does not present a question of reliability—but scientific

disagreement. *Dzielak*, 2017 WL 1034197, at *26.

g. Coherence

The coherence factor, as described by Dr. McTiernan, demonstrates that "[t]he cause-and-effect interpretation of the data should not significantly conflict with the known facts about the natural history and biology of the disease." (McTiernan Expert Rep., at 29.) Dr. McTiernan did not weigh this factor heavily, explaining

> [t]he cause-and-effect interpretation of the data on talcum powder product use and risk of ovarian cancer clearly do not significantly conflict with the known facts about the natural history and biology of the disease. Increase[d] inflammation has been linked to risk of ovarian cancer, and talc and other contents of talcum powder products elicit inflammatory responses within areas of the body in which they have been found . . . . While these factors support a causal association and my opinions in this regard, I do not weigh them as heavily as the strength and consistency of the association.

(McTiernan Expert Rep., at 67.) Similarly, Dr. Carson opines that

> [t]he proposal that talcum powder product use results in the occurrence of ovarian cancer is entirely consistent with what is known about other factors related to ovarian cancer, *i.e.* early menarche, late menopause, pregnancies, breastfeeding history, oral contraceptive use, etc. All are factors that influenced the local inflammatory environment of the ovary and its surroundings and have the potential to promote existing transcriptional errors and mutations.

(Carson Expert Rep., at 10.) Dr. Clarke-Pearson likewise opines that the "[e]pidemiological data, *in vitro* and *in vivo* research are consistent in explaining the pathogenesis of [epithelial ovarian cancer] through . . . inflammatory mechanisms," as well as the causes of other cancers." (Clarke-Pearson Expert Rep., at 9.)

Defendants present three arguments as to why the experts' opinions on coherence are unreliable: (1) "there are numerous subtypes of ovarian cancer, and the notion that talc would cause all of them is incoherent"; (2) no animal studies have shown that use of talc causes ovarian cancer; and (3) the experts do not reconcile their opinions "with studies that have investigated the use of talcum powder on diaphragms and condoms and have found no increased risk."[45] (Defs.' General Causation Br., at 84–88.) Plaintiffs maintain that coherence is demonstrated by the observational studies which "are long enough to account for the development of ovarian cancer and the biologic evidence relied on is consistent with the natural course of ovarian cancer." (Pls.' General Causation Br., at 186.)

Under Bradford Hill, the coherence factor ensures that the association (talc use and ovarian cancer), does not conflict with other known scientific facts, *i.e.*, coherent with existing knowledge of the development of the disease (ovarian cancer) in question. On this issue, Plaintiffs' general causation experts have presented the theory that talc use causes inflammation, which leads to ovarian cancer. Defendants' arguments do not question whether this particular opinion was reached in an unreliable manner. Rather, Defendants argue that the experts' theory is implausible

---

[45] The condom and diaphragm studies evaluated whether application of talcum powder to condoms and diaphragms, which are inserted directly into the genital tract, increased the risk of a woman developing ovarian cancer. (*See* Defs.' General Causation Br., at 87 & n.206.) For example, case-control studies and meta-analyses that considered the risk of ovarian cancer resulting from application of talc to diaphragms before insertion did not show a positive association. (*See* McTiernan *Daubert* Hr'g Tr., at 904–08.) Dr. McTiernan acknowledged the studies' findings, but criticized the studies' lack of clarity as to the amount of talc exposure that results from diaphragm application. (*See id.*)

because "there are numerous subtypes of ovarian cancer," and that it would be incoherent to suggest that talc causes all of them, particularly since, according to Defendants, some types of ovarian cancer are developed as a result of genetic mutations. However, whether a plaintiff's ovarian cancer is caused by genetic mutations or use of talc, is a question of specific causation that each plaintiff would have to separately prove. Rather, in assessing coherence, it is sufficient that the causation experts examined generally known facts regarding inflammation and cancer, and opined that these facts are coherent with their theory that talc, which may contain carcinogens, can inflame epithelial cells resulting in cancer. That there are different types of ovarian cancer does not undermine the experts' opinion on this factor.

Defendants' remaining arguments merely show disagreement with the conclusion on coherence drawn by the causation experts. On one hand, the experts point to scientific knowledge on the potential for talcum powder to cause cellular inflammation, which may lead to cancer. In that connection, the experts opine that it is entirely coherent with known scientific fact for the studies upon which they rely to show a causative relationship between talc use and ovarian cancer. Notwithstanding this scientific knowledge, Defendants insist that the experts failed to consider the lack of animal studies of talc use and ovarian cancer, and the studies based on condom and diaphragm usage. However, the experts did consider the studies cited by Defendants, though they interpreted the studies differently. For example, with respect to the condom and diaphragm studies, Dr. McTiernan

acknowledged the studies' findings, but criticized the studies' lack of clarity as to the amount of talc exposure that results from diaphragm application. (*See id.*) Indeed, Dr. McTiernan found that they were flawed because they did not consider "whether "the woman rinsed the diaphragm before putting spermicidal jelly and before inserting. So we don't know about the amount of real exposure." (*Id.* at 906–07.) With respect to the relevant animal studies, Defendants fault the experts for not considering the 2009 Keskin study[46] or the 1984 Hamilton study.[47] (Defs.' General Causation Br., at 86.) Again, Plaintiffs' experts, in fact, considered these studies. Notably, they rely on these studies to support their opinion that application of talc causes *inflammation*, which may lead to cancer. (*See* McTiernan Expert Rep., at 62–63 (opining that the animal studies "demonstrate that talcum powder products and its attendant inflammation can induce carcinogenesis"); Clarke-Pearson Expert Rep., at 4 ("Talcum powder is known to elicit an inflammatory response in animals and humans."); Carson Expert Rep., at 5 ("When implanted under the skin or into tissues of laboratory animals, talcum powder induces an inflammatory response.").) That

---

[46] In the 2009 Keskin study, researchers treated rats with intravaginal and perineal talc. Nadi Keskin, et al., *Does Long-Term Talc Exposure Have a Carcinogenic Effect on the Female Genital System of Rats? An Experimental Pilot Study*, 280 Archives Gynecologic Obstet. 925, 925 (2009). The study concluded that "[t]alc has unfavorable effects on the female genital system," but that "this effect is in the form of foreign body reaction and infection, rather than being neoplastic." *Id.*

[47] The 1984 Hamilton study involved exposing rat ovaries to talc by intrabursal injection. T.C. Hamilton, et al., *Effects of Talc on the Rat Ovary*, 65(1) J. Exp. Pathol. 101 (1984). The Hamilton study found that the talc injection "was followed by changes in the ovary and its associated tissues" and observed "papillary changes . . . in the surface epithelium of a proportion of the injected ovaries." *Id.* at 105.

these studies only showed inflammation as a result of the talc application, and not neoplastic transformation, *i.e.*, formation of cancer cells, does not undermine the experts' coherence analysis which only refers to the scientific knowledge that talc can cause inflammation. Importantly, Defendants do not dispute the known fact about the link of cellular inflammation to cancers in general, (*see* Defs.' Bio. Plausibility Br., at 49), which is the basic premise of the experts' opinion on coherence. Defendants, instead, raise issues on this *Daubert* motion beyond whether the experts' opinions were reached using sound methodology; because Plaintiffs' general causation experts have presented scientific grounds for their opinion on coherence, that opinion and its bases must be explored on cross-examination. *See Daubert*, 509 U.S. at 596.

h. Remaining Bradford Hill Factors

Finally, Defendants argue that Plaintiffs' general causation experts' analysis of the final two Bradford Hill factors—analogy and experiment—are unreliable. Defendants raise these arguments only in their moving briefs and do not address the factors in their Post-Hearing briefing because the factors "were not covered extensively at the hearing." (Defs.' Post-Hr'g Br., at 29 n.89.)

