

UNITED STATES DISTRICT COURT  
DISTRICT OF SOUTH DAKOTA  
SOUTHERN DIVISION

DEANE BERG,	)	CIV. 09-4179-KES
	)	
Plaintiff,	)	
	)	
vs.	)	MEMORANDUM OPINION
	)	AND ORDER
JOHNSON & JOHNSON;	)	
JOHNSON & JOHNSON	)	
CONSUMER COMPANIES, INC.;	)	
LUZENAC AMERICA, INC.;	)	
JOHN DOES/JANE DOES 1-30;	)	
UNKNOWN BUSINESSES	)	
AND/OR CORPORATIONS A-Z,	)	
	)	
Defendants.	)	

Defendants Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. move for summary judgment on all of plaintiff's claims (Docket 149) and also move to exclude the testimony of four of plaintiff's experts (Dockets 140, 143, 145, and 147). Defendant Luzenac America, Inc. joins in the motions (Dockets 151, 153, 155, 156, and 157). For the following reasons, defendants' motions to exclude are granted in part and denied in part. Defendants' motion for summary judgment is denied.

**FACTUAL BACKGROUND**

Berg was diagnosed with ovarian cancer in December of 2006. She was 49 years old at the time. Prior to her diagnosis, Berg used Johnson & Johnson products—Johnson's Baby Powder and Shower to Shower—to dust her

perineum for feminine hygiene purposes. She applied the products on a daily basis from 1975 until 2007.

Talc is one of the main ingredients in Johnson's Baby Powder and Shower to Shower. Talc is a naturally occurring mineral that is mined from the ground and used in various applications. Luzenac supplies talc to Johnson & Johnson.

Research has been ongoing studying how talc affects the female reproductive system for a number of years. For example, Dr. Daniel Cramer, one of Berg's proposed experts, published a study in 1982 that found that an association existed between the application of talc to a woman's genital area and the development of ovarian cancer. Defendants stayed current on the various studies that analyzed any potential hazards associated with talc.

Berg alleges that her application of talc to her perineum caused her ovarian cancer and brought this product liability action against defendants because their products did not include any warnings regarding the possible hazards of applying talc to a woman's perineum. Berg has identified four expert opinions in support of her claims.

First, Dr. Cramer is an epidemiologist and is prepared to testify that talc use in the genital area has a strong causal association with ovarian cancer. Further, Dr. Cramer's opinion is that Berg's frequent application of talc to her genital area was "the major cause of her invasive serous ovarian cancer[.]"  
Docket 148-1 at 18.

Second, Dr. Gary Rosenthal is a toxicologist and is prepared to testify about talc's immunotoxic potential and how such potential relates to ovarian cancer. His opinion is that Berg's frequent talc use "played a role in disease processes leading to her ovarian cancer." Docket 144-1 at 11.

Third, Dr. John Godleski is an expert in microscopy, and he examined tissues taken from Berg's reproductive system following her diagnosis of ovarian cancer. He is prepared to testify that talc particles were present in Berg's tissues.

Fourth, Dr. David R. Lenorovitz and Dr. Edward E. Karnes are experts in the field of forensic human factors and warnings. Their designation as experts is to: (1) ascertain if talc posed a hazard to the populace; (2) ascertain if any such hazard was open and obvious to a reasonable user; (3) determine if there was a feasible way to place a warning on the talc product; and (4) determine if there was a financially and technically reasonable alternative to talc. Docket 173 at 2.

### **MOTIONS TO EXCLUDE EXPERT TESTIMONY**

In this diversity action, federal law governs whether expert testimony is admissible. *Wagner v. Hesston Corp.*, 450 F.3d 756, 760 (8th Cir. 2006). Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony. *Russell v. Whirlpool Corp.*, 702 F.3d 450, 456 (8th Cir. 2012). The rule provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill,

experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. In applying Rule 702, the trial judge becomes a “gatekeeper” who screens evidence to ensure its reliability and relevance. *Russell*, 702 F.3d at 456. “The rule clearly is one of admissibility rather than exclusion.”

*Sappington v. Skyjack, Inc.*, 512 F.3d 440, 448 (8th Cir. 2008). An expert’s opinion should be excluded “only if it is so fundamentally unsupported that it can offer no assistance to the jury.” *Id.*

The district court applies a three-part test when screening proposed testimony for experts under Rule 702:

First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy. Second, the proposed witness must be qualified to assist the finder of fact. Third, the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires.

*Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001). To satisfy the reliability requirement, the party offering the expert testimony must show by a preponderance of the evidence “that the methodology underlying [the expert’s] conclusions is scientifically valid.” *Barrett v. Rhodia, Inc.*, 606 F.3d 975, 980 (8th Cir. 2010). In making the reliability determination, the court may consider: (1) whether the theory or technique can be or has been tested; (2) whether the

theory or technique has been subjected to peer review or publication; (3) whether the theory or technique has a known or potential error rate and standards controlling the technique's operations; and (4) whether the theory or technique is generally accepted in the scientific community. *Russell*, 702 F.3d at 456. Additional factors to consider include: "whether the expertise was developed for litigation or naturally flowed from the expert's research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case." *Polski v. Quigley Corp.*, 538 F.3d 836, 839 (8th Cir. 2008). "This evidentiary inquiry is meant to be flexible and fact specific, and a court should use, adapt, or reject" these factors as the particular case demands. *Russell*, 702 F.3d at 456.

When making this inquiry, the court should focus on "principles and methodology, not on the conclusions that they generate." *Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 625 (8th Cir. 2012) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 595 (1993)). At times, conclusions and methodology are not entirely distinct from one another, and the court "need not completely pretermitt judicial consideration of an expert's conclusions." *Id.* With these principles in mind, the court will now address defendants' motions to exclude expert testimony.

## **I. Dr. Daniel Cramer**

Defendants' sole argument in support of their motion to exclude Dr. Cramer's testimony goes to the issue of whether his testimony is reliable.<sup>1</sup> Defendants attack Dr. Cramer's testimony regarding both specific causation and general causation, arguing that the testimony put forth to support each is not reliable. For purposes of defendants' motion to exclude Dr. Cramer's testimony, the court only considers whether the testimony is admissible and does not consider whether it is sufficient to prove an element in plaintiff's case.<sup>2</sup> See *Daubert*, 509 U.S. at 596 (noting the difference between admissibility and sufficiency).

Dr. Cramer is the Professor of Obstetrics, Gynecology, and Reproductive Biology at Harvard Medical School and is a practicing obstetrician and gynecologist. He has a doctorate degree in epidemiology from the Harvard School of Public Health.

Dr. Cramer's expert report relies on epidemiology<sup>3</sup> to address two issues: (1) "the association between use of cosmetic talc powders in the genital area and

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<sup>1</sup> It appears to be undisputed that Dr. Cramer is qualified to give expert testimony and that his testimony is relevant.

<sup>2</sup> Sufficiency is addressed in the portion of this order dealing with defendants' motion for summary judgment.

