UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	Case No. 3:16-md-2738 (MAS) (RLS) MDL No. 2738 **REPORT & RECOMMENDATION**

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

TABLE OF CONTENTS

Page

I. INTRODUCTION 1
II. BACKGROUND AND PROCEDURAL HISTORY 2
A. The Talc MDL 2
B. The First Round of Rule 702 Motions 3
C. Johnson & Johnson's Bankruptcy Proceedings 4
D. The Current Round of Rule 702 Motions 5
E. The Pending Daubert Motions 6
F. My Appointment and Duties as Special Master 8
III. OVERVIEW OF THE 2020 OPINION 9
A. Dr. Ghassan Saed 10
B. Dr. William Longo 11
C. Drs. Anne McTiernan, Daniel Clarke-Pearson, and Arch Carson 14
D. Dr. Gregory Diette 16
E. Dr. Cheryl Saenz 18
F. Dr. Benjamin Neel 19
IV. LEGAL STANDARD 21
A. Federal Rule of Evidence 702 21
B. 2023 Amendment to Rule 702 22
1. The Amendments 22
2. The Impact of the 2023 Amendment 23
C. Daubert and its Progeny 25
D. Admissibility Versus Weight 30
E. Publication and Peer Review Status 34
V. GENERAL CAUSATION 41
A. A Brief Primer Regarding Talc and Asbestos 42
B. Defendants' General Causation Motions 45
1. Scope of Review 46
2. Plaintiffs' Experts 50

3. The Bradford Hill Factors 55
4. Scientific Developments Since 2020 59
5. The Parties' Bradford Hill Arguments 68
   i. Strength of the Association 68
   ii. Consistency 92
   iii. Biological Gradient (or Dose-Response Relationship) 111
   iv. Biological Plausibility 126
      a. Ovarian Cancer Subtypes 130
      b. Migration 141
      c. Inflammation, Oxidative Stress, and Macrophage-Impairment 179
         (1) Talcum powder and chronic inflammation, oxidative stress 186
         (2) Chronic inflammation and ovarian cancer 212
         (3) Macrophage-impairment and ovarian cancer 234
   v. The Remaining Bradford Hill Factors 242
      a. Specificity 242
      b. Coherence 247
      c. Analogy 252
      d. Experiment 255
      e. Temporality 257
6. Asbestos 260
7. Heavy Metals and Fragrances 279
   i. Consideration of Defendants' Arguments in the 2020 Opinion 280
   ii. Summary of Plaintiffs' Heavy Metals and Fragrances Experts and Opinions 282
      a. Drs. Cook's and Krekeler's opinions 283
      b. Dr. Michael Crowley's opinions 285

c. Other experts 292
iii. Admissibility Analysis 304
a. Qualifications and Fit 304
(1) Dr. Cook's and Dr. Krekeler's qualifications and fit 306
(2) Dr. Crowley's qualifications and fit 309
(3) Other experts' qualifications and fit 310
(a) Heavy metals 310
(b) Fragrances 314
(c) Fit 315
b. Reliability 315
(1) Heavy metals 315
(a) Lack of connection to ovarian cancer 316
(b) Dose-response 325
(2) Dr. Crowley—fragrance chemicals 328
(a) Lack of a link to ovarian cancer 329
(b) Dose-response 335
(c) Other experts' opinions on fragrance chemicals 337
C. Plaintiffs' Motions to Exclude Defendants' Rebuttal Experts' Genetics-Related General Causation Opinions and Biological Plausibility Opinions 340
1. Defendants' Experts 342
i. Drs. Saenz, Finan & Holcomb 343
a. Qualifications 343
b. Relevant Opinions 346
ii. Dr. DiFeo 350
a. Qualifications 350
b. Relevant Opinions 351
iii. Dr. Permuth 353
a. Qualifications 353

b. Relevant Opinions 354
iv. Dr. Boyd....356
a. Qualifications 356
b. Relevant opinions....357
2. Plaintiffs' Arguments 363
i. Genetics-Related General Causation Opinions 366
ii. Biological Plausibility Causation Opinions....378
a. Constituents of Talcum Powder 378
b. Biological Plausibility Standard....388
iii. Dr. Boyd....395
a. Qualifications 396
b. Reliability 399
c. Fit....408
iv. Plaintiffs' Motion to Exclude the Opinions of Dr. Kornak 410
a. O'Brien 2024....411
(1) The Sister Study....412
(2) O'Brien 2024's quantitative bias analysis corrections....413
(3) O'Brien 2024's recall bias adjustments....416
(4) O'Brien 2024's results 418
b. Dr. Kornak....418
(1) Qualifications....418
(2) Methodology and opinions 419
(3) Reliability....424
VI. CONTAMINATION AND TESTING MOTIONS....433
A. Asbestos....435
1. Defendants' Motion to Exclude Plaintiffs' Experts' Asbestos-Related Opinions....435
i. Drs. William Longo and Mark Rigler....435

a. Qualifications 437
b. Methodology and Conclusions.....439
c. Analysis 442
ii. Drs. Robert Cook and Mark Krekeler 454
a. Qualifications 455
b. Dr. Robert Cook's Methodology and Conclusions 456
c. Dr. Mark Krekeler's Methodology and Conclusions 458
d. Drs. Robert Cook and Mark Krekeler's "Counsel-Generated Charts" 460
e. The Adequacy of Drs. Robert Cook and Mark Krekeler's Factual Foundation 463
2. Plaintiffs' Motion to Exclude the Geology Opinions of Drs. Mary Poulton and Laura Webb 473
i. Rule 702's Qualification Requirement is Liberally Construed.....474
ii. Dr. Mary Poulton's Qualifications.....475
iii. Dr. Laura Webb's Qualifications 478
iv. Analysis Regarding Dr. Mary Poulton 481
v. Analysis Regarding Dr. Laura Webb.....488
B. Tissue Sample Motions 495
1. Defendants' Motion to Exclude the Opinions of Dr. Godleski 497
i. Qualifications.....498
ii. Methodology and Opinions 500
iii. Reliability 507
iv. Fit.....538
2. Plaintiffs' Motion to Exclude The Opinions Of Dr. Juan Felix And Dr. Teri Longacre 540
i. Qualifications.....542
ii. Methodology and Opinions 545

iii. Reliability 548
VII. REGULATORY, MARKETING, AND CORPORATE KNOWLEDGE OPINIONS 551
A. Defendants' Motion to Exclude the Opinions of Drs. David Kessler, Laura Plunkett, William Sage, and George Newman 551
1. Dr. Kessler 551
i. Qualifications 551
ii. Summary of Dr. Kessler's Opinions 554
iii. Specific Exclusion Arguments and Legal Standards 556
a. Factual Narrative Challenge 557
b. Legal Conclusions Challenge 560
c. State of Mind Challenge 566
d. Ethical Opinion Challenge 569
iv. Reliability and Fit 574
v. Scope 576
2. Dr. Plunkett 579
i. Dr. Plunkett's Qualifications 579
ii. Summary of Dr. Plunkett's Opinions 582
iii. The Parties' Exclusion Arguments 585
iv. Reliability 589
a. Risk-Assessment Methodology 590
b. Regulatory-Based Methodology 596
v. Fit, Scope, and Specific Challenges 597
3. Dr. Sage 600
i. Dr. Sage's Qualifications 600
ii. Summary of Dr. Sage's Opinions 602
iii. The Parties' Exclusion Arguments 603
iv. Reliability and Scope 606
v. Fit 608
4. Dr. Newman 610
i. Dr. Newman's Qualifications 610

ii. Summary of Dr. Newman's Opinions 612
iii. The Parties' Exclusion Arguments.....614
iv. Reliability 617
v. Fit and Scope 621
5. Conclusion 623
B. Plaintiffs' Motion to Exclude Dr. Kathleen Sutcliffe.....623
1. Summary of Dr. Sutcliffe's Opinions.....624
2. The Parties' Exclusion Arguments.....627
3. Dr. Sutcliffe's Qualifications.....629
4. Reliability.....634
5. Fit and Scope.....637
VIII. CONCLUSION.....638
IX. REPORT AND RECOMMENDATION DECISION CHART 640

SPECIAL MASTER, Hon. Freda L. Wolfson (ret.):

I. INTRODUCTION

This multidistrict litigation ("MDL") consists of thousands of lawsuits filed by individual consumers, represented by the Plaintiffs' Steering Committee ("Plaintiffs"), who claim that prolonged perineal use of Johnson & Johnson's talcum powder products causes ovarian cancer. As part of coordinated pretrial proceedings, Plaintiffs and the moving defendants—Johnson & Johnson and LLT Management, LLC, and now known as Red River Talc, LLC ("Defendants")—have filed multiple *Daubert*[1] motions.

Pursuant to Federal Rule of Civil Procedure 53(a), the Court appointed me as the Special Master for the limited purpose of addressing the parties' Federal Rule of Evidence 702 *Daubert*-related motions. As detailed below, the parties filed a total of 17 motions challenging the admissibility of expert testimony. I have been tasked with issuing a Report and Recommendation addressing whether the challenged experts' opinions satisfy Rule 702 and the related *Daubert* standard. Consistent with my rigorous gatekeeping obligation, these recommendations address whether (1) certain proffered experts are qualified to testify, (2) the proffered experts' opinions are based on a reliable methodology, and (3) the proffered experts' testimony fits within this case. My recommendations are based on the totality of materials

[1] *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

submitted, as well as arguments presented by the parties at an in-person hearing held on November 25, 2025.

Specifically, I have considered the parties' briefs, expert reports, deposition transcripts, presentations during oral argument, and other supporting documents, including the volume of studies upon which the experts relied in reaching their conclusions. My reasonings and findings are set forth below, and my decisions are summarized in a Chart attached at the conclusion of this Report and Recommendation.[2]

II. BACKGROUND AND PROCEDURAL HISTORY

A. The Talc MDL

Starting in October 2016, the U.S. Judicial Panel on Multidistrict Litigation ("JPML") began transferring all federal actions involving talc-related ovarian cancer to the U.S. District Court for the District of New Jersey for coordinated pretrial proceedings. (*See* ECF Nos. 1; 3; 9; 10; 14; 48; 61; 76; 77; 78; 80; 81.) The JPML assigned this MDL to me in my then-role as a District Judge. I oversaw this MDL until my retirement as Chief U.S. District Court Judge on February 1, 2023. Indeed, I not only have institutional knowledge of this case, but I rendered various substantive rulings in the MDL, including the *Daubert* opinion that is the subject of

[2] For purposes of this review, the terms 'Report and Recommendation' and 'Opinion' are used interchangeably.

the parties' motions here. Following my retirement from the court, the JPML assigned the MDL to Hon. Michael A. Shipp, U.S.D.J., who currently presides over this litigation. (ECF No. 26591.) Since its inception, tens of thousands of cases have been filed in the MDL. According to the JPML, as of January 5, 2026, this litigation has over 67,000 actions now pending, with additional short form complaints filed on a daily basis, making this the largest pending MDL in the United States by a significant margin.

B. The First Round of Rule 702 Motions

After years of discovery in this MDL, in 2019, the parties proffered experts on various scientific issues related to general causation and the testing of talcum powder for asbestos and other contaminants. Each side moved to exclude the testimony of certain of the other side's experts. As discussed at length in Section III of this Report and Recommendation, on April 27, 2020, I issued an Opinion and Order denying Plaintiffs' motions and granting in part, denying in part Defendants' motions. *See In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liab. Litig.*, 509 F. Supp. 3d 116 (D.N.J. 2020) ("2020 Opinion").

In short, while I limited certain conclusions drawn by Plaintiffs' experts, I declined to exclude their ultimate opinions that Defendants' talcum powder products contained trace amounts of asbestos and that, when applied to the perineum, Defendants' talc-based products may cause ovarian cancer in females. Prior to

issuing my Opinion, I held a multi-day *Daubert* hearing at which five experts testified on behalf of Plaintiffs (Drs. Ghassan Saed, William Longo, Anne McTiernan, Daniel Clarke-Pearson, and Arch Carson) and three experts testified on behalf of Defendants (Drs. Gregory Diette, Cheryl Saenz, and Benjamin Neel). *Id.* at 128 & n.2. The parties selected these experts as representatives of each field of science involved in this action. *Id.* at 128 n.2. After the issuance of my 2020 Opinion, the parties proceeded to select bellwether trials.

C. Johnson & Johnson's Bankruptcy Proceedings

However, starting in October 2021, Johnson & Johnson—by and through LTL Management, LLC and later Red River Talc, LLC—attempted, on three separate occasions, to use the bankruptcy court system to resolve all talc litigation. They were unsuccessful. As a result of these bankruptcy proceedings, this MDL has been subject to various stay orders over the years. Most recently, Red River Talc, LLC filed suit in the U.S. Bankruptcy Court for the Southern District of Texas in September 2024, resulting in an automatic bankruptcy stay. However, on March 31, 2025, Hon. Christopher Lopez, U.S.B.J., entered a Memorandum Decision and Order denying confirmation of Red River Talc LLC's plan of reorganization and dismissing its Chapter 11 case. (ECF No. 33426.) In April 2025, Defendants declined to pursue an appeal of that decision, (*id.*), and thus, the stay terminated, resuming this MDL.

D. The Current Round of Rule 702 Motions

On March 27, 2024, after the second, but before the third, bankruptcy proceeding, the Court entered the following Text Order allowing a full refiling of the Rule 702 motions:

> This matter comes before the Court upon Plaintiffs' and Defendants' August 23, 2023 correspondences detailing a disagreement as to the scope of *Daubert* motions. Upon review of the parties' contentions, the Court is persuaded that the recent changes to Federal Rule of Evidence 702, the emergence of new relevant science, and the language of Chief Judge Wolfson's previous *Daubert* Opinion make a full refiling of *Daubert* motions appropriate.

(ECF No. 30260.) Thereafter, Plaintiffs filed a motion for reconsideration of the Court's March 27, 2024 Text Order, which Defendants opposed. (ECF Nos. 31080; 32026; 32118.) The parties fundamentally disagreed (and perhaps still do) regarding the purpose and scope of the renewed Rule 702 motions.

On April 30, 2024, the Court issued a Memorandum Order denying Plaintiffs' motion for reconsideration and providing the parties "in more vivid detail how it intends for [renewed] *Daubert* motions to proceed." (ECF No. 32122 (the "April 30, 2024 Memorandum Order") at 5.) The Court explained that, in holding that a full refiling of the motions is appropriate, it intended "to open up all expert opinions to *Daubert* challenges, even those previously considered by Chief Judge Wolfson." (*Id.*) However, the Court made clear that it did not intend to review *de novo* my prior

findings or "to start *Daubert* motions over from scratch." (*Id.* at 3.) To that end, the Court provided the following guidance to the parties:

> To ensure there is no room for confusion by the parties, the *Daubert* procedure moving forward is as follows: if Chief Judge Wolfson entered a decision on an issue and either party wishes to challenge that decision, briefing on the upcoming in limine motions should set forth Chief Judge Wolfson's previous decision and on what basis the party contends that decision should be reconsidered. In other words, the briefing should identify either: (1) that Chief Judge Wolfson's previous Opinion demonstrably fails to adhere to Rule 702 as clarified by the 2023 amendments; or (2) new science is shown to directly contradict or challenge Chief Judge Wolfson's previous findings. To the extent that the parties seek to file new *Daubert* motions not previously considered by the Court, the parties may file traditional *Daubert* motions without restriction.

(*Id.* at 6.) On July 23, 2024, the parties filed their second round of Rule 702 motions in accordance with the Court's directive.

E. The Pending *Daubert* Motions

The parties have collectively filed a total of 17 Rule 702 motions, which generally fall into four (sometimes overlapping) categories: (1) general causation; (2) contamination and testing; (3) specific causation; and (4) corporate knowledge, safety, regulatory compliance, and marketing. The parties seek to exclude, in whole or in part, the testimony of at least 39 experts.

Specifically, Plaintiffs have filed the following nine motions:

1. Motion to Exclude the Geology Opinions of Drs. Mary Poulton and Laura Webb (ECF No. 32996);
2. Motion to Exclude the Opinions of Dr. Kathleen Sutcliffe (ECF No. 32998);
3. Motion to Exclude the Opinions of Drs. Michael Finan, Cheryl Saenz, and Kevin Holcomb (ECF No. 32999);
4. Motion to Exclude the Opinions of Dr. Jennifer Permuth (ECF No. 33001);
5. Motion to Exclude the Opinions of Drs. Juan Felix and Teri Longacre (ECF No. 33002);
6. Motion to Exclude the Asbestos Testing Opinions of Matthew S. Sanchez, Ph.D., Ann G. Wylie, Ph.D. and Shu-Chun Su, Ph.D. (ECF No. 33006);
7. Motion to Exclude the Opinions of Dr. Analisa DiFeo (ECF No. 33010);
8. Motion to Exclude the Opinions of Dr. John Kornak (ECF No. 33011); and
9. Motion to Exclude the Opinions of Defense Expert Witness Dr. Jeff Boyd (ECF No. 33060).

In addition, Plaintiffs have filed (1) a Brief regarding the Rule 702 Standard, (ECF No. 32994); and (2) a Response to the Court's April 30, 2024 Memorandum Order, (ECF Nos. 33009; 33109).

Defendants have filed the following eight motions:

1. Motion to Exclude the Opinions of Drs. David Kessler, Laura Plunkett, William Sage and George Newman (ECF No. 33000);
2. Motion to Exclude the Specific Causation Opinions Offered by Dr. Judith Wolf (ECF No. 33003);
3. Motion to Exclude the Opinions of Dr. John Godleski (ECF No. 33004);
4. Motion to Exclude Plaintiffs' Experts' Opinions Regarding Alleged Heavy Metals and Fragrances in Johnson's Baby Powder and Shower to Shower (ECF No. 33005);

5. Motion to Exclude the Opinions of Dr. Daniel Clarke-Pearson (ECF No. 33007);
6. Motion to Exclude Plaintiffs' Experts' General Causation Opinions (ECF No. 33008);
7. Motion to Exclude Plaintiffs' Experts' Asbestos-Related Opinions (ECF No. 33012); and
8. Motion to Exclude Plaintiffs' Experts' Opinions Regarding Biological Plausibility/Mechanism (ECF No. 33013).

After the bankruptcy stay terminated and this MDL resumed, the parties urged, and the Court agreed, that the Rule 702 motions should be decided in an expeditious manner so that the first bellwether trial can be conducted in *Carter Judkins v. Johnson & Johnson, et al.*, No. 3:19-cv-12430-MAS-RLS.

F. My Appointment and Duties as Special Master

On June 26, 2025, with the consent of the parties, the Court appointed me "as a limited-purpose Special Master to address the Rule 702 Motions in this MDL." (ECF No. 39429 ¶ 1.) The Court explained that my appointment is both necessary and appropriate because "there are numerous pending pretrial disputes 'that cannot be effectively and timely addressed' by this Court," and that my appointment "would facilitate the prompt adjudication of these disputes and minimize delay in these proceedings." (*Id.* at 1, ¶ 1.)

As I previously advised the parties, the most efficient and orderly means of resolving the pending Rule 702 motions is through a comprehensive Report and

Recommendation, rather than deciding them piecemeal.[3] In that regard, as directed by the Court's April 30, 2024 Memorandum Order, the purpose of filing the present round of motions is not to seek a wholesale reconsideration of my prior Opinion. Rather, my review of the motions is limited in two material respects: to the extent a party challenges one of my prior rulings, reconsideration is warranted only if the party establishes: (1) that my "previous Opinion demonstrably fails to adhere to Rule 702 as clarified by the 2023 amendments" with respect to the challenged ruling, or (2) "new science is shown to directly contradict or challenge" my prior findings. (ECF No. 32122 at 6.) Accordingly, I will confine this Report and Recommendation to those circumstances expressly identified by the Court, including a full review of new experts' conclusions that were not previously addressed in my 2020 Opinion.

III. OVERVIEW OF THE 2020 OPINION

As mentioned above, I issued my Opinion and Order addressing the parties' first round of Rule 702 motions on April 27, 2020. As to the scope of that Opinion, I determined whether the parties' eight representative experts were qualified to testify in this MDL and whether their proffered testimony was admissible under the prior iteration of Federal Rule of Evidence 702. *See In re Johnson & Johnson*, 509

[3] As discussed more fully below, I am holding separate *Daubert* hearings with respect to Dr. William Longo's new PLM-chrysolite opinions and Plaintiffs' experts on specific causation on a schedule consistent with the availability of counsel and the experts. As a result, so as not to delay the issuance of this Report and Recommendation, I will issue a separate Report and Recommendation addressing those issues and experts.

F. Supp. 3d at 128. Because my Opinion only addressed motions related to the representative experts, I applied my reasoning "with equal force to the remainder of the pending *Daubert* motions" and directed the parties "to confer and raise any issues with respect to specific experts, e.g., qualifications, that are not covered by this Opinion." *Id.* at 129. I also recognized that the scientific landscape is not static, with new studies being released addressing talc's alleged carcinogenic properties. *Id.* at 129 n.6. Thus, I advised the parties that "I may amend my rulings at a later time" in light of new and relevant studies. *Id.* Against that backdrop, I now provide an overview of the parties' then-filed *Daubert* motions, arguments, and my rulings.

A. Dr. Ghassan Saed

Dr. Ghassan Saed, who has not been proffered as an expert in this new round of motion practice, was introduced by Plaintiffs as an expert in inflammation and oxidative stress. *Id.* at 132. At Plaintiffs' request, Dr. Saed and his laboratory conducted an *in vitro* study to explore the role of talc in the carcinogenesis of ovarian cancer. *Id.* at 133. After finding Dr. Saed qualified to testify as an expert, *id.* at 132 n.8, I discussed the design of Dr. Saed's study and his methodologies, *id.* at 133–34. Based on the results of his study, the relevant literature, and his experience, Dr. Saed made several conclusions in his report, including that Johnson's Baby Powder causes cellular inflammation and oxidative stress, and that exposure to Johnson's Baby Powder can cause ovarian cancer. *Id.* at 134–35.

Defendants sought to exclude Dr. Saed's testimony by challenging the admissibility of his opinions on multiple grounds. *Id.* at 135. I granted in part and denied in part Defendants' motion, *id.* at 129 n.3, upon consideration of the parties' arguments and the reliability of Dr. Saed's methodology and opinions, *id.* at 135–47. First, I barred Dr. Saed from testifying "at any trial in this matter that his study demonstrated a link between the use of talcum powder and ovarian cancer." *Id.* at 140; *see id.* at 129 n.3. I found that "Dr. Saed's opinion that talc causes ovarian cancer is unsupported by the findings of his study" and that "Dr. Saed's extrapolation from inflammation to ovarian cancer is a step too far to constitute a reliable scientific opinion." *Id.* at 139; *see id.* at 135–40.

Nevertheless, I found Dr. Saed's study "sufficiently reliable under *Daubert* to show that the use of talc may cause inflammation and oxidative stress." *Id.* at 140; *see id.* at 140–47. Since there was a sufficient basis to support this opinion, I concluded that the potential flaws highlighted by Defendants related to Dr. Saed's lab practices impacted the weight of his testimony, not admissibility. *Id.* at 146–47.

B. Dr. William Longo

Defendants moved to exclude the testimony of Dr. William Longo, who Plaintiffs proffered as an expert in materials sciences. *Id.* at 147. I found Dr. Longo "qualified to testify as an expert on the issue of whether the subject talc products contain asbestos." *Id.* At that time, Dr. Longo and his company, Materials Analytical

Services, LLC ("MAS"), had tested 72 historical talc samples from the 1960s, 1970s, 1980s, 1990s, and early 2000s for the presence of asbestos using two different methods: transmission electron microscopy ("TEM") and polarized light microscopy ("PLM"). *Id.* After performing these tests, Dr. Longo concluded that 50 out of 72 of the historical samples contained amphibole asbestos. *Id.* Dr. Longo further opined that individuals who used Johnson & Johnson talcum powder products "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.* (citation modified).

After carefully considering the parties' arguments, Dr. Longo's *Daubert* hearing testimony, and the reliability of Dr. Longo's TEM and PLM methodologies, I granted in part and denied in part Defendants' motion. *Id.* at 129 n.3; *see id.* at 147–57. I found that Plaintiffs "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*." *Id.* at 147–48. I addressed in detail Defendants' arguments related to Dr. Longo's application of the three-step TEM methodology, including Defendants' objections regarding Dr. Longo's reliance on, and application of, the U.S. Environmental Protection Agency's ("EPA") "counting rules" under the Asbestos Hazard Emergency Response Act ("AHERA") regulations. *Id.* at 148–54.

I concluded that Defendants' bases for exclusion did not render Dr. Longo's TEM analysis unreliable. *Id.* Rather, they were questions for a factfinder.

However, I held that Dr. Longo is not permitted to opine at trial as to his findings of amphibole asbestos in Johnson & Johnson's talcum powder products based on his PLM analysis. *Id.* at 129 n.3, 148, 154–55. I determined that Dr. Longo improperly, and unexplainedly, used the less sensitive International Organization for Standardization ("ISO") 22262-1 method to analyze the talc samples for the presence of asbestos. *Id.* at 154–55. I found that Dr. Longo should have used ISO 22262-2 due to the ultra-trace amount of asbestos allegedly contained in the samples. *Id.* I also took issue with 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 that his PLM methodology "was replete with subjectivity and reproducibility problems." *Id.* at 155.

Furthermore, I barred Dr. Longo from testifying that females who used talcum powder products in the past were exposed to asbestos. *Id.* at 129 n.3, 148, 156–57. I found that Dr. Longo failed "to offer any scientific support for his opinion that the use of Defendants' talc products causes exposure, let alone significant exposure, to asbestos." *Id.* at 156–57. Critically, Dr. Longo failed to conduct an exposure analysis, rendering his exposure-related opinion "too attenuated from his findings of trace levels of asbestos in talc." *Id.* at 157.

Finally, I permitted Dr. Longo to opine "on the presence of 'ultra-trace' asbestos in Defendants' talc products" because "the issue of whether there is asbestos, and the amount of asbestos, in Defendants' talc products are key issues in this litigation." *Id.* I also permitted other Plaintiffs' experts in this litigation to rely on Dr. Longo's findings but limited their reliance solely to his finding that Defendants' talc products contain asbestos. *Id.*

C. Drs. Anne McTiernan, Daniel Clarke-Pearson, and Arch Carson

Defendants also sought to exclude Plaintiffs' experts from opining on general causation. I addressed three experts who "testified on behalf of Plaintiffs" at the *Daubert* hearing "on the issue of general causation," specifically "Dr. Anne McTiernan, an epidemiologist; Dr. Daniel Clarke-Pearson, a gynecologic-oncologist; and Dr. Arch Carson, a toxicologist." *Id.* I found these individuals qualified in their respective fields of expertise. *Id.* at 157–60.

In their reports, Drs. McTiernan, Clarke-Pearson, and Carson generally opined that the use of Defendants' talcum powder products in the genital perineal area can cause ovarian cancer. *Id.* Each expert conducted a Bradford Hill analysis to form their opinions. *Id.* The Bradford Hill 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." *Id.* at

160. In weighing these nine factors, these experts reviewed "the available epidemiologic studies, which included 28 case control studies, 3 cohort studies, 3 meta-analyses, and 1 pooled analysis." *Id.* at 161.

Defendants argued, as they do now, that the Bradford Hill analyses conducted by Plaintiffs' experts are unreliable and conclusion driven, thereby warranting exclusion. *Id.* I disagreed, with one significant exception described below. After finding that the Bradford Hill methodology itself is generally reliable for determining a causal relationship, *id.*, I evaluated whether Plaintiffs' experts reliably applied each Bradford Hill factor, *see id.* at 161–87. This analysis involved engaging with the parties' arguments, the law, and the science, including the epidemiologic studies addressing the association between talc use and ovarian cancer. *Id.*

Ultimately, I found that Plaintiffs' experts' application of the Bradford Hill methodology was reliable, "even if their conclusions in the context of some of these factors demonstrate a relatively minimal causal relationship between talc use and ovarian cancer." *Id.* at 187. Specifically, I permitted Plaintiffs' experts to testify at trial that talcum powder can migrate up and through the female reproductive system when applied to the perineum, and that once present in the ovaries, talcum powder can cause chronic inflammation, which may lead to ovarian cancer. *Id.*; *see id.* at 172–76. However, I barred Plaintiffs' experts from testifying "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." *Id.* at 129 n.3; *see id.* at 176–77, 187. I found that particular theory unreliable and not supported by the scientific evidence. *Id.* at 176–77.

Finally, I recognized my important but limited role as gatekeeper under *Daubert*. I acknowledged that "there does not appear to be scientific consensus on the issue of the association between talc use and ovarian cancer." *Id.* at 186. What was (and still is) "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." *Id.* at 187. "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." *Id.* Since Plaintiffs' experts provided a sufficiently reliable basis to support their general causation opinions, I determined that "the question of whose experts are correct is a question for the jury" and that "it would be erroneous for this Court to make those factual findings on a *Daubert* motion." *Id.*

D. Dr. Gregory Diette

Plaintiffs also filed motions to exclude various defense experts during the initial round of motion practice. First, Plaintiffs sought to exclude the testimony of Dr. Gregory Diette, an epidemiologist, who opined after conducting a Bradford Hill analysis that the "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." *Id.* at 188 (citation modified). The doctor focused on "the strength of association, consistency, dose-response, and biological plausibility factors," concluding they "did not demonstrate a causal relationship." *Id.*

While Plaintiffs implied "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," I found that "Dr. Diette has extensive training and experience in epidemiology and, further, that his medical training affords him the expertise to interpret epidemiological studies." *Id.*

Plaintiffs further claimed Dr. Diette failed to reliably apply the Bradford Hill factors. *Id.* at 189. However, I found Dr. Diette's opinions admissible because his "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." *Id.* at 190; *see id.* at 190–92.

Accordingly, I denied Plaintiffs' motion because Dr. Diette's opinions are supported by good grounds. *Id.* at 192. While the parties fundamentally disagreed "as to which experts' opinion and interpretation is best," it is not the Court's role as

gatekeeper under *Daubert* to determine which interpretation is best. "To do so would usurp the role of the jury." *Id.*

E. Dr. Cheryl Saenz

Plaintiffs also moved to exclude the opinions of Dr. Cheryl Saenz, a gynecologic oncologist. *Id.* I found Dr. Saenz qualified to act as an expert, and after finding her opinions admissible under *Daubert*, I denied Plaintiffs' motion. *Id.* at 195; *see id.* at 192–95.

Dr. Saenz opined that "perineal application of talcum powder does not cause ovarian cancer." *Id.* at 193 (internal quotation marks and citation omitted). In forming her opinions, Dr. Saenz performed an extensive review of the epidemiologic literature and relied on her experience as a gynecologic oncologist. *Id.* Dr. Saenz did not conduct a full Bradford Hill analysis, choosing instead to focus on the strength of association, consistency, coherence, dose-response, and biological plausibility factors. *Id.*

Plaintiffs argued, in support of their motion, that Dr. Saenz improperly gave greater weight to cohort studies over case-control studies, and that she "dismissed statistically significant case-control studies simply because they had a relative risk of less than 2.0" offering " no epidemiologic authority for her dismissal of the case control studies." *Id.* at 193–94.

I found that Dr. Saenz "provided 'good grounds' for her opinions with respect to the weight she placed on the varying case-control and cohort studies." *Id.* at 194. Dr. Saenz explained that she placed more weight on cohort studies because they are more scientifically credible than, and less prone to the biases of, case-control studies. *Id.*

In addition, I concluded that "Dr. Saenz's deliberate choice to not review" several *in vitro* studies that Plaintiffs claim demonstrate their theory of biological plausibility "does not render her opinion inadmissible." *Id.* at 194–95. Dr. Saenz reasonably "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." *Id.* at 195. Because experts are not required to review every single study in the relevant body of literature, Plaintiffs' line of attack was "better explored on cross-examination." *Id.* at 194–95.

F. Dr. Benjamin Neel

Finally, Plaintiffs sought to exclude the opinions of Dr. Benjamin Neel, a cancer biologist, who proffered general causation opinions as well as a rebuttal to Dr. Saed's testimony regarding cellular inflammation. *Id.* at 195–96. Over Plaintiffs' objection, I found Dr. Neel qualified "to render an opinion with respect to the epidemiological studies under *Daubert*." *Id.* at 197.

Dr. Neel opined, after reviewing the epidemiologic literature and conducting a Bradford Hill analysis, that "there is no evidence to support Plaintiffs' claim that perineal use of talcum powder can cause ovarian cancer." *Id.* at 196. Next, Dr. Neel opined 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." *Id.* (citation omitted). He further opined 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." *Id.* at 195–96 (alteration in original) (internal quotation marks and citation omitted).

Plaintiffs argued that Dr. Neel's opinion regarding biological plausibility is unreliable because he did not consider the alleged components of talcum powder, such as asbestos and heavy metals. *Id.* at 196–97. I disagreed, finding the alleged contamination of talc irrelevant to Dr. Neel's opinions because he was proffered to rebut Dr. Saed's methodology in his *in vitro* study, which made no findings as to whether any component of talc is carcinogenic. *Id.* at 197. Plaintiffs further argued that Dr. Neel's Bradford Hill analysis is unreliable because he placed too much weight on biological plausibility. *Id.* Again, I disagreed. *Id.* at 197–98. I found that "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." *Id.* at 197. Accordingly, I denied Plaintiffs' motion to exclude Dr. Neel's opinions. *Id.* at 198.

IV. LEGAL STANDARD

A. Federal Rule of Evidence 702

Federal Rule of Evidence 702 governs the admission of expert testimony. As amended effective December 1, 2023, Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if *the proponent demonstrates to the court that it is more likely than not that*:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the *expert's opinion reflects a reliable application of* the principles and methods to the facts of the case.

Fed. R. Evid.702 (emphasis added to reflect the changes from the prior rule).

Based on the Rule, the party offering expert testimony bears the burden of establishing its admissibility by a preponderance of the evidence, consistent with Federal Rule of Evidence 104(a). *Daubert*, 509 U.S. at 592 & n.10; *see* Fed. R. Evid.104(a) ("The court must decide any preliminary question about whether a witness is qualified, a privilege exists, or evidence is admissible."); Fed. R. Evid.702 advisory committee's note to 2000 amendment ("[T]he admissibility of all expert

testimony is governed by the principles of Rule 104(a).”). “The preponderance standard ensures that before admitting evidence, the court will have found it more likely than not that the technical issues and policy concerns addressed by the Federal Rules of Evidence have been afforded due consideration.” *Bourjaily v. United States*, 483 U.S. 171, 175 (1987).

B. 2023 Amendment to Rule 702

1. The Amendments

First, and critically, Rule 702 was “amended to clarify and emphasize that expert testimony may not be admitted unless the proponent demonstrates to the court that it is more likely than not that the proffered testimony meets the admissibility requirements set forth in the rule.” Fed. R. Evid.702 advisory committee’s note to 2023 amendment (citing Fed. R. Evid.104(a)). The Advisory Committee explained that, in the years leading up to the amendment, “many courts” had erroneously “held that the critical questions of the sufficiency of an expert’s basis, and the application of the expert’s methodology, are questions of weight and not admissibility.” *Id.* Therefore, the amendment is meant to clarify that “the preponderance standard” under Rule 104(a) “applies to the three reliability-based requirements added in 2000—requirements that many courts have incorrectly determined to be governed by the more permissive Rule 104(b) standard.” *Id.*

Before admitting expert testimony, a court must ensure that the party offering the testimony has established—by a preponderance of the evidence—that the testimony will assist the trier of fact and that it is "based on sufficient facts or data," "the product of reliable principles and methods," and is "a reliable application of those principles and methods to the facts of the case." Fed. R. Evid.702(a)–(d).

Second, Rule 702(d) was "amended to emphasize that each expert opinion must stay within the bounds of what can be concluded from a reliable application of the expert's basis and methodology." Fed. R. Evid.702 advisory committee's note to 2023 amendment. The Advisory Committee reiterated the importance of the court's gatekeeping role "because just as jurors may be unable, due to lack of specialized knowledge, to evaluate meaningfully the reliability of scientific and other methods underlying expert opinion, jurors may also lack the specialized knowledge to determine whether the conclusions of an expert go beyond what the expert's basis and methodology may reliably support." *Id.*

2. The Impact of the 2023 Amendment

The Advisory Committee made clear that the amendment to Rule 702 is limited in nature, stating: "Nothing in the amendment imposes any new, specific procedures. Rather, the amendment is simply intended to clarify that Rule 104(a)'s requirement applies to expert opinions under Rule 702." *Id.* The Committee further explained that the Rule does not require "the court to nitpick an expert's opinion in

order to reach a perfect expression of what the basis and methodology can support." *Id.* Nor does the preponderance standard "require perfection." *Id.* On the other hand, Rule 702 "does not permit the expert to make claims that are unsupported by the expert's basis and methodology." *Id.*

Since the amendments, courts have consistently concluded, and the parties do not dispute, that the amendments "did not substantively change the relevant [Rule 702] standard." *EcoFactor, Inc. v. Google LLC*, 137 F.4th 1333, 1339 n.8 (Fed. Cir. 2025); *see Le v. Zuffa*, LLC, No. 2:15-cv-01045, 2024 WL 195994, at *5 n.5 (D. Nev. Jan. 18, 2024) ("[The 2023] amendment codified what was already the prevailing understanding of Rule 702's requirements."); *Reflex Media, Inc. v. SuccessfulMatch.com*, 758 F. Supp. 3d 1046, 1049 (N.D. Cal. 2024) (explaining that the 2023 "amendment is not intended to be a 'seachange' in the performance of the Court's 'gatekeeper' function with respect to the admissibility of expert opinions"); *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, No. 19-md-02875, 2025 WL 1024048, at *9 n.15 (D.N.J. Apr. 7, 2025) (stating that "[t]he amendment does not substantively alter Rule 702"); *In re Acetaminophen—ASD-ADHD Products Liab. Litig.*, 707 F. Supp. 3d 309, 335 n.27 (S.D.N.Y. 2023) ("Nothing in the amendment imposes any new, specific procedures." (quoting Fed. R. Evid.702 advisory committee's note to 2023 amendment)).[4] Indeed, Judge Shipp, in his April

[4] *In re Acetaminophen* is currently on appeal in the Second Circuit.

30, 2024 Memorandum Order here, likewise concluded that the 2023 amendment to "Rule 702 did not change evidentiary standards, but clarified them." (ECF No. 32122, at 4.) Consequently, cases interpreting Rule 702 that "predate the 2023 amendments remain fully applicable." *Reflex Media, Inc.*, 758 F. Supp. 3d at 1049.

C. *Daubert* and its Progeny

The U.S. Supreme Court has long recognized that, in determining admissibility under Rule 702, courts serve "a gatekeeping role" to ensure "an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597; *see Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147–48 (1999) (applying the gatekeeping role to all expert testimony, not just scientific testimony). Similarly, in the Third Circuit, courts apply this "rigorous gatekeeping function" to prevent the jury from hearing expert testimony that does not have the proper indicia of reliability. *Cohen v. Cohen*, 125 F.4th 454, 460 (3d Cir. 2025) (citation modified).

It is well settled that "Rule 702 contains three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability, and fit." *Id.* (citation modified); *see Schneider*, 320 F.3d at 404 ("Rule 702 embodies a trilogy of restrictions on expert testimony . . . .").

"First, the witness must be qualified to testify as an expert." *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003). "Qualification

requires that the witness possess specialized expertise." *Id.* (citation modified). This requirement is liberally construed, and courts have held that "a broad range of knowledge, skills, and training qualify an expert as such." *Id.* (citation modified).

"Second, the testimony must be reliable." *Id.* "*Daubert*'s reliability requirement ensures that an expert's testimony is based on the methods and procedures of science, not on subjective belief and unsupported speculation." *Cohen*, 125 F.4th at 461 (citation modified). However, "admissibility does not hinge on whether a particular scientific opinion has the best foundation, or even whether the opinion is supported by the best methodology or unassailable research." *Id.* at 462 (citation modified). "The court instead looks to whether the expert's testimony is supported by good grounds." *Id.* (citation modified). "This inquiry applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, and the link between the facts and the conclusion." *Id.* (citation modified).

To determine whether an expert's testimony is supported by good grounds, the 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.

Id. (citation modified). These factors are not "a definitive checklist or test." *Daubert*, 509 U.S. at 593. Rather, the court's inquiry is "a flexible one" that focuses "on principles and methodology, not on the conclusions that they generate." *Id.* at 594–95.

With that said, "conclusions and methodology are not entirely distinct from one another" and a court is not required "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). "A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Id.* As such, it is appropriate for the court to "examine the expert's conclusions in order to determine whether they could reliably follow from the facts known to the expert and the methodology used." *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 153 (3d Cir. 1999).

Third, and finally, "the expert testimony must fit, meaning the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact." *Calhoun*, 350 F.3d at 321 (citation modified). "Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." *Cohen*, 125 F.4th at 464 (citation modified). The fit requirement "goes primarily to relevance, so an expert's testimony will be excluded if it is not scientific knowledge for purposes of the case." *Id.* (citation modified); *Hoefling v. U.S. Smokeless Tobacco Co., LLC*, 576 F. Supp. 3d 262, 279 (E.D. Pa.

2021) ("Although they may be logically relevant in the evidentiary sense, they lack a specific connection to general causation here. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994) (stating the fit standard is 'higher than bare relevance')." (citation omitted)).

Rule 702 equally applies to rebuttal experts. *See* Fed. R. Evid.702; *Capri Sun GmbH v. Am. Beverage Corp.*, 595 F. Supp. 3d 83, 139 (S.D.N.Y. 2022) ("[R]ebuttal experts must [still] meet *Daubert*'s threshold standards regarding the qualifications of the expert, sufficiency of the data, reliability of the methodology, and relevance of the testimony." (alterations in original) (quoting *In re Digital Music Antitrust Litig.*, 321 F.R.D. 64, 78 (S.D.N.Y. 2017)); *In re E. I. du Pont de Nemours & Co. C-8 Pers. Inj. Litig.*, 348 F. Supp. 3d 680, 696 (S.D. Ohio 2016) (noting that rebuttal expert "testimony must still be based upon reliable science, as required by *Daubert*."); *accord In re Generic Pharms. Pricing Antitrust Litig.*, No. 16-md-2724, 2024 WL 4980784, at *14 (E.D. Pa. Dec. 3, 2024); *Cohen*, 125 F.4th at 461 ("[T]he proponent of [rebuttal expert] testimony must still be 'offering a qualified expert with good grounds to support his criticism.'" (quoting *U.S. v. Mitchell*, 365 F.3d 215, 247 (3d Cir. 2004)).

However, even so, parties offering rebuttal expert evidence often do not bear the burden of proof, such as demonstrating causality. Accordingly, rebuttal experts are generally not required to conduct a parallel analysis mirroring the methodology

being critiqued. *See Capri Sun GmbH*, 595 F. Supp. 3d at 138 ("Rebuttal experts thus 'have a less demanding task because they have no burden to produce models or methods of their own; they need only attack those of plaintiff['s] expert[].'" (alterations in original) (quoting *In re Digital Music*, 321 F.R.D. at 78)); *U.S. Bank, N.A. v. Glogowski L. Firm, PLLC*, 339 F.R.D. 579, 581 (W.D. Wash. 2021) ("Defendants, on the other hand, will often produce expert reports solely for the purpose of contradicting or rebutting a plaintiff's report because defendants generally need not produce any evidence to prevail.").

Instead, courts recognize that "the proper role of rebuttal experts [is] to critique plaintiffs' expert's methodologies and point out potential flaws in the plaintiffs' experts' reports." *Aviva Sports, Inc. v. Fingerhut Direct Mktg., Inc.*, 829 F. Supp. 2d 802, 835 (D. Minn. 2011); *see Crowley v. Chait*, 322 F. Supp. 2d 530, 551 (D.N.J. 2004) ("Rebuttal evidence is properly admissible when it will 'explain, repel, counteract or disprove the evidence of the adverse party.'" (quoting *Step-Saver Data Sys., Inc. v. Wyse Tech.*, 752 F. Supp. 181 (E.D. Pa. 1990), *aff'd in part, rev'd in part on other grounds*, 939 F.2d 91 (3d Cir. 1991))); *see also, e.g.*, *Mahaska Bottling Co.*, 441 F. Supp. 3d at 759 (explaining that courts routinely permit defense experts to testify "even if the expert primarily critiques the opposing expert's approach without offering an alternative approach"); *In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d at 1368 (stating that defense experts' "opinions

properly may be limited to criticizing the analysis and conclusions presented by another party"); *Capri Sun GmbH*, 595 F. Supp. 3d at 140 ("At bottom, a rebuttal expert need not proffer a methodology or model, but only critique the opposing expert's."); *In re Zyprexa*, 489 F. Supp. 2d at 285 ("[D]efendants' experts have a less demanding task, since they have no burden to produce models or methods of their own; they need only attack those of plaintiffs' experts."); *Aviva Sports, Inc.*, 829 F. Supp. 2d at 834 ("A number of other district courts have held that rebuttal expert witnesses may criticize other experts' theories and calculations without offering alternatives.") (collecting cases).

That said, it is the court that serves as the gatekeeper of expert evidence, not a rebuttal expert. To the extent that a rebuttal expert usurps the court's role in determining the admissibility of expert evidence offered by the opposing party, those opinions may be inadmissible. *See T.N. Incorporation, Ltd. v. Fid. Nat'l Info. Servs., Inc.*, No. 18-cv-5552, 2021 WL 5980048, at *14 (E.D. Pa. Dec. 17, 2021) ("It is the role of the trial court, not expert witnesses, to act as 'gatekeepers' to ensure the relevance and reliability of all expert testimony.").

D. Admissibility Versus Weight

While this issue will be addressed in greater detail in each relevant context for the expert(s) being challenged, the governing principle is well established and straightforward: "Determinations of admissibility, which fall within the gatekeeping

role of the court, are separate from determinations of weight and credibility, which are within the province of the jury in a jury case." *EcoFactor, Inc.*, 137 F.4th at 1339. In practice, however, the boundary between the court's gatekeeping role and the factfinder's function has often proven difficult to delineate, particularly where, as here, Rule 702 challenges implicate highly technical and complex scientific issues.

Recognizing this difficulty, the Advisory Committee explained that certain "challenges to expert testimony will raise matters of weight rather than admissibility even under the Rule 104(a) standard." Fed. R. Evid.702 advisory committee's note to 2023 amendment. According to the Committee, and consistent with the preponderance standard, "once the court has found it more likely than not that the admissibility requirement has been met, any attack by the opponent will go only to the weight of the evidence." *Id.* For instance, if a court finds that an expert has a sufficient basis to support an opinion, "the fact that the expert has not read every single study that exists will raise a question of weight and not admissibility." *Id.* However, the Committee did not address the types of deficiencies that would render an expert's methods or results unreliable in the first instance.

In a law review article that predated the 2023 amendment, Hon. Thomas D. Schroeder, who at the time was a Member of the United States Judicial Conference Advisory Committee on the Federal Rules of Evidence and Chair of the Subcommittee on Rule 702, addressed what he saw as "lingering confusion in the

caselaw as to the proper standard for the trial court's discharge of its gatekeeping role for the admission of expert testimony." Thomas D. Schroeder, *Toward a More Apparent Approach to Considering the Admission of Expert Testimony*, 95 Notre Dame L. Rev. 2039, 2040 (2020). As a result, Judge Schroeder proposed "several suggestions for trial and appellate courts to consider for better decisionmaking in discharging their duty to apply Rule 104(a)'s preponderance standard to the elements of Rule 702." *Id.*

Relevant here, one of Judge Schroeder's suggestions provides helpful guidance regarding the point at which a particular challenge to an expert's method or results crosses the line from a question of weight to one of admissibility:

> [T]here will be challenges to the weight of an opinion's basis even under a proper Rule 104(a) analysis. This does not automatically render the question one for a jury, as some of the cases suggest. Rather, the trial judge, as gatekeeper, must determine whether such challenges are so significant that the factual basis for the opinion fails to reach the preponderance standard or, instead, whether the alleged defects are sufficiently minor, such that they do not undermine the remaining basis. In the latter instance, the alleged flaws do not impugn the reliability or validity of the method or results. For example, an expert who allegedly failed to include a handful of patients in a study of over 100 patients, or an expert whose opinion is supported by a dozen studies but is contrary to a study that would not undermine her ultimate conclusion would likely pass the Rule 104(a) bar. Of course, where there is a legitimate question of fact on which the admissibility of the expert opinion turns, Rule 104(a) does not allow the trial court to make that call, and the jury must decide.

Id. at 2061–62.

In distinguishing between "significant" and "minor" defects, the Sixth Circuit's recent decision in *In re Onglyza*, 93 F.4th 339 (6th Cir. 2024), is instructive.[5] *See Federal Rules of Evidence—Expert Testimony—Judicial Conference Amends Rule 702*, 138 Harv. L. Rev. 899, 905 (2025) ("Drafters of the amendments may be encouraged by the Sixth Circuit," including its *In re Onglyza* decision, "which has enthusiastically embraced the amendments to Rule 702.").

In that MDL, the plaintiffs alleged that saxagliptin, a diabetes drug, caused their heart failure. *In re Onglyza*, 93 F.4th at 342. The district court excluded Dr. Parag Goyal, the plaintiffs' sole general causation expert, finding that methodological flaws rendered his testimony unreliable under Rule 702. *Id.* at 342, 344. The Sixth Circuit affirmed the district court's decision, concluding that the lower court had three valid reasons to find Dr. Goyal's testimony unreliable. *Id.* at 348. First, his reliance on a single study "to the exclusion of all other studies involving human data," including four studies that found no association between saxagliptin and heart failure, "was unreliable." *Id.* at 345. "By ignoring all other human studies" without adequate explanation, "Dr. Goyal failed to base his opinion

[5] The Sixth Circuit applied the "old" version of Rule 702 "because it was still in force at the time of the district court's decision (January 5, 2022)." *In re Onglyza*, 93 F.4th at 345 n.4. Nevertheless, the court explained that "the district court's reasoning aligns with the updated Rule 702, since it placed the burden of showing that Dr. Goyal was admissible on plaintiffs," and that its "decision here would be the same under either version of the Rule." *Id.*

on 'sufficient facts or data.'" *Id.* at 346 (citing Fed. R. Evid.702(b)). Second, "Dr. Goyal's use of animal data was unreliable because he has no expertise in interpreting animal studies." *Id.* at 347. In addition to being unqualified and relying on studies that did not diagnose the animals with heart failure, "Dr. Goyal admitted to ignoring multiple peer-reviewed animal studies dispelling a causal link between saxagliptin and heart failure." *Id.* Finally, "Dr. Goyal did not reliably apply Bradford Hill" since he "cherry-picked data to bolster his case" and "inconsistently applied several Bradford Hill factors." *Id.* In light of these significant defects, the plaintiffs failed to establish by a preponderance of the evidence that Dr. Goyal satisfied Rule 702's admissibility requirements. *Id.* at 348.

E. Publication and Peer Review Status

While not dispositive, "publication in a peer reviewed journal is relevant 'in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.'" *United States v. Van Wyk*, 83 F. Supp. 2d 515, 520 (D.N.J. 2000) (quoting *Daubert*, 509 U.S. at 594); *accord In re TMI Litig.*, 193 F.3d 613, 663–64 (3d Cir. 1999). As such, "[p]ublication in a peer-reviewed journal typically satisfies" the consideration of whether "'the theory and procedures have been submitted to the scrutiny of the scientific community.'" *United States v. Gissantaner*, 990 F.3d 457, 464 (6th Cir. 2021) (quoting *United States v. Bonds*, 12 F.3d 540, 559 (6th Cir. 1993)). This is so because peer review "'conditions

publication on a bona fide process' of review by other scientists and experts in the field." *Id.* (quoting *Daubert v. Merrell Dow Pharms.*, 43 F.3d 1311, 1318 n.6 (9th Cir. 1995)). Indeed, the peer review process for publication in a scientific journal is far more rigorous than that of a student publication or a law journal. *Gissantaner*, 990 F.3d at 464–65 ("No offense to former, current, and future members of law journals everywhere: But it is one thing to convince lawyers in training to publish a piece; it is quite another to convince peers in a professional community to publish a piece. That is why readership and citation are pivotal when it comes to legal scholarship and why publication itself is noteworthy in scientific scholarship—and ultimately why publication in a peer-reviewed journal alone typically satisfies this *Daubert* inquiry."); *see id.* (collecting cases). "[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." *Daubert*, 509 U.S. at 593.

As such, expert testimony based on sound conclusions reasonably drawn from peer-reviewed studies is typically considered reliable. Even "'flaws in methodology' uncovered by peer review do not necessarily equate to a lack of scientific validity, since the methods may be based on scientific principles and the alleged flaws go merely to the weight, not the admissibility, of the evidence and the testimony." *Bonds*, 12 F.3d at 559. Rather, "peer review and publication should be viewed as

evidence that the theory and methodology are scientific knowledge capable of being scrutinized and have in fact been scrutinized by the scientific community." *Id.*

However, peer review and publication status of a study do not insulate it from judicial scrutiny. *Goodrich v. John Crane, Inc.*, No. 4:17-cv-00009, 2018 WL 4677773, at *23 (E.D. Va. Sept. 28, 2018) (rejecting argument that study was reliable simply because it "ha[d] been peer reviewed" and "published"). One such instance where a court may exclude expert testimony based on a peer-reviewed study is when the study's methodology is so flawed, the court cannot ignore its deficiencies. *See In re Roundup Prods. Liab. Litig.*, 737 F. Supp. 3d 898, 902–03, 908–09 (N.D. Cal. 2024) (excluding expert who relied on a peer-reviewed, published meta-analysis because "simply intoning that a paper was peer-reviewed and that it was (apparently) produced before the author was thinking about getting involved in litigation isn't enough to compensate for methodological problems as glaring as those described here," the flaws being that the hypothesis contemplated a dose-response relationship even though at least one study showed no dose-response relationship, diluting the results by mixing study types and data, using inconsistent exposure measurements, and failure to adjust results for exposure to other potential toxins), *aff'd sub nom.*, *Bulone v. Monsanto Co.*, No. 24-cv-4241, 2025 WL 2730843 (9th Cir. Sept. 25, 2025)); *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075, 1164–65, 1171–73 (S.D. Fla. 2022) (criticizing experts' reliance on two

published, peer-reviewed studies in part because the court found, upon its own "substantive review," that both studies failed to control for confounding factors, and "even if general acceptance of the methodologies used in these two studies was established, acceptance in the scientific community and peer review are not necessarily sufficient to establish the reliability of a scientific methodology"); *Valentine v. Pioneer Chlor Alkali Co., Inc.*, 921 F. Supp. 666, 678 (D. Nev. 1996) (excluding the testimony of an expert whose "study suffer[ed] from very serious flaws" because the expert "took no steps to eliminate selection bias in the study group, he failed to identify the background rate for the observed disorders in the [relevant] community, he failed to control for potential recall bias, he simply ignored the lack of reliable dosage data, he chose a tiny sample size, and he did not attempt to eliminate so-called confounding factors which might have been responsible for the incidence of neurological disorders in the subject group"); *Riddell, Inc. v. Schutt Sports, Inc.*, 724 F. Supp. 2d 963, 974 (W.D. Wis. 2010) (citing with approval a case where "the district court rejected a peer-reviewed article, but only after pointing out that the reviewers were not in a position to identify certain flaws in the protocol used in the study, were not given the results of trials showing different results and were not given the comments of the FDA 'concerning the inadequacies of the . . . results'" (quoting *Zeneca, Inc. v. Eli Lilly & Co.*, 1999 WL 509471, at *29–30 (S.D.N.Y. July 19, 1999))).

Moreover, articles published in peer-reviewed journals are not always sufficient to support an expert's opinion. *See, e.g.*, *In re Paraquat Prods. Liab. Litig.*, 730 F. Supp. 3d 793, 849 (S.D. Ill. 2024) (explaining that, when considering the "brevity and lack of scientific analysis" in an "opinion article" published in a peer-reviewed journal, "the Court was and still is skeptical of its ability to independently validate Dr. Wells' general causation opinion").[6] Nor can an expert support his or her opinion with one peer-reviewed article to the complete exclusion of other relevant data. *In re Onglyza*, 93 F.4th at 343, 345–47 (affirming exclusion of an expert who relied on one published human study and several animal studies because the expert (1) without explanation, ignored other human studies, and (2) conceded he was not qualified to interpret animal studies' data as it applied in humans).

---

[6] When analyzing the peer-review status, a court may distinguish between "true peer review" and pre-publication peer review or "editorial peer review." "True peer review" is "the essence of science" and is accomplished when "[o]ne investigator makes her methods and findings public, so that others can attack or support her conclusion by following the same protocols while asking what besides the stated principle could account for the documented results." *Valentine*, 921 F. Supp. at 675. In contrast, "'editorial peer review' consists of the reference by a journal editor of an article submitted for publication to two or more outside reviewers," who "make confidential comments on the article's scientific accuracy, style, originality and importance, and make a recommendation to the journal that the article be accepted or rejected." *Id.* "Because the scope of editorial peer review is necessarily narrower than true peer review, it is a serious error to conflate the two processes, and, by extension, to assume that because an article is accepted for publication, even in a prestigious scientific journal, that the science it contains is therefore val*Id.*" *Id.* However, this is not to suggest that articles subject to "editorial peer review" should *per se* fail under *Daubert*, or that the distinction will necessarily arise in every case, particularly since peer review is not, on its own, dispositive. Indeed, "expert testimony does not have to obtain general acceptance or be subject to peer review to be admitted under Rule 702." *Schneider v. Fried*, 320 F.3d 396, 406 (3d Cir. 2003). And "[w]here there are other factors that demonstrate the reliability of the expert's methodology, an expert opinion should not be excluded simply because there is no literature on point." *Id.* For instance, "the particular application at issue may never previously have interested any scientist," leaving no opportunity for peer review. *Kumho Tire Co.*, 526 U.S. at 151.

Critically, courts must bear in mind that the above-cited peer-review examples represent the exception, not the rule. Indeed, peer review remains a "matter[] far afield from the expertise of judges," and as such, courts should exercise "great caution in deciding more than" is necessary. *Daubert*, 509 U.S. at 599 (Rehnquist, C.J., concurring in part and dissenting in part). As such, it will apparently be the case more often than not that the factfinder is permitted to hear the expert testimony, as parties' disputes or critiques regarding the testimony will go to its weight rather than admissibility. *Boncher v. 3M Co.*, No. 5:24-cv-01403, 2025 WL 511116, at *7 (E.D. Pa. Feb. 14, 2025) ("The Court notes Defendants' objections to the limitations of the design and implementation of [a seminal study], including its failure to avoid or address potential confounding by other infection control measures instituted by the hospital. However, these limitations and potential shortcomings in the research do not make the study *per se* unreliable, as the strength of the study goes to its weight, not admissibility." (citation omitted)). "A test need not perfectly and identically recreate real-world conditions to be reliable enough to clear *Daubert*'s low admissibility bar: *Daubert* 'does not require a paradigm of scientific inquiry as a condition precedent to admitting expert testimony.' Admissibility just requires good grounds . . . ." *VanDine v. Summit Treestands, LLC*, 738 F. Supp. 3d 599, 613 (E.D. Pa. 2024) (citation modified) (quoting *Oddi v. Ford Motor Co.*, 234 F.3d 136, 156 (3d Cir. 2000)). As the First Circuit summarized: "As long as an expert's scientific

testimony rests upon 'good grounds, based on what is known,' it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies." *Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998) (citation omitted) (quoting *Daubert*, 509 U.S. at 590, 596).

In sum, when evaluating expert testimony under Rule 702, the court must undertake its gatekeeping function with rigor, ensuring—by a preponderance of the evidence—that the expert is qualified, that his or her opinion is grounded in sufficient facts or data, that it flows from reliable principles and methods, and that those methods have been reliably applied to the case-specific facts. This inquiry is flexible, but it is not perfunctory; the court must examine both methodology and the logical connection between underlying facts and the conclusions drawn, excluding opinions that rest on speculation, cherry-picking, or analytical gaps too great to overlook. At the same time, the Rule recognizes that not every flaw is fatal—once the minimum reliability threshold is met, remaining criticisms generally speak to weight, not admissibility, and become the province of the factfinder. Ultimately, the court's task is to admit only those opinions supported by "good grounds," while reserving unreliable or methodologically unsupported conclusions from reaching the jury.

V. GENERAL CAUSATION

The parties have filed five motions concerning general causation, which addresses "whether an agent increases the incidence of disease in a group" as compared to specific causation, which asks "whether the agent caused any given individual's disease." Michael D. Green et al., *Reference Guide on Epidemiology*, in *Reference Manual on Scientific Evidence* 623, 627 (3d ed. 2011).[7]

In this MDL, each side has proffered multiple, distinguished experts who opine on the question of whether exposure to Defendants' talcum powder products—including all alleged contaminants—is capable of causing ovarian cancer. I will first address Defendants' general causation motions, along with Defendants' causation-related arguments concerning asbestos, fibrous talc, heavy metals, and fragrances, before turning to Plaintiffs' general causation motions.

[7] As in my prior Opinion, I rely on the *Reference Guide on Epidemiology* for guidance on issues of general causation. *In re Johnson & Johnson*, 509 F. Supp. 3d at 160 n.34. This guide is part of the *Reference Manual on Scientific Evidence*, a compilation of reference guides intended "to provide the tools for judges to manage cases involving complex scientific and technical evidence." Fed. Judicial Ctr., *Reference Manual on Scientific Evidence* xv (3d ed. 2011). Relevant here, epidemiology is the "study of the distribution and determinants of disease or other health-related states and events in populations and the application of this study to control of health problems." Green at 623.

A. A Brief Primer Regarding Talc and Asbestos[8]

Talc is a naturally occurring mineral that is mined from the Earth for commercial purposes. In its pure mineral form, talc "is a hydrous magnesium phyllosilicate mineral with a chemical composition of Mg3Si4O10(OH)2." (Interagency Working Grp. on Asbestos in Consumer Prods., *White Paper: IWGACP Scientific Opinions on Testing Methods for Asbestos in Cosmetic Products Containing Talc* 27 (Dec. 2021) ("IWGACP White Paper").)[9] Talc morphology is typically described as platy or lamellar—that is, flat and plate-like. (*Id.* at 18 n.38; *see also* Int'l Agency for Research on Cancer, World Health Org., *Monographs on the Evaluation of Carcinogenic Risks to Humans, vol. 93: Carbon Black, Titanium Dioxide, and Talc* 277 (2010) ("IARC Monographs vol. 93").) However, talc may also exhibit a fibrous morphology. (IWGACP White Paper at 18; *see also* IARC Monographs vol. 93 at 277.) And in some instances, talc may "form as true mineral fibres that are asbestiform." (IARC Monographs vol. 93 at 277.)

---

[8] This section is not intended to serve as a definitive scientific exposition of talc and asbestos. Rather, the purpose of this general overview is to provide relevant background and context for the parties' arguments.

[9] In 2018, the U.S. Food and Drug Administration ("FDA") established an interagency working group composed of subject-matter experts to develop, among other objectives, standardized testing methodologies for detecting asbestos in cosmetic products manufactured with talc as an ingredient. The working group published a white paper setting forth foundational scientific principles, relevant background information regarding testing, and various recommendations. In this section, I have referenced the working group's white paper as well as other neutral, third-party resources, such as IARC Monographs.

Asbestiform means the "specific variety of a mineral or type of mineral fibrosity, associated with a unique fibrous habit of crystal growth, in which the fibers are long and thin and possess high tensile strength and flexibility." (IWGACP White Paper at 24.) Habit is defined as the "characteristic external shape of an individual crystal or crystal group due to crystal growth." (*Id.* at 26.) "A mineral may exhibit multiple habits due to different conditions (e.g., temperature, pressure, geological events) that were prevalent when crystal growth took place." (*Id.*)

Because of its unique properties—"platyness, softness, hydrophobicity, organophilicity and inertness"—talc is used in a wide variety of products "including paint, polymers, paper, ceramics, animal feed, rubber, roofing, fertilizers, cosmetics and pharmaceuticals." (IARC Monographs vol. 93 at 289.) Relevant here, talc-based personal care products have been used widely, either as baby powders or adult body powders to absorb sweat and odors. It is undisputed that Defendants used talc sourced from mines in Italy, the United States (specifically, Vermont) and China for its Johnson's Baby Powder and Shower to Shower products.

Asbestos is a generic term with "many definitions" that are "used in the commercial, geological, and regulatory domains." (IWGACP White Paper at 8–9; *see also* Int'l Agency for Research on Cancer, World Health Org., *Monographs on the Evaluation of Carcinogenic Risks to Humans, vol. 100C: Arsenic, Metals, Fibres, and Dusts* 221 (2012) ("IARC Monographs vol. 100C").) The lack of

consistent usage has contributed to uncertainty and confusion in both academic literature and laboratory testing related to asbestos. (*Id.*) In commercial and mineralogical contexts, asbestos describes a "group of fibrous silicate minerals that occur in an asbestiform habit of growth in which the bulk mineral readily separates into long, thin, strong fibers." (IWGACP White Paper at 24.) Thus, asbestos does not refer to a single mineral but rather encompasses a set of minerals with specific characteristics. These minerals fall into two principal groups: serpentine and amphibole.

Like talc, asbestos minerals are mined for their commercially useful properties. Asbestos fibers possess high tensile strength, flexibility, excellent thermal stability, adsorption capacity, and resistance to chemical, thermal, and biological degradation. (IARC Monographs vol. 100C at 221.) These properties make asbestos fibers "desirable for a wide range of industrial applications" such as "roofing, thermal and electrical insulation, cement pipe and sheets, flooring, gaskets, friction materials (e.g., brake pads and shoes), coatings and compounds, plastics, textiles, paper, mastics, thread, fibre jointing, and millboard." (*Id.*) "Since peaking in the 1970s, there has been a general decline in world production and consumption of asbestos" due to increased government regulations and outright bans. (*Id.* at 222.)

In the regulatory context, U.S. government agencies define asbestos as "the following six minerals, which historically have been used in commerce: chrysotile

(a member of the serpentine group) and five species of the amphibole mineral group, specifically asbestiform riebeckite (also known as 'crocidolite'), asbestiform grunerite-cummingtonite (also known as 'amosite'), tremolite asbestos, actinolite asbestos, and anthophyllite asbestos." (IWGACP White Paper at 8.) Asbestos is regulated by various agencies including the EPA, 40 C.F.R. § 763.83 and 40 C.F.R. § 61.141; the Occupational Safety and Health Administration ("OSHA"); 29 C.F.R. § 1910.1001(b); and the Mine Safety and Health Administration, 30 C.F.R. § 56.5001(b)(1).

B. Defendants' General Causation Motions

Defendants have filed two general causation motions: Motion to Exclude Plaintiffs' Experts' General Causation Opinions, (ECF No. 33008), and Motion to Exclude Plaintiffs' Experts' Opinions Regarding Biological Plausibility/Mechanism, (ECF No. 33013). Plaintiffs strenuously oppose both motions, which seek to preclude 14 of their experts from testifying regarding any alleged causal link between Defendants' talc-based products and ovarian cancer. The thrust of Defendants' motions is that Plaintiffs' experts unreliably applied the Bradford Hill criteria, which are traditionally employed to distinguish a causal connection from a mere association, with Defendants devoting an entire motion to a single factor—biological plausibility. There is no question that general causation is among the most significant issues in this MDL, as reflected by the parties'

submission of 285 pages of briefing and thousands of pages of supporting exhibits related to these motions. Before I turn to the parties' arguments, several preliminary matters must be addressed to place Defendants' motions in context.

1. Scope of Review

Defendants filed largely similar motions addressing general causation and biological plausibility during the first round of motion practice. (*See* ECF No. 33008-2 ("Defs.' 2024 General Causation Br."); ECF No. 33013-1 ("Defs.' 2024 Biological Plausibility Br."); *see also* ECF No. 9736 ("Defs.' 2019 General Causation Br."); ECF No. 9736-1 ("Defs.' 2019 Biological Plausibility Br.").)

As noted above, I ruled on the opinions of Plaintiffs' representative general causation experts—Drs. Carson, Clarke-Pearson, and McTiernan. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 157–87. I then applied that reasoning "with equal force to the remainder of the pending *Daubert* motions" and directed the parties to raise any issues regarding specific experts not addressed in the Opinion "within 45 days of the date of the accompanying Order." *Id.* at 129. All parties were aware of, and agreed to, this representative-expert approach. Neither party raised any expert-specific concerns within the 45-day period, nor did either side seek timely reconsideration under the Federal Rules of Civil Procedure.

Defendants have renewed their motions challenging general causation and biological plausibility. In these motions—as well as in their motions concerning

asbestos, heavy metals, and fragrances—Defendants address Plaintiffs' experts collectively, asserting that the experts' methodologies suffer from deficiencies purportedly common to all. By way of illustration, Defendants' heavy metals and fragrances motion seeks to exclude the opinions of eighteen experts. Given the number of experts and the complexity of the scientific issues presented, it is understandable that Defendants elected to proceed through consolidated, issue-specific motions rather than expert-specific challenges. This approach, however, obscures important differences among the experts and makes it more difficult to assess the reliability of any particular expert's opinion. Although many experts ultimately reach similar conclusions, they do not employ identical methodologies or rely on the same exact body of materials. By presenting their challenges collectively, Defendants effectively place upon the Special Master and the Court the burden of disentangling a voluminous record to determine, expert by expert, whether the proffered methodologies and conclusions satisfy the requirements of Rule 702 and *Daubert*. In that connection, Defendants' arguments frequently focus on one or a few experts without clearly specifying whether or how those arguments apply to the remaining experts, and they often rely on extensive record citations embedded in footnotes rather than developed analysis. As a result, the Special Master and the Court are left to infer the scope and substance of many of Defendants' arguments. Nonetheless, because Plaintiffs have likewise briefed these issues on a collective

basis, this Report and Recommendation addresses the parties' arguments in the same manner, while at the same time, endeavoring to account for the distinct opinions and methodologies of each expert at issue, resulting in this lengthy opinion.

Furthermore, under Judge Shipp's April 30, 2024 Memorandum Order, Defendants are not entitled to a wholesale reconsideration of my prior rulings, as I have already addressed the vast majority of the issues raised in their general causation motions. In an effort to comply with the limitations set forth in that Order, Defendants have reframed their arguments, now asserting that my prior rulings failed to adhere to Rule 702 as amended and that newly available scientific evidence requires revisiting my findings. Their core contention, however, remains unchanged: Plaintiffs' experts' opinions should be excluded "because the experts distort epidemiology in a results-oriented manner," "disregard longstanding concepts such as statistical significance," and do not meaningfully grapple with scientific evidence undermining a causal relationship.[10] (Defs.' 2024 General Causation Br. at 3.)

It is undisputed that "new science" has become available since my 2020 Opinion, with multiple relevant epidemiological studies having been published in the intervening years. In light of these developments, I find it both necessary and

[10] For comparison, Defendants opened their prior general causation brief as follows: "Plaintiffs' experts' general causation opinions are methodologically unsound and should be excluded under *Daubert* because they misapply scientific principles, engage in unsupported leaps of logic, and distort epidemiology in a results-oriented manner that transforms an important tool for advancing public health into an unprincipled weapon for litigation." (Defs.' 2019 General Causation Br. at 1.)

appropriate to reexamine my prior general causation rulings, particularly given the parties' competing interpretations of the current scientific record. Plaintiffs assert that "post-2020 developments" bolster the opinions of their general causation experts. (ECF No. 33129 ("Pls.' General Causation Opp. Br.") at 3.) Defendants, by contrast, contend that "the most recent developments on which plaintiffs and their experts hang their hats have confirmed that the relevant science has not established a causal link." (Defs.' 2024 General Causation Br. at 1.)

Thus, I will address the parties' arguments as they relate to each of the Bradford Hill factors below, focusing—as Plaintiffs correctly note—on "scientific evidence that is *truly* new" and "the impact of any *truly* new law." (Pls.' General Causation Opp. Br. at 6.) I will not disturb any prior Bradford Hill ruling unless, as Defendants argue, I determine that I was less than faithful to the requirements of Rule 702 with respect to a specific ruling.

2. Plaintiffs' Experts[11,12]

Defendants' general causation motions seek to exclude the testimony of the following Plaintiffs' experts, all of whom—except for Dr. Bernard Harlow—performed a Bradford Hill analysis to establish an alleged causal relationship between the use of talcum powder products and ovarian cancer:

- Dr. Arch Carson: Dr. Carson is a physician specializing in medical toxicology who holds an M.D. from Ohio State University College of Medicine and a Ph.D. in toxicology from the Kettering Laboratory at the University of Cincinnati, and has taught medical students, graduate students, and post-graduate medical trainees at the University of Texas School of Public Health in Houston since the 1990s. (ECF No. 33008-42 ("Carson Rep.") at 1.)

- Dr. Daniel Clarke-Pearson: Dr. Clarke-Pearson, who holds a B.A. from Harvard College and an M.D. from Case Western Reserve University School of Medicine, is currently "a Professor in the Department of Obstetrics and

[11] Almost all expert reports and deposition transcripts appear multiple times in the record under different exhibit numbers and ECF numbers. For ease of reference, and to avoid unnecessary repetition, this Report and Recommendation identifies each report and transcript by a single representative ECF number and refers to it consistently throughout, regardless of duplicative filings elsewhere in the docket.

[12] I note that Drs. Carson, Kane, and Smith did not issue updated reports since the prior round of motions in 2019. Defendants nonetheless continue to cite to these experts' reports. (*See, e.g.*, Defs.' 2024 General Causation Br. at 65 n.161, 67.) Plaintiffs' position is that because these experts have not issued supplemental reports, that I need not reconsider those experts' analyses. (Oral Argument on 2024 Motions dated Nov. 25, 2025 ("Nov. 25, 2025 Tr.") 111:9 to 113:9.) I agree. Defendants' general causation brief notes, for example, that Dr. Carson "failed to provide an updated report or testimony to address any of the recent objective scientific literature that undermines and discredits the methodology [he] utilized to reach his general causation opinions," and "[a]ccordingly, Dr. Carson's opinions are outdated." (Defs.' 2024 General Causation Br. at 27 n.73.) However, and notably, Defendants have not made any specific arguments as to why those experts' methodologies are unreliable based on any change in the legal landscape or how my previous decision misapplied Rule 702 specifically as to those experts' general causation analyses. Instead, Defendants have a ripe opportunity for questioning on cross-examination, as to how, if at all, new science post-dating Dr. Carson's report affects his opinions. The same is true for Dr. Kane and Dr. Smith. (*See* Nov. 25, 2025 Tr. 111:16–21.) Accordingly, on this record, I do not find a basis on which to consider these three reports anew in the context of general causation.

Gynecology and the Division of Gynecologic Oncology at the University of North Carolina" and is "certified by the American Board of Obstetrics and Gynecology as a specialist in obstetrics and gynecology as well as a subspecialist in gynecologic oncology." (ECF No. 33008-15 ("Clarke-Pearson 3d Amend. Rep.") at 2–3.)

- Dr. Michele Cote: Dr. Cote is a cancer epidemiologist specializing in female cancers and health disparities who obtained a "Master of Public Health with a concentration in Epidemiology from the University of Alabama, Birmingham" and a Ph.D. in Epidemiologic Sciences from the University of Michigan, and who is the Director of the Susan G. Komen Tissue Bank and "a tenured Professor of Epidemiology at the Fairbanks School of Public Health in the Department of Epidemiology at Indiana University." (ECF No. 33008-16 ("Cote Amend. Rep.") at 3–5.)

- Dr. Bernard Harlow: Dr. Harlow, who is a Professor of Epidemiology at the Boston University School of Public Health, received a Ph.D. in Epidemiology from the University of Washington and, over the past 35 years, "has focused on epidemiologic research specifically in women's cancers and other benign gynecological disorders," including coauthoring four published research articles addressing talc use and ovarian cancer. (ECF No. 33008-10 ("Harlow Rep.") at 1–2.)[13]

- Dr. Sarah Kane: Dr. Kane is a gynecologic pathologist "certified by the American Board of Pathology in Anatomic Pathology, Clinical Pathology, and Cytopathology," who received her M.D. from Ohio State University College of Medicine, and completed a residency in Anatomic and Clinical Pathology at Massachusetts General Hospital, as well as a two-year gynecologic and cytology fellowship as the Robert E. Scully Fellow in

[13] I note that instead of analyzing the Bradford Hill factors, Dr. Harlow's methodology involves establishing a causal hypothesis and then identifying and rejecting non-causal explanations of an association. During oral argument on November 25, 2025, defense counsel explained that Defendants' critique of Dr. Harlow's methodology "is the same critique that we have of folks who are employing a Bradford Hill methodology." (Nov. 25, 2025 Tr. at 92:14–93:12.) Accordingly, I will analyze Dr. Harlow's methodology and opinions in connection with Plaintiffs' other general causation experts.

Pathology at the same hospital, during which she studied the causes and mechanisms of disease, including gynecologic cancer and disease. (ECF No. 33005-20 ("Kane Rep.") at 2.)

- Dr. Anne McTiernan: Dr. McTiernan, who holds a Ph.D. in Epidemiology from the University of Washington and an M.D. from New York Medical College, is "a Full Professor at the Fred Hutchinson Cancer Center in Seattle, Washington, Division of Public Health Sciences, Program in Epidemiology" as well as "a Full Research Professor at the University of Washington School of Public Health, Department of Epidemiology, and the University of Washington School of Medicine, Department of Medicine, Division of Geriatrics." (ECF No. 33008-9 ("McTiernan 3d Amend. Rep.") at 3–6.)

- Dr. Patricia Moorman: Dr. Moorman, who earned a Master of Science in Public Health and a Ph.D. in Epidemiology from the University of North Carolina-Chapel Hill, is "an epidemiologist with more than 25 years of experience in conducting research on women's health issues including ovarian cancer" and is "a tenured professor in the Department of Community and Family Medicine, Duke University School of Medicine." (ECF No. 33005-23 ("Moorman Rep.") at 3.)

- Dr. Jack Siemiatycki: Dr. Siemiatycki obtained an M.Sc. in Mathematical Statistics and a Ph.D. in Epidemiology and Medical Statistics from McGill University in Canada, completed a post-doctoral fellowship with IARC, taught epidemiology at McGill University and the University of Montreal, and has devoted most of his "research career to investigating links between environmental, occupational and lifestyle factors and various types of cancer" including, relevant here, chairing the IARC Monograph panel tasked with evaluating the carcinogenicity of talc.[14] (ECF No. 33008-6 ("Siemiatycki 3d Amend. Rep.") at 3–6, 24–25; *id.*, Ex. A at 3.)

[14] In 2010, IARC published Monographs Volume 93, which addresses talc and is cited by both parties as an authoritative reference. In 2025, after the parties briefed the instant motions, IARC issued a new Monographs—Volume 136—reexamining the potential carcinogenicity of talc.

- Dr. Sonal Singh: Dr. Singh, who holds a medical degree and a Master of Public Health, devotes most of his professional time to epidemiologic research, has taught at Johns Hopkins University and the Wake Forest University School of Medicine, and is currently an Associate Professor of Family Medicine and Community Health at UMass Chan School of Medicine, with joint appointments in the Division of Health Systems Science, Department of Medicine, and the Department of Population and Quantitative Health Sciences. (ECF No. 33008-50 ("Singh Rep.") at 3–5; ECF No. 33008-53 ("Singh Supp. Rep."), Ex. A.)

- Dr. Ellen Blair Smith: Dr. Smith is a physician with an M.D. from the University of North Carolina "who specializes in the treatment of women with cancer (including ovarian cancer)," has treated hundreds of women with epithelial ovarian cancer during her more than 28 years in private practice, and pursued further education in Hospice and Palliative Care to enhance the end-of-life care of her gynecologic oncology patients. (ECF No. 33008-51 ("Smith Rep.") at 1; *id.*, Ex. A at 1.)

- Dr. Rebecca Smith-Bindman: Dr. Smith-Bindman is a clinician-scientist who earned an M.D. from the University of California, San Francisco, has extensive expertise in epidemiology, biostatistics, and a range of research study designs, and is presently "a professor of Epidemiology and Biostatistics, Obstetrics, Gynecology and Reproductive Medicine, and Health Policy" at her alma mater, as well as the Director of the Radiology Outcomes Research Laboratory. (ECF No. 33008-8 ("Smith-Bindman 3d Amend. Rep.") at 4–6; *id.*, Ex. A at 1.)

- Dr. Judith Wolf: Dr. Wolf is a board-certified gynecologic oncologist and physician with more than thirty years' experience who specializes in the care of women with cancer, attended medical school at Northeast Ohio Universities College of Medicine, and completed her residency at the University of Texas at San Antonio, as well as a fellowship at MD Anderson Cancer Center, where she remained on faculty for more than twenty years as a Professor in the Department of Gynecologic Oncology. (ECF No. 33008-7 ("Wolf 3d Amend. Rep.") at 1–2.)

(*See* Defs.' 2024 General Causation Br. at 1 n.3; Defs.' 2024 Biological Plausibility Br. at 1 n.2.)

In addition to the experts discussed above, Defendants' biological plausibility motion seeks to exclude two additional experts:

- Dr. Shawn Levy: Dr. Levy received his "Ph.D. in biochemistry and completed a postdoctoral fellowship in genetics at Emory University," has taught various courses at Vanderbilt University Medical Center, the University of Alabama at Birmingham, and the University of Alabama in Huntsville, and is currently "the Chief Scientific Officer at Element Biosciences," where he focuses "on developing disruptive DNA sequencing technology on the AVITI platform." (ECF No. 33013-13 ("Levy 2d Amend. Rep.") at 2–3.)

- Dr. Laura Plunkett: Dr. Plunkett is "a pharmacologist, toxicologist, United States Food and Drug Administration (FDA) regulatory specialist and partner in a consulting company known as BioPolicy Solutions, LLC" who "received a B.S. degree in 1980 from the University of Georgia and a Ph.D. in pharmacology from the University of Georgia, College of Pharmacy in 1984," and has "worked in both government and academic research" and has "taught pharmacology and toxicology at the undergraduate and postgraduate levels." (ECF No. 33013-27 ("Plunkett 3d Amend. Rep.") at 3–6.)

(*See* Defs.' 2024 Biological Plausibility Br. at 1 n.2.)

Defendants do not dispute the qualifications of any of the experts at issue in their general causation motions, nor do they challenge my prior ruling that Drs. Carson, Clarke-Pearson, and McTiernan are qualified to testify as experts in this MDL. *In re Johnson & Johnson*, 509 F. Supp. 3d at 157–60. I also find that Plaintiffs have established, by a preponderance of the evidence, that their general causation experts possess specialized knowledge and expertise based on their academic

backgrounds and professional experience, and that they satisfy Rule 702's liberally construed qualification requirement. *See Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008). Accordingly, Drs. Carson, Clarke-Pearson, and McTiernan remain qualified as experts, as no new issues have been raised regarding their expertise, and Drs. Cote, Harlow, Kane, Levy, Moorman, Plunkett, Siemiatycki, Singh, Smith, Smith-Bindman, and Wolf are likewise qualified to testify as experts in their respective fields.

Having determined qualifications, I turn to the Bradford Hill factors.

3. The Bradford Hill Factors

In 1965, Sir Austin Bradford Hill published an article that provided guidance on a fundamental question that had long plagued the field of medicine: when "an association between two variables"—the exposure to an agent and the development of a disease—is "perfectly clear-cut and beyond what we would care to attribute to the play of chance," "what aspects of that association should we especially consider before deciding that the most likely interpretation of it is causation?" Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 Proc. R. Soc'y Med. 295 (1965). To answer that question, Dr. Hill set forth nine factors—which he referred to as "viewpoints"—to consider in determining whether an association reflects a true causal relationship: (1) strength; (2) consistency; (3)

specificity; (4) temporality; (5) biological gradient; (6) plausibility; (7) coherence; (8) experiment; and (9) analogy.[15] *Id.* at 295–99.

In the article, Dr. Hill discussed the limitations of his approach and cautioned against mechanistically applying his "viewpoints" in making causal judgments, stating:

> Here then are nine different viewpoints from all of which we should study association before we cry causation. What I do not believe—and this has been suggested—is that we can usefully lay down some hard-and-fast rules of evidence that must be observed before we accept cause and effect. None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as a *sine qua non*. What they can do, with greater or less strength, is to help us to make up our minds on the fundamental question - is there any other way of explaining the set of facts before us, is there any other answer equally, or more, likely than cause and effect?

Id. at 299.

The *Reference Guide on Epidemiology* sets forth a modern iteration of the nine factors used to determine whether a cause-and-effect relationship exists: (1) temporal relationship; (2) strength of the association; (3) dose-response relationship; (4) replication of the findings; (5) biological plausibility (coherence with existing knowledge); (6) consideration of alternative explanations; (7) cessation of exposure;

[15] The Bradford Hill factors are discussed in greater detail in connection with the parties' arguments below.

(8) specificity of the association; and (9) consistency with other knowledge. Green at 599–600. "These guidelines reflect criteria proposed by the U.S. Surgeon General in 1964 in assessing the relationship between smoking and lung cancer and expanded upon by Sir Austin Bradford Hill in 1965 and are often referred to as the Hill criteria or Hill factors." *Id.* at 600.

Like Dr. Hill's 1965 article, the *Reference Guide* makes clear that applying these factors to demonstrate a causal link requires reasoned judgment:

> There is no formula or algorithm that can be used to assess whether a causal inference is appropriate based on these guidelines. One or more factors may be absent even when a true causal relationship exists. Similarly, the existence of some factors does not ensure that a causal relationship exists. Drawing causal inferences after finding an association and considering these factors requires judgment and searching analysis, based on biology, of why a factor or factors may be absent despite a causal relationship, and vice versa. Although the drawing of causal inferences is informed by scientific expertise, it is not a determination that is made by using an objective or algorithmic methodology.

Id. Critically, "epidemiology cannot prove causation; rather, causation is a judgment for epidemiologists and others interpreting the epidemiologic data." *Id.* at 598.

I call attention to the different versions of the Bradford Hill criteria because some of Plaintiffs' experts apply Dr. Hill's original factors, while others apply a modern iteration of those factors. In addition, Defendants' general causation brief cites the original factors, while Plaintiffs' opposition refers to the *Reference Guide*.

Nevertheless, both formulations of the Bradford Hill criteria are widely recognized as reliable methods for assessing causation. *See In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 795–96 (3d Cir. 2017) (concluding that the original Bradford Hill factors are "generally reliable"); *In re Deepwater Horizon BELO Cases*, 119 F.4th 937, 941 (11th Cir. 2024) (citing the *Reference Guide* factors); *see also In re Abbott Lab'ys, Preterm Infant Nutrition Prods. Liab. Litig.*, MDL No. 3026, No. 22-md-00071, 2025 WL 1283927, at *5 & n.15 (N.D. Ill. May 2, 2025) (noting that the *Reference Guide* "articulates the nine Hill factors slightly differently" from the original formulation, but finding no "meaningful difference between the two articulations of the Bradford Hill analysis"). For purposes of this Report and Recommendation, and because neither party disputes the inherent reliability of either version, I find both versions of the Bradford Hill factors to be reliable in determining causal relationship between talc and ovarian cancer.

Nevertheless, as stated in my prior Opinion, while the Bradford Hill methodology itself may be the proper analytical framework, experts must reliably apply the factors in forming their general causation opinions. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 161. This is the crux of Defendants' position: Plaintiffs' experts failed to reliably apply the factors. Indeed, the Third Circuit in *In re Zoloft*—which remains one of the seminal cases on this topic—explained that "despite the

fact that both the Bradford Hill and the weight of the evidence analyses are generally reliable, the 'techniques' used to implement the analysis must be 1) reliable and 2) reliably applied." 858 F.3d at 796. Because Bradford Hill is a flexible methodology—meaning that experts "can theoretically assign the most weight to only a few factors, or draw conclusions about one factor based on a particular combination of evidence"—the way in which "an expert conducts such an analysis must be reliable; all of the relevant evidence must be gathered, and the assessment or weighing of that evidence must not be arbitrary, but must itself be based on methods of science." *Id.* (internal quotation marks and citation omitted). Accordingly, to reliably apply the methodology, an expert must explain, at a minimum, "1) how conclusions are drawn for each Bradford Hill criterion and 2) how the criteria are weighed relative to one another." *Id.*

4. Scientific Developments Since 2020

Against that backdrop, I noted in my prior Opinion that Plaintiffs' "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." *In re Johnson & Johnson*, 509 F. Supp. 3d at 161. After evaluating Plaintiffs' experts' application of each Bradford Hill criterion—including the epidemiologic studies they considered and the weight they assigned to each criterion—I found their general causation opinions admissible under Rule 702 and

Daubert, with one exception. *See id.* at 157–87 (excluding the experts' inhalation theory of biological plausibility). Since then, additional peer-reviewed epidemiologic studies have been published, examining the alleged relationship between genital powder use and ovarian cancer.

By way of brief background, "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')." Green at 557. Simply put, cohort studies follow groups of individuals with and without exposure to an agent, and then the groups are observed over time to determine whether the exposed group is more likely to develop the disease. *Id.* at 621. Case-control studies, on the other hand, start with people who already have the disease, and then compare them to a group of individuals who do not, in order to identify potential risk factors. *Id.* at 620. In addition, a meta-analysis is a "technique used to combine the results of several studies to enhance the precision of the estimate of the effect size and reduce the plausibility that the association found is due to random sampling error." *Id.* at 624. Finally, a pooled analysis combines individual-level data from multiple studies and reanalyzes them together as if they were one large dataset. *In re Johnson & Johnson*, 509 F. Supp. 3d at 161.

Epidemiologic studies typically report their results in terms of the odds ratio ("OR"), relative risk ("RR"), or hazard ratio ("HR"), which are related but not the same. As Defendants correctly observe, for purposes of evaluating general causation in this MDL, "these are essentially interchangeable concepts that describe the increase (or decrease) in risk between exposure and disease." (Defs.' 2024 General Causation Br. at 8.) Dr. McTiernan provides a clear explanation of these measures in her report:

> The strength of a relationship between an exposure and the occurrence of disease is commonly expressed in terms of relative risk. In cohort studies, relative risk is the ratio of risk (or incidence) of a disease among people with an exposure to that among people without that exposure. In cohort studies, the hazard ratio can be used, and is the chance of an event occurring in one group (exposed) divided by the chance of the event occurring in another group (nonexposed). In case-control studies, the odds ratio is used, which is the ratio of the odds of exposure among cases to the odds of exposure among controls. Relative risks, odds ratios, and hazard ratios above 1.0 indicate an increased risk, while those below 1.0 imply a protective effect. Therefore, a relative risk of 1.3 represents a 30% increased risk.

(McTiernan 3d Amend. Rep. at 13–14.) Importantly, a value of 1.0 for any of these measures indicates "no association between exposure to the agent and disease." Green at 567.

Relatedly, an association refers to the "degree of statistical relationship between two or more events or variables." *Id.* at 619. "Events are said to be

associated when they occur more or less frequently together than one would expect by chance" or random error. *Id.* However, association "does not necessarily imply a causal relationship." *Id.* "Events are said not to have an association when the agent (or independent variable) has no apparent effect on the incidence of a disease (the dependent variable)." *Id.* "This corresponds to a relative risk of 1.0." *Id.*

In an epidemiologic context, causation describes "an event, condition, characteristic, or agent being a necessary element of a set of other events that can produce an outcome, such as a disease." *Id.* at 620. This does not require that the agent be the only cause of disease. *Id.* For instance, "smoking is a necessary element of a set of events that result in lung cancer, yet there are other sets of events (without smoking) that cause lung cancer." *Id.* As such, "a cause may be thought of as a necessary link in at least one causal chain that results in an outcome of interest." *Id.* at 620–21.

One final foundational concept is important to understand before turning to the discussion of the new epidemiologic studies. A confidence interval ("CI") "provides both the relative risk (or other risk measure) found in the study and a range (interval) within which the risk likely would fall if the study were repeated numerous times." Green at 573. "Thus, if a confidence level of .95 is selected for a study, 95% of similar studies would result in the true relative risk falling within the confidence interval." *Id.* at 621. "The width of the confidence interval provides an indication of

the precision of the point estimate or relative risk found in the study; the narrower the confidence interval, the greater the confidence in the relative risk estimate found in the study." *Id.* "Where the confidence interval contains a relative risk of 1.0, the results of the study are not statistically significant"—meaning one cannot rule out the possibility of no association based on the data. *Id.*

With these concepts in mind, I now turn to the epidemiologic studies published since 2020 that address talc use and ovarian cancer:

- O'Brien et al. 2020[16] conducted a pooled prospective cohort analysis to evaluate whether genital powder use is associated with ovarian cancer. Data were pooled from four large, U.S.-based cohorts: Nurses' Health Study, Nurses' Health Study II, Sister Study, and Women's Health Initiative Observational Study. The pooled sample included 252,745 women (median baseline age 57), of whom 38% reported ever using powder in the genital area, with 22% reporting frequent use (≥1/week) and 10% reporting long-term use (≥20 years). During 11.2 years of median follow-up (3.8 million person-years), 2,168 ovarian cancers occurred (58 per 100,000 person-years). Compared to never use, the HR for ever use was 1.08 (95% CI, 0.99-1.17), with similarly modest estimates for frequent and long-term use. The authors concluded there was no statistically significant association between genital powder use and ovarian cancer but noted that the study may have been underpowered to identify a small increase in risk.

- Davis et al. 2021[17] conducted a pooled case-control analysis to evaluate associations between genital powder use and ovarian cancer among

[16] Katie M. O'Brien et al., Association of Powder Use in the Genital Area With Risk of Ovarian Cancer, 323 JAMA 49 (2020) ("O'Brien 2020").

[17] Colette P. Davis et al., *Genital Powder Use and Risk of Epithelial Ovarian Cancer in the Ovarian Cancer in Women of African Ancestry Consortium*, 30 Cancer Epidemiol. Biomarkers &

African-American and white women. The study used data from five studies in the Ovarian Cancer in Women of African Ancestry Consortium. The analysis included 620 African-American cases and 1,146 controls, and 2,800 white cases and 6,735 controls who reported genital powder use prior to 2014. Genital powder was defined as any powder applied directly to the genital/perineal/rectal area or indirectly via pads, tampons, or underwear. Exposure was categorized by frequency (≤1/week, >1/week) and duration (<20 years, ≥20 years). Ever genital powder use was reported by 35.8% of African-American cases and 29.5% of white cases. Among all women combined, ever use was associated with 32% higher odds of ovarian cancer (OR = 1.32; 95% CI = 1.17–1.48). Stratified analyses showed a significant association among White women (OR = 1.36; 95% CI = 1.19–1.57) and a non-significant association among African-American women (OR = 1.22; 95% CI = 0.97–1.53).

- Phung et al. 2022[18] conducted a pooled analysis of nine case-control studies from the Ovarian Cancer Association Consortium to assess whether ovarian cancer risk factors, including genital talcum powder use, differ in women with and without endometriosis. In total, this analysis included 8,500 cases and 13,592 controls for all risk factors; however, there were fewer cases and controls included in the estimation of the association between ovarian cancer and talc use because one of the nine studies did not collect information on talc use. Genital powder use was categorized based on the area of application (genital or nongenital) and by ever versus never use. Genital talc use was positively associated with risk for women with and without endometriosis. Among women without endometriosis, ever use of genital powder was associated with a modestly increased risk of ovarian cancer (OR = 1.12; 95% CI = 1.01-1.25). Among women with endometriosis, the association was stronger (OR = 1.38; 95% CI =

Prev. 1660 (2021) ("Davis 2021"). One of the coauthors, Dr. Moorman, is an expert for Plaintiffs in this MDL.

[18] Minh Tung Phung et al., *Effects of Risk Factors for Ovarian Cancer in Women With and Without Endometriosis,* 118 Fertil. & Steril. 960 (2022) ("Phung 2022").

1.04-1.84). The authors concluded that, although associations between ovarian cancer and most risk factors were similar among women with and without endometriosis, there was some suggestion of differences by endometriosis status for risk factors such as body mass index, menopausal hormone therapy use, and genital talcum powder use.

- Woolen et al. 2022[19] conducted a systematic review and meta-analysis to evaluate the association between frequent perineal talcum powder use and ovarian cancer. The authors noted that prior systemic reviews focused on ever use—"a non-specific exposure that could dilute or obscure a meaningful association as ever use would combine women with low and high exposures to talcum powder." The analysis involved 11 studies (10 case-control and one cohort—O'Brien 2020) and included 66,876 patients and 6,542 ovarian cancer cases. Study selection criteria included publication of primary data, reporting on multiple times per week (≥ 2 times per week) perineal exposure to talcum powder, including direct genital/perineal application or indirect use via pads, underwear, or intravaginal devices. Across the studies, frequent talc use was associated with a 47% higher risk of ovarian cancer (adjusted pooled summary OR = 1.47; 95% CI = 1.31-1.65), with no evidence of bias and low statistical heterogeneity. The authors concluded that frequent use of perineal talcum powder use is associated with increased risk of ovarian cancer.

- Chang 2024[20] conducted a prospective cohort analysis within the Sister Study, a U.S. nationwide cohort of 50,884 women aged 35–74 who had a sister with breast cancer but were themselves breast cancer-free at enrollment. In this analysis, 49,899 participants reported the frequency of use for 41 personal care products ("PCPs"), including

[19] Sean A. Woolen, Ann A. Lazar & Rebecca Smith-Bindman, *Association Between the Frequent Use of Perineal Talcum Powder Products and Ovarian Cancer: A Systematic Review and Meta-Analysis*, 37 J. Gen. Intern. Med. 2526 (2022) ("Woolen 2022"). Dr. Smith-Bindman, a coauthor of the study, is one of Plaintiffs' experts in this MDL.

[20] Che-Jung Chang et al., *Use of Personal Care Product Mixtures and Incident Hormone-Sensitive Cancers in the Sister Study: A U.S.-Wide Prospective Cohort*, 183 Env't. Int'l 108298 (2024) ("Chang 2024").

genital talc use. The "study utilized a sophisticated mixtures approach"—using beauty, hygiene, and skincare product groupings—to examine the relationship between PCPs and the incidence of hormone-sensitive cancers. Genital talc use was included within the hygiene mixture analysis. Over an average of 11.6 years of follow-up, the cohort experienced 4,226 breast cancer cases, 277 ovarian cancer cases, and 403 uterine cancer cases. In adjusted models, the hygiene mixture was positively associated with ovarian cancer risk (HR = 1.35; 95% CI = 1.00–1.83), the beauty mixture was positively associated with postmenopausal breast cancer (HR = 1.08; 95% CI = 1.01–1.16), and the skincare mixture was inversely associated with breast cancer risk (HR = 0.91; 95% CI = 0.83–0.99). No significant associations were observed for individual products—including genital talc use—after correcting for multiple comparison. The authors concluded that their findings from this multi-product, joint-effect approach contribute to the growing body of evidence for associations between PCPs and breast cancer and provide novel information on ovarian and uterine cancer.

- O'Brien et al. 2024[21] reanalyzed the association between intimate care products, primarily genital talc use, and ovarian cancer in the Sister Study cohort using updated exposure data and quantitative bias analysis. Genital talc use was initially reported at enrollment (2003–2009), with additional exposure information collected in a follow-up survey (2017–2019). Because many ovarian cancer cases were diagnosed before the follow-up survey, the authors applied multiple imputation and quantitative bias analysis to address differential misclassification and missing data.[22] In models adjusted for exposure misclassification, genital talc use was positively associated with

[21] (ECF No. 33011-5, Katie M. O'Brien et al., *Intimate Care Products and Incidence of Hormone-Related Cancers: A Quantitative Bias Analysis*, 42 J. Clin. Oncol. 2645 (2024) ("O'Brien 2024).)

[22] Differential misclassification is a type of "bias that is due to the misclassification of individuals or a variable of interest when the misclassification varies among study groups." Green at 622. "This type of bias occurs when, for example, it is incorrectly determined that individuals in a study are unexposed to the agent being studied when in fact they are exposed." *Id.*

> ovarian cancer (HRs ranging from 1.17 to 3.34). Under moderate assumptions, ever use was associated with an approximately 40% higher rate of ovarian cancer (HR = 1.40; 95% CI = 1.04–1.89), compared to never use, with consistently increasing dose-response patterns for both frequency and duration of use. No comparable positive associations were observed between genital talc use and breast or uterine cancer. The authors cautioned that the results do not establish causality and do not implicate any specific cancer-inducing agent. They reasoned that those reporting talc use could be recalling products that contained talc, cornstarch, or a mixture, and women may have used different products at different times. Some talc may have also been contaminated with asbestos or other potentially harmful chemicals. Chronic irritation of the ovaries or fallopian tubes from talc or talc-like products could also potentially contribute to carcinogenesis. In addition, the authors explained that their findings of a positive association between genital talc use and ovarian cancer are consistent with prior studies, noting that pooled or meta-analyses of case-control studies have produced odds ratios of 1.2–1.4. Ultimately, the authors concluded that their results support a positive association between genital talc use and ovarian cancer incidence, but they do not pinpoint a specific cause or mechanism. They also emphasized remaining uncertainty about how much recall bias and missing data may have inflated risk estimates.

As I explained in my prior Opinion, what is "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." *In re Johnson & Johnson*, 509 F. Supp. 3d at 187. That remains true even in light of recent epidemiologic studies. Although there is no clear scientific consensus as to whether a causal relationship exists between genital talcum powder use and ovarian cancer, the available evidence is

"open to different interpretations." *Id.* As discussed above at length, the Bradford Hill analysis requires the exercise of expert judgment in assessing causation. So long as that analysis is reliably conducted and draws conclusions adequately supported by sufficient facts or data, the resulting opinions more likely than not satisfy Rule 702's reliability standard. Ultimately, if the analyses are reliable, the expert is permitted to espouse his/her view before a jury.

5. The Parties' Bradford Hill Arguments

In their motions, Defendants principally focus on four Bradford Hill factors: strength of the association, consistency, biological gradient (or dose-response relationship), and biological plausibility. They also briefly address the remaining factors: specificity, coherence, analogy, experiment, and temporality. My discussion will follow the parties' arguments.

i. Strength of the Association

This Bradford Hill factor concerns the strength of the association between exposure to an agent and disease—that is, the relative risk—which "is one of the cornerstones for causal inferences." Green at 602. "The higher the relative risk, the greater the likelihood that the relationship is causal." *Id.* A lower relative risk "can reflect causality," but such associations should be more closely scrutinized "because there is a greater chance that they are the result of uncontrolled confounding or

biases."[23] *Id.* However, Dr. Hill cautioned, "[w]e must not be too ready to dismiss a cause-and-effect hypothesis merely on the grounds that the observed association appears to be slight. There are many occasions in medicine when this is in truth so." Hill at 296.

As to this gating factor, Plaintiffs' experts conclude that it supports a causal relationship because the epidemiologic evidence reflects a positive association between genital talc use and ovarian cancer, with reported relative risks ranging from approximately 20% to 60% higher among users compared to non-users. (Carson Rep. at 8–9, 10; Clarke-Pearson 3d Amend. Rep. at 13; Cote Amend. Rep. at 35–36; Kane Rep. at 33–34; McTiernan 3d Amend. Rep. at 96–97; Moorman Rep. at 11–29; Siemiatycki 3d Amend. Rep. at 70–71; Singh Supp. Rep. at 19–20; Smith Rep. at 19, 21; Smith-Bindman 3d Amend. Rep. at 32, 34–36; Wolf 3d Amend. Rep. at 18–19.) Indeed, as discussed above, in addition to studies that I previously reviewed in my 2020 Opinion, there are subsequent studies that the experts relied upon to further strengthen their opinions on the association between talc use and ovarian cancer, which will be discussed, *infra*.

[23] "Confounding refers to a situation in which an association between an exposure and outcome is all or partly the result of a factor that affects the outcome but is unaffected by the exposure." Green at 621. Bias refers to an "effect at any stage of investigation or inference tending to produce results that depart systematically from the true values." *Id.* at 620. Importantly, "[i]n epidemiology, the term bias does not necessarily carry an imputation of prejudice or other subjective factor, such as the experimenter's desire for a particular outcome." *Id.* "This differs from conventional usage, in which bias refers to a partisan point of view." *Id.*

As I noted in my prior Opinion, and which remains true, Defendants "do not suggest that the experts' calculation of relative risk, based on the aggregate studies, was not reliably reached." *In re Johnson & Johnson*, 509 F. Supp. 3d at 164. Instead, they argue that the strength of the association cannot support the causal inference drawn by Plaintiffs' experts. (Defs.' 2024 General Causation Br. at 36–37 ("Here, the relative risk is much lower (approximately 1.3–1.6 in the meta-analyses on which plaintiffs' experts rely), weighing heavily against causation.").) Defendants also challenge the experts' discussion of public-policy considerations and their comparisons to other exposures with similar relative risks, such as secondhand smoke and lung cancer, asserting that in those contexts other Bradford Hill factors were uniquely compelling. (*Id.* at 37–40.)[24] Finally, Defendants contend that the epidemiologic studies relied on by Plaintiffs' experts are affected by both recall bias and confounding. (*Id.* at 40–47.)

[24] While public policy is indeed an important consideration for resolution of the ultimate issue in this case, I do not address this argument in this Report and Recommendation for several reasons. First, Plaintiffs' experts' passing comments on public policy do not inform the foundation for their ultimate purpose in seeking to testify in this litigation, i.e., their scientific expertise on the general causation issue. Second, Defendants introduce associations like secondhand smoke and lung cancer as comparators to the agent-disease relationship here—*not* for the purpose of my evaluation or analysis of the link between smoking and cancer. In their reports, Plaintiffs' experts reference these comparators to establish that a causal relationship can exist even if the strength of association is moderate. Defendants take issue with these comparisons. I need not analyze the purported comparators because, according to Hill, even moderately strong associations can support causation, *see* Hill at 296, and because I find it more likely than not that the experts' conclusions regarding the strength of association are supported by good grounds, making analysis of comparators unnecessary.

Having reviewed the reports of Plaintiffs' experts as amended and updated since the prior motion practice,[25] as well as the parties' arguments and submissions, I do not find that: (1) my prior ruling regarding the strength of association factor demonstrably failed to adhere to Rule 702 as clarified by the 2023 amendments; or (2) the epidemiologic studies published since 2020 cause me to change any of my previous findings related to this factor. Indeed, there have been no seismic shifts in the scientific landscape that would warrant reconsideration of my ruling here. In fact, the majority of additional studies support the association between talc and ovarian cancer, without any new studies concluding that no causal link exists. I therefore find, by a preponderance of the evidence, that the Plaintiffs' experts have applied reliable methodologies to arrive at their opinions that the pre- and post-2020 epidemiologic studies, taken as a whole, demonstrate a positive, statistically significant association between genital talc powder use and ovarian cancer.

Moreover, I thoroughly addressed and rejected Defendants' substantially similar arguments in my prior Opinion, finding that Plaintiffs' experts' opinions regarding this factor were admissible under Rule 702 and *Daubert*, and that their "decisions to place significant weight on the strength of association factor" were

[25] Each proffered expert has issued updated reports since I decided the 2020 *Daubert* motions, which address the post-2020 scientific landscape, except Drs. Carson, Kane, and Smith. I have already discussed why I need not reconsider those experts' analyses at this juncture. (*See supra* Part III.)

supported by good grounds. *In re Johnson & Johnson*, 509 F. Supp. 3d at 163; *see id.* at 162–68. As Rule 702 requires, my analysis focused 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." *Id.* at 164. I found that Plaintiffs' experts reliably applied their methodology in evaluating this Bradford Hill factor because they "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." *Id.* Consequently, and after careful consideration, I determined that Defendants' arguments regarding the magnitude of the association, recall bias, and confounding went to the weight of the evidence, and not its admissibility. *Id.* at 162–68. Simply put, Defendants' challenges reflected "their disagreement with the conclusions of the experts—not the methodology employed in consideration of the studies." *Id.* at 168.

While I find no reason to depart from my prior ruling on this factor, for the parties' and the Court's benefit, I will fully address Defendants' current arguments. Defendants contend that Plaintiffs' experts' opinions should be excluded because they erroneously "all claim that a 'strong' association has been reported between talc use and ovarian cancer." (Defs.' 2024 General Causation Br. at 37.) I rejected this argument in my prior Opinion, finding there is "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." *In re Johnson & Johnson*, 509 F. Supp. 3d at 163. Defendants now cite two recent cases—*In re Acetaminophen* and *In re Viagra*—in support of the same proposition previously rejected: that risk ratios between 1.0 and 2.0 are too small or weak to support a causal inference. (Defs.' 2024 General Causation Br. at 37; *see also* Defs.' 2019 General Causation Br. at 31–35.) However, neither case holds that a relative risk below 2.0 is legally insufficient to support causation; instead, both courts excluded the experts' testimonies because of methodological shortcomings, *not* because of the magnitude of the reported associations. *See In re Acetaminophen*, 707 F. Supp. 3d at 346–48 (excluding expert's opinion for, *inter alia*, failing to "separately address" studies evaluating disparate diagnoses, e.g., autism spectrum disorder, attention-deficit/hyperactivity disorder, and other neurodevelopmental disorders, and failing to "explain how the strength (or weakness) of association evidence for each of them has impacted his overarching assessment"); *In re Viagra (Sildenafil Citrate) & Cialis (Tadalafil) Prods. Liab. Litig.*, 424 F. Supp. 3d 781, 794–96 (N.D. Cal. 2020) (excluding expert's opinion because she was unable to specify grounds upon which she perceived a strong association, instead testifying generally "that she found it in the 'totality' of the evidence"). Accordingly, Defendants cite no legal authority holding that, as a matter of law, a relative risk in the range of 1.2 to 1.6 is facially insufficient to support Plaintiffs' experts' conclusion that this Bradford Hill factor is met.

Furthermore, because Defendants' challenge amounts to a debate over whether the observed association should be characterized as weak, moderate, or strong, (Pls.' General Causation Opp. Br. at 74), in my view, this argument attacks the experts' conclusions on the ground that the observed association appears slight, while disregarding the central reliability inquiry: whether the expert has reviewed all relevant evidence and explained "(1) how conclusions are drawn for each Bradford Hill criterion and (2) how the criteria are weighed relative to one another." *In re Zoloft*, 858 F.3d at 796. Specifically, Plaintiffs' experts' positive associations derive directly from their independent reviews of the relevant studies—which were all authored by practitioners with relevant expertise, peer-reviewed within their fields, and published in scientific journals. (*See, e.g.*, O'Brien 2020; O'Brien 2024; Woolen 2022; Chang 2024; and Davis 2021.) As discussed in detail above, the more recent studies are largely comprised of cohort and pooled analyses, rather than case studies, analyzing hundreds of thousands of women's health and hygiene patterns across decades. (*See supra* Part V.B.4.)

For the majority of these studies, Defendants do not critique the researchers' methodologies, but instead take issue with the experts' characterizations of the studies' conclusions and outcomes, and purported failure to adequately account for confounding factors and recall bias. (*See* Defs.' General Causation Br. at 17–20 (disputing Plaintiffs' interpretation of the findings of O'Brien 2020, Davis 2021, and

Chang 2024).) They do, however, attack Woolen 2022, describing it as having been "discredited" by the National Cancer Institute ("NCI"), on the basis that the NCI later advised readers that Woolen 2022's "results should be interpreted with care," because, in Defendants' words, the study reflects a "post hoc analysis that used subjective and inconsistent criteria to narrow the data it examined." (Defs.' General Causation Br. at 20–21, 30.) Yet cautionary language advising the audience to "interpret [a study's results] with care" stops short of a methodological condemnation that renders a study unreliable; measured academic consideration does not equate to scientific repudiation. Nor do Defendants point to any other support for the criticism that the study is insufficient such that Plaintiffs' experts' opinions should be excluded for having cited and relied on this study.

As discussed above, Woolen 2022 was a meta-analysis that examined the association between frequent perineal talc use and ovarian cancer using pooled data from 11 studies. (Woolen 2022 at 2528.) The study found a "pooled adjusted odds ratio of 1.47% (95% CI 1.31, 1.65)," for frequent use of perineal talcum powder. (*Id.* at 2530.) As Woolen 2022 was "the first systematic review to focus on multiple times per week users," the authors also acknowledged the design's limitations, including variations across surveys that may have excluded certain frequent-use patients "if the questionnaire did not explicitly capture" multiple-times-per-week usage information, as well as potential variances in the definitions of talcum powder

use by frequency and duration. (*Id.* at 2531–32.) While these constraints may provide grounds for caution in interpretation, they do not rise to the level of wholesale methodological unreliability by Plaintiffs' experts' that would justify exclusion under Rule 702, particularly since this is but one of many studies that the experts relied upon to reach their conclusions on strength of association.

Indeed, Plaintiffs' experts acknowledge and account for those limitations when explaining why, however, they do not discount the study's conclusion in their assessments. For example, Dr. McTiernan noted that despite its constraints, the study is consistent with, and confirms, prior data by "add[ing] to the previously published literature which shows a consistent elevated risk of ovarian cancer with genital exposure to talcum powder product." (McTiernan 3d Amend. Rep. at 81). She also explained that although "[s]ome included studies were unable to differentiate between perineal talcum powder product and cornstarch users," "other research shows only 1–2% of perineal powder users reported cornstarch." (*Id.* (citing Daniel W. Cramer et al., *The Association Between Talc Use and Ovarian Cancer: A Retrospective Case-Control Study in Two U.S. States*, 27 Epidemiol. (3) 334–346 (2016) ("Cramer 2016")); *see also, e.g.*, Moorman Supp. Rep. at 4 (explaining that the pooled OR was higher than the summary ORs from other published analyses which was "to be expected given that other meta-analyses defined the exposure as any use of talc whereas the exposure was defined as frequent use of talc in this meta-

analysis").) Accordingly, such limitations are more appropriately addressed through cross-examination and competing expert testimony, which allow the factfinder to evaluate the weight to be afforded to Woolen 2022 in the overall causation analysis. *See, e.g.*, *Tree-Removal Rts. In re Land in Gordon Cnty., Ga.*, 283 F. Supp. 3d at 1346 (applying a preponderance of the evidence standard under Rule 702 to explain that (1) "the gatekeeping function under Rule 702 is not intended to supplant the adversary system or the role of the jury: vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof," and (2) "in most cases, objections to the inadequacies of a study are more appropriately considered an objection going to the weight of the evidence rather than its admissibility") (first quoting *Adams v. Lab. Corp. of Am.*, 760 F.3d 1322, 1334 (11th Cir. 2014); and then quoting *Rosenfeld v. Oceania Cruises, Inc.*, 654 F.3d 1190, 1193 (11th Cir. 2011)).