First, with respect to the experiment factor, which considers whether there is experimental evidence to support the association, Defendants posit there is "no reliable support for [P]laintiffs' experts' causation opinions." (Defs.' General Causation Br., at 92–93.) The experts generally did not afford this factor great weight because of the ethical implications for conducting a randomized trial on women to explore the relationship between talc use and ovarian cancer. (*See* McTiernan Expert

Rep., at 67; Clarke-Pearson Expert Rep., at 9). Nevertheless, the experts reference certain *in vitro* experiments and animal studies as support for causation. (*See* McTiernan Expert Rep., at 67; Clarke-Pearson Expert Rep., at 9.) To the extent Defendants assert that contradictory animal and *in vitro* studies do not otherwise support causation, that is a question of weight for the jury to decide. As the Court has reiterated throughout this Opinion, the fact that experts may disagree as to how to interpret the relevant studies at issue does not indicate one expert is more reliable than the other. *See, e.g.*, *Stecyk*, 295 F.3d at 414–15. Moreover, to the extent there are competing studies relied upon by the parties' experts, a weighing of those studies is reserved for the factfinder at trial.

Second, the analogy factor of Bradford Hill provides that "[s]ubstantiation of relationships similar to the putative causal relationship increases the likelihood of causation." *In re Mirena Ius Levonorgestrel-Related Prods. Liab. Litig. (No. II) ("Mirena II")*, 341 F. Supp. 3d 213, 243 (S.D.N.Y. 2018); *see also* Carson Expert Rep., at 10 (framing analogy criteria as considering whether "there [have] been other environmental exposures that have been associated with ovarian cancers that act via similar mechanisms."). On this factor, the general causation experts compare the relationship between talc and ovarian cancer to the relationship between asbestos and the development of ovarian and lung cancer. (*See* McTiernan Expert Rep., at 67; Clarke-Pearson Expert Rep., at 9; Carson Expert Rep., at 10.) Dr. McTiernan explains that "a similar mechanism has been reported by which asbestos causes ovarian cancer. These mechanisms are consistent with one another and the accepted

understanding of the role of inflammation in carcinogenesis." (McTiernan Expert Rep., at 67.) The experts do not weigh this factor heavily. (*See id.*)

The Court finds the weighing of this factor by Plaintiffs' experts to be reliable. There is no dispute that asbestos is carcinogenic and that asbestos has been shown to cause cancer. In that connection, it is not unreliable for the experts to opine that because asbestos has been found in talc, it can similarly cause ovarian cancer. Defendants, nevertheless, argue that because the asbestos mineral that has been most associated with ovarian cancer—crocidolite—was not found in its talcum powder products, this analogy is inappropriate.[48] To better understand Defendants' argument, the Court reiterates that crocidolite is in the same family as the types of asbestos (anthophyllite and tremolite) that were found in talc—amphibole asbestos; all of these asbestoses are regulated. *See* Int'l Agency for Research on Cancer, World Health Org., *100 Monographs on the Evaluation of Carcinogenic Risks to Humans: Arsenic, Metals, Fibres, and Dusts* 220 (2012) (defining as "the five amphibole minerals – actinolite, amosite . . . , anthophyllite, crocidolite, . . ., and tremolite"). Based on that science, the general causation experts analogize that the asbestos

---

[48] The studies to which Defendants referred specifically examined the effect of occupational exposure to asbestos. (See Defs.' Longo Br., at 88–89.) For example, Defendants point to the 2011 Reid meta-analysis, which identified three studies that associated occupational exposure to crocidolite asbestos with ovarian cancer. Reid, et al., *Does Exposure to Asbestos Cause Ovarian Cancer? A Systematic Literature Review and Meta-Analysis*, 20(7) Cancer Epidemiol Biomarkers Prev. 1287, 1289–90 (2011). While Defendants rely on this study to suggest that only crocidolite asbestos has been associated with ovarian cancer, (*see* Defs.' Asbestos Br., at 89), the Court notes that the Reid meta-analysis also highlights four studies that found an association between asbestos and ovarian cancer, that did not indicate what type of asbestos to which the women were exposed. *See id.*

present in talc, like crocidolite, may cause ovarian cancer. Indeed, the purpose of the analogy factor is to compare the causal association at issue to other similarly known causative relationships. *See Mirena II*, 341 F. Supp. 3d at 243. The factor does not require an expert to prove causation, *i.e.*, that anthophyllite or tremolite indeed cause ovarian cancer, as Defendants have suggested; in fact, to adopt Defendants' argument would turn the analogy factor on its head. Rather, it is sufficient, under this factor, that the causation experts compared the known relationship between a similar carcinogen (crocidolite) and ovarian cancer to the putative carcinogenic effect of anthophyllite and tremolite on the ovaries.

Defendants further challenge the experts' conclusion that talc and asbestos are comparable minerals. Defendants assert that it is improper to compare talc and asbestos because "asbestos and talc are distinct minerals with distinct chemical structures and morphology, and talc lacks the unique chemical and physical properties that make asbestos harmful." (Defs.' General Causation Br., at 89.) Putting aside that the experts assumed, by relying on certain studies, that talc contains asbestos, it is, nevertheless, apparent that the experts' comparison of asbestos and talc is based on these minerals' tendency to cause inflammation, which could lead to carcinogenesis. (*See* McTiernan Expert Rep., at 67.) I cannot find that such a comparison is not supported by science, such that it was unreliable or inapt. Defendants may disagree with the experts' findings, but that, in and of itself, is not grounds for exclusion.

iii. Consistency with Public Health Agencies

Finally, Defendants argue that the opinions of Plaintiffs' general causation experts should be excluded as unreliable because "they are generally inconsistent with the scientific consensus that a causal relationship between talc use and ovarian cancer has not been established." (Defs.' General Causation Br., at 108.) Defendants assert that the opinions of the causation experts are contrary to the findings of the FDA, NCI, and IARC which have declined to find any association between ovarian cancer and perineal application of talc. (*See id.* at 110.) For example, Defendants highlight that in 2014, the FDA conducted a review of the literature available at that time and "did not find that the data submitted presented conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer." (*Id.* (quoting FDA Denial Letter).)