<sup>3</sup> Epidemiology is the "field of public health and medicine that studies the incidence, distribution, and etiology of disease in human populations." Reference Manual on Scientific Evidence 551 (3d ed. 2011), *available at* 2011 WL 7724261, \*2.

ovarian cancer with regard to the likelihood that this is cause-and-effect” and (2) “the possible relevance of talc use to the occurrence of ovarian cancer in the specific case of Ms. Deane Berg[.]” Docket 148-1 at 3. The report concludes by opining that (1) there is a causal association between the use of talc and ovarian cancer, and (2) chronic talc use was the major cause of Berg’s invasive serous ovarian cancer. *Id.* at 18.

Defendants make two arguments in support of their motion to exclude Dr. Cramer’s testimony.<sup>4</sup> First, they argue that Dr. Cramer’s report is inadmissible because it fails to rule out alternative causes of Berg’s cancer. Second, they argue that Dr. Cramer’s report is inadmissible because the odds ratios established in the report and Dr. Cramer’s interpretations of those odds ratios stem from unreliable methods.

#### **A. Ruling Out Alternative Causes**

Defendants argue that Dr. Cramer’s methodology is not reliable because he fails to rule out alternative causes of Berg’s cancer. Defendants rely on these four Eighth Circuit Court of Appeals opinions to support their proposition that Dr. Cramer was required to rule out alternative causes of Berg’s cancer:

*Barrett*, 606 F.3d 975; *Bland v. Verizon Wireless, (VAW) L.L.C.*, 538 F.3d 893 (8th

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<sup>4</sup> Defendants argue extensively in their briefs that Dr. Cramer’s testimony fails to establish either specific or general causation. Such arguments go to the sufficiency of Dr. Cramer’s testimony and not the admissibility of it. Because a motion to exclude expert testimony is concerned only with admissibility, these arguments will not be addressed in this part of the order.

Cir. 2008); *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748 (8th Cir. 2006); and *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202 (8th Cir. 2000). None of these cases, however, require an epidemiologist to rule out all alternative causes in order for his testimony to be admissible.

In *Barrett*, the Eighth Circuit found that the district court did not abuse its discretion when it limited the expert testimony of a toxicologist and a treating physician. 606 F.3d at 981-82. The toxicologist conceded that she lacked “significant scientific knowledge underpinning [her] opinion and that she did not rule out alternative causes of [plaintiff’s] injury. . . . Her opinion . . . was admittedly based on assumption, without any scientific testing or exposure analysis.” *Id.* at 981. The treating physician was not allowed to testify about the cause of the plaintiff’s toxic exposure because he “assumed that [plaintiff] had been injured by hydrogen sulfide gas exposure without any scientific verification and without considering any alternative causes.” *Id.* at 982. Neither expert witness was offering epidemiologic evidence. Both experts had glaring deficiencies in their opinions because they failed to do any scientific verifications, relied on unsupported assumptions, and did not consider alternative causes.

In *Bland*, the Eighth Circuit found that the district court did not abuse its discretion by excluding a treating physician’s expert testimony. 538 F.3d at 897-98. The treating physician intended to testify about the differential

diagnoses that he conducted. *Id.* at 897. “A differential diagnosis is a technique that identifies the cause of a medical condition by eliminating the likely causes until the most probable cause is isolated.” *Bland*, 538 F.3d at 897. The treating physician’s differential diagnosis was inadmissible because he failed to eliminate other possible causes. *Id.* The very nature of a differential diagnosis requires a consideration and elimination of other possible causes. By failing to consider other causes, a differential diagnosis cannot, by definition, be reliable. Thus, *Bland* stands for the proposition that an admissible differential diagnosis requires the expert to consider and eliminate other possible causes. *Bland* does not stand for the proposition that an expert offering epidemiologic evidence must rule out all other possible causes for his testimony to be admissible.

In *Marmo*, the Eighth Circuit found that the district court acted within the bounds of discretion when it precluded a toxicologist from testifying. 457 F.3d at 758. The toxicologist did not examine the plaintiff, did not inquire about other toxic exposures, did not exclude confounding factors, and “admitted that the causation standard she employed was not subject to expression in terms of a potential rate of error and was a much lower standard than medical causation.” *Id.* *Marmo* does not support defendants’ proposition that an expert offering epidemiologic evidence must rule out all other possible causes for his testimony to be admissible.

Lastly, in *Turner* the Eighth Circuit concluded that the district court did not abuse its discretion by excluding a treating physician's expert opinion. 229 F.3d at 1208-09. Just as in *Bland*, the treating physician's opinion was based on a differential diagnosis in which he "admitted that he made no attempt to consider all the possible causes, or to exclude each potential cause until only one remained, or to consider which of two or more non-excludable causes was the more likely to have caused the condition." *Id.* at 1208. Again, failing to properly administer a differential diagnosis resulted in an inadmissible differential diagnosis. But *Turner* does not require that an epidemiologist perform a differential diagnosis, which would require consideration of other possible causes.

After a review of these cases, the appropriate legal proposition created from these opinions is that an expert witness who performs a differential diagnosis must consider all other possible causes and exclude each potential cause until only one remains, or consider which of two or more non-excluded potential causes was the more likely to have caused the condition. Dr. Cramer, however, does not claim to have performed a differential diagnosis. Indeed, his testimony is based on epidemiology. Moreover, Dr. Cramer's report indicates that he did in fact consider other possible causes of Berg's cancer. Therefore, Dr. Cramer's opinion will not be excluded on the basis that he failed to rule out all alternative causes. *See In re Prempro Prod. Liab. Litig.*, 586 F.3d 547, 566 (8th

Cir. 2009) (noting that an expert’s “explanations as to conclusions not ruled out went to weight and not admissibility”).

**B. Dr. Cramer’s Methodology**

Defendants’ second argument goes to the general methodology applied by Dr. Cramer. In his expert report, Dr. Cramer notes that, in general, there is an odds ratio<sup>5</sup> of 1.33 between perineal talc use and ovarian cancer. Dr. Cramer further asserts that a woman with Berg’s characteristics has an odds ratio of 3.53. Defendants argue that the 3.53 odds ratio established in Dr. Cramer’s report comes from unreliable methods. The court begins its analysis by addressing defendants’ specific concerns with Dr. Cramer’s findings and then moves to a more general examination of the methodology employed by Dr. Cramer.

First, defendants claim Dr. Cramer’s testimony is unreliable because it conflicts with existing scientific literature that shows the appropriate odds ratio is more in line with the 1.33 figure that Dr. Cramer generated. But there is “no requirement that published epidemiological studies supporting an expert’s opinion exist in order for the opinion to be admissible.” *Bonner v. ISP Tech., Inc.*,

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<sup>5</sup> An odds ratio “expresses in quantitative terms the association between exposure to an agent and a disease.” Reference Manual on Scientific Evidence 568 (3d ed. 2011), *available at* 2011 WL 7724261, \*10-\*11. Typically, if the odds ratio equals 1.0, the risk in exposed individuals is the same as the risk in unexposed individuals. *Id.* at 567. The greater the odds ratio the greater the risk in exposed individuals. *Id.* For example, an odds ratio of 4.0 indicates that the risk of disease in the exposed group is four times as high as the risk of disease in the unexposed group. *Id.*

259 F.3d 924, 929 (8th Cir. 2001). Dr. Cramer’s testimony will be admitted so long as his methodology is reliable even if his conclusions are novel. *See id.* (“The district court could not exclude scientific testimony simply because the conclusion was ‘novel’ if the methodology and the application of the methodology were reliable.”).