Defendants direct more pointed criticism at O'Brien 2024, asserting that the study "imputed—i.e., made up" a substantial volume of missing exposure data when evaluating retrospective talc-use information from Sister Study participants. (Defs.' General Causation Br. at 21–22.) That characterization, however, obscures the actual methodological detail underlying the study's analysis. Confronted with incomplete follow-up responses, the authors employed a multiple-imputation framework to estimate exposure status and generate adjusted effect estimates. The study explained that "[d]ata on intimate care product use were sometimes contradictory or missing,"

from follow-up questionnaires in the Sister Study, specifically because, for example, "those who died of their disease could not have completed the follow-up questionnaire." (O'Brien 2024 at 3, 14; *see also* Pls.' General Causation Opp. Br. at 30 (acknowledging that some "women [] were lost to the cohort before they could answer the follow-up questions about lifetime use (for example, those who had already died)").) Therefore, the researchers "used quantitative bias analyses to implement different approaches for imputing exposure in women who initially reported never use but did not complete the follow-up questionnaire. These comparisons were crucial for understanding potential biases, as women with incident cancer were *overrepresented* in this undefined group." (O'Brien 2024 at 3 (emphasis added).) Using quantitative bias analysis, O'Brien 2024 "compared four possible scenarios . . . : (1) no correction; (2) contradictory data correction; (3) contradictory data correction plus categorizing missing or undefined as exposed; and (4) contradictory data correction with multiple imputation of missing or undefined data." (*Id.* at 4.) Specifically, the researchers conducted ten iterations correcting for conflicting responses and then summarized the results across 100 imputed data sets to address confounding and uncertainty. (*Id.*) The study described in detail the steps taken using "multiple imputation with chained equations (MICE; PROC MI, SAS v9.4 [Cary, NC]) to generate covariate-informed probabilistic imputations of the exposure status of participants who were undefined or missing," resulting in an

approach that they call "our best estimate of the true association in the absence of recall or other unknown biases." (*Id.*)

Several of Plaintiffs' experts, such as Dr. Singh, (Singh Rep. at 1), cited to what is known across the scientific literature as "Rubin's Rule," based on the 1987 publication by Donald B. Rubin that is often credited as codifying this methodology. *See, e.g.*, Romuladus E. Azuine et al., *Prenatal Risk Factors and Perinatal and Postnatal Outcomes Associated With Maternal Opioid Exposure in an Urban, Low-Income Multiethnic U.S. Population*, 2 JAMA Netw. (6) (2019); David C. Whiteman et al., *The Effect of Screening on Melanoma Incidence and Biopsy Rates*, 187 Br. J. Dermatol. 515 (2022). Scholars invoke this method when faced with a situation where there is missing data that is not possible to obtain for a variety of unavoidable reasons, ranging from material "missing completely at random" to "missingness dependent on the unobserved values," e.g., when a participant has died due to the disease being studied. Peng Li, Elizabeth A. Stuart & David B. Allison, *Multiple Imputation: A Flexible Tool for Handling Missing Data*, 314 J. Am. Med. Ass'n (18) 1966–67 (2015). Multiple imputation has been described in the peer-reviewed literature as "the process of replacing missing data with 1 or more specific values, to allow statistical analysis that *includes all participants and not just those who do not have any missing data*." *Id.* (emphasis added). While missing data can be approximated by "estimat[ing] what each missing value might have been and replace

it with a single value in the data set," Rubin's multiple imputation approach "better handles missing data by estimating and replacing missing values many times." *Id.* This "reduces the change of false-positive or false-negative conclusions." *Id.*

This accords with Plaintiffs' experts' characterizations of this process as consistent with "well-established epidemiologic methods of multiple imputation that have been in existence for decades," and as a means of producing the most informative estimate where recall bias and missing data are present. (Singh Rep. at 1 (citing Donald B. Rubin, *Multiple Imputation for Nonresponse in Surveys*, Wiley & Sons (1987)); ECF No. 33130-5, ("Harlow Supp. Rep.") at 1; Cote Amend. Rep. at 25; McTiernan 3d Amend. Rep. at 49 (explaining that multiple imputation does not involve "making up data," but instead fills in missing values based on observed relationships within the dataset); Smith-Bindman 3d Amend. Rep. at 22 ("[T]he authors used established techniques of multiple imputation to generate covariate-informed probabilistic imputations of exposure status for participants with undefined or missing values.").) In her report, Dr. McTiernan described in detail, relying on many of the same principles expounded upon above, how and why she agreed that this methodology is sound. (*See* McTiernan 3d Amend. Rep. at 50.)

Accordingly, I do not find Defendants' characterization of O'Brien 2024 as having "made up" data to be persuasive for purposes of assessing the reliability of the methodology in the context of Rule 702. As I have described above, the study's

use of multiple imputation and quantitative bias analysis reflects well-established statistical methodologies long accepted within the epidemiologic and broader scientific communities for addressing missing data and recall bias—particularly in longitudinal studies where loss to follow-up is unavoidable. Both the study's authors and Plaintiffs' experts in detail describe the assumptions, limitations, and analytical steps underlying this approach, and the methodology is grounded in peer-reviewed principles dating back decades. Defendants' objections therefore challenge the inferences drawn from the imputed data and the weight to be accorded to those results, not the reliability of the methods employed. Such criticisms are properly explored through cross-examination and competing expert testimony, rather than exclusion under Rule 702.

In sum, while Defendants disagree with Plaintiffs' experts' conclusions, I find that the experts have reviewed the epidemiologic evidence and articulated, in a sufficiently reliable manner to satisfy the more likely than not standard, how they evaluated the strength of association under the Bradford Hill framework and how that factor fits within their overall causal assessment. For example, relying on both pre- and post-2020 epidemiologic studies, Dr. Cote states that the "effect sizes seen in most of the studies examining the association between the genital use of talcum powder and ovarian cancer are around 1.25 in magnitude." (Cote Amend. Rep. at 36.) Dr. McTiernan similarly concludes that pooled and meta-analyses show that

"risk of ovarian cancer among ever users of talcum powder products is 22–31% higher than in women who never used these products." (McTiernan 3d Amend. Rep. at 96.) Dr. Siemiatycki opines that the "meta-RR estimate is 1.3," meaning "the best estimate from the epidemiologic literature is that women who regularly used talcum powder products in the genital area had a 30% higher risk of ovarian cancer than women who did not use such powders." (Siemiatycki 3d Amend. Rep. at 71.) He asserts that such a "meta-RR could not have occurred by chance." (*Id.*) Other experts estimate that the risk among genital talc users may be as high as 50 to 60%, particularly among frequent users. (Singh Supp. Rep. at 19–20; Smith Rep. at 19, 21; Smith-Bindman 3d Amend. Rep. at 32, 34–36.)

Next, Defendants claim that "the very small reported relative risk" between talc use and ovarian cancer "is likely being driven by recall bias, thanks in part to extensive lawyer advertising that has scared women." (Defs.' 2024 General Causation Br. at 4.) Recall bias refers to the tendency of participants in case-control studies who have been diagnosed "with disease (cases) . . . to recall past exposures more readily than individuals with no disease (controls)." Green at 585. I addressed Defendants' recall bias arguments in my prior Opinion, including their concerns about case-control studies and external influences such as media attention, which I will not repeat here. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 164–68.

Defendants now rely on three recent studies—Goodman 2024[26], O'Brien 2023[27], and Davis 2021—which they contend "conclusively demonstrate" that recall bias explains the observed association between talc use and ovarian cancer. (Defs.' 2024 General Causation Br. at 40–43.) I disagree. None of these studies conclude that recall bias actually occurred in the underlying epidemiologic literature. Rather, they identify recall bias as a potential source of error and, in some instances, use hypothetical or modelled scenarios to illustrate how differential misclassification could influence risk estimates. Critically, none establish that the epidemiologic evidence on which Plaintiffs' experts rely is materially distorted by recall bias or that such bias would nullify the positive associations consistently observed across multiple studies. That is not to say that recall bias could not have affected the underlying data. However, as discussed below, Plaintiffs' experts have adequately accounted for recall bias and other potential confounders in forming their opinions.

Defendants also challenge the experts' reliance on O'Brien 2024, arguing, *inter alia*, that Dr. McTiernan twisted the study's findings by stating it "proved that recall bias does not explain the relative risks seen for ovarian cancer with genital talc exposure over decades of research around the world." (Defs.' 2024 General

[26] Julie E. Goodman et al., *Quantitative Recall Bias Analysis of the Talc and Ovarian Cancer Association*, 7 Glob Epidemiol. (2024) ("Goodman 2024").

[27] Katie M. O'Brien et al., *Douching and Genital Talc Use: Patterns of Use and Reliability of Self-reported Exposure*, 34 Epidemiol. (3) 376–84 (2023) ("O'Brien 2023").

Causation Br. at 43; McTiernan 3d Amend. Rep. at 53.) As discussed above, O'Brien 2024 ran ten iterations across 100 imputed data sets to specifically "investigate[] the potential impact of recall bias on the association between genital talc use and ovarian cancer." (O'Brien 2024 at 4.) The study's authors described these quantitative bias analyses as "a major strength," of the study because "they provide a comprehensive illustration of the possible impacts of missing data and recall bias under a variety of scenarios." (*Id.* at 14.) In that regard, while Defendants are correct in asserting that O'Brien 2024 did not *prove* the lack of recall bias, and that Dr. McTiernan's above statement overstates this specific finding in O'Brien 2024, Defendants nonetheless overlook the broader context of Dr. McTiernan's and other experts' discussions of the study. (*See infra*, note 26.)

In her report, Dr. McTiernan began with a detailed analysis of O'Brien 2024. (McTiernan 3d Amend. Rep. at 48–54.) She set forth what she viewed as the study's strengths, when considered in the context of prior analyses *and* reasoning why the potential for recall bias cannot adequately explain updated findings. I find that Dr. McTiernan *accurately* described the *study's* methods and *findings* and reasonably interpreted its results and overall significance in light of her review of the Bradford Hill analysis, with the possible exception of the above discussion of Dr. McTiernan's overstatement of the impact of recall bias. Specifically, she emphasized that the study had a "more stable estimate of hazard ratios (relative risk)" and "more power

to detect statistically significant associations," because it was able to evaluate "more cases accrued over a longer period of follow-up." (*Id.* at 53.) O'Brien 2024 also analyzed lifetime exposure, rather than the more limited period used in prior studies. (*Id.*) Even with these more concentrated findings, the resulting HRs were consistent with "genital talc exposure over decades of research around the world," establishing that recall bias *alone* cannot explain the ultimate conclusions.[28] (*Id.*) Accordingly, Dr. McTiernan's discussion of O'Brien 2024 does not bespeak a lack of scientific rigor, as Defendants contend.

Defendants also assert that Drs. Harlow and Cote distort the study's conclusions. (Defs.' General Causation Br. at 43 n.108.) I disagree. I find that these experts have applied reliable methodologies and made adequately supported extrapolations from O'Brien 2024 in arriving at their conclusions. For example, Dr. Harlow addressed the potential for recall bias, noting that O'Brien 2024 applied a recall bias correction to the reported risk ratio for "ever use" of perineal talc to arrive at 1.40—a figure "similar to what many earlier studies have reported." (Harlow

[28] I emphasize that despite Defendants' selective quote from Dr. McTiernan that O'Brien 2024 "proved that recall bias does not explain the relative risks," a closer read of her analysis demonstrates that despite this phraseology in her summary of the study, her longer discussion and analysis of the study appropriately accounted for how the study mitigated recall bias in its methodology. In other words, I understand Dr. McTiernan's comment in this regard to summarize the high-level finding that based on the iterations of analysis O'Brien 2024 applied, the approach resulted in the authors' "best estimate of the true association in the absence of recall bias or other unknown biases." (McTiernan 3d Amend. Rep. at 50 (quoting O'Brien 2024 at 4).) Of course, Defendants are free to use the expert's words against her and probe this language on cross-examination; however, I do not find this a sufficient ground to exclude her opinion on this point.

Supp. Rep. at 4.) Indeed, the corrected estimate resulted in even more elevated increased risk ratios for both "frequent use" and "long term use" subjects. (*Id.*) Further, Dr. Harlow added that while "the authors [of the O'Brien 2024 study] state that they cannot rule out the presence of unmeasured confounding," any such presence "would have had to occur before the first onset of talc exposure" *and* have a "magnitude . . . sufficient to offset the observed talc and ovarian cancer association present in this analysis." (*Id.*) Based on this reasoning, Dr. Harlow concluded that "unmeasured confounding is highly unlikely to have any impact on these findings." (*Id.*) Dr. Cote made similar assessments based on hypothetical over-estimations of potential recall bias, explaining that even assuming "90% of women were reassigned to never use" from either "infrequent or short term use," the "analyses . . . showed positive associations," thus bolstering her conclusion that despite potential recall bias, "there remained a positive association between genital talc use and ovarian cancer." (Cote Amend. Rep. at 25.)

None of these analyses rise to the level of Defendants' claim that the "experts are drawing conclusions that study authors were not willing to make." (Defs.' General Causation Br. at 43 (internal quotation marks omitted).) Instead, O'Brien 2024, in its own words, concluded that the study's "findings support the hypothesis that there is a positive association between genital talc use and ovarian cancer incidence," even though "there is still uncertainty as to how much recall bias and

missing data could upwardly bias effect estimates." (O'Brien 2024 at 14.) Moreover, O'Brien 2024 assessed findings from nearly 50,000 women over the span of nearly two decades, making it "one of the largest studies to collect data on intimate care product use," and therefore significantly powered to detect statistically significant associations and account for potential recall bias. (*Id.* at 2, 14.) The experts' explanations of same applied sound methodology to attempt to account for those gaps that O'Brien 2024 identified; they accordingly arrived at the same finding of "a positive association" between talc use and ovarian cancer. (*Id.*) Any further challenges that Defendants have to the experts' characterizations of the study on this point are therefore a question of weight based on the scientists' conclusions, rather than their methodologies in reaching those conclusions.

Defendants next assert that Plaintiffs' experts "fail to meaningfully address" potential confounding in case-control studies. (Defs.' General Causation Br. at 44.) Again, I disagree. Despite Defendants' characterization that Dr. Harlow "ignore[d]" the issue in his report, in addition to the recall bias analysis discussed above, Dr. Harlow "[a]ddress[ed] skepticism related to this research," explaining that "[a]lthough case-control studies have long been disparaged as being backwards versions of cohort studies . . . epidemiologists today understand case-control studies to be conceptually identical to cohort studies, apart from an efficiency gain that comes from sampling the denominators rather than conducting a complete census."

(Harlow Rep. at 17–18 (citing Kenneth J. Rothman, *Six Persistent Research Misconceptions*, 29 J. Gen. Intern. Med. (7) 1060–1064 (2014).) As a general matter, Dr. Harlow also concluded that "none of the non-causal explanations can account adequately for the consistent positive association across so many studies," when considered in conjunction with the other Bradford Hill criteria such as consistency and biological plausibility. (*Id.* at 20.)[29]

More specifically on the issue of confounders, Defendants fault Plaintiffs' experts for giving little attention to douching as a potential confounder. (Defs.' General Causation Br. at 45–47.) However, they do not meaningfully address that recent data—including O'Brien 2024—reported that "[d]ouching was not strongly associated with any of the examined outcomes," ovarian cancer among them. (O'Brien 2024 at 12; *see also id.* at 7, Table 2.) In fact, O'Brien 2024 *only* found "a *possible* positive association between douching and ovarian cancer" for those classified as "[f]requent douch[ers] and douch[ers] age 20–39 years." (*Id.* at 13 (emphasis added).) In light of those findings, the absence of a detailed discussion of

[29] Defendants also claim that Dr. Clarke-Pearson "ignore[d]" confounding in case-control studies in his report. (Defs.' General Causation Br. at 44.) But his report acknowledged that, in his "opinion, meta-analysis studies are much stronger [than cohort and case-control studies] in that they include larger numbers of patients resulting in greater statistical power." (Clarke-Pearson 3d Amend. Rep. at 9.) He therefore emphasized meta-analyses and pooled studies, rather than case-control or cohort studies, to arrive at his conclusions. This directly tracks his opinions that I previously considered. *See In re J&J*, 509 F. Supp. at 165–66. If Defendants seek to probe that evaluation and the weight he affords certain types of studies over others, they may do so on cross-examination, but his analyses and methodologies survive the preponderance of the evidence standard.

douching as a confounder in Plaintiffs' expert reports is not entirely unexpected or unreasonable.

Moreover, Defendants criticize Dr. Moorman's treatment of two pre-2020 studies, Nicole L. Gonzalez, *Douching, Talc Use, and Risk of Ovarian Cancer*, 27 Epidemiol. 797 (2016) ("Gonzalez 2016") and Iwona M. Gabriel, *Douching, Talc Use, and Risk for Ovarian Cancer and Conditions Related to Genital Tract Inflammation*, 28 Cancer Epidemiol. Biomarkers Prev (11), 1835 (2019) ("Gabriel 2019").[30] (Defs.' General Causation Br. at 45–47.) In her most recent report, however, Dr. Moorman explained why she viewed Gonzalez 2016's finding of a relative risk below one as an outlier, noting that it is "only 1 of 3 studies out of the 27 studies included in the major meta-analyses" to report such a result and that its estimate was based solely on talc use during the 12 months before enrollment, which yielded a talc-use prevalence of just 14 percent. (ECF No. 33130-63 ("Moorman 2d Supp. Rep.") at 5.) She then evaluated more recent post-2020 literature in further assessing the weight Gonzalez 2016 should be afforded. (*Id.* at 5–7.) Drawing on

[30] In her 2023 report, Dr. Moorman characterized Gabriel 2019 as finding that "[i]n contrast to the talc findings, douching was not significantly associated with ovarian cancer (OR 0.98, 95% CI 0.83–1.17 overall; OR 1.03, 95% CI 0.77–1.38 among talc users; and OR 0.94, 95% CI 0.76–1.16 among those who never used talc).") (ECF No. 33130-62 ("Moorman Supp. Rep.") at 3.) And indeed, the study itself concluded that "[d]ouching is not an independent risk factor for ovarian cancer, but the combination of talc use and store-bought douches may modestly increase the risk." (*Id.* at 1.) I therefore do not find that Dr. Moorman's conclusions are "unauthorized by the data she cites." (Defs.' General Causation Br. at 46 (internal quotation marks omitted).) Dr. Moorman does not undertake further discussion of this study in her most recent report. (*See generally* ECF No. 33130-63, "Moorman 2d Supp. Rep.")

O'Brien 2024, Dr. Moorman observed that the reported associations for talc use were generally stronger than those for douching, which, in her view, supports specificity because one would expect recall errors to affect the two exposures similarly; if recall bias alone explained the observed associations, comparable associations with douching would be expected. (*Id.* at 9.) In light of these considerations, and given the current scientific record, it is methodologically reasonable for experts to place greater emphasis on factors and studies supported by more consistent or robust data.

More to the point, as Plaintiffs note, Defendants previously "made [these] exact claim[s]" before me in the prior *Daubert* motions, upon which I found that the expert reports were not lacking in their consideration of recall bias and confounding. (Pls.' General Causation Opp. Br. at 78 (citing *In re Johnson & Johnson*, 509 F. Supp. 3d at 166–68).) And the post-2020 "new science" only includes one case-control study (Davis 2021), which was in fact founded upon data from the WHI cohort study—minimizing concerns of recall bias because of the nature of the prospective study. (*See* Pls.' General Causation Opp. Br. at 32.) Finding the relevant circumstances substantially unchanged on this issue, I find no reason to depart from my prior assessment of the experts' reasonable accounting for potential confounding factors. I reiterate that to the extent Defendants observe that Plaintiffs' experts have not assessed the studies "for all potential confounders," those questions are ripe for

cross-examination at trial—particularly since Defendants only focused on douching as their point of contention in their papers. (*Id.* at 45.)

To conclude, Plaintiffs' experts generally gave this factor significant weight in their Bradford Hill analyses. I do not find the experts' conclusions regarding the strength of association to be *ipse dixit*, but are instead based upon reliable study results, having drawn adequately supported conclusions from the existing data, and satisfying the more likely than not standard. To be clear, my determination that Plaintiffs' experts may opine on why they perceive a strength of association between talc and ovarian cancer based on the available literature does not equate to a holding that the factor is satisfied for purposes of establishing causation. That is ultimately a question for the factfinder. *See* Fed. R. Evid.702 advisory committee's note to 2023 amendment ("The evidentiary requirement of reliability is lower than the merits standard of correctness."). Accordingly, "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." *In re Johnson & Johnson*, 509 F. Supp. 3d at 163. I find, however, that Plaintiffs' experts have met their burden by a preponderance of the evidence under Rule 702 to demonstrate that they applied reliable methodology and extrapolated conclusions adequately supported by the literature on strength of association, such that their opinions are admissible for inclusion at trial.

ii. Consistency

This factor measures the consistency of the observed association and examines whether the result has "been repeatedly observed by different persons, in different places, circumstances and times." Hill at 296. "Rarely, if ever, does a single study persuasively demonstrate a cause-effect relationship." Green at 602. Consistency in research findings "is an important factor in making a judgment about causation." *Id.* "Different studies that examine the same exposure-disease relationship generally should yield similar results." *Id.*

In my 2020 Opinion, I addressed Defendants' arguments concerning this factor and concluded that the experts' methodologies were sufficiently reliable under *Daubert*. *In re Johnson & Johnson*, 509 F. Supp. 3d at 168–172. At that time, Defendants advanced two primary contentions. First, they argued that the epidemiologic literature was not truly consistent because cohort and case-control studies reached different outcomes, emphasizing that since no cohort study had identified a statistically significant association between talc use and ovarian cancer, consistency is lacking. *Id.* at 169. Second, Defendants contended that Plaintiffs' experts did not adequately grapple with the cohort data, taking issue with the experts' views on the cohort studies' limited statistical power, the assertedly insufficient duration of follow-up relative to ovarian cancer's latency period, and the studies' inability to ascertain each participant's talc exposure with precision. *Id.* at 171–72.

To assess consistency in light of Defendants' arguments, I reviewed Dr. McTiernan's "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." *Id.* at 169. I reasoned the expert found that over half of those studies were statistically significant, while the others "had a sample size lower than that estimated to be needed to have power to detect a statistically significant result." *Id.* My opinion then detailed Dr. McTiernan's methodology in "consider[ing] statistical significance with respect to both cohort and case control studies," including evaluating the type of analysis performed, "whether *p*-value or confidence interval." *Id.* at 170–71. I cited to leading epidemiologists' corroboration of Dr. McTiernan's approach, concluding that "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." *Id.* at 171.

Defendants reprise similar arguments here. In the first portion of their argument, they claim that Plaintiffs' experts improperly downplay O'Brien 2020's findings because they do not support their positions, i.e., that the study had "the power to detect a statistically significant risk if it existed," but did not so conclude. (Defs.' 2024 General Causation Br. at 52.) Specifically, they fault the experts for stretching the O'Brien 2020 data to "attempt to show consistency" by relying on a

subgroup analysis that found a "very small, but statistically significant, association for women with a patent reproductive tract." (*Id.*) Defendants also attack Plaintiffs' experts' reliance on O'Brien 2024, which according to Defendants, only yielded data that supports Plaintiffs because the "authors imputed a number of 'corrections' and 'assumptions' into the Sister Study cohort data." (*Id.* at 53–54.) They then advance, as they did in 2020, their disagreement with Plaintiffs' critiques around latency and follow-up periods, emphasizing that Plaintiffs' "concerns about imprecise exposure data would apply to case-control studies as well." (*Id.* at 54–58.) Defendants rely on public health agencies, such as the NCI and FDA, purportedly recognizing that studies do not show a consistent association between perineal talc use and ovarian cancer. (*Id.* at 47 & n.120.)

Second, Defendants contend that Plaintiffs' experts "improperly disregard statistical significance" in order to "manufacture consistency." (*Id.* at 58, 64.) Defendants assert that courts have repeatedly rejected efforts by plaintiffs' experts to minimize the role of statistical significance. (*Id.* at 58–60 (citing *In re Zantac*, 644 F. Supp. 3d at 1222, 1237–38; *In re Lipitor*, 892 F.3d 624, 641–42 (4th Cir. 2018)).) In their view, Plaintiffs' consistency assessments rely primarily on point estimates that trend toward increased risk, which Defendants characterize as "effectively ignor[ing] statistical significance." (*Id.* at 60.) Defendants also disagree with my prior description of their position, stating that they "have never argued that statistical

significance is a litmus test for consistency," but they maintain that the concept cannot be disregarded altogether. (*Id.* at 61–62.) Finally, Defendants argue that Plaintiffs' experts apply statistical significance inconsistently, highlighting, for example, the experts' attention to statistically significant subgroup findings in O'Brien 2020, while giving less weight to the remainder of that study's results. (*Id.* at 62.)

Plaintiffs first respond that my 2020 Opinion found "there was adequate evidence of consistency in 2020, even though the three cohort studies available at the time did not clearly show an association that was statistically significant," and that the only thing that has changed is that now, "the scientific record is even stronger and better described," with "[n]othing in the new science rebut[ting the] existing findings." (Pls.' General Causation Opp. Br. at 79, 82.) To illustrate this point, they focus on Health Canada's 2021 assessment, O'Brien's follow-up commentary to her 2020 study, and O'Brien 2024—all finding consistency among the existing epidemiological studies across decades.[31] (*Id.* at 80–81.)

[31] Both parties rely on statements and findings by public health agencies—including the FDA, Health Canada, and WHO—in support of their respective positions regarding the carcinogenicity of Defendants' talcum powder products. Although I addressed this issue briefly in my prior Opinion, I pause here to clarify how such materials are considered in resolving the parties' pending motions. I am mindful of the role played by public health agencies in evaluating potential health risks. Their mandate is to protect the public at large, often through precautionary risk assessment intended to inform regulatory policy or public guidance. In carrying out that mandate, agencies may reasonably err on the side of caution and may employ standards that differ in material respects from those governing expert admissibility under Rule 702 and *Daubert*. Accordingly, I do not treat agency findings as dispositive of the causation issues presented, nor do I assign greater or lesser

In response to Defendants' second argument, Plaintiffs assert that "the modern trend is to take statistical significance into account without rigidly excluding all studies that are not statistically significant," citing scientific literature and case law that supports their position. (*Id.* at 84–87.) Because "[n]othing in the science of statistics has changed since 2020 to upend [my] findings," they reason that there is "all the more reason to reject J&J's rehashed argument" based on the updated literature. (*Id.* at 88.) If anything, Plaintiffs claim, now "the shoe is on the other foot," because *Defendants* are the ones who appear to "ignore the statistically significant results of O'Brien 2020 and O'Brien 2024." (*Id.* at 89–90.)

As a preliminary matter, I must address the correct standard for considering statistical significance within the context of the Bradford Hill factors. The *Reference Guide* explains that "significance testing only bears on whether the observed magnitude [of an association between an agent and an outcome] arose as a result of random chance, not on whether the null hypothesis [i.e., that there is no association] is true." Green at 577 n.81.[32] In other words, a finding that a study's results are

weight to the views of one agency over another or attempt to resolve differences among them. This does not mean, however, that such materials are to be disregarded. Rather, they form part of the broader scientific landscape and often reflect a reasoned and methodologically sound engagement with the existing body of scientific evidence on which the parties' experts also rely. In that context, I note only that no public health agency has affirmatively concluded that there is no causal connection between talc use and ovarian cancer.

[32] In mathematical terms, "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. Thus, an outcome is statistically significant when the observed *p*-value for the study falls below the preselected significance level." Green at 576–77. "The most common

statistically significant indicates a degree of confidence that a real effect or relationship exists within the population being studied. However, "[t]here is some controversy among epidemiologists and biostatisticians about the appropriate role of significance testing," because "[e]pidemiologists have become increasingly sophisticated in addressing the issue of random error . . . *without the necessity of rejecting all studies that are not statistically significant*." *Id.* at 579 (emphasis added). Specifically, meta-analyses can "ameliorate concerns about random error." *Id.*

In line with those scientific principles, as I explained in my prior Opinion, the Third Circuit has "declined to adopt a bright-line rule" regarding statistical significance. *In re Johnson & Johnson*, 509 F. Supp. 3d at 170 (citing *In re Zoloft*, 858 F.3d at 793; *see also In re Lipitor*, 892 F.3d at 642 (same). Instead, *Zoloft* explained that "[a] causal connection may exist despite the lack of significant findings, due to issues such as random misclassification or insufficient power," and at the same time, "[i]f 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." 858 F.3d at 793; *see also* Green at 24 ("What role should statistical significance play in assessing the value of a study? Epidemiological studies that are

significance level, or alpha, used in science is .05," which means that "the probability is 5% of observing an association at least as large as that found in the study when in truth there is no association." *Id.* at 577; s*ee also, e.g.*, *In re Lipitor*, 892 F.3d at 634 (same).

not conclusive but show some increased risk do not prove a lack of causation."). Of course, statistical significance can overlap with the strength of association factor because it implicates level of risk and strength of causation; however, the parties here have addressed this issue under the consistency factor because it also necessarily involves whether the data studying the relationship between talc and ovarian cancer is sufficiently consistent across the board.

Accordingly, I emphasize that this factor evaluates "*consistency*" across differing studies *not* "statistical significance," which means that statistical significance is not the only data that I must consider related to this factor. In that connection, despite Defendants claiming that they "have never argued that statistical significance is a litmus test for consistency," they nonetheless base their entire argument in support of this factor on that exact measure. (Defs.' 2024 General Causation Br. at 63; *see id.* at 49–58 (focusing on Plaintiffs' experts' attacks on the cohort studies pertaining to statistical significance); *id.* at 58 (subsection entitled, "Plaintiffs' Experts Improperly Disregard Statistical Significance In Reaching Their Conclusions On Consistency").) Even so, to the extent that statistical significance is an aspect of consistency, as I noted in 2020 and I find no basis to depart from here, "the causation experts considered statistical significance with respect to both cohort and case control studies, and did so in a reliable fashion." *In re Johnson & Johnson*, 509 F. Supp. 3d at 170.

I will first review the relevant post-2020 studies. To begin, O'Brien 2020 evaluated whether genital powder use is associated with ovarian cancer by pooling data from four large cohort studies covering over 250,000 women, but only 2,168 ovarian cancers developed in that population. (O'Brien 2020 at 49.) The authors conducted approximately 11 years of follow-up reporting. (*Id.*) The study did not find a statistically significant association on this measure but acknowledged that it "may have been underpowered to identify a small increase in risk." (*Id.*) The results showed a "possible positive association among women with patent reproductive tracts," but "the association was not significantly different from that observed in women with nonpatent reproductive tracts," and the authors therefore clarified that "this finding should be considered only exploratory and hypothesis generating." (*Id.* at 56.) However, in a follow-up Letter to the Editor, Dr. O'Brien agreed with critiquing colleagues "that our results, particularly the analyses limited to women with intact reproductive tracts, should not be discounted because of lack of statistical significance," and that as applied broadly to the study, they "never equated the lack of statistical significance to evidence of no association." (ECF No. 33130-38, O'Brien et al., Letters to the Editor 323 JAMA 2095, 2096–97 (May 26, 2020).)

In a study published by the same lead author four years later, O'Brien 2024 used updated exposure data and quantitative bias analysis to reanalyze the association between "intimate care products," including genital talc, and ovarian

cancer. (O'Brien 2024 at 1.) As has already been discussed at length, O'Brien 2024 "used quantitative bias analyses to implement different approaches for imputing exposure" where follow-up data was lacking, by running and summarizing effect estimates across 100 imputed data sets. (*Id.* at 4.) The authors "found evidence supporting a positive association between ever genital talc use and incident ovarian cancer," collecting ORs across pooled and meta-analyses of case-control studies and HRs from a pooled analysis of prospective cohort studies, as well as analyses of the targeted age range (20–39 years)—"which is consistent with previous studies that considered ages of use." (*Id.* at 13.)

Indeed, since my 2020 Opinion, the experts now have a more robust record of scientific evidence upon which to make their assessments, given the post-2020 cohort studies. Tellingly, Defendants' prior attack on the consistency factor rested in large part on, in their view, the absence of a statistically significant cohort study; yet throughout their current moving brief, they do not seriously engage with O'Brien 2024, which updated findings for a cohort of nearly 50,000 women and found "a positive association between use of intimate care products, including genital talc, and ovarian cancer." (*Id.* at 1.) The sum total of their discussion of O'Brien 2024 is focused on condemning its usage of imputed data. (Defs.' 2024 General Causation Br. at 53–54.) I have already explained, *supra*, why that argument is unavailing to

entirely discount or reject the findings of O'Brien 2024 at this evidentiary stage. (*See supra* Part V.C.2.iv.)

Plaintiffs' experts, on the other hand, relied on post-2020 cohort study literature to "confirm[] that the associations between perineal talcum powder product use and ovarian cancer risk are present" for diverse groups, including across races and endometriosis histories.[33] (McTiernan 3d Amend. Rep. at 82–83; *see also* Smith-Bindman 3d Amend. Rep. at 21–23 (explaining that O'Brien 2024 reported a "significant increase in ovarian cancer risk for genital powder use, with effect estimates that are in range with previous studies" and consistent with studies like Woolen 2022 and the Nurses Health Study); Cote Amend. Rep. at 25 (noting the

[33] I acknowledge that the parties also rely on differing statements from public health agencies in support of their positions on this factor. Defendants note that the NCI and FDA have "recognized" inconsistency in the epidemiologic literature. (Defs.' General Causation Br. at 47.) A closer review of the cited materials, however, shows that the NCI source is a PDQ webpage "written and maintained by the PDQ Screening and Prevention Editorial Board, which is editorially independent of NCI," and therefore does not constitute an official NCI or NIH policy statement. Ovarian, Fallopian Tube, and Primary Peritoneal Cancer Prevention (PDQ)–Health Professional Version, National Cancer Institute ("NCI 2024 PDQ"), https://www.cancer.gov/types/ovarian/hp/ovarian-prevention-pdq (last updated Apr. 9, 2025). Defendants' reliance on the FDA is grounded in a 2014 letter evaluating the body of evidence available at that time. (*See* ECF No. 33008-4, "FDA 2014 Denial Letter.") I do not view either source as providing a basis to revisit my prior conclusions on this factor—particularly given that the FDA letter was addressed in my 2020 Opinion and is now even more dated. *In re Johnson & Johnson*, 509 F. Supp. 3d at 185–86. Plaintiffs, by contrast, cite Health Canada's 2021 screening assessment, which found "a high degree of consistency in the epidemiological studies across several decades conducted in different parts of the world." (Pls.' General Causation Opp. Br. at 80 (quoting Health Canada, *Screening Assessment: Talc*, 1, 33 (Apr. 2021).) Although Health Canada's conclusions are similarly non-binding, that assessment considered more recent literature and evaluated the Bradford Hill criteria in detail under international scientific standards. None of the various agency statements, standing alone, is determinative of whether the challenged experts' consistency analyses satisfy Rule 702. I address them here only to clarify the nature and limitations of the sources upon which the parties rely.

"consistency of the positive association between genital talc use and ovarian cancer," as well as the "strikingly similar estimates of association" derived from "decades of studies in various populations and different investigators across the globe"); ECF No. 33130-58 ("Singh 2d Supp. Rep.") at 5 (observing that O'Brien 2024's confidence intervals findings overlap with "the entire body of evidence . . . from case-control studies, cohort studies, pooled analysis of cohorts and meta-analysis.").)

The experts acknowledged the aspects of O'Brien 2020 that Defendants emphasize—such as the absence of an overall statistically significant association—but they also explained why, notwithstanding those findings, they continued to view the consistency factor as satisfied. In doing so, they noted that the study's authors themselves observed that the analysis "may have been underpowered," and they articulated how that limitation informed their interpretation of the results. (O'Brien 2020 at 49; s*ee, e.g.*, McTiernan 3d Amend. Rep. at 19, 50, 75; Smith-Bindman 3d Amend. Rep. at 30–31; Harlow Rep. at 13; Cote Amend. Rep. at 18–19; Singh Supp. Rep. at 6–7, 10–12, 20; Moorman 2d Supp. Rep. at 17–18; Clarke-Pearson 3d Amend. Rep. at 9; Wolf 3d Amend. Rep. at 11.) Having reviewed each of these reports, I cannot find that the experts unreasonably extrapolated or misinterpreted O'Brien 2020 such that their opinions can be excluded on that basis. Moreover, the findings and concordant analyses that Plaintiffs' experts made based on the follow-

up study, O'Brien 2024, provide more recent, updated data upon which the experts' opinions on this factor were also based. I therefore find a sound methodological basis upon which Plaintiffs' experts may testify as to their interpretations of consistency across the existing data, acknowledging that Defendants will have the opportunity to question them as to how they interpret the literature to support their conclusions.

In response to Defendants' second point, I do not find that Plaintiffs' experts "ignore" statistical significance in the literature writ large. (Defs.' 2024 General Causation Br. at 62.) The experts instead explained *how* they accounted for statistical significance and *why* they afforded it certain weight. Indeed, as discussed above, the case law and scientific treatises make clear that statistical significance is far from the be-all end-all of consistency calculations. For example, Defendants fault Dr. Moorman for "selectively rely[ing] on statistical significance" when it supports her opinion, by citing to her analysis of O'Brien 2020's subset of talc users with patent reproductive tracts. (*Id.* at 63.) But, upon a further examination, Dr. Moorman explained in detail not only why she focused her analysis on that cohort but also surveyed other experts in the field who support that position—most notably, the O'Brien 2020 authors' own response that "***agree[d] that the analyses limited to women with intact reproductive tracts should not be discounted***." (O'Brien et al., Letters to the Editor 323 JAMA at 2096–97.) (emphasis added).) It is a well-reasoned methodology that does not amount to "cherry-picking," (Defs.' 2024

General Causation Br. at 63 (quoting *In re Acetaminophen I*, 707 F. Supp. 3d 309, 364 (S.D.N.Y. 2023))), but instead reflects how an expert examined and explained the available data. Whether Dr. Moorman's opinion should ultimately prevail is not my determination here, so long as her conclusions proceed from a reliable application of the methodology. I find that they do. Defendants are free to challenge the doctor's conclusions before a jury.

Highlighting additional examples, Dr. Siemiatycki reiterated that "the absence of statistical significance is not tantamount to proof of the absence of an association." (Siemiatycki 3d Amend. Rep. at 10 (citations omitted); *see also Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 40–41 (2011) ("A lack of statistically significant data does not mean that medical experts have no reliable basis for inferring a causal link between a drug and adverse events. . . . [M]edical professionals and researchers do not limit the data they consider to the results of randomized clinical trials or to statistically significant evidence.").) He further described how a study's sample size relates to its statistical power, depending on the type of study and its characteristics—including observing that Sir Bradford Hill himself did not "explicitly list[]" statistical significance as a factor due, in part, to the complications with measuring that figure depending on RR and sample size. (Siemiatycki 3d Amend. Rep. at 16–17, 20–21.) The doctor instead opined that "the single number which reflects quite well the statistical strength of a study, be it case-control or

cohort, is the number of exposed cases," which he distilled by analyzing 34 studies' exposed cases and RRs. (*See id.* at 84–86 (Table 2).) Based on that calculation, 31 results showed an RR of over 1.0, which "is clearly strong and in defiance of the null hypothesis," that there is no true association, which would result in "as many of the RR estimates to be below 1.0 as to be above 1.0." (*Id.* at 37.)

Dr. Smith-Bindman concurred that "it is more important to estimate the effect size and the uncertainty surrounding the estimate (with a point estimate and confidence interval) rather than using a significance level and *p*-value to determine if there is/or is not a meaningful association," because, for example, "[t]here is no inherent or meaningful difference between a study with a *p*-value of 0.04 compared with 0.06, and yet these are often wrongly considered reflective of significant and non-significant results respectively." (Smith-Bindman 3d Amend. Rep. at 16.)[34] She acknowledged that of the dozens she reviewed, "the sample size of some studies was small and resulted in high statistical uncertainty," which made "quantifying a precise association between exposure and cancer . . . difficult." (*Id.* at 18.) Specifically, she acknowledged that the WHI study did "not demonstrate a statistically significant association," but that the study admitted limitations based on its "short period of follow up and limited exposure information," which "would tend to bias the results

[34] This accords with the quoted testimony from Dr. McTiernan in my 2020 Opinion on the same issue. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 170–71.

toward the null." (*Id.* at 22–23.) I reiterate that I considered and dispensed with Defendants' challenges to those positions in my 2020 Opinion, concluding that this is "a dispute over whether the experts are correct in discounting the causative results of the cohort studies," which "relate[s] to the weight of their testimony, not their reliability." *In re Johnson & Johnson*, 509 F. Supp. 3d at 172. Because I find, by a preponderance of the evidence, that the experts' methodologies on the consistency factor are reliable, and that their opinions reliably proceed therefrom, I recommend that the Court not depart from that holding at this juncture.

Before leaving this factor, I must note that Defendants' invocation of other courts' treatment of certain experts, is not only taken out of context, but also does not have any bearing on those experts' proffered opinions here regarding the relationship between talcum powder and ovarian cancer. For example, Defendants cite *In re Lipitor*, 892 F.3d at 641–42, where the Fourth Circuit affirmed excluding Dr. Singh's general causation opinion regarding Lipitor, stemming from his reliance on non-statistically significant trends in the field. (Defs.' 2024 General Causation Br. at 59–60.) But that example differs here, where Dr. Singh *has* explained the methodology he used to support his opinions in relation to statistically significant findings, and why he accounted for certain findings and studies over others. (*See generally* Singh 2d Supp. Rep.) Similarly lacking, Defendants quote *In re Zantac* to posit that the Southern District of Florida "excluded Drs. McTiernan and Moorman

for 'routinely . . . disregard[ing] the concept of statistical significance.'" (Defs.' 2024 General Causation Br. at 59 (quoting 644 F. Supp. 3d at 1222; *id.* at 1237–38).) But Defendants omit that court's distinction drawn between Dr. McTiernan's approach *in this very litigation* and *Zantac*:

> Before this MDL, Dr. McTiernan characterized statistically insignificant data (under the conventional definition) as statistically insignificant. In *In re Johnson & Johnson Talcum Powder Products Marketing, Sales Practices & Products Litigation* (*In re Talc*), another MDL, Dr. McTiernan authored a 77-page expert report. 509 F. Supp. 3d at 130. In that report, Dr. McTiernan characterizes studies as either statistically significant or statistically insignificant. McTiernan Dep. Ex. 26 at 41 ("Among the 8 studies which were not statistically significant . . . "). Dr. McTiernan's opinion in that litigation was expressly based upon risk rates that were statistically significant; she did not ground her opinion on statistically insignificant data. *Id.* at 9 ("I base this opinion on the statistically significant elevated risk estimates . . . ").

644 F. Supp. 3d at 1231–32 (citation modified). The court went on to find that Dr. McTiernan's methodology had evidently changed in relation to her testimony in *Zantac*, where she, according to that court, "at some point [changed] her understanding of the concept of statistical insignificance." *Id.* at 1232. But whether that was in fact the situation in *Zantac* is (1) of no moment here, where other courts have noted the difference between her methodology here and in that unrelated case; and (2) does not take into account my fulsome discussion of the proper role of

statistical significance, as well as Dr. McTiernan's exploration of that concept. (*See supra* Part V.B.4.)

As to Dr. Moorman, the *Zantac* court in fact excluded her opinion despite explaining that it "does not question the reliability of Dr. Moorman's expert opinion because she fails to adequately explain her methodology," instead observing that in contrast to Dr. McTiernan, "Dr. Moorman clearly explains what studies most influence her opinion, and she explains why those studies influence her," as well as noting that she "relied upon statistically insignificant data with less frequency than Dr. McTiernan." *Id.* at 1243 & n.138. Rather, the court excluded Dr. Moorman because, in that court's view, "although the primary focus of a *Daubert* inquiry is an expert's *methodology*, this Court is permitted to consider the fact that the Plaintiffs' experts' general causation *conclusions* . . . are unique and isolated to this litigation," despite noting that the factor "weighs moderately in favor of exclusion." *Id.* at 1254. I reiterate that these cases are not analogous to these very experts' methodologies and approaches here—as the *Zantac* court itself distinguished them.

Again, nowhere do Defendants respond to these experts' methodologies finding O'Brien 2024 to be statistically significant, except to reiterate their challenges to its imputed data.

In sum, Plaintiffs' experts concluded that the Bradford Hill consistency criterion is met because more than four decades of epidemiologic research reliably

show an elevated risk of ovarian cancer associated with perineal talc use across different study designs, populations, geographic regions, and time periods. (*See* McTiernan 3d Amend. Rep. at 45–48; Siemiatycki 3d Amend. Rep. at 72–73; Smith-Bindman 3d Amend. Rep. at 28, 36; Harlow Rep. at 12–13, 20; Cote Amend. Rep. at 36; Singh Supp. Rep. at 17–18; Moorman Rep. at 15–29; Clarke-Pearson 3d Amend. Rep. at 13; Wolf 3d Amend. Rep. at 7–9, 11–12.) Dr. Siemiatycki, for example, explained that dozens of studies across decades "have produced an RR greater than the null value of 1.0. If there [] were no association between talcum powder use and ovarian cancer, we would expect to see as many RRs lower than 1.0 as higher than 1.0," analogizing the pattern to "flipping a coin 30 times and getting a heads 28 or 29 times." (Siemiatycki 3d Amend. Rep. at 72; *see also* Cote Amend. Rep. at 36 ("In my opinion, having reviewed hundreds of epidemiologic studies and publishing my own pooled and meta-analyses, the consistency of the effect sizes seen across populations is strikingly consistent.").)

The replication of the association between perineal talcum powder and ovarian cancer across diverse settings, tumor subtypes, and decades of research reflects the type of uniform, reproducible pattern that Bradford Hill identified as evidence of a consistent relationship. As Plaintiffs' experts explained, these studies repeatedly produce positive associations, including statistically significant increased risks in the majority of case-control studies and confirmed elevations in recent large

pooled and meta-analytic analyses, even across variations in methodology, exposure assessment, and demographic composition.

Indeed, as emphasized throughout this Report and Recommendation, my role as a Rule 702 gatekeeper is to assess whether the experts have adequately considered the existing literature and applied a reliable methodology in interpreting it to support their opinions which must be based upon good grounds—*not* to determine whether I ultimately agree with their purported conclusions. *See Cohen*, 125 F.4th at 461–62 (holding that *Daubert*'s standard "does not hinge on whether a particular scientific opinion has the best foundation, or even whether the opinion is supported by the best methodology or unassailable research," but instead "looks to whether the expert's testimony is supported by good grounds," including methodology, facts, and the links between the facts and conclusion) (internal citations and quotation marks omitted). With respect to the consistency factor, for the reasons stated above, I find that Plaintiffs' experts have done so. As in the prior round of motion practice, the parties continue to debate the relative weight to assign particular studies or findings; however, the briefs and expert reports reflect that Plaintiffs' experts have, by a preponderance of the evidence, reliably applied their methodologies to review and interpret published, peer-reviewed research. In this respect, the parties' disagreement over the strengths and limitations of the post-2020 studies relates more to an evidentiary dispute appropriate for the factfinder than to a methodological flaw or

unsound conclusion requiring exclusion under Rule 702. I therefore find no basis to exclude Plaintiffs' experts' opinions on this factor, and conclude that the remaining disputes are matters of weight for the jury, not admissibility.

iii. Biological Gradient (or Dose-Response Relationship)

Dose "refers to the intensity or magnitude of exposure to an agent multiplied by the duration of exposure." Green at 622. A dose-response relationship exists when "a change in amount, intensity, or duration of exposure to an agent is associated with a change—either an increase or a decrease—in risk of disease." *Id.* "Generally, higher exposures should increase the incidence (or severity) of disease." *Id.* at 603. However, this pattern is not universal. Some causal agents "do not exhibit a dose-response relationship when, for example, there is a threshold phenomenon (i.e., an exposure may not cause disease until the exposure exceeds a certain dose)." *Id.* Accordingly, "a dose-response relationship is strong, but not essential, evidence that the relationship between an agent and disease is causal." *Id.*

In my 2020 Opinion, I summarized the parties' dispute as centered on two core issues: (1) the weight that the dose-response factor should be afforded in a Bradford Hill analysis, including what type of data can establish a sufficiently strong dose-response; and (2) whether Plaintiffs' experts' opinions on the existence of a dose-response relationship are "adequately supported by the studies on which they rely." *In re Johnson & Johnson*, 509 F. Supp. 3d at 179. I noted that, in accordance

with the above-mentioned epidemiological principles, "a strong dose-response is not necessarily required for an expert to find a causal nexus." *Id.* at 179 (citing *Ferguson v. Riverside Sch. Dist. No. 416*, No. 00-cv-0097, 2002 WL 34355958, at *6 (E.D. Wash. Feb. 5, 2002)).

My discussion of the parties' dispute then centered largely on their "competing interpretations" of the Terry 2013 pooled analysis study. *Id.* at 177 n.42, 180. Dr. McTiernan described the Terry 2013 methodology that divided study participants into categories depending on their usage level of talcum powder products, and found an increased relative risk based on level of use. *Id.* at 177–78. In response, Defendants claimed that Terry 2013 actually "concluded that there was no trend in risk with increasing talc use" because including non-users as a category of subjects skewed the data to find a cumulative dose-response. *Id.* at 180. Evaluating the parties' arguments then, I found reasonable Dr. McTiernan's opinion that it is "appropriate to include non-users when you are looking at a dose-response effect," in the same way that a randomized trial would compare findings among users of an agent to a placebo group. *Id.* I independently reviewed Terry 2013 and explained that the study "did not wholly rule out a dose-response relationship, but instead found the data to be inconsistent," and therefore I concluded that despite the parties' "different interpretations of the Terry study," this dispute boiled down to a question of weight, rather than admissibility because "it is not the Court's position

as a gatekeeper to determine whose interpretation of the studies is correct," so long as there are good grounds to support the opinions. *Id.* at 180.

In their current motion, Defendants repeat many of the same arguments I previously considered. They contend that the dose-response relationship factor weighs against causation and that Plaintiffs improperly minimize it despite its central importance in toxicology. (Defs.' 2024 General Causation Br. at 65–67.) Instead, they claim, the epidemiologic record does not evince a true dose-response relationship between perineal talc exposure and ovarian cancer, but that "plaintiffs' experts half-heartedly attempt to manufacture" one "by twisting the epidemiologic data." (*Id.* at 67.) Defendants explore the same pre-2020 studies they raised in the prior round of motion practice to reiterate that none of the studies conclusively determined that a dose-response relationship exists. (*Id.* at 67–69.) Lastly, they repeat their prior objection to Plaintiffs' experts' opinions regarding threshold exposure. (*Id.* at 69–70.) In Defendants' view, the absence of a dose-response trend—together with methodological problems in the studies used by the experts—means this Bradford Hill factor weighs against causation, and the experts' efforts to discount it are methodologically unreliable.

In response, Plaintiffs emphasize that Defendants' arguments are "largely recycled attacks" from the prior round of motion practice, and that in fact, the evidence for a biological gradient has strengthened, particularly with post-2020

cohort studies. (Pls.' General Causation Opp. Br. at 90.) In their view, improved prospective data (O'Brien 2024), the patent-tract subgroup in pooled cohorts (O'Brien 2020), and meta-analytic results focused on heavier users, (Woolen 2022), collectively demonstrate that ovarian cancer risk increases with greater talc exposure, particularly with frequent and long-term use. (*Id.* at 91–92.)

As Plaintiffs correctly observe, Defendants' briefing does not engage with any of the post-2020 epidemiologic literature that was unavailable at the time of my 2020 Opinion, with the exception of O'Brien 2020. Instead, Defendants rely primarily on earlier studies, a 2014 FDA letter, and a PDQ Screening and Prevention Editorial Board webpage that expressly "does not provide formal guidelines or recommendations for making health care decisions." (Pls.' General Causation Opp. Br. at 90; *see* NCI, *Ovarian, Fallopian Tube, and Primary Peritoneal Cancers Prevention (PDQ) – Health Professional Version*, available at https://www.cancer.gov/types/ovarian/hp/ovarianprevention-pdq ("NCI PDQ")). Even so, Defendants—and the sources they cite—characterize the evidence as "sorely lacking," which is not equivalent to affirmative evidence demonstrating the absence—let alone "inverse"—of a dose-response relationship, and reflects an assessment based solely on pre-2020 science. (Defs.' 2024 General Causation Br. at 64, 69; *see also* NCI PDQ ("the data are inadequate" to establish a clear dose-response relationship).) Defendants further argue that "imprecision" in exposure

measurements is a "fundamental weakness" that weighs against any causal inference, citing cases in which none of the underlying studies recorded actual dosages. (Defs.' 2024 General Causation Br. at 66–67 (quoting *In re Acetaminophen I*, 707 F. Supp. 3d at 350).) But it is a considerable leap to suggest that a record entirely devoid of dosage information is analogous to the presence of some degree of imprecision in exposure assessment—an issue that arises with some frequency in observational epidemiology and does not, standing alone, bar reliance on the literature. Because I find the analogy inapposite to the evidence and methodologies at issue here, I do not find Defendants' argument on this point persuasive.[35]

Defendants claim that my prior Opinion "misread" certain case law, including *Ferguson*, because general causation was not at issue in that matter. (*Id.* at 66.) *Ferguson* grappled with the dose-response factor in assessing whether the expert's causative opinion between the presence of mold in school and injuries suffered by students was sound under Rule 702. 2002 WL 34355958, at *1. The court explained that dose-response is not essential if there is no threshold level for injury from exposure to a harmful agent; rather, the court stated that "'it makes little sense to require a plaintiff to establish a dose/response relationship or threshold level in a

[35] Measuring talc exposure is not analogous to, for example, measuring the amount of cigarettes a person smokes or the dose of medicine a person consumes. Measuring the amount of talcum powder a person applies each time varies, and therefore does not lend itself to accurate measurement. This "impression" in and of itself does not render plaintiffs' experts' opinions unreliable, and is a matter for cross-examination.

situation . . . where the dose/response relationship or threshold level will always vary from individual to individual.'" *Id.* at *6 (quoting *Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 263–64 (6th Cir. 2001)). The court went on to say, "'[w]hile 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 therefore it does not need to "'invariably provide the basis for an expert's opinion on causation.'" *Id.* (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 264 (4th Cir. 1999)). Indeed, in *Westberry*, the Fourth Circuit admitted expert testimony that exposure to talc caused sinus problems despite the inability to determine threshold level of exposure necessary to cause the plaintiff's injuries. 178 F.3d at 264. Consistent with that line of cases, I explained that "a strong dose-response is not necessarily required for an expert to find a causal nexus." *In re Johnson & Johnson*, 509 F. Supp. 3d at 179. In any event, this case is not devoid of *any* evidence of dose-response which is further explained, *infra*.

Defendants next argue that my prior determination—that "Terry did not wholly rule out a dose-responsive relationship"—was insufficient to support my conclusion that Plaintiffs met their burden under Rule 702 on this factor. (Defs.' 2024 General Causation Br. at 67–68.) They rely on *In re Onglyza*, for the principle

that epidemiologic literature should not be interpreted as demonstrating a causal relationship absent compelling evidence. 93 F.4th at 346. That decision, however, is materially distinguishable from the circumstances presented here. In *Onglyza*, the Sixth Circuit upheld the exclusion of an expert who "failed to engage with" multiple large-scale studies involving approximately 175,000 users and dismissed them as limited due to confounding without identifying any specific confounders or explaining the methodological basis for discounting them. *Id.* at 345. Moreover, the expert—not the court—asserted that studies "should be interpreted as cause-and-effect" unless compelling evidence suggests otherwise. *Id.*

Nothing in *Onglyza* undermines the reasoning of my 2020 Opinion or the positions advanced by Plaintiffs' experts in this MDL. In 2020, I first cited authoritative scientific sources to explain that a dose-response relationship "is strong, but not essential, evidence" of causation, *In re Johnson & Johnson*, 509 F. Supp. 3d at 180 (quoting Green at 603), and then observed that Terry found "the data inconsistent"—not that a dose-response relationship existed by default in the absence of contrary findings, *id.* at 180. Nor does *Onglyza* suggest otherwise. There, the Sixth Circuit emphasized that the district court excluded the expert because he failed to explain how he inferred causation from a study that itself did not reach a causal conclusion. 93 F.4th at 346. Here, by contrast, and as discussed below, Plaintiffs' experts articulate the methodological basis for their interpretations of the

literature and explained how they reached their views on dose-response using the available evidence.

Although the parties agree that the "new science" issued since 2020 provides the impetus for the renewed motions, Defendants' arguments on this factor primarily challenge Plaintiffs' experts' interpretations of pre-2020 literature that was already addressed in my 2020 *Daubert* ruling. (Defs.' 2024 General Causation Br. at 67–69; *In re Johnson & Johnson*, 509 F. Supp. 3d at 177–80.) Notably, Defendants do not meaningfully engage with the post-2020 scientific developments on which Plaintiffs' experts now rely. In this respect, Defendants have not identified how the "new science is shown to *directly contradict or challenge*" my earlier findings. (Apr. 30, 2024 Memorandum Order (emphasis added).) Accordingly, I proceed to evaluate Plaintiffs' experts' current opinions in light of the full evidentiary record, including the post-2020 landscape, to address the Rule 702 standard.

As I previously discussed, O'Brien 2020 conducted a pooled prospective cohort analysis based on four large cohort studies comprising over 250,000 women. (*See supra* Part V.B.5.ii; O'Brien 2020 at 49.) The study found "no clear dose-response trends for duration and frequency of powder use in the genital area in relation to ovarian cancer risk," despite noting that "the study was underpowered to detect small changes in risk." (O'Brien 2020 at 56.) O'Brien 2020 did detect "a possible positive association among women with patent reproductive tracts," a

finding the authors considered to be "exploratory and hypothesis generating" because "the association was not significantly different" from that among women with nonpatent reproductive tracts. (*Id.*) The authors also "avoided" recall bias "by excluding those with preexisting ovarian cancer." (*Id.* at 57.) Additionally, the study noted that "information on powder exposure is typically more limited in cohort studies compared with case-control studies, particularly with respect to dose and duration of use," and suggested that "ongoing or future" studies collect such information. (*Id.*)

Two years later, Woolen 2022 issued a meta-analysis to examine in depth the association between frequent perineal talc use and ovarian cancer using pooled data from eleven studies. (Woolen 2022 at 2528.) The study found a "pooled adjusted odds ratio of 1.47% (95% CI 1.31, 1.65)," for frequent use of perineal talcum powder. (*Id.* at 2530.) Although the meta-analysis could not model a single continuous gradient across all studies due to differing exposure metrics, it highlighted that studies using higher-frequency or higher-cumulative-use categories (for example, daily use, > 30 times per month, or > 10,000 lifetime applications) consistently showed elevated risks. (*Id.* at 2529.) The paper specifically noted prospective cohort evidence demonstrating increased risk correlated to increasing frequency, including a higher hazard in daily users, which the authors characterized as supportive of a dose-response pattern. (*Id.* at 2531.) The authors acknowledged

that by restricting inclusion to studies explicitly reporting frequent use, they necessarily excluded some studies whose questionnaires did not capture higher-use categories, as well as the fact that exposure definitions varied across studies. (*Id.* at 2531–32.)

The last major study that bears upon dose-response is O'Brien 2024. Those researchers used updated exposure data and quantitative bias analysis to reanalyze the association between "intimate care products," including genital talc, and ovarian cancer. (O'Brien 2024 at 1.) As has already been discussed at length, they "used quantitative bias analyses to implement different approaches for imputing exposure" wherein follow-up data was lacking, by running and summarizing effect estimates across 100 imputed data sets. (*Id.* at 4.) The authors "found evidence supporting a positive association between ever genital talc use and incident ovarian cancer," including specifically finding an approximately 40% higher rate of ovarian cancer compared to never-users "with consistently increasing dose-response patterns for both frequency and duration of use." (*Id.* at 13.) Despite acknowledging limitations such as "unmeasured confounding" and the potentially non-generalizable demographics of the study participants, O'Brien 2024 announced that "higher rates [were] seen for frequent and long-term users." (*Id.* at 2.)

In broad strokes, Plaintiffs explain that Woolen 2022 specifically studied the frequency of use of perineal talcum powder products in relation to ovarian cancer,

and that O'Brien 2024 analyzed dose-response focusing on frequent and long-term users, calculating increased risks of 82% and 100%, respectively. (*See* Pls.' General Causation Opp. Br. at 91–92.) Indeed, NIH's issuance of a press release in June 2024 announcing O'Brien 2024's findings is a strong indicator of the advent of "new science" in this regard—science that Plaintiffs advocate supports *their* position, because the study's "key findings" include a "[p]ersistent positive association between genital talc use and ovarian cancer, *with the strongest associations observed for frequent and long-term users* and for use during the reproductive years." (ECF No. 33130-8, National Institute of Environmental Health Sciences, *Genital Talc Use May Be Linked to Increased Risk of Ovarian Cancer*, NIEHS (June 2024) ("NIEHS Press Release") (emphasis added).) Defendants' only response to this appears to be that O'Brien 2024 cannot be trusted because of the imputed data discussed above. I have already explained why I do not find that argument convincing. (*See supra* Part V.B.5.iii.)

Based on the studies themselves and the experts' interpretations of them, I do not find that any of the post-2020 literature "directly contradicts or challenges" the evidentiary record before me in 2020. (Apr. 30, 2024 Memorandum Order.) Rather, the newer studies provide additional grounds upon which Plaintiffs' experts may reliably extrapolate that the dose-response factor is satisfied. For example, Dr. Singh explained that O'Brien 2024's pooled data demonstrated "a consistent and

statistically significant increased risk of ovarian cancer for both frequent genital talc users (HR 1.99, 95% CI 1.43–2.78) and long-term genital talc users (HR 2.2, 95% CI 1.52–3.19) compared to never users," and that "sometime use of genital talc (HR 1.56, 95% CI 1.09–2.22) and use for one decade only (HR 1.48, 95% CI 1.06–2.06) was also associated with a statistically significant increased risk." (Singh 2d Supp. Rep. at 1; O'Brien 2024 at 10 (Table 3).) He further calculated that the data showed "[l]ong-term users of genital talc had a more than doubling in the risk of ovarian cancer," and concluded that the "strong monotonic dose-response effect, accompanied by statistically significant positive tests for trend, and the large magnitude of the dose-response, provides strong support" for this factor. (Singh 2d Supp. Rep. at 6.)

Dr. McTiernan similarly stated in her supplemental report that "frequent use of genital talcum powder products doubled risk of ovarian cancer," and noted that the statistical test for trend—a standard measure of dose-response—was "highly significant at $P < 0.001$." (McTiernan 3d Amend. Rep. at 51; *see also* O'Brien 2024 at 10 (Table 3).) She concluded that O'Brien 2024, which considered data on lifetime patterns of talc use, "provided a more accurate picture of dose-response," including when accounting for recall bias, and "showed clearly that increased exposure to

genital talc was associated with increased risk, which was statistically significant."[36] (*Id.* at 54.)

Dr. McTiernan also discussed Woolen 2022, emphasizing its value as the first meta-analysis to focus on frequent use (rather than ever use), and noting that it reported "strong data that women who used perineal talcum powder products two or more times per week had a statistically significant 47% increased risk of developing ovarian cancer." (*Id.* at 81; Woolen 2022 at 2531.) She identified certain limitations, such as the exclusion of studies that did not capture frequent-use patterns and occasional inability to distinguish between talc and cornstarch products. (Woolen 2022 at 2531–32.) She ultimately considered the latter issue of minimal significance because "other research shows only 1–2% of perineal powder users report using cornstarch." (McTiernan 3d Amend. Rep. at 81 (citing Cramer 2016).) The analyses offered by Dr. Singh and Dr. McTiernan are grounded in the cited literature and

[36] Defendants again rely on *Zantac*, noting that the court there excluded Dr. McTiernan's opinion regarding the dose-response relationship. (Defs.' 2024 General Causation Br. at 69.) In *Zantac*, the court's ruling rested in part on the conclusion that "no study concluded [that a dose-response] relationship existed, with some even observing the inverse." 644 F. Supp. 3d at 1240. That factual premise, however, is not present here. Defendants quote this excerpt from *Zantac* to suggest it applies here; yet none of the studies the parties cite found an inverse dose-response relationship, nor do Defendants assert they do beyond simply quoting *Zantac* in this regard. (Defs.' General Causation Br. at 69.) Instead, as discussed above, Defendants present an argument about *imprecision* in the exposure data—an asserted methodological weakness that, in their view, counsels against drawing causal inferences. (*Id.* at 66.) As already explained, methodological imprecision is not equivalent to evidence of an inverse dose-response relationship. (*See supra* V.B.5.i. & ii.) Accordingly, the reasons for excluding an expert's testimony in another proceeding do not control where, as here, the underlying record and factual circumstances are materially different.

generally align with other Plaintiffs' experts who ascribed significant weight to this factor. (*See* Siemiatycki 3d Amend. Rep. at 44–55; Moorman 2d Supp. Rep. at 3–11; Harlow Rep. at 8; *see also* Harlow Supp. Rep. at 3 (not using standard Bradford Hill criteria but addressing the same factors in his analysis).)

Some experts, by contrast, explained why they did not ascribe substantial weight to the dose-response factor in their Bradford Hill analyses. For example, Dr. Smith-Bindman stated that, based on her review of the literature, "most studies of talcum powder products and ovarian cancer show a dose response, with the caveat that some studies do not, and several studies did not assess." (Smith-Bindman 3d Amend. Rep. at 37.) She noted that both O'Brien 2020 and O'Brien 2024 "confirm[ed] a dose response relationship where women with more lifetime applications had higher risks as did women who reported long-term talc use or the most applications," but she assigned this factor less weight because not all carcinogenic exposures necessarily demonstrate a linear dose-response pattern; some, she explained, follow a threshold model. (*Id.*) She further stated that this consideration is particularly relevant here because asbestos is understood to exhibit a threshold dose-response, and thus, in her view, while the presence of a dose-response relationship supports causation, the absence of such a pattern in any given study would not alter her overall conclusion. (*Id.*; *see also id.* at 11–12.) This reasoning is consistent with both pre- and post-2020 literature. (*See, e.g.*, O'Brien

2020 at 56; Woolen 2022 at 2531; O'Brien 2024 at 1–2, 13.) Certain other experts similarly assigned moderate or limited weight to the factor while still recognizing that many studies collecting frequency or duration data report evidence of dose response. (*See* Cote Amend. Rep. at 37; Clarke-Pearson 3d Amend. Rep. at 13; Wolf 3d Amend. Rep. at 19.)

Defendants renew their objection to what they characterize as a "threshold" theory, arguing that it is speculative because Plaintiffs' experts cannot identify a specific threshold dose. (Defs.' 2024 General Causation Br. at 69–70.) But this argument does not engage with any post-2020 scientific literature, nor does it identify case law that interprets Rule 702 differently from my prior analysis. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 179–80. Moreover, courts applying the amended Rule 702 have reiterated that the absence of a quantified exposure threshold does not, by itself, render an expert's causation opinion inadmissible. *See, e.g.*, *Ruffin v. BP Expl. & Prod., Inc.*, 137 F.4th 276, 282–83 (5th Cir. 2025) (dose-response is "but one factor" and "does not require an expert to provide a specific, quantitative exposure dose" so long as the expert reliably explains how the substance is capable of causing the condition); *Thompson v. Orkin, LLC*, No. 20-cv-13085, 2025 WL 18639, at *14 (E.D. Mich. Jan. 2, 2025) (collecting cases recognizing that precise exposure levels are not always necessary where other evidence supports causation).

For these reasons, I find that Plaintiffs' experts have continued to apply well-reasoned methodologies and to draw conclusions that are supported by the literature—whether they afforded the dose-response factor significant, moderate, or limited weight—based on their analyses of both pre- and post-2020 peer-reviewed studies. Defendants' critiques do not meaningfully address the more recent scientific evidence that informs the experts' current opinions. I reiterate that I do not opine, let alone conclude, whether the existing data ultimately proves the existence of a dose-response relationship between talc and ovarian cancer. While the studies support this Bradford Hill factor, I also acknowledge that this factor does not share some of the same force in the literature as do other factors. But I do find that, under Rule 702, by a preponderance of the evidence, Plaintiffs' experts have met the reliability requirements with respect to this factor and may offer their opinions at trial. Defendants remain free to challenge the strength or interpretation of those conclusions, including their assertion that no dose-response relationship has been conclusively demonstrated, through cross-examination and competing expert testimony.

iv. Biological Plausibility

In his 1965 article, on the factor of biological plausibility, Sir Bradford Hill advised: "It will be helpful if the causation we suspect is biologically plausible. But this is a feature I am convinced we cannot demand. What is biologically plausible

depends upon the biological knowledge of the day." Hill at 298. Similarly, the *Reference Guide* counsels that to demonstrate biological plausibility "depends upon existing knowledge about the mechanisms by which the disease develops." Green at 604. "When biological plausibility exists, it lends credence to an inference of causality." *Id.* "However, observations have been made in epidemiologic studies that were not biologically plausible at the time but subsequently were shown to be correct." *Id.* Accordingly, these authorities caution that while biological plausibility may support a causal inference, plausibility necessarily depends on the state of scientific knowledge at the relevant time, and a limited or weak showing of biological plausibility does not, standing alone, negate causation. *See In re Viagra*, 424 F. Supp. 3d at 791 ("In the abstract, there is no independent requirement that a plaintiff establish it to be biologically plausible that exposure to a particular drug or substance could cause the disease or condition at issue," and therefore, "'[b]iological plausibility' thus is only a subsidiary consideration in the larger question of general causation."); *see also In re Abilify*, 299 F. Supp. 3d at 1308 ("[A]n expert on biological plausibility need not definitively prove the biological means by which a drug acts in the body."); *In re Neurontin Mktg. Sales Practices & Prods. Liab. Litig.*, 612 F. Supp. 2d 116, 149 (D. Mass 2009) (finding that biological plausibility supported expert's opinion on causation despite the fact that there was "robust debate in the scientific community" on the proposed mechanism); *In re*

Phenylpropanolamine (PPA) Prods. Liab. Litig., 289 F. Supp. 2d 1230, 1247 (W.D. Wash. 2003) ("The fact that the mechanism remains unclear does not call the reliability of the opinion into question."); *Berg v. Johnson & Johnson*, 940 F. Supp. 2d 983, 993 (D.S.D. 2013) (in permitting expert testimony that it was biologically plausible for talcum powder to cause ovarian cancer, the court observed that "[a]t times, mechanistic explanations are merely hypothesized—although hypotheses are sometimes accepted in showing exposure can cause a disease" (citation and quotations omitted)).

Here, Defendants advance a series of challenges to Plaintiffs' experts' opinions on biological plausibility, contending that because those opinions rest on a multi-step causal theory, Plaintiffs must reliably establish each component of that theory under Rule 702. In particular, Defendants argue that the experts: (1) improperly conflate distinct ovarian cancer subtypes with differing etiologies and risk factors; (2) rely on insufficient evidence to demonstrate that externally applied talc can migrate to the ovaries or fallopian tubes; (3) fail to establish that talc exposure causes chronic inflammation and/or oxidative stress; (4) lack reliable scientific support that such chronic inflammation can cause ovarian cancer; and (5) improperly rely on *in vitro* studies to support theories involving oxidative stress or macrophage impairment. (Defs.' 2024 Biological Plausibility Br. at 2–4, 9–48.)

These arguments are framed against Defendants' broader contention that my prior rulings applied an unduly permissive interpretation of Rule 702 by treating asserted gaps in biological plausibility as matters of weight rather than admissibility, and that the 2023 amendments to Rule 702 require courts to resolve such issues at the admissibility stage. Defendants also argue that I improperly shifted the burden of proof by requiring them to disprove Plaintiffs' theories, and that intervening scientific developments undermine the experts' opinions. Plaintiffs dispute each of these assertions, maintaining that the correct Rule 702 standard was applied and that Defendants identify no conclusive new scientific evidence warranting reconsideration of the prior rulings.

To assess Defendants' present motion within the framework set forth in the Court's April 30, 2024 Memorandum Order, it is necessary to revisit the earlier *Daubert* rulings addressing biological plausibility. During the initial round of *Daubert* motions, Defendants advanced materially similar challenges, including that Plaintiffs' experts improperly treated ovarian cancer as a single disease, failed to establish a plausible migration pathway for talc, and lacked reliable evidence that talc exposure could lead to chronic inflammation or carcinogenesis. Those arguments were considered in detail and largely rejected, except for the inhalation-and-lymphatic-transport theory, which I excluded. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 175–76, 181–83.

Defendants' current motion reprises the same core thesis: that Plaintiffs' biological plausibility opinions rest on a speculative, multi-step causal chain unsupported by reliable evidence. Although Defendants now refine those objections by reference to amendments in Plaintiffs' experts' reports, the selection of bellwether Plaintiffs, recently published literature, and the amended text of Rule 702, these refinements do not materially alter the substance of the challenge. Nor do they demonstrate that my prior admissibility analysis fails to comport with Rule 702 as amended. Importantly, Defendants identify no "new science" that directly contradicts or undermines the evidentiary bases on which the prior rulings rested.

a. Ovarian Cancer Subtypes

Defendants first argue that Plaintiffs' experts' biological plausibility opinions are unreliable because they treat "ovarian cancer" as a unitary disease, notwithstanding heterogeneity in sites of origin, carcinogenic pathways, and risk factors across ovarian cancer subtypes. (Defs.' 2024 Biological Plausibility Br. at 9–12.) In Defendants' view, any biological mechanism offered in support of general causation must be subtype-specific, given that different subtypes arise in different tissues and involve distinct etiologies. Defendants also emphasize that the selected bellwether cases involve different ovarian cancer subtypes and contend that the experts improperly rely on studies examining ovarian epithelial cells, which

Defendants assert are not the cells of origin for high-grade serous carcinoma arising in the fallopian tube fimbriae. (*See id.* at 12–14.)

Defendants contend that I did not adequately address this issue in 2020. My prior Opinion found the experts' opinions reliable as they relate to the evaluation of epithelial ovarian cancer. I reasoned that the fact that Plaintiffs' experts do not opine on the biological mechanism for different epithelial ovarian cancer subtypes does not call into question the reliability of their opinions. Then, as now, I examined the reliability of the experts' methodology and whether it is reliably applied to the facts of this case.

As a general matter, ovarian cancer is an umbrella term encompassing several distinct categories of malignancies, traditionally classified by cell type of origin, including epithelial tumors, germ cell tumors, and sex cord–stromal tumors. Epithelial ovarian cancer—the most common category—comprises multiple histologic subtypes, such as serous, endometrioid, clear cell, and mucinous carcinomas. (*See, e.g.*, Brett M. Reid et al., *Epidemiology of Ovarian Cancer: A Review*, 14 Cancer Biol. Med. (1), 9–32 (2017) ("Reid 2017"); *see also* Wolf 3d Amend. Rep. at 3; McTiernan 3d Amend. Rep. at 20; Clarke-Pearson 3d Amend. Rep. at 4.) Importantly, as Defendants' referenced literature suggests, "[m]ost epidemiologic research . . . focuses on epithelial" ovarian cancer, since "*more than 90%* of malignant ovarian tumors are epithelial in origin." (*See* Reid 2017 at 9

(emphasis added).) It is, therefore, unsurprising that the studies underlying the experts' opinions principally examine the association between talcum powder use and epithelial ovarian cancer.

At the outset, it bears repeating that a finding of biological plausibility "depends upon existing knowledge about the mechanisms by which the disease develops." Green at 604. Accordingly, biological plausibility must be grounded in "reliable scientific knowledge and reasoning," not in scientific proof that has yet to be developed. *In re Abilify*, 299 F. Supp. 3d at 1308. Based on that standard, Defendants' contention—that Plaintiffs' experts either failed to account for, or that the record lacks, epidemiologic studies stratified by epithelial ovarian cancer subtype—does not render the experts' methodologies unreliable. As the experts explain, *infra*, and as the scientific literature reflects, epithelial ovarian cancer is a heterogeneous disease in which certain subtypes—particularly high-grade serous carcinoma—have been studied far more extensively than others. Where dispositive data is limited or unavailable, it is scientifically appropriate for experts to rely on a broader body of supportive epidemiologic, mechanistic, and pathological evidence bearing on, for example, epithelial ovarian cancer generally. *See, e.g.*, *In re Roundup*, 390 F. Supp. 3d at 1126–27, 1129 ("[T]he Bradford Hill framework asks experts to survey all the available evidence that might support or disprove causation. A broad survey of the available evidence is neither unusual in expert testimony nor

necessarily inappropriate."); *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, MDL No. 2545, 2017 WL 1833173, at *9, 14 (N.D. Ill. May 8, 2017) ("The Court agrees with plaintiffs that there is nothing inherently unreliable about a method that relies on the totality of the evidence, provided that the expert considers the evidence carefully and explains how the weight of the various pieces of evidence led him to his conclusion."). These experts' opinions therefore rest on the application of existing scientific knowledge to the question of biological plausibility, rather than on speculation or unsupported extrapolation. The absence of definitive subtype-specific studies reflects the current state of the science, not a methodological flaw, and does not preclude experts from offering biologically plausible opinions grounded in the available evidence.

That said, several experts do in fact discuss different subtypes of epithelial ovarian cancer in forming their biological plausibility opinions. (*See, e.g.*, McTiernan 3d Amend. Rep. at 20 (providing overview of "different subtypes of cancer of the ovary," highlighting that only "epithelial ovarian cancer has been studied in relation to use of talcum powder products," and emphasizing importance for "epidemiological studies of cancer . . . to identify . . . the type of cancer, stage of cancer at diagnosis, and subtype of cancer"); Smith-Bindman 3d Amend. Rep. at 3 ("Talcum powder exposure is most clearly demonstrated to be associated with serous cancer and other epithelial cancer subtypes (in particular, clear cell and endometrioid

carcinoma), but because these other cancers are less common, and because fewer studies have evaluated these cancers in sufficient numbers, quantifying the associations is more difficult. In my opinion, this risk is likely overall in approximately the same range as for serous cancer."); Wolf 3d Amend. Rep. at 3 ("[Epithelial cancer] subtypes include serous, endometrioid, clear cell, mucinous, undifferentiated or mixed. Of these, serous is by far the most common and accounts for 70% of EOC. Epithelial ovarian cancers are those that are associated with talcum powder products."); *see also, e.g.*, Levy 2d Amend. Rep. at 22–25 (recognizing bellwether Plaintiffs' varied diagnoses).) Based on the available science, and the underlying epidemiological studies upon which Plaintiffs' experts rely in forming their opinions, I find these discussions grounded in sound methodology.

Nevertheless, Defendants rely on *Hoefling v. U.S. Smokeless Tobacco Co., LLC* in arguing that the experts' failure to account for distinct subtypes of epithelial ovarian cancer renders their methodologies unreliable. (*See* Defs.' 2024 Biological Plausibility Br. at 9–10 (citing *Hoefling*, 576 F. Supp. 3d 262).) Defendants' argument is misplaced. In *Hoefling*, the district court excluded an expert's general causation opinion because the sources on which the expert relied did not support causation for the specific anatomic site at issue—namely, the tonsil and oropharynx. 576 F. Supp. 3d at 272–75. The expert impermissibly extrapolated from evidence of oral-cavity cancers without scientific justification and failed to meaningfully engage

with the full body of relevant epidemiologic literature, among other methodological deficiencies. *See id.*

By contrast, the sources relied on by Plaintiffs' experts support the biological plausibility theories concerning talcum powder use and epithelial ovarian cancer. Plaintiffs' experts do not derive subtype-specific conclusions from literature that exceed the scope of the underlying studies. Rather, as discussed above and reflected in their respective reports, the experts evaluate the association at the level of epithelial ovarian cancer because both the relevant studies and the scientific literature more broadly have focused predominantly on that category of disease, rather than its sub-types. Nor do Plaintiffs' experts disregard heterogeneity among ovarian cancer subtypes. Instead, they accounted for the current state of the science, which recognizes such heterogeneity. In that context, the experts' reliance on epithelial ovarian cancer as the relevant analytical frame is methodologically sound and does not reflect the sort of unsupported extrapolation identified in *Hoefling*.

Defendants' reliance on *Siharath v. Sandoz Pharmaceuticals Corp.* is similarly misplaced. (*See* Defs.' 2024 Biological Plausibility Br. at 10 (citing *Siharath v. Sandoz Pharmaceuticals Corp.*, 131 F. Supp. 2d 1347 (N.D. Ga. 2001).) In *Siharath*, the court excluded the plaintiffs' expert testimony and granted summary judgment because every step of the proposed causal chain lacked independent scientific support. *Id.* at 1370–71, 1373–74. After reviewing the full body of

available medical evidence—including peer-reviewed epidemiologic studies, learned treatises, case reports, and animal models—the court concluded that the record did not demonstrate, or even meaningfully suggest, that Parlodel caused hemorrhagic stroke. *Id.* at 1370–71. In short, the experts in *Siharath* advanced a theory for which the scientific literature provided no reliable evidentiary foundation.

This case presents a materially different record. Here, Plaintiffs' experts rely on a substantial and evolving body of epidemiologic, mechanistic, and experimental literature supporting the biological plausibility of an association between perineal talc use and epithelial ovarian cancer, even if that literature does not resolve every mechanistic question or permit exhaustive differentiation among all epithelial subtypes. Unlike *Siharath*, this is not a case in which the scientific literature uniformly contradicts—or fails to support—the proposed causal mechanism.

The distinction is further illustrated by the nature of the biological comparison at issue. In *Siharath*, the court relied on a clear and well-established biological dichotomy between ischemic strokes—caused by impaired blood flow—and hemorrhagic strokes—caused by vascular rupture—and concluded that evidence supporting one could not be reliably extrapolated to the other absent a scientific foundation. *Id.* at 1355, 1371. Here, Defendants seek to analogize that dichotomy to differences among epithelial ovarian cancer subtypes. But that analogy is not borne out by the scientific literature on which Plaintiffs' experts rely. Unlike the literature

at issue in *Siharath*, the epidemiologic and mechanistic studies addressing talc use and ovarian cancer are not framed in a manner that materially distinguishes among epithelial subtypes or limits their findings to only certain subtypes. Rather, those studies generally evaluate epithelial ovarian cancer as a category and do not identify biological distinctions that would preclude the application of their findings across epithelial subtypes. In that context, Plaintiffs' experts' reliance on this body of literature does not involve the kind of unsupported extrapolation that concerned the court in *Siharath*.

In short, *Siharath* involved a scientific record in which the asserted causal relationship was unsupported at each analytical step. In contrast, Defendants' arguments here challenge the *scope* and *precision* of the evidence supporting Plaintiffs' experts' opinions, not the absence of such evidence. The analytical gaps identified in *Siharath* were fatal under Rule 702 and *Daubert*; the asserted limitations here instead present scientific disputes that should be explored through cross-examination and the presentation of competing expert testimony, rather than exclusion.

Finally, Defendants argue that Plaintiffs' experts improperly rely on two *in vitro* studies to bridge a subtype gap, because neither study is tied to the distinct sites

of origin or biology to endometroid cancer or clear cell cancer.[37] This argument is distinct from Defendants' challenge to the reliability of the experts' macrophage-inhibition theory, which is premised on Mandarino 2020 and Tania Emi et al., *Transcriptomic and Epigenomic Effects of Insoluble Particles on J774 Macrophages*, 16 Epigenetics (10), 1053–70 (2021) ("Emi 2021"), and which I will separately address, *infra*.

One of the *in vitro* studies is Harper/Saed 2023, which exposed normal human ovarian epithelial cells and fibroblasts to varying concentrations of talcum powder or titanium dioxide for 72 hours, assessed anchorage-independent growth using a cell-transformation assay, and performed immunohistochemical analyses. (*See generally* Harper/Saed 2023.) The authors reported a dose-dependent increase in transformed colonies in talc-exposed ovarian epithelial cells, with no such findings in control samples. (*See id.*) Mandarino 2020 similarly examined the biological effects of talc exposure by exposing mice macrophages—with and without estradiol—to talc, measuring reactive oxygen species and gene-expression changes, and co-culturing those macrophages with murine ovarian epithelial cells. (*See generally* Mandarino 2020.) The authors reported increased oxidative stress and

[37] (*See* Defs.' 2024 Biological Plausibility Br. at 13–14 (citing Angelo Mandarino et al., *The Effect of Talc Particles on Phagocytes in Co-Culture with Ovarian Cells*, 180 Env't Res. (2020) ("Mandarino 2020"); Amy K. Harper et al., *Talcum Powder Induces Malignant Transformation in Normal Human Primary Ovarian Epithelial Cells*, 75 Minerva Obstetrics & Gynecology (2) (2023) ("Harper/Saed 2023").)

alterations in macrophage gene expression relevant to cancer development and immunosurveillance. (*See id.*)

Defendants argue that Harper/Saed 2023 is of minimal relevance to high-grade serous carcinoma because it examined ovarian epithelial cells *in vitro* rather than fallopian tube fimbrial epithelium, from which high-grade serous carcinoma is now understood to predominantly arise. Defendants raise a similar critique of Mandarino 2020, asserting that it is not tied to any specific epithelial ovarian cancer subtype or site of origin.

I do not find that Plaintiffs' experts' reliance on these studies renders their opinions or methodologies unreliable under Rule 702. Although Defendants correctly observe that neither study evaluates every epithelial ovarian cancer subtype nor is tethered to a specific anatomic site of origin, those limitations do not render the studies irrelevant for purposes of biological plausibility. Plaintiffs' experts do not rely on these *in vitro* studies to advance subtype-specific causation opinions. Rather, the studies are cited as part of a broader mechanistic body of evidence that talc can induce cellular changes—such as oxidative stress, inflammation, and altered immune function—consistent with carcinogenic processes. The experts explicitly situate these findings alongside epidemiologic data, other *in vitro* and animal studies, and regulatory assessments. In that context, Harper/Saed 2023 and Mandarino 2020 represent two recent contributions to a much larger evidentiary record, not

standalone proof of biological plausibility, and certainly not standalone proof of general causation. (*See, e.g.*, Clarke-Pearson 3d Amend. Rep. at 6 ("Recently, Harper and Saed demonstrated that exposure to Johnson's Baby Powder causes p53 mutations, cell proliferation and malignant transformation in normal ovarian epithelial cells."); Wolf 3d Amend. Rep. at 16 ("[Harper/Saed 2023] reported cell proliferation, neoplastic transformation and p53 mutations when cells in culture were exposed to Johnson's Baby Powder."); Levy 2d Amend. Rep. at 16 ("Mandarino and colleagues independently published separate work showing the pro-oxidant effect of talc in a cell culture system."); *see also* Plunkett 3d Amend. Rep. at 46–47 (discussing Mandarino 2020).)

Indeed, multiple Plaintiffs' experts cited Mandarino 2020 in conjunction with numerous additional studies spanning several decades of research. For example, Dr. Plunkett cites Mandarino 2020 and twenty-five other studies for support of the proposition that scientific literature since the 1960s "has continued to accumulate showing that . . . [cosmetic grade] talc has adverse effects in cells, tissues, animals and humans." (Plunkett 3d Amend. Rep. at 27–28.) Dr. Wolf similarly cites Mandarino 2020 and ten other studies for support of the proposition that "[t]alcum powder causes inflammation/oxidative stress both *in vitro* and *in vivo* (in both animal and human tissues)." (Wolf 3d Amend. Rep. at 16.)

In sum, Defendants have not shown that my prior ruling addressing Plaintiffs' experts' treatment of epithelial ovarian cancer subtypes "demonstrably fail[ed] to adhere to Rule 702 as clarified by the 2023 amendments." (April 30, 2024 Memorandum Order.) Rather, I find that Plaintiffs' experts more likely than not employ a sufficiently reliable methodology—grounded in experimentation, interpretation, and application of a cumulative, multidisciplinary body of scientific evidence—and that their use of the two *in vitro* studies for purposes of biological plausibility does not warrant exclusion under *Daubert*.

b. Migration

Next, Defendants challenge Plaintiffs' central premise that externally applied perineal talc can reach the ovaries or fallopian tubes. (Defs.' 2024 Biological Plausibility Br. at 14–27.) Defendants contend that the experts' migration opinions are inadmissible and advance three principal grounds for exclusion. First, Defendants argue that the human experimental studies cited by Plaintiffs' experts do not involve the external application of talc to the perineum. (*Id.* at 15–19.) Second, Defendants maintain that certain animal studies are inapposite and/or inconsistent. (*Id.* at 19–21.) Third, Defendants claim that reports identifying talc within gynecologic or pelvic tissues do not establish that such talc originated from perineal use. (*Id.* at 21–25.) Additionally, Defendants reiterate their position that the experts' alternative migration theory—via inhalation and/or lymphatic transport—lacks

sufficient evidentiary support.[38] (*Id.* at 25–27.) Indeed, the bulk of Defendants' challenge to the experts' migration opinions generally rests on the fact that literature "do[es] not directly support their theory that *externally applied* talc can migrate up [or reach] the vagina to the ovaries." (Defs.' 2024 Biological Plausibility Br. at 14–15 (citing *In re Johnson & Johnson*, 509 F. Supp. 3d at 174).)

Since the issuance of my 2020 Opinion, neither party has presented new evidence establishing whether externally applied perineal talc does—or did—result in talc being present in an individual's ovaries. Indeed, I have already addressed Defendants' arguments raised here in my prior Opinion. Critically, as I stated then, *see In re Johnson & Johnson*, 509 F. Supp. 3d at 174–75, and elsewhere in this Report and Recommendation, (*see, infra*, at Part V.C.2.ii.b), biological plausibility—as its name suggests—does not require definitive proof of the biological mechanism by which talc reaches ovaries. An expert need only "provide reliable support that demonstrates that the mechanism is *plausible*." *In re Johnson & Johnson*, 509 F. Supp. 3d at 175; *see also In re Abilify*, 299 F. Supp. 3d at 1308 ("[A] biological plausibility opinion is admissible so long as it is derived from and supported by reliable scientific knowledge and reasoning." (collecting cases)).

[38] It appears that Plaintiffs are reasserting the inhalation theory, which I excluded previously. (*See* Pls.' Opp. to Defs.' 2024 Biological Plausibility Br. at 30 ("[Plaintiffs'] experts' opinions on inhalation as a secondary mechanism are reliable and admissible."); *see also* Kane Rep. at 4; McTiernan 3d Amend. Rep. at 89; Moorman Rep. at 33; Plunkett 3d Amend. Rep. at 30; Wolf 3d Amend. Rep. at 15, 19–20.) I will address this issue even though Plaintiffs have not, on these motions, sought to formally reintroduce this theory of migration.

Neither party has provided convincing arguments or case law to suggest that the admissibility of a biological plausibility opinion is held to a different standard than I applied in my prior Opinion.

On these bases, I find that both parties have failed to establish that: (1) my prior Opinion "demonstrably fail[ed] to adhere to Rule 702 as clarified by the 2023 amendments" as it related to the admissibility of Plaintiffs' experts' migration opinions, and (2) "new science . . . directly contradict[s] or challenge[s]" my previous findings on the same. (*See* April 30, 2024 Memorandum Order.) I will address the parties' arguments in full.

In support of their first argument, Defendants contend that the design differences of studies relied on by Plaintiffs' experts create an analytical gap that precludes extrapolation to external perineal use. Defendants highlight that those studies[39] involved particles deposited into the internal reproductive tract, not externally on the perineum. Defendants also criticize the experts' reliance on studies that used non-talc tracers (e.g., carbon, albumin microspheres), often with subjects positioned to facilitate upward transport, such as pelvis being elevated, prolonged

[39] (*See* Defs.' 2024 Biological Plausibility Br. at 15–17 (citing G.E. Egli & Michael Newton, *The Transport of Carbon Particles in the Human Female Reproductive Tract*, 12 Fertil. & Steril. (2), 151–55 (1961) ("Egli & Newton 1961"); P.F. Venter & M. Iturralde, *Migration of a Particulate Radioactive Tracer from the Vagina to the Peritoneal Cavity and Ovaries*, 55 S. Afr. Med. J. (23), 917–19 (1979) ("Venter & Iturralde 1979"); G. Kunz et al., *The Uterine Peristaltic Pump. Normal and Impeded Sperm Transport Within the Female Genital Tract*, in *The Fate of the Male Germ Cell* 267, 270 (Ivell & Holstein eds. 1997) ("Kunz 1997").)

supine positioning, and sometimes with use of oxytocin to promote uterine contractions.[40]

Plaintiffs respond that Defendants' criticisms go to the weight, not admissibility, because biological plausibility does not require a study precisely replicating real-world perineal use to be reliable. (*See* Pls.' Opp. to Defs.' 2024 Biological Plausibility Br. at 14–21.) In that regard, Plaintiffs emphasize that regulatory authorities and medical sources recognize perineal use as a primary exposure route and the plausibility of upward migration, citing the FDA, the IARC, and Health Canada. (*See id.* at 15.) Plaintiffs also argue that ordinary behavior and female anatomy make perineal-to-vaginal transfer plausible, as acknowledged by some of Defendants' experts. (*See id.* at 15–16.) In Plaintiffs' view, studies that begin with material in the vagina are probative of what occurs after perineal application. (*See id.* at 15–17.) Plaintiffs suggest, as do their experts, that once in the reproductive tract, documented physiological mechanisms—uterine peristalsis and retrograde menstruation—drive transport to the uterus, fallopian tubes, and ovaries. (*See id.* at 17–18.) Additionally, Plaintiffs cite multiple human tracer and particulate studies showing upward migration within minutes to days, which I previously deemed a reliable basis for expert migration opinions. (*See id.* at 18–21 (citing, e.g.,

[40] (*See* Defs.' 2024 Biological Plausibility Br. at 18–19 (citing Egli & Newton 1961; Venter & Iturralde 1979; A.C.E. Sjösten et al., *Retrograde Migration of Glove Powder in the Human Female Genital Tract*, 19 Hum. Reprod. (4), 991–995 (2004) ("Sjösten 2004").)

Egli & Newton 1961; Venter & Iturralde 1979).) Finally, Plaintiffs contend the studies' use of particles other than talc is not fatal to their admissibility because the particles are similar in size and morphology to talc and show the same upward behavior. (*See id.* at 20–21.)

Taken together, Defendants' critiques of individual studies do not establish that Plaintiffs' experts' methodologies are unreliable; rather, the totality of the evidence—principally human studies, supplemented by animal data, *in vitro* experiments, and regulatory assessments—reliably supports the biological plausibility, though not with certainty or definitively, that perineally applied talc may migrate to the upper reproductive tract.

To begin, Defendants take issue with the experts' reliance on three studies, (*see* Defs.' 2024 Biological Plausibility Br. at 16 & n.22),[41] which I previously considered in my prior Opinion, *see In re Johnson & Johnson*, 509 F. Supp. 3d at 173–74. Admittedly, they do not specifically involve the perineal application of talc to research subjects. Rather, these studies generally sought to demonstrate that inert,

[41] Specifically, Defendants highlight that Drs. Carson, Clarke-Pearson, Cote, McTiernan, Plunkett, and Wolf rely on Egli & Newton 1961, (*see* Carson Rep. at 7; Clarke-Pearson 3d Amend. Rep. at 12; Cote Amend. Rep. at 13; McTiernan 3d Amend. Rep. at 88; Plunkett 3d Amend. Rep. at 31–32; Wolf 3d Amend. Rep. at 14); that Drs. Carson, Clarke-Pearson, McTiernan, and Wolf rely on Venter & Iturralde 1979, (*see* Carson Rep. at 7; Clarke-Pearson 3d Amend. Rep. at 12; McTiernan 3d Amend. Rep. at 88–89; Wolf 3d Amend. Rep. at 14); and that Drs. Plunkett and Wolf rely on Kunz 1997, (*see* Plunkett 3d Amend. Rep. at 31, 38–39, 41; Wolf 3d Amend. Rep. at 14).

sperm-sized particles placed in the vagina can rapidly and passively ascend through the uterus into the fallopian tubes.

- In Egli & Newton 1961, clinicians "deposited" "[s]terile carbon particles" "in the posterior fornix" of three women at or near the day of ovulation and, after giving oxytocin, found particles in tubes within approximately 30 minutes in two cases. (*See* Egli & Newton 1961 at 152–54.)

- In Venter & Iturralde 1979, doctors "deposited" "human albumin microspheres" in the "posterior fornix" of 24 women "placed in the supine position with the buttocks slightly elevated" and showed with imaging and tissue counts that the microspheres moved up through the uterus into the tubes and ovaries. (*See* Venter & Iturralde 1979 at 917–18.)

- In Kunz 1997, the authors tracked "[a]lbumin macrospheres" placed "at the external os of the uterine cervix"[42] and showed that, among other things, uterine peristaltic contractions rapidly carry these sperm-sized particles from the cervix into the uterus. (*See generally* Kunz 1997.)

In sum, these studies all observed upward transport of the particles from their deposit location, which all involved some measure of internal application.

Defendants similarly challenge several studies on which Plaintiffs' experts rely for their transport-via-retrograde menstruation theory.[43, 44]

---

[42] "External os" refers to the external opening of the cervical canal at the vaginal end of the cervix, adjacent to the posterior vaginal fornix, or the cervix's opening into the vagina. (*See, e.g.*, Kunz 1997 at 268.)

[43] (*See* Defs.' 2024 Biological Plausibility Br. at 16–17 (citing M.J. Blumenkrantz et al., *Retrograde Menstruation in Women Undergoing Chronic Peritoneal Dialysis*, 57 Obstet. & Gynecol. (5), 667–70 (1981) ("Blumenkrantz 1981"); Juoko Halme et al., *Retrograde Menstruation in Healthy Women and in Patients with Endometriosis*, 64 Obstet. & Gynecol. (2), 151–54 (1984) ("Halme 1984")).)

[44] Defendants contend that Plaintiffs' experts' retrograde migration theory should have been excluded because in my previous Opinion, I expressly stated that "migration has never been demonstrated in circumstances analogous to perineal dusting." (*See* Defs.' 2024 Biological Plausibility Br. at 14–15 (citing *In re Johnson & Johnson*, 509 F. Supp. 3d at 174).)

- Blumenkrantz 1981 examined whether retrograde menstruation occurs routinely by monitoring peritoneal fluid in 11 premenopausal women on chronic peritoneal dialysis. (*See* Blumenkrantz 1981 at 667–68.) Peritoneal blood was seen in 9 of 11 women and was otherwise rare in men or non-menstruating women, leading the authors to conclude, among other things, that retrograde flow into the peritoneal cavity is common. (*See id.* at 668–70.)

- Halme 1984 prospectively assessed 331 pelvic fluid samples at laparoscopy and classified its color by cycle timing. (*See generally* Halme 1984.) During perimenstrual phase, the authors observed that 90.4% of sampled women with open fallopian tubes "had an appreciable amount of red blood cells," versus 15.4% of sampled women with occluded fallopian tubes having the same or similar result. (*See id.* at 153.) The authors concluded that retrograde menstruation through patent tubes is a common physiologic event and that occlusion limits peritoneal blood. (*See id.* at 153–54.)

In short, these studies observed the upward movement of menstrual blood through the fallopian tubes—a mechanism which was observed in nearly all investigated women. (*See generally id.*)

With that context, Defendants' migration challenge largely rests on the absence of studies that begin with the external application of talc to the perineum and then directly demonstrate talc's presence in the ovaries or fallopian tubes. But this framing misapprehends both the nature of biological plausibility analysis and the way the scientific literature addressing reproductive tract transport is structured. As I have previously explained, biological plausibility does not require definitive proof of the precise mechanism by which an exposure reaches a target organ. Rather, an expert must provide reliable scientific support demonstrating that the proposed

mechanism is plausible in light of existing biological knowledge. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 175; *In re Abilify*, 299 F. Supp. 3d at 1308. That standard has not changed under the 2023 amendments to Rule 702.

Viewed through that lens, the analogies employed by Plaintiffs' experts are scientifically apt. The human transport studies on which they principally rely—including, among others, Egli & Newton 1961, Venter & Iturralde 1979, and Kunz 1997—were designed to examine whether inert, tiny particles placed at or near the vaginal opening can move upward through the reproductive tract via normal physiologic processes. Although those studies do not involve perineal dusting per se, they directly address the critical biological question at issue: whether particles of comparable size and morphology can ascend from the lower reproductive tract to the uterus, fallopian tubes, and ovaries.

The studies uniformly demonstrate that upward transport occurs rapidly and passively, driven by well-established physiologic mechanisms such as uterine peristalsis. Importantly, the materials in these studies were placed at shallow, distal locations within the reproductive tract—often in the posterior fornix or at the cervical os—making them probative of what may occur once material enters the vaginal canal, regardless of the precise initial mode of entry as opined by the experts. In this context, the experts' inference that perineally applied talc may enter the vagina through ordinary hygiene practices and thereafter be subject to the same

transport mechanisms is not speculative but grounded in known anatomy and physiology reflected in the studies they cite.

The same is true of the experts' reliance on studies documenting retrograde menstruation. Blumenkrantz 1981 and Halme 1984 establish that retrograde flow of menstrual material through patent fallopian tubes into the peritoneal cavity is a physiologic occurrence. As Plaintiffs' experts are well aware, these studies do not purport to model talc exposure directly; rather, they demonstrate the existence of a biologically plausible pathway by which particulate matter present in the lower reproductive tract may reach the upper tract and surrounding tissues. The absence of talc-specific tracing in these studies does not negate their relevance to biological plausibility.

Defendants' criticisms—that these studies involve internal placement, non-talc tracers, or experimental conditions facilitating transport—do not render the experts' methodology unreliable. Such critiques speak to the degree of analogy, not to whether the analogy itself is scientifically reasonable. As courts have recognized, biological plausibility may be established through multiple lines of evidence, such as transport physiology, analog particle studies, and known anatomic mechanisms, particularly where ethical and practical constraints preclude direct human experimentation. *See Milward v. Acuity Specialty Prods Grp., Inc.*, 639 F.3d 11, 17–19, 23–24 (1st Cir. 2011) (finding a reliable inference of biological plausibility and

reversing the district court's "reasoning that because no one line of evidence supported a reliable inference of causation, an inference of causation based on the totality of the evidence was unreliable"); *see also id.* at 24–25 (recognizing that the absence of dispositive epidemiological studies due to "difficulties of data collection in the United States" is not fatal and citing cases); *In re Roundup*, 390 F. Supp. at 1129–30 (holding that Bradford Hill framework requires experts to survey all available evidence and admitting mechanistic evidence supporting biological plausibility despite absence of direct human data). Indeed, Plaintiffs' experts explain that prospective human studies involving perineal talc application, repeated tissue sampling, or long-term cancer outcome measurement would be unethical and infeasible. (*See* Singh Rep. at 7; Singh Supp. Rep. at 23; McTiernan 3d Amend. Rep. at 33; Smith-Bindman 3d Amend. Rep. at 33.) In that setting, reliance on analog studies and mechanistic inference is not only accepted scientific practice but may be the only method by which biological plausibility can reasonably be assessed.

Thus, the use in certain studies of non-talc tracers or migration-facilitating conditions does not, standing alone, render Plaintiffs' experts' methodologies—or their application to the facts here—unreliable. Plaintiffs' experts cite tracer studies not to establish talc-specific chemistry, but to illustrate a plausible migration pathway governed principally by reproductive tract anatomy and particle transport mechanics, rather than by the chemical composition of talc itself. (*See, e.g.*, Wolf 3d

Amend. Rep. at 13–15; Smith-Bindman 3d Amend. Rep. at 32–33.) To be clear, Plaintiffs' experts do not ignore the studies' use of non-talc particles to demonstrate migration. (*See, e.g.*, Wolf 3d Amend. Rep. at 14; McTiernan 3d Amend. Rep. at 88–89; Clarke-Pearson 3d Amend. Rep. at 12.) Rather, they use these studies, among others, to reasonably extrapolate that talc applied to the perineum can migrate to the upper reproductive tract. Under the governing standards, Plaintiffs need not definitively prove biological plausibility. It is enough for these experts to demonstrate that their biological plausibility opinions are reliably supported, even if such support is not definitive proof of their opinions.

Consistent with that approach, Health Canada has recognized that the inert particles used in several foundational migration studies—including, among others, Egli & Newton 1961, De Boer 1972,[45] Venter & Iturralde 1979, and Kunz 1996[46]—were "similar in size to talc." (Health Canada Screening Assessment 2021.) Where, as here, the proposed mechanism turns on particle size, form, and transport dynamics, the use of inert particulates with comparable physical characteristics provides a scientifically appropriate basis for demonstrating a plausible migration pathway.

---

[45] C.H. De Boer et al., *Transport of Particulate Matter Through the Human Female Genital Tract*, 28 J. Reprod. Fert. 295–97 (1972) ("De Boer 1972").

[46] G. Kunz et al., *The Dynamics of Rapid Sperm Transport Through the Female Genital Tract: Evidence From Vaginal Sonography of Uterine Peristalsis and Hysterosalpingoscintigraphy*, 11 Hum. Reprod. 627–32 (1996) ("Kunz 1996").

Lastly, Defendants criticize Drs. Cote's and Plunkett's reliance on De Boer 1972, a study that observed varying degrees of transportation of inert carbon particles deposited in the uterine cavity, cervical canal, and vagina. Specifically, De Boer 1972 found that inert India ink placed in the uterine cavity was often and rapidly transported to the fallopian tubes in over half of cases; transport from the cervix occurred in roughly a third of cases; and movement from the vagina into the uterus was rare, *i.e.*, twice in thirty-seven cases. (*See generally* De Boer 1972.)

Defendants stress as unsupportive De Boer 1972's own data,[47] which shows frequent transit to the fallopian tubes when particles were placed in the uterus, but almost never when placed in the vagina—highlighting that the study does not support migration from the external perineum through the vagina. (*See* Defs.' 2024 Biological Plausibility Br. at 17.) Defendants also claim that Dr. Cote ignored De Boer 1972's arguably unfavorable data, since Dr. Cote only referenced De Boer 1972's findings concerning frequent movement from the uterus to the fallopian tubes and not its observation of rare migration from the vagina to the uterus. (*See id.*; *see also* Cote Amend. Rep. at 13 (summarizing De Boer 1972 as providing "evidence [that] ink traveled to the fallopian tubes at least half of the time when placed in the uterus").)

[47] It is unclear whether Defendants challenge Plaintiffs' experts' reliance on De Boer 1972 as it relates to retrograde migration, or as it may relate to migration-via-perineal application.

But Defendants mischaracterize Drs. Cotes' and Plunkett's reliance on this study. They did not rely on or reference De Boer 1972 as sole or primary proof of upward migration; instead, they relied on and referenced a large body of literature, both predating and following the publication of De Boer 1972, that uses non-talc substances sufficiently similar in size and morphology to talc to show the plausibility of upward migration. (*See* Cote Amend. Rep. at 13 (citing, *inter alia*, De Boer 1972 and, *inter alia*, Egli & Newton 1961 and Venter & Iturralde 1979, as collectively providing "[i]nsight as to how talc products and their components can migrate from the perineum through the genital tract to the ovaries and fallopian tubes"); Plunkett 3d Amend. Rep. at 32–33 (summarizing De Boer 1972 and other migration-related studies as "provid[ing] *early* notice of the ability of particles to move up the female reproductive tract" (emphasis added)).) To be sure, the parties do not discuss or challenge every study, experiment, or assessment that Plaintiffs' experts rely on or refer to in support of the plausibility of a migratory mechanism. While I have reviewed this support, this Report and Recommendation does not endeavor to discuss or otherwise consider every study relied on or referred to by each of Plaintiffs experts that Defendants do not expressly challenge.[48] For this same reason, the fact

[48] (*See, e.g.*, Cote Amend. Rep. at 13–14 (citing, *e.g.*, Carl G. Hartman, *How Do Sperms Get Into the Uterus?*, 8 Fertil. & Steril. (5), 403–27 (1975); J.C. Phillips et al., *Studies on the Absorption and Disposition of 3H-Labelled Talc in the Rat, Mouse, and Guinea-Pig and Rabbit*, 16 Food & Cosmet. Toxicol. (2) 161–63 (1978); Heather N. Lynch et al., *Systematic Review of the Association Between Talc and Female Reproductive Tract Cancers*, Front. in Toxicol. (2023)); Plunkett 3d Amend. Rep. at 31 (citing, e.g., Tim H. Parmley & J. Donald Woodruff, *The Ovarian*

that Dr. Cote did not expressly discuss the infrequent transportation to the uterus of inert carbon particles when they are placed in the vagina does not render her opinions regarding migration unreliable.

Defendants' criticisms of flaws or findings of a particular study—here, De Boer 1972—do not undermine the ultimate conclusions that Plaintiffs' experts draw from them, given that they cite to a robust grouping of studies showcasing the relative evolution of migratory evidence.[49] Drs. Cote and Plunkett accurately characterize De Boer 1972, and do not draw or enlarge opinions that the study's authors themselves fail to make. Moreover, De Boer 1972 did not produce evidence disproving upward migration from the vagina to the uterus following application or insertion of inert particles into the vagina, since it did not demonstrate that no migration occurred. Defendants' criticisms of Plaintiffs' reliance on De Boer 1972 go to the weight owed to their migratory opinions, not to their admissibility.

Mesothelioma, 120 Am. J. Obstet. Gynecol. (2), 234–41 (1974); David L. Gardner et al., *Potential Delivery of Contraceptive Agents to the Female Reproductive Tract*, Controlled Release of Pesticides & Pharms. 99–109 (1981); M.G. McCalley et al., *Radionuclide Hysterosalpingography for Evaluation of Fallopian Tube Patency*, 26 J. Nucl. Med. (8), 868–74 (1985); S. Kadanali, *Evaluation of Active and Passive Transport Mechanisms in Genital Tracts of IUD-Bearing Women with Radionuclide Hysterosalpingoscintigraphy*, 63 Contraception (1), 41–45 (2001); Stefan Kissler et al., *Uterine Contractility and Directed Sperm Transport Assessed by Hysterosalpingoscintigraphy (HSSG) and Intrauterine Pressure (IUP) Measurement*, 83 Acta Obstetricia et Gynecologica Scandinavica (4), 369–74 (2004); I. Zervomanolakis et al., *Physiology of Upward Transport in the Human Female Genital Tract*, 1101 Ann. of the New York Acad. of Sci. (1), 1–20 (2007)).)

[49] *See supra* note 48; *see also* Egli & Newton 1961; Venter & Iturralde 1979; Kunz 1997; Blumenkrantz 1981; Halme 1984.

Next, in support of their argument related to animal studies, Defendants assert that the experts' biological plausibility opinions are unreliable because they rely on animal studies that cannot be validly extrapolated to human perineal talc use. (*See* Defs.' 2024 Biological Plausibility Br. at 19–21.) To that end, they criticize certain experts' reliance on two studies that involved the application or insertion of talc in rodent genital tracts.[50] They fault these experts for "ignor[ing]" primate studies that found no talc translocation to fallopian tubes or ovaries,[51] and for inadequately addressing at least one primate study that artificially maximized upward transportation.[52]

Plaintiffs respond that their experts' reliance on animal data is appropriate for establishing biological plausibility, but, in any event, their experts ground their migration and mechanism opinions on human-based evidence and use animal-based studies only for supplemental support. (*See* Pls.' Opp. to Defs.' 2024 Biological Plausibility Br. at 21–23.) Plaintiffs further submit that courts routinely allow animal

---

[50] (*See* Defs.' 2024 Biological Plausibility Br. at 19–20 (citing Nadi Keskin et al., *Does Long-Term Talc Exposure Have a Carcinogenic Effect on the Female Genital Systems of Rats? An Experimental Pilot Study*, 280 Arch. Gynecol. Obstet. (6), 925–31 (2009) ("Keskin 2009")); W.J. Henderson et al., *The Demonstration of the Migration of Talc from the Vagina and Posterior Uterus to the Ovary in the Rat*, 40 Env't Research (2), 247–50 (1986) ("Henderson 1986").)

[51] (*See* Defs.' 2024 Biological Plausibility Br. at 20 (citing Alfred P. Wehner et al., *On Talc Translocation from the Vagina to the Oviducts and Beyond*, 24 Food Chem. Toxicol. (4) 329–38 (1986) ("Wehner 1986").)

[52] (*See* Defs.' 2024 Biological Plausibility Br. at 20–21 (citing Alfred P. Wehner et al., *Do Particles Translocate from the Vagina to the Oviducts and Beyond*, 23 Food Chem. Toxicol. (3) 367–72 (1985) ("Wehner 1985").)

studies to inform biological plausibility, and the animal-based literature relied upon by their experts does not undercut their opinions. (*See id.*)

As a general matter, the reliance on animal studies for purposes of establishing ***general causation*** has two often-recognized disadvantages. "First, animal study results must be extrapolated to another species—human beings—and differences in absorption, metabolism, and other factors may result in interspecies variation in responses." Green at 346; s*ee also Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 466 (W.D. Pa. 2003); *In re Valsartan*, 2025 WL 3141002, at *24–25. Second, "the high doses customarily used in animal studies require consideration of the dose-response relationship and whether a threshold no-effect dose exists." *Id.* Therefore, the admissibility of animal studies for proving causation in humans requires "good grounds to extrapolate from animals to humans." *In re Paoli*, 35 F.3d at 743.

Here, Defendants challenge Plaintiffs' experts' reliance on animal studies for their ***biological plausibility*** opinions as they relate to their theories on the upward migration of talc—***not*** their general causation opinions. To be sure, animal studies may be relied upon for demonstrating biological plausibility. *See, e.g., In re 3M Combat Arms Earplugs Prods. Liab. Litig.*, No. 3:19-md-2885, 2021 WL 4132269, at *4 (N.D. Fla. Sept. 12, 2021) ("Animal studies may support a biological plausibility opinion so long as an expert explains how and why the animal data can be reliably extrapolated to support conclusions about humans." (citing *In re Abilify*,

299 F. Supp. 3d at 1310)). Along these lines, there is an analytical difference regarding the admissibility of biological plausibility opinions premised on, among other things, animal studies, compared to the admissibility of general causation opinions supported by the same. After all, biological plausibility "lends credence to an inference of causality," Green at 604, but is not itself dispositive of general causation.

Defendants do not acknowledge that there is a distinction to be drawn when assessing reliance on animal studies for general causation purposes as opposed to for biological plausibility purposes. (*See* Defs.' 2024 Biological Plausibility Br. at 19–20 ("[A]nimal studies are not admissible to prove *human causation* absent 'good grounds to extrapolate from animals to humans.'" (emphasis added) (quoting *In re Hum. Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 657 (D.N.J. 2008).) Following a review of those Plaintiffs' experts who rely on or discuss animal studies for support of the biological plausibility of a migratory mechanism, I find that the experts have sufficiently "explain[ed] how and why the animal data can be reliably extrapolated to support conclusions about humans." *In re 3M Combat Arms Earplugs*, 2021 WL 4132269, at *4. For example, Dr. Plunkett explained that rodent ovaries are "completely covered by a bursal sac," unlike human ovaries, which makes migration to ovarian tissue via vaginal penetration more unlikely in rats and mice—thereby limiting detection of ovarian translocation in those species compares with humans.

(*See* Plunkett 3d Amend. Rep. at 35–36, 43–45.) Dr. Cote contrasted species, noting that animal evidence of translocation is inconsistent and "may be species-dependent," with rats showing ovarian talc after intrauterine or, with sufficient time, intravaginal exposure, but rabbits and primates generally not showing translocation in specific experiments. (*See* Cote Amend. Rep. at 13.) These experts, among others, compare or acknowledge human and animal reproductive anatomy to explain why migration observed—or not observed—in animals informs but does not control the plausibility of particle migration in humans.

Additionally, Plaintiffs' experts make clear that their reliance on animal studies is neither the only nor their primary basis for their migration-related biological plausibility opinions. Instead, Plaintiffs' experts rely on a totality-of-evidence approach for determining biological plausibility, for which animal studies provide other support. (*See, e.g.*, McTiernan 3d Amend. Rep. at 94 ("In my opinion, these animal studies . . . . provide[] *further* evidence of a biologically plausible mechanism supporting causation of ovarian cancer from the use of talcum powder products." (emphasis added)); Kane Rep. at 6 ("[A]nimal studies on exposure and disease are performed to advance our understanding of the human response to the same dose-adjusted exposure, and thus animal data is often relevant and important in that it can provide important information that forms part of the total evidence assessment.").) Despite Defendants' objections to certain experts' use of a few select

animal studies, those objections do not render the experts' opinions unreliable just because they are not dispositive, human-based evidence. *See In re Testosterone Replacement Therapy*, WL 1833173, at *14.

Furthermore, several of Plaintiffs' experts recognize that the applicability of animal studies to humans is limited. (*See, e.g.*, Carson Rep. at 7 ("There are a limited number of animal studies suggesting that this transport does not occur. These are not as compelling as the human evidence because of anatomical and physiological differences between animals and humans in this regard, as well as the overwhelming evidence in humans." (citations omitted)); Cote Rep. at 13 ("[A]nimal studies do not provide consistent evidence of translocation of talc—it may be species dependent."); *id.* at 37 ("Human studies were more convincing than animal studies, likely due to the difficulties in replicating what is often a lifetime of use of talc in humans to dosing and administration in animals (whose physiology may not closely align with human female genital tract)."); Kane Rep. at 6 ("Human data is generally more relevant than animal data when assessing causation in humans."); McTiernan 3d Amend. Rep. at 32 ("Given the differences between animals and humans in terms of anatomy of the genital tract, the studies in humans are the most reliable in terms of human health risk assessment and the toxicokinetics of talc applied externally to the perineal area.").)

The experts' discussion of contrary evidence further bolsters the reliability of their methodologies and application. *See In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 449, 461 (E.D. Pa. 2014) (finding expert's "fail[ure] to account adequately for contrary evidence . . . not reliable or scientifically sound"); *In re Mirena Ius Levonorgestrel-Related Prods. Liab. Litig. (No. II)* ("*Mirena II*"), 341 F. Supp. 3d 213, 243 (S.D.N.Y. 2018) ("Where an expert ignores evidence that is highly relevant to his conclusion, contrary to his own stated methodology, exclusion of the expert's testimony is warranted.").