Plaintiffs counter that the scientific community has not "reached any consensus that talcum powder does not cause ovarian cancer." (Pls.' General Causation Br., at 197.) At the outset, I note that Defendants overstate IARC's position on this issue. IARC, in their 2006 Monograph, concluded that talc is "possibly carcinogenic." *See* IARC, 93 *Monographs on the Evaluation of Carcinogenic Risks to Humans: Carbon Black, Titanium Dioxide, and Talc* 412 (2010). In that regard, IARC made no definitive pronouncement that talc use is not linked to ovarian cancer. *See id.* (noting that "[t]here is *limited evidence* in humans for carcinogenicity of perineal use of talc-based body powder"). In fact, Plaintiffs argue that IARC's categorization of talc as a possible carcinogen supports their position. (*See* Pls.' Post-

Hr'g Br., at 24.) In addition, Plaintiffs point to Health Canada's 2018 report on talc, which examines the association between talc and ovarian cancer and concluded, after applying the Bradford Hill criteria, that "available data are indicative of a causal effect" and that "[g]iven that there is potential for perineal exposure to talc from the use of various self-care products . . . , a potential concern for human health has been identified." Health Canada, *Draft Screening Assessment: Talc*, at iii (Dec. 2018). Plaintiffs' general causation experts maintain that the Health Canada report is generally supportive of their findings. (*See* McTiernan *Daubert* Hr'g Tr., at 721.) Indeed, Dr. McTiernan testified that Health Canada's analysis differed slightly from her own, but that overall its conclusion is consistent with her conclusion on the association between talc and ovarian cancer.[49]

The Court agrees with Plaintiffs—there does not appear to be scientific consensus on the issue of the association between talc use and ovarian cancer. The case law cited by Defendants to support their argument that the lack of consensus renders the experts' opinions unreliable present a very different picture than the case at hand. For example, Defendants rely on *Norris v. Baxter Healthcare Corp.*, 397

---

[49] In arguing that the Plaintiffs' general causation experts improperly rely on Health Canada's report, Defendants highlight differences between the experts' Bradford Hill analyses and those of Health Canada. (*See* Defs.' Post-Hr'g Br., at 7–9.) However, the question of whether Health Canada and the general causation experts identically applied the Bradford Hill factors does not affect the reliability of the experts' opinions. Each of the experts, here, has conducted his or her own analysis under Bradford Hill by examining the available epidemiological evidence to reach his or her own conclusions on the association between talc use and ovarian cancer. That Health Canada may have assessed certain Bradford Hill factors differently or come to a slightly different conclusion as to each factor does not undermine the reliability of the experts' opinions.

F.3d 878, 885–86 (10th Cir. 2005), in which the expert's opinion was "flatly contrary to *all* of the available epidemiological evidence." That is simply not the case here. The public health agencies have not reached any consensus that talc does not cause ovarian cancer. Indeed, the groups identified by Defendants have simply interpreted and weighed the relevant epidemiological evidence differently than Plaintiffs' experts and other agencies. The Court cannot, in its capacity as a gatekeeper under *Daubert*, weigh the findings of the public health groups against those of Plaintiffs' general causation experts and the various scientific, peer-reviewed, studies on which they rely. *See, e.g.*, *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings,* MDL No. 2545, 2017 WL 1833173, at *13 (N.D. Ill. May 8, 2017) (finding that expert's disagreement with FDA report did not undermine reliability of testimony and instead was issue of weight for jury to resolve).

In conclusion, what remains clear from the general causation evidence relied on by the experts on both sides in this matter, is that there is scientific evidence supporting each side's opinion. At best, that the body of relevant scientific evidence is inconclusive and may be open to different interpretations—does not mean one side's interpretation is more reliable than the other. *See Roundup*, 390 F. Supp. 3d at 1126 (finding that "[t]he upshot of all this is that the epidemiology evidence is open to different interpretations"). Ultimately, the question of whose experts are correct is a question for the jury; it would be erroneous for this Court to make those factual findings on a *Daubert* motion. *See Mitchell*, 365 F.3d at 244 ("*Daubert* does not require that a party who proffers expert testimony carry the burden of proving to the

judge that the expert's assessment of the situation is correct" (quoting *Ruiz–Troche*, 161 F.3d at 85); *In re Processed Egg Prods. Antitrust Litig.*, 81 F. Supp. 3d 412, 416 (E.D. Pa. 2015) ("Proponents of expert testimony do not 'have to prove their case twice—they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable.'" (citation omitted)).

Accordingly, the Court finds that the opinions of Plaintiffs' general causation experts are admissible under *Daubert*, subject to the limitations on certain testimony as set forth above. The experts reliably applied each factor of the Bradford Hill analysis as required under *Zoloft*, even if their conclusions in the context of some of these factors demonstrate a relatively minimal causal relationship between talc use and ovarian cancer. 858 F.3d at 795–96; *see Mathis v. Exxon Corp.*, 302 F.3d 448, 461 (5th Cir. 2002) (explaining that the *Daubert* analysis was never intended to supplant trial on the merits). Where, as here, the causation experts' opinions are based on facts, a reasonable investigation (including documented findings), and traditional technical/mechanical expertise, and the experts provide a reasonable link between the information and procedures they use and the conclusions reached, the *Daubert* requirements are met. *See id.*; *Bigelow v. N.Y. Lighter Co., Inc.*, No. 03-340, 2005 WL 67424971, at *1–*3 (W.D. Tex. June 27, 2005); *see also Tassin v. Sears, Roebuck & Co.*, 946 F. Supp. 1241, 1248 (M.D. La. 1996). To the extent any of the causation experts' analyses are "shaky but admissible," Defendants ought to raise these issues

on cross-examination before the fact finder. It is the role of the adversarial system, not the Court, to highlight weak evidence. *See Primrose Operating Co. v. Nat'l Am. Ins. Co.*, 382 F.3d 546, 562 (5th Cir. 2004).[50]

III. DEFENSE EXPERTS[51]

A. Dr. Gregory Diette

Defendants proffer Dr. Gregory Diette as an expert in epidemiology. Dr. Diette is a professor of medicine at Johns Hopkins University School of Medicine and holds joint appointments in the Departments of Environmental Health Sciences and Epidemiology at the Johns Hopkins Bloomberg School of Public Health. (Diette

---

[50] In addition to challenging the reliability of the methodology employed by Plaintiffs' general causation experts, Defendants assert that these experts should be excluded because they "are not employing the same level of rigor in the courtroom that characterizes their activities in the field." (Defs.' Post-Hr'g Br., at 76.) Specifically, Defendants fault Dr. Clarke-Pearson for not advising patients of the dangers of talc, (*id.* at 76–78); Dr. McTiernan for previously acknowledging a hierarchy of epidemiological evidence, (*id.* at 78–79); and Dr. Carson for contradicting his previous statement made clinically that even some exposure to a carcinogen, *i.e.*, benzene, does not necessarily raise a health concern. (*Id.* at 79–80.) Unlike in other cases where experts have been excluded because their litigation opinions on an ultimate issue contradicted other of their published opinions, *see In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig*, 26 F. Supp. 3d 449, 460 (E.D. Pa. 2014) (excluding expert whose testimony contradicted her own peer-reviewed publications), the so-called contradictory statements suggested by Defendants appear to be more akin to credibility issues that may be raised on cross-examination.