Second, defendants argue that the testimony is unreliable because he “cherry-picked” data in order to form an opinion solely for purposes of litigation. “That an expert testifies based on research he has conducted independent of litigation provides important, objective proof that the research comports with the dictates of good science.” *Lauzon*, 270 F.3d at 692. Dr. Cramer has been studying the association between talc use and ovarian cancer since at least 1982. He has published several articles on the subject over the past 30 years. While it is true that his specific findings relevant to this case were generated during the course of litigation, the methods he employed in reaching his conclusions are very similar to the methods used in his previous research. Indeed, the data he used to generate the odds ratios came mostly from his past research. The only difference between his past and present research seems to exist in how he categorized his data. Defendants label this “cherry-picking.” The court views it as simply looking at the existing data from a different perspective. Therefore, the court concludes that although Dr. Cramer’s opinion was

developed during the course of this litigation, the opinion “naturally flowed from [his] research.”<sup>6</sup> *Polski*, 538 F.3d at 839.

Third, defendants assert that the testimony is unreliable because Dr. Cramer’s conclusions conflict with his non-litigation research and also conflict internally. If Dr. Cramer’s previous, or even present, research contradicts his testimony in this case, certainly defendants can challenge his credibility during cross-examination. *See Kuhn*, 686 F.3d at 627 (noting that when an expert offers testimony that conflicts with his opinion, the appropriate response from the court is to allow the opposing party to challenge the credibility of the expert). But unless his methodology is unreliable, the court will not preclude his testimony.

Defendants also identify alleged inconsistencies in Dr. Cramer’s findings (i.e., noting a protective effect for limited talc application). Again, this is a criticism of Dr. Cramer’s results, not his methodology. Defendants will have the chance at trial during cross examination to attack his results.

The court will now analyze Dr. Cramer’s methodology from a broader perspective under the seven factors articulated by the Eighth Circuit in *Polski*

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<sup>6</sup> Additionally, Dr. Cramer testified that he is attempting to get his latest findings published in a scientific journal. This is important because it shows that Dr. Cramer has a stake in his findings independent from this litigation. Suspensions would arise if an expert were to propose testimony for litigation and then refuse to stand behind those findings in the scientific community. That is not the case here.

and previously set forth herein, while also addressing additional issues raised by defendants.<sup>7</sup>

As indicated in his report, Dr. Cramer performed a case-control study<sup>8</sup> to generate his final conclusions. A case-control study is commonplace in the field of epidemiology. According to Dr. Cramer, there have been nineteen *published* case-control studies addressing the talc and ovarian cancer association since 1982.<sup>9</sup> Docket 148-1 at 5, 20-21. Thus, the technique of using a case-control study to assess the association between talc use and ovarian cancer has been both tested and subjected to peer review.

Defendants are quick to note that Dr. Cramer's *specific findings* have not been tested or peer reviewed, specifically pointing to Dr. Cramer's categorization that allowed for a determination of the "[a]ssociation between genital talc use

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<sup>7</sup> The court has already discussed whether the expertise was developed for litigation or naturally flowed from the expert's research and found that it weighs in favor of admission. *Polski*, 538 F.3d at 839.

<sup>8</sup> "In case-control studies, the researcher begins with a group of individuals who have a disease (cases) and then selects a similar group of individuals who do not have the disease (controls). The researcher then compares the groups in terms of past exposures. If a certain exposure is associated with or caused the disease, a higher proportion of past exposure among the cases than among the controls would be expected." Reference Manual on Scientific Evidence 559 (3d ed. 2011), *available at* 2011 WL 7724261, \*6.

<sup>9</sup> In other words, the technique of using a case-control study to analyze the association between talc use and genital cancer is generally accepted in the scientific community, even if the results of Dr. Cramer's specific study are outliers.

and ovarian cancer among non-Jewish serous invasive cases and controls without a family history of ovarian or early onset breast cancer, stratified by menopausal status.” Docket 148-1 at 17. This is mostly an attack on the results and not the methodology, and as a result goes to the weight to be given to the evidence and not its admissibility. Even if one were to consider defendants’ argument an attack on Dr. Cramer’s methodology, their argument is unpersuasive. First, although Dr. Cramer’s specific categorization has not been tested, there is no reason why testing cannot occur using either Dr. Cramer’s data or alternative data. Second, as discussed above, Dr. Cramer is in the process of getting his findings published. Third, and perhaps most important, Dr. Cramer’s categorization was his attempt to connect his research with the facts of the case. His technique makes sense under the facts of this case because it shows the odds ratio of a woman in Berg’s position.

Defendants criticize Dr. Cramer’s choice to exclude menopausal, non-Jewish women who do not have a history of ovarian or early onset breast cancer. But as Dr. Cramer explains, this decision was made because Berg is not Jewish, was premenopausal at the time of her diagnosis, and did not have a history of ovarian or early onset breast cancer.

Moreover, Dr. Cramer’s categorization is also a recognition of alternative causes of ovarian cancer. As Dr. Cramer points out in his report, women who are Jewish or have a history of breast or ovarian cancer are at an increased risk

for ovarian cancer. Berg is neither Jewish nor has a history, family or personal, of breast or ovarian cancer. Additionally, she tested negative for the full panel of BRCA1 and BRCA2 mutations—additional factors that increase one’s risk for ovarian cancer.

Lastly, defendants argue that Dr. Cramer’s theory of biological plausibility<sup>10</sup> is unreliable, making his ultimate conclusions equally as unreliable. Dr. Cramer’s two models of biological plausibility. One model relies on the assertion that talc induces inflammation, down regulates immunity, and enhances ovarian tumor development. The second model theorizes that talc’s inflammatory properties lead to dysregulation of immunity that would otherwise help suppress cancerous cells. Defendants assert that neither of these models has been proven. But defendants have not shown that either model is undoubtedly incorrect. In epidemiology, the “saliency of [biological plausibility] varies depending on the extent of scientific knowledge about the cellular and subcellular mechanisms through which the disease process works.” Reference Manual on Scientific Evidence 605 (3d ed. 2011), *available at* 2011 WL 7724261, \*30. At times, “mechanism explanations are merely hypothesized—although hypotheses are sometimes accepted” in showing

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<sup>10</sup> Biological plausibility is the “[c]onsideration of existing knowledge about human biology and disease pathology to provide a judgment about the plausibility that an agent causes a disease.” Reference Manual on Scientific Evidence 620 (3d ed. 2011), *available at* 2011 WL 7724261, \*38.

exposure can cause a disease. *Id.* Furthermore, Berg’s toxicologist expert, Dr. Rosenthal, is prepared to offer additional support for Dr. Cramer’s models of biological plausibility. Thus, Dr. Cramer’s biological plausibility models are not so fundamentally unsupported that they fail to assist the jury. *Sappington*, 512 F.3d at 448.

After a careful review of the record, the court concludes that Dr. Cramer’s expert testimony is reliable. Defendants can certainly attack his testimony at trial. *See Kuhn*, 686 F.3d at 625 (“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.”). But his testimony will not be precluded based on the arguments that defendants put forward.

