

Companies' motion regarding Berg's strict products liability and negligent products liability claims. J&J Consumer Companies renewed its motion at the conclusion of the evidence, and the court again reserved ruling. The jury returned a verdict in favor of J&J Consumer Companies on Berg's strict products liability claim, returned a verdict in favor of Berg on her negligent products liability claim, and awarded no damages. The court now takes up J&J Consumer Companies' motion for judgment as a matter of law on Berg's claim for negligent products liability.¹ Berg resists the motion. For the following reasons, the motion is denied.

BACKGROUND

The pertinent facts to this order, viewed in the light most favorable to Berg, the nonmoving party, are as follows:

Berg used J&J Consumer Companies' products—Johnson's Baby Powder and Shower to Shower—on a daily basis in her perineum area to relieve chafing and for feminine hygiene purposes from 1975 until 2007. Some time in late 2006, Berg began feeling fatigued and bloated and noticed some spotting between her periods. She underwent a pelvic exam in early December 2006, which revealed blood clotting in her ovaries. Her ovaries were removed before

¹ J&J Consumer Companies' motion for judgment as a matter of law on Berg's strict products liability claim is moot following the jury's verdict in favor of J&J Consumer Companies on that claim.

Christmas of that year. On December 26, 2006, Berg was diagnosed with ovarian cancer.

Talc is one of the main ingredients in Johnson's Baby Powder and Shower to Shower. Berg alleges the talc found in defendant's products caused her ovarian cancer and claims J&J Consumer Companies should have included a warning on its products. Berg would not have used defendant's products in the manner in which she did if the products had included a warning. J&J Consumer Companies stipulated that placement of a warning on its products is physically feasible, but it argued that no warning is necessary because talc does not cause ovarian cancer, either generally or specifically in Berg's case.

Studies have articulated an association between perineal talc use and ovarian cancer dating back to 1971. Over twenty studies have shown a positive association between talc and ovarian cancer. J&J Consumer Companies admitted that it was aware of all literature regarding talc use and cancer at all times.

Dr. Daniel Cramer, an epidemiologist and one of Berg's expert witnesses, performed a meta-analysis using data from several studies and testified that women have between a 20 to 40 percent increased risk (1.3 odds ratio) of developing ovarian cancer with perineal talc use. He examined the Bradford Hill criteria and concluded talc use in the perineal area causes ovarian cancer. Dr. Cramer also testified that Berg's specific odds ratio, which he calculated

after taking into consideration the duration and quantity of her usage, menopausal status, heritage, genetics, type of cancer, and family history, was around 3.5 (a 250 percent increased risk). Dr. Cramer believed Berg's perineal talc use more likely than not caused her ovarian cancer.

Berg's second expert, Dr. John Godleski, was a pathologist. Dr. Godleski examined tissue from Berg's ovaries, fallopian tubes, and lymph nodes. He found nineteen talc particles in tissue samples from her left ovary, fallopian tube, and lymph nodes. He testified that the talc particles did not naturally occur in the human body and should not have been in Berg's tissue. Lastly, Dr. Godleski testified that he believed the presence of talc particles in Berg's tissue is evidence of a causal link between talc and Berg's ovarian cancer.

Berg's third expert, Dr. Gary Rosenthal, was a toxicologist who provided testimony regarding biological plausibility, i.e., whether it is biologically plausible that talc causes ovarian cancer. Dr. Rosenthal testified that talc has immuno-toxic potential (which leads to inflammation) as well as immuno-suppressive capacities (a down-regulation of the normal functions of the immune system). These two characteristics may result in the development of cancerous cells. He further testified that talc can get to the ovaries by way of simple application of talcum powder to the perineum area, after which the talc migrates up the female reproductive tract. Dr. Rosenthal concluded by asserting talc is toxic and capable of causing cancer through either inflammation or immuno-suppression (or a combination of the two).

STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 50, a party can move for judgment as a matter of law if the party against whom relief is sought has been fully heard on that issue. Fed. R. Civ. P. 50(a)(1). “When federal jurisdiction is premised on diversity of citizenship, a federal district court applies the sufficiency standards of the state in which it sits.” *In re Levaquin Prods. Liab. Litig.*, 700 F.3d 1161, 1165 (8th Cir. 2012). Thus, South Dakota’s sufficiency standards apply for purposes of J&J Consumer Companies’ motion. Under South Dakota law,

the trial court must determine whether there is any substantial evidence to sustain the action. The evidence must be accepted which is most favorable to the nonmoving party and the trial court must indulge all legitimate inferences therefrom in [her] favor. If sufficient evidence exists so that reasonable minds could differ, [judgment as a matter of law] is not appropriate.

Roth v. Farner-Bocken Co., 667 N.W.2d 651, 658-59 (S.D. 2003); *see also* SDCL 15-6-50(a).

DISCUSSION

In its motion for judgment as a matter of law, J&J Consumer Companies makes five arguments: (1) Berg’s claim is barred by the applicable statute of limitations; (2) Berg failed to produce legally sufficient evidence to support a finding of recognized danger; (3) Berg did not offer required expert testimony on the applicable standard of care or breach of that standard; (4) Berg failed to produce legally sufficient evidence to support a finding that J&J Consumer

Companies' conduct was a legal cause of her injuries; and (5) Berg failed to produce legally sufficient evidence as to when any duty to warn arose.

I. Statute of Limitations

The applicable statute of limitations under South Dakota law for Berg's negligent products liability claim is found in SDCL 15-2-12.2, which provides as follows:

An action against a manufacturer . . . of a product, regardless of the substantive legal theory upon which the action is brought, for or on account of personal injury . . . caused by or resulting from the manufacture, construction, design, formula, installation, inspection, preparation, assembly, testing, packaging, labeling, or sale of any product or failure to warn or protect against a danger or hazard in the use, misuse, or unintended use of any product, or the failure to provide proper instructions for the use of any product may be commenced only within three years of the date when the personal injury . . . occurred, became known or should have become known to the injured party.

The issue then is on what date did Berg's injuries become known or should have become known to her. "Statute of limitations questions are generally for a jury to decide." *Robinson v. Ewalt*, 808 N.W.2d 123, 126 (S.D. 2012). This is because "the point at which a period of limitations begins to run must be decided from the facts of each case." *Strassburg v. Citizens State Bank*, 581 N.W.2d 510, 513 (S.D. 1998).

Here, the parties dispute the date on which Berg knew or should have known of her injuries. Berg claims she did not know of her injuries until December 26, 2006, the date she was diagnosed with cancer. J&J Consumer Companies contends Berg knew or should have known of her injuries before

December 26, 2006, because Berg previously noticed some spotting between her periods and felt fatigued and bloated; Berg underwent a pelvic exam in early December 2006 and learned that there was blood clotting in her ovaries; and Berg had her ovaries removed before Christmas. Because reasonable minds could differ as to the exact date on which Berg knew or should have known of her injuries, the court finds judgment as a matter of law is inappropriate, and such a question was properly submitted to the jury.²

II. Dangerous or Likely to be Dangerous

Berg must establish that J&J Consumer Companies knew or reasonably should have known that its products are dangerous or likely to be dangerous when used in a reasonably foreseeable manner. *Burley v. Kyttec Innovative Sports Equip., Inc.*, 737 N.W.2d 397, 410 (S.D. 2007). Whether J&J Consumer Companies' products are unreasonably dangerous is a factual determination for the jury. *See Peterson v. Safway Steel Scaffolds Co.*, 400 N.W.2d 909, 914 (S.D. 1987) ("These issues of reasonableness and foreseeability . . . are usually jury issues."). J&J Consumer Companies argues Berg failed to produce legally sufficient evidence to support a finding that its products create a recognized

² Indeed, when the jury was asked to "determine the date on which Deane Berg's personal injuries became known to her or should have become known to her," the jury found "12/26/06" to be the appropriate date. Docket 327 at 1. As this court previously held in its September 21, 2010, order, a finding that Berg's injuries became known or should have become known to her on December 26, 2006, results in the conclusion that she commenced her cause of action within the three-year statutory period. *Berg v. Johnson & Johnson*, No. CIV. 09-4179, 2010 WL 3806141, at *4 (D.S.D. Sept. 21, 2010).

danger. Specifically, J&J Consumer Companies claims that Berg's experts who testified such a danger exists are not qualified and did not provide reliable evidence, that controlling governmental agencies have concluded that there is no danger, that the scientific consensus demonstrates that there is no recognized danger, and that Dr. Cramer, Berg's expert, failed to show a danger.