[51] Like Defendants, Plaintiffs have filed motions to exclude various defense experts. Unlike, for example, Drs. Longo and Saed, Defendants' experts, for the most part did not conduct their own individual testing, *i.e.,* testing the components of talc or the effect of talc exposure on ovarian cells. Instead, Defendants' experts rebut the opinions offered by Plaintiffs' experts. In this regard, Plaintiffs' briefing on their motions to exclude repeat many of the arguments already raised in their opposition to Defendants' motions to exclude. I note that neither Plaintiffs nor Defendants address the arguments raised in Plaintiffs' motions to exclude in their Post-Hearing briefing.

Daubert Hr'g Tr., at 1005.) In that capacity, Dr. Diette has three major roles: (1) evaluate patients at the clinic; (2) educate medical students, residents, fellows, and other trainees; and (3) conduct research. (*Id.*) He received his M.D. from Temple University School of Medicine. (Diette Expert Rep., at 1.) The doctor also holds an M.H.S. in epidemiology and clinical epidemiology from the Johns Hopkins Bloomberg School of Public Health. (*Id.*) His areas of clinical expertise include internal medicine, pulmonary medicine, and critical care medicine. (*Id.*) While Plaintiffs imply in their briefing that Dr. Diette is not qualified to provide an epidemiological opinion as to the relationship between talc use and ovarian cancer, because the primary focus of his research is pulmonary disease, (*see* Pls.' Mem. Of Law in Supp. of Mot. To Exclude Opinions of Defendants' Epidemiology Experts ("Pls.' Epidemiology Br."), at 6), the Court is satisfied that Dr. Diette is qualified to testify on epidemiology. *Daubert*'s qualification requirement is liberally construed, and the Third Circuit has instructed that an expert should not be excluded "merely because the court feels that the expert is not the best qualified or that the expert does not possess the most appropriate specialization." *In re Human Tissue*, 582 F. Supp. 2d at 655. I find that Dr. Diette has extensive training and experience in epidemiology and, further, that his medical training affords him the expertise to interpret epidemiological studies. As such, to the extent Plaintiffs seek to exclude Dr. Diette based on a lack of qualifications, I decline to do so.

Dr. Diette opines that "[t]he body of relevant epidemiological evidence does not support a causal connection between perineal use of talcum powder products

(whatever constituents those products may contain in addition to talc) and ovarian cancer." (Diette Expert Rep., at 2.) Dr. Diette, like Plaintiffs' general causation experts, performed a Bradford Hill analysis and explains that, most notably, the strength of association, consistency, dose-response, and biological plausibility factors did not demonstrate a causal relationship. (*Id.* at 3.) In sum, Dr. Diette opines

> 1. The epidemiological literature shows a non-existent association or, at most, a small association between perineal talc use and ovarian cancer that constitutes only weak epidemiological evidence. Because any purported association demonstrated in the literature is weak, it may well be attributed to factors such as confounding, bias or chance.
>
> 2. Studies have not consistently shown an association. The prospective epidemiological studies (cohort studies) do not show a statistically significant association; the hospital based case-control studies do not show a statistically significant association; and only a subset of the population-based case-control studies show a statistically significant association. If consistency could be drawn from these inconsistent results, it would be a consistency of null results because case-control studies, which are more easily subject to certain biases and confounding facts, are not the best evidence for proving causation.
>
> 3. Evidence of a dose-response relationship is lacking. None of the cohort studies reveals a dose-response relationship, and only a handful of case-control studies, including those analyzing "cumulative" talc use, have purported to find one. Moreover, study authors and plaintiffs' experts all agree that there are major challenges to interpreting the study findings on dose-response because there can be no assurance that any estimates of talc use are accurate or valid. Indeed, there is not a single epidemiologic study that has used, or purports to have used, a validated measure of talcum powder use. Without a validated measure of talcum powder use, it is impossible to correctly determine

> whether or not an exposure occurred or the quantity of purported exposure, casting considerable doubt on any purported causative relationship between perineal talcum powder use and ovarian cancer.
>
> 4. The theories as to how talc or asbestos would reach the ovaries have not been validated, and the scientific community has repeatedly expressed the opinion that the potential mechanism by which talcum powder is associated with ovarian cancer remains speculative.
>
> 5. Additional Bradford Hill factors–temporality, coherence of the association and analogy–are not satisfied based on the available epidemiologic evidence and do not support the allegation that talcum powder use can cause ovarian cancer.

(Diette Expert Rep., at 3.)

Plaintiffs contend that Dr. Diette's opinions are unreliable and specifically challenge his assessment of the consistency of association, dose-response, and biological plausibility criteria. (*See* Pls.' Epidemiology Br., at 7–57.) First, with respect to the consistency of association, Plaintiffs contend that Dr. Diette's methodology is flawed as he conducted statistical significance testing and erroneously applied a "'hierarchy of the evidence' principle to assess the talc studies by *generic* design or category of study," as opposed to considering the specific strengths and weaknesses of each individual study. (*Id.* at 20–47.) Second, as to dose-response, Plaintiffs argue that Dr. Diette incorrectly requires, against the Bradford Hill principles, that there be consistent findings of dose-response across the studies. (*See id.* at 52–53 & n.110.) Finally, Plaintiffs contend that Dr. Diette similarly misdefined and misapplied the biological plausibility factor by conflating biological plausibility with biological proof. (*Id.* at 57–61.)

Defendants maintain, however, Dr. Diette reliably applied the Bradford Hill criteria. Defendants reason that, in addition to considering statistical significance in addressing the consistency factor, Dr. Diette also "considers and rejects Plaintiffs' experts' arguments criticizing the cohort studies," and addresses other inconsistencies in the epidemiological studies. (Defs.' Opp. To Pls.' Mot to Exclude Defs.' Epidemiology Experts ("Defs.' Epidemiology Br."), at 18–20.) With respect to dose-response, Defendants maintain that Dr. Diette correctly found that the studies do not present evidence of a dose-response and "that even the studies plaintiffs' experts believe provide the strongest indication of a dose-response instead refute [their] theory." (*See id.* at 41–50.) Finally, as to the biological plausibility factor, Defendants contend that Dr. Diette applied the correct standard for biological plausibility and reliably opines that a plausible biological mechanism has not been shown by the relevant studies. (*Id.* at 50–55.)