## **II. Dr. Gary Rosenthal**

Dr. Rosenthal is prepared to offer expert testimony on the issue of “whether talc can be considered an immunotoxic<sup>11</sup> agent and the relevance of this to the biological plausibility of talc as an agent capable of causing ovarian cancer.” Docket 144-1 at 3. Defendants argue that Dr. Rosenthal is not qualified to offer his expert opinion and that his opinion is unreliable.<sup>12</sup>

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<sup>11</sup> Immunotoxicology is a “branch of toxicology concerned with the effects of toxic agents on the immune system.” Reference Manual on Scientific Evidence 682 (3d ed. 2011), *available at* 2011 WL 7724262, \*27.

<sup>12</sup> The court assumes, for purposes of this motion, that Dr. Rosenthal’s testimony is relevant.

### **A. Qualifications**

“A witness can be qualified as an expert by knowledge, skill, experience, training or education, and it is the responsibility of the trial judge to determine whether a particular expert has sufficient specialized knowledge to assist jurors in deciding the specific issues in this case.” *Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc.*, 254 F.3d 706, 715 (8th Cir. 2011) (internal quotations omitted). “The relative skill or knowledge of an expert goes to the weight of that witness’s testimony, not its admissibility.” *Loudermill v. Dow Chemical Co.*, 863 F.2d 566, 569 (8th Cir. 1988).

Dr. Rosenthal received his Ph.D. in environmental medicine from New York University. He has been certified as a toxicologist by the American Board of Toxicology since 1990. His research includes the study of the toxicity of various agents on the immune system, including mineral dusts. He has also studied causative and preventative measures of inflammation and cancer.

Defendants argue that because Dr. Rosenthal has no experience specifically with talc or ovarian cancer, he is not qualified. Such a narrow view of an expert’s qualifications is not required under Rule 702. “Rule 702 only requires that an expert possess knowledge, skill, experience, training, or education sufficient to ‘assist’ the trier of fact, which is satisfied where expert testimony advances the trier of fact’s understanding to any degree.” *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1100 (8th Cir. 2006) (internal quotations

omitted). Dr. Rosenthal has experience studying the toxicity of mineral dust on the immune system. His expert testimony addresses whether talc can be considered an immunotoxic agent. Further, Dr. Rosenthal has experience studying the causative and preventative measures of inflammation and cancer. His expert testimony also addresses the biological plausibility of talc as an agent capable of causing ovarian cancer. Thus, the court finds that Dr. Rosenthal's qualifications are sufficient to assist the trier of fact in deciding the issues in this case.

### **B. Reliability**

Dr. Rosenthal's expert report offers the following conclusions: (1) talc has immunotoxic<sup>13</sup> potential; (2) it is biologically plausible that talc-mediated neoplastic events<sup>14</sup> can be evoked through various mechanisms; (3) talc can translocate from the vagina, cervix, or fallopian tube to the ovary; (4) it is biologically plausible that Berg's daily talc use for over 30 years led to chronic inflammation in target tissues; (5) neoplastic events related to chronic inflammation and/or immune modulation would likely have been elicited in

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<sup>13</sup> Immunotoxic means that the agent in question exerts toxicity toward the immune system or its components.

<sup>14</sup> A neoplastic event is a pathologic process that results in the formation and growth of abnormal tissue that grows by cellular proliferation more rapidly than normal and continues to grow after the stimuli that initiated the new growth cease. Stedman's Medical Dictionary 1288 (28th ed. 2006).

Berg; and (6) the foregoing would have played a role in disease processes leading to Berg's ovarian cancer. Docket 144-1 at 11.

Defendants argue that Dr. Rosenthal's biologically plausible opinions are merely speculative, untested, and unreliable. An examination of Dr. Rosenthal's methods is required to determine whether defendants' arguments have merit.

In reaching his conclusions, Dr. Rosenthal first addresses talc's physicochemical aspects. Docket 144-1 at 5. He asserts that talc's "poorly-soluble particulate nature" is significant because it allows talc "to be taken up by cells of the immune system . . . and transported to other parts of the body[.]" *Id.* He notes that talc shares this property with "other members of the mineral dust family, including silicates and asbestos." *Id.* He further notes that "an extensive literature exists showing that similar to asbestos and other mineral dusts, exposure to talc can result in cellular toxicity." *Id.* (citing published studies).

Dr. Rosenthal next addresses the biological evidence that supports his conclusions. He first asserts that the immune consequences of talc being "taken up" by cells "depends on the fate(s) of the cell and the engulfed talc particle." *Id.* at 6. Some fates result in the recruitment of other immune cells (because the body recognizes talc as a foreign particle) while others lead to an injury that

causes unique structures such as Giant cells<sup>15</sup> and granulomas.<sup>16</sup> *Id.* (citing published studies that show Giant cells and granulomas have been seen in response to talc exposure). Alternatively, the talc particle may be taken up by cells through the process of endocytosis.<sup>17</sup> Any of these “fates” may “play some part in the response to mineral dust deposition on mucosal surface and would be associated with measures of inflammation[.]” *Id.* at 7. Dr. Rosenthal notes that several “studies show markers of inflammation following talc exposure, including intravaginal delivery.” *Id.* (citing several published articles).

To further support his opinions, Dr. Rosenthal discusses studies that show how talc can affect the immune system. He notes several studies that show talc induces granulomas in a variety of different organs. He then cites an animal study that found talc-induced granulomas resulted in deficient cellular immune functions that “have been noted to precede cancer in man.” *Id.* at 7. After discussing additional studies, Dr. Rosenthal generalizes that talc causes

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<sup>15</sup> Giant cells granuloma is a “nonneoplastic lesion characterized by a proliferation of granulation tissue containing numerous multinucleated giant cells[.]” Stedman’s Medical Dictionary 832 (28th ed. 2006).

<sup>16</sup> Granuloma is a “[t]erm applied to nodular inflammatory lesions[.]” Stedman’s Medical Dictionary 831 (28th ed. 2006). “Granuloma formation is a special type of immune response to foreign agents, where the body produces a collection of immune and related cells in an attempt to wall off a foreign agent that has resisted digestion.” Docket 144-1 at 7.

<sup>17</sup> Endocytosis is the “[i]nternalization of substances from the extracellular environment through the formation of vesicles formed from the plasma membrane.” Stedman’s Medical Dictionary 640 (28th ed. 2006).

two biologic responses—immune system suppression and inflammation—both of which have been found to be associated with cancer. *Id.* at 8-10. Moreover, he notes that the “intimate relationship between talc, inflammation, phagocytic cells,<sup>18</sup> and ovary-derived chemotactic factors<sup>19</sup> provides a mechanistic connection for talc translocation to the ovary where it can alter tissue homeostasis.” *Id.* at 9.

To summarize, Dr. Rosenthal’s report essentially provides that talc particles that are applied in the perineal area can move to the ovaries where they can be problematic for immune cells by causing chronic inflammation and/or immunity suppression. Chronic inflammation and immunity suppression have been shown to play roles in disease processes that lead to cancer. Based on Berg’s thirty-plus years of perineal exposure to talc, it is likely that she would have experienced such chronic inflammation and/or immunity suppression in her ovaries, thus playing a “role in disease processes leading to her ovarian cancer.” *Id.* at 11. Dr. Rosenthal relied on several published scientific articles as well as his own experience in immunotoxicology to form his conclusions.