In terms of Berg's experts, the court has already addressed the reliability of their testimony and their qualifications in its April 12, 2013, order. *Berg v. Johnson & Johnson*, ___ F. Supp. 2d ___, No. CIV. 09-4179, 2013 WL 1563227 (D.S.D. Apr. 12, 2013). J&J Consumer Companies merely asks the court to reconsider its ruling and has not offered new arguments. Because J&J Consumer Companies has not offered any new arguments, the court maintains its findings in its April 12, 2013, order regarding the qualifications of Berg's experts as well as the reliability of the methodologies they used in forming their opinions.

Next, J&J Consumer Companies contends that because government agencies have not identified talc as carcinogenic, no jury could find talc is dangerous or likely to be dangerous. But the fact that some government agencies have not concluded that talc is dangerous does not end the jury's inquiry. Compliance with government regulations should be considered as evidence of the exercise of reasonable care, but such compliance is not conclusive on the issue of negligence. *Zacher v. Budd Co.*, 396 N.W.2d 122, 134 (S.D. 1986). J&J Consumer Companies' compliance with government

regulations is just one piece of evidence the jury can consider when determining whether J&J Consumer Companies acted reasonably. See Restatement (Second) of Torts § 295A (1965) (“In determining whether conduct is negligent, the customs of the community, or of others under like circumstances, are factors to be taken into account, but are not controlling where a reasonable man would not follow them.”).

J&J Consumer Companies also claims that the consensus in the scientific community is that there is no danger with the perineal use of talc. The evidence presented at trial, particularly by Berg’s experts, conflicts with such a broad statement. Not only did Dr. Cramer testify that he believed talc was the cause of Berg’s ovarian cancer, he also testified that over twenty studies have shown an overall association between talc and ovarian cancer. After considering the combined data from all these studies, Dr. Cramer testified that women have somewhere between a 20 to 40 percent increased risk of developing ovarian cancer if they use talc in their perineal area. Additionally, Dr. Rosenthal testified that talc has immuno-toxic and immuno-suppressive capacities, which may lead to the development of cancer. He also testified that talc is toxic and toxins oftentimes lead to cancer once exposed to the body. Thus, some individuals in the scientific community believe talc is dangerous or likely to be dangerous when used in and around a woman’s perineum.

Berg introduced substantial evidence on the issue of whether J&J Consumer Companies’ products are dangerous or likely to be dangerous. She

offered evidence from two qualified scientists who testified regarding the potential harms talc may cause to a woman's ovaries. One of the experts, Dr. Cramer, testified that Berg's genital use of talc was more likely than not the cause of her ovarian cancer. A reasonable juror could believe this testimony and conclude that talc is dangerous or likely to be dangerous. Therefore, judgement as a matter of law on the issue of whether talc is dangerous or likely to be dangerous is denied.

III. Expert Testimony

J&J Consumer Companies also argues judgement as a matter of law should be granted in its favor because Berg did not offer expert testimony on the applicable standard of care or on the breach of that standard. To prove her claim for negligent products liability, Berg must establish, along with other elements, that (1) J&J Consumer Companies failed to exercise reasonable care and adequately warn of the danger or instruct on the safe use of the products; and (2) a reasonable manufacturer under the same or similar circumstances would have warned of the danger or instructed on the safe use of the products. *Burley*, 737 N.W.2d at 410. The issue here is whether Berg was required to offer expert testimony to prove these elements of her claim.

Under South Dakota law, expert testimony typically must be offered to prove causation when claiming negligent failure to warn. *See Burley*, 737 N.W.2d at 411 ("As with her previous claims, causation for failure to warn requires expert testimony."). *But see id.* at 411 ("Had the product not been

altered before the accident, Burley may have had sufficient evidence without expert testimony because absent a misuse or alteration it may be reasonable to infer the [product] was the legal or proximate cause of her injuries.”). J&J Consumer Companies claims Berg is required to offer expert testimony not only on the issue of causation, but also to show the applicable standard of care and breach of such standard.