Turning to Defendants' substantive challenges, Defendants criticize Drs. McTiernan and Wolf's reliance on Keskin 2009, and Drs. McTiernan and Plunkett's reliance on Henderson 1986, arguing that neither animal study reliably demonstrates talc migration in the context of human perineal application. (*See* Defs.' 2024 Biological Plausibility Br. at 19–20 & n.32, 34 (citing McTiernan 3d Amend. Rep. at 90, 93; Wolf 3d Amend. Rep. at 16; Plunkett 3d Amend. Rep. at 31, 35–36).)

Keskin 2009 assessed whether long-term perineal or intravaginal talc exposure can be associated with potential carcinogenic effects on the female genital organs of rats. (*See generally* Keskin 2009.) The authors assigned 28 rats to four groups of seven: two control groups, one group receiving intravaginal talc, and one group receiving perineal talc. (*See generally id.* at 925.) After undergoing talc exposure for three months, the authors performed histopathologic evaluation of the

vulva, vagina, uterus, fallopian tubes, ovaries, and peritoneum, and found consistent foreign body reactions, inflammatory changes, and infections in talc-exposed groups. (*See id.* at 925–26.)

Henderson 1986 sought to determine whether exogenous talc can migrate from the lower female genital tract to the ovaries. (*See* Henderson 1986 at 247.) The authors instilled talc suspensions into eight female rats intrauterinely and intravaginally. The study confirmed the presence of talc particles after intrauterine instillation and after four days of intravaginal exposure. (*See id.* at 248.) In other words, the study showed that talc particles introduced into a rat vagina or uterus can migrate to the ovary and localize in ovarian tissue within about four days. (*See id.*)

Defendants first argue that Keskin 2009 is not sufficiently supportive of Plaintiffs' migration theory because "talc was applied in enormous quantities not analogous to human exposure." (Defs.' 2024 Biological Plausibility Br. at 19.) But Drs. McTiernan and Wolf cite Keskin 2009 for support of their theory that talc use causes inflammation and/or oxidative stress, and not for support of talc's migratory potential. (*See* McTiernan 3d Amend. Rep. at 90 ("Talc exposure has also been linked to increased inflammation. It can induce granulomous and other inflammatory responses *in vivo*."); Wolf 3d Amend. Rep. at 16 ("Talcum powder causes inflammation/oxidative stress both *in vitro* and *in vivo* (in both animal and human tissues).").) Therefore, whether these experts appropriately extrapolated Keskin

2009's inflammation-and oxidative stress-related findings to humans will be detailed in the appropriate section below.[53]

Moreover, Plaintiffs' experts appropriately caveat Henderson 1986's findings, noting that animal studies, generally, and Henderson 1986 specifically cannot be solely relied upon for migratory or causal conclusions. (*See, e.g.*, McTiernan 3d Amend. Rep. at 93–94 (assessing animal studies within "weight of evidence" approach); Cote Amend. Rep. at 13 (discussing varied results in talc-related animal studies and concluding that "animal studies do not provide consistent evidence of translocation of talc—it may be species dependent.").)

Defendants next argue that Plaintiffs' experts failed to give due weight to, or improperly ignored, Wehner 1986, which Defendants characterize as demonstrating "no talc migration in monkeys." (Defs.' 2024 Biological Plausibility Br. at 20.) In Wehner 1986, the authors examined whether repeated vaginal depositions of talc in primates would result in translocation to the uterus, oviducts, ovaries, or peritoneal cavity. Over a 45-day period, six primates received more than thirty talc depositions in the posterior vaginal fornix, after which the animals underwent peritoneal lavage and tissue collection, with six untreated primates serving as controls. (*See* Wehner

[53] Even if Dr. McTiernan and Dr. Wolf relied on Keskin 2009 for support "of a mechanism of action opinion rather than a general causation opinion," it constitutes reliable methodology. *See In re Trasylol Prods. Liab. Litig.*, 2010 WL 1489730, at *8 (S.D. Fla. Mar. 19, 2010). Indeed, Keskin 2009 offers evidence of a plausible pathway for talc to migrate from the perineum to the upper reproductive tract, despite lacking an established dose-response scale that can be applied to humans for purposes of causation.

1986 at 329–30.) The authors detected talc in the vagina and cervix of treated animals, but not in the uterus, oviducts, ovaries, or peritoneal lavage flu*Id.* (*See id.* at 329, 331–32.)

Contrary to Defendants' assertion, Wehner 1986 was not ignored by Plaintiffs' experts. Several experts cited, discussed, or expressly analyzed the study. (*See* Plunkett 3d Amend. Rep. at 35–37; Singh Rep. at 57; Wolf 3d Amend. Rep. at 21; Smith-Bindman 3d Amend. Rep. at 21; Carson Rep. at 51.) Dr. Plunkett, in particular, discussed Wehner 1986 at length, noting that it was the only animal study at the time reporting no translocation of talc to the oviducts and contrasting it with other animal and primate studies that did report migration. (*See* Plunkett 3d Amend. Rep. at 35–37.) She further highlighted that the Wehner 1986 authors themselves acknowledged potential explanations for their findings, including lower dosing, use of different materials, and prolonged maintenance of the primates in a supine position, as compared to other studies. (*See* Wehner 1986 at 337.) Dr. Singh similarly observed that differences in timing, assessment techniques, and interspecies considerations in Wehner 1986 preclude ruling out talc migration altogether. (Singh Rep. at 57.) Both Drs. Plunkett and Singh also noted that the study was industry funded, which they considered in assessing its weight. (Plunkett 3d Amend. Rep. at 36; Singh Rep. at 57.)

Rule 702 does not require that every expert address every study bearing on an issue. The fact that only some of Plaintiffs' experts discuss Wehner 1986 does not render their migration-related biological plausibility opinions inadmissible. More to the point, those experts who did consider Wehner 1986 reasonably assessed its limitations, distinguished its unfavorable findings, and evaluated it in the context of other animal studies, human evidence, and regulatory assessments. Any disagreement with the weight those experts accorded the study is properly addressed through cross-examination, not exclusion.[54]

Finally, in support of their third argument, Defendants contend that studies identifying talc in human reproductive tissues do not necessarily or reliably support migration from perineal use, pointing to five specific tissue-identification studies on which several of Plaintiffs' experts rely.[55]

---

[54] Though not discussed by Defendants, it is clear from my prior Opinion that, given my recitation of Dr. Carson's testimony, I considered the implication of Wehner 1986's primate observation and its finding that there was no measurable translocation of talc beyond the cervix. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 173. Defendants do not explain how my prior consideration of Wehner 1986 was erroneous or whether such consideration undermined my biological plausibility ruling under the amended Rule 702.

[55] (*See* Defs.' 2024 Biological Plausibility Br. at 21–25 (citing W.J. Henderson et al., *Talc and Carcinoma of the Ovary and Cervix*, 78 J. Obstet. Gynaecol. Br. Commonw. (3), 266–72 (1971) ("Henderson 1971"); D.S. Heller et al., *The Relationship Between Perineal Cosmetic Talc Usage and Ovarian Talc Particle Burden*, 174 Am. J. Obstet. Gynecol (5), 1507–1510 (1996) ("Heller 1996"); Sandra A. McDonald et al., *Migration of Talc from the Perineum to Multiple Pelvic Organ Sites: Five Case Studies with Correlative Light and Scanning Electron Microscopy*, 152 Am. J. Clinical Pathology (5), 590–607 (2019) ("McDonald I 2019"); Sandra A. McDonald et al., *Correlative Polarizing Light and Scanning Electron Microscopy for the Assessment of Talc in Pelvic Lymph Nodes*, 43 Ultrastruct. Pathol. (1), 13–27 (2019) ("McDonald II 2019"); Kurt E. Johnson et al., *Analytic Comparison of Talc in Commercially Available Baby Powder and in Pelvic*

More specifically, Defendants argue that: (i) Henderson 1971 did not report users' talc exposure, thereby precluding any inference regarding perineal use; (ii) Heller 1996 detected talc in the ovaries of both reported users and non-users, with particle counts unrelated to exposure history, which Defendants contend undermines any association with perineal dusting; (iii) McDonald I 2019 and McDonald II 2019 are anecdotal case reports involving small samples, including findings of talc in certain purportedly unexposed controls, with no reported blinding and an asserted risk of contamination or bias—particularly given the involvement of several Plaintiffs' litigation experts as co-authors; and (iv) Johnson 2020 failed to reliably establish that talc identified in resected pelvic tissue originated from patients' use of Johnson's Baby Powder. (Defs.' 2024 Biological Plausibility Br. at 22–25.) Defendants contend that these studies do not reliably support the biological plausibility of perineal talc migration.

As with the experts' reliance on animal studies, Defendants overstate the import of these studies on Plaintiffs' experts' broader biological plausibility opinions. The experts do not rely solely on these studies to establish the plausibility of talc migration from the perineum to the ovaries or fallopian tubes. Instead, they consider these studies with other migratory-focused studies, as discussed above, that

Tissues Resected from Ovarian Carcinoma Patients, 159 Gynecologic Oncology (2), 527–33 (2020) ("Johnson 2020").)

collectively support their biological plausibility theories. Significantly, in addition to this body of literature, Plaintiffs' experts also rely on regulatory assessments that have acknowledged or endorsed migration as a plausible biological pathway. For example, several of Plaintiffs' experts expressly rely on statements from the FDA, IARC and Health Canada to support their opinion that perineally applied talc can migrate from the perineum through the genital tract and thus provide a biologically plausible pathway to the ovaries. (*See, e.g.*, Moorman Rep. at 33 (finding support of migration from pathology studies and FDA's 2014 response stating that "the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable"); Singh Supp. Rep. at 14 (relying on, *inter alia*, Health Canada's assessment to support migration as "mode of action"); McTiernan 3d Amend. Rep. at 94 (considering Health Canada assessment and its determination that "perineal application of talc results in migration to ovaries and fallopian tubes").)

Of particular note is Health Canada's "mode of action" section in its recent April 2021 Screening Assessment of talc, which expressly recognizes retrograde particle movement as a biologically plausible pathway, noting that "[m]igration or retrograde movement of talc particles from the vagina to the ovaries has been identified as a plausible explanation of . . . talc particles in the upper reproductive tract." (*See* Health Canada Screen Assessment 2021 at 19 (citing Henderson 1986;

Heller 1996; 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 Obstet. & Gynecol. (2), 498–501 (2007) ("Cramer 2007").); *see also id.* at 34 ("Overall, the available animal and human studies described . . . clearly indicate that particles, including talc, may transfer from the vagina to the fallopian tubes and ovaries following perineal application.").)[56]

Substantively, the experts' reliance on the challenged studies does not undermine the reliability of their biological plausibility opinions or the manner in which those opinions were reached. Defendants' critiques largely isolate individual studies and fault them for acknowledged limitations. In that regard, they first challenge the reliance of Drs. Clarke-Pearson, Cote, Kane, McTiernan, Singh, and Smith on Henderson 1971—which reported talc particles embedded in ovarian and cervical tumor tissue but did not identify the exposure source or trace an anatomic route—by arguing it "does not plausibly show migration" because the study did not report whether the tissue donors used perineal talc. (*See generally* Henderson 1971.)

Plaintiffs' experts do not suggest otherwise. As reflected in their reports, the experts characterize Henderson 1971 as providing indirect support for migration by

[56] I also note that Defendants strenuously object to my consideration of the Health Canada Screening Assessment 2021, which they contend is unreliably based on a meta-analysis, is ripe with bias, and fails to support the conclusions drawn therefrom. (*See* Nov. 25, 2025 Tr. at 48:25–52:10.) But Defendants' objections are not specific to migration. Moreover, as indicated, other agencies than Health Canada have made similar conclusions regarding talc migration.

demonstrating that talc can be present in upper genital tract tissues, while recognizing that the study does not establish how the particles arrived there. (*See, e.g.*, Clarke-Pearson 3d Amend Rep. at 7, 12; Cote Amend. Rep. at 13; Smith Rep. at 18.) Indeed, as observed by the experts, while Henderson 1971 does not purport to prove migration, it nevertheless provides an early observational data point consistent with the plausibility of transport, which the experts then evaluate alongside later and more targeted studies. Used in this limited manner, the experts did not unreasonably extrapolate Henderson 1971's conclusion.

Defendants similarly object to the experts' reliance on Heller 1996, arguing that the study cannot support their opinions because it detected talc in ovarian tissue from both reported perineal users and non-users and found talc particle counts to be "completely unrelated" to reported exposure, thereby failing, in Defendants' view, to demonstrate migration or causation. (Defs.' 2024 Biological Plausibility Br. at 22–23.) Plaintiffs' experts, however, do not overstate the significance of Heller 1996's findings.

Heller 1996 examined ovarian tissue from twenty-four women to assess whether talc burden correlated with reported perineal talc use. (*See generally* Heller 1996.) The study detected talc in all ovaries examined, regardless of self-reported use, and did not find a clear exposure–burden correlation. (*See generally id.*) Plaintiffs' experts acknowledge that Heller 1996 does not establish trace exposure

source. Instead, they rely on the study for the narrower proposition that talc can be found in ovarian tissue, and thus, can reach that anatomical site—an inference that bears on plausibility of mode of migration. Several experts, including Dr. Plunkett, expressly recognize the study's limited findings, including the potential for misclassification of exposure, while explaining why those limitations do not negate the study's relevance to the migration question. (Plunkett 3d Amend. Rep. (discussing limitations but opining that "the results showing higher overall particles counts in women reporting perineal application of talc are nevertheless consistent with the ability of talc particles to migrate up the female reproductive tract"); *see also* Singh Rep. at 57 (acknowledging that in Heller 1996, the "talc particle counts were unrelated to reported levels of perineal talc exposure," which "reflects the challenges in measuring exposure to talc"); Cote Amend. Rep. at 13 (recognizing the authors' suggestion that the results may be "due to widespread exposure to talc during diapering").)

More recent studies provide additional context and support.[57] McDonald I 2019 identified talc particles in multiple pelvic tissues—including lymphatic sites—of women with a reported history of perineal talc use. (*See generally* McDonald I

[57] By Defendants' account, Drs. Cote, Clarke-Pearson, and Harlow reference or specifically rely on McDonald I 2019, and Drs. Plunkett and Singh cite to or expressly rely on McDonald II 2019, in broad support of their biological plausibility opinions. (*See* Defs.' 2024 Biological Plausibility Br. at 22 n.42.) Similarly, Drs. Cote, Plunkett, and Singh reference Johnson 2020 for the same or similar reasons. (*See id.*)

2019.) Plaintiffs' experts rely on this finding for the limited and appropriate purpose of assessing the plausibility of a migration pathway. In their reasoned view, the presence of talc across multiple pelvic locations, rather than in a single isolated site, supports the inference that talc is capable of tissue transport and deposition within the pelvic region. (*See, e.g.*, Cote Amend. Rep. at 13; Clarke-Pearson 3d Amend. Rep. at 12; Plunkett 3d Amend. Rep. at 39–40.) The experts do not extrapolate from these observations to draw definitive conclusions regarding exposure, dose, or causation, nor do they treat the study as dispositive. *Compare id.*, *with* McDonald I 2019 at 590, 603, 605; *see also id.* at 590, 605 (concluding that this study "offer[s] new insight into the biologic potential of talc, its inflammatory potential, and its migration via pelvic lymphatics from the perineum").)

McDonald II 2019, which was expressly designed to address contamination concerns raised in earlier literature, similarly detected talc in pelvic lymph nodes under controlled conditions. (*See generally* McDonald II 2019.) Plaintiffs' experts cite this study to corroborate the biological feasibility of migration via pelvic or lymphatic pathways, again stopping short of asserting proof. (*See, e.g.*, Plunkett 3d Amend. Rep. at 39–40.) Used in this circumscribed manner, the experts' reliance on McDonald I and McDonald II reflects a reasoned and methodologically sound application of the literature, not an unreasonable or unsupported extrapolation under Rule 702.

Likewise, Johnson 2020 compared talc particle size and morphology in commercial talc products with particles identified in pelvic tissues from ovarian cancer patients reporting perineal talc use. The study found that the dominant particle class in consumer talc products closely matched the dominant class detected in pelvic tissues. (*See* Johnson 2020 at 531–32.) The authors interpreted this similarity as consistent with externally applied talc reaching pelvic sites. (*See, e.g.*, *id.* at 523 ("In conclusion, our study lends support to the contention, also evidenced by other literature reports, that externally-applied talc can migrate from the perineum to other pelvic sites . . . .").) In that regard, Plaintiffs' experts rely on Johnson 2020 for precisely that limited inference—consistency in particle characteristics—not as a standalone proof of exposure pathway.

While Defendants devote much of their argument in this context to attacking the studies underlying Plaintiffs' experts' opinions, I cannot find that Plaintiffs' experts overstated or mischaracterized these studies' conclusions. To the contrary, the experts' reports consistently and accurately describe what each study does—and does not—demonstrate, and explain how each fits within a broader evidentiary framework. (*See, e.g.*, Clarke-Pearson 3d Amend. Rep. at 7 (reporting Henderson 1971's findings of "talc ha[ving] been identified deeply imbedded in ovarian cancer tissue samples"), 12 (citing Henderson 1971, Heller 1996, Johnson 2020, and other studies to support opinion that "the female reproductive tract is open and allows

migration of potential pathogens into peritoneal cavity"); Cote Rep. at 13 ("[Henderson 1971, Heller 1996, McDonald I 2019, Johnson 2020] suggest that perineal use of talc can and does make its way into tissues in the reproductive tract, including the ovaries and fallopian tubes."); Kane Rep. at 14 ("[Henderson 1971, Heller 1996, and other studies] have demonstrated the presence of talc in ovarian tissue."), 16 ("Henderson [1971] first observed talc particles embedded in both ovarian tumors and normal ovaries."); McTiernan 3d Amend. Rep. at 88–89 (discussing studies that "have shown that talcum powder products can migrate to the ovaries and fallopian tubes"); Singh Rep. at 18 (citing Henderson 1971, Heller 1996, and other studies for the theory that "[t]alcum powder particles can migrate to the fallopian tubes and ovaries"), 57 (citing Henderson 1971, Heller 1996, and other studies for support that "[g]enital talc can migrate up the fallopian tubes and ovaries and talc particles have been detected within the ovaries of women who report perineal talc use"); Singh Supp. Rep. at 14–15 (summarizing McDonald I 2019 and McDonald II 2019 as evidence of retrograde migration and citing Johnson 2020 for "additional proof of retrograde migration of talc particles"); Plunkett 3d Amend. Rep. at 31 (citing, *inter alia*, Heller 1996 as "demonstrating the presence of talc particles in the ovaries of women who had reported use of talcum products in the genital area"), 31 (finding the McDonald studies corroborate the FDA's 2014 migratory plausibility conclusion), 37–38 (recognizing Heller 1996 as "a small piece

of the overall evidence that supports the ability of talc to migrate from the vagina to the ovaries"); Wolf 3d Amend. Rep. at 14 (citing Henderson 1971, Heller 1996, and other studies for "conclud[ing] that [the presence of talc particles in the adnexa, ovaries, and peritoneum] occurs as a result of migration of talc particles from the vagina through the cervix, uterus, and fallopian tubes"); Smith Rep. at 16 (citing Henderson 1971, among other studies, for support that "the female genital tract functions as a conduit for foreign material to enter the peritoneal cavity").

Far from treating any single study as conclusive, Plaintiffs' experts expressly acknowledge the limitations of the literature on which they rely, including contrary findings, contamination concerns, species differences in animal models, and the absence of direct human experimentation. They nevertheless explain—through reasoned analysis—why the collective body of evidence supports the biological plausibility of talc migration through the female reproductive tract. This acknowledgment of limitations, coupled with an explanation of why the experts find the supporting evidence more persuasive, reflects methodological rigor rather than unreliability. (*See, e.g.*, Plunkett 3d Amend. Rep. at 37–38 (acknowledging criticism of Heller 1996 "that women reporting no perineal use had talc detected in ovarian tissue"); Clarke-Pearson 3d Amend. Rep. at 12 ("I have reviewed the small body of literature suggesting that migration of particles does not occur and do not think these studies are compelling."); Wolf 3d Amend. Rep. at 14–15 ("I have considered the

limited evidence to the contrary and find it non-persuasive."); Carson Rep. at 7 ("There are a limited number of animal studies suggesting that this transport does not occur. These are not as compelling as the human evidence because of anatomical and physiological differences between animals and humans in this regard, as well as the overwhelming evidence in humans."); *see also* Plunkett 3d Amend. Rep. at 37 (discussing no evidence of translocation in Wehner 1986).)

From a Rule 702 standpoint, this approach is consistent with accepted scientific practice. Plaintiffs' experts do not present indirect or incomplete studies as definitive proof.[58] Instead, they synthesize multiple lines of evidence—including human observational findings, tissue-identification studies, mechanistic research, and anatomical considerations—to assess biological plausibility. In other words, the experts' conclusions drawn from the confluence of these studies are reasonable.

As before, Defendants ask that I disaggregate the literature and reject plausibility unless each study independently establishes migration. Rule 702 does not impose that requirement. Biological plausibility may be supported by cumulative, indirect, and mechanistic evidence, so long as the expert explains how that evidence is reasonably interpreted. *See, e.g.*, *In re PPA*, 289 F. Supp. 2d at 1241 (finding an expert's opinion on biological plausibility reliable when supported by

[58] Nor have Defendants identified intervening "new science" that undermines the evidentiary foundation upon which these opinions rest or demonstrates that the experts' reasoning is unsound under the amended Rule 702 standard.

the "cumulative effect" of evidence, including reliance on "reports, textbooks and treatises, and the clinical experience of several experts and other scientists" as well as other evidence). Accordingly, I find, as I did previously, that Plaintiffs' experts have established by a preponderance of the evidence that their biological plausibility opinions regarding talc migration are grounded in sufficient facts and data and reflect a reliable application of scientific principles to the available evidence.

As to Plaintiffs' inhalation-and-lymphatic transport migration theory, Defendants assert that I correctly excluded this theory in my prior Opinion and urge that I do so again. (*See* Defs.' 2024 Biological Plausibility Br. at 25–27.) Plaintiffs respond by arguing that the reliability of their experts' opinions on inhalation has strengthened with the advent of additional evidence. (*See* Pls.' Opp. to Defs.' 2024 Biological Plausibility Br. 28–30.) I disagree with Plaintiffs and find that there remains an insurmountable absence of data supporting this theory.[59]

Plaintiffs point to additional studies and regulatory assessments that they contend support their expert's opinions that talc can reach the ovaries via inhalation.[60] As an initial matter, Plaintiffs' experts appear to, again, rely upon

[59] Additionally, Plaintiffs do not argue that my prior exclusion of the inhalation theory "demonstrably fail[ed] to adhere to Rule 702 as clarified by the 2023 amendments." (*See generally* Pls.' Opp. to Defs.' 2024 Biological Plausibility Br.; *see also* April 30, 2024 Memorandum Order.) Therefore, to the extent Plaintiffs' experts rely on studies previously considered, I see no basis to revisit my prior decision excluding Plaintiffs' theory on inhalation.

[60] (*See* Pls.' Opp. to Defs.' 2024 Biological Plausibility Br. 28–30 (citing, *e.g.*, Health Canada Screening Assessment 2021; Joan E. Steffen et al., *Serous Ovarian Cancer Caused by Exposure*

studies that I considered or addressed in my prior Opinion. (*See, e.g.*, Kane Rep. at 4, 14; Moorman Rep. at 33; McTiernan 3d Amend. Rep. at 89, 101; Wolf 3d Amend. Rep. at 15; Plunkett 3d Amend. Rep. at 30.) But the new studies referenced by these experts are insufficient to bridge the "analytical gap" between inhalation of talcum powder and its potential migration to ovaries and/or fallopian tubes. *See In re Hum. Tissue*, 582 F. Supp. 2d at 656.

First, Plaintiffs point to the "extensive review of the scientific evidence on inhalation of talc" contained within Health Canada Screening Assessment 2021, which includes discussion of McDonald II 2019. (*See* Pls.' Opp. to Defs.' 2024 Biological Plausibility Br. at 28–30.) Contrary to Plaintiff's position, however, Health Canada Screening Assessment 2021 states, among other things, that "whether inhalation of talc particles could result in ovarian exposure due to lymphatic transfer of particles or whether responses may be immune-mediated has not been adequately investigated for use in mode of action analysis." (*See* Health Canada Screening Assessment 2021 at 45.) Indeed, Plaintiffs' reference to the identified health effects following inhalation of "respirable talc particles" does not address or support the migration of those talc particles via inhalation to ovaries or fallopian tubes. (*See* Pls.' Opp. to Defs.' 2024 Biological Plausibility Br. at 28 (citing Health Canada

to Asbestos and Fibrous Talc in Cosmetic Talc Powders-A Case Series, 62 J. Occup. & Env't Med. (2), e65–e77 (2020) ("Steffen 2020"); McDonald II 2019 at 13–27.)

Screening Assessment 2021 at 41); *see also* Health Canada Screening Assessment 2021 at 43 ("Based on the available data, ovarian cancer was identified as a critical health effect for the perineal route of exposure to talc.").) Similarly, Health Canada's assessment of McDonald II 2019 does not support migration via inhalation, because McDonald II 2019 was a method-focused study observing talc entry into pelvic tissues and regional nodes after perineal exposure. (*See generally* McDonald II 2019.)

Lastly, and as discussed in greater length with respect to the admissibility of Dr. Godleski's opinions and testimony, Steffen 2020 is not sufficiently supportive of this inhalation theory. Steffen 2020 reports a litigation-linked case series of 10 women with serous ovarian cancer who used cosmetic talc. (*See generally* Steffen 2020.) The case series asserts that perineal use can produce "important inhalation exposure to asbestos," and characterizes inhalation as an "accepted route of transmigration to the peritoneum and ovary." (*See id.* at e69.) But standing alone, Steffen 2020 does not offer sufficient scientific support or reasoning for a migration-via-inhalation theory.

In sum, Plaintiffs' renewed reliance on inhalation-and-lymphatic transport does not cure the fundamental analytical deficiencies that led to exclusion of this theory in my prior Opinion. The additional studies and regulatory materials cited by Plaintiffs do not supply reliable data linking inhalation of cosmetic talc to deposition

in the ovaries or fallopian tubes, nor do they meaningfully narrow the analytical gap between pulmonary exposure and ovarian tissue presence. To the contrary, the Health Canada Screening Assessment expressly acknowledges that ovarian exposure via inhalation and lymphatic transfer has not been adequately investigated, and it identifies ovarian cancer as a critical health effect associated with perineal—not inhalation—exposure. The McDonald studies, including McDonald II 2019, address migration following perineal exposure and do not support inhalation-based transport. Steffen 2020, standing alone, offers a litigation-linked case series that asserts—but does not scientifically substantiate—a migration pathway via inhalation.

Accordingly, despite Plaintiffs' characterization of the record as "strengthened," the evidentiary landscape remains materially unchanged. The inhalation theory continues to rest on speculation rather than reliable scientific evidence and fails to satisfy Rule 702's requirement that expert opinions be grounded in sufficient facts and data and the reliable application of scientific principles. I therefore recommend the Court reaffirm my prior ruling excluding Plaintiffs' experts' inhalation-and-lymphatic transport migration theory, and I preclude Plaintiffs' experts from testifying regarding this unsubstantiated theory.

c. Inflammation, Oxidative Stress, and Macrophage-Impairment

Lastly, Defendants move to exclude the experts' biological plausibility opinions on the ground that they have not identified a biologically plausible mechanism by which perineal talc could cause ovarian cancer. (*See, e.g.*, Defs.' 2024 Biological Plausibility Br. at 27.)

Defendants take the same tack here as with migration, urging exclusion by attacking the literature on which Plaintiffs' experts rely. In broad terms, Defendants first contend that the experts ignore the absence of histological evidence that talcum powder causes chronic inflammation; that animal studies are non-analogous and therefore uninformative; and that clinical uses of talc, i.e., pleurodesis, reflect reactions unrelated to chronic inflammation and carcinogenesis. (*See id.* at 28–31.) Second, Defendants argue that Plaintiffs' experts' reliance on *in vitro* studies for evidence of "subcellular markers of inflammation or oxidative stress" is unreliable both in principle and in application—i.e., as a general scientific approach and as the basis for the specific conclusions they draw. (*See id.* at 31–35.) Third, Defendants attack "review articles," among other studies on which Plaintiffs' experts rely, arguing they are methodologically weak and do not establish that chronic inflammation causes ovarian cancer. (*See id.* at 36–41.) Fourth, Defendants challenge Plaintiffs' experts reliance on Harper/Saed 2023 for the proposition that talc exposure allegedly induces "malignant transformation" of normal human

primary epithelial cells *in vitro*. (*See id.* at 41–45.) Finally, Defendants argue that Plaintiffs' macrophage-inhibition theory should be excluded because it rests only on two *in vitro* mouse-cell studies that generate a hypothesis, thereby making the theory impermissibly speculative and not plausible under the correct Rule 702 standard. (*See id.* at 45–58.)

Plaintiffs oppose exclusion on these grounds by arguing that their experts meet Rule 702's reliability standard because biological plausibility requires a credible, evidence-based mechanism—not definitive proof—and their experts synthesize the totality of available evidence that talc can plausibly cause ovarian cancer via chronic inflammation and related oxidative stress. (*See* Pls.' Opp. to Defs.' 2024 Biological Plausibility Br. at 30–31.) Substantively, Plaintiffs point to peer-reviewed literature linking chronic inflammation to carcinogenesis in ovarian tissue and documenting pro-inflammatory and oxidative effects from talc and/or asbestos exposure. (*See id.* at 31–43.) Plaintiffs emphasize that their experts' reliance on *in vitro* studies is appropriate—both as a general scientific approach and in specific studies—to show that talc can trigger chronic inflammation and oxidative stress. (*See id.* at 43–45.) Plaintiffs also summarize the literature linking chronic inflammation to ovarian cancer, including Harper/Saed 2023, to correct what they claim are Defendants' misunderstandings and mischaracterizations of the studies upon which their experts rely. (*See id.* at 45–52.) Additionally, Plaintiffs respond

that opinions premised on certain macrophage studies are admissible under a totality of evidence approach to demonstrate that talc can alter macrophage function, which may in turn cause ovarian cancer. (*See id.* at 52–53.)

Once again, Defendants' arguments largely rest on the premise that my prior Opinion applied the wrong legal standard or otherwise departed from Rule 702 as clarified in 2023. In relevant part, my prior Opinion evaluated the admissibility of opinions regarding the association between talc use and inflammation and oxidative stress, as well as the related association between inflammation and oxidative stress and ovarian cancer. During the first round of *Daubert* motions, Plaintiffs offered Dr. Saed as an expert in oxidative stress and ovarian cancer. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 130, 132. Ultimately, I permitted Dr. Saed to testify that talcum powder exposure can induce cellular inflammation and oxidative stress based on his *in vitro* work because his methods were testable, peer-reviewed, and involved generally accepted techniques. *See id.* at 140. I excluded, however, Dr. Saed's extrapolation that such inflammation, which itself is represented as a pro-carcinogenic process involving oxidative stress, causes ovarian cancer because his *in vitro* study did not demonstrate malignant transformation, actual single nucleotide polymorphisms mutations, or clinically relevant biomarkers. *See id.* at 135–140.

For Plaintiffs' previously proffered experts' Bradford Hill analyses, I allowed testimony that talc can plausibly migrate through the female reproductive tract and

that chronic inflammation and oxidative stress in ovarian tissue could contribute to carcinogenesis. *See id.* at 172–75. I reviewed the current science as provided by the parties, which largely consisted of peer-reviewed *in vitro* work and otherwise accepted methods, and noted the absence of definitively contrary evidence. *See id.* In permitting admission, I emphasized that biological plausibility requires a credible, science-based mechanism rather than certainty or proof; opinions must be grounded in reliable science rather than an expert's say-so. *See id.* Consistent with these boundaries, I permitted Defendants' expert, Dr. Benjamin Neel, to rebut only Dr. Saed's admissible inflammation and oxidative stress opinions, reinforcing the gatekeeping line between plausible cellular-level effects and unsupported causation inferences. *See id.* at 195–98.

Now, and in view of my prior ruling, Defendants essentially contend that my prior ruling cannot stand because a biological plausibility hypothesis based on scientific research and reasoning is inadmissible if it is not definitively proven. (*See* Defs.' 2024 Biological Plausibility Br. at 27–28 (citing *In re Acetaminophen*, 707 F. Supp. 3d at 350; *In re Accutane Prods. Liability*, 511 F. Supp. 2d 1288, 1296 (M.D. Fla. 2007)); *see also id.* at 7–8.) That is not the governing standard, and my prior Opinion correctly declined to require definitive proof. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 175.

I start with Defendants' reliance on *In re Acetaminophen* and *In re Accutane*, which I find unpersuasive. (*See* Defs.' 2024 Biological Plausibility Br. at 27–28.) In *In re Acetaminophen*, the district court excluded plaintiffs' experts' biological plausibility opinions because their methodologies and evidence did not reliably establish a mechanism by which prenatal acetaminophen exposure causes neurodevelopmental disorders, including autism spectrum disorder ("ASD") and/or attention deficit/hyperactivity disorder ("ADHD"). 707 F. Supp. 3d at 309. Specifically, the court excluded Dr. Baccarelli's plausibility conclusions because the physiological processes for ASD/ADHD were unknown at the time of writing and because his theories were premised on the unreliable opinions of other experts. *See id.* at 351. The court also excluded Dr. Cabrera's mechanistic opinions because, among other things, he failed to "identify a mechanism by which either ASD or ADHD is created in utero." *Id.* at 358–59. The court criticized Dr. Cabrera's reliance on the Organisation for Economic Co-operation Development's "Adverse Outcome Pathway 20," which is built around mercury and oxidative stress leading to learning and/or memory impairment, because it did not reliably map to acetaminophen or to ASD or ADHD. *Id.* On the key-oxidative stress step, the court emphasized the absence of replicated data and the misplaced reliance on inapposite human studies and inconsistent behavioral animal evidence. *See id.* at 359–61. In other words, the court excluded Dr. Cabrera's biological plausibility opinion because his

methodologies created an analytical gap and failed reliable application, not because causation was not conclusively proven. *In re Acetaminophen* did not alter Rule 702 or impose any requirement of "definitive" mechanistic proof; rather, the court applied the ordinary gatekeeping standard—which asks whether, more likely than not, the opinion rests on sufficient facts, reliable principles, and a reliable application.

In *In re Accutane*, the District Court for the Middle District of Florida excluded plaintiffs' expert's biological plausibility opinion that Accutane disrupts gastrointestinal mucosal integrity, which can initiate or amplify inflammatory responses, and thus, induce or exacerbate inflammatory bowel syndrome ("IBS"). 511 F. Supp. 2d at 1295–96. In excluding plaintiffs' expert's opinion, the court observed that the three proposed mechanisms were largely untested hypotheses lacking general acceptance in the scientific community at the time—and, critically, that plaintiffs' expert expressly acknowledged these limitations. *See id.* at 1296–97.

The court's statement that plaintiffs' expert's biological theory was "merely plausible, not proven" does not impose a requirement of definitive proof; it reflects the lack of reliable, scientifically validated support for any proposed mechanism or epidemiologic evidence of increased incidence, and thus falls squarely within Rule 702's reliability inquiry rather than a demand for correctness. *See id.* Accordingly, *In re Accutane* does not alter the admissibility standard under amended Rule 702. It

instead reaffirms that plausibility, absent reliable methodology and data, is insufficient for admissibility—not that definitive proof is required. *See id.*

Here, Plaintiffs' experts' biological plausibility opinions do not suffer from the same fatal flaws that led the courts in *In re Acetaminophen* and *In re Accutane* to exclude biological plausibility and mechanistic opinions. As will be explained below, Plaintiffs' experts' reliably employ methodologies that support their respective opinions. Unlike in *In re Acetaminophen*, for example, Plaintiffs' experts here do not "cherry-pick[] isolated findings, ignor[e] inconsistent findings, and disregard[] limitations expressed by" the studies' authors. *In re Acetaminophen*, 707 F. Supp. 3d at 361.

Defendants also contend that, in admitting testimony regarding the biological plausibility of talc leading to chronic inflammation, I impermissibly shifted the burden of proof. (*See* Defs.' 2024 Biological Plausibility Br. at 5 (citing *In re Johnson & Johnson*, 509 F. Supp. 3d at 175 ("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.")).) Defendants misinterpret my prior ruling. The language Defendants seize upon was used to underscore the absence of meaningful scientific criticism or contrary evidence in the relevant literature that would call into question the plausibility of Plaintiffs' experts' theory. In context, my prior observation that

Defendants had not introduced evidence disproving the hypothesis did not serve as the basis for admissibility. Instead, it reflected that Plaintiffs' experts' opinions were not contradicted by established scientific findings that would render their proposed mechanism implausible. The admissibility determination rested on Plaintiffs' affirmative showing—through reliable scientific literature, mechanistic reasoning, and expert analysis—that perineal talc migration and resulting chronic inflammation and/or oxidative stress constitute plausible biological mechanisms under *Daubert* and Bradford Hill. Defendants' argument ignores that context and mischaracterizes the rationale for the prior ruling.

Against that backdrop, I will now turn to Defendants' substantive arguments. As follows, I will first address the parties' arguments on the admissibility of expert opinion and testimony concerning the association between talcum powder use and chronic inflammation and oxidative stress; second, on the association between inflammation and oxidative stress and the development of ovarian cancer; and finally, on Plaintiffs' macrophage-inhibition theory.

(1) Talcum powder and chronic inflammation, oxidative stress

I begin with Defendants' objections to expert testimony concerning the purported association between perineal talc use and chronic inflammation and oxidative stress. Plaintiffs' experts—including Drs. Carson, Clarke-Pearson, Kane, Levy, McTiernan, Moorman, Plunkett, Siemiatycki, Singh, Smith, Smith-Bindman,

Wolf, and Cote—opine that talc use is associated with chronic inflammation and oxidative stress. In forming these opinions, Plaintiffs' maintain that their experts rely on various bodies of scientific literature,[61] as well as their professional experience and subject-matter knowledge.

First, Defendants argue that Plaintiffs' experts, including Dr. Cote, ignore the absence of histological evidence that talcum powder causes chronic inflammation. (*See* Defs.' 2024 Biological Plausibility Br. at 28–29.) For support, Defendants point to Henderson 1971 and Heller 1996 as examples of studies that demonstrate that talc does *not* induce inflammation. (*See id.*) As discussed within the context of Plaintiffs' experts' migration-related opinions, Henderson 1971 is a study that used extraction and replication "to examine tissue from patients with ovarian and cervical tumours" and that ultimately revealed talc particles embedded within ovarian and cervical tumor tissues. Henderson 1971 did not assess or report inflammatory histopathology. Heller 1996 was a pathoepidemiologic study that examined ovaries from women with and without reported perineal talc use and explicitly looked for histologic evidence of tissue reaction. Ultimately, the authors found no inflammatory response associated with ovarian talc particles.

---

[61] It bears emphasis that Defendants challenge many of the same studies on which Plaintiffs' experts rely to support both their migration opinions and their opinions that talc use is associated with chronic inflammation as a causally relevant mechanism. Accordingly, in addressing Defendants' objections to the studies relied upon by Plaintiffs' experts in support of their chronic-inflammation theory, I incorporate by reference the earlier substantive discussion of those studies to the extent relevant to the arguments presented here.

Responding to Defendants' contention, Plaintiffs point to a vast body of largely unchallenged research and regulatory assessments relied upon and referenced by their experts that show the plausible association between talc exposure and chronic inflammation. (*See* Pls.' Opp. to Defs.' 2024 Biological Plausibility Br. at 31–30 & n.94–125.) As I have stressed, Plaintiffs' experts anchor their biological plausibility opinions in the totality of evidence, and not any one particular study. (*See, e.g.*, Singh Supp. Rep. at 22 (emphasizing that "body of evidence" strengthens biological plausibility); Smith-Bindman 3d Amend. Rep. at 33–34, 37–38 (addressing, *inter alia*, biological plausibility within "totality of evidence" framework); Clarke-Pearson 3d Amend. Rep. at 2, 13 (considering "extensive body of literature in its totality" and "using the concepts outlined by Bradford Hill" in forming causation-related opinions); Kane Rep. at 37–38 (detailing biologically plausible mechanisms as part of integrated analysis).) As such, Defendants' criticism of one or two isolated studies does not undermine the remaining body of evidence upon which the experts rely.

But even solely focusing on the substance of Henderson 1971 and Heller 1996, while these two older studies did not report that talc exposure causes chronic ovarian inflammation, their findings do not undercut the reliability of Plaintiffs' experts' methodologies. Henderson 1971 did not discuss inflammation as a mechanism or histologic finding. Therefore, Defendants' contention that Henderson

1971 did "not report that [talc] induced any inflammation" is misleading. (*See* Defs.' 2024 Biological Plausibility Br. at 28 & n.53.) Defendants notably omit, however, the authors' conclusion that "[a]lthough it is impossible to incriminate talc as a primary cause of carcinomatous changes within either the cervix or ovary on the preliminary observations described [in the study], the possibility that talc may be related to other predisposing factors should not be disregarded and further investigations are obviously required." (*See* Henderson 1971 at 271.)

Furthermore, while Heller 1996 found "no evidence of response to talc, such as foreign body giant cell reactions or fibrosis in the tissue," (Heller 1996 at 1508), Plaintiffs rely on or reference other, more recent studies to assert the link between talc use and inflammation, (*see* Pls.' Opp. to Defs.' 2024 Biological Plausibility Br. at 31–30 & n.94–97, 99–103, 105–115, 117–125).[62] Despite Heller 1996's contrary findings, the existence of conflicting evidence is not a sufficient basis to exclude an expert's opinion or anticipated testimony. *See ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 290 (3d Cir. 2012). Emphasis on a methodologically unchallenged, albeit purportedly contrary, study in view of a larger body of evidence is fodder for cross-examination and does not upend an expert's opinion under the governing standard.

---

[62] *See* Woolen 2022; Paul K. Mills et al., *Perineal Talc Exposure and Epithelial Ovarian Cancer Risk on the Central Valley of California*, 112 Int'l J. of Cancer (3), 458–64 (2009); Melissa A. Merritt, *Talcum Powder, Chronic Pelvis Inflammation and NSAIDs in Relation to Risk of Epithelial Ovarian Cancer*, 122 Int'l J. of Cancer (1), 170–76 (2008); *see also* Health Canada Screening Assessment 2021.

Defendants further fault Dr. Cote and other experts for purportedly lacking knowledge of studies examining an association between talcum powder use and chronic inflammation in humans. (*See* Defs.' 2024 Biological Plausibility Br. at 29 (citing, e.g., Cote Dep. at 217:6–14 ("I don't know of a systematic study that has examined [inflammation or granulomatous reaction in the reproductive tract or gynecologic tissue of a woman who used talc and got ovarian cancer]."); ECF No. 33013-54 ("Harlow Dep.") at 392:3–8 ("I don't know of any studies [reporting talc in the presence of inflammation in the ovary before ovarian cancer has been diagnosed].")).) That argument mischaracterizes both the testimony and the context in which it was given. Neither Dr. Cote nor Dr. Harlow conceded a lack of familiarity with relevant scientific literature. Rather, Dr. Cote testified that she was unaware of any study specifically assessing inflammation in the reproductive tract or other gynecologic tissues of women who used talc and *later* developed ovarian cancer. (*See* Cote Dep. at 217:6–14.) Dr. Harlow similarly testified that he was not aware of studies documenting talc in the presence of ovarian inflammation *prior* to an ovarian cancer diagnosis. (*See* Harlow Dep. at 392:3–8.) Notably, neither Plaintiffs nor Defendants identify the existence of any such studies. In other words, Defendants do not point to overlooked or ignored literature; instead, they rely on testimony acknowledging the absence of studies that would directly resolve the question. The absence of dispositive human studies, however, does not require exclusion of an

expert opinion, so long as other factors support the reliability of the methodology employed. *See In re Hum. Tissue*, 582 F. Supp. 2d at 656–57 (recognizing that the lack of studies either proving or disproving a causal hypothesis is not, standing alone, fatal to admissibility).

Second, Defendants argue that Plaintiffs' experts rely on several animal studies that they contend are unsupportive of their opinions regarding the association between talc exposure and chronic inflammation. (*See* Defs.' 2024 Biological Plausibility Br. at 29–30.) They challenge the reliability of Plaintiffs' experts' methodologies on the basis that they improperly rely on Keskin 2009.[63] First, Defendants contend that Keskin 2009 does not demonstrate talc-induced neoplastic change.[64] (*See* Defs.' 2024 Biological Plausibility Br. at 29.) Second, Defendants assert that certain Plaintiffs' experts—such as Drs. McTiernan, Wolf, and Moorman—ignored that limitation. (*See id.*) Both arguments are unavailing.

As discussed, Keskin 2009 provides experimental evidence that repeated intravaginal or perineal talc exposure elicits a local inflammatory response in rat genital tissue. (*See* Keskin 2009 at 925 (concluding that "[t]alc has unfavorable

---

[63] Defendants previously challenged Plaintiffs' experts' reliance on Keskin 2009, insofar as it failed to demonstrate upward migration following perineal application.

[64] Interestingly, Defendants argued during the last round of *Daubert* motions that Plaintiffs' experts improperly failed to consider Keskin 2009 in forming their coherence opinions—not that their consideration of Keskin 2009 undermined their biological plausibility opinions. (*See* Defs.' 2024 General Causation Br. at 86.) I addressed this argument in my prior Opinion. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 183.

effects on the female genital system," but that "this effect is in the form of foreign body reaction and infection, rather than being neoplastic").)[65] Defendants do not adequately explain how the authors' observation that the study did not identify neoplastic change undermines Plaintiffs' experts' methodologies or opinions. Plaintiffs' experts cite Keskin 2009 for the limited and appropriate purpose of demonstrating talc's capacity to induce inflammatory responses, not as proof of tumorigenesis. (*See* McTiernan 3d Amend. Rep. at 90 ("Talc exposure has also been linked to increased inflammation. It can induce granulomas and other inflammatory responses *in vivo*."); Wolf 3d Amend. Rep. at 16 ("Talcum powder causes inflammation/oxidative stress both *in vitro* and *in vivo* (in both animal and human tissue)."); Moorman Rep. at 34 ("Animal studies also confirm that talc causes inflammation, as experiments in rats treated with intra-vaginal or perineal talc showed inflammatory changes in the genital tract.").) But even in the context of neoplasm, contrary to Defendants' interpretation, Keskin 2009 itself cautions against drawing firm conclusions regarding neoplastic effects, expressly calling for additional experimental and clinical studies and noting that prior research has supported neoplastic effects, particularly in ovarian tissue. (*See* Keskin 2009 at 927.) Defendants' interpretation of the study's limited findings therefore does not

[65] Neither the parties nor their experts clearly define what "neoplastic transformation" entails. Defendants briefly equate it to "the development of tumor-like properties." (*See* Defs.' 2024 Biological Plausibility Br. at 44.)

meaningfully call into question Plaintiffs' experts' use of the study for purposes of assessing inflammation. Moreover, under Rule 702, any alleged failure to emphasize a study's limitations bears on weight, not admissibility. *See In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 530 (6th Cir. 2008) (citing *Quiet Tech. DC–8, Inc. v. Hurel–Dubois UK Ltd.*, 326 F.3d 1333, 1343–44 (11th Cir. 2003)).

Defendants also challenge these experts' reliance on experiments conducted by the National Toxicology Program ("NTP"),[66] which they contend are unreliable, and consequently, lack relevance to the experts' opinions. (*See id.* at 30.) I disagree in part. NTP 1993 evaluated the chronic inhalation toxicology and carcinogenic potential of non-asbestiform cosmetic-grade talc in mice and rats. (*See generally* NTP 1993.) To do so, the authors exposed male and female rats and mice to aerosolized, asbestos-free talc at target concentrations for a set period. (*Id.*) In rats, chronic granulomatous inflammation was nearly universal in exposed groups. (*See id.* at 7.) In mice, chronic active inflammation with macrophage accumulation was similarly observed, though no evidence of carcinogenic activity was observed. (*See id.*)

Several Plaintiffs' experts cite the study—alongside other literature—for the limited proposition that talc exposure can elicit *inflammatory* responses. (*See, e.g.*,

[66] National Toxicology Program, *Toxicology and Carcinogenesis Studies of Talc (CAS No. 14807-96-6) in F344/N Rats and B6C3F1 Mice (Inhalation Studies)*, U.S. Dep't of Health & Hum. Serv., 421 (1993).

Wolf 3d Amend. Rep. at 16 ("Talcum powder causes inflammation/oxidative stress, both *in vitro* and *in vivo* (in both animal and human tissues)." (citing, *inter alia*, NTP 1993); Clarke-Pearson 3d Amend. Rep. at 6 ("Talcum powder is known to elicit an inflammatory response in animals and humans.") (citing, *inter alia*, NTP 1993); Levy 2d Amend. Rep. at 16 ("Additional studies have also shown the effects of talc on the immune responses.") (citing, *inter alia*, NTP 1993).) This is an accurate characterization of NTP 1993's findings and is properly relied upon by Plaintiffs' experts for the propositions that it asserts.

Other experts, including Dr. Plunkett, reference NTP 1993 more generally in discussing talc toxicity and carcinogenic potential, while expressly acknowledging its limitations and the reported absence of ovarian tumors, which they explain is unsurprising given the inhalation exposure route and species-specific anatomical differences. (*See, e.g.*, Plunkett 3d Amend. Rep. at 44–45.) Dr. McTiernan, however, takes a different approach by extrapolating from NTP 1993 opinions that are too attenuated and go beyond the bounds drawn by the authors themselves. Dr. McTiernan asserts that NTP 1993 is "highly relevant to the role of talc in carcinogenesis" because, among other things, it provides "important 'signal' information of talc toxicity relevant to talc and ovarian cancer." (*See* McTiernan 3d Amend. Rep. at 93–94.) But Dr. McTiernan makes no mention of the experiments' shortcomings as they relate to evidence of the association between talc and ovarian

cancer risk: that NTP 1993's primary tumor signals were confined to the lungs of female rats; that NTP 1993's conclusions of carcinogenic activity relate to respiratory tract outcomes under conditions of chronic inhalation, not genital or peritoneal exposure; and that NTP 1993's recitation of migratory studies found no evidence of talc reaching the ovaries in relevant translocation testing. (*See generally* NTP 1993.)

Simply put, NTP 1993 does not support the association between talc and ovarian cancer risk because its design, findings, and ancillary data do not implicate the ovary or perineal exposure in carcinogenesis. Therefore, to the extent that any expert intends to use NTP 1993 to support the association between talcum powder and ovarian carcinogenesis, they may not do so. To be clear, this is not to say that NTP 1993 may not be relied upon to support the general proposition of an association between talc use and inflammation or talc toxicity and carcinogenic potential, or that such reliance by experts undermines the reliability of their methodology or its application to this case.

Importantly, several Plaintiffs' experts expressly address the criticisms that have been leveled at NTP 1993, including challenges to its design and conclusions, but explain why the study nonetheless provides relevant toxicological information regarding talc-induced inflammation. (*See, e.g.*, Plunkett 3d Amend. Rep. at 43–45 (acknowledging that NTP 1993 "has been criticized and conclusions reached by the

original authors have been questioned," yet concludes "even with its limitations, the study provides important information on talc toxicity that is relevant to assessing the risks of cancer in humans"); Carson Rep. at 7 ("There are a limited number of animal studies suggesting that this transport does not occur." (citing NTP 1993).) That acknowledgment and contextualization of the study's limitations supports, rather than undermines, the reliability of the experts' methodologies. Plaintiffs' experts reasonably and adequately extrapolated NTP 1993's conclusion to support their opinion on inflammation.

In sum, I find that although NTP 1993 did not—and was not designed to—evaluate ovarian carcinogenesis, it remains relevant to the broader question of talc toxicity and inflammatory response. Under Rule 702, objections grounded in alleged flaws or limitations of a study generally go to weight, not admissibility. *See Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 81–83 (3d Cir. 2017) ("The question of whether a study's results were properly calculated or interpreted ordinarily goes to the weight of the evidence, not to its admissibility."). Accordingly, I find that Defendants' criticisms of NTP 1993 do not warrant exclusion of the experts' opinions that rely on it for the limited purposes outlined above.

Finally, it bears emphasizing that the experts who rely on or reference Keskin 2009 and NTP 1993 do so in conjunction with a broader body of evidence, including other animal studies, epidemiologic studies, case reports, literature reviews, and *in*

vitro research. Plaintiffs' experts marshal this collective evidence to support their view that talcum powder is consistently associated with chronic inflammatory responses. Under the commonly employed totality-of-the-evidence approach, Plaintiffs' experts use animal studies as one component of their analysis, but do not rely on them in isolation to support their biological plausibility opinions. (*See, e.g.*, Plunkett 3d Amend. Rep. at 55 ("The animal cancer data, when considered in conjunction with the cellular data, indicate that talc is a carcinogen and there likely is a dose-response threshold for tumor development in rodents. There are several human studies that provide evidence of a dose-response relationship for talc exposure and ovarian cancer in women." (citations omitted)); Moorman Rep. at 9 ("Evidence from epidemiological investigations is combined with relevant studies from other disciplines, including pathology, animal and mechanistic studies, to make an assessment of the evidence for a causal association between genital exposure to talcum powder and ovarian cancer.").)

Defendants next argue that Plaintiffs' experts' reliance on pleurodesis is misplaced because pleurodesis involves administering large amounts of talc to intentionally invoke an acute inflammatory response that is not analogous to the alleged chronic mechanism; other agents besides talc can cause the same effect; and long-term data show no increased rates of cancer following pleurodesis. (*See* Defs.' 2024 Biological Plausibility Br. at 30–31.) Despite similarly structured arguments

elsewhere in Defendants' motion, Defendants do not, however, argue against the applicability of pleurodesis to biological plausibility of talc exposure and inflammation based on anatomical differences between pulmonary tissue and ovarian tissue. (*See id.*)

Plaintiffs' experts' references to pleurodesis do not undermine the reliability of their methodologies or the application of their methodologies to this case. Dr. Plunkett explained that while talc pleurodesis involves lung-related cells, it is nonetheless a clinical procedure that intentionally uses talc to provoke an acute inflammatory response albeit to scar and fuse pleural[67] layers, thereby treating pleural effusions. (*See* Plunkett 3d Amend. Rep. at 52–53; *see also* Moorman Rep. at 33–34 ("[T]alc pleurodesis [is] a treatment for malignant pleura effusions or pneumothorax that involves instillation of talc into the pleural space.").) However, Dr. Plunkett emphasized that this pleurodesis inflammation is acute rather than chronic, the latter of which she notes is typically the type of inflammation linked to carcinogenesis, with no regard to origin of site. (*Id.* at 53.) Dr. Plunkett further noted that the severity of inflammatory effects in pleurodesis depends on particle size, citing data that small-particle talc, i.e., approximately 50% less than 10 μm, is

[67] The pleural space is the thin, fluid-filled gap between the two layers of the pleura (membranes) that surround the lungs. (*See* Plunkett 3d Amend. Rep. at 52–53; Moorman Rep. at 33–34.)

associated with worse inflammatory outcomes and recalling that consumer talc powders generally contain mostly small-particle talc, i.e., less than 10 μm. (*Id.*)

Likewise, Dr. McTiernan cites clinical and experimental work showing that talc pleurodesis elicits both local and systemic inflammatory responses. (*See* McTiernan 3d Rep. at 90–91.) Dr. McTiernan uses this data to support a mechanistic pathway in which talc-induced inflammation promotes cellular proliferation and other tumorigenic processes. (*See id.*) Along the same line, Dr. Moorman invokes talc pleurodesis as evidence that talc causes inflammation and fibrosis. (*See* Moorman Rep. at 33–34.) The doctor explains that pleurodesis results in inflammation and fibrotic adhesion of pleural layers, and, coupled with additional evidence like pulmonary talcosis, talc exposure can drive inflammatory processes that fit within recognized cancer biology frameworks involving inflammation. (*See id.*) According to Dr. Moorman, talc pleurodesis is just one line in "several lines of evidence" establishing that "talc can cause inflammation." (*Id.*)

Furthermore, the experts cited to Elena Arellano-Orden et al., *Small Particle-Sized Talc Is Associated with Poor Outcome and Increased Inflammation in Thoracoscopic Pleurodesis*, 86 Respiration 201–09 (2013) ("Arellano-Orden 2013") to document the inflammatory biology of talc pleurodesis and particle-size gradient in responses, which they used as a part of the mechanistic evidence that talc induces inflammation in human tissue. By studying 227 consecutive malignant pleura

effusion patients undergoing thoracoscopic talc pleurodesis and observing, among other things, inflammatory responses with small-particle talc, Arellano-Orden 2013 provided human clinical and mechanistic evidence that talc pleurodesis causes pleural and systemic inflammatory response.

Having reviewed these opinions, I find that the experts' discussion of pleurodesis as evidence that talc can induce inflammation does not warrant exclusion under Rule 702. At the outset, the experts' reliance on pleurodesis-related literature is sufficiently reliable because it is grounded in studies that Plaintiffs' experts accurately characterize. (*See, e.g.*, Plunkett 3d Amend. Rep. at 52 (citing Arellano-Orden 2013); McTiernan 3d Amend. Rep. at 90–91 (citing Arellano-Orden 2013).) Notably, Defendants do not contend that these studies are misdescribed or inaccurately reported.

Defendants' argument that the pleurodesis studies demonstrate only acute, rather than chronic, inflammation likewise misses the mark at this stage of the analysis. Plaintiffs' experts rely on pleurodesis-related studies to support the limited proposition that talc can provoke a cellular inflammatory response, albeit in pulmonary tissue. Whether that inflammatory response progresses to chronic inflammation, and whether such inflammation can in turn contribute to ovarian carcinogenesis, implicates subsequent steps in the causal chain that are addressed elsewhere in this section. Importantly, Plaintiffs' experts do not rely on pleurodesis

studies alone to support those later steps, nor can they, but instead draw on additional bodies of evidence to do so.

Next, Defendants challenge Plaintiffs' experts' use of *in vitro* studies generally because they purportedly fail to provide "good grounds" for "extrapolating" from them. (*See* Defs.' 2024 Biological Plausibility Br. at 31–32.) I disagree.

As a preliminary matter, "*in vitro* tests provide useful information about metabolic processes at a cellular level, and may supplement existing animal and human data." *In re Johnson & Johnson*, 509 F. Supp. 3d at 143 (quoting *Bourne ex rel. Bourne v. E.I. Dupont de Nemours & Co., Inc.*, 189 F. Supp. 2d 482, 496 (S.D. W. Va. 2002)). While "*in vitro* evidence alone cannot serve as a basis for a general causation opinion," *In re Abilify*, 299 F. Supp. 3d at 1310, it still can bolster "predict[ions] of causation in humans" if consistent and supportive data exists from human epidemiologic studies, *In re Zoloft*, 26 F. Supp. 3d at 464. Notably, Defendants identify no portion of my prior Opinion that misstates or misapplies the role of *in vitro* studies in supporting general causation or biological plausibility opinions.

Rather, Defendants point to several *in vitro* studies that they contend undercut the experts' opinions that talc causes chronic inflammation.[68] Specifically, Defendants challenge Plaintiffs' experts' reliance on Fletcher 2019 and Shukla 2009 to support the proposition that talc exposure causes oxidative stress, which in turn increases the risk of ovarian cancer development. (*See id.* at 32–35 (citing Levy 2d Amend. Rep. at 16; McTiernan 3d Amend. Rep. at 91; Singh Supp. Rep. at 15; Smith-Bindman 3d Amend. Rep. at 14–15; Wolf 3d Amend. Rep. at 16).)

The authors of Fletcher 2019, which include Dr. Saed, aimed to determine whether and how talcum powder can induce cellular and molecular changes that would mechanistically support an association between genital talc use and increased risk of epithelial ovarian cancer, by testing talc's effects on oxidative stress pathways, inflammatory markers, cell proliferation, apoptosis, and selected gene variants in normal and ovarian cancer cell models. (*See generally* Fletcher 2019.) Fletcher 2019 was built on a similar group of authors' earlier work—a series of *in vitro* and molecular studies from Dr. Saed's laboratory. (*See generally id.*; *see also* Plunkett 3d Amend. Rep. at 48; Defs.' 2024 Biological Plausibility Br. at 32.)

---

[68] (*See* Defs.' 2024 Biological Plausibility Br. at 32–36 (citing Nicole M. Fletcher et al., *Molecular Basis Supporting the Association of Talcum Powder Use with Increased Risk of Ovarian Cancer*, 26 Reprod. Sci. (12), 1603–1612 (2019) ("Fletcher 2019"); Arti Shukla et al., *Alterations in Gene Expression in Human Mesothelial Cells Correlate with Mineral Pathogenicity*, 41 Am. J. of Respiratory Cellular Molecular Biology (1), 114–23 (2009) ("Shukla 2009")).)

Notably, it does not appear that Fletcher 2019 is precisely the same study by Dr. Saed that my prior Opinion previously examined. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 133–47. However, Defendants lodge many of the same criticisms against Fletcher 2019 as they did against Dr. Saed's previously examined experiments. Therefore, I infer methodological similarities between the two experiments.

Fletcher 2019 used *in vitro* experiments exposing multiple human cell lines—normal cells human macrophages, human primary normal ovarian epithelial cells, immortalized human ovarian epithelial cells, immortalized human fallopian tube secretory epithelial cells, and ovarian cancer cells—to Johnson & Johnson talcum baby powder, at 5, 20, or 100 μg/mL doses for up to 72 hours to assess, among other things, dose-response effects. (*See* Fletcher 2019 at 2.) Experiments were run in triplicate under standard culture conditions per manufacturer protocols. (*See id.* at 2, 4–5.) The authors quantified, among other things, mRNA and protein/activity for key antioxidant enzymes and pro-oxidant/inflammatory markers, inflammation/tumor marker CA-125 for inflammation, and assessed cell proliferation and measured apoptosis. (*See generally* Fletcher 2019.) Fletcher 2019 reported that talc exposure drove a shift toward oxidative stress and inflammation across normal ovarian, normal fallopian, and ovarian cancer cells. (*See id.* at 3–5.)

As discussed below, Drs. Levy, McTiernan, Singh, Smith-Bindman, and Wolf cite Fletcher 2019, among other studies, for the proposition that talc causes oxidative stress. Defendants first challenge the credibility of Fletcher 2019's reported data as it relates to that conclusion. (*See* Defs.' 2024 Biological Plausibility Br. at 33–34.) In doing so, Defendants largely repeat arguments that were previously raised and addressed in my prior Opinion. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 144–47 & n.21. For example, Defendants point to alleged irregularities in laboratory records, asserting that "portions of the lab notebook are whited out with contradictory information written over, and basic mathematical calculations (like averages) are done incorrectly." (Defs.' 2024 Biological Plausibility Br. at 33.) Defendants also contend that the reported treatment time is inconsistent, noting that "the treatment time is reported as 48 hours, which is consistent with Dr. Saed's initial and rejected manuscript, but inconsistent with [Fletcher (2019)], which claimed 72 hours of treatment." (*Id.*) As Defendants acknowledge, however, I previously considered these same criticisms and concluded that they "do not fundamentally undermine the methodologies Dr. Saed utilized when conducting" the experiments. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 144–46. Here, as before, Defendants do not identify how Dr. Saed's experimental methodology fails to satisfy Rule 702, either as it existed at the time of my prior ruling or as clarified by the 2023 amendments. At bottom, Defendants' arguments amount to a renewed request for

reconsideration of issues already decided. Consistent with my prior ruling, without repeating those discussions, I again find no basis to conclude that the credibility concerns raised by Defendants render Dr. Saed's experimental methodology unreliable. Rather, these criticisms bear on the weight to be afforded to the study and the conclusions drawn from it, not on the admissibility of the opinions under Rule 702.

Defendants also make passing reference to potential bias concerns underlying the propriety of Fletcher 2019. Fletcher 2019 disclosed that Dr. Saed served as a paid consultant and expert witness in talcum powder litigation, though the article stated that the authors received no financial support "for the research, authorship, and/or publication of" the article. (*See* Fletcher 2019 at 9.) Defendants disagree, arguing that the article "incorrectly states that '[t]he author(s) received no financial support' for it." (*See* Defs.' 2024 Biological Plausibility Br. at n.64.) On that statement alone, without more particular information, I am unable to assess the potential impropriety of Fletcher 2019 or confirm that the authors were otherwise financially influenced, other than Defendants' say-so. However, this is not to say Defendants may not fully explore this issue further at trial. And in any event, it "is well-established that an expert's bias is not a proper basis to bar testimony under *Daubert*." *Cage v. City of Chicago*, 979 F. Supp. 2d 787, 827 (N.D. Ill. 2013) (collecting cases).

Next, Defendants mount a merit-based challenge to Fletcher 2019 and the opinions derived from it, contending that the study fails to use or establish any physiologically relevant dose and rests on a mischaracterization of oxidative stress. To begin, I note that Drs. Levy, McTiernan, Singh, Smith-Bindman, and Wolf cite Fletcher 2019, among other studies, for the proposition that talc causes oxidative stress. (*See, e.g.*, Levy 2d Amend. Rep. at 16 ("Talcum powder exposure to normal and epithelial ovarian cancer cells resulted in an increased pro-oxidant state as evidenced by observing increased levels of CA-125, caspase-3, nitrate/nitrite, and key redox enzymes."); Singh Supp. Rep. at 15 ("Talc showed an increase in inflammation as shown by a significant increase in CA-125 ($P<0.05$)."); Smith-Bindman 3d Amend. Rep. at 14–15 ("Talc exposure also resulted in a significant increase in inflammation as determined by increased tumor marker CA-125 ($P < .05$)."); Wolf 3d Amend. Rep. at 16 ("Talcum powder causes inflammation/oxidative stress both *in vitro* and *in vivo* (in both animal and human tissues).").) Several other Plaintiffs' experts articulate the association between talcum use, oxidative stress, and the increased risk of ovarian cancer development, based on Fletcher 2019. (*See, e.g.*, McTiernan 3d Amend. Rep. at 91 ("This study supports the role of talc in inducing oxidative stress, providing a molecular basis for epidemiologic studies demonstrating an increased risk of ovarian cancer with perineal talcum powder product exposure."); Singh Supp. Rep. at 15 ("Fletcher [2019] . . . demonstrated that

talc induces changes in key redox enzymes and enhances the prooxidant state in normal and EOC cells. This confirms the cellular effect of talc and provide a molecular mechanism linking genital use to increased ovarian cancer risk through oxidative stress and inflammation." (citation omitted)); Smith-Bindman 3d Amend. Rep. at 15 ("These findings confirm the cellular effect of talc and provide a molecular mechanism to previous reports linking genital use to increased ovarian cancer risk.").)

Having reviewed these opinions, I do not find that Defendants' substantive challenges warrant exclusion of Plaintiffs' experts or those of their opinions grounded in Fletcher 2019. My prior Opinion already rejected Defendants' contention that Dr. Saed's laboratory experiment, upon which Fletcher 2019 is ostensibly based, is inapplicable because it did not use a "physiologically relevant dose." As explained at length, the absence of such a dose does not diminish the study's value, as the study did not purport to establish definitive causation. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 143. Defendants offer nothing new to this argument, and I do not find a basis to revisit that reasoning under Rule 702 as amended or newly proffered evidence.

Defendants also contend that Fletcher 2019 did not, in fact, find oxidative stress. (*See* Defs.' 2024 Biological Plausibility Br. at 34–35.) That argument rests on an overly narrow characterization of the study's findings. Fletcher 2019 reports

mechanistic evidence demonstrating pro-inflammatory and pro-oxidant effects of talc exposure across multiple human cell types. (*See* Fletcher 2019 at 1 (finding "that talc induces significant changes in key redox enzymes and enhances the prooxidant state in normal and [epithelial ovarian cancer] cells").) Although Defendants argue that the study reflects changes in indirect markers rather than direct measurement of oxidative stress, Fletcher 2019 itself characterizes the observed redox alterations as evidence of an induced pro-oxidant state. Disagreement over whether those findings should be labeled "oxidative stress," or overstate the strength of the inference drawn from the reported biomarkers, goes to the interpretation and weight of the evidence—not to whether Plaintiffs' experts have mischaracterized the study or relied on it in a methodologically unreliable manner under Rule 702. Rather, the experts have reasonably extrapolated Fletcher 2019 for its intended purpose. *See In re Paoli*, 35 F.3d at 744 (Plaintiffs' experts "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. . . . The evidentiary requirement of reliability is lower than the merits standard of correctness.").

Similarly, the experts' reliance on Shukla 2009 does not render their opinions unreliable or inadmissible under Rule 702. Defendants argue that Shukla 2009 does not support Plaintiffs' experts' inflammation theories because it observed significant

gene-expression changes and greater toxicity in human mesothelial cells, not human ovarian cells. (*See* Defs.' 2024 Biological Plausibility Br. at 35.)

Shukla 2009 investigated whether exposure to different mineral particles—including asbestos and nonfibrous talc—induces inflammatory and oxidative-stress–related molecular responses in human mesothelial cells and human ovarian surface epithelial cells. Using surface-area-matched dosing and genome-wide gene-expression profiling, the authors found that asbestos produced the most extensive and robust transcriptional changes, particularly in mesothelial cells, strongly activating genes associated with inflammation, oxidative stress, cytokine signaling, and cellular stress responses. (Shukla 2009 at 118–19.) Importantly, nonfibrous talc also induced measurable gene-expression changes at higher exposures, including upregulation of inflammatory and oxidative-stress–related genes such as ATF3, IL-8, PTGS2 (COX-2), and SOD2, demonstrating that talc is not biologically inert under experimental conditions. (*See id.* at 118, 121.) As to the human ovarian surface epithelial cells, which were tested under the same conditions, the authors observed no meaningful change at the lower dose but observed mRNA levels increase at a higher dose in two genes—NR4A2 and CXCL2 or MIP2—at eight hours and further increase in expression of 16 genes at 24 hours. (*See id.* at 118.)

The authors concluded that mineral pathogenicity correlates with the ability to trigger early inflammatory and oxidative molecular events, even in the absence of

neoplastic transformation. (*Id.* at 121–22.) Although talc's effects were less pronounced than those of asbestos, the study identified overlapping stress-response and cytokine-regulatory pathways that are widely recognized as contributors to chronic inflammation and carcinogenic processes. (*Id.* at 121.) Critically, the authors emphasized that these findings reflect early mechanistic cellular responses, not proof of cancer causation, and are therefore relevant to assessing biological plausibility rather than establishing tumorigenesis. (*Id.* at 121–22.) As such, the study concludes talc exposure can induce pro-inflammatory and pro-oxidant cellular states that may be relevant to disease development when considered alongside other lines of evidence.

Drs. Plunkett, McTiernan, and Clarke-Pearson, among others, cite and discuss Shukla 2009 to support the mechanistic plausibility that talc can trigger biological responses—particularly oxidative stress and inflammation—in cell types relevant to this litigation. (*See, e.g.*, Plunkett 3d Amend. Rep. at 45–46; McTiernan 3d Amend. Rep. at 92; Clarke-Pearson 3d Amend. Rep. at 6.) Dr. Clarke-Pearson, for example, specifically found Shukla 2009 supportive of the association between talcum powder and inflammation because it demonstrated that "non-fibrous (platy) talc caused expression of genes in ovarian epithelial cells producing inflammatory cytokines." (*See* Clarke-Pearson 3d Amend. Rep. at 6.) Dr. Plunkett similarly relied upon Shukla 2009 to illustrate, among other things, that asbestos elicits stronger adverse response

than nonfibrous talc under the reported *in vitro* conditions. (*See* Plunkett 3d Amend. Rep. at 45–46.) However, Dr. Plunkett noted that the study "did reveal statistically significant increases in ATF3 and IL8 expression by asbestos and non-fibrous talc at certain conditions," and "that some of the genes affected [by asbestos and talc] are involved in cellular processes that relate to oxidative stress and inflammation." (*Id.* at 46.)

Based on these opinions, I do not find that these experts' conclusions exceed those espoused in Shukla 2009, particularly since Shukla 2009 demonstrated adverse cellular changes following talc and asbestos exposure.[69] *See In re Accutane*, 511 F. Supp. 2d at 1291 ("When an expert relies on the studies of others, he must not exceed the limitations the authors themselves place on the study. That is, he must not draw overreaching conclusions.") (citing *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1245–1247 (11th Cir. 2005)).

It also bears repeating that Plaintiffs' experts' opinions regarding the association between talc use and inflammation is supported by other animal studies, *in vitro* studies, and clinical data, and not solely Shukla 2009 or Fletcher 2019. (*See, e.g.*, Arellano-Orden 2013 (showing post-talc increases in pro-inflammatory

[69] Plaintiffs' experts also discuss and distinguish the study's limitations. For example, Dr. Plunkett addresses the lesser effects of talc exposure on ovarian cell gene expression by commenting that the authors "failed to test talc with the same rigor that asbestos was tested in their study, limiting the data collected on talc itself." (*See* Plunkett 3d Amend. Rep. at 46; *see also id.* ("[H]owever, testing of only two doses of asbestos limit the conclusions that can be drawn about differences between cells.").)

cytokines from talc pleurodesis patients); Britton Trabert et al., *Pre-Diagnostic Serum Levels of Inflammation Markers and Risk of Ovarian Cancer in the Prostate, Lung, Colorectal and Ovarian Cancer (PLCO) Screening Trial*, 135 Gynecologic Oncology (2), 297–304 (2014) ("Trabert 2014") (linking higher systemic inflammatory markers to increased ovarian cancer risk); *see also* Eduardo Henrique Genofre, et al., *Inflammation and Clinical Repercussions of Pleurodesis Induced Intrapleural Talc Administration*, 62 Clinics (San Paolo) (5), 627–34 (2007).)

(2) Chronic inflammation and ovarian cancer

Next, Defendants argue Plaintiffs' experts cannot reliably connect chronic inflammation to ovarian carcinogenesis because their evidence is non-probative, inconsistent, and/or misinterpreted. (*See* Defs.' 2024 Biological Plausibility Br. at 36–41.) Defendants cite several different categories of studies and contend that the experts ignored the underlying data, where applicable, and that the studies themselves do not support Plaintiffs' experts' opinions. (*See id.*) I disagree.

At the outset, I note again that Plaintiffs' experts do not confine their biological plausibility opinions to the challenged classes of studies. Rather, they draw on a broader and more diverse evidentiary base. Even within the specific categories Defendants target, Plaintiffs' experts rely on multiple studies beyond those singled out for criticism. And the very studies Defendants attack substantively support the limited propositions for which Plaintiffs' experts cite them.

To start, Defendants contend that Plaintiffs' experts improperly rely on so-called "review articles" that synthesize existing literature rather than generate new primary data, and that the experts therefore fail to independently analyze the underlying studies. (*See* Defs.' 2024 Biological Plausibility Br. at 37 (citing Fran Balkwill & Alberto Mantovani, *Inflammation and Cancer: Back to Virchow?*, 357 Lancet (9255), 539–545 (2001) ("Balkwill & Mantovani 2001"); Roberta B. Ness & Carrie Cottreau, *Possible Role of Ovarian Epithelial Inflammation in Ovarian Cancer*, 91 J. of the Nat'l Cancer Inst. (17), 1459–1467 (1999) ("Ness & Cottreau 1999")).) That argument, however, warrants careful contextualization. Defendants do not challenge Ness & Cottreau 1999 or Balkwill & Mantovani 2001 on the substance of the scientific propositions for which they are cited. Instead, Defendants' objection is directed solely to the fact that these publications are classified as "review articles." At its core, these so-called "review articles" are peer-reviewed, published, and widely cited articles that discuss the works of other experts that have also been peer-reviewed and published. As *Daubert* notes, "an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation." 509 U.S. at 592.

Aside from the fact that these studies conducted reviews of other literature, Plaintiffs' experts rely on these sources for scientific propositions regarding the role of inflammation in carcinogenesis. (*See, e.g.*, Carson Rep. at 6; Clarke-Pearson 3d

Amend. Rep. at 5; Levy 2d Amend. Rep. at 11; Wolf 3d Amend. Rep. at 15.) For example, citing to the subject review articles, Dr. Wolf writes that "[i]nflammation resulting from talcum powder use has been proposed as a potential mechanism for the association with [epithelial cancers]." (Wolf 3d Amend. Rep. at 15 (citing, e.g., Ness & Cottreau 1999 and Balkwill & Mantovani 2001).) Dr. Singh opines that "[i]nflammation has long been understood to be an important mechanism underlying the development of ovarian cancer." (Singh Rep. at 58 (citing Ness & Cottreau 1999); *see also* Kane Rep. at 10 (discussing Ness & Cottreau 1999 and its reporting of inflammation of ovarian epithelium as a risk factor for ovarian cancer).) Dr. Smith-Bindman also asserts that "[c]hronic inflammation, and even subtle, subclinical inflammation, is associated with an increased risk of cancer." (Smith-Bindman 3d Amend. Rep. at 10 (citing, e.g., Balkwill & Mantovani 2001).)

Indeed, both Ness & Cottreau 1999 and Balkwill & Mantovani 2001 sufficiently support the scientific propositions for which they are used. Ness & Cottreau 1999, entitled "Possible Role of Ovarian Epithelial Inflammation in Ovarian Cancer," synthesizes decades of epidemiologic and biological research to advance the hypothesis that inflammation plays a central role in ovarian carcinogenesis, while Balkwill & Mantovani 2001 revisits a hypothesis first articulated in the nineteenth century by surveying extensive experimental and clinical evidence linking inflammation to tumor initiation, promotion, and

metastasis. Notably, this article documents that numerous chronic inflammatory conditions are associated with increased cancer incidence and estimates that approximately fifteen percent of cancers worldwide are attributable to chronic infection and inflammation. (*See generally* Balkwill & Mantovani 2001.) Although Defendants claim that Balkwill & Mantovani 2001 "is not focused on ovarian cancer," (*see* Defs.' 2024 Biological Plausibility Br. at 37), the article expressly identifies ovarian cancer as associated with inflammatory cofactors and details ovarian-specific evidence. (*See* Balkwill & Mantovani 2001 at 539–40.)

Under Rule 702, reliance on peer-reviewed synthesis literature to contextualize and integrate primary findings is not methodologically improper, particularly where, as here, the propositions drawn from those sources are well supported by decades of scientific research and are not meaningfully disputed. Plaintiffs' experts accurately characterize these review articles, employ them for limited and appropriate purposes, and situate them within a broader evidentiary record that includes epidemiologic, mechanistic, and experimental studies—many of which Defendants do not challenge. Accordingly, Defendants' objection to the experts' use of these review articles does not undermine the reliability of their methodologies or warrant exclusion.

Defendants next challenge "original research" that Plaintiffs' experts relied on to demonstrate an association between chronic inflammation and

carcinogenicity.[70] Defendants primarily highlight three studies— Buz'Zard 2007, Trabert 2014, and Phung 2022—that they argue fail to provide a reliable basis for Plaintiffs' experts' opinions. (*See* Defs.' 2024 Biological Plausibility Br. at 37–40.) Defendants contend that Buz'Zard 2007 undermines Plaintiffs' experts' causation theories by showing decreases in indications of oxidative stress, cell proliferation, and soft agar growth with talc exposure. (*See id.* at 37–38.) Defendants point out that Trabert 2014 reports only weak biomarker associations that likely reflect chance findings or reverse causation and do not withstand statistical correction. (*See id.* at 38–39.) Defendants go on to say that Phung 2022 does not support Plaintiffs' experts' inflammation-based mechanism because the study found no statistically significant interaction between genital talc use and endometriosis. (*See id.* at 39–40.) According to Defendants, these three studies fail to provide a reliable basis for Plaintiffs' experts' opinions.

I will analyze each of the studies in turn within the context of the parties' arguments. Buz'Zard 2007 tested whether talc exposure can induce pro-carcinogenic changes in two human ovarian cell lines and whether Pycnogenol can mitigate those changes. (*See generally* Buz'Zard 2007.) The authors exposed immortalized normal

[70] (*See* Defs.' 2024 Biological Plausibility Br. at 37–39 (citing Amber R. Buz'Zard et al., *Pycnogenol® Reduces Talc-Induced Neoplastic Transformation in Human Ovarian Cell Cultures*, 21 Phytother. Res. 579–86 (2007) ("Buz'Zard 2007"); Trabert 2014; Minh Tung Phung et al., *Effects of Risk Factors for Ovarian Cancer in Women With and Without Endometriosis*, 118 Fertil. & Steril. (5), 960–69 (2023) ("Phung 2022")).)

ovarian epithelial and immortalized normal ovarian granulosa cell lines to talc, or pretreated with Pycnogenol and then talc, across different concentrations and timing to assess cell viability, soft-agar growth as an *in vitro* transformation assay, and reactive oxygen species generation. (*See id.*) The authors found that talc caused an initial increase in cell viability of immortalized normal ovarian epithelial cells at 5 µg/mL at 24 hours, but a decrease at 200 µg/mL at 24 hours and 500 µg/mL at both 24 and 72 hours. (*See id.* at 580.) The authors also reported that talc caused an initial increase in cell viability of immortalized normal ovarian granulosa at 5, 20, 50 and 100 µg/mL over 72 hours but decreased at 500 µg/mL over 24 hours. (*See id.* at 581.) For soft-agar growth, the authors observed an increase in the number of transformed colonies following talc exposure to immortalized normal ovarian epithelial cells at 5 and 20 µg/mL, and an increase in the same following talc exposure to immortalized normal ovarian granulosa at 5, 20, and 100 µg/mL. (*See id.*) The authors noted an "exception" to these results in 100 µg/mL talc treatment in immortalized normal ovarian epithelial cells, which caused a significant reduction in the number of transformed colonies. (*See id.*) Finally, the authors observed initial dose-dependent decreases in reactive oxygen species in both cell lines but a subsequent rising at different times under different doses. (*See id.* at 582.) Specifically, they observed that talc caused an initial dose-dependent decrease at 24 hours for both human ovarian cell lines, but an increase was observed at 20 µg/mL at 72 hours and 120

hours, respectively, and 50 µg/mL at 120 hours, in immortalized normal ovarian epithelial cells. (*See id.* at 582.) Similarly, the authors observed reactive oxygen species increased at .5, 20, and 50 µg/mL at 72 hours and 120 hours, and at 5 and 100 µg/mL at 120 hours. (*See id.*)

In simpler terms, Buz'Zard 2007 demonstrates a positive correlation between talc exposure to two human ovarian cell lines and increases in reactive oxygen species generation over a longer period and greater dose. (*See id.* at 582.) The authors opine, with scientific support, that reactive oxygen species "at high concentrations or expressed in a chronic nature can damage cellular macromolecules and contribute to neoplastic transformation and cell growth." (*Id.* at 584.) Therefore, the authors concluded, among other things, that talc may increase the likelihood of ovarian cancer by causing abnormal reactive oxygen species—a by-product of inflammation—and that Pycnogenol can blunt this effect in laboratory experiments. (*See* Buz'Zard 2007 at 584, 586.) Furthermore, Buz'Zard 2007 shows a similarly positive correlation between talc exposure and soft-agar growth and cell proliferation, but only up to a certain point. (*See id.* at 581–82.)

Defendants contend that the paper does not reliably support Plaintiffs' mechanism opinions because, among other things, in immortalized ovarian epithelial cells, reactive oxygen species generally decreased with talc and cell proliferation decreased at the highest dose. (*See* Defs.' 2024 Biological Plausibility Br. at 37–38

(asserting that "almost every talc treatment in immortalized ovarian cells decreased [reactive oxygen species] levels," and noting that "[c]ell proliferation decreased at the highest dose of talc treatment" (emphasis omitted).)[71]

First, Defendants selectively cite data from Buz'Zard 2007 for their argument that the study does not support Plaintiffs' position. Defendants emphasize that "talc treatment in immortalized ovarian cells decreased" reactive oxygen species levels but omit that this decrease was only observed at the lowest exposure amount of talc and at the shortest exposure time. (*Compare* Defs.' 2024 Biological Plausibility Br. at 38, *with* Buz'Zard 2007 at 582.) While Defendants focus on this early data point, Plaintiffs focus on the time-course and overall pattern of the study, which demonstrates a positive correlation between talc dose, time, and reactive oxygen species generation. Similarly, Defendants highlight that cell proliferation "also decreased at the highest dose of talc treatment" but fail to mention the increase in cell viability observed at a lower dose. (*Compare* Defs.' 2024 Biological Plausibility Br. at 38, *with* Buz'Zard 2007 at 582.)

Relatedly, Defendants ignore the practical significance of Buz'Zard 2007's findings of increased reactive oxygen species generation within the context of the

[71] Plaintiffs acknowledge this but argue that Defendants ignore findings that align with Plaintiffs' proposed mechanism; that the study shows time-dependent reactive oxygen species increases in normal cells; and that the study reports increased anchorage-dependent growth in both normal stromal and epithelial ovarian cells. (*See* Pls.' Opp. to Defs.' 2024 Biological Plausibility Br. at 46–47.)

case. Plaintiffs here are long-term users of cosmetic talcum powder and not test tube samples subject to mere hours of exposure. The purpose of Buz'Zard 2007, according to the authors themselves, was to "investigate talc-induced carcinogenesis and Pyc-induced chemoprevention." (Buz'Zard 2007 at 579.) In doing so, the authors found, among other things, that talc "increased proliferation, induced neoplastic transformation and increased [reactive oxygen species] generation time-dependently in the ovarian cells." (*Id.*)

Furthermore, Plaintiffs' experts who rely on or refer to Buz'Zard 2007 do so for the limited purpose of reiterating the study's authors' findings. Specifically, Plaintiffs' experts, including, without limitation, Drs. Levy, McTiernan, Plunkett, and Cote, invoke Buz'Zard 2007 to support oxidative stress and transformation mechanisms, and accurately characterize the study's favorable results. (*See* Levy 2d Amend. Rep. at 16 ("[Buz'Zard 2007] reported an increase in [reactive oxygen species], increased cell proliferation, and neoplastic transformation (conversion into cancerous cells) in human ovarian cells treated with talcum powder."); McTiernan 3d Amend. Rep. at 91 ("Exposing human ovarian stroma; and epithelial cells to talc resulted in increases reactive oxygen species (oxidative stress), cell proliferation and neoplastic transformation of cells."); Cote Amend. Rep. at 14 ("Buz'Zard [2007] also noted in ovarian cancer cell lines that talc increased production of [reactive oxygen species], which plays a role in the modulation of cell survival,

differentiation, cell signaling, and inflammation-related factor production."); *see also* Plunkett 3d Amend. Rep. at 27–28, 45, 55; Kane Rep. at 10.) These experts do not extrapolate from the study opinions that the authors' themselves fail to make. Of course, Plaintiffs' experts will have to explain certain of the inconsistent results highlighted by Defendants, but at their core, Defendants' challenges are against the authors' conclusions, which is an issue of weight and not admissibility.

For similar reasons, Defendants' argument against Trabert 2014 and Phung 2022 do not undermine the reliability of Plaintiffs' experts' methodology or opinions. Trabert 2014 measured 46 inflammation-related markers in stored blood from women years before any cancer diagnosis and then asked who later developed ovarian cancer. (*See generally* Trabert 2014.) The study found that women with higher pre-diagnosis levels of markers had greater future ovarian cancer risk, with two markers remaining associated even five or more years before diagnosis. (*See id.*) Defendants argue that only three markers "showed association," one of which had a small sample size caution, and that applying stricter standards to account for false positives would have likely nullified nominal findings, thus, providing for at most slight evidence for inflammation as a causal pathway. (*See* Defs.' 2024 Biological Plausibility Br. at 38–39.) Again, Defendants narrowly interpret Trabert 2014's

findings, which strengthen the role of inflammation as a plausible mechanistic pathway for ovarian cancer despite not involving a measurement of talc exposure.[72]

Phung 2022 conducted a pooled analysis of nine population-based case-control studies in the Ovarian Cancer Association Consortium, using standardized in-person or phone interviews and self-completed questionnaires to collect self-reported endometriosis and risk factor data from 8,500 cases and 13,592 controls. (*See generally* Phung 2022.) The study noted a p-for-interaction[73] of 0.65, which Defendants contend is indicative that the apparent difference in risk of endometriosis was likely due to chance. (*See* Defs.' 2024 Biological Plausibility Br. at 39–40.) Yet Phung 2022 concluded, among other things, that "[g]enital talc use was . . . positively associated with risk for women with and without endometriosis, although its magnitude seemed to be greater for women with than women without." (Phung 2022 at 964; *see also id.* at 961 (same).) Plaintiffs' experts rely on or refer to Phung 2022 for the proposition set forth by the authors of the study. (*See, e.g.*, Cote Amend. Rep.

---

[72] Plaintiffs' experts who reference Buz'Zard 2007 and Trabert 2014 do so not in isolation, but in further support of their opinions regarding the association between chronic inflammation and ovarian carcinogenicity. In other words, Plaintiffs' experts do not rely solely on these studies for support of the association. (*See, e.g.*, Clarke-Pearson 3d Amend. Rep. at 5–6; Kane Rep. at 10–12; Plunkett 3d Amend. Rep. at 45, 50.) Thus, even if Buz'Zard 2007 and Trabert 2014 have little value in supporting the experts' biological plausibility opinions, Plaintiffs' experts rely on other reliable sources of support for the association between chronic inflammation and carcinogenicity, as discussed herein.

[73] I take judicial notice that a "p-for-interaction" is an estimated measure used in comparing three variables that quantifies whether an association between the exposure and outcome variables is statistically different for different levels of the third variable measured. (*See* Jillian Cotter et al., *How to Interact With Interactions: What Clinicians Should Know About Statistical Interactions*, 13 Hospital Pediatrics (10), e319, e321 (Oct. 2023).)

at 17; Wolf 3d Amend. Rep. at 17.) Again, Defendants' challenge is one to weight, not admissibility, of the strength that Plaintiffs' experts attribute to the study.

In sum, the experts' reliance on these three studies does not warrant the exclusion of their opinions that chronic inflammation may increase the likelihood of ovarian cancer. Defendants' challenges to them are essentially challenges to the conclusions drawn by the authors' of the respective studies and not attacks on the studies' respective methodologies or the methodologies of Plaintiffs' experts. The fact that parties or their experts disagree on how to interpret or apply an otherwise peer-reviewed and published study does not render that study or the opinions premised on that study inadmissible, *see Karlo*, 849 F.3d at 83 (explaining that challenges to a study's results or interpretation ordinarily goes to the weight of the evidence and not the admissibility); *Hemmings v. Tidyman's*, 285 F.3d 1174, 1188 (9th Cir. 2002) ("[I]n most cases, objections to the inadequacies of a study are more appropriately considered an objection going to the weight of the evidence rather than its admissibility."); *see also 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."), so long as the conclusions drawn therefrom are reliable, supported, and within the parameters drawn by the authors themselves, *see In re*

Acetaminophen, 707 F. Supp. 3d at 353; *In re Abilify*, 299 F. Supp. 3d at 1351; *McClain*, 401 F.3d at 1247.

Defendants also argue that Plaintiffs' experts' reliance on anti-inflammatory drug research is methodologically unreliable because the findings are mixed and vary across drug classes and durations of use.[74] Defendants also contend that the experts "cherry-pick" favorable results while disregarding contrary data. (Defs.' 2024 Biological Plausibility Br. at 40–41.) These arguments are unpersuasive. Plaintiffs' experts who reference anti-inflammatory drug research do so for the limited and appropriate purpose of supporting the broader proposition that chronic inflammation is implicated in ovarian carcinogenesis—not to establish a uniform or definitive protective effect for any particular medication. (*See, e.g.*, Wolf 3d Amend. Rep. at 16.)

Despite Defendants' assertions, the experts do not ignore conflicting evidence. To the contrary, they expressly acknowledge that the literature concerning anti-inflammatory drugs and cancer risk is mixed and, in some respects, inconsistent. (*See, e.g.*, Wolf 3d Amend. Rep. at 16; Levy 2d Amend. Rep. at 14 ("The earlier

[74] (*See* Defs.' 2024 Biological Plausibility Br. at 40–41 (citing Britton Trabert et al., *Analgesic Use and Ovarian Cancer Risk: An Analysis in the Ovarian Cancer Cohort Consortium*, 111 J. Nat'l Cancer Inst. (2), 1–9 (2019) ("Trabert 2019"); Britton Trabert et al., *Aspirin, Nonaspirin Nonsteroidal Anti-Inflammatory Drug, and Acetaminophen Use and Risk of Invasive Epithelial Ovarian Cancer: A Pooled Analysis in the Ovarian Cancer Association Consortium*, 106 J. Nat'l Cancer Inst. (2), 1–11 (2014) ("Trabert 2014 II"); Lauren M. Hurwitz et al., *Association of Frequent Aspirin Use with Ovarian Cancer Risk According to Genetic Susceptibility*, 6 JAMA Netw. Open (2), 1–8 (2023) ("Hurwitz 2023").)

studies focusing on [nonsteroidal anti-inflammatory drugs] NSAIDs were preliminary and results were somewhat inconsistent."); Kane Rep. at 12 (recognizing that while some studies suggest a protective effect, others do not).) This acknowledgment of contradictory findings undermines, rather than supports, Defendants' claim of cherry-picking and reflects a balanced engagement with the scientific record.

Moreover, the studies Defendants challenge are consistent with the experts' limited use of this literature. Trabert 2014 II reported an association between regular aspirin use and reduced ovarian cancer risk, while finding weaker or inconsistent effects for non-aspirin NSAIDs and acetaminophen. Trabert 2019 similarly observed a modest reduction in risk associated with daily aspirin use, alongside mixed findings for long-term use of aspirin and other NSAIDs. More recently, Hurwitz 2023 associated frequent aspirin use with a modestly lower risk of several ovarian cancer subtypes across varying levels of genetic risk. Taken together, these studies support—among other studies relied upon—the experts' conclusion that inflammation plays a role in carcinogenesis, even if the magnitude and consistency of risk modification vary by drug and usage pattern. Plaintiffs' experts rely on this body of literature in a circumscribed and appropriate manner, and their consideration of mixed results does not render their methodologies unreliable under Rule 702.

Fourth, Defendants' seek to exclude those Plaintiffs' experts who rely on Harper/Saed 2023. (*See* Defs.' 2024 Biological Plausibility Br. at 41–45.) Defendants substantively challenge the study's findings as flawed. (*See id.*) Defendants further emphasize peer-reviewed criticisms of Harper/Saed 2023 concerning the use of non-physiologic doses, non-tubal cells lines, flawed statistics, and high seeding density. (*See id.*)

As discussed above, Harper/Saed 2023 describes an *in vitro* study that treated human primary ovarian epithelial cells, ovarian epithelial cells, and primary peritoneal fibroblast cells to talcum powder at 100 or 500 μg/mL for 72 hours, using titanium dioxide as an inert particulate control. (*See* Harper/Saed 2023 at 150.) After 72 hours, the exposed cells were assessed with "a cell transformation assay," and transformation was confirmed by P53 and Ki-67 immunohistochemistry.[75] (*See id.* at 150, 154.) The authors reported a dose-dependent increase in transformed ovarian epithelial cells for talcum powder, but no observed transformation in untreated ovarian cells, titanium dioxide-treated ovarian cells, and talc-treated primary fibroblasts. (*See id.*) Talc-treated ovarian cells showed a mutant-type p53 staining pattern, and a rise in Ki-67 proliferation index, which the authors found consistent

[75] Dr. Smith-Bindman explains that "P53 gene codes for a protein that acts as a tumor suppressor, which means that it regulates cell division by keeping cells from growing and dividing too fast or in an uncontrolled way." (Smith-Bindman 3d Amend. Rep. at 14.) Dr. Smith-Bindman also describes Ki-67 as "a nuclear protein that is a market of active cell proliferation." (*Id.*)

with transformation. (*See id.* at 154.) From these results, the authors concluded that "[e]xposure to talcum powder induces malignant transformation in ovarian epithelial cells," which they opine represents "a direct effect of talcum powder exposure that is specific to normal ovarian cells and further supports previous studies demonstrating an association between the genital use of talcum powder and an increased risk of [ovarian cancer]." (*See id.* at 150, 154–56.)

Several of Plaintiffs' experts accordingly refer to, or rely on, Harper/Saed 2023 for the proposition that exposure to talcum powder causes malignant transformation. (*See, e.g.*, Clarke-Pearson 3d Amend Rep. at 6 ("Recently, Harper and Saed also demonstrated that exposure to Johnson's Baby Powder causes p53 mutations, cell proliferation and malignant transformation in normal ovarian epithelial cells."); McTiernan 3d Amend. Rep. at 91 ("A recent study found that talcum powder induced malignant transformation in normal primary ovarian epithelial cells, in a dose-dependent manner."); Smith-Bindman 3d Amend. Rep. at 14 (describing Harper/Saed 2023 and its support with previous studies of talc exposure inducing malignant transformation in normal human ovarian cells); Wolf 3d Amend. Rep. at 16 ("Harper 2023 reported cell proliferation, neoplastic transformation and p53 mutations when cells in culture were exposed to Johnson's Baby Powder"); *see also* Singh Supp. Rep. at 13.)

At the outset, I acknowledge that Harper/Saed 2023 is not without substantive criticism. But Defendants' substantive challenges to Harper/Saed 2023 neither render Plaintiffs' experts' opinions unreliable nor the study itself inadmissible.

Substantively, Defendants claim that the study's observation of malignant transformation is incorrect, and that it is instead indicative of neoplastic transformation. (*See* Defs.' 2024 Biological Plausibility Br. at 44–45.) They argue that the study fails to report the dose of applied talc and only reports the concentration of the solution. (*See id.* at 43 (citing Harper/Saed 2023 at 155).) They also contend the authors selected cell models that are not the site of origin for a common ovarian cancer subtype despite the availability of purportedly appropriate cells. (*See id.* at 43–44.)

But at their core, Defendants' substantive challenges are against the study's methodology and the authors' conclusions, and not against Plaintiffs' experts' methodologies, conclusions, or the application of either to the facts of this case. This is a fatal distinction, as the former improperly expands my limited role as gatekeeper into a scientific factfinder. My role as Special Master under *Daubert*, as well as the Court's subsequent role under the same standard, is not to address or resolve scientific disagreements. *See Trs. of University of Pennsylvania v. Eli Lilly & Co.*, No. 15-cv-6133, 2022 WL 3973276, at *11 (E.D. Pa. Jan. 14, 2022) ("Although [a study] may have flaws, 'it is not the district court's role under *Daubert* to evaluate

the correctness of facts underlying an expert's testimony.'" (quoting *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 856 (Fed. Cir. 2010)). Defendants' substantive criticisms are more appropriate for cross-examination at trial, as they go toward the weight of Plaintiffs' experts' opinions premised on the study and not to the admissibility of their opinions generally. *See Karlo*, 849 F.3d at 83 (explaining that challenges to a study's results ordinarily goes to the weight of the evidence not the admissibility).[76]

Second, Defendants highlight Harper/Saed 2023's rejections from multiple journals whose reviewers criticized it as substantively flawed in an attempt to further discount the value of the study. (*See* Defs.' 2024 Biological Plausibility Br. at 41–42.) As retold by Defendants and corroborated by the peer-reviewers' own correspondence with Dr. Saed, the study, as presented, did not meet publication standards in the targeted journals. Across these journals, the consensus was that the manuscript was premature and methodologically insufficient to support claims of malignant transformation or human biological plausibility. Concerns in this regard

[76] For the avoidance of doubt, I find no evidence to suggest that the study's methodology or results cannot otherwise be trusted due to potential bias. Although Dr. Saed "has served as a paid consultant and expert witness for the plaintiffs in the talcum powder litigation," the "remaining [six] authors have no potential conflicts of interest to report." (Harper/Saed 2023 at 157.) The study also concedes that a "portion of [Dr. Saed's] time conducting this *research* was paid for by the lawyers representing plaintiffs in the talcum powder litigation," but that Dr. Saed "received no financial support for the authorship or publication of" Harper/Saed 2023. (*Id.* (emphasis added).) Dr. Saed's research in this area spans years, and he is one of several authors who contributed to the design, performance, and writing of this study. (See id. (noting authors' contributions).)

generally revolved around methodology, interpretation, relevance, and statistics. For example, a reviewer from Gynecologic Oncology, a peer-reviewed medical journal, primarily criticized on the study's "reliance on a single commercial assay for assessment of transformation that has not been established in the literature." (*See* ECF No. 033013-3 at SAED_SEPT222021_SUPPL_000069.) This reviewer called the results "overinterpreted" due to, among other things, an insufficient correlation to immunohistochemistry, questioned the clinical relevance "given the arbitrary dose selection of talcum powder," and faulted the study's absence of statistical analysis and insufficient particle characterization. (*See id.* at SAED_SEPT222021_SUPPL_000069–70.) A different reviewer from PLOS One, a peer-reviewed journal published by the Public Library of Science, wrote that the "authors' conclusions suggesting acute exposure of talc powder to ovary epithelial cells is associated with ovarian cancer are outrageous and not supported by the manuscript's data" "[b]ased on the minimal amount of data provided in [the] manuscript." (*See* ECF No. 033013-3 at SAED_SEPT222021_SUPPL_000101.)

It is also worth noting that Dr. Jeff Boyd, a molecular geneticist and gynecologic cancer researcher offered by Defendants to, among other things, criticize Harper/Saed 2023, voiced credibility concerns surrounding the publication of the article. (*See generally* ECF No. 33060-5 ("Boyd Rep.").) Dr. Boyd characterized Minerva Obstetrics & Gynecology, the English-language rebrand of

the Italian journal Minerva Ginecologica that published Harper/Saed 2023, as an extremely obscure journal and emphasized its low standing relative to leading outlets in the field. (*See* Boyd Rep. at 14.)

Defendants' emphasis on peer-review criticisms of Harper/Saed 2023 or on the quality of Minerva Obstetrics & Gynecology does not render Plaintiffs' experts' opinions regarding the association between talcum powder and cellular inflammation and oxidative stress unreliable under Rule 702. I acknowledge that prior to publication, Harper/Saed 2023 faced criticism during the peer-review process and that the study is *not without limitations*. But, as discussed throughout this Report and Recommendation, my gatekeeping role is to assess the reliability of the experts' methodologies in this case—not to adjudicate the merits, design, or ultimate correctness of any individual peer-reviewed study.

To be sure, if a study on which experts rely was so fundamentally flawed as to have no or little evidentiary value, reliance on that study could call into question the reliability of the experts' methodology overall. But "'flaws in methodology' uncovered by peer review do not necessarily equate to a lack of scientific validity," particularly where "the methods may be based on scientific principles and the alleged flaws go merely to the weight, not the admissibility, of the evidence and the testimony." *Bonds*, 12 F.3d at 559. Harper/Saed 2023 is undisputedly a peer-reviewed and published study and has therefore been subject to scientific scrutiny.

Excluding expert testimony solely because an expert relies on or references a peer-reviewed study that has drawn criticism would improperly elevate peer-review disputes into dispositive admissibility barriers under Rule 702. Indeed, the converse is also true: peer-review approval or general acceptance does not, standing alone, establish methodological reliability. *See In re Zantac*, 644 F. Supp. 3d at 1172 ("[E]ven if general acceptance of the methodologies used in these two studies was established, acceptance in the scientific community and peer review are not necessarily sufficient to establish the reliability of a scientific methodology."). Accordingly, criticisms of Harper/Saed 2023 bear on the weight of the evidence and the persuasiveness of the experts' conclusions—not on the admissibility of their opinions under Rule 702.

For further support, Defendants point to my prior ruling excluding then-expert Dr. Saed's opinion that talcum powder causes ovarian cancer, which I found to be methodologically unreliable under *Daubert*. (*See* Defs.' 2024 Biological Plausibility Br. at 42–43 (citing *In re Johnson & Johnson*, 509 F. Supp. 3d at 137).) In that ruling, I also noted that reviewer feedback reinforced—but was not dispositive of—my conclusion that Dr. Saed's extrapolation from his *in vitro* work was unsupported and that his methodology lacked sufficient reliability for presentation to a jury. *In re Johnson & Johnson*, 509 F. Supp. 3d at 137.

The circumstances here are materially different. Plaintiffs do not now proffer Dr. Saed as an expert witness. At the time of my prior ruling, Dr. Saed's biological plausibility and general causation opinions were premised largely, if not entirely, on an *in vitro* study he conducted for purposes of the litigation. By contrast, Plaintiffs' experts here do not premise their opinions on any single study, much less litigation-generated research. Instead, they rely on a broad body of epidemiologic, mechanistic, and biological literature, as well as case studies and review articles, to support their opinions linking inflammation to cancer risk. Harper/Saed 2023 is cited by Plaintiffs' experts as one study among many, not as the exclusive or primary foundation for their conclusions.

Finally, even if I were inclined to discount Harper/Saed 2023 and preclude any discussion of the study, that preclusion would not justify excluding "any expert who relies on the paper." (*See* Defs.' 2024 Biological Plausibility Br. at 42.) As noted above, Plaintiffs' experts cite Harper/Saed 2023 *and other studies* as evidence that exposure and use of talcum powder may cause inflammation, oxidative stress, and other biological mechanisms that prompt ovarian carcinogenesis. (*See, e.g.*, Clarke-Pearson 3d Amend. Rep. at 6; McTiernan 3d Amend. Rep. at 91; Smith-Bindman 3d Amend. Rep. at 14; Wolf 3d Amend. Rep. at 16; Singh Supp. Rep. at 13.) Therefore, the preclusion of Harper/Saed 2023, in light of Plaintiffs' experts' reliance, would not justify wholesale exclusion of Plaintiffs' experts.

Based on the foregoing, I find that Plaintiffs' experts reasonably relied on Harper/Saed 2023, *together* with other bodies of scientific evidence, and accurately limited their extrapolation of that study's conclusions in support of their opinions regarding talc's effects on cellular inflammation.

(3) Macrophage-impairment and ovarian cancer

Lastly, Defendants challenge Plaintiffs' macrophage inhibition theory, which purportedly is based on the results of two *in vitro* studies, i.e., Mandarino 2020 and Emi 2021.[77] Defendants generally contend that the data from these two studies does not reliably support the theory that talc-induced inflammation or oxidative stress impairs macrophage function in a manner relevant to ovarian carcinogenesis. (*See* Defs.' 2024 Biological Plausibility Br. at 4, 45–48.) Defendants maintain that without a showing that talc can lead to malignant transformation of macrophages (immune cells that can destroy cancer cells), discussion of any such impairment "is irrelevant." (*Id.* at 46.) Moreover, because the studies analyzed mice, Defendants argue that the findings are even more limited than *in vitro* studies generally. (*Id.*) They claim that Plaintiffs' experts "entirely ignore" that the animal subjects were treated with an "excessive" amount of estrogen—and that even under those "highly

[77] My prior Opinion did not consider this theory. I will therefore address it now. However, I note that as with biological plausibility and other Bradford Hill factors, neither party squares their arguments on Plaintiffs' experts' reports but instead largely debate the literature from which they extrapolate their opinions. I will therefore briefly describe each study and refer to the few experts' reports that discuss them.

artificial conditions, the authors made no claims that any of the observed changes were clinically significant." (*Id.* at 46–47.) Defendants then conclude that despite the studies "stopp[ing] well short of mechanistic conclusions," the experts "exceed the limitations the authors themselves placed on the stud[ies]," which demonstrates their unreliability. (*Id.* at 47–48.)

Plaintiffs respond that Defendants' argument on this point centers on two isolated studies, even though the experts "do not rely on Mandarino [2020] or Emi [2021] in isolation as a basis for a new theory of biological plausibility." (Pls.' Opp. to Defs.' 2024 Biological Plausibility Br. at 52.) Plaintiffs emphasize that both studies tested the effect of talc combined with estrogen "on reducing the anti-tumor abilities of macrophages." (*Id.* at 52–53.) They quote Emi 2021's finding that *in vitro* "exposure to . . . talc particles alone, and especially to a combination of talc with oestrogen leads to substantial genome-wide gene expression changes," while Mandarino 2020 determined that "talc alone and especially in combination with [estrogen] produced changes in gene expression [] may promote pro-tumorigenic environment and less efficient surveillance (tumoricidal) activity of the macrophages." (*Id.* at 53 (quoting Emi 2021 at 1064 & Mandarino 2020 at 6).) They cite Dr. Smith Bindman's opinion that these "noted changes in expression of macrophage genes are pertinent to cancer development." (Pls.' Opp. to Defs.' 2024 Biological Plausibility Br. at 53.)

I will first summarize the two studies, both of which applied *in vitro* models to test whether talc alters macrophage function in ways that could promote ovarian cancer development, particularly in an estrogen-rich milieu. Mandarino 2020 exposed mouse macrophage lines to asbestos-free talc with or without estradiol, then co-cultured these macrophages with murine ovarian surface epithelial cancer cells for 72 hours. (*See* Mandarino 2020 at 3–6.) The researchers observed a range of outcomes for the estradiol and talc combination treated cells, including (1) reactive oxygen species generation and upregulation of gene clusters for the phagocytes,[78] leading the authors to conclude that the combination "produced changes in gene expression that may promote pro-tumorigenic environment and less efficient surveillance (tumoricidal) activity of the macrophages"; and (2) a "microscopic observation" that talc-treated MOSEC cells "appeared more fragile than any controls," i.e., that the combination of talc and estradiol "affected the macrophages to permit higher MOSEC-GFP survival." (*Id.* at 5–7.) As "the first study linking the macrophage, talc particles and estrogen in a potential mechanism to explain the effect of talc" on ovarian cancer, the authors emphasized that their "focus . . . was to demonstrate whether talc is inert when phagocytized in high-estrogen milieu,"

[78] Phagocytosis is "the engulfing and usually the destruction of particulate matter by phagocytes (e.g. macrophage cells) that serves as an important bodily defense mechanism against infection by microorganisms and against occlusion of mucous surfaces or tissues by foreign particles and tissue debris." Phagocytosis, *Merriam-Webster.com Dictionary*, https://www.merriam-webster.com/dictionary/phagocytosis (last visited Jan. 10, 2026).

concluding that "it is not inert"; they admittedly "did not investigate carcinogenic properties of talc *per se*." (*Id.* at 7, 9–10.) Additionally, the authors noted that one limitation of the study was that it applied an estradiol dosage that was "likely at the higher end of concentration ranges," despite justifying same with the high concentration within ovarian tissue that "may be an indication of why talc use is associated with *ovarian* cancer rather than at other sites." (*Id.* at 9.)

One year later, Emi 2021 profiled transcriptomic and epigenomic changes in mice macrophages following 24-hour exposure to talc or the control substance titanium dioxide, with or without estradiol. (*See* Emi 2021 at 1054.) The authors tested some of the same cells with some of the same types of substances and formulas as in Mandarino 2020. (*Id.*) The results showed that all of the talc combined with estrogen samples "were most dissimilar with vehicle control samples," while samples consisting only of talc were similar to the talc-estrogen combination samples. The authors concluded that "talc alone, and especially talc with oestrogen, has induced the most changes in the dataset compared to vehicle control." (*Id.* at 1055 (internal parentheticals omitted).) The authors also found that "approximately 10 times more genes were significantly different after talc and oestrogen exposure vs. titanium dioxide and oestrogen when either was compared to the vehicle control." (*Id.* at 1056–57 (internal parentheticals omitted).) Their other methods of testing produced similar results and assessments. (*See id.* at 1057–64.) The authors

discussed the biological mechanism by which talc can enter the genital tract and that "talc association was more apparent in premenopausal women and those postmenopausal women who were taking oestrogen replacement therapy suggesting higher oestrogen may fuel the pathogenesis." (*Id.* at 1065.) After a lengthy discussion of their epigenomic analysis, they emphasized that their study was "the first to show that a single short-term exposure of microphages *in vitro* to particles can be linked to epigenome-wide DNA methylation changes"—despite noting that several of the effects were detected by both the talc and non-talc samples. (*Id.* at 1068.) They concluded that their findings and further hypotheses based on the talc and titanium dioxide results "merits further testing." (*Id.*)

As Defendants note, only a handful of Plaintiffs' experts considered these studies in their reports and depositions. (*See generally* Smith-Bindman 3d Amend. Rep.; Smith-Bindman Dep.; Levy 2d Amend. Rep.; Singh Supp. Rep.; Plunkett 2021 Dep.) Although I do not find that the experts mischaracterized the two challenged studies *per se*, I am not satisfied that the evidence they have provided meets the more likely than not standard that Rule 702 demands.

The only expert that Plaintiffs cite in their response to Defendants' argument on this point is Dr. Smith-Bindman. In her report, the doctor accurately described both Mandarino 2020 and Emi 2021. (*See* Smith-Bindman 3d Amend. Rep. at 14.) However, after quoting Mandarino 2020's methods and conclusions at length, she

cursorily stated that based on the study, the finding that exposure to talc in a high-estrogen environment can compromise macrophage function, "could apply *in vivo* to exposure to talc." (*Id.*) She not only provided no further explanation for why or *how* she reaches that conclusion, but no citations to scientific literature supporting this opinion. Based on Mandarino's own conclusion that "further studies [are needed] to elucidate [the observed mouse-based] mechanism," (Mandarino 2020 at 1), I cannot find that Dr. Smith-Bindman applied a reliable methodology or sufficiently sound basis in extrapolating the data in reaching her opinion on this issue. *See, e.g.*, *Heller*, 167 F.3d at 153 (The court "must examine the expert's conclusions in order to determine whether they could reliably follow from the facts known to the expert and the methodology used."). The same is true of Dr. Smith-Bindman's passing comment that Emi 2021's discussion and analysis "provides evidence of the impact of these particles for initiating cellular changes that would lead to cancer." (Smith-Bindman 3d Amend. Rep. at 14.) As to Emi 2021, she did not even mention that the study was limited to mice—not human subjects—nor did she link the study to ovarian cancer specifically. (*Id.*) This so-called analysis misses the mark and fails to satisfy the preponderance of the evidence standard under Rule 702 to admit this portion of her opinion.

The other experts that Defendants cite in footnotes similarly fail to adequately engage with the studies' actual data and conclusions in arriving at their perfunctory

statements on this potential biological mechanism. (*See, e.g.*, Levy 2d Amend. Rep. at 16 (neglecting to mention that the challenged studies were only conducted on mice, then summarizing Mandarino's study by saying it "show[ed] the pro-oxidant effect of talc in a cell culture system," the effects of which "were not observed" with the control substances, adding that Emi 2021 made "[s]upporting observations"); Singh Supp. Rep. at 22 (citing Emi for the proposition that studies have shown talcum powder can induce malignant transformation "in normal *human* ovarian cell lines," without providing any explanation for such extrapolation from mice subjects).) Indeed, Mandarino 2020 clearly stated that this was the first study of its kind and that its "focus . . . was to demonstrate whether talc is inert when phagocytized in high-estrogen milieu," but it "did not investigate carcinogenic properties of talc *per se*." (Mandarino 2020 at 7, 9–10.) Emi 2021 also concluded that their findings and further hypotheses based on the talc and titanium dioxide results "merit[] further testing." (Emi 2021 at 1068.) Where the Plaintiffs' experts' opinions are based on a sum total of two animal studies in the last five years, which both attested to needing further experimentation and evaluation to confirm whether their hypotheses can be supported in humans, I do not find that they have sufficiently met their burden under Rule 702 in this regard. *See Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002) ("[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the

conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony.").

For the avoidance of any doubt, I emphasize that my recommendation on this sub-issue does not mean that I find an absence of biologically plausible mechanisms connecting talcum powder to ovarian cancer. I simply find that the data upon which the experts seek to rely in forming their opinions that talc-induced inflammation and oxidative stress impairs macrophage function in a manner relevant to the development of ovarian cancer is inadequate to support the conclusions they purport to draw. My limited recommendation on this point determines only that, under my charge under Rule 702, "there is simply too great an analytical gap between the data and the opinion proffered" to support admission of these testimonies. *Joiner*, 522 U.S. at 146. I therefore find that Plaintiffs' experts' opinions on the microphage inhibition theory should be excluded as they only rely on the two studies Defendants have challenged in their motion.