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<sup>18</sup> Phagocytic cells are cells that can ingest bacteria, foreign particles, and other cells. Stedman’s Medical Dictionary 1470 (28th ed. 2006).

<sup>19</sup> Chemotactic factors are factors that cause movement of cells in response to chemicals, whereby the cells are attracted or repelled by substances exhibiting chemical properties. Stedman’s Medical Dictionary 358 (28th ed. 2006).

Defendants attack Dr. Rosenthal's opinion from several perspectives. First, defendants challenge Dr. Rosenthal's comparison of talc with other mineral dusts, arguing that he is not qualified to discuss the relevant properties of the three mineral dusts. The main assertion that Dr. Rosenthal makes, however, is that talc, asbestos, and silica all have poorly-soluble particulate natures that encourage uptake by immune cells. It is this property, he opines, that would cause the three mineral dusts to act similar from an immunotoxicology perspective. *See, e.g., Reference Manual on Scientific Evidence* 664 (3d ed. 2011) (noting toxicologists often compare the structures of different compounds to infer toxicity). Dr. Rosenthal only relies on *one* physical property that the three substances share. Defendants urge the court to require Dr. Rosenthal to be an expert on *all* physicochemical properties of each substance if he is to compare any of them. Such expansive expertise, however, is not required. If defendants have issue with the factual basis for his comparisons, they are welcome to challenge it at trial, but such a challenge goes to the weight to be given to the evidence, not its admissibility. *Bonner*, 259 F.3d at 929 (“[T]he factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility.”).

Second, defendants argue that Dr. Rosenthal's reference to historic accounts of asbestos in cosmetic talc is unreliable. Regardless of its reliability, the court finds this part of Dr. Rosenthal's opinion to be irrelevant. Berg has not

alleged that asbestos was in the talc that allegedly caused her ovarian cancer. Instead, she argues that the talc itself caused her ovarian cancer. Thus, any reference to historic accounts of asbestos in cosmetic talc is irrelevant and is also likely to confuse the jury. As a result, Dr. Rosenthal is precluded from testifying about historic accounts of asbestos in cosmetic talc.

Third, defendants take issue with Dr. Rosenthal's assertions relating to cellular toxicity. The general crux of defendants' arguments deal with the factual basis of the opinion and not the methodology. Further, defendants misinterpret Dr. Rosenthal's opinion. When disputing Dr. Rosenthal's claim that talc causes cellular toxicity, defendants argue that cellular toxicity is a general term not necessarily related to cancer. Nowhere in Dr. Rosenthal's expert report does he make the assertion that all cellular toxicity causes cancer. Thus, defendants' argument lacks merit.

Fourth, defendants argue that Dr. Rosenthal's references to metallic components in talc make his entire opinion unreliable, noting his deposition testimony in which he states that the "combination of these compounds together in the context of talc have not been studied in a detailed way[.]" Docket 144-2 at 14. The court agrees that Dr. Rosenthal's reference that he "would not completely dismiss a potential role for contaminating immunotoxic metals" is an unreliable statement because Dr. Rosenthal did not provide an adequate basis in science to support it. Nevertheless, this statement is a small part of his

report and has little or nothing to do with the rest of his expert opinion. Thus, his references to metallic components do not make his entire opinion unreliable.

Fifth, defendants attack Dr. Rosenthal's efforts to show biologic plausibility. They argue that because Berg's tissues did not indicate that the specific mechanisms that Dr. Rosenthal offered were present, his testimony is irrelevant.<sup>20</sup> The court disagrees and finds that Dr. Rosenthal's offering of mechanisms that provide biologic plausibility to Berg's claim that talc caused her ovarian cancer are relevant.<sup>21</sup>

Sixth, defendants argue that Dr. Rosenthal's opinion should be excluded because of his word choices in his report. The court will not entertain such a meritless objection.

Defendants' seventh challenge is similar to its third. They argue that because one of the mechanisms (TNF-alpha<sup>22</sup>) that Dr. Rosenthal offers has not been conclusively proven to cause cancer, it is unreliable. This again misstates Dr. Rosenthal's report. The report asserts that talc has been shown to cause

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<sup>20</sup> Defendants' argument goes to the sufficiency of specific causation rather than admissibility. This argument is more properly addressed as part of the motion for summary judgment.

<sup>21</sup> If defendants had conclusive proof that the mechanisms were not present, then such testimony would likely be irrelevant.

<sup>22</sup> TNF-alpha stands for tumor necrosis alpha, which is a pleiotropic cytokine synthesized widely throughout the female reproductive tract. Stedman's Medical Dictionary 698 (28th ed. 2006).

inflammation through an increase in TNF-alpha. The report does not state that TNF-alpha causes cancer—the basis for defendants’ challenge.

Defendants’ eighth challenge attacks the factual basis for Dr. Rosenthal’s opinion. First, they argue that one of the studies he relied on is a case report. But their citation to *Glastetter v. Novartis Pharmaceuticals Corporation*, 252 F.3d 986 (8th Cir. 2001), is not dispositive. *Glastetter* simply states that “causal attribution based on case studies must be regarded with caution.” 252 F.3d at 990. Here, Dr. Rosenthal is not using case studies as the entire foundation for his opinions, but just as one piece of the puzzle. Further, defendants argue that Dr. Rosenthal’s admission that there is a scientific debate about whether talc is immunosuppressive precludes his testimony. This admission does not make his opinion unreliable. *See Kuhn*, 686 F.3d at 625 (“Proponents of expert testimony need not demonstrate that the assessments of their experts are correct, and trial courts are not empowered to determine which of several competing scientific theories has the best provenance.”) (internal quotation omitted).

Defendants’ ninth challenge is not actually a challenge at all. Instead, defendants simply reference various statements made by Dr. Rosenthal in relation to Dr. Cramer’s theories.

Tenth, defendants take issue with Dr. Rosenthal’s proffer that the immunosuppressive effects of asbestos may contribute to malignancy by decreasing natural killer cells. Dr. Rosenthal offers this statement to support

his conclusion that substances that have immunosuppressive effects play a role in the disease processes leading up to cancer development. He does not assert, as defendants suggest, that talc exposure decreases natural killer cells. Again, defendants' misstatement of Dr. Rosenthal's opinion makes their objection meritless.

Defendants' eleventh challenge shares many of the shortcomings as their previous challenges. Defendants muddle sufficiency with admissibility, arguing that Berg's medical records did not show evidence of inflammation and thus any theory of inflammation is irrelevant. They challenge the factual basis of Dr. Rosenthal's opinion, claiming his interpretation of various animal studies makes his opinion unreliable. Lastly, they take Dr. Rosenthal's reluctance to definitively state that talc exposure causes ovarian cancer to mean that his opinions are speculative and unreliable. Dr. Rosenthal's report, however, does not assert that talc exposure causes ovarian cancer. Instead, Dr. Rosenthal's report states that Berg's talc exposure "would have played a role in disease processes leading to her ovarian cancer." Docket 144-1 at 11.