J&J Consumer Companies directs the court to two South Dakota Supreme Court opinions in support of its argument that Berg must present expert testimony to establish the applicable standard of care for a failure to warn claim: *Burley v. Kyttec Innovative Sports Equipment, Inc.*, 737 N.W.2d 397 (S.D. 2007) and *Luther v. City of Winner*, 674 N.W.2d 339 (S.D. 2004).

In *Burley*, the plaintiff brought a product liability action against a manufacturer of a sports training product, claiming defective design and failure to warn under theories of both strict liability and negligence. The South Dakota Supreme Court held expert witness testimony was required for the defective design claims because it is not “within the common expertise of a jury to deduce merely from an accident and injury that a product was defectively designed.” *Id.* at 407. With respect to the failure to warn claims, the South Dakota Supreme Court held expert testimony was required, under the specific circumstances of that case, to show causation as well as whether the product was unreasonably dangerous because those areas were beyond the common expertise of a jury. *Id.* at 410-11 (“As with her previous claims, causation for

failure to warn requires expert testimony.”). *Burley*, therefore, calls for expert testimony in three situations: (1) to show that a product is defectively designed and, thus, should have been designed differently; (2) to show that a product is unreasonably dangerous; and (3) if the specific circumstances demand it, to show that a manufacturer’s failure to warn was the legal cause of plaintiff’s injuries.

In *Luther*, the plaintiff brought suit against a city and city engineer, claiming negligent design and failure to warn in relation to a public sidewalk. Just as in *Burley*, the South Dakota Supreme Court held expert testimony was required to prove the sidewalk was designed and constructed improperly. *Id.* at 345 (requiring expert testimony on the standard of care for designing and constructing the sidewalk). This was because “determining how to design the project” required the city engineer “to take issues into consideration that are not within the typical lay person’s realm of knowledge.” *Id.* at 346. With respect to plaintiff’s failure to warn claim, the South Dakota Supreme Court reversed the trial court’s dismissal of the claim, finding that expert testimony was not necessary for the failure to warn claim. *Id.* at 347-48. The fact that the plaintiff failed to present expert testimony as to the standard of care in designing the project was not fatal to his failure to warn claim. *Id.*

In both *Burley* and *Luther*, the South Dakota Supreme Court required expert testimony to show a design defect, which necessarily calls into question the standard of care used in designing the product. The *Burley* court also

required expert testimony on the issue of causation in a failure to warn case because, under the circumstances, such a determination was outside a typical layperson's realm of knowledge.³ The *Luther* court made no indication that expert testimony was required for any of the necessary showings for the failure to warn claim. Therefore, the court disagrees with J&J Consumer Companies' broad assertion that South Dakota law requires Berg to offer expert testimony on the applicable standard of care (or breach thereof) for her failure to warn claim.⁴

Under South Dakota law, “[t]here is no requirement that a party produce expert testimony when the question is within a layperson’s knowledge.” *Luther*, 674 N.W.2d at 344. The question becomes then, what issues pertaining to Berg’s negligent failure to warn claim are outside a typical layperson’s

³ The South Dakota Supreme Court in *Burley* suggested expert testimony may not, in some circumstances, even be required to prove causation. See 737 N.W.2d at 411 (“Had the product not been altered before the accident, Burley may have had sufficient evidence without expert testimony because absent a misuse or alteration it may be reasonable to infer the [product] was the legal or proximate cause of her injuries.”).

⁴ J&J Consumer Companies’ argument relies, in large part, on the following quote from *Burley*: “Indeed, expert testimony is ordinarily required to establish a claim of negligence in a products liability action. . . . [A]bsent expert testimony, there is no basis for the jury to evaluate the actions of an ordinary prudent person.” 737 N.W.2d at 408-09 (citing *Dancy v. Hyster Co.*, 127 F.3d 649, 654 (8th Cir. 1997) (applying Arkansas law)). But this discussion in *Burley* was with respect to the standard of care pertaining to the claim for defective design, not the failure to warn claim. Indeed, the case the *Burley* court cited for this proposition was exclusively a design defect claim. *Dancy*, 127 F.3d at 651. The court sees no reason to extend this requirement to the failure to warn context presented in this case.

knowledge. Similar to the finding in *Burley*, the court finds the issue of causation here is outside a layperson's knowledge because determining whether a product causes cancer requires a high level of expertise. For the same reason, whether the products at issue in this case are dangerous or likely to be dangerous is a matter outside a layperson's knowledge and thus requires expert testimony. Berg offered expert testimony on each of these issues.