Where, as here, the parties have offered competing expert testimony, the testimony of each expert is admissible so long as it is reliable and meets the other *Daubert* requirements. *See Perry v. Novartis Pharm. Corp.*, 564 F. Supp. 2d 452, 464 (E.D. Pa. 2008). Indeed, "[t]hat two different experts reach opposing conclusions from the same information does not render their opinions inadmissible." *Walker v. Soo Line R.R. Co.*, 208 F.3d 581, 589 (7th Cir. 2000); *see also Pritchard*, 705 F. Supp. 2d at 483 (noting that "it will be left to the jury to establish the relative credibility of the parties' competing experts" (citing *Perry*, 564 F. Supp. 2d at 464)); *Allapattah Servs, Inc. v. Exxon Corp.*, 61 F. Supp. 2d 1335, 1340-41 (S. D. Fla. 1999)

("Merely because two qualified experts reach directly opposite conclusions using similar, if not identical, data bases or disagree over which data to use or the manner in which the data should be evaluated, does not necessarily mean that, under *Daubert*, one opinion is *per se* unreasonable."). Instead, such a situation presents a classic "battle of the experts" scenario which is for the jury to resolve. *In re Asbestos*, 714 F. Supp. 2d at 547 (observing that "[t]he ultimate determination of whether expert testimony is correct and 'reliable' in this sense remains with the jury" (quoting *Cook v. Rockwell Int'l Corp.*, 580 F. Supp. 2d 1071, 1085 (D. Colo. 2006))); *see also Abilifiy*, 299 F. Supp. 3d at 1336 ("To the extent Defendants' experts draw a different conclusion from those same facts, this presents a proverbial 'battle of the experts,' which appropriately should be decided by a jury."); *Dzielak*, 2017 WL 1034197, at *26 ("What is presented here is a classic battle of the experts over disputed facts, to be settled by the finder of fact; it does not affect admissibility.").

The Court finds that Dr. Diette's opinions are reliable and admissible pursuant to *Daubert*. Dr. Diette's testimony at the *Daubert* hearing and his expert report demonstrate that his opinions reasonably flow from the epidemiological studies and that he followed a reliable methodology in reaching his conclusions. As to Dr. Diette's analysis of consistency, the parties, again, dispute the role of significance testing, or statistical significance, in assessing the consistency of an association. Plaintiffs' arguments related to Dr. Diette's analysis of the consistency factor restate the arguments raised by the parties with respect to Plaintiffs' general causation experts' assessment of the same factor. As the Court discussed above, the parties

fundamentally disagree as to the weight that should be given to the cohort and case-control studies, respectively, and, further, what role statistical significance should play in the assessment of the consistency of association. These disputes, based on each experts' interpretation of the relevant studies' results and trends, cannot be resolved in the context of this *Daubert* motion. Rather, pursuant to *Daubert*, my review of Dr. Diette's testimony and his expert report is only confined to whether Dr. Diette's methodologies in interpreting the studies are reliable, and on the issue, I find that his opinion is based on a fair interpretation of the relevant epidemiological studies and is not methodologically flawed. In his expert report, Dr. Diette explains in detail his consistency findings:

> the prospective epidemiologic studies (cohort studies) do not show a statistically significant association, while only a subset of the population-based case-control studies do. This disparity reflects inconsistent results across different types of studies, undermining the conclusion that cosmetic talc use causes ovarian cancer. The fact that none of the cohort studies found a statistically significant association between talc use and ovarian cancer is critical in this regard, because it calls into doubt even the modest association in some of the population-based case-control studies.

(Diette Expert Rep., at 24 (footnotes omitted).) Dr. Diette goes on to criticize the consistency findings of Plaintiffs' general causation experts, notably disagreeing with their assessment of the cohort studies. (*See id.* at 24–25.) At the *Daubert* hearing, the doctor elaborated on his methodology for this analysis, explaining that

> I'm not saying that the entire consistency criterion is fulfilled by whether things are statistically significant or not. What I really focused on primarily was that the different [study] designs produce different answers, and it

> is not because of something that looks like that. It's because there is a null effect from the cohort studies and not the case-control.

(Diette *Daubert* Hr'g Tr., at 1160.) The Court finds this analysis to be reliable. It is evident that Dr. Diette considered the totality of the studies and that his assessment of the studies is based on "good grounds." That Dr. Diette interprets the studies' results differently than Plaintiffs' experts is not a ground for exclusion.

Next, as to his findings on a dose-response relationship, Dr. Diette explained that "none of the prospective cohort studies showed a dose-response," and "[w]here the case-control studies that had some estimate of dose-response, the results were highly variable." (*Id.* at 1051.) Dr. Diette read these results as "highly inconsistent" and possibly demonstrative of a lack of a causal relationship. (*See id.* at 1052–53.) While Plaintiffs assert that Dr. Diette unreliably required consistency in dose-response results, Plaintiffs overstate Dr. Diette's analysis. It is apparent from his hearing testimony that Dr. Diette's finding of a lack of dose-response is not because of the inconsistent dose-response results, but instead, based on his opinion that the inconsistent results demonstrate the lack of a clear dose-response trend. This is a fair reading of the epidemiologic studies. Dr. Diette reviewed the results of the studies and assessed whether they were sufficient to show a dose-response relationship. Based on the inconsistent data, Dr. Diette determined there is not such a relationship. That determination rests on "good grounds" and is reliable. That Plaintiffs disagree with that interpretation is a question for cross-examination. *See Roundup*, 390 F. Supp. 3d at 1150–51 (finding that "different interpretations of

[epidemiology] studies are not necessarily evidence of unreliability" so long as each interpretation is "sufficiently grounded in scientific principles").

And, finally, with respect to biological plausibility, Dr. Diette in his expert report assessed the studies relied upon by Plaintiffs' experts as to their theory that it is biologically plausible that talc can travel from the perineal area to the ovaries, where it causes inflammation that can lead to ovarian cancer. (*See* Diette Expert Rep., at 36–42.) Dr. Diette opines that the there is "insufficient" scientific evidence to support that theory. (*See id.*) Again, the record demonstrates that Dr. Diette reliably reached this opinion based on his interpretation of the available data. Simply because Dr. Diette and Plaintiffs' experts "reach directly opposite conclusions using similar, if not identical data bases, or disagree over which data to use or the manner in which the data should be evaluated, does not necessarily mean that, under *Daubert*, one opinion is per se unreliable." *Allapattah Servs.*, 61 F. Supp. 2d at 1341.

Indeed, the dispute over the reliability of Dr. Diette's testimony mirrors the dispute over the admissibility of the opinions of Plaintiffs' general causation experts. The parties fundamentally disagree as to which experts' opinion and interpretation is best and, further, which experts reached the correct conclusions. Where the Court has determined that the experts on both sides have applied a reliable methodology in reaching their conclusions, "it is up to the jury to decide whether the expert used the best or most reliable methodology, what weight to accord to his testimony and which of [the] competing experts' opinions should be credited." *In re Asbestos*, 714 F. Supp. 2d at 547 (alteration in original) (quoting *Cook*, 580 F. Supp. 2d at 1085). That is

because "[t]he ultimate determination of whether expert testimony is correct and 'reliable' in this sense remains with the jury." *Id.*; *see also Phillips v. Cohen*, 400 F.3d 388, 400 (6th Cir. 2005) (observing that "competing expert opinions present the 'classic battle of the experts' and it [is] up to a jury to evaluate what weight and credibility each expert opinion deserves" (alteration in original)); *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK, Ltd.*, 326 F.3d 1333, 1341 (11th Cir. 2003) (noting that on a *Daubert* motion, "it is not the role of the district court to make ultimate conclusions as to the persuasiveness of the proffered evidence"). The Court, in its capacity as a gatekeeper under *Daubert*, cannot determine whose opinions or conclusions are more sound. To do so would usurp the role of the jury. For these reasons, Plaintiffs' motion to exclude Dr. Diette is denied.