In summary, the court finds that the majority of defendants' challenges to Dr. Rosenthal's expert testimony are unpersuasive. In making his ultimate conclusions, Dr. Rosenthal relied on his own expertise in the field of toxicology, his past research, and several other published scientific studies. Any gaps or limitations in Dr. Rosenthal's reasoning can be presented to the jury. *See Kuhn*,

686 F.3d at 632 (“The studies’ limitations may be presented to the jury, and [the expert’s] reliance on the studies may be tested through the traditional means of cross examination and presentation of contrary evidence.”). Indeed, “[v]igorous 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.” *Daubert*, 509 U.S. at 596.

### **III. Dr. John Godleski**

Dr. Godleski reviewed histopathological<sup>23</sup> slides taken from Berg following her diagnosis of ovarian cancer using advanced microscopic methodologies. In his review of twenty-six slides, Dr. Godleski found three particles of talc. He asserts that his findings indicate that talc was present in Berg’s ovary tumor. Dr. Godleski opines that the talc found in Berg’s tissues “is evidence for a causal link between the presence of talc and the development of [her] ovarian cancer.” Docket 141-1 at 4.

Defendants argue that Dr. Godleski is unqualified and that his opinions are irrelevant and unreliable.

#### **A. Qualifications**

Dr. Godleski is the head of Pulmonary Pathology at Brigham and Women’s Hospital, a major teaching hospital of Harvard Medical School. He also

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<sup>23</sup> Histopathology is the science or study dealing with the cytologic and histologic structure of abnormal or diseased tissue. Stedman’s Medical Dictionary 893 (28th ed. 2006).

leads a research group at the Harvard School of Public Health. He earned his medical degree from the University of Pittsburgh School of Medicine where he did research using electron microscopy. He has published more than 140 papers related to pulmonary pathology including a number using analytical electron microscopy. He is a “recognized expert whose opinion is sought by pathologists from other hospitals in the diagnosis of foreign material in tissues throughout the body using scanning electron microscopy and energy dispersive X-ray analyses.” Docket 141-1 at 2.

Defendants note that Dr. Godleski’s background does not include determining the causes of ovarian cancer. They argue that Dr. Godleski has done limited research on the relationship between talc and ovarian cancer, that his knowledge of the causes of ovarian cancer is limited, and that he is not an epidemiologist. On the other hand, defendants do not dispute that Dr. Godleski is an expert at identifying foreign particles in human tissue. Because his testimony is limited to identifying foreign particles in human tissue, the court finds he is qualified to offer his expert opinion.

#### **B. Relevancy**

Defendants argue that Dr. Godleski’s opinions are irrelevant because he cannot tie the talc particles found in Berg’s tissues to defendants’ products. This argument goes to the sufficiency of the testimony, not the relevancy of it. Berg claims that talc from defendants’ products caused her ovarian cancer.

Certainly, testimony that establishes that talc particles were found in Berg's ovary tumor is relevant to this case.

**C. Reliability**

Defendants' reliability arguments are based on a mischaracterization of Dr. Godleski's expert opinion. Their arguments suggest that Dr. Godleski is opining that the talc particles he found caused Berg's ovarian cancer.

Dr. Godleski's opinion stops well short of such a conclusion. His report notes that "the talc found in this case is evidence for a causal link between the presence of talc and the development of [Berg's] ovarian cancer." Docket 141-1 at 4. His opinion merely states the obvious: the talc found in Berg's tissues is evidence in this case.

Defendants again argue that Dr. Godleski is required to rule out alternative causes. Because Dr. Godleski is not opining that talc was the cause of Berg's ovarian cancer through a differential diagnosis, he need not rule out other potential causes of her cancer. The fact that he found particles other than talc goes to the sufficiency of his testimony. The remainder of defendants' arguments are based on their mischaracterization of Dr. Godleski's opinions and will not be addressed. Therefore, Dr. Godleski's expert testimony will not be excluded.

#### **IV. Dr. David R. Lenorovitz and Dr. Edward E. Karnes**

Dr. Lenorovitz and Dr. Karnes are prepared to provide expert testimony “addressing certain forensic human factors and warnings issues.”<sup>24</sup> Docket 146-3 at 3. Defendants argue that the expert report goes far beyond the boundaries applicable to human factors experts. In addition, defendants argue that any proposed testimony that is related to human factors is unreliable.

##### **A. Qualifications**

The court begins its evaluation by addressing the experts’ qualifications. Dr. Lenorovitz has 44 years of professional experience as a human factors engineer, ergonomist, and cognitive psychologist. He received his Ph.D. in human factors engineering from the State University of New York and is certified as a professional ergonomist by the Board of Certification in Professional Ergonomics. He has spent the last six years as a forensic human factors consultant with a special emphasis on warnings systems design, development, and warnings adequacy evaluation.

Dr. Karnes has 50 years of professional experience as a human factors professional. He received his Ph.D. in experimental psychology from Temple University and is board-certified. He has served as a human factors consultant for plaintiffs and defendants in several different legal cases. The majority of his

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<sup>24</sup> According to Berg, forensic human factors and warnings is the “multidisciplinary field examining how humans interact with the world around them.” Docket 173 at 1.

research has concerned the development of warnings and user understanding of safety issues associated with the use of consumer and industrial products.

Both experts are qualified to render an expert opinion within their field.

### **B. Defendants' Challenges**

Defendants first take issue with any attempt by the experts to offer testimony regarding defendants' intent as well as testimony regarding defendants' purported lobbying efforts. *See, e.g.*, Docket 146-3 at 14 ("The defendants have knowingly decided to ignore the hazard present in their products."); Docket 146-3 at 5 ("The defendants collaborated and joined forces with other 'talc-interested parties' to pool resources and fund . . . programs intended to . . . defeat any research study[.]"). Both Dr. Karnes and Dr. Lenorovitz admit that the basis for their opinions about defendants' intent and lobbying efforts comes from "reading the documents that were provided." Docket 146-2 at 20; 22. "Where the subject matter is within the knowledge or experience of lay people, expert testimony is superfluous." *Ellis v. Miller Oil Purchasing Co.*, 738 F.2d 269, 270 (8th Cir. 1984). There is no reason why the jury cannot review the same documents and form their own opinions about defendants' intent and lobbying efforts. Thus, Drs. Karnes and Lenorovitz are precluded from offering an expert opinion about defendants' intent or lobbying efforts because such testimony would be superfluous.

Next, defendants seek to preclude Drs. Karnes and Lenorovitz from testifying about any legal conclusions, e.g., any duties that defendants owed to Berg. Under South Dakota law, whether a duty exists is a question of law. *Bland v. Davison Cnty*, 507 N.W.2d 80, 81 (S.D. 1993). Any expert testimony on a legal conclusion will not assist the trier of fact and is thus inadmissible. *United States v. Wells*, 63 F.3d 745, 753 (8th Cir. 1995) (“[I]nstruction on the law is the function of the court, not a defense expert.”), *rev’d on other grounds*, 519 U.S. 482 (1997); *Peterson v. City of Plymouth*, 60 F.3d 469, 475 (8th Cir. 1995) (“The legal conclusions were for the court to make. It was an abuse of discretion to allow the testimony.”). Thus, Drs. Karnes and Lenorovitz are precluded from testifying about any duties or responsibilities that defendants allegedly owed to Berg.