J&J Consumer Companies argues Berg should also be required to offer expert testimony on a manufacturer's standard of care in a failure to warn context (i.e., whether a reasonable manufacturer in J&J Consumer Companies' position would have warned). The court disagrees. The jury must first determine whether the products here are dangerous or likely to be dangerous, and only if the jury answers in the affirmative to this question does it reach the standard of care issue. If the jury gets to the standard of care question of whether a reasonable manufacturer would warn, it has already determined that the products are dangerous or likely to be dangerous without a proper warning/instruction.

Assuming the jury determines the products are dangerous or likely to be dangerous without a proper warning/instruction, the jury then weighs (1) the likelihood of harm and gravity of such harm if it occurs with (2) the costs to the manufacturer associated with placing a warning on its products. The expert testimony Berg offered regarding whether the products are dangerous or likely

to be dangerous goes directly to the first issue (likelihood and gravity of the harm). And the second issue was addressed through a stipulation by the parties, which expressed that it was physically feasible for J&J Consumer Companies to place a warning on its products. Thus, under the circumstances of this case, the jury was capable of performing its analysis without additional expert testimony regarding the applicable standard of care.⁵

This result also makes sense practically. Who better to determine whether a warning should be provided than the people to whom the warning would be addressed? A layperson is in a position (if not the best position) to know whether a particular harm or possible harm is deserving of a warning. As a result, the court finds that the applicable standard of care and breach thereof involved in this negligent failure to warn case is within a typical layperson's realm of knowledge. *See Mattis v. Carlon Elec. Prods.*, 295 F.3d 856, 863 (8th Cir. 2002) (finding expert testimony is not necessary to show that a warning is inadequate if the alleged inadequacy of the warning is within the comprehension of the average layperson) (applying federal law). Therefore, Berg

⁵ The jury also had evidence before it that other participants in the talc industry were warning of the possible dangers associated with perineal talc use. For example, J&J Consumer Companies' talc supplier, Luzenac, placed a warning on its products starting in 2006. GlaxoSmithKline, a healthcare company and competitor of J&J Consumer Companies, published a pamphlet in 2005 that warned of the increased risk of ovarian cancer that talc use creates.

was not required to offer expert testimony on the applicable standard of care or breach thereof.

IV. Legal Cause

J&J Consumer Companies also contends Berg failed to offer sufficient evidence to support a finding that its failure to warn was a legal cause of her injuries. To succeed on her negligent failure to warn claim, Berg must prove J&J Consumer Companies' failure to warn or instruct was a proximate or legal cause of her injury. *Burley*, 737 N.W.2d at 410. Legal cause means "an immediate cause which, in the natural or probable sequence, produces the injury complained of. For legal cause to exist, the harm suffered must be a foreseeable consequence of the act complained of." S.D. Pattern Jury Instruction (Civil) 20-10-20. J&J Consumer Companies argues Berg failed to provide sufficient evidence to show its products are capable of causing ovarian cancer and, more specifically, whether they in fact caused Berg's ovarian cancer.

Berg offered testimony from three experts to establish causation: Dr. Cramer, Dr. Rosenthal, and Dr. Godleski. Dr. Cramer provided testimony in the area of epidemiology and how it relates to talc use and ovarian cancer. He stated that twenty-three studies have shown a positive association between genital talc use and ovarian cancer. After combining the data from these reports into a meta-analysis, Dr. Cramer concluded genital talc use generates a