B. Dr. Cheryl Saenz

Dr. Saenz has been presented as an expert in gynecologic-oncology. She received her M.D. at the University of California, Irvine, and completed her residency in obstetrics and gynecology at the University of California, San Diego. (Saenz *Daubert* Hr'g Tr., at 1799.) Following her residency, Dr. Saenz completed a fellowship in gynecologic oncology at Memorial Sloan Kettering Cancer Center. (*Id.*) The doctor is currently a clinical professor in gynecologic oncology at the University of California, San Diego, in the Department of Obstetrics, Gynecology, and Reproductive Sciences. (*Id.* at 1800.) In that position, Dr. Saenz testifies that she frequently teaches medical students and trainees risk factors for developing ovarian cancer. (*Id.*) Plaintiffs do

not dispute that Dr. Saenz is qualified to act as an expert in gynecologic-oncology. [52]

In this proceeding, Dr. Saenz opines that "perineal application of talcum powder does not cause ovarian cancer." (Saenz *Daubert* Hr'g Tr., at 1807.) Dr. Saenz came to that opinion using the following methodology:

> I went about researching this question as to whether or not talc is a risk factor for the development of ovarian cancer, much like I would go about asking any other question in the field of gynecologic oncology. I did a very extensive literature search. I reviewed somewhere around 30 case-control studies. I reviewed the four published cohort studies. I reviewed seven meta-analyses and one pooled analysis.
>
> I went back and looked at the literature surrounding what are the known established risk factors for ovarian cancer, and put together a report based on that research.
>
> I also relied very heavily upon my experience in the field practicing in the subspecialty of gynecologic oncology for almost 25 years . . . , and considered all of the patients that I have taken care of that have had the diagnosis of ovarian cancer, as well as the women that are in my practice and that I have taken care of that are at high risk for developing ovarian cancer, including all of the slides that I

---

[52] Plaintiffs argue that Dr. Saenz's critique of the opinion of Dr. Rebecca Smith-Bindman, another of Plaintiffs' epidemiology experts, should be excluded because Dr. Saenz's criticisms are unfounded. In that connection, Plaintiffs contend that because Dr. Saenz is not an epidemiologist she "lacks the basic qualifications to critique Dr. Smith-Bindman's epidemiological assessment." (Pls.' Br. in Supp. Mot. to Exclude Defs.' Gynecology-Oncology Experts ("Pls.' Gynecology-Oncology Br."), at 32.) The Court will not disqualify Dr. Saenz on these grounds. As the Court has explained, it is well-established that medical doctors are qualified to opine as to epidemiology studies. *See, e.g.*, *In re Mirena IUD Prods. Liab. Litig. ("Mirena I")*, 169 F. Supp. 3d 396, 426 (S.D.N.Y. 2016) ("[M]edical doctors do not need to be epidemiologists in order to testify regarding epidemiological studies."); *Wolfe v. McNeil-PPC, Inc.*, 881 F. Supp. 2d 650, 659 (E.D. Pa. 2012). Indeed, the Third Circuit has cautioned that a court may not exclude an expert's testimony because he or she does not have the particular degree that the court views to be "most appropriate." *In re Paoli*, 916 F.2d at 855. Accordingly, the Court does not find it appropriate to exclude Dr. Saenz on this basis.

> have looked at from their surgeries, all of the findings that I find when I'm operating. I relied upon the breadth and depth of my experience.

(*Id.* at 1308–09.) While Dr. Saenz did not complete a full Bradford Hill analysis as part of her methodology, she considered certain of the Bradford Hill criteria in rendering her opinion and criticized the Bradford Hill analyses conducted by Plaintiffs' experts. (*See id.* at 1974–76.) Dr. Saenz specifically considered the following Bradford Hill factors: (1) strength of association, (2) consistency, (3) coherence, (4) dose-response, and (5) biological plausibility. (*Id.* at 1974.) In sum, Dr. Saenz found that

> the epidemiologic literature on the association between the use of talc in the genital area and the development of ovarian cancer does not support a causal role for talc. The case-control studies are inconsistent, both between studies and within individual studies and they are unable to demonstrate a dose-response curve; the cohort studies do not demonstrate any statistically significant associations across the tens of thousands of women studied over decades and they undermine the hypothesis of biologic[al] plausibility; and lastly the meta-analyses bring nothing new to the discussion, again rehashing the same data many times over and still being unable to demonstrate any changes in the purported strength of association or any evidence of a dose-response curve.

(Saenz Expert Rep., at 17.)

Plaintiffs raise two key arguments as to why Dr. Saenz's testimony in this matter should be excluded. First, Plaintiffs posit that Dr. Saenz did not properly consider the "totality of the evidence" because she gave greater weight to the cohort studies than the case-control studies. (Pls.' Gynecology-Oncology Br., at 6–22.) Notably, Plaintiffs assert that Dr. Saenz dismissed statistically significant case-

control studies simply because they had a relative risk of less than 2.0 and that she relies on no epidemiologic authority for her dismissal of the case control studies. (*Id.* at 14–22.)

I first address the contention that Dr. Saenz unreliably weighed the case-control and cohort studies. At the *Daubert* hearing, Dr. Saenz explained that she placed greater weight on the cohort studies because she "think[s] they are more scientifically credible because they are not as subject to the biases of the case-control studies." (Saenz *Daubert* Hr'g Tr., at 1912.) In her expert report, Dr. Saenz provides detailed reasons as to why she placed more weight on the cohort studies than the case-control studies. (*See* Saenz Expert Rep., at 9–13.) Indeed, Dr. Saenz identifies certain internal inconsistencies of the case-control studies and highlights the high risk of recall bias "that is inherent not just in the case-control studies on talc and ovarian cancer, but all case-control studies." (*See id.*) The Court is satisfied that Dr. Saenz has provided "good grounds" for her opinions with respect to the weight she placed on the varying case-control and cohort studies. Plaintiffs may disagree with Dr. Saenz's assessment of the epidemiology studies, but, as this Court has stated repeatedly, "*Daubert* neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance." *Mitchell*, 365 F.3d at 244 (quoting *Ruiz-Troche*, 161 F.3d at 85. It is clear from the extensive briefing in this matter that the experts disagree about how to assess and weigh the relevant epidemiological studies related to the question of whether talc use causes ovarian cancer. Resolution of that disagreement is reserved for the finder of fact.