Defendants also move the court to preclude any testimony Drs. Karnes and Lenorovitz may offer that is outside their expertise, such as the medical risks of ovarian cancer, whether talc is hazardous, and whether there is a feasible alternative product. “An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed.” Fed. R. Evid. 702. Thus, Drs. Karnes and Lenorovitz can form their opinions based on the testimony of other experts in this case. But Drs. Karnes and Lenorovitz cannot make unsupported statements that are outside of their field of expertise. *See Anderson v. Raymond Corp.*, 340 F.3d 520, 523 (8th Cir. 2003) (noting that

the district court did not abuse its discretion in deciding that an expert could not testify about matters outside of his expertise). In addition, the court need not admit cumulative evidence. Fed. R. Evid. 403. Any detailed description of testimony provided by Berg's other experts regarding the medical risks of ovarian cancer, whether talc is hazardous, and whether there is a feasible alternative product would certainly be cumulative because Drs. Karnes and Lenorovitz are not capable of offering their novel opinions in such areas as they are not qualified to do so. Therefore, the testimony of Drs. Karnes and Lenorovitz regarding these areas must be limited. For purposes of their testimony, Drs. Karnes and Lenorovitz may only "assume" that ovarian cancer has medical risks, talc is hazardous, and there is a feasible alternative product.<sup>25</sup> They cannot, however, go into detail on any of these subjects.

More generally, Berg asserts that Drs. Karnes and Lenorovitz were designated (1) to ascertain if talc posed a hazard to the populace; (2) to determine whether the hazard was open and obvious to a reasonable user; (3) to determine if there was a feasible way to place a warning on the talc product; and (4) to determine if there was a financially and technically reasonable alternative to talc. Docket 173 at 2. As discussed above, Drs. Karnes and

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<sup>25</sup> This assumes that plaintiff will present evidence that there is a feasible alternative product.

Lenorovitz are not qualified to provide an opinion on whether talc is hazardous to the populace or whether there is a financially reasonable alternative to talc.

Moreover, Drs. Karnes and Lenorovitz cannot assist the jury on the issue of whether the alleged hazard was open and obvious to a reasonable user. The basis for Drs. Karnes and Lenorovitz concluding that the alleged hazard was not open and obvious is based solely on the fact that Berg, Dr. Karnes, and Dr. Lenorovitz were not aware of the hazard prior to this litigation. A jury can rely on its own common sense and experiences in forming its conclusion on whether the alleged hazard was open and obvious.

Therefore, the testimony of Drs. Karnes and Lenorovitz will be limited to whether there was a feasible way to place a warning on defendants' products.<sup>26</sup> The court will now turn to defendants' summary judgment motion.

#### **SUMMARY JUDGMENT LEGAL STANDARD**

Summary judgment is appropriate if the movant "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party can meet this burden by presenting evidence that there is no dispute of material fact or that the nonmoving party has not presented evidence to support an element of her

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<sup>26</sup> After reviewing the remainder of the report in light of the extensive limitations discussed above, the court finds that any additional proposed testimony outside of the issue of placing a warning on the product is not admissible because it is either cumulative or outside the expertise of Drs. Karnes and Lenorovitz.

case on which she bears the ultimate burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). “The nonmoving party may not ‘rest on mere allegations or denials, but must demonstrate on the record the existence of specific facts which create a genuine issue for trial.’” *Mosley v. City of Northwoods, Mo.*, 415 F.3d 908, 910 (8th Cir. 2005) (quoting *Krenik v. County of Le Sueur*, 47 F.3d 953, 957 (8th Cir. 1995)).

Summary judgment is precluded if there is a dispute in facts that could affect the outcome of the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). For purposes of a summary judgment motion, the court views the facts and the inferences drawn from such facts “in the light most favorable to the party opposing the motion.” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986).

Because this is a diversity action, the court applies the law of the state in which it sits. *Prudential Ins. Co. of Am. v. Kamrath*, 475 F.3d 920, 924 (8th Cir. 2007). Thus, South Dakota law applies to Berg’s claims.<sup>27</sup>

### **ANALYSIS**

Defendants move for summary judgment on three grounds: (1) Berg’s experts do not present admissible evidence of causation and have failed to rule out other potential causes; (2) there is no evidence that would impose upon

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<sup>27</sup> The parties do not dispute that South Dakota law applies.

defendants a duty to warn; and (3) Berg cannot demonstrate that defendants' failure to warn caused her ovarian cancer.

### **I. Evidence of Causation**

Defendants argue that Berg has not presented admissible evidence of causation and thus all of her claims must fail. To survive summary judgment, Berg must present evidence beyond unsupported conclusions and speculative statements that defendants' products caused her injuries. *Burley v. Kytac Innovative Sports Equip., Inc.*, 737 N.W.2d 397, 407-10 (S.D. 2007). Expert testimony is ordinarily required to establish causation in a products liability action, particularly in a toxic tort action. *Id.*; see also *Junk v. Terminix Int'l Co.*, 628 F.3d 439, 450 (8th Cir. 2010) ("To succeed in her claims, [plaintiff] needed to present expert testimony showing that the [substance] could have caused [the] injuries and that it did in fact cause those injuries.").

The majority of defendants' arguments rely on the assumption that the court would grant their motions to exclude expert testimony analyzed above. But because the court found that the majority of the expert testimony offered by Berg is admissible, most of defendants' arguments are moot. The court will nonetheless evaluate the admissible evidence that Berg has put forth to ensure that she has met her burden of creating a genuine issue of fact on the causation element.

As a preliminary matter, Berg asserts, and defendants do not dispute, that she began using talc in her genital area in 1975. She claims that the talc came from defendants' products—"Johnson's Baby Powder" and "Shower to Shower"—and that her use continued until 2007. It is undisputed that Berg was diagnosed with ovarian cancer in December of 2006.

Berg has put forth admissible expert testimony to support her claim that defendants' products caused her ovarian cancer. First, Dr. Cramer, an epidemiologist, opines generally that talc use in the genital area has a strong causal association with ovarian cancer. *See Glastetter*, 252 F.3d at 992 (noting that epidemiological evidence can assist in establishing causation). He goes further to opine that Berg's frequent application of talc to her genital area was "the major cause of her invasive serous ovarian cancer[.]" Docket 148-1 at 18. In forming his opinions, Dr. Cramer relied on various facts: Berg was premenopausal when she was diagnosed; she has no personal or family history of breast or ovarian cancer; she is not Jewish; she tested negative for the full panel of BRCA1 and BRCA2 mutations; and the odds ratio for someone with similar characteristics is 3.53.