1.3 relative risk, or a 30 percent increase in the risk for ovarian cancer. He next considered Berg's specific characteristics in light of the meta-analysis and found her individual odds ratio⁶ to be roughly 3.5, or a 250 percent increased risk. Dr. Cramer then examined the Bradford Hill criteria, which is a set of criteria used to assess causation. *In re Viagra Prods. Liab. Litig.*, 572 F. Supp. 2d 1071, 1079 (D. Minn. 2008). After testifying in detail about the specific Bradford Hill criteria, Dr. Cramer concluded perineal talc use is a cause of ovarian cancer. Lastly, he testified that Berg's exposure to talc, taking into consideration her specific odds ratio of 3.5, combined with other individual characteristics (e.g., no family history of ovarian/breast cancer, not Jewish, and lacking the BRCA 1 and BRCA 2 genes) leads him to conclude that her perineal talc use more likely than not caused her ovarian cancer.

Dr. Godleski, a pathologist, examined tissue from Berg's ovaries, fallopian tubes, and lymph nodes. He found nineteen talc particles in tissue samples from her left ovary, fallopian tube, and lymph nodes. He testified that talc particles are not naturally occurring in the human body and should not have been in Berg's tissue. Lastly, Dr. Godleski testified that he believed the presence of talc particles in Berg's tissue is evidence of a causal link between talc and Berg's ovarian cancer.

⁶ Dr. Cramer used relative risk and odds ratio interchangeably in his testimony.

Berg's third expert, Dr. Rosenthal, was a toxicologist who provided testimony regarding the biological plausibility of talc causing ovarian cancer. Dr. Rosenthal testified that talc has immuno-toxic potential as well as immuno-suppressive capacities, and he testified in detail how these two characteristics may result in the development of cancerous cells. He further testified that applying talc to the perineum area allows talc particles access to the ovaries because they can migrate up the female reproductive tract. Dr. Rosenthal concluded his testimony by asserting talc is toxic and capable of causing cancer through either inflammation or immuno-suppression (or a combination of the two).

The court finds that the totality of the evidence Berg presented at trial, which must be accepted most favorable to her and all legitimate inferences therefrom be made in her favor, amounts to substantial evidence and creates a factual question in which reasonable minds could differ. J&J Consumer Companies' arguments regarding whether there was *enough* evidence to establish that talc was an "immediate" or "natural and probable" cause of Berg's ovarian cancer go to the weight to be given to Berg's evidence. The same holds true for its arguments pertaining to specific causation. Under South Dakota law, "[i]ssues of negligence, contributory negligence, and proximate cause are ordinarily questions of fact and it must be a clear case before a trial judge is justified in taking these issues from the jury." *Luther*, 674 N.W.2d at

348. The court finds Berg satisfied her burden by offering substantial evidence in which a reasonable jury could find in her favor on the issue of legal cause.

V. When Duty Arose

Lastly, J&J Consumer Companies claims Berg failed to provide legally sufficient evidence as to when any duty to warn arose. A manufacturer has a duty to warn when it knows or reasonably should know that its products are dangerous or likely to be dangerous when used in a reasonably foreseeable manner. *Burley*, 737 N.W.2d at 410. The duty to warn arises, therefore, when the manufacturer knew or reasonably should have known of the possible danger. This is a fact issue for the jury. *See Peterson*, 400 N.W.2d at 914 (“[I]ssues of reasonableness and foreseeability . . . are usually jury issues.”).

Berg introduced evidence of studies articulating an association between perineal talc use and ovarian cancer dating back to 1971. Evidence was also introduced that J&J Consumer Companies stayed current on all relevant literature pertaining to any alleged association between talc and cancer. Therefore, a reasonable jury could find that J&J Consumer Companies reasonably should have known of a possible danger as early as 1971. Because sufficient evidence exists, judgment as a matter of law is denied.

CONCLUSION

After reviewing the evidence presented during the course of trial, the court finds substantial evidence exists to sustain Berg’s negligent products

liability action. Therefore, judgment as a matter of law on Berg's negligence claim is denied. Accordingly, it is

ORDERED that defendant's motion for judgment as a matter of law (Docket 308) is denied. Judgment will be entered in favor of plaintiff, Deane Berg, on her negligent failure to warn claim.

Dated November 19, 2013.

BY THE COURT:

/s/ Karen E. Schreier

KAREN E. SCHREIER
UNITED STATES DISTRICT JUDGE