Next, Plaintiffs challenge Dr. Saenz's testimony as to biological plausibility. In this regard, Plaintiffs raise two arguments: (1) Dr. Saenz incorrectly requires proof of a mechanism, and (2) Dr. Saenz's testimony on biological plausibility is unreliable because she admittedly did not review all the relevant studies cited by Plaintiffs' experts with respect to this Bradford Hill criteria. (*See* Pls.' Gynecology-Oncology Br., at 22–31.) Plaintiffs specifically take issue with Dr. Saenz's failure to review five *in vitro* studies which they allege demonstrate Plaintiffs' theory of biological plausibility: (1) the 2007 Buz'Zard study, (2) the 2009 Shukla study, (3) the 2010 and 2014 Ahktar studies, and (4) Dr. Saed's 2019 *in vitro* study. (*See* Saenz *Daubert* Hr'g Tr., at 1936–37.) Dr. Saenz explained that she "knew about the studies, and [she] knew from reading the expert reports that none of these studies actually showed malignant transformation," and thus, she determined they were not important to her analysis. (*Id.* at 1938, 1976.) Dr. Saenz further testified that she did, in fact, read and consider Dr. Saed's 2019 study as set forth in his expert report in this matter. (*See id.* at 1937.)

It is axiomatic that "[w]here an expert ignores evidence that is highly relevant to [her] conclusion, contrary to [her] own stated methodology, exclusion of the expert's testimony is warranted." *Mirena II*, 341 F. Supp. 3d at 241. There is not, however, any requirement that an expert review every single study in the relevant body of literature. *See, e.g.*, *In re C .R. Bard, Inc. v. Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2187, 2018 WL 4220616, at *5 (S.D. W. Va. Sept. 5, 2018) (observing that "nothing in *Daubert* requires an expert to consider every single article on a topic in

order to be admitted as an expert"); *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, MDL No. 2545, 2018 WL 4030585, at *6 (N.D. Ill. Aug. 23, 2018) (finding that simply because an expert did not consider all studies deemed relevant by the opposing party or overlooked a study "does not mean that he unreliably applies his methodology"). Here, Dr. Saenz's deliberate choice to not review these articles identified by Plaintiffs, does not render her opinion inadmissible. Dr. Saenz explained that because the studies referred to, but did not reveal, any malignancy from talc, she did not view them as relevant on the question of biological plausibility. While Plaintiffs dispute Dr. Saenz's opinion, that disagreement is better explored on cross-examination.

As to Dr. Saenz's opinion on biological plausibility, Plaintiffs submit that Dr. Saenz unreliably requires that there be "proof" that talc can migrate from the perineum to the ovaries, notably in the form of a mechanistic study. (Pls.' Gynecology-Oncology Br., at 22–23.) However, at the *Daubert* hearing, Dr. Saenz testified that biological plausibility does not require "proof positive, nor does it need to be an exact representation of whatever is your hypothesis," but that there needs to be "enough science to make sense and extend it." (Saenz *Daubert* Hr'g Tr., at 1827–28.) Dr. Saenz disagrees with both the aspects of biological plausibility theory put forth by Plaintiffs' general causation experts—migration and inflammation—based on her clinical experience as a gynecologic-oncologist and her review of the epidemiological literature. (*See id.* at 1828–32.) Based on her testimony, Dr. Saenz questions the scientific basis of the biologic mechanism presented by Plaintiffs'

general causation experts. Where those experts purport to present a supported hypothetical mechanism, Dr. Saenz asserts that they have proffered a guess that is not based on sufficient scientific evidence. Again, resolution of that question would require the Court to weigh the credibility or reliability of each expert's theory to determine which is more correct; that is not within the province of a judge on a *Daubert* motion. *See Gutierrez*, 2006 WL 3246605, at *8.

In what has become a repeated refrain in this Opinion, I again note that the dispute between the parties on the admissibility of various causation experts, here, boils down to which experts are more accurate in their opinions based on competing interpretations of the relevant studies. While Plaintiffs attempt to undermine the reliability of Dr. Saenz's testimony, the Court finds that Dr. Saenz's opinions are admissible under *Daubert*. Accordingly, Plaintiffs' motion to exclude Dr. Saenz is also denied.

C. Dr. Benjamin Neel

Dr. Neel is proffered by Defendants as an expert in cancer biology. Dr. Neel is currently the Acting-Director of the Laura and Issac Perlmutter Cancer Center at NYU Langone Health. (Neel *Daubert* Hr'g Tr., at 279–80.) He is a Professor of Medicine at NYU School of Medicine, where he also runs a 13-person research laboratory. (*Id.* at 280.) The focus of Dr. Neel's research laboratory is "cell signaling in normal cells and how that is regulated in cancer" and "on generating new models of ovarian cancer and the cell of origin of ovarian cancer. (*Id.* at 282.) Dr. Neel received a Ph.D. in viral oncology at the Rockefeller University in 1982 and his M.D.

from Cornell University Medical School in 1983. (Neel Expert Rep., at 2.)

Dr. Neel opines that "[t]alc is not genotoxic, does not cause mutations, does not cause inflammation in the female genitourinary tract and has not been shown to cause ovarian cancer." (Neel Expert Rep., at 14.) The core of Dr. Neel's opinions are focused on the experiment conducted by Dr. Saed, and in that connection, Dr. Neel opines that Dr. Saed's *in vitro* study was "flawed on multiple levels" and that the results of his study do not support his conclusion that Defendants' products can cause ovarian cancer. (Neel *Daubert* Hr'g Tr., at 303.) Dr. Neel additionally reviewed the epidemiological literature and, based on his interpretation of the relevant studies and his weighing of the Bradford Hill criteria, he concludes that there is no evidence to support Plaintiffs' claim that perineal use of talcum powder can cause ovarian cancer. (*Id.* at 296; *see also* Neel Expert Rep., at 14–28.)

Plaintiffs attack Dr. Neel's opinions on two grounds. First, Plaintiffs argue that Dr. Neel's opinion with respect to biological plausibility is not reliable because he is unaware of the constituent components of talc products, *i.e.*, whether such products are fibrous, contain asbestos, or contain heavy metals. (Pls.' Br. in Supp. Mot. to Exclude Defs.' Molecular Biologists ("Pls.' Molecular Biology Br."), at 13.) Second, Plaintiffs contend that Dr. Neel is not qualified to testify "regarding the strengths and weaknesses of the epidemiological studies," nor is he qualified to conduct a Bradford Hill analysis, as he did here. (*Id.* at 28.) Defendants maintain that Dr. Neel need not consider the components of talc in his opinion because his report is focused on criticizing the methodologies of Plaintiffs' experts and, to the

extent he offers an opinion on biological plausibility, his testimony is focused on *in vitro* studies that considered the carcinogenic effect of talc, notwithstanding talc's components. (Defs.' Br. in Opp. Pls.' Mot. to Exclude Defs.' Molecular Biologists ("Defs.' Molecular Biology Br.")., at 14–17.) Defendants additionally argue that Dr. Neel, as a medical doctor, is qualified to opine as to the epidemiologic evidence. (*Id.* at 19–22.)