Second, Dr. Rosenthal, a toxicologist, provides biologic plausibility to Dr. Cramer's opinions. *See Marmo*, 457 F.3d at 758 ("[A] toxicologist may testify that exposure to a chemical caused a person's symptoms and injuries."). He asserts that talc has immunotoxic potential and can evoke neoplastic events,

which may lead to ovarian cancer. Further, he claims that it is biologically plausible that Berg's frequent application of talc led to chronic inflammation and/or immune modulation of tissues and cells in her ovaries. Thus, he concludes that Berg's frequent genital application of talc "played a role in disease processes leading to her ovarian cancer." Docket 144-1 at 11.

Third, Dr. Godleski, an expert in microscopy, provides evidence that talc was actually present in the tissues that were removed from Berg's ovaries and fallopian tubes following her diagnosis. Lastly, Berg claims that had she known of any dangers involved in applying talc to her genital area, she would not have done so.

Defendants urge the court to grant summary judgment because Berg has not ruled out other potential causes of her ovarian cancer. But Berg is not required to "eliminate all other possible explanations of causation[.]" *Burley*, 737 N.W.2d at 407. She needs only to "set forth sufficient evidence establishing a causal connection between the [defendants' product] and the resulting injury." *Id.* The court finds that she has done so here. Determining the weight of the evidence Berg has put forth is an issue for the jury.

## **II. Duty to Warn**

Defendants argue that Berg cannot move forward with her failure to warn claims because she has not established the existence of a duty to warn. The

court must separate Berg's failure to warn claims to address defendants' argument.

**A. Strict Liability Failure to Warn**

Defendants argue that they did not owe Berg a duty to warn because their product is not dangerous. "The issue under strict liability is whether the manufacturer's failure to adequately warn rendered the product unreasonably dangerous without regard to the reasonableness of the failure to warn judged by negligence standards." *Peterson v. Safway Steel Scaffolds Co.*, 400 N.W.2d 909, 912 (S.D. 1987). "[K]nowledge of the potential risk is imputed to the manufacturer." *Id.* Thus, defendants cannot defend "on grounds that, at the time of production, [they] neither knew nor could have known of the risk." *Id.* Thus, if Berg can establish at trial that a "danger existed associated with a foreseeable use of [defendants'] product," the duty to warn element is automatically satisfied for purposes of her strict liability failure to warn claim. *Burley*, 737 N.W.2d at 409.

**B. Negligent Failure to Warn**

To establish liability for negligent failure to warn, Berg must show, among other things, that defendants "knew or reasonably should have known that the product was dangerous or was likely to be dangerous when used in a reasonably foreseeable manner." *Id.* at 410. Defendants argue that there was and still is no duty to warn because there lacks any substantial evidence that

their products are dangerous. Additionally, defendants argue that any evidence that Berg puts forth that allegedly shows dangers associated with defendants' products falls short of creating a duty to warn.

Defendants' arguments are premature at this time. Defendants are correct in stating that under South Dakota law "the existence of a duty is a question of law to be determined by the court." *Janis v. Nash Finch Co.*, 780 N.W.2d 497, 500 (S.D. 2010). But in a negligent failure to warn case, whether defendants owed Berg a duty to warn depends, first, on whether defendants' products are unreasonably dangerous. *See Burley*, 737 N.W.2d at 410 (requiring plaintiff to show that the "manufacturer knew or reasonably should have known that the product was dangerous"). Indeed, if defendants' products are not dangerous, no warning would be necessary. Whether defendants' products are unreasonably dangerous is a factual determination for the jury. *See Peterson*, 400 N.W.2d at 914 ("[I]ssues of reasonableness and foreseeability . . . are usually jury issues."). Thus, the court cannot make its legal determination of whether a duty existed until the jury has the opportunity to determine if the products are dangerous. *See Reiss v. Komatsu America Corp.*, 735 F. Supp. 2d 1125, 1146 (D.N.D. 2010) ("The existence of a duty to warn is generally a preliminary question of law for the court, but if the existence of a duty depends

upon factual determinations, their resolution must be resolved by the trier of fact.”).<sup>28</sup>

### III. Proximate Cause

Defendants also argue that Berg has failed to put forth sufficient facts to show that defendants’ failure to warn was the legal cause of her ovarian cancer. Defendants’ argument raises the issue of when the duty to warn arose. They claim that even if a duty to warn exists, such duty arose much later than 1975—the year Berg began dusting her perineum with talc. Thus, defendants argue, Berg cannot prove that defendants’ failure to warn was the legal cause of her cancer because the duty did not arise in time to prevent her cancer.

As discussed above, Berg’s strict liability claim does not necessitate the finding that a duty existed. Moreover, the issue of *whether* a duty ever existed must first be determined in order to ascertain *when* such a duty arose. Even so, Berg has put forth evidence that defendants were aware of the alleged dangers of talc as early as 1971. Thus, there is a material issue of fact as to whether defendants “knew or reasonably should have known that the product was dangerous” as far back as 1971. *See Burley*, 737 N.W.2d at 410.

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<sup>28</sup> Defendants’ reliance on *Brech v. J.C. Penney Co.*, 698 F.2d 332, 334 (8th Cir. 1983), in support of their assertion that federal standards are relevant in determining if a duty to warn existed is misplaced. In review of District Court Judge Nichol’s factual findings from a bench trial, the Eighth Circuit stated that “[a]lthough evidence that the gown surpassed federal standards is not necessarily conclusive proof that the garment was not *unreasonably dangerous*, it is nevertheless evidence which the court can consider on the issue.” *Id.* (emphasis added).

In summary, Berg has put forth sufficient, admissible evidence to show that there exists genuine issues of material fact. Also, the court is unable to determine whether defendants owed Berg a duty to warn at this time. Thus, defendants' motion for summary judgment is denied.

### **CONCLUSION**

Dr. Cramer's expert opinion is admissible because it was the product of reliable methodologies, and he was not required, as an epidemiologist, to rule out all alternative causes of Berg's ovarian cancer. The majority of Dr. Rosenthal's opinions are admissible because he is qualified to render such opinions, and he used reliable methodologies in forming his opinions.

Dr. Godleski's opinion is admissible because he is qualified, and the opinion is relevant and stems from reliable methodologies. Lastly, Dr. Lenorovitz and Dr. Karnes, as human factors experts, can only testify on the limited issue of whether there was a feasible way to place a warning on defendants' products.

Moreover, Berg has put forth sufficient evidence to show that there exists genuine issues of material fact that preclude summary judgment. Furthermore, the court is unable to determine whether defendants owed Berg a duty to warn at this time. Accordingly, it is

ORDERED that defendants' motion to exclude the testimony of Dr. Godleski (Dockets 140 & 153) is denied.

IT IS FURTHER ORDERED that defendants' motion to exclude the testimony of Dr. Rosenthal (Dockets 143 & 156) is granted in part and denied in part.

IT IS FURTHER ORDERED that defendants' motion to exclude the testimony of Dr. Lenorovitz and Dr. Karnes (Dockets 145 & 155) is granted in part and denied in part.

IT IS FURTHER ORDERED that defendants' motion to exclude the testimony of Dr. Cramer (Docket 147 & 151) is denied.

IT IS FURTHER ORDERED that defendants' motion for summary judgment (Docket 149) is denied.

Dated April 12, 2013.

BY THE COURT:

*/s/ Karen E. Schreier*

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KAREN E. SCHREIER  
UNITED STATES DISTRICT JUDGE