For the detailed reasons stated above, I recommend that the Court grant in part and deny in part Defendants' Motion to Exclude Plaintiffs' Experts' Opinions Regarding Biological Plausibility/Mechanism. Plaintiffs' experts' opinions regarding the plausibility of upward migration, as well as the association between talcum powder and inflammation and oxidative stress, and association between chronic inflammation and oxidative stress and ovarian carcinogenesis, are largely

admissible by a preponderance of the evidence. As noted, I recommend that the Court exclude Plaintiffs' experts' migration-via-inhalation theory and macrophage-inhibition theory, as they respectively fail to satisfy the preponderance standard under Rule 702 as amended. As for all of Plaintiffs' experts and their respective opinions, Defendants may, of course, cross-examine these experts to show that particular studies are unreliable or that the experts have improperly derived opinions from them.

v. The Remaining Bradford Hill Factors

I turn next to the remaining Bradford Hill factors—specificity, coherence, analogy, experiment, and temporality.[79]

a. Specificity

"An association exhibits specificity if the exposure is associated only with a single disease or type of disease." Green at 605. While most agents do not cause a wide variety of effects, *id.* at 605–06, Dr. Hill advised against overemphasizing the importance of specificity because an agent may cause more than one disease, Hill at 297. This is especially true for agents that "are not in fact single agents but consist of numerous harmful agents." Green at 606. For example, cigarette manufacturers

[79] It bears noting that, notwithstanding Judge Shipp's guidance, much of Defendants' argument regarding the remaining Bradford Hill factors effectively seeks reconsideration of prior rulings, which I will highlight, *infra*. Indeed, Defendants' contentions rest largely on disagreement with my earlier conclusions, and on these motions, such disagreement does not provide a proper basis for revisiting those determinations, except to evaluate whether my prior 702 rulings comport with Amended Rule 702.

"long claimed that because cigarettes have been linked to lung cancer, emphysema, bladder cancer, heart disease, pancreatic cancer, and other conditions, there is no specificity and the relationships are not causal." *Id.* As such, "whereas evidence of specificity may strengthen the case for causation, lack of specificity does not necessarily undermine it where there is a good biological explanation for its absence." *Id.*

In my 2020 Opinion, I explained that at the time, "[e]ach of Plaintiffs' experts found this factor to weigh in support of causation, but did not place significant weight on the factor." *In re Johnson & Johnson*, 509 F. Supp. 3d at 180. For example, Dr. Clarke-Pearson noted that the epidemiologic studies appear to be specifically linking talc use to ovarian cancer, as opposed to other types of cancer; Dr. Carson reasoned that compared to the typical incidence rate of ovarian cancer in the general population of women, the research shows that the disease "occurs more often in women who use talcum powder for hygienic purposes on a regular basis." *Id.* at 181. Defendants' opposition then was based on "the undisputed fact that ovarian cancer is not a single disease," because there exist subtypes with different risk factors and origins. *Id.* I concluded that the experts' opinions rested on "good grounds and considered scientific evidence" to find a specific association to ovarian cancer, with a focus on epithelial ovarian cancer. *Id.* Despite there being "various subtypes," I found that Defendants failed to "sufficiently demonstrate[] that

Plaintiffs' findings are unreliable," and further, that their disagreements with the experts' conclusions "is fodder for cross-examination and not exclusion under *Daubert*." *Id.*

Defendants present the same argument here, contending that "[t]he proposed association in this litigation is highly ***unspecific*** because ovarian cancer is not a single distinct disease; rather there are many different subtypes"; they suggest that this is why "many of plaintiffs' experts place little weight on the specificity factor." (Defs.' 2024 General Causation Br. at 72–73.) They take particular issue with my prior focus on epithelial and serous ovarian cancer because only two of the six bellwether plaintiffs have that subtype. (*Id.* at 73–74.) And, they challenge certain experts' position that O'Brien 2024 supports a finding of specificity based on the study's conclusion that uterine and breast cancer were not associated with talc use, claiming those outcomes are irrelevant to the question at hand.

Before addressing these points, I reiterate that Defendants advanced a materially similar argument in the prior round of briefing. At that time, I concluded that Defendants had "not sufficiently demonstrated" that the existence of ovarian cancer subtypes rendered the experts' methodologies unreliable. *In re Johnson & Johnson*, 509 F. Supp. 3d at 181. Defendants have not identified any new evidence, nor any change in the application of Rule 702, that would warrant departing from that conclusion here.

In any event, Defendants' argument is founded on a generalized claim about cancer subtypes, focusing on selective portions of the experts' opinions. For example, they critique Dr. Siemiatycki for ascribing less weight to this factor, reasoning that he chose to do so *post-hoc* because the factor does not support his position. (Defs.' 2024 General Causation Br. at 73.) However, he in fact opined that he de-emphasized this factor because in the sixty years since Bradford Hill announced these criteria, it has become even more widely understood "that some agents can indeed provoke multiple different pathologies." (Siemiatycki 3d Amend. Rep. at 74.) This accords with the *Reference Manual* excerpt cited above, as well as Sir Bradford Hill's own warning that "[w]e must not . . . over-emphasize the importance of the characteristic," because "multi-causation is generally more likely than single causation." Hill at 297.

Similarly, Dr. Siemiatycki explained that O'Brien 2024 is relevant not because it reflects a process-of-elimination analysis, but because it bears on whether the observed association between talc use and ovarian cancer is specific rather than the product of a generalized reporting bias. (Siemiatycki 3d Amend. Rep. at 54–55.) O'Brien 2024 found no association between talc use and either uterine or breast cancer. (O'Brien 2024 at 13.) While that absence may, in a limited sense, be viewed as consistent with the Bradford Hill concept of specificity, Dr. Siemiatycki placed greater emphasis on the implications of those findings for evaluating recall bias.

(Siemiatycki 3d Amend. Rep. at 55.) Relying on the accompanying editorial by Harris 2024, he explained that uterine cancer—like ovarian cancer—is a malignancy of the reproductive system and relies on similar self-reported exposure histories. (*Id.* (citing Harris et al., *Epidemiologic Methods to Advance Our Understanding of Ovarian Cancer Risk*, 42 J. Clin. Oncol. (22) 2619 (May 15, 2024).) If ovarian cancer cases were systematically over-reporting talc exposure, one would reasonably expect a comparable association to appear among uterine cancer cases as well. (*Id.*) The absence of such an association therefore weighs against recall bias as a nonspecific explanation and supports the inference that the talc–ovarian cancer association is disease-specific. (*Id.* at 54–55.)

This reasoning does not rest on the mere absence of associations with other cancers, but on a comparative assessment of how potential reporting biases would be expected to manifest across related outcomes. Other experts applied similar logic in their analyses. (*See, e.g.*, McTiernan 3d Amend. Rep. at 54; Cote Amend. Rep. at 36; Moorman 2d Supp. Rep. at 9 (also addressing analogous considerations with respect to douching).) I find no basis to conclude that Plaintiffs' experts' methodologies regarding specificity are unreliable or unreliably applied; specifically, I find that their methodologies evince extrapolations that are adequately supported by the existing data. To the extent Defendants dispute the experts'

ultimate conclusions, which are supported by their analyses, those disagreements may be explored through cross-examination at trial.

b. Coherence

The coherence factor ensures that the observed association does "not seriously conflict with the generally known facts of the natural history and biology of the disease." Hill at 298.

In my prior Opinion, I summarized Defendants' three arguments on this factor: (1) there exist subtypes of ovarian cancer and "the notion that talc would cause all of them is incoherent"; (2) no animal studies have shown that talc causes ovarian cancer; and (3) the experts failed to account for studies investigating talc powder in conjunction with diaphragms or condoms that show no increased risk of ovarian cancer. *In re Johnson & Johnson*, 509 F. Supp. 3d at 182. Plaintiffs responded then that observational studies "are long enough to account for the development of ovarian cancer," and that the existing biologic evidence was consistent with the mechanics of the disease. *Id.* When evaluating the parties' arguments, I noted that to assess coherence, the 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." *Id.* at 182–83. As with the specificity factor, I did not find the fact that different types of ovarian cancer exist, to "undermine the experts'

opinion on this factor." *Id.* at 183. I explained why I found Defendants' arguments to "merely show disagreement with the *conclusion* on coherence drawn by the causation experts," rather than with their methodology, because the experts considered the same studies that Defendants raised, but rather "interpreted [them] differently." *Id.* (emphasis added). "Importantly," I concluded, "Defendants do not dispute the known fact about the link of cellular inflammation to cancers in general, which is the basic premise of the experts' opinion on coherence," but instead challenge Plaintiffs' experts' interpretations based on the data, which goes to weight rather than admissibility. *Id.* (internal citation omitted).

On this motion, Defendants first argue that population-level trends undermine Plaintiffs' theory of coherence, pointing to declining ovarian cancer incidence rates between 1990 and 2019, including periods during which talcum powder products remained on the market. In their view, this trend renders it "incoherent to suggest that talc causes cancer." (Defs.' 2024 General Causation Br. at 76.) They also note that perineal talc use has been reported as more prevalent among African-American women, while ovarian cancer incidence rates in that population are comparatively lower—an observation they contend is inconsistent with talc being a causal factor. (*Id.* at 76–77.) Relatedly, Defendants emphasize testimony from Dr. Clarke-Pearson acknowledging that talc is not "'the only cause of ovarian cancer,'" which they argue further undermines Plaintiffs' theory. (*Id.* (quoting ECF No. 33118-9 ("Clarke-

Pearson Dep.") at 134:3–136:9).) Finally, Defendants assert that although several of Plaintiffs' experts assign "considerable weight" to the coherence factor, those experts do not adequately reconcile their opinions with the epidemiologic and demographic data Defendants highlight. (*Id.* at 77.) According to Defendants, the experts instead conflate coherence with biological plausibility, relying on what Defendants characterize as untested and speculative hypotheses regarding the mechanisms by which talc could cause ovarian cancer. (*Id.* at 77–78.)[80]

I begin by noting, as Dr. Hill himself emphasized, that coherence requires only that the proposed causal association "not seriously conflict with the generally known facts of the natural history and biology of the disease." Hill at 298. Based on my review of the record, Plaintiffs' experts have applied that standard in a methodologically sound manner.

Dr. Singh, for example, explained that recent epidemiologic studies demonstrate an increased risk of ovarian cancer among women with patent

[80] Defendants also take issue with my prior reasoning that "whether a plaintiff's ovarian cancer is caused by genetic mutations or use of talc[] is a question of specific causation." (Defs.' 2024 General Causation Br. at 75 n.178.) They say that the absence of evidence tying talc to genetic mutations "underscores the incoherence between the proffered theory of general causation and what is known about ovarian cancer." (*Id.*) But Defendants' argument here is misplaced because Plaintiffs' theory rests on the claim that talc (along with its constituents) directly cause cancer—separate and apart from any possibility that genetic mutations can independently cause ovarian cancer. I therefore reiterate that Defendants' argument does not undermine Plaintiffs' experts' general causation opinions. For further explanation of Plaintiffs' theory regarding inflammation causing cell damage, as opposed to ovarian cancer stemming from genetic mutations, I refer to my prior discussion on the biological plausibility factor. (*See supra* Part V.C.2.iv.)

reproductive tracts, consistent with earlier findings, as well as a higher risk among women with endometriosis, an inflammatory condition. (Singh Rep. at 22–23.) He concluded that these observations are coherent with an association between talc use and ovarian cancer because inflammation is a biologically recognized mechanism relevant to carcinogenesis in this context, and he therefore accorded this factor significant weight. (*Id.*; *see also* Singh Supp. Rep. at 6 (explaining that O'Brien 2024's finding that ovarian cancer risk was highest among women in their twenties and thirties is coherent with known disease biology and patterns of genital talc use).) (*See supra* Part V.C.2.iv.)

Dr. McTiernan likewise recognized that increased inflammation has been associated with ovarian cancer risk and that talc and other components of talcum powder products elicit inflammatory responses in tissues where talc has been detected, including the ovary. (McTiernan 3d Amend. Rep. at 101.) At the same time, she explained that broader population-level trends—such as changes over time in oral contraceptive use, hysterectomy and tubal ligation rates, and obesity prevalence—complicate efforts to isolate temporal coherence, and she therefore assigned this factor comparatively less weight. (*Id.* at 32–33; *see also* Siemiatycki 3d Amend. Rep. at 22–23 (drawing similar comparisons in other disease contexts).)

Other experts treat coherence as closely overlapping with biological plausibility, as Defendants themselves acknowledge. (Defs.' 2024 General

Causation Br. at 77–78; *see, e.g.*, Smith-Bindman 3d Amend. Rep. at 38; Cote Amend. Rep. at 38; Moorman Rep. at 37–38.) Indeed, some formulations of the Bradford Hill framework describe biological plausibility as coherence with existing scientific knowledge. Green at 600. It is therefore appropriate to consider these factors in tandem, and as such, I incorporate my discussion of biological plausibility, *supra* Part V.C.2.iv, into my analysis of coherence.

Contrary to Defendants' suggestion, coherence does not require talc to be the sole cause of ovarian cancer. The inquiry is whether the proposed association seriously conflicts with established biological understanding—not whether alternative causal pathways exist. Accordingly, Dr. Clarke-Pearson's acknowledgment that talc is not the only cause of ovarian cancer does not support a finding of incoherence. The same is true of Defendants' reliance on declining ovarian cancer incidence rates during periods when talcum powder products remained on the market. While such trends may be an appropriate subject for cross-examination, they do not, standing alone, render the experts' coherence analyses methodologically unreliable. As the Rule 702 gatekeeper, I may not substitute population-level observations selectively emphasized by one party for the experts' scientific analyses; that task belongs to the factfinder.

Finally, I do not find any methodological infirmity in the fact that different experts assign differing weight to the coherence factor. So long as those differences

are supported by empirically grounded reasoning, the relative emphasis placed on this criterion is a matter for the jury to assess. Indeed, as the Rule 702 advisory committee notes explain, the experts' varied evaluations of the same body of data may assist the factfinder by framing competing interpretations at trial. Regardless of the weight that each Plaintiffs' expert ascribed to this factor in their individualized analyses, my role is to determine whether they faithfully applied reliable methodologies to arrive at their conclusions that this factor is satisfied. I find that they did. To the extent Defendants wish to question any experts on how and why their colleagues weighted this factor differently, that is appropriate fodder for cross-examination.

c. Analogy

Dr. Hill in his 1965 article provides little guidance with respect to this factor, simply stating: "In some circumstances it would be fair to judge by analogy." Hill at 299. Courts have interpreted this factor to mean that "causal inference is supported where relationships similar to the putative causal relationships have been substantiated." *In re Acetaminophen*, 707 F. Supp. 3d at 337.

In my prior Opinion, I noted that the proffered experts compared the relationship between talc and ovarian cancer to that between asbestos and the development of ovarian and lung cancer. *In re Johnson & Johnson*, 509 F. Supp. 3d at 184. I also noted that the experts did not weigh this factor heavily. *Id.* Nonetheless,

I explained that "[t]here is no dispute that asbestos is carcinogenic" and therefore "it is not unreliable for the experts to opine that because asbestos has been found in talc, it can similarly cause ovarian cancer." *Id.* Defendants found this analogy "inappropriate," because the asbestos mineral most associated with ovarian cancer (i.e., crocidolite) has not been found in talc powder products. *Id.* at 184–85. However, I "reiterate[d] that crocidolite is in the same family as the types of asbestos (anthophyllite and tremolite) that were found in talc—amphibole asbestos"—all of which are regulated. *Id.* at 185. I emphasized that the purpose of this factor is to "compare the causal association at issue to other similarly known causative relationships," *not* to "prove causation." *Id.* I therefore explained that the comparison the experts made between asbestos and talc was "based on these minerals' tendency to cause inflammation, which could lead to carcinogenesis," and that this comparison was more likely than not reliable under Rule 702. *Id.*

Defendants incorporate by reference their Motion to Exclude Asbestos-Related Opinions to challenge the experts' assertions that "asbestos—at least at levels below heavy occupational exposure—causes ovarian cancer," to form their argument that my prior Opinion should not be followed. (Defs.' 2024 General Causation Br. at 78.) They rehash their argument that asbestos and talc are "distinct minerals with distinct chemical structures and morphology," challenging the experts' "conclusory opinions" which, they say, "fail to . . . suggest what particular

qualities of asbestos that make it dangerous are ostensibly shared by talc." (*Id.* at 79.)

In this portion of their argument, Defendants do not cite to any new law aside from a parenthetical about a case I have already addressed, *In re Acetaminophen*, nor to any "new science" since my prior Opinion. Indeed, their argument squares on the same claims I previously considered—albeit without any new reasoning upon which I must depart from my decision. I have already explained my finding that the "particular qualities of asbestos" that Plaintiffs' experts invoke in support of their analogy here, (*id.*), relate to their "tendency to cause inflammation, which could lead to carcinogenesis," *In re Johnson & Johnson*, 509 F. Supp. 3d at 185. (*See, e.g.*, McTiernan 3d Amend. Rep. at 33, 102 (linking increased inflammation with carcinogenesis, analogizing to talc causing an inflammatory response in the ovaries); Siemiatycki 3d Amend. Rep. at 75 (same, acknowledging that this is "a more tenuous aspect" than the prior factors); Cote Amend. Rep. at 38 (same, affording this "a low factor in assessment of causality"); Moorman Rep. at 38 (same); Wolf Rep. at 20 (same).) Finally, to the extent Defendants' arguments here overlap with their Asbestos-Related Motion, I incorporate by reference my discussion of that issue here. (*See infra* Part VI.A.1.)

d. Experiment

Dr. Hill explained that, in limited circumstances, it may be "possible to appeal to experimental, or semi-experimental, evidence." Hill at 298. By way of example, he noted that where an association has been observed, a reduction in exposure followed by a corresponding decrease in disease incidence may support a causal inference. *Id.* Such evidence, where available, may therefore inform the causation analysis.

In my prior Opinion, I addressed Defendants' contention that there was "no reliable support" for Plaintiffs' experts' opinions under this factor, while recognizing that the experts "generally did not afford this factor great weight because of the ethical implications" associated with conducting a randomized trial on talc exposure and ovarian cancer. *In re Johnson & Johnson*, 509 F. Supp. 3d at 184. I further noted that the experts nonetheless referenced *in vitro* and animal studies in support of their opinions, and concluded that Defendants' objections—that contrary experimental studies undermined causation—presented issues of weight for the jury, not admissibility. *Id.*

Defendants now observe that some experts conclude this factor is not satisfied, while others do not address it at all. (Defs.' 2024 General Causation Br. at 80.) They again argue that Plaintiffs' experts selectively rely on certain experimental data while disregarding other studies. (*Id.*) As before, however, Defendants identify

no intervening scientific developments or changes in governing law that would warrant revisiting my prior analysis of this factor. Moreover, Hill himself cautioned that experimental evidence is only "[o]ccasionally" available in observational settings. Hill at 298. Consistent with that understanding, the *Reference Manual* does not include this factor in its articulation of the Bradford Hill considerations. *See* Green at 600–06. Where Plaintiffs' experts did engage with this factor, they explained that a randomized trial would be unethical because genital talcum powder use may pose a risk of harm. (McTiernan 3d Amend. Rep. at 101–02; *see also* Singh Supp. Rep. at 23; Cote Amend. Rep. at 38.) That explanation is consistent with accepted scientific practice and does not reflect a methodological deficiency.

Because this is not a motion for wholesale reconsideration, and Defendants have not identified any basis under Judge Shipp's Order requiring a renewed finding, I decline to revisit this issue. To the extent the parties dispute how particular experimental or semi-experimental studies should be weighed, those disagreements concern evidentiary weight and are properly presented to the jury. My role as the Rule 702 gatekeeper is limited to determining whether the experts have reliably applied their methodologies, and whether their resulting opinions more likely than not are supported by those methodologies, which I find they have done here.

e. Temporality

This factor poses a straightforward—though not always simple—question: "which is the cart and which the horse?" Hill at 297. As the *Reference Guide* explains, "[a] temporal, or chronological, relationship must exist for causation to exist." Green at 601. Put differently, "[i]f an exposure causes disease, the exposure must occur before the disease develops"; if the exposure occurs after disease development, it cannot be causal. *Id.*

In my prior Opinion, I noted that Plaintiffs' experts assigned significant weight to temporality based on evidence indicating that talc exposure generally precedes the onset of ovarian cancer. *In re Johnson & Johnson*, 509 F. Supp. 3d at 181. Defendants responded that this chronology was "unremarkable," given that talc use often begins in early adulthood while ovarian cancer is typically diagnosed later in life. *Id.* I concluded that "[b]oth positions are true," and that the proper weight to assign this factor was a matter for the factfinder, as Defendants' objection reflected scientific disagreement rather than a methodological flaw. *Id.*

Defendants now reprise that argument, asserting that the experts' assignment of "high weight" to the temporality factor is inappropriate. (Defs.' 2024 General Causation Br. at 80–81.) They further argue that the inquiry should focus on disease development rather than diagnosis and contend that, given ovarian cancer's long latency period, disease onset may precede talc exposure in some women. (*Id.* at 81–

82.) In support, they cite testimony acknowledging the difficulty of pinpointing temporality where latency periods are extended. (*Id.*)

As with several other Bradford Hill factors, Defendants do not identify any intervening scientific developments or changes in governing law that would call for reconsideration of my prior ruling. Instead, their argument focuses primarily on the degree of weight certain experts assign to temporality, rather than on any unreliability in the methodologies used to evaluate it. (*Id.* at 80–82.) For example, Defendants criticize Dr. Smith-Bindman for describing temporality as an "important" consideration, but do not identify any methodological deficiency in her analysis. (*Id.* at 80 n.194.) In fact, Dr. Smith-Bindman expressly addressed the concern of reverse causality—where behavior is influenced by disease-related symptoms—and explained why it does not meaningfully affect the epidemiologic studies at issue. Specifically, she noted that most case-control studies asked participants to report only past, not current, talc use, and that cohort studies necessarily assessed exposure among women who had not yet been diagnosed with ovarian cancer. (Smith-Bindman 3d Amend. Rep. at 37; *see also* Moorman Rep. at 29.)

It may be true, as Defendants argue, that such data cannot conclusively establish that talc exposure preceded the earliest biological development of ovarian cancer rather than its diagnosis. But that limitation is inherent in the study of diseases

with long and uncertain latency periods and does not render the experts' analyses methodologically unsound. As several experts acknowledged, temporality can be difficult to determine with precision in this context, yet the available data consistently indicate that reported talc exposure preceded disease onset as understood in epidemiologic practice. (*See, e.g.*, Siemiatycki 3d Amend. Rep. at 21, 103 (Table 13); McTiernan 3d Amend. Rep. at 60–61.) Notably, O'Brien 2024 attempted to address latency concerns by collecting data on talc use beginning at very young ages, including ages 10 to 13. (O'Brien 2024 at 3–4.)

In the context of my gatekeeping role, it is not within my purview to determine whether the temporal relationship between talc and ovarian cancer indeed demonstrates that the former causes the latter. Instead, my role is simply to assess whether the Plaintiffs' experts have reliably described, analyzed, and extrapolated from the relevant data to opine as they propose to testify at trial. I find that they have. On the temporality factor, Plaintiffs' experts have again satisfied their burden, by a preponderance of the evidence, to offer opinions grounded in reliable methodologies; drawing conclusions that are adequately supported by the data and consistent with existing scientific knowledge; while appropriately accounting for the limitations inherent in latency-based disease research. I see no basis to depart from my prior conclusion that the remaining disputes concerning temporality concern the weight of the evidence rather than its admissibility. Those issues are properly

reserved for the factfinder, particularly where Defendants have not presented any new evidence that "directly contradict[s] or challenge[s]" my 2020 findings on this factor. (Apr. 30, 2024 Memorandum Order at 5.)

For these reasons, I recommend that the Court find, by a preponderance of the evidence, that Plaintiffs' experts have reliably applied the Bradford Hill framework in assessing general causation. The experts reviewed the relevant scientific literature, addressed limitations and sources of uncertainty, and articulated reasoned explanations for how they weighed each factor in reaching their conclusions. To the extent Defendants challenge the experts' conclusions or the relative weight assigned to particular Bradford Hill factors, those arguments reflect disputes over evidentiary weight rather than methodological reliability. Such disagreements are fodder for cross-examination and competing expert testimony, but not for exclusion under Rule 702.

6. Asbestos

In addition to their General Causation motion papers, Defendants also move to exclude the opinions of sixteen of Plaintiffs' experts who, according to Defendants, "piggyback off of Drs. Longo and Rigler's testing and opine that the alleged asbestos in cosmetic talc causes ovarian cancer." (Defs.' Asbestos Br. at 83.) In my prior Opinion, I considered this issue within the scope of the "analogy" factor under the Bradford Hill analysis. *In re Johnson & Johnson*, 509 F. Supp. 3d at 184–

85. I explained that "[t]here is no dispute that asbestos is carcinogenic," and that IARC has classified the types of asbestos that had been found in talc (anthophyllite and tremolite) with the type that Defendants argue the literature shows can cause ovarian cancer (crocidolite). *Id.* As discussed below, Defendants raise similar arguments in the context of their Motion to Exclude Asbestos-Related Opinions. (*See* Defs.' Asbestos Br. at 88–93.) Therefore, due to the importance of this issue and for the parties' and the Court's benefit, I will provide a fulsome review of the evidence and arguments in this Report and Recommendation. Accordingly, this portion of the Report and Recommendation applies as well to the three experts who have not issued new reports since the prior round of motion practice—Drs. Carson, Kane, and Smith. (*See* Carson Rep.; Kane Rep.; Smith Rep.) I further note that, in support of their asbestos-related motion, Defendants attach the reports of the remaining thirteen challenged experts that predate the 2024 supplemental reports many of those experts later issued addressing general causation and the Bradford Hill factors. (*See* Defs.' Asbestos Br. at 83 n.212.) Plaintiffs do not attach the experts' 2024 supplemental reports to their Opposition. Accordingly, for purposes of this portion of the Report and Recommendation, I limit my analysis to the expert reports submitted by Defendants in support of the asbestos motion.[81]

[81] Defendants also challenge Dr. Godleski's case-specific expert reports for the Newsome and Gallardo Plaintiffs, which I do not address here. (*See* Defs.' Asbestos Br. at 83 n.212.)

The sum total of what Defendants seek to exclude is the Plaintiffs' experts' opinions that asbestos can cause ovarian cancer. Specifically, Defendants argue that I should exclude such opinions because (1) the studies that the experts rely on to demonstrate an association with ovarian cancer are "confounded by peritoneal mesothelioma diagnoses," (2) the literature "does not support an association between asbestos and ovarian cancer at the levels described by Dr. Longo and Dr. Rigler," and (3) the studies the experts rely on involve a different type of asbestos (crocidolite) than that detected in talc (chrysotile and non-crocidolite amphibole types). (*Id.* at 88–93.) In support of their mesothelioma confounding claim, they reason that Reid 2011[82] and Slomovitz 2021[83] explained that "until very recently peritoneal mesothelioma was often misdiagnosed as ovarian cancer," which, according to Defendants, "rais[es] a significant likelihood that the ovarian cancer cases associated with occupational asbestos exposure in prior studies were actually cases of mesothelioma." (*Id.* at 88–89 (internal quotation marks omitted).)

Next, Defendants emphasize that most of the studies Plaintiffs' experts cite examined "high levels of occupational exposure to the most potent forms of asbestos," which are "not remotely comparable" to the low levels of asbestos Drs.

---

[82] Allison Reid et al., *Does Exposure to Asbestos Cause Ovarian Cancer? A Systematic Literature Review and Meta-Analysis*, 20 Cancer Epidemiol. Biomarkers & Prev. (7), 1287 (2011) (ECF No. 33016-34 ("Reid 2011")).

[83] Brian Slomovitz et al., *Asbestos and Ovarian Cancer: Examining the Historical Evidence*, 31 Int'l J Gynecol. Cancer (1), 122 (2021) (ECF No. 33017-7 ("Slomovitz 2021")).

Longo and Rigler detected in Defendants' talcum powder products—arguing that "[c]ourts routinely reject" those types of analogies. (*Id.* at 89 & n.229 (collecting cases), 90.) They add that the studies of "non-occupational environmental exposure to asbestos have not found a statistically significant association" to ovarian cancer. (*Id.* at 90–91 (emphasis omitted).) Finally, they assert that the studies Plaintiffs' experts invoke "primarily involve exposure to large amounts of ***crocidolite*** asbestos, which is not alleged to be a contaminant of talc." (*Id.* at 91.)

Plaintiffs respond that major regulatory and health bodies—including IARC, the NCI, the EPA, and the multi-agency IWGACP—recognize asbestos as a human carcinogen that causes ovarian cancer without confining that conclusion to occupational settings, and that IARC's 2012 evaluation (reaffirmed in 2024) applies to all six asbestos fiber types and expressly encompasses talc containing asbestiform fibers.[84] (Pls.' Asbestos Br. at 76–77, 87–90.) Plaintiffs quote extensively from

[84] Defendants also move to exclude certain Plaintiffs' experts' opinions on the ground that elongated non-asbestiform talc fibers—which Defendants label "fibrous talc"—cannot cause cancer. (Defs.' Asbestos Br. at 97–102.) The record, however, does not support Defendants' characterization of Plaintiffs' experts' testimony. The terminology used by the parties and experts warrants clarification. Defendants use the term "fibrous talc" to refer to talc fibers that are non-asbestiform and, in their view, distinct from asbestos. Plaintiffs' experts, by contrast, use the term "fibrous talc" to denote talc that occurs in an asbestiform habit—that is, asbestiform talc. As reflected in the scientific literature, "fibrous talc" is not a term of art with a single meaning and may be used to describe talc that occurs either in an asbestiform or non-asbestiform habit. This distinction is critical to understanding the scope of the opinions at issue. Relying on IARC's classifications, Plaintiffs' experts opined that exposure to asbestos and to asbestiform talc can cause ovarian cancer. (*See, e.g.*, Pls.' Asbestos Opp. Br. at 77 (citing IARC 2012's conclusion that exposure to asbestos of six fiber types and to asbestiform talc causes ovarian cancer); *see also, e.g.*, McTiernan Rep. at 10; Wolf Rep. at 76.) A review of the expert reports and deposition testimony demonstrates that Plaintiffs' experts consistently confined their opinions to asbestiform

IARC Monographs vol. 100C to demonstrate that the agency "considered all published occupational exposure studies *and* non-occupational environmental studies" to arrive at its conclusion that "'a causal association . . . was clearly established.'" (*Id.* at 78–79 (quoting IARC 2012 at 256).) Plaintiffs reason that the sources their experts cite "considered the genital application of talcum powder as a primary route of asbestos exposure for the general population," referring specifically to "dermal contact (i.e. through perineal application of talcum powders)," and did not limit their findings to only heavy occupational exposure, although "they clearly could have done so" if that was the authors' intention. (*Id.* at 79 (quoting IARC 2012 at 232).) They further add that the FDA, NCI, and EPA also do not "limit their conclusions . . . to occupational exposure," again, despite recognizing that the majority of the relevant data studied that type of exposure. (*Id.* at 80–82.)

Plaintiffs also dispute Defendants' contention that "the amount of exposure is negligible" in the bellwether cases, reiterating that those individual plaintiffs "used and applied Johnsons Baby Powder and/or Shower to Shower in their genital area *daily* for decades." (*Id.* at 83–84.) Rejecting Defendants' mesothelioma confounder argument, they add that IARC considered and largely discounted misdiagnosis as an

talc and did not define "fibrous talc" as elongated, non-asbestiform talc fibers. (*See, e.g.*, McTiernan Rep. at 10 ("Talc fibers grown in an asbestiform habit are often referred to as 'fibrous talc.'"); Plunkett Rep. ¶ 101 (noting that fibrous talc contains "asbestiform fibers").) Because these experts' opinions are limited to asbestiform talc and those opinions reliably flow from IARC's similar treatment of asbestos and talc grown in an asbestiform habit, Defendants' argument is premised in part on a terminological mismatch rather than a substantive disagreement.

explanation, and that more recent meta-analyses (e.g., Kim 2023[85]; Turati 2023[86]) report statistically significant associations and conclude that misclassification cannot explain the excess risk. (*Id.* at 84–87.)

I begin by reviewing the scientific literature that the parties interpret differently, focusing on the studies to which they devote substantive discussion. In doing so, I note that the parties' dispute centers primarily on competing interpretations of what those studies examined and what conclusions may properly be drawn from them. Defendants do not meaningfully challenge—indeed, largely do not address—the methodologies employed by Plaintiffs' experts, which is the core inquiry in my gatekeeping role under Rule 702. Instead, Defendants contend that the scientific literature, properly understood, supports their position. Absent a showing of methodological deficiencies—such as the improper derivation of conclusions from the cited studies—that would render Plaintiffs' experts' opinions unreliable or insufficient to satisfy the preponderance of the evidence standard, such disagreements concerning interpretation and evidentiary weight are matters for the jury, not grounds for exclusion.

The summaries of the relevant studies are as follows:

---

[85] Seo Young Kim et al., 15 *Asbestos Exposure and Ovarian Cancer: A Meta-analysis* (1) Saf. Health Work (2023) (ECF No. 33132-12 Ex. 91) ("Kim 2023").

[86] Federica Turati et al. *Occupational Asbestos Exposure and Ovarian Cancer: Updated Systematic Review*, 73 Occup. Med. (Lond) (9), 532–40 (2023) (ECF No. 33132-12 Ex. 92) ("Turati 2023")).

- Reid 2011: This meta-analysis reviewed fourteen cohort and two case-control studies between 1950 to 2008. (Reid 2011 at 1287.) Inclusive of all studies, the analysis revealed that the effect size was 1.75 (95% CI, 1.45–2.10), meaning that a review of all studies "showed a 75% excess risk of ovarian cancer in women who had been exposed to asbestos." (*Id.* at 1287, 1291.) This was attenuated to 1.29 (95% CI, 0.97–1.73) in studies with confirmed ovarian cancer cases. (*Id.* at 1287.) Statistically significant excess mortality or incidence of ovarian cancer was reported in four out of 14 of the cohort studies. (*Id.* at 1291.) The authors noted that when "[t]aken without further analysis, women thought to have ovarian cancer had an increased rate in the meta-analysis if reporting having been exposed to asbestos, compared with reference populations," but cautioned that the result "may have occurred because of disease misclassification," *i.e.*, peritoneal mesothelioma—despite noting that misclassification between those two diseases could shift numbers either upward or downward. (*Id.* at 1291, 1293.) The authors also cautioned that there was a "small number of cases" because "[m]uch fewer women than men have been exposed to asbestos, particularly in more heavily exposed occupational settings," while in domestic exposure, "levels have generally been relatively low so that risks and hence numbers of cases have also been few." (*Id.*) The study concluded that the actual cases of ovarian cancer were low in an absolute sense but proportionate in the context of cases in the general reference population. (*Id.* at 1288.) The study did not limit its findings to the occupational context, but rather considered data deriving from environmental exposure as well. (*Id.* at 1287–88, 1294.)

- Camargo 2011[87]: This meta-analysis pooled data from 20 distinct cohorts of women with documented occupational asbestos exposure in literature through March 2010. (Camargo 2011 at 1211.) The analysis found an overall standardized mortality ratio ("SMR") of 1.77 (95% CI, 1.37–2.28), leading the authors to conclude that their "study supports the IARC conclusion that exposure to asbestos is associated with increased risk of ovarian cancer"—a conclusion they asserted generally across both occupational and non-occupational exposure. (*Id.* at 1211, 1216.) The pooled SMRs were also "larger for cohorts exposed predominantly to crocidolite (SMR = 2.18; 95% CI, 1.40–3.37) or mixed asbestos (SMR = 2.00; 95% CI, 1.41–2.84) than for cohorts exposed to chrysotile (SMR =

[87] Camargo et al., *Occupational Exposure to Asbestos and Ovarian Cancer: A Meta-Analysis*, 119 Env't Health Perspectives 1211 (2011) (ECF No. 33017-6 Ex. 100) ("Camargo 2011").

1.40; 95% CI, 1.40–3.37)." (*Id.* at 1214.) The authors noted that "[a] major concern in interpreting our findings is that until recently it has been very difficult to distinguish pathologically between peritoneal mesothelioma and ovarian cancer," but that they "did not observe a difference in pooled SMRs between studies with and without pathologic confirmation" of the disease. (*Id.* at 1216.) However, the "power of this test was limited because there were only two studies with pathologic confirmation." (*Id.* (internal citation omitted).) Another limitation was an "inability to account for nonoccupational risk factors for ovarian cancer other than age," but that when "restricted to highly exposed women [the findings are] compatible with an underlying dose-response effect." (*Id.*)

- Kim 2023: This study conducted a meta-analysis of occupational *and* environmental studies, covering literature through July 2022. (ECF No. 33131 ("Pls.' Asbestos Opp. Br."), Ex. 91 at 1–2.) For data collected after the 2012 IARC Monograph publication, the results yielded an SMR of 2.04 (95% CI, 1.03–4.05); for the combined analysis of studies before and after 2012, the SMR was 1.72 (95% CI, 1.43–2.06). (*Id.* at 1.) The authors noted that crocidolite "is considered the most carcinogenic," but that the studies included exposure to chrysotile and amosite, as well as asbestos in "mixed form." (*Id.* at 3.) As do other studies, the authors noted the potential for misdiagnosis as peritoneal mesothelioma, (*id.* at 2), as well as the "differentiation between occupational and nonoccupational exposure," (*id.* at 6–7), but when only accounting for occupational exposure cases, "the overall direction of the effect estimate did not fundamentally alter our conclusions but rather increased the effect size slightly," (*id.* at 6–7).

The IARC 2012 Monograph was published with the objective "to prepare, with the help of international Working Groups of experts . . . critical reviews and evaluations of evidence on the carcinogenicity of a wide range of human exposures." (IARC 2012 at 12.) "The *Monographs* are used by national and international authorities to make risk assessments, formulate decisions concerning preventative measures, provide effective cancer control programmes and decide among alternative options for public health decisions." (*Id.* at 13.) These evaluations are

"scientific, qualitative judgements on the evidence for or against carcinogenicity provided by the available data." (*Id.*) The Working Group "reviews all pertinent epidemiological studies and cancer bioassays in experimental animals," and "reports that have been published or accepted for publication in the openly available scientific literature." (*Id.* at 13–14.)

As relevant here, the IARC 2012 Monograph noted that "published literature examining the association between asbestos exposure and cancer of the ovaries is relatively sparse, because the workforce occupationally exposed to asbestos . . . has been predominantly male." (*Id.* at 253.) Despite these limitations, the Working Group reviewed and synthesized 11 cohort studies in 13 populations—ten analyzing occupational exposure and three focusing on community-based or residential exposure. (*Id.* at 254–59.)[88] The Monograph explained that its "conclusions . . . about asbestos and its carcinogenic risks apply to these six types of fibers [serpentine mineral chrysotile, actinolite, amosite, anthophyllite, crocidolite, and tremolite] wherever they are found, and that includes talc containing asbestiform fibers"; in other words, the Monograph did not limit its findings to crocidolite or any other particular type of fiber. (*Id.* at 219.) Having reviewed the data, the Working Group found "a causal association between exposure to asbestos and cancer of the ovary,

[88] These include many of the same studies the above meta-analyses reviewed, including those referenced directly in the parties' briefs, e.g., Acheson 1982, Ferrante 2007, Reid 2008, and Reid 2009.

based on five strongly positive cohort mortality studies of women with heavy occupational exposure to asbestos (Acheson et al., 1982; Wignall & Fox, 1982; Germani et al., 1999; Berry et al., 2000; Magnani et al., 2008)," adding that "[t]he conclusion received additional support from studies showing that women and girls with environmental, but not occupational exposure to asbestos (Ferrante et al. 2007; Reid et al. 2008, 2009) had positive though non-significant increases in both ovarian cancer incidence and mortality." (*Id.* at 256.) The Monograph also concluded that while exposure can happen in occupational settings, "[c]onsumer products (e.g., cosmetics, pharmaceuticals) are the primary sources of exposure to talc for the general population. Inhalation and dermal contact (i.e. through *perineal application of talcum powders) are the primary routes of exposure*." (*Id.* at 232 (emphasis added).)

As of 2024, IARC classifies asbestos as a Group 1 carcinogen, *i.e.* "carcinogenic to humans," and talc as Group 2A, i.e., a "probable carcinogen." (ECF No. 33132-11, *IARC Monographs Evaluate the Carcinogenicity of Talc and Acrylonitrile*, IARC Monographs vol. 136, Questions & Answers (Q&A), at 5 (July 5, 2024).) IARC explained these classifications as supported by the fact that there is "sufficient evidence that asbestos causes . . . cancers of the . . . ovary in humans," and "contamination of talc with asbestos remains a major concern and may lead to exposure of workers and the general population," because as the Working Group

noted, "contamination of talc products with asbestos has been documented and [] industry standards used to assess talc in cosmetic and pharmaceutical products have often not been sufficiently sensitive to rule out contamination with asbestos." (*Id.*)[89]

Plaintiffs also rely on similar conclusions reached by the NCI, EPA, and IWGACP (which includes representatives from the FDA, National Institutes for Occupational Safety and Health ("NIOSH"), National Institute of Health ("NIH"), National Institute of Environmental Health Sciences ("NIEHS"), OSHA, EPA, Consumer Product Safety Commission ("CPSC"), National Institute of Standards and Technology ("NIST"), and United States Geological Survey ("USGS")). (*See* Pls.' Asbestos Opp. Br. at 80–82, 87–88.) They emphasize, for example, that the IWGACP arrived at the same conclusion that "[e]xposure to asbestos may also lead to diseases . . . including cancers of the . . . ovaries" in their analyses of cosmetic talc products—without limiting their findings along fiber-specific or exposure type grounds. (IWGACP White Paper at 9; *see also* ECF No. 33132-11, Ex. 84, *Final Rule Regulating Use of and Limiting Exposure to Chrysotile Asbestos* (March 28,

[89] Defendants, however, interpret IARC 2024's conclusions differently. Echoing their argument writ large, they claim that IARC's analyses were "based on five studies involving heavy occupational exposure predominantly to crocidolite asbestos." (Defs.' Asbestos Br. at 92.) They therefore do not consider IARC 2024 to support Plaintiffs' position in this litigation. However, as discussed above, IARC did not confine its findings to those contexts. Also, during the November 25, 2025 Oral Argument, Defendants invoked the IARC 2025 Monographs in the context of being "entirely consistent with what the agency put out in 2024"—that is, in their view, finding "inadequate evidence of an association [between talc and] ovarian cancer"—despite agreeing that the 2025 documents are not part of the record in this matter. (Nov. 25, 2025 Tr. 10:11 to 13:4.)

2024) (noting that "[m]any authorities have established causal associations between asbestos exposures and . . . cancer of the ovary").)

Having summarized the relevant literature and publications, I next reviewed the expert reports that Defendants seek to exclude to determine whether the opinions regarding the potential for asbestos in talc to cause ovarian cancer are grounded in the application of reliable methodologies. At the outset, I reiterate that neither party meaningfully tailors its arguments to the methodologies employed by individual experts. Instead, the parties focus on competing interpretations of what the existing data demonstrate. Defendants do not challenge the experts' methodologies in general terms; rather, they argue for a particular interpretation of the science—namely, that only crocidolite asbestos, at high doses and through occupational exposure, bears a causal relationship to ovarian cancer—and criticize Plaintiffs' experts for reaching a broader conclusion that exposure to asbestos, in any form and at any level, has the potential to cause ovarian cancer.

The starting point of my review, however, is an assessment of the experts' methodologies under Rule 702, including whether their interpretations of the studies on which they rely are adequately supported. In that regard, I refer to certain expert reports as illustrative examples of the methodologies employed. To be clear, the portions of Plaintiffs' experts' reports that Defendants seek to exclude here are distinct from the Bradford Hill analyses addressing the carcinogenic properties of

talcum powder itself, discussed *supra*. (*See supra* Part V.5.) Instead, the challenged asbestos-related opinions are offered in the causation context to support the proposition that asbestos is one component of talc that may cause ovarian cancer. Defendants move to preclude Plaintiffs' experts from testifying that asbestos can cause ovarian cancer at all. Thus, the dispute is not whether Plaintiffs' experts may opine as to a particular fiber type, exposure level, or dose, but whether asbestos possesses carcinogenic qualities capable of causing ovarian cancer.

With this in mind, I find that Plaintiffs' experts undertook a faithful review of the scientific literature discussed above—including its respective strengths and limitations—to assess whether, in their professional judgment, a sufficient foundation exists to support their opinions that asbestos contained in talc can cause ovarian cancer. For example, Dr. Smith cited evidence from medical literature that talcum powder contains asbestos, which accords with Dr. Longo's and Defendants' own testing revealing the same result. (Smith Rep. at 18.) She explained that "[a]sbestos is well known to be one of the most potent human carcinogens," including causing ovarian cancer specifically. (*Id.*) Dr. Smith discussed that the IARC 2012 Monograph determined that "all forms of asbestos" are carcinogenic, finding a "causal association" between ovarian cancer and asbestos. (*Id.*) She cited Camargo 2011's finding of an SMR of 1.77 for risk of ovarian cancer mortality, which "corroborate[d] the finding of the IARC Working Group." (*Id.*) Dr. Smith

acknowledged Defendants' argument that distinguishing diagnoses of peritoneal mesothelioma and ovarian cancer "can be difficult," but cited several studies in support of her opinion that "[e]ven with such discrimination, asbestos increases ovarian cancer risk." (*Id.* at 19.)

Dr. Kane took a similar methodological approach in arriving at her proffered opinion. (*See* Kane Rep. at 29–33.) The doctor reported seeing "evidence that talcum powder products manufactured by Johnson & Johnson . . . contained and continue to contain asbestos," and explained that asbestos has "been identified as [a] known carcinogen[] by IARC," adding that NIOSH has determined that there is "no safe level of asbestos exposure for any type of asbestos fiber." (*Id.* at 29 (internal quotation marks omitted).) After discussing the different asbestos types and how they may induce inflammation, she noted that despite asbestos' widely accepted causative relationship with mesothelioma, "[t]he relationship between asbestos exposure and ovarian cancer had been less studied." (*Id.*) However, she noted, IARC has "concluded that there is sufficient evidence to show that asbestos exposure can cause ovarian cancer." (*Id.*) Dr. Kane then reviewed the limited literature from the 1960s through the 1980s, which found higher than expected death rates from ovarian cancer in connection with asbestos exposure—albeit a connection manifested in small absolute numbers. (*Id.* at 30.) As part of her report, she also discussed, where available, 1960s through 2000s studies' Standardized Incidence Ratio ("SIR"), the

types of asbestos involved (whether known, unknown, or a mixture of types), and the magnitude of exposure (i.e., occupational or environmental). (*Id.* at 30–32.) She then reviewed the two 2011 meta-analyses, Reid 2011 and Camargo 2011, which both found evidence of a link between ovarian cancer and asbestos—the latter a stronger association than the former. (*Id.* at 33.) Based on her review of this body of literature, she opined with "a reasonable degree of scientific certainty that asbestos exposure can cause ovarian cancer," and that "to the extent that talcum powder products contain even small amounts of asbestos, the evidence of causation is even more compelling." (*Id.*)

Furthermore, Dr. Smith-Bindman considered the properties of asbestos and the research of their presence in talc—specifically in Defendants' products. (*See* ECF No. 33016-30 ("Bindman 2d Amend. Rep.") at 11–12.) She then discussed the scientific findings and public pronouncements regarding asbestos being a carcinogen. (*Id.* at 12.) She reviewed similar studies to those discussed above to support IARC's conclusion that "there is sufficient evidence that asbestos is carcinogenic in humans (Group 1) and that asbestos causes cancer of the ovary." (*Id.*) She added that "IARC explicitly stated that the findings . . . applied to all forms of asbestos." (*Id.*)

Having summarized these experts' methodologies, I further note that the remaining experts employ materially similar approaches—namely, a review of the

pertinent scientific literature followed by a reasoned synthesis of that evidence—to reach their respective opinions regarding the association between asbestos exposure and ovarian cancer. Where, as here, Plaintiffs' experts seek to testify only that asbestos contained in talc powder possesses carcinogenic properties capable of causing ovarian cancer, that methodological consistency supports the reliability of their opinions under Rule 702. The challenges that Defendants raise here go to the weight of the testimony and should be reserved for cross-examination, rather than exclusion.

Against this methodological backdrop, Plaintiffs further point to the policies and statements of relevant regulatory agencies mentioned *supra*, which are largely consonant with the opinions offered by Plaintiffs' experts. At the outset, I emphasize that those agency determinations are not themselves the subject of my Rule 702 inquiry, nor do I assess whether the agencies' conclusions were reached in a manner that would satisfy the evidentiary standards governing expert admissibility. My review remains confined to the reliability of the experts' own methodologies and analytical processes.

That said, in evaluating whether Plaintiffs' experts employed reliable methods, it is not insignificant that the analytical approaches they adopted mirror those employed by regulatory bodies charged with assessing the causal relationship between asbestos exposure and ovarian cancer. Those agencies relied on the same

general body of scientific literature disputed here and reached conclusions that substantially align with those of Plaintiffs' experts. This provides additional support for the reasonableness of the experts' methods and their extrapolations from the available data. In particular, notwithstanding Defendants' substantive criticisms regarding asserted limitations in the underlying studies, regulatory agencies have concluded that the existing evidence is relevant to cosmetic talc products and have not confined their guidance or warnings to occupational exposures or to particular asbestos fiber types, such as crocidolite. Viewed in that context, there is adequate support and basis for Plaintiffs' experts—having conducted their own independent review of the literature—to have applied comparable analytical frameworks in reaching their respective conclusions.

I emphasize that, in reaching the above conclusion, I do not make any determination as to whether Plaintiffs' experts are ultimately correct on the merits. My role at this stage is limited to assessing whether the challenged opinions are more likely than not grounded in the application of reliable methodologies and are sufficiently supported to be presented to a jury under Rule 702. Yet, Defendants' entire argument in this context bears on criticisms of Plaintiffs' experts' conclusions drawn from the studies cited by the experts. But whether the experts' conclusions are persuasive in light of the full evidentiary record is a matter for the jury to resolve. I find that Plaintiffs' experts have not mischaracterized the methods or findings of

the studies on which they rely. The experts opined at a general level—that asbestos can cause ovarian cancer—based on a comprehensive review of the relevant scientific literature. Even if Defendants dispute whether particular agencies or researchers properly interpreted asbestos exposure data under specific conditions, Plaintiffs' experts have not misstated those studies or their results. Rather, they accurately presented the data and conclusions as part of a broader analytical framework supporting their opinions.

Nevertheless, Defendants' substantive critiques of the evidence are not without force. As they emphasize repeatedly, much of the epidemiological literature addressing asbestos and ovarian cancer focuses on occupational exposure, and even within that body of research, data specific to women are limited—an observation that takes on added significance when contrasted with the ultra-trace levels of asbestos identified by Drs. Longo and Rigler, ranging from 0.0092% to 0.0000033%. (Defs.' Asbestos Br. at 90.) These considerations, however, bear on the weight of the experts' opinions, not on the reliability of the methodologies they employ in order to simply opine that asbestos, as a component of talcum powder within Defendants' products, can cause cancer.

For that reason, I decline to rely on the non-binding authority Defendants cite to argue that such differences compel exclusion. Those cases are readily distinguishable. In *Boyer v. Weyerhaeuser Co.*, No. 14-286, 2016 WL 705233 (W.D.

Wis. Feb. 19, 2016), the court addressed whether workers' alleged asbestos-related injuries stemmed from occupational or non-occupational exposure in the context of workers' compensation exclusivity. The dispositive issue there was the need to distinguish among different exposure pathways—such as workplace exposure versus exposure from living or attending school near a facility. *Id.* at *19. No such dispute exists here, where all parties agree that the alleged exposure pathway is cosmetic talc through perineal application.

The remaining cases Defendants invoke are similarly inapposite. *Cerna v. South Florida Bioavailability Clinic, Inc.*, 815 So. 2d 652 (Fla. Dist. Ct. App. 2002) applied the *Frye* standard rather than *Daubert*. *Sutera v. Perrier Group of Am., Inc.*, 986 F. Supp. 655, 662 (D. Mass. 1997) excluded expert testimony where the plaintiffs had produced no peer-reviewed epidemiological studies demonstrating an association between the agent and the disease. And *Bostic v. Georgia-Pacific Corp.*, 439 S.W.3d 332 (Tex. 2014) concerned whether the plaintiffs satisfied Texas substantive causation standards—not whether any of the exerts' opinions were the product of reliable methodology under Rule 702.

As with all expert testimony, Defendants remain free to rigorously challenge the experts' assumptions, reasoning, and conclusions through cross-examination and the presentation of contrary evidence. At this time, I recommend that the Court

permit these experts to opine on the causative effect of the types of asbestos that Drs. Longo and Rigler detected in Defendants' products and ovarian cancer.

7. Heavy Metals and Fragrances

Defendants move to exclude Plaintiffs' experts from testifying that certain heavy metals and fragrance chemicals found in Defendants' products contribute to the ovarian carcinogenicity of Defendants' talc products. Defendants' central contention is that the experts have not established and cannot establish, through scientific evidence, a causal link between exposure to the heavy metals or fragrance chemicals allegedly present in Defendants' talc products and ovarian cancer.

With respect to heavy metals, Defendants generally argue that Plaintiffs' mineralogy experts, Drs. Robert B. Cook, Ph.D., and Mark Krekeler, Ph.D., "were primarily asked to opine on mining processes" but they nevertheless "seek to testify that the heavy metals at issue are human carcinogens" despite having "zero expertise in biology or medicine." (ECF No. 33005-2 ("Defs.' Heavy Metals and Fragrances Br.") at 8.) They further argue that twelve other Plaintiffs' causation "experts each devote a few sentences buried in their otherwise lengthy reports to the purported opinion that heavy metals are present in [Defendants' talc products] and that these substances cause ovarian cancer." (*Id.* at 8–9.) Defendants also contend that these experts' heavy metal opinions are unreliable and should be excluded. (*Id.* at 15–26.)

As to fragrance chemicals, Defendants argue that several of Plaintiffs' causation experts impermissibly "parrot" the opinions of Plaintiffs' fragrance chemicals expert, Dr. Michael Crowley, Ph.D., that the fragrances added to Defendants' products contribute to their alleged carcinogenicity. (*Id.* at 6, 14–15.) Defendants claim that thirteen of Plaintiffs' "experts who have no expertise on this topic and did not undertake their own, independent analysis blindly adopt Dr. Crowley's conclusion." (*Id.* at 14.) Defendants posit that Dr. Crowley's opinions, and those advanced by all experts who simply mechanically repeat Dr. Crowley's opinions, "do not pass muster under Rule 702 or *Daubert*." (*Id.* at 27.)

i. Consideration of Defendants' Arguments in the 2020 Opinion

Before addressing the substantive aspects of Defendants' motion, I must first address the permissible scope, under Judge Shipp's April 30, 2024 Memorandum Order, of Defendants' challenges.

I addressed the issue of heavy metal contamination in my prior Opinion, specifically as it related to the biological plausibility factor of the Bradford Hill analysis. *In re Johnson & Johnson*, 509 F. Supp. 3d at 172 & n.39. My analysis discussed the opinions of Dr. Arch Carson as a representative causation expert. *See id.* at 172 & n.39. I observed that "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." *Id.* at 172. In a corresponding

footnote, I addressed Defendants' argument 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." *Id.* at n.39.

I permitted Dr. Carson "to testify that it is *plausible* that, as carcinogens, these heavy metals may cause ovarian cancer with respect to his Bradford Hill analysis only." *Id.* Dr. Carson explained during the *Daubert* hearing that "while there are no studies linking these specific metals to ovarian cancer, they have been identified by the IARC as carcinogens, and these metals have been linked to specific types of cancer." *Id.* Relying on IARC's recognition that identification of a carcinogen's target organ or tissue does not preclude the possibility that it may cause cancer at other sites, Dr. Carson "opined that similar to asbestos, the carcinogenic heavy metals found in talc may plausibly cause other types of cancer, such as ovarian cancer." *Id.* "To the extent Defendants take issue with that opinion," I stated, "they may cross-examine Dr. Carson on that basis." *Id.*

Defendants argue that their motion addressing heavy metals is appropriate, under Judge Shipp's April 30, 2024 Memorandum Order, because my ruling related to Dr. Carson "was not a fulsome *Daubert* analysis" and "did not address any other experts' opinions" on the topic of heavy metals. (Defs.' Heavy Metals and Fragrances Br. at 2.) Defendants have filed a motion to exclude that encompasses all

experts who opine on the subject of heavy metals and fragrance chemicals. In addition, Plaintiffs do not object to my consideration of Defendants' heavy metals arguments. Based upon Defendants' arguments, and because my prior ruling was confined to Dr. Carson's opinion and did not consider the opinions of other experts concerning heavy metals, including Drs. Cook and Krekeler, I believe revisiting my prior analysis is appropriate. Therefore, I will consider the parties' heavy metal arguments (including those arguments that relate to Dr. Carson's opinion) without limitation. Likewise, because my prior decision did not analyze the admissibility of Plaintiffs' experts' opinions regarding fragrance chemicals, I will consider the parties' arguments on this matter without limitation.

ii. Summary of Plaintiffs' Heavy Metals and Fragrances Experts and Opinions

I begin my analysis of Defendants' Motion to Exclude Plaintiffs' Experts' Opinions Regarding Alleged Heavy Metals and Fragrances by discussing the relevant experts' qualifications and summarizing the opinions that concern heavy metals and/or fragrances. I start by discussing the qualifications and opinions of Drs. Cook and Krekeler that Plaintiffs seek to offer at trial, followed by the qualifications and opinions of Dr. Crowley. I then discuss the opinions of other Plaintiffs' experts that rely on the opinions of Drs. Cook, Krekeler, and Crowley.

a. Drs. Cook's and Krekeler's opinions

Both Dr. Cook and Dr. Krekeler offer opinions regarding the presence of heavy metals—such as nickel, chromium, and cobalt—in the mines used by Defendants and in their talcum powder products.

Dr. Cook holds an E.M. degree in Mining Engineering from the Colorado School of Mines, and an M.S. and Ph.D. degrees in geology from the University of Georgia. (ECF No. 33005-5 ("Cook Rep.") at 2.) He later entered academia, serving as a professor and, ultimately, as head of the geology department at Auburn University. (*Id.*) He has consulted with the United Nations, NASA, the Department of Defense, and the Department of Justice, and is a registered geologist in Alabama, Georgia, and Florida. (*Id.*) He has authored the state mineralogies for Alabama and Georgia, describing all minerals known to occur in each state, including deposits containing talc, asbestos, and heavy metals, and has published approximately 100 research papers concerning geology and related subjects. (*Id.*) His non-academic experience includes exploration and consulting for mining companies, specifically concerning the exploration for and mineralogy of talc deposits independent from his work on this litigation. (*Id.*)

Dr. Krekeler holds a Ph.D. in Geotechnical Engineering and Earth Science from the University of Illinois at Chicago and is a tenured Associate Professor in the Department of Geology and Environmental Earth Science at Miami University in

Oxford, Ohio. (ECF No. 33005-4 ("Krekeler Rep.") at 1.) His academic and research work centers on mineral properties and mineral-based geotechnologies, with particular emphasis on metals and industrial minerals occurring in igneous, sedimentary, and metamorphic systems, among others. (*Id.*) As reflected in his curriculum vitae, Dr. Krekeler has authored or co-authored multiple publications on mining-related topics. (*Id.*; *see also id.*, Ex. A.) Beyond his scholarship, Dr. Krekeler has consulted for mining companies on mineral sampling procedures and techniques and has provided detailed analyses of ore minerals and waste materials. (*Id.* at 1.) He also teaches undergraduate and graduate courses in mineralogy, geochemistry, ore geology, and analytical techniques. (*Id.*)

Turning to both experts' opinions, Dr. Cook explained in his report that "talc deposits can contain asbestos, asbestiform minerals, or minerals containing elevated levels of heavy metals and arsenic, making their ores potentially unsafe." (Cook Rep. at 4 (footnote omitted).) He opined that the Vermont talc deposits used by Defendants in their talcum powder products "contained high levels of heavy metals including nickel and chromium, known carcinogens, and cobalt which has been classified as a possible human carcinogen." (*Id.* at 42; *see also id.* at 4, 37.) Dr. Cook reached these conclusions after examining, among other things, the mineralogy of the Vermont talc deposit, Defendants' testing, and IARC's 2012 Monographs. (*Id.* at 3–4, 11–13, 30–37, 43.) He further opined, based on Defendants' internal testing,

that nickel, chromium, and cobalt were present in Defendants' "finished talc products in amounts above Johnson & Johnson's . . . specified limits." (*Id.* at 36.)

Dr. Krekeler similarly reported that "talc often is associated with or contains arsenic, and heavy metals such as cadmium, cobalt, chromium, lead, and nickel." (Krekeler Rep. at 31; *see also id.* at 6–7.) He also reported that "IARC has classified chromium (Cr) and nickel (Ni) as human carcinogens, and cobalt (Co) as a Group 2B carcinogen, or a possible carcinogen to humans." (*Id.* at 6.) Dr. Krekeler opined, after reviewing various documents and test results related to heavy metals, that there is sufficient evidence to conclude that the talc mined in Vermont for Defendants' talcum powder products contained excess amounts of nickel, chromium, and cobalt. (*Id.* at 34–39.) Dr. Krekeler further opined that the presence of these heavy metals at such elevated levels is consistent with the geology of the Vermont talc deposits. (*Id.* at 35, 37, 39.)

b. Dr. Michael Crowley's opinions

Plaintiffs proffer Dr. Crowley as an expert in chemistry and pharmaceutical science. (ECF No. 33005-17 ("Crowley Dep.") at 30:12-19.) Dr. Crowley holds a Ph.D. in molecular pharmaceutics from the University of Texas. (ECF No. 33005-14 ("Crowley Rep.") at 206.) He is the President of Theridian Technologies, LLC, a pharmaceutical consulting group, and co-founder of Oticara, Inc., a specialty pharmaceutical company. (*Id.*) He has consulted for more than fifty companies,

primarily in the pharmaceutical industry, regarding "proof of concept, formulation and product development, drug delivery and clinical development, including generation of FDA regulatory submissions." (*Id.* at 15.) He has developed over fifty formulations that have been tested in human clinical studies and has authored or co-authored over fifteen clinical study protocols. (*Id.*) He has also authored or co-authored over thirty published articles and abstracts and four book chapters. (*Id.* at 16.) Further, he has served as a reviewer for peer-reviewed journals and is an inventor on five U.S. patents, as well as multiple foreign patents and pending applications. (*Id.*)

Regarding Dr. Crowley's opinions, the doctor was tasked to evaluate "the fragrance components of Johnson and Johnson's talcum powder products and the question of whether these substances contribute to the development of ovarian cancer."[90] (Crowley Rep. at 12.) According to Dr. Crowley, "Johnson's Baby Powder contains a mixture of 141 fragrance chemicals, some of which are extracts that are themselves a mixture of chemicals," and "the Shower to Shower product contains a fragrance mixture comprising 53 fragrances, some of which are mixtures themselves." (*Id.*) Dr. Crowley opines, after accounting for fragrance chemicals

[90] Dr. Crowley testified in his deposition that some of the substances he reviewed would not technically be classified as fragrances. (*See, e.g.*, Crowley Dep. at 199:16–20, 342:12–343:3.) For simplicity, this Report and Recommendation collectively refers to all substances that were the subject of Dr. Crowley's analysis as "fragrance chemicals."

present in both products, "there are at least 175 fragrance chemicals between the two products." (*Id.*)

In his report, Dr. Crowley answered two questions: (1) "Are the fragrance chemicals in compliance with governmental and industry standards?" and (2) "Can the fragrance chemicals in the talcum powder products contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the products?" (*Id.*) To answer these questions, Dr. Crowley "conducted an independent review of the regulatory standards, safety, toxicological, medical, pharmacological and other scientific literature concerning the fragrance chemicals present in Johnson's Baby Powder and Shower to Shower talcum products." (*Id.*)

During his deposition, Dr. Crowley stated that he "tried to examine the totality of the evidence for each and every chemical and collate. . . in a meaningful way to examine their properties and to answer the questions that were posed to [him]." (Crowley Dep. at 111:10–15.) Specifically, Dr. Crowley testified as follows regarding his methodology:

> Q. What methodology did you use in reaching your opinions in this case?
>
> A. I was given the list of fragrance chemicals. I set about identifying them. The names of the chemicals were in the Thomas Dydek report. That often started by just plugging that into Google or PubChem to see what I could find.

> After doing that, I would then try to identify a CAS [Chemical Abstracts Service] number so I could cross-reference it into various databases and gather the physical and chemical properties, as well as the safety profile, *in vitro* or *in vivo* studies, and any published or known pharmacological properties.
>
> I would then go to IFRA [International Fragrance Association] and CIR [Cosmetic Ingredient Review] websites and look at their - the information they had on it, the FDA [U.S. Food and Drug Administration] website, in particular the Inactive Ingredient Database.
>
> I looked in some of the journals, specifically Food and Chemical Toxicology, to see what the studies were. I looked at the EFSA website, the European Food Safety Authorities, you know, all the different places that I've identified in my report and gathered as much information as I could on it.
>
> Once Appendix A and Appendix B [to the report] were built, then I started classifying them. How many of them are considered - are classified as irritants? Which ones are allergens? Which ones are eye irritants? And so forth.
>
> I also looked at, you know, the RTECS database, the Registry of Toxic Effects of Chemical Substances, and so forth.

(*Id.* at 109:5–110:16.)

After conducting his review of the fragrance chemicals, and based on his "education, training, and experience in the fields of molecular pharmaceutics, chemistry and drug delivery," Dr. Crowley concluded that certain fragrance chemicals used by Defendants in their talcum powder products are not in compliance

with governmental and industry standards. (Crowley Rep. at 65.) Additionally, Dr. Crowley opined that "the fragrance chemicals in the Johnson & Johnson talcum powder products contribute to the inflammatory properties, toxicity, and potential carcinogenicity of these products." (Crowley Rep. at 66; *see also* Crowley Dep. at 199:22–200:12 (opining that "perineal application of the talc products is associated with a higher risk of cancer . . . and fragrance chemicals . . . contribute to that").) In summary, he based this opinion on the following:

- Only 1 of the 141 fragrance chemicals in the Baby Powder product have been investigated for safety in the vagina in a product approved by the FDA.
- Only 2 of the 53 chemicals in Shower to Shower have been investigated for safety in the vagina in a product approved by the FDA.
- Several fragrance chemicals are irritants, sensitizers, and allergens that can cause inflammation and oxidative stress.
- *In vitro* and *in vivo* studies have demonstrated that several fragrance chemicals have biological activity, including reproductive and developmental effects. These studies have been published in peer reviewed scientific journals.
- Four chemicals in Johnson and Johnson's Baby Powder product have been identified by the International Agency for Research on Cancer (IARC) as potential carcinogens: styrene, coumarin, eugenal and d-limone.
- Styrene has been recognized as a carcinogen by multiple governmental regulatory bodies.

- The U.S. Environmental Protection Agency considers p-cresol, also known as 4-methylphenol, to be "possibly carcinogenic."

- p-Cresol was co-carcinogenic and promoted tumors on mouse skin.

- Three fragrance chemicals added to Johnson and Johnson's Shower to Shower are included in the IARC monographs as possible carcinogens: benzophenone, eugenol and coumarin.

- Benzophenone was recently removed from use in foods by FDA due to histiocytic sarcoma observed in ovaries and uterus, higher incidences of kidney tumors and leukemia in animal studies, and *in vivo* estrogenic activity.

- Musk ketone is suspected of being a carcinogen, and has been classified as a Category 3 carcinogen by the Scientific Committee on Health and Environmental Risks (SCHER)

- Methyl Hydrogenated Rosinate is present in Baby Powder and Shower to Shower. Methyl Hydrogenated Rosinate is a film former and used to adhere the fragrance chemicals to the talcum powder.

- The safety margins of the 175 fragrance chemicals were determined for foods (oral administration) or cosmetics (topical application to the skin).

- Only 3 fragrance chemicals are present in an approved drug product administered to the vagina according to the FDA IID.

(Crowley Rep. at 65–66.)

Dr. Crowley clarified, however, that he did not opine that fragrance chemicals alone can cause or increase the risk of ovarian cancer or other cancers. (Crowley Dep. at 105:19–106:14.) He was not asked to consider epidemiological evidence supporting the notion that fragrance chemicals can cause ovarian cancer. (*Id.* at 199:2–21.) Nor did he independently research individual chemicals found in Defendants' product; his task was to review the "totality of the evidence" concerning the chemicals. (*Id.* at 126:13–127:11.) He also was unaware of any scientific publication that links the fragrance chemicals in Defendants' products to human ovarian cancer. (*Id.* at 114:9–115:7.)

Dr. Crowley also clarified that he was not asked to, and did not perform, a risk assessment, exposure assessment, or dose-response analysis in this matter with respect to any substance. (*Id.* at 123:5–8, 124:21–125:5.) Importantly, he testified that he would have been unable to conduct a risk assessment, exposure assessment, or dose-response analysis because he did not have the exact composition of fragrance chemicals in Defendants' products. (*See id.* at 200:13–202:6, 204:15–22.) According to Dr. Crowley, the absence of that data also prevented him from opining that Defendants' products violated certain regulatory standards as he could not measure the concentration of a chemical in the product against any regulatory threshold. (*See id.* at 328:15–331:2.)

c. Other experts

Several of Plaintiff's experts refer and/or rely on the analyses of Drs. Cook, Krekeler, and/or Crowley. These experts include Drs. Carson, Clarke-Pearson, Cote, Kane, Levy, McTiernan, Moorman, Plunkett, Siemiatycki, Sage, Singh, Smith, Smith-Bindman, Wolf, and Zelikoff. I discuss each of these experts and their reference to the analyses of Drs. Cook, Krekeler, and/or Crowley.[91]

Dr. Carson: Citing the deposition and an exhibit thereto of Julie Pier,[92] the corporate representative of Imerys Talc America, a talc mining company that supplied Defendants, Dr. Carson noted that Defendants' talcum powder products contain nickel and chromium (which are classified as known carcinogens by IARC) and cobalt (which is classified as a possible carcinogen by IARC). (*See* Carson Rep. at 5–6.) At his deposition, Dr. Carson agreed that IARC has not classified nickel, chromium, and cobalt as carcinogenic to the ovaries. (ECF No. 33005-12 ("Carson Dep.") at 300:20–24.)

---

[91] Defendants seek to exclude the opinions of the following experts with respect to heavy metals: Drs. Clarke-Pearson, Cote, Kane, Levy, McTiernan, Moorman, Siemiatycki, Sage, Singh, Smith, Smith-Bindman, and Wolf. (Defs.' Heavy Metals and Fragrances Br. at 9 n.24.) Although Defendants do not specifically seek to exclude Dr. Carson's opinion on heavy metals, because I am reviewing the issue of heavy metals without limitation, my analysis applies to his opinion as well. Defendants seek to exclude the opinions of the following experts with respect to fragrances: Drs. Carson, Clarke-Pearson, Cote, Kane, Levy, Moorman, Plunkett, Sage, Singh, Smith, Smith-Bindman, Zelikoff, Wolf, and McTiernan. (*Id.* at 14 n.42.) The qualifications of these experts are discussed elsewhere in this Report and Recommendation.

[92] No party appears to have offered the relevant deposition testimony or deposition exhibit from Ms. Pier's deposition as an exhibit. It appears that Ms. Pier testified that certain heavy metals were present in the talc supplied to Defendants by Imerys Talc America.

Dr. Carson noted that talc contains fragrance chemicals, "some of which have been shown to produce cancer in laboratory animals." (Carson Rep. at 6.) He acknowledged that these fragrance chemicals are "likely to be present in very small or trace quantities, and likely present a lower level of risk than the major components, by mass," but he nonetheless opines that "any additional risks are added as part of a total risk profile." (*Id.*) He has reviewed the report of Dr. Crowley and concurred that certain fragrance chemicals "may contribute to the inflammatory properties, toxicity, and potential carcinogenicity of [Defendants'] products." (*Id.* (citing Crowley Rep.).) At his deposition, Dr. Carson admitted that he has never published on or researched fragrance chemicals. (Carson Dep. at 63:6–18.) He also admitted that he does not "have the specific formulation or quantities of [the fragrance chemicals]" in Defendants' products. (*Id.* at 73:15–20; *see also id.* at 175:13–176:9.) He also agreed that "[t]here is no information available to do a dose-response estimate for the fragrances" in Defendants' products. (*Id.* at 174:3–10.) He could not say what quantity of fragrance chemicals reach the ovaries, but maintains that the chemicals do reach the ovaries. (*Id.* at 177:12–19.)

Dr. Clarke-Pearson: Citing the deposition of Ms. Pier, Dr. Clarke-Pearson noted that talcum powder contains carcinogens including "heavy metals such as nickel, chromium and cobalt." (ECF No. 33005-18 ("Clarke-Pearson Rep.") at 7–8.) Citing Dr. Crowley's report, Dr. Clarke-Pearson further noted that talcum powder

contains "inflammatory agents, toxins, and carcinogens contained in the fragrance chemicals in talcum powder." (*Id.*) In discussing the plausibility factor of his Bradford Hill analysis, Dr. Clarke-Pearson noted that talc includes numerous constituents such as . . . heavy metals and/or chemicals contained in fragrances added to talcum powder, [both] of which cause an inflammatory reaction leading to carcinogenesis." (*Id.* at 13.) At his deposition, Dr. Clarke-Pearson clarified that he was not opining that any individual component of talcum powder, such as heavy metals or fragrance chemicals, independently causes ovarian cancer, but rather that talcum powder as a whole causes ovarian cancer. (*See* ECF No. 33005-43 ("Clarke-Pearson Dep.") at 288:11–23.) He further acknowledged that he was unaware of scientific evidence causally linking the heavy metals and fragrance chemicals identified in Defendants' products to ovarian cancer and would defer to IARC as to the carcinogenicity of those substances. (*Id.* at 290:19–292:10.) Dr. Clarke-Pearson further acknowledged that his overall causation opinions in this matter do "[n]ot necessarily" depend on carcinogenic metals or fragrances. (*Id.* at 291:16–21.)

Dr. Cote: Citing Ms. Pier's deposition, Dr. Cote opined that talc contains heavy metals "known to be carcinogenic." (ECF No. 33005-19 ("Cote Rep.") at 11.) She further noted that Defendants' products contain "fragrance chemicals that have been identified as carcinogenic or inflammatory agents." (*Id.* (citing Crowley Rep.).) In her opinion, heavy metals "can induce an inflammatory response" once they are

"present in the fallopian tubes and/or ovaries." (*Id.* at 37.) At her deposition, Dr. Cote acknowledged that she did not search for, and is not aware of, any studies supporting the theory that trace amounts of heavy metals or fragrances cause ovarian cancer. (ECF No. 33005-33 ("Cote Dep.") at 142:24–143:4, 146:25.) Dr. Cote further acknowledged that heavy metals and fragrances are not "necessary" to her causation opinion that talcum powder and all its constituents in its entirety can cause ovarian cancer. (*Id.* at 147:7–17.)

Dr. Kane: Citing Ms. Pier's deposition, Dr. Kane noted that talc contains heavy metals such as nickel and chromium, which are known carcinogens, and cobalt, which has been identified as a possible carcinogen by IARC, and that those metals provide "additional evidence of biological plausibility for talcum powder products to cause ovarian cancer." (Kane Rep. at 5, 29, 36.) She also noted that the alleged presence of the fragrance chemicals (according to Dr. Crowley's report) in Defendants' products "provides additional evidence of biological plausibility for causation regarding talc and ovarian cancer." (*Id.* at 5, 36.) At her deposition, Dr. Kane acknowledged that she has not specifically analyzed the biological plausibility of heavy metals or fragrances as ovarian-cancer-causing agents but considered both together along with other components of talcum powder in her analysis. (*See* ECF No. 33005-39 ("Kane Dep.") at 133:12–136:1.)

Dr. Levy: Dr. Levy also noted that talc may contain nickel, chromium, and cobalt, which have carcinogenic properties based on IARC's classification of them. (ECF No. 33005-21 ("Levy Rep.") at 18–20.) According to Dr. Levy, this "supports the conclusion that talcum powder causes chronic inflammation." (*Id.* at 19.) He also agreed with Dr. Crowley that certain fragrance chemicals added to Defendants' products "contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the products," and the presence of those chemicals "provides additional evidence of biological plausibility for talcum powder and ovarian cancer." (*Id.*) At his deposition, Dr. Levy explained that his opinion concerned "the totality of talc and its components," and that he had not "performed an analysis to specifically break apart the relative contributions of any components that may or may not be present in talc." (ECF No. 33005-36 ("Levy Dep.") at 118:9–18; *see also id.* at 127:10–24.) He conceded that he did not "specifically look at heavy metals" in his analysis. (*Id.* at 155:24–156:12.)

Dr. McTiernan: Dr. McTiernan noted that IARC concluded that "chromium and nickel are Group 1 human carcinogens" and cobalt is a "possible carcinogen." (ECF No. 33005-22 ("McTiernan Rep.") at 87–88.) Citing Ms. Pier's deposition, Dr. McTiernan noted that all three metals have been found in Defendants' products. (*Id.*) She concluded that the presence of heavy metals and fragrance chemicals "have been shown to induce cancer" through "inflammatory response which mediates oxidative

stress, release of cytokines and resulting genotoxicity which can induce malignant transformation." (*Id.* at 101.) At her deposition, Dr. McTiernan testified that she does not have "evidence one way or the other" as to whether Defendants' products contain any chromium, nickel, and cobalt, and did not address that question. (ECF No. 33005-31 ("McTiernan Dep.") at 270:20–272:10.)

Dr. Moorman: Citing Ms. Pier's deposition, Dr. Moorman noted that talcum powder contains chromium and nickel, which are established carcinogens, and cobalt which is considered a possible carcinogen based on IARC's findings. (Moorman Rep. at 35.) She also reviewed and agreed with Dr. Crowley's report, and thus concluded that the presence of heavy metals and fragrance chemicals "provide further evidence that exposure to talc products could result in cancer[.]" (*Id.* at 35.) At her deposition, Dr. Moorman acknowledged that she had not independently reviewed scientific evidence that heavy metals in cosmetic talc powders cause ovarian cancer to reach her opinion. (ECF No. 33005-40 ("Moorman Dep.") at 120:16–121:6.) She also admitted that she did not consider any evidence beyond an IARC monograph in determining that nickel, chromium, and cobalt were carcinogenic. (*Id.* at 122:12–123:6.)

Dr. Plunkett: Citing Dr. Crowley's report, Dr. Plunkett noted that several of the fragrance chemicals used in Defendants' product "have been associated with potential carcinogenic activity." (Plunkett 3d Amend. Rep. ¶ 36.) Citing Ms. Pier's

deposition and other documents produced by Defendants, Dr. Plunkett also noted that Defendants' product contains heavy metals "known to be carcinogenic in animals and/or humans." (*Id.* ¶ 37.) At her deposition, Dr. Plunkett acknowledged that she has not "attempted to define an independent risk" for chromium, nickel, and cobalt individually, or for fragrances. (ECF No. 33005-13 ("Plunkett 2021 Dep.") at 271:24–272:8; see also *id.* at 274:5–275:25.) In her view, because those metals share a similar mechanism to talc, she factored them into her risk assessment for talc overall. (*See id.* at 272:9–273:6.) She testified that when faced with the presence of multiple . . . carcinogens with similar mechanisms of action, you would assume in [your] risk assessment that those risks could be additive." (*Id.* at 275:9–25.)

Dr. Sage: Dr. Sage opined that "[t]alcum powder products contain or may contain ingredients that pose health hazards to consumers." (ECF No. 33005-24 ("Sage Rep.") at 5.) Citing Ms. Pier's deposition, Dr. Sage noted that these ingredients include chromium and nickel (both known carcinogens), and cobalt (a possible carcinogen). He also adopted Dr. Crowley's opinion that the talc products contain fragrance chemicals that are "potential and known carcinogens, toxins, and allergens." (*Id.* at 6.) Dr. Sage further opined that certain of these ingredients "could be considered adulterants in talcum powder products." (*Id.* at 7.) At his deposition, however, Dr. Sage clarified that he is "not offering an opinion as a scientific expert as to whether . . . talcum powder exposure causes ovarian cancer" or an opinion "on

the causal connection between any one of the[] particular ingredients [found in talcum powder] and any particular health injury." (ECF No. 33005-35 ("Sage Dep.") at 292:14–20.) Dr. Sage further acknowledged that he did not independently investigate any scientific evidence linking heavy metals to a risk of ovarian cancer. (*See id.* at 293:10–21.)

Dr. Siemiatycki: Dr. Siemiatycki noted that talcum powder products generally contain "carcinogens, namely nickel and chromium."[93] (Siemiatycki 3d Amend. Rep. at 27.) But he conceded that the "extent of the contamination of talcum powder products by these metals, during the entire period of commercial production of talcum powder products over the past several decades" is unknown. (*Id.*) He further conceded that how exposures to the metals in the products "measure up to the exposure levels to these metals that may cause cancer" is also unknown. (*Id.*) In opining that there is a biologically plausible mechanism through which talc can cause ovarian cancer, Dr. Siemiatycki opined that "there is also evidence that commercially-distributed talc powder contained some heavy metals that are themselves carcinogenic." (*Id.* at 73–74.) At his deposition, Dr. Siemiatycki clarified that, in his opinions on talcum powder, he was not relying on observations that

[93] Dr. Siemiatycki does not identify his basis for noting that Defendants' products contain potentially carcinogenic heavy metals, but he includes in the references section of his report the Deposition of Julie Pier, the same source that most Plaintiffs' causation experts cite in support of their opinions that Defendants' products contain heavy metals. (Siemiatycki 3d Amend. Rep., Ex. B, at 7.)

Defendants' products contain heavy metal. (*See* ECF No. 33005-38 ("Siemiatycki Dep.") at 55:20–56:7.)

Dr. Singh: In connection with his opinion on biological plausibility, Dr. Singh noted that "talcum products contain fibrous talc, heavy metals and fragrance ingredients which are known or suspected carcinogens" based on Ms. Pier's deposition. (Singh Rep. at 60.) He opined that "the presence of these known or suspected carcinogens provides a plausible biologic explanation for the increased risk seen in the epidemiologic studies." (*Id.*) At his deposition, Dr. Singh indicated that he has not analyzed how much, if any, heavy metal exposure (from talcum powder) reaches a woman's ovaries. (ECF No. 33005-42 ("Singh Dep.") at 184:9–13.) He also clarified that he is not specifically opining that heavy metals and fragrance chemicals are causally associated with ovarian cancer. (*Id.* at 185:15–19, 298:20–300:11.) Nor was he aware of epidemiological evidence supporting the theory that exposure to trace amounts of chromium, nickel, and cobalt can cause ovarian cancer. (*Id.* at 298:20–300:11.)

Dr. Smith: Dr. Smith opined that the heavy metals allegedly in Defendants' products "likely contribute to the carcinogenicity of talcum powder products by the inflammatory mechanism" that she elaborated on in her report and is discussed elsewhere in this Report and Recommendation. (ECF No. 33005-27 ("Smith Rep.") at 19.) She also agreed with Dr. Crowley's opinion that certain fragrance chemicals

"likely contribute to the inflammatory properties, toxicity and/or carcinogenicity" of Defendants' products. (*Id.* at 19.) At her deposition, Dr. Smith admitted that she did not conduct a "comprehensive review" of the evidence supporting a causal connection between heavy metals and fragrance chemicals with ovarian cancer. (*See* ECF No. 33005-34 ("Smith Dep.") at 61:3–62:3.)

Dr. Smith-Bindman: Dr. Smith-Bindman opined that carcinogenic heavy metals such as nickel, chromium, and cobalt "can cause ovarian cancer through an inflammatory mechanism." (ECF No. 33005-28 ("Smith-Bindman Rep.") at 15.) She also agrees with Dr. Crowley's opinion that certain fragrance chemicals "may contribute to the inflammatory response, toxicity, and potential carcinogenicity of [Defendants'] talcum powder products." (*Id.*) At her deposition, Dr. Smith-Bindman stated that talcum powder contains trace amounts of heavy metals and contains fragrance chemicals, but she acknowledged that she has only high-level estimates of the concentration of heavy metals and chemicals in Defendants' products and interpreting those concentrations is not part of her expertise. (*See* ECF No. 33005-37 ("Smith-Bindman Dep.") at 138:7–139:21.)

Dr. Wolf: Citing Ms. Pier's deposition, Dr. Wolf noted that "talcum powder products have been shown to contain nickel, chromium, and cobalt" and that the "inflammatory mechanism for carcinogenesis for these metals is similar to that described for asbestos, fibrous talc, and platy talc." (ECF No. 33005-29 ("Wolf

Rep.") at 12.) She also opined that many of the fragrance chemicals identified by Dr. Crowley "are known to be irritants, toxins, and carcinogens," and some "have been shown to be harmful to the reproductive organs and function." (*Id.*) Dr. Wolf suggested that the "chemicals would be expected to accompany the talcum powder as it migrates or is transported through the genital tract to the fallopian tubes and ovaries" and "[a]t least some of these chemicals would also be expected to be absorbed through the vaginal mucosa." (*Id.*) Dr. Wolf opined that the chemicals "likely contribute to the inflammatory properties, toxicity, and carcinogenicity of these talcum powder products." (*Id.*)

At her deposition, Dr. Wolf agreed that she did not individually evaluate the data for heavy metals and/or fragrances to assess their causal relationship to ovarian cancer. (*See* ECF No. 33005-30 ("Wolf Dep.") at 399:22–402:12.) She also agreed that the inflammatory response caused by foreign substances can—but does not always—cause ovarian cancer. (*Id.* at 407:5–14.) Dr. Wolf acknowledged that she was not fully aware of the roles chromium, cobalt, and nickel played in the human body as potential nutrients. (*See id.* at 432:17–435:12.) And Dr. Wolf admitted that the IARC monographs on which she relies do not indicate that chromium, cobalt, and nickel are carcinogenic to the ovaries. (*See id.* at 430:15–432:3, 434:7–10.)

Dr. Zelikoff: Citing IARC's classifications, Dr. Zelikoff noted that nickel and chromium are known carcinogens and cobalt is a possible or probable carcinogen

depending on whether it is accompanied by tungsten chloride. (ECF No. 33005-6 ("Zelikoff Rep.") at 8-10.) She explained that the "exact mechanisms of nickel-induced carcinogenesis are not known, but likely involve genetic and epigenetic routes" and aggravation "through the generation of DNA-damaging reactive oxygen species (ROS) and the inhibition of DNA repair." (*Id.* at 8.) She also noted that animal studies have found "nickel compounds induce tumors at virtually all sites of application." (*Id.* at 9.)

Dr. Zelikoff noted that chromium comes in different forms, including trivalent and hexavalent chromium. (*Id.*) She explained that hexavalent chromium is considered carcinogenic by IARC and has been "shown to cause direct DNA damage . . . , mutation, genomic instability, aneuploidy, . . . cell transformation," and "can cause damage leading to dysfunctional DNA replication, aberrant cell cycle, DNA strand breaks, dysfunctional DNA repair and DNA-protein crosslinks and directly causing genotoxicity." (*Id.*) Separately, Dr. Zelikoff opined that chromium compounds "can activate transcription factors involved in inflammation and tumor growth" by "cellular integrity and functions." (*Id.* at 9–10.)

Dr. Zelikoff explained that cobalt can cause genotoxicity through 2 mechanisms: "(1) DNA breakage induced by cobalt metal and especially hard metal particles, and (2) inhibition of DNA repair by cobalt (II) ions." (*Id.* at 10.) Both mechanisms "contribute to the carcinogenic potential of cobalt compounds." (*Id.*)

With respect to fragrances, Dr. Zelikoff agreed with Dr. Crowley's conclusion that certain fragrance chemicals "likely contribute to the inflammatory properties, toxicity, and carcinogenicity of these talcum powder products." (*Id.* at 12.) At her deposition, Dr. Zelikoff conceded that she did not opine on a specific causal connection between heavy metals and ovarian cancer. (ECF No. 33005-11 ("Zelikoff Dep.") at 281:1–282:1.) She also conceded that she has no information to suggest a threshold level for which heavy metals increase a woman's risk for ovarian cancer. (*Id.* at 282:2–286:4.)

iii. Admissibility Analysis

Defendants challenge the admissibility of certain experts that opine on whether the heavy metals and fragrance chemicals in Defendants' products cause or contribute to the causation of ovarian cancer. I address these challenges below in my independent analysis of the qualifications, reliability, and fit of each expert's opinion as it concerns heavy metals and/or fragrances.

a. Qualifications and Fit

Defendants challenge certain experts' qualifications. (Defs.' Heavy Metals and Fragrances Br. at 7–15.) Their arguments first address the qualifications of Drs. Cook and Krekeler to opine that the heavy metals found in talc are carcinogenic. (*Id.* at 8–9.) Defendants further challenge the qualifications of other experts who rely on the opinions of Drs. Cook, Krekeler, and Crowley. (*Id.* at 8–15.) I follow the same

sequence below, addressing Defendants' challenge to Drs. Cook's and Krekeler's qualifications, and also address Dr. Crowley's qualifications, before turning to Defendants' qualifications arguments regarding the experts who rely on Dr. Cook's and Dr. Krekeler's opinions. In addition, although Defendants do not challenge the fit of any of the expert opinions discussed above, I must independently assess it.

As noted above, the qualifications element of Rule 702 "requires that the witness possess specialized expertise." *Calhoun*, 350 F.3d at 321. But that requirement is "liberally" construed. *Id.* (quoting *In re Paoli*, 35 F.3d at 741; *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." (quoting *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 782 (3d Cir. 1996))); *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 809 (3d Cir. 1997), *as amended* (Dec. 12, 1997) ("If the expert meets [Rule 702's] liberal minimum qualifications, then the level of the expert's expertise goes to credibility and weight, not admissibility."). Even so, "[a]n expert may be generally qualified but may lack qualifications to testify outside his area of expertise." *Calhoun*, 350 F.3d at 322. Experts "are permitted to rely on materials used by other experts in developing their own opinions" but may not "simply 'parrot' ideas of other experts." *In re Suboxone (Buprenorphine Hydrochloride & Naloxone)*

Antitrust Litig., 13-MD-2445, 2020 WL 6887885, at *5 (E.D. Pa. Nov. 24, 2020) (citation omitted).

(1) Dr. Cook's and Dr. Krekeler's qualifications and fit

Defendants argue that Drs. Cook and Krekeler are unqualified to testify that the heavy metals allegedly in Defendants' products are carcinogenic because neither has the necessary expertise to opine on carcinogenicity.[94] (Defs.' Heavy Metals and Fragrances Br. at 8 ("Although [Drs. Cook and Krekeler] also seek to testify that the heavy metals at issue are human carcinogens, they have zero expertise in biology or medicine and expressly disclaimed having the requisite credentials to weigh in on these specialized topics.").) Plaintiffs respond that "Drs. Krekeler and Cook do not provide medical or epidemiological testimony." (ECF No. 33120 ("Pls.' Heavy Metals and Fragrances Opp. Br.") at 9.) To Plaintiffs' point, Drs. Cook and Krekeler disclaim any opinion that heavy metals cause cancer. Despite such a disclaimer, they nevertheless suggest that certain heavy metals are carcinogenic, citing academic and/or regulatory sources in support. (*See* Krekeler Rep. at 6; Cook Rep. at 27–28, 30, 32; ECF No. 33005-9 ("Krekeler Dep.") at 25:6–22; ECF No. 33005-10 ("Cook Dep.") at 17:3–10, 96:20–22.) For example, Dr. Krekeler cited IARC's classification

[94] Defendants do not appear to challenge Dr. Cook's or Dr. Krekeler's qualifications to opine on the contents of Defendants' commercial products (aside from the alleged presence of asbestos) and instead focus on opinions that heavy metals potentially in their products are carcinogens. (*See* Defs.' Heavy Metals and Fragrances Br. at 8.) As further discussed *infra*, I independently find that Drs. Cook and Krekeler are qualified to opine to the mineralogic and geologic contents of talc used by Defendants based on their credentials and experience.

of chromium, nickel and cobalt as carcinogens in support of his view that they are carcinogenic. (Krekeler Rep. at 6; *see also id.* at 33–34, 36–37.) He further explained that "[a]cademic and research literature have long-recognized many toxic metals commonly found in talc as known or possible carcinogens, including: Chromium (Cr), nickel (Ni), cobalt (Co), arsenic (As)." (*Id.*) Dr. Cook similarly cited IARC sources in support of the conclusion that arsenic, nickel, chromium, and cobalt are carcinogens. (Cook Rep. at 27–28, 30, 32.)

I find that Drs. Cook and Krekeler are qualified to identify certain heavy metals as carcinogens based on their experience in geology and mineralogy under Rule 702's liberal standard for qualifications. Notably, and as further discussed *infra*, neither expert opines that the heavy metals they discuss cause ovarian cancer. While identifying a mineral as a carcinogen certainly involves the life-sciences disciplines, such identification does not unreasonably fall outside of Dr. Cook's and Dr. Krekeler's expertise, which admittedly involves the characterization of minerals and the evaluation of their "geology," "mineralogy," and "geochemistry." (Krekeler Dep. at 24:8–24; *see* Cook Rep. at 6–7 (citing a variety of articles and sources characterizing certain heavy metals as toxic or carcinogenic from geologic and industrial publications).) Accordingly, I find both experts' background and expertise in identifying and characterizing such minerals to meet Rule 702's liberal standard

for expert qualifications. Therefore, I find Drs. Cook and Krekeler qualified to identify certain heavy metals as carcinogens.

With respect to fit, I note that neither Dr. Cook nor Dr. Krekeler opine that the heavy metals they discuss cause *ovarian* cancer. They stop short at identifying the metals as carcinogens, in contrast from Plaintiffs' other experts, who affirmatively opine that heavy metals and/or fragrance chemicals may cause ovarian cancer. As I conclude *infra*, those experts do not use reliable methods in reaching their opinions that heavy metals and/or fragrance chemicals may cause ovarian cancer. Given that conclusion, I find that Dr. Cook's and Dr. Krekeler's opinions generally identifying certain heavy metals as carcinogenic do not meet *Daubert*'s fit criterion because they "lack[] a 'valid scientific connection to the pertinent inquiry,'" which is whether the metals, as constituents of talc, can cause ovarian cancer. *Hoefling*, 576 F. Supp. 3d at 278–79 (excluding an expert's opinion because the expert could only discuss a substance's general carcinogenicity, not its tendency to cause the specific cancer the plaintiff contracted) (quoting *Daubert*, 509 U.S. at 591–92); *accord Allen v. Pa. Eng'g Corp.*, 102 F.3d 194, 196 (5th Cir. 1996) ("[T]he fact that [a chemical] has been classified as a carcinogen . . . is not probative of the question whether [the plaintiff's] cancer was caused by [the chemical]."). Given the lack of fit, allowing Drs. Cook and Krekeler to testify at trial regarding the heavy metals' general carcinogenicity, without reference to ovarian cancer, will likely confuse the issues

and mislead the jury. Accordingly, I recommend that the Court grant this aspect of Defendants' motion and exclude Dr. Cook's and Dr. Krekeler's opinions that certain heavy metals are carcinogenic.

(2) Dr. Crowley's qualifications and fit

Defendants do not appear to challenge Dr. Crowley's qualifications to opine on the contents of their products or the characterization of those contents. Nonetheless, I independently find that Dr. Crowley is qualified to opine as to the contents and characterization of Defendants' products based on his credentials and his experience as chemist and consultant in the pharmaceutical industry. His work in analyzing the contents of potential pharmaceutical products and making recommendations to companies manufacturing those products concerning their risk mirrors the analysis supporting his opinion. That said, I note that Dr. Crowley professes no experience as a medical doctor or with cancer but opines that certain substances are carcinogenic. (Crowley Dep. at 62:10–63:1.) Nor does he have expertise in cancer. (*Id.* at 213:21–214:4.) There does not appear to be any dispute that Dr. Crowley's opinion that fragrance chemicals in Defendants' products contribute to the causation meets the fit *Daubert* criterion. I independently find that Dr. Crowley's opinion fits because it concerns the principal causation issue raised in this case: whether Defendants' products cause ovarian cancer.

(3) Other experts' qualifications and fit

Defendants next challenge the qualifications of other experts who rely in part on the opinions of Drs. Cook, Krekeler, and Crowley. With respect to heavy metals, Defendants argue that twelve[95] of Plaintiffs' medical experts are unqualified to opine that heavy metals are present in Defendants' products or that these substances cause ovarian cancer. (*Id.* at 8–13.) Defendants similarly argue that thirteen[96] of Plaintiffs' experts are unqualified to opine that fragrance chemicals in Defendants' products cause ovarian cancer. (*Id.* at 14–15.) I first discuss Defendants' challenges to experts' qualifications to opine on heavy metals and then discuss challenges to their qualifications to opine on fragrances.

(a) Heavy metals

Defendants argue that the medical experts relying on Dr. Cook's and Dr. Krekeler's analyses "lack independent knowledge and expertise in this area and performed no expert analysis of their own on this subject." (*Id.* at 9.) They further argue that in light of those experts' lack of qualifications, their opinions impermissibly parrot the opinions of other experts. (*Id.* at 13.)

---

[95] These experts are Drs. Clarke-Pearson, Cote, Kane, Levy, McTiernan, Moorman, Siemiatycki, Sage, Singh, Smith, Smith-Bindman, and Wolf. (Defs.' Heavy Metals and Fragrances Br. at 9 n.24.)

[96] These experts are Drs. Carson, Clarke-Pearson, Cote, Kane, Levy, McTiernan, Moorman, Plunkett, Sage, Singh, Smith, Smith-Bindman, Wolf, and Zelikoff. (*Id.* at 14 n.42.)

I agree with Defendants that the causation experts are not qualified to independently opine on whether Defendants' products contain heavy metals. As Plaintiffs point out, they are epidemiologists, geneticists, toxicologists, pathologists, or other related medical professionals—not mineralogists or mining experts. (*See id.* at 8.)

Drs. Cook and Krekeler are mineralogists and, as discussed above, are qualified to opine on the presence and characterization of heavy metals in the talc products at issue. Accordingly, to the extent other experts rely on Drs. Cook's and Krekeler's analyses for the proposition that Defendants' products contain heavy metals, such reliance is permissible. *See* Fed. R. Evid.702 advisory committee's notes to 2000 Amendments ("The term 'data' is intended to encompass the reliable opinions of other experts."); Fed. R. Evid.703; *Raritan Baykeeper, Inc. v. NL Indus., Inc.*, No. 09-cv-4117, 2017 WL 3568401, at *7 (D.N.J. Aug. 16, 2017) ("In forming an opinion, experts may rely on other experts' opinions," but may not "unblinking[ly] rel[y] on those experts' opinions.") (alterations in original) (internal quotations omitted) (quoting *In re TMI*, 193 F.3d at 716); *Comm'r of Dep't of Plan. Nat. Res. v. Century Aluminum Co., et al.*, No. 05-cv-62, 2013 WL 4534742, at *4 (D.V.I. Aug. 26, 2013). If there are any weaknesses in Dr. Cook's and Dr. Krekeler's analyses, those are matters of weight. Whether those weaknesses in turn weaken or impact the analyses of experts who rely on Dr. Cook's and Dr. Krekeler's analyses

is similarly a matter of weight. *See In re Suboxone*, 2020 WL 6887885, at *5 ("Experts 'may use a mix of objective data and subjective analysis from another expert to . . . create an admissible report,' and the testifying expert's knowledge regarding the underlying facts 'go[es] to the weight accorded to [that expert's] report and testimony, rather than its admissibility.'" (alterations in original) (quoting *I.B.E.W. Loc. Union 380 Pension Fund v. Buck Consultants*, No. 03-cv-4932, 2008 WL 2265269, at *3 (E.D. Pa. June 3, 2008)). Accordingly, I conclude that the causation experts' lack of qualifications to opine as to the mineral contents of Defendants' products is not a basis for outright exclusion. These experts may not independently opine on the composition of the talc products at issue. They may, however, rely on the opinions of Drs. Cook and Krekeler regarding the presence of heavy metals in those products as a factual predicate in rendering their own opinions on carcinogenicity.

As to the characterization of heavy metals as carcinogenic, I conclude that most of Plaintiffs' causation experts are qualified. As noted above, they are experts in the life-sciences who are qualified to determine whether certain substances cause cancer. They reviewed literature that they are qualified to review and made a scientific judgment based on their review. (*See, e.g.*, Clarke-Pearson Rep. at 8; Levy Rep. at 18–20; McTiernan Rep. at 88; Moorman Rep at 25; Plunkett 3d Amend. Rep.

¶ 37; Singh Rep. at 60; Smith-Bindman Rep. at 15; Wolf Rep. at 13; Zelikoff Rep. at 8–10.)

The one exception is Dr. Sage. As discussed *infra*, Dr. Sage's opinions concern Defendants' compliance with various regulations and he does not purport to offer causation opinions and did not undertake a causation analysis. (Sage Dep. at 118:15–122:3.) Nor does he have the qualifications to do so. Aside from a brief period working as a physician, Dr. Sage has worked as a corporate lawyer and law professor. (Sage Rep. ¶¶ 1–9.). Despite that, like Drs. Cook and Krekeler, Dr. Sage still ventures into offering causation opinion testimony by referring to certain substances present in Defendants' products as carcinogens or carcinogenic. (*See* Sage Rep. at 5.) Although Dr. Sage has experience with regulations that pertain to public health, neither he nor Plaintiffs explain why that experience qualifies him to offer scientific opinions on the carcinogenicity of heavy metals or fragrance chemicals. Accordingly, I do not find Dr. Sage not qualified to opine as to causation.[97]

Finally, Defendants' arguments that the experts identified above failed to properly analyze a causal association between heavy metals and ovarian cancer concern whether the experts' opinions are reliable, not whether the experts are qualified to make such an opinion. I therefore consider those arguments below.

[97] I fully discuss Dr. Sage's opinions and Defendants' challenges to them *infra*.

(b) Fragrances

Defendants' fragrance chemicals challenge concerning Plaintiffs' causation experts is premised on their argument that the experts improperly "parrot" Dr. Crowley's opinions (i.e., the experts simply incorporate Dr. Crowley's opinions without any independent analysis or validation). (Defs.' Heavy Metals and Fragrances Br. at 14–15.) However, issues of improper parroting are issues of methodology, not qualification. *See In re TMI*, 193 F.3d at 716 (noting that an expert's "failure to assess the validity of the opinions of the experts he relied upon . . . demonstrates that the *methodology* he used to formulate his opinion was flawed under *Daubert* as it was not calculated to produce reliable results." (emphasis added)). I therefore consider Defendants' arguments when assessing the reliability of Plaintiffs' experts' opinions on fragrances.

As noted above, where an expert simply serves as the mouthpiece of another, the expert's opinions may be inadmissible as the product of unreliable methods. *See In re TMI*, 193 F.3d at 715–16. I therefore discuss Defendants' arguments concerning Plaintiffs' causation experts below. It does not otherwise appear that Defendants challenge any of Plaintiffs' experts' *qualifications* to opine on a causal connection between ovarian cancer and fragrance chemicals. Based on my independent review, I find all of these experts qualified to opine on whether fragrance chemicals are carcinogenic under Rule 702's liberal standard for

qualification for the same reasons that I find them qualified to opine that certain heavy metals are carcinogenic.

(c) Fit

As for the other experts' fit, as the absence of any challenge to fit suggests, those experts' opinions readily fit the issues raised in this litigation. Each opinion concerns whether heavy metals and/or fragrance chemicals can cause ovarian cancer, which as noted above, is the central issue in this multidistrict litigation. Accordingly, I find that each expert satisfies the fit element.

b. Reliability

Defendants make several reliability challenges. They challenge Plaintiffs' experts' opinions that heavy metals cause ovarian cancer as unreliable. (Defs.' Heavy Metals and Fragrances Br. at 15–26.) Defendants further challenge Dr. Crowley's opinion that fragrance chemicals contribute to the development of ovarian cancer as the product of unreliable methods. (*Id.* at 26–43.) As noted above, Defendants also challenge the opinions of any Plaintiffs' experts who rely on Dr. Crowley's opinion as improper parroting. (*Id.* at 14–15.)

(1) Heavy metals

Defendants challenge Plaintiffs' experts' opinions that heavy metal exposure can cause ovarian cancer as unreliable on two grounds: (1) the experts cite no evidence linking heavy metal exposure to ovarian cancer and (2) the experts cite no

evidence supporting a dose-response relationship between heavy metal exposure and ovarian cancer. (Defs.' Heavy Metals and Fragrances Br. at 15-26.) I address each of these arguments in turn.

(a) Lack of connection to ovarian cancer

With respect to a causal association between heavy metal exposure and ovarian cancer, Defendants argue that although the experts cite evidence that heavy metals can be carcinogenic in general, no expert cites evidence showing a specific link between heavy metal exposure and ovarian cancer. (*Id.* at 16–21.) Defendants argue that the experts must present scientific evidence connecting heavy metals to ovarian cancer—the specific cancer at issue in this litigation—and the lack of reference to any literature on this issue is fatal. (*Id.* at 19–20.) Defendants further argue that these experts' identification of a biologically plausible mechanism by which heavy metals cause ovarian cancer is also unreliable. (*Id.*) They incorporate their arguments as to the biological plausibility factor in the Bradford Hill analysis that inflammation is an untested hypothesis. (*Id.*) But even assuming that inflammation satisfies the biological plausibility factor, Defendants further argue that there is no evidence that heavy metals cause inflammation in the ovaries.[98] (*Id.*)

[98] As I have already addressed Defendants' biological plausibility arguments regarding talc, *see supra* Part V.B.1, and recommended that the Court admit that portion of Plaintiffs' experts' causation opinions, in this section, I only address Defendants' arguments concerning the lack of evidence that heavy metals cause inflammation in the ovaries.

Plaintiffs respond that a specific link between heavy metals and ovarian cancer is unnecessary because their experts opine that Defendants' talc products "as a whole" cause ovarian cancer, and heavy metals are just one constituent. (Pls.' Heavy Metals and Fragrances Br. at 13–14, 17.) Plaintiffs emphasize evidence that the heavy metals at issue are carcinogenic in humans. (*See id.* at 14–16 (citing reports from IARC, the Agency for Toxic Substances and Disease Registry ("ATSDR"), and the NTP.)) Plaintiffs also argue that the presence of a biologically plausible mechanism through which talcum powder (and the heavy metals it may contain) causes inflammation, and ultimately carcinogenesis, supports their experts' opinions that heavy metals contribute to ovarian cancer. (*See id.* at 13–14.)

Contrary to Plaintiffs' position, when analyzing the reliability of general causation opinions in similar product liability cases, courts across the nation typically require experts to cite evidence linking the product to the specific medical condition at issue. *See, e.g.*, *Hoefling*, 576 F. Supp. 3d at 274; *Ruffin v. BP Expl. & Prod., Inc.*, 137 F.4th 276, 285 (5th Cir. 2025) (noting, in excluding general causation expert, that "[w]hile [the expert's] testimony does link benzo(a)pyrene to cancer, his connection of it to prostate cancer, [the plaintiff's] condition, is lacking."); *see also In re Paulsboro Derailment Cases*, 746 Fed. App'x 94, 99 (3d Cir. 2018) (affirming exclusion of expert where she "admitted during her deposition that there 'is no literature' showing a link between short-term exposure to vinyl

chloride and [liver] cancer"); *In re Roundup*, 737 F. Supp. 3d at 905 ("But saying there is a 'compelling link' or an 'association' isn't the same as saying that Roundup is capable of causing [non-Hodgkin's lymphoma, a type of cancer] in humans—which is what a plaintiff's general causation evidence must enable the jury to conclude.").

The lack of literature supporting a connection between heavy metal exposure and ovarian cancer militates in favor of exclusion of the challenged experts' heavy metals causation opinions. Although an expert's opinion "should not be excluded simply because there is no literature on point," there must be "other factors that demonstrate the reliability of the expert's methodology" to warrant admission. *Schneider*, 320 F.3d at 406; *see also Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1237 (9th Cir. 2017) ("Causation can be proved even when we don't know precisely *how* the damage occurred, if there is sufficiently compelling proof that the agent must have caused the damage *somehow*."). Here, the only other theory that Plaintiffs' experts offer is that the heavy metals at issue may cause inflammation, which can contribute to ovarian carcinogenicity. (*See, e.g.*, Smith-Bindman Rep. at 15; Smith Rep. at 19; Levy Rep. at 18; Zelikoff Rep. at 12–13.)

Courts have consistently recognized that the existence of a biologically plausible mechanism, standing alone, does not compensate for the absence of data supporting general causation. *Hoefling*, 576 F. Supp. at 274; *accord In re Abilify*,

299 F. Supp. 3d at 1308 ("Although biological plausibility, without more, cannot establish general causation; its existence 'lends credence to an inference of causality' drawn from other, more substantial evidence."); *In re Viagra*, 424 F. Supp. 3d at 791 ("Biological plausibility thus is only a subsidiary consideration in the larger question of general causation.").

Applied here, these cases stand for the principle that even where evidence suggests a substance is generally carcinogenic or is associated with one type of cancer, an expert may not, consistent with *Daubert*, extrapolate from that evidence to opine that the substance causes a different cancer in the absence of supporting data. The presence of a biologically plausible mechanism does not cure that evidentiary gap. An opinion resting solely on such an extrapolation amounts to an untested hypothesis and does not satisfy Rule 702's reliability requirements.

Hoefling is particularly instructive. There, the plaintiff's general causation expert relied on authorities' (including IARC) conclusions that smokeless tobacco caused *oral* cancer and other *oral* conditions. 576 F. Supp. 3d at 272.[99] The plaintiff,

[99] The *Hoefling* court's summary of the basis of the plaintiff's general causation expert's opinion was as follows: (1) [IARC] concluded "[s]mokeless tobacco causes cancers of the oral cavity"; (2) the U.S. Surgeon General determined smokeless tobacco "can cause cancer and a number of non-cancerous oral conditions and can lead to nicotine addiction and dependence"; (3) the American Academy of Otolaryngology ("AAO") and CDC determined "smokeless tobacco products contain cancer causing chemicals," the most harmful of which include tobacco-specific nitrosamines ("TSNAs"); and (4) every "major public health organization," such as the WHO, American Cancer Society and National Cancer Institute, has identified smokeless tobacco as a "cause of oral cancer." *Id.*

however, contracted *tonsil* cancer, and the court noted that "IARC did not conclude smokeless tobacco causes tonsil or oropharyngeal cancer." *Id.*; *Culliver v. BP Expl. & Prod., Inc.*, No. 21-cv-4942, 2024 WL 1478659, at *4 n.3 (N.D. Fla. Apr. 3, 2024) ("IARC's designation of benzo[a]pyrene as a carcinogen, generally, is not sufficient to show it can cause prostate cancer." (citing *Allen*, 102 F.3d at 196–97)). The *Hoefling* court therefore found that the general causation expert's analysis was unreliable because his sources did not justify his view that the defendants' products caused tonsil cancer. 576 F. Supp. at 272.

The *Hoefling* court also rejected the expert's reliance on a biologically plausible mechanism as a sufficient basis to opine that smokeless tobacco can cause tonsil cancer. *See id.* at 274. The expert's belief in the mechanism did "not account for the absence of data to support general causation." *Id.*; *see also id.* at 279 (noting, with respect to a different general causation expert, that, "like his colleagues, he ultimately could not move past biological plausibility and identify data to support general causation"). The court emphasized the expert's acknowledgment of the "lack of epidemiological research establishing the necessary causal link between smokeless tobacco and *tonsil cancer*." *Id.* However, the court did not reject the expert's testimony solely due to the absence of literature or epidemiological evidence establishing a causal connection between smokeless tobacco and tonsil cancer. *See id.* at 275 ("When an expert's causation opinion is 'equivocal or

inconsistent with' epidemiological research, the expert must 'thoroughly analyze' its 'strengths and weaknesses.'" (quoting *In re Zoloft*, 26 F. Supp. 3d at 475)). The court also pointed out that the expert offered no additional support for his opinion other than a biologically plausible mechanism and the general carcinogenic nature of smokeless tobacco, and therefore, failed to meet the reliability prong of *Daubert*. *See id.* That the expert made "'speculative leaps' in claiming that a causal link exists simply because it is biologically plausible" demonstrated that his analysis was unreliable. *Id.*

Beyond its speculative nature, the *Hoefling* court also found that the expert's opinion was not the product of a reliable scientific methodology. *See id.* As the expert had no evidence to shore up his opinion, it was not falsifiable or testable, which also rendered the opinion unreliable under *Daubert*. *See id.* ("But it is 'impossible to test a hypothesis' produced by a subjective methodology because only its 'creator' can 'test[] or falsify[]' it." (alterations in original) (quoting *In re TMI*, 193 F.3d at 703 n.144.)) In sum, the *Hoefling* court excluded the expert's opinion because it was speculative and unscientific. *See id.* (concluding that the expert's opinion that smokeless tobacco "can cause tonsil cancer is not reliable because it is nothing more than an 'untested hypothesis'" and because "it is 'mere subjective

belief" propped up by biological plausibility rather than an 'objective inference[] from the relevant scientific evidence'" (citations omitted)).[100]

Here, on the subject of heavy metals, Plaintiffs' experts offer substantially similar opinions in scope as to those excluded in *Hoefling*. Each expert relies on a similar body of literature that heavy metals are generally carcinogenic. (*See* Clarke-Pearson Rep. at 7–8 (citing IARC classifications of chromium, cobalt, and nickel); Carson Rep. at 6–7 (same); Kane Rep. at 5 (same); Levy Rep. at 18–19 (same); McTiernan Rep. at 85 (same); Moorman Rep. at 7 (same); Plunkett 3d Amend. Rep. at 26 (citing IARC classifications and NTP classification of chromium and cobalt); Sage Rep. at 2, 6 (citing IARC classifications); Siemiatycki 3d Amend. Rep. at 27, 115 (same); Singh Rep. at 14 (citing academic article on mineral characterization of talcum powder); Smith Rep. at 19 (citing IARC classifications); Smith-Bindman Rep. at 4 (same); Wolf Rep. at 13 (same); Zelikoff Rep. at 8–10 (same).) Like the experts in *Hoefling*, some of Plaintiffs' causation experts point to the biologically plausible mechanism as evidence through which heavy metals could cause ovarian cancer. (*See, e.g.*, Carson Dep. at 171:16–21; Carson Rep. at 8–10; Levy Rep. at 16, 19; Plunkett 3d Amend. Rep. at 50–51; Plunkett 2021 Dep. at 268:7–13.)

[100] The *Hoefling* court excluded the opinions of two other general causation experts with similar opinions for same reasons. *See id.* at 276–80.

Like the *Hoefling* court, I conclude that the presence of a biologically plausible mechanism cannot compensate for the lack of data or evidence connecting heavy metal exposure to ovarian cancer.[101] Without such data, Plaintiffs' experts have presented only a hypothesis that heavy metal exposure causes ovarian cancer, albeit such substances are purportedly contained in talc. That is not a reliable method under *Daubert*. Additionally, the experts' analyses do not appear to have considered a wider body of literature on the subject of heavy metal exposure causing ovarian cancer through the mechanism they suggest or otherwise. As Defendants point out, some experts say that consideration of heavy metal exposure is not necessary to their opinions on the causative effect of talc on ovarian cancer. (*See* Siemiatycki Dep. at 55:16–56:7; Levy Dep. at 127:5–128:6; Kane Dep. at 133:23–135:2; Moorman Dep. at 119:10–123:12; Clarke-Pearson Dep. at 291:16–18; Plunkett 2021 Dep. at 271:15–274:16.) Others acknowledge that they have not specifically investigated the causal connection between heavy metal exposure and ovarian cancer, are unaware of any evidence that a connection exists, and/or unaware if anyone has investigated such a connection. (*See* Clarke-Pearson Dep. at 289:22–291:18; Carson Dep. at 299:18–300:5; Wolf Dep. at 431:23–432:7, 434:7-10; Cote: Dep. at 111:13–21,

[101] It bears emphasis that, with respect to talc, as distinguished from its component parts, Plaintiffs' experts do not rely on biological plausibility in isolation. Rather, they conduct a Bradford Hill analysis that encompasses not only a biologically plausible mechanism by which talc may cause ovarian cancer, but also a substantial body of epidemiologic, mechanistic, and observational evidence supporting an association—and, in their view, a causal link—between talc exposure and ovarian cancer.

142:24–143:4; Smith Dep. at 61:9–14; Sage Dep. at 293:10–294:2; Singh Dep. at 184:9–13, 298:24–300:6.) These analytical gaps highlight the hypothetical nature of these experts' opinions on heavy metal. While future research may substantiate the causal connection on which Plaintiffs' experts seek to opine in this litigation, without such research, I cannot find, on this record, that the experts' opinions are reliable.

Finally, I am unpersuaded by Plaintiffs' argument that evidence connecting heavy metals to ovarian cancer is unnecessary because the experts opine on talcum powder "as a whole." (Pls.' Heavy Metals and Fragrances Br. at 14.) Plaintiffs cite no legal authority for the proposition that when the Defendants' product is a mixture of substances, it is unnecessary to demonstrate evidence of a causal connection for any potentially harmful constituent substance, when Plaintiffs themselves have chosen to opine that the constituent substances cause the cancer at issue. Moreover, Plaintiffs' experts concede that they cannot establish the relative contribution of heavy metals and the other substances in Defendants' talc products to the causation of ovarian cancer. Nor have Plaintiffs' experts explained that heavy metals and other substances act in concert to cause ovarian cancer. This is in contrast with one substance, asbestos, where Plaintiffs have proffered sufficient evidence causally associating asbestos with ovarian cancer. But Plaintiffs have failed to do the same for heavy metals. For the foregoing reasons, I recommend that the experts' opinions concerning heavy metals should be excluded in their entirety.

(b) Dose-response

Defendants further challenge Plaintiffs' experts' heavy metals opinions because the experts fail to identify a concentration at which heavy metals may cause cancer. (Defs.' Heavy Metals and Fragrances Br. at 21–26.) They argue that the failure to identify a threshold above which heavy metals are toxic is independently fatal to the reliability of Plaintiffs' experts' causation opinions. (*Id.*)

Plaintiffs respond that the lack of a dose-response relationship does not necessarily undermine the reliability of their experts' opinions, pointing out that neither Bradford Hill nor qualitative risk assessments require consideration of a dose-response relationship. (*Id.* at 24–25.) They also reprise their arguments that the presence of a biologically plausible mechanism through which talc (as well as the heavy metals) can cause ovarian cancer overcomes the absence of a dose-response relationship. (*Id.* at 24–28.) While I have already recommended that the experts' heavy metal opinions be excluded, to be complete, I will address this argument as well.

Contrary to Plaintiffs' position, courts generally require *some* evidence of a dose-response relationship or evidence compensating for the lack of a dose-response relationship. *See Pinares v. Raytheon Techs. Corp.*, 19-cv-14831, 2023 WL 2661521, at *3 (11th Cir. Mar. 28, 2023) ("[W]e have never required an expert to 'give precise numbers about a dose-response relationship,' . . . we do require an

expert to lay a 'reliable groundwork for determining the dose-response relationship.'" (alterations in original) (quoting *Williams v. Mosaic Fertilizer, LLC*, 889 F.3d 1239, 1248 (11th Cir. 2018))); *Sutherland v. Matrixx Initiatives, Inc.*, No. 04-cv-0129, 2006 WL 6617000, at *11 (N.D. Ala. Nov. 7, 2006) ("If an expert offers no evidence related to the dose-response relationship, there is an unsurmountable methodology problem."); *Hartle v. FirstEnergy Generation Corp.*, No. 08-cv-1019, 2014 WL 868913, at *8 (W.D. Pa. Mar. 5, 2014) (citing *McClain*, 401 F.3d at 1241 n.6).

This requirement is evident from my 2020 Opinion, which Plaintiffs cite in support of their argument that no evidence of dose-response is required. (*See* Pls.' Heavy Metals and Fragrances Br. at 24 (citing *In re Johnson & Johnson*, 509 F. Supp. 3d at 179).) As I concluded in the 2020 Opinion, "a *strong* dose-response is not necessarily required for an expert to find a causal nexus." 509 F. Supp. 3d at 17 (emphasis added). Although Plaintiffs and Defendants disputed the strength of the dose-response relationship concerning talc and ovarian cancer both now and in 2020, Plaintiffs' experts provided *some* evidence of dose-response. *See id.* ("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."). As discussed *supra* Part V.B.5.iii, the experts' reference to a body of

evidence concerning a connection, and dose response, between talc and ovarian cancer is sufficient under *Daubert*.

Unlike with talc and asbestos, however, Plaintiffs appear to concede that they have provided no evidence of a dose-response relationship between heavy metals and ovarian cancer. (*See* Pls.' Heavy Metals and Fragrances Br. at 24–35.) Their experts similarly appear to concede that there is no evidence of such a relationship. (*See, e.g.*, Zelikoff Dep. at 282:10–24; Carson Dep. at 169:17–23, 175:6–176:10; Plunkett 2021 Dep. at 263:24–264:1; Clarke-Pearson Dep. at 292:6–10.)

Turning to Plaintiffs' arguments in opposition, I first am unpersuaded that the presence of a biologically plausible mechanism obviates the need to consider a dose-response relationship. As noted above, Plaintiffs have provided evidence of a dose-response relationship between both asbestos and talc with ovarian cancer, as well as a biologically plausible mechanism. Here, they do not have the requisite evidence of a dose-response relationship with heavy metals.

For similar reasons, I am also unpersuaded that the experts' use of qualitative risk assessment and a Bradford Hill analysis on *talcum powder* generally obviates the need for a dose-response relationship to establish the reliability of their experts' opinions concerning heavy metals. I have recommended, based on the fulsome discussion *supra* Part V.B.5.iii, that Plaintiffs' experts may testify that under their qualitative risk assessments and attendant Bradford Hill analyses of talcum powder

there is a causative relationship, including a dose-response relationship between talc and ovarian cancer—without evaluating the individual constituent substances (except for asbestos) that are included in Defendants' products, such as heavy metals. But Plaintiffs seek to offer expert opinions that those heavy metals are carcinogenic and can contribute to the causation of ovarian cancer. For that scientific proposition, Plaintiffs must provide a sufficiently reliable analysis under Rule 702 and *Daubert*, whether it takes the form of qualitative risk assessment, a Bradford Hill analysis, or some other reliable methodology. *Cf. In re Denture Cream Products Liab. Litig.*, 795 F. Supp. 2d 1345, 1357 n.28 (S.D. Fla. 2011) ("[T]he lack of *any* analytic epidemiological studies does weaken Plaintiffs' experts' assertion of causation.").

Because Plaintiffs' experts failed to substantiate their opinions on heavy metal, I recommend that the Court grant Defendants' motion to exclude Plaintiffs' causation experts' opinions that heavy metals contribute to the toxicity and/or carcinogenicity of Defendants' products.

(2) Dr. Crowley—fragrance chemicals

Defendants challenge the reliability of Dr. Crowley's opinions. Like their heavy metals challenge, Defendants argue that Dr. Crowley's method is unreliable because (1) he fails to cite evidence linking fragrance chemical exposure to ovarian

cancers, and (2) and fails to analyze dosage. (Defs.' Heavy Metals and Fragrances Br. at 27–43.)

In response, Plaintiffs contend that Dr. Crowley does not offer a medical causation opinion. According to Plaintiffs, Dr. Crowley instead opines on whether the "chemical properties of J&J's fragrance chemicals met regulatory standards, and whether they can contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the Talcum Powder Products as a whole." (Pls.' Heavy Metals and Fragrances Br. at 32.) As for reliability, Plaintiffs offer similar responses to those that they offered with respect to heavy metals. Plaintiffs assert that Dr. Crowley's methods are reliable based on his past experience as a chemist and in the pharmaceutical field and were reliably applied here because he followed the methods he uses in the industry. (*Id.* at 32–42.) They further respond that there is sufficient evidence indicating a relationship between certain fragrance chemicals and ovarian cancer. (*Id.* at 42–47.) Lastly, Plaintiffs argue that it was unnecessary for Dr. Crowley to conduct a dose-response assessment. (*Id.* at 47–52.)

(a) Lack of a link to ovarian cancer

At the outset, I disagree with Plaintiffs that Dr. Crowley does not offer an opinion that concerns medical causation. Even under Plaintiffs' own formulation, Dr. Crowley's opinion that fragrance chemicals "contribute to the inflammatory properties, toxicity, and potential carcinogenicity" is an opinion suggesting that

certain substances in Defendants' products may cause cancer. (*Id.* at 32.) Characterizing his opinion as one of causation or one of "contribution to carcinogenicity" is a distinction without difference because the functional import of the opinion is the same: Dr. Crowley opines that the fragrance chemicals can cause (or contribute to) ovarian cancer. (Crowley Dep. at 327:14–328:13 ("Q. You're not expressing an opinion as to whether or not the chemical substances that you identify in this section of your report, [Section] 4.8, either cause or contribute to ovarian cancer. Correct? [objection omitted] A. Actually, I am . . . I've stated fairly clearly, I feel, that, you know, you've got a whole bunch of irritants, . . . sensitizers, . . . allergens, . . . where that talc particle goes, those fragrance chemicals go with it. . . . [M]any of them – demonstrated biological activity in animal and *in vitro* cell models that demonstrates toxicity and carcinogenicity. . . . I think they can absolutely contribute to the carcinogenicity of the product in total.").) This conclusion frames the rest of the analysis of Dr. Crowley's opinions. As Dr. Crowley seeks to offer testimony on causation, he is subject to the same standards that I have applied above to Plaintiffs' causation experts with respect to talc, asbestos, and heavy metals.

In that regard, on the issue of a scientific link, Dr. Crowley concedes that there is no evidence of such a connection between the fragrance chemicals and *human* ovarian cancer. (*See* Crowley Dep. at 114:9–15, 199:16–19 ("I am not aware of an epidemiological study substantiating the causation of ovarian cancer from the so-

called fragrance chemicals."), 234:5–20, 252:12–17, 261:18–24, 264:15–23, 271:5–19.) Dr. Crowley cites several sources that identify certain fragrance chemicals as generally carcinogenic and cause specific cancers that are not ovarian cancer. (*See, e.g.*, Crowley Rep. at 12 (citing classifications of chemicals by IARC, NTP, the EPA); Crowley Dep. at 249:15–252:17; 256:11–257:21; 262:1–8, 264:15–265:24, 276:22–277:3.) Dr. Crowley also relies on animal studies, primarily studies involving animal ovary cells to support his opinion.[102] (*See, e.g.*, Crowley Rep. at 21, 23–25; Crowley Dep. at 115:14–119:8, 217:12–218:5, 221:20–222:2; *see also* Pls.' Heavy Metals and Fragrances Br. at 43–44 (identifying animal studies Dr. Crowley relies upon).)

To reiterate, "[g]enerally, courts are 'reluctant to allow expert testimony based upon animal studies to prove causation in humans unless there are good grounds to extrapolate data and results from animals to humans.'" *In re Valsartan*, 2025 WL 3141002, at *24 (quoting *In re Hum. Tissue*, 582 F. Supp. 2d at 670); *see also Leake v. United States*, 843 F. Supp. 2d 554, 560, n.8 (E.D. Pa. 2011) ("Animal studies

[102] Plaintiffs argue in opposition that certain studies on fragrance chemicals and ovaries would be unethical. But as Defendants point out, this does not relieve Plaintiffs of their burden to demonstrate that their expert opinion testimony is reliable. *See De Los Santos v. Johnson & Johnson*, No. 21-01208, 2024 WL 3700205, at *23 (N.D. Ala. Aug. 7, 2024) ("Regardless of any sympathy this Court may have for Plaintiff's asserted inability to produce such reliable scientific evidence as controlled experiments firmly establishing the effects of benzene on humans, which would be unethical, 'courts may only admit the state of science as it is.' Thus, this Court does not today hold that benzene cannot or did not cause Plaintiff's alleged injuries; only that he has failed to prove it with reliable evidence." (quoting *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1202 (11th Cir. 2002)).

may also provide sufficient scientific basis for an expert's general causation opinion, provided there are 'good grounds to extrapolate [the findings] from animals to humans[.]'") (alterations in original) (quoting *Fabrizi v. Rexall Sundown, Inc.*, No. 01-cv-289, 2004 WL 1202984, at *7 (W.D. Pa. Jun. 2, 2004)); *In re Paraquat*, 730 F. Supp. 3d at 808. The level of support for extrapolation required will vary with the circumstances of the study, but sufficiently reliable extrapolation generally involves accounting for metabolic and physiological differences between the animals studied and humans, as well as differences in dosage. *See In re Valsartan*, 2025 WL 3141002, at *24; *Soldo*, 244 F. Supp. 2d at 466.

Here, Dr. Crowley does not appear to offer any grounds, much less good grounds, for extrapolating from the animal studies he cites to humans. Indeed, Dr. Crowley admits that there "is no animal model for ovarian cancer," which would logically require that Dr. Crowley offer a strong basis for extrapolating animal data to humans. (Crowley Dep. at 278:18–279:8); *see In re Hum. Tissue*, 582 F. Supp. 2d at 657 ("[T]here must be good grounds to extrapolate from animals to humans, just as the methodology of the studies must constitute good grounds to reach conclusions about the animals themselves. Thus, the requirement of reliability, or 'good grounds,' extends to each step in an expert's analysis all the way through the step that connects the work of the expert to the particular case." (quoting *In re Paoli*, 35 F.3d at 742–43)).

Plaintiffs suggest that the fact that Dr. Crowley relied on studies assessing hamster ovaries is sufficient to extrapolate the hamster study. (*See* Pls.' Heavy Metals and Fragrances Br. at 43–44 ("Dr. Crowley identifies the studies in his report, and he also listed the fragrance chemicals in Baby Powder that have specifically been linked to *ovarian* abnormalities in animal studies at his deposition: [citing examples]").) But the identity of the target organ alone is not sufficient. Dr. Crowley does not discuss whether there are meaningful differences between hamster ovaries and human ovaries that may impact extrapolating data. Nor does Dr. Crowley purport to identify any general differences or similarities between humans and hamsters that would permit the extrapolation of hamster studies to humans. *See In re Valsartan*, 2025 WL 3141002, at *25 ("[R]ats typically have much shorter lifespans than humans, meaning that the timelines of disease in rodents and humans differ considerably."). At one point, Dr. Crowley notes that the routes of administration (*i.e.*, whether the chemical was administered orally, vaginally, or through a different route) of the chemical in a study impacts its extrapolation, but he does not explain how he can effectively extrapolate from a study using oral administration to the vaginal administration of fragrance chemicals in humans. (*See* Crowley Dep. at 269:8–14.)

In addition, Dr. Crowley also fails to provide a reliable method for extrapolating the dosages of fragrance chemicals used in the animal studies he cites.

For example, Dr. Crowley cites to one study concerning eugenol that caused "endometrial stromal polyps" in the reproductive systems of rats and explains the dosage used in the study. (*See* Crowley Dep. at 271:20–273:7.) But he fails to explain how that dosage can be extrapolated to humans. (*See id.*) In another example, Dr. Crowley relies on a 2006 NTP animal study of benzophenone that observed certain tumors in rats, including in the rats' ovaries. (Crowley Dep. at 277:17–280:13.) But, as Defendants contend, the rats in the NTP were given different doses of benzophenone, and only certain doses resulted in tumors. (Defs.' Heavy Metals and Fragrances Br. at 34.) Dr. Crowley does not account for this variation in dose in his analysis.

Moreover, Dr. Crowley *only* offers animal studies to support a causal connection between certain fragrance chemicals and human ovarian cancer. While other Plaintiffs' experts have relied on animal studies, as is discussed elsewhere in this Report and Recommendation, in those instances, the experts relied on other forms of evidence as well, such as epidemiological studies. Here, Dr. Crowley offers only animal studies in support of his opinion and he does not reliably extrapolate from them or provide a reliable basis to extrapolate from them. Given these failures,

I recommend that the Court exclude his opinions that fragrance chemicals contribute to the toxicity and carcinogenicity of Defendants' products.[103]

(b) Dose-response

As to Dr. Crowley's alleged failure to consider a dose-response relationship, I reiterate that the case law generally requires *some*, but not necessarily strong, evidence of a dose-response relationship. I am not persuaded that Dr. Crowley has advanced sufficient evidence concerning dosage to make his opinions reliable.

Plaintiffs argue that they were not given sufficient information for Dr. Crowley to consider dosage. (Pls.' Heavy Metals and Fragrances Br. at 47–48.) However, Plaintiffs do not specify that they sought the information that they now claim Defendants failed to provide. Neither party clarifies whether Plaintiffs sought or moved to compel more specific information concerning the concentrations of various fragrance chemicals in Defendants' products. (*See id.* at 40–42.) However, Plaintiffs carry the burden to demonstrate that Dr. Crowley's opinions are based on sufficient facts and data under Rule 702. Barring any issues of improper withholding of relevant discovery information (which does not appear to be the case here, and,

[103] Although I exclude Dr. Crowley's causation opinion (i.e., fragrance chemicals in talc contribute to talc's toxicity) as the product of an unreliable methodology, that exclusion does not extend to, or undermine, his identification of the fragrance chemicals *present* in Defendants' talc products.

in any event, is not an issue before me), if Dr. Crowley does not have sufficient facts and data to support one of his opinions, it is inadmissible.

Nonetheless, Plaintiffs argue that no consideration of dose-response concerning the fragrance chemicals is required for the same reasons that it was not required for heavy metals. (*See id.* at 48–52.) Plaintiffs first note that consideration of dose-response is unnecessary when conducting a qualitative risk assessment. (*See id.* at 48–49.) Yet Dr. Crowley admits that he did not conduct a risk assessment. (*See* Crowley Dep. at 200:13–202:6, 204:15–22.) Nor has any other expert conducted a qualitative risk assessment specifically focused on fragrance chemicals. Plaintiffs also raise the presence of a biologically plausible mechanism by which the fragrance chemical can cause ovarian cancer as support for the reliability of Dr. Crowley's opinions. But as I concluded above with respect to heavy metals, the presence of a biologically plausible mechanism and the general carcinogenicity of the fragrance chemicals alone is insufficiently reliable in the absence of some additional supporting evidence, such as a more specific connection to ovarian cancer or a dose-response relationship. Accordingly, I recommend that the Court exclude Dr. Crowley's opinions that fragrance chemicals in Defendants' products contribute to those products' toxicity or carcinogenicity.

(c) Other experts' opinions on fragrance chemicals

As noted above, I construe Defendants' argument that certain experts merely "parrot" Dr. Crowley's opinions as a challenge to the reliability of those experts' methodologies. Simply adopting or repeating another expert's conclusions—particularly where, as here, the underlying opinion is itself unreliable—does not constitute a reliable method under Rule 702. *See In re TMI*, 193 F.3d at 716. Accordingly, to the extent any expert's opinion on the toxicity of fragrance chemicals in Defendants' talc products rests solely on uncritical acceptance of Dr. Crowley's conclusions, such testimony is subject to exclusion.

Indeed, with one exception discussed below, each expert who offers opinions regarding fragrance chemicals indicates that he or she reviewed Dr. Crowley's report and concurs with its conclusions, or merely cites that report while providing little to no independent analysis addressing any causal association between fragrance chemicals and ovarian cancer. (*See* Carson Rep. at 6 (citing Crowley Rep.); Clarke-Pearson Rep. at 8 (same); Cote Rep. at 11–12; Kane Rep. at 5 (same); Levy Rep. at 19 (same); McTiernan Rep. at 88 (same); Moorman Rep. at 35; Sage Rep. at 6–7 (same); Singh Rep. at 60 (same); Smith Rep. at 21–22 (concluding that fragrances contribute to talc's carcinogenicity without citation or analysis); Smith-Bindman Rep. at 15 (citing Crowley Rep.); Wolf Rep. at 12–13 (same); Zelikoff Rep. at 12 (same); *see also* Sage Dep. at 290:6–291:3; Cote Dep. at 110:22–112:2, 144:24–

147:6; Wolf Dep. at 171:15–174:11; McTiernan Dep. at 272:11–273:16; Smith Dep. at 61:15–62:3, 331:3–22; Levy Dep. at 122:22–128:6; Kane Dep. at 130:25–131:7.)

Because these experts appear to have accepted Dr. Crowley's conclusions wholesale, without undertaking any independent analysis or validation, I conclude that they impermissibly parrot his opinions in violation of Rule 702. Accordingly, I recommend that the Court exclude their opinions concerning whether fragrance chemicals contribute to the toxicity or carcinogenicity of Defendants' products. *See In re TMI*, 193 F.3d at 716 (noting that failure to assess the validity of another expert's work warrants exclusion).[104]

The only exception appears to be Dr. Plunkett, who explains that she did not rely on Dr. Crowley's report but reviewed it after completing an independent analysis. (ECF No. 33005-13 ("Plunkett 2018 Dep.") at 336:5–339:14; *see also* Plunkett 3d Amend. Rep. ¶¶ 35–36.) Accordingly, I do not conclude that Dr. Plunkett improperly parrots Dr. Crowley's opinions. However, I do otherwise conclude that

[104] As I have not excluded Dr. Crowley's opinions concerning the contents of Defendants' products, Dr. Crowley's work may serve as a factual predicate establishing the presence of specific fragrance chemicals in the products at issue. Had Plaintiffs' causation experts then employed reliable, independent methodologies to assess whether those identified fragrance chemicals cause ovarian cancer, their opinions could be admissible notwithstanding the exclusion of Dr. Crowley's causation conclusions. That is, reliance on Dr. Crowley for the limited purpose of identifying which fragrance chemicals are present in the talc products is permissible. However, Plaintiffs' causation experts stopped there, and did not conduct an independent analysis of whether fragrance chemicals cause ovarian cancer. Instead, they adopted Dr. Crowley's carcinogenicity conclusions wholesale, without validation or separate methodological support. Because their opinions merely echo Dr. Crowley's excluded causation opinions—rather than applying independent scientific reasoning to the identified chemicals—they must likewise be excluded under Rule 702.

Dr. Plunkett's opinions suffer from the same methodological problems discussed above with respect to Dr. Crowley's opinions. Dr. Plunkett similarly has no evidence to connect any fragrance chemicals specifically to ovarian cancer, (*see id.* at 275:9–25), and is similarly unable to determine the relative contribution of any fragrance chemical to the overall risk of Defendants' products, (*see* Plunkett 2018 Dep. at 167:24–171:15). As such, I recommend excluding Dr. Plunket's causation opinion of fragrance chemicals in talc.

To summarize my recommendations with respect to Defendants' motions concerning heavy metals and fragrance chemicals, I recommend that the Court (i) exclude the opinions of Drs. Cook and Krekeler insofar as either expert opines that a substance is carcinogenic for a lack of fit, (ii) exclude Plaintiffs' experts' opinions[105] that heavy metals cause or contribute to the causation of ovarian cancer because those experts did not use reliable methods in causally connecting heavy metals to ovarian cancer, (iii) exclude the causation opinion of Dr. Crowley related to fragrance chemicals as he similarly did not use reliable methods in causally connecting those chemicals to ovarian cancer, and (iv) exclude Plaintiffs' experts'

[105] As noted above, the relevant Plaintiffs' causation experts are Drs. Carson, Clarke-Pearson, Cote, Kane, Levy, McTiernan, Moorman, Siemiatycki, Singh, Smith, Smith-Bindman, and Wolf. As noted above, my recommendation excluding Plaintiffs' experts' heavy metals opinions applies to Dr. Carson's opinions notwithstanding the reference to Dr. Carson in the 2020 Opinion.

opinions[106] that fragrance chemicals cause or contribute to the causation of ovarian cancer because, *inter alia*, those opinions impermissibly parrot Dr. Crowley's excluded opinions or are not the product of reliable opinions.[107]

C. Plaintiffs' Motions to Exclude Defendants' Rebuttal Experts' Genetics-Related General Causation Opinions and Biological Plausibility Opinions[108]

Plaintiffs move to exclude portions of the opinions offered by three of Defendants' designated gynecologic oncologists—Dr. Cheryl Saenz, Dr. Kevin Holcomb, and Dr. Michael Finan. (*See generally* ECF No. 32999-1 ("Pls.' Finan, Saenz & Holcomb Br.").) Plaintiffs also move to exclude portions of the opinions offered by Dr. Analisa DiFeo, an ovarian cancer researcher, (*see* ECF No. 33010-1 ("Pls.' DiFeo Br.")), Dr. Jennifer Permuth, a molecular epidemiologist, (*see* ECF

---

106 As noted above, the relevant Plaintiffs' causation experts are Drs. Carson, Clarke-Pearson, Cote, Kane, Levy, McTiernan, Moorman, Plunkett, Singh, Smith, Smith-Bindman, Wolf, and Zelikoff.

107 I do not find that Plaintiffs' experts' failure to reliably link heavy metals or fragrance chemicals to ovarian cancer undermines the admissibility of their opinions that Defendants' talc products, considered as a whole, cause ovarian cancer. As explained throughout this section and elsewhere in this Report and Recommendation, both Plaintiffs and Defendants have consistently framed the causation inquiry at the product level—examining the carcinogenicity of cosmetic talc as a whole and its effects on ovarian tissue. Indeed, Defendants' own experts expressly adopt that same approach, evaluating talc in its entirety without parsing causation by individual constituents. (*See, e.g.*, ECF No. 32999-5 ("Saenz Rep.") at 58; ECF No. 32999-7 ("Finan Rep.") at 4; ECF No. 32999-6 ("Holcomb Rep.") at 3.)

108 As explained above, I will issue a separate Report and Recommendation addressing the portions of Plaintiffs' motions seeking to exclude certain of Defendants' experts' specific causation opinions. Therefore, my decisions resolving Plaintiffs' motions to exclude the opinions and testimony of Drs. Finan, Saenz, Holcomb, Permuth, DiFeo, and Boyd, will not substantively address these experts' specific causation opinions or Plaintiffs' arguments to exclude them. Rather, I will focus on the opinions of these experts on general causation.

No. 33001-1 ("Pls.' Permuth Br.")), and Dr. Jeff Boyd, a molecular geneticist and gynecologic cancer researcher, (*see* ECF No. 33060-1 ("Pls.' Boyd Br.")).

As an overview, Plaintiffs challenge: (i) those portions of Defendants' experts' opinions suggesting that unidentified genetic mutations, yet-to-be-discovered genetic mutations, and/or genetic variants of uncertain significance ("VUS") may explain Plaintiffs' ovarian cancers—or ovarian cancer more generally—on the grounds that such opinions are speculative and insufficiently supported;[109] (ii) certain experts' biological plausibility opinions as lacking scientific reliability and posing a risk of confusing or misleading the jury; and (iii) what Plaintiffs characterize as the application of an incorrect standard for assessing biological plausibility, which they contend warrants exclusion of related opinions. Plaintiffs further move to exclude Dr. Boyd's critique of mechanistic and *in vitro* studies, along with any associated biological plausibility conclusions, arguing that his opinions are not supported by his qualifications, are methodologically unreliable, and are not relevant to issues the jury must decide.

Given the substantial overlap between Plaintiffs' arguments for, and Defendants' arguments against, the partial exclusion of Dr. Saenz, Dr. Holcomb, Dr. Finan, Dr. DiFeo, Dr. Permuth, and Dr. Boyd, I will address common issues in

[109] It is important to note that Plaintiffs are not seeking to exclude the experts' opinions on genetic testing as a general matter; rather, Plaintiffs only seek to preclude opinions regarding unidentified genetic mutations, yet-to-be-discovered genetic mutations, and/or VUS.

tandem and recommend rulings accordingly based on my assessment of the Parties' positions. Although Plaintiffs do not contest most of these experts' qualifications or opinions, it is necessary to contextualize my forthcoming recommendations in this section. Therefore, I will first provide an overview of Defendants' challenged experts, the scope of their engagement as Defendants' experts, and their general causation and biological plausibility opinions. Next, I will evaluate Plaintiffs' arguments as they apply to Defendants' experts' pertinent methodologies and opinions.

My prior Opinion addressed only Dr. Cheryl Saenz and did not address the remainder of Defendants' experts challenged here. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 192–95. As discussed below, however, my prior Opinion addressed certain arguments Plaintiffs now raise, which were largely presented during the first round of motion practice. These arguments will be addressed in turn, in accordance with the Court's April 30, 2024 Memorandum Order.

1. Defendants' Experts

Defendants offer Drs. Saenz, Holcomb, Finan, DiFeo, Permuth, and Boyd as rebuttal experts to certain of Plaintiffs' proffered experts. Each has submitted one or several expert reports that purport to challenge, among other things, Plaintiffs' experts' general causation opinions that perineal use of cosmetic talcum powder causes ovarian cancer. Many of these experts also offer affirmative opinions based

on, among other things, their review of epidemiological and mechanistic literature, their professional experiences, and their independent review of certain Plaintiffs' experts' methodologies and opinions.

In resolving Plaintiffs' motions to exclude, I will first address the qualifications of Defendants' experts and consider their general causation and biological plausibility opinions.

i. Drs. Saenz, Finan & Holcomb

a. Qualifications

Dr. Cheryl C. Saenz is a board-certified gynecologic oncologist with decades of clinical and academic experience. (*See* Saenz Rep. at 1–2; *see generally id.*, Ex. A.) Dr. Saenz earned a B.A. in Biopsychology from Cornell University in 1985, obtained her M.D. from the University of California, Irvine, in 1991, and completed residency in Reproductive Medicine at the University of California Medical Center in San Diego, California, in 1995. (*See id.* at 2.) During residency, Dr. Saenz was awarded a Galloway Fellowship at Memorial Sloan Kettering Cancer Center, and shortly thereafter became a Fellow in Gynecologic Oncology at Memorial Sloan Kettering Cancer Center. (*Id.*)

Dr. Saenz currently serves as a Clinical Professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Diego, where she has served as an attending physician since 1998. (*Id.* at 1–2 &

Ex. A.) In her academic and clinical roles, Dr. Saenz has directed multidisciplinary treatment planning for gynecologic malignancies for over two decades, served as Chair of the Cancer Committee at the Moores Cancer Center at the University of California, San Diego, for twelve years, and is the Medical Director of the Strauss Family Center for the Early Detection of Ovarian Cancer. (*Id.* at 2–3 & Ex. A.) Plaintiffs do not dispute that Dr. Saenz is qualified to act as an expert in gynecologic oncology.

Dr. Kevin Holcomb is a board-certified gynecologic oncologist who received his medical degree from New York Medical College, completed residency in Obstetrics and Gynecology at The New York Hospital-Cornell Medical Center, and undertook an American Board of Obstetrics and Gynecology-approved fellowship in Gynecologic Oncology at Downstate Medical Center/Kings County Hospital. (*See* Holcomb Rep. at 1.) Following faculty service as an Assistant Professor at Downstate Medical Center/Kings County Hospital, Dr. Holcomb became Director of Gynecologic Oncology at Beth Israel Medical Center, and in 2006 returned to Weill Cornell Medicine/New York-Presbyterian, where he has served as Director of Gynecologic Oncology, Vice-Chairman of Gynecology, Director of Minimally Invasive Surgery, and Associate Professor and Associate Dean of Admissions at the Weill-Cornell Medical College. (*Id.*)

Clinically, Dr. Holcomb maintains a high-volume practice, performing roughly 200 surgeries annually and managing chemotherapy, immunotherapy, and targeted therapy for ovarian-cancer patients. (*Id.*) Dr. Holcomb describes his clinical responsibilities to include, among other things, "the identification of genetic, reproductive, and environmental risk factors." (*Id.*) Academically, Dr. Holcomb has authored or co-authored more than 90 peer-reviewed publications, leads multi-institutional prospective trials, and reviews for leading journals. (*Id.* at 2.) Plaintiffs do not dispute that Dr. Holcomb is qualified to act as an expert in gynecologic oncology.

Dr. Michael A. Finan is a board-certified obstetrician-gynecologist and gynecologic oncologist with more than three decades of clinical practice. (*See* Finan Rep. at 2.) Dr. Finan earned his undergraduate degree from the University of New Orleans and his medical degree from Louisiana State University Health Sciences Center in Shreveport, Louisiana. (*Id.*) Dr. Finan completed his Obstetrics and Gynecology residency at the University of South Florida in Tampa and at the Tampa General Hospital, where he received multiple teaching awards and was elected to the Alpha Omega Alpha Honor Medical Society. (*Id.* at 2–3.) Dr. Finan was thereafter accepted into a fellowship in Gynecologic Oncology at the University of South Florida, with clinical training at the H. Lee Moffitt Cancer Center and Tampa General Hospital. (*Id.* at 3.)

Dr. Finan subsequently joined the Ochser Clinic in New Orleans as a Gynecologic Oncologist, where he maintained a high-volume surgical and clinical practice, directed resident research, and later served as the Obstetrics and Gynecologic Residency Program Director. (*Id.*) Dr. Finan joined the University of South Alabama as a Professor of Gynecologic Oncology in 2005 and the University of South Alabama Mitchell Cancer Institute in 2007. (*Id.*) From 2014 to 2018, he served as Cancer Center Director of the Mitchell Cancer Institute, overseeing strategic, research, and faculty development initiatives. (*Id.* at 4–5.) Since 2020, Dr. Finan has served as Chief of Cancer Services and Chief of Women's Services for the Singing River Health System in Mississippi, where he continues an active clinical gynecologic oncology practice and leads systemwide cancer services, clinical research oversight, and cancer risk assessment programs that include "genetic testing and a more intense screening." (*Id.* at 5.) Plaintiffs do not dispute that Dr. Finan is qualified to act as an expert in gynecologic oncology.

b. Relevant Opinions

Drs. Saenz, Finan, and Holcomb each offer nearly the same five general causation opinions: (1) established factors—apart from talc—are known to increase or decrease ovarian cancer risk; (2) the epidemiology does not show that genital talc use is a risk factor; (3) talc cannot migrate from the perineum to the fallopian tubes or ovaries; (4) talc does not cause ovarian cancer by inducing inflammation; and (5)

there is no evidence talc causes malignant transformation of epithelial cells. (*See generally* Saenz Rep.; Holcomb Rep.; Finan Rep.)

Drs. Saenz, Finan, and Holcomb also all assert in their respective discussions of established risk factors that an individual's genetic predisposition may cause or contribute to the development of ovarian cancer. As previewed above, Plaintiffs move to exclude a narrow aspect of these discussions as they generally relate to the development of ovarian cancer: that presently unidentified genetic mutations, yet-to-be-discovered genetic mutations, and/or VUS may cause the development of ovarian cancers.

Dr. Saenz submits a general expert report that evaluates whether genital use of cosmetic talc causes ovarian cancer and concludes that it does not, based on a critique of the epidemiology and biological plausibility evidence. (*See generally* Saenz Rep.)[110]

Across all of Dr. Saenz's reports, Dr. Saenz critiques the expert opinions of Dr. Judith Wolf and Dr. Daniel Clarke-Pearson on general and specific causation. (*See, e.g.*, Saenz Rep. at 10, 15, 45, 51; Saenz Converse Rep. at 4–5 (Dr. Clarke-Pearson); Saenz Judkins Rep. at 5–6 (Dr. Wolf); Saenz Newsome Rep. at 5–6 (Dr.

[110] Dr. Saenz also submits reports containing case-specific opinions regarding Plaintiff Converse, (*see* ECF No. 32999-8 ("Saenz Converse Rep.")), Plaintiff Judkins, (*see* ECF No. 32999-9 ("Saenz Judkins Rep.")), Plaintiff Newsome, (*see* ECF No. 32999-10 ("Saenz Newsome Rep.")), and Plaintiff Rausa, (*see* ECF No. 32999-11 ("Saenz Rausa Rep.")).

Clarke-Pearson); Saenz Rausa Rep. at 6–7 (Dr. Clarke-Pearson).) Dr. Saenz also challenges Dr. Saed's methodology and conclusions, (*see, e.g.*, Saenz Rep. at 51–52), and addresses Dr. Godleski's pathology opinions as to specific Plaintiffs, (*see, e.g.*, Saenz Converse Rep. at 7–8; Saenz Judkins Rep. at 5–6; Saenz Newsome Rep. at 5, 7).

Generally, Dr. Saenz opines, among other things, that hereditary predisposition is a well-established driver of epithelial ovarian cancer, with approximately 70% of inherited cases stemming from BRCA1 and BRCA2 mutations. (*See* Saenz Rep. at 5–6; *see also id.* at 13 ("The most influential of [well-established factors that have been associated with a woman having an increased risk of developing ovarian cancer] are mutations in genes that can be inherited and increase the risk of developing ovarian cancer to as high as 50–60% over the course of a woman's lifetime.").) Dr. Saenz emphasizes that genetic testing previously only tested for BRCA1 and BRCA2; that modern genetic testing examines over 25 genes; and that "new genes are being identified and added to testing panels every year." (*See* Saenz Rep. at 3, 5–6.)

Dr. Holcomb "was asked to review the relevant scientific literature to furnish an opinion as to whether perineal use of talcum powder can cause ovarian cancer as a general matter, and, specifically, whether it caused [Plaintiff] Anna Gallardo to develop ovarian cancer." (Holcomb Rep. at 3.) Dr. Holcomb submits a single expert

report, wherein he critiques Dr. Wolf's general causation opinions, (*see, e.g.*, *id.* at 3), Dr. Wolf's specific causation opinions of Plaintiff Gallardo, (*see id.* at 3, 29–34), and Dr. Saed's methodology and conclusions, (*see id.* at 26).

Like other defense experts, Dr. Holcomb generally opines, among other things, that genetic mutations found in the BRCA1 and/or BRCA2 tumor suppressor genes are major causes of hereditary ovarian cancer. (*See id.* at 5–6.) But the "number of genes potentially associated with an increased risk of ovarian cancer is continually expanding." (*Id.* at 6.)

Dr. Finan "was asked to render an opinion as to whether talcum powder can cause or contribute to the development of ovarian cancer in general, and specifically, whether it did so with regards to Linda Bondurant." (*See* Finan Rep. at 2.) Dr. Finan also submits a single expert report, wherein he rebuts Dr. Wolf's general causation opinions, (*see, e.g.*, *id.* at 12–13, 45, 50, 55, 61, 64), her specific causation analysis of Plaintiff Bondurant, (*see, e.g.*, *id.* at 63–67), and Dr. Saed's *in vitro* methodology and "malignant transformation" claims, (*see, e.g.*, *id.* at 62).

Dr. Finan asserts, among other things, that approximately 30% of women with serous ovarian cancer have a known pathogenic germline mutation, the majority of which are attributable to alterations in BRCA1 or BRCA2. (*Id.* at 7.) But "[a]dditional genetic mutations continue to be identified, with more than 2 dozen reported mutations related to ovarian cancer having been identified to date." (*Id.*)

According to Dr. Finan, genetic testing is continually evolving, so a negative result does not exclude a hereditary cause. (*Id.* at 7–8; *see also id.* at 64 ("[G]enetic testing is a dynamic field with new genetic variants found to be associated with ovarian cancer on a regular basis.").) Dr. Finan also posits that VUS "are commonly found to be associated with diseases as further testing is refined over time" and that "genetic testing is constantly being developed, expanded, and updated." (*Id.* at 7.)

ii. Dr. DiFeo

a. Qualifications

Dr. Analisa DiFeo is an ovarian cancer researcher with more than two decades of experience in ovarian cancer genetics and biology research. (*See* ECF No. 33010-5 ("DiFeo Rep.") at 2.) Dr. DiFeo earned a B.S. in Biochemistry from the State University of New York at Binghamton and a Ph.D. in Cancer Genetics from the Icahn School of Medicine at Mount Sinai, followed by postdoctoral training in Genetics and Genomic Sciences at Mount Sinai. (*See id.* at 3; *see also id.*, Ex. A at 1.) In 2012, Dr. DiFeo joined Case Western Reserve University School of Medicine as an Assistant Professor in the Division of General Medical Sciences (Oncology), later holding a joint appointment in Genetics and Genome Sciences, and was named the Norma C. and Albert I. Geller Designated Professor in Ovarian Cancer Research. (*See id.*) While at Case Western Reserve University School of Medicine, Dr. DiFeo founded and led a research laboratory. (*See id.* at 3.)

Recruited in 2018 to the University of Michigan Medical School, Dr. DiFeo served as a tenured Associate Professor in the Departments of Pathology and Obstetrics & Gynecology and, as of May 2024, is a tenured Professor in both departments. (*See id.* at 3; *see also id.*, Ex. A at 1.) Dr. DiFeo directs the Michigan Ovarian Cancer Science and Innovation Consortium and co-leads the institution's gynecologic cancer tumor repository, which supports extensive collaborative research. (*Id.* at 2.) Dr. DiFeo's work focuses on ovarian cancer genetics and biology, chemotherapy resistance, tumor initiation, and development of patient-relevant models, resulting in more than 70 peer-reviewed publications, multiple federal and foundation awards, and editorial service for several leading journals. (*See id.* at 3–5; *see also generally id.*, Ex. A.) Plaintiffs do not dispute that Dr. DiFeo is qualified to act as an expert in her proffered area of expertise.

b. Relevant Opinions

In her expert report, Dr. DiFeo provide[d] "an overview of cancer, what is known about ovarian cancer, the origins of ovarian cancer, modeling malignant transformation, bioassays to assess neoplastic transformation, and an overview on inflammation." (*Id.* at 6.). Dr. DiFeo also opined "on the hypothesized role of talc in ovarian cancer development and discuss[es] numerous concerns with the data presented" relied upon by Plaintiffs' experts and "why the results of their research

do not constitute scientifically sound evidence that cosmetic talc use can cause ovarian cancer." (*Id.*)

Dr. DiFeo largely concurred with Drs. Saenz, Holcomb, and Finan. She agreed that scientific evidence does not support a causal link between perineal use of cosmetic talc and ovarian cancer. (*See generally* DiFeo Rep.) Dr. DiFeo asserted that epidemiology does not show an increased risk and that there is no evidence of meaningful transformation, (*see, e.g.*, *id.* at 27–31), adding further that cosmetic talc—regardless of its exact constituents or alleged contaminants—does not cause or contribute to ovarian cancer, (*see, e.g.*, *id.* at 6). But unlike Drs. Saenz, Holcomb, and Finan, Dr. DiFeo did not separately opine on known risk factors or migration. Rather, Dr. DiFeo concluded that cosmetic talc has not been shown to migrate by way of reliable study, *(see, e.g.*, *id.* at 28–29), to trigger chronic inflammation preceding cancer development, (*see, e.g.*, *id.* at 16–17), or to induce malignant transformation, (*see, e.g.*, *id.* at 17–22, 29–50).

To be sure, Dr. DiFeo explained that genetics is an established risk factor for ovarian cancer. Dr. DiFeo opined, among other things, that while known hereditary mutations account for a significant share of ovarian cancer causes—"approximately 24% of ovarian cancer[s] diagnosed have at least one predisposing germline mutation," with BRCA1 and BRCA2 being the most common at approximately "18% of the germline mutations"—the genetic picture is incomplete and evolving.

(*See id.* at 13.) Even within known pathways, which include at least 16 genes, Dr. DiFeo asserted that "there are mutations that remain unknown, have an unclear impact on cancer progression, or cannot be detected by current tests." (*Id.*) In Dr. DiFeo's view, although certain genes are recognized to predispose individuals to ovarian cancer, the "exact mutation in those genes"—classified as VUS—may not be clear. (*Id.* at 13.) Moreover, beyond new variants in known genes, "new genes continue to be identified." (*Id.* at 13–14.)

iii. Dr. Permuth

a. Qualifications

Dr. Jennifer Blythe Permuth is a molecular epidemiologist and tenure-track Associate Professor in the Department of Cancer Epidemiology at the H. Lee Moffitt Cancer Center and Research Institute in Tampa, Florida, where she also serves as Vice Chair of Research in Gastrointestinal Oncology. (*See* ECF No. 33001-5 ("Permuth Rep.") at 4.) Dr. Permuth holds a B.S. in Biology from the University of South Florida, an M.S. in Molecular, Cellular, and Developmental Biology and Genetics with a specialization in Genetic Counseling from the University of Minnesota, and a doctorate in Epidemiology from the University of South Florida College of Public Health. (*See id.*) Beyond her graduate training in genetics, Dr. Permuth practiced as a genetic counselor, providing counseling and education to hundreds of women newly diagnosed with ovarian, fallopian tube, and primary

peritoneal cancers about hereditary risk, testing options, and implications for family members. (*See id.*)

Dr. Permuth has a grant-funded research portfolio and has authored more than 100 peer-reviewed publications, reviews, and book chapters spanning genetics, epidemiology, molecular biology, and gynecologic and gastrointestinal oncology. (*See id.*) Dr. Permuth also serves as a peer reviewer for leading scientific journals and as a grant reviewer for the National Cancer Institute. (*See id.*) Plaintiffs do not dispute that Dr. Permuth is qualified to act as an expert in her proffered area of expertise.

b. Relevant Opinions

In her expert report, Dr. Permuth addressed "causes of and risk factors for ovarian cancer" and challenged "the fundamental bases of [P]laintiffs' experts' hypotheses and contentions regarding talc as a causal agent." (*See id.* at 4.) Throughout her report, Dr. Permuth also provided "commentary" "on the reports submitted by Plaintiffs' epidemiology experts," including, without limitation, Dr. McTiernan, Dr. Moorman, Dr. Singh, Dr. Smith-Bindman, Dr. Siemiatycki, Dr. Cote, Dr. Harlow, and Dr. Levy, and specifically addressed specific causation opinions for Plaintiffs Bondurant, Converse, Judkins, and Newsome. (*See, e.g.*, *id.* at 135–47.)

Like Dr. DiFeo, Dr. Permuth largely shared the conclusions of Drs. Saenz, Finan, and Holcomb, identifying known risk and protective factors, (*see, e.g.*, *id.* at 9–52), concluding that the epidemiology did not demonstrate a causal talc-ovarian cancer relationship, (*see, e.g.*, *id.* at 53–115), and opining that there is a lack of evidence of talc carcinogenicity, (*see, e.g.*, *id.* at 149). Instead of directly commenting on migration, Dr. Permuth appears to broadly emphasize the failure of literature to demonstrate migration as a biologically plausible mechanism. (*See, e.g.*, *id.* at 53, 69, 111–12.)

Dr. Permuth opined that genetics and family history are the strongest risk factors for ovarian cancer, with first-degree relatives of affected individuals experiencing a three- to seven-fold increased risk and women with a prior breast cancer diagnosis having approximately a 70% increase in risk. (*See id.* at 9–10.) Dr. Permuth explained that up to 20% of ovarian cancers arise from "rare, high-penetrant mutations in genes"—most notably in BRCA1 and BRCA. (*See id.*) Dr. Permuth conceded that although BRCA1 and BRCA2 gene mutations are relatively uncommon in the general population, they are more prevalent in certain groups such as those of Ashkenazi Jewish ancestry. (*See id.* at 10.) Beyond BRCA1 and BRCA2, Dr. Permuth identifies pathogenetic variants across approximately 20 additional genes. (*See id.*)

iv. Dr. Boyd

a. Qualifications

Dr. Jeff Boyd is a molecular geneticist and gynecologic cancer researcher with more than three decades of leadership in oncology research and academic medicine. (*See* Boyd Rep. at 2.) Dr. Boyd holds a B.S. from Duke University and an M.S. and Ph.D. in Toxicology and Biochemistry from North Carolina State University. (*Id.*) Dr. Boyd completed postdoctoral training at the Lineberger Comprehensive Cancer Center of the University of North Carolina at Chapel Hill. (*See id.*) Subsequently, Dr. Boyd served as a section head of Gynecologic Pathobiology at the National Institutes of Health's National Institute of Environmental Health Science, an Associate Professor in the Department of Obstetrics and Gynecology, Division of Gynecologic Oncology, and the Department of Genetics, at the University of Pennsylvania. (*See id.*)

From 1997 to 2006, Dr. Boyd directed the Gynecologic and Breast Research Laboratory in Memorial Sloan Kettering Cancer Center's Department of Surgery, and the Diagnostic Molecular Genetics Laboratory in Memorial Sloan Kettering Cancer Center's Department of Medicine. (*Id.*) Dr. Boyd later held senior research and academic leadership roles at Memorial Sloan Kettering Cancer Center, the Anderson Cancer Institute at the Memorial University Medical Center, and the Mercer University School of Medicine. (*Id.*)

Dr. Boyd now serves as Director of the Institute of Cancer Research at the Feinstein Institutes (Northwell Health), and Vice President, Chief Scientific Officer, and Director of the Northwell Health Cancer Institute's Center for Genomic Medicine, with professorships at the Zucker School of Medicine at Hofstra/Northwell's Department of Obstetrics and Gynecology and Department of Pathology and Laboratory Medicine and the Cold Spring Harbor Laboratory. (*Id.*) Dr. Boyd has received over $25 million in peer-reviewed funding and has authored or co-authored over 200 publications "on the molecular and genetic bases of gynecologic or breast cancers." (*Id.* at 2–3.) Discussed in greater detail below, Plaintiffs argue that Dr. Boyd is not qualified to "opine on the design and methodologies of *in vitro* studies." (*See* Pls.' Boyd Br. at 19–20.)

b. Relevant opinions

Within the scope of his engagement in this matter, Dr. Boyd was asked to review: (1) two poster presentations by Dr. Saed and the associated 2023 publication by Dr. Saed and colleagues, (*see* Boyd Rep. at 2–16); (2) two mechanistic studies on which Plaintiffs' experts rely, involving rodent macrophages and talcum powder, led by Dr. Angelo Mardino in 2020 and Dr. Tania Emi in 2021, respectively, (*see id.* at 2, 16–20); and (3) selected opinions of Plaintiffs' expert Dr. Levy concerning genetics and ovarian cancer, (*see id.* at 2, 22–26).

Dr. Boyd concluded that Plaintiffs' mechanistic theory that perineal talc causes ovarian carcinogenesis is speculative and lacked support from scientific evidence. In his view, the *in vitro* studies Plaintiffs' experts relied upon are methodologically unsound and do not establish a plausible biological mechanism for human carcinogenesis at real-world exposures to cosmetic talcum powder.

With respect to Dr. Saed's work, Dr. Boyd first criticized a poster presented by Dr. Saed and his co-authors that claimed talc "induces malignant transformation" in normal ovarian epithelial cells, thereby implying a direct causal mechanism. *See generally* Amy K. Harper et al., *Talcum Powder Induces Malignant Transformation of Human Primary Normal Ovarian Epithelial Cells But Not Human Primary Normal Peritoneal Fibroblasts*, 159 Gynecol. Oncol. (1), 140 (2020) ("Harper/Saed 2020 Poster").[111] Notwithstanding Dr. Boyd's concerns with the publication of the Harper/Saed 2020 Poster, (*see* Boyd Rep. at 4–5),[112] Dr. Boyd concludes that the

[111] Plaintiffs did not attach the Harper/Saed 2020 Poster to its moving papers. Through independent research, I located it as an abstract published in a 2020 issue of *Gynecologic Oncology*.

[112] Dr. Boyd provides a critical overview of the publication process underlying Harper/Saed 2020 Poster's dissemination. Dr. Boyd explains that the Harper/Saed 2020 Poster appeared only in a supplemental issue of *Gynecologic Oncology* because it had been accepted for poster presentation at the Society of Oncology 2020 Annual Meeting on Women's Cancer, which was later canceled due to the COVID-19 pandemic. (*See* Boyd Rep. at 4–5.) Dr. Boyd emphasizes that poster acceptance is not equivalent to peer-reviewed publication: 842 abstracts were submitted to the Society of Oncology 2020 Annual Meeting, and 743 (88%) abstracts were accepted for presentation. (*See id.*) Dr. Boyd also notes that the corresponding manuscript—reiterating the same research and conclusions—was repeatedly rejected by journals, including *Gynecologic Oncology* in 2021 even after additional testing, underscoring that the work did not meet publication standards and likely would have been rejected in its 2020 form. *(See id.*)

study's "objective" misstates prior findings and overreaches, (*see id.* at 5–6). Dr. Boyd further finds the study's dosing and assay methods woefully deficient. (*See id.* at 6–8.) For example, Dr. Boyd claims that the Harper/Saed 2020 Poster omits essential parameters such as cell numbers, volume, and plate surface area, which make the actual dose per cell unknowable. (*See id.* at 6.) Dr. Boyd concludes the "commercial cell transformation assay kit" was used beyond its validated purpose, and that asserting "malignant transformation" after a 72-hour exposure is biologically implausible. (*See id.* at 7.) Finally, Dr. Boyd states that the purported results of the Harper/Saed 2020 Poster are unreliable because it wrongly treats colony growth as proof of cancer, claims a dose-response without valid counting, and reports 11% and 20% increases over zero, which makes no mathematical sense. (*See id.* at 8–9.)

Dr. Boyd next criticizes a subsequent poster presented by Dr. Saed and his co-authors that claims to supplement Harper/Saed 2020 by performing the same experiments and assaying with cell transformation assay and added p53 and Ki-67 immunohistochemistry ("Harper/Saed 2021 Poster"). (*See* Boyd Rep. at 10–14 & n.41.[113]) According to Dr. Boyd, the Harper/Saed 2021 Poster was presented at the

[113] Plaintiffs did not attach the Harper/Saed 2021 Poster to its moving papers. Dr. Boyd cites the Harper/Saed 2021 Poster as "Saed GM, Harper AK, Morris R, Talcum Powder Induces a Malignant Transformation in Normal Ovarian Epithelial Cells," but the citation does not contain sufficiently precise information to permit location or review.

68th Annual Meeting of the Society for Reproductive Investigation on July 8, 2021. (*Id.* at 10.) Dr. Boyd concludes, among other things, that the Harper/Saed 2021 Poster improperly claims to "confirm" malignant transformation that was never established in the Harper/Saed 2020 Poster; that its reliance on certain published studies is misplaced because they fail to support the opinions drawn therefrom; and that its methods still use unrealistic, poorly-described doses and the same commercial assay that cannot prove malignancy. (*See id.* at 10–12.) Consequently, Dr. Boyd claims that the Harper/Saed 2021 Poster's results are misinterpretations of the presented date. (*See id.* at 12–13.) Therefore, Dr. Boyd fundamentally disagrees with the study's conclusion, finding the continued claim of malignant transformation and a causal mechanism unsupported—a view he notes was shared by peer reviewers who called the work premature and unreliable. (*See id.* at 13–14.)

Like the Harper/Saed 2020 Poster, Dr. Boyd underscores the publication issues surrounding the Harper/Saed 2021 Poster as illustrative of its inherent unreliability. According to Dr. Boyd, Dr. Saed submitted a slightly altered manuscript of the Harper/Saed 2021 Poster to *Gynecologic Oncology* on January 4, 2021 (the "Harper/Saed 2021 Manuscript"). (*See* Boyd Rep. at 10 n.41 & 13–14.) *Gynecologic Oncology* subsequently rejected the manuscript, as did two other scientific journals. (*See id.* at 13–14.) Dr. Boyd explains that he was unsurprised that *Gynecologic Oncology* rejected the 2021 poster's manuscript for "several major

issues," "questionable" clinical relevance, and interpretive difficulties with potentially premature data. (*See id.*) Shortly thereafter, an Italian medical journal called *Minerva Obstetrics and Gynecology* accepted the Harper/Saed 2021 Manuscript for publication. (*See id.* at 14 (citing Amy K. Harper et al., *Talcum Powder Induces Malignant Transformation in Normal Human Primary Ovarian Epithelial Cells*, 75 Minerva Obstetrics & Gynecology (2) (2023) ("Harper/Saed 2023 Article")); *see also* discussion at *supra* Part V.B.2.iv.e.).

Dr. Boyd notes that the Harper/Saed 2023 Article used softer language than its previous iterations but is otherwise an insufficient repackaging of the Harper/Saed 2020 Poster and the Harper/Saed 2021 Poster. (*See* Boyd Rep. at 14–15.) Like its previous iterations, Dr. Boyd claims that the Harper/Saed 2023 Article uses "no new experiments or methodological updates" and therefore perpetuates its same core flaws. (*Id.* at 15–16.)

Regarding two macrophage-based mechanistic studies relied on by Plaintiffs' experts, Dr. Boyd finds them minimally informative to ovarian carcinogenesis because, among other things, they "do not attempt to demonstrate the effects of talc on normal human ovarian cells and are of minimal relevance to the biological

plausibility questions raised in this litigation. (*Id.* at 16; *see also id.* at 17–20 (citing Mandarino 2020[114] & Emi 2021[115]).

Dr. Boyd criticizes Mandarino 2020 because "it has nothing to do with transformation (malignant or not) of normal ovarian cells." (*See* Boyd Rep. at 17.) He further criticizes Emi 2021 for using a mouse macrophage cell line as opposed to human ovarian cells and testing only a single high dose, among suffering from other flaws. (*See id.* at 19–20.) Dr. Boyd also faults Plaintiffs' experts' reliance on Emi 2021, which he describes as "an extension of Mandarino" 2020, because the study offers only a "hypothesis that merits further testing" and not evidence of biological plausibility. *(See id.* at 18–19.)[116]

On Dr. Levy's genetics-related causation opinions, Dr. Boyd critiques what he identifies as misinterpretations or overstatements—such as implying that carcinogenic exposure increases the penetrance of inherited risk alleles (e.g., BRCA1 and BRCA2) without evidentiary support, conflating post-initiation tumor

---

[114] Plaintiffs do not attach Mandarino 2020 to their moving papers. Defendants attach it to their opposition. (*See* ECF No. 33111-34.)

[115] Plaintiffs do not attach Emi 2021 to their moving papers. Defendants attach it to their opposition. (*See* ECF No. 33111-35.)

[116] Because I recommend that the Court not permit Plaintiffs' experts to offer their macrophage-inhibition theory, which is largely premised on Mandarino 2020 and Emi 2021, *see supra* Part V.B.5.iv.c.3, there is no basis for Dr. Boyd to offer a rebuttal opinion against Plaintiffs' experts' use of these studies for this now-impermissible purpose. This is not to say, however, that Dr. Boyd is precluded from criticizing Mandarino 2020 or Emi 2021 for any other purpose. Thus, to the extent that Plaintiffs' experts rely on these studies for a purpose other than for support of their macrophage-impairment theory, then Dr. Boyd may rebut those opinions based on these two studies.

behavior with carcinogenesis, and relying on Dr. Saed's oxidative stress claims despite serious methodological flaws. (*See id.* at 22–25.) Dr. Boyd underscores that most somatic mutations arise stochastically with DNA replication and that Plaintiffs' mechanistic bridge from talc to initiated ovarian cancer remains unsubstantiated. (*See id.*) Dr. Boyd also criticizes, among other things, Dr. Levy's reliance on certain studies that he posits do not support the propositions for which they are used. (*See id.*)

2. Plaintiffs' Arguments

As a preliminary matter, it is necessary to clarify the scope of Plaintiffs' motions to exclude genetics-related opinions. Plaintiffs state that they seek to exclude all genetics-related opinions except for the observation that certain bellwether Plaintiffs "have no known genetic mutations that are associated with ovarian cancer." (*See* Pls.' Finan, Saenz & Holcomb Br. at 8; Pls.' Permuth Br. at 8; Pls.' DiFeo Br. at 5.) In substance, however, Plaintiffs' motions focus on challenging the specific causation opinions offered by Drs. Saenz, Holcomb, Finan, and Permuth as applied to particular bellwether Plaintiffs. (*See* Pls.' Finan, Saenz & Holcomb Br. at 5–6; Pls.' Permuth Br. at 4–6.) Plaintiffs do not meaningfully address, or expressly seek exclusion of, these experts' genetics-related *general* causation opinions. Those opinions mirror, in substance, Dr. DiFeo's conclusion that deleterious genetic mutations can play a causal role in the development of ovarian cancer. Unlike Drs.

Saenz, Holcomb, Finan, and Permuth, Dr. DiFeo offers only general genetics-related causation opinions and does not opine on specific causation for any bellwether Plaintiff.[117]

In light of Plaintiffs' arguments, and to ensure a clear and consistent resolution of the admissibility issues presented, I address the genetics-related general causation opinions of Drs. Saenz, Holcomb, Finan, and Permuth together with those of Dr. DiFeo. As clarified above, *see supra* note 1, this Report and Recommendation does not address the portions of Plaintiffs' motions seeking to exclude Defendants' specific causation opinions.

Turning to the merits of their arguments, with respect to Drs. Finan, Saenz, Holcomb, Permuth, and DiFeo, Plaintiffs first contend that the experts' genetics-related general causation opinions are unreliable because they rest on inadmissible speculation about alternative causes—here, unidentified or yet-to-be-discovered genetic mutations and/or VUS. Plaintiffs reason that admitting such speculative opinions risks confusing or misleading a jury.

Second, with respect to Drs. Finan, Saenz, Holcomb, DiFeo, Permuth, and Boyd, Plaintiffs contend that the experts' biological plausibility opinions are

[117] Indeed, Defendants have expressly stated that Dr. DiFeo does not seek to opine on specific causation. (*See generally* DiFeo Rep.; *see also* ECF No. 33111 ("Defs.' Opp. to Pls.' Permuth, DiFeo & Boyd Brs.") at 46 ("Section IV of plaintiffs' motion against Dr. DiFeo is moot because Dr. DiFeo is not offering case-specific opinions.").)

unreliable because they apply a flawed methodology that disregards the actual constituents of talcum powder. Plaintiffs also argue that the opinions do not fit the facts of this case, because they apply an improperly heightened "proof" standard rather than the accepted "plausibility" standard.

Third, Plaintiffs contend that Dr. Boyd's critiques of peer-reviewed studies rest on subjective belief rather than a reliable methodology. In that regard, Plaintiffs maintain that his testimony will not assist the trier of fact and risks confusing or misleading a jury by inviting re-evaluation of research and methods already vetted through the peer-review process. Finally, Plaintiffs argue that Dr. Boyd is not qualified to opine on *in vitro* study design or methods.

Defendants oppose Plaintiffs' motions, arguing that the genetics-related general causation opinions are admissible as proper rebuttal that offer the jury alternative causes. Moreover, Defendants argue that Plaintiffs are impermissibly rehashing arguments already rejected by the Court, and that both science and law require evaluating general causation based on the talcum powder product as sold—not its isolated constituents—consistent with how the literature and analogous case law frame the issue. Finally, Defendants maintain that contrary to Plaintiffs' contention, Defendants' experts did not impose an improperly heightened biological plausibility standard.

As to Plaintiffs' specific challenges to Dr. Boyd, Defendants contend his opinions are proper defense-side critiques grounded in his extensive research and peer-review experience. In that connection, Defendants insist that peer review does not immunize published studies from expert criticism, and more to the point, Dr. Boyd's testimony will assist the trier of fact by explaining why certain mechanistic claims are unreliable. Lastly, Defendants maintain that Dr. Boyd is amply qualified—as a long-time cancer researcher, professor, and reviewer/editor—to opine on the design and methodology of *in vitro* studies.

i. Genetics-Related General Causation Opinions

Plaintiffs argue that the experts' genetics-related general causation opinions, which suggest that "imaginary" genetic mutations may cause ovarian cancer, are inadmissible because they are unreliably speculative, unsupported by current science, and risk misleading or confusing the jury. (*See* Pls.' DiFeo Br. at 3–7; *see also* Pls.' Finan, Saenz & Holcomb Br. at 5–10; Pls.' Permuth Br. at 4–10.) Across their motions to exclude, Plaintiffs argue that these experts should only be permitted to opine that the "science and testing [regarding genetics] to date demonstrate that Plaintiffs have no known genetic mutations that are associated with ovarian cancer." (*See* Pls.' Finan, Saenz & Holcomb Br. at 8; Pls.' Permuth Br. at 8; Pls.' DiFeo Br. at 5.)

Defendants oppose Plaintiffs' efforts to exclude these opinions by arguing that their experts' discussions of unidentified genetic mutations, yet-to-be-discovered genetic mutations, or VUS are proper rebuttal opinions, sufficiently supported by scientific and medical bases, and do not risk jury confusion because their opinions are framed as possibility, not inevitability. I agree with Defendants.

First, Plaintiffs appear to have misapplied the burden of proof. They cite several cases for the proposition that an expert's opinions must be based on existing scientific validity and not speculation. (*See* Pls.' Finan, Saenz & Holcomb Br. at 7; Pls.' Permuth Br. at 7; Pls.' DiFeo Br. at 4.) But the cases that Plaintiffs rely on do not directly deal with a defense expert offered to rebut a plaintiff's expert. *See, e.g.*, *Fedorczyk v. Caribbean Cruise Lines*, 82 F.3d 69, 75 (3d Cir. 1996) (affirming the exclusion of plaintiff's expert's affirmative opinions); *Hoefling*, 576 F. Supp. 3d at 275–76 (excluding plaintiff's expert's affirmative opinions); *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1168–69 (E.D. Wash. 2009) (same); *In re Bausch & Lomb Contacts Lens Solution Prods. Liab. Litig.*, 693 F. Supp. 2d 515, 520 (D.S.C. 2010) (holding plaintiff expert's opinion regarding future causation as insufficiently speculative to overcome summary judgment).

As discussed throughout this Report and Recommendation, "the proper role of rebuttal experts [is] to critique plaintiffs' expert's methodologies and point out potential flaws in the plaintiffs' experts' reports." *Aviva Sports, Inc.*, 829 F. Supp.

2d at 835; *see also Mahaska Bottling Co., Inc. v. PepsiCo, Inc.*, 441 F. Supp. 3d 745, 759 (S.D. Iowa 2019) (explaining that courts routinely permit defense experts to testify "even if the expert primarily critiques the opposing expert's approach without offering an alternative approach"). Indeed, "a rebuttal expert need not proffer a methodology or model, but only critique the opposing expert's." *Capri Sun GmbH*, 595 F. Supp. 3d at 140.

Importantly, Plaintiffs concede that Defendants' experts at issue here do not purport to establish causation through unidentified genetic mutations, yet-to-be-discovered genetic mutations, or VUS. (*See* Pls.' Finan, Saenz & Holcomb Br. at 5 ("Drs. Saenz, Holcomb, and Finan all theorize that unknown genetic mutations . . . *may* have caused Plaintiffs' ovarian cancers." (emphasis added)); Pls.' DiFeo Br. at 3 ("Dr. DiFeo theorizes that unknown genetic mutations . . . *may* cause ovarian cancer." (emphasis added)); Pls.' Permuth Br. at 4 ("Dr. Permuth theorizes that unknown genetic mutations . . . *may* have caused Plaintiffs' ovarian cancers." (emphasis added)).) Put another way, none of these experts have opined or testified that an alternative cause is the *actual* cause of ovarian cancer.

Courts routinely admit the opinions and testimony of defense experts who offer potentially alternative causes for injury or product defect despite not having conducted their own differential diagnoses. *See, e.g., In re 3M Combat Arms Earplug Prods. Liab. Litig.*, Case No. 3:19md2885, 2022 WL 823474, at *4 (N.D.

Fla. Mar. 19, 2022) ("The fact that Dr. Chatham's opinions on AIHL are not definitive diagnoses does not compel their exclusion. A defense expert 'may offer evidence of potential alternative causes of [an] injury without needing to prove those alternative-cause theories with certainty or probability.'" (citation omitted)); *see also In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, No. 3:07-cv-00088, 2010 WL 1782272, at *4 (M.D. Ga. Apr. 29, 2010) (admitting four experts who "opine that Plaintiffs' experts did not adequately identify and rule out alternative causes for Plaintiffs' injuries" despite not having done a differential diagnosis themselves, but precluding them from testifying that "alternative causes . . . actually caused Plaintiffs' injuries"); *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-cv-00931, 2017 WL 6396852, at *2 (S.D. W. Va. Dec. 13, 2017) ("Defendants, however, need not conduct a differential diagnosis to identify the specific cause of an injury because they do not bear the burden of proving causation. Indeed, a defendant's specific causation expert's testimony should not be excluded because it fails to identify the specific cause of a plaintiff's injury. In lieu of conducting traditional differential diagnoses, defendants may instead provide expert testimony suggesting alternative causes for the plaintiff's injury in order to rebut the plaintiff's specific causation testimony." (citations omitted)). Moreover, the "alternative causes suggested by a defendant normally affect the weight that the jury should give the expert's testimony and not the

admissibility of that testimony." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001).

Still, the admissibility of a defense expert's opinions must nonetheless satisfy Rule 702's admissibility requirements. *See* Fed. R. Evid.702; *In re E. I. du Pont de Nemours & Co. C-8 Pers. Inj. Litig.*, 348 F. Supp. 3d 680, 696 (S.D. Ohio 2016) ("The defendant's expert need not give an alternate causal factor within a reasonable degree of medical certainty. But, the testimony must still be based upon reliable science, as required by *Daubert*.").

Plaintiffs contend that Defendants' experts offer unreliable opinions lacking scientific support because VUS have no proven effect on, or causal link to, ovarian cancer generally. (*See* Pls.' Finan, Saenz & Holcomb Br. at 8–9; Pls.' DiFeo Br. at 5–6; Pls.' Permuth Br. at 8–9.) They also argue that the evolving state of genetics does not justify allowing unsupported speculation to reach the jury, and that opinions premised on unidentified or unvalidated mutations are too speculative to be admissible. (*See* Pls.' Finan, Saenz & Holcomb Br. at 7–8; Pls.' DiFeo Br. at 4–5; Pls.' Permuth Br. at 7–8.)

Defendants respond that their experts' opinions show that there are scientific bases to posit alternative, genetic causes of ovarian cancer generally. (*See* Defs.' Opp. to Pls.' Finan, Saenz & Holcomb Br. at 3–10, 18–23.) Additionally, Defendants contend that the opinions are grounded in their experts' clinical experience, reflect

the current state of the relevant science, are supported by clinical evidence that predates their involvement, and align with views expressed by certain of Plaintiffs' own experts. (*See id.* at 12–16.)

After carefully reviewing the motion papers, the expert reports, and the sworn testimony of Defendants' contested experts, I conclude that the general causation opinions of Drs. Finan, Saenz, Holcomb, DiFeo, and Permuth regarding unidentified or yet-to-be-discovered genetic mutations, as well as VUS, are products of reliable methods and therefore admissible.

First, these experts all base their genetics-related causal opinions on their professional qualifications and experiences. To be sure, the unchallenged qualifications of Drs. Finan, Saenz, Holcomb, Permuth, and DiFeo bolster the reliability of the methodology underlying their opinions. *See Schneider*, 320 F.3d at 406–07.

Dr. Finan has decades of clinical experience, and his role in, among other responsibilities, the Cancer Risk Assessment program for the Singing River Health System grounds his opinions on family-history-based genetic testing, mutation identification, and ovarian cancer development. (*See, e.g.*, Finan Rep. at 4; *see also id.* at 2, 63 (basing causation opinions on, *inter alia*, "education, training, and 30 years of medical practice," as well as a review of peer-reviewed scientific literature and "relevant statements of national and international organizations").)

Dr. Saenz similarly has decades of clinical and academic experience directing multidisciplinary treatment plans for gynecologic malignancies. (*See* Saenz Rep. at 1; *see also id.* at 3 (basing general causation opinions on, *inter alia*, "education, experience and expertise," as well as review of "peer-reviewed published scientific literature").)

Dr. Holcomb likewise has decades of experience in clinical and academic settings, with clinical responsibilities including, among other things, assessing cancer risk in patients and their families by identifying genetic risk factors. (*See* Holcomb Rep. at 1–2; *see also id.* at 3, 29, 35–46 (relying on, *inter alia*, his "education, [his] experience as a gynecologic oncologist and [his] review of the peer-reviewed published scientific literature" for causation opinions).)

Dr. DiFeo holds a Ph.D in Cancer Genetics from Mount Sinai School of Medicine, has over two decades of research experience in ovarian cancer genetics, and leads a translational laboratory that, among other things, detects and analyzes genetic drivers responsible for the development and progression of ovarian cancer. (*See* DiFeo Rep. at 2; *see also id.* at 2 (basing general causation opinions on "education, training and expertise as a cancer biologist" and "review of the relevant literature").)

Dr. Permuth is, among other things, a former genetics counselor who has personally counseled hundreds of women with ovarian and related cancers, serves

in national ovarian cancer research consortia, and has authored over 100 peer-reviewed publications on genetics, risk factors, and molecular epidemiology. (*See* Permuth Rep. at 4; *see also, e.g.*, *id.* at 53–54 (basing general causation opinions on "educational background, training, and experience," as well as a "review of epidemiologic studies, lab-based molecular and toxicology studies, and other relevant studies").)

The Third Circuit has recognized that an expert opinion not explicitly supported by peer-reviewed published scientific or medical literature can still be reliable and admissible when the expert has extensive clinical experience. *See Schneider*, 320 F.3d at 406; *Heller*, 167 F.3d at 155. Here, Defendants' experts not only rely on their own clinical experience, but also relevant literature in forming their opinions. Moreover, Plaintiffs do not attempt to distinguish or denounce any specific scientific or medical study relied on by Defendants' experts' genetics-related causation opinions.

It is with this backdrop—educational experience, clinical experience, Plaintiffs' medical records, and an extensive review of scientific and medical literature—that Defendants' experts assert their genetics-related general causation opinions. These experts generally agree that while a significant subset of ovarian cancer is hereditary, the genetic landscape is continuously evolving: BRCA1 and BRCA2 account for most known mutation-driven cases, but many additional genes

are implicated as testing panels continue to advance. These experts also agree that the potentially deleterious effects of new mutations—discussed herein as unidentified genetic mutations, yet-to-be-discovered genetic mutations, or VUS—will be discovered as genetic testing and research advance.

As discussed above, Plaintiffs do not appear to directly challenge the genetics-related general causation opinions of Dr. Finan, Dr. Saenz, Dr. Holcomb, and Dr. Permuth as substantively incorrect, other than to suggest that they are too speculative. (*See, e.g.*, Pls.' Finan, Saenz & Holcomb Br. at 9–10; Pls.' Permuth Br. at 9–10.)

Notably, as Defendants rightly point out, (*see* Defs.' Opp. to Pls.' Permuth, DiFeo & Boyd Brs. at 14–15), several of Plaintiffs' own experts concede at least some of Defendants' experts' opinions that Plaintiffs now seek to exclude, (*see* Clarke-Pearson Dep. at 584:13–15 ("[T]here are factors that we don't know today that cause mutations that in aggregate result in cancer."); *see also id.* at 453:1–4 ("[Q.] . . . [Y]ou are not of the view that scientists completely understand what causes ovarian cancer, right? A. Yes."); *id.* at 473:15–19 ("In addition to the talc and in addition to the possible ovarian cancer, there are other factors that we don't know about."); Wolf Dep. at 401:24–402:3 ("Certainly there can always be unknown as yet hypothetical things that at sometime in the future could be associated with an increased risk of ovarian cancer or some other type of cancer.").)

At its core, this litigation focuses on the general and specific cause of ovarian cancer; specifically, whether the perineal application of cosmetic talcum powder causes ovarian cancer generally, and caused ovarian cancer to develop in the gynecologic tissue of the bellwether Plaintiffs. Putting aside admissibility concerns regarding specific causation opinions, which will be addressed in a separate Report and Recommendation, Defendants are entitled to proffer experts to opine on or rebut opinions regarding the potential causes of ovarian cancer, so long as those opinions are "based on the methods and procedures of science rather than on subjective belief or unsupported speculation." *In re Paoli*, 35 F.3d at 742 (citation modified). Here, these genetics-related general causation opinions are supported by sufficiently "good grounds," in that they are supported by experts' educational experience, clinical experience, medical records, and extensive review of scientific and medical literature. *See Karlo*, 849 F.3d at 81 ("'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.'" (quoting *In re TMI*, 193 F.3d at 665) (citation omitted)).

Finally, Plaintiffs argue that admitting Defendants' experts' genetics-related causal opinions risk confusing or misleading the jury because they are framed in terms of inevitability, not possibility. (*See* Pls.' Finan, Saenz & Holcomb Br. at 9–

10; Pls.' Permuth Br. at 9–10; Pls.' DiFeo Br. at 6–7.) Plaintiffs appear to rely on Federal Rule of Civil Procedure 403 for this argument. (*See* Pls.' Saenz & Holcomb Br. at 1; Pls.' Permuth Br. at 1; Pls.' DiFeo Br. at 1.) Pursuant to that Rule, courts may exclude evidence that risks "confusing the issues[] [or] misleading the jury." Fed. R. Civ. P. 403; *see also Elcock v. Kmart Corp.*, 233 F.3d 734, 756 n.13 (3d Cir. 2000) ("Permitting . . . a witness to offer an opinion unsupported by a sufficient factual foundation would significantly increase the risk of misleading the jury and confusing the issues, the very dangers against which Rule 403 defends.").

First, and as discussed above, Defendants' experts do not argue that unidentified genetic mutations, yet-to-be-discovered genetic mutations, or VUS cause the development of ovarian cancer generally. In other words, these opinions are appropriately expressed in terms of possibility, not probability or inevitability. Moreover, the Court can cabin the opinions of these experts to ensure these defense experts do not overstate their conclusions and testify within the guardrails of expressing opinions on possible causes. Indeed, Drs. Finan, Saenz, Holcomb, DiFeo, and Permuth identify alternative causes for the development of ovarian cancer generally and, in doing so, rebut the corresponding opinions offered by Plaintiffs' experts. Defendants' experts do not exaggerate their educational backgrounds or clinical experience, nor do they mischaracterize the scientific and medical literature

on which they rely. As I mentioned above, Plaintiffs' own expert express similar views.

Second, I find that the probative value of these experts' genetics-related *general* causation opinions substantially outweighs any prejudicial effect. Plaintiffs' challenges to Defendants' experts' general causation opinions, which I find reflect a reliable application of their methodology, go toward the weight of their opinions. Given that they are otherwise admissible, the opinions of Defendants' experts' genetics-related general causation opinions will aid the jury in understanding the complex scientific landscape underlying this case and help them determine the ultimate resolution.

Given the foregoing, I find that Defendants have established by a preponderance of the evidence the admissibility of the genetics-related general causation conclusions of Drs. Saenz, Holcomb, Finan, DiFeo, and Permuth. Again, at this stage, I am not deciding the admissibility of these experts' genetics-related *specific* causation opinions. Accordingly, I recommend that the Court deny the portions of Plaintiffs' motions premised on the inadmissibility of genetics-related general causation opinions, but limit their opinions on unidentified genetic mutations, yet-to-be-discovered genetic mutations, and/or VUS to being possible, not inevitable, causes.

ii. Biological Plausibility Causation Opinions

Plaintiffs next argue that the experts' biological plausibility opinions must be excluded because they are supported by an unreliable methodology, i.e., ignore the constituents of talcum powder. Plaintiffs also argue that the opinions must be excluded because they do not fit the facts of this case and risk misleading or confusing a jury by applying an improperly heightened standard of proof. Defendants oppose by contending that Plaintiffs' argument violates the Court's April 30, 2024, Memorandum Order, and that its experts properly assess general causation of talcum powder as sold rather than its isolated constituents.

a. Constituents of Talcum Powder

Plaintiffs argue that the experts fail to consider all individual constituents of talcum powder—namely, fibrous talc, platy talc, asbestos, heavy metals, fragrances, and/or other constituents—in forming their biological plausibility opinions.[118] More specifically, Plaintiffs contend that Defendants' experts' "cherry-pick" scientific and

[118] To be precise, Plaintiffs advance slightly different arguments for excluding the opinions of Drs. Finan, Saenz, Holcomb, Permuth, DiFeo, and Boyd. Unlike Drs. Finan, Saenz, Holcomb, and DiFeo, Drs. Permuth and Boyd expressly opine that asbestos is carcinogenic. (*See* Pls.' Permuth Br. at 11–12; Pls.' Boyd Br. at 13.) Plaintiffs fault Drs. Permuth and Boyd for failing to research the impact that asbestos-containing talc—and other constituents potentially present in talc—may have on cancer development. (*See id.*) By contrast, Plaintiffs fault Drs. Finan, Saenz, Holcomb, and DiFeo for failing to consider the carcinogenic properties of asbestos at all, or to evaluate the effects of individual talc constituents, including asbestos. (*See* Pls.' Finan, Saenz & .) For purposes of resolving Plaintiffs' motions, however, this distinction is immaterial. Across all six experts, Plaintiffs' central contention is the same: that a biological plausibility analysis which does not account for the potential carcinogenic effects of individual constituents of cosmetic talc is methodologically unreliable under Rule 702.

medical literature that focuses on talc rather than, for example, asbestos-containing talcum powder.

Defendants oppose by first arguing that Plaintiffs are rehashing an argument that the Court rejected in direct contravention of this Court's April 30, 2024, Memorandum Order. (*See* Defs.' Opp. to Pls.' Finan, Saenz & Holcomb Br. at 25–27; Defs.' Opp. to Pls.' Permuth, DiFeo & Boyd Brs. at 18–19.)

Defendants correctly observe that I addressed this argument in the context of Plaintiffs' motion to exclude the opinions of Defendants' expert, Dr. Benjamin Neel. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 195–98. Then, Plaintiffs argued that Dr. Neel's opinion regarding biological plausibility was unreliable because he did not consider the individual constituents of talcum powder, such as asbestos and heavy metals. *Id.* at 196–97. I disagreed by finding that the composition of talc was irrelevant to Dr. Neel's rebuttal of Dr. Saed's *in vitro* methodology, which itself did not evaluate the carcinogenicity of the individual constituents of talcum powder such that Dr. Neel's lack of analysis of asbestos or other constituents did not undermine the reliability of his opinions. *See id.* Because my prior Opinion only addressed motions related to representative experts, I applied my reasoning "with equal force to the remainder of the pending *Daubert* motions," to the extent such reasoning could be applied to other motions. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 128–29.

Here, reprising their former argument, Plaintiffs contend that Drs. Finan, Saenz, Holcomb, Permuth, DiFeo, and Boyd employed a flawed methodology by ignoring the constituents of talc when opining about biological plausibility. (*See* Pls.' Finan, Saenz & Holcomb Br. at 11–15; Pls.' Permuth Br. at 10–14; Pls.' DiFeo Br. at 7–12.) In response to Plaintiffs' challenge, Defendants maintain that the proper scientific and legal framing of their experts' biological plausibility assessments is that of the product consumers actually use—talcum powder—rather than its separate constituents. (*See* Defs.' Opp. to Pls.' Finan, Saenz & Holcomb Br. at 27–33; Defs.' Opp. to Pls.' Permuth, DiFeo & Boyd Brs. at 20–26.) Defendants contend that the scientific and medical literature that both sides rely on—epidemiology, *in vitro*, and other mechanistic studies—generally evaluates talcum powder in its commercial form and not as asbestos, fibrous talc, platy talc, heavy metals, or fragrance chemicals in isolation. (*See* Defs.' Opp. to Pls.' Finan, Saenz & Holcomb Br. at 27–28; Defs.' Opp. to Pls.' Permuth, DiFeo & Boyd Brs. at 20–22.) Defendants stress that, as a result, their experts' opinions are responses to Plaintiffs' experts' opinions, which often evaluate talcum powder without consideration of its individual constituents. (*See* Defs.' Opp. to Pls.' Finan, Saenz & Holcomb Br. at 29–31; Defs.' Opp. to Pls.' Permuth, DiFeo & Boyd Brs. at 22–24.)

I agree with Defendants.[119] As an initial matter, Plaintiffs' framing of the issue is misleading. Plaintiffs contend that Defendants' experts "ignore" individual constituents of cosmetic talcum powder, including asbestos, and employ an unreliable methodology that "impermissibly cherry-picks" by focusing solely on talc. (*See* Pls.' Finan, Saenz & Holcomb Br. at 14–15; Pls.' DiFeo Br. at 10–12; Pls.' Permuth Br. at 12–13; Pls.' Boyd Dr. at 13–14.) The record does not support that characterization. Defendants' experts do not disregard the individual components of talcum powder. Rather, they deliberately evaluate talcum powder as a finished consumer product, based on their view that the central causation question in this case is whether perineal use of cosmetic talcum powder—considered as a whole—causes ovarian cancer. (*See, e.g.*, Saenz Rep. at 58 ("My opinion does not change regardless of the composition of the talcum powder because the published, peer-reviewed literature does not support the increased risk of developing ovarian cancer with perineal application of talc."); Finan Rep. at 4 ("The application of talcum powder, regardless of its constituents, to the female perineum does not cause or contribute to the development of ovarian cancer); Holcomb Rep. at 3 ("I was asked to review the

[119] In further support of their argument, Defendants cite analogous case law to maintain that general causation opinions must be framed around the product used, not the isolated constituents of said product. (*See* Defs.' Opp. to Pls.' Finan, Saenz & Holcomb Br. at 31–33 (citing *In re Zantac*, 644 F. Supp. 3d at1075; *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1156 (E.D. Wash. 2009); *Burst v. Shell Oil Co.*, No. 14-cv-109, 2015 WL 3755953, at *9 (E.D. La. June 16, 2015), *aff'd*, 650 F. App'x 170 (5th Cir. 2016)); Defs.' Opp. to Pls.' Permuth, DiFeo & Boyd Brs. at 24–26 (citing *In re Zantac*, 644 F. Supp. 3d at 1075; *Henricksen*, 605 F. Supp. 2d at 1156; *Burst*, No. 2015 WL 3755953, at *9). These cases are in accord with my analysis.

relevant scientific literature to furnish an opinion as to whether perineal use of talcum powder can cause ovarian cancer as a general matter . . . ."), ECF No. 32999-14 ("Holcomb Dep.") at 40:16–19 ("[M]y opinion is whatever is in that [Johnson & Johnson] bottle that has been subjected to decades of testing does not increase the risk of ovarian cancer."); ECF No. 33001-6 ("Permuth Dep.") at 42:11–13 ("I looked at . . . the bulk of epi[demiological] literature, which considered talc as a substance or as a whole."); DiFeo Rep. at 6 ("I conclude that cosmetic talc, regardless of its exact constituents or alleged contaminants, does not cause or contribute to the development of ovarian cancer.").)

In this context, phrases such as "regardless of the composition" or "regardless of its constituents" reflect inclusivity, not exclusion. That is, Defendants' experts consider talcum powder inclusive of whatever constituents it may contain, rather than isolating talc to the exclusion of other components. Accordingly, their biological plausibility analyses or critiques do not "impermissibly cherry-pick" evidence, but instead rest on a product-level assessment consistent with their articulated methodological approach.

Even if Defendants' experts could be criticized for "cherry-picking" by evaluating talc or talc-focused literature without considering talc's potentially carcinogenic constituents, they are not required to analyze each purported component of talcum powder to address biological plausibility for several reasons.

As I have referenced when addressing Defendants' motion to preclude, the experts are not required to review every medical or scientific study available about the topic on which they are opining. *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"); *see also 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).

In that regard, Defendants' experts often express their opinions as critiques of Plaintiffs' experts' opinions and underlying methodologies. For example, Dr. Saenz devotes a substantial portion of her reports to rebutting the opinions of Dr. Wolf, Dr. Clarke-Pearson, Dr. Saed, and Dr. Godleski. (*See, e.g.*, Saenz Rep. at 10, 15, 45, 51–52; Saenz Converse Rep. at 4–5 (Dr. Clarke-Pearson), 7–8 (Dr. Godleski); Saenz Judkins Rep. at 5–6 (Dr. Wolf & Dr. Godleski); Saenz Newsome Rep. at 5–7 (Dr. Clarke-Pearson & Dr. Godleski); Saenz Rausa Rep. at 6–7 (Dr. Clarke-Pearson).) Dr. Finan and Dr. Holcomb respectively rebut Dr. Wolf's causal opinions and Dr. Saed's methodology and conclusions. (*See* Finan Rep. at 12–13, 45, 50, 55, 61, 63–67; Holcomb Rep. at 3, 26, 29–34.) Dr. Permuth provides "commentary" on reports submitted by Plaintiffs' epidemiological experts, including, among others, Dr. Cote and Dr. Levy. (*See* Permuth Rep. at 135–47.) Dr. DiFeo "discuss[es] numerous

concerns with the data presented by" some of the scientific and medical studies relied on by Plaintiffs. (*See* DiFeo Rep. at 53–115.) And Dr. Boyd criticizes Dr. Saed's methodologies and opinions drawn therefrom, as well as other Plaintiffs' experts' reliance on the work of Dr. Saed. (*See* Boyd Rep. at 2–16.)

Most of Plaintiffs' experts, at one point or another, opine only as to talc or talcum powder—not its individual constituents—when assessing biological plausibility.[120] For example, Dr. Wolf testified that her opinion on whether perineal application of talcum powder causes ovarian cancer does not depend on the presence of asbestos because she evaluated cosmetic talcum powder "as a whole." (Wolf Dep. at 110:16–111:9.) Dr. Clarke-Pearson similarly testified that while he cannot identify which specific component of talcum powder caused Plaintiff Converse's ovarian cancer, he maintains that talcum powder causes ovarian cancer regardless of the precise constituents. (*See* Clarke-Pearson Dep. at 293:4–22.) In conducting a review of the epidemiological research on talc and ovarian cancer, Dr. Michele Cote looked to "talc as a whole," or "whatever was in the bottles or containers of talc that the women were using," and not its individual components. (*See* ECF No. 33118-10 ("Cote Dep.") at 112:17–113:2; *see also, e.g.*, Siemiatycki 3d Amend. Rep. at 2

[120] Indeed, as discussed *supra*, in recommending exclusion of Plaintiffs' experts' opinions regarding the carcinogenic effects of heavy metals and fragrance chemicals, I made clear that those experts may nonetheless opine on the causal relationship between cosmetic talc—as a product, inclusive of its constituents—and ovarian cancer. That conclusion reflects the fact that much of the epidemiologic literature on which the experts rely evaluates talc exposure without distinguishing among talc's individual constituents, including asbestos.

("[T]here are biologically plausible mechanism to explain how powdering with talc-based powders can contribute to the development of ovarian cancer."), 74 ("[T]here are credible biologically plausible mechanisms by which talcum powder products can reach the upper genital tract causing an inflammatory response . . . .").)[121] Therefore, as rebuttal to Plaintiffs' experts, Defendants must necessarily be entitled to address these experts' talc-based opinions regarding biological plausibility.

To be sure, some of Plaintiffs' experts do opine on talcum powder as inclusive of its individual constituents, and/or its individual constituents separately. (*See, e.g.*, Levy 2d Amend. Rep. at 18–20; McTiernan 3d Amend. Rep. at 3 ("When I refer to talc or talcum products in this report, I am referring to commercially available talcum powder products and all constituent elements contained within."), 89 ("In my opinion it is biologically plausible that talcum powder products can reach the ovaries

[121] Additionally, Dr. Godleski's methodology sought to identify talc and other potentially deleterious particulates in the gynecologic and pelvic tissue of certain bellwether Plaintiffs to determine their contribution to the development of ovarian cancer. (*See generally* Godleski Gallardo Rep.; Godleski Converse Rep.; Godleski Rausa Rep.; Godleski Judkins Rep.; Godleski Rausa Rep.)

But Dr. Godleski did not attempt to identify other potentially deleterious materials outside of talc and asbestos. (*See generally id.*) Defendants contend that Dr. Godleski's failure to identify every foreign particle observed within each tissue sample undermines his causation conclusion. (*See* Defs.' Godleski Br. at 17–18.) In response, Plaintiffs argue, among other things, that this argument "targets the weight of the evidence offered" and not its admissibility. (*See* Pls.' Godleski Opp. Br. at 17–18.) Although Defendants challenge Dr. Godleski's failure to consider all birefringent material in his causal conclusions, Plaintiffs here challenge these experts' failure to consider individual constituents of talcum powder as it may relate to their biological plausibility opinions. While the arguments Plaintiffs advance differ in some respects across these motions and in their opposition to Plaintiffs' motion to exclude Dr. Godleski, the similarities are nonetheless sufficient to diminish their credibility.

via migration from the perineum and via inhalation into the lungs, blood stream, and lymphatic system.").) A defense expert, however, is not required to address and/or rebut every assertion contained within every plaintiff's expert's opinion. *See, e.g.*, *Quidel Corp. v. Siemens Med. Solutions USA, Inc.*, No. 16-cv-3059, 2019 WL 4727939, at *2 (S.D. Cal. Sept. 27, 2019) ("Indeed, there is no requirement that a rebuttal expert read the opening expert report cover to cover, and then write a rebuttal report outlining each and every criticism of the opening expert's opinions." (citation modified)); *see also Whereverty, Inc. v. Comcast Cable Commc'ns, LLC*, No. 2:18-cv-529, 2022 WL 4017049, at *3 & n.3 (M.D. Fl. Sept. 4, 2022).

Moreover, defense experts attack the epidemiologic, *in vitro*, and mechanistic studies on which Plaintiffs' experts rely. Many of these scientific and medical studies assess talcum powder as a whole—rather than its individual constituents—when evaluating biological plausibility. For example, several of Plaintiffs' experts rely on Dr. Saed's research. (*See, e.g.*, Levy 2d Amend. Rep. at 15–16; Wolf 3d Amend. Rep. at 16 (citing Harper/Saed 2023 Article); Clarke-Pearson 3d Amend. Rep. at 5–6 (citing Dr. Saed's 2019 study and the Harper/Saed 2023 Article).) Much of the research makes no effort to differentiate between talc and the individual constituents of talcum powder.

Finally, an expert is not required to review every single study within a relevant body of literature. *See Johnson v. Vane Line Bunkering*, 01-cv-5819, 2003 WL

23162433, at *8 (E.D. Pa. Dec. 30, 2003) (noting, in rejecting a *Daubert* challenge for alleged failure to meet the reliability requirement, that "the Third Circuit does not require that an expert review every medical report available to him or her and does not require that a physician make citations to publications to support his medical conclusions"); *In re Testosterone Replacement Therapy*, 2018 WL 4030585, at *6 ("The fact that [plaintiff's expert] does not discuss every study . . . view[ed] as relevant, or that he may have overlooked a study, does not mean that he unreliably applies his methodology."). It is clear, however, 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." *In re Mirena II*, 341 F. Supp. 3d at 241.

This is not the case here. Although Defendants' experts do not cite every relevant study in the universe of available literature, the admissibility inquiry focuses on the reliability of their methods. Here, the record demonstrates that their opinions rest on a reliable body of peer-reviewed evidence, educational background, professional experience, and reasoned application of established scientific principles. In this context, the omission of some studies goes to the weight of an opinion, not admissibility. *See, e.g.*, *Luppino v. Mercedes-Benz USA, LLC*, Civil Action No. 09-5582, 2015 WL 12819051, at *6 (D.N.J. June 29, 2015) ("[T]he absence of a study conducted by an expert is relevant to the weight, not the

admissibility, of his or her conclusion." (citation omitted)). Of course, Plaintiffs may cross-examine defense experts' on the sources they rely upon in forming their biological opinions. After all, "'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 . . . .'" *Heller*, 167 F.3d at 152 (quoting *Daubert*, 509 U.S. at 596).

b. Biological Plausibility Standard

Plaintiffs argue that Defendants' experts' biological plausibility opinions must be excluded on the ground that the experts improperly apply a heightened standard of proof—rather than a plausibility analysis—thereby rendering their opinions irrelevant, confusing, or misleading. Defendants respond that Plaintiffs mischaracterize their experts' testimony, and that the experts properly apply biological plausibility principles under Bradford Hill by requiring more than untested hypotheses to support a causal inference. I agree with Defendants.

At the outset, as I have discussed at length, Plaintiffs are correct that biological plausibility does not require a proven biological mechanism, or even overwhelming evidence of biological mechanism. (*See* Pls.' Finan, Saenz & Holcomb Br. at 19–22; Pls.' Permuth Br. at 14–17; Pls.' DiFeo Br. at 16–19.) Indeed, even if the scientific community has not reached consensus on the biological mechanism, that does not mean the pathway proposed by an expert is not accepted as "plausible." *See*

In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 183 (S.D.N.Y. 2009). Still, although biological plausibility need not require proof certain, any biologically plausible opinion must be "derived from and supported by reliable scientific knowledge and reasoning." *In re Abilify*, 299 F. Supp. 3d at 1308.

Here, contrary to Plaintiffs' framing, Defendants' experts do not impose a requirement of scientific certainty or definitive proof. Rather, they offer general causation opinions regarding perineal talcum powder use and ovarian cancer and, in doing so, critique Plaintiffs' experts' proposed biological mechanisms on the ground that those mechanisms lack adequate support in the scientific and medical literature. Their opinions are thus directed at the sufficiency and reliability of the evidentiary foundation for Plaintiffs' theories, not at demanding proof beyond what biological plausibility requires.

Plaintiffs' criticism of Dr. Saenz is illustrative. Plaintiffs contend that Dr. Saenz misapplied biological plausibility by insisting on "proof" that talc migrates from the perineal area to the ovaries or that such migration causes inflammation. (*See* Pls.' Finan, Saenz & Holcomb Br. at 16–17 (citing Saenz Rep. at 17–18; ECF No. 32999-16 ("Saenz Dep.") at 285:23–286:1; ECF No. 32999-17 ("Saenz Dep. II") at 325:14–17.) I disagree. A closer examination of Dr. Saenz's report and deposition testimony does not support that characterization. Dr. Saenz does not require definitive proof of migration or inflammation; rather, in her role as a rebuttal

expert, she explains that Plaintiffs' biological plausibility theory is not supported by the existing epidemiologic and medical literature. She reaches that conclusion based on her review of the literature and her professional experience. (*See* Saenz Rep. at 17–18.) To preclude Dr. Saenz—or similarly situated defense experts—from offering such rebuttal opinions would improperly deprive the factfinder of competing expert views concerning the relevance, sufficiency, and interpretation of the scientific evidence. Rule 702 does not require exclusion merely because an expert concludes that the literature fails to support an opposing party's theory of biological plausibility.

I reach the same conclusion with respect to Plaintiffs' arguments concerning Drs. Holcomb and Finan. Plaintiffs contend that Dr. Holcomb misapplies the biological plausibility standard regarding talc migration from perineal use and the role of inflammation in ovarian carcinogenesis because he testified that he has not seen literature "proving" either theory.(*See* Pls.' Finan, Saenz & Holcomb Br. at 17–18 (citing ECF No. 32999-14 ("Holcomb Dep.") at 108:10–19; 131:14–22, 392:22–393:4, 421:15–423:20).) That argument mischaracterizes his testimony.

Dr. Holcomb makes clear that he does not require definitive proof to accept a theory of biological plausibility. Rather, he explains that Plaintiffs' proposed mechanisms are not supported by the existing scientific or medical literature. (*See* Holcomb Dep. at 131:14–22 ("I don't believe that the theory of chronic

inflammation, to the degree that it's been studied, supports the concept that . . . chronic inflammation from talc . . . causes mutations [or] causes malignant transformation."), 422:20–23 ("I have not seen where chronic inflammatory states have been shown to cause malignant transformation of cancer cells.").) His use of the term "convince[]," read in context, reflects his assessment of the sufficiency of the supporting evidence—not an insistence on scientific certainty. (*See id.* at 108:15–19 ("I'm not convinced of that *based on the literature*." (emphasis added).) Indeed, Dr. Holcomb testified that biological plausibility requires "an explanation that at least is possible," (*id.* at 104:17–22), and that he disagrees with Plaintiffs' experts' plausibility theories because he finds that the relevant literature does not adequately support their hypotheses. (*See id.* at 105:6–107:20.)

Plaintiffs argue Dr. Finan improperly applied the biological plausibility standard for talc migration and malignant transformation by relying on the absence of "precise" studies. (*See* Pls.' Finan, Saenz & Holcomb Br. at 18 (citing Finan Expert Report at 5, 54; ECF No. 32999-15 ("Finan Carl Dep.") at 60, 68:8–13, 169:12–170:8).) Dr. Finan's opinion on the absence of "studies that demonstrate that talcum powder as a dusting to the female perineum can migrate upwards through the female genital tract and reach the fallopian tubes or ovaries" is not indicative of an improperly heightened biological plausibility standard. (Finan Carl Dep. at 68:8–13; *see also id.* at 69:10–16 (explaining that "much" of the research into biological

plausibility of inflammation involves "advanced ovarian cancer," which Dr. Finan opines causes the inflammation), 60:5–8 (cautioning against taking his expert report's introductory bullet points out of context because they are meant to summarize his expert report).) Like Dr. Saenz and Dr. Holcomb, Dr. Finan is commenting on the lack of evidence supporting certain theories of biological plausibility. This is not the same as requiring evidence that proves Plaintiffs' experts' theories. Accordingly, Dr. Finan applies the correct Bradford Hill standard that biological plausibility must rest on some evidentiary support.

Plaintiffs largely repeat this line of argument against Drs. Permuth and DiFeo. I remain unconvinced. In short, Plaintiffs argue Dr. Permuth misapplied the biological plausibility standard for perineal-to-ovarian talc migration, citing her testimony that she found no evidence "prov[ing] that hypothesis." (*See* Pls. Permuth Br. at 14–15 (citing ECF No. 33001-6 ("Permuth Dep." at 176:16–177:7).) Again, a broader review of Dr. Permuth's testimony shows that this challenged statement is criticizing a specific study for not supporting the upward migration of talc from the perineum to the ovaries. (*Compare* Permuth Rep. at 113, 121–22, *with* Permuth Dep. at 176:16–177:7.) This is admissible rebuttal opinion.

Plaintiffs also argue that Dr. DiFeo misapplies biological plausibility with respect to talc migration, talc-induced malignant transformation, and the role of inflammation in ovarian cancer. (*See* Pls.' DiFeo Br. at 12–16 (citing Permuth Rep.

at 6, 16–17, 28, 29, 50; ECF No. 33001-6 ("DiFeo Dep.") at 52:25–53:4, 72:20–21, 74:1–19, 93:8–14, 169:1–15:22, 221).) In support, Plaintiffs point to portions of Dr. DiFeo's report and deposition testimony in which she concludes that certain studies do not support the biological mechanisms they purport to establish, or do not support Plaintiffs' experts' opinions. (*See id.*)

That characterization misconstrues Dr. DiFeo's analysis. In those instances, Dr. DiFeo does not conclude that a biological mechanism is impossible simply because it has not been conclusively proven. Rather, she opines that the cited studies do not, in her view, support the specific mechanistic conclusions that Plaintiffs' experts draw from them. For example, Plaintiffs challenge Dr. DiFeo's statement that certain studies "*do not conclusively show* that talc can migrate to the fallopian tubes or ovaries" because they "were conducted under artificial conditions that do not mimic the use or perineal application of cosmetic talc." (*See* DiFeo Rep. at 28.) In that context, Dr. DiFeo is not imposing a requirement of conclusive proof; she is critiquing the studies for failing to substantiate the conclusions they claim to support.[122] (*See id.*; *see also id.* at 6, 50.) Elsewhere, Dr. DiFeo similarly notes gaps or limitations in the evidence underlying Plaintiffs' biological plausibility theories. (*See, e.g.*, *id.* at 16–17, 29.) Identifying an absence or insufficiency of supporting

[122] Moreover, Dr. DiFeo previously testified that something "doesn't have to be conclusive to be plausible, but to strengthen the . . . plausibility of it, you want to conclusively confirm that it has a biological effect." (DiFeo Dep. at 169:18–22.)

evidence, however, is not the same as demanding definitive proof. Rather, it reflects a permissible expert assessment of whether the cited literature adequately supports the proposed biological mechanisms.

Moreover, Plaintiffs cite to no legal authority for the proposition that a defense expert may not opine on the existence or absence of relevant scientific or medical studies. Plaintiffs similarly cite to no legal authority for the proposition that a defense expert may not base his or her general causation opinions on, among other things, the existence or absence of relevant studies. And again, "the proper role of rebuttal experts [is] to critique plaintiffs' expert's methodologies and point out potential flaws in the plaintiffs' experts' reports." *Aviva Sports, Inc.*, 829 F. Supp. 2d at 835. An otherwise qualified expert may attack an opposing expert's methodology by criticizing the methodology, i.e., scientific and medical studies, on which they rely. *See, e.g.*, *id.* at 834 ("A number of other district courts have held that rebuttal expert witnesses may criticize other experts' theories and calculations without offering alternatives." (collecting cases); *see also In re Proton-Pump Inhibitor Prods. Liab. Litig.*, 2:17-MD-2789, 2022 WL 18999830, at *29 (D.N.J. July 5, 2022) ("[C]riticisms of an expert's explanations for reliance on, or rejection of, particular studies, are appropriately addressed through cross-examination, not through wholesale exclusion of the expert testimony.").

It also bears repeating that Plaintiffs do not challenge most of these experts' general causation rebuttal opinions on *Daubert* grounds. Plaintiffs do not appear to contend that these experts failed to employ reliable methodologies in reaching their respective conclusions. A central component of each expert's methodology is a review of the relevant scientific and medical literature. As explained throughout this Report and Recommendation, Defendants' experts often reach conclusions that differ from those of Plaintiffs' experts regarding the applicability, reliability, or significance of the same body of literature. That divergence, however, does not render the opinions inadmissible. The fact "[t]hat two different experts reach opposing conclusions from the same information does not render their opinions inadmissible," so long as they still meet *Daubert*'s threshold requirements concerning qualifications, reliability, and relevance. *Walker v. Soo Line R.R. Co.*, 208 F.3d 581, 589 (7th Cir. 2000); *see also Capri Sun GmbH*, 595 F. Supp. 3d at 139 (applying to rebuttal experts).

I find that the biological plausibility opinions of Drs. Finan, Saenz, Holcomb, Permuth, and DiFeo apply the correct standard. They are relevant and do not pose a risk of confusing or misleading the jury.

iii. Dr. Boyd

As previewed above, Plaintiffs move to exclude Dr. Boyd on three grounds independent from their efforts to exclude other defense experts set forth in this

section. Plaintiffs first contend that Dr. Boyd is unqualified to opine on the design and methodologies of certain *in vitro* studies. Next, Plaintiffs argue that Dr. Boyd's challenges to various peer-reviewed studies are speculative and lack a reliable methodology. Finally, Plaintiffs assert that Dr. Boyd's testimony will not assist the trier of fact.

Defendants respond that Dr. Boyd is well qualified to opine on *in vitro* study design and methodology, that his opinions are proper, helpful methodological critiques grounded in his expertise and peer-review experience, and that his testimony is relevant because peer review does not immunize the challenged studies.

a. Qualifications

Plaintiffs contend that Dr. Boyd is unqualified to opine on *in vitro* study design and methodology because he lacks experience conducting *in vitro* experiments or lab-based research of his own. (*See* Pls.' Boyd Br. at 19–20.) Plaintiffs highlight that Dr. Boyd has not conducted hands-on basic laboratory research in decades and has not, in a professional capacity, researched or experimented with genital talcum powder usage and its association with the development of ovarian cancer. (*See id.*)

Defendants argue in response that Dr. Boyd's decades of laboratory-centered cancer genetics experience, his active role in collaborative lab research programs, and his longstanding service as a reviewer and journal editor qualify him to assess,

among other things, *in vitro* design and ovarian cancer studies. (*See* Defs.' Opp. to Pls.' Permuth, DiFeo & Boyd Brs. at 43–46.)

Defendants have the better argument. As an initial matter, Plaintiffs mischaracterize Dr. Boyd's relevant experience. (*See* Pls.' Boyd Br. at 19–20 (citing ECF No. 33060-6 ("Boyd Dep.") at 49:23–50:16).) Without citation, Plaintiffs assert that "Dr. Boyd does not do lab-based research and does not do *in vitro* studies." (*See* Pls.' Boyd Br. at 19.) Dr. Boyd's testimony makes clear, however, that while he does not "own [a] personal research laboratory at this time in [his] career," he nonetheless conducts laboratory research, participates in collaborative laboratory research programs, and has an active laboratory-based research program. (*See* Boyd Dep. at 49:21–50:9; *see also id.* at 134:10–12 ("I don't have an active research laboratory any longer, although I have a clinical laboratory . . . .).)

Plaintiffs also argue that Dr. Boyd's failure to conduct talc-specific research and talc-specific experimentation makes him unqualified to opine on the objectives, design, and methodology of talc-specific studies. (*See* Pls.' Boyd Br. at 19–20.) That argument misses the mark. Rule 702 does not require Dr. Boyd to propose a competing methodology or replicate the challenged analyses as a precondition to offering methodological critiques of talc-specific study objectives, designs, or methods. *See, e.g.*, *Capri Sun GmbH*, 595 F. Supp. 3d at 138. The "proper role of rebuttal experts [is] to critique *plaintiffs' expert's* methodologies and point out

potential flaws in the plaintiffs' experts' reports." *Aviva Sports, Inc.*, 829 F. Supp. 2d at 835 (emphasis added).

Finally, it is worth reiterating that an expert's qualifications must still meet the *Daubert* qualification standards regardless of whether the expert's opinions are offered in rebuttal. The *Daubert* standard for qualification is liberally construed. Defendants need not put on the "best qualified" expert to offer a rebuttal opinion. *See In re Hum. Tissue*, 582 F. Supp. 2d at 655 (quoting *Pineda*, 520 F.3d at 244). Rather, Dr. Boyd possesses the requisite specialized expertise to allow him to opine on the design and methodology of proffered studies conducted or relied on by Plaintiffs' experts. Dr. Boyd is, among other things, a credentialed gynecologic cancer researcher who has held senior research and academic leadership positions in some of the world's leading cancer research institutions. (*See* Boyd Rep. at 1–2; *see also* ECF No. 33111-2 ("Boyd CV").) Dr. Boyd has led or worked in numerous esteemed cancer research laboratories. (*See* Boyd CV at 1–4.) Dr. Boyd has authored or co-authored over 200 peer-reviewed publications "on the molecular and genetic bases of gynecologic or breast cancers," and has served in several editorial positions for reputable medical journals. (*See, e.g.*, Boyd Rep. at 2; *see also* Boyd CV at 7 (naming editorial positions on Molecular and Cellular Differentiation, Molecular Carcinogenesis, Gynecologic Oncology, Journal of Clinical Oncology, American Journal of Pathology, and Anticancer Research).) The fact that Dr. Boyd has not

personally replicated Dr. Saed's experiments does not disqualify him from opining on the design or methodology of these studies. Therefore, I find that Dr. Boyd to be qualified to offer the opinions challenged by Plaintiffs.

b. Reliability

Plaintiffs seek to exclude Dr. Boyd's opinions regarding the Harper/Saed 2020 Poster, the Harper/Saed 2021 Poster, the Harper/Saed 2023 Article, Mandarino 2020, Emi 2021,[123] and certain of Dr. Levy's opinions on the ground that Dr. Boyd employed an unreliable methodology. In support, Plaintiffs point to portions of Dr. Boyd's deposition testimony in which he purportedly admitted that he conducted no independent research. (*See* Pls.' Boyd Br. at 4–5.) That characterization is not supported by the cited testimony. The excerpts reflect that, at the time of his deposition, Dr. Boyd could not recall specific aspects of the research he conducted in connection with his literature review—not that he failed to conduct any independent analysis. Elsewhere in his deposition testimony and supplemental expert report, Dr. Boyd describes the steps he undertook in forming his opinions, including reviewing the relevant literature and drawing on his decades of experience in cancer research. (*See, e.g.*, Boyd Dep. at 49:16–20, 139:13–19.)

[123] I note that these studies are no longer at issue with respect to Plaintiffs' experts' macrophage-inhibition theory.

In any event, Plaintiffs' criticism misses the mark. Dr. Boyd offers rebuttal opinions critiquing Plaintiffs' experts' studies and their interpretation of the scientific literature. He was not required to conduct original experimental research to do so. His methodology—reviewing the literature, evaluating the cited studies, and applying his expertise to assess their reliability and relevance—is a standard and permissible approach for rebuttal testimony under Rule 702.

Plaintiffs next emphasize the absence of support underlying Dr. Boyd's opinions regarding Dr. Saed's dosing, use of a cell transformation assay kit, and use of ovarian surface epithelial ovarian cells rather than fallopian tubes cells.[124] (*See* Pls.' Boyd Br. at 5–9.) As a general matter, Plaintiffs appear to misunderstand Dr. Boyd's role as a rebuttal expert. A rebuttal expert need not conduct his or her own experimental study or parallel analysis to attack an opposing experts' methodology or model. *See, e.g.*, *In re Zyprexa*, 489 F. Supp. 2d at 285 ("[D]efendants' experts have a less demanding task, since they have no burden to produce models or methods

[124] In this context, Plaintiffs' brief cites to Dr. Boyd's criticisms of methodology described in the Harper/Saed 2020 Poster, (*see* Pls.' Boyd Br. at 5–9), which Dr. Boyd alleges is repeated across Dr. Saed's subsequent studies, including Harper/Saed 2023. In short, this study sought to "demonstrate whether exposure to talcum powder induces malignant transformation in human primary normal ovarian epithelial cells and human primary normal peritoneal fibroblasts." (See Harper/Saed 2020 Poster.) The study exposed human primary normal ovarian epithelial cells and peritoneal fibroblasts in triplicate to Johnson & Johnson talcum baby powder at two exposure concentrations, 100 μg/mL and 500 μg/mL, for 72 hours. (*See id.*) The cells were then assessed using a cell transformation assay in accordance with manufacturer protocols. (*See id.*) Following assessment, the authors observed the formation of colonies in ovarian epithelial cells that indicated cell malignant transformation increasing by approximately 11% at 100 μg/mL and 20% at 500 μg/mL, while fibroblasts and titanium dioxide controls showed no detectable transformation at either dose. (*See id.*)

of their own; they need only attack those of plaintiffs' experts."). It is sufficient for the rebuttal expert to ground his critique in his expertise and a review of the materials on which the opposing expert relied. Accordingly, Dr. Boyd does not, and need not, offer affirmative opinions. Dr. Boyd may instead criticize Dr. Saed's methodology and highlight flaws in his studies' design. So long as Dr. Boyd's opinions otherwise satisfy *Daubert*'s threshold standards regarding qualifications, reliability, and fit, he may "critique plaintiffs' expert's methodologies and point out potential flaws in the plaintiffs' experts' reports." *Aviva Sports, Inc.*, 829 F. Supp. 2d at 835.

More specifically, as to Dr. Boyd's opinions on Dr. Saed's dosing, Plaintiffs argue that he failed to conduct independent research that comparable dosing appears in other peer-reviewed studies, and that even Defendants' experts endorsed the appropriateness of Dr. Saed's dosing. (*See* Pls.' Boyd Br. at 6–7.) However, as explained below, I find that Dr. Boyd offers proper rebuttal opinions challenging the methodology and conclusions underlying Dr. Saed's dose-related opinions. To be sure, Dr. Boyd does not suggest a proper dosage, other than to explain that in his view, Dr. Saed's dosage used in a 2019 study was "extraordinarily high." Boyd Dep. at 96:9–11; *see also* Boyd Rep. at 6 ("Dr. Saed's 2019 study treated cells with very high, non-physiologic doses of talcum powder, making it untenable to extrapolate those experiments to perineal talcum powder application by women."). Dr. Boyd goes further to criticize Dr. Saed's failure to follow accepted scientific methodology

by not "begin[ning] with the lowest dose possible [and] working up to the point where a biological effect is observed." (Boyd Dep. at 97:8–20.) Dr. Boyd then criticized Dr. Saed's apparent omission from the Harper/Saed 2020 Poster of dosage information because of the poster's claimed reliance on the 2019 study for dosing. (*See* Boyd Rep. at 6, 8.)

In forming his opinions that Dr. Saed used an improper dose of talcum powder, Dr. Boyd relied on his "understanding of [Dr. Saed's] scientific methodology, [and his] review of laboratory notebooks and previous work [of Dr. Saed]." (Boyd Dep. at 93:1–15.) Dr. Boyd also relied on the opinions of other peer reviewers who came to the same conclusion. (*See, e.g.*, Boyd Rep. at 6 & n.16, n.17, n.18, n.19; Boyd Dep. at 94:2–9.) These bases are sufficient to support Dr. Boyd's rebuttal testimony as reliable. Plaintiffs' references to comparable dosing or purported testimony about proper dosage do not, standing alone, call into question the reliability of Dr. Boyd's methodology. Rather, these are scientific disputes that go to the weight of Dr. Boyd's testimony, not its admissibility.

Plaintiffs next argue that Dr. Boyd's opinions regarding Dr. Saed's use of a specific cell transformation assay kit should be excluded because Dr. Boyd lacks experience with that particular kit as well as commercial assay kits generally and cannot say whether this kit or commercial assay kits generally are used in the scientific community. (*See* Pls.' Boyd Br. at 7–9.) For further support, Plaintiffs

point to Dr. Boyd's deposition testimony, wherein he admitted to not understanding how the term "cell transformation" was used in the kit's product guide and was unaware of whether any existing commercial assay kit tested for "malignant transformation." (*See* Pls.' Boyd Br. at 8 (citing Boyd Dep. at 115:19–116:4, 120:2–11, 122:25–123:5).)

I agree with Plaintiffs and recommend that the Court exclude Dr. Boyd's opinions and testimony regarding Dr. Saed's use of the commercial cell transformation assay kit, "ab235698," manufactured by Abcam. Dr. Boyd may still, however, opine on malignant cell transformation and whether he believes it can be observed within 72 hours following exposure as a general, scientific principle. And to be clear, this recommendation does not extend to limiting any other portion of Dr. Boyd's opinions or testimony challenged by Plaintiffs, as I find they are sufficiently reliable, by way of both underlying methodology and application to this case.

Dr. Boyd specifically opines that Dr. Saed misused the commercial cell transformation assay kit that he employed as a part of the Harper/Saed 2020 Poster by claiming that it demonstrated malignant transformation—a purpose for which the assay is not validated—and that asserting malignant transformation after only 72 hours is scientifically incoherent and biologically implausible. (*See* Boyd Rep. at 7.)

In forming his opinion, Dr. Boyd reviewed the assay kit's product guide, which states that the kit is intended to measure "cell transformation in mammalian

adherent or suspension cells in response to stimuli that inhibit or induce transformation." (*See* Boyd Rep. at 7 n.20; *see also* Boyd Dep. at 113:11–12 ("I'm referencing this kit based on what I've read from the pamphlet provided.").) Based solely on his review and that description, Dr. Boyd opines that the kit does not support conclusions regarding malignant transformation, as distinct from the more limited phenomenon of cell transformation as marketed. (*See* Boyd Rep. at 7.) But this review, which reflects the methodology underlying Dr. Boyd's opinions on Dr. Saed's use of the commercial cell-transformation assay kit at issue, is not sufficiently reliable. Dr. Boyd concedes to having never used the particular assay kit that he is now challenging. (*See* Boyd Dep. at 111:15–23.) Dr. Boyd also admitted that he has never used a commercial cell transformation assay kit of any kind. (*See id.* at 112:2–5.) Instead, Dr. Boyd explains that he "produced [his] own reagents" instead of using a cell transformation assay kit, though he admits that he has not done so for over 25 years. (*See id.* at 112:4–13.) In sum, Dr. Boyd admits to having neither familiarity with the cell transformation assay kit used by Dr. Saed, nor commercial cell transformation assay kits generally. And although he admits to using a cell transformation assay kit earlier in his career, it was a product of his own creation used over 25 years ago. Therefore, his criticisms of Dr. Saed's use of the commercial cell transformation assay kit, "ab235698," manufactured by Abcam, are not supported by a reliable methodology.

Plaintiffs also cite portions of Dr. Boyd's deposition in which he testified that he did not understand how the term "cell transformation" was used in the kit's product guide. (*See* Pls.' Boyd Br. at 8 (citing Boyd Dep. at 115:19–116:4, 120:2–11, 122:25–123:5).) Dr. Boyd also criticizes the kit's language as an oversimplification of the carcinogenic process. (*See* Boyd Dep. at 113:18–114:13.) For the same reasons as outlined above, Dr. Boyd's methodology underlying his kit-specific opinions is without sufficient support and therefore unreliable.

However, Dr. Boyd has demonstrated that his opinions regarding cell transformation as they relate to the broader carcinogenic process are supported by his reliance on "several decades of experience in how cells are transformed into malignant cells." (Boyd Dep. at 138:8–13.) Thus, he should be permitted to testify about cell transformation and his 72-hour exposure opinions, but not as they relate to his criticisms of Dr. Saed's use of commercial cell transformation assay kit, "ab235698," manufactured by Abcam.

Lastly, Plaintiffs argue that Dr. Boyd's critique of Dr. Saed's use of ovarian surface epithelial ovarian cells rather than fallopian tube cells lacks support because Dr. Boyd has never personally experimented with fallopian tube cells, cites no studies using such cells, and did not consider *in vitro* testing of them. (*See* Pls.' Boyd Br. at 8–9 (citing Boyd Dep. at 134:4–12, 136:22–25, 137:4–13).)

According to Dr. Boyd, "the great majority of high-grade serous ovarian cancers, which are the majority of ovarian cancer type, occurs in the fallopian tube, in which case the use of some normal type of fallopian tube cell would have been more appropriate." (Boyd Dep. at 133:22–134:3.) Dr. Boyd cites other peer reviewers who were critical of Dr. Saed's studies. (*See* Boyd Rep. at 6 ("I also agree with later peer reviewers that Dr. Saed's decision to use ovarian surface epithelial cells rather than fallopian tube cells significantly marginalizes his study given that scientists now agree that most high-grade serous ovarian cancers originate in the fallopian tubes.").) Therefore, Plaintiffs cannot credibly argue that Dr. Boyd's criticisms lack support, since he supported this opinion not only based on his own experience, but on other peer-reviewed conclusions.[125]

Additionally, Plaintiffs mischaracterize Dr. Boyd's testimony as it relates to his reliance or lack thereof on studies where fallopian tube cells are used in ovarian cancer research. When asked whether he could recall "any studies where fallopian tubes were used," Dr. Boyd responded that he was unable to "from memory." (*See* Boyd Dep. at 136:22–137:2.) Dr. Boyd similarly could not recall whether he considered "*in vitro* testing using fallopian tube cells." (*See* Boyd Dep. at 137:4–13.) But, even if Dr. Boyd did not personally test, research, or consider use of

[125] Plaintiffs spend much time arguing about the significance of the peer review process, (*see* Pls.' Boyd Br. at 17–19), but lose sight of Dr. Boyd's reliance on peer-reviews of Dr. Saed's posters.

fallopian tube cells when studying high-grade serous ovarian cancer, Dr. Boyd may nevertheless opine "that scientists now agree that most high-grade serous ovarian cancers originate in the fallopian tubes," (Boyd Rep. at 6; *see also* Boyd Dep. at 136:4–8), because, as discussed, the methodology on which he relies in forming such an opinion is reliable.

Finally, Plaintiffs argue that Dr. Boyd's criticisms of Dr. Levy's talc, inflammation and ovarian cancer opinions are unreliable and should be excluded because Dr. Boyd ignored several peer-reviewed studies that Dr. Levy considered. (*See* Pls.' Boyd Br. at 9–10.) Defendants rightly point out that Plaintiffs fail to explain the significance of these studies to Dr. Boyd's opinions. (*See* Defs.' Opp. to Pls.' Permuth, DiFeo & Boyd Brs. at 38.) Plaintiffs do not address the substance of the studies that Dr. Boyd purportedly ignored, and do not argue how these studies undermine the reliability of Dr. Boyd's methodology or opinions. While exclusion of an expert's opinions is warranted where "an expert ignores evidence that his highly relevant to his conclusion, contrary to his own stated methodology," Plaintiffs fail to explain how these studies are relevant to Dr. Boyd's opinions. *See In re Mirena II*, 341 F. Supp. 3d at 241.[126] The absence of explicit citations to every study Dr. Levy cites does not, by itself, render Dr. Boyd's methodology unreliable under

[126] In any event, "a proper rebuttal expert's opinion is not required to be based on the same data as the expert opinion that it is offered to rebut." *Better Holdco, Inc. v. Beeline Loans, Inc.*, 666 F. Supp. 3d 328, 361 (S.D.N.Y. 2023) (citation omitted) (collecting cases).

Daubert. Moreover, most of Dr. Boyd's critiques of Dr. Levy's opinions rest on Dr. Levy's misreadings of specific studies or on unsupported assertions, (*see, e.g.*, Boyd Rep. at 22–25), not on affirmative analyses susceptible to challenge by overlooked literature.

Accordingly, I find Dr. Boyd's methodology sufficiently reliable under *Daubert*, and therefore, I recommend the Court to admit Dr. Boyd as a rebuttal expert subject to the constraint I detailed above.

c. Fit

Plaintiffs argue that Dr. Boyd's post hoc critiques of published studies will not assist the jury and instead risk confusion or unfair prejudice. (*See* Pls.' Boyd Br. at 17–19.) Defendants respond that peer review does not insulate scientific studies from scrutiny in litigation, and that Plaintiffs' position is particularly inconsistent given that Plaintiffs' own experts criticize peer-reviewed cohort literature. (*See* Defs.' Opp. to Pls.' Permuth, DiFeo & Boyd Brs. at 39.) Defendants further note that Plaintiffs' acknowledgment that peer reviewers are "typically experts" underscores the relevance of Dr. Boyd's testimony, particularly where multiple expert reviewers at reputable journals criticized and rejected Dr. Saed's work. (*See id.* at 41.)

I agree with Defendants. Plaintiffs cite no authority—and I am aware of none—holding that peer-reviewed or published literature is categorically immune from critique by rebuttal experts. Adopting such a rule would improperly confer a

presumption of reliability on all published research, regardless of its methodology or the rigor of the review process. As discussed above, Dr. Boyd's critique of Plaintiffs' experts' methodologies and the studies on which they rely goes to weight, not admissibility.

Under *Daubert*, courts may evaluate relevance by assessing whether a theory or method has been peer reviewed or published. *See Daubert*, 509 U.S. at 593. "Although it is not dispositive of admissibility, publication in a peer reviewed journal is relevant 'in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.'" *Van Wyk*, 83 F. Supp. 2d at 520 (quoting *Daubert*, 509 U.S. at 593). It follows that a defense expert offered in rebuttal may properly scrutinize and critique the methodology and conclusions of peer-reviewed studies relied upon by an opposing expert. Such testimony is relevant and may assist the trier of fact in evaluating complex scientific evidence.

Here, Dr. Boyd does not opine on the admissibility of Plaintiffs' expert evidence or usurp the Court's gatekeeping function. Rather, he critiques the methodologies underlying Dr. Saed's research and related studies cited by Plaintiffs' experts. Specifically, Dr. Boyd opines that the Harper/Saed 2020 and 2021 posters and the Harper/Saed 2023 article suffer from experimental and interpretive deficiencies; that Mandarino 2020 and Emi 2021 do not meaningfully advance the relevant mechanistic inquiry; and that Dr. Levy's genetics-related causation opinions

overstate the data on which they rely. These critiques address scientific design and interpretation, not admissibility.

Accordingly, I recommend that the Court grant in part and deny in part Plaintiffs' motion to exclude the expert testimony of Dr. Boyd.

iv. Plaintiffs' Motion to Exclude the Opinions of Dr. Kornak

Plaintiffs move to exclude the opinions of Dr. John Kornak, Ph.D. Defendants offer Dr. Kornak's testimony to rebut the PSC's experts' opinions to the extent that those opinions are based on O'Brien 2024. Several of Plaintiffs' experts rely on O'Brien 2024, as is discussed elsewhere in this Report and Recommendation.

Generally, O'Brien 2024, which concludes that genital talc use is associated with an increased risk of ovarian cancer, uses statistical methods to compensate for missing data points in the underlying dataset, which came from the Sister Study, a cohort study exploring the relationship between various risk factors and cancer. (*See* O'Brien 2024 at 13.) Dr. Kornak primarily criticizes the imputation methods employed by the authors of O'Brien 2024. (*See* ECF No. 33011-9 ("Kornak Rep.").)

Plaintiffs move to exclude Dr. Kornak on primarily two bases. (*See generally* ECF No. 33011-1 ("Pls.' Kornak Br.").) First, they argue that the methodology used in O'Brien 2024 deserves great deference such that Dr. Kornak's opinion critiquing that methodology should be excluded. (*Id.* at 21-22.) Second, they maintain that Dr. Kornak's critique of O'Brien 2024's methodology is unreliable because the doctor

hastily prepared his report and did not review key materials cited by the study. (*Id.* at 23-24.)

Defendants argue in opposition that the soundness of O'Brien 2024's methodology is not a legal basis on which a court can exclude Dr. Kornak's criticism, and Plaintiffs' other criticisms of Dr. Kornak are factually baseless. (*See* ECF No. 33107 ("Defs.' Kornak Br.") at 13–23.)

As set forth above, Dr. Kornak's rebuttal analysis is subject to the standards set forth in Rule 702 and *Daubert*. With that in mind, I will detail O'Brien 2024, again to the extent it is helpful to address the parties' argument in this context, followed by Dr. Kornak's criticisms of O'Brien 2024. I then turn to the Plaintiffs' arguments to exclude Dr. Kornak's opinions on the flaws of O'Brien 2024.

a. O'Brien 2024

O'Brien 2024, discussed numerous times in this Report and Recommendation, was published to address issues in the Sister Study data to shed further light on a potential association between genital talcum powder use and cancer. (*See* O'Brien 2024 at 1.) To fully understand Dr. Kornak's criticisms of O'Brien 2024, one must understand O'Brien 2024's data and methods,[127] both of which I discuss below in turn.

[127] O'Brien 2024 enjoys much ink in this Report and Recommendation as it permeates the parties' briefs since it is a post-2020 Opinion study. In the context of considering the instant motion, an in-depth discussion of O'Brien 2024 and its methods is necessary.

(1) The Sister Study

As noted above, O'Brien 2024 is an analysis of data collected through the "Sister Study," which is a cohort study conducted from 2003 to 2009 of approximately 50,000 women residing in the United States, aged 35 to 74, who never had breast cancer when they enrolled in the study but had a sister who had breast cancer. (O'Brien 2024 at 2.) The authors of the study monitored the respondents for the incidence of cancers, including ovarian cancer, and confirmed cancer cases among the respondents, including fatal ones, with medical data when possible. (*Id.* at 3.) Respondents received a questionnaire approximately every three years. (*See* O'Brien 2023 at 377.)

The initial Sister Study questionnaire, utilized at enrollment, asked respondents whether they never, sometimes, or frequently applied talcum powder to their vaginal area at ages 10 to 13 and whether they applied talcum powder in the year preceding enrollment[128] in the Sister Study. (O'Brien 2024 at 2.)[129] Following its collection, several studies analyzed the data for various reasons, one of which is

[128] The frequency options for selection in the year preceding enrollment were as follows: never, less than once per month, 1–3 times per month, 1–5 times per week, and more than 5 times per week. (O'Brien 2024 at 2–3.)

[129] The Sister Study also collected information regarding each respondents' race/ethnicity, attained education, examiner-measured BMI, BMI age 30–39 years, age at menarche, duration of hormonal birth control use, parity, menopausal status, hormone therapy use, geographic region of residence, smoking status, alcohol use, childhood household income level, adult household income, highest attained education level in the household when the participant was age 13 years, marital status, and weight relative to peers in teen years. (*Id.* at 4.)

the association of talcum powder use and ovarian cancer. A 2016 analysis found no statistically significant association in that respect. (*See* Gonzalez 2016.) Dr. Katie O'Brien, the principal author of O'Brien 2024, similarly found no statistically significant association in another, earlier, study conducted in 2020. (*See* O'Brien 2020.)

However, Dr. O'Brien coordinated a 2023 analysis that collected additional data from Sister Study respondents through a follow-up questionnaire.[130] (*See id.*) The follow-up questionnaire, administered between 2017 and 2019, asked respondents whether they had ever used talcum powder, and, if so, their age at first and most recent use, as well as their frequency of use during each decade. (O'Brien 2024 at 3.) The key finding was that most respondents were more likely to report talcum powder use at enrollment, whereas respondents who had been diagnosed with cancer prior to the follow-up were more likely to report talcum powder use at follow-up. (*See* O'Brien 2023 at 383.).

(2) O'Brien 2024's quantitative bias analysis corrections

The gap between the Sister Study enrollment and follow-up questionnaires presented additional issues. For different reasons, data on respondents' talcum powder use "were sometimes contradictory or missing." (O'Brien 2024 at 4.) For

[130] The purpose of O'Brien 2023 was to document and analyze patterns in respondents' use and reliability of recall with respect to intimate care products such as talcum powder and douching thought to be associated with gynecological cancers. (*See* O'Brien 2023 at 376.)

instance, respondents who passed away before 2017 obviously did not respond at follow-up. (*See id.*) Other respondents stated that they had used talcum powder at enrollment, but at follow-up, gave contradictory responses that they never used it. (*See id.*)

As mentioned earlier, O'Brien 2024 sought to address these issues by using "quantitative bias analysis," which "estimates what the observed association would have been had systematic error been absent given a set of assumptions that determine the extent of bias." Julie M. Petersen et al., *A Systematic Review of Quantitative Bias Analysis Applied to Epidemiological Research*, Int'l J. of Epidemiology 1708, 1709 (2021).[131] O'Brien 2024's quantitative bias analysis involved four scenarios[132] in which corrections were made to the data:

No correction, fill in missing data ("Scenario 1"): O'Brien 2024 did not correct any contradictory responses, but filled in missing data, prioritizing a respondent's answers to the initial questionnaire at enrollment (*i.e.*, respondents who reported use at enrollment but failed to respond at follow-up were considered users). (O'Brien 2024 at 4, Table A5, App. 1.) Scenario 1 found a statistically insignificant association between genital talcum powder use and ovarian cancer, with a hazard ratio ("HR") of 1.07 (CI: .84 to 1.35). (*Id.* at 9, 12, Table 2.)

---

131 I take judicial notice of the definition of quantitative bias analysis. The parties do not specifically address its general definition, but also do not appear to dispute it.

132 I identify O'Brien 2024's four scenarios using the same titles that the study used.

Fill in missing data, correct contradictory data, assume unexposed ("Scenario 2"): O'Brien 2024 corrected contradictory data in addition to filling in missing data. (*Id.* at 4, Table A5, App. 1.) For respondents who reported nonuse at enrollment at a certain age but later indicated use at that same age, O'Brien 2024 assumed that 80% were users. (*Id.*) For respondents who reported use at enrollment and nonuse at follow-up, O'Brien 2024 assumed that 90% were users. (*Id.*) Respondents who did not answer at follow-up were assumed to be nonusers. (*Id.*) Scenario 2 found a statistically insignificant association between genital talcum powder use and ovarian cancer, with an HR of 1.17 (CI: .92 to 1.49). (*Id.* at 9, 12, Table 2.)

Fill in missing, correct contradictory data, if undefined, assume exposed extreme exposed ("Scenario 3"): Supplementing Scenario 2, O'Brien 2024 categorized all respondents that reported nonuse at enrollment but no answer at follow-up as users. (*Id.* at 4, Table A5, App. 1.) Scenario 3 found a statistically significant association between genital talcum powder use and ovarian cancer, with an HR of 3.34 (CI: 2.51 to 4.44). (*Id.* at 9, 12, Table 2.)[133]

Correct contradictory data, use multiple imputation to fill in missing or undefined ("Scenario 4"): O'Brien 2024 used multiple imputation with chained

[133] Scenarios 2 and 3 therefore present extreme cases with respect to respondents who did not answer at follow-up, with the true measure of use in respondents who failed to answer at follow-up falling somewhere in between Scenarios 2 and 3.

equations[134] ("MICE") "to generate covariate-informed probabilistic imputations of the exposure status of participants" who reported nonuse at enrollment but did not provide an answer about genital talc use at follow-up. (*Id.* at 4, Table A5, App. 1.) The covariates O'Brien 2024 used in Scenario 4 included demographic information, socioeconomic information, and cancer history, among other categories. (*Id.* at Table 2, n.d.)

Put differently, in Scenario 4, O'Brien 2024 used existing data to probabilistically determine what missing data would likely show. For example, if hypothetical respondents A and B were otherwise identical with respect to demographics, socioeconomic status, and health, but A did not answer a question (or gave a contradictory response), A's true answer is likely to track B's answer. Scenario 4 found a statistically significant association between genital talcum powder use and ovarian cancer, with an HR of 1.82 (CI: 1.36 to 2.43). (*Id.* at 9, 12, Table 2.)

(3) O'Brien 2024's recall bias adjustments

In addition to the missing data, O'Brien 2024 also sought to address the more general problem of recall bias. (*Id.* at 2, 4.) As discussed elsewhere in this Report

[134] As more fully discussed *infra*, multiple imputation is a statistical method that fills in missing data points for a given respondent who did not answer a question by finding another respondent with similar key characteristics who did answer the question. The method then "imputes" the answering respondent's data for the missing respondent, on the assumption that two respondents who share key characteristics probably would give the same answer. (*See also supra* Part V.B.)

and Recommendation, recall bias in this context exists because self-reporting respondents who have ovarian cancer may be more likely to report prior talcum powder use than respondents without cancer. (*See* O'Brien 2023 at 383.) The increased likelihood of such a bias may be due to public attention to a potential connection between talcum powder use and ovarian cancer. (*See id.*)

To account for recall bias, O'Brien 2024 started with Scenario 4, which reflected contradictory data correction and imputation of missing data. (*Id.* at 4.) O'Brien 2024 then "implemented recall bias corrections by changing the exposure status of a specified percentage of women with certain characteristics." (*Id.* at 4, 9, App. 1.) First, O'Brien 2024 recategorized certain percentages (10%, 25%, 50%, 75%, 90%) of respondents who contracted ovarian cancer to be nonusers. (*Id.* at 4, 9, App. 1.) These respondents initially reported nonuse or failed to answer but were categorized as users based on their post-diagnostic status or imputation. (*Id.* at 4, 9, App. 1.) If 25% of cancer cases are recategorized to be nonusers, there is still a statistically significant association between talcum powder use and ovarian cancer, but the HR drops to 1.41 (CI: 1.06 to 1.87). (*Id.* at 9.)

Second, O'Brien 2024 modified the first set of corrections by recategorizing certain percentages (10%, 25%, 50%, 75%, 90%) of ovarian cancer cases as nonusers based on their infrequent or short-term use of talcum powder. (*Id.* at 4, 9, App. 1.) If 90% of infrequent users are recategorized as nonusers, there is still a

statistically significant association between talcum powder use and ovarian cancer, but the HR drops to 1.48 (CI: 1.06 to 1.87). (*Id.* at 9.)

Third, O'Brien 2024 recategorized certain percentages (5%, 10%, 15%, 25%, 50%) of respondents who did not contract ovarian cancer and were nonusers to be infrequent or short-term users. (*Id.* at 4, 9, App. 1.) If 10% of noncancer cases are recategorized, there is still a statistically significant association between talcum powder use and ovarian cancer, but the HR drops to 1.53 (CI: 1.15 to 2.04). (*Id.* at 9.)

(4) O'Brien 2024's results

O'Brien 2024 concluded that, after quantitative bias and recall bias corrections are made, the data support a hypothesis that genital talcum powder use is associated with ovarian cancer. (*Id.* at 14.) The authors caution that their results "do not establish causality and do not implicate any specific cancer-inducing agent" and are still subject to confounding or external variables. (*Id.*)

b. Dr. Kornak

(1) Qualifications

Plaintiffs do not appear to challenge Dr. Kornak's qualifications. (*See* Pls.' Kornak Br. at 20–25.) In any event, such a challenge would not prevail.

Dr. Kornak is a Professor in Residence of Biostatistics in the Department of Epidemiology and Biostatistics in the School of Medicine at the University of

California, San Francisco ("UCSF"). (Kornak Rep., App'x A.) He also serves as the head of the Health Data Science Program and the Director of the UCSF Biostatistics Consulting Unit, part of the UCSF Clinical and Translational Sciences Institute. (*Id.*) He received his Bachelor of Science in Mathematics with Statistics in 1996, and his Ph.D. in statistics in 2000, both from the University of Nottingham in the United Kingdom. (*Id.*)

Dr. Kornak has over twenty years of research experience in applying biostatistics across a number of disciplines, including epidemiology. (*Id.*) Notably, he has led research projects funded by the National Institutes of Health, which also employs Dr. Katie O'Brien. (*Id.*) Dr. Kornak has published more than 150 peer-reviewed publications concerning biostatistics. (*Id.*)

Accordingly, I recommend that the Court find Dr. Kornak to be qualified to opine on O'Brien 2024's quantitative bias and recall bias corrections.

(2) Methodology and opinions

In general, Dr. Kornak opines that O'Brien 2024's two data correction measures (*i.* quantitative bias analysis correction of missing and contradictory data, and *ii.* correction for recall bias) are flawed and unreliable. (*See* Kornak Rep. ¶¶ 10-14.)

In his rebuttal report, Dr. Kornak first examines Scenarios 1 through 3 and identifies flaws in each that he opines skew the overall results in favor of finding an

association between genital talc use and ovarian cancer. (*See id.* ¶¶ 32–39.) His primary focus, however, is on Scenario 4 (multiple imputation). He explains that application of quantitative bias analysis is both inappropriate for the Sister Study dataset, and even if appropriate, was unreliably applied to that dataset, leading to flawed results. (*See id.* ¶¶ 40–71.) Dr. Kornak also identifies flaws in O'Brien 2024's recall bias corrections. (*See id.* ¶¶ 72–76.)

As I explain in further detail below, Dr. Kornak's analysis involves an application of accepted statistical principles to the methods used in O'Brien 2024. He points out where he believes O'Brien 2024 deviates from these principles and identifies the consequences of those deviations. Dr. Kornak applies the methodology that rebuttal experts generally undertake, particularly in this litigation, *i.e.*, criticizing the opinions and methodology of the adverse expert or a study relied upon by the expert. For most of the criticisms he raises, Dr. Kornak appears to rely on his experience generally in biostatistics and his experience dealing with missing data in particular. (*See* Kornak Dep. at 103:20–104:19.) He expresses that the use of multiple imputation requires some level of scientific judgment. (*See id.* at 105:8–106:5.)

Rationale for Using Multiple Imputation. At the outset, Dr. Kornak questions O'Brien 2024's rationale for using multiple imputation. He notes that O'Brien 2023 observed that "[d]iscrepancies in self-reported genital talc use were

primarily driven by women who initially reported using during early adolescence, but later reported never using." (*Id.* (quoting O'Brien 2023 at 384).) Based on that observation, Dr. Kornak questions why O'Brien 2024 assumes that misreporting was a substantial problem in respondents who indicated nonuse at enrollment but did not answer at follow-up. (*Id.*)

Appropriateness of Using Multiple Imputation. Dr. Kornak then turns to the methodology of multiple imputation and its applicability to the Sister Study dataset. Dr. Kornak directs most of his attention to O'Brien 2024's Scenario 4.[135] Dr. Kornak describes O'Brien 2024's use of MICE as "comput[ing] the probability that any particular survey respondent was a genital talc user based on her demographic, economic, and health characteristics."[136] (*Id.* ¶ 44.) Appearing to rely on an academic article describing the methodology of applying MICE, he opines that MICE is an inappropriate method for the Sister Study dataset because MICE is not appropriate

---

[135] Although the focus of Dr. Kornak's rebuttal is Scenario 4, he offers the following criticisms of the other scenarios:
Scenario 1: Dr. Kornak opines that the adjustments made in Scenario 1 introduce further recall bias into O'Brien 2024's analysis. (Kornak Rep. ¶¶ 33–34.) This is because when a respondent did not answer on talcum powder use at enrollment but claimed use at follow-up, the follow-up answer is retrospective and more prone to recall bias. (*Id.*)
Scenario 2: Largely following his criticism of Scenario 1, Dr. Kornak attacks O'Brien 2024's recategorization of 80% of respondents who did not answer at enrollment but reported use at follow-up as genital talc users. (*Id.* ¶ 36.) This recategorization, in Dr. Kornak's view, exacerbated the effect of recall bias. (*Id.*)
Scenario 3: Dr. Kornak accepts that Scenario 3 is an intentionally extreme analysis to provide an illustration rather than a true measure of the association between genital talc use and ovarian cancer. (*Id.* ¶ 39.)

[136] Dr. Kornak notes that some information about how O'Brien 2024 applied MICE is missing, thus complicating any analysis of it. (*See id.*)

for data missing not at random ("MNAR")[137] (*i.e.*, a situation where respondents with a particular characteristic are more likely to skip a question, but that characteristic is related to the endpoint being measured). (*Id.* ¶¶ 48–51 (citing M.J. Azur et al., *Multiple Imputation by Chained Equations: What Is It and How Does It Work?*, 20 Int'l J. Methods Psych. Rsch. (1), 40, 40–49 (2011)).) Dr. Kornak believes that the Sister Study data is MNAR because, as O'Brien 2024 recognizes, respondents with cancer were more likely to not answer questions about talcum powder use at follow-up. (*Id.* ¶ 50.)[138]

Lastly, Dr. Kornak also notes that in these circumstances, imputation exacerbates the problem of recall bias because O'Brien 2024's imputation uses existing data from the Sister Study that may already be affected by recall bias. (*See id.* ¶¶ 45–46.)

Application of Multiple Imputation. Assuming that MICE is an appropriate method for the Sister Study dataset, Dr. Kornak submits that it was not reliably

---

[137] As Dr. Kornak explains, data can be categorized in three ways: (1) data that are missing completely at random (*i.e.*, respondents who accidentally skip a question in a way unrelated to their characteristics); (2) data missing at random (*i.e.*, respondents in a particular category are more likely to skip a certain question, but that question is unrelated to the endpoint being measured); and (3) missing data that is not at random, *i.e.*, MNAR. (*See* Kornak Rep. ¶ 39.) In Dr. Kornak's view, there are specific methods to address MNAR data, but O'Brien 2024 did not use them. (*Id.* ¶ 51.)

[138] Additionally, Dr. Kornak opines that imputation is not as reliable when the group of respondents for which data is missing (and thus must be imputed) is markedly different from the set of respondents whose data is existing (and serves as the basis for imputation. (*Id.* ¶ 47.) The difference in incident cancer between the two groups negatively affects the reliability of the analysis, in Dr. Kornak's view. (*See id.*)

applied for three reasons. First, Dr. Kornak opines that the demographic, socioeconomic, and health data that O'Brien 2024 used to impute genital talcum powder use are not reliable predictors of use based on prior studies of the Sister Study data. (*Id.* ¶¶ 52–54 (citing Chang 2024.) Second, relying on his independent assessment of the O'Brien 2024 data, Dr. Kornak opines that O'Brien 2024's use of ovarian cancer status as a data point in the imputation creates a circular feedback loop. (*Id.* ¶¶ 56–57.) This loop occurs for two reasons: a generally higher prevalence of genital talcum powder use among women with ovarian cancer and recall bias. (*Id.* ¶ 57.) Both, in Dr. Kornak's view, lead to more imputation of genital talcum powder use than may be warranted. (*Id.*) Dr. Kornak faults O'Brien 2024 for not completing a separate imputation analysis without using ovarian cancer status as a data input. (*Id.* ¶ 58.) Third, again relying on his independent assessment of the data, Dr. Kornak opines that the percentage of respondents subject to correction or imputation (40%) in O'Brien 2024 is unreasonably high, generating significant uncertainty in the results. (*Id.* ¶¶ 59–61.)[139]

Results of Multiple Imputation. Dr. Kornak lastly addresses the results of O'Brien 2024's multiple imputation methodology. (*See id.* ¶¶ 66–71.) He argues

[139] Dr. Kornak also identifies certain inconsistencies in the Sister Study questionnaires that could affect the results of applying MICE to its data. For example, the enrollment questionnaire allowed respondents to indicate that they did not know about their genital talcum powder use but the follow-up questionnaire did not. (*Id.* ¶ 63.) To the extent that inconsistencies in the questionnaire generated flawed data, imputation based on that data would carry over those flaws. (*Id.* ¶ 65.)

that to be reliable, O'Brien 2024's results should remain robust even if minor modifications are made to the multiple imputation methodology used. (*Id.* ¶ 70.) Dr. Kornak then illustrates how small changes to the methodology result in a statistically insignificant finding. (*See id.* ¶ 71.)

Recall Bias. With respect to O'Brien 2024 recall bias corrections, Dr. Kornak first notes that the O'Brien 2024 authors' corrections for recall bias are arbitrarily applied in discrete scenarios that do not account for all of the ways recall bias can affect the analysis. (*Id.* ¶ 73.) Based on his independent review of the data, he notes that there is an inverse relationship between the percentage of respondents who are recategorized and the resultant HR. (*Id.*) As there are no validated estimates for the number of respondents who are affected by recall estimates, he believes higher recategorizations (which lead to lower HRs) are more appropriate. (*Id.* ¶ 74.)

(3) Reliability

As noted above, Plaintiffs argue that Dr. Kornak's opinions should be excluded because O'Brien 2024 deserves deference as a peer-reviewed study and because Dr. Kornak's rebuttal is unreliable and "made for litigation." (*See* Pls.' Kornak Br. at 21–25.) Defendants argue in opposition that the soundness of O'Brien 2024's methodology is no reason to exclude Dr. Kornak's criticisms of it and Dr. Kornak's methods are reliable and reliably applied. (*See* Defs.' Kornak Br. at 13-23.) I agree.

Plaintiffs' first argument does not directly engage with Dr. Kornak's opinions. Instead, Plaintiff asserts that because O'Brien 2024 is "sufficiently reliable," any critique offered by Dr. Kornak must necessarily be unfounded. (Pls.' Kornak Br. at 21.) Plaintiffs highlight that O'Brien 2024 underwent multiple rounds of peer review, and that none of the reviewers identified the concerns now raised by Dr. Kornak. (*Id.*) This argument is misplaced. Plaintiffs cite no authority for the proposition that the perceived reliability of a study itself furnishes a legal basis to preclude a rebuttal expert from critiquing that study. No such precedent exists. By suggesting that the asserted reliability of O'Brien 2024 forecloses any expert criticism, Plaintiff fundamentally misapprehends the *Daubert* framework, which permits—indeed, expects—experts to address the strengths and weaknesses of the scientific materials on which other experts rely. As noted above, rebuttal experts serve a limited role in litigation, particularly where, as here, the party offering them bears no burden of proof. *See Capri Sun GmbH*, 595 F. Supp. 3d at 138, 140 ("Rebuttal experts thus 'have a less demanding task because they have no burden to produce models or methods of their own; they need only attack those of plaintiff['s] expert[].'" (alterations in original) (quoting *In re Digital Music*, 321 F.R.D. at 78)); *see id.* at 140 ("At bottom, a rebuttal expert need not proffer a methodology or model, but only critique the opposing expert's."); *In re Abilify*, 299 F. Supp. 3d at 1368 (defense experts' "opinions properly may be limited to criticizing the analysis

and conclusions presented by another party"). Their task is to critique and test the reasoning, assumptions, and methods of an opposing expert, not to construct an affirmative model of their own. I do not doubt that in certain disciplines, standardized and peer-reviewed methodologies exist for evaluating another expert's work. *See In re Generic Pharms. Pricing Antitrust Litig.*, No. 16-md-2724, 2024 WL 4980784, at *14 (E.D. Pa. Dec. 3, 2024) ("[A]ll experts must meet the *Daubert* standards, if a rebuttal expert is to discredit another expert's model by making affirmative statements or findings of their own they must still provide good grounds based in methods and principles of analytical evaluation to ground their opinions that discredit an analytical expert opinion."). Nevertheless, because the methods employed by a rebuttal expert necessarily depend on the particular analyses being challenged, it would be inconsistent with *Daubert* and with the practical realities of expert practice to require that a rebuttal expert's critiques themselves be peer-reviewed as a precondition to admissibility. The methods employed by a rebuttal expert, such as Dr. Kornak, remain a proper subject for cross-examination.

Furthermore, Plaintiffs' talismanic focus on the fact that O'Brien 2024 was peer reviewed misses the mark. Peer review is but one of many factors that courts consider in applying the flexible *Daubert* standard.[140] *See Kumho Tire Co.*, 526 U.S.

[140] Some courts have expressed doubts concerning pre-publication peer review's significance in the *Daubert* analysis. *See In re Roundup*, 737 F. Supp. 3d at 908 ("There are a vast number of

at 141–42 ("[A]s the Court stated in *Daubert*, the test of reliability is 'flexible,' and *Daubert*'s list of specific factors neither necessarily nor exclusively applies to all experts or in every case. Rather, the law grants a district court the same broad latitude when it decides *how* to determine reliability as it enjoys in respect to its ultimate reliability determination."). Therefore, to the extent Dr. Kornak criticizes how the authors of O'Brien 2024 conducted the study, the fact that the study underwent several rounds of peer review does not immunize it from being challenged in this litigation.[141]

Indeed, my conclusion that the methods underlying Dr. Kornak's opinions are reliable is based on other factors, such as the statistical principles Dr. Kornak cites to illustrate how O'Brien 2024's deviations from these principles potentially produce inaccurate results, and Dr. Kornak's experience with missing data and imputation generally. (*See, e.g.*, Kornak Rep. ¶¶ 24, 48, 53, 70; *see also* Kornak Dep. at 103:20–104:19, 148:8–149:6.) For example, Dr. Kornak identifies the three categories of

peer-reviewed journals out there. Pre-publication editorial peer review, just by itself, is far from a guarantee of scientific reliability.").

[141] That said, the reliability of O'Brien 2024 is not the subject of Plaintiffs' motion; rather, it is the reliability of Dr. Kornak's criticism of O'Brien 2024 that is at issue. Focusing again on peer review, Plaintiffs appear to argue that Dr. Kornak's methods were not peer reviewed. Although Plaintiffs do not meaningfully develop that argument, and Defendants do not appear to address it, I am unpersuaded that the lack of methodological peer review in Dr. Kornak's rebuttal warrants exclusion. It bears emphasis that peer review is only one factor among many, and need not be present in every case. *See Kumho Tire*, 526 U.S. at 141; *Schneider*, 320 F.3d at 406 ("[W]e note that expert testimony does not have to obtain general acceptance or be subject to peer review to be admitted under Rule 702.").

datasets with missing datapoints and explains why he believes the Sister Study is MNAR and why MICE is inappropriate for an MNAR dataset. (*Id.* ¶¶ 48–50.) He then identifies alternative methods that would be more appropriate for an MNAR dataset. (*Id.* ¶ 51.) In another example, Dr. Kornak cites prior studies of the Sister Study dataset showing that the demographic, economic, and health characteristics the O'Brien 2024 authors used as predictors in their imputation model are not strong predictors of talcum powder use and explains how this leads to unreliability in O'Brien 2024's analysis. (*See id.* ¶¶ 52–55.) These are the quintessential analyses of a rebuttal expert as Dr. Kornak identifies infirmities in O'Brien 2024 and offers alternative methodologies. *See Capri Sun GmbH.*, 595 F. Supp. at 138; *Mahaska Bottling Co.*, 441 F. Supp. 3d at 759 (courts routinely permit defense experts to testify "even if the expert primarily critiques the opposing expert's approach without offering an alternative approach"); *In re Abilify*, 299 F. Supp. 3d at 1368 (defense experts' "opinions properly may be limited to criticizing the analysis and conclusions presented by another party"); *In re Zyprexa*, 489 F.Supp. 2d at 285 ("[D]efendants' experts have a less demanding task, since they have no burden to produce models or methods of their own; they need only attack those of plaintiffs' experts.").

Plaintiffs, for their part, contend that Dr. Kornak's criticisms lack merit. They argue that the scientific literature supports the use of MICE in these circumstances

and that the method does not invariably require strong predictors to yield accurate imputations. (*See* Rebuttal Rep. of Dr. Elizabeth A. Stuart, Ph.D., ECF No. 33011-11, at 7-8, 10.) This disagreement, however, reflects nothing more than a reasonable and legitimate divergence of views within the biostatistical community. Such professional differences do not warrant exclusion under Rule 702. Rather, they present a paradigmatic "battle of the experts"—one that is properly explored through cross-examination and resolved by the jury, not by pretrial disqualification of competing methodologies. *See United States v. Maxwell*, No. 20-CR-330, 2021 WL 5283951, at *2 (S.D.N.Y. Nov. 11, 2021) ("But if experts disagree on the proper interpretation of evidence, 'it is not the Court's role to resolve the dispute through exclusion of one of the expert's opinions.'" (quoting *In re Digital Music*, 321 F.R.D. at 80)); *Templeton v. Bishop of Charleston*, No. 18-CV-02003, 2021 WL 3419442, at *9 (D.S.C. Aug. 5, 2021) ("*Daubert* principles support admission of a scientific theory if it is within 'the range where experts might reasonably differ.' In other words, where legitimate disagreement exists within the scientific community, it is for the jury, not the judge, 'to determine which of several competing scientific theories has the best provenance.'" Further, "Rule 702 does not require exclusion of all but the most scientifically supported view, and it clearly contemplates the admission of testimony by experts who have fundamental disagreements about the scientific principles at issue.") (internal citations omitted); *Grasinger v. Caterpillar*,

Inc., No. 21-CV-956, 2023 WL 4846843, at *9 (W.D. Pa. July 28, 2023) ("'*Daubert* neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance.'") (quoting *Ruiz-Troche*, 161 F.3d at 85).

Next, I turn to Plaintiffs' other arguments that challenge different aspects of Dr. Kornak's methodology. Plaintiffs fault Dr. Kornak for (i) preparing his opinion hastily; (ii) consulting with Cornerstone Research ("Cornerstone"), an expert search firm used by Defendants, in preparing his opinions; and (iii) failing to read materials supporting O'Brien 2024's methodology.[142] None of Plaintiffs' arguments are adequate bases for preclusion under *Daubert*.

With respect to Plaintiffs' contention that Dr. Kornak's report reflects undue haste, I do not find that the limited time available to prepare his analysis warrants exclusion. The parties do not dispute that all experts—on both sides—had a compressed window in which to address O'Brien 2024, which was published on May 15, 2024. (O'Brien 2024 at 1.) Pursuant to the Court's scheduling order, expert reports were due May 28, 2024. Defendants correctly note that Plaintiffs were subject to the same constraints and indeed opposed Defendants' request for

[142] Plaintiffs further contend that the purportedly "incendiary" and inflammatory language used in Dr. Kornak's report renders his analysis unreliable. (Pls.' Kornak Br. at 19.) I disagree. While experts should avoid unnecessary rhetoric and vitriol, Rule 702 and *Daubert* focus on the reliability of an expert's principles, methods, and application of those methods—not the stylistic choices reflected in the report. If the underlying methodology satisfies the governing standards, an expert's word choice, whether restrained or intemperate, does not bear on admissibility. Any concerns regarding tone are more appropriately addressed through cross-examination or in limine motion practice, not exclusion.

additional time. (Defs.' Kornak Br. at 19–20.) Plaintiffs' own experts submitted supplemental reports responding to O'Brien 2024 within that same short interval.

Against that backdrop, the fact that Dr. Kornak prepared his report under time pressure does not render his methodology unreliable. The record shows that he devoted more than 70 hours to the task. (*See* ECF No. 33011-8, Dr. Kornak Invoice.) Any alleged haste, therefore, goes to the substance and weight of his opinions rather than their admissibility, and is an issue appropriately explored through cross-examination.

The compressed timeline likewise explains Dr. Kornak's reliance on Cornerstone[143] to conduct preliminary research and assist in the preparation of his opinions. Plaintiffs do not contend, however, that Cornerstone's involvement—or that of Defendants' counsel—was improper or that it exerted any undue influence on the substance of Dr. Kornak's analysis. To the contrary, Dr. Kornak testified that he independently formulated his opinions, and nothing in the record suggests that the report was drafted by Cornerstone or counsel without his input or substantive analytical work. (*See* ECF No. 33011-10 ("Kornak Dep.") at 48:10–22.) Accordingly, the participation of Cornerstone and counsel implicates the weight of

[143] Cornerstone is a consulting firm that connects attorneys with applicable experts to provide testimony on litigation matters, among other things, and at times, will provide administrative support to the testifying expert. (*See* Kornak Dep. at 28:17–30:3, 33:22–35:15.) Dr. Kornak does not have an employment relationship with Cornerstone. (*Id.*)

Dr. Kornak's opinions, not their admissibility under Rule 702. *See Venus v. Seville Food, LLC*, No. 14-cv-2476, 2017 WL 2364192, at *17 (D.N.J. May 31, 2017).

Finally, Plaintiffs contend that Dr. Kornak's opinions are unreliable because he did not fully read certain articles cited in O'Brien 2024, pointing to portions of his deposition testimony in support of this claim. (Pls.' Kornak Br. at 23.) Plaintiffs center their argument on Dr. Kornak's purported failure to thoroughly digest one such article—White & Royston, *Imputing Missing Covariate Values for the Cox Model*, 28 Statist. Med. 1982 (2009)—which O'Brien 2024 cited in support of including ovarian cancer status in its imputation model. Although Dr. Kornak acknowledged that his review of White & Royston was limited, the record does not support the inference that he ignored or refused to consider the study. Rather, his testimony reflects that he reviewed the article for its relevance to O'Brien 2024 and concluded that it did not alter his assessment of the methodology employed. (Kornak Dep. at 332:14–336:9.) Plaintiffs' criticism therefore challenges his review and conclusion of lack of relevance of this article, not the reliability of the methods he applied.

Such challenges go to the weight of Dr. Kornak's testimony. They are appropriately addressed through cross-examination, not through exclusion under Rule 702. *See In re Testosterone Replacement Therapy*, 2018 WL 4030585, at *6 (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").

Therefore, I recommend that the Court deny Plaintiffs' Motion to Exclude the Opinions of Dr. Kornak.

VI. CONTAMINATION AND TESTING MOTIONS

The parties have filed six motions addressing issues generally related to contamination and testing. These motions concern, *inter alia*, (1) the testing of Defendants' talcum powder products for the presence of asbestos; (2) whether the mines from which Defendants obtained talc for their products were contaminated with asbestos; (3) whether asbestos, heavy metals, and fragrance chemicals allegedly present in Defendants' talcum powder products cause or contribute to ovarian cancer; and (4) whether the gynecologic tissue of certain bellwether Plaintiffs contained talc or other deleterious particles.

Before turning to these motions, I address two preliminary matters. First, Defendants seek to preclude Dr. Longo from testifying in this MDL regarding his findings of chrysotile asbestos in Defendants' talcum powder products, based on his new—and purportedly improved—PLM methodology. Defendants have requested, and I agreed to, a *Daubert* evidentiary hearing to assess the reliability of Dr. Longo's PLM-chrysotile opinions. Those hearings took place on January 15 and 16, 2026. Importantly, Plaintiffs represent that Dr. Longo's PLM-chrysotile testing will not be

offered during any of the six bellwether trials, including the first of such bellwethers, *Judkins*.

To expedite resolution of the Rule 702 motions and to ensure that the first bellwether trial proceeds without unnecessary delay, I have reserved decision on the admissibility of Dr. Longo's PLM-chrysotile opinions pending the *Daubert* evidentiary hearing. Accordingly, this Report and Recommendation does not address the portion of Defendants' asbestos motion challenging Dr. Longo's new PLM methodology. (ECF No. 33012-2 ("Defs.' Asbestos Br.") at 18–57.) Likewise, I have reserved decision on Plaintiffs' Motion to Exclude the Asbestos Testing Opinions of Matthew S. Sanchez, Ph.D., Ann G. Wylie, Ph.D., and Shu-Chun Su, Ph.D.[144] (ECF No. 33006), as these doctors rebut Dr. Longo's new PLM opinions. A separate Report and Recommendation addressing Dr. Longo's PLM-chrysotile opinions will issue following the hearing.

Second, two of Defendants' motions advance causation-related arguments that are more appropriately considered in the context of general causation. Defendants' asbestos motion seeks to exclude more than a dozen of Plaintiffs' experts from testifying that the asbestos and "fibrous talc" allegedly contained in Defendants' products causes ovarian cancer. (Defs.' Asbestos Br. at 83–93, 97–102.)

[144] Dr. Su testified at a Rule 104 hearing before me on January 15, 2026. Due to time constraints, Dr. Wylie's testimony is being separately rescheduled.

In addition, Defendants' heavy metals and fragrances motion exclusively advances causation-related arguments; Defendants seek to exclude eighteen Plaintiffs' experts from testifying that Defendants' products "contain trace amounts of purportedly carcinogenic heavy metals (nickel, chromium and cobalt) and fragrances that cause, or contribute to causing, ovarian cancer." (Defs.' Heavy Metals and Fragrances Br. at 1.) Consequently, I have addressed Defendants' causation-related arguments concerning asbestos, heavy metals, and fragrances in the general causation section above. (*See supra* Parts V.B.6, 7.)

A. Asbestos

In this section, I address two motions: Defendants' Motion to Exclude Plaintiffs' Experts' Asbestos-Related Opinions (ECF No. 33012) and Plaintiffs' Motion to Exclude the Geology Opinions of Drs. Mary Poulton and Laura Webb (ECF No. 32996).

1. Defendants' Motion to Exclude Plaintiffs' Experts' Asbestos-Related Opinions

i. Drs. William Longo and Mark Rigler

In this this round of *Daubert* motions, Defendants have again moved to "exclude Dr. Longo's TEM testing for amphibole asbestos." (Defs.' Asbestos Br. at 57.) In my prior Opinion, after considering Defendants' arguments and evaluating the reliability of Dr. Longo's three-step TEM methodology, I concluded that Plaintiffs met their burden of establishing that Dr. Longo's opinion concerning the

results of his TEM analysis is reliable for purposes of admissibility under *Daubert*. *In re Johnson & Johnson*, 509 F. Supp. 3d at 147–54.

Defendants seek reconsideration under Judge Shipp's April 30, 2024 Memorandum Order, contending that my ruling "rests on a basis that is no longer viable under the amendments to Rule 702." (Defs.' Asbestos Br. at 67.) They reason that portions of my prior Opinion in this context improperly characterized their challenges to Dr. Longo's methodology as matters of weight for the jury. (*Id.* at 65–67.) Aside from that contention, Defendants' arguments made here concerning Drs. Longo's and Rigler's TEM-amphibole opinions remain substantially unchanged—*often repeating verbatim*—the arguments previously raised during the initial round of motion practice. (*Compare* Defs.' Asbestos Br. at 57–82 *with* ECF No. 9736-3 ("Defs.' 2019 Asbestos Br.").)

For the reasons set forth below and in the 2020 Opinion, I recommend that the Court deny Defendants' motion to exclude the TEM-amphibole opinions of Drs. Longo and Rigler. Defendants have not demonstrated that my prior ruling admitting TEM testing demonstrably failed to adhere to Rule 702 as clarified by the 2023 amendment. Nor have they presented any new science in support of their current position that would materially change the outcome. In essence, Defendants simply disagree with my prior ruling, which is not a valid basis for reconsideration under the April 30, 2024 Order. Nonetheless, for the sake of completeness and for the

benefit of the Court, I will again examine whether Drs. Longo and Rigler reliably applied their three-step TEM methodology in identifying amphibole asbestos particles in Defendants' talcum powder products.

a. Qualifications

I must first address whether Drs. Longo and Rigler are qualified to testify as experts in this MDL. In my prior Opinion, I found Dr. Longo, a materials scientist, "qualified to testify as an expert on the issue of whether the subject talc products contain asbestos." *In re Johnson & Johnson*, 509 F. Supp. 3d at 147. Defendants do not challenge this particular ruling. Accordingly, since no new issues have been raised regarding his expertise, my prior reasoning and ruling that Dr. Longo is qualified to testify as an expert in this litigation stands.

Defendants' motion also addresses Dr. Rigler, a microbiologist who was the Chief Science Officer at Dr. Longo's company, MAS. Defendants state that Dr. Rigler "had a much more limited role related to the talc testing at issue and has since left MAS," but "he was listed as a co-author of one of the earlier MAS reports." (Defs.' Asbestos Br. at 10–11.)

I noted in my prior Opinion that Plaintiffs "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." *In re Johnson & Johnson*, 509 F. Supp. 3d at 147 n.23. However, I did not rule on Dr. Rigler's qualifications.

In opposition to Defendants' motion, Plaintiffs argue that "Drs. Longo and Rigler are uniquely qualified to analyze the asbestos content of" Defendants' talcum powder products, and that "their testimony is admissible under the Federal Rules of Evidence." (ECF No. 33131 ("Pls.' Asbestos Opp. Br.") at 18.) Defendants do not dispute Dr. Rigler's qualifications in their briefing.

I find that Dr. Rigler is qualified to testify in this matter. Dr. Rigler received a Ph.D. in Microbiology from the University of Georgia. (ECF No. 33132-2 Ex. 9 ("Rigler Curriculum Vitae") at 1.) He worked at MAS with Dr. Longo for approximately 30 years, holding various positions including Chief Science Officer and Senior Consulting Scientist. (*Id.*) Dr. Rigler specializes in electron microscopy and has experience testing for the presence of asbestos. (ECF No. 33132-2, Ex. 11 ("Rigler Dep. Tr.") at 8:24-9:17; 219:21-223:2.) Dr. Rigler has authored or coauthored dozens of scientific publications and is a member of several professional organizations, including the American Society for Testing and Materials. (Rigler Curriculum Vitae at 1–4.) Since 2019, Dr. Rigler has worked at MAS as a Senior Consulting Scientist. (*Id.* at 1.) Based on these past experiences and academic background, I find Dr. Rigler qualified to offer his expert opinion in microbiology, electron microscopy, and whether Defendants' talc products contain asbestos.

b. Methodology and Conclusions

In their Second Supplemental Report dated February 1, 2019, which was the subject of my prior TEM-amphibole ruling, Drs. Longo and Rigler describe the three-step TEM methodology used by MAS to detect asbestos in Defendants' talc products.[145] (ECF No. 33014-25 ("Longo 2d Supp. Rep.").) Dr. Longo also testified about TEM methodology during the previous *Daubert* evidentiary hearing over which I presided.

In their report, Drs. Longo and Rigler explained that MAS tested historical samples of Johnson's Baby Powder, Shower to Shower, and "Imerys' railroad car cosmetic talcum powder"[146] from the 1960s through the early 2000s "for the possible presence of amphibole asbestos." (*Id.* at 2.) MAS's TEM analysis purportedly established that 42 of the 70 samples tested "contained detectable amounts of amphibole asbestos fibers and bundles (tremolite solid solution series and or anthophyllite solid solution series)." (*Id.* at 8; *see id.* at 17–18, 22, 31–32.) For perspective, the report stated: "The total amount of regulated asbestos structures counted in the 42 positive . . . samples was 187 bundles and fibers." (*Id.* at 25.)

---

[145] I note that neither Dr. Longo's Third Supplemental Report of November 17, 2023, nor his Fourth Supplemental Report of April 29, 2024, reported any new studies or information regarding the TEM methodology or results; they are directed to his PLM testing.

[146] Imerys Talc America, Inc. f/k/a Luzenac America, Inc. f/k/a Rio Tinto Minerals, Inc. is a former supplier of talc to Defendants.

To prepare the talcum powder samples for TEM testing, MAS analysts used a heavy liquid separation technique. (*Id.* at 11–12; *see* ECF No. 33132-1, Ex. 5 ("*Daubert* H'rg Tr.") at 474:21–477:24; 483:6–20.) This method concentrated the samples by placing the talcum powder into a test tube containing a heavy liquid solution and spinning it in a centrifuge, which caused lower density materials, such as talc, to "go to the surface" and higher density materials, such as amphibole asbestos, to "go to the bottom of the test tube." (*Id.* at 477:11–24.) Dr. Longo testified that heavy liquid separation is a generally accepted preparation method.[147] (*Id.* at 652:2–5.)

Next, MAS analysts examined the samples under a transmission electron microscope.[148] (Longo 2d Supp. Rep. at 12–13; *see Daubert* H'rg Tr. at 486:8–16.) Drs. Longo and Rigler explained that it is "well recognized" that the use of a transmission electron microscope "is the only analytical method with the appropriate sensitivity for the analysis of trace mineral concentrations that can be much less than

[147] Defendants do not challenge or otherwise object to the reliability of Drs. Longo's and Rigler's heavy liquid separation method, and I have no basis to find that this method has not been generally accepted in the scientific community or is otherwise unreliable.

[148] Transmission electron microscopes work by generating and passing a beam of electrons through a sample to form an image. (IWGACP White Paper at 27.) Dr. Longo testified that such a microscope can cost approximately $750,000. (*Daubert* H'rg Tr. at 463:2–9.) PLM, by contrast, "is an optical microscopy technique where the illumination of the object under view involves polarized visible light." (IWGACP White Paper at 26.) "This technique can be used to identify minerals based on optical properties." (*Id.*)

0.01 wt. %." (Longo 2d Supp. Rep. at 5.) At the *Daubert* hearing, Dr. Longo explained the advantages of using TEM over PLM:

> Q. What is briefly transmission electron microscopy, and how does it compare to PLM, polarized light microscopy in terms of the advantages and disadvantages when you are testing talc for asbestos?
>
> A. The advantages are it allows you to get a much higher sensitivity. It allows you to identify the asbestos fibers according to the rules using microchemistry. It allows you to determine the crystalline structure using the diffraction technique. It doesn't use light. It uses electrons. So that because you are using electrons, you could see much smaller size asbestos fibers than you see in the polarized light microscopy because you are using light. It is a much more sensitive instrument, and it is probably the instrument that should be used for the analysis of asbestos for talc.

(*Daubert* H'rg Tr. at 487:8–23.)

Dr. Longo then set forth the three-step TEM methodology that MAS used to identify amphibole asbestos in the talcum powder samples:

> Q. Is there a general consensus in the scientific community as set forth in the published methods as to the three steps that have to be undertaken when doing transmission electron microscopic analysis on a material to determine whether it contains asbestos?
>
> A. Yes, there is.
>
> Q. We're looking at page 12 of your report, and I circled step No. 1. That is step No. 1?
>
> A. It is called morphology, the dimensions of the fiber or bundle of asbestos you are looking at. Step 1 has

> to have an aspect ratio greater than or equal to 5-to-1. The length of the asbestos structure has to be at least a half a micrometer in length or greater. It has to have substantially parallel sides so that each side of the asbestos structure essentially is almost straight. You could have a little bit of crookedness, but substantially parallel. That is Step 1.
>
> Q. What is Step 2 as shown in your report?
>
> A. Step 2 is once you have made, that you can see and measure that Step 1 is satisfied, you perform mineral chemistry called energy dispersive X-ray analysis to determine the chemistry of that particular asbestos structure. So it gives you the ability to do that. That's Step 2.
>
> Q. What is Step 3 as shown in the slide and in your expert report?
>
> A. Step 3 is to perform what's called selected area electron diffraction or SAED, which gives you information on the crystalline structure of that asbestos structure.

(*Id.* at 487:24–489:4; *see id.* at 645:16–646:12.) Dr. Longo testified that only fibers or fiber bundles that satisfied all three steps of this TEM methodology were considered positive for asbestos. (*Id.* at 517:13–519:6; 524:1–5; 648:16–649:19; *see* Longo Second Suppl. Rep. at 12–13.)

c. Analysis

Defendants argue that Drs. Longo's and Rigler's TEM methodology is unreliable because they ignore "clear definitions for 'asbestos' and 'asbestiform' in the methodologies and regulations they rely on," instead defining "what they call 'asbestos' solely by reference to whether a mineral structure meets certain 'counting

criteria.'" (Defs.' Asbestos Br. at 65.) Defendants specifically object to Drs. Longo's and Rigler's reliance on the counting criteria (or rules) set forth in the EPA's AHERA regulations. (*Id.* at 68–69.)

Defendants contend that AHERA defines asbestos as the asbestiform varieties of the six regulated minerals, but the AHERA counting criteria relied upon by MAS—that a particle "has an aspect ratio greater or equal to 5:1, a length greater or equal to .5 microns, and parallel sides"—"sweeps in minerals that cannot be asbestos because they are not asbestiform," including cleavage fragments. (*Id.*) Defendants further contend that "the fact that a particle meets this definition under the counting criteria means simply that it is a fiber; it doesn't provide any information about what kind of fiber it is." (*Id.* at 69.) As a result, "Dr. Longo and Dr. Rigler will count all 'fibers' of the minerals as 'asbestos' even if not asbestiform and therefore not asbestos." (*Id.*) Defendants claim this "methodological failing renders their purported identification of asbestos wholly unreliable." (*Id.* at 68.)

Next, Defendants argue that, because "AHERA relates to remediation," its counting criteria apply only when "asbestos is known to be present" and not when, "as here, the presence of asbestos is disputed." (*Id.* at 69–70.) According to Defendants, "it would clearly be impermissible for Drs. Longo and Rigler to import a methodology developed for identifying the amount of asbestos known to be present to a context where the entire point of the analysis is to determine whether or not

asbestos is present in the first instance;" therefore, their TEM method "fails to answer the relevant question and is thus inherently unreliable." (*Id.* at 71–72.)

In my prior Opinion, I found Drs. Longo's and Rigler's three-step TEM methodology reliable under *Daubert* and generally accepted in the scientific community. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 148–54. I expressly rejected Defendants' arguments regarding AHERA, finding the "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." *Id.* at 150; *see* Fed. R. Evid.702 advisory committee's note to 2023 amendment ("[O]nce the court has found it more likely than not that the admissibility requirement has been met, any attack by the opponent will go only to the weight of the evidence.").

After noting that Dr. Longo agreed with Defendants that—at the first step of the TEM methodology—"certain cleavage fragments could be counted as asbestos" under the AHERA counting criteria, I reasoned that Defendants' position "does not take into account" that steps two and three of the TEM methodology seek to eliminate certain fibers, which are counted in step one, that are not asbestos. *In re Johnson & Johnson*, 509 F. Supp. 3d at 149–50. As Dr. Longo testified, steps two and three of the methodology "eliminate most of those fragments based on their chemistry and electron diffraction pattern." *Id.* at 150. Furthermore, Defendants did not then—and do not now—challenge whether MAS performed its "counting in

accordance with the AHERA counting rules." *Id.* Instead, both then and now, "Defendants take issue with the rules themselves" as applied to the testing of consumer talc products. *Id.* Finally, I found that Dr. Longo set forth good grounds to apply the AHERA counting criteria in situations where the substances being tested were not previously confirmed to contain asbestos. *Id.* at 149–50. I further highlighted that, while they "contend the AHERA counting rules are not accurate," Defendants did "not identify to which set of rules Dr. Longo should have adhered." *Id.* at 150.

I find no reason to depart from my prior ruling because Plaintiffs have established, by a preponderance of the evidence, that the three-step TEM methodology employed by Drs. Longo and Rigler satisfies the admissibility requirements under Rule 702 and *Daubert*. I am persuaded, after reviewing the evidence and the parties' arguments, that Drs. Longo's and Rigler's methodology is generally accepted within the scientific community and constitutes a sufficiently reliable means of identifying asbestos in talc-based consumer products. I am also satisfied that MAS's analysts reliably applied this methodology in conducting their testing. Notably, Defendants' challenges focus primarily on the alleged unreliability of the methodology itself, rather than its application by MAS's analysts. Accordingly, I turn to Defendants' arguments and explain why, within the

framework of Rule 702, their criticisms of Drs. Longo's and Rigler's TEM methodology go to the weight of the evidence, not its admissibility.

Testing for trace amounts of asbestos is no simple feat, as asbestos fibers are exceedingly small. To this day, there is little dispute within the scientific community that no standardized, U.S. government-approved microscopy method exists for detecting asbestos in talc-containing cosmetic products. (IWGACP White Paper at 4–7.) But that does not mean tests are not performed, or should not be performed, to detect asbestos—particularly since such testing is necessary to identify and prevent exposure to potential carcinogens. Laboratories have employed multiple analytical techniques, including scanning electron microscopy, PLM, and TEM. (*Id.* at 14–16.) Each of these methods has advantages and limitations, (*id.*), although "most accredited laboratories with expertise in asbestos-testing routinely perform TEM when testing talc-containing cosmetic products," (*id.* at 10). Admittedly, the absence of a standardized testing method for talc-based cosmetic products has led "laboratories to combine and/or adapt published testing methods developed for the analysis of asbestos in air or building materials," (*id.* at 11), including those established under AHERA. (*Id.* at 11–16.) Thus, Defendants' argument that Drs. Longo's and Rigler's TEM methodology is unreliable simply because "AHERA relates to remediation, *i.e.*, the process of removing asbestos from schools and other environments where asbestos is known to be present," is not only unavailing, but

misses the mark. (Defs.' Asbestos Br. at 69.) At the outset, I note that if I were to adopt Defendants' position and find that it is unreliable for laboratories such as Dr. Longo's MAS to use and incorporate microscopy methods for asbestos in air, bulk building materials, and other matters, it would follow that no reliable method exists to identify asbestos in cosmetic products. This defies conventional wisdom.

Furthermore, and more importantly, Drs. Longo and Rigler did not rely solely on AHERA in formulating the counting criteria that MAS used to determine morphology at step one of the TEM methodology. Their Second Supplemental Report provided that "fibers or bundles with substantially parallel sides and an aspect ratio of 5:1 or greater, and at least 0.5 μm in length were counted as regulated asbestos fibers and bundles per standard TEM counting rules as described by ASTM D5755, ASTM D5756, ISO 10312, ISO 13794, AHERA (TEM section only) and D7712-11."[149] (Longo 2d Supp. Rep. at 12.) Dr. Longo testified at the *Daubert* evidentiary hearing that the counting rules that MAS used are "pretty much the same counting rules for all the standard TEM methods, the American Society of Testing Materials, International Standards Organization, and EPA. They all use the counting rules to determine the morphology." (*Daubert* H'rg Tr. at 495:5–14.) He further

[149] ASTM International, formerly known as American Society for Testing and Materials ("ASTM"), is a standards organization that develops and publishes voluntary consensus standards, including test methods. Similarly, the International Organization for Standardization ("ISO") is an independent, non-governmental international organization that develops and publishes standards such as test methods.

testified regarding the preamble to the AHERA regulations, which explains the rationale for classifying a particle with an aspect ratio of 5:1 or greater as asbestos: "It is consistent with the panel of microscopists' observations that asbestos structures have aspect ratios equal to and greater than 5:1 whereas the majority of nonasbestos structures, minerals and particles . . . have aspect ratios of less than 5:1." 52 Fed. Reg. 41826, 41840 (Oct. 30, 1987). Thus, a particle that satisfies AHERA's counting criteria exhibits a fibrous morphology consistent with asbestos (which is then to be confirmed at steps two and three of the TEM methodology).

Defendants nevertheless contend that the counting criteria used by MAS cannot reliably distinguish between asbestos and non-asbestos cleavage fragments, reasoning that "because of the way amphibole rocks break, you can get some pieces that would be longer and thinner and could resemble asbestos fibers if examined individually." (Defs.' Asbestos Br. at 65, 67–68.) Dr. Longo testified that cleavage fragments—that is, crushed up pieces of non-asbestiform rock—are not asbestos. (*Daubert* H'rg Tr. at 569:15–20.) He also acknowledged that cleavage fragments can resemble asbestos fibers under a transmission electron microscope, and that there is a "slight chance" that some fragments can have a minimum length greater than or equal to .5 microns, an aspect ratio of 5:1, and substantially parallel sides, "but the probability is not too high." (*Id.* at 574:5–23.) Dr. Longo explained that the "overwhelming majority of these cleavage fragments" have an aspect ratio less than

3:1. (*Id.* at 574:24–575:18; *see* ECF No. 33132-1 ("Longo Dep.") at 238:13–19; 240:21.) Therefore, while it is possible that a cleavage fragment could satisfy the AHERA counting criteria, Plaintiffs have presented good grounds to conclude that, at step one of the TEM methodology, the criteria used by MAS can reliably distinguish between asbestos and non-asbestos, including cleavage fragments.

Additionally, Defendants contend that "AHERA defines asbestos as the ***asbestiform*** varieties of the six regulated minerals" but "Drs. Longo and Rigler act as though" the AHERA counting criteria are "AHERA's definition of asbestos." (Defs.' Asbestos Br. at 69.) According to Defendants, the AHERA counting criteria relied upon by MAS cannot distinguish between asbestiform and non-asbestiform minerals, which they claim is necessary to determine whether a mineral qualifies as asbestos.[150] (*Id.*) Plaintiffs counter that asbestiform versus non-asbestiform is a "false distinction" in this context, and that the generally accepted three-step TEM methodology was designed to identify regulated asbestos. (Pls.' Asbestos Opp. Br. at 29–33.) I agree with Plaintiffs on this issue.

Drs. Longo and Rigler do not treat the AHERA counting criteria as AHERA's definition of asbestos, and any suggestion to the contrary reflects a misunderstanding

[150] In their brief, Defendants explain that the term asbestiform is an adjective describing the distinctive way a mineral forms in nature, *i.e.*, its habit. (Defs.' Asbestos Br. at 57–58.) "Minerals that crystallize in an asbestiform habit have a crystal structure that can be separated into fibers with high tensile strength and flexibility." (*Id.* at 58.)

of the distinction between how U.S. regulatory agencies define asbestos and how laboratories identify the presence of asbestos using TEM analytical methods. It is undisputed that the AHERA counting criteria do not require a microscopist to determine whether a particle is "asbestiform"—that is, the microscopist does not need to determine the particle's habit of growth, but that limitation does not render Drs. Longo's and Rigler's TEM methodology unreliable. Dr. Longo testified that the purpose of the AHERA counting criteria, at step one, is to identify minerals exhibiting a fibrous morphology consistent with asbestos. (*Daubert* H'rg Tr. at 467:6–468:19.) Since a fibrous morphology alone does not establish that a mineral is asbestos, Drs. Longo's and Rigler's TEM methodology incorporates two complementary analytical techniques to confirm the presence of asbestos. At step two of the methodology, MAS performed an energy dispersive X-ray analysis ("EDXA") to confirm that the chemical composition of the mineral is consistent with that of asbestos, as opposed to talc or some other unregulated mineral. (Longo Second Suppl. Rep. at 12–13; *see Daubert* H'rg Tr. at 487:24–489:4; 524:1–5; 645:16–646:12.) At step three, MAS conducted selected-area electron diffraction ("SAED") to confirm that the crystalline structure of the mineral matched reference standards for asbestos. (*Id.*) Only fibers or bundles that satisfied all three steps were

counted as amphibole asbestos.[151] (*Id.*) Defendants' argument focuses solely on step one of the methodology without regard for the remaining two steps, and thus, they fail to account for the reliability of the methodology as a whole. I am not persuaded, in light of the evidence presented by Plaintiffs, that Drs. Longo's and Rigler's reliance on the AHERA counting criteria at step one renders their methodology unreliable.

Tellingly, Johnson & Johnson previously used a similar TEM method to identify "asbestiform minerals in powdered talc." (ECF No. 33132-3 ("J&J Test Method TM7024") at 2.) Dr. Mary Poulton, a geological engineer and one of Defendants' experts in this MDL, confirmed that this method was used to test talc from Johnson & Johnson's source mines. (ECF No. 32996-8 ("Poulton Rep.") at 13.) The method, TM7024, states that the "combined techniques of transmission electron microscopy (TEM), selected area electron diffraction (SAED) and energy dispersive x-ray analysis (EDXRA) permit the detection of asbestiform minerals based on morphological characteristics, followed by a definitive mineralogical identification of each fiber." (J&J Test Method TM7024 at 2.) Additionally, this method defines a fiber similar to Drs. Longo and Rigler: "An elongated particle with parallel sides and

[151] In my prior Opinion, I found Drs. Longo's and Rigler's EDXA and SAED methods sufficiently reliable for purposes of *Daubert*. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 152–54. Defendants no longer challenge those methods, like they did during the first round of motions. (*See* Defs.' 2019 Asbestos Br. at 50–72.)

an aspect ratio K3:1." (*Id.* at 8.) In fact, Dr. Longo testified that using an aspect ratio of 5:1, like he did, is more conservative and restrictive than using an aspect ratio of 3:1. (*Daubert* H'rg Tr. at 497:11–499:3.) Defendants do not claim otherwise.

Finally, Defendants contend that Drs. Longo's and Rigler's TEM analysis cannot reliably distinguish between a single fiber and a bundle of fibers. (Defs.' Asbestos Br. at 74–83.) I considered this same argument in my prior Opinion, finding that "these issues go to the weight of Dr. Longo's opinions, rather than reliability." *In re Johnson & Johnson*, 509 F. Supp. 3d at 151; *see id.* at 150–52.

I previously concluded that "any errors in differentiating between fibers and bundles" at step one of the TEM methodology "do not ultimately demonstrate that Dr. Longo's testing is unreliable," because steps two and three "further confirm whether the counted fibers or bundles" identified at step one are, in fact, asbestos. *Id.* at 151–52. Other than a conclusory claim in a footnote that this "puts the cart before the horse," (Defs.' Asbestos Br. at 74 n.198), Defendants do not meaningfully address this conclusion, nor do they adequately explain how an alleged inability to distinguish between a single fiber and a bundle of fibers renders Drs. Longo's and Rigler's methodology unreliable. It is undisputed that the TEM method does not require a determination that a particle formed in an asbestiform habit. (*Daubert* H'rg Tr. at 524:1–5; 587:17–582:3; 582:9–17; 589:25–590:5.) Rather, the method applies counting criteria to identify a particle's fibrous morphology, then confirms its

elemental composition and crystal structure through EDXA and SAED analyses. (*Id.*) Only particles satisfying all three steps of the methodology are classified as asbestos, regardless of whether the particle is a fiber or a bundle of fibers. (*Id.*) According to Dr. Longo, a bundle of fibers is simply further confirmation that the particle is asbestiform. (*Id.*)

In conclusion, Defendants' motion that my prior ruling be reconsidered and the outcome changed is rejected. Plaintiffs have demonstrated, by a preponderance of the evidence, that Drs. Longo's and Rigler's three-step TEM methodology can reliably detect the presence of amphibole asbestos in talc-containing products and is generally accepted in the scientific community. In fulfilling my role as gatekeeper, I am not required to find that Drs. Longo's and Rigler's methodology is perfect or that every MAS testing result is correct. *See Daubert*, 43 F.3d at 1318 (explaining the test "is not the correctness of the expert's conclusions but the soundness of his methodology"); *In re Paoli*, 35 F.3d at 744 (stating that the grounds for an expert's opinion "do not have to be perfect" and "good grounds for an expert's conclusions" may exist "even if the judge thinks that a scientist's methodology has some flaws"); *see also Best v. Lowe's Home Centers, Inc.*, 563 F.3d 171, 181 (6th Cir. 2009) ("Admissibility under Rule 702 does not require perfect methodology."). Furthermore, Defendants have not presented any new evidence that would warrant reconsideration of the TEM testing technique or the bases upon which the

conclusions drawn from that testing rest. Defendants' criticisms of Drs. Longo's and Rigler's methodology primarily concern the inherent limitations of TEM, albeit an accepted method, as an analytical technique, rather than the specific methodology employed here. However, these criticisms do not move the needle on my finding that Drs. Longo's and Rigler's overall TEM methodology is more likely than not reliable for the reasons set forth above and in my prior Opinion. Accordingly, to the extent Defendants take issue with the limitations of TEM or the results of MAS's testing, such concerns are appropriately explored through cross-examination.

ii. Drs. Robert Cook and Mark Krekeler

Next, Defendants argue that "Drs. Cook and Krekeler's opinions about the alleged presence of asbestos in talc" or from Defendants' source mines should be excluded "because their opinions are not derived from reliable methods and are not supported by the data on which they rely." (Defs.' Asbestos Br. at 93.) Defendants claim that both experts "unreliably base their opinions on counsel-generated collections and summaries of documents." (*Id.* at 94.) They further contend that "Drs. Cook and Krekeler's opinions are also unreliable and inadmissible because the documents on which they rely do not support their conclusions."[152] (*Id.* at 95.)

[152] Notably, Defendants only dedicate a few pages of their asbestos brief to the alleged unreliability of Drs. Cook and Krekeler's opinions. And they do not address Drs. Cook's and Krekeler's reports and methodologies in any meaningful way. For the purposes of completeness, I will discuss these experts in greater detail.

In opposition, Plaintiffs argue that Drs. Cook's and Krekeler's opinions are supported by reliable scientific evidence that establishes asbestos was present in the talc ore used to source Defendants' talcum powder products. Plaintiffs further argue that the charts compiled by counsel were merely clerical summaries of documents that the experts independently reviewed and relied on. While Plaintiffs admit that the charts contain "a few inadvertently included examples not sourced from the correct mines or intended for industrial use" (Pls.' Asbestos Opp. Br. at 89), they maintain that Defendants' criticisms go to weight, not admissibility.

I did not address Drs. Cook's and Krekeler's proposed testimony in my prior Opinion. Accordingly, my analysis of this portion of Defendants' motion is not controlled by Judge Shipp's April 30, 2024 Order. I will fully consider the parties' positions.

a. Qualifications

Plaintiffs proffer Dr. Cook as an expert in the fields of geology and mining, and Dr. Krekeler in the fields of geology, mineralogy, and environmental geoscience. (ECF Nos. 33017-9 and -10 ("Cook Amend. Rep."); Krekeler Rep.) Defendants do not dispute that Drs. Cook and Krekeler are qualified to testify within their proffered fields of expertise.[153] In light of their training and experience, and

[153] Defendants do, however, argue that Drs. Cook, Krekeler, and nearly all of Plaintiffs' other experts are not qualified to testify regarding the carcinogenicity of heavy metals. As noted above, I addressed Defendants' causation-related arguments in the general causation section. (*See supra*

Defendants' lack of objection to their qualifications, I find, and thus recommend to the Court, that Dr. Cook is qualified to act as an expert in the fields of geology and mining, and that Dr. Krekeler is qualified to act as an expert in the fields of geology, mineralogy, and environmental geoscience.

b. Dr. Robert Cook's Methodology and Conclusions

Dr. Cook stated in his report that he was "asked to review the geology of the talc deposits that sourced Defendants' talcum powder products, to evaluate the mining practices employed, and to assess Defendants' sampling and testing from a mining perspective." (Cook Amend. Rep. at 2.)

Dr. Cook explained that, in forming his opinions, he "reviewed the following: results of my professional experience examining talc and related mineral occurrences, my experience with optical examination of drill core and commercial rock products for asbestos and other related minerals, the published literature, and documents produced in this litigation." (*Id.* at 3; Ex. B at 1–21.) He testified at his deposition that he reviewed over a thousand pages of documents, and that he approached this matter "as I would any research project" or consulting project for a mining company. (Cook Dep. at 456:1–462:16.) Dr. Cook's report addressed, among other topics, the mining and processing of talc ore, the specific mines from which

Part V.A.) In that section, I also addressed Drs. Cook's and Krekeler's credentials and professional experience, which I will not repeat here.

Defendants sourced their talc, the mineralogical characteristics of those deposits, and historical testing that purportedly identified asbestos and other contaminants in the source mines. (Cook Amend. Rep. at 3–21.)

Relevant to Defendants' arguments, Dr. Cook included in his report a chart summarizing testing "conducted by or for J&J and Imerys," which he claimed represents "some of the reported instances within Defendants' internal documents where serpentine asbestos (chrysotile), amphibole asbestos, or potentially asbestiform amphiboles have been found in samples of talc used to source J&J talcum powder products." (*Id.* at 13.) This chart compiled documents from the 1950s through the 2000s and contains roughly 100 entries. (*Id.* at 13–21.) For each entry, it provided—where available—the date of the document, the testing laboratory, the type of material tested (including talc ore, mill samples, and finished product), the source mine, and the corresponding test results. (*Id.*) Dr. Cook stated that this chart "is largely composed of the chart produced during the deposition of Johnson & Johnson corporate representative Dr. John Hopkins." (*Id.* at 13 n.17.) Dr. Cook testified that the first draft of his report contained lengthy narrative descriptions of Defendants' historical testing results, which he found cumbersome. (Cook Dep. at 55:19–60:8.) After reviewing the chart from Dr. Hopkins's deposition, Dr. Cook asked Plaintiffs' counsel to assist in preparing the charts, using information he instructed counsel to include. (*Id.*) He further testified that he reviewed all the

documents cited in those charts, and that he substantively reviewed the charts themselves before issuing his report. (*Id.*)

As it relates to asbestos, Dr. Cook concluded, based on his "education, training, and experience in the fields of mining and geology" as well as his "review of the relevant information," (Cook Amend. Rep. at 2–3), that it is his "opinion to a reasonable degree of scientific certainty that the talc deposits that were used to source Defendants' talcum powder products (Italy, Vermont, and China) contain fibrous talc, and chrysotile and/or fibrous amphiboles, all known human carcinogens." (*Id.* at 42.)

c. Dr. Mark Krekeler's Methodology and Conclusions

In his report, Dr. Krekeler stated that he was "asked to examine whether Imerys and Johnson & Johnson acted in accordance with industry standards and/or maintained adequate quality control in mining talc for use in cosmetic talcum powder products (Johnson's Baby Powder and Shower to Shower)." (Krekeler Rep. at 1.) Like Dr. Cook, Dr. Krekeler's report addressed the locations and geology of the mines from which Defendants sourced their talc, the mining and processing methods employed, and historical testing data reflecting the presence of asbestos and other potential contaminants in the talc deposits at those mines.

To reach the opinions set forth in his report, Dr. Krekeler "reviewed documents, both those produced by the defendants as well as deposition transcripts

of company witnesses." (*Id.* at 2; *see id.*, Ex. B at 72–97.) He "also conducted an extensive review of peer-reviewed literature and other works, such as geologic survey documents and government agency information." (*Id.* at 2.) Finally, he relied on his "experience and methodology in both the academic and private sector in preparing [his] opinions." (*Id.*)

In pertinent part, Dr. Krekeler opined to "a reasonable degree of certainty within the confines of [his] discipline as an expert in mineralogy, geology and environmental geoscience," (*id.* at 1), that "asbestos and fibrous talc was and is present in the mines Defendants used for cosmetic talc." (*Id.* at 45.)

In support of that opinion, Dr. Krekeler explained that the documents he "reviewed provide strong evidence that the talc used by Imerys and Johnson & Johnson to produce Johnson's Baby Powder and Shower to Shower came from mines that contained asbestos minerals, or fibrous talc in an asbestiform habit." (*Id.* at 14.) His report also included a chart summarizing documents that allegedly establish the presence of asbestos in Defendants' source mines. (*Id.* at 14–23.) Dr. Krekeler's asbestos-related chart is largely identical to the chart contained in Dr. Cook's report, and sets forth information such as the date of the document, the testing laboratory, the type of material tested, the source mine, and the corresponding test results. (*Compare id.*, *with* Cook Amend. Rep. at 13–21.) At his deposition, Dr. Krekeler testified that he "asked counsel to create the charts that are in the report,"

and that he reviewed the documents and directed counsel as to which documents to include in those charts. (Krekeler Dep. at 39:9–41:14.)

d. Drs. Robert Cook and Mark Krekeler's "Counsel-Generated Charts"

As an initial matter, relying on *State Farm Fire & Cas. Co. v. Electrolux Home Products, Inc.*, 980 F. Supp. 2d 1031, 1048 (N.D. Ind. 2013) and *Crowley v. Chait*, 322 F. Supp. 2d 530, 546 (D.N.J. 2004), Defendants argue that Drs. Cook's and Krekeler's opinions are unreliable because they serve as mere conduits for "counsel-generated collections and summaries of documents." (Defs.' Asbestos Br. at 94.) According to Defendants, Drs. Cook and Krekeler included "virtually identical" charts in both of their reports, and "the analyses of the documents reflected in these charts plainly were not the work of Drs. Cook and Krekeler but of counsel." (*Id.*)

Plaintiffs insist that Defendants' argument "is directly contravened by Drs. Cook and Krekeler's testimonies and reports." (Pls.' Asbestos Opp. Br. at 89.) Plaintiffs explain that "Drs. Cook and Krekeler requested the creation of the charts based on their examinations of the underlying documents, reviewed the charts, and contributed to their entries," and that counsel merely "performed the clerical task of creating the chart." (*Id.* at 92.) In other words, "the charts were simply clerical compilations of documents reviewed by Drs. Cook and Krekeler." (*Id.* at 93.) On that basis, Plaintiffs argue that the cases Defendants cite—*State Farm* and *Crowley*—are factually distinguishable. (*Id.* at 92–93.)

In *State Farm*, the court barred Dr. Christine Wood, an expert for Electrolux, from testifying as to any conclusion she derived from her comparative analysis of the risk of fire involving Electrolux dryers and dryers in general, including her conclusion that Electrolux dryers are not unreasonably dangerous. *State Farm Fire & Cas. Co.*, 980 F. Supp. 2d at 1035, 1045–51. The court found Dr. Wood's statistical analysis unreliable because she relied solely on data provided by Electrolux regarding its dryer fires and "admittedly did nothing to independently verify the reliability of this information before she used it in her calculations." *Id.* at 1049. The court further observed that Dr. Wood could have—but did not—obtain data on Electrolux dryer fires from one of the same sources she used to determine the number of fires involving dryers manufactured by other companies. *Id.* at 1048–1050. In effect, Dr. Wood merely parroted the information provided to her by Electrolux.

In *Crowley*, the court limited the testimony of expert Loren Kramer because he "relied upon information that is simply too unreliable to be trusted." *Crowley*, 322 F. Supp. 2d at 547. Specifically, "Kramer prepared his reports on the basis of statements prepared by Plaintiff's counsel about the testimony of only eight out of more than 150 deponents" in the case. *Id.* at 545. The court faulted Kramer for relying "on summaries prepared by counsel" and for conducting "little independent investigation into the witnesses beyond the summaries prepared for him." *Id.* at 546.

The court reasoned that "to make Kramer the mouthpiece of these deponents, and to allow him to offer testimony to a jury as to conclusions he has reached on the basis of this highly filtered version of events, is unacceptable." *Id.* at 546–47. Finally, the court stated that "Kramer's reliance upon the spoonfed depositions led him to draw questionable conclusions . . . that he might not have drawn had he properly reviewed all of the depositions in an unfiltered fashion." *Id.* at 547.

State Farm and *Crowley* are inapposite. In both of those cases, the experts formed their opinions based on limited or incomplete information supplied to them by a party or counsel, without independently reviewing or verifying the underlying data. Those are not the circumstances here. Having reviewed their testimony and the charts themselves, I find that Drs. Cook's and Krekeler's deposition testimony clearly reflects that they requested counsel's assistance in preparing the charts, but using information that they directed to be included, such as historical testing results from Johnson & Johnson, and that both experts independently reviewed the documents summarized therein. (*See* Cook Dep. at 55:19–60:8; Krekeler Dep. at 39:9–41:14.) According to Dr. Cook, the chart was intended to improve the overall readability of his final report by replacing the detailed narrative summaries in his draft report with a more concise and organized presentation. (Cook Dep. at 55:19–60:8.) Moreover, and as discussed more fully below, Drs. Cook's and Krekeler's opinions are not based solely on the information contained in the charts; they

reviewed and relied upon additional materials and data, including scientific literature and other documents produced in this litigation, in forming their opinions. In short, unlike *State Farm* and *Crowley*, I do not find that the information included in the subject charts is "highly filtered" data "spoonfed" to the experts by counsel.

Accordingly, I find that Drs. Cook's and Krekeler's inclusion of "counsel-generated" charts in their reports does not render their testimony unreliable because, unlike the experts in *State Farm* and *Crowley*, they did not serve as mere conduits for Plaintiffs and their counsel.

e. The Adequacy of Drs. Robert Cook and Mark Krekeler's Factual Foundation

Defendants next argue that Drs. Cook's and Krekeler's opinions should be excluded as unreliable because some of the documents on which they rely—including certain historical documents and testing results—do not support their conclusions regarding the alleged presence of asbestos in the mines from which Defendants sourced their talc. (Defs.' Asbestos Br. at 95–97.)

First, Defendants contend that "Drs. Cook and Krekeler rely on documents that have nothing to do with the issues presented in this litigation because they are from geographic regions and mines that were not sources of talc for Defendants' talc products." (*Id.* at 95 & n.240.) Second, they assert that "many of the data on which Drs. Cook and Krekeler rely were derived from testing in mines that were used to produce industrial talc—not cosmetic grade talc." (*Id.* at 95–96.) Finally, Defendants

argue that "Drs. Cook and Krekeler fail to differentiate between asbestiform and nonasbestiform minerals" which renders their opinions unreliable because the "presence of nonasbestiform minerals in the mines where [D]efendants sourced their talc cannot support Drs. Cook and Krekeler's logical leap to the conclusion that those mines also contained the asbestiform variety of those minerals." (*Id.* at 96–97.)

Plaintiffs maintain that Defendants' arguments are "meritless" because they "fail to discredit or even acknowledge the numerous examples of Defendants' data that Drs. Cook and Krekeler reference, all showing positive test results for asbestos" in the talc used to source Johnson & Johnson's products. (Pls.' Asbestos Opp. Br. at 89.) Plaintiffs concede, however, that Drs. Cook and Krekeler "inadvertently included" a few "examples not sourced from the correct mines or intended for industrial use." (*Id.*) They nevertheless claim that the "presence of a few documents and reports allegedly involving other mines does not invalidate the substantial data from the mines the parties agree were used to source talc." (*Id.* at 94.) According to Plaintiffs, Drs. Cook's and Krekeler's asbestos-related opinions are supported by a comprehensive body of evidence. (*Id.* at 94–96.) I agree.

It is undisputed that, over the span of approximately a century, Defendants sourced talc from different mines around the world. Dr. Mary Poulton, one of Defendants' own experts, explains that Defendants sourced talc from: (1) the Fontane mine in the Val Chisone region of Italy; (2) southern Vermont, including

the Argonaut, Hamm, Hammondsville, and Rainbow mines; and (3) mines in Guangxi Province, Longsheng County in China. (*See* Poulton Rep. at 2–5.)

After considering their reports, deposition testimony, and the parties' submissions, I find that Plaintiffs have established, by a preponderance of the evidence, that Drs. Cook's and Krekeler's opinions regarding the presence of asbestos at Defendants' source mines in Italy, Vermont, and China are sufficiently supported by general geological principles corroborated by region-specific data. Indeed, by providing "background information, discuss[ing] regional geology and its application, and then focus[ing] on specific mines using Defendants' internal documents," (Pls.' Asbestos Opp. Br. at 96), Drs. Cook's and Krekeler's methodologies are sufficiently reliable under *Daubert*'s more-likely-than-not standard, such that I find their opinions regarding the source mines are admissible.

Drs. Cook and Krekeler began by discussing the formation of talc deposits. (Cook Amend. Rep. at 4; Krekeler Rep. at 2–5.) They explained that talc deposits typically form over millions of years, as preexisting rocks are altered through geological processes that involve heat, pressure, and chemical reactions. (*Id.*) As a result of these geological processes, also known as metamorphism, talc deposits are often accompanied by contaminants such as asbestos. (*Id.*) Simply put, the same metamorphic conditions that produce talc can also produce asbestos. According to Dr. Cook, the distribution of asbestos "can be quite irregular within individual talc

deposits themselves or their immediately adjacent host rocks." (Cook Amend. Rep. at 4.) Dr. Krekeler similarly explained that "natural talc formation is commonly accompanied by veins of other minerals, including asbestiform minerals like tremolite" and that the "presence of asbestos in talc deposits [has] been common knowledge amongst industrial mineral companies, research professionals and mining geologists, dating back to as early as the 1930's (Hess, 1933)." (Krekeler Rep. at 5.) Defendants do not dispute these geological principles.

Next, I address Defendants' argument that Drs. Cook and Krekeler fail to distinguish between asbestiform and non-asbestiform minerals. This assertion raises several issues relevant to the evaluation of historical documents. In addressing this argument, I will also address some of the region-specific data that Drs. Cook and Krekeler rely on in support of their opinions related to Defendants' source mines in Italy, Vermont, and China.

In support of their position, Defendants assert that "Drs. Cook and Krekeler each cite reports from the Battelle Memorial Institute, an organization that tested cosmetic talc samples in the 1950s, for the proposition that cosmetic talc contained tremolite." (Defs.' Asbestos Br. at 96.) They further claim that "the Battelle report does not indicate that the tremolite identified was of the asbestiform variety." (*Id.*)

Defendants' argument is unpersuasive. Drs. Cook and Krekeler have not "ignored" the distinction between asbestiform and non-asbestiform minerals. (*Id.*)

Dr. Krekeler explained in his report that "asbestiform refers to a mineral that has grown into a fibrous aggregate of long, thin and flexible crystals that readily separate into smaller crystals" and noted that the "term fiber is an important qualifier for asbestos" because "there are asbestiform and nonasbestiform varieties of tremolite, actinolite, crocidolite and anthophyllite." (Krekeler Rep. at 4.) Dr. Cook likewise testified that the term asbestiform pertains to a mineral's "fibrous nature." (Cook Dep. at 105:20–106:7.)

Furthermore, Defendants' criticism that Drs. Cook and Krekeler relied on historical documents that did not specify whether the referenced minerals are asbestiform or non-asbestiform is misplaced. Many of the documents from the 1950s, 1960s, and 1970s—including Defendants' own records—do not reflect the level of mineralogical precision that Defendants now demand. That is hardly surprising given that asbestos is a general term with varying definitions, which has contributed to uncertainty in the interpretation of historical evidence. (IWGACP White Paper at 8–9; IARC Monographs vol. 100C at 221.) In that connection, the fact that a document does not expressly state that the tremolite identified in Defendants' talcum powder was of the asbestiform variety does not preclude the reasonable inference that the reference was to tremolite asbestos, for the reasons described below.

For example, both Drs. Cook and Krekeler cited a 1973 memorandum in support of their opinions that Defendants' source mines were contaminated with asbestos. (Cook Amend. Rep. at 15; Krekeler Rep. at 17.) At that time, Defendants were sourcing talc from Vermont. In the memorandum, a Johnson & Johnson executive discussed potential strategies related to the company's asbestos "controversy" and acknowledged that the company had identified "tremolite or actinolite" that "might be classified as asbestos fibers" in its Baby Powder:

> 1. It is our joint conclusion that we should not rely on the "Clean Mine" approach as a protective device for Baby Powder in the current Asbestos or Asbestos-Form controversy. We believe this mine to be very clean; however, we are also confident that fiber forming or fiber type minerals could be found. The usefulness of the "Clean Mine" approach for asbestos only is over.
>
> 2. It is possible that the technique of identification for asbestos or asbestos-form minerals will be an optical approach. It probably will be some variation of the McCrone method. This method with appropriate concentrating techniques will permit a good laboratory to identify asbestos or tremolite in a talc sample.
>
> * * *
>
> b. As for Baby Powder, the entire thrust of our communications with the FDA has concentrated on asbestos as harmful fiber-like material. Sophisticated techniques have been proposed to make sure that fiber-form materials present in samples were identified as being asbestos. The implication is that all other fiber-forms, if present, were talc or other minerals and these were safe. This posture will no longer be satisfactory. If the FDA Food Division, which is moving more rapidly than the

> Cosmetics Division, publishes a standard, it will probably be to ban asbestos-form or fibrous material in talc. That could eliminate the current use of talc in packaging materials. These talcs contain widely varying amounts of tremolite or fibrous talc. Our Baby Powder contains talc fragments classifiable as fiber. Occasionally sub-trace quantities of tremolite or actinolite are identifiable (optical Microscope) and these might be classified as asbestos fiber.

(ECF No. 33132-1, Ex. 2 ("April 26, 1973 Memorandum") at 1–2.) This memorandum plainly indicates that the tremolite and actinolite identified in Defendants' talc were likely asbestos. Thus, Drs. Cook and Krekeler reasonably relied on the memorandum—which was just one of roughly 100 entries in their asbestos-related charts—to support their contamination opinions.

In fact, there is ample evidence to support the conclusion that Defendants' source mines in Vermont were contaminated. Drs. Cook and Krekeler relied on multiple other test results—as set forth in their asbestos-related charts—confirming, for example, the presence of chrysotile, fibrous tremolite, and fibrous actinolite at the Argonaut, Hamm, and Hammondsville mines. (Cook Amend. Rep. at 16, 19–21; Krekeler Rep. at 18–19, 22–23.) Notably, Defendants do not challenge the validity of those other test results, many of which were performed by or for Johnson & Johnson.

Additionally, contrary to Defendants' contention, Drs. Cook and Krekeler reasonably relied on the 1958 Battelle Report in support of their opinions regarding

the presence of asbestos in Defendants' source mines in Italy. In the 1950s, Defendants engaged the Battelle Memorial Institute to conduct testing to determine why their talcum powder exhibited a highly undesirable characteristic known as grit. (W.L. Smith, *Progress Report on Further Studies on the Measurement and Correlation of the Physical Properties of Talc to Johnson and Johnson*, Battelle Mem'l Inst., (1958)). In the 1958 Report, Battelle explained what was causing the grittiness in Defendants' talcum powder:

> Grit consists of that portion of ground talc which is angular, or oversize, particularly in thickness. Grit includes both oversize and nonplaty talc particles as well as mineral contaminants. It occurs as aggregates of talc and contaminants, as acicular and fibrous particles of talc and amphibole, as shards and granules of amphibole or carbonate, and as prismatic grains of titanite, rutile, zircon, apatite, and other accessory minerals.

(*Id.* at 3.) Battelle further stated: "The Italian No. 1 talc contains from less than 1 percent to about 3 percent of contaminants. The contamination is natural and consists mostly of carbonate with minor amphibole and rare accessory minerals . . . . The amphibole component has been established to be the variety tremolite." (*Id.*) While the Battelle Report does not use the term asbestiform—or even the word asbestos—it concludes that Defendants' talcum powder was contaminated with amphibole tremolite, and highlights the presence of fibrous amphibole particles. Thus, it was reasonable for Drs. Cook and Krekeler to conclude that the Battelle Report evidences the presence of tremolite asbestos in Defendants' Italian talc.

While there is ample region-specific data regarding the mines in Italy and Vermont, it is undisputed that there is limited publicly available information concerning the region of China from which Defendants sourced talc, specifically Guangxi Province. Laura Webb, one of Defendants' experts, states in her report: "Little information is available in the peer-reviewed published literature on the talc deposits in the Guangxi Province in China." (ECF No. 32996-9 ("Webb Rep.") at 23.) Dr. Cook agrees that little "is known about Chinese talc deposits." (Cook Amend. Rep. at 12.) Despite these informational gaps, both Drs. Cook and Krekeler explain that talc ore from Guangxi Province occurs in carbonate rock types, which are commonly associated with the presence of actinolite and tremolite. (*Id.* at 4, 10, 12–13; Krekeler Rep. at 10–11.) Defendants do not dispute this general geological principle. Additionally, in reaching his opinions, Dr. Krekeler relied on an article by Dr. Wilhelm Schober entitled "Asia Pacific Talc," (Krekeler Rep., Ex. B at 84), which reports that most mines in Guangxi contain talc deposits hosted in magnesium carbonate rock and that accompanying minerals include tremolite. (Wilhelm Schober, *Asia Pacific Talc*, Indus. Minerals, at 59 (1998); *see* IARC, *Monographs on the Identification of Carcinogenic Hazards to Humans*, vol. 136: Talc and Acrylonitrile 55 (2025) (citing Dr. Schober's article in support of its determination that mines located in Guangxi Province may contain tremolite asbestos).) Further, during oral argument on November 25, 2025, Plaintiffs' counsel noted that a 2019

report prepared by AMA Analytical Services, Inc. for the FDA identified the presence of asbestos in Defendants' talcum powder products. (ECF No. 33132-9 ("AMA Certificate of Analysis dated July 24, 2019").) It is undisputed that Defendants were sourcing talc from China during this period. Although this testing post-dates Dr. Cook's and Dr. Krekeler's reports, it corroborates their opinions regarding the potential presence of asbestos in Defendants' talc supply sourced from China.[154]

Finally, I disagree with Defendants' contention that the presence of a few potentially irrelevant data points renders the opinions of Drs. Cook and Krekeler wholly unreliable. Although an expert's methodology may raise reliability concerns if it relies heavily on test results unrelated to the mines or talc products at issue, that is not the circumstance here. Defendants identify only a small number of allegedly irrelevant items, and the majority of the evidence on which Drs. Cook and Krekeler rely is directly attributable to the regions and mines from which Defendants sourced talc. Put differently, Drs. Cook and Krekeler base their conclusions on a broad body of materials that extends well beyond the isolated test results Defendants claim have tainted their analyses. Even if the challenged data were excluded, the unchallenged data would remain more than sufficient to support their conclusions by a

[154] Plaintiffs' counsel also noted, during oral argument, that Dr. Longo found asbestos in Chinese talc samples. However, these tests were performed using his PLM methodology, not the TEM methodology, the only testing I have found to be admissible under Rule 702 and *Daubert*.

preponderance of the evidence. As case law makes clear, factual imperfections in the data underlying an expert's opinion do not, standing alone, warrant exclusion under *Daubert* so long as the opinion rests on a sufficiently reliable factual foundation. *See Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1299 (Fed. Cir. 2015) ("To the extent [an expert's] credibility, data, or factual assumptions have flaws, these flaws go to the weight of the evidence, not to its admissibility."). Thus, Defendants' criticisms of certain underlying data go to the weight of the evidence and the experts' credibility, not to admissibility.

In conclusion, having reviewed these experts' supporting evidence, taken together, it adequately buttresses their opinions that asbestos was present in Defendants' source mines in Italy, Vermont, and China. Thus, because I find it more likely than not that Drs. Cook's and Krekeler's opinions satisfy Rule 702's admissibility requirements, "any attack by the opponent will go only to the weight of the evidence." Fed. R. Evid.702 advisory committee's note to 2023 amendment. For the reasons set forth above, I recommend that the Court deny Defendants' motion to preclude Drs. Cook and Krekeler from opining on the alleged presence of asbestos in Johnson & Johnson's source mines.

2. Plaintiffs' Motion to Exclude the Geology Opinions of Drs. Mary Poulton and Laura Webb

Plaintiffs seek to exclude the opinions of Defendants' experts, Mary Poulton, Ph.D. and Laura Webb, Ph.D. First, Plaintiffs argue that Drs. Poulton and Webb are

not qualified because they lack the requisite academic or practical experience necessary to support their opinions regarding the lack of asbestos at the mines used by Defendants to source talc. Second, Plaintiffs contend that the opinions of Drs. Poulton and Webb are unreliable and not based on any discernible methodology.

In opposition, Defendants assert that Drs. Poulton and Webb are eminently qualified to offer their opinions in this MDL and that Plaintiffs' argument on this point is frivolous. Defendants further argue that Plaintiffs' challenges to the methodologies employed by Drs. Poulton and Webb are equally unfounded. According to Defendants, Drs. Poulton and Webb reliably rebut the opinions of Plaintiffs' geology experts, Drs. Cook and Krekeler.

I did not address these experts or issues in my prior Opinion, and thus, I will consider the parties' arguments without restriction.

i. Rule 702's Qualification Requirement is Liberally Construed

As noted *supra*, a witness qualifies as an expert if he or she possesses "specialized knowledge regarding the area of testimony." *Elcock*, 233 F.3d at 741 (internal quotation marks and citation omitted). "The basis of this specialized knowledge can be practical experience as well as academic training and credentials," but "at a minimum," the witness "must possess skill or knowledge greater than the average layman." *Id.* (internal quotation marks and citation omitted). The Third Circuit has "eschewed imposing overly rigorous requirements of expertise and [has]

been satisfied with more generalized qualifications." *In re Paoli*, 35 F.3d at 741. Indeed, it 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." *Pineda*, 520 F.3d at 244 (internal quotation marks and citations omitted). "If the expert meets [Rule 702's] liberal minimum qualifications, then the level of the expert's expertise goes to credibility and weight, not admissibility." *Kannankeril*, 128 F.3d at 809.

ii. Dr. Mary Poulton's Qualifications

Plaintiffs argue that Dr. Poulton fails to meet even the liberal qualification standard applied in federal court because she lacks the credentials, training, and "hands-on" experience necessary to opine on issues related to talc, asbestos, and mining. (ECF No. 32996-1 ("Pls.' Geology Br.") at 10–13.) They contend that Dr. Poulton does not hold a degree in geology and is not a certified professional geologist, an exploration geologist, or a licensed professional engineer. (*Id.*) Plaintiffs further assert that she has not published any peer-reviewed articles on talc or asbestos and is unfamiliar with the geology of the mining regions from which Defendants obtained their talc. (*Id.*) They also fault her for having visited only one talc mine and for never having worked for or consulted with a mining company. (*Id.*) According to Plaintiffs, "Dr. Poulton's career in academia without any first-hand

knowledge of the issue on which she offers opinions does not qualify her as an expert." (*Id.* at 13.)

Defendants contend—and I agree—that Dr. Poulton is qualified to opine on talc mining and to serve as a rebuttal expert witness.[155] (ECF No. 33113 ("Defs.' Geology Opp. Br.") at 8–11.) They offer her as an expert in geological engineering, a discipline that integrates geology with mining and civil engineering. (ECF No. 32996-5 ("Poulton Dep.") at 40:22–41:11.) Dr. Poulton holds B.S., M.S., and Ph.D. degrees in Geological Engineering from the University of Arizona. (Poulton Rep. at 2.) She served on the University of Arizona faculty for 28 years, achieving the rank of Distinguished Professor in Mining and Geological Engineering. (*Id.*) She also served as head of the University's Department of Mining and Geological Engineering for 14 years. (*Id.*)

Furthermore, Dr. Poulton has authored more than 100 research papers, conference papers, abstracts, and reports, and has taught courses in mineral exploration, mineralogy and petrology for mining engineers, field methods in geophysical exploration, computer methods in geological engineering, mine surveying, introduction to the global mining industry, and international mine safety and health law. (*Id.*) She has received multiple honors—including the National

[155] The manner in which rebuttal experts are reviewed is discussed in the legal standard section, *see supra* Part IV.D and below as relevant to the parties' arguments here.

Engineering Award from the American Association of Engineering Societies and the Daniel C. Jackling Award from the Society of Mining, Metallurgy, and Exploration—and has held leadership roles in professional organizations, a research publication, and a government advisory committee. (*Id.*) She has also testified before Congress on workforce needs in mining and petroleum. (*Id.*)

Dr. Poulton is distinguished within her field, and her specialized knowledge closely aligns with her proffered testimony. Based on her engineering experience, her review of the reference literature, and her analysis of the reports of Drs. Cook and Krekeler and the documents cited therein, Dr. Poulton intends to testify that Drs. Cook and Krekeler used "flawed methodologies, incomplete sampling results, and incorrect facts about ore body characterization and selective mining" at the source mines "to reach their conclusions that the talc sourced for Johnson's Baby Powder and Shower to Shower was known to contain asbestos and heavy metals that exceeded product specifications." (*Id.* at 1.)

Defendants have established, by a preponderance of the evidence, that Dr. Poulton satisfies Rule 702's qualification requirement. In light of her academic credentials, professional experience, and subject-matter expertise, Dr. Poulton possesses specialized knowledge relevant to her proffered testimony. Her advanced degrees in geological engineering, decades of teaching and research in mining and geological engineering, and professional accomplishments demonstrate a depth of

knowledge far exceeding that of a layperson. Plaintiffs' arguments, at best, go to the weight and credibility of her opinions. As the Third Circuit has made clear, it would be an abuse of discretion to deem Dr. Poulton unqualified simply because she is not a certified professional geologist or has not published any peer-reviewed articles on talc or asbestos, particularly in light of the fact that she is being proffered to rebut Plaintiffs' geology experts. *See Pineda*, 520 F.3d at 244 (it is an abuse of discretion if the court excludes testimony because the proposed expert is not the "best qualified" or lacks what the court views as the "most appropriate" specialization); *see also In re Paoli*, 35 F.3d at 741 ("Rule 702's liberal policy of admissibility extends to the substantive as well as the formal qualification of experts.").

Accordingly, I find that Dr. Poulton is qualified to testify as an expert in geological engineering and to offer rebuttal opinions concerning the methodologies and conclusions of Drs. Cook and Krekeler.

iii. Dr. Laura Webb's Qualifications

Plaintiffs argue that "Dr. Webb lacks both academic qualifications and practical experience to support her opinions." (Pls.' Geology Br. at 13.) According to Plaintiffs, Dr. Webb rarely "encounters talc in her work" and "has never examined samples of talc for the purpose of identifying asbestos." (*Id.* at 13–14.) They further claim that "Dr. Webb has never performed any academic research or studies focused on talc or asbestos" and has not published any peer-reviewed articles regarding talc,

asbestos, or "the talc deposits in Vermont, Italy, or China used to source J&J's Baby Powder and Shower to Shower." (*Id.* at 14.) Finally, Plaintiffs argue that Dr. Webb lacks the knowledge and "hands-on" experience necessary "to provide an opinion regarding the presence (or absence) of asbestos at the talc mines used to source J&J talcum powder products." (*Id.* at 14–15.)

In response, Defendants assert that Dr. Webb "is eminently qualified to opine on the scientific principles that govern the formation of mineable high-grade talc deposits and the possible relationship, or lack thereof, of such deposits with amphibole asbestos" because, among other reasons, she is "a tenured professor of geology who has almost 20 years of experience in the field, with a particular specialization in the origin and history of mineral deposits." (Defs.' Geology Opp. Br. at 11.) I agree with Defendants.

Dr. Webb obtained a B.S. in Geology from the University of California, Los Angeles, and a Ph.D. in Geological and Environmental Sciences from Stanford University. (Webb Rep. at 1.) Dr. Webb describes herself as "a geologist who specializes in using the tools of petrology (the origin and evolution of rocks discerned from mineralogical evidence), structural geology (interpreting rock deformation), and geochronology (radiometric dating) to understand the histories of rocks and regions." (*Id.*) Dr. Webb served as a Research Assistant Professor at Syracuse University for nine years and is currently a tenured Associate Professor in

the Department of Geology at the University of Vermont. (*Id.*) Dr. Webb teaches courses in petrology, microstructures, geochronology, and tectonics, and has coauthored 33 peer-reviewed scientific papers addressing geology and petrology. (*Id.* at 2.) Dr. Webb has also "worked extensively in regions with complex geologic histories, such as those in Italy, Vermont and China," and is familiar "with the regional geology of the Fontane and Guangxi mine regions and [has] experience working near the southern Vermont mines." (*Id.*)

Defendants offer Dr. Webb as an expert in the field of geology and, according to her report, she was asked to opine "on the scientific principles that govern the formation of mineable high-grade talc deposits used in the manufacture of Johnson's Baby Powder and Shower to Shower, and to investigate the possible relationship of such deposits . . . to amphibole asbestos." (*Id.* at 1.) She was also asked to evaluate "plaintiffs' experts' reports by Dr. Cook and Dr. Krekeler, and address[ ] differences in the formation of amphibole minerals with different crystal habits (e.g., asbestiform vs. prismatic) and the physical and chemical properties that impact biopersistence and toxicity." (*Id.*) Based on her review of the scientific literature and other materials, her educational background, and her professional experience as a geologist, Dr. Webb opined that "the cosmetic talc sources used for Johnson's Baby Powder and Shower to Shower were limited to mines that were free of asbestiform minerals." (*Id.* at 24.) She further opined that, based on general geologic principles

and the available data, Drs. Cook and Krekeler inappropriately concluded that the talc deposits mined for use in Defendants' talcum powder products were contaminated with asbestos. (*Id.* at 1.)

Defendants have established, by a preponderance of the evidence, that Dr. Webb satisfies Rule 702's qualification requirement. Dr. Webb holds advanced degrees in the field of geology from leading universities. She teaches and publishes in the areas of geology and petrology, and has extensive experience working in geologically complex regions. Without a doubt, Dr. Webb's specialized knowledge in "the histories of rocks and regions" directly relates to the opinions she offers regarding the formation of the talc deposits at issue, regardless of whether she possesses specific expertise related to talc or asbestos. The alleged deficiencies identified by Plaintiffs—such as her lack of peer-reviewed articles addressing talc, asbestos, and the relevant talc deposits in Italy, Vermont, and China—bear on the weight of her opinions, not their admissibility. Consistent with the Third Circuit's liberal approach to expert qualification, I find that Dr. Webb is qualified to testify as an expert in geology and to offer rebuttal opinions concerning Drs. Cook's and Krekeler's methodologies and conclusions.

iv. Analysis Regarding Dr. Mary Poulton

Plaintiffs first argue that Dr. Poulton's testimony should be excluded because "her opinions, as she admitted, amount to nothing more than a critique of" the

opinions of Drs. Cook and Krekeler "rather than an expert evaluation." (Pls.' Geology Br. at 17–19.) While their argument is neither a model of clarity nor supported by any legal authority, Plaintiffs appear to contend that Dr. Poulton's methodology—namely, attacking the opinions of Drs. Cook and Krekeler—is unreliable. Defendants counter that Plaintiffs fundamentally misunderstand the role of a defense expert and assert that federal courts recognize that "assessing the methodology of plaintiffs' experts' opinions is an appropriate methodology for a defense expert" like Dr. Poulton. (*Id.* at 13–16.) Again, I agree with Defendants.

All experts who seek to testify in federal court must satisfy Rule 702's admissibility requirements, including defense experts. *See* Fed. R. Evid.702. However, as Defendants correctly note, courts recognize that "the proper role of rebuttal experts [is] to critique plaintiffs' expert's methodologies and point out potential flaws in the plaintiffs' experts' reports." *Aviva Sports, Inc.*, 829 F. Supp. 2d at 835; *see also Mahaska Bottling Co.*, 441 F. Supp. 3d at 759 (courts routinely permit defense experts to testify "even if the expert primarily critiques the opposing expert's approach without offering an alternative approach."); *In re Abilify*, 299 F. Supp. 3d at 1368 (defense experts' "opinions properly may be limited to criticizing the analysis and conclusions presented by another party"). Simply put, defense experts "have a less demanding task, since they have no burden to produce models

or methods of their own; they need only attack those of plaintiffs' experts." *In re Zyprexa*, 489 F. Supp. 2d at 285.

Here, I reject Plaintiffs' argument that Dr. Poulton's testimony is improper or unreliable merely because her methodology involves critiquing Drs. Cook's and Krekeler's opinions. Dr. Poulton testified regarding the scope of her assignment at her deposition, explaining that she was asked to review the reports of Drs. Cook and Krekeler and to determine whether she "agreed with what they did, what they found, and then if not, why." (Poulton Dep. at 22:20–23:13.) The primary focus of her analysis was on Drs. Cook's and Krekeler's opinions concerning "mining and beneficiation practices."[156] (*Id.*) With respect to her methodology, Dr. Poulton testified that she "started with the assumption that" Drs. Cook and Krekeler "were correct in their findings, and then [attempted to] corroborate[] their statements with what [she] saw in the documents." (*Id.* at 23:14–24:2.) She further explained that "if they said information was missing, then I asked for that information or looked for it within the documents they had" and that she "basically constructed the areas where" she felt Drs. Cook and Krekeler "were incorrect." (*Id.*) I find nothing inherently unreliable regarding Dr. Poulton's stated methodology, as it is consistent with the

[156] Dr. Cook explained in his report that beneficiation means "any process that improves the economic value of the ore by removing the gangue minerals which results in a higher-grade product." (Cook Amend. Rep. at 9 n.12.) This includes applying processes to talc ore such as "primary (jaw) crushing, grinding circuits including roller mills, shear disc devices, flotation, thickening, filtering, and drying." (*Id.* at 9.)

general role of a rebuttal expert. *See In re Abilify*, 299 F. Supp. 3d at 1368 (finding defense experts' opinions, which "were, essentially, critiques of Plaintiffs' experts' evidence, methodologies, and conclusions," "entirely appropriate").

Since her methodology is sufficiently sound, I must now determine whether Dr. Poulton's opinions are supported by sufficient facts or data and whether she reliably applied her methodology to the facts of the case. In her report, Dr. Poulton concluded that "Drs. Cook and Krekeler use flawed methodologies, incomplete sampling results, and incorrect facts about ore body characterization and selective mining to reach their conclusions that the talc sourced for Johnson's Baby Powder and Shower to Shower was known to contain asbestos and heavy metals that exceeded product specifications." (Poulton Rep. at 1.) Specifically, Dr. Poulton identified the following alleged deficiencies in Drs. Cook's and Krekeler's reports:

> A. Drs. Cook and Krekeler improperly conflate non-ore samples with ore samples.
>
> B. Drs. Cook and Krekeler improperly conflate non-asbestiform minerals with asbestiform minerals.
>
> C. Drs. Cook and Krekeler improperly extrapolate general mineralogy from different regions to the exact mineralogy of ore that went into Johnson's Baby Powder or Shower to Shower.
>
> D. Dr. Cook improperly conflates the mineralogy of non-cosmetic grade talc mines with cosmetic grade ore that went into Johnson's Baby Powder or Shower to Shower.

> E. Dr. Krekeler improperly cites data regarding regions in China where talc was never sourced for Johnson's Baby Powder or Shower to Shower to opine that the specific Chinese ore body sourced for Johnson's Baby Powder or Shower to Shower was contaminated with asbestos.
>
> F. Drs. Cook and Krekeler rely on irrelevant test results for their opinions that Johnson's Baby Powder and Shower to Shower were contaminated with asbestos.
>
> G. Dr. Cook relies on test results that postdate production for cosmetic talc at the Argonaut mine, which cannot be extrapolated to ore sourced from earlier sections of the mine as mines are continually in development.
>
> H. Drs. Cook and Krekeler's opinions regarding inadequate sampling are premised on misrepresentations of documents and sampling theory and lack evidentiary support.
>
> I. Drs. Cook and Krekeler incorrectly assert that selective mining was impossible, make improper assumptions about how drill campaigns must be conducted, misstate facts regarding mine planning and rely on incomplete data to opine that quality control was ineffective.

(*Id.*; *see id.* at 5–33.) In forming these opinions, Dr. Poulton relied on her "analysis of the reports of Drs. Cook and Krekeler, examination of documents presented, use of reference literature, and [her] engineering experience." (*Id.* at 1; *see id.* at 34–47; Poulton Dep. at 19:20–24.) In addition to critiquing Drs. Cook's and Krekeler's opinions, Dr. Poulton also addressed the mines used by Defendants to source talc in

Italy, Vermont, and China, including discussing matters related to mine design and mining practices. (Poulton Rep. at 2–5.)

After reviewing Dr. Poulton's report, deposition testimony, and the parties' submissions, I find that Defendants have established, by a preponderance of the evidence, that Dr. Poulton's opinions rest on a sufficient factual foundation and reflect a sound application of her methodology to the facts of this case. Dr. Poulton reviewed and relied on the documents cited by Drs. Cook and Krekeler in their reports, along with other relevant materials. As a rebuttal expert, she was asked to identify, and did so, specific shortcomings in their opinions, provided a reasoned basis for each of her criticisms, and relied on facts and data to support her conclusions. *See In re Abilify*, 299 F. Supp. 3d at 1368 (denying motion to exclude defense experts' testimony on similar grounds). I am satisfied that Dr. Poulton's opinions are admissible under Rule 702 and *Daubert* because they are grounded in her expertise in geological engineering and mining and are supported by ample scientific and record evidence.

Plaintiffs nevertheless contend that Dr. Poulton's opinions are unreliable because they lack scientific rigor, are based on cherry-picked scientific evidence, constitute *ipse dixit*, lack credibility, and are irrelevant and incorrect. (*See* Pls.' Geology Br. at 17–31.) I disagree. "[T]he question of whether the expert is credible or the opinion is correct is generally a question for the fact finder, not the court."

Summit 6, LLC, 802 F.3d at 1296. None of Plaintiffs' arguments establish that Dr. Poulton's methods are unreliable, her data legally or factually insufficient, or her reasoning disconnected from the facts of the case. Indeed, most of Plaintiffs' arguments go to weight rather than reliability. For example, Plaintiffs assert that Dr. Poulton failed to employ sufficient scientific rigor because she only "reviewed materials *cited* by Plaintiff's [sic] experts but not all of the materials they *considered*" in preparing their reports. (Pls.' Geology Br. at 18.) Plaintiffs claim, after comparing the experts' "reliance lists," that "Dr. Poulton's conclusions about the PSC's experts' analyses are based upon only a mere fraction of the information that was actually relied upon by PSC's experts in reaching their conclusions." (*Id.*) In support of this position, Plaintiffs did not identify any specific documents that Dr. Poulton failed to consider—relative to Drs. Cook and Krekeler—that would or could have affected her conclusions. Regardless, Rule 702's reliability inquiry does not rise or fall on the number of documents an expert reviews in forming an opinion. The proper question here is whether Dr. Poulton's opinions are supported by sufficient facts and data to rebut the opinions of Plaintiffs' experts. I answer that in the affirmative.

Because Dr. Poulton's opinions are reliable under Rule 702 and *Daubert*, I find that Plaintiffs' objections go to the weight of her testimony, not its admissibility. *See Summit 6, LLC*, 802 F.3d at 1299 ("Where the methodology is sound and the

evidence relied upon is sufficiently related to the case, disputes over the expert's credibility or over the accuracy of the underlying facts are for the jury."). Accordingly, I recommend that the Court deny Plaintiffs' motion to exclude Dr. Poulton.

v. Analysis Regarding Dr. Laura Webb

First, Plaintiffs argue that Dr. Webb's opinions are unreliable because "she failed to use the very observation-based methodology that she normally uses in the field and outside of the courtroom." (Pls.' Geology Br. at 32–33.) Specifically, Plaintiffs maintain that Dr. Webb departed from her customary "field-based" practices such as collecting and testing rock and mineral samples. (*Id.* at 33–36.)

Next, Plaintiffs contend that Dr. Webb's methodology is flawed because she based her opinions on a limited selection of cherry-picked materials and ignored various maps, testing, samples, observations, and other data from the actual mines used to source Defendants' talcum powder products. (*Id.* at 36.) Plaintiffs claim that Dr. Webb's "extremely narrow review of relevant materials is important" because she does not opine that there is no asbestos in the mines, but rather, her opinion is that the evidence she reviewed does not support the conclusion that asbestos is present in the mines. (*Id.* at 36–37.)

In opposition, Defendants argue that Plaintiffs' attacks on Dr. Webb's methodology are baseless. (Defs.' Geology Opp. Br. at 33–42.) They assert that there

is "no truth" to Plaintiffs' argument that Dr. Webb failed to use the same type of methodology she normally uses in her practice as a scientist. (*Id.* at 33–37.) They further claim that even a cursory review of Dr. Webb's report reveals that she performed a comprehensive review of the relevant scientific literature and that her opinions are not based on cherry-picked data. (*Id.* at 38–42.)

After reviewing Dr. Webb's report, deposition testimony, and the parties' submissions, I find that Defendants have established, by a preponderance of the evidence, that Dr. Webb's opinions are based on sufficient facts and data, are grounded in reliable principles and methods, and reflect a sound application of those principles and methods to the facts of this case. Plaintiffs mischaracterize Dr. Webb's deposition testimony to support their position that she practices only a field-based approach to geology. Rather, the record reveals that Dr. Webb employed the same research-based methodology she uses in her academic and peer-reviewed work, and that performing work in the field is merely one of her skill sets. The record further reveals that Dr. Webb's opinions regarding the formation of the talc deposits at issue are grounded in her extensive expertise in geology and petrology and are supported by ample scientific evidence.

In her report, Dr. Webb stated that her opinions focus primarily on "the scientific principles that govern the formation of [the] mineable high-grade talc deposits" used by Defendants to produce their products. (Webb Rep. at 1.) She began

by defining key terms and outlining important concepts related to minerals, such as talc and those belonging to the serpentine and amphibole groups. (*Id.* at 2–6.) She then discussed the essential characteristics of asbestos and the general principles underlying the formation of talc deposits. (*Id.* at 6–11.) She explained, "while talc is a common metamorphic mineral in metamorphosed ultramafic and carbonate rocks, mineable high-purity talc deposits are the result of rare instances of rather extreme metasomatism, in which the bulk composition of a protolith is changed to something effectively matching (or very close to) the talc mineral composition." (*Id.* at 14.) Put differently, mineable high-purity talc deposits, like those allegedly used by Defendants, form through rare geological processes that result in deposits made up almost entirely of talc.

In addition to these general scientific principles, Dr. Webb analyzed the available scientific literature to determine the specific characteristic of the talc deposits used by Defendants in Italy, Vermont, and China. (*Id.* at 14–24.) She explained that, in forming her opinions, she "relied on peer-reviewed, published scientific literature and the examination of *primary sources* of data and observations." (*Id.* at 14.) Because information concerning certain mines is limited, she "integrated regional studies" into her analysis "to understand the broader context and metamorphic conditions associated with the formation of the talc deposits." (*Id.*)

Her report cited approximately eighty sources of scientific authority, among other materials, such as the reports of Drs. Cook, Krekeler, and Longo. (*Id.* at 25–39.)

Ultimately, relying on her "knowledge of petrologic systems, extensive searching and evaluation of the published scientific literature, and examination of limited industry reports," which she used to obtain background information, Dr. Webb opined that the talc sources used by Defendants "were limited to mines that were free of asbestiform minerals." (*Id.* at 24.) She reasoned that the data she evaluated "weighs in favor of the conclusion that there is no scientific merit to any claims of asbestos in the cosmetic talc ores utilized." (*Id.*)

Dr. Webb testified that the methodology she applied in forming her opinions is "the same approach" she would apply to any aspect of her science, "whether it's writing a paper or a peer review." (ECF No. 32996-10 ("Webb Dep.") at 125:1–7.) She conducted "an extensive search of the peer-reviewed literature" and other scientific resources, including U.S.G.S. reports. (*Id.* at 125:7–126:20.) She also "tried to really dig into the primary citations" and review "anything written about the talc bodies" and "surrounding rocks" "to understand the petrology of those systems." (*Id.*) Dr. Webb's testimony regarding her methodology is consistent with both the form and substance of her report, and, tellingly, Plaintiffs do not dispute her ability to perform research-based assignments.

Plaintiffs instead argue that, because she describes herself as a field-based geologist, Dr. Webb was required to conduct fieldwork before rendering her opinions, including, for example, driving "from where she works in Burlington, Vermont" to "the Hamm, Hammondsville and Argonaut mines" in southern Vermont to collect samples. (Pls.' Geology Br. at 33–36.) Plaintiffs' argument is based on a factually unfounded and an unsupported assumption that Dr. Webb can only offer a scientific opinion if she personally collected and tested field samples.

First, Dr. Webb's work is not limited to field-based geology, and she neither testified that fieldwork is a prerequisite to forming opinions about mineral deposit formation, nor have Plaintiffs suggested that there is such a requirement in the scientific community. When asked, "What is a field-based geologist?" Dr. Webb testified that "in many cases [she is] actually out in the field making structural measurements" and "collecting oriented samples." (Webb Dep. at 109:10–24.) Whether she conducts fieldwork "depends on the nature of—of the question that [she is] trying to address." (*Id.*) She further stated that being a field-based geologist means she possesses "the ability to recognize different rock types in the field, the ability to recognize and document structures, [and] to make the appropriate measurements." (*Id.*) Thus, Dr. Webb was describing one component of her professional expertise, not expressing a preference for or against any particular methodology. More

importantly, she did not represent that she cannot form expert opinions without field studies.

In addition, Dr. Webb testified that whether she goes out into the field to collect samples "depends on what's known and documented for the region" and whether she needs to "build off the existing knowledge base." (*Id.* at 118:12–24.) She concluded that it was not necessary for her to "go out into the field" in this case because, at least with respect to the Vermont mines, she relied on "the decades of work of geologists and petrologists" who came before her. (*Id.* at 127:14–128:6.) According to Dr. Webb, "if I feel like there is a big gap in that information, that would drive that need to go out into the field to collect samples, and I just didn't arrive at that position in this case." (*Id.*) Notably, Drs. Cook and Krekeler also did not visit any of the mines at issue in this litigation, nor did they conduct any testing.

Second, Plaintiffs cite no legal authority directly supporting their assertion that Dr. Webb was required to apply a field-based methodology. (*See* Pls.' Geology Br. at 32 n.173.) Defendants correctly note that the cases cited by Plaintiffs are distinguishable. (Defs.' Geology Opp. Br. at 36–37.) For example, Plaintiffs rely on two cases in which the expert acknowledged that a Bradford Hill analysis is the accepted methodology for establishing a causal link but nevertheless applied a different and unreliable method. *McMunn v. Babcock & Wilcox Power Generation Grp., Inc.*, 2013 WL 3487560, at *22 (W.D. Pa. July 12, 2013); *Rimbert v. Eli Lilly*

& Co., 2009 WL 2208570, at *14 (D.N.M. July 21, 2009). Plaintiffs also cite several cases in which the expert purported to apply a particular methodology but, in practice, failed to do so. *Brown v. Burlington N. Santa Fe Ry. Co.*, 765 F.3d 765, 776 (7th Cir. 2014); *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268–69 (2d Cir. 2002); *Truck Ins. Exch. v. MagneTek, Inc.*, 360 F.3d 1206, 1213 (10th Cir. 2004). Neither scenario is applicable here.

Critically, Plaintiffs cite no authority for the proposition that field-based geology is the generally accepted methodology for determining the histories of rocks and regions. Moreover, nothing in the record indicates that Dr. Webb represented she applied a field-based approach in forming her opinions. Her assignment was to review the scientific literature and determine the characteristics of the talc deposits at issue in this litigation, which is precisely what she d*Id.* Thus, the cases cited by Plaintiffs are neither applicable nor persuasive.

In conclusion, I find that Dr. Webb's opinions are grounded in a sufficiently reliable factual foundation, and Defendants have established that she applied the same level of intellectual rigor in this case that she employs in her professional work outside the courtroom. *See Kumho Tire Co.*, 526 U.S. at 152 (the objective of *Daubert*'s gatekeeping requirement "is to make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field"). Consequently, Plaintiffs' criticisms of Dr. Webb—

including her alleged lack of experience working with talc and asbestos and her failure to perform any fieldwork—go to the weight, not the admissibility, of her testimony. Accordingly, I recommend that the Court deny Plaintiffs' motion to exclude Dr. Webb's testimony and opinions.

B. Tissue Sample Motions

As previewed above, the parties have moved to exclude expert opinions and anticipated testimony concerning the detection, origination, and evaluation of talc and asbestos-type particles, fragments, and/or fiber in certain bellwether Plaintiffs' gynecologic and pelvic tissue samples.

Over the course of this litigation, preserved tissue from five bellwether Plaintiffs—Anna Gallardo, Hilary Converse, Pasqualina Rausa, Carter Judkins, and Tamara Newsome, respectively—was submitted to Dr. John J. Godleski, a pulmonary pathologist and analytical microscopist affiliated with Harvard Medical School, Harvard T.H. Chan School of Public Health, and Mass General Brigham f/k/a Brigham and Women's Hospital. (*See* ECF Nos. 33117-7 ("Godleski Gallardo Rep."), 33117-8 ("Godleski Converse Rep."), 33117-9 ("Godleski Rausa Rep."), 33117-10 ("Godleski Judkins Rep."), 33117-11 ("Godleski Newsome Rep.").)

In a methodology described in greater detail below, Dr. Godleski reported the presence of talc within the sampled tissue of all five of the individual Plaintiffs and, in two Plaintiffs, tremolite asbestos particles, fragments, and/or fibers. (*See*

generally id.) In all of his expert reports, Dr. Godleski concluded that the talc and, where present, tremolite asbestos "found in the tissues of th[ese] case[s] are *contributory evidence* for a causal link between the presence of these materials and the development of th[ese] patient[s'] ovarian cancer[s]." (*See* Godleski Newsome Rep. at 7 (emphasis added); *see also* Godleski Gallardo Rep. at 8 (talc and tremolite particles/fibers); Godleski Converse Rep. at 6 (talc); Godleski Rausa Rep. at 5–6 (talc); Godleski Rausa Rep. at 5 (talc).)

Defendants move to exclude Dr. Godleski's expert opinions, (*see* ECF No. 33004-2 ("Defs.' Godleski Br.")), and further rebut Dr. Godleski's findings through Defendants' own experts—Dr. Juan Felix and Dr. Teri Longacre, (*see, e.g.*, ECF Nos. 33108-2 ("Felix Converse Rep."), 33108-3 ("Longacre Newsome Rep."), 33108-8 ("Felix Judkins Rep."), 33108-9 ("Felix Gallardo Rep.")).[157] In turn, Plaintiffs move to exclude portions of Drs. Felix's and Longacre's opinions, which opine, in relevant part,[158] that any talc- and asbestos-like particles identified by Dr. Godleski are more likely a product of post-excision laboratory contaminants rather than *in vivo* findings. (*See generally* ECF No. 33002-1 ("Pls.' Felix & Longacre Br.").)

---

[157] To clarify, Defendants submit Dr. Longacre's expert report with respect to Plaintiff Newsome, and the expert reports of Dr. Felix pertaining to Plaintiffs Converse, Judkins, and Gallardo.

[158] Plaintiffs appear to only contest the admissibility of Drs. Felix's and Longacre's opinions as they relate to the likelihood of particulate contamination in Dr. Godleski's tissue sample testing.

My prior Opinion did not address these experts or their respective opinions and proffered testimony. Therefore, I will evaluate the admissibility of their expert opinions and testimony under Rule 702, in the first instance, rather than by limitations set forth by the Court's April 30, 2024 Memorandum Order.

1. Defendants' Motion to Exclude the Opinions of Dr. Godleski

Defendants move to exclude the opinions of Dr. Godleski on the basis that they are unreliable and do not fit this case.[159] Defendants primarily argue that Dr. Godleski's core premise—that detecting any amount of talc particulates in sample tissue evidences a causal link to ovarian cancer—is neither supported by the scientific studies relied upon by Dr. Godleski, nor by the scientific community at large. (*See* Defs.' Godleski Br. at 9–12.) Assuming *arguendo* that a causal link can be drawn by sufficient scientific support, Defendants further argue that alleged inadequacies in Dr. Godleski's methodology and conclusions warrant exclusion of his opinions related to the presence of talc or tremolite asbestos in the tissue sample of the individual Plaintiffs. (*Id.* at 12–18.) Alternatively, Defendants assert that Dr. Godleski fails to establish that the presence of talc particulates in each of the five

[159] Defendants do not challenge Dr. Godleski's qualifications as a proffered expert of pulmonary pathology and analytical microscopy. (*See generally* Defs.' Godleski Br.) Yet Defendants appear to take issue with Dr. Godleski's prior admission that he is not a gynecologic pathologist or a gynecologic oncologist. (*See id.* at 2–3.) For the sake of completeness, I will assess, *infra*, the qualifications of Dr. Godleski. *See, e.g.*, *Cohen*, 125 F.4th at 462.

bellwether Plaintiffs' tissue can be traced to their perineal use of Defendants' products. (*Id.* at 18–20.)

In opposition, Plaintiffs argue that Defendants misconstrue Dr. Godleski's methodology, which they assert is reliable. (*See, e.g.*, ECF No. 33117 ("Pls.' Godleski Opp. Br.") at 13–15.) Plaintiffs further oppose Defendants' challenge to Dr. Godleski because it is based on an improperly heightened Rule 702 requirement, insofar as it relates to Dr. Godleski's causal conclusion. (*See id.* at 15–19.)

i. Qualifications

Plaintiffs proffer Dr. Godleski as an expert in pathology and analytical microscopy. (*See* Pls.' Godleski Opp. Br. at 1.) Dr. Godleski holds a B.S. in Biology from King's College and an M.D. from the University of Pittsburgh, completed pathology training at Massachusetts General Hospital, and has been certified in anatomic pathology since 1975. (*Id.*) Dr. Godleski has more than five decades of academic and clinical experience at Harvard Medical School, the Harvard T.H. Chan School of Public Health, and Mass General Brigham f/k/a Brigham and Women's Hospital, among other academic and medical institutions. (*See generally id.*) He directed Harvard School of Public Health's Electronic Microscopy Laboratories from 1988 to 2017 and led the Pulmonary Pathology Division at Brigham and Women's Hospital from 1978 to 2015. (*Id.*) In his capacity as Director of Harvard School of Public Health's Electron Microscopy Laboratories, Dr. Godleski used and

oversaw use of light microscopy, scanning electron microscopy, and energy dispersive x-ray spectroscopy. (*Id.*) Dr. Godleski has authored hundreds of peer-reviewed scientific publications, including several relevant to talc in the female genital tract and ovarian cancer.[160] (*Id.*) He currently holds emeritus status as a Professor of Pathology at Harvard Medical School. (*See id.*)

On this record, I find that Dr. Godleski possesses specialized expertise in pathology and microanalytical methods relevant to the detection, localization, and characterization of talc in gynecologic and pelvic tissue. Although Defendants imply—without substantive analysis—that Dr. Godleski lacks qualifications in gynecologic pathology, (*see* Defs.' Godleski Br. at 2–3), I recommend that the Court determine he is qualified to opine regarding his pathology and microscopy methodologies and the conclusions drawn therefrom as to the presence of talc. Defendants have articulated no reason, let alone a persuasive reason, why Dr. Godleski's expertise in pathology and microscopy could not be applied to the detection of talc or other foreign particulates within gynecologic specimens. Moreover, the qualification standard under *Daubert* must be construed liberally, and

[160] (*See* Godleski Gallardo Rep. at 1–2 ("I have recently published six papers regarding talc and tissue pathology (references 1–6). The first paper used tissue digestive procedures and SEM/EDXS to quantify talc in lymph nodes in comparison to the use of in situ SEM/EDXS; the second described the migration and detection of talc in pelvic tissues from the perineum in a series of exposed patients who also had ovarian malignancy. The third concerned the use of spectroscopic magnesium and silicon weight % ratio standards to diagnose talc in human tissues, and the expected mathematical distribution for such measurements. Three other publications also pertain to talc identification in tissue and resultant pathology (references 4–6).")

the Third Circuit has made clear 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 Hum. Tissue*, 582 F. Supp. 2d at 655. Having reviewed Dr. Godleski's curriculum vitae and extensive background, to the extent Defendants seek to exclude Dr. Godleski based on a lack of qualifications, I reject that argument and recommend that the Court find Dr. Godleski qualified to provide his expert opinions in this case.

ii. Methodology and Opinions

To determine the admissibility of Dr. Godleski's expert opinions, I find it necessary to first review the methodologies underlying them. For each of the five bellwether Plaintiffs with tissue samples, Dr. Godleski employed the same methodology. Each Plaintiff had undergone a surgical procedure, from which various tissue samples were removed and preserved.[161] (*See, e.g.*, Godleski Gallardo

[161] More specifically, Plaintiff Gallardo underwent a "hysterectomy, bilateral salpingo-oophorectomy, omentectomy, multiple soft tissue biopsies of the anterior and posterior cul-de-sac, right and left gutter, right and left pelvic side wall, and diaphragm, and multiple lymph node excisions including right and left external iliac, right and left obturator, and right and left peri-aortic nodes." (Godleski Gallardo Rep. at 2.) Plaintiff Converse underwent a "hysterectomy, bilateral salpingo-oophorectomy, excision of bilateral pelvic and para-aortic lymph nodes, and peritoneal and diaphragm biopsies." (Godleski Converse Rep. at 2.) Plaintiff Rausa underwent a "hysterectomy, bilateral salpingo-oophorectomy, left and right external iliac lymph node excision, right and left common iliac lymph node excision, right and left para-aortic lymph nodes excision, right and left pelvic sigmoid peritoneum biopsies, bladder peritoneum biopsy, omen tum biopsy, right and left diaphragm peritoneum biopsies, small bowel mesentary and serosa nodules biopsies, right and left paracolic gutter peritoneum biopsies, and right peritoneum paericolic plaque excision." (Godleski Rausa Rep. at 2.) Plaintiff Judkins underwent a "hysterectomy, bilateral salpingo-oophorectomy, left and right pelvic lymph nodes excision, right para-aortic lymph nodes excision, pelvic sigmoid adhesion biopsy, and infracolic omentum biopsy." (Godleski Judkins Rep.

Rep. at 2.) The various surgical medical hospitals or institutions where the surgeries were performed prepared and stored surgical slides containing the sampled tissue,[162] which were stained with hematoxylin and eosin. (*See, e.g.*, *id.*) The histological slides were then provided to Dr. Godleski.

Dr. Godleski first studied the histological slides using light microscopy and confirmed each of the sampled Plaintiffs' diagnoses by comparing the observed morphology to the diagnosis in the original hospital surgical pathology report.[163] (*See, e.g.*, *id.*) Dr. Godleski also described the representative microscopic features consistent with the reported tumor type. (*See, e.g.*, *id.*) Dr. Godleski next reviewed

---

at 2.) Plaintiff Newsome underwent a "hysterectomy, bilateral salpingo-oophorectomy, omentectomy, and right pelvic lymph node excision." (Godleski Newsome Rep. at 2.)

[162] Plaintiff Gallardo's histological slides were prepared by the Department of Pathology at Barnes-Jewish Hospital at Washington University Medical Center in St. Louis, Missouri. (*See* Godleski Gallardo Rep. at 2.) Plaintiff Converse's histological slides were prepared by the Department of Pathology at Yale Medical Center in New Haven, Connecticut. (*See* Godleski Converse Rep. at 2.) Plaintiff Newsome's histological slides were prepared by the Department of Pathology at Holy Cross Health in Silver Spring, Maryland. (*See* Godleski Newsome Rep. at 2.) Plaintiff Rausa's histological slides were prepared by the Department of Pathology at Ascension St. Vincent's Southside Hospital in Jacksonville, Florida. (*See* Godleski Rausa Rep. at 2.) Finally, Plaintiff Judkins' histological slides were prepared by the Department of Pathology and Laboratory Medicine at Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire. (*See* Godleski Judkins Rep. at 2.)

[163] For Plaintiff Gallardo, Dr. Godleski confirmed the diagnosis of "poorly differentiated endometrioid adenocarcinoma of the ovary." (Godleski Gallardo Rep. at 2.) For Plaintiff Converse, Dr. Godleski confirmed the diagnosis of "clear cell carcinoma of the ovary." (Godleski Converse Rep. at 2.) For Plaintiff Judkins, Dr. Godleski confirmed the diagnosis of "poorly differentiated serous carcinoma of the ovary." (Godleski Judkins Rep. at 2.) For Plaintiff Rausa, Dr. Godleski confirmed the diagnosis of "high grade serous carcinoma of the left and right ovaries." (Godleski Rausa Rep. at 2.) For Plaintiff Newsome, Dr. Godleski confirmed the diagnosis of "endometrioid carcinoma of the ovary." (Godleski Newsome Rep. at 2.)

the histological slides using polarized light microscopy,[164] which allowed him to "highlight and detect birefringent[165] foreign material in the same plane of focus with the tissues." (*See, e.g.*, *id.* at 3.) Varying amounts of birefringent material were discovered in Plaintiffs' respective tissue samples. (*See id.* at 2–3; Godleski Converse Rep. at 2–3; Godleski Newsome Rep. at 2; Godleski Rausa Rep. at 2–3; Godleski Judkins Rep. at 2.)

According to Dr. Godleski, the discovery of birefringent material in tissue is "robustly correlated" with the likely discovery of talc particulate in examined areas, since "talc is a strongly birefringent material." (*See, e.g.*, Godleski Gallardo Rep. at 4.) Therefore, to detect and identify talc, Dr. Godleski requested paraffin tissue blocks that corresponded with areas showing the greatest concentration of birefringent particles and anatomic locations consistent with expected particle migration pathways—such as ovary, fallopian tube, service, regional lymph nodes, and omentum. He obtained the corresponding paraffin tissue blocks from the surgical medical institutions for each sampled Plaintiff for further analysis using SEM and EDXS.

---

[164] As discussed above, polarized light microscopy is a form of optical microscopy that uses polarized light and dispersion to identify minerals by their optical properties, including, *inter alia*, indices of refraction, birefringence, sign of elongation, and size. (*See* ECF No. 33132-7 ("Wylie Rep.") at 4.)

[165] According to Plaintiffs, birefringence, in the context of this case, "is an optical property of talc and other magnesium silicates that causes them to stand out from the carbonaceous tissue background." (Pls.' Godleski Opp. Br. at 6.) Defendants do not offer a competing definition.

In order to avoid introducing contamination from handling the paraffin blocks, Dr. Godleski used powder-free gloves on pre-cleaned services, trimmed off approximately 50 micrometers from the block face with a fresh microtome blade to remove any potential surface contamination from previous handling and/or storage, rinsed the trimmed surfaces in distilled deionized water to remove soluble residues from tissue processing, and stored the paraffin tissue blocks, when not in use, in closed plastic container boxes. (*See, e.g.*, *id.* at 4.)

For testing of the paraffin tissue blocks, Dr. Godleski examined the face of the blocks directly ("in situ") using variable-pressure SEM, which allows the viewing microscopist to view magnified particles and fibers contained within the block. (*See, e.g.*, *id.* at 4.) Once detected, Dr. Godleski used EDXS to measure the particular particles' and fibers' elemental makeup. (*See, e.g.*, *id.*) Dr. Godleski confirmed the detection of talc particles by observing their characteristic elemental signature, e.g., magnesium, silicon, and oxygen in a well-established proportion. (*See, e.g.*, *id.*) Talc fibers were detected using this method to confirm their elemental signature, in addition to a specific shape criterion, *i.e.*, length-to-width ratio greater than about 3:1 with roughly parallel sides. (*See, e.g.*, *id.*) Using SEM/EDXS, Dr. Godleski identified other foreign particles and distinguished non-talc magnesium silicates and other exogenous materials from endogenous elements—such as

calcium, sodium, phosphorus, and iron—that commonly appear in human tissue, especially in cancer. (*See, e.g.*, *id.* at 4–6.)

For Plaintiff Gallardo, Dr. Godleski detected birefringent particles in 25 of the 65 histological slides. (*See id.* at 3–5.) He selected five paraffin tissue blocks corresponding to those histological slides, from which there was SEM/EDXS analysis of 795 particles. (*Id.* at 4–5.) From that number, a total of 208 talc particles and fibers were detected. (*Id.*) Additionally, Dr. Godleski identified 30 tremolite asbestos fiber/fragments as being within the acceptable range of magnesium and silicon atomic weight percentage ratio. (*Id.* at 5–6.)

For Plaintiff Converse, Dr. Godleski detected birefringent particles in 25 of the 45 histological slides. (*See* Godleski Converse Rep. at 2–4.) He selected seven paraffin tissue blocks corresponding to those slides, from which there was SEM/EDXS analysis of 255 particles. (*Id.* at 3–4.) Of the 255, a total of four talc particles were detected. (*Id.*)

For Plaintiff Newsome, Dr. Godleski detected birefringent particles in eight of the 31 histological slides. (*See* Godleski Newsome Rep. at 2–4.) He selected five paraffin tissue blocks corresponding to those slides, from which there was SEM/EDXS analysis of 821 particles. (*Id.*) Thirty-one talc particles were detected among the 821 particles. (*Id.*) Additionally, Dr. Godleski identified one tremolite

asbestos fiber fragment, the detection of which was grounded in its composition of an acceptable range of magnesium and silicon atomic weight percentage ratio. (*Id.*)

For Plaintiff Rausa, Dr. Godleski detected birefringent particles in 25 of the 46 histological slides. (*See* Godleski Rausa Rep. at 2–4.) He examined eight corresponding paraffin tissue blocks, from which he conducted SEM/EDXS analysis of 515 particles. (*Id.* at 3–4.) From this, a total of two talc particles were detected. (*Id.*)

For Plaintiff Judkins, Dr. Godleski detected birefringent particles in 21 of the 31 histological slides. (*See* Godleski Judkins Rep. at 2–4.) He selected eight paraffin tissue blocks corresponding to those slides, from which he conducted SEM/EDXS analysis of 932 particles. (*Id.* at 3–4.) A total of 17 talc particles were detected. (*Id.*)

Dr. Godleski offered several interpretations of these results. First, he opined that the microscopy record demonstrates the presence of talc within pelvic tissues, and in some cases tremolite asbestos, as well. (*See* Godleski Gallardo Rep. at 4–7; Godleski Converse Rep. at 4–5; Godleski Newsome Rep. at 3–5; Godleski Rausa Rep. at 4–5; Godleski Judkins Rep. at 4.)

Second, while Dr. Godleski explained that his techniques only study "an extremely small volume of tissue," based on established comparisons from tissue analyses focused on the detection of asbestos fibers, he nevertheless opined to a reasonable degree of medical certainty that the talc particles and fibers detected

within the very small SEM/EDXS sampling plane suggest a substantially larger presence within the whole tissue. (*See* Godleski Gallardo Rep. at 6; Godleski Converse Rep. at 4–5; Godleski Newsome Rep. at 4; Godleski Rausa Rep. at 4; Godleski Judkins Rep. at 4; *see also* ECF No. 33004-4 ("Godleski Dep.") at 111:5–14 (confirming that Dr. Godleski did not "attempt to count all the particles in the tissue," but instead "extrapolate[d]" a tissue burden from the number of particles actually observed based on a study's methodology); ECF No. 33004-13 ("Godleski Dep. II") at 83:20–84:7 (explaining that Dr. Godleski did not "try to identify every particle in" tissue, but instead "extrapolate[d] that to what [he] anticipate[d] would be the total particles per gram of tissue based on" a study's methodology).)

Finally, Dr. Godleski concluded in a final paragraph of all reports of the five sampled bellwether Plaintiffs, "to a reasonable degree of medical certainty," that the confirmed presence of talc—and where present, tremolite asbestos—is "contributory evidence for a causal link between the presence of these materials and the development of th[ese] patient[s'] ovarian cancer[s]." (*See* Godleski Newsome Rep. at 7; *see also* Godleski Gallardo Rep. at 8 (talc and tremolite particles/fibers); Godleski Converse Rep. at 6 (talc); Godleski Rausa Rep. at 5–6 (talc); Godleski Rausa Rep. at 5 (talc).)

iii. Reliability

Defendants primarily argue that Dr. Godleski's opinion regarding the causal link between talc usage and the development of ovarian cancer must be excluded because it is (1) unsupported by the scientific and medical literature that Dr. Godleski relies upon, and (2) supported by an unreliable methodology. As to Dr. Godleski's methodology, Defendants specifically criticize Dr. Godleski's identification of talc particulates and his extrapolation of a substantial exposure of talc and asbestos based on the detection rate measured within an "extremely small volume of tissue."

For the reasons that follow, I find that Plaintiffs have not demonstrated by a preponderance of the evidence that Dr. Godleski's opinions linking the presence of talc or tremolite asbestos as a contributory cause of ovarian cancer survive Rule 702 scrutiny and, thus, are not admissible. I also find that Plaintiffs have not satisfied by a preponderance of the evidence the admissibility of Dr. Godlkeski's opinions that the quantity of talc present suggests a broader level of exposure, consistent with methods commonly used in asbestos-related pathology. However, based upon the scientifically acceptable testing methods used, Dr. Godleski should be permitted to opine on the identification of talc and/or tremolite asbestos in the tissue samples from each Plaintiff.

Plaintiffs first contend that Defendants misconstrue—and thus overstate—the scope of Dr. Godleski's opinion regarding the causal relationship between talc and ovarian cancer. They assert that his conclusion is narrowly framed and does not purport to establish general causation. According to Plaintiffs, "Dr. Godleski's findings are just one piece of the causation puzzle" and do not amount to a determination of "complete causation." (Pls.' Godleski Opp. Br. at 17.) They maintain that rather, "Dr. Godleski's opinion is merely that the presence of talc and asbestos in the tissue offers 'contributory evidence'—that is, one piece of evidence contributing to the overall causation analysis." (*Id.* at 16.) However, the flaw in Plaintiffs' position is that Dr. Godleski does not rely on scientific studies sufficient to support even this more limited, contributory opinion on causation.

Indeed, along with his detection of talc particulates (and where present, tremolite asbestos), Dr. Godleski appeared to rely on only a limited number of published studies to support a "contributory" connection between the sampled bellwether Plaintiffs' ovarian cancer diagnosis and his findings concerning that Plaintiff's talc (or asbestos) exposure. (*See, e.g.*, Godleski Judkins Rep. at 4 ("In published studies (references 1, 2, 5, 9),[166] significant numbers of talc particles were

[166] *See* McDonald II 2019 at 13–27; McDonald I 2019 at 590–607; Erika Sato et al., *Analysis of Particles from Hamster Lungs Following Pulmonary Talc Exposures: Implications for Pathogenicity*, 17 Particle and Fibre Toxicol. (20), 1–16 (2020) ("Sato 2020"); Cramer 2007 at 498–501.

detected in pelvic tissues in women with ovarian cancer and a history of perineal talc use."); *see also, e.g.*, Godleski Gallardo Rep. at 6 ("The finding of one fiber with the magnesium/silicon atomic weight percent ratio of a tremolite asbestos fiber, a known and widely accepted carcinogen and a known component of cosmetic talc found in the pelvic tissues (References 11–13)[167] is similarly of great importance in linking Ms. Gallardo's ovarian cancer to cosmetic talc exposure."); Godleski Newsome Rep. at 5 ("The finding of this [t]remolite fiber fragment by the method used here is highly significant since this form of asbestos is a known contaminant of cosmetic talc and has been shown in recent tissue digestion studies of pelvic tissue to be found in women using talc for personal hygiene." (citing Steffen 2020).)

As to Dr. Godleski's talc-related causal conclusion, Dr. Godleski referenced Cramer 2007, a case report of a stage III serous ovarian cancer patient with decades of perineal talc use. (*See, e.g.*, Godleski Judkins Rep. at 4.) In that study, the patient's pelvic lymph nodes were examined by polarized light microscopy and confirmed by SEM/EDXS. (*See* Cramer 2007 at 498–99.) Plate-like birefringent particles with a

[167] *See* Joan E. Steffen et al., *Serous Ovarian Cancer Caused by Exposure to Asbestos and Fibrous Talc in Cosmetic Talc Powders–A Case Series*, 62 J. Occupational & Env't Med. (2), e65–e77 (2020) ("Steffen 2020"); Ronald E. Gordon et al., *Asbestos in Commercial Cosmetic Talcum Powder as a Cause of Mesothelioma in Women*, 20 Int'l J. Occup. & Env't Health (4), 318–332 (2014) ("Gordon 2014"); Hans Weill et al., *Medical Section of the American Lung Association: Health Effects of Tremolite*, 142 Am. Rev. Respiratory Disease (6), 1453–1458 (1990) ("ATS 1990").

magnesium and silicate signature were detected, which the authors found "compatible with talc." (*Id.* at 499.)

Defendants criticize that Cramer 2007 is a single, anecdotal, non-causal case report wherein the authors themselves disclaim any causal relationship between ovarian cancer and talc usage. (*See* Defs.' Godleski Br. at 11–12 & n.43.) Moreover, Defendants point out that Dr. Godleski makes no statements or suggestions regarding talc's tendency to cause inflammation. Plaintiffs did not substantively respond to Defendants' criticism of Dr. Godleski's reliance on Cramer 2007.[168]

I agree with Defendants' position. Cramer 2007 is a single case report describing the presence of talc particles in the pelvic lymph nodes of a woman with long-term genital talc use and ovarian cancer. As the authors explain, the purpose of their report was merely to "infuse a fresh perspective on the talc and ovarian cancer association." (Cramer 2007 at 500.) The authors explicitly acknowledge the limitations of their observations, noting that "case reports cannot establish causality," and expressly disclaim "that a causal relationship between ovarian cancer and talc use is proven for this case or in general." (*Id.*) Rather than supporting even a contributory causal inference, the article concludes that "this *description* of talc in

[168] I evaluated the applicability of Cramer 2007 in my prior Opinion to a conclusion made by one of Plaintiffs' general causation experts, Dr. Anne McTiernan, which is 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." *See In re Johnson & Johnson*, 509 F. Supp. 3d at 176 & n.41. I found that Cramer 2007 did not support the biological plausibility of an inhalation theory. *See id.* at 176–77.

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 (emphasis added).) While the report "may prompt new studies and offer new insights" into the debated association, it neither confirms nor supports the association. (*Id.* at 498.)

Moreover, the study's scope and methodology underscore its exploratory nature. It is based on a single patient and lacks any control group, quantitative analysis, or epidemiological framework to test causation. As courts have noted, "case reports are merely accounts of medical events. They reflect only reported data, not scientific methodology." *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002). "Both from a scientific perspective and for legal causation purposes, the distinction between epidemiological evidence and anecdotal evidence (i.e., case series and case reports) is substantial and consequential." *In re Abilify*, 299 F. Supp. 3d at 1360.

Thus, courts consistently disfavor case reports and case studies as evidence of causation because they lack controls and statistical context, do not isolate alternative causes or explain a causal mechanism, and are susceptible to reporting biases—so while they may sometimes be considered cautiously alongside other scientific information, they cannot, standing alone, establish causation. *See, e.g.*, *In re Mirena*

IUD Prods. Liab. Litig. ("*Mirena I*"), 169 F. Supp. 3d 396, 451 (S.D.N.Y. 2016) ("Case reports are generally disfavored by courts as evidence of causation because they merely describe 'reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group; [they] do not isolate and exclude potentially alternative causes; and [they] do not investigate or explain the mechanism of causation.'") (quoting *Siharath*, 131 F. Supp. 2d at 1361 (alterations in original).[169] Cramer 2007 is no exception to this recognized principle, in that it does not and cannot distinguish between association and causation.

The authors themselves state that a "more extensive study" is necessary to determine whether talc is found in the lymph nodes of women who did or did not use talc and whether such presence bears any relationship to ovarian cancer. (*See* Cramer 2007 at 500.) Thus, far from offering causal or even contributory proof,

---

[169] *See also In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 406 (S.D.N.Y. 2005) ("'Case reports lack controls and thus do not provide as much information as controlled epidemiological studies do. However, case reports are often all that is available on a particular subject. . . . Causal attribution based on case studies must be regarded with caution. However, such studies may be carefully considered in light of other information available, including toxicological data.' The difficulty with case reports, in other words, is distinguishing between association and causation. Simply because a patient exposed to a particular substance exhibited a set of symptoms does not mean that it was the substance that caused the symptoms." (quoting Mary Sue Henifin, Howard M. Kipen & Susan R. Poulter, *Reference Guide on Medical Testimony*, in *Reference Manual on Scientific Evidence* 439, 475 (Fed. Jud. Ctr., 2d ed. 2000)); *In re Abilify*, 299 F. Supp. 3d at 1309 (explaining that case studies "do not address prior medical history, use of other medications or drugs, risk factors, or the myriad of other issues necessary to scientifically evaluate whether the drug actually produced the observed adverse effect. . . .[,] have no controls, are susceptible to inherent reporting biases, lack statistical context, and are not verifiable through meaningful peer review," and therefore "cannot, standing alone, prove causation." (footnote omitted)).

Cramer 2007 merely hypothesizes a possible line of inquiry. Glaringly, Dr. Godleski drew from Cramer 2007 a conclusion that its authors themselves neither reached nor suggested. Accordingly, this undermines the reliability of Dr. Godleski's talc-related contributory causal conclusion. *See, e.g.*, *Happel v. Walmart Stores, Inc.*, 602 F.3d 820, 826 (7th Cir. 2010) ("To the extent that Dr. Hirsch does rely on medical literature to support his theory, the articles to which he cites stop short of reaching the same conclusion [he did]. . . . At best, Dr. Hirsch's testimony would have amounted to an 'inspired hunch,' and the district court certainly did not abuse its discretion in excluding it."); *McClain*, 401 F.3d at 1247, 1251–52 (affirming exclusion of expert who, among other things, exhibited an "inclination to draw overreaching conclusions from self-limiting medical articles, show[ing] the speculative nature of his opinions").[170]

Dr. Godleski also relied on a collection of case studies, McDonald I 2019, which followed five patients with ovarian cancer and a history of perineal talc use in whom talc particles were identified in pelvic tissues using polarized light microscopy and SEM/EDXS. (*See, e.g.*, Godleski Judkins Rep. at 4.) The authors

[170] *See also, e.g.*, *In re Onglyza*, 93 F.4th at 346 ("So Dr. Goyal drew 'unauthorized conclusions from limited data—conclusions the authors of the study d[id] not make,' betraying a 'lack of scientific rigor.'" (alteration in original) (quoting *McClain*, 401 F.3d at 1248)); *In re Acetaminophen*, 707 F. Supp. 3d at 353 ("Dr. Baccarelli is also willing to press conclusions that study authors are not willing to make. This willingness creates an 'analytical gap' between the conclusions reached by the authors and the conclusions he draws from their work."); *In re Abilify*, 299 F. Supp. 3d at 1351 ("Dr. Glenmullen may not extrapolate from this information a finding, conclusion, or implication about Abilify that the Moore Study authors themselves did not make.").

sought to document the presence and distribution of talc in pelvic tissue of talc-exposed patients and explore a biological pathway—migration via lymphatics—for talc to reach pelvic organs. (*See generally* McDonald I 2019.)

Defendants similarly challenge McDonald I 2019 as an unreliable case series for purposes of demonstrating causation. (*See* Defs.' Godleski Br. at 11–12 & n.43.) Again, Plaintiffs do not substantively respond to Defendants' specific attack of Dr. Godleski's reliance on McDonald I 2019. And I, again, must agree with Defendants' position.

The patients described in McDonald I 2019 were evaluated across multiple pelvic sites, i.e., ovary, fallopian tube, uterus/cervix, and pelvic lymph nodes, using polarized light microscopy and in situ SEM/EDXS, and compared against six non-exposed control patients with ovarian carcinoma. (*See generally* McDonald I 2019.) Talc was confirmed in two to four distinct pelvic sites per exposed person, with particles often eliciting inflammation. (*See id.* at 593.) Notably, the authors also observed the rare presence of talc in some control patients with no reported talc use. (*See id.* at 605.) Consistent with their morphological findings, the authors observed multi-site evidence of migration and tissue deposition consistent with lymphatic dissemination and inflammatory responses. (*See, e.g.*, *id.* at 603.)

But the study does not purport to establish individual-level causation and does not provide reliable support for that conclusion. It is a descriptive case series without

a defined source population or outcome comparison group. It does not imply temporality or dose-response, and does not control for confounding factors relevant to ovarian carcinogenesis. The presence of talc in tissues—particularly where the "non-exposed" also had ovarian cancer and talc was observed—supports only biological plausibility and exposure documentation. And although the authors themselves reference epidemiological literature and regulatory assessments classifying perineal talc as "possibly carcinogenic," the authors' conclusion is not causally related. (*See id.* at 590, 606 (concluding that this study "offer[s] new insight into the biologic potential of talc, its inflammatory potential, and its migration via pelvic lymphatics from the perineum").) As with Cramer 2007, a case series such as McDonald I 2019 primarily generates a hypothesis.

Although some courts have deemed case reports reliable for purposes of causal opinions when they exist in large quantities, *see, e.g.*, *Bee v. Novartis Pharms. Corp.*, 18 F. Supp. 3d 268, 304–05 (E.D.N.Y. 2014), neither Cramer 2007 nor McDonald I 2019 provide such support. *See also In re Fosamax*, 645 F. Supp. 2d at 184–85 (noting that "hundreds of published case reports," among other things, "adds to the reliability of [expert] opinions").

While Cramer 2007 and McDonald I 2019 do not undermine Dr. Godleski's assertion that "published studies" have shown that "significant numbers of talc particles were detected in pelvic tissues in women with ovarian cancer and a history

of perennial talc use," (*see, e.g.*, Godleski Converse Rep. at 5),[171] they do not provide reliable contributory evidence to conclude, to a reasonable degree of medical certainty, that talc caused or contributed to the development of ovarian cancer.

Dr. Godleski relied on at least two other published studies in support of his conclusion that talc presence in human tissue is "contributory evidence for a causal link between" such presence and the development of ovarian cancer. (*See* Godleski Judkins Rep. at 4 (citing McDonald II 2019 & Sato 2020).)

Like the other studies, neither of these two studies bridges the "analytical gap between the data and the opinion proffered." *See In re Hum. Tissue*, 582 F. Supp. 2d at 656. McDonald II 2019 is a method-focused study assessing talc in pelvic lymph nodes from patients with ovarian tumors that aimed to distinguish true tissue deposition from laboratory surface contamination. (*See generally* McDonald II 2019.) The study strengthens the evidence that talc can migrate to pelvic lymph nodes and that careful methodology is required to avoid overcalling contamination as in-tissue deposition, but it does not evaluate disease risk or causation or provide

[171] To be precise, McDonald I 2019 reported that "[a]ll patients had significant numbers of birefringent particles" in two or more pelvic sites. (McDonald I 2019 at 593.) Subsequent SEM/EDXS confirmed "substantial talc particle counts in the same tissue blocks corresponding to where birefringent particles were identified by light microscopy." (*See id.* at 594.) And although Cramer 2007 is not a quantitative series, the authors observed talc in three of four examined pelvic lymph nodes and documented plate-like talc particulates with corresponding elemental signatures compatible with talc. (*See* Cramer 2007 at 499.) Therefore, Cramer 2007 corroborates the observation in principle by documenting talc in pelvic lymph nodes in a long-term perineal talc user with ovarian cancer, though it is a single case without broader quantification. (*See generally* Cramer 2007.)

a basis for Dr. Godleski's own opinion that talc is a contributory cause to ovarian cancer. (*See id.*)

Sato 2020 re-analyzed archived materials from a 1987 hamster intratracheal instillation experiment to characterize the talc exposure and cellular responses using modern microscopy and spectroscopy. (*See generally* Sato 2020.) After confirming the talc powder contained no detectable asbestos, the authors observed talc induced acute and persistent inflammatory changes when compared with controls. (*See id.* at 11–14.) The authors interpreted these results as evidence that talc can cause inflammation and functional immune alterations independent of asbestos contamination, thereby strengthening biological plausibility for inflammation-based mechanisms. (*See id.*)

But the study is distinguishable from Dr. Godleski's opinion, in that it was a pulmonary, short-duration, high-dose instillation model in hamsters, not pelvic exposure to humans. (*See generally* Sato 2020.) *See also Wade-Greaux v. Whitehall Lab'ys, Inc.*, 874 F. Supp. 1441, 1480 (D.V.I. 1994), *aff'd*, 46 F.3d 1120 (3d Cir. 1994) ("The notion that one can accurately extrapolate from animal data to humans to prove causation without supportive positive epidemiologic studies is scientifically invalid because it is inconsistent with several universally accepted and tested scientific principles."). Additionally, Sato 2020 is being used by Dr. Godleski to support the proposition that "published studies" have shown "significant numbers of

talc particles were detected in pelvic tissues in women with ovarian cancer and a history of perineal talc use." (*See, e.g.*, Godleski Gallardo Rep. at 6.) But Sato 2020 involves neither women nor a history of perineal use of talc in hamsters. (*Compare, e.g.*, Godleski Gallardo Rep. at 6, *with* Sato 2020 at 1.) It is therefore wholly unsupportive of the proposition for which it is cited.

Furthermore, courts are "reluctant to allow expert testimony based upon animal studies to prove causation in humans unless there are good grounds to extrapolate data and results from animals to humans." *In re Hum. Tissue*, 582 F. Supp. 2d at 670 (citing *In re Paoli*, 35 F.3d at 742–43). Here, Dr. Godleski did not attempt to explain the import of Sato 2020 on his methodology. Dr. Godleski neither discussed "differences in absorption, metabolism, and other factors [that] may result in interspecie[s] variation in responses," nor consideration of the dose-response relationship. *Soldo*, 244 F. Supp. 2d at 466 (quoting Fed. Jud. Ctr., *Reference Manual* on Scientific Evidence at 130 (1994)); *see also In re Valsartan*, 2025 WL 314002, at *24–28 (criticizing expert's failure to "reliably extrapolate any of the data or results in the animal studies to humans" and excluding expert's opinions as, *inter alia*, unreliable).

In sum, Plaintiffs have not established the reliability of Dr. Godleski's causal opinions by a preponderance of the evidence. *See Daubert*, 509 U.S. at 592. The scientific and medical sources relied on by Dr. Godleski do not support his drawn

link between the presence of talc and its possible contribution to the development of ovarian cancer, thereby violating *Daubert*'s requirement that his opinion be supported by "good grounds." *See id.* at 590 ("Proposed testimony must be supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known."); *see also* Fed. R. Civ. P. 702(b) (requiring testimony that is "based on sufficient facts or data"). Indeed, "when an expert relies on the studies of others, he must not exceed the limitations the authors themselves place on the study." *In re Accutane Prods. Liab.*, No. 04-md-2523, 2009 WL 2496444, at *2 (M.D. Fla. Aug. 11, 2009), *aff'd*, 378 F. App'x 929 (11th Cir. 2010); *Mirena I*, 169 F. Supp. 3d at 431, 452 (same). And unlike Plaintiffs' other experts discussed in this Report and Recommendation, Dr. Godleski neither engaged with the relevant epidemiological literature nor conducted a Bradford Hill analysis to substantiate his causation opinion, further undermining the reliability of his methodology.

In short, Dr. Godleski's "[r]eliance upon medical literature for conclusions not drawn therein is not an accepted scientific methodology." *Rutigliano v. Valley Bus. Forms*, 929 F. Supp. 779, 785 (D.N.J. 1996). Therefore, I recommend that the Court preclude Dr. Godleski's causal opinions regarding talc usage and ovarian cancer because they are not based on a reliable scientific methodology.

Next, in this particular motion, Defendants do not directly contest Dr. Godleski's opinion as it relates to the causal connections drawn from the presence

of tremolite asbestos found in Plaintiffs Gallardo's and Newsome's tissue samples. (*See generally* Defs.' Godleski Br.) In their Asbestos-Related Motion, however, Defendants make such a challenge.[172] (*See* Defs.' Asbestos Br. at 83–84 & n.212.) I recommend that the Court preclude Dr. Godleski from opining that "tremolite asbestos found in the tissues of [Plaintiff Gallardo and Plaintiff Newsome is] contributory evidence for a causal link between the presence of [this] material[] and the development of [these patients'] ovarian cancer[s]."[173] (*See* Godleski Newsome Rep. at 7; *see also* Godleski Gallardo Rep. at 8.)

Dr. Godleski explained that tremolite asbestos fiber is a "known and widely accepted carcinogen and a known component of cosmetic talc." (*See* Godleski Gallardo Rep. at 6.) Therefore, according to Dr. Godleski, the detection of even a single tremolite asbestos fiber within Plaintiff Gallardo's pelvic tissue is "of great importance in linking Plaintiff Gallardo's ovarian cancer to cosmetic talc exposure."

---

[172] In relevant part, Defendants highlight that Dr. Godleski's identification of a particle of tremolite asbestos would likely not be recognized as such by Dr. Longo. (*See* Defs.' Asbestos-Related Br. at 83–84 n.212.) Defendants also argue that "[e]ven if these findings represented asbestos, [Dr. Godleski's] case-specific causation opinions regarding asbestos should be excluded for the same reasons discussed below: Dr. Godleski makes no attempt to compare these results to the epidemiology literature high occupational levels of exposure to a far more potent type of asbestos." (*See id.*) This notwithstanding, Defendants do appear to question through this motion Dr. Godleski's extrapolation of the presence of a larger amount of tremolite asbestos because of its detection within a small tissue sample. (*See* Defs.' Godleski Br. at 7 n.34.) I address this argument below with my discussion regarding the admissibility of Dr. Godleski's extrapolation-related opinions generally.

[173] As discussed below, I recommend, however, that the Court permit Dr. Godleski to opine on his identification of tremolite asbestos particles, fragments, and/or fiber detected within Plaintiff Gallardo's and Plaintiff Newsome's respective tissue samples.

(*Id.*; *see also* Godleski Newsome Rep. at 4–5; Godleski Dep. at 103:21–22 ("A. It's known that asbestos is a cause of ovarian cancer.").)

But sources relied on by Dr. Godleski do not provide a scientifically reliable basis for him to conclude that the presence of tremolite asbestos in gynecologic or pelvic tissue is contributory evidence of a causal link to ovarian cancer.[174] (*See* Godleski Gallardo Rep. at 6 (citing *supra* note 167); Godleski Newsome Rep. at 6 (citing Steffen 2020).) Moreover, Dr. Godleski has previously testified that he cannot cite to "any study that has tried to correlate ovarian cancer risk with the amount of tremolite found in reproductive tract tissue." (03/28/24 Godleski Dep. at 103:24–104:3; *see also id.* at 116:12–16 ("Q. . . . [T]here are no studies that have attempted to correlate the finding of talc or tremolite in tissue to a risk of developing endometrioid carcinoma, right? A. That's correct.").)

First, Dr. Godleski's reliance on Gordon 2014 for this proposition is misplaced. Gordon 2014 sought to investigate a "historic" cosmetic talc brand[175] linked to mesothelioma in women by determining whether it contained asbestos, whether normal use generated inhalable fibers, and whether those same fiber types were present in user tissue. (*See generally* Gordon 2014.) To do this, the authors

---

[174] I note that my finding in this section is limited to Dr. Godleski, who cannot opine on the causal connection between asbestos and ovarian cancer. Other experts who Plaintiffs proffer for such a connection are separately addressed in this Report and Recommendation. (*See supra* Part V.B.6.)

[175] Gordon 2014 does not identify the brand(s) by name.

tested more than 50 product containers of this specific brand of cosmetic talcum powder, conducted releasability experiments simulating normal use in a glovebox and in a bathroom-sized chamber, and performed analyses of lung and lymph node tissues from a woman who used the product and died of mesothelioma. (*See, e.g.*, *id.* at 319–320, 323.)

The study concluded that the cosmetic talc product contained asbestos, including tremolite, that typical application can aerosolize measurable asbestos concentrations, and that inhalation of those fibers likely contributed to the development of mesothelioma in the reported decedent. (*See id.* at 318–19, 325, 331; *see also id.* at 330 ("Our findings indicate that historic talcum powder exposure is a causative factor in the development of mesotheliomas and possibly lung cancers in women.").)

But these methods and conclusions pertain to product contamination, airborne exposure during use, and deposition in respiratory and lymphatic tissues with a mesothelioma outcome. (*See id.*) The study provides no epidemiologic analysis linking tremolite burdens in gynecologic or pelvic tissue to ovarian cancer incidence. (*See generally id.*) It also does not involve the perineal application of asbestos-containing cosmetic talcum powder, and it does not test ovarian tissue. (*See id.*) Even within its mesothelioma analysis, the study detects both anthophyllite and tremolite and does not isolate tremolite's effect from other amphiboles or talc particles. (*See,*

e.g., *id.* at 322.) It, therefore, does not support the claim that the mere presence of tremolite asbestos is contributory evidence of a causal link to ovarian cancer.[176]

Second, Dr. Godleski's reliance on an Official Statement of the American Thoracic Society, adopted in June 1990, is similarly unsupportive of his broader conclusion that the presence of tremolite asbestos in gynecologic or pelvic tissue is contributory evidence of a causal link to ovarian cancer. The American Thoracic Society's statement reviews scientific and regulatory questions surrounding the health risks of tremolite. (*See generally* ATS 2019.) It confirms that tremolite asbestos may cause the same diseases associated with other amphiboles, with particular emphasis on mesothelioma and lung cancer. (*See, e.g.*, *id.* at 15.) But it does not offer ovarian cancer-specific causal data for tremolite. It also limits its observations to occupational and airborne exposures in humans, and intrapleural instillation in animals. (*See, e.g.*, *id.* at 3–12.) While the statement may bolster Dr. Godleski's assertion that tremolite asbestos is "a known and widely accepted carcinogen," (*see, e.g.*, Godleski Gallardo Rep. at 6), it does not purport to draw a causal link between the presence of tremolite asbestos within gynecologic tissue and the development of ovarian cancer.

---

[176] Moreover, Gordon 2014 acknowledges the existence of "a few studies that have examined talcum powder and its potential to cause ovarian tumors." (Gordin 2014 at 330). However, the authors concede that these "studies were inconclusive, but suggested that talc, asbestos, or both may cause these cancers through vaginal exposure." (*Id.*) Importantly, Dr. Godleski neither addresses this disclaimer in the study nor other studies that have focused on ovarian cancer.

Lastly, Dr. Godleski's reliance on Steffen 2020 likewise fails to bridge the analytical gap. *In re Hum. Tissue*, 582 F. Supp. 2d at 656. The Steffen 2020 case series describes ten women with serous ovarian cancer who reported long-term cosmetic talc use. (*See generally* Steffen 2020.) Talc was detected in all ten women, and asbestos (e.g., tremolite and anthophyllite) was detected in eight of the ten women, using transmission electron microscopy. (Steffen 2020 at e65–e66, e73.) The authors sought to recreate perineal talc application in a controlled room and measured inhalation exposure of asbestos-containing cosmetic talc.[177] (*See, e.g.*, *id.* at e66.) They then combined those measurements with each case's reported talc-use history to calculate a lifetime inhalation dose. (*See id.* at e67.) After analyzing each case's gynecologic and pelvic tissue (e.g., ovaries, fallopian tubes, pelvic lymph nodes) using transmission electron microscopy to detect, in part, talc and tremolite asbestos, they estimated ovarian cancer risk by adapting an EPA mesothelioma dose-response model to ovarian cancer, and mapping each case's asbestos-dose estimate to that model.[178] (*See, e.g.*, *id.* at e65, e67.)

---

[177] The authors analyzed the talc containers for asbestos and talc. (*See, e.g.*, Steffen 2020 at e65, e69.) "The asbestos fibers found in the 'cosmetic' talc containers matched those found in tissues." (*See id.* at e65.)

[178] In this context, the EPA mesothelioma dose-response model refers to the EPA's 1986 Airborne Asbestos Health Assessment Update table that gives predicted lifetime mesothelioma risk from continuous, environmental asbestos exposure, which is assumed to be 24 hours/day, 365 days/year. *See* Steffen 2020 at e67 n.92 (citing U.S. Env't Protection Agency, Airborne Asbestos Health Assessment Update (1986)).

The authors ultimately concluded that, among other things, these "cases provide more evidence of the causal link between asbestos, talc, and ovarian cancer and indicate that asbestos is present in consumer talc products at a level sufficient to cause disease." (*Id.* at e73.) But Dr. Godleski's reliance on Steffen 2020 for a contributory causal link between tremolite asbestos and the development of ovarian cancer suffers from several flaws that undermine the reliability of his methodology.

First, Steffen 2020 is a litigation-derived case series. The paper itself has a disclaimer that the work "was not experimental and was originally conducted pursuant to a lawsuit," whereby plaintiffs' counsel[179] funded the tissue analyses and patient examinations and interviews. (*See* Steffen 2020 at e65.) Indeed, unsurprisingly, courts have found litigation-derived research to weigh against reliability. *See, e.g.*, *Awad v. Merck & Co.*, 99 F. Supp. 2d 301, 304 (S.D.N.Y. 1999), *aff'd sub nom.*, *Washburn v. Merck & Co.*, 213 F.3d 627 (2d Cir. 2000) ("[A] significant consideration is whether research was conducted independently or for the sole purpose of litigation."); *see also Mirena I*, 169 F. Supp. 3d at 456 (finding litigation-derived opinion to be "another factor that demonstrates Dr. Wray's opinion is not sufficiently reliable under *Daubert* and would not stand up in a scientific setting").

[179] The funding and disclosure sections of Steffen 2020 do not identify the specific attorneys or law firms by name beyond describing them collectively as "Plaintiffs' attorneys in litigation against Johnson & Johnson (Ingham et al. v. Johnson & Johnson et al.)." (*See* Steffen 2020 at e65.)

Second, the study is a case series without controls that focuses on inhalation exposure—as opposed to perineal exposure—of asbestos. As explained above, a case report or case series standing alone cannot ordinarily establish causation. *See, e.g.*, *id.* at 451. But, Steffen 2020 purports to be more than a case series. The authors employ a simulation separate from the study's case series to demonstrate that the application of talc can create an asbestos-containing dust cloud that users will then inhale. Taken together, Steffen 2020 purports to establish that when using cosmetic talc powders, asbestos can be inhaled and migrate to pelvic tissues, which could cause ovarian cancer. However, because this is a small case series with no control group—assembled in a litigation context—Steffen 2020 does not reliably demonstrate that tremolite, when present in gynecologic or pelvic tissue, causes the development of ovarian cancer. It may support the suggestion of a general causal link when combined with other epidemiological literature, but Steffen 2020, alone, cannot support a "link[] [between] Plaintiff Gallardo's ovarian cancer [and] cosmetic talc exposure." (*See* Godleski Gallardo Rep. at 6.)

I acknowledge that expert testimony should generally "not be excluded simply because there is no literature on point," so long as there are "other factors that demonstrate the reliability of the expert's methodology." *Schneider*, 320 F.3d at 406; *see Heller*, 167 F.3d at 155 (explaining a medical expert need not "always cite published studies on general causation in order to reliably conclude that a particular

object caused a particular illness"). Here, however, there is an absence of other factors demonstrating the reliability of Dr. Godleski's cursory methodology supporting his causal conclusion—even if his opinion is focused on contributory evidence and not general causation. For example, Dr. Godleski did not discuss any temporal relationship between the sampled Plaintiffs' perineal talc usage and their development of ovarian cancer. Dr. Godleski did not differentiate between potential degrees of exposure and does not offer alternative explanations for the alleged association.

Further, Plaintiffs rely on *Milward v. Acuity Specialty Products Group, Inc.*, 639 F.3d 11 (1st Cir. 2011), for the proposition that *Daubert* does not require each scientific study or line of proof to independently establish causation; instead, an expert may reliably synthesize multiple non-dispositive sources of evidence to reach a causation opinion. (*See* Pls.' Godleski Opp. Br. at 16–17.) Plaintiffs' reliance is misplaced. *Milward* addresses the admissibility of a general causation opinion grounded in a "weight of the evidence" methodology, which is not used by Dr. Godleski. *Milward*, 639 F.3d at 17.

In reversing the district court's exclusion of the plaintiffs' general causation expert, Dr. Martyn Smith, the First Circuit emphasized Dr. Smith's use of integrated

mechanistic and epidemiologic evidence,[180] despite the absence of statistically significant epidemiology. *See id.* at 19–26. Unlike Dr. Godleski's methods, *Milward* does not endorse using case-specific sampled tissue findings to suggest causation absent other evidence such as scientific consensus, dose/threshold or reliable attribution, or differential etiology.

As proponents of Dr. Godleski's opinions, Plaintiffs bear the burden of demonstrating admissibility by a preponderance of the evidence. *See* Fed. R. Evid.702; *see also* Fed. R. Evid.702 advisory committee's note to 2023 amendment ("[T]he rule has been amended to clarify and emphasize that expert testimony may not be admitted unless the proponent demonstrates to the court that it is more likely than not that the proffered testimony meets the admissibility requirements set forth in the rule." (citing Fed. R. Evid.104(a)); *Crowley*, 322 F. Supp. 2d at 537 ("The proponent bears the burden of establishing admissibility by a preponderance of the evidence."). Because Plaintiffs' arguments center on the narrowness of Dr. Godleski's causal-related opinion, Plaintiffs advocate that the opinion need not be based on vast scientific support. I recognize the carefully crafted language used by Dr. Godleski insofar as it does not expressly opine that a causal relationship exists

[180] Dr. Smith employed a "weight of the evidence" framework that included multiple sources of evidence: scientific consensus that benzene causes acute myeloid leukemia generally, common etiology across acute myeloid leukemia subtypes, mechanistic toxicology showing benzene metabolites cause stem-cell chromosomal damage, epidemiological data suggestive (though not statistically significant) of an association between benzene exposure and acute promyelocytic leukemia, and other evidence. *See id.* at 19–20.

between the presence of talc and/or asbestos in pelvic tissue and the development of ovarian cancer. According to Dr. Godleski, such presence is merely "contributory evidence for a causal link" between them. However, fine tuning language does not save the unreliability of his opinion. Without the benefit of reliance on epidemiological studies,[181] sufficiently numbered and/or analogous case reports, or other "good grounds," Dr. Godleski lacks adequate support to opine even on the contributory impact talc and/or tremolite asbestos may have on the causal link between these materials and ovarian cancer.

Based on the foregoing, I find that Plaintiffs have not shown, by a preponderance of the evidence, that Dr. Godleski's opinion is reliable. In particular, Plaintiffs have not demonstrated through Dr. Godleski that the presence of talc or tremolite asbestos in gynecological or pelvic tissue reliably supports a contributory cause to the development of ovarian cancer. Accordingly, I recommend that the Court exclude Dr. Godleski's opinion and testimony as to these causal conclusions. *See In re Pfizer Inc. Secs. Litig.*, 819 F.3d 642, 665 (2d Cir. 2016) (excluding unreliable portions of an expert's testimony "[w]hen faced with . . . testimony that contains both reliable and unreliable opinions").[182]

---

[181] After all, the "best evidence of general causation in a toxic tort case" is epidemiological, and it cannot be ignored where available. *See, e.g.*, *In re Zoloft*, 176 F. Supp. 3d at 492 (quoting *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005) (collecting cases)).

[182] Defendants also contend that Dr. Godleski fails to offer evidence that any of the sampled Plaintiffs crossed a scientifically supported "threshold" connecting particle counts to ovarian cancer risk, including for specific ovarian cancer subtypes, (*id.* at 12–14), and that Dr. Godleski's

Next, Defendants challenge Dr. Godleski's identification of talc particulates. (*See* Defs.' Godleski Br. at 16–17.)[183] However, as Plaintiffs correctly point out, Defendants appear to misconstrue Dr. Godleski's methodology, (*see* Pls.' Godleski Opp. Br. at 13–14), which I find reliable for purposes of identifying the presence of talc and/or asbestos.

Defendants argue that Dr. Godleski evaluated birefringent materials using a "homespun criteria" in detecting that such material is talc. (Defs.' Godleski Br. at 16–17.) In so arguing, Defendants do not specify what part of Dr. Godleski's methodology is "homespun," or how his testing of talc and/or asbestos materials are flawed. In fact, Defendants' challenge of Dr. Godleski's testing method is quite cursory. Indeed, without any specificity, Defendants' arguments essentially amount to a criticism of Dr. Godleski's conclusions, but not his methodology. Case law is clear that the focus "is on the expert's principles and methodology, not on his conclusions." *Equinox Props., LLC v. Harford Mut. Ins. Co.*, Civ. No. 21-15929, 2023 WL 5447279, at *3 (D.N.J. Aug. 24, 2023) (citing *Daubert*, 509 U.S. at 595).

---

failure to identify every foreign particle observed within each tissue sample undermines his causation conclusion, (*id.* at 17–18). But because these assertions go directly to Dr. Godleski's causal conclusion, which I recommend be excluded, I need not address them.

[183] Defendants do not appear to directly take issue with Dr. Godleski's identification of tremolite asbestos particles, fibers, and/or fragments. (*See generally* Defs.' Godleski Br.) As discussed above, *supra* Part VI.B.i, Defendants argue in their Asbestos-Related Motion that Dr. Godleski's identification of a single tremolite asbestos fragment in Plaintiff Newsome's tissue sample may not be recognized as such by Dr. Longo. (*See* Defs.' Asbestos Br. at 83–84 n.212.)

In any event, I find Dr. Godleski's methodology for identifying the presence of talc within human tissue reliable. The method by which he receives, prepares, and studies the paraffin tissue blocks has been subject to peer review and is generally accepted within the scientific community. (*See, e.g.*, Godleski Judkins Rep. at 3 (citing Charu Thakral, Jerrold L. Abraham, *Automated Scanning Electron Microscopy and X-ray Microanalysis for in situ Quantification of Gadolinium Deposits in Skin*, J. Electron Microscopy (Tokyo), 56(5), 181–7 (2007)); *see also* McDonald et al., *Magnesium/Silicon Atomic Weight Percent Ratio Standards for the Tissue Identification of Talc by Scanning Electron Microscopy and Energy Dispersive X-ray Analysis*, Ultrastructural Pathology, 43:6, 248–260 (2019) (defining an empirical, reliable magnesium-to-silicon atomic weight percent ratio for identifying talc in human tissues using SEM/EDXS).)

In accordance with cited medical and scientific literature, Dr. Godleski uses SEM/EDXS, observes morphological characteristics, and conducts a spectral analysis. (*See generally e.g.*, Godleski Judkins Rep.) From there, Dr. Godleski classified a particle as talc only if its magnesium-to-silicon atomic weight ratio matches the established talc standard (around 0.649, within a tight acceptance window, typically ±5%), with oxygen present, and with morphology consistent with talc (platy particles and, when present, fibers showing a length-to-width ratio greater than about 3:1 and roughly parallel sides). (*Id.*) While this data, along with particles'

locations, is retained and available for confirmatory testing, Defendants' rebuttal experts have not independently verified Dr. Godleski's findings by performing their own tests. (*See* Pls.' Godleski Opp. Br. at 7–8.) *See also Cohen*, 125 F.4th at 462 (noting that "whether a method consists of a testable hypothesis" is "good grounds" to support the reliability of an expert's testimony).

Moreover, Dr. Godleski's qualifications as, among other things, an expert in analytical microscopy lend sufficient credence to the reliability of his methods of particle detection and identification. *See In re Paoli*, 35 F.3d at 742 n.8 (recognizing that "the qualifications of the expert witness testifying based on the methodology" support reliability). Plaintiffs have thus demonstrated the reliability of Dr. Godleski's opinions by a preponderance of the evidence as they relate to the identification of talc and tremolite asbestos.

Finally, Defendants seek exclusion of Dr. Godleski's extrapolation from a small, in-situ SEM/EDXS sampling plane to a larger tissue burden. (*See* Defs.' Godleski Br. at 14 (citing Godleski Rausa Rep. at 4; Godleski Newsome Rep. at 4).) Plaintiffs do not meaningfully address this argument in their opposition brief. (*See generally* Pls.' Godleski Opp. Br.) In subsequent supplemental briefing, Plaintiffs argue that Dr. Godleski's extrapolation opinions are mischaracterized by Defendants and supported by relevant literature and Dr. Godleski's education, training, and professional experience. (*See* Pls.' December 8, 2025, Ltr. at 4–6.)

Defendants first highlight Dr. Godleski's failure to rely on supportive medical or scientific literature.[184] (*See* Defs.' Godleski Br. at 14 (citing Godleski Rausa Rep. at 4; Godleski Newsome Rep. at 4).) Dr. Godleski asserted reliance on "[c]omparable studies [that] have been done with asbestos fibers in tissue sections," and suggested that "the finding of one fiber in a tissue section comparable to the amount of tissue studied here would indicate at least 100 fibers per gram of tissue which is indicative of a substantial exposure." (*See, e.g.*, Godleski Rausa Rep. at 4 (citing Victor L. Roggli et al., *Numbers of Asbestos Bodies on Iron-Stained Tissue Sections in Relation to Asbestos Body Counts in Lung Tissue Digests*, 14 Hum. Pathology (4), 355–61 (1983) ("Roggli 1983"))[185]; *see also* Godleski Dep. at 223:8–12 (confirming use of "Roggli paper to estimate what the total volume would be per gram of tissue").)

As an initial matter, and despite Plaintiffs' supplemental arguments to the contrary, (*see* Pls.' December 8, 2025, Ltr. at 4), Defendant do not "mischaracterize[]" Dr. Godleski's extrapolation opinions or the methodology underlying said opinions. As outlined above, Dr. Godleski extrapolates a substantial

---

[184] Defendants also rely on *Wade-Greaux v. Whitehall Laboratories, Inc.*, for the proposition that such extrapolation cannot be based on speculation. (*See* Defs.' Godleski Br. at 14 (citing *Wade-Greaux*, 874 F. Supp. at 1485).) However, *Wade-Greaux* is distinguishable, because that case involved an expert's extrapolation of data from animal studies to human condition, which is not comparable to the context here.

[185] Neither party attached Roggli 1983 to their briefs for and against the exclusion of Dr. Godleski's opinions and anticipated testimony. (*See generally* Defs.' Godleski Br.; Pls.' Godleski Opp. Br.)

exposure of talc and asbestos based on the detection rate measured within an "extremely small volume of tissue." (*See, e.g.*, Godleski Rausa Rep. at 4.) Plaintiffs assert that Dr. Godleski utilized a "formula-based extrapolation founded on actual observation" that is actually "not an extrapolation," but an "objective clinical observation." (*See* Pls.' December 8, 2025, Ltr. at 5; *see id.* (arguing that Dr. Godleski's extrapolation opinions are "qualitative—not quantitative").) But this is inconsistent with Dr. Godleski's own testimony, which described a quantitative methodology based on Roggli 1983's formulaic methodology. (*See* Godleski Dep. at 228:1–9 (confirming that, based on Roggli 1983, "one particle or fiber can represent hundreds in the tissue per gram, if we have more than one . . . you can do the math to determine what the number might be expected to be"); *see also id.* at 223:8–12 (confirming use of "Roggli paper to estimate what the total volume would be per gram of tissue").) Therefore, I find that Defendants have not mischaracterized Dr. Godleski's methodology in this context.

Next, I find that Roggli 1983 does not support Dr. Godleski's extrapolation of a detection of a small amount of talc to a larger burden. Roggli 1983 examined how *asbestos* body counts observed on iron-stained paraffin *lung* sections correlate with counts obtained from wet-tissue digestions. (*See generally* Roggli 1983.) After using correction factors, the authors propose that roughly 200 asbestos bodies per gram of wet lung tissue corresponded to two asbestos bodies in a 2 × 2 cm tissue section.

(*See generally id.*) The authors repeatedly cautioned that local variability and sampling error—especially in small specimens—undermine the reliability of extrapolating from a small sample to a whole-tissue burden. (*See, e.g.*, *id.* at 359–61.)

In addition, neither the authors of Roggli 1983 nor Dr. Godleski attempted to reconcile Roggli 1983's applicability of asbestos to the detection of talc in this case. Additionally, neither the authors of Roggli 1983 nor Dr. Godleski attempted to address whether the anticipated distribution of asbestos or talc would differ if the examined tissue was sampled from gynecologic or pelvic tissue as opposed to lung tissue. Dr. Godleski impermissibly extrapolated conclusions from Roggli 1983 that "exceed the limitations the authors themselves place[d] on the[se] stud[ies]." *Mirena I*, 169 F. Supp. 3d at 431 (alterations in original) (citation omitted).

Lastly, the record does not sufficiently support Plaintiffs' assertion that Dr. Godleski's education, training, and/or experience sufficiently support the reliability of his methodology for his extrapolation opinions. (*See, e.g.*, Nov. 25, 2025 Tr. at 203:12–17 (claiming Dr. Godleski's "40 years of experience" support the reliability of his extrapolation methodology).) None of Dr. Godleski's expert reports indicate—much less affirmatively state—that his background or professional experience played any role in forming his extrapolation. (*See generally* Godleski Gallardo Rep.; Godleski Converse Rep.; Godleski Newsome Rep.; Godleski Rausa Rep.; Godleski

Judkins Rep.) Instead, all of his expert reports expressly anchor his extrapolation to Roggli 1983. (*See id.*) With one very recent exception, most of Dr. Godleski's testimony so far in this case and others relies solely on Roggli studies for support of his extrapolation methodology and opinions, with no mention of reliance on his education, training, or experience. (*See, e.g.*, 03/28/24 Godleski Dep. at 111:5–13; 115:2–10; 223:8–12; 228:5–9.)

Dr. Godleski only recently testified that, in many of his studies, his "*experience* is that if we cut additional sections [of tissue] and look at both the block as well as those additional sections, we'll have essentially the same number of particles in each section as we do in the . . . block. So the number of particles we have, if we find three or four, means there's three or four at every level all the way through the block." (*See* Pls.' Dec. 8, 2025 Ltr., Ex. 9 ("Godleski Dep. III") at 112:27–113:13 (emphasis added).) He further asserted that the literature and his own experience "support[] making an extrapolation or an assumption" that one would find comparable levels of talc and/or asbestos throughout a larger tissue sample based on observations drawn from a smaller sample. (*Id.* at 145:3–12; *see also id.* at 145:13–18 (asserting that "this is not a vague extrapolation; this is experience").)

I am not persuaded that this deposition testimony is sufficient. At the outset, it appears to be the only evidence suggesting that Dr. Godleski relies on personal experience as a basis for his extrapolation methodology. That testimony suffers from

several defects. First, it was given in an action before the Superior Court of the State of California, County of Los Angeles—not in this MDL. Second, it was elicited more than four years after Dr. Godleski authored the expert reports at issue here. As a result, I cannot discern when Dr. Godleski allegedly acquired the experience that Plaintiffs now invoke to support a methodology introduced years earlier. Importantly, Dr. Godleski provided no comparable testimony in any deposition taken in this MDL, nor did he reference such experience in any of his expert reports submitted in these proceedings. To the contrary, at other points in time, Dr. Godleski testified that his extrapolation-related opinions were based on his reading of Roggli 1983, without reference to any independent expertise or experience supporting that approach. (*See, e.g.*, Godleski Dep. at 111:5–13, 115:2–10, 223:8–12, 228:5–9; Godleski Dep. II at 84:1–7.) Under these circumstances, I do not find that the belated deposition testimony submitted by Plaintiffs cures the fundamental deficiency I find fatal to Dr. Godleski's extrapolation opinion.

In sum, the record demonstrates that Dr. Godleski's extrapolation is grounded in unsupportive literature and not in any sufficiently articulated, independent expertise he claims to possess. Accordingly, I conclude that Dr. Godleski lacks

sufficiently "good grounds" for such an extrapolation and recommend that the Court preclude his extrapolation-related opinions. *See Paoli*, 35 F.3d at 742.[186]

iv. Fit

Defendants argue that Dr. Godleski's opinions are irrelevant to this case because his opinion is silent on whether the five bellwether Plaintiffs actually used Defendants' products. (Defs.' Godleski Br. at 18–20.) Dr. Godleski need not, however, draw such a conclusion in his capacity as Plaintiffs' expert on these testing issues, and importantly, he need not have made that conclusion for purposes of helping the trier of fact. *See* Fed. R. Evid.702(a).

In pertinent part, Dr. Godleski "offers the opinion to a reasonable degree of medical certainty that the particles that he identified [in each Plaintiff] are talc or asbestos." (Pls.' Godleski Opp. Br. at 18.) Dr. Godleski did not opine on each

[186] Defendants also argue that the manner with which Dr. Godleski selects tissue samples to examine showcases impermissible sampling bias and casts doubt on his conclusion that a greater presence of talc—and, where present, tremolite asbestos—likely exists within the overall tissue. (*See* Defs.' Godleski Br. at 14–15.) Since I recommend that the Court preclude Dr. Godleski from opining on this inference, I need not fully address this argument.

For the avoidance of doubt, however, I note that this argument mischaracterizes both Dr. Godleski's assignment and his approach. Dr. Godleski did not purport to analyze every tissue sample available to him, nor was he required to do so. His task was to examine Plaintiffs' tissue samples for the presence of foreign materials, including talc. In carrying out that assignment, Dr. Godleski used his "past experience and the medical literature on the diagnosis of talc in tissues" to select for additional evaluations those samples that were most likely to contain foreign particulates, without knowing beforehand the elemental composition of those particulates. (*See, e.g.*, Godleski Gallardo Rep. at 4.) This selection process does not constitute selection bias. As the record reflects, not every birefringent particle subjected to further testing was ultimately determined to be talc, undermining Defendants' premise that he targeted only samples he already believed would confirm his hypothesis. His methodology thus reflects a reasoned, scientifically grounded approach—not an outcome-driven effort to curate favorable samples.

bellwether Plaintiffs' perineal application of talc, or their respective uses of Defendants' products; instead, the affected Plaintiffs and their experts provide that evidence.[187] (*See generally e.g.*, Godleski Judkins Rep.) Even without such conclusions, Dr. Godleski's opinions would no doubt "help the trier of fact understand the evidence," "determine a fact in issue," or provide "scientific knowledge for purposes of the case." *In re Paoli*, 35 F.3d at 741, 743–74 & n.12. Indeed, the "standard for fitness is 'not that high' but it is 'higher than bare relevance.'" *In re Hum. Tissue*, 582 F. Supp. 2d at 657 (quoting *In re Paoli*, 35 F.3d at 745). Any issue Defendants have regarding whether these Plaintiffs applied their talcum powder products to the perineum area should be probed on cross-examination. Therefore, I find that Dr. Godleski's opinions squarely fit the facts of this case under Rule 702.

Given the foregoing, I find that Plaintiffs have proven by preponderance of the evidence that Dr. Godleski is qualified to give his expert opinion on his identification of talc and tremolite asbestos in the tissue samples from each examined

[187] To be clear, Dr. Godleski's testimony on talc use is not at issue, given my recommended ruling on causation. Plaintiffs offer evidence through other experts' testimony and opinions that Plaintiffs used Defendants' cosmetic talcum powder. (*See, e.g.*, Pls.' General Causation Opp. Br. at 23–24 ("The bellwether plaintiffs *daily* applied Johnson's Baby Powder and/or Shower to Shower to their genital area for decades—the shortest period being 2 years, the longest being 55 years, and the average being just over 42 years. The number of lifetime applications range from approximately 7,000 to 20,000. Over the course of three decades, bellwether Plaintiffs used between 221 and 568 containers of Johnson's Baby Powder and Shower to Shower." (alteration in original) (citing ECF No. 33130-37).)

Plaintiff; however, I recommend that he cannot opine on whether the presence of talc or tremolite asbestos within gynecologic or pelvic tissue may be a contributory cause to the development of ovarian cancer. I further recommend that Dr. Godleski cannot opine on whether the measured quantity of talc within tissue samples implies a broader exposure level in a manner consistent with asbestos-related pathology methods. Those portions of his opinions that I recommend are admissible, I find, are reliable and "fit" the facts at issue in this case. Therefore, I recommend that the Court grant in part and deny in part Defendants' Motion to Exclude the Opinions of Dr. John J. Godleski.

2. Plaintiffs' Motion to Exclude The Opinions Of Dr. Juan Felix And Dr. Teri Longacre

Plaintiffs move to exclude, under Rule 702, certain opinions and expected testimony of Drs. Juan Felix and Teri Longacre because they are speculative, methodologically unsupported, and outside their expertise in particle identification. (*See generally* Pls.' Felix & Longacre Br.) Plaintiffs seek to bar both doctors from testifying that Dr. Godleski's detection of talc and, where present, tremolite asbestos, in five of bellwether Plaintiffs' gynecologic and pelvic tissue samples is the result of surgical or post-surgical contamination. (*See generally id.*) Defendants oppose, arguing these are permissible, well-founded critiques of Dr. Godleski's methods and conclusions and are therefore admissible under Rule 702. (*See generally* ECF No. 33108 ("Defs.' Felix & Longacre Opp. Br.").)

At the outset, I again address rebuttal experts and the standard by which they are evaluated on a motion to exclude. Plaintiffs contend that their opinions regarding contamination are inadmissible because, among other things, they are not supported by proffered methodology, "evidence," "a single study or journal article, or "reference of any kind." (Pls.' Felix & Longacre Br. at 7.) Defendants cite several cases outside of the Third Circuit to suggest that the role of a rebuttal expert is different than that of an affirmative expert. (*See* Defs.' Felix & Longacre Opp. Br. at 8–11.)

As a general matter, a rebuttal expert need not conduct a parallel analysis mirroring the methodology being critiqued. *See, e.g.*, *Capri Sun GmbH*, 595 F. Supp. 3d at 140 ("At bottom, a rebuttal expert need not proffer a methodology or model, but only critique the opposing expert's."); *In re Zyprexa*, 489 F. Supp. 2d at 285 ("[D]efendants' experts have a less demanding task, since they have no burden to produce models or methods of their own; they need only attack those of plaintiffs' experts."); *see also Aviva Sports, Inc.*, 829 F. Supp. 2d at 834 ("A number of other district courts have held that rebuttal expert witnesses may criticize other experts' theories and calculations without offering alternatives." (collecting cases)). No authority within the Third Circuit suggests otherwise.

Nonetheless, because all expert testimony must satisfy *Daubert*, a rebuttal expert who seeks to undermine another expert's model through affirmative

conclusions or findings must still articulate reliable bases for those views, grounded in sound methods and principles of analytical evaluation sufficient to support their opinions and to challenge the opposing opinion. *See, e.g.*, *In re Generic Pharms. Pricing Antitrust Litig.*, No. 16-md-2724, 2024 WL 4980784, at *14 (E.D. Pa. Dec. 3, 2024).

With these considerations in mind, I will first turn to Plaintiffs' qualification-based arguments for exclusion, followed by Plaintiffs' reliability arguments.

i. Qualifications

Plaintiffs appear to challenge the qualifications of both Dr. Felix and Dr. Longacre to offer opinions regarding "particle identification" and the use of "methodological tools (i.e., SEM)" employed in that process ("SEM/EDXS Qualifications"). (Pls.' Felix & Longacre Br. at 6.) As Defendants correctly note, Plaintiffs' challenge to these experts' SEM/EDXS Qualifications is misplaced. Plaintiffs seek exclusion only of opinions and testimony related to the alleged contamination of certain Plaintiffs' tissue samples during and after their respective surgical procedures. Accordingly, the SEM/EDXS Qualifications do not pertain to contamination-related issues. (*See generally* Pls.' Felix & Longacre Br.) Nonetheless, for the sake of completeness, I will evaluate Dr. Felix's and Dr. Longacre's qualifications within the limited scope of Plaintiffs' narrow motion to

exclude certain opinions and testimony. Ultimately, I find both Dr. Felix and Dr. Longacre qualified to opine on the issue of tissue-sample contamination.

Dr. Felix is a board-certified anatomic pathologist and cytopathologist with subspecialty expertise in gynecologic pathology. (*See, e.g.*, Felix Judkins Rep. at 2.) He earned his B.A. from Columbia College and M.D. from Cornell University Medical College. (*Id.*) Subsequently, Dr. Felix completed residency in anatomic pathology and a gynecologic pathology fellowship at the New York Hospital-Cornell Medical Center, joining the faculty there. (*Id.*) He spent 25 years at the University of Southern California, advancing to Full Professor, and currently serves as Chief of Anatomic Pathology, Professor, and Vice Chair in the Department of Pathology at the Medical College of Wisconsin. (*Id.*) Prior to his current position, Dr. Felix acted as Chief of Cytopathology at the Los Angeles County, University of Southern California Medical Center and Director of Gynecological Pathology at the Keck Medical Center of the University of Southern California. (*Id.*)

Dr. Felix has founded two anatomic pathology laboratories and maintains an active clinical practice, rendering daily diagnoses in gynecologic malignancies, including ovarian, uterine, and cervical cancers. (*Id.*) His career reflects substantial laboratory leadership, academic teaching, and collaborative research focused on ovarian and uterine cancers. (*Id.*)

Dr. Longacre is a board-certified diagnostic surgical pathologist and Professor of Pathology at Stanford University School of Medicine, where she holds the Emerita Richard L. Kempson Endowed Chair in Surgical Pathology. (*See* Longacre Newsome Rep. at 2–3.) She received her M.D. from the University of New Mexico School of Medicine in 1985, completed residency in anatomic and clinical pathology there, and subsequently completed a fellowship in surgical pathology at Stanford. (*Id.*) Dr. Longacre directs Gynecologic Pathology and Gastrointestinal Pathology at Stanford, having founded Accreditation Council for Graduate Medical Education-approved fellowships in both Gynecologic Pathology (2007) and Gastrointestinal Pathology (2013). (*Id.*) Her leadership roles include prior service on key institutional committees and presidency of the Association of Directors of Anatomic and Surgical Pathology. (*Id.*)

Dr. Longacre has an extensive publication record and senior editorial roles, including co-author and expert editor for World Health Organization tumor classifications and editor of Sternberg's Diagnostic Surgical Pathology. (*Id.*) Clinically, she maintains a high-volume practice (approximately 5,000–7,500 cases annually) that primarily involves examination of surgical gynecologic and gastrointestinal specimens, participates regularly in multidisciplinary tumor boards, provides regional to international consultations, and has served on the American Board of Pathology Test Committee for gynecologic pathology. (*Id.*) In her capacity

as a board-certified clinical pathologist, Dr. Longacre provides clinical and pathologic consultations to physicians at Stanford, which includes, among other things, "microscopic review of surgical pathology specimens." (*Id.*)

Based on their academic and professional backgrounds, I find that Drs. Felix and Longacre both possess the requisite qualifications to opine on the likelihood of specimen contamination during or following surgical procedures. Both have "practical experience as well as academic training and credentials" relevant to their opinions regarding specimen contamination. *Elcock*, 233 F.3d at 741 (quoting *Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998)). Both highlight their ongoing clinical practices, which involve microscopic specimen examination and diagnostic pathology. Neither claim expertise in SEM/EDXS utilization, and as such, they have not attempted to offer their opinions on that topic.

Therefore, I recommend that the Court find Drs. Felix and Longacre respectively qualified to opine on the alleged potential contamination of certain Plaintiffs' tissue samples.

ii. Methodology and Opinions

Dr. Longacre opined, in relevant part, that birefringent particles reported in Plaintiff Newsome's gynecologic tissues—whether identified as talc or asbestos-like—are, more likely than not, artifacts introduced during or after surgery and/or during histologic processing rather than evidence of true *in vivo* exposure. (*See*

Longacre Newsome Rep. at 14–17.) Dr. Longacre emphasized that talc "is known" to elicit a characteristic foreign body reaction in living tissue. (*Id.* at 11.) Through her review of relevant medical records and available histological slides from Plaintiff Newsome's surgical procedure, (*see id.* at 14), Dr. Longacre "found no foreign body reactions supportive of talc exposure" and "no evidence of particulate in macrophages," (*see id.* at 16). Dr. Longacre therefore opined that the consistent absence of such histologic responses—particularly acute inflammation, the formation of foreign body giant cells, and particle-laden macrophages—undermines any inference that the talc and, where applicable, asbestos-like particles reside in tissue because of biological migration or exposure. (*See generally id.*)

Dr. Felix likewise concluded, in relevant part, that particles characterized as talc or talc-like in gynecologic tissue samples, including those from Plaintiffs Converse, Judkins and Gallardo, are more consistent with post-surgical and processing contamination and not evidence of biological exposure. (*See, e.g.*, Felix Judkins Rep. at 5, 7–9.) Following his review of each respective Plaintiffs' pathology report and histological slides, Dr. Felix concluded that there is no evidence of exposure to foreign material, including talcum powder. (*Id.*) For support, Dr. Felix pointed to the absence of a discernible foreign body reaction, which, according to the doctor, is expected from the introduction of a foreign body, like talc, to vital tissue. (*Id.*) Normally, according to Dr. Felix, such a reaction would be

discernable by using routine light microscopy and polarized light microscopy, though Dr. Felix's analysis using such methods yielded no expected tissue reaction. (*Id.*)

Methodologically, both Drs. Longacre and Felix applied standard surgical pathology principles, reviewed relevant scientific and medical literature, and offer pointed criticisms of Dr. Godleski. For example, Dr. Longacre pointed out that despite attempts to prevent contamination of paraffin tissue samples, Dr. Godleski "did not control for the tissue processing following surgery." (*See* Longacre Newsome Rep. at 15.) Dr. Longacre further criticized Dr. Godleski's failure to "recognize that laboratory processing of tissue specimens for histology can not only introduce contaminants on the surface of the specimen, but also deep within tissue." (*Id.*)

Dr. Felix offered similar criticisms to Dr. Godleski's opinions and methods, such as Dr. Godleski's "failure to address the absence of foreign body reactions in [Plaintiff] Converse's tissue" and failure to consider post-surgical contamination as the source of detected particulate. (*See, e.g.*, Felix Judkins Rep. at 8.) Dr. Felix also faulted Dr. Godleski's attempt to "remove" potential contaminants by "removing 50 microns of the [paraffin] block surface" because "tissue specimens . . . are exposed sequentially to a number of organic compounds that permeate the tissue at the cellular level." (*Id.*)

iii. Reliability

Plaintiffs argue that both doctors' opinions regarding alleged sample contamination must be excluded because they are methodologically deficient and lack scientific support. (*See generally* Pls.' Felix & Longacre Br.) In opposition, Defendants argue that their experts' contamination-related criticisms of Dr. Godleski's opinions are supported by science and by their own experiences, both of which suffice as foundation for admissible expert opinions. (*See generally* Defs.' Felix & Longacre Opp. Br.) I agree with Defendants and recommend that the Court deny Plaintiffs' motion to exclude Dr. Felix's and Dr. Longacre's contamination-related opinions.

First, Defendants' experts articulate a specific rationale for their contamination theory: the absence of any foreign body reaction (e.g., giant cells or macrophage ingestion) around the particles purportedly identified indicates the material was more likely introduced post-surgery during processing, not present *in vivo*. Plaintiffs, however, do not substantively respond to this foreign-body-reaction premise. Instead, they characterize the contamination explanation as speculative and methodologically unsupported.

Drs. Felix and Longacre did not purport to re-identify particles via SEM/EDXS; instead, they used routine and polarized light microscopy on histological slides to determine tissue exposure to foreign material, such as talc.

Having found none, they criticized Dr. Godleski's conclusion that identified talc and, where applicable, asbestos particles, demonstrate *in vivo* presence and causation. Under Rule 702, it is appropriate for defense experts to criticized another expert's methodology and conclusions. *See, e.g.*, *In re Zyprexa*, 489 F. Supp. 2d at 285. Both defense experts' opinions are based on reliable "methods and procedures of science," as opposed to "subjective belief or unsupported speculation." *Schneider*, 320 F.3d at 404 (citation omitted).

Second, Plaintiffs claim that Dr. Felix's and Dr. Longacre's contamination-related opinions lack scientific support by way of literature and by their own methodology. (*See* Pls.' Felix & Longacre Br. at 4–7.) But both experts relied on a litany of published scientific studies that support their contamination theory, which is premised on the absence of a foreign body reaction. (*See, e.g.*, Longacre Newsome Rep. at 11 ("Talc is known to elicit a foreign body reaction in human tissue." (citing sources)); *id.* at 13 ("[L]aboratory processing of tissue specimens for histology can not only introduce contaminants on the surface of the specimen, but also deep within tissue." (citing sources)); *see, e.g.*, Felix Converse Rep. at 9 ("It is well known that talc, like virtually any foreign body, will cause a foreign body granulomatous reaction when introduced into vital (living) tissue." (citing sources)).) Nor do Plaintiffs dispute the general proposition that the introduction of talc into living tissue would cause a discernible foreign body reaction.

Both experts also explained from their own experience that processing steps and reagents can permit particulate penetration beyond the block surface. Experts may base their opinions on their experiences within their respective fields of expertise. *See, e.g.*, *Kumho*, 526 U.S. at 152 (explaining that the purpose of *Daubert* "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field"); *Schneider*, 320 F.3d at 399–400 (holding abuse of discretion excluding experts' testimony regarding medical standard of care where testimony was based on "considerable professional experience" and knowledge of the "standard of care in the medical field"). As gynecological pathologists, Drs. Felix and Longacre have decades of experience evaluating tissue responses to foreign material. Their literature citations and clinical experience support their conclusions about expected tissue reactions and contamination risk.

Therefore, I recommend that the Court deny Plaintiffs' Motion to Exclude the Opinions of Dr. Felix and Dr. Longacre.

VII. REGULATORY, MARKETING, AND CORPORATE KNOWLEDGE OPINIONS

A. Defendants' Motion to Exclude the Opinions of Drs. David Kessler, Laura Plunkett, William Sage, and George Newman

Defendants move to exclude the opinion testimony of four expert witnesses proffered by Plaintiffs on subjects ranging from regulatory and industry standards to marketing to whether exposure to talc increases the risk of ovarian cancer: (i) David Kessler, M.D., J.D.; (ii) Laura Plunkett, Ph.D., DABT; (iii) William Sage, M.D., J.D.; and (iv) George E. Newman, Ph.D. (*See* ECF No. 33000-2 ("Defs.' Regulatory P Br.").) Plaintiffs oppose exclusion of these experts (*See* ECF No. 332998-1 ("Pls.' Regulatory Opp. Br.").)

Because I was not asked to analyze testimony from these experts when I rendered my prior Opinion, Defendants filed "traditional *Daubert* motions" with respect to these experts. (April 30, 2024 Memorandum Order at 6.) In analyzing the admissibility of their testimony below, I address Defendants' arguments in connection with making independent findings on qualification, reliability, and fit. *See Cohen*, 125 F.4th at 460 (explaining district courts have an "independent obligation" to "take into account all of the *Daubert* factors" (citation modified)).

1. Dr. Kessler

i. Qualifications

Plaintiffs proffer Dr. Kessler as an expert on "the responsibilities of cosmetic manufacturers, focusing on the regulatory interface between cosmetic manufacturers

and the FDA, as well as industry standards." (ECF No. 33000-6 ("Kessler Rep.") ¶ 22).

Dr. Kessler graduated from Harvard Medical School and the University of Chicago Law School in the late 1970s. (Kessler Rep. ¶ 1). From 1990 to 1997, Dr. Kessler served as Commissioner of the United States Food and Drug Administration. (*Id*. ¶¶ 2–3). As FDA Commissioner, Dr. Kessler's responsibilities included overseeing the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, the Center for Food Safety and Applied Nutrition (which regulates cosmetics), and the Center for Biologics Evaluation and Research. (*Id*. ¶ 8). Serving in these roles required familiarity with the United States Food, Drug, and Cosmetic Act ("FDCA"), FDA regulations, and related laws and regulations pertaining to the marketing, sale, labeling, and safety of consumer products. (*See id.*) Dr. Kessler does not recall being "substantially involved in talc cosmetic matters" during his tenure as FDA Commissioner. (*Id*. ¶ 24.)

Dr. Kessler has published articles and testified before the United States Congress on the regulation of food, drugs, and medical devices, as well as on consumer protection issues. (*Id.* ¶¶ 6, 9.) From January 2021 to January 2023, Dr. Kessler served as Chief Science Officer of the United States COVID-19 Response and co-led Operation Warp Speed. (*Id*. ¶ 5.) He previously taught food and drug law

at Columbia University Law School and is currently a professor at the University of California, San Francisco. (*Id*. ¶¶ 4, 6.)

Dr. Kessler also has served as: a senior advisor to a private equity firm that owns pharmaceutical and biomedical companies; a board member of three pharmaceutical companies; and a board member of a medical device and biologics company. (*Id*. ¶ 10.) In those capacities, he has advised companies on the "standards and duties of care within the pharmaceutical and medical device industry." (*Id*.). Dr. Kessler previously chaired the compliance committee of Aptalis Pharma and currently chairs the quality committee at Immucor, Inc. (*Id*.). He attests that his role as quality committee chair "involves ensuring compliance with the FDA's regulations and requirements." (*Id*.).

Except as noted below, Defendants do not dispute that Dr. Kessler is qualified to testify about the regulatory framework and industry standards for cosmetics. Based on Dr. Kessler's "broad range of knowledge, skills, and training" as FDA Commissioner and continued interaction—as a C-Suite advisor, author, and academic—with regulations and industry standards that inform cosmetic manufacturers' standard of care, I find that Dr. Kessler is qualified to testify about those topics. *Schneider*, 320 F.3d at 404.

ii. Summary of Dr. Kessler's Opinions

Dr. Kessler was "asked to address the duties and conduct of defendant cosmetic companies in the face of a potential health hazard." (Kessler Rep. ¶ 1.) He explained that to formulate his "regulatory and safety opinions," he reviewed the "epidemiology, laboratory testing methodology, chemical and geological relationship between talc and asbestos, health consequences with asbestos and elongated mineral particles, and product formulation and manufacturing." (*Id*.) He had access to documents exchanged in discovery, deposition and trial transcripts, and publicly available information. (*Id*. ¶¶ 12–13.) This approach, Dr. Kessler submitted, tracked the methods he used while at the FDA, in academia, and on corporate boards. (*Id*. ¶ 15). Based on his review, Dr. Kessler reached the following main conclusions:

- Cosmetic products are "among the least regulated" products that fall under the FDA's jurisdiction, with less federal regulation of cosmetics than drugs, medical devises, or food additives. "This is reflected in the fact that there is no premarket approval of cosmetic products." (*Id.*, Summary of Opinions ¶¶ 1, 3.)

- Consistent with FDA regulations, statutes, and industry standards, cosmetic manufacturers "have a responsibility to substantiate the safety of their product," including the safety of its ingredients, before marketing them. Manufacturers must have "reasonable certainty in the judgment of competent scientists" that the product is safe and that there is "no evidence to suspect their cosmetic product may pose harm. (*Id.*, Summary of Opinions ¶¶ 3, 5–6.)

- "If there is evidence that there are reasonable grounds to suspect that the cosmetic product may pose harm for the proposed conditions of use, such

product does not meet the industry standards for safety." (*Id.*, Summary of Opinions ¶ 7.)

- If the safety of a product cannot be substantiated, the manufacturer must "warn consumers that the safety of their product has not been determined or not sell their product." If a "health hazard may be associated with the product, a cosmetic manufacturer must include a warning on their product." (*Id.*, Summary of Opinions ¶ 3.)

- Beginning in the 1970s, Johnson & Johnson "had evidence of a) the presence of asbestos because of its known carcinogenicity and absence of a threshold dose; or b) the presence of non-asbestiform amphiboles or fibrous talc." This evidence prevented Johnson & Johnson from substantiating the safety of the talc products, and created a "reasonable basis to believe that such an association between the product and health risks." Johnson & Johnson continued to receive information that prevented it from substantiating the safety of its products in the following decades, including "a) the FDA's 2014 petition response acknowledging that there remains some evidence to suspect or question the safety of talcum powder products, b) the totality of the medical literature since 2014 that continues to raise safety questions;" and c) findings from IARC. (*See id.*, Summary of Opinions ¶¶ 8–15, 17).

- Once Johnson & Johnson could not substantiate the safety of the talc products, Johnson & Johnson should have withdrawn them from the market. (*See id.*, Summary of Opinions ¶ 9).

- Because Johnson & Johnson was "[u]nable to substantiate the safety of their talcum powder products," Johnson & Johnson was required, under 21 CFR § 740.10, "to place the following conspicuous statement on the principal display panel: 'Warning-The safety of this product has not been determined." Johnson & Johnson's failure to do so violated the FDA's labeling requirements. (*Id.*, Summary of Opinions ¶ 14 (quoting 21 CFR §740.10).)

- Johnson & Johnson's findings and notice of fibrous or asbestiform material in talc samples rendered the talc products "adulterated" under the FDCA, thereby prohibiting their sale. (*Id.*, Summary of Opinions ¶ 14 (quoting 21 U.S.C. §361).)

- A "reasonable and prudent" company, confronted with evidence that asbestos is a carcinogen with no safe threshold—evidence that Dr. Kessler submits was in Johnson & Johnson's possession—would have improved testing sensitivity, reformulated the talc products with cornstarch in the 1970s, adopt the most conservative and protective procedures, or discontinued sale. (*Id.*, Summary of Opinions ¶¶ 14, 24, 28, 33.)

- Johnson & Johnson "decided in the 1970's to aggressively defend its product. That strategy kept their product on the market for fifty years but put the public's health at risk. It need not have been that way if Johnson & Johnson was willing to bear any additional cost and reformulate the product." Johnson & Johnson also initiated studies "only as required by confrontation." (*Id.*, Summary of Opinions ¶¶ 18, 26, 30, 36-37, 40–42.)

- Johnson & Johnson knew that "false negative results would occur with its testing methodology, in part because these tests were not sensitive enough." Yet Johnson & Johnson opposed "efforts to improve the sensitivity of the testing methods" for asbestos in its talc products. (*Id.* ¶¶ 201–223.)

- "For more than fifty years, J&J made representations that were misleading and not transparent." Johnson & Johnson's deceptive conduct included: (i) failing "to report to the FDA that laboratory tests found evidence of naturally occurring mineral silicate fibers of the serpentine and amphibole series"; (ii) "J&J's representation to the FDA in their March 17, 2016, letter that no asbestos-form structures have ever been found during any testing"; (iii) creating the false impression, as an active participant in the Cosmetic, Toiletry, and Fragrance Association ("CTFA"), that "changes in testing resolved the asbestos controversy in talc by researchers and health agencies"; and (iv) making false and misleading statements to the public, "gynecologic oncologists and the medical community." (*Id.*, Summary of Opinions ¶¶ 27, 29, 39–40; *id.* ¶ 195).

iii. Specific Exclusion Arguments and Legal Standards

Defendants argue that Dr. Kessler (a) constructs a factual narrative that does not constitute proper expert testimony, (b) draws impermissible legal conclusions,

(c) speculates about Defendants' state of mind and motivations, and (d) renders subjective opinions about compliance with ethical standards. To varying degrees, both parties assert that I should bar other expert testimony for these same reasons. Thus, before making findings on the reliability, fit, and scope of Dr. Kessler's testimony, I will address these specific arguments and explain more generally the law on expert witnesses constructing factual narratives, offering legal conclusions, and testifying about a corporation's state of mind, intent, or compliance with ethical standards.

a. Factual Narrative Challenge

Defendants argue that Dr. Kessler simply rehashes internal corporate documents and deposition testimony, without offering independent analysis. (*See* Defs.' Regulatory Br. at 10 (arguing Dr. Kessler "summarizes internal documents and testimony in Section II.C of his report," like quoting "straightforward statements from an internal J&J PowerPoint"); *id*. at 10–11 (characterizing Dr. Kessler's "discussion of the safety and geology of asbestos and purportedly positive findings of asbestos"—and Section VI.A of his report—as "merely a narrative" of internal documents produced by Defendants, which Dr. Kessler "quotes" "verbatim" without analysis); *id.* at 11 (arguing "majority of Section IV of his report consists of Dr. Kessler rehashing documents").) Defendants posit that Dr. Kessler's "narrative account of events" is a "lay opinion," which will not help the jury. (*Id*. at 13).

In response, Plaintiffs contend that Dr. Kessler must identify, and can summarize, the facts and data underlying his report. (Pls.' Regulatory Opp. Br. at 15–16). Plaintiffs also argue that like other courts, I should reject Defendants' factual narrative argument because it is a trial objection, not a basis for barring Dr. Kessler's testimony altogether. (*See id.* 17–18 & n.51 (citing cases).)

Under Federal Rule of Evidence 703, experts may rely on "facts or data in the case that the expert has been made aware of or personally observed." "If the facts are of the type 'reasonably relied upon' by experts in the particular field in forming opinions or inferences upon a subject, the facts or data need not be independently admissible in evidence." *Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414 (3d Cir. 2002) (quoting Fed. R. Evid.703); *see also* Fed. R. Civ. P. 26(a)(2)(B)(ii) (requiring expert witnesses to identify "the facts or data considered by the witness in forming" opinions in expert report). "It is an abuse of discretion to admit expert testimony which is based on assumptions lacking any factual foundation in the record." *Stecyk*, 295 F.3d at 414.

While expert testimony must have a sufficient factual foundation, an expert witness "'cannot be presented to the jury *solely* for the purpose of constructing a factual narrative based on record evidence.'" *Krys v. Aaron*, 112 F. Supp. 3d 181, 206 (D.N.J. 2015) (quoting *Highland Cap. Mgmt., L.P. v. Schneider*, 379 F. Supp. 2d 461, 469 (S.D.N.Y. 2005)); *see O'Bryant v. Johnson & Johnson*, No. 20-cv-2361,

2022 WL 7670296, at *13 (D.N.J. Oct. 13, 2022) ("An expert may testify to a review of internal documents for the purpose of explaining the basis for his or her admissible opinions" but "simply parroting [d]efendant's corporate documents or offering a narrative account of events from them will not be helpful to the jury." (citation omitted)). Instead, such "testimony is properly presented through fact witnesses and documentary evidence." *O'Bryant*, 2022 WL 7670296, at *13.

As noted below, Dr. Kessler may testify as to the FDA regulations and industry standards that inform the standard of care for cosmetics manufacturers and may offer his assessment of how Defendants' actions comported with that framework. In offering that testimony at trial, Dr. Kessler may not quote extensively from corporate documents, testimony, or other evidence that "should be presented to the jury directly." *In re Fosamax*, 645 F. Supp. 2d at 192. Instead, Dr. Kessler's "commentary on any documents and exhibits in evidence will be limited to explaining the regulatory context in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge." *Id.*

Because portions of Dr. Kessler's report help contextualize the information that he cites, I decline to parse the report "paragraph-by-paragraph to determine where the report turns from expert analysis to factual narrative." *Liberty Media Corp. v. Vivendi Universal, S.A.*, 874 F. Supp. 2d 169, 174 (S.D.N.Y. 2012). Instead,

like many other courts that have considered the same challenges to Dr. Kessler's testimony, I find that Defendants can object if Dr. Kessler's trial testimony turns into a factual narrative. *See McCoy v. DePuy Orthopaedics, Inc.*, No. 22-cv-2075, 2024 WL 1705952, at *20 (S.D. Cal. Apr. 19, 2024) ("Dr. Kessler may testify regarding the facts he relied upon in forming his opinions if such facts are relevant, are not cumulative, and do not constitute a mere rehashing of otherwise admissible evidence" and "any specific objections to narrative testimony must wait for trial."); *King v. DePuy Orthopaedics Inc.*, No. 23-cv-00196, 2023 WL 5624710, at *4 (D. Ariz. Aug. 31, 2023) (same); *Wells v. Allergan, Inc.*, No. 12-cv-973, 2013 WL 7208221, at *2 (W.D. Okla. Feb. 4, 2013) (same); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 646 (S.D.W. Va. 2013) (same); *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Pracs. & Prods. Liab. Litig.*, No. 09-md-02100, 2011 WL 6302287, at *8 (S.D. Ill. Dec. 16, 2011) (same); *In re Testosterone Replacement Therapy*, 2017 WL 1836443, at *15 (same); *In re Actos (Pioglitazone) Prods. Liab. Litig.*, No. 12-cv-00064, 2014 WL 120973, at *10 (W.D. La. Jan. 10, 2014) (same).

b. Legal Conclusions Challenge

Defendants argue that Dr. Kessler impermissibly testifies as to his own legal conclusions. (Defs.' Regulatory Br. at 13.) Specifically, Defendants argue that Dr. Kessler improperly concludes that: (i) "the J&J defendants violated legal standards by failing to 'substantiate the safety of their talcum powder products,'" (*id.* at 15

(citing Kessler Rep. §§ III–IV & ¶¶ 106, 154, 232)); (ii) "'J&J was required to place the following conspicuous statement on the principal display panel: Warning – The safety of this product has not been determined. 21 C.F.R. § 740.10,'" (*id.* (citing Kessler Rep. ¶¶ 68–69, 106)); and (iii) "J&J's talcum powder products were contaminated with asbestos and therefore 'adulterated' under 21 U.S.C. § 361.44," (*id.* (citing Kessler Rep. ¶ 139)). Defendants argue that these types of legal conclusions usurp the jury's role. (*See id.* at 14 (citing cases)).

Plaintiffs contend that Defendants miss a critical distinction in the caselaw. (*See* Pls.' Regulatory Opp. Br. at 21 & n.58 (citing cases).) That is, rather than offering "ultimate legal conclusions," Dr. Kessler's opinions "address the relevant regulatory standards Defendants were subject to, relevant industry standards, and the appropriateness of Defendants' actions given the information they possessed at the time." (*Id.* at 21.) In this regard, Plaintiffs argue that Dr. Kessler does not overstep the Court's role instructing the jury on negligence and failure to warn or the jury's role in deciding liability. (*See id*. 21–22.) Rather, according to Plaintiffs, Dr. Kessler's opinions merely help the jury assess the reasonableness of Defendants' actions by explaining industry standards and applicable regulatory schemes. (*See id*.)

In determining whether expert testimony will help the factfinder, courts must "ensure that an expert does not testify as to the governing law of the case." *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006). While "Federal Rule of

Evidence 704 permits an expert witness to give expert testimony that 'embraces an ultimate issue to be decided by the trier of fact,' an expert witness is prohibited from rendering a legal opinion." *Id*. (citing Fed. R. Evid.704). That prohibition ensures that experts do not "usurp the District Court's pivotal role in explaining the law to the jury." *Id.*

The "line between admissible and inadmissible expert testimony as to the customs and practices of a particular industry often becomes blurred when the testimony concerns a party's compliance with customs and practices that implicate legal duties." *Id*. at 218. In *Berckeley*, a company accused of violating the securities laws proffered testimony from a former SEC lawyer with expertise in the relevant securities transactions. *Id*. The court permitted her "background testimony" on the "customs and business practices in the securities industry" because it would "aid the jury in determining whether" the defendant "had the requisite scienter." *Id*. By contrast, the court prohibited testimony as to whether the company "complied with legal duties that arose under the federal securities laws"—that is, "as to what was required under the law, or whether the defendant complied" with the law. *Id*.

In *Krys v. Aaron*, the court "endeavor[ed] to better define the line between permissible testimony on ultimate issues and an impermissible legal opinion." 112 F. Supp. 3d 181, 192 (D.N.J. 2015). Judge Simandle's guidance remains instructive:

> Taken together, these authorities therefore instruct that any qualified expert . . . may provide an opinion on

> whether a party's conduct or actions meet the underlying bases for an ultimate issue in a case (by, for example, testifying concerning whether certain acts would in the abstract be improper and/or inconsistent with a party's legal duties), but may not merely instruct the jury on the result to reach based upon a party's specific conduct or actions (by, for example, stating that a party did indeed violate an applicable duty through certain actions).

Id. at 193.

The *Krys* plaintiffs proffered testimony from a former CFTC director about CFTC and CEA segregation requirements. *See id*. at 191. Applying the principles noted above, the court excluded the expert's testimony "to the extent he reaches the specific conclusion that any Defendant acted in compliance with and/or in violation of applicable legal duties or segregation requirements." *Id*. at 193; *see id*. at 192 (barring testimony on whether defendants: "complied with their obligations under federal securities law"; violated CFTC and CEA segregation and auditing requirements; and "committed fraud, breaches of their fiduciary duties, and conversion"). But the court permitted expert testimony as to "contextual information on segregation issues and on common customs and practices in the securities industry" because that "background information may prove infinitely helpful to the jury in unpacking the intricacies of" the "complex litigation." *Id*. at 193.

Here too, I find that Dr. Kessler offers both admissible testimony relevant to the ultimate issues in this case and impermissible legal opinions that require

exclusion. Dr. Kessler may provide background information regarding industry standards and the FDA's regulation of cosmetics manufacturers. (*See, e.g.*, Kessler Rep., Summary of Opinions ¶¶ 1, 4, 5.) This testimony will help the jury understand "the complex regulatory framework that informs the standard of care" in the cosmetics industry. *In re Fosamax*, 645 F. Supp. 2d at 191; *see United States ex rel. Silver v. Omnicare, Inc.*, No. 11-cv-01326, 2023 WL 2808098, at *11 (D.N.J. Mar. 31, 2023) ("Qualified experts may provide background on a statutory or regulatory scheme so long as their opinions do not state whether the statute or regulation was violated.").

Similarly, Dr. Kessler may make factual observations about Defendants' conduct in reference to that standard of care. That includes opining—based on his experience and understanding of industry standards—on the steps that reasonably prudent manufacturers take to substantiate the safety of cosmetic products and Defendants' actions in comparison to those standards.[188] *See In re Fosamax*, 645 F. Supp. 2d at 191 ("A lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care in the pharmaceutical industry. Dr. Parisian's assessment of the reasonableness of Merck's conduct in light

[188] As detailed below, however, Dr. Kessler cannot testify that Defendants in fact violated any law, regulation, or legal duty, or that Defendants acted negligently.

of her experience and her understanding of FDA regulations will be helpful to the jury.").

Rather than staying within those bounds, however, Dr. Kessler also drew several inadmissible legal conclusions. For example, Dr. Kessler concluded that Johnson & Johnson "was required," under 21 C.F.R. § 740.10, "to place the following conspicuous statement on the principal display panel: 'Warning – The safety of this product has not been determined.'" (Kessler Rep., Summary of Opinions ¶ 14; Kessler Rep. ¶ 106.) And he testified that under 21 U.S.C. § 361, Johnson & Johnson was "prohibited" from selling talcum powder products because they "contained poisonous and deleterious substances" and "were therefore adulterated." (Kessler Rep. ¶ 139.)

These examples are not exclusive, but should serve as guideposts for the ultimate admissibility decisions made at trial. In short, Dr. Kessler may provide background testimony about FDA regulations and industry standards that inform the standard of care for cosmetics manufacturers.[189] He may generally testify about whether Defendants' conduct was consistent with those requirements. But he must

[189] In rendering a similar ruling, one court explained that it would "instruct the jury, if applicable under relevant state law, that evidence of violation of FDA standards may be evidence of, but does not necessarily establish, negligence." *Mirena I*, 169 F. Supp. 3d at 479, n.78. The court further explained that if there "is any dispute as to what FDA regulations are applicable to Mirena, the issue can be raised with the Court, and the Court will outline the relevant statutes and regulations for the jury." *Id*. Nothing in this decision precludes either party from seeking a similar instruction before or during trial.

stop short of testifying that Defendants violated any law or legal duty, or on the interaction (if any) between the regulatory scheme that he explains and tort law liability. And while Dr. Kessler can opine on Defendants' conduct in comparison to industry standards, he cannot draw legal conclusions reserved for the jury, including that the talc products were not safe as a matter of law, that Defendants failed to warn, or that Defendants were negligent. *See In re C.R. Bard*, 948 F. Supp. 2d at 629 (barring Dr. Kessler from testifying that manufacturer "failed to warn on its label" and that products "were not reasonably safe").

c. State of Mind Challenge

Defendants argue that Dr. Kessler improperly opined on Defendants' state of mind and motivations. (*See* Defs.' Regulatory Opp. Br. 17–18.) Plaintiffs dispute that Dr. Kessler offered speculative testimony regarding Defendants' state of mind. (Pls.' Regulatory Opp. Br. at 28). According to Plaintiffs, Dr. Kessler's opinion addressed (1) when, based on his review of internal company documents, corporate representative testimony, and other record evidence, Defendants had notice of risks, and (2) the reasonableness of Defendants' conduct, based on compliance with FDA regulations and other regulatory requirements and industry standards. (*See id.* at 28–29.)

Experts "may not provide testimony concerning 'the state of mind' or 'culpability' of Defendants." *Krys*, 112 F. Supp. 3d at 203 (citation omitted); *see*

Bracco Diagnostics, Inc. v. Amersham Health, Inc., 627 F. Supp. 2d 384, 440 (D.N.J. 2009) ("[E]xperts cannot opine on intent."); *In re Rezulin*, 309 F. Supp. 2d at 547 ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony."). I agree with Defendants that portions of Dr. Kessler's report violate this prohibition, including his assertions that:

- Johnson & Johnson "was *aware* that false negative results would occur with its testing methodology, in part because these tests were not sensitive enough." (Kessler Rep. ¶ 201 (emphasis added).)

- Johnson & Johnson "*had concerns* regarding asbestos and the safety of its product." (*Id.* at 68 (emphasis added).)

- Johnson & Johnson "*decided* in the 1970's to aggressively defend its product. That strategy kept their product on the market for fifty years but put the public's health at risk. It need not have been that way if J&J was *willing* to bear any additional cost and reformulate the product." (*Id.* ¶ 88 (emphasis added).)

- Johnson & Johnson "continues to *mislead* the public on its website factsabouttalc.com." (*Id.* ¶ 241 (emphasis added).)

- Johnson & Johnson's "approach to the asbestos issue in talc was to initiate studies only as required by confrontation." (*Id.* ¶ 103.)

- Johnson & Johnson "created confusion and doubt when the safety of their product was brought into question." (*Id.* ¶ 104.)

Because these assertions concern the state of mind, motives, or culpability of Defendants, they "lie outside the bounds of expert testimony." *In re Rezulin*, 309 F. Supp. 2d at 547; *see, e.g.*, *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at *2, 9

(E.D. Pa. June 20, 2000) (precluding expert from testifying that failure to change drug label was "driven by [corporation's] desire to increase profits" because "intent is a classic jury question"). Thus, I recommend that the Court grant Defendants' motion to the extent that it seeks to bar Dr. Kessler from opining about Defendants' state of mind, motivations, or culpability.

As to notice specifically, Dr. Kessler's report contains both impermissible and permissible testimony. Dr. Kessler cannot testify directly—based on his review of documents—that Defendants knew of, actually recognized, or deliberately ignored certain risks. (*See, e.g.*, Kessler Rep., Summary of Opinions ¶ 15 (impermissibly speculating about when Defendants had "notice of naturally occurring mineral silicate fibers of the serpentine and amphibole series").) Those notice findings are reserved for the jury.

Based on his regulatory expertise, however, Dr. Kessler may help the jury make those findings by explaining the types of information sufficient to alert a reasonably prudent cosmetics manufacturer to potential safety issues and other risks. In so doing, Dr. Kessler also may discuss the types of scientific and regulatory data that Johnson & Johnson possessed, and whether that data indicated risks. The studies and data analyzed by Dr. Kessler are complex and, without his expertise, it may not be apparent to a layperson why certain information would alert a reasonably prudent manufacturer to potential safety risks. *See Deutsch v. Novartis Pharms. Corp.*, 768

F. Supp. 2d 420, 443 (E.D.N.Y. 2011) (prohibiting expert from testifying on defendant's state of mind, but allowing testimony on "whether certain information contained in the [defendant's] internal documents indicated certain risks.").

d. Ethical Opinion Challenge

Next, Defendants argue that Dr. Kessler improperly offers subjective views on the ethical appropriateness of Defendants' actions, without citing objective standards or otherwise using any reliable scientific methodology. (Defs.' Regulatory Br. at 21–23; *see id.* at 22, n.78 ("Dr. Kessler's experience as a former FDA commissioner does not salvage his claims about defendants' ethics. As another court in this circuit explained, 'ethical standards for [pharmaceutical] companies do not come from the FDA'") (citation omitted)). According to Defendants, this includes opining that, a "'reasonable and prudent company would attempt to improve the sensitivity of its testing' for asbestos, which J&J purportedly did not do." (*Id.* at 22 (citing Kessler Rep. ¶¶ 189, 201–202, 214, 222, 250).) Defendants also challenge Dr. Kessler's opinion that it was "concerning" that Johnson & Johnson claimed "'its product was 'asbestos free' without sufficiently 'vigorous efforts to improve' testing." (*Id.* at 23 (citing Kessler Rep. ¶ 210).) And even if Dr. Kessler's ethical opinions were reliable and relevant, Defendants argue they are inadmissible under Rule 403 because any probative value would be "vastly outweighed by the tendency

of such testimony to encourage the jury to impose liability on an improper basis." (*Id.* at 25 (citation omitted).)

Plaintiffs contend that Dr. Kessler opines on the reasonableness of Defendants' actions in comparison to "relevant, objective regulatory requirements and industry standards," not his own subjective ethical views. (Pls.' Regulatory Opp. Br. at 36.) According to Plaintiffs, in rendering these opinions, Dr. Kessler permissibly relied on: (i) record evidence (testimony and corporate documents); (ii) legislation, regulations, and other FDA documents; (iii) his review of "epidemiology, laboratory testing methodology, chemical and geological relationship between talc and asbestos, health consequences with asbestos and elongated mineral particles, and product formulation and manufacturing"; and (iv) his own "extensive experience in the regulatory sphere," including answering regulatory questions as a professor, government official, and corporate board advisor. (*See id.* at 37–38).

Under Rule 702, expert testimony must be grounded in reliable principles and methods, reliably applied to the facts, and "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid.702. When addressing similar challenges, courts applying this standard have distinguished (1) permissible regulatory and industry standards opinions (which may help the jury), from (2) impermissible ethics or corporate motives opinions (which are unhelpful and

subjective). *See In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1054 (D. Minn. 2007) (finding expert "may be allowed to testify as to the standard of care for pharmaceutical companies," but "may not infuse his personal views as to whether Bayer acted ethically, irresponsibly or recklessly").

On the permissible side of that boundary, experts may explain the regulatory framework and industry standards that inform a manufacturer's standard of care and may assess compliance with those standards. *See In re Fosamax*, 645 F. Supp. at 191 (allowing testimony explaining "complex regulatory framework that informs the standard of care in the pharmaceutical industry" and expert's "assessment of the reasonableness of Merck's conduct in light of her experience and her understanding of FDA regulations"). As noted above, such testimony is "helpful to the jury" because it contextualizes complex matters beyond the experience of lay persons. *Id*.

By contrast, moral assessments of "corporate conduct and ethics are not appropriate subjects of expert testimony because" they are subjective, invade the province of the factfinder, and have the tendency to unfairly prejudice and confuse the jury. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 611; *In re Baycol*, 532 F. Supp. 2d at 1053 ("Personal views on corporate ethics and morality are not expert opinions."). Thus, courts prohibit expert opinions that characterize a manufacturer's conduct as "unethical," "irresponsible," "immoral," or "bad." *See Bartoli v. Novartis Pharms. Corp.*, No. 13-cv-0724, 2014 WL 1515870, at *6 (M.D. Pa. Apr. 17, 2014)

(explaining "'bad company' opinions are not admissible"); *see, e.g.*, *In re Rezulin*, 309 F. Supp. 2d at 543 (excluding "opinions concerning purported ethical standards" because they were "based on [experts] personal, subjective views" and "so vague as to be unhelpful to a fact-finder"); *Wolfe v. McNeil-PPC, Inc.*, No. 07-cv-348, 2011 WL 1673805, at *8– 9 (E.D. Pa. May 4, 2011) (excluding "subjective views" about manufacturer's "social responsibility and ethical obligations" to "develop a better warning" and "better communicate the risks of their product" as unreliable and unfairly prejudicial under Rule 403); *In re Fosamax*, 645 F. Supp. 2d at 192 (excluding "mere 'bad company' testimony").

Once again, Dr. Kessler offers admissible and inadmissible testimony. As explained above, Dr. Kessler may explain the regulatory framework and industry standards applicable to cosmetic manufacturers. That includes explaining FDA standards for substantiating product safety and labeling products, as well as the role of the Cosmetic Ingredient Review ("CIR"). (*See* Kessler Rep. ¶¶ 27–29, 31–41, 48–54). And as long as he stays within the limits set forth in this decision (*i.e.*, avoids testifying that Defendants violated the law or endangered the public), Dr. Kessler may compare Defendants' conduct to that framework. These opinions are admissible because they flow from Dr. Kessler's "extensive and specialized experience," and will help the jury "understand the complex regulatory framework that informs the

standard of care" in the cosmetics industry. *In re Fosamax*, 645 F. Supp. 2d at 190–91.

In contrast, some opinions in Dr. Kessler's report reflect his personal, subjective views of Defendants' conduct, rather than the application of any reliable methodology. For example, Dr. Kessler asserts that:

- "making claims that its product was asbestos free without vigorous efforts to improve the sensitivity of the testing methods *is concerning*." (Kessler Rep. ¶ 210 (emphasis added); *id.*, Summary of Opinions ¶ 25 (same));
- Defendants engaged in conduct that "put the public at risk." (*Id.* ¶ 242; *id.* ¶ 250; *id.* ¶¶ 209–211; *id.*, Summary of Opinions ¶¶ 18, 23–24, 26);
- Defendants "made representations that were misleading and not transparent." (*Id.*, Summary of Opinions ¶ 27; *id.* ¶¶ 212, 241, 256).

Dr. Kessler also goes so far as to rely on a CTFA employee's statement that "'[t]he talc industry has a moral and legal responsibility to supply products that can be used safely.'" (*Id.* ¶ 56 (citation omitted).)

These statements do not rest on a reliable scientific or regulatory foundation; they reflect only Dr. Kessler's subjective views. And they do not help the jury assess Defendants' compliance with relevant objective standards; they invite the jury to impose liability based on Dr. Kessler's personal views and assessment of Defendants' corporate ethics. *See In re Rezulin*, 309 F. Supp. 2d at 545 (precluding ethics testimony because it would "prejudice and confuse the trier by introducing the experts' opinions and rhetoric concerning ethics as alternative and improper grounds

for decision on bases other than the pertinent legal standards"). Because these opinions are both unreliable under Rule 702 and unfairly prejudicial under Rule 403, I recommend that Dr. Kessler be precluded from offering subjective testimony at trial about Defendants' corporate behavior.

iv. Reliability and Fit

While many of the above rulings pertain to my assessment of reliability and fit, for clarity I set forth my findings on those restrictions here.

Reliability. To meet Rule 702's reliability requirement, Plaintiffs must demonstrate, by a preponderance of the evidence, that Dr. Kessler's opinions are grounded in a reliable method and that he reliably applied that method to this case. *See Cohen*, 125 F.4th at 462. Other than the specific challenges above, Defendants do not challenge the reliability of Dr. Kessler's testimony.

Based on my independent review, I find that Dr. Kessler's testimony, as limited above, satisfies the reliability requirement. Dr. Kessler reviewed case documents and scientific literature, identified regulatory and industry standards, and applied his extensive regulatory, professional, and academic expertise to draw conclusions about whether Johnson & Johnson's conduct comported with that framework. Courts have repeatedly found that this is a reliable method for qualified regulatory experts, including Dr. Kessler. *See, e.g.*, *McCoy*, 2024 WL 1705952, at *21 (finding Dr. Kessler's method of applying his experience to review of data and

documents reliable); *In re Testosterone Replacement Therapy*, 2017 WL 1836443, at *14 (finding Dr. Kessler used reliable method by applying "professional experience" assessing FDA compliance as FDA Commissioner and advising "pharmaceutical companies on" compliance "with FDA regulations and industry standards").

Fit. "An expert's testimony 'fits' the proceedings" if it "will help the trier of fact to understand the evidence or to determine a fact in issue." *Cohen*, 125 F.4th at 464. Dr. Kessler's testimony meets this standard.

The regulation of cosmetics—both by the FDA and through the self-regulatory structure explained by Dr. Kessler—are complex subjects beyond the ken of a lay juror. As noted above, because Dr. Kessler's explanation of statutes, regulations, and industry standards is relevant to the "complex . . . framework" governing cosmetics manufacturers, his testimony will help the jury evaluate Defendants' conduct. *In re Fosamax*, 645 F. Supp. at 191.

Dr. Kessler's opinions also will help the jury understand how a reasonable and prudent cosmetics manufacturer would respond to scientific data indicating potential safety risks, and what information would place such a manufacturer on notice of those risks. This testimony has relevance to Plaintiffs' claims, including their failure-to-warn and negligence claims.

By contrast, the testimony that I recommend be precluded above would not assist the jury and risks unfair prejudice. This includes his overt legal conclusions and characterization of Johnson & Johnson's conduct as "misleading," "unethical," or "putting the public at risk," which do not assist the jury and risk unfair prejudice. Those statements are excluded under Rules 702 and 403.

In short, the portions of Dr. Kessler's testimony that explain regulatory duties, industry standards, and reasonable-manufacturer expectations "fit" the case. His legal conclusions, moral assessments, and comments on Defendants' state of mind or corporate intent do not.

v. Scope

Finally, Defendants argue that Dr. Kessler's opinions exceed the scope of his expertise in three ways: (i) he "opines that J&J's talc products contained asbestos"; (ii) "he challenges the adequacy of industry asbestos testing"; and (iii) "he addresses the supposed geological formation of asbestos in the Vermont talc mines." (Defs.' Regulatory Br. 36, n.104 (citing Kessler Rep. ¶¶ 80–140, 161–168.5, 201–202.6); *see id.*, n.105 (citing Kessler Dep. at 109:7–15, 113:3–25, 283:1–20).) In challenging these opinions, Defendants submit that Dr. Kessler is not "a mineralogist, geologist, or microscopist"—the "specialists who are actually credentialed to opine on these complex subjects." (*Id.* at 36 (citing Kessler Dep. at 75:19–77:25); *see id.* at 37 & n.110 (citing alleged Kessler admissions that other experts should testify on geology,

mineralogy, and microscopy aspects).) Defendants contend that Dr. Kessler has never tested talc or any other material for the presence of asbestos and was not familiar with talc testing methods before this lawsuit. (*See id.* at 37). They also argue that Dr. Kessler's criticisms of Johnson & Johnson's talc testing method are not based in mineralogy or microscopy. (*See id.*).

Plaintiffs counter that Dr. Kessler's experience as the FDA Commissioner qualifies him to offer his asbestos testing and geological opinions. (*See* Pls.' Regulatory Opp. Br. at 52; *id.* at 53 (arguing "[u]nderstanding the intersection of geology, chemistry, testing methodology, and health effects of toxic substances are a key component of Dr. Kessler's background and expertise").) Plaintiffs contend that many of the documents that Dr. Kessler reviewed were communications with and discussions concerning the FDA. (*See id.* at 53–54). And based on Dr. Kessler's "unique background," Plaintiffs claim that he can offer a public-health-focused opinion that most microscopists and geologists cannot—that "'the failure to adopt a public health approach to asbestos in talc testing, even if that led to overinclusion and false positives, put consumers at risk.'" (*Id.* at 54 (quoting Kessler Rep. ¶ 100).)

Dr. Kessler's experience qualifies him to analyze and opine on the challenged data and studies in his report, but with limits. In his varied experiences, including as FDA Commissioner, Chief Science Officer of the United States COVID-19 Response, and compliance advisor for pharmaceutical companies, Dr. Kessler is

familiar with analyzing scientific data from different disciplines. (*See* Kessler Dep. at 170:1–5 (explaining that the "FDA finds itself regulating substances that intersect with environmental, geological, mineralogical substances all the time").) Based on his experience analyzing scientific information through the lens of the FDA and as a regulatory advisor, I find that Dr. Kessler is permitted to testify about how the FDA evaluates testing data submitted by manufacturers and how testing relates to safety substantiation obligations under the FDCA. He also may testify, based on his experience, on whether the testing methods that Johnson & Johnson used were generally consistent with FDA and industry standards. *See Mirena I*, 169 F. Supp. 3d at 477 (finding, while FDA expert was "not an epidemiologist," she had "been involved with epidemiological studies" and this "experience is sufficient to allow her to analyze studies and reports and rely on them in forming her opinions").

Because Dr. Kessler is not a mineralogist, geologist, or microscopist, however, Dr. Kessler must stop short of opining on the technical validity, strength, or aspects of any particular test. And while he can testify about studies he relied on in forming his opinions and how the FDA might interpret testing results, he cannot testify on whether any talc sample contained asbestos or offer opinions on the geological properties of talc.

For these reasons, I recommend the Court grant in part and deny in part Defendants' motion to exclude the testimony of Dr. Kessler.

2. Dr. Plunkett

i. Dr. Plunkett's Qualifications

Plaintiffs proffer Dr. Plunkett as an expert in "pharmacology, toxicology, pharmacokinetics, human health risk assessment[s], and the regulation of cosmetic products in the United States." (Pls.' Regulatory Opp. Br. at 7.) Dr. Plunkett received a Ph.D. in pharmacology from the University of Georgia, College of Pharmacy in 1984. (Plunkett 3d Amend. Rep. ¶ 3.) She then spent two years as a pharmacology research associate training fellow at the National Institute of General Medical Sciences. (*Id*. ¶ 4.)

From 1986 to 1989, Dr. Plunkett was an assistant professor of pharmacology and toxicology at the University of Arkansas for Medical Sciences. (*Id*. ¶ 5.) In addition to teaching courses in pharmacology, toxicology, and neurosciences, she performed research in the areas of neuropharmacology and toxicology and cardiovascular pharmacology and toxicology. (*Id*.) More generally, throughout her professional career Dr. Plunkett has taught "graduate students, law students and pharmacy students on FDA regulations as they apply to all types of FDA-regulated products, including cosmetics." (*Id*. ¶ 9.) Dr. Plunkett has published peer-reviewed articles and book chapters on pharmacology and toxicology. (*Id*. & App'x A.)

From 1989 to the present, Dr. Plunkett has worked as consultant for several private companies: she was a manager at ENVIRON Corporation from 1989 to 1997;

she owned Plunkett & Associates from 1997 to 2001; she was the president of Integrative Biostrategies (IB) LLC from 2001 to 2020; and she has been a partner of BioPolicy Solutions LLC since 2020. (*Id.* ¶¶ 1, 6–9 & App'x A.) Dr. Plunkett has "worked on a variety of projects dealing with the regulation of products by the FDA, including human drugs (both prescription and over-the-counter drugs), veterinary drugs, biologics, medical devices, cosmetics, consumer products, dietary supplements and foods." (*Id*. ¶ 6.) In those roles, Dr. Plunkett has advised clients on "regulatory issues and strategies for their products, designed preclinical and clinical studies for both efficacy and safety, advised clients on issues related to statements regarding efficacy and warnings for their products based on the current labeling regulations, and generally acted as a regulatory affairs staff for small companies in early stages of product development." (*Id*.)

Dr. Plunkett has "done a great deal of work on projects related to regulation of cosmetics and cosmetic ingredients." (*Id*. ¶¶ 6–7.) As part of that "regulatory practice," she has consulted "cosmetic ingredient manufacturers and manufacturers of cosmetic products on issues related to ingredient safety, product safety, labeling claims, and general regulatory compliance issues which include US regulations and regulations in other countries." (*Id.* ¶ 7). That includes advising companies during the "initial commercialization process, where the client was trying to decide how to market their product, e.g., as a cosmetic or a drug, as well as to determine if their

product was safe for human exposure." (*Id*. ¶ 7.) It also includes advising companies on "the safety of ingredients used to manufacture cosmetic products." (*Id*.)

Dr. Plunkett "worked on the safety of talc itself" in the 1990s, advising condom manufacturers "on the safety of talcum powder that was used on the surfaces of the devices as a dry lubricant." (*Id*.) In that capacity, Dr. Plunkett assessed "the scientific literature, including epidemiology, animal and *in vitro* studies that discussed potential adverse health effects linked to talc exposure, including both local tissue toxicity and systemic toxicity." (*Id*.)

Dr. Plunkett attests to using "risk assessments" across her consultancy work, including in "many projects where risks related to exposure to chemicals in consumer products were at issue." (*Id*. ¶ 6.) In performing risk assessments, she often reviews and relies on "epidemiology data, as well as animal and *in vitro* data in order to assess risks to human health." (*Id*.) In many of Dr. Plunkett's cosmetic safety projects, determining whether an ingredient is "generally-recognized as safe" ("GRAS") is "critical to determining what type of toxicity testing is needed to establish that a product or an ingredient is safe for human use." (*Id*. ¶ 8.) Dr. Plunkett states that, like analyses conducted by CIR, her GRAS reviews have involved "consideration of animal and human toxicity data, cellular and mechanistic data, human product experience reports, and the type and level of exposure that may occur when humans are exposed to the ingredient or product." (*Id*.)

As a pharmacologist and American Board of Toxicology-certified toxicologist, Dr. Plunkett's consulting work often relates to "understanding and explaining the mechanisms of action" and "toxic effects" of "chemicals of all types." (*Id.* ¶¶ 2, 9.) She also has "designed clinical trials and analyzed pharmacokinetic data." (*Id.*)

Based on her broad range of knowledge, professional experience, and education, Dr. Plunkett is qualified to testify as an expert in pharmacology, toxicology, pharmacokinetics, and human health risk assessments. Fed. R. Evid.702. Dr. Plunkett has spent decades applying toxicology principles, including risk assessments and weight-of-the-evidence assessments, to evaluate potential hazards associated with cosmetic products and ingredients. She is qualified to testify in those areas. Based on her consulting and academic experience, Dr. Plunkett is also qualified to testify, from a non-legal standpoint (as explained below), about the general regulatory framework applicable to cosmetics products, cosmetic ingredients, and the cosmetics industry. Dr. Plunkett's ability to testify in the foregoing areas is subject to the limitations set forth below.

ii. Summary of Dr. Plunkett's Opinions

Dr. Plunkett was asked to "provide opinions related to the human health hazards posed by exposure to talcum powder products and how those hazards relate to the regulatory requirements for marketing cosmetic ingredients and cosmetic

products in the United States." (Plunkett 3d Amend. Rep. ¶ 10.) To formulate her opinion, she reviewed: (1) "scientific literature relating to the biological effects and toxic effects of talc and other constituents that are present in talc body powder"; (2) FDCA provisions and FDA regulations "relating to the development and marketing of cosmetic ingredients and finished cosmetic products"; (3) "publicly available information on safety assessments of talc and products containing talc"; and (4) documents produced in discovery, including "internal company documents, depositions of company employees, reports of other experts in the litigation, or documents found on public sites." (*Id*. ¶ 10.) Dr. Plunkett stated that these sources mirror those used in her work as a "pharmacologist, toxicologist, risk assessor," and FDA "regulatory specialist." (*Id*.)

Dr. Plunkett used "standard and generally accepted methods" that she applies in her "work as a pharmacologist and toxicologist" to assess "the safety of products." (*Id.* ¶ 11.) Specifically, as detailed below, Dr. Plunkett performed a "human health risk assessment" to evaluate whether the talc products at issue pose a human safety risk. (*Id*.) Based on her review, Dr. Plunkett reached the following main conclusions:

- The "weight-of-the evidence indicates that genital exposure to talcum powder products increases the risk of ovarian cancer in women." Evidence supporting that conclusion includes: (1) "the known toxic effects of talc and the other components of talcum powder products"; (2) "studies that have identified biologically plausible mechanisms for cancer in humans"; (3) " the likelihood that talc particles can reach the ovaries"; (4) "the existence of a dose-response relationship for toxicity including the risk of cancer"; and (5) "the large human database that includes studies conducted

over a period of 40 years showing a consistent signal for ovarian cancer in women exposed to talcum powder products." (*Id*. ¶ 120.)

- The "use of talc in cosmetic products does not meet the CIR standard of safety." That standard provides that a cosmetic ingredient is safe if there is "no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard to the public under the conditions of use that are now current or that might reasonably be expected in the future." Given the "the presence of asbestos, fibrous talc, cobalt, chromium, and nickel, in the talc body powders manufactured by Imerys and Johnson & Johnson, a significant biologically plausible human health risk was identified as a hazard related to talc body powder use at least by the 1940's. These risks included a risk of cancer with exposure to constituents of talc body powders, and even death with acute inhalation of large." (*Id*. ¶¶ 82, 121.)

- "Failure to meet the CIR standard for safety meant that Johnson & Johnson failed to properly substantiate and ensure the safety of their cosmetic body powder products." (*Id*. ¶ 121.)

- "Given that Johnson & Johnson was aware that cornstarch-based body powder products represented a safer alternative, their failure to replace talc with cornstarch over the years that they marketed talc-based body powders put consumer health at risk." (*Id.* ¶ 121.)

- "Based on the knowledge available by the 1950's, talc body powders manufactured and sold by Imerys and Johnson & Johnson should have warned consumers about the toxic constituents, such as asbestos, fibrous talc, nickel, chromium and cobalt and fragrance, in their products and the effects that could be produced by exposure to talc dusts." (*Id.*)

- FDA regulations require cosmetic product labels to "bear a warning statement "'*whenever necessary or appropriate to prevent a health hazard that may be associated with the product*,'" and a "cause and effect" need not "be proven for such a warning to be put into place." (*Id.* ¶ 122 (quoting 21 CFR 740.1(a)).)

- "There was evidence from at least the 1960's of the risk of ovarian cancer in women exposed to components of talc body powders," including

"asbestos," and such evidence "has only gained strength over the last six decades." Because this "specific ovarian cancer risk was evident by the 1960's," under FDA regulations "talc-based cosmetic products, including products used by women for genital dusting, should have been labeled to warn of the risk of ovarian cancer with such use." (*Id.* ¶ 121–22.)

- Defendants "have never placed an adequate warning onto its containers of talcum powder products" and this "failure to provide consumers with such information puts public health at risk." (*Id.* ¶ 122.)

- The "presence of carcinogenic constituents in talc such as asbestos, fibrous talc, nickel, chromium, and cobalt meant that Johnson & Johnson's failure to list those talc constituents on its labeling was consistent with the FDA's definition of a misbranded product, and also consistent with the FDA's definition of an adulterated product." (*Id.* ¶ 123.)

- Rather than performing appropriate safety studies or providing consumers with adequate and timely "safety information about the human health risks of talc when it was used for genital dusting, industry worked together with the" Personal Care Products Council ("PCPC") "to influence the scientific and regulatory processes related to cosmetic talcum powder products." (*Id.* ¶ 124.)

As discussed below, Dr. Plunkett expressly disclaimed offering opinions on general causation or specific causation. (*See* ECF No. 33000-8 ("Plunkett 2023 Dep.") at 72:15–73:1). She instead framed her opinions as addressing whether exposure to talc products increases the "risk" of ovarian cancer, from the vantage point of a regulator or toxicologist conducting a precautionary risk assessment. (*See id.*)

iii. The Parties' Exclusion Arguments

Defendants assert five main arguments for excluding Dr. Plunkett's testimony, each of which Plaintiffs dispute:

First, while Defendants agree that a risk assessment is "a generally accepted method," they argue that Dr. Plunkett "did not reliably perform that analysis" because she did not conduct "a general causation analysis" in "reaching her opinion that talc increases the risk of ovarian cancer." (Defs.' Regulatory Br. at 34–35.) Defendants argue that Dr. Plunkett's "exclusion of a causation analysis (and the Bradford Hill criteria for causation) as part of a risk assessment contradicts generally recognized scientific approaches, including those outlined in the authorities" she cites. (*Id.*) Based on that purported omission, Defendants argue that Dr. Plunkett's risk assessment must be excluded as unreliable. (*Id.* at 34–35.)

In response, Plaintiffs argue that Dr. Plunkett "is not testifying as to causation but only as to risk." (Pls.' Regulatory Opp. Br. at 50.) Plaintiffs submit that Dr. Plunkett's opinion, "as a toxicologist, is that the weight-of-the evidence indicates that genital exposure to talcum powder products increases the risk of ovarian cancer in women." (*Id.*) According to Plaintiffs, Dr. Plunkett reaches that opinion by conducting a human health risk assessment, a tool routinely used by toxicologists (including herself) and government bodies to "assess risks to human health related to exposure to chemicals in the everyday environment." (*Id.* at 51.) Plaintiffs contend that Dr. Plunkett reliably performs each step of the risk-assessment methodology. (*Id.* 51–52.)

Second, Defendants argue that Dr. Plunkett offers improper factual narratives, quoting at length from Johnson & Johnson corporate documents. (Defs.' Regulatory Br. at 12–13.) In response, Plaintiffs contend that Dr. Plunkett should be permitted to testify about documents underlying her report, particularly because she "relies on this same type of information" when providing toxicology, pharmacology, and regulatory consulting services in the private sector. (Pls.' Regulatory Opp. Br. at 19.) Plaintiffs further contend that because these documents contain "information unfamiliar to a layperson (*e.g.*, industry jargon and acronyms, description of industry and regulatory processes, etc.)," Dr. Plunkett's explanations will help the jury. (*Id.* at 18–19.)

Third, Defendants argue that Dr. Plunkett offers improper legal opinions about FDA regulations applicable to cosmetic products and whether Defendants met them. According to Defendants, these improper opinions include: (1) comparing FDA regulations applicable to cosmetic and drug manufacturers; (2) stating that cosmetics must "carry warnings based on a standard of a possibility of health hazard"; (3) asserting that Defendants "failed to properly substantiate and ensure the safety of their cosmetic body powder products" and, as such, "should have warned consumers about the toxic constituents" of the talc products and provided a label that "warn[ed] of the risk of ovarian cancer"; and (4) opining that "these alleged failures rendered Johnson's Baby Powder an 'adulterated product.'" (Defs.' Regulatory Br.

at 15–16 (quoting Plunkett 3d Amend. Rep. ¶¶ 16, 92).) Defendants state that other courts have precluded Dr. Plunkett from offering similar legal conclusions. (*See* Defs.' Regulatory Br. at 14 (collecting cases).)

Plaintiffs dispute that Dr. Plunkett offers improper legal conclusions. According to Plaintiffs, Dr. Plunkett (1) explains the regulatory landscape for cosmetics, and (2) evaluates—from her perspective as a toxicologist and FDA regulatory specialist, not as a lawyer—whether talc posed a health hazard that required a warning. Plaintiffs argue that these regulatory and labeling opinions do not usurp the Court's role instructing the jury on the law or the jury's role deciding liability. Plaintiffs claim that courts have allowed Dr. Plunkett to testify on "FDA requirements," including similar "regulatory and labeling issues." (Pls.' Regulatory Opp. Br. at 24–25 (citing cases).)

Fourth, Defendants argue that Dr. Plunkett renders impermissible state-of-mind opinions about what Defendants knew about purported risks posed by the talc products and when. Defendants also argue that Dr. Plunkett "speculates about defendants' intent and motive," including opining that Defendants' "goal was to mount a defense strategy around talc" and that the "industry had no interest in sponsoring any new research." (Defs.' Regulatory Br. at 18–19 (quoting Plunkett 3d Amend. Rep. ¶¶ 78, 96, 104, 115; Plunkett 2021 Dep. at 136:16–24).) Defendants cite a California state court decision barring Dr. Plunkett from offering similar

testimony in a talc case, *Lloyd v. Johnson & Johnson*, No. BC628228 (JCCP No. 4872) (Cal. Super. Ct.) (the "*Echeverria* Opinion"). (*See* Defs.' Regulatory Br. at 18). Plaintiffs dispute that Dr. Plunkett is testifying about Defendants' intent. According to Plaintiffs, Dr. Plunkett "can rely on company documents to demonstrate what the defendants knew or should have known at a given time." (Pls.' Regulatory Opp. Br. at 29–30.)

Fifth, Defendants contend that Dr. Plunkett renders subjective judgments about the ethical appropriateness of Defendants' conduct. (Defs.' Regulatory Br. at 22 (citing Plunkett 2021 Dep. at 217:20–24).) Plaintiffs respond that Dr. Plunkett's opinion about "whether Defendants acted reasonably in the face of mounting evidence of the risk of talc-induced ovarian cancer" is based on the FDCA, FDA regulations, and industry standards relating to the development and marketing of cosmetic ingredients and products, rather than subjective standards. (Pls.' Regulatory Opp. Br. at 38–40.)

I address these disputes when analyzing the reliability and fit of Dr. Plunkett's opinions below.

iv. Reliability

As noted above, to meet their burden on reliability, Plaintiffs must show that it is more likely than not that Dr. Plunkett's testimony is based on sufficient facts, reliable methods, and a reliable application of those methods. Fed. R. Evid.702. For

the reasons below, I find that Plaintiffs have met their burden of showing that, in general, Dr. Plunkett's risk-assessment opinions generally reflect a reliable application of a recognized human health risk-assessment methodology. Similarly, Dr. Plunkett's regulatory and industry standard opinions generally satisfy Rule 702's reliability requirement. In both contexts, however, certain of Dr. Plunkett's conclusions do not flow from her general reliable methods and must be excluded.

a. Risk-Assessment Methodology

Dr. Plunkett performed a human health risk assessment to form her opinion that exposure to talc products increases the risk of ovarian cancer. (Plunkett 3d Amend. Rep. ¶ 11.) Government bodies and toxicologists have long used risk assessments to evaluate the safety of chemicals and determine whether they present a human health risk. (*Id*.). In 1983, the National Research Council promulgated a four-step process for performing a risk assessment that remains in effect today: (1) hazard identification, (2) dose-response assessment, (3) exposure analysis, and (4) characterization of the risks. (*Id*.)

Defendants concede that a risk assessment is a "generally accepted method for determining risk." (Defs.' Regulatory Br. at 33.) Based upon such general acceptance, Dr. Plunkett's own experience conducting risk assessments, and the standards controlling risk assessments, I find that Dr. Plunkett's risk assessment methodology is reliable. *See UGI Sunbury LLC v. A Permanent Easement for 1.7575*

Acres, 949 F.3d 825, 834 (3d Cir. 2020) (identifying factors for determining reliability of method).

While the parties agree that a risk assessment may be a reliable method, they dispute whether Dr. Plunkett's application of that method was reliable. As noted above, Defendants contend that Dr. Plunkett failed to reliably perform a risk assessment because she did not conduct a causation analysis at step one. (Defs.' Regulatory Br. at 34 (arguing "to identify a hazard (i.e., the first step in a risk assessment), a scientist must first determine whether a particular toxin is causally linked to certain health effects").). Plaintiffs disagree, arguing that Dr. Plunkett properly applied a weight-of-the-evidence analysis at step one, rather than a Bradford Hill causation analysis. (*See* Pls.' Regulatory Opp. Br. 50–51.) Because this reliability dispute implicates the relationship between (1) a human health risk assessment in the regulatory and toxicology sphere, and (2) a causation analysis in toxic-tort and products-liability litigation, I begin by briefly summarizing the differences between those two standards.

"Regulatory and advisory bodies such as IARC, OSHA and EPA" conduct risk assessments, often using a "weight of the evidence" analysis, to "assess the carcinogenicity of various substances in human beings and suggest or make prophylactic rules governing human exposure." *Allen*, 102 F.3d at 198. Risk assessments are conducted "from the preventive perspective that the agencies adopt

in order to reduce public exposure to harmful substances." *Id.* at 198. Put differently, "the basic goal underlying risk assessments" is "to determine a level that will protect the most sensitive members of the population." *Rowe v. E.I. duPont de Nemours & Co.*, No. 06-cv-1810, 2008 WL 5412912, at *16 (D.N.J. Dec. 23, 2008).

As a result, the "threshold of proof is reasonably lower than that appropriate in tort law, which 'traditionally make[s] more particularized inquiries into cause and effect' and requires a plaintiff to prove 'that it is more likely than not that another individual has caused him or her harm.'" *Allen*, 102 F.3d at 198 (quoting *Wright v. Willamette Indus., Inc.*, 91 F.3d 1105, 1107 (8th Cir. 1996)); *see Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001) ("The FDA will remove drugs from the marketplace upon a lesser showing of harm to the public than the preponderance-of-the-evidence or more-likely-than-not standards used to assess tort liability."). Indeed, the *Reference Manual* on Scientific Evidence explains this exact distinction:

> Proof of risk and proof of causation entail somewhat different questions because risk assessment frequently calls for a cost–benefit analysis. The agency assessing risk may decide to bar a substance or product if the potential benefits are outweighed by the possibility of risks that are largely unquantifiable because of presently unknown contingencies. Consequently, risk assessors may pay heed to any evidence that points to a need for caution, rather than assess the likelihood that a causal relationship in a specific case is more likely than not.

Margaret A. Berger, *The Supreme Court's Trilogy on the Admissibility of Expert Testimony*, in *Reference Manual on Scientific Evidence* 33 (Fed. Jud. Ctr., 2d ed. 2000.)

Given those distinctions, courts have rejected attempts to use the outcome of risk assessments, without more, to establish general or specific causation. *See*, *e.g.*, *Rowe*, 2008 WL 5412912, at *13 ("While the Rowe Plaintiffs tout the risk assessment method as the ideal means of proving common exposure among the class members, the Court finds that this method establishes nothing more than an assumption of common exposure."); *Glastetter*, 252 F.3d at 991 ("The FDA's 1994 decision that Parlodel can cause strokes is unreliable proof of medical causation in the present case because the FDA employs a reduced standard (vis-a-vis tort liability) for gauging causation when it decides to rescind drug approval.").

Step 1: Hazard identification. Dr. Plunkett began her analysis by "identifying, collecting, reviewing, assessing, and evaluating" peer-reviewed literature on the biological and toxic effects of talc and talc-based products. (Plunkett 3d Amend. Rep. ¶ 12.) As part of those efforts, Dr. Plunkett performed systematic searches across databases to capture relevant studies and evidence, including *in vitro* and *in viv*o toxicological evidence, mechanistic data, and epidemiological studies. (*See id.* ¶¶ 58–60.)

Dr. Plunkett then synthesized this data using a weight-of-the-evidence approach, a recognized method used in her field of toxicology to evaluate whether the totality of evidence supports a hazard conclusion. *See* Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology*, in *Reference Manual on Scientific Evidence*, 651 (Fed. Jud. Ctr., 3d. ed. 2011) ("The hazard identification process often uses 'weight of evidence' approaches in which the toxicological, mechanistic, and epidemiological data are rigorously assessed to form a judgment regarding the likelihood that the agent produces a specific effect."); (Plunkett 3d Amend. Rep. ¶ 13 ("Weight-of-the-evidence methodology, is used as part of regulatory decision making by regulatory and scientific bodies such as the FDA," EPA, OSHA, WHO, and IARC).) By identifying the evidence she reviewed and explaining how it informed her risk conclusion, I find that Dr. Plunkett reliably performed a weight-of-the-evidence assessment at the hazard identification step.[190]

Step 2: Dose-response. Using the same weight-of-the-evidence method, Dr. Plunkett evaluated the relationship between talc exposure and ovarian cancer. (*See Id.* ¶ 11.) In conducting that assessment, Dr. Plunkett evaluated a broad range of studies and data, including *in vitro* studies, human studies, and regulatory

[190] In this regard, I disagree with Defendants' claim that hazard identification in a risk assessment necessarily requires a general or specific causation-type analysis. As long as Dr. Plunkett limits the nature of the conclusion that she offers to risk—rather than rendering a tort-causation opinion—her application satisfies the reliability requirement.

classifications. (*Id.* ¶¶ 73–75.) Defendants do not challenge Dr. Plunkett's application at the dose-response step and I find that Dr. Plunkett reliability applied the weight-of-the-evidence method to evaluate dose response.

Step 3: Exposure assessment. Because Dr. Plunkett is not being proffered as a case-specific expert, she did not attempt to "define any specific exposure for any specific person in quantitative terms." (*Id.* ¶ 12.) Instead, Dr. Plunkett assessed exposure at the general population level by "defining the routes of human exposure that would be relevant for evaluating the risks posed by use of the powders and the type of exposure patterns that have been linked to risks posed by the use of powders." (*Id.*; *see id.* ¶ 94.) As noted above, regulatory risk assessments often operate at such levels of generality, focusing on general populations or conditions of use. Within that limited risk-based scope, I find that Dr. Plunkett's application of the exposure assessment step was reliable.

Step 4: Risk characterization. Finally, Dr. Plunkett integrates the above steps to reach her risk-characterization conclusion: that the "weight-of-the-evidence indicates that genital exposure to talcum powder products increases the risk of ovarian cancer in women." (*Id.* ¶ 120.) I find that Dr. Plunkett's risk characterization is reliable.

Even so, aspects of Dr. Plunkett's report do not reflect a reliable application of a risk assessment and should be excluded. While Plaintiffs characterize Dr.

Plunkett's opinion as risk-based and disclaim offering her to prove causation, certain statements in her report cross the line from risk assessment into de facto general causation opinions. (*See, e.g.*, *id.* ¶ 72 (referencing "a cause and effect relationship between talc exposure and human ovarian cancer risk").) Because these statements do not flow from Dr. Plunkett's risk-assessment method, I recommend they be excluded. More generally, at trial Dr. Plunkett must confine her testimony to a risk-assessment framework that discusses hazard signals and risk, without presenting those assessments as determinations of or substitutes for causation.[191]

Subject to those constraints, I find that Dr. Plunkett reliably applied a reliable human health risk assessment methodology and has "good grounds" for her core risk assessment opinions. *Cohen*, 125 F.4th at 462.

b. Regulatory-Based Methodology

In addition to her risk-assessment opinions, Dr. Plunkett also testified more generally as to the regulatory framework and industry standards applicable to cosmetic product manufacturers. (*See, e.g.*, Plunkett 3d Amend. Rep. ¶¶ 15–16.) Dr. Plunkett's explanation of those standards flowed from her broad "personal

[191] Nothing in this Report and Recommendation precludes either party from seeking an instruction regarding the distinction between causation in product liability cases and risk in the context of a human health risk assessment. Nor does my recommendation preclude either party from seeking a limiting instruction; e.g.—that the jury may consider Dr. Plunkett's testimony only for the limited purpose of understanding how toxicologists and regulatory bodies assess and characterize potential health risks associated with product exposure; that her testimony is not evidence that talc or asbestos cause ovarian cancer; and that the jury may not treat any discussion of "risk" as proof of causation.

knowledge" and "experience," reflecting a reliable application of non-scientific testimony. *Kumho Tire Co.*, 526 U.S. at 150; *see United States v. Bridges*, No. 21-cv-1679, 2022 WL 4244276, at *8 (3d Cir. Sept. 15, 2022) (finding "experience based" testimony "satisfies reliability").

v. Fit, Scope, and Specific Challenges

Plaintiffs have met their burden of proving that limited portions of Dr. Plunkett's testimony regarding risk-assessment and the applicable regulatory framework fit this case. Other portions of her testimony, however, must be excluded as irrelevant, improper, or otherwise unduly prejudicial.

As discussed above, because risk assessments operate under different assumptions and evidentiary thresholds than tort law, Dr. Plunkett's risk-based testimony cannot substitute for proof of general or specific causation in this case. Even so, risk-assessment testimony may be relevant for limited, non-causation purposes, particularly where (as here) the proponent offers separate expert testimony on general and specific causation. *See* Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology*, in *Reference Manual on Scientific Evidence* 649 (Fed. Jud. Ctr., 3d. ed. 2011) ("risk assessment information about a chemical can be somewhat useful in a toxic tort case").

Here, Dr. Plunkett's risk-assessment and regulatory framework testimony, if properly cabined to avoid any discussion of causation, will help the jury understand

facts relevant to Plaintiffs' failure-to-warn and negligence claims. For example, her testimony on how toxicologists and regulatory agencies conduct risk assessments and weigh scientific evidence is relevant to the jury's assessment of the reasonableness of Defendants' conduct in light of available information. And her testimony on the regulatory framework in which cosmetics manufacturers operate will help the jury understand issues relevant to the standard of care, including whether any identified risks would prompt a reasonable cosmetic manufacturer to take further investigative steps or communicate risks to the public. (*See*, *e.g.*, Plunkett 3d Amend. Rep. ¶¶ 15–27.) Thus, I find that Dr. Plunkett's testimony has sufficient fit to be admissible for those limited purposes, subject to the above and below restrictions.

Legal conclusions. While Dr. Plunkett may describe the regulatory framework governing cosmetics and explain how toxicologists and regulatory professionals assess safety and risk communication within that framework, Dr. Plunkett cannot draw inadmissible legal conclusions. Thus, as with Dr. Kessler, Dr. Plunkett cannot offer opinions that Defendants violated FDA regulations, failed to comply with legal labeling requirements, marketed products that were "adulterated" or "misbranded," failed to warn, or were negligent as a matter of law. As explained above, those opinions constitute impermissible legal conclusions and risk substituting Dr. Plunkett's judgment for that of the Court and jury.

State of mind, intent, motives, and ethics. For substantially the same reasons addressed in my analysis of Dr. Kessler's testimony, Dr. Plunkett's opinions regarding what Defendants "knew," what their "goal" was, or whether they acted to influence scientific or regulatory processes do not fit. Determinations of corporate intent, motive, or state of mind are "classic jury" questions and do not require expert assistance. *In re Diet Drugs*, No. MDL 1203, 2000 WL 876900, at *2, 9 (E.D. Pa. June 20, 2000.) Dr. Plunkett may not testify that Defendants definitely knew of specific risks, deliberately ignored evidence, or acted with particular motives. To the extent Dr. Plunkett discusses whether the types of scientific and regulatory data that Defendants possessed could have altered them to a risk, she must do so only from the perspective of a reasonable cosmetics manufacturer and not make overt statements about Defendants' state of mind. *Deutsch v*, 768 F. Supp. 2d at 443–44.

Similarly, Dr. Plunkett may not offer subjective assessments regarding the ethical propriety or appropriateness of Defendants' conduct. *In re Rezulin*, 309 F. Supp. 2d at 543. Dr. Plunkett may testify regarding objective industry practices and risk-assessment norms relevant to cosmetic safety, but she may not offer moral or ethical judgments. Nor can she make statements that Defendants in fact put the public at risk.

Factual Narratives. As with Dr. Kessler, because portions of Dr. Plunkett's report help contextualize the information she cites, I decline to parse the report

"paragraph-by-paragraph to determine where the report turns from expert analysis to factual narrative." *Liberty Media*, 874 F. Supp. 2d at 174. Defendants can object if Dr. Plunkett's trial testimony turns into a factual narrative.

For these reasons, I recommend the Court grant in part and deny in part Defendants' motion to exclude the testimony of Dr. Plunkett.

3. Dr. Sage

i. Dr. Sage's Qualifications

Plaintiffs proffer Dr. Sage as an expert in the "science of policymaking" and "regulatory design." (Sage Rep. ¶ 9.) He claims "particular expertise" in "the regulation of health and safety," including in "information-based regulation" and "self-regulatory models." (*Id*. ¶ 9.) Dr. Sage attests that the self-regulation in which he has expertise "includes government-supervised health and financial self-regulation, corporate compliance and corporate governance, and the regulation of self-governing professions." (*Id*.)

Dr. Sage received an M.D. in anesthesia and critical care medicine and a J.D. from Stanford University. (*Id*. ¶ 2.) After completing a medical internship, Dr. Sage spent one year as an anesthesiology and crucial care medicine resident at Johns Hopkins Hospital. (*Id*.) He then worked as a corporate lawyer for five years. (*Id*.)

Dr. Sage left private practice to enter academia in 1995. During his tenures at Columbia University (1995–2006), the University of Texas at Austin (2006–2022),

and Texas A&M University (2022–present), he has served as a professor in law and medical schools, often concurrently. (*See id.* ¶¶ 1, 4–5.) At Texas, he was also the vice provost for Health Affairs. (*Id.* ¶ 4.) In his current role at Texas A&M, Dr. Sage is a professor in the law school, medical school, and Bush School of Government and Public Service, and an assistant vice president in the Health Center. (*Id.* ¶ 1.)

Dr. Sage has taught classes in health law and policy, legislation, regulatory theory and design, and professional ethics and self-governance. (*See id*. ¶ 6 & Ex. A.) He has published many articles and several books, addressing topics like public health, regulation, and corporate responsibility. (*See id.*, Ex. A.) Dr. Sage also has advised governmental, academic, and professional organizations, including as a working group member on President Clinton's 1993 Health Care Reform Task Force. (*Id*. ¶ 7.) He is a member of the National Academy of Medicine and the American Law Institute and the co-editor of the most recent edition of the Oxford Handbook of U.S. Health Law. (*Id*., Ex. A.)

Dr. Sage has taught classes on FDA regulations, including in relation to drugs, medical devices, and over-the-counter medications. (Sage Dep. at 26:21–27:2.) But he has never worked for the FDA, has never served on an FDA committee, and has never communicated with anyone at the FDA about a cosmetic product. (*See* Sage Dep. at 45:18–20, 48:2–11.) He has not worked in the cosmetics industry, has not advised cosmetics manufacturers, had not performed "specific work on cosmetic

regulations" prior to this case, and has not taught classes on cosmetic manufacturing. (*See* Sage Dep. at 25:14–17, 32:22–33:6, 44:4–45:21.)

Based on these facts and my review of Dr. Sage's report and deposition transcript, I find that Dr. Sage is qualified to testify only as to regulatory design and self-regulation in the health and consumer products sectors. Because he lacks direct experience with cosmetic manufacturers and FDA (and Canadian) regulatory compliance, however, he is unqualified to offer opinions applying those regulations to Defendants' conduct. I further illustrate this limitation in analyzing the admissibility of Dr. Sage's proposed testimony below.

ii. Summary of Dr. Sage's Opinions

Dr. Sage stated that he was retained to answer two questions: "(a) What are the regulatory practices and standards under which manufacturers of cosmetics operate? and (b) Did Johnson & Johnson comply with these standards in its general development, manufacture, marketing, and sale of talcum powder products." (Sage Rep. ¶ 11.) In answering those questions, Dr. Sage reviewed applicable laws and regulations, industry standards, peer-reviewed literature, corporate documents, and publicly available information. (*Id.* ¶ 12.) Based on his review, Dr. Sage reached the following main conclusions:

- The cosmetics industry relies on a "self-regulated" framework that the FDA does not closely supervise. This system is "principally firm-based," and relies on manufacturers to voluntarily comply with FDA standards and industry codes of conduct. This includes (i) selling "only safe products

containing safe ingredients," (ii) responsibly disclosing product information to consumers, and (iii) voluntarily reporting product information to the FDA. (Sage Rep. ¶¶ 174–175.)

- Johnson & Johnson "did not establish or maintain the safety of its" talc products. Even though Johnson & Johnson "knew its products contained carcinogens, including asbestos, fibrous talc, and heavy metals," Johnson & Johnson did not: (i) perform studies to address rising concerns; (ii) notify the FDA that the talc products contained ingredients that "may be associated with a health hazard"; or (iii) accurately register its products, inform the FDA of positive test results, or consistently report adverse events. (Sage Rep. ¶¶ 176–177, 180, 182.)

- Johnson & Johnson did not (i) provide consumers with "required warnings" of "health hazards associated" with the talc products, (ii) inform consumers that consuming talc products posed risks, or (iii) disclose that the safety of the talc products "had not been determined." (Sage Rep. ¶¶ 178–179, 183.)

- Johnson & Johnson "misled" consumers with "continued reassurance about safety and purity," and "marketed and sold a misbranded and adulterated product. (Sage Rep. ¶¶ 181, 183.)

- Johnson & Johnson "did not follow its own safety standards or corporate pledge of legal compliance and ethical self-governance beyond what the marketplace had always accepted." (Sage Rep. ¶ 184.)

iii. The Parties' Exclusion Arguments

Defendants assert four main arguments for excluding Dr. Sage's testimony, each of which Plaintiffs dispute:

First, Defendants argue that Dr. Sage is unqualified to opine on the alleged relationship between the talc products and ovarian cancer, and that the opinions he does offer are not the product of a reliable method. (Defs.' Regulatory Br. 31–33.) In response, Plaintiffs assert that Dr. Sage "is not offering any general causation

opinions regarding whether talcum powder products cause ovarian cancer," and merely "discusses the scientific literature, including opinions by Plaintiffs' other experts, as part of his broader discussion and opinions related to regulatory practices and standards." (Pls.' Regulatory Opp. Br. 49.)

Second, Defendants argue that Dr. Sage's opinions constitute legal conclusions about whether Johnson & Johnson violated federal regulations and legal duties. These include his opinion that Johnson & Johnson (i) marketed and sold a misbranded and adulterated product, (ii) did not substantiate the safety of the talc products, and (iii) failed to provide legally required warnings. (*See* Defs.' Regulatory Br. 13–16.)

Plaintiffs assert that Dr. Sage is a "legal expert on health law and corporate responsibility" who "should be allowed to offer his opinions on industry standards and the regulatory framework and whether Defendants complied with these standards in the marketing and sale" of the talc products. Plaintiffs argue that Dr. Sage explains those industry standards and regulatory framework "through the lens of Defendants' actions," but does not offer "ultimate legal conclusions about Defendants' liability." (*See* Pls.' Regulatory Opp. Br. 22–23.)

Third, Defendants argue that Dr. Sage renders ethical judgments about Defendants' corporate conduct and state-of-mind opinions that are speculative and unduly prejudicial. According to Defendants, this includes opining that Johnson &

Johnson: (i) knew about health risks associated with the talc products, (ii) did not engage in "responsible corporate behavior," and (iii) violated its own representations regarding ethics. (*See* Defs.' Regulatory Br. 19–25.)

Plaintiffs disagree, pointing to portions of Dr. Sage's deposition transcript where he promises not to offer opinions on Defendants' intent. Plaintiffs assert that Dr. Sage may testify about what information Defendants possessed at certain points in time and whether their actions were reasonable. Plaintiffs also contend that Dr. Sage may testify about whether Defendants complied with industry, regulatory, and internal guidelines, and will not state his personal feelings about Defendants' actions at trial. (*See* Pls.' Regulatory Opp. Br. 30–31, 34–36, 40–41).

Fourth, Defendants argue that Dr. Sage narrates corporate documents—including Johnson & Johnson communications, a patent application, and CIR communications—without adding any expert analysis. (*See* Defs.' Regulatory Br. 11–13.) Plaintiffs disagree, arguing that Dr. Sage's analysis adds helpful context on the applicable regulatory and industry framework. (*See* Pls.' Regulatory Opp. Br. 19.)

I address these disputes when analyzing the reliability and fit of Dr. Sage's opinions below.

iv. Reliability and Scope

Plaintiffs must show that it is more likely than not that Dr. Sage's testimony is based on sufficient facts, reliable methods, and a reliable application of those methods. Fed. R. Evid.702. I find that Plaintiffs have met that burden only as to a limited portion of Dr. Sage's testimony.

Dr. Sage "formulated" his opinions by using his "professional knowledge, experience, and expertise" to review corporate documents, "peer-reviewed literature," "laws and regulations," and industry standards. (Sage Rep. ¶ 12.) According to Dr. Sage, this is the same methodology that he has "applied in [his] professional and academic career." (Sage Rep. ¶ 12.) He identifies no other scientific or non-scientific methodology, such as a comparative analysis of other cosmetic manufacturer's practices.

While "extensive and specialized experience" can serve as a reliable method for making non-scientific observations under *Kumho*, that only gets Dr. Sage so far. 526 U.S. at 156. As noted above, Dr. Sage's experience and expertise is in health law and regulatory design, including industry self-regulation. Given his specialized background, I find that Dr. Sage's qualifications and methods are sufficient to permit him to explain the FDA's overall regulatory scheme for cosmetics (including the distinction between the FDA's oversight of drugs and cosmetics) and the concept of self-regulation generally and in the cosmetics sector.

But the balance of Dr. Sage's opinions are not the product of specialized expertise or a reliable method. Dr. Sage has no experience working for the FDA or analyzing FDA disclosures or communications. Nor has he worked for a cosmetic manufacturer or otherwise previously analyzed compliance efforts or obligations of a cosmetic company. Because Plaintiffs rely only on Dr. Sage's experience—identifying no other methodology—his inexperience in these areas renders the rest of his testimony unreliable. *See In re Rezulin*, 309 F. Supp. 2d at 549 (excluding opinions on compliance with FDA standards as unreliable where experts lacked relevant experience and cited no other methodology). That inadmissible testimony includes his opinions that Johnson & Johnson (i) failed to substantiate safety, (ii) failed to warn and misled consumers, and (iii) marketed and sold misbranded and adulterated products. It also includes all of Dr. Sage's compliance opinions, such as Johnson & Johnson's purported violations of FDA regulations and disclosure requirements, industry standards, and internal policies. Finally, it includes his opinions about Johnson & Johnson's actions or the information that Johnson & Johnson allegedly possessed.[192]

[192] Plaintiffs and Dr. Sage submit that he "is not offering any general causation opinions regarding whether talcum powder products cause ovarian cancer." (Pls.' Regulatory Opp. Br. 49; Sage Dep. at 396:5-6 ("I'm not offering a scientific expert opinion on causation.").) For the avoidance of doubt, I recommend the Court find that Dr. Sage is not qualified to opine on any alleged relationship between talc products and ovarian cancer—either from a tort-law or risk-assessment perspective—and that such testimony would not stem from a reliable methodology. Moreover, given the limitations I have recommended be imposed on his testimony, Dr. Sage should also be precluded from offering any testimony related to: Johnson & Johnson's knowledge or risks,

v. Fit

With these limitations, Dr. Sage's cabined testimony will help the factfinder understand evidence or determine a fact in issue, and thus satisfy Rule 702's fit requirement. As noted above, Dr. Sage may testify about the regulatory scheme applicable to cosmetics manufacturers, including the role of self-regulation. This information will help the jury understand the complex regulatory environment in which Defendants operated, and thus better evaluate Defendants' conduct in relation to the standard of care. *See United States ex rel. Silver v. Omnicare, Inc.*, No. 11-1326, 2023 WL 2808098, at *11 (D.N.J. Mar. 31, 2023) ("Qualified experts may provide background on a statutory or regulatory scheme so long as their opinions do not state whether the statute or regulation was violated.").

By contrast, many of the opinions that I recommend be excluded above also fail the fit requirement or are unduly prejudicial under Rule 403. Dr. Sage's opinions that Johnson & Johnson violated FDA regulations and other legal requirements—including regulations on labeling, disclosures, and substantiating product safety—are improper legal conclusions. *See Rowland v. Novartis Pharms. Corp.*, 9 F. Supp. 3d 553, 561 (W.D. Pa. 2014) (allowing expert to "testify as to the general FDA

alleged hazards posed by the talc products (*e.g.*, whether they contained asbestos, posed health risks, or cause cancer), or Defendants' testing methods. Indeed, in their own *Daubert* motion, Plaintiffs state that "opinions on what [Johnson & Johnson] knew—and when—about the alleged presence of asbestos . . . require the application of knowledge about mineralogy, geology, or talc mining and testing." (Pls.' Regulatory Opp. Br. at 11). Because Dr. Sage lacks such knowledge, he fails Plaintiffs' own test.

regulatory scheme governing pharmaceutical drugs," but finding opinion on whether "specific conduct . . . complied with FDA regulations" was "an improper legal conclusion"); *In re Rezulin*, 309 F. Supp. 2d at 550 (finding "[e]xpert testimony interpreting [defendant's] conduct in disclosing information to the FDA" would "not assist the fact-finder.") The same finding applies to his opinion that Johnson & Johnson misled consumers and sold adulterated and misbranded products. These statements apply the law to the facts and thus invade the province of the Court and the jury.

Similarly, during his deposition, Dr. Sage made the types of subjective "bad company" comments that courts regularly exclude as irrelevant, unhelpful, and unduly prejudicial. (*See, e.g.*, Sage Dep. at 302:2–7 (describing content of Johnson & Johnson's website as "disappointing, frankly shocking, and directly at odds with its regulatory obligations")); *see Bartoli*, 2014 WL 1515870, at *6 (explaining "'bad company' opinions are not admissible").

Dr. Sage also made speculative inferences about Johnson & Johnson's state-of-mind or motives based on his review of documents. (*See, e.g.*, Sage Rep. at 8 ("Johnson & Johnson has known about risk and uncertainty regarding talc and ovarian cancer for decades."); *id.* ¶ 176 ("Johnson & Johnson knew its products contained carcinogens"); *id.* ¶ 50 ("Johnson & Johnson's resistance to the presence in talcum powder products of fibrous constituents that pose risk to human health is

strikingly at odds with the factual history.").) Because Dr. Sage is unqualified to add scientific or industry context to these documents, the jury can draw these inferences without his expert testimony. *See In re Diet Drugs*, 2000 WL 876900, at *9 (finding if expert "witnesses' bases for the opinions concerning improper intent come from" letters and employee statements, "that is what the jury should hear and the question of . . . intent would flow from such evidence to be determined by the jury."); *In re Rezulin*, 309 F. Supp. 2d at 550 (explaining whether defendant purposefully "'buried' certain lab results" was a "simple inference" drawn from documents "plaintiffs' counsel may present directly to the fact-finder".)[193]

For these reasons, I recommend the Court grant in part and deny in part Defendants' motion to exclude the testimony of Dr. Sage.

4. Dr. Newman

i. Dr. Newman's Qualifications

Plaintiffs proffer Dr. Newman as an expert on "marketing, advertising, and consumer psychology." (Pls.' Regulatory Opp. Br. 43.) Dr. Newman holds three post-graduate degrees from Yale University: an M.S. in Psychology (2005); an M. Phil. in Psychology (2006); and a Ph.D. in Cognitive Psychology (2008). (ECF No.

[193] Based on the limits that I have imposed on Dr. Sage's testimony, I need not reach Defendants' factual narrative objection. If the need arises, Defendants may raise a factual narrative objection at trial, similar to my discussion of this issue, *supra* Part VII.A.1.iii.a.

33000-13 ("Newman Rep.") ¶ 2.) In 2011, he completed a three-year post-doctoral associate program in Marketing at the Yale School of Management. (*Id.*)

Between 2011 and 2022, Dr. Newman was an associate professor of management and marketing at the Yale School of Management. (*Id.* ¶ 1.) During that tenure, he also held affiliations with Yale University's Psychology and Cognitive Science departments and the Yale Center for Customer Insights. (*Id.*) Since 2022, Dr. Newman has served as an associate professor of organizational behavior, human resource management, and marketing at the University of Toronto. (*Id.*) He also has served as a visiting professor of marketing at New York University, the University of Hawaii (Manoa), and Seoul National University. (*Id.* ¶ 4.) During his career in academia, Dr. Newman has "taught classes in marketing, consumer behavior, and marketing management at the undergraduate and graduate (MBA and PhD) levels." (*Id.*)

Dr. Newman also has "taught several seminars on the topics of marketing and management to executives in senior leadership positions in industry and the U.S. federal government." (*Id.*) He has held advisory roles for academic and professional organizations, including serving on the editorial boards of the Journal of Consumer Psychology and the Journal of Sustainable Marketing. (*Id.* ¶ 5.) And he has published book chapters and dozens of peer-reviewed articles, including "on the topics of

marketing communications, brand heritage, brand authenticity, consumer perceptions of trust, and corporate social responsibility." (*Id*. ¶ 7.)

Based on these facts, Defendants do not dispute—and I find—that Dr. Newman is qualified to testify as an expert witness in marketing, branding, and consumer psychology, in accordance with the limitations set forth below. To that end, in connection with limiting portions of Dr. Newman's testimony on reliability and fit grounds below, I explain that certain opinions (such as his statements about the alleged health risks posed by consumption of the talc products) exceed the scope of his marketing expertise.

ii. Summary of Dr. Newman's Opinions

Dr. Newman states that he was engaged to (i) review Johnson & Johnson's marketing practices for the talc products, and (ii) "assess whether the company engaged in misleading and deceptive conduct that created confusion and misunderstanding among consumers by failing to communicate and appropriately inform consumers of health risks associated with" the talc products. (Newman Rep. ¶ 9.) Dr. Newman reviewed Johnson & Johnson consumer marketing materials (including print advertisements, messaging, and promotions), internal corporate documents, testimony from Johnson & Johnson employees, and newspaper and magazine articles. (*Id*. ¶ 10.)

Dr. Newman submits that he considered those materials in light of his professional experience, and in consideration of established principles in the disciplines of psychology, consumer behavior, and behavioral economics. (*See id.* ¶¶ 10–11.) Based on his review, Dr. Newman reached the following main conclusions:

- For over a century, Johnson & Johnson's marketing communications—including "product labeling, advertisements, public statements, and endorsements from medical professionals" reflect a strategy that centered on making the "brand synonymous with trust." Johnson & Johnson's messaging "promised to prioritize the health and well-being" of "customers above all else." (*Id.* ¶ 12.)

- As part of its effort to build a "Trustmark" and "deep, personal trust," Johnson & Johnson associated its talc products with the "mother-infant bond." (*Id.* ¶¶ 12–13.)

- Johnson & Johnson succeeded in building consumer trust. Consumers perceive Johnson & Johnson as a "caregiver" and "innocent" brand. These favorable consumer perceptions created a brand "halo" that shaped consumer beliefs on the safety of Johnson & Johnson's products, reduced consumers' sensitivity to risk information, and led to increased sales. (*See id.* ¶¶ 14, 37–44.)

- Johnson & Johnson was aware of potential health risks concerning the talc products as early as the 1970s and developed a feasible, market-tested cornstarch alternative in the 1980s. Even so, Johnson & Johnson continued to market and sell talc products as safe in the U.S. and Canada until 2020 and globally until 2023. (*See id.* ¶¶ 16–19.)

- By continuing to market the talc products as safe after it knew of potential health risks, Johnson & Johnson violated its promise to prioritize customers' safety and well-being above all else. Through its marketing efforts, including its targeting of specific demographics, Johnson & Johnson engaged in "misleading and deceptive conduct that created

confusion and misunderstanding among consumers." (*See id.* ¶¶ 18–19, 98.)

- Johnson & Johnson's "actions needlessly exposed millions of women to a potential hazard and violated the central promise of trust and safety upon which their relationship with customers was built." (*Id.* ¶ 20.)

iii. The Parties' Exclusion Arguments

Defendants argue that Dr. Newman's opinions should be excluded for five main reasons, each of which Plaintiffs contest:

First, Defendants argue that Dr. Newman's marketing opinions are unreliable because he considered only Johnson & Johnson internal market research to conclude that Johnson & Johnson cultivated trust with consumers. Defendants contend that Dr. Newman failed to conduct experiments or cite any empirical data or hard evidence—such as public opinion surveys, anthropological, market, or sociological studies, or other impact evidence—to support those opinions, departing from his normal professional practices and rendering his testimony speculative. Defendants argue that the same problems plague Dr. Newman's opinions that Defendants engaged in misleading and deceptive conduct. (*See* Defs.' Regulatory Br. at 25–29.)

In response, Plaintiffs argue that Dr. Newman used a methodology that courts and the consumer-behavior industry accept as reliable, and that he uses in his professional and academic career. That is, after starting with a null hypothesis, Dr. Newman compared (i) what he learned about Defendants' marketing and advertising practices to (ii) industry codes of conduct promulgated by the American Marketing

Association, Association of National Advertisers, American Advertising Federation, and Federal Trade Commission. Plaintiffs argue that Dr. Newman permissibly relied on Defendants' own internal documents and communications, deposition testimony, and marketing materials, studies, and surveys to reach conclusions on the impact of its marketing over time. Plaintiffs dispute that Dr. Newman was required to conduct his own survey. (*See* Pls.' Regulatory Opp. Br. at 42–48.)

Second, Defendants argue that even if Dr. Newman's method were reliable, his opinions do not fit the facts here. In that regard, Defendants contend that Dr. Newman's marketing opinions would not help the factfinder understand evidence or determine a fact in issue because (i) he does not attempt to tether his opinions to marketing that any individual plaintiff reviewed, and (ii) his opinions about the factsabouttalc.com website lack relevance because the website was created years after any bellwether plaintiff used talc products. (*See* Defs.' Regulatory Br. at 30.) In opposition, Plaintiffs argue that Dr. Newman's experience and testimony will help explain how Johnson & Johnson's marketing practices impacted consumers. (*See* Pls.' Regulatory Opp. Br. at 42–43.)

Third, Defendants argue that Dr. Newman offers an improper narrative by regurgitating facts from "straightforward documents." (*See* Defs.' Regulatory Br. at 12 (arguing Dr. Newman rehashes Johnson & Johnson's internal documents, a 1982 study on talc, the 1994 and 2008 Citizens' Petitions to the FDA, an FDA request,

and Health Canada's 2021 report.).) Plaintiffs disagree, arguing that Dr. Newman "offers meaning to Defendants' actions and inactions and the purposes served in developing Defendants' brand." (Pls.' Regulatory Opp. Br. at 20.)

Fourth, Defendants argue that Dr. Newman speculates on Defendants' state of mind based on his review of documents. (Defs.' Regulatory Br. at 20.) In response, Plaintiffs argue that based on his review of "thousands of corporate internal documents," Dr. Newman opines on the "messaging" that Johnson & Johnson conveyed—"what J&J promised to its consumers, what J&J stated its motivations were, and what J&J was aware of and when"—but does not speculate as to Defendants' state of mind. (Pls.' Regulatory Opp. Br. at 34.)

Fifth, Defendants argue that Dr. Newman renders subjective ethical opinions by stating that Defendants violated both Johnson & Johnson's own company "credo" and "what he teaches as 'best practices'" by "not disclosing" any "health risk associated with" talc products. (Defs.' Regulatory Br. at 22–23.) Defendants also argue that any probative value of these statements is vastly outweighed by their tendency to encourage the jury to improperly impose liability, requiring their exclusion under Rule 403. (*Id.* at 25.)

Plaintiffs disagree, arguing that Dr. Newman's testimony on Defendants' compliance with marketing and advertising codes of conduct promulgated by professional organizations informs the standard of care and will help the jury

understand how Johnson & Johnson's marketing practices impacted consumers. Plaintiffs also contend that Dr. Newman can testify about Johnson & Johnson's corporate credo. (*See* Pls.' Regulatory Opp. Br. at 34–36, 41–43.)

I resolve each of these disputes in connection with analyzing the reliability and fit of Dr. Newman's opinions below.

iv. Reliability

Plaintiffs have met their burden on reliability by demonstrating, by a preponderance of the evidence, that some—but not all—of Dr. Newman's opinions are based on sufficient facts and data, a reliable methodology, and the reliable application of that methodology.

For topics that do not involve scientific testimony, the "relevant reliability concerns may focus upon personal knowledge or experience," rather than the traditional *Daubert* reliability factors. *Kumho*, 526 U.S. at 150. Courts within and outside the Third Circuit have held that a "marketing professional's review and analysis of company documents to extrapolate marketing strategies, coupled with the expert's experience and background may be enough to establish that the expert's methodology is reliable." *In re: Tylenol*, MDL No. 2436, 2016 WL 807377, at *5 (E.D. Pa. Mar. 2, 2016) (collecting cases).

In *Tylenol*, for example, consumers proffered an expert who had taught marketing research, consumer behavior, and consumer psychology, in addition to

publishing many articles on how advertising affects consumer perceptions of a product's health effects. 2016 WL 807377, at *4. That expert "synthesized" the defendants "own extensive market research and consumer surveys" and "offered opinions about how the defendants employed various marketing and psychological techniques to build the Tylenol brand" as "the 'safest' analgesic." *Id*. at *5. He also explained how those techniques "created a certain effect on consumers' perception of Tylenol products," including why it was "reasonable for a consumer" to downplay certain overuse risks. *Id*. Because the expert "drew on his background and expertise in rendering his opinions," and because his methods reflected a "careful review of the information presented," the court found his methodology to be reliable. *Id.*

Here too, I find that Dr. Newman used a reliable method and reliably applied it. Starting with a null hypothesis, Dr. Newman used the same systematic analysis that he applies in his professional and academic career to analyze Defendants' marketing materials and communications, internal corporate documents about the talc products, and other data and information. In conducting that review, he identified and considered six areas of inquiry: relevance; messaging; strategy; impact; product risks; and response. (*See* Newman Rep. ¶ 10.) Based on his expertise in marketing, branding, and consumer psychology, Dr. Newman identified recurring themes across a century of Johnson & Johnson marketing evidence, linked them to research on "halo effects," and contextualized them within Johnson & Johnson's

brand-heritage strategy. Subject to the limits discussed herein, those steps constitute a reliable application of a reliable qualitative method.

Defendants argue that because Dr. Newman did not perform his own survey or conduct his own experiments, his opinions lack empirical support and his testimony must be excluded. I disagree, in part. Based on his methodology, Dr. Newman may synthesize Johnson & Johnson's branding and messaging strategies, provide context on industry standard marketing codes, and explain how he expects messaging themes (including those he identifies) influenced consumer beliefs. *See, e.g.*, *In re Juul Labs, Inc. Mktg., Sales Pracs. & Prods. Liab. Litig.*, No. 19-cv-02913, 2022 WL 1814440, at *4 (N.D. Cal. June 2, 2022) (finding "marketing experts' experience, review of relevant literature," and "review of [defendant's] own documents provide[d] a reasoned and reliable basis" to "opine generally" about defendants' "health messaging and its impact").[194] Dr. Newman also may explain consumer-psychology principles concerning brand trust, halo effects, and risk perception.

Other portions of Dr. Newman's report, however, lack a reliable foundation or are otherwise inadmissible. While Dr. Newman may analyze Johnson &

[194] In rendering those opinions, Dr. Newman does not simply regurgitate facts. He identifies common themes and adds explanatory context, which courts permit. *See, e.g.*, *In re: Tylenol*, 2016 WL 807377, at *9 (rejecting factual narrative argument because marketing expert "translate[d] the meaning of" defendants' actions in creating Tylenol brand and explained "what purpose they serve in branding"). If Dr. Newman starts to quote or simply rehash corporate documents at length at trial, Defendants can object.

Johnson's marketing evidence and offer objective opinions on how those materials could influence consumer perceptions, he cannot testify on how Johnson & Johnson's marketing actually impacted or influenced consumers. To that end, because Dr. Newman did not validate the Johnson & Johnson consumer surveys that he relied on—by conducting his own experiments, issuing his own surveys, or speaking to any individual plaintiffs—his conclusion that Johnson & Johnson in fact "engaged in misleading and deceptive conduct that created confusion and misunderstanding among consumers" is speculative and does not reliably flow from his methodology.

Put differently, Dr. Newman may testify about how the advertising themes he identifies *could* influence consumer perceptions but may not testify that Johnson & Johnson's marketing *in fact* influenced consumer perceptions. *See Montera v. Premier Nutrition Corp.*, No. 16-06980, 2022 WL 1225031, at *5–6 (N.D. Cal. Apr. 26, 2022), *aff'd in part*, 111 F.4th 1018 (9th Cir. 2024) (permitting marketing expert to explain general marketing principles and synthesize defendant's marketing strategies based on review of defendant's documents, but precluding testimony on "how consumers actually interpreted the messages" given lack of impact data.)

For the same reasons, Dr. Newman cannot offer causation opinions linking Johnson & Johnson's marketing to product use or injury. Dr. Newman engages in no scientifically accepted methodology to render such testimony. Thus, his opinions

that Johnson & Johnson's marketing "needlessly exposed millions of women to a potential hazard" are inadmissible. (Newman Rep. ¶ 20.)

Dr. Newman also makes several inadmissible assertions about Johnson & Johnson's state of mind and corporate conduct. (*See, e.g.*, Newman Rep. at 12 ("By as early as 1966, Johnson & Johnson was aware of health risks associated with the use of talcum powder products."); *id.* ¶ 65 (opining on Johnson & Johnson's awareness of "the potential links between talcum powder use and ovarian cancer").) As noted above, this type of subjective testimony does not stem from reliable principles and usurps the role of the factfinder. *See, e.g.*, *O'Bryant*, 2022 WL 7670296, at *12 (barring testimony concerning "alleged knowledge and state of mind," including whether defendant misled and what defendant "knew at the time" it developed warnings and labeling.) At trial, Dr. Newman cannot speculate about Johnson & Johnson's state of mind or testify that Johnson & Johnson violated ethical duties.

v. Fit and Scope

Dr. Newman's admissible testimony (as set forth above) fits the case because it will help the factfinder understand how branding, imaging, and messaging could shape consumer perceptions of safety. Indeed, because "[a]dvertising methodologies are esoteric; the average juror could be helped by an explanation of how they work and were used by defendants." *Schwab v. Philip Morris USA, Inc.*, No. 04-cv-1945,

2005 WL 2401647, at *5 (E.D.N.Y. Sept. 29, 2005); *see In re: Tylenol*, 2016 WL 807377, at *6 ("The average person may not know about the subtle applied psychological techniques drug companies use to market their products."). Here, Dr. Newman's analysis of Johnson & Johnson's "Trustmark" and "mother-child" marketing themes may help the jury evaluate whether Johnson & Johnson's marking conveyed an impression of safety inconsistent with the alleged risks.

By contrast, Dr. Newman's opinions about Johnson & Johnson's state of mind, corporate intent, and alleged false and misleading advertising invade the province of the factfinder, and are inadmissible. *See In re: Tylenol*, 2016 WL 807377, at *8 ("[A]n opinion that the advertising was misleading or false would properly come from the jury, not from an expert."). And to avoid unfairly prejudicing the factfinder and exceeding the scope of his expertise, other than offering limited, general references needed to contextualize the admissible marketing opinions noted above, Dr. Newman cannot opine on (i) whether using talc products posed health hazards, (ii) when Defendants were allegedly aware of such risks, or (iii) the history or purpose of Defendants' development of a cornstarch alternative.

For these reasons, I recommend the Court grant in part and deny in part Defendants' motion to exclude the testimony of Dr. Newman.

5. Conclusion

For the reasons set forth above, I recommend the Court grant in part and deny in part Defendants' Motion to Exclude the Opinions of Drs. Kessler, Plunkett, Sage, and Newman, as follows:

1. Dr. Kessler may testify, within the bounds of his expertise, regarding the regulatory framework governing cosmetics and general industry practices. But he is precluded from offering legal conclusions, opinions on Defendants' intent or state of mind, ethical judgments, or testimony outside his qualifications, including on the technical validity or aspects of any particular test or the geological properties of talc.

2. Dr. Plunkett may testify concerning toxicological and risk-assessment principles and industry practices relevant to cosmetic safety. But she may not offer legal conclusions, definitive causation opinions, testimony about Defendants' knowledge or motives, or subjective ethical assessments.

3. Dr. Sage may offer limited testimony regarding regulatory structures and industry standards from a policy perspective. But he is barred from offering legal conclusions, causation opinions, speculative inferences regarding Defendants' intent or knowledge, as well as subjective "bad company" characterizations.

4. Finally, Dr. Newman may testify regarding general marketing principles and consumer-behavior concepts. But his opinions concerning Defendants' intent and definitive statements about how Defendants marketing materials in fact influenced consumers are excluded.

5. To the extent any expert testimony veers into impermissible factual narrative, legal conclusion, or speculation at trial, appropriate objections may be raised at that time.

B. Plaintiffs' Motion to Exclude Dr. Kathleen Sutcliffe

Plaintiffs move to exclude the opinion testimony of Dr. Kathleen Sutcliffe, an expert proffered by Defendants to opine on Johnson & Johnson's corporate

knowledge and conduct. (*See* ECF No. 32998-1 ("Pls.' Regulatory Br.").) Defendants oppose exclusion. (*See* ECF No. 33116 ("Defs.' Regulatory Opp. Br.").) My prior Opinion did not cover Dr. Sutcliffe's testimony. In addressing Plaintiffs' arguments for excluding Dr. Sutcliffe below, I make independent findings on qualification, reliability, and fit.

1. Summary of Dr. Sutcliffe's Opinions

Defendants proffer Dr. Sutcliffe as an "expert in organization science, behavior, and theory." (*Id.* at 4.) They state that Dr. Sutcliffe "studies how companies process and respond to information in order to determine what they could have done better in a given situation and how they can anticipate and prevent future issues." (*Id.*) Dr. Sutcliffe claims particular expertise in understanding "how organizations process and make sense of ambiguous and equivocal information" and "make decisions under uncertainty." (ECF No. 33116-2 ("Sutcliffe Rep.") ¶ 2.)

Dr. Sutcliffe defined the scope of her work as assessing: (i) what Johnson & Johnson "knew—and when—about the alleged presence of asbestos in its cosmetic talc products," (ii) "what actions it took to acquire this knowledge," and (iii) "the extent to which Johnson & Johnson's actions were consistent with an organizational commitment to the wellbeing of consumers." (*Id.* ¶ 9.) To answer those questions, Dr. Sutcliffe reviewed internal Johnson & Johnson documents and other information, drew on her experience, and applied a qualitative method and

"sensemaking" framework that she describes as "widely used and highly cited" in the field of organizational science. (*Id.* ¶¶ 40, 42.) In her report, Dr. Sutcliffe reaches the following main conclusions:

- The early 1970s was a period of "disruptive ambiguity" regarding the safety of cosmetic talc. During that period, "confusion regarding definitions of asbestos, and how to identify asbestos in talc, collided with a lack of regulatory testing standards and evolving science on these questions." (*See id*. ¶ 90.)

- In this period of disruptive ambiguity, Johnson & Johnson "actively pursued knowledge regarding the potential health risks associated with its baby powder." That pursuit included Johnson & Johnson's engagement, in the "early 1970s," with "consumers, regulators, scientists, the media, other manufacturers, suppliers, and trade organizations to make sense of new scientific knowledge and competing perspectives." These efforts "were intended to advance the science—and to promulgate accurate information—related to whether asbestos was present in cosmetic talc." Johnson & Johnson's efforts led to the creation of a "new 'map'" of knowledge that "codified Johnson & Johnson's understanding of the potential health risks associated with exposure to asbestos and talc and the safety of its baby powder." (*Id*. ¶¶ 14, 91, 161.)

- The creation of Johnson & Johnson's "map" in the mid-1970s "resolved much of the earlier ambiguity." (*Id*. ¶¶ 120, 161.) Over that period, "some of the key figures who instigated the disruptive ambiguity abandoned their stances and acknowledged the safety of cosmetic talc, reaffirming Johnson & Johnson's 'map.'" One testing lab and the "FDA would later remark that much of the testing from this time period was incorrect or suspect, or used inappropriate definitions of asbestos." (*Id*. ¶¶ 120, 161.)

- "Since the disruptive ambiguity of the early 1970s, J&J has devoted significant resources and attention to developing, validating, disseminating, and challenging" its "map" that "codifies the existing scientific knowledge regarding the detection of asbestos in talc and the safety of talc." Those efforts include (i) "developing and implementing industry-leading methods for testing its talc sources and its baby powder for the presence of asbestos," and (ii) committing "to continued discussion,

validation, and dissemination of scientific knowledge among researchers and external stakeholders." (*Id*. ¶¶ 15, 190.)

- Johnson & Johnson's "active pursuit, testing, and validation of knowledge regarding the potential health risks associated with its baby powder reflect best practices in organizational sensemaking." Sensemaking "enables organizations to understand, articulate, and act on knowledge in ways that are consistent with organizational perspectives and priorities." (*Id.* ¶ 16.)

- Johnson & Johnson's actions, during and after the period of disruptive ambiguity, demonstrate: (i) behavior that Dr. Sutcliffe "would expect to see in an organization committed to the wellbeing of consumers," (ii) Johnson & Johnson's "ongoing concern about the quality and safety of its baby powder," and (iii) proactive engagement "in sensemaking with regards to the possibility it was not safe." "Put differently, J&J's actions and decisions have been, and continue to be, consistent with the actions of a responsible company that prioritizes the wellbeing of consumers." (*Id.* ¶¶ 16, 189–190, 192.)

- By contrast, Johnson & Johnson's actions "are inconsistent with behaviors that indicate carelessness or disregard" for consumer wellbeing. "Allegations that J&J 'knew' or hid the 'truth' about the alleged health risks associated with its baby powder are inconsistent with the record of J&J's actions, decisions, and organizational commitment to the wellbeing of consumers." (*Id.* ¶ 17.)

- Plaintiffs make "broad generalizations" about Johnson & Johnson, including that Johnson & Johnson: knew of and concealed "test results showing that its baby powder contains asbestos and research studies linking its baby powder to cancer"; manipulated testing results to conceal asbestos findings from the FDA; violated a duty to warn consumers; had unethical interactions with regulators; and declined to replace talc-based baby powers with a cornstarch-alternative to protect profits. (*Id.* ¶¶ 20–30.)

- Plaintiffs' conclusions about Johnson & Johnson are "based on an incomplete and biased view of the evidence that is not grounded in a framework for understanding it or a scientific approach to evaluating it." To "adequately support their conclusions," Plaintiffs "would need to conduct an organizational assessment" that uses "an established

> conceptual framework and research methodology based in organizational theory. Instead, they engage in cherry-picking, a biased review of the evidence, and inappropriate extrapolation." (*Id*. ¶¶ 31, 191.)

2. The Parties' Exclusion Arguments

Plaintiffs move to exclude Dr. Sutcliffe's opinions for three main reasons, each of which Defendants dispute:

First, Plaintiffs argue that Dr. Sutcliffe is unqualified to testify about "scientific, technical," and regulatory topics covered by her report. For example, Plaintiffs argue that because Dr. Sutcliffe is "no expert in mineralogy, geology, talc mining, talc testing, or microscopy," she cannot opine on what Johnson & Johnson knew and when about the alleged presence of asbestos in talc and "how it responded to science" on asbestos, talc, testing, and mining. They also argue that she cannot opine on "J&J's warnings" because she knows "nothing about" cosmetic manufacturers' responsibilities under the FDCA, and "has never consulted with the FDA or any company regulated by the FDA." (*See* Pls.' Regulatory Br. 1, 8–13.)

In response, Defendants explain that Dr. Sutcliffe is not offering an opinion on the presence of asbestos in talc, testing or sensitivity, or other "scientific aspects of talc safety." Instead, Defendants submit that Dr. Sutcliffe opines "on J&J's corporate knowledge and corporate actions"; i.e., "what information J&J knew over the past several decades and how it responded to that information." Because Dr. Sutcliffe has focused her career researching and assessing how organizations process

information and make decisions under uncertainty, Defendants contend that Dr. Sutcliffe "has the precise qualifications necessary to offer that opinion." (*See* Defs.' Regulatory Opp. Br. at 1–3, 8–10.)

Second, Plaintiffs argue that Dr. Sutcliffe's opinions fail the reliability test. In that regard, Plaintiffs argue that Dr. Sutcliffe's "sensemaking" is a subjective, qualitative methodology that cannot be tested or repeated. Plaintiffs also argue that Dr. Sutcliffe fails to reliably apply her own standards, instead "cherry-picking evidence that supports Johnson & Johnson's litigation position, while ignoring (and not even reading) evidence that is harmful to J&J." According to Plaintiffs, these information gaps make Dr. Sutcliffe's opinions unreliable. (*See* Pls.' Regulatory Br. at 1–2, 13–30.)

Defendants submit that Dr. Sutcliffe employed a qualitative methodology within the "widely cited conceptual framework of 'sensemaking.'" Defendants contend that this methodology draws on decades of organizational science research, and that similar qualitative research has been accepted in analogous social science contexts. Defendants dispute that Dr. Sutcliffe ignored information or limited research to the 1970s. (*See* Defs.' Regulatory Opp. Br. at 2, 10–23.)

Third, Plaintiffs argue that Dr. Sutcliffe's opinions do not fit the facts. To that end, Plaintiffs contend that their product liability claims turn "on the presence of a defect in J&J's products at the time those products left J&J's hands, which defect

made the products unreasonably dangerous." Plaintiffs argue that these "questions are answerable by straightforward reference to hard sciences: toxicology; medicine; epidemiology; material science; the science of consumer warnings." They submit that "J&J's organizational behavior," ability to engage in "sensemaking," and "pure-hearted feelings about the 'wellbeing' of consumers" is not on trial. (*See* Pls.' Regulatory Br. at 33–35.)

Defendants contest Plaintiffs' characterization of their claims, arguing that Plaintiffs assert negligence and fraud claims that "put J&J's organizational knowledge, motivations, and behavior at issue." Defendants highlight Plaintiffs' allegations that Johnson & Johnson (i) knew "for decades that talc may pose health risks to consumers," (ii) "ignored data regarding these risks," (iii) concealed or misrepresented material facts, and (iv) "failed to adequately ensure the safety of its consumers." According to Defendants, Dr. Sutcliffe's testimony fits because she explains that Plaintiffs' allegations are "inconsistent with the record of J&J's actions, decisions, and organizational commitment to the wellbeing of consumers." (*See* Defs.' Regulatory Opp. Br. at. 24–25.)

3. Dr. Sutcliffe's Qualifications

Dr. Sutcliffe holds a Ph.D. in organization theory and behavior from the University of Texas at Austin. (Sutcliffe Rep. ¶ 1.) She currently serves as a Bloomberg Distinguished Professor at Johns Hopkins University, with appointments

in its Carey Business School, School of Medicine, School of Nursing, and Bloomberg School of Public Health. (*Id*.) Dr. Sutcliffe previously had a twenty-plus-year tenure on the faculty of the University of Michigan's Stephen M. Ross School of Business and a three-year tenure on the faculty of Minesota's Carlson School of Management. (*Id*. ¶ 1.) Dr. Sutcliffe has taught many courses on organizational behavior and theory. (*Id*. ¶ 6.)

For decades, Dr. Sutcliffe has researched organizational behavior and decision-making. (*Id*. ¶¶ 2–3.) Her work focuses on how organizations interpret complex information, respond to risks, and make decisions under uncertainty. (*See id*.) Dr. Sutcliffe is a prolific publisher of peer-reviewed research, having authored, co-authored, or co-edited four books and dozens of journal articles on organizational behavior. (*Id*. ¶ 4.) Her research spans many industries, including healthcare, manufacturing, and transportation. (*Id*. ¶ 3.) She touts her published research assessment of "Toyota's organizational design and sensemaking system as it pertained to the problem of its slow recognition" of "unintended acceleration difficulties." (*Id*. ¶ 4.)

Dr. Sutcliffe also has consulted for government agencies, healthcare institutions, and private companies. (*Id*. ¶ 5.) That includes helping reshape a multinational firm's organizational processes and practices. (*Id.*) Among other professional organizations, Dr. Sutcliffe is a member of the of the Academy of

Management, the European Group for Organizational Studies, the Institute for Operations Research and Management Sciences, and the Strategic Management Society. (*Id*. ¶ 1.) By appointment of the National Academy of Sciences, Dr. Sutcliffe also sits on the Committee on Emerging Trends in Aviation Safety. (*Id*..)

Based on these facts and my full review of Dr. Sutcliffe's report and deposition transcript, I find that Dr. Sutcliffe is qualified by specialized knowledge, under Rule 702, to testify on organizational behavior and theory, including the structures, processes, and information-management of large corporations. *See In re Paoli*, 35 F.3d at 741 (explaining "Rule 702's liberal policy of admissibility" extends to experts qualified by "specialized knowledge"). As applied to Johnson & Johnson, she is qualified to testify generally as to the manner in which Johnson & Johnson processed and acquired information, subject to the relevance and fit limitations discussed below.

While Dr. Sutcliffe is generally qualified to opine on how corporations (including Johnson & Johnson) process information and acquire knowledge, her report is replete with opinions that exceed the scope of her knowledge, skill, experience, training, and education. The claims at issue in this case involve highly technical, scientific inquiries. Both parties have retained a host of experts trained in hard sciences. At trial, those experts will be called upon to help the jury understand issues related to the alleged presence of asbestos and other materials in the talc

products, talc mining, talc testing, and the alleged link between the talc products and ovarian cancer.

Dr. Sutcliffe lacks the scientific, technical expertise needed to offer opinions in those areas. *See Calhoun*, 350 F.3d at 322. To that end, Dr. Sutcliffe never worked for the FDA or consulted for the FDA. (ECF No. 32998-6 ("Sutcliffe Dep.") at 57:15–20, 63:15–16.) She has never advised a consumer products company on complying with the FDCA or assessing product risks. (*See* Sutcliffe Dep. at 57:21–60:1.) She has no expertise in FDA regulations, including the standards for cosmetic warnings, adulteration, or misbranding. (*Id.* at 55:4–20.) As of her deposition, she did not know the "ins and outs" of the FDCA, had never taught about the FDCA, and did not know whether the talc products were subject to the FDCA. (*Id.* at 27:16–28:16, 67:10–17.) She is not a mineralogist, geologist, toxicologist, microscopist, expert in mining for talc, or expert for testing in talc. (*Id.* at 49:12–50:12.)

Despite disclaiming expertise those areas, Dr. Sutcliffe's report reached many conclusions that required this technical and scientific knowledge. For example, despite disclaiming any expertise in testing, she characterized Johnson & Johnson's "testing program" as "rigorous." (Sutcliffe Rep. ¶ 192; *id.* ¶ 95 ("J&J invested time and resources to refine its own testing methodology, which was more rigorous than that adopted by the industry.").) Even though she lacks expertise in cosmetics safety, talc, and asbestos, she testified at deposition that after the 1970s 'it was pretty clear

that talc was safe." (Sutcliffe Dep. at 141:8–10.) And even though she lacks any expertise on the FDA's regulatory structure, she challenged Plaintiffs' labeling and failure to warn claims by relying on communications with the FDA. (Sutcliffe Rep. ¶ 33 ("Moreover, plaintiffs' allegations disregard the fact that the FDA as the relevant regulatory body had considered and rejected both asbestos and ovarian cancer warning labels for talc on several separate occasions.").)

In sum, Dr. Sutcliffe is qualified to explain generally how corporations process and acquire information, the sensemaking framework, and the general types of decision-making structures or information channels characteristic of corporations focused on safety and consumer well-being. Subject to the limitations discussed herein, she may also opine—generally, and without crossing the line into scientific inquiries outside her expertise—on whether Johnson & Johnson's information acquisition and decision-making processes aligned with that framework. But Dr. Sutcliffe is not qualified to offer opinions on any of the scientific or technical matters described above, including Johnson & Johnson's testing methods, the safety or health risks of the talc products, and the presence of asbestos or other materials in Talc. This means that Dr. Sutcliffe can testify, generally, about *how* Johnson & Johnson processed information, but cannot testify as to the technical details of *what* information Johnson & Johnson processed.

4. Reliability

"*Daubert*'s reliability requirement ensures that an expert's testimony is 'based on the methods and procedures of science, not on subjective belief and unsupported speculation.'" *Cohen*, 125 F.4th at 461–62 (citation omitted). Meeting reliability does not require that "a particular scientific opinion has the best foundation, or even whether the opinion is supported by the best methodology or unassailable research." *Karlo*, 849 F.3d at 81 (citation omitted.) Instead, the court examines whether the testimony "is supported by 'good grounds.'" *Id*. This "inquiry 'applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, [and] the link between the facts and the conclusion." *Cohen*, 125 F.4th at 462 (citation omitted).

The Rule 702 analysis is a "flexible one." *Daubert*, 509 U.S. at 594; *see Pineda*, 520 F.3d at 248 (3d Cir. 2008) (explaining *Daubert* reliability factors "'are neither exhaustive nor applicable in every case'" (citation omitted)). As the Advisory Committee on Evidence Rules has explained:

> Some types of expert testimony will be more objectively verifiable, and subject to the expectations of falsifiability, peer review, and publication, than others. Some types of expert testimony will not rely on anything like a scientific method, and so will have to be evaluated by reference to other standard principles attendant to the particular area of expertise.

Fed. R. Evid.702, advisory committee's note to 2000 amendment.

When expert testimony is based on "'soft social sciences'"—like Dr. Sutcliffe's testimony—such "flexibility is necessary." *Bowers v. Nat'l Collegiate Athletic Ass'n*, 564 F. Supp. 2d 322, 361 (D.N.J. 2008); *see United States v. Simmons*, 470 F.3d 1115, 1123 (5th Cir. 2006) ("Because there are areas of expertise, such as the 'social sciences in which the research, theories and opinions cannot have the exactness of hard science methodologies," courts have "broad discretion to determine 'whether *Daubert*'s specific factors are, or are not, reasonable measures of reliability.'" (citations omitted)). Thus, a social science approach is not necessarily unreliable based on "inherent methodological limitations" or because it cannot "produce 'a testable hypothesis' or a 'known or potential rate of error.'" *Bowers*, 564 F. Supp. 2d at 361 (citation omitted). Instead, the Court "must perform its gatekeeping assessment on measures of reliability that are appropriate to the particular testimony in question." *Id*.

Applying those principles, courts have found that qualitative, social-sciences methods are reliable when experts review "data, documents, and testimony," apply specialized "knowledge and experience," use a peer-reviewed framework, and support conclusions through the discussion of relevant literature. *Id.*; *see, e.g.*, *Louis Vuitton Malletier S.A. v. Sunny Merch. Corp.*, 97 F. Supp. 3d 485, 505 (S.D.N.Y. 2015) (admitting testimony when expert used "qualitative" method based on experience, review of documents and deposition testimony, and field research).

Here, Dr. Sutcliffe followed a qualitative method for assessing how corporations process ambiguous information that is generally accepted in the field of organizational behavior. Dr. Sutcliffe's method draws on peer-reviewed literature from leaders in her field, including Matthew B. Miles and A. Michael Huberman's publication on qualitative data and Karl E. Weick's publication on sensemaking in organizations. (*See* Sutcliffe Rep. ¶ 40 & n.18; *id*. ¶ 42 & n.20.) Dr. Sutcliffe has researched the same or similar methods for decades, published dozens of scholarly works on sensemaking and organizational behavior more generally, and has personal experience applying that method. *See* Fed. R. Evid.702, advisory committee's note to 2000 amendment (explaining non-scientific testimony must "be evaluated by reference to other standard principles attendant to the particular area of expertise"; *i.e.*, a showing that the testimony is "grounded in an accepted body of learning or experience in the expert's field"). Within the narrow area in which I found Dr. Sutcliffe qualified to testify, Dr. Sutcliffe's method was reliable and she reliably applied it.[195]

[195] As noted above, Dr. Sutcliffe is not qualified to offer opinions on the scientific or technical matters discussed in her report, including Defendants' testing methods, the safety of the talc products, and the presence of certain substances in Talc. While that ends the inquiry with respect to those subjects, even putting qualifications aside, Dr. Sutcliffe's conclusions in many of those areas do not reflect a reliable application of a reliable method. For example, Dr. Sutcliffe lacks good grounds to opine that "much of the ambiguity and concern regarding the safety of cosmetic talc had been resolved" by 1978, (Sutcliffe Rep. ¶ 118), when she admits that she did not review "specific studies" (Sutcliffe Dep. at 335:18–21).

5. Fit and Scope

Under Rule 702's fit restriction, even reliable methods that are reliably applied will be excluded if there is no connection between the expert's testimony and the disputed factual issues in a case. *In re Paoli*, 35 F.3d at 743. Here, Defendants have met their burden of proving, by a preponderance of the evidence, that Dr. Sutcliffe's testimony (as limited above and below) will assist the jury.

To that end, Plaintiffs assert state law negligence and fraud claims that place Defendants' corporate knowledge and conduct squarely at issue. (*See, e.g.*, ECF No. 226636-2, Pls.' 2d Amend. Compl. dated Aug. 14, 2023 ¶ 208 ("Defendants engaged in wrongful conduct and were negligent" by "selling talcum powder products which contained asbestos and fibrous talc, which Defendants knew or should have known were dangerous and posed substantial risks of harm").) Dr. Sutcliffe can help jurors evaluate those claims by providing background information on how reasonable corporations process information and make decisions under uncertainty. In that way, her organizational framework could provide a useful context for evaluating Defendants' conduct. *Cf. Bridges*, 2022 WL 4244276, at *8 (explaining "an expert educating a jury on general principles of sex trafficking and sexual abuse can be helpful to the fact finder in assessing fact witnesses' credibility").

For these reasons, I recommend the Court to grant in part and deny in part Plaintiffs' Motion to Exclude the Opinions of Dr. Sutcliffe. Based on her

qualifications and experience, Dr. Sutcliffe can offer general testimony on how organizations process information and make decisions under uncertainty. That includes explaining the types of decision-making structures or information channels she sees in corporations focused on consumer safety and, subject to the limits herein, whether Johnson & Johnson's information acquisition and decision-making processes aligned with that framework.

Given her lack of scientific expertise or regulatory experience in the areas relevant to this case, Dr. Sutcliffe cannot opine on Defendants' testing methods, the safety of the talc products (including when any period of "disruptive ambiguity" regarding Talc began or ended), and the presence of certain substances in Talc. And for the same reasons discussed in my analysis of Defendants' motion to exclude Plaintiffs' regulatory and marketing experts, Dr. Sutcliffe cannot draw legal conclusions, opine on Defendants' state of mind, or make subjective assessments of Defendants' conduct, such as what Defendants "knew" or whether they acted like a good company.

VIII. CONCLUSION

Mindful of the significance of this MDL and the impact the pending Rule 702 motions may have on its course, this Report and Recommendation reflects the seriousness with which I approached my assignment as a limited-purpose Special Master. I have undertaken an exhaustive review of the seventeen motions referred to

me by the Court, engaging closely with an extensive record that includes, *inter alia*, voluminous briefing, expert reports, deposition testimony, and the scientific literature—including new scientific evidence since my 2020 Opinion—on which the parties rely. In evaluating the admissibility of the challenged expert opinions, I applied Rule 702 as clarified by the 2023 amendments, while remaining within the bounds established by the Court's April 30, 2024 Memorandum Order. Having afforded the parties' submissions the careful consideration they warrant, and for the foregoing reasons, I respectfully recommend that the pending Rule 702 motions be resolved in accordance with the determinations set forth in this Report and Recommendation, as summarized in the chart that follows. A second Report and Recommendation addressing the motions on which I have reserved decision will issue following the two *Daubert* evidentiary hearings presently scheduled for January 26 and February 6, 2026.

/s/ Freda L. Wolfson
Hon. Freda L. Wolfson (ret.)
Special Master

Dated: January 20, 2026

IX. REPORT AND RECOMMENDATION DECISION CHART

In re: Johnson & Johnson Talcum Powder Products Marketing, Sales Practices, and Products Litigation
MDL Case No. 3:16-md-02738-MAS-RLS
Special Master Report and Recommendation Decision Chart

No.	Movants	Motion Title (ECF No.)	Contested Expert(s) and Field(s) of Expertise	Recommendation(s)
1	Plaintiffs	Motion to Exclude the Geology Opinions of Drs. Mary Poulton and Laura Webb (32996)	Dr. Mary Poulton; geological engineering Dr. Laura Webb; geology	**Deny**
2	Plaintiffs	Motion to Exclude the Opinions of Dr. Kathleen Sutcliffe (32998)	Dr. Kathleen Sutcliffe; organization science, theory, and behavior	**Grant in part, deny in part** **Exclude** opinions regarding legal conclusions, scientific/technical matters (e.g., Defendants' testing methods, the safety of talc products, the presence of asbestos or other materials in talc), Defendants' state of mind, and subjective assessments of Defendants' conduct.
3	Plaintiffs	Motion to Exclude the Opinions of Drs. Michael	Dr. Michael Finan; gynecologic oncology	**Deny**

No.	Movants	Motion Title (ECF No.)	Contested Expert(s) and Field(s) of Expertise	Recommendation(s)
		Finan, Cheryl Saenz and Kevin Holcomb (32999)	Dr. Cheryl Saenz; gynecologic oncology Dr. Kevin Holcomb; gynecologic oncology	
4	Plaintiffs	Motion to Exclude the Opinions of Drs. Juan Felix and Teri Longacre (33002)	Dr. Juan Felix; gynecologic pathology Dr. Teri Longacre; gynecologic pathology	**Deny**
5	Plaintiffs	Motion to Exclude the Asbestos Testing Opinions of Matthew S. Sanchez, Ph.D., Ann G. Wylie, Ph.D. and Shu-Chun Su, Ph.D. (33006)	Dr. Matthew Sanchez; geology with an emphasis in mineralogy Dr. Ann Wylie; geology Dr. Shu-Chun Su; optical minerology and microscopy	**Reserved** pending *Daubert* evidentiary hearing on Dr. William Longo's PLM-chrysotile testing opinions.
6	Plaintiffs	Motion to Exclude the Opinions of Dr. John	Dr. John Kornak; biostatistics	**Deny**

No.	Movants	Motion Title (ECF No.)	Contested Expert(s) and Field(s) of Expertise	Recommendation(s)
		Kornak (33011)		
7	Plaintiffs	Motion to Exclude the Opinions of Dr. Jennifer Permuth (33001)	Dr. Jennifer Permuth; molecular epidemiology	**Deny**
8	Plaintiffs	Motion to Exclude the Opinions of Dr. Analisa DiFeo (33010)	Dr. Analisa DiFeo; gynecology and cancer genetics	**Deny**
9	Plaintiffs	Motion to Exclude the Opinions of Defense Expert Witness Dr. Jeff Boyd (33060)	Dr. Jeff Boyd; gynecology	**Grant in part, deny in part** **Exclude** opinions regarding Dr. Boyd's criticisms of Dr. Saed's use of commercial cell transformation assay kit, "ab235698," manufactured by Abcam. **Note**: It is unnecessary for Dr. Boyd to offer his rebuttal opinions of Plaintiffs' macrophage-impairment theory premised on Angelo Mandarino et al., *The Effect of Talc Particles on Phagocytes in Co-Culture with Ovarian Cells*, 180 Env't Res. (2020) ("Mandarino

No.	Movants	Motion Title (ECF No.)	Contested Expert(s) and Field(s) of Expertise	Recommendation(s)
				2020"), and/or Tania Emi et al., *Transcriptomic and Epigenomic Effects of Insoluble Particles on J774 Macrophages*, 16 Epigenetics (10), 1053–70 (2021) ("Emi 2021"), because it has been recommended that Plaintiffs' experts cannot opine on that theory.
10	Defendants	Motion to Exclude the Opinions of Dr. Daniel Clarke-Pearson (33007)	Dr. Daniel Clarke-Pearson; gynecologic oncology	**Reserved** pending *Daubert* evidentiary hearing on specific causation opinions.
11	Defendants	Motion to Exclude Plaintiffs' Experts' Opinions Regarding Biological Plausibility/ Mechanism (33013)	Dr. Arch Carson; medical toxicology Dr. Daniel Clarke-Pearson; gynecologic oncology Dr. Michele Cote; cancer epidemiology Dr. Bernard Harlow; epidemiology	**Grant in part, deny in part** **Exclude** opinions regarding inhalation/lymphatic migration and macrophage-impairment. **Note**: Experts may not rely on or reference National Toxicology Program, *Toxicology and Carcinogenesis Studies of Talc (CAS No. 14807-96-6) in F344/N Rats and B6C3F1 Mice*

No.	Movants	Motion Title (ECF No.)	Contested Expert(s) and Field(s) of Expertise	Recommendation(s)
			Dr. Sarah Kane; gynecologic pathology Dr. Shawn Levy; biochemistry Dr. Anne McTiernan; epidemiology Dr. Patricia Moorman; epidemiology Dr. Laura Plunkett; pharmacology and toxicology Dr. Jack Siemiatycki; epidemiology Dr. Sonal Singh; epidemiology Dr. Ellen Blair Smith; gynecologic oncology Dr. Rebecca Smith-Bindman; epidemiology and biostatistics	*(Inhalation Studies)*, U.S. Dep't of Health & Hum. Serv., 421 (1993) ("NTP 1993"), or otherwise offer opinions using NTP 1993, for support of the association between talc and ovarian cancer risk.

No.	Movants	Motion Title (ECF No.)	Contested Expert(s) and Field(s) of Expertise	Recommendation(s)
			Dr. Judith Wolf; gynecologic oncology	
12	Defendants	Motion to Exclude Plaintiffs' Experts' Asbestos-Related Opinions (33012)	Dr. William Longo; materials science Dr. Mark Rigler; microbiology and electron microscopy Dr. Mark Krekeler; geology Dr. Robert Cook; geology	**Deny in part, reserved in part** pending *Daubert* evidentiary hearing on Dr. William Longo's PLM-chrysotile testing opinions.
13	Defendants	Motion to Exclude Plaintiffs' Experts' General Causation Opinions (33008)	Dr. Arch Carson; medical toxicology Dr. Daniel Clarke-Pearson; gynecologic oncology Dr. Sarah Kane; gynecologic pathology Dr. Anne McTiernan; epidemiology	**Deny** **Note**: I excluded, in connection with Defendants' biological plausibility motion, opinions regarding inhalation/lymphatic migration and macrophage-impairment.

No.	Movants	Motion Title (ECF No.)	Contested Expert(s) and Field(s) of Expertise	Recommendation(s)
			Dr. Patricia Moorman; epidemiology Dr. Jack Siemiatycki; epidemiology Dr. Sonal Singh; epidemiology Dr. Ellen Blair Smith; gynecologic oncology Dr. Rebecca Smith-Bindman; epidemiology and biostatistics Dr. Judith Wolf; gynecologic oncology Dr. Michele Cote; cancer epidemiology Dr. Bernard Harlow; epidemiology	
14	Defendants	Motion to Exclude the Opinions of Dr. John	Dr. John Godleski; anatomic	**Grant in part, deny in part**

No.	Movants	Motion Title (ECF No.)	Contested Expert(s) and Field(s) of Expertise	Recommendation(s)
		Godleski (33004)	pathology and microscopy	**Exclude** opinions linking the presence of talc or tremolite asbestos as a contributory cause of ovarian cancer; and opinions suggesting that the quantity of talc detected suggests a broader level of exposure.
15	Defendants	Motion to Exclude the Opinions of Drs. David Kessler, Laura Plunkett, William Sage and George Newman (33000)	Dr. David Kessler (medical doctor, attorney, former FDA Commissioner); cosmetics regulatory framework and industry standards Dr. Laura Plunkett; pharmacology, toxicology, cosmetics regulatory framework, and human health risk assessments Dr. William Sage (medical doctor and attorney); regulatory design and	**Grant in part; deny in part** **Kessler**: exclude opinions regarding legal conclusions, opinions on Defendants' intent or state of mind, ethical judgments, or testimony outside his qualifications, including on the technical validity or aspects of any particular test or the geological properties of talc. **Plunkett**: exclude opinions regarding legal conclusions, definitive causation opinions, testimony about Defendants' knowledge or motives, or subjective ethical assessments.

No.	Movants	Motion Title (ECF No.)	Contested Expert(s) and Field(s) of Expertise	Recommendation(s)
			science of policymaking Dr. George Newman; marketing, branding, and cognitive consumer psychology	**Sage**: exclude opinions regarding legal conclusions, causation opinions, speculative inferences regarding Defendants' intent or knowledge, testimony outside his limited qualifications, as well as subjective "bad company" characterizations. **Newman**: exclude opinions regarding Defendants' intent, all scientific opinions, and definitive statements about how Defendants marketing materials in fact influenced consumers.
16	Defendants	Motion to Exclude Plaintiffs' Experts' Opinions Regarding Alleged Heavy Metals and Fragrances in Johnson's Baby Powder and Shower to	Dr. Arch Carson; medical toxicology Dr. Daniel Clarke-Pearson; gynecologic oncology Dr. Robert Cook; geology	**Grant** **Note**: Dr. Crowley's opinions concerning the contents of Defendants' products have not been excluded. Additionally, Plaintiffs' experts may nonetheless opine on the causal relationship between cosmetic talc—as a product, inclusive of its constituents—and ovarian cancer.

No.	Movants	Motion Title (ECF No.)	Contested Expert(s) and Field(s) of Expertise	Recommendation(s)
		Shower (33005)	Dr. Michele Cote; cancer epidemiology Dr. Michael Crowley; pharmaceutics Dr. Sarah Kane; gynecologic pathology Dr. Mark Krekeler; geology Dr. Shawn Levy; biochemistry Dr. Anne McTiernan; epidemiology Dr. Patricia Moorman; epidemiology Dr. Laura Plunkett; pharmacology and toxicology Dr. Jack Siemiatycki; epidemiology	

No.	Movants	Motion Title (ECF No.)	Contested Expert(s) and Field(s) of Expertise	Recommendation(s)
			Dr. William Sage; science of policymaking, including the science of regulatory design Dr. Sonal Singh; epidemiology Dr. Ellen Blair Smith; gynecologic oncology Dr. Rebecca Smith-Bindman; epidemiology and biostatistics Dr. Judith Wolf; gynecologic oncology Dr. Judith Zelikoff; toxicology	
17	Defendants	Motion to Exclude the Specific Causation Opinions Offered by Dr. Judith Wolf (33003)	Dr. Judith Wolf; gynecologic oncology	**Reserved** pending *Daubert* evidentiary hearing on specific causation opinions.