At the outset, it appears that Plaintiffs do not move to exclude Dr. Neel's rebuttal opinion to Dr. Saed's testimony. Indeed, Plaintiffs' briefing makes no mention of Dr. Neel's testimony in this regard, or otherwise suggests it to be unreliable or inadmissible under *Daubert*. The Court, after hearing Dr. Neel's testimony at the *Daubert* hearing and reviewing his expert report, finds that Dr. Neel can reliably serve as a rebuttal expert as to Dr. Saed's opinion that talc causes cellular inflammation.[53] *Cf. In re Front Loading Washing Machine Class Action Litig.*, No. 08-51, 2013 WL 3466821, at *4–5 (D.N.J. July 10, 2013) (admitting testimony of rebuttal expert where he reliably reviewed testing conducted by other experts in the proceeding). In short, there is no basis for the Court to find that Dr. Neel's opinions in this specific context are unreliable under *Daubert*.

What Plaintiffs argue is that Dr. Neel's opinion is unreliable because he did

---

[53] The Court notes that to the extent Dr. Neel is called to rebut the expert testimony of Dr. Saed, his opinions must be limited to Dr. Saed's admissible opinions. As the Court determined above, Dr. Saed's testimony is limited to his finding that talc causes inflammation and oxidative stress. Dr. Saed will not be permitted to opine as to whether such inflammation leads to ovarian cancer. Correspondingly, Dr. Neel will not be permitted to rebut any portion of Dr. Saed's report that has been excluded by the Court.

not consider the components of talc. In other words, Plaintiffs fault Dr. Neel for not analyzing whether talc contains known carcinogens, such as asbestos or other heavy metals, because, they argue, knowledge of the components of talc is essential to any opinion as to whether talc causes ovarian cancer. (*See* Pls.' Molecular Biology Br., at 12–14.) Defendants argue Plaintiffs ignore the "core" of Dr. Neel's report and opinion—that is, to critique the methodologies employed by Plaintiffs' experts. (Defs.' Molecular Biology Br., at 12.) Defendants maintain that "the alleged contamination of talc with other substances is utterly irrelevant to" Dr. Neel's opinion. (*See id.* at 15.) The Court agrees. There is no requirement that Dr. Neel opine as to the components of talc; indeed, Dr. Neel has been proffered as an expert to rebut the methodology employed by Dr. Saed in conducting his *in vitro* study. That study does not make any finding as to whether any component of talc is carcinogenic, but instead opines that talc *itself* can cause inflammation and oxidative stress. The issue of the composition of talc is, thus, irrelevant to Dr. Neel's testimony, and his silence as to those components does not render his testimony unreliable.

Plaintiffs additionally argue that Dr. Neel is not qualified to provide an opinion as to the strengths and weaknesses of the epidemiological studies, because he is not an epidemiologist. (Pls.' Molecular Biology Br., at 32–33.) In so arguing, Plaintiffs concede that "the law recognizes that 'most arguments about an expert's qualifications relate more to the weight to be given the expert's testimony than to its admissibility." (*Id.* at 28 (quoting *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 782 (3d Cir. 1996).) Nevertheless, Plaintiffs state, without support, that because Dr. Neel

is not an epidemiologist, he cannot reliably opine as to causation determined by epidemiological grounds. Again, I disagree. The Third Circuit has made clear that an expert should not be excluded because he or she does not have "a certain kind of degree or background." *In re Paoli*, 916 F.2d at 855; *see also Pineda*, 520 F.3d at 244 ("[I]t is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate." (alteration in original) (quoting *Holbrook*, 80 F.3d at 782)). Dr. Neel has extensive medical training, which establishes his qualifications to interpret the relevant epidemiologic literature. In addition to being a cancer biologist, Dr. Neel holds an M.D. This is sufficient to qualify him to render an opinion with respect to the epidemiological studies under *Daubert*. *See, e.g.*, *Wolfe*, 881 F. Supp. 2d at 659; *Mirena I*, 169 F. Supp. 3d at 424.

Finally, Plaintiffs argue that Dr. Neel incorrectly applies the Bradford Hill criteria as he places too much weight on biological plausibility. Defendants, in response, maintain that Plaintiffs' position distorts Dr. Neel's testimony on this issue to make it appear that Dr. Neel, in his opinion, requires proof of biological plausibility as "essential." (Defs.' Molecular Biology Br., at 23–24.) Plaintiffs' argument relies on Dr. Neel's deposition testimony in which he explained that where "a series of epidemiological associations . . . are conflicting and weak, the biological plausibility becomes essential." (Neel Dep. Tr., at 148.) Dr. Neel expanded on this testimony at the *Daubert* hearing, explaining that biological plausibility is "particularly important

when the other evidence is relatively inconsistent or weak." (Neel *Daubert* Hr'g Tr., at 294.) The doctor elaborated further that he understands biological plausibility to require "some credible scientific evidence supporting the hypothesis." (*Id.* at 295.) This is an issue that goes to the weight of Dr. Neel's testimony. Dr. Neel presented good grounds for his opinion that, where an association is weak and inconsistent, biological plausibility may become more important in the overall Bradford Hill analysis. While Plaintiffs disagree, that is not a reliability issue for this Court to decide. For these reasons, the Court denies Plaintiffs' motion to exclude Dr. Neel.

IV. CONCLUSION

For the foregoing reasons, the Court rules as follows:

1. Defendants' Motion to Exclude the Expert Testimony of Dr. Saed is GRANTED in part and DENIED in part. Specifically, Dr. Saed's testimony is limited to his opinion and testing that talcum powder causes inflammation and oxidative stress. Dr. Saed is not permitted to opine as to any connection between talcum powder use and ovarian cancer.
2. Defendants' Motion to Exclude the Testimony of Dr. Longo is GRANTED in part and DENIED in part. Dr. Longo is permitted to opine as to his findings of asbestos in Defendants' talcum powder products based on his TEM analysis; however, any opinions based on his PLM analysis are excluded. Further, his opinion that women who used talcum powder products were exposed to asbestos is excluded as unreliable.
3. Defendants' Motion to Exclude the Testimony of Plaintiffs' General

Causation Experts—Drs. McTiernan, Carson, and Clarke-Pearson, is GRANTED in part and DENIED in part. Plaintiffs' General Causation Experts will not be permitted to testify as to their secondary theory of biological plausibility—*i.e.*, that ovarian cancer may be caused by inhalation of talcum powder that travels through the lymphatic system to the ovaries. They may otherwise testify as to their opinions on all other Bradford Hill factors.

4. Plaintiffs' Motion to Exclude the Testimony of Dr. Diette is DENIED.
5. Plaintiffs' Motion to Exclude the Testimony of Dr. Saenz is DENIED.
6. Plaintiffs' Motion to Exclude the Testimony of Dr. Neel is DENIED.

DATED: April 27, 2020

s/ Freda L. Wolfson
Freda L. Wolfson
Chief U.S. District